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Commission General Report on the operation of REACH and review of certain elements

Conclusions and Actions

{COM(2018) 116 final}

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GLOSSARY

ADCO	Administrative Cooperation Groups for European cooperation on market surveillance
ANSES	French Agency for Food, Environmental and Occupational health and Safety
ASO	Accredited Stakeholder Organisations
ATP	Adaptation to Technical Progress
BPR	Biocidal Products Regulation
C&L	Classification and Labelling
CA	Competent Authority
CAD	Chemical Agents Directive
CARACAL	Competent Authorities for REACH and CLP
CBA	Cost-benefit analysis
CCA	Cumulative cost assessment study
CCH	Conformity check
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CoRAP	Community Rolling Action Plan
COSME	Competitiveness of Small and Medium-sized Enterprises
CSR	Chemical Safety Report
DecaBDE	Decabromodiphenyl Ether
DMF	Dimethylfumarate
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECVAM	European Centre for the validation of alternative methods
EEA	European Environment Agency
EEB	European Environmental Bureau
EEN	Enterprise Europe Network
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENES	Exchange Network on Exposure Scenarios
EOGRTS	Extended One-Generation Reproductive Toxicity Study
ES	Exposure Scenario
ESR	Existing Substances Regulation
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
FCM	Food Contact Materials
FORUM	Forum for Exchange of Information on Enforcement
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

GDP	Gross domestic product
GPSD	General Product Safety Directive
HBCDD	Hexabromocyclododecane
HPVCs	High Production Volume Chemicals
IATA	Integrated Approach to Testing and Assessment
ICCM	International Conference on Chemicals Management
IOELVs	Indicative Occupational Exposure Limit Values
IOMC	Internet-based Toolbox for Decision Making in Chemicals Management
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
MS	Member State(s)
MSC	Member State Committee
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJEU	Official Journal of the European Union
OPC	Open Public Consultation
OSH	Occupational Safety and Health
PACT	Public Activities Coordination Tool
PBDEs	Polybrominated diphenyl ethers
PBDs	Polybrominated diphenyls
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCB	Polychlorinated biphenyl
PfAs	Proposals for Amendments
PFAS	Per and Perfluoro Alkyl substances
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
PPPR	Plant Protection Products Regulation
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
RMM	Risk management measure

RMOA	Regulatory Management Options Analysis
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
SAICM	United Nations Strategic Approach to Chemicals Management
SCCPs	Short chain chlorinated paraffins
SCOEL	Scientific Committee for Occupational Exposure Levels
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SMEs	Small and Medium Sized Enterprises
SVHC	Substance of Very High Concern
t/y	Tonnes per year
TSD	Toy Safety Directive
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
US EPA	Environmental Protection Agency of the United States
US	United States
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvBs	Very Persistent and Very Bioaccumulative substances
WEEE	Waste Electrical and Electronic Equipment
WHO	World Health Organisation
WoE	Weight of Evidence
WTO	World Trade Organisation

1. INTRODUCTION

The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH[1]) came into force in 2007 and aims at improving the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances while promoting alternative methods for the assessment of hazards of substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

1.1. Purpose of the REACH evaluation

The 2017 evaluation of the operation of REACH is part of the regular assessment and reporting by the European Commission on progress in achieving the objectives of the Regulation. This evaluation accompanies the second Commission report[2] on the functioning of REACH pursuant to Article 117(4) and Article 138 of REACH.

Regular monitoring and reporting provides information that allows for adjustment to improve the implementation of the Regulation. Being part of the Commission's Regulatory Fitness and Performance Programme (REFIT)[3], the 2017 REACH evaluation examines to what extent REACH is fit for purpose and looks at what works well and what does not, as well as why this is the case. In line with the Better Regulation Guidelines, the evaluation covers the five compulsory criteria: effectiveness, efficiency, relevance, coherence and EU added value, including the potential for burden reduction and simplification and improving the delivery of the objectives.

1.2. Scope of the REACH evaluation

The 2013 REACH review provided a first in-depth assessment of the overall operation of REACH, presenting a broad assessment of what the first five years of REACH had brought about. The 2017 REACH evaluation builds on those findings and examines key developments since then, in particular those that have emerged or developed substantially (e.g. the authorisation process); thus, mainly on the period 2010 - 2016, and assesses REACH's contribution to meeting the World Summit Sustainability Development 2020 goals and the Sustainable Development goals.

The 2017 REACH evaluation focuses on assessing the areas where there has been a sufficient level of implementation to allow for a meaningful evaluation at this stage. Some recent developments that are still in early stages of implementation (e.g. implementing regulation on data sharing) or that are being developed (amendment of technical annexes as regards nanomaterials) will be addressed to the extent possible[4].

The evaluation builds on information obtained from Member States, ECHA, a series of thematic studies and other relevant sources, covering the following aspects:

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[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[2] In 2013, the Commission published the first review of REACH – 2013 REACH review, a broad assessment of the first five years of REACH – COM(2013)49 final and SWD(2013)25final

[3] http://ec.europa.eu/smart-regulation/index_en.htm

[4] 2017 REACH evaluation Roadmap available at http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

I. Main issues resulting from the information obtained from regular reports from Member State Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and enforcement. These reports allow monitoring of the practical implementation of REACH and how it contributes to the protection of health and the environment in all Member States.

Member State reports provide an overview of the functioning of REACH in the territories of the 28 Member States and the EEA countries.

ECHA's reports provide an overview of the operation of REACH, including information on joint submission of information by multiple registrants (Article 11) and the state of use of non-animal testing.

Furthermore, Article 138 of the REACH Regulation specifies some elements that are relevant for the general REACH report, namely registration requirements for 1 – 10 tonnes substances, including the CSA and CSR obligation for substances that are carcinogenic, mutagenic or toxic to reproduction - CMRs category 1A or 1B.

II. The status of implementation of the work launched as a follow-up to the 2013 REACH review and the actions that the Commission, ECHA, the Member States, and, where relevant, stakeholders have already implemented or are implementing in that context. This includes also other significant legislative and policy developments since 2013, notably:

- Implementation of Roadmap on Substances of Very High Concern (SVHC) for 2020
- Streamlining of the restriction procedure
- Ongoing implementation work until 2017 on registration (including data sharing) and authorisation requirements with a view to improve effectiveness and lessen the administrative burden stemming from the Regulation.

III. Further detailed topics to be covered include:

- Assessment of the benefits of chemical legislation on human health and the environment as well as socio-economic benefits
- Assessment of the achievements made regarding the use of alternative test methods and non-test methods in REACH and in general
- Perception of chemical safety by citizens
- Support measures to assist SMEs (e.g. information concerning the use of EU funding programmes, guidance through the Europe Enterprise Network (EEN))
- Progress in the registration process, results of 2013 registrations and preparations for the 2018 deadline
- Review of the obligations on registration requirements for low tonnage (1-10 t/y) substances in relation to the REACH objectives
- Review of the obligations on the need, if any, to register certain types of polymers in relation to the REACH objectives
- Consideration of substance identity issues
- Assessment of the optimisation of substance evaluation
- Activities to improve the implementation of the requirements related to extended Safety Data Sheets (eSDS)
- Assessment of the costs and benefits of authorisation

- Interface with other legislation (including in particular the coherence between REACH and the occupational safety and health – OSH – legislation, coherence with legislation on waste as well as other relevant developments since 2013)
- Monitoring of enforcement of REACH via a new indicator system (and a public consultation on enforcement)
- Assessment of the impact of REACH on innovation, competitiveness and SMEs
- Assessment of the impact of REACH on the international competitiveness of the EU chemicals industry and selected Downstream User sectors
- Evaluation of ECHA and its Committees
- Information on substances in articles
- Review of Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency
- Ability of REACH to tackle nanomaterials, cumulative effects of chemicals, endocrine disruptors and other emerging issues

1.3. Co-ordinated strategy for ensuring chemicals legislation is fit for purpose

The EU legislative framework for the risk management of chemicals comprises a number of interacting and linked legal acts. These range from horizontal chemicals legislation (e.g. the Classification, Labelling and Packaging (CLP) Regulation) to product-specific and sectorial legislation, related to particular uses of chemicals in downstream industries. This is why a fitness check is also being undertaken of the wider legislative framework for the risk management of chemicals in the EU in parallel to the REACH evaluation, scheduled to finish in 2018[5].

The REACH evaluation focuses on the effects of REACH, whereas the fitness check focuses on the interactions between the different pieces of legislation. In contrast to the REACH evaluation, the fitness check does not carry out an evaluation of the individual pieces of legislation but rather focuses on specific elements within the legislation and the interlinkages between the pieces of legislation. In particular it:

- Assesses the consistency, effectiveness and efficiency of the chemicals legislation in applying generic risk and specific risk based risk management decisions;
- Assesses the accessibility of all relevant information available within the group of chemicals legislation when making a decision on a substance;

On the basis of a comprehensive impact assessment, the Commission is presently modifying the technical Annexes of REACH on substance identification, information requirements and chemicals safety assessment, to more effectively address nanomaterials when they are subject to registrations.

Additionally, the results of this evaluation and the Fitness Check will form the basis of a general stock-taking of the EU's existing legislative framework for chemicals risk management. It will also feed into the Commission's future chemicals strategy for achieving the objective of a non-toxic environment.

[5] Fitness Check Roadmap available at http://ec.europa.eu/DocsRoom/documents/21364

The obligation to report on the results of the official controls, and other enforcement measures taken under the CLP Regulation will be addressed under the fitness check exercise.

2. BACKGROUND

Increasing concerns that the pre-REACH EU chemicals acquis did not provide sufficient protection led to a debate at the informal Council of Environment Ministers in April 1998[6], in which it was recognised that a review of the existing policy on chemicals was necessary.

The reason for the pre-REACH policy debate was the slow progress of risk assessment under the Existing Substances Regulation (ESR – Regulation (EEC) No 793/93) and the implementation of risk management by e.g. Restrictions Directive (Directive No 76/769/EEC). The policy driver throughout was therefore the need to speed up the risk assessment and risk management of existing chemicals (i.e. those already on the market in 1981), but as the discussions progressed, other drivers and conditions were identified.

In line with dissatisfaction with the progress of ESR in 1999, the Joint Research Centre (JRC) published a technical study[7] showing that basic data necessary to carry out a screening level initial risk assessment was only publicly available for a minority of chemicals (less than 20%) and that this situation had not changed compared to what the US National Academy of Sciences had estimated to be the case in the 1980s. This added another, albeit related, policy driver, namely the need to obtain the necessary data for existing substances to enable the risk assessment and risk management of existing chemicals to take place.

The assessment of the functioning of the ESR showed that placing the responsibility on authorities to collect and assess the information on priority substances was ineffective. In fact, authorities needed to request industry to provide information to conduct risk assessments and decide on the need for risk management measures. This triggered the conclusion that, in line with the 'polluter pays principle', it should be the responsibility of industry to ensure the safe use of their chemicals and therefore carry out the risk assessment and ensure the risk management of their chemicals, including testing, and the responsibility of authorities to check if this responsibility is properly implemented and, where not, to quickly and efficiently propose measures to manage potential risks appropriately. Thus, the 'reversal of burden of proof' drove much of the design of REACH.

Though environment and health concerns related to the marketing and use of existing chemicals were the initial driver of the policy debate, that debate was also shaped by the general EU policy objectives of ensuring a level playing field in the EU (preserving the internal market), ensuring the competitiveness of EU industry and fostering innovation, being non-discriminatory internationally (respecting WTO) and promoting non animal test methods (supporting animal welfare). Furthermore, the legislation contributes to the

[6] http://europa.eu/rapid/press-release_PRES-01-201_en.htm (CHEMICALS POLICY - Council Conclusions)

[7] JRC report on data availability for EU HPV; http://publications.jrc.ec.europa.eu/repository/handle/JRC27012; http://publications.jrc.ec.europa.eu/repository/handle/JRC27013

aim of the EU to achieve the goals agreed at the 2002 World Summit on Sustainable Development[8].

2.1. **Description of the initiative**

2.1.1. Objectives

The objectives of REACH are to ensure a high level of protection of human health and the environment, including the promotion of alternative methods to animal testing for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing the competitiveness and innovation. In addition, REACH should contribute to the fulfilment of the World Summit on Sustainable Development 2020 goals.

Protection of human health and the environment.

REACH replaced the previously existing Regulations, Directives, Communications and Recommendations governing so-called new and existing chemicals by one unified systematic registration system, ensuring that the same obligations apply to all chemicals. In line with the polluter pays principle, REACH shifted the burden of proof by making industry responsible for safety, extending responsibility along the supply chain. The registration system introduced requirements to make sufficient information available about the properties of all chemicals including for the previously so-called existing chemicals in order to conduct risk assessments and introduce risk reduction measures where so required for hazardous substances. Health and environment benefits should result from the application of appropriate risk reduction measures.

Harmonisation of the internal market.

REACH aims at harmonising the general chemicals legislation at Union level for all cases where no more specific product legislation exists that also concerns chemicals. This was implemented by choosing a Regulation based on Article 95 of the EC Treaty (now Article 114 TFEU), which ensures uniform application in all Member States, by establishing a central Agency, the European Chemicals Agency (ECHA) to implement most of the scientific and technical work and by establishing detailed rules for the manufacture, placing on the market and use of substances throughout the EU.

Enhancing competitiveness and innovation.

The Regulation was designed to shape the innovative behaviour of firms in the chemical industry as it ended the disadvantages of the previous system for new chemicals by raising the registration threshold to 1 tonne per year per company (compared to 10 kg before for new substances) and by requiring the same amount of data for new and existing chemicals. REACH should therefore promote the competitiveness of the chemical industry and encourage innovation, by facilitating the development of safer chemicals, in particular chemicals aimed at replacing substances of very high concern (SVHCs).

Promotion of non-animal testing.

Registrants are obliged to systematically collect all available information. Only where this information is insufficient to fulfil the information requirements should a test be considered. Furthermore most testing involving animals needs prior approval by ECHA

[8] Recital 4 of Regulation (EC) 1907/2006

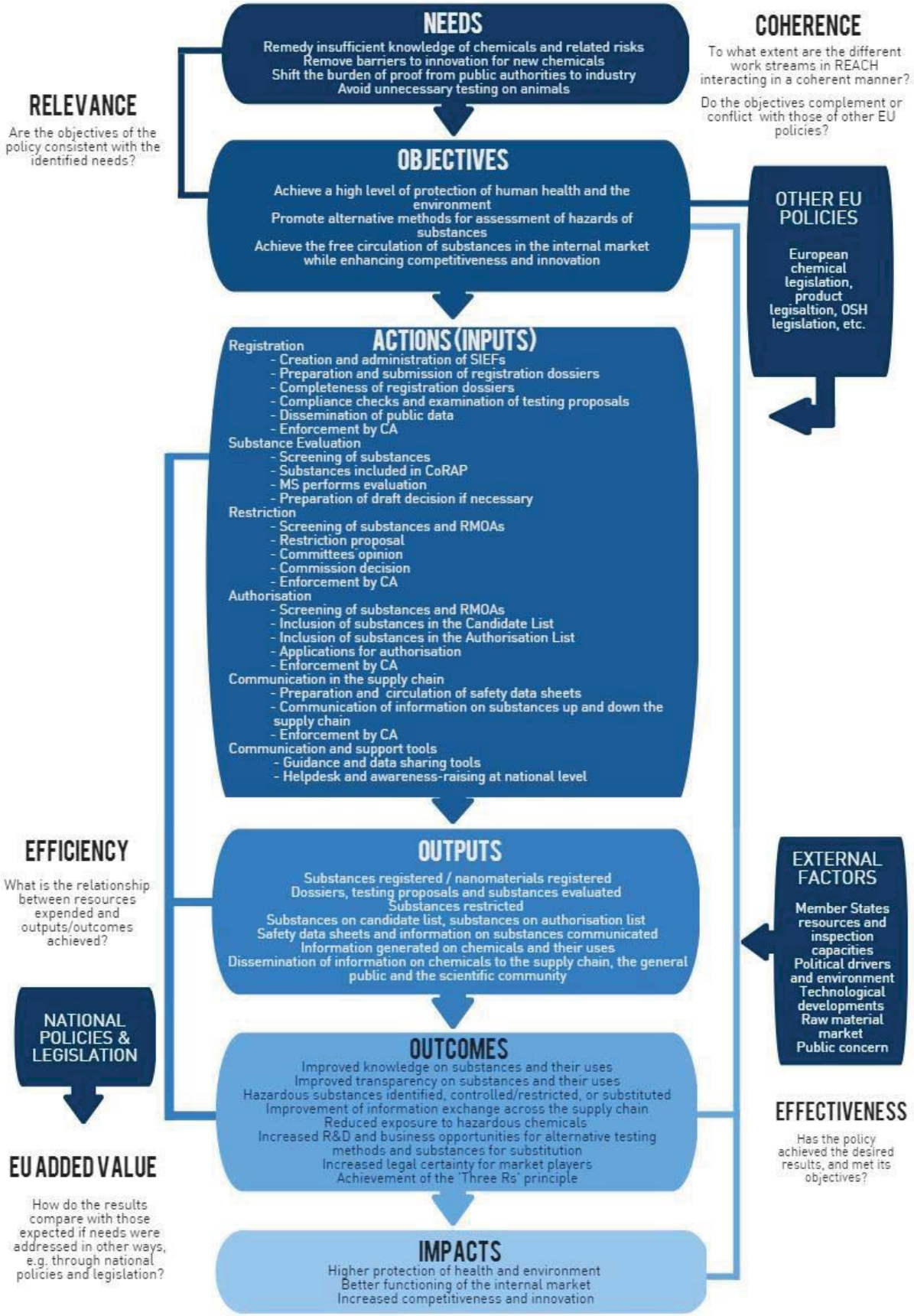
and legal possibilities to use alternative methods to fill information gaps (e.g. through read across, in vitro testing) were introduced to promote non-animal testing.

Separately the Commission has committed itself to stimulating and funding the development of new non-animal test methods.

2.1.2. Intervention Logic of the REACH Regulation

The intervention logic summarises how the intervention is envisaged to work. A visual representation is given of the logical links between the needs for the REACH Regulation, the objectives to be pursued, the actions taken by Member States, duty holders, the Commission and ECHA under each REACH process, the related output of these actions (e.g. substances registered or restricted) and general outcomes of the implementation and application of REACH (e.g. improved knowledge on substances, hazardous substances identified) leading to positive impacts on health, the environment and the functioning of the internal market as well as to enhanced competitiveness and innovation.

Figure 1: intervention logic of the REACH Regulation

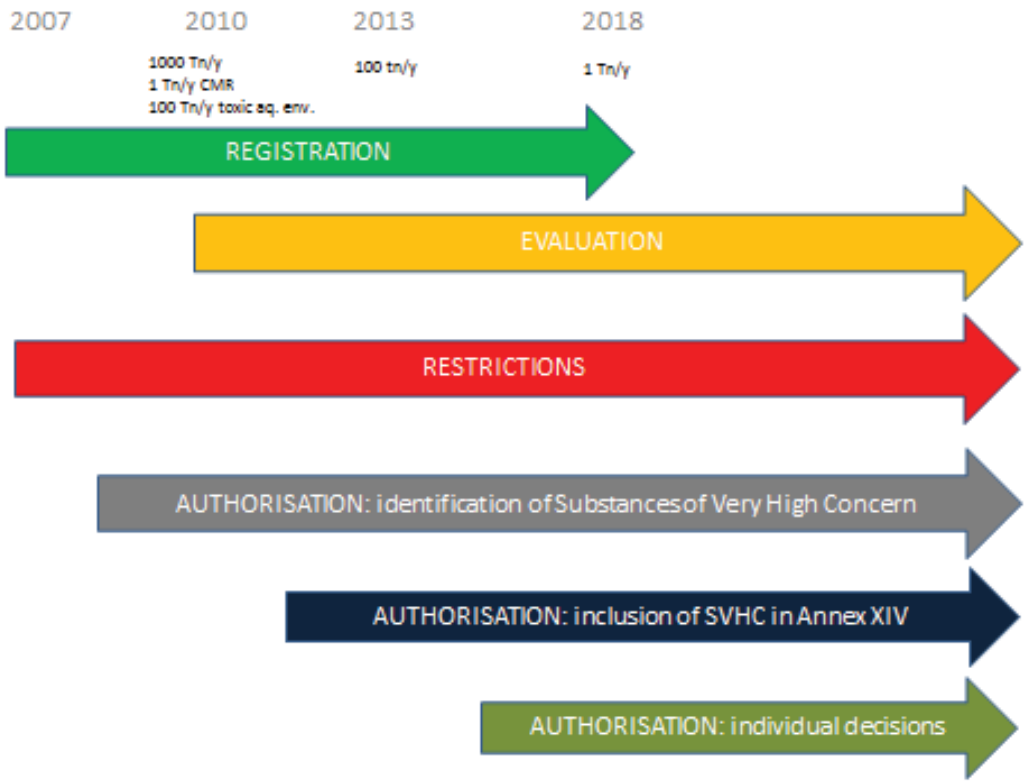

NEEDS
Remedy insufficient knowledge of chemicals and related risks
Remove barriers to innovation for new chemicals
Shift the burden of proof from public authorities to industry
Avoid unnecessary testing on animals
COHERENCE
To what extent are the different work streams in REACH interacting in a coherent manner?
Do the objectives complement or conflict with those of other EU policies?
RELEVANCE
Are the objectives of the policy consistent with the identified needs?
OBJECTIVES
Achieve a high level of protection of human health and the environment
Promote alternative methods for assessment of hazards of substances
Achieve the free circulation of substances in the internal market while enhancing competitiveness and innovation
OTHER EU POLICIES
European chemical legislation, product legisaltion, OSH legislation, etc.
ACTIONS (INPUTS)
Registration
- Creation and administration of SIEFs
- Preparation and submission of registration dossiers
- Completeness of registration dossiers
- Compliance checks and examination of testing proposals
- Dissemination of public data
- Enforcement by CA
Substance Evaluation
- Screening of substances
- Substances included in CoRAP
- MS performs evaluation
- Preparation of draft decision if necessary
Restriction
- Screening of substances and RMOAs
- Restriction proposal
- Committees opinion
- Commission decision
- Enforcement by CA
Authorisation
- Screening of substances and RMOAs
- Inclusion of substances in the Candidate List
- Inclusion of substances in the Authorisation List
- Applications for authorisation
- Enforcement by CA
Communication in the supply chain
- Preparation and circulation of safety data sheets
- Communication of information on substances up and down the supply chain
- Enforcement by CA
Communication and support tools
- Guidance and data sharing tools
- Helpdesk and awareness-raising at national level
EFFICIENCY
What is the relationship between resources expended and outputs/outcomes achieved?
OUTPUTS
Substances registered / nanomaterials registered
Dossiers, testing proposals and substances evaluated
Substances restricted
Substances on candidate list, substances on authorisation list
Safety data sheets and information on substances communicated
Information generated on chemicals and their uses
Dissemination of information on chemicals to the supply chain, the general public and the scientific community
EXTERNAL FACTORS
Member States resources and inspection capacities
Political drivers and environment
Technological developments
Raw material market
Public concern
NATIONAL POLICIES & LEGISLATION
OUTCOMES
Improved knowledge on substances and their uses
Improved transparency on substances and their uses
Hazardous substances identified, controlled/restricted, or substituted
Improvement of information exchange across the supply chain
Reduced exposure to hazardous chemicals
Increased R&D and business opportunities for alternative testing methods and substances for substitution
Increased legal certainty for market players
Achievement of the 'Three Rs' principle
EFFECTIVENESS
Has the policy achieved the desired results, and met its objectives?
EU ADDED VALUE
How do the results compare with those expected if needs were addressed in other ways, e.g. through national policies and legislation?
IMPACTS
Higher protection of health and environment
Better functioning of the internal market
Increased competitiveness and innovation

2.1.3. REACH elements

The REACH Regulation came into force in 2007 and aims at improving the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances it manufactures, uses or places on the market. Manufacturers and importers have to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in ECHA in Helsinki, Finland, to be able to manufacture, import or place on the market ("No data no market"). ECHA is the central point in the REACH system: it manages the databases necessary to operate the system, verifies that the data submitted complies with the requirements, and co-ordinates the in-depth evaluation of chemicals suspected to be of concern and is building up a public database in which consumers and professionals can find hazard information. The following section describes each of the main processes in REACH in greater detail and the timing of how they work together is illustrated in Figure 2 below.

Figure 2: Timelines for implementation of the main REACH processes.



It should be noted that some of the processes were new or had new elements and started immediately (such as registration), whereas others started only later (e.g. evaluation and

authorisation); others were a continuation from the pre-REACH system improved by a stronger integration of risk management with the risk identification process (e.g. restriction). Outputs and outcomes were expected to materialise with some delay, starting 10 years after the begin of the REACH implementation, and persisting for another 20 years, in particular actual benefits in terms of improved health and environment protection.

Registration, data sharing and avoidance of unnecessary testing

Industry has to provide information on all chemicals it places on the market in volumes at or higher than 1 tonne per company per year (t/y); special attention is given to long-term and chronic effects at the higher tonnages. The registration information requirements depend on the proven or suspected hazardous properties, on uses, exposure and volumes of chemicals that are produced or imported.

REACH puts the obligation on economic operators placing on the market hazardous substances and in particular for volumes above 10 t/y to apply a consistent and comprehensive approach to risk management in the chemical safety assessment (CSA) and to document the results in the chemical safety report (CSR) and the safety data sheet (SDS), containing also recommendations regarding the safe use of those chemicals which downstream users then must follow.

To ensure proportionality, the system provides for a tiered approach (information requirements depend on volume of substance manufactured or imported) and staggered registration deadlines, where high volume[9] and the most dangerous chemicals[10] had to be registered by the first registration deadline in 2010, followed by medium volume[11] substances in 2013 and lower volume[12] substances will follow in 2018.

Furthermore, under certain conditions, producers and importers of articles have to notify to ECHA the Substances of Very High Concern (SVHCs) listed on the candidate list[13] which are present in their articles.

To avoid unnecessary testing and reduce costs, data must be shared by companies registering the same substance. This is done in Substance Information Exchange Fora (SIEF) for substances already on the market when REACH entered into force (the so-called phase-in substances) or through the inquiry process for new substances (non phase-in substances). The data sharing obligations aim to ensure that studies, in particular those involving vertebrate animals, which are already available, are shared, as well as their costs. If the information is not available, potential registrants have to agree who will undertake the necessary testing and ensure that the test is carried out only once.

Information in the supply chain and downstream users

Improving the communication within the supply chain is a central theme of REACH. In the previous legislation, communication was required from the manufacturer or importer down the supply chain to downstream users in the form of Safety Data Sheets (SDS). As

[9] Above 1000Tn/year and registrant

[10] Carcinogenic, mutagenic and toxic for reproduction (CMR) and substances dangerous to aquatic organisms or the environment (the latter above 100 tonnes a year)

[11] Above 100Tn/year and registrant

[12] Above 1Tn/year and registrant

[13] SVHCs and candidate list are described later under authorisation

under the past legislation there were significant difficulties in obtaining information on the use of substances in the EU, a new requirement was introduced in REACH: Downstream users (DUs) and distributors have to communicate up the supply chain enabling registrants to better understand the uses of their substances for registration and thereby also increasing the knowledge of authorities about all uses of substances. This two-way communication aims at ensuring more transparency and safer use of chemicals in the EU, leading to more innovation and benefits for health and environment.

Some elements for this new communication approach are well-known, some have been newly introduced:

- SDSs were a well-accepted and effective tool before REACH. One of the major adaptations was the creation of the so-called "extended SDS" which is a SDS containing the relevant exposure scenarios from the CSR.
- A new obligation to provide information, *interalia* enabling appropriate risk management measures also for substances that do not require transmission of a SDS.
- The new duty for all suppliers of articles to communicate information on SVHCs present in articles above a concentration threshold of 0.1 % weight by weight to any recipient, including consumers who so request.

For the first time in chemical legislation, REACH made DUs a distinct category of duty holders and gave them an important role within its framework. In this respect, it is important to note that in REACH the concept of use is very wide, covering a very broad area of industrial and professional operations and processes extending far beyond the chemical industry. DUs have obligations and rights stemming from many REACH titles: registration (if not covered by their supplier), information in the supply chain, evaluation, authorisation, restrictions.

Dossier and Substance Evaluation

REACH provides that the ECHA, and the Member States can evaluate the information submitted by companies, examine the quality of the registration dossiers and the testing proposals contained therein.

Dossier evaluation covers two different processes:

- Examination of testing proposals submitted by registrants, where ECHA – in cooperation with the Member States - decides whether the tests are necessary and if so, under which conditions.
- Compliance check, where ECHA – in close cooperation with the Member States verifies and decides whether the information in the technical dossiers submitted by registrants meets the standard information requirements.

Under substance evaluation, Member States evaluate substances based on initial concerns to clarify whether their use poses a risk to human health or the environment. Registrants may be required to submit further information on the substance to assist this evaluation. In cooperation with the Member States, ECHA defines prioritisation criteria and then selects the substances that are to be evaluated following the opinion of the Member State Committee. The selected substances are listed by ECHA in the 'Community rolling

action plan' (CoRAP[14]). An evaluating Member State is designated for each substance on the final CoRAP.

Authorisation and restriction

REACH also aims at managing the risks from hazardous substances through the authorisation and restriction processes.

- The authorisation requirement aims to ensure the good functioning of the EU internal market while assuring that the risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. The authorisation procedure comprises several successive steps:

  - SVHC identification and candidate listing (on initiative of a Member State or ECHA on request from the Commission),
  - prioritisation and recommendation of substances for inclusion into Annex XIV (by ECHA),
  - inclusion in Annex XIV (by the Commission), thereby subjecting substances to the authorisation requirement. Once included in this Annex, a substance cannot be placed on the market for a use or used after a given date ('sunset date') unless the companies concerned are granted an authorisation for the specific use(s),
  - application for authorisation (by industry) followed by opinions by the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC) and
  - authorisation decisions (by the Commission following a vote by the Member States in the REACH Committee).

  Authorisation is a new process introduced by REACH, where operators need to have an authorisation for continued use of a substance based on a dossier prepared by them.

- The restriction process addresses unacceptable risks to human health or the environment posed by any substance that requires Union-wide action. The manufacture, use or placing on the market of those substances on their own, in mixtures or in articles may be restricted or even banned, if necessary.

  There was already an EU-wide restriction process under the pre-REACH system to address risks at EU level and ensure the proper functioning of the internal market. REACH introduced the possibility for Member States to initiate the restriction process. It sets out clear deadlines and was expected to considerably shorten the time between the moment the risk was identified and the adoption of the restriction. New restrictions may be proposed under different procedures:

  - the *standard* procedure, launched on the initiative of a Member State or by ECHA(acting on a request from the Commission[15]), which requires

[14] Community Rolling Action Plan

the preparation of an Annex XV dossier, public consultation, opinions by RAC and SEAC and the consultation of the Forum for Exchange of Information on Enforcement (Forum);

- the *simplified* procedure, for CMR substances with consumer uses[16], where there is no preparation of an Annex XV dossier and no involvement of the Committees;
- the procedure for substances subject to authorisation; if, after the sunset date, ECHA considers that the use of the substance in articles presents a risk that is not adequately controlled and ECHA prepares an Annex XV Dossier[17].

The European Chemicals Agency (ECHA)

The REACH Regulation set up a central entity for the administration of the system, the European Chemicals Agency. ECHA ensures the effective management of the technical, scientific, and administrative aspects of REACH, providing information on REACH to companies and the general public. It also develops IT tools and guidance documents to support industry and public authorities in fulfilling their obligations under REACH.

The organisational structure of ECHA has been adapted to reflect new tasks entrusted to it under the CLP Regulation, Biocidal Products (BPR)[18] and Prior Informed Consent (PIC) Regulation. ECHA's internal structure now comprises:

- A Management Board, responsible for adopting the financial planning, work programme, and annual reporting of ECHA, inter alia.
- An Executive Director: the legal representative of ECHA, responsible for the day to day management and administration of ECHA, including responsibility over its finances. The Executive Director reports to the Management Board.
- A Member State Committee (MSC), responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs), it also provides opinions on draft Decisions of ECHA on testing proposals, compliance checks and substance evaluation. If an unanimous agreement is not reached at the MSC, the matter is referred to the European Commission for decision making. The MSC also provides non-binding opinions on ECHA's draft recommendations on priority substances for inclusion into the authorisation list (Annex XIV) and on the draft Community Rolling Action Plans (CoRAP) of substances selected for evaluation.
- A Risk Assessment Committee (RAC), prepares the opinions of ECHA on hazard and risks of substances for human health and the environment in REACH processes, i.e. on applications for authorisation, on proposals for restrictions, and on other questions relating to risk assessment of proposed legislative action (on

[15] Article 68(1)

[16] Article 68(2)

[17] Article 69(2)

[18] ECHA's structure comprises also a Biocidal Products Committee to prepare opinions on applications for approval and renewal of active substances, identification of active substances which are candidates for substitution, applications for inclusion in Annex I, applications for Union authorisation, scientific and technical matters concerning mutual recognition.

request of ECHA's Executive Director)[19].The final decisions are taken by the European Commission. The members of RAC are appointed by ECHA's Management Board based on candidates nominated by the Members States.

- A Committee for Socio-economic Analysis (SEAC), prepares the opinions of ECHA related to the socio-economic impact on applications for authorisation, on proposals for restrictions and on other questions relating to the socio-economic impact of possible legislative action (on request of ECHA's Executive Director). The final decisions are taken by the European Commission. The members of SEAC are appointed by ECHA's Management Board based on candidates nominated by the Members States.
- A Forum for Exchange of Information on Enforcement to coordinate a network of Member State competent authorities responsible for enforcement. The Forum is composed of one representative from each Member State.
- A Secretariat, under the leadership of the Executive Director, to support the Committees and Forum, and to undertake work on registration and evaluation processes as well as the preparation of guidance, maintenance of databases and provision of information.
- A Board of Appeal, to decide on appeals against certain decisions taken by ECHA.

Member States

Member States have established national helpdesks[20] to provide advice to duty holders concerning their obligations under REACH. National helpdesks are part of the HelpNet network, hosted by ECHA that promotes the provision of uniform advice to companies.

Member States have also appointed the Competent Authorities responsible for performing the tasks stipulated in the Regulation, in particular concerning evaluation, restrictions and authorisation, as well as for cooperating with the Commission and ECHA in its implementation. The Member States have to ensure that the Competent Authorities are sufficiently resourced to support their ECHA Committee Members and can fulfil their duties to prepare restrictions, identification of substances as SVHC, or proposals for harmonised classification and labelling.

Member States' authorities are responsible for enforcement by conducting official controls and establishing penalties for non-compliance. They exchange information and coordinate their enforcement activities through the Forum for Exchange of Information on Enforcement[21].

European Commission

The Commission has the ultimate responsibility to take decisions on risk management measures (such as restrictions and authorisations), and takes decisions under the

[19] RAC also prepares opinions of ECHA on proposals for harmonised classification under CLP

[20] The countries of the European Union, Norway, Iceland and Liechtenstein run helpdesks who give support on questions related to REACH obligations. In many cases, they are located in national competent authorities. These national helpdesks are the first point of contact for companies based in those countries.

[21] More information is available on the website of the Forum for Exchange of Information on Enforcement

evaluation process, where ECHA does not succeed to decide due to lack of unanimity in its Member States Committee.

The Commission has the right of initative related to risk management measures: it can initiate the restriction process (either directly or via ECHA), and it can request ECHA to initiate the process for the identification of substances of very high concern.

Furthermore, the Commission oversees activities to ensure the harmonised implementation of REACH by organising regular meetings of the competent authorities where all issues requiring agreements among the authorities, such as interpretative questions, are discussed.

Lastly, the Commission has to monitor the operation of the Regulation and is empowered to adopt amendments to its Annexes for adaptation to technical progress. The Commission is also empowered to adopt regulations to supplement the REACH Regulation (e.g. through Regulations on test methods, fees and charges) and implementing Regulations (e.g. data sharing).

2.2. An overview of the chemical industry and related sectors

The chemical industry is one of Europe's largest manufacturing sectors, with annual EU chemical sales estimated at EUR 519 billion[22], equivalent to around 14.7% of global sales. While absolute sale figures remained relatively stable over the last ten years, EU production has fallen strongly as a percentage of the global market as a result of the growth of emerging markets, especially China. The sector comprises over 28,000 companies, who employ around 1.13 million persons. Around 96% of European chemical companies are SMEs. They provide more than one third of all the industry's employment and generate about one third of the sector's value added. The sector generates a value added of about EUR 115 billion[23] (representing about 0.8% of EU GDP) and has a trade surplus of over EUR 40 billion per year. In 2016, extra-EU chemicals exports were EUR 146.3 billion and extra-EU imports reached EUR 98.6 billion.

Besides the chemical industry described above, one of the manufacturing sectors considered to be most directly affected by REACH is metal manufacturing. Altogether, those two sectors (chemical industry and metal manufacturing) account for a comparable proportion of GDP, contribute roughly EUR 126 billion in Gross Value Added, and account for around 1.5 million jobs[24].

As an "enabling industry", the chemical industry is at the heart of the EU manufacturing industry, supplying two-thirds of its production to other sectors within the manufacturing industry. Thus, a large range of downstream sectors rely on the use of chemicals in their everyday activities, such as the automotive and aerospace sectors, the paper and pulp sector, as well as the manufacture of everyday goods such as textiles, cosmetics, toys, etc. Other important links exist with agriculture activities and services.[25] It should be

[22]Estimations by CEFIC for 2015, based on NACE 20

[23] Eurostat 2014 figure for NACE 20

[24] Fitness Check final report

[25] Further details and economic figures are provided and analysed under the sections dealing with internal market and competitiveness

noted that REACH does not only affect the chemicals industry, but also all of these downstream user industries.

2.3. Baseline: pre-REACH (extended Impact Assessment) and the 2013 REACH review

In order to assess the progress of REACH over its full 10 years this second REACH evaluation uses the pre-REACH situation and the expectations foreseen in the original extended impact assessment[26]or the estimates for ECHA annual workload[27] as the baseline. At the time, estimations were made on the costs of REACH, the number of substances that would be registered and the timing and the subsequent regulatory REACH measures

That baseline has already been considered, through the first assessment of the implementation of REACH that was carried out after five years of operation of the Regulation and published in 2013 – the "REACH Review 2013"[28]. The Commission undertook a broad assessment based on Member State and ECHA reports, as well as thematic studies carried out by external consultants under the supervision of the relevant units of the Commission.

The REACH Review 2013 concluded that REACH functioned well and delivered on all objectives that could be assessed at that time. Some needs for adjustment were identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concluded that changes to the enacting terms of REACH would not be necessary.

The Commission noted however, a need to reduce the impact of REACH on SMEs and set out measures that would contribute to that goal. Many other opportunities for improvement at all levels were set out in the Commission Report and were further described in a Staff Working Document. Where relevant, the state of play of implementation of the different REACH chapters at the time of the REACH Review 2013 is also taken into account for this REFIT evaluation.

3. EVALUATION QUESTIONS

The Commission services will examine the effectiveness, efficiency, proportionality, coherence, relevance and EU added value of the provisions of the REACH Regulation, focusing on the elements set out in the previous sections. The evaluation will be guided by the following questions:

3.1.1. Effectiveness

1. To what extent does REACH meet its objectives?

[26] SEC (2003) 1171

[27] 2006 Revised Legislative Financial Statement – SEC(2006)924 2006 Revised Legislative Financial Statement – SEC(2006)924

[28] COM (2013) 49 final and SWD (2013) 25 final

2. What have been the effects of REACH (whether socio-economic, environmental or health-related, both positive and negative), including also effects not originally planned?
3. What factors (including external ones) influenced the observed effects and to what extent?
4. To what extent is REACH contributing to meeting the World Summit Sustainability Development 2020 goals?

3.1.2. Efficiency

1. What are the costs and benefits associated with the implementation of REACH? To what extent are the costs proportionate to the benefits achieved?
2. What are the key drivers for those costs and benefits? What factors influenced the efficiency with which the accomplishments of REACH were attained?
3. Was the distribution of costs proportionate between the different stakeholders (e.g. larger companies vs. SMEs, or among different industrial sectors)? To what extent are there unnecessary burdens on stakeholders?
4. How are costs distributed among public authorities at EU and national levels?
5. What aspects of REACH (including procedural aspects) are the most efficient and what are the least efficient (including the development of scientific opinions, work of scientific committees, urgency procedures, etc.)? Are there case studies demonstrating highly efficient or inefficient working of REACH processes? Are there differences in efficiency between Member States (both in terms of delivery of objectives and the costs of doing so)?

3.1.3. Coherence

1. To what extent are the different work processes, including their output, in REACH interacting in a coherent manner?
2. The REACH review 2013 examined the coherence of REACH with other chemical legislation. To what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?
3. To what extent is REACH coherent with international efforts, including chemical legislation in third countries?

3.1.4. Relevance

1. To what extent is REACH capable of adapting to evolving needs (e.g. through adaptations to technical and scientific progress)?
2. To what extent is REACH relevant to the EU and its citizens?
3. To what extent is REACH capable of taking into account health, consumer and environmental concerns, and social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?

3.1.5. EU added value

1. What is the additional value of regulating the risk management of chemicals at EU rather than at Member State level?

4. METHODOLOGY

4.1. Evidence collected since 2013

The first REACH review concluded that more information was necessary to determine whether to review information requirements for the registration of substances produced in low tonnages and of certain polymers. In addition, the Commission proposed a more systematic approach concerning the collection of information and reporting on Member States' activities, including their enforcement activities, as well as work to address difficulties in relation to substance identity and sameness. Moreover, there was a need to improve the methodology to assess and quantify the benefits arising from the implementation of REACH.

The need to monitor regularly the effects of the implementation of REACH was also highlighted in the REACH review 2013, in particular as regards industry preparedness for the 2013 and 2018 registration deadlines, and effects on innovation, SMEs and international competitiveness. A number of thematic studies were launched in those areas as a follow-up to the REACH review 2013 (overview in Annex 3).

As well as those thematic studies, extensive evidence on the functioning of REACH is periodically reported to the Commission by Member States and ECHA in accordance with the requirements of Article 117 of the Regulation. Member States submitted their latest reports in 2015, while ECHA submitted its report on the functioning of REACH in 2016 and two reports on the use of alternative methods to animal testing (in 2014 and in 2017). In addition, ECHA published reports and other relevant documents[29] on particular areas of REACH implementation that present additional evidence for this REFIT evaluation.

A wide range of stakeholders (companies, associations, NGOs, trade unions, MSs etc) exchange views regularly[30] with the Commission services, highlighting key issues in relation to the implementation of REACH. In this context, the Commission has underlined the importance of presenting data to describe and possibly quantify the issues raised when providing input for the REACH evaluation process.

Several thematic studies were launched in the course of 2015 and 2016 in order to further develop the knowledge and evidence base for the second REACH review. Those studies aimed to enable the Commission services to undertake a systematic analysis, address information gaps and monitor progress towards achievement of the REACH objectives. In particular, studies were designed to monitor reduction of risks and improvement of the quality of data available for chemical risk assessment, to review the performance of ECHA and to assess the impacts of the authorisation process. All relevant details can be found in Annex 3.

A roadmap[31] was developed and published presenting the key questions to be addressed by the evaluation, as well as a consultation strategy to ensure stakeholders' engagement in the evaluation process.

[29] E.g. annual reports, implementation report for the SVHC roadmap, regulatory strategies

[30] E.g. Competent Authorities for REACH and CLP (CARACAL)

[31] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

The Commission Services involved in the development of REACH and its implementation over the last 10 years have accumulated significant experience and insights to the implementation and functioning of REACH. This experience and insights are also used in this evaluation to draw conclusions and identify key findings to prioritise for immediate action. Priorities were established on the basis of the main shortcomings with the implementation of REACH in the last five years, considering also the concerns raised by stakeholders.

4.1.1. Approach to quantification

The REACH Regulation provides a comprehensive regulatory system expected to deliver short term benefits but also long-term benefits, such as positive effects on human health, which were expected to materialise 10 years after the start of REACH implementation. On the other hand, other effects such as the costs and resources necessary for companies and public authorities to adapt to the requirements of REACH materialise immediately. In spite of the experience gained so far, the implementation of REACH is still in a relatively early stage and benefits are only starting to materialise and cannot yet be quantified; accordingly, at this stage, the evaluation does not (and cannot) aim for a full quantitative comparison of benefits with costs.

The evaluation thus focuses on monitoring progress, assessing the outcomes of the intervention so far and comparing those results with expectations. A first strand of work is comparing the costs (to the extent that relevant costs can be quantified) with the expectations stated in the Impact Assessment for the REACH proposal. Moreover, attempts to qualify and quantify benefits have been carried out, while keeping in mind the present limitations. In addition, the evaluation seeks to identify key issues and opportunities for improvement in all areas of REACH implementation.

4.1.2. Data collection[32]

Several thematic studies (see Annex 3 for the details of the 16 studies) have been carried out by external consultants for the Commission services. The main methodologies applied in the context of those studies are described below:

- Desk research was conducted in the early stages of most thematic studies in order to review existing literature, gather available data and identify information gaps that would need to be filled. Reports from Member States and ECHA were also analysed to extract key issues and data. Results from ECHA meta-analysis studies were also used to derive costs and benefits for the authorisation and restriction processes
- Surveys were conducted in several studies in order to gather information available from particular stakeholders (e.g. costs information from companies) as well as to get a systematic collection of stakeholders' views on specific areas (e.g. performance of ECHA).
- Interviews have been conducted in several studies to complement surveys and obtain in-depth insights into issues raised by stakeholders in the context of surveys.

[32] An extensive list of the studies used as evidence-base for the REACH evaluation is included in Annex 3 to this Staff Working Document, including details about the individual approach and methodology for data collection and models applied by each study. All studies are publicly available in the webpage of the REACH evaluation (http://ec.europa.eu/DocsRoom/documents/26825)

- Workshops and ad hoc focus groups were arranged in the context of several studies to discuss the early findings and obtain feedback and additional expert opinions on the topics addressed by the studies.

According to the objectives stated in the consultation strategy[33] for the REACH evaluation, stakeholder consultation is a key component to gather evidence, data and information on REACH implementation. Thus, a structured approach was developed to collect information from stakeholders. Feedback from all the categories of stakeholders identified in the consultation strategy has been obtained through the consultation activities carried out.

Table 1: Feedback collected through consultation activities by stakeholder group

	Public authorities	Industry associations	Companies / SMEs	Civil society (NGOs)	Consumer associations	Trade unions	Consumers / workers / citizens	Third countries
Online public consultation	√	√	√	√	√	√	√	√
SME panel			√					
Stakeholder questionnaires	√	√		√	√	√		√
Stakeholder interviews	√	√		√	√	√		√
Stakeholder workshop	√	√		√	√	√		
Expert group	√	√		√				√
Eurobarometer Survey							√	

Annex 2 to this report provides a detailed summary of the consultation activities and results obtained, including the online public consultation and SME consultation that ran between the end of October 2016 and the end of January 2017.

4.1.3. Limitations and robustness of findings

Despite best efforts, there are a number of challenges in the analysis:

- While extensive information on the functioning of REACH is available, it is often rather general, based on individual appreciations and it is difficult to say how representative these views or examples are. Thus, one of the difficulties for the evaluation was to extract relevant, robust and reliable evidence from a "large pool of information" that would allow a qualitative and quantitative description of the effects of REACH. Therefore great care was taken to accurately report the context and relevance of reported information.
- The relatively early stage of implementation mentioned above is one of the challenges for a comprehensive evaluation of REACH and in particular its benefits. It is acknowledged that some benefits will still manifest in the next 10 years.
- The complexity and far-reaching effects of REACH, affecting society and a broad range of sectors well beyond the chemical industry as well as the environment make it difficult to provide a systematic and detailed account of all the effects. Therefore the evaluation concentrates on the main objectives of REACH.

[33] Published at http://ec.europa.eu/DocsRoom/documents/17785

- Verified data are difficult to obtain. Efforts were made to estimate costs using a statistically robust sample of respondents and, where possible, to crosscheck with findings of previous studies on the implementation of REACH or additional sources of data. However, cost estimates often rely on data collected through company surveys with limited possibilities to establish whether questions have been understood in the same way, and whether the data are representative, or to compare and validate them.
- Finally, assessing causality between REACH and the effects observed on the ground is not straightforward. REACH in itself is complex but it is also designed to complement obligations stemming from a multiplicity of other EU legislation and national rules. An economic operator therefore often does not clearly understand if an obligation actually stems from another piece of legislation or from REACH. In addition REACH replaced a significant number of directives and regulations and therefore the assessment of REACH needs to disentangle the baseline (continuation of the pre-REACH legislation) from the additions coming from REACH. In addition, there are a large number of intervening factors at play (e.g. economic cycles, evolution of chemical markets worldwide) making it very difficult to attribute the parts of an observed effect to REACH.

5. IMPLEMENTATION STATE OF PLAY

This section provides an overview of the state of implementation of REACH, presenting key findings on the main chapters of the Regulation. A detailed analysis and evaluation of the technical dimension of the implementation of each chapter is presented in Annex 4.

5.1. Registration

A key chapter of REACH is the requirement for registration of substances. The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these.

The first registration deadline in 2010 was assessed as part of the 2013 REACH Review, which drew a number of conclusions on, for example, compliance of registration dossiers. The second registration deadline was in 2013 (after adoption of the REACH Review) and the third deadline is in 2018.

Since the 2013 REACH Review progress can be observed on how industry fulfils its obligations as regards submission of dossiers and how more data are becoming available for the risk assessment of chemicals. Generally, the system is working well and as envisaged; however, some issues have been identified in particular in relation to the quality of dossiers. The costs of registrations are dealt with in Annex 4 - part of registration and in efficiency questions.

Key findings on the implementation of registration include:

- Registration is taking place. By December 2017[34], ECHA had received and disseminated more than 65 000 dossiers for approximately 17 000 unique registered substances since REACH came into operation, which is broadly in line with the original estimates of the Commission. The 'one substance, one registration' principle is largely respected, and is being further promoted.
- The availability of data for risk management (through registration dossiers) is improving as seen in the quality scores[35]. In particular availability of exposure scenarios has improved. This is making more information available to manage the risks from substances.
- Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action.
- The update of registration dossiers by companies is still a weak point, only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA. ECHA concluded in 2016 that stronger incentives may be needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. The only incentive working in practice might be enforcement actions by the Member State Competent Authorities on dossiers which updates are overdue.
- REACH provisions concerning the registration of intermediates[36] are not fully coherent and have caused uncertainty for both registrants and regulators.
- A review of the Commission Recommendation on the definition of a nanomaterial is ongoing. Work is also ongoing for the amendment of Annexes to the REACH Regulation to clarify the registration requirements for nanoforms of substances.
- Further work is needed for the development of a useful system for the possible registration of polymers of concern for human health and/or environment, taking account of competitiveness and innovation.
- Two changes to the registration requirements in the low tonnage band (1-10t) are being considered by the Commission to improve risk management of hazardous substances due for registration by 2018; increasing standard information requirements and obliging the Chemical Safety Report for the CMR 1A or 1B. Both need further study to assess the affordability for SMEs.
- In the light of data-sharing obligations that will continue to apply for registration and evaluation, the consequences of the time limitation of the obligation for SIEFs to stay operational until 1 June 2018 as stated in Article 29 of REACH need further consideration.

[34] More information available on ECHA's website: Registration statistics infograph - ECHA

[35] REACH Baseline study: 10 years update (2017) - http://ec.europa.eu/growth/sectors/chemicals/reach/studies_en

[36] A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (Article 3 (15)).

- There is work ongoing to improve the completeness and compliance of registration dossiers and to support the 2018 registration deadline, which is expected to involve a large number of SMEs.

5.2. Data sharing, test methods and avoidance of unnecessary testing

The hazardous properties of chemicals cannot be sufficiently determined using currently available in vitro (non-animal) testing methods. As REACH requires information to be gathered, the implication would be an increased use of laboratory animals. To minimise animal testing, REACH requires companies to share data and obtain approval in advance for certain tests. The Commission is also active in the field of developing, validating and promoting the regulatory use of alternative test methods, for example through the Framework Programme for Research and the European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM).

Key findings on the implementation of data sharing, test methods and the avoidance of unnecessary testing include:

- Since the 2013 REACH Review, the data sharing process has been further improved, and is the most important contributor to avoiding animal testing.

- The REACH principles of sharing and joint submission of data on intrinsic properties of a substance generally work well. Data sharing between structurally similar substances suitable for read across and categorisation purposes has the potential to further avoid animal testing and also to identify hazards earlier and thereby manage risks faster, but is hampered by the absence of obligatory data sharing between structurally similar substances in REACH.

- Amendments to the standard information requirements have introduced test methods that lead to a reduction or replacement of testing on vertebrate animals, such as the requirement for the extended one-generation reproductive toxicity study (EOGRTS). However, test methods containing optional modulation, as in the case of EOGRTS, cause difficulties in implementation and may lead to re-testing should conditions change.

- 38 new (alternative) test methods have been introduced in Regulation (EC) No 440/2008 and 24 methods have been updated in the last 5 years via Adaptations to Technical Progress (ATPs); these methods were first endorsed by the OECD Test Guidelines Programme. ECHA and the Commission's Joint Research centre provide initial advice on new OECD Test Guidelines and their possible use for the purpose of REACH, while inclusion in the Regulation provides legal clarity but only after a time- and resource-intensive process. Further assessment is needed to determine whether the current process can be improved, in particular in terms of regulatory readiness and regulatory acceptance of alternative methods and whether the process could be further optimised while retaining scientific soundness and legal certainty.

- Information from the third ECHA report[37] on the use of alternatives to testing on animals for the REACH Regulation confirms that the main source of experimental data for low tier endpoints are studies performed before REACH came into force.

[37] Link to Third ECHA report on the use of alternatives to animal testing

Endpoints outlined in REACH Annexes VII and VIII are considered as low-tier endpoints, while endpoints listed in REACH Annexes IX and X are considered as high tier endpoints. Less experimental data is available for high tier human health endpoints. For high tier environmental endpoints adaptations (such as QSAR or read across) are much more common than experimental data. This report also shows a continued high use of the adaptation possibilities offered in Annex XI, in particular read-across. This confirms that many registrants seriously implement the legal requirements to propose testing on animals only as a last resort. However, the adaptations used by registrants have often been found to be insufficiently justified, especially when the conclusion is the absence of a given hazard and in case of non-compliance, further testing is requested. ECHA has recently increased efforts to provide improved information and guidance to registrants, in order to improve the quality of adaptations. Consequently, less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted.

- Although validated and accepted alternative test methods are available for certain endpoints (notably skin and eye irritation), and these methods are frequently used in REACH Registration dossiers, there are still a significant number of recent in vivo tests submitted for those endpoints. The reasons for this need to be further explored in detail, but limited analyses point to regulatory requirements in third countries as an important driver for animal testing, highlighting the need to further work towards the international acceptance of alternative methods.
- The Commission makes significant and sustained financial efforts to support the research on alternative methods, as well as the subsequent steps (e.g. validation and test guideline development) leading to regulatory acceptance. During the period 2012-2016, Commission expenditure has been around EUR 40 million per annum. However, there are still gaps in terms of alternatives for some endpoints.

5.3. Communication of information in the supply chain

Communication within the supply chain is a central theme in REACH, as it ensures the passing on of information on hazards of substances, risks associated with their use and the necessary risk management measures down the supply chain to ensure safe use. In addition, downstream users need to pass information on how they use chemicals up the supply chain.

Since the 2013 REACH Review efforts have been made to improve communication along the supply chain. Companies are increasingly engaged in the elaboration and transmission of extended safety data sheets (SDSs), with the support of different activities launched by ECHA (see Annex 4, paragraphs 3.1.1 and 3.1.2 for more details), resulting in improved communication promoting safer use of chemicals including complying with the requirements of occupational safety and health legislation. However, information flows do not always work well.

Key findings on information in the supply chain include:

- The introduction of extended SDS has led to improvements in communication and more transparency in the supply chain. Around a half of companies have adopted changes in risk management measures on the basis of information received via extended SDS. However, in a significant number of cases, the information

communicated is too lengthy and technical, or does not provide enough practical information to implement appropriate risk management measures.

- Responding to the problems identified in the 2013 REACH Review, a number of tools have been put in place to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS. These appear to be having a positive effect, but could be more fully used.
- Many companies, and in particular SMEs, consider extended SDS as burdensome and too technical to be fully understood mainly due to lack of in-house expertise. This prevents SMEs from using the information on the properties and use of substances in order to manage risks at their workplaces. In some cases the lack of information or the poor quality of particular exposure scenarios was underscored as an obstacle for formulators to prepare good quality SDS for their mixtures. The costs associated with the obligation to transmit information in the supply chain (which includes management of extended SDS and their translation) was also raised as problematic, in particular as most of the transmission is currently done manually (i.e. on paper).

5.4. Information on substances in articles

Producers and importers have to notify to ECHA the substances listed on the Candidate list which are present in their articles, under certain conditions:

- The substance is present in their relevant articles above a concentration of 0.1% weight by weight.
- The substance is present in these relevant articles in quantities totalling over one tonne per year.

The notification information can be used together with other sources (e.g. registration information) to support identification of further needs for risk management. If there are grounds for suspecting that the substance is released from the articles under normal or reasonably foreseeable conditions of use and such a release presents a risk to human health or the environment, then the producer or importer of articles may be required to submit a registration.

Since the 2013 REACH Review progress can be observed as to how industry fulfils its obligations as regards substances in articles, and how this information is communicated and used. However, whilst the situation may be improving, it is still not working as well as originally envisaged.

Key findings on substances in articles include:

- Divergence between Member States in the interpretation of the 0.1% threshold limit regarding notifications to be submitted to ECHA (Article 7(2)) and regarding communication in the supply chain and to consumers (Article 33) of REACH has been resolved by a ruling of the European Court of Justice. This provides a common basis for the harmonised implementation of the requirements related to SVHCs in articles, and for increased and coordinated enforcement activities.
- The amount and adequacy of information in registrations dossiers for the safe use of substances in articles is still very limited. Fewer than expected notifications to ECHA have been provided, because of: a lack of awareness; difficulties to get the information needed, especially from third country suppliers; descriptions of uses in articles in registration dossiers being too broad; costs of communication for example

due to complexity; a lack of methods to assess the safety of substance uses in articles (e.g. release and exposure estimation methods); a lack of methods to measure the content and release of SVHCs in articles. This limits the usefulness of such information for the identification of appropriate regulatory measures.

- The obligations to communicate the presence of SVHCs in articles allows operators along the supply chain to implement appropriate risk management measures as well as enabling operators and consumers to make informed purchasing decisions. This is happening, as information flows improve, but slower than foreseen reflecting perhaps the costs of managing the information flows and the need to learn from experience.
- Efficient functioning of supply chain communication is necessary for economic operators to implement appropriate risk management measures and to make informed purchasing decisions as well as for the ability of suppliers to respond to consumer requests. The communication requirement in Article 33 has triggered the development and potential use of information management tools by companies promoted by EU-projects or activities of some Member States. However, it remains difficult for actors in the supply chain to retrieve, verify and communicate information on SVHCs in articles. The transfer of information to the consumer greatly depends on a well-functioning communication in the supply chain as well as on the awareness and understanding of consumers about their "right to know".
- Better tracking of chemicals of concern in products would facilitate recycling and improve the uptake of secondary raw materials, as part of the Circular Economy. However, this would require transfer of information on the chemical content of end-of-life articles to the waste management sector.

5.5. Substance and dossier evaluation

Evaluation is a set of processes in which ECHA and the Member States evaluate the information submitted by companies in registration dossiers to (1) under dossier evaluation, check compliance of the registration dossiers and examine the registrant's testing proposals for higher tier studies that require the use of vertebrate animals[38], and to (2) clarify under substance evaluation if the use of a given substance constitutes a risk to human health or the environment.

The evaluation processes often result in legally binding decisions whereby registrants are required to update their dossier(s) with further information on the substance within a specified deadline. Further regulatory risk management action(s) may be initiated by the authorities as a follow-up of the evaluation conclusions.

Both dossier and substance evaluation processes are operational and contributing to an important extent to the generation of relevant data on chemicals. Both processes are continuously evolving as challenges are identified and addressed on the basis of experience. This however requires time and resources from ECHA, the Member States and the industry. Further modifications to the existing procedures could be considered to improve the level of efficiency and effectiveness.

[38]In case information (study) is not already available, it must be proposed, unless an adaptation is provided, in accordance with the general rules for adaptation set out in Annex XI to REACH or the specific rules for adaptation set out in column 2 of Annexes VII to X to REACH.

Key findings on the implementation of dossier and substance evaluation include:

The integrated regulatory strategy developed by ECHA[39] provides an adequate framework to identify and prioritise "substances that matter".

- By the end of 2016, in terms of dossier evaluation, 748 testing proposal examination decisions had taken place. Around 220 compliance checks a year were taking place. Follow up to dossier evaluation decisions is an increasingly important part of ECHA's work. There are technical challenges, such as the changes in the reproductive testing approach. These need to be addressed given that dossier evaluation is the main means to ensure the required information is being gathered in registration, which has a direct impact on ensuring REACH delivers its objectives.
- Fewer substance evaluations have taken place than predicted, with 82 decisions by ECHA on substance evaluation adopted so far. This falls far short of expectations of 448 substances evaluated by 2016. If more substances would be evaluated by the Member States, this would benefit the implementation of the integrated regulatory strategy conducted by ECHA.
- The administrative processes associated to dossier and substance evaluation and the time needed to generate information is taking a lot of time. An effort needs to be made to speed up the processes by: improving choices about whether to initiate dossier evaluation or substance evaluation; whether to run substance evaluation and compliance checks in parallel; whether to start substance evaluation in parallel to restrictions or authorisation.
- Dossier and substance evaluation processes are working but need to be improved so that they can deliver faster and better, and do not represent the bottleneck in the 'pipeline' of the integrated regulatory strategy. Over half of the registration dossiers have been found non-compliant, suggesting that industries have to generate further information.
- Modifications of individual steps in the formal evaluation procedure may also be considered to further improve its efficiency and effectiveness in particular with regard to the third party and the two-step registrant consultation, but also the roles of the Member State competent authorities and the MSC.
- With compliance checks limited to 5% of dossiers[40] and a comparatively even much smaller number of substance evaluations, the formal evaluation processes cannot be the main data-gap filling solution. The compliance check target linked to individual tonnage bands seems ineffectual in light of the evolution of the integrated regulatory strategy, the common screening which already now combs through all registrations and the possibility of addressing groups of substances. Therefore the compliance check target should be revised accordingly.
- In the longer-term, evaluation will need to move from successfully addressing dossier deficiencies and concerns of high volume substances (due to some specific endpoints such as carcinogenicity, reproductive toxicity), to the assessment and improvement of other endpoints. Evaluation should eventually reduce to monitoring the continuous

[39] The integrated regulatory strategy is further described in section 6.3.1.1 (internal coherence of REACH)

[40] The 5% target applies per tonnage band without time limit and it is multiannual by nature

compliance of all the dossiers in light of technological development and registration of new substances.

- Evaluation decisions are an important driver to generate new information; also in the recent decision of the European Ombudsman concerning the delay by the European Commission in processing files on reproductive toxicity of chemicals, the lack of incentives for registrants to spontaneously update their registration files despite their obligation is, together with the enforcement difficulties, have been identified as the main cause of the delay to generate new information.

5.6. Authorisation

Substances with specific hazard effects on human health and the environment can be identified as substances of very high concern (SVHCs)[41] and added in a Candidate List for possible inclusion in the Authorisation List (Annex XIV) and thus be subject to authorisation.

Manufacturers, importers or downstream users need to have an authorisation for the placing on the market or the use of a substance on the Authorisation List. Authorisations are granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. If not, an authorisation may still be granted if it is proven that the socio-economic benefits of using the substance outweigh the risk to human health or the environment and that there are no suitable alternative substances or technologies.

There is some evidence[42] that the objectives of authorisation are being achieved through the progressive substitution of SVHCs by suitable alternatives and the reduction of the risks through controlled use.

Key findings on the way in which substances of SVHCs are identified and added to the Candidate List, and subsequently prioritised and included in the Authorisation List (Annex XIV) include:

- The SVHC Roadmap is proving an effective tool[43] through setting out priority criteria and a methodology to ensure that, by 2020, all known relevant SVHCs are included in the Candidate List. It is improving regulatory coherence, transparency and predictability. For more information see annex 4 paragraph 6.1.2 and 6.2.
- The work under the SVHC Roadmap is progressing beyond expectations. More than 600 substances have been screened and for the relevant ones (159) a Regulatory Management Options Analysis[44] (RMOA) has been prepared. All the substances with

[41] Meeting criteria for classification as carcinogenic, mutagenic and toxic for reproduction 1a and 1b (CMR), persistent, bio accumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and other hazard substances such as endocrine disruptors raising an equivalent level of concern.

[42] Link to Study on the impacts of REACH authorisation - final report

[43] According to the public consultation conducted for REACH Evaluation, industry stakeholders perceive the implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), as a positive factor contributing to coherent implementation of authorisation and restriction under REACH.

[44] Originally the RMO stood for risk management options. To avoid confusion with the obligations under Article 69 to prepare an annex XV dossier when a risk has been identified and the obligation in Annex XV to determine the most appropriate Union wide measure to address the identified risk and to better reflect the actual work done, the RMO is now called Regulatory Management Options. Regulatory

confirmed SVHC properties have been assessed. Further work is on-going for 500 cases where data are being assessed or further information and data generation is needed before analysing the most appropriate regulatory action. The focus should now move to identifying new SVHCs, generating information on hazard properties and speeding up the process through addressing similar substances together in groups.

- Encouraging as many companies as possible to substitute SVHCs early enough so that they do not have to apply for authorisation at all is one of the main challenges in the implementation of REACH authorisation. Inclusion of substances in the Candidate List works as a driver for the companies concerned to look at the possibilities of substitution[45] (more information can be found in annex 4 paragraph 6.2)
- Between 2013 and 2017, 36 substances were included in the Candidate list, meaning that in total 174 substances were listed. The rate of inclusion has slowed down compared with the period of 2007-2012 where 138 substances were included in the candidate list. This is due to the fact that, since 2012, more complex cases, such as Persistent, Bioaccumulative and Toxic (PBT), very Persistent, very Bioaccumulative (vPvB) substances and substances of equivalent level of concern[46,] were screened out, requiring more detailed RMOAs and, in some cases, generation of new data.
- The Authorisation List (Annex XIV) contains 43 substances by June 2017, less than estimated in the baseline (approximately 120 substances by 2016[47]). As announced in the Commission REFIT Communication in 2014[48], the Commission has introduced some measures to improve the authorisation process and is considering further measures to improve the authorisation process and make it more predictable. These measures include reducing the frequency of amendments of the Authorisation list (done), simplifying the authorisation process for some specific low-risk cases (ongoing) and consideration of socio-economic impacts when including new substances in the Authorisation list (done).
- ECHA had received by March 2016 applications for authorisation for only 21 out of the 31 substances included in Annex XIV. This may be an indication that substitution is taking place for all or at least part of the remaining 10 substances. The authorisation process is leading to substitution even from the early point of inclusion in the candidate list.
- The implementation of the new authorisation application process has met numerous challenges; being a new process, the general working procedures still have significant

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Management Option (RMO) Assessment is the process for identifying the best regulatory option for a substance. The RMO Analysis is the document presenting the information on the substance, the possible options and the preferred one.

45 Survey of (CSES 2015 et al) found that about 20% companies responded to placing of a substance relevant for their business on candidate list by launching R&D to develop new substances and further 30% launched initiatives to find alternative formulations of existing substances

46 Meeting criteria set out in Article 57(f)

47 8 substances in 2011, then 12 added in 2012 and 25 per year thereafter as it was expected that the identification of substances of very high concerns would become easier due to a better knowledge of chemicals through the REACH processes

48 COM (2014) 368 " Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook"

margin for improvement. Although important efforts have been made such as in the case of use in low volume or in the case of use of legacy spare parts[49] by the Commission services to make the process clearer and simpler.

- There is still room for improvement in particular for applications submitted by upstream operators in the supply chain and a guidance document has been recently published on *How to apply to authorisation* to help companies to be more precise on the description of uses, on the representative exposure scenarios, on the socio-economic analysis.
- The costs of applying for authorisation remain high for individual companies, even though they have decreased (i.e. from EUR 230 000 on average per substance, use and applicant for the first applications in 2013 to EUR 120 000 in 2016). More details are included in the Annex 4, paragraph 6.7
- Recent efforts to clarify the required information for applications for a wide scope of uses or covering many different operators should be assessed as soon as sufficient evidence becomes available to see whether they have led to good quality applications. Such improvement will be key in making the process work efficiently, and will make it less controversial to subject new substances to authorisation in the future.
- When substitution is not possible, there is evidence that authorisation has led to an improvement in the risk management of SVHCs, reducing workers' exposure and emissions to the environment. This was proved by several applications for authorisation prepared by the companies. Companies are actively seeking to substitute and investing in substitution related activities.
- Feedback from applicants, the ECHA Committees, Member States and interested stakeholders will continue to be necessary for identifying and resolving remaining challenges. Ongoing activities such as Commission workshops and ECHA dialogues with the applicants will help to reinforce such improvement.
- As an example, for non-threshold substances applicants should describe the remaining risk quantitatively/semi-quantitatively assuring that the exposure levels are as low as technically and practically possible which then has to be assessed by RAC. This information on the remaining risk is an input to the socio-economic analysis of the applicant to be assessed by SEAC in order to consider if the benefits of continued use outweigh the health and environmental impact[50].
- In relation to the competitiveness and innovation of EU industry both negative effects (possible relocation and competitive disadvantage for EU industry as a result of imported articles not being subject to authorisation) and positive effects (development of alternatives) have been raised by industry. Those are further described in section 6.1.1.3. and annex 5 paragraph 2.4.2.

[49] uses of Annex XIV substances to produce legacy spare parts for certain articles (for example aircraft and motor vehicles) where the substance is required for repairing an article that is no longer produced after the sunset date

[50] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0814&from=EN

5.7. Restriction

Restrictions limit or ban the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article, including imports.

A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Union wide basis. ECHA can also propose a restriction on articles containing substances that are in the Authorisation list (Annex XIV). Anyone can comment on a proposal to restrict a substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

Since the 2013 REACH Review, new restrictions have been proposed but at a slower pace than expected. This seems to be driven by a number of factors including lack of information to identify good candidates, and a demanding process that puts Member States off from proposing restrictions. A number of efforts are being made to improve the efficiency of the process.

Key findings on the implementation of the restriction process include:

- During the period between January 2011 and December 2016, the Commission adopted 13 restrictions under Article 68(1). Overall, the number of restrictions initiated per year is about the same as in the final years of the pre-REACH system. This falls far short of expectations at the time of adoption of REACH of 11 restrictions per annum.
- A barrier to effectiveness is that it is difficult for Member States to find and invest resources in the preparation of Annex XV dossiers, which are demanding in terms of their technical/economic content. One Member State estimated the costs of preparing a proposal for restrictions under REACH to be between EUR 0.5 -1 million. Other barriers include high demands by the ECHA Committees during their opinion-making process.
- The evaluation has shown that EU companies are at a competitive disadvantage in relation to imported articles containing CMR substances because they are generally not used in the EU in consumer articles. In these cases, a restriction can be enacted to prevent the introduction of articles containing these CMR substances in the EU market via the simplified procedure envisaged in article 68(2)[51]. This would provide a level playing field between EU and non-EU companies. The competitive disadvantage of economic operators in EU should also be considered when introducing a restriction by advancing the start of the restriction process initiated by ECHA (see Annex 4 paragraph 7.3) for substances subject to authorisation and present in articles (Article 69(2)[52]).
- The efficiency of the REACH restriction process has so far not met original expectations, but it has been improved since 2013 on the basis of the recommendations of the Restriction Task Force[53] and of the enhanced cooperation of

[51] A restriction for consumer articles for CMR (categories 1A and 1B) substances listed in Annex XIV.

[52] The Agency shall prepare an annex XV dossier when a risk has not been adequately controlled for the use of the substance (listed in Annex XIV) in articles.

[53] The Restriction Task force is composed of members from Commission, ECHA, RAC and SEAC and Member States as Dossier submitters.

authorities (Commission services, ECHA and Member States eg through common screening and regulatory management option analysis) in the preparation of new proposals for restrictions. (Further information is provided in annex 4 paragraph 7.4.1).

- There is room for further improvement in the restriction process. The implementation of the recommendations of the Task Force is "work in progress". The activities will continue on the basis of experience gained in the preparation of Annex XV dossiers, ECHA should review the requirements for the conformity check and continue its efforts to obtain a maximum of information through the public consultation. RAC and SEAC should diligently scrutinise the information submitted in the dossier and via the public consultation, including in particular requests for exemptions. Finally, the Commission services intend to provide guidance to RAC and SEAC as to how to adopt opinions when, despite all efforts, information is lacking.

5.8. Member State activities other than enforcement

Every five years, Member States submit to the Commission a report on the operation of this Regulation in their respective territories. These Member State reports provide information on issues such as Competent Authorities activities, work of the helpdesks, and the Member State involvement in many of the different REACH activities (evaluations, restrictions, SVHC dossiers, etc.).

Member States authorities submitted reports on their activities in 2015 that had improved in terms of completeness and consistency compared to the 2010 reports. These reports provide part of the evidence base for this evaluation and the conclusions from the report include:

- There are 45 REACH Competent Authorities (CAs) operating in the 28 Member States and the 3 EEA countries. 6 Member States have more than one CA. Competent Authorities are generally satisfied with their technical expertise, while some consider their financial and human resources too limited to achieve all activities required under REACH.
- CAs generally expressed a high level of satisfaction with the cooperation between CAs at EU and national levels and with ECHA and the Commission. However, there are concerns about the resources available for fulfilling the REACH tasks.
- The Commission underlines the crucial role of Member States to support duty-holders and facilitate the fulfilment of their obligations by providing guidance through national helpdesks and awareness-raising activities. Two third of Member States have targeted SMEs for such activities. Most common awareness raising activities include the production of easily accessible information content, (leaflets and newsletter), organisation of seminars, development of websites and use of social media.
- The next version of the Member States' questionnaire will be re-evaluated with the view to being further streamlined.

5.9. Enforcement

The Member States, ECHA and the Commission all play a role in enforcement. The Member States have the legal powers to enforce against duty holders. However, REACH delegated some 'enforcement powers' to ECHA, for example, in the case of dossier evaluation. Moreover, ECHA hosts information (e. g. registration dossiers), which in case of non-compliance, needs enforcement action by Member States' enforcement authorities. The Commission's enforcement role is to check the proper application of REACH, making sure Member States and ECHA apply and enforce REACH.

To improve enforcement, new procedures and communication channels have been developed between Member States and ECHA in specific FORUM enforcement projects and also between Member States. Particularly relevant is the Forum for Exchange of Information on Enforcement (Forum), which is a network of authorities responsible for the enforcement of the REACH, CLP and PIC regulations.

Since the 2013 REACH Review, an effort has been made to improve enforcement and progress can be seen in a number of areas, but it is clear that enforcement is still weak in some aspects and in some Member States.

Key conclusions on enforcement include:

- The amount of work carried out by Member States authorities, progress towards common enforcement strategies and the increase of activities of the Forum have provided good results but improvements are needed.
- In response to the 2013 REACH Review, the Commission developed enforcement indicators in cooperation with Forum members. 50 enforcement indicators were proposed at three levels (EU, Forum and Member States)[54]. This is the first time that such an approach has been developed in the field of enforcement of chemicals legislation in the EU. It is still premature to draw final conclusions on the reliability of the first quantitative results of the indicators.
- The average level of REACH compliance[55] reported by the Member States and ECHA has varied from 79 % to 89 % in the period from 2007 to 2014[56]. In this period, the areas with lower level of compliance are the ones related to control of imports and supply chain obligations (e.g. 52% non-compliance for safety data sheets).
- The indicators show differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end). These findings may be influenced by substantial differences in enforcement culture between Member States.

[54] Enforcement indicators for REACH and CLP within http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280

[55] The average level of compliance is calculated annually as the median value of the average levels of compliance reported by Member States. The average level of compliance experienced at MS levels take into account all controls carried out to REACH duties holders specific year.

[56] Information provided in accordance with Article 117.1 of REACH on Member States reporting obligations

- Enforcement activities are complex since they are carried out at different levels. The Member States have the main role in enforcing the Regulation but ECHA, and in particular the Forum, play important roles by supporting enforcement activities in small Member States.
- Enforcement activities have increased over time: Member States are now reporting close to 100 000 controls per year, and there is some prioritisation of these (eg reflecting risks). Member States should carry out further activities in order to increase the harmonisation of enforcement across the EU as also requested by industry during the public consultation (more information in annex 4 paragraph 9.2). REACH is of direct application in all Member States and further implementation efforts are needed to create a level playing field among Member States and all the actors involved in particular from those Member States which are not particularly active in the enforcement projects developed by the Forum.
- The result of the open public consultation shows that there is negative perception with regard to the question if REACH is uniformly enforced across the EU[57]. Stakeholders identified particular shortcomings with regard to imported goods. Mostly businesses and industry organisations stated that Member States should significantly increase controls in this area. This was seen of such importance because the lack of controls puts at risk Member States' enterprises competitiveness in a globalised trade system.
- The effectiveness of national enforcement activities could be further improved (e.g. in the areas of safety data sheets and imported goods), and also needs to be better communicated (e.g. by publishing Member State level enforcement indicators, developing and communicating national enforcement strategies and broadening national capabilities).
- The Commission services, the Forum and the Member States should further refine the enforcement indicators in the light of experience gained with their implementation. This system allows progress to be monitored (e.g. comparing different years) to better inform enforcement authorities, duty holders and the public in general.

5.10. Fees and charges

ECHA undertakes work related to REACH and other chemicals legislation (CLP, Biocides, etc). For REACH, it receives income from fees and charges for work that ECHA does on registration and authorisation. This income covers only part of the costs of the services provided by ECHA, and so there is a balancing EU subsidy.

Key findings include:

- The fees and charges revenue was foreseen to amount to EUR 510 million over the period 2007-2016 and the total REACH budget over the same period to EUR 757 million (implying a balancing subsidy of around EUR 247 million).

[57] 70% of the respondents said that REACH is not uniformly enforced. Such negative views were predominantly expressed by businesses (most of the respondents), but also by NGOs and consumer organisations.

- Revenue has been higher than expected, which has had an impact on the level of the EU subsidy. In practice, the fees and charges revenue over the period 2007-2016 was EUR 581 million (14% higher than expected) and the EU balancing subsidy was EUR 225 million for this period.
- The amount of fees and charges collected allowed ECHA to be self-financed for the period 2013-2015. Income from registration will be significantly less for the upcoming period (as all 'old' chemicals have been registered now, and only new ones will incur fees). From 2016 on, a significant EU contribution is needed to balance ECHA's budget.
- Half of the registrations over 2013-2016 relate to substances produced outside the EU.
- In line with the conclusions of the 2013 REACH Review, the Commission introduced in March 2013 fee reductions in favour of small and medium enterprises (SMEs) for both registration and authorisation; the reduction reaches up to 95% for micro-enterprises. For the period 2013-2016 the additional total fee reduction for SMEs represented a total amount of EUR 1.7 million.
- Stakeholders generally perceive registration fees and charges as adequate, but for authorisation they are generally considered too high. The Commission services are considering the possibility to abolish the additional fee per applicant in a joint application and increase the fee (to 90% of the base fee) for each additional use of a substance. This should contribute to reduce significantly the authorisation costs since companies will have an incentive to introduce joint applications.

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1. Effectiveness

6.1.1. TO WHAT EXTENT DOES REACH MEET ITS OBJECTIVES?

The evaluation of effectiveness looks at the extent to which REACH fulfils the objectives it is meant to achieve. Based on the intervention logic, the main objectives are:

1) to achieve a high level of protection of human health and the environment
2) to promote alternative methods for assessment of hazards of substances
3) to achieve the free circulation of substances in the internal market
4) while enhancing competitiveness and innovation

Assessment question: "To what extent does REACH meet its objectives?"

Progress has been made towards the REACH objectives.

The impact on protection of human health and the environment will take a number of years to become visible. However, evidence indicates that the outcomes defined in the intervention logic are being delivered in line with expectations. Information on substances is generated, passed to some extent along the supply chain and used to better assess and manage chemical risks, implying that REACH is being effective in terms of protecting human health and the environment to some extent.

The development and consideration of alternative methods have greatly improved during the last ten years, although this may have been at the expense of delivering (hazard)

information. In fact, alternative methods are not yet available for high-tier endpoints but registrants tended to avoid animal testing.

Regarding the free circulation of substances on the internal market, it can be concluded that REACH is delivering towards this objective. No clear effects are seen on the competitiveness and innovation as those depend on other more important factors that influence the market.

What is the issue?

The Intervention Logic sets out the sequencing from actions to outputs to outcomes to impacts, with the impacts relating directly to the objectives of the legislation. This question considers the degree to which the objectives are being met through an assessment of how effective the different actions envisaged in the intervention logic are proving. As such, answering the question leans heavily on the state of implementation as discussed in Section 5, considering also details set out in Annexes 4 and 5. However, the answer stops short of an assessment of the costs and benefits, which is instead considered under the efficiency questions.

6.1.1.1. Protection of human health and environment

The high level of protection of human health and the environment can be reached via improved knowledge on substances and their uses and properties as such knowledge allows reducing risks through improved risk management measures. This requires registration and evaluation to work well. This in turn can result in improved risk management measures through the passing of information along the supply chain and the operation of the restrictions and authorisation processes. This section looks first at the evidence on the effectiveness of the actions as indicated in the intervention logic, and then at the evidence on the end impacts.

6.1.1.1.1. Availability of information on substance properties and uses

The results of the 10-year update of the REACH baseline study show that 81% of the registered chemicals have a Chemical Safety Report[58] and most (75%) of those contain worker exposure information; this is a clear increase in the availability of data compared to 2012 and especially 2007. Given that the baseline for the study was the situation before REACH, it suggests as a result of REACH, there has been progress in the generation of information on chemical substances and significant progress on making available information on chemical substances. This has led to a constant increase in the number of hazardous substances identified, controlled, restricted or substituted. Exposure limits (Derived No-Effect Levels (DNELs)) are available for more substances compared with the pre-REACH situation. This means more and better data are available to perform chemical risk assessments[59].

REACH has also enhanced the knowledge within companies on the properties and uses of the chemicals including the exposure of substances to human health and the release to the environment. Companies also reported that the data base on substances under REACH has improved and classification is regarded as more trustworthy.

[58] For the remaining dossiers, Chemical Safety Report is not legally required

[59] The increased availability of information on chemical substances is identified by the REACH Baseline Study – 10 years' update linked to registration.

In addition, communication throughout the supply chain has increased and more information is available to chemical suppliers about the uses by downstream users. Nonetheless, there are still important gaps in the information passed down and an important share of downstream users still remain unaware of their REACH obligations. This is notably the case for article suppliers that have problems in obtaining and monitoring information on SVHC in their articles.

In spite of these positive trends, REACH has not yet produced the amount of new information on chemicals that was expected when REACH was adopted, in particular concerning the long term endpoints. As an example, the number of new studies generated and submitted [by registrants] since REACH entered into force is less than originally predicted (for further details see table 4.1 on number of tests per end point in Annex 4 paragraph 1.5). This means that less new hazard information than expected has been generated to enable identification of substances of very high concern.

The registration process has been generally effective and 95% of all registrations have been submitted as joint registrations. This shows that the infrastructure built by industry to share information and develop joint dossiers has worked. Non-compliance on at least one information requirement has been identified in at least 63% of the dossiers checked for compliance over the 2009-2016 period. This seems a high fraction but it has to be understood within its context in order to assess the real impact on the effectiveness. Deficient dossiers do contain useful information, as those deficiencies only include gaps not necessarily related to toxicology or exposure (e.g. substance identity) and double-counting cannot be excluded.

In order to improve the safety of chemicals ECHA has issued an integrated regulatory strategy which came into effect in 2015 by launching a common screening approach for all substances and registration dossier. This strategy focuses mainly on substances manufactured or imported in high volume and having a potential exposure/emission, which are prioritised for further risk management measures, such as substances evaluation, listing as very high concerns substances, restrictions, classification and labelling). This would enhance further the good functioning of other REACH processes and controlling the safety of chemicals of concern.

While REACH is able to address emerging issues such as the risks from nanoforms of substances, the lack of specific information about nanoforms covered by REACH registration dossiers remains an issue. Several compliance check decisions by ECHA on the registrations of substances with nanoforms have been appealed to the Board of Appeal, and four were annulled. The Commission has addressed these shortcomings through the recently proposed amendments of various REACH Annexes to clarify the information requirements for the registration of nanoforms. Some scientific gaps remain as to the suitability of test methods for nanoforms of substances and these are addressed in the OECD test guidelines programme.

Overall, update of registration dossiers and subsequent evaluation is a time-consuming process, as it, when data needs to be provided by the registrant, normally takes two to four years from the date of the decision.
Therefore, although it is too early to appreciate the overall impact of substance evaluation on risk management, a significant impact is anticipated in the coming years.

Shifting the burden of proof to industry

An important driver of the generation of information under REACH was the shift in the burden of proof to industry mainly through the registration and authorisation processes.

However, REACH does not eliminate the necessity of authorities to justify when they require action under REACH. The evaluation, restrictions and authorisation actions are designed to enable authorities to justify action in an easier and more efficient way than in the past.

The output of the registration process (more than 65 000 registration dossiers for some 17 000 substances) illustrates that industry has adhered to this shift in the burden of proof and taken up their legal obligations by submitting registration dossiers. Although this brings in additional costs for industry[60], it also results in a comprehensive data generation and assessment system for the main chemicals manufactured, imported and used in the EU, delivering an unprecedented amount of information compared to the pre-REACH system and to other regulatory systems[61] and enabling companies to better control the risks of all their registered chemicals by introducing appropriate and target risk management measures compared to the pre-REACH system..

However, the identified non-compliance of registration dossiers shows that although the burden of proof is on industry, the information provided is often not sufficient for authorities to identify and prioritise the need for action. In addition to the actions envisaged in REACH, ECHA and Member States invest resources to get the additional information from other sources, causing delays and returning to the 'pre-REACH' system where the full burden of proof was on authorities.

The REACH conference hosted by the Dutch presidency emphasised[62] the importance for companies – instead of governments – to demonstrate that the chemicals they place on the market can be used safely, by providing and updating information in the registration dossiers[63]. It was considered that real proactive ownership on the part of industry should be encouraged so that they view REACH as a working instrument rather than just a one-off obligation.

6.1.1.1.2. Reduction of risks

The development of risk is monitored by a Risk & Quality Indicator system consisting of an element assessing the nominal risk and an element assessing the quality of the underlying data. The resulting Risk Scores and Quality Scores are calculated for four impact areas: workers, environment, consumers and human health via the environment. (more information is given in Annex 5 paragraph 1.5)

A positive trend is observed from monitoring risk scores[64] which show a clear improvement[65]. The trend was already evident in the five-year update and is now observed for a larger dataset, related to the substances registered so far.

More proactive risk management activities have been introduced in companies as a result

[60] Costs are further analysed in section 6.2 on efficiency of REACH and Annex 5 on horizontal issues

[61] This is further developed in section 6.1.2 on other effects of REACH

[62] Information note from the Presidency to the Council on the policy conference "REACH forward"

[63] Information on toxicological properties, uses, exposure and risk management measures

[64] Risk Characterisation Rations and Risk Scores established according to the methodology developed for the Baseline study and calculated at different points in time to monitor risk reduction. See the Report of the REACH baseline study: 10 years update

[65] From the REACH Baseline Study – 10 years' update

of REACH, leading to improved risk management procedures and improving communication in the supply chain. Some of the companies involved in applications for authorisation confirmed that they improved their risk management measures at the workplace ²when preparing their applications. As a result of new information received through safety data sheets from companies submitting applications for authorisation, users of authorised substance usually improve their risk management measures[6667].

However, there is still limited awareness about REACH requirements (in particular among downstream users) and the appropriateness of information for risk management passed along the supply chain could be further improved (i.e. SDS), especially among SMEs, as indicated by the relatively high level non-compliance (52%) related to the communication of information in the supply chain that has been observed through enforcement actions (more information in annex 4 paragraph 9.1.1). Information received with extended SDS in some cases leads to improvement of risk management measures[68]. However, limited awareness may result in risk reduction measures not being applied by downstream users.

Risk reduction results from risk management measures applied through the different REACH processes:

- Registration provides information on a substance (hazard, exposure) and appropriate risk management measures identified in the chemical safety assessment and safety data sheets .
- Evaluation refines the information identifying some properties linked to the hazard and exposure.
- Authorisation reduces risks of Substances of Very High Concern by encouraging their substitution by safer suitable alternatives and by ensuring risk control for specific uses.
- Restriction reduces identified uncontrolled risks through appropriate risk management measures and operational conditions during the manufacture and use of a substance.

The progressive restriction of use and banning substances and groups of substances of very high concern as a result of REACH should lead to lowering the human and environmental exposure to these substances and groups of substances. The evaluation and compliance check procedure is playing a major role in the identification of dangerous substances.

The number of restrictions (19 in 5 years) enacted under REACH is comparable to the situation pre-REACH (16 in 5 years). This falls short of what was expected from REACH at the time of adoption, on the basis of the Commission estimates that Member States would prepare 11[69] Annex XV dossiers for restriction per year, particularly given

[66] Study monitoring the impacts of REACH on competitiveness, innovation and SMEs – CSES, 2015, page 72

[67] The ongoing study on the effects of authorisation provides similar indications.

[68] Study monitoring the impacts of REACH on competitiveness, innovation and SMEs – CSES, 2015, page 73

[69] Estimation made by the Commission services during the drafting of the proposal for the REACH Regulation and discussed with Member States in the so-called Commission Working Group to prepare for REACH (2005-2006). These estimations formed the basis of the financial Fiche accompanying the

that more information would be available. However, this number provides only a limited indication of the effectiveness of REACH, as the REACH information requirements for technical dossiers to start a REACH restriction process are more complete than in the pre-REACH system. One of the difficulties compared to the pre-REACH system, in which the restriction proposal and the socio-economic analysis were developed by the Commission, is that under REACH the Member States have to prepare a restriction proposal within a much shorter timeframe (1 year versus up to 10 years).

Application of the precautionary principle to reduce risks

The precautionary principle is one of the three principles guiding environment policy under the Treaty. As stated in Article 1(3), the precautionary principle underpins REACH and its implementation. The Commission Communication on the precautionary principle[70] sets out the mechanism used by the Commission, and by analogy Union agencies, for the implementation of the precautionary principle. This mechanism when applied to REACH in effect has two steps:

(1) a scientific step, where the responsible scientific body (ECHA) assesses if the uncertainties are bigger than normal and if the consequences of those uncertainties could lead to a significant undesirable impact;
(2) a risk management step, where the responsible risk management body (the Commission and REACH Committee) decide what action, if any, is required.

The assessment set out in the scientific step was routinely applied under the previous legislation (existing substances). Under REACH, step 1 has been assessed by the scientific committee leading to two cases where the bigger than normal uncertainties were identified but no further risk management steps were taken on the basis of the Precautionary Principle. In two cases a decision was taken to generate further information[71].

Since the entry into force of REACH, the Commission has not proposed measures where action was based on the precautionary principle as ECHA opinions have not triggered such principle. In most cases, the ECHA and its Committees did not assess the scientific uncertainties to enable the Commission to consider possible action based on the Precautionary Principle.

The principle could be invoked by ECHA in cases where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question. In such cases, ECHA should highlight to the Commission which information is needed to clarify the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction. The restriction task force has identified this issue and recently the Committee assessment on uncertainties has been conducted.

Commission Proposal and the Extended Impact Assessment. The assumption for restrictions was that better information in the registration dossiers, more information on the hazard properties of substances (e.g. through substance evaluation), the ability to target the risk assessment and strict deadlines would significantly increase both efficiency and the ability to identify substances needing restrictions.

[70] The Precautionary Principle is enshrined in the Treaty on the Functioning of the EU and its definition and scope are set out in the Commission communication (COM(2000) 1final)

[71] Bisphenol-A (more information where requested on the alternative Bisphenol-S (same risk profile)), and D4/D5 (more information was requested on products similar to the ones restricted).

Substitution and risk reduction of substances of very high concern (SVHC)

Increased obligations on SVHC through the candidate listing[72] and authorisation provisions are leading to some substitution of those substances along the supply chain. Substances have been dropped from the market or not registered due to their properties (*good withdrawal*). The authorisation process is leading to the substitution of SVHCs at all stages[73] as a result of the substances being listed on the candidate list and in ECHA's recommendation of priority substances to be included in Annex XIV, as well as the actual listing of substances in Annex XIV.

Applications for authorisation were made for 23 substances out of the 31 subject to authorisation in March 2016, which is an indication that some substitution has taken place, although it is difficult to distinguish to which extent REACH has been the driver for that (See further details in annex 4 paragraph 6.5 and in annex 5 paragraph 1.8). Many of the applications for authorisation that have been assessed requested the time necessary to substitute the SVHC with a safer alternative[74] and seem directly related to the effect of REACH authorisation.

Overall, there is some evidence that the objectives of authorisation are being achieved. The SVHC Roadmap is proving an effective tool and work at this stage is progressing as expected in terms of effectiveness.

An additional issue to consider is the effect of delays in the adoption of restrictions of substances of very high concern subject to authorisation[75], when present in articles placed on the EU market. In particular, the delay in the adoption of restrictions for imported articles containing those substances after the sunset date could affect negatively the level of protection of human health and environment as well as create a competitive disadvantage for EU producers of articles.

Substances with endocrine disrupting properties

The potential for Endocrine Disrupting (ED) properties is one of several factors in the prioritisation of substances in ECHA's common screening approach, in evaluation and the implementation of the SVHC Roadmap to 2020. REACH has routinely been able to identify substances as having ED properties: to date, seven (groups) of substances have been added to the Candidate List using the WHO/IPCS definition when sufficient data exists on adverse effects, the underlying mechanisms of action and the causal relationship between the two. The criteria for the determination of substances with ED properties under the Biocidal Products (BP) Regulation will become applicable in June 2018[76] and it is expected that the criteria under the Plant Protection Products (PPP) Regulation will become applicable in November 2018. Those criteria are based on the WHO/IPCS

[72] Link to Candidate List of Substances of Very High Concern for Authorisation - ECHA

[73] Report on operation of REACH and CLP, ECHA, 2016, page 92

[74] About a quarter of the opinions have concerned "bridging" applications, where the applicant has identified its substitution strategy and applied for a specific period identifying when the substitution would take place[74.] (ECHA, 2016c p. 93).

[75] According to Article 69(2)

[76] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (Text with EEA relevance) C/2017/5467, OJ L 301, 17.11.2017, p. 1–5

definition. Also the joint scientific guidance of EFSA and ECHA for the identification of EDs will be established in 2018. The data requirements in the PPP and BP Regulations will be adapted accordingly in order to be able to assess whether the criteria are met. As the data requirements in the PPP and BP Regulations differ from the REACH data requirements, and the level of protection foreseen in the REACH legislation should be safeguarded, the applicability of the criteria to identify ED properties under the PPP and BP Regulations needs to be evaluated. This further emphasises the need to have effective testing methods available. Whilst the REACH standard information requirements have limited capacity for providing data on ED properties, a number of adverse effects related to ED mode of actions (human health and environmental) can be identified by the extended one-generation reproduction toxicity study (EOGRTS), as well as by some of the other information requirements[77]. Further details are described under the relevance questions (Part 7.4).

6.1.1.1.3. Impact on the incidence of diseases

The section above has shown that the steps of the intervention to a great extent take place as envisaged in the intervention logic, suggesting effectiveness for this objective. This should (eventually) lead to a positive impact reducing diseases and environmental damage. However, providing evidence on the impact is challenging because the main expected impact is the absence of certain adverse effects, and furthermore:

- the majority of impacts will materialise in the future, for example, because of latency periods;
- even if changes in incidence (such as rates of cancer cases) can be observed, it is difficult to attribute these changes to different drivers/interventions.

In terms of the expected impacts, the *Extended Impact Assessment* prepared during the adoption process of the REACH Regulation describes some of the potential health benefits of REACH resulting from health benefits for workers through reduced occupational exposure, effects of restrictions on the reduction of the risks to the environment and the general public. The health benefits were expected to be in the order of magnitude of EUR 50 billion over the next 30 years (in net present value terms)[78], assumed to start to occur 10 years after REACH implementation begins, and persist for another 20 years.

At present, a lot of challenges and knowledge gaps remain to assess the impact of REACH on health and environment (e.g. impacts on diseases). However, even the limited available information suggests that REACH has had a positive impact on health and the environment (e.g. human health benefits as a result of the enacted restrictions).

So far, information on changes in health resulting from a decrease in exposure to chemicals is only available for occupational skin diseases and occupational asthma[79]. A

[77] Effects related to human health for repeated dose toxicity, carcinogenicity and reproductive toxicity (e.g. according to OECD TG 421, OECD TG 422, OECD TG 414, OECD TG 408)77, while additional data on ED adverse effects related to environmental endpoints are gathered via tests on short and long term toxicity

[78] Based on the assumption that on average 10 DALYs are equivalent to 1 life saved, then 45 000 Disability-Adjusted Life Years (DALYs) would be equivalent to 4 500 lives saved per year due to REACH.

[79] RPA study - Information used in the RPA study was coming from two national OSH databases (the UK Health and Safety Executive and the German Social Accident Insurance).

progressive reduction in the occurrence of occupational skin diseases and occupational asthma has been observed, resulting in total cost savings of, respectively, around EUR 1.59-1.87 billion and EUR 249.9 million, respectively for the period 2004-2013. The trends observed are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some skin and respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes. Nevertheless, REACH is a factor for many of these aspects and so seems to have played a major role in reducing the number of cases of occupational skin diseases and occupational asthma.

ECHA has also assessed the expected annual human health related benefits[80] from restrictions processed under REACH since 2009 indicating also positive impacts for at least 81,000 consumers and workers, the value of which could not be estimated. An example with direct effects on consumers is the restriction of chromium (VI) in leather articles that applies since May 2015, which has been estimated to enable approximately 1.3 million people with chromium allergy to use leather articles without fear of symptoms and to avoid approximately 10 800 new cases of chromium allergy in the Union each year. The benefits, in terms of avoided healthcare costs, productivity losses (due to lost working hours) and avoided suffering (the willingness to pay for avoided allergy and symptom days) amounts to an estimated EUR 350 million per year.

6.1.1.2. Promotion of alternative methods

The available information, though limited, suggests that REACH enhanced the development, use and acceptability of alternative methods to replace, reduce, refine animal testing (see details in annex 4 paragraph 2.1.2.1).

In particular, there was a replacement of in vivo tests with validated and internationally accepted in vitro tests in the standard information requirements of REACH or in other cases the refinement of in vivo tests to reduce the number of test animals or improve data adequacy for classification and risk assessment (see Annex 4 chapter data sharing, test methods and avoid unnecessary animal testing).

For practical reasons e.g. lengthy administrative procedures of adoptions of the test methods regulation as well as inclusion of new OECD methods in the REACH Annexes, the uptake of alternative methods coming from OECD is taking considerable time and sometimes leads to discrepancies due to ongoing developments between the test methods regulation and the OECD guidelines, which may have evolved in the meantime.

For skin sensitisation the introduction of the first Adverse Outcome Pathway[81]-based test (alternative) approach has proven challenging, due to the inherent flexibility of the approach, which affects e.g. industry confidence as well as enforcement from Member States. Also in the alternative higher tier testing for reproduction toxicity the inherent flexibility has proven challenging. Reflections are necessary how in future such (flexible) approaches, which are expected to increasingly emerge in the near future, can be accommodated in the framework of REACH information requirements.

[80] Cost and benefit assessment in the REACH restriction dossiers, ECHA, April 2016

[81] A structured representation of biological events leading to adverse effects relevant for risk assessment

Because of the strong emphasis in the REACH text on the use of alternatives and the "last resort principle", REACH, together with the Cosmetics Regulation, is one of the principle drivers in the EU for the use of alternatives to animal testing[82].

Many registrants rigorously implement the legal requirements to propose testing on animals only as a last resort. However, a significant number of recently conducted in-vivo tests are still being submitted. The reasons for this need to be further explored; one could be the non-acceptance of alternative methods in Third Countries.

Positively, alternative approaches like read-across and weight of evidence are being used to a large extent to avoid or limit the need for (any) new testing (more information in Annex 4 paragraphs 2.1.2.1., 2.1.2.3.and 2.1.2.5). However, the scientific validity of such approaches needs to be better substantiated in many of those dossiers.

ECHA concludes in its third report on the use of non-animal test methods[83] that registrants generally made extensive use of existing information and adaptation possibilities before conducting new studies or proposing new high tier vertebrate animal tests, whereas regulatory requirements are updated to take up new reduction and replacement methods. The uptake and regulatory acceptability of the new methods in the EU also heavily stimulates validation and acceptance of alternatives in different jurisdictions.

Available information suggests that REACH enhanced the development, use and acceptability of alternative methods to replace, reduce, refine animal testing, but there are still areas of improvements regarding the use of adequate alternative methods. ECHA, which is putting a lot of effort into promoting new test methods through, among others, the update of guidelines on test methods stresses that the recognition of an alternative method by amendments under REACH and the Test Method Regulation[84] takes considerable time. However, formal recognition of new testing methods through inclusion in the Test Method Regulation remains a challenge due to the inherent administrative processes and the time required for translation of the long and highly technical test protocols in all EU languages.

The experience from recent modifications of standard information requirements in Annexes VII-X to REACH have also highlighted a number of challenges for regulatory acceptance of new methods. This can significantly influence the time needed to complete the process of gaining acceptance, in particular related to concerns raised in relation to assessing the equivalence of information generated via in vitro or in vivo testing, maintaining the previous level of protection for human health and the environment, addressing flexibility in test guidelines as well as testing costs and availability of test laboratories able to perform new tests.

6.1.1.2.1. Avoidance of unnecessary testing

Regarding data sharing, ECHA built a publicly accessible database of available data on substances registered under REACH, encouraging data sharing and avoidance of unnecessary duplication of tests. These effects are reaching beyond the EU as the information available through this database is being used in other jurisdictions.

[82] The interplay between REACH and the Cosmetics Regulation is further analysed in section 6.3.2.3

[83] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016

[84] Commission Regulation (EC) No 440/2008

In addition, since 26 January 2016, it is no longer possible to submit an individual registration for a substance where a joint submission exists (95% of all registrations were joint registrations). However, some 700 previously existing individual registrations including notified substances and intermediates are still in breach of the joint submission obligation. Further data sharing could be enhanced by accommodating data sharing for structurally similar substances to allow better read-across.

Overall, effort has gone into the development and promotion of alternative methods. This is reducing the need for animal testing, but this may have been at the expense of delivering (hazard) information as for high-tier endpoints, alternative methods are not yet available and registrants have applied data waivers, adaptations or submitted testing proposals.

Until 31 December 2016, ECHA has taken decisions on 953 testing proposals, some of which concerned several studies that are already being or will be performed. 467 of the 953 testing proposals concerned prenatal developmental toxicity and 359 concerned repeated dose toxicity. 183 testing proposal decisions on reproductive toxicity are being finalised by the Commission. On the one hand this means that less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted either. Where no new data has been generated, the dossiers either contain data waivers or adaptations.

The cost of data sharing seems to affect SMEs considerably, as data sharing negotiations take a long time, putting time pressure on new registrants and reducing possibilities to place the substance on the market.

6.1.1.3. Internal market, competitiveness and innovation

The changes in the internal market, competitiveness and innovation are all linked, and can be especially felt by SMEs. Strengthening the internal market through harmonisation allows for a more level playing field, lowers costs for businesses and allows for greater economies of scale. A stronger internal market is one of the positive factors for competitiveness, but REACH can also hinder competitiveness, for example, through increased costs for businesses. At the same time, REACH can affect the incentives to innovate, which in the long term underpins the chemical sector's competitiveness.

At the time of adoption, there were no quantified expectations with regards to competitiveness.

6.1.1.3.1. Free circulation of substances in the internal market

The REACH Regulation has among its objectives to ensure the free circulation of substances on the internal market through harmonisation and reduction of the barriers for intra-EU trade.

Europe has a large and integrated market made up of a customer base of over 500 million consumers and with chemicals sales worth EUR 519 billion in 2015[85]. The importance of the internal market for chemicals is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports'[86]. There has been a continuous increase in the intra-EU trade of chemicals over the last decade, strengthened by the removal of trade and non-trade barriers within the EU and the enlargements of the European Union

[85] CEFIC, chemdata international, 2015

[86] European Chemical Industry Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017

in 2004 and 2007. Intra-EU sales increased from EUR 197.2 billion in 2005 to EUR 282.3 billion in 2015 – a 43.2 % increase during the last 10 years. How much this increase can be attributed to REACH is not certain, but these figures suggest that REACH is contributing to achieving the internal market.

Companies from the chemicals sector, as well as with their downstream users[87], report no effects (neither negative, nor positive) on the trade of chemical substances within the EU/EEA due to the implementation of the REACH Regulation. While no discernible impact of REACH was identified, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European chemicals legislation / integration of the Single Market. They also flagged the need for further efforts to make market surveillance and enforcement practices more aligned (see 7.1.3.2 for more detail) across the Member States by, among others, approaching the inspections and the relative resources (quantity and quality) allocated to ensuring compliance with REACH[88].

ECHA also recommended that to achieve a fair level-playing field throughout the single market, all Member States should consistently enforce ECHA and Commission decisions in their territory (this issue is further discussed in chapter 7.1.3.2.).

6.1.1.3.2. Competitiveness

Trends for the EU and global markets

As described above, intra-EU trade of chemicals has increased over the last decade, while the total EU chemicals sales remained relatively stable, though with some fluctuations. Moreover, as a result of a solid recovery from the aftermath of the economic crisis in 2008, the extra-EU trade balance showed clear signs of recovery, reaching over EUR 40 billion in 2015. This means that domestic (home) sales have decreased while the increase in intra EU exports combined with an increase in exports to non-EU countries has led to an increase of the total chemicals sales over the period 2005-2015 (from EUR 458 billion to EUR 519 billion)[89].

At the same time, the share of the EU industry on the global market has been decreasing over the past 20 years[90]. It is not possible to say if REACH has contributed to this change given the global trends in play such as cheap energy in the US, China's economic boom and hence increase in domestic demand for chemicals.

Market effects observed in relation to REACH

The costs of specific REACH processes are presented in detail in Annex 5. However, some positive and negative effects can be observed. The effects of registration on competitiveness seem broadly in line with the expectations (as discussed in detail in Annex 5, paragraph 2.4.2), although concerns about the vulnerability of some specific sub-sectors (e.g. essential oils, textile dyes) and SMEs remain. ECHA, the Commission and Member States are providing specific support to mitigate those concerns in preparation for the 2018 registration deadline.

[87] A large majority (80-85%) of respondents to a business survey conducted by CSES in the context of the study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, commissioned by the European Commission, 2015

[88] Further analysis in Annex 4- enforcement section

[89] CEFIC, Chemdata international 2015

[90] The share of the EU in world sales was 32% in 1995 and 15% in 2015.

Registration costs are claimed also to be the main driver for some substance withdrawals observed[91]. Around half of the registrations with ECHA have been for substances not produced in the EU (50% over the 2008-2016 period, 40% in 2016).

Downstream users have also expressed concerns about the control of SVHCs through the authorisation process, perceived as a competitive disadvantage vis-a-vis companies from third countries, or the information requirements for SVHCs in articles[92].

Compliance with REACH affect SMEs more significantly than larger companies[93] and SMEs perceive the benefits of the Regulation to a much lesser extent[94]. Some concerns were expressed by industry about increases in the cost base of companies, which may force smaller firms out of the market or inhibit the entry of new ones, thereby reducing the industry's overall supplier base[95].

As anticipated in the extended Impact Assessment conducted in the preparation of the REACH Regulation some market consolidation seems to have occurred due to decision of manufacturers/importers to remove some of their substances from their portfolio. However, this seems to have been done after consideration of the cost of registering, the profitability of the chemicals and the availability of adequate substitutes. Therefore, despite the effect on individual companies, there is no evidence of any major negative impact at EU scale resulting from the non-availability of substances.

6.1.1.3.3. Innovation behaviour

Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on Research & Development (R&D) and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting R&D resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and the higher transparency enable the users of chemicals to make better choices in the design of products and in their use.

Further details and evidence underpinning this analysis is developed in Annex 5, paragraph 2.4.2)

R&D and general innovation drivers

The 'Porter hypothesis' states that stricter environmental legislative requirements may encourage companies to increase spending on research programmes, thus acting as a trigger for innovation towards sustainability, which may provide first movers with competitive advantages[96]. However, effects of the REACH processes on innovation are

[91] Study on Monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al): Near to one third of companies (including downstream users) having reported to be affected by a withdrawal of a substance from the market due to registration cost

[92] Similar views have been gathered through the online-public consultation, where industry respondents were rather negative about the achievement of the competitiveness and innovation objective.

[93] Study *Monitoring the impacts of REACH on innovation, competitiveness and SME*s, page 101 onwards

[94] SME panel

[95] Similar views have been gathered through the online public consultation and the SME panel.

[96] As acknowledged by WWF, 2003, CIEL, 2013, OECD, 2014 and ChemSec 2016 (add link to the bigger picture)

CIEL (2013) notes that the implementation of stricter measures with REACH has enabled significantly increased patenting of alternatives by major chemical manufacturers. Chemsec (2016) reports that chemicals and chemicals-

complex and different companies perceive the impact of REACH on their capacity to innovate differently[97].

On the one hand, the costs incurred by companies in implementing the Regulation may detract from the resources from R&D and innovation activities[98]. On the other hand, the implementation of REACH has also led to an increase in R&D activity[99] [100].

The improved communication (upstream and downstream) in the supply chain should logically be providing potential for more innovation, business development opportunities and more efficient and effective supply chain management practices. However, those effects could not be quantified. Furthermore, improved availability of information and transparency can help downstream users to make better informed choices when developing new or applying existing products, hence increasing their ability to innovate.

Companies on the one hand capitalise on the information and knowledge generated as part of the registration process by e.g. launching new products or services. On the other hand, companies that experienced a withdrawal from the market may have been negatively affected or they may have responded with R&D activity to identify alternative substances.

Authorisation also affects the innovation activity as the inclusion of substances into the candidate list and the authorisation list works as a driver for research to find alternative substances or technologies. However some industry stakeholders highlighted that the authorisation process is slowing down the product development and diverting resources from innovation that would improve competitiveness. Other expressed the view that the candidate list and other instruments[101] is increasing the transparency and providing guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.

Innovation and substitution

A positive trend can be observed concerning innovation and substitution[102] as there is the general tendency to change the product range to replace hazardous substances. REACH encourages substitution by safer substances but it is difficult to attribute substitution

related legislation triggers investment in R&D and leads to innovation on a number of fronts including chemical substitution, improved manufacturing processes, product design, etc. And in some cases these innovations confer a first mover competitive advantage to the EU-based manufacturer both in domestic as well as international markets.

[97] The business survey conducted in the context of the study monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al, 2015) suggests that, for some companies, REACH does not seem to provide any major incentive for innovation, in the sense of improving their competitiveness in comparison to non-EU competitors. 35% of respondents perceive a negative impact of REACH on their capacity to innovate, whilst 11% who perceive a positive impact and 54% did not see REACH having a notable effect, either way, on their innovation activities.

[98] Study Monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al, 2015),

[99] Study monitoring the impact of REACH on competitiveness, innovation and SMEs (CSES et al, 2015) such an increase was reported by about a quarter of respondents to the business survey .

[100] Industry stakeholders consulted in the framework of the study for a non-toxic environment strategy (Milieu et al)

[101] PACT and CORAP list –;

[102] REACH - Evaluation of the impact on the affected industries and the whole economy in Austria, Denkstatt, March 2015

effects only to REACH as substitution is also encouraged by other legislation (e.g. OSH) and supported by drivers, such as consumer demands, market circumstances and initiatives such as e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme.

Improving substitution and innovation was one of the topics debated under the Dutch presidency, and the debate[103] concluded that there are clear signals that REACH already promotes substitution of toxic substances in those cases where phasing out is anticipated. It was also emphasised how substitution contributes to innovation and a green economy.

However, there is little clear evidence thus far that chemical legislation in general terms, is in itself a stimulus to more fundamental development of alternative technologies and substances, new business models and non-chemical solutions, as innovation is predominantly market driven (beyond the above mentioned anticipation of phasing out).

Overall it was felt that encouraging innovation was something that would need the active involvement of other policy fields, such as research and economic policy.

Product and Process Oriented Research and Development (PPORD) notifications[104] and registration of new substances

There was an increasing trend for the overall number of Product and Process Oriented Research and Development notifications (PPORDs) [105] although used only by a relatively small number of companies in Europe (~350), which were typically large and mainly from a relatively limited number of Member States. The SME panel[106] revealed that PPORD is perceived as useful or very useful by nearly half of participating companies while nearly a third was not aware of this mechanism. So far, about 20% of the PPORD notifications have led to the registration of the substances concerned, demonstrating that the PPORD notification has the potential to pave the way for new products on the market.

New substances placed on the market are continuously being registered with a steady upward trend[107]. Since REACH has been in force almost 1,500 new substances have been registered.

As a summary, it can be concluded that innovation is certainly taking place, but there is room for more, specifically with respect to the innovation activity among SMEs. REACH mechanisms to foster new products are being used and pave the way for the upward trend to create new substances but they could be extended to more companies from more Member States. SVHCs are being phased out and replaced by safer alternatives, often as a result of innovative thinking and developments.

6.1.1.4. Stakeholder views

Stakeholder views concerning the achievement of REACH objectives differ by objective. Most stakeholders have fairly positive views regarding the improvement of protection of consumers, workers and the environment as well as promoting alternative methods for

[103] Information note from the Presidency to the Council on the policy conference "REACH forward"

[104] Article 3(22)

[105] Report on operation of REACH and CLP, ECHA, 2016

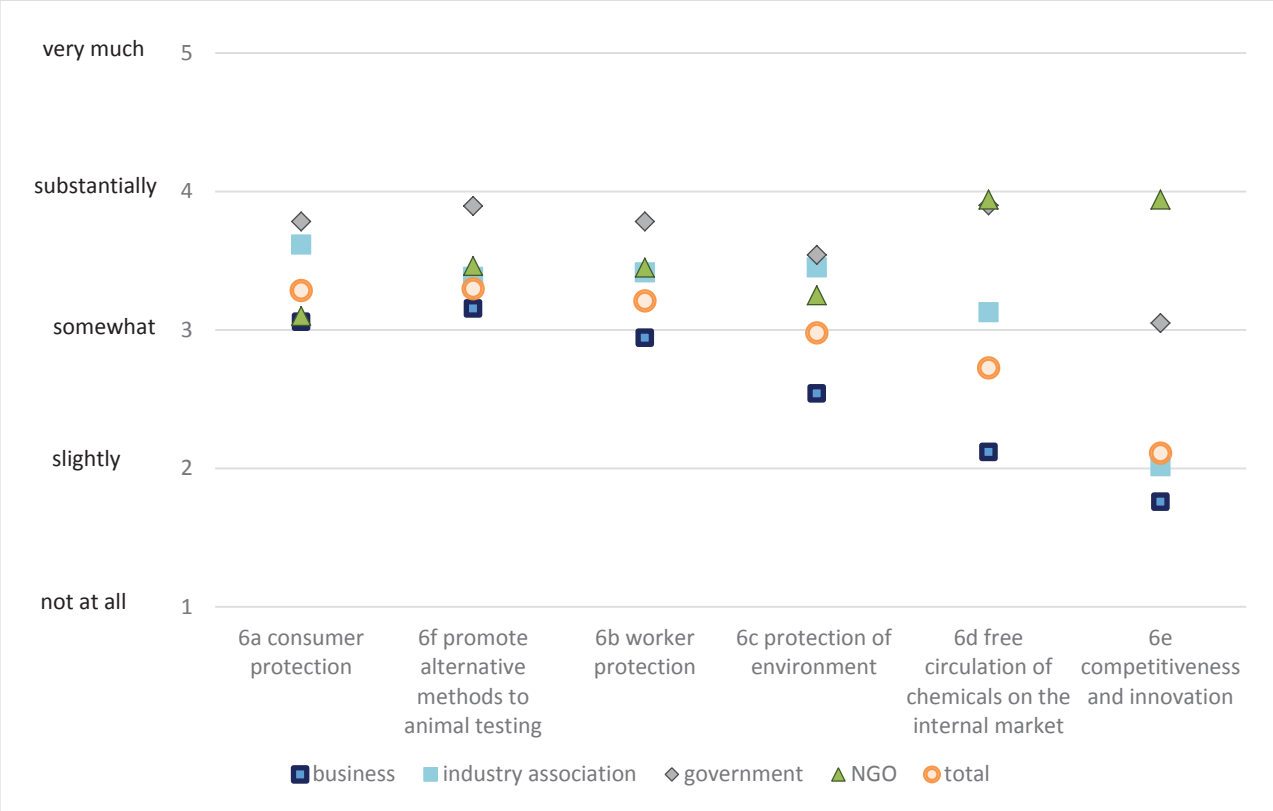
[106] Stakeholder consultation: report of the SME panel

[107] ECHA report 2016

animal testing. Respondents have more diverging views concerning the objectives of free circulation of chemicals on the internal market and in particular competitiveness and innovation. Businesses are rather critical concerning the achievement of the internal market and the improvement of competitiveness and innovation, whereas governments, trade unions, consumer associations and NGOs were much more positive. For example, European environmental Bureau (EEB) considers that REACH is promoting not only EU but global innovation, as the candidate list has become a worldwide reference for substitution.

Figure 3: Question 6 of the online public consultation in relation to the REACH evaluation:

To what extent do you think REACH is achieving the following objectives? (Marker points show average values of responses by stakeholder group and across all respondents)



As regards delivery of results by REACH, all different stakeholder groups express a rather positive tendency on generation of data and information for risk assessment and management. Concerning the shifting of the burden of proof, most stakeholders express positive views, except for NGOs and consumer associations which are more critical in this respect. Consumer organisations flag concerns about data requirements for the approximately 20.000 low volume chemicals, which they consider currently insufficient to achieve a more complete picture of the properties of the chemicals on the European market.

Stakeholders also raise certain issues that hinder the achievement of REACH objectives, mainly the high level of non-compliance of registration dossiers, which also impairs the level-playing field between duty holders. There are also concerns on the enforcement of the ‘no data, no market’ principle, as non-compliant dossiers are not sanctioned.

Moreover, the registration process, as it currently is, induces bad practices such as free-riding in the preparation of joint submission and even more in the updating of registration dossiers. It was considered that registrants do not have a strong incentive to provide high quality data as they risk to be targeted more often by regulatory actions if they do.

6.1.2. WHAT ARE OTHER EFFECTS OF REACH?

Assessment question: "What have been the effects of REACH (whether socio-economic, environmental or health-related, both positive and negative), including also effects not originally planned?"

Besides the results described in the previous section, REACH is bringing about other effects such as the increased expertise on chemicals for public authorities and industry to carry out risk assessment and risk management. In addition, REACH is seen as the most complete chemical regulation in the world and is thus influencing legislation in other jurisdictions. REACH is also contributing to international harmonisation in the implementation of chemicals policy.

A number of other effects – foreseen or not - have been reported by industry stakeholders in relation to market concentration, withdrawal of substances, the competitive advantage of non-EU producers of articles, increased business uncertainty and possible relocation of activities. There is relatively little evidence for some of these, but where available and relevant they are addressed in detail in other sections.

What is the issue?

The first effectiveness question asked whether REACH is meeting its objectives, including the environment and health benefits (described further in Annex 5 paragraph 1.5). But beyond those intended effects, the implementation of REACH has led to some other effects – either expected or unplanned effects, which are described below. Consultation with stakeholders is the main information source for these other effects.

6.1.2.1. Employment effects

Sale figures for the EU chemical industry remained broadly stable between 2007 and 2015[108], with figures of EUR 524 billion and EUR 519 billion respectively. On the other hand, there has been a gradual reduction in employment in the chemical industry from 2003 to 2013 (from 1.37 million to 1.16 million employees),[109], with a bigger reduction during the period 2003-2008 than the period 2009-2013. Nonetheless, none of the studies reviewed identify any evidence of a correlation between the REACH Regulation and EU economic growth and employment in the chemical industry or downstream users.

There is some evidence that the entry into force of the REACH Regulation has increased the market of REACH-related consultancy (technical and legal) services as a result of activities outsourced by industry and public authorities[110] but no figures are available to quantify those effects.

[108] CEFIC data: Facts and Figures of the European chemicals industry, 2016

[109] CEFIC data: Facts and Figures of the European chemicals industry, 2016, page 30

[110] Monitoring the impacts on competitiveness, innovation and SMEs (CSES et al 2015), page 140

6.1.2.2. Increased expertise on chemicals

Member State authorities are generally satisfied with the level of technical expertise and the cooperation at EU and national levels[111] although the competences and resources of Member States are not equally distributed. The implementation of REACH involves a sharing of the workload (e.g. SVHC identification, restriction proposals) and exchanging knowledge between the public authorities as well as enhancing the coordination of their approaches.

Different bodies and activities organised to exchange expert opinions and coordinate the views of different national authorities such as the European networks (e.g. CARACAL, HelpNet, Forum) facilitate the coordination of Member State activities, ensuring coherence between risk assessment practices at national level and avoiding duplication (see also section 6.5.1.1 on EU added value).

Overall, the level of expertise on chemicals is increasing as a result of cooperation among different Member State authorities through REACH activities. For example, in specific cases such as the preparation of proposals for restriction, ECHA provided support to Member States inviting national experts to spend time in ECHA and gain expertise in the preparation of a restriction dossier (Annex XV dossier) for restriction. Some experts indicated that their expertise increased e.g. on socio-economic analysis as a result.

Industry respondents acknowledge REACH's contribution to the increased knowledge on chemicals, the communication in the supply chain and the substitution of SVHCs but also refer to other, negative effects on the competitiveness and innovation.

6.1.2.3. International effects

REACH is currently the most complete regulatory system for chemicals in the world as further elaborated below. It encompasses a combined inventory and data collection with a self-assessment obligation in registration, with an evaluation of the registration dossiers and the two most commonly applied risk management approaches of restrictions and authorisation. It largely places the burden of proof on industry.

Most pieces of legislation in other jurisdictions have comparable elements with parts of REACH. When looking at the influence of REACH on other legislation outside the EU it is therefore important to consider the policy influence (e.g. on the objectives set), the actual legislative influence and finally the influence of the REACH tools used to implement the legislation.

A study on the impacts of REACH on international competitiveness of EU industry[112] showed that REACH has influenced the chemicals legislation in third countries to different extents. The study looked at the key aspects, which explains many differences in the legislative frameworks in place in the EU and the third countries, such as the principle of where the 'burden of proof' is placed as well as the links to the relevant differences in the legal systems of the concerned countries.

- South-Korea has developed a legislation[113] based on the model of REACH, where the burden of proof lies with manufacturers who have to register their substances,

[111] Review of Member State reports under Article 117(1)

[112] Study on the impacts of REACH on international competitiveness of EU industry

[113] Korean regulation: Law No. 11789 Act on Registration and Evaluation of Chemical Substances—"K-REACH" Come into force 1 Jan 2015

includes post-registration obligations on communication of information in the supply chain, and bans or restricts hazardous substances (no substances are listed as subject to authorisation yet). In addition, there is work ongoing to allow companies in South Korea to use EU data to register chemicals.

- REACH has influenced the legislation in China[114], developing a "REACH like" legislation, although differences in the scope and implementation are substantial (e.g. notification of new substances, proactive compliance practices by industry, prioritisation of chemicals). Due to the chemical management programme being still new compared to EU or US, there is in China some reserve in using QSAR and read across data.
- Some commonalities can be observed with Japan, and regarding information requirements, with Canada e. g. volume, use, exposure and hazard information. The Canadian legislation[115] requires information from companies so that authorities can make an assessment on the risk and management of chemicals categorised in 3 specific priority phases (high, medium and low).
- Major differences remain between REACH and the new legislation in the United States[116], which notably places the burden of proof on the authorities and not on manufacturers to assess the risk on some selected prioritised chemicals similar to how it was in the EU under the previous Existing Substance Regulation (EC) No 793/93.

The scope of the study is limited to five countries, which provides a limited picture of the influence of REACH on third-country legislation and does not allow for firm conclusions on the international harmonisation of chemicals regulation.

In the EU, with REACH, most chemicals are being assessed prior/during registration, i.e. since REACH came into operation already 17 000 unique substances were registered and therefore assessed by industry, which have the burden of proof for placing safe chemicals on the market. Other systems, e.g. that of the US Environmental Protection Agency (EPA) does these assessments only for a limited number of selected chemicals and the assessment is done by the regulatory authorities. By comparison, the 2012 Toxic Substances Control Act (TSCA) Work Plan for Chemical Assessments identified 83 chemicals for assessment by EPA as part of its chemical safety program, and the updated TSCA 2014 Work Plan had a total of 90 chemicals included, for which 4 assessments were concluded. In the last ten years, no new restrictions have been adopted in the US.

Some cost estimates for the registration of new substances indicate that REACH costs are in the middle range compared with other regimes. While the costs per substance under

[114] Several pieces of legislation (non exhaustive): New Chemical Substance Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (2010);Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) (updated in 2013);Hazardous Chemicals Decree 591 – The Regulations on Safe Management of Hazardous Chemicals(comes into force on 1 Dec 2011) - Main Law;Toxic Chemicals Restricted To Be Imported/Exported Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994);List of toxic chemicals severely restricted to be imported into or exported from China(revised in 2011);

[115] https://www.canada.ca/en/health-canada/services/chemical-substances.html

[116] https://www.epa.gov/chemicals-under-tsca

REACH are EUR 86 000, they are EUR 6 500 in the US, EUR 50 000 in Korea, EUR 116 000 in Canada, EUR 120 000 in Japan and EUR 125 000 in China[117].

The differences with other jurisdictions in terms of principles, approaches and processes result in a complex regulatory situation for companies as they must comply with both the regulation in the country where they produce and in their export markets. From the authorities' perspective, a better exchange of the approach and acceptance on some principles would help to have more harmonisation in the control and management of chemicals.

However, the ECHA chemical substances database, containing data collected through REACH processes, notably registration, contributes to the influence of REACH worldwide. According to ECHA, the use of ECHA's data by regulatory authorities outside the EU, and notably authorities in Canada and Australia has increased[118]. The government of Canada, for instance, considers ECHA as a key source of information during substance assessment work.

In addition to the influence on third country legislation, REACH is contributing to international harmonisation in the implementation of chemicals policy. Since 2010, ECHA has signed cooperation agreements with regulatory agencies in four countries: Australia, Canada, Japan and the United States of America. Activities are focused on exchanging information, best practice and scientific knowledge.

6.1.2.4. Stakeholder feedback

The online public consultation carried out in the context of this REFIT evaluation provides an overview of other issues raised by the different groups of stakeholders, including also effects not originally planned. These are, where there is evidence, discussed in Annexes 4 and 5 or under the other evaluation questions:

- Compliance costs and risk management measures (e.g. authorisation and restriction) may have resulted in the possible relocation of some activities outside the EU. (Costs are addressed under efficiency, relocation under Annex 4 paragraph 6.6)
- Difficulties in the registration of low volumes substances may be forcing market concentration. Market consolidation was expected under REACH: this also occurred for the Plant Protection Products[119] and Biocides [120]Regulation but was not seen only as a negative effect. (Addressed under efficiency questions, under Annex 4, paragraph 1.2.2 and Annex 5, paragraph 2.4.2)
- Disruption in the supply chains of certain products because of substance withdrawal. It was anticipated that those substances which were not essential would be taken off the market if the profit margins for a substance could not compensate for the costs of generating safety information (or if there was a close alternative). (Addressed under efficiency questions, Annex 4, paragraph 1.3.1 and Annex 5, paragraph 2.4.2)

[117] Study on the impacts of REACH on international competitiveness of EU industry

[118] ECHA Report on the Operation of REACH and CLP 2016 page 126

[119] Regulation (EC) No 1107/2009

[120] Regulation (EU) 528/2012

- Business uncertainty caused by the placing of a substance on the Candidate List. (Addressed under efficiency questions, Annex 4, paragraph 6.2 and Annex 5, paragraph 2.4.2)
- Competitive advantage of non-EU producers, which can export to the EU articles containing SVHC as they do not need to apply for authorisation. (Addressed under Annex 4, paragraph 6.5.3 and Annex 5, paragraph 2.4.2)
- Re-allocation of R&D resources (staff and budget) towards compliance which hinders market-driven innovation as well as more focus on substitution activities, which can be seen as a driver for innovation. (Addressed under effectiveness question 1 and Annex 5, paragraph 2.6.2)
- Bad practices such as free-riding in registration or the maintenance of dossiers. While the extent of such practices is expected to be limited, they may contribute to a negative perception of REACH by other companies (section 1.7 Public consultation, and Annex 4 part 10).
- NGOs have underlined that the assessment of applications for authorisation disfavours suppliers of alternatives as it focuses on the applicant's perspective. On the other hand, certain affected industries claim the misuse of public consultations as marketing tools for alternatives to substances subject to authorisation.

6.1.3. WHICH FACTORS INFLUENCED EFFECTIVENESS?

Assessment question: "What factors (including external ones) influenced the observed effects and to what extent?"

The effective cooperation between the Commission, ECHA and Member States Competent Authorities has been important for improving effectiveness. In addition, enforcement activities are important: these are increasingly prioritised to ensure that the key requirements of REACH are better implemented, but there is room for further improvements in enforcement, in particular for imported goods. More generally, the EU chemical sector operates in an increasingly global market, and has been affected by developments elsewhere including the global recession.

What is the issue?

This section examines some of the factors influencing effectiveness, and that are otherwise not directly addressed in the analysis above.

6.1.3.1. Coordination between ECHA, the Commission and Member States

The coordination of the public authorities involved in the implementation of REACH is one of the key factors contributing to the achievement of REACH objectives. Bodies intended to facilitate coordination such as the Commission expert group made up of the competent authorities for REACH and CLP (CARACAL) or the network of national and ECHA's helpdesks (HelpNet)[121] are working effectively. The ECHA Committees (MSC, RAC, SEAC) and the Forum provide additional fora for exchanging expert opinions and coordinate the views of different national authorities.

[121] HelpNet is hosted by ECHA and aims to ensure consistent responses to companies by National Helpdesks

ECHA and the Member States have, among other issues, addressed several new and scientifically challenging issues such as new test methods, read-across and other alternative methods. Furthermore, the activities focused on proper identification and assessment of Substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances, characterisation and safety assessment of nanomaterials and the assessment of complex toxicological modes of action such as endocrine disruption. This has increased scientific knowledge and understanding of the issues among EU authorities, industry, other stakeholders, and the scientific community.

Common screening and the implementation of the SVHC Roadmap are other processes where cooperation between Member States, ECHA and the Commission has promoted a coherent management of substances of concern, and has supported less experienced authorities in joining the implementation work. By that the number of substances addressed did increase. Compliance check and substance evaluation are also processes whose effectiveness is supported by very close cooperation between ECHA and Member States.[122]

In addition to the coordination of public authorities, it is notable the involvement of stakeholders (industry, NGOs, trade unions, etc.) in the bodies and networks organised by the Commission and ECHA that provide platform for discussion and capacity building.

6.1.3.2. Role of enforcement

Enforcement actions by Member States influence greatly the correct implementation of REACH requirements. Member State enforcement strategies are broadly in line with the strategy of the Forum[123] and are an important prioritisation tool to focus activities on actual non-compliance risks.

The organisation of enforcement activities is complex as in most EU and EEA Countries several national authorities are responsible for enforcing different parts of REACH (e.g. health and/or consumer protection authorities, national chemical agencies, labour inspectorates, environmental authorities or customs authorities). Such complexity requires enhanced coordination at national level (e.g. via regular meetings, memoranda of understanding or development of legislation to define responsibilities among authorities).

Effort has gone into improving enforcement and progress can be seen in a number of areas, although it is clear that it can still improve as shown by the indicators on enforcement activity which indicated lower level of compliance in particular with respect to control of imports and supply chain obligations (see Section 5.9 and Annex 4, paragraph 9.1.1 and 9.1.2). For example, market surveillance activities follow the adoption of new restrictions, identifying non-compliant products on the market and taking action by withdrawing such products from the market and notifying other Member States through the RAPEX Network.

The Forum coordination activities have increased from 2011 to 2015, focusing more on the practical harmonisation of enforcement operations through concrete projects[124]. Most

122 See further details in the evaluation section

123 https://echa.europa.eu/about-us/who-we-are/enforcement-forum

124 Further details in the Annex 4, chapter 9.

Member States (on average 28 of the 31 EU/EEA countries in every REACH Enforce REF project) participate in Forum projects and express appreciation, considering it to be an effective instrument to coordinate and harmonise the enforcement of REACH across the EU, exchange experience, and develop procedures for cooperation between national authorities and ECHA.

The results of the Forum's coordinated enforcement projects[125] have shown that the effectiveness of the enforcement activities of the Member States can still be improved in particular regarding registration obligations and Safety Data Sheets where a relatively high level of non-compliance have been found. These are the main tools for identifying hazards and risks and for communication along supply chains, respectively, as well as for controlling imported goods. Custom controls are based on non-compliance risk but nonetheless, insufficient control on imported goods is considered to pose risks for consumer safety as well as prevent an effective level playing field for EU manufacturers. An ECHA Forum project dealing with registration revealed that the highest proportion of non-compliant companies is among only-representatives (34 %), compared to importers (15 %) and manufacturers (6 %). The preliminary results of a Forum project in the area of restrictions show a similar trend, as 10% of EU-manufactured products are non-compliant, while 17% of non-EU products are not compliant and 39% of products of unknown origin are non-compliant.

The enforcement projects also revealed some differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end). However, no comparable information is available to assess the effect on the internal market.

While the coordination activities of the Forum are highly appreciated, according to the public consultation many stakeholders are of the view that the effectiveness of enforcement is not yet equal throughout the Union and more efforts should be done at national level suggesting targets for enforcement. Up to date, the Commission has started one infringement procedure for a breach of the harmonised implementation of REACH in relation to information requirements for SVHCs in articles[126].

6.1.3.3. External factors

The effects observed and the achievement of REACH objectives are also influenced by factors that are external to REACH. For example, the performance of the EU chemical industry was severely affected by the 2008/2009 global recession and after a rapid cyclical recovery, production has been growing more slowly than global demand since early 2011[127].

Global demand for chemicals is strongly driven by China, India and other emerging countries whose economies (and also chemical sectors) are growing faster than those of Europe and North America, where the EU chemical sector sells most of its products. In addition, energy prices, currency appreciation, the cumulative regulatory and tax

[125] On the basis of the projects REF-1, REF-2 and REF-3, available at https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

[126] See section 5.4 as regards the infringement procedure in relation to information requirements for SVHCs in articles.

[127] The EU production of chemicals fell significantly in 2008 and 2009 (by -3.4% and -11.8% respectively in volume terms). Production enjoyed a strong recovery in 2010 posting a 10.2 % growth rate compared to the year before (Cefic, Chemdata International).

burdens[128] or labour costs are important factors that impact on the competitiveness of the EU chemical industry (see also 7.3.3.1 International coherence).

Another factor are the activities of international fora (in particular the OECD) as regards the development, validation and acceptance of alternative test methods determine to a large extent the effectiveness in promoting the use of such alternative methods.

As regards the objective of REACH to increase the level of protection of human health and the environment, other chemicals related legislation (e.g. CLP Regulation) and additional factors also influence the effects observed. For example, the trends observed in the reduction of cases of occupational skin diseases and occupational asthma are not only the result of REACH related factors[129] but also of increased awareness and implementation of the legislation on health and safety in workplaces (see Annex 5, paragraph 1.5), a better knowledge of the hazard properties of the substances, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes (for details see 7.1.1.1 Reduction of risks)[130].

6.1.3.4. Conclusions

REACH's implementation has included efforts to improve the coordination of the main public actors involved, especially through the establishment of mechanisms that avoid fragmentation and increase the efficiency of their work. The effective cooperation between ECHA and Member States authorities in improving the compliance of registration dossiers and between Member States, ECHA and the Commission in the common screening and the SVHC Roadmap implementation contribute to achieving the objectives of REACH.

In addition, enforcement activities are increasingly prioritised through enforcement strategies to ensure that the key requirements of REACH such as registration obligations and communication through the supply chain are better implemented. Whilst improving, there is room for further improvement of national enforcement activities as regards harmonisation throughout the Union, including controls on imported goods. It is also clear that enforcement is still weak in some aspects in particular with respect to control of imports and supply chain obligations and in some Member States.

More generally, the EU chemical sector operates in an increasingly global market and, as evidenced by economic indicators such as sales and employment, the chemicals industry has been has been affected by developments elsewhere including the global recession.

[128] The cumulative cost assessment for the EU chemical industry (Technopolis 2016) estimated the cumulated weight of all legislation relevant to chemical companies for the period 2004-2014 to represent around 2% of their turnover, 12% of the value added and 30% of the gross operating surplus. The full report is available at: http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

[129] For example: (better) risk management measures introduced as a result of the registration process, increased communication along the supply chain and further actions via authorisation and restrictions (leading to the withdrawal of some skin and/or respiratory sensitisers)

[130] Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment – Development of a system of indicators, RPA, April 2016

6.1.4. TO WHAT EXTENT IS REACH CONTRIBUTING TO MEETING THE WORLD SUMMIT SUSTAINABILITY DEVELOPMENT (WSSD) 2020 GOALS?

Assessment question: "To what extent is REACH contributing to meeting the World Summit Sustainability Development 2020 goals?"
There has been considerable progress since the first target was adopted in 2002. Notably, many of the targets set out by the International Conference on Chemicals Management (ICCM) in 2006 have been met or are on track to be met by 2020. However, a number of actions needed to fully meet the WSSD 2020 goals have not been achieved yet, such as: information gaps identified in the registration dossiers; better targeting consumers or civil society at large; enhanced delivery of risk management measures

What is the issue?

At the 2002 Johannesburg World Summit on Sustainable Development (WSSD) the target of ensuring "*that by 2020 chemicals are produced and used in ways that minimise significant adverse impacts on the environment and human health"* was adopted. The goal was further developed emphasising the closing link between the chemicals and waste policies, and in 2012 at the Rio+20 summit[131] the revised target was "*to achieve by 2020 sound management of chemicals throughout their life cycle and of hazardous waste in ways that lead to minimization of significant adverse effects on human health and the environment"*. Finally in 2017 this was further refined as the Sustainable Development Goal 12.4

- *"By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment*."

The main differences, for the purpose of this evaluation, of the two goals is the strengthening in 2017 of the 2002 goal by removing 'significant' as a qualifier of the adverse impacts and the introduction of the means of achieving the goal through significant reduction in exposure. This question considers the contribution of REACH to the achievement of both the 2002 and the 2017 targets, which is analysed by using in addition the following:

- the objectives adopted by the International Conference on Chemicals Management (ICCM) in 2006 as part of an Overarching Policy Strategy designed to meet the WSSD target
- the roadmap for actions developed in a 2013 study[132] to achieve the WSSD target.

6.1.4.1. International Conference on Chemicals Management (ICCMs) overarching policy strategy

The ICCM in 2006 adopted an overarching policy strategy in order to operationalise the WSSD goal and to define in detail what is needed to achieve the goal. Therefore, five priority areas were identified in which a number of concrete objectives were specified that countries would have to achieve in order to meet the goal: knowledge and

[131] http://www.un.org/disabilities/documents/rio20_outcome_document_complete.pdf

[132] Link to the report on the Interpretation of the WSSD 2020 chemicals

information, risk reduction, governance, capacity-building and technical cooperation, and illegal international traffic. The contribution of REACH to achieving the objectives in the different areas is analysed in this section.

- Knowledge and information – Significant progress is being made under REACH in obtaining more information on chemicals and their potential risks. However, the level of non-compliance to the information requirements in REACH identified shows that less new reliable information has been generated than expected. With REACH, the EU created ECHA and put strong obligations on the Member States and the Commission to establish a chemical management infrastructure. Equally in industry, the submission of 95% of all registrations as joint registrations shows that the infrastructure built by industry to share information and develop joint dossiers has worked. An expected consequence of this infrastructure is therefore an improved understanding and knowledge of chemical safety issues.

- Risk reduction - The improved knowledge and information as well as improved risk management measures has led to risk reduction. For example, many applicants for authorisation reported improved risk management at the workplace as a result of the preparation of an application for authorisation or as a result of the discussions in ECHA concerning the application (See Annex 4 paragraph 6.5.1. and 6.5.2). Similarly, but to a lesser extent, industry reported improvements as a result of the registration requirements. REACH promotes substitution of SVHCs, though both the restriction and authorisation procedures could still be more effective and efficient. Also, non-compliance to the information requirements in REACH results in SVHCs remaining unidentified and hence in slowing down the phase-out process. Whilst the processes are underpinned by the precautionary principle, the principle itself has not been explicitly applied.

- **Governance** - REACH provides a comprehensive legal framework on chemicals management, completes the infrastructure of the Union by creating ECHA and assigns clear roles and responsibilities to the stakeholders involved. Procedures and tools have been put in place to inform and consult stakeholders and to address their concerns in the implementation of the different REACH processes. Enforcement has been strengthened, but still has weaknesses, and REACH has had a positive influence on international chemical governance.

- **Capacity-building and technical cooperation** – There are some indications that REACH is inspiring chemical legislation internationally and is contributing to improving the management of chemical risks. ECHA has developed a range of comprehensive guidance documents and has carried out awareness raising campaigns to support the implementation of REACH. IT tools for which ECHA contributes, jointly with the OECD, to the continued development such as IUCLID or the QSAR Toolbox, are made available and used globally. These activities contribute to capacity-building at global level and are elements of technical cooperation. (Activities further described under the evaluation question on coherence of REACH with international efforts). ECHA is internationally recognised as source of information for chemical risk management and cooperates with authorities in third countries.

- Illegal international traffic - REACH has limited impact on the reduction of illegal international traffic in chemicals, since it does not address export of chemicals. However, REACH provides rules on the import of chemicals, including enforcement and requirements applying to imported chemicals. Therefore, it can be assumed that REACH contributes to the reduction of illegal international trade by protecting the Union from illegal imports. REACH may further help reducing illegal international trade through the

improved market control in the Union and the better exchange of information on the legal status of chemicals.

6.1.4.2. Roadmap of actions

The 2013 study[2] (Figure 43, page 346) set out a roadmap of legally mandated, policy and other actions deemed necessary to reach the WSSD 2020 goal. The study explains why these actions are considered necessary to meet the WSSD 2002 goal assuming that the work on evaluation will effectively ensure compliant registrations dossiers and an efficient implementation of restrictions and authorisation. The following table gives a short overview of which actions were carried out and which ones not.

Table 2: roadmap to reach the WSSD 2020 goal

Roadmap Action	Action
2013	
Registration deadline for phase-in substances >100 t/y by 1 June (Art. 23(2))	Done
Clarify the relationship between OELs and DNELs in ECHA guidance and SDS	Ongoing
Review regarding Endocrine Disruptors(Art. 138(7))	Done
Draft implementing act on nanomaterials by December 2013	Ongoing
Reduce registration fees and other actions for SMEs	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
Improve awareness of REACH and safety data sheets with downstream users	Ongoing
2014	
Review of chemical safety assessment for CMRs 1 June 2014 (Art. 138(1))	Ongoing
Support for the identification of substances and efficient data sharing	Done
ECHA report on non-animal test methods, by 1 June (Art. 117(3))	Done
Tests for physical hazards to be carried out from 1 Jan 2014 (CLP Art. 8(5))	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
2015	
Possibility of implementing act on substance identification and "sameness"	Done
Member States' reports on the operation of REACH, 1 June 2015 (Art. 117(1))	Done

Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
2016	
Consider options for the development of rules and guidelines to protect children	Not yet started
ECHA report on the operation of REACH, 1 June 2016 (Art. 117(2))	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
Awareness raising on recognition of CLP hazard labels	Not yet started
Industry voluntarily action develop product packaging that is consistent with CLP	Not yet started

The still ongoing or not yet commenced actions are delaying either the efficient generation of information (for example nanomaterials) or information use (all other actions) and hence delaying the ability to ensure that adverse effects are minimised.

6.1.4.3. Conclusions

REACH contributes to meeting the WSSD 2020 goal to achieve the environmentally sound management of chemicals also beyond the EU borders. Indeed, there has been considerable progress since the first goal was adopted in 2002. Notably, many of the targets set out by the ICCM in 2006 have been met or are on track to be met by 2020. However, a number of actions needed to meet the WSSD 2020 goals have not or only partially been carried out such as: information gaps identified in the registration dossiers; better targeting consumers or civil society at large; enhanced delivery of risk management measures. This contributes to the conclusion that it is not likely that the EU will meet the 2020 goal as set out in 2002 and hence also not the one of 2017.

It can therefore be concluded that progress has been made towards meeting the 2020 goal but additional efforts are needed.

6.2. Efficiency

6.2.1. HOW DO COSTS AND BENEFITS OF REACH COMPARE?

Assessment question: What are the benefits and the costs and the corresponding key drivers associated with the implementation of REACH? To what extent are the costs proportionate to the benefits achieved?

Overall, the estimates of benefits and costs available indicate that the costs seem to be justified by the benefits. The biggest source of costs is the registration process: the costs for the first two registration deadlines, which were higher than originally predicted (in part because of mandatory data sharing, which was not considered in the Commission proposal), amounted to a total of EUR 2.3- 2.6 billion (compared to an estimate of EUR 1.7 billion). Even if in the same order of magnitude (the observed costs are approximately 35% higher than forecast), there is still scope to improve the efficiency.

6.2.1.1. Benefits associated to the REACH Regulation

The enabling factors for the benefits are the actions that allow REACH to deliver its objectives of protection of human health and the environment, enhancement of the single market, competitiveness and innovation. These can be associated to each of the processes:

- The REACH Registration requirement leads to new and better physicochemical and (eco)toxicological information for substances (including for their classification), while avoiding unnecessary animal testing and improving the knowledge on their uses and level of exposure, which in turn allows companies to decide on the most appropriate risk management measures to be put in place on site and to communicate these across the supply chain
- The number of substances and registration dossiers going through the Evaluation process, which leads to better information and confirmation (or not) of initial concerns
- The progressive restriction of substances and groups of substances of concern, which contributes to reduce the exposure to chemicals, thus increasing the level of protection of human health and the environment
- The continuous inclusion of SVHC in the Candidate List and in Annex XIV, which leads to these being progressively replaced by suitable alternatives and eventually phased-out; the authorised use assures that the risks from the substances of very high concern are identified, assessed and properly controlled, resulting in an improvement of the workplace conditions and thus increasing the protection of human health and the environment
- The increase in the number of substances with self (CLP) and harmonised classification and labelling (CLH) denotes an improvement in knowledge of the hazardous properties of chemicals. The ECHA database on CLP for substances allows industry to identify differences in how one substance is classified, and this database would, ideally, over time lead to coherent self-classification of substances by companies.
- The exchange of the enforcement activities across Member States.

Human health and environmental benefits

Information allowing the quantification of the health benefits arising from a reduction in chemicals' exposure is partial (at this stage of the implementation, information on trends is limited and is circumscribed to specific substances, uses and/or endpoints). Besides, as originally expected, the full benefits associated to the implementation of REACH will still take time to materialise. Nevertheless, on the basis of the evidence in terms of outputs (e.g. progress on registration) and outcomes (e.g information generated and risk reduction trends) so far, the potential scale of the benefits of REACH remains still as already stated in the 2013 REACH review. For human health over a 30-year period was estimated EUR 50 billion and the avoided environment damage over a 25-year period EUR 50 billion (both figures net present values after discounting).

Most of the interviewees in a survey for a study comparing the impacts of REACH with the corresponding regulations of third countries on chemicals and downstream sectors[133] shared the view that chemicals legislation (particularly REACH) will indeed have positive benefits on health and the environment over the long term. Nonetheless, they were not able to provide any examples of improved working environment, health, or environmental benefits yet, which is in line with the expectation that most of the benefits of REACH will only be quantified in the coming years.

Some specific evidence confirms the progress towards expected results at this stage and that benefits have started to materialise:

- The 10 years update of the so called REACH Baseline Study[134], which includes a set of indicators to monitor trends in the availability of data for risk assessment and reduction of risks, observes a continuation of the trend that was already noted in the 5 years update showing a reduction of the risks caused by chemicals and an improvement of the quality of substance-specific data available for risk assessment.
- The information generated in the registration process has contributed to building knowledge about chemical substances. It has provided as well transparency about what knowledge is still missing and better awareness of the needs of the upstream and downstream value chains. As a result, 23% of respondents to the survey by CSES et al (2015) launched new products or services thanks to the knowledge gained through the compliance process. Another study (RPA, 2015) concludes that the current registration requirements for low tonnage substances provide about EUR 10 benefits for every EUR 1 of cost and that by increasing the information requirements, there would be a roughly proportional increase in benefit in terms of damage costs avoided[135] (although the affordability by industry of potential increased information requirements remains uncertain).
- The benefits of the information generated under the Evaluation processes (dossier and substance evaluation) should complement the benefits generated by the registration, with their efficiency offset by the additional procedural cost that is however still below the cost for the data generation. As a more intangible but crucial benefit, as concluded in the specific section, they are, in conjunction with the regulatory management option analysis (RMOA) by Member States, an essential part of the system that ensure its consistency and improve the communication with industry, thus providing for an equal playing field for companies and contributing to the achievement of the overall benefits of REACH. The conclusions from the Impact Assessment for the modification of the REACH Annexes to ensure that the Regulation is fit for the purpose of nanomaterials[136] can also be applied to the Evaluation process that a better knowledge, where

[133] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry, ECSIP, 2016

[134] REACH Baseline Study – 10 years update, Öko Institut et al, commissioned by the European Commission, November 2016

[135] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015

[136] Impact assessment to be published

necessary through additional testing, means a better basis for the implementation of more appropriate risk management and, thus, increased avoided human health and environmental damage, as well as new innovation potential, improved trust for investors that there are no hidden liabilities and general demand side trust in the safety of products.

- The health and environmental benefits of the restrictions adopted during the reporting period for this review have outweighed the costs of their implementation. It is estimated that 9 of the restrictions submitted and adopted in this period under Article 68(1) for the introduction of new restrictions, as well as the amendment of current ones, produce health and environmental benefits of more than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, resulting in positive health impacts or removed risk for thousands of consumers and workers (compared to an estimated cost of about EUR 170 million per year)[137].
- Further benefits, although not quantified, can be expected from the specific restriction of CMR 1A and 1B substances in mixtures or in articles supplied to the general public[138].
- The benefits estimated in the two impact assessments[139] accompanying the first and second amendments to the Directive on carcinogens or mutagens at work[140] associated to the setting of exposure limit values for Chromium (VI) and Trichloroethylene are of, respectively, EUR 591 million to 1.7 billion and EUR 118 to 430 million for the period 2010-2069 related to avoided cancer cases. As explained in the Annex 5 paragraph 1.5, these values can be used to estimate the minimum benefits expected for the same substances listed in the Authorisation list (Annex XIV) which, on their own, cover 73% out of the 60 first applications received by ECHA.
- In the case of individual authorisations granted, the benefits calculated in the socio-economic assessments established by applicants for authorisation for 30 uses of 17 substances showed that the benefits of continued use of the authorised substances would amount to EUR 32-38 million per applicant per use[141]. ECHA further stressed in a later assessment that the socio-economic benefits of the

[137] Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016. Please note that these figures include only the quantified and monetised benefits, and thus do not represent the absolute value of the benefits of the adopted restrictions. The benefits figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[138] From 2010, the Commission has restricted more than 600 substances in mixtures sold to the general public.

[139] SWD(2016) 152 final; SWD (2017) 7 final

[140] Directive 2004/37/EC

[141] Report on the operation of REACH and CLP, European Chemicals Agency ECHA, May 2016

authorisations granted for the first 60 uses would amount to EUR 4.6 – 6.4 billion per year[142,143]

- Companies have improved their risk management procedures; as a matter of fact, according to CSES et al (2015), because of REACH 53% of companies say to have improved their risk management approach at the workplace and 39% to have improved their management and control of environmental emissions and waste.
- CSES et al (2015) collected some views that the candidate list and other communication instruments (Public Activities Coordination Tool - PACT and CORAP list) are increasing transparency and provide guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.
- More and more evidence starts accumulating that substitution is already happening as a result of a substance being listed on the Candidate List and the recommendation on priority substances for inclusion into Annex XIV, and when an intention for restriction is published in the Registry of Intentions (ROI) or through the investigation of analysis of alternatives in the Annex XV dossier for restriction. Indeed, from the sample of respondents affected by the inclusion of a substance in the candidate list, CSES et al (2015) concluded that about 9% had launched initiatives to develop new substances and 30% had launched initiatives to find an alternative formulation. The response of companies to the inclusion of substances in Annex XIV (Authorisation list) was broadly similar. According to Milieu et al (2017)[144], the legislative requirements are seen as the main driver of substitution, with respondents to their survey indicating that placing a substance on the Candidate List for Authorisation is the key mechanism that initiates the search for safer alternatives. ChemSec provides in the report *"The bigger picture"* a number of illustrative examples of companies that have decided to anticipate regulatory pressure and to undertake substitution[145], although not in direct relation to REACH.
- Product and Process Oriented Research and Development (PPORD) is perceived as a useful tool by Industry, as concluded by the SME panel[146]. Indeed, data from ECHA show that there is an increasing trend for the overall number of PPORD notifications. So far, around 20% of them have led to the registration of the substances concerned, demonstrating that the PPORD exemption has the potential to pave the way for new products on the market.

[142] Benefits and Costs of Authorising the Use of Substances of Very High Concern under REACH, presentation given at the 9th annual meeting of the Society for Benefit-Cost Analysis (Washington D.C.), Vainio M., Peltola J., Rheinberger C.M., 16-17 March 2017

[143] In the context of the individual authorisation decisions, benefits are the avoided costs for industry (opportunity cost that society would have to bear if the applicant could no longer use the substance applied for) and costs are the monetised costs that arise from damage to humans or the environment

[144] Link to the study for the strategy for a non-toxic environment of the 7th Environment Action Programme

[145] The bigger picture, assessing economic aspects of chemicals substitution, ChemSec, 2016

[146] Stakeholder consultation: report of the SME panel

- The recent communication from the Commission on the 'Modernisation of the EU Occupational Safety and Health Legislation and Policy'[147] states that the "Protection of workers from exposures to dangerous chemicals is fostered by the occupational and safety health chemicals directives and significantly reinforced by the REACH Regulation and other legal acts regulating chemicals".

Innovation and internal market benefits

These benefits have been examined in the effectiveness questions. Briefly, to recap:

- There have been positive impacts of REACH in terms of delivering an internal market. The wider cost impacts are considered in the following section.
- Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on R&D and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting R&D resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and increased communication across the supply chain enable the users of chemicals to make better choices in the design of products and in their use.
- Furthermore, the listing of SVHC in the candidate list or in Annex XIV triggers communication across the supply chain, initiates substitution activities at all supply chain levels, and triggers considerations of reformulation for some products and of withdrawal for some others. The continuous inclusion of new substances in the candidate list and in Annex XIV is however associated with uncertainty and perceived as a challenge for international competitiveness. On the other hand, data confirm that there has been a continuous flow of new substances on the EU market.

Table 3: Benefit summary

	Type of benefits	Monetised benefits (where available)	Remarks
Registration (including communication in the supply chain, i.e. extended Safety Data Sheets)	Information generated		Latency period
	Improvement of data available for hazard assessment (Classification &Labelling)		
	Improvement of data available for risk assessment		

[147] COM(2017) 12 final: Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy

	Improvement of risk management procedures, resulting in a decline of risk scores		
Dossier and substance evaluation	Complementary to registration process: generate additional knowledge about chemical substances		Latency period
Authorisation			
	Potentially avoided cancer cases from use of Chromium VI compounds and trichloroethylene	EUR 591 million – 1.7 billion (2010 - 2069) EUR 118 million – 430 million (2010-2069)[148]	Estimates associated to the setting of exposure limit values for those substances under OSH legislation. Figures provided for illustrative purposes
Restriction	Health benefits derived from reduced risks for workers and consumers	EUR 380 million per year	Expected benefits of new restrictions adopted under the REACH "standard" procedure[149]
	Environmental benefits derived from reduction of 70 tonnes of releases of substances of concern		

Conclusion on the benefits

Suitable datasets to quantify health and environmental benefits arising from a reduction in chemicals' exposure are largely missing and those that exist are representative for some national situations only. A direct comparison with the estimates provided in the Extended Impact Assessment is thus very difficult, but nevertheless the scale of potential benefit of REACH remains still, as already stated in the 2013 REACH Review, at least EUR 50 billion for human health by 2030 and EUR 50 billion for the environment by 2025.

When looking at the specific actions under REACH, it can be observed that some of those benefits are already materialising.

[148] Caveat: trichloroethylene is mainly used as intermediate

[149] Article 68(1)

6.2.1.2. Costs associated with the REACH Regulation

Direct compliance costs

Whilst the different actions of REACH facilitate the benefits, they also have direct costs. These are analysed in Annex 5 in more detail.

Registration

Among the REACH processes, Registration remains the main cost driver for EU industry, as it has the largest impact on business activity (production, prices, downstream sectors).

The cost drivers in the registration process are associated to the fees, which can vary according to the volume of the substance (the higher the volume, the higher the fee) and the size of the company (as SMEs benefit from lower registration fees), and to the preparation of the registration dossiers, which can vary according to the complexity of the dossier (depending on the intrinsic properties of the substance, the volume placed on the market and the use spectrum of the substance), the level of data sharing between registrants, the complexity of the Substance Information Exchange Forum (SIEF) and the availability of information (e.g. already existing information vs. new tests to be performed).

According to the General Report on REACH 2013[150], ECHA's fees in some cases represented 50% or more of the total costs companies incur when registering, especially in the case of simpler registration dossiers and smaller firms. In the case of more complicated dossiers, data collection, costs related to SIEF and consortia (including management and other fees) were the main cost elements. According to ECHA, "the major cost item in Registration is formed from the costs of compiling and generating the necessary data to fulfil the REACH information requirements", when registration fees only represent a minor part of the overall cost of registration.

The results from the Online Business Survey conducted by CSES et al (2015) confirm the views of ECHA, and suggest that the two costliest activities in the registration of substances in the tonnage band 100 to 1 000 tonnes (2013 registration deadline) were those associated with the fulfilment of the information requirements and with the preparation of the registration dossiers, while the registration fees represented 14% of the costs only.

The *Extended Impact Assessment* of the Commission accompanying the proposal on REACH estimated testing and registration costs of REACH to amount to EUR 2.3 billion in 2003 values (EUR 2.6 billion in 2011 values[151]) over the 11 years planned for completing the registration of all substances. This amount includes registration fees, estimated at EUR 300 million, registration costs, estimated at EUR 500 million, testing costs estimated at EUR 1 250 million (assuming the validation and acceptance of QSARs can be applied within this timeframe), costs linked to safety data sheets, estimated at EUR 250 million, authorisation procedures, estimated at EUR 100 million, and savings of EUR 100 million for new substances below 1 tonne. Compulsory data sharing was not considered in the extended Impact Assessment as it was not envisaged in the original Commission proposal.

[150] General Report on REACH 2013, European Chemicals Agency (ECHA), April 2014

[151] Cumulative cost assessment CCA for the EU Chemical Industry, Technopolis Group, commissioned by the European Commission, April 2016

For the first registration deadline of 2010, which concerns phase-in substances produced or imported in quantities over 1 000 tonnes[152], the Extended Impact Assessment had anticipated a cost of around EUR 1.15 billion for the industry, when recalculated into 2011 prices. According to the General Report on REACH 2013, the industry survey of 2011 concluded that the cost incurred by duty holders had been higher than forecast, EUR 2.1 billion (with a broader range of EUR 1.1 - 4.1 billion). Although in 2011 there was a significantly lower use of QSAR compared to what was anticipated in the Extended Impact Assessment, this was partially compensated by a higher use of read-across than expected. The difference between the 2003 estimate and the 2011 survey comes thus from the reporting of sums paid by firms for participating in the SIEFs and for accessing data from existing studies (these payments between companies were not included in the 2003 Extended Impact Assessment as they are not a net cost to the sector, and relate rather to transfer payments that benefit companies that had already undertaken testing – they are not a cost of REACH for the sector as a whole and should thus not be included in the overall cost assessment).

CSES et al (2015) focused on the 2013 registration deadline and estimated that the total costs incurred by companies (including registration, testing and safety data sheets) was of the order of EUR 459 million, for the 2 998 phase-in substances registered in 2013 deadline[153]. These estimations are within the range of the costs anticipated in the *Extended Impact Assessment*.

Under these estimates, the first two registration periods cost approximately EUR 2.1 billion (2010) and EUR 459 million (2013) respectively. Adjusting these figures for transfer payments between firms gives a cost of around EUR 2.3 billion in total[154].

Other relevant findings are that:

- The average cost per substance (covering registration, testing and SDS) from the study surveys is around EUR 153 195 when, for the same cost items, the Extended Impact Assessment anticipated a cost per substance of EUR 193 367[155].
- The study on monitoring the impact of REACH on innovation, competitiveness and SMEs[156] provided estimates of the costs of producing and translating extended SDS as part of the 2013 registration activities. The average costs related to SDS (per registered substance) were estimated at EUR 36 358, which is higher than the estimate in the Impact Assessment accompanying the REACH proposal

[152] Phase-in substances are substances that have been on the European market for a long time, unlike non-phase-in substances, which are all those newly invented; phase-in substances are subject to three different registration deadlines (2010, 2013 and 2018), depending on the tonnage band (between 1 and 100 tonnes, between 100 and 1 000 tonnes, and over 1 000 tonnes, respectively), whereas non-phase-in substances must be registered at any time before their placing in the market

[153] These estimates have been built from the results of the Open-ended online business survey (OBS) conducted for the study, which gathered 566 responses from all types of duty holders. The scope for error within this estimate is potentially large given that it is based in a combination of estimates and relatively small proportion of respondents to the survey as a whole (86/566 or 15%)

[154] ECSIP (2016): the cost model includes an assumption that these transfer payments account for 11 % of the registration costs, but this estimate is subject to uncertainty

[155] Own calculation based on the estimates provided in the *Extended Impact Assessment*

[156] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (CSES, RPA, Okopol 2015) http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations

(EUR 19 844). The comparison by company size suggests that the costs of producing extended Safety Data Sheets appear to be moderately higher for SMEs compared with larger enterprises. A plausible explanation is that the SMEs need to learn and familiarise with those obligations, whereas larger enterprises already gained more experience as part of 2010 registration.

- In order to provide an estimate of the 'typical' costs borne by companies, the study provided median costs per substance and per registrant for substances registered in the 100-1 000 tonnage range. These were EUR 5 763 for producing extended SDS and EUR 4 473 for translation. Furthermore, these figures show that the median costs were somewhat higher for SMEs (EUR 11 899 as the total of producing extended SDS and translation) than for large companies (EUR 8 016).
- There are also costs associated with duty to communicate information on substances in articles (Article 33 of REACH), and with Risk Management Measures undertaken downstream. Additional direct costs may result depending on the duty holder role.
- CSES estimated the costs of registration for the 2018 deadline. The estimates for the 1 to 10 tonnes substances appear to be in the range of the Extended Impact Assessment (EUR 228 million compared to the estimate of EUR 295 million), but the total cost of registering 10 to 100 tonnes substances is estimated to be significantly higher than formerly estimated (up to EUR 1 136 million as compared to EUR 581 million). This is partially explained by the fact that this last estimation is based on a worst case scenario with the assumption that validation and acceptance of negative and positive QSAR and read-across does not occur within the time frame envisaged in the earlier Extended Impact Assessment.

The studies discussed above have mainly considered the costs incurred by the registrants (manufacturers, importers and only representatives). The specific costs incurred by distributors are briefly described in both the Technopolis Group (2016) and CSES et al (2015) studies, but have not been quantified. These costs have been mostly linked to the pre-registration obligation (pursuant to Article 28 of REACH) and the preparation, translation, coordination, update and modification of Safety Data Sheets.

A check on the findings above, which are based on responses from industry for the large part, are the actual fees and charges paid to ECHA. The fees and charges revenue over the period 2007-2016 was EUR 581 million and the EU balancing subsidy amounted to EUR 225 million. However, the revenue (which is included in the registration cost estimates above) includes payments by non-EU firms (who account for half the registrations) and also payments for other services.

Evaluation

The drivers for the costs are the cost for the registrants to generate the required information, and the 'overhead' for all actors in identifying substances and information needs through the formal process. The generation of information following dossier evaluation is driven by information gaps, either due to lack of high tier information (testing proposals) or non-compliance with the standard information requirements (compliance check). There is also uncertainty for manufacturers, about the ultimate cost of registration of the substances under evaluation, and for downstream users, about the ultimate development cost of the products necessitating those substances. It may also

lead to product withdrawal, with the associated knock-on effects for the firm concerned by the withdrawal, upstream suppliers (if present) and downstream users, although there is limited evidence of this so far.

The cost for generating data under dossier evaluation were estimated to be for the period 2009 - 2016, only for the 1 907 requests on 'super-endpoints' in the 1 695 final decisions, in the order of EUR 200 million[157]. It should be noted that these costs should be attributed to registration, as they are merely covering the information gaps due to pending registration obligations or non-compliance.

For substance evaluation, the combined cost estimation is not available but is comparatively smaller due to a much lower number of substances addressed; in the same time interval, 82 decisions were issued. In 26 decisions taken in 2016, 84 data generation requests were made. While the requests are of course very case specific, tailored only to the information required to clarify the concern, they can be assumed to be in cases substantial for the individual companies addressed by the decision.

Evaluation is however also time and resource intensive for the Competent Authorities: excluding the time to perform the test itself, the average time for dossier evaluation is 461 days, and for substance evaluation more than 2 years. For the latter, an additional time for placing the substance on the list prior to the assessment (13 months on average) needs to be counted. In order to provide support to Competent Authorities in the work they perform for substance evaluation, ECHA decided to transfer a proportion of the fees collected by ECHA to Member States. The estimated average time in this Decision is of around 65 days for year 2017[158].

According to ECHA's 2016 Final Work Programme[159], 106 Full Time Equivalent (FTE) are dedicated to evaluation (this includes both dossier and substance evaluation assessment and decision making, as well as the evaluation decisions follow-up, management, scientific support and related IT development). Significant effort is put into the evaluation also by MSCA[160] and the Commission[161], but no consistent information is available.

Authorisation

The main cost driver for actors that have substituted Annex XIV substances before their

[157] See chapter 5, subchapter on Evaluation, for more details. Super-endpoints cover most important information from the perspective of integrated regulatory strategy. Other requests beyond these endpoints were made as well. No precise cost figures are available; this estimate is based on the statistics on the number of individual data requests in the period and the costs per each test as used in the draft Impact assessment accompanying the Proposal for revision of REACH Annexes on nanomaterials. As the proposal is still in decision making, the impact assessment has not yet been published

[158] Decision of the Management Board on the financial arrangements for the transfer of a proportion of the fees to the Member States, December 2014

[159] ECHA's Work Programme 2016, European Chemicals Agency ECHA, December 2015

[160] Commenting all evaluation draft decisions and performing as an evaluating authority for the selected substances under substance evaluation. For example, the figures reported by Member States for persons-day dedicated per year to dossier evaluation vary from 0.02 to 1 000 and the figures for substances evaluated (2012-2014) from 0 to 18

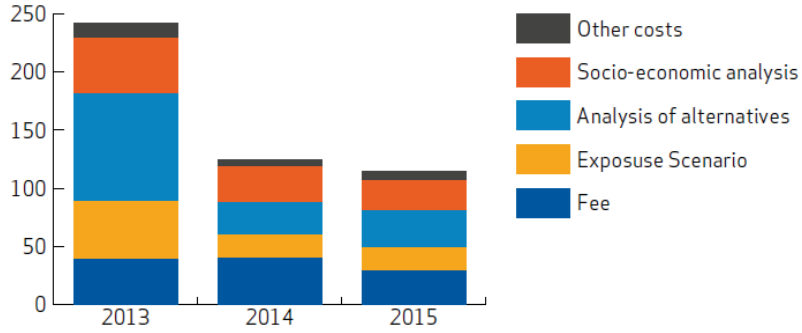
[161] The Commission is required to process all evaluation decisions for which no unanimity has been achieved in the ECHA Member States Committee

sunset dates, and therefore their uses did not need an authorisation, lies in costs of substitution. The main direct cost drivers for companies applying for authorisations are the fees, the preparation of the application, including charges for consultancy services, and the interactions with authorities after an application is submitted. There are further follow-up costs for companies, including those resulting from the compliance with the conditions set out in the granted authorisations, R&D costs, the adaptation of the production process or the implementation of the alternative.

From industry's perspective, the biggest cost driver is the uncertainty about the future legislative requirements for the substances that companies manufacture or use. Such uncertainty arises already at the stage of placing a substance on the candidate list and is in general associated with potential negative effects on investment decisions and/or on the choice by companies on where to locate their production facilities. Evidence of this actually happening is however limited to anecdotal facts and the issue would need to be studied further.

Direct costs of applications for authorisation for companies include fees paid to ECHA and the administrative cost of preparing, submitting and defending the application dossier. The costs of the applications have been estimated by ECHA (2016) to be currently around EUR 120 000 per use per applicant in 2016 (in average), down from nearly EUR 230 000 in 2013 (reduction of about 50%)[162].

Figure 4: Application costs per applicant per use in 2013-2015



Source: ECHA, 2016

However, there are administrative burden and capital costs not taken into account in these figures, such as the time to prepare the applications for authorisation or the subsequent costs of complying with certain conditions of the authorisations imposed by the Decisions, and costs of substitution. The data available from ECHA include only the costs of preparing an application for authorisation, but no information on R&D and capital cost of substituting or costs of fulfilling the conditions of authorisation (monitoring, improving risk management etc).

[162] The estimates are based on a systematic collection of application costs from ECHA, no explanations are provided in ECHA's report about the causes, although it may be assumed that the reduction is linked to a better expertise from applicants as well as a better understanding of the applicants with regard to the information required by the ECHA scientific committees

Restriction

The main cost drivers for industry are the substitution of the concerned substances by their alternatives or the compliance with the newly set thresholds or content limit values due to the availability of reliable analytical methods. There can be additional indirect costs linked to the non-availability of the restricted substance or constraints in the use (which would affect the production costs and the price of the final product). The costs for Member States when submitting a proposal for restriction occur mainly when preparing the dossier (data are not always easy to retrieve[163], lack of expertise or resources) or when the proposal does not pass the conformity check and additional information is requested to Member States in order to have the dossier in conformity. Other general costs for all Member States are those related to the enforcement of the restrictions, once they enter into force.

The report on *Cost and benefit assessments in the REACH restriction dossiers*[164] evaluates the total substitution costs linked to restrictions in the EU to EUR 290 million per year. Variation between cases is however significant, between EUR 0 and EUR 100 million per year per case, and the five most expensive restrictions contributed to around 88% of the total costs. Based on that study conducted by ECHA, it is estimated that 9 of the restrictions submitted and adopted during the review period under Article 68(1) for the introduction of new restrictions and the amendment of current ones have an estimated cost of about EUR 170 million per year[165].

Indirect costs

The indirect costs are mainly generated by the withdrawal of a substance from the market due to economic reasons (e.g. the registration cost is too high), or by the withdrawal of a substance from the EU market in certain uses following a restriction or a change in classification. For example CSES et al (2015) show that near to one third of companies (including downstream users) have reported to be affected by a withdrawal of a substance from the EU market due to registration costs. According to affected companies in a case study[166], this leads to R&D expenditure for reformulating mixtures, increased manufacturing costs and increased price of substances, loss of markets or even ceasing business activity and supply chain effects (e.g. the impacts of substance withdrawal and increased price on downstream users).

CSES et al (2015) concluded from their survey results that the 2013 registration deadline is unlikely to have resulted in a significant increase in prices of chemical substances, as the main reaction from companies was to absorb costs rather than increase prices to recuperate costs. The survey results suggest that only around 20% of companies

[163] Report of the Task Force on Restriction Efficiency, European Chemicals Agency ECHA, October 2014

[164] Cost and benefit assessment in the REACH restriction dossiers, European Chemicals Agency ECHA, April 2016

[165] This figure includes only the quantified and monetised costs, and thus do not represent the absolute value of the costs of the adopted restrictions. The costs figures presented in the ECHA report (costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[166] 31 companies participated in the case study on the business impacts of withdrawals

increased their prices, which implies that, overall, the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances.

Other examples of costs transferred to downstream users are the cases where costs of application for authorisation fell on downstream users as a result of chemical suppliers not applying for small volume uses, for which the cost of the application was not profitable. An example is the in-vitro diagnostic industry that typically tends to use smaller amounts of critical substances relative to the end-user clinical laboratories.

Table 4: Cost summary

	Costs quantified[167]	Remarks
Industry costs		
Registration (including also communication in the supply chain, i.e. extended Safety Data Sheets)	Overall estimated costs for 2010 and 2013 registration deadlines EUR 2.3 – 2.6 billion	Estimates based on two surveys. Compared with EUR 1.7 billion estimated for the extended Impact Assessment. The main reason for this difference appears to be the limited use of the QSARs testing method, in contrast to initial expectations.
	Costs/substance (2013 deadline) - Average EUR 153 195 - Extended Safety Data Sheet EUR 36 358 Costs/substance and registrant - Median Extended Safety Data Sheet EUR 10 236	
Dossier and substance evaluation	Dossier evaluation (2009-2016) EUR 200 milion	Estimates for 1907 requests on "super-endpoints"
Authorisation	Substitution costs could not be quantified Application for authorisation costs per use per applicant – EUR 250 000 in 2013 EUR 120 300 in 2015 - 2016	
Restriction	EUR 170 million per year	Expected benefits of new restrictions adopted under the REACH "standard" procedure[168]

[167] Other costs could not be quantified but are described in the text above

[168] Article 68(1)

		Mainly substitution costs (higher prices of alternatives and investment costs). In some cases the lost consumer surplus, enforcement costs and compliance control costs to industry were quantified.

Conclusion on the costs

Overall, the main direct costs under REACH are observed to be mainly arising from the registration obligations and from the communication of information along the supply chain (extended Safety Data Sheets). Whilst there is some uncertainty over the costs incurred so far, the costs for the first two registration deadlines appear to be between EUR 2.3 -2.6[169] billion, in the range of the Impact Assessment. The evaluation costs can still be significant, in the order of EUR 200 million only for dossier evaluation (for the period 2009-2016). The costs of the restrictions adopted during the review period are estimated to be EUR 170 million per year. The costs for the authorisations have been quantified in relation only to the preparation of individual applications for authorisation, currently around EUR 120 000 per use per applicant in 2015 (in average), down from nearly EUR 250 000 in 2013 (reduction of about 50%).

There are also indirect costs triggered by registrations, authorisations and restrictions.

6.2.1.3. Proportionality of the costs to the benefits

Direct comparison between quantified costs and benefits can be made for the time being only for the Restriction and the individual applications for Authorisation.

Calculations from ECHA (2016) show that the expected health and environmental benefits of the restrictions outweigh the estimated costs of their implementation. The estimated annual cost of the restrictions adopted during the reporting period is more than EUR 170 million per year, while the monetised benefits reach EUR 380 million per year.

As for the authorisation process, the overall benefits for the human health and environment result from reduced exposure and emission of substances placed on the authorisation list through their substitution and the improvement of risk management at the workplace. These overall benefits have not been quantified; however, estimations of avoided costs related to occupational cancer cases provide an approximation of the human health benefits. Costs have been quantified only in relation to the preparation of individual applications for authorisation. The comparison between benefits and costs should thus be taken with caution when assessing the overall efficiency of the authorisation process.

Granting authorisation allows for continued use in justified cases, i.e. when risk is adequately controlled or when socio-economic benefits outweigh the risk. The case-by-case evaluation involves assessment of costs and benefits of continued use for individual authorisations, and so allows for avoiding excessive costs. The application costs of EUR 120 000 per application per use represent 0.2% of the benefits of EUR 32-38 million per

[169] This range reflects some uncertainty regarding the value of transfer payments

applicant per continued use. One published article on the *Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH* also confirmed that the application costs are low compared to the benefits of continued use[170]. However, even if still low compared to the benefits, it could be inferred from the responses from companies in the CSES study (2015) and in the SME panel that the costs may still be significant for SMEs. The socio-economic benefits of the continued use of up to 366 metric tonnes per year of 17 different substances would amount to EUR 4.6 – 6.4 billion per year, to be compared to monetised health impacts in the range of EUR 230-340 million per year.

A study made in the UK on environmental legislation[171] shows that the implementation of chemicals legislation, transposed mostly from European regulation, would provide a best benefit cost ratio of 20 to 1 in the medium-long term. Although this study has limited direct applicability to the benefits attributable to REACH, it is relevant to illustrate the potential benefits/costs ratio of EU chemicals legislation.

6.2.1.4. Views of stakeholders

Respondents to the open public consultation showed a mixture of positive and negative views to the question of proportion of costs on registration and information in the supply chain. Concerning the costs linked to dossier and substance evaluation, negative views are slightly more pronounced (around 40%) than those holding positive views (20%), with the rest thinking that costs are somewhat proportionate. For costs related to restriction, positive views are slightly more common. Negative views prevail to a large extent for costs related to authorisation and to requirements for substances in articles, for which large shares (30% - 40%) think that costs are not at all proportionate. However, NGOs, consumer associations and public authorities hold much more positive views than the other stakeholder groups on the proportion of costs related to all of the mentioned chapters.

6.2.1.5. Conclusion

The data gaps reported above make it difficult to draw direct statistically robust comparisons between the costs and any identified or potential benefits that may result from the implementation of REACH. It needs to be stressed that any conclusion at macro level does not prejudge whether compliance costs are sustainable for SMEs.

With the evidence at hand, it can, however, be concluded that:

- The Registration costs have been somewhat higher than anticipated in the Extended Impact Assessment, which can be explained by the administrative costs of mandatory data sharing (not considered in the Impact Assessment as it was not envisaged in the original Commission proposal) and less than predicted use of QSARs. Overall, the registration costs for the two first registration deadlines in 2010 and 2013 appear to be between EUR 2.3 -2.6[172] billion, in the range of the Extended Impact Assessment, which anticipated costs of around between EUR 1.7 billion.

[170] Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH, Philipp Hennig, 2016

[171] The costs and benefits of Defra's regulations, Defra, 2015

- Although there is limited data on indirect costs, the costs of registering the substances have been absorbed by the chemicals industry, rather than passed on further down the supply chain.
- It needs also to be stressed that while the large bulk of costs have already occurred with the two first registration deadlines in 2010 and 2013, most of the expected associated benefits will only be quantified later.
- It is too early to conclude on the costs and benefits from Evaluation, but it can be asserted that it is an essential part of the system to ensure that the objective of protecting health and the environment is met and to allow a level playing field amongst registrants.
- The data requirements for the Restriction process are clear for the Dossier Submitter although the collection of that data is still difficult for most of the Member States. The benefits of the restrictions adopted during the review period clearly offset the associated costs. In addition, more benefits result for the environment (see Annex 5, part on benefits) and are expected from the restriction of CMR substances in mixtures sold to the general public, as well as from reducing potential exposure to CMR substances through consumer products.
- As for the Authorisation process, the overall benefits and costs of the process as a regulatory risk management instrument have not yet been quantified. However, the case-by-case evaluation of costs and benefits of continued use of a substance allows for avoiding excessive costs from the societal perspective. There are clear indications that the socio-economic benefits of the continued use of the substances for which authorisations have been granted, or conversely, the avoided costs which would have been caused by not using those substances, outweigh the risk for human health and the environment by a significant margin. There is evidence that substitution is happening and that companies are improving their risk management measures, which are direct indicators of the benefits of the Authorisation process.

Overall, the estimates of benefits and costs available indicate that the costs seem to be justified by the benefits. This is not to say that there is not scope to improve their efficiency, or to comment on the proportionality of the burden for an individual firm.

6.2.2. HOW ARE COST DISTRIBUTED BETWEEN DIFFERENT STAKEHOLDERS?

Assessment question: Was the distribution of costs proportionate between the different stakeholders (e.g. larger companies vs SMEs, or among different industrial sectors)? To what extent are there unnecessary burdens on stakeholders?

The evidence available so far provides indication about how REACH has impacted companies of different size or different sectors. Compliance costs affect the business activity of SMEs, which remain more vulnerable than large companies. On the other hand, the support provided to smaller companies to comply with REACH is perceived as useful, although there is still margin for improvement.

6.2.2.1. Impact of compliance costs on SMEs and on larger companies

Two studies (CSES, 2012[173] and CSES et al, 2015), as well as the open public consultation and the SME Panel carried out in the framework of this evaluation[174], indicate that there are some differences between large companies and SMEs in terms of the economic impacts of REACH.

Compared to SMEs, larger companies have in general more resources and markets from which to recover costs, greater financial capacity to make upfront investments as well as a larger capacity to recruit specialised staff to deal with REACH compliance. Small or micro-firms are also often more dependent on one or a few specific chemical substances than large companies. Furthermore, SMEs depend more on the use of external service providers to ensure compliance with REACH[175]. As a consequence, the business activity of SMEs has generally been more affected by REACH.

Since the REACH Review 2013, several support measures have been introduced to alleviate the burden on SMEs. Among those, the registration fees were revised and reduced for SMEs (an additional 5% compared to the earlier situation and applicable already for the 2013 registration deadline). Furthermore, an Implementing Regulation on data sharing was adopted and entered into force on 25 January 2016 to benefit SMEs from a fairer and more transparent framework. The data from the SME panel survey show that the reduction in fees of 2013 is perceived as useful or very useful by nearly half of the respondents (46 %), whereas a quarter was not aware of this measure. Similar feedback was given for the Regulation on data sharing.

In some cases, the cost of the registration of substances was a reason for an SME to withdraw from a business line or decide to cease operations. In concrete terms, data from CSES et al (2015) provide a basis for a comparison that shows that SMEs have been experiencing more substance withdrawals than large companies as a result of the 2013 registration deadline[176] and have more often withdrawn substances from the market because of registration costs[177]. According to the study, this effect is linked to the relatively lower capacity of SMEs to absorb the registration costs and the resulting reduced profit margins. Furthermore, the existence of entry barriers for companies in the chemical industry has been raised in the SME Panel by several companies, as well as the fact that some micro and small firms find it increasingly difficult to compete with large companies due to REACH[178].

With regards to the cost of Registration, CSES et al (2015), the average registration costs (per substance per registrant) for the 2013 deadline were found to be 5-25% higher for SMEs than for large companies. Although in general the costs seem to be slightly higher

[173] Interim Evaluation: Functioning of the European chemical market after the introduction of REACH, CSES, 2012

[174] Report on the results of the REACH Evaluation open public consultation, Milieu, 2017 and SME panel, 2016

[175] In the CSES et al survey (2015), large firms reported more often than SMEs that they have a dedicated REACH unit (33% compared to 17%) and more often have a dedicated REACH manager (48% compared to 29%)

[176] 36% for SMEs as opposed to 25% for large companies

[177] 47% of SMEs that withdrew substances did it because of registration costs, compared to 35% of large companies

[138] 22% SMEs consider loss of business to big companies as an important indirect cost of REACH

for SMEs, given the large variability of costs it is difficult to draw firm assumptions on the scale of cost difference between SMEs and large companies.

Table 5: Average registration cost per substance per registrant by tonnage band and by size of companies[179]

	>1 000 tpa	**100 - 1 000 tpa**	**10 - 100 tpa**
SMEs	EUR 86 733	EUR 63 723	EUR 73 250
Large companies	EUR 80 619	EUR 88 603	EUR 69 839

There has not been enough experience yet for a full assessment of the impacts of the Authorisation process on SMEs. However, SMEs appear to have been less affected by both the placing of substances on the candidate list[180] and the Authorisation procedure. On the other hand, the SME Panel results indicate that the costs of the application for Authorisation are a concern for approximately one quarter to one third of participating SMEs and broadly similar figures apply to the restriction process[181].

This evidence confirms the conclusions from the 2013 REACH Review Report indicating that compliance costs affected more negatively the business activity of SMEs than of large companies and it is not surprising that concerns remain with regard to the potential loss of smaller businesses and reduction of suppliers both from within and outside the EU/EEA. However, the differences revealed via surveys vary between specific areas of impacts and their extent is rather limited.

6.2.2.2. Support received by duty holders to comply with REACH

As a follow-up to the findings of the 2013 REACH review, the Commission and ECHA enhanced the support and tools made available to REACH duty holders in order to facilitate their understanding and fulfil their legal obligations, focusing on the needs of SMEs.

Over 90% of respondents, across all REACH roles, stated that they used ECHA's supporting instruments. Over half of the respondents found the support 'quite' or 'slightly' useful. Also, the support provided by industry associations is regarded as very useful by the majority of respondents, although some comments from stakeholders criticised the fact that the instruments are not suited for SMEs or even discriminate such market actors, as the solutions often do not reflect the situation of such companies.

The SME panel provides similar indications, as suppliers and helpdesks are the most common source of information. When considering the mechanisms put in place to support companies, the information published by ECHA is seen as the most useful for all sort of companies, closely followed by sector specific information and information published on national, local or regional level.

[179] *Source: CSES, 2015, p. 41*

[180] 34% of SMEs have not been affected compared to 17% of large companies in the on-line business (OBS) survey; and 25% of SMEs compared to 42% of large companies in the computer aided telephone interview (CATI) survey

[181] The preparation of an application for authorisation was seen as a moderately important challenge by 13% of participants and as a very important challenge by 19%. Costs associated with the application were moderately important for 10% of respondents and very important for further 15%. The costs of the Restriction were moderately important for 20% of the respondents and very important for further 17%

6.2.2.3. Impact of compliance cost on different sectors and subsectors of the chemical industry and on downstream users

While Registration costs are primarily borne by the chemicals industry (manufactures and importers of chemicals), the Authorisation process and the obligations to pass on information on SVHC in articles have mainly impacted the downstream users. Since the ability of chemicals producers to pass through the registration costs to customers is generally low[182], the larger part of them had to be absorbed by the chemical industry. However, since the chemicals market is segmented and a highly diverse group of enterprises and downstream users participate in market activities, the implementation of REACH affected different parts of the market in different ways.

The feedback to the public consultation indicates that the sectors perceiving the impacts of REACH include a large number of downstream industries such as metals, automotive and mechanical engineering and consumer product industries (textile, plastics, pharmaceutical products and electronics), all of which depend on the use of chemicals. The issues most frequently raised by the downstream sectors concerned the general complexity and administrative burden related to the Authorisation process, as well as to the obligations to communicate information in the supply chain[183]. A few examples provided by Industry during the public consultation also indicate that the uncertainty and recurring costs associated with the Authorisation process have been an important factor for decisions on whether to locate the manufacture of certain products in the EU or not.

The SME panel indicated additional challenges such as the complexity of the Regulation, the communication of information in the supply chain and the access to data, which seem to have a significant impact on companies, regardless of their type, size or sector. When looking at differences based on the role under REACH, distributors, importers, only representatives and suppliers of articles generally score these challenges higher than other stakeholders. On the other hand, downstream users systematically score the different challenges lower than average (with the exception of the requirements regarding substances in articles). Those challenges are bigger for micro-enterprises. No major differences were found between sectors.

6.2.2.4. Conclusion

The registration costs may be somewhat higher for SMEs than for large companies, particularly for lower tonnage bands, which indicate that the registration costs might be high for SMEs in the last registration deadline in 2018[184]. SMEs' business activity has

[182] The ability of passing through costs is rather sector-specific. The generally low ability to pass registration costs to customers was confirmed in the SME Panel Consultation, where 64% respondents stated they were not able to pass on the increase in the costs on customers and 20% only to a small extent

[183] Out of the 153 statements submitted in the framework of the open questions which can be deemed relevant to efficiency of REACH implementation, 43 concerned streamlining of the authorisation procedure and 110 complexity of the Regulation and information requirements

[184] The findings from CSES 2015 report show that specific cost elements appear to be higher for SMEs which can be explained by lower experience and lower know-how among SMEs with respect to collecting data. In addition , the recent estimates point to potential high costs, specifically for the 10-100 tonnage

generally been more affected than large companies' because SMEs have experienced more substance withdrawals[185].

However, since the differences revealed via surveys are relatively limited and the extent of these differences varies between studies, the observed effects do not allow for a firm conclusion.

The support provided to SMEs at national, EU and industry sector levels is seen as useful by a majority of small companies and to a certain extent have helped compensate their lower capacity to absorb compliance costs. However, the feedback from SMEs also suggests that there is still room to facilitate compliance with REACH for small firms for example by providing more practical and user-friendly guidance from authorities, more seminars on REACH and better availability of information in national languages. With regards to the sectorial aspect, since the mechanisms to control SVHC affect the whole manufacturing value chains, and in absence of robust statistical data, any statement of disproportionality of impacts for individual sectors would also be premature.

6.2.3. WHAT ARE THE COSTS FOR PUBLIC AUTHORITIES?

Assessment question: How are costs distributed among public authorities at EU and national levels?

ECHA's fees collected (2007 and 2016) amounted to EUR 581 million. In addition, the EU budget subsidy has amounted to EUR 225 million, slightly below the expectations due to higher than anticipated fees and charges revenues. Member States' participation in the REACH processes activities has increased, although some processes still appear to be driven by a small number of Member States and a few Competent Authorities do not have the resources to participate in all activities/committees.

6.2.3.1. EU level costs

Between 2007 and 2016, ECHA's budget for REACH amounted to EUR 757 million and the fees collected by ECHA amounted to EUR 581 million, which is above the forecasted fees and charges income for the same period (EUR 509 million)[186]. The cost of ECHA in terms of EU budget (i.e. subsidy) has amounted to EUR 225 million, slightly below the expectations in the 2006 Legal Financial Statement. This difference is mainly due to higher than expected fees and charges revenues.

It is worth noting that the fees collected by ECHA should already be included in the estimates of costs for the different processes, such as registration. Fees and charges were received not only from EU companies but also from companies outside the EU as, for example, half the registrations relate to substances manufactured outside the EU.

[185] According to CSES at all (2015), SMEs reported in a survey experiencing a higher level of substance withdrawal than large firms as a result of the 2013 registration requirements (36% as opposed to 25%)/ More information in Annex 5

[186] 2006 Revised Legislative Financial Statement – SEC(2006)924 2006 Revised Legislative Financial Statement – SEC(2006)924

ECHA has 517 staff working on REACH and CLP and the Commission services in charge of REACH implementation consist of two units in two different DGs with a total involvement of 35 staff.

6.2.3.2. Member States' direct costs

Direct costs for public authorities include staff and operating costs linked to the management of the registration system, dossier and substance evaluation, management and/or participation in the different committees, preparation of Annex XV restriction dossiers and responding to comments from the public consultation, preparation of Annex XV SVHC identification dossiers, preparation of guidance documents, and publication, communication of information and awareness raising activities, organisation of capacity building workshops and seminars, operation of the helpdesks, IT tools and translation.

The resources devoted to the national level activities such as enforcement or those related to advice to companies (e.g. through National Helpdesks, awareness raising activities) depend on the size of the (chemical) industry in the Member State, the administrative capacity and the enforcement strategies. Regarding the costs incurred by national Competent Authorities (CAs)[187] very little information is available in the 2015 Member States' reports[188]. Those provided have large variations[189], resulting from a combination of differences in resources devoted to REACH implementation, but also from a different understanding of the figures to be reported[190]. Only 6 CAs provided a quantitative estimate of their annual budget for substance evaluation (which ranges from EUR 35 000 in Portugal to around EUR 480 000 in Sweden). 6 CAs provided quantitative data on their resources dedicated to SVHC identification, either the annual budget, full-time equivalents (FTEs), person-days, or number of staff. This does not make it possible to provide an average cost of these different activities. It should however be underlined that several CAs expressed concerns about the burdens and costs of developing restriction proposals due to the non-availability of specific expertise within the Member States. Overall, with some exceptions, the level of satisfaction of CAs with the financial and human resources they can dedicate to REACH is generally relatively low.

Member States also participate in ECHA bodies Member States Committee (MSC), Risk Assessment Committee (RAC), Socio-Economic Committee (SEAC), Forum), in EU level activities such as evaluation (decision-making but also in the manual screening for prioritisation of evaluation under the integrated regulatory strategy), implementation of the SVHC roadmap (in particular conducting RMOAs), or proposals for SVHC identification and restrictions as well as in the CARACAL and the REACH Committee.

The participation and the resources invested by Member States in ECHA Committees has significantly improved in comparison with the first years of implementation of REACH (ECHA, 2016); nonetheless, some Member States still find the high workload required by the Committees challenging, especially the Forum, RAC and SEAC.

[187] Understood as Member States and EEA countries

[188] Member States Reports on the operation of REACH (Article 117(1)), June 2015

[189] For example, the figures reported by Member States for persons-day dedicated per year to dossier evaluation vary from 0.02 to 1 000 and the figures for substances evaluated (2012-2014) from 0 to 18

[190] Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting, Milieu, April 2016

The participation of Member States in substance evaluation activities has been increasing over the last years and 22 Member States and Norway have completed at least one substance evaluation. However, until 2014 substance evaluation was mostly carried out by a relatively small number of Member States (6 Member States have evaluated 60% of the substances). This may be due to the relative size of the EU chemicals industry in these 6 countries[191]. When asked about the difficulties encountered in substance evaluation, few CAs complained about the lack of human and financial resources, or the lack of scientific expertise. However, CAs generally mentioned that the fees transferred from ECHA for evaluation did not cover their expenses, and that the situation might worsen since they anticipate an increase of resources dedicated to substance evaluation in the coming years.

About two-thirds of the CAs are now actively involved in the different activities linked to the SVHC Roadmap and this number is increasing (ECHA, 2016)[192]. As regards restrictions, only 8 Member States and Norway have been involved in the preparation of Annex XV dossiers for restrictions, as this is considered a resource-intensive activity[193].

Moreover, the Authorisation process needs to be seen from a broader perspective, which includes not just the actual process of applying for an authorisation, but the whole preceding process starting with Member States Competent Authorities or ECHA proposing substances for SVHC identification, the inclusion in the Candidate List, and the inclusion of substances in Annex XIV (list of substances subject to authorisation), all of which are drivers of costs for duty holders.

Furthermore, the non-compliance of registration dossiers increases the overall costs. ECHA needs to invest additional resources to check the dossiers and request further information from registrants. Member States need to invest resources for substance evaluation and for obtaining data needed for regulatory measures such as authorisation and restrictions.

6.2.3.3. Enforcement costs

Enforcement costs include staff and operating costs linked to enforcement, inspections, investigation or monitoring. More specifically, according to CSES et al (2015) these costs can include one-off adaptation costs (costs of recruiting and/or retraining staff and purchase equipment to adapt to the new regulation), information costs and administrative burdens (costs of gathering and collecting information needed to effectively monitor compliance), monitoring costs (costs of monitoring compliance with the legislation e.g. border checks collecting statistics, etc.), pure enforcement costs (costs of running inspections, investigations, processing sanctions, handling complaints etc.), and adjudication/litigation costs (costs of using the legal system or an alternative dispute resolution mechanism, to solve controversies generated by the legal rule).

No relevant data have been provided by CAs in the 2015 Member States' reports. Only Ireland provided an estimate of the annual budget allocated. 12 CAs indicated that it was impossible to provide an estimate of the annual budget dedicated to REACH enforcement since it is not separated from other activities of the National Enforcement Authorities. 15

[191] There are no obligatory quotas for Member State participation in substance evaluation. It was expected that the numbers would be roughly proportional to the regulatory capacity of each Member State.

[192] For further details, please see Annex 4 – part on Authorisation

[193] For further details, please see Annex 4 – part on Restriction

Member States provided an estimate of the time dedicated to the enforcement of REACH. The data submitted is however rather heterogeneous (expressed in number of staff, FTEs, man-year etc.) and does not provide a clear picture of time spent on enforcement of REACH across the EU[194].

6.2.3.4. Conclusion

Information is available about the cost to run ECHA: ECHA's budget for REACH amounted to EUR 757 million and the fees collected by ECHA amounted to EUR 581 million so far. The EU budget subsidy has amounted to EUR 225 million, slightly below the expectations due to higher than expected fees and charges revenues.

There is little data on costs incurred by national CAs but Member States' participation in the REACH processes activities has increased, although some processes still appear to be driven by a small number of Member States and a few CAs claim not to have the resources to participate in all activities/committees. The level of satisfaction of CAs with the financial and human resources they can dedicate to REACH is generally relatively low.

Most REACH activities done by all EU actors are supported by IT systems developed or made available by ECHA, which represents a cost for EU authorities. But at the same time, this provides large economies of scale at EU level, compared to a situation where every Member State would need to do it separately, which redounds to increased efficiency.

6.2.4. WHAT WORKS WELL, WHAT CAN BE IMPROVED?

Assessment question: What aspects of REACH (including procedural aspects) are the most efficient and what are the least efficient (including the development of scientific opinions, work of scientific committees, urgency procedures, etc.)? Are there case studies demonstrating highly efficient or inefficient working of REACH processes?

There is evidence of efficiency gains in all the REACH processes since the 2013 REACH Review. Some margin for further simplification has been identified in several areas though, namely in relation to the information requirements, the extended Safety Data Sheets, the process to apply for authorisation and the requirements for substances in articles.

6.2.4.1. Efficiency of the implementation of the REACH processes

As reported in Section 5 (and further detailed in Annex 4), there are a number of ongoing actions by the Commission and ECHA to improve efficiency both in terms of improving effectiveness and simplifying processes. These ongoing efforts reflect the experiences gained with REACH over the past years, and continued discussion between the Commission, ECHA, Competent Authorities and stakeholders.

Registration

The majority of companies respect the '*one substance, one registration*' (OSOR) principle, which improves efficiency for all actors due to the sharing of data. The

[194] Differences in data provided are too large to allow for a meaningful extrapolation

Implementation Regulation on joint submission of data and data sharing has further strengthened the OSOR principle and has made a major contribution to the avoidance of unnecessary testing, thus resulting in a reduction of the burden on companies. Also, there is some evidence that the guidelines and the ongoing initiatives by ECHA to standardise the information requirements, such as the setting of templates or the definition of a roadmap for the 2018 registration deadline[195], have been appreciated by duty holders.[196]

Furthermore, several solutions have been developed to increase the efficiency of the registration of complex substances. Indeed, the experience so far indicates that while the requirements can be well complied with for concrete, individual substances, industry is facing difficulties in sufficiently identifying more complex substances (e.g. substances of unknown or variable composition (UVCBs)), with a risk of wrongly assessing substance sameness, preparing inappropriate justifications for read-across and not ensuring that adequate hazard data are submitted for their substance. To address these difficulties, ECHA has developed the Substance Identity Profile, which describes the scope of the substance in joint registration dossiers and helps understand whether the joint dossier is indeed for the same substance, adapting the IT systems (e.g. IUCLID) accordingly. Also, ECHA together with the Commission, have helped sectors facing particular difficulties in the registration of their substances by providing them with specific guidance e.g. essential oils, hydrocarbon solvents, inorganic pigments, biofuels.

An issue that still needs to be addressed is the information on substances used in articles. Currently this is often limited and not adequate to assess the risk arising from these uses in the different stages of the article life cycle. The main problems encountered relate to the descriptions of uses, and to the assessment of exposure and risks arising from articles.

Other ongoing efforts to improve the registration process include:

- Work is also ongoing for the amendment of Annexes to the REACH Regulation to clarify the registration requirements for nanoforms of substances;
- A system for the possible registration of polymers of concern for human health and/or environment is being investigated;
- The standard information requirements for 1 – 10 t substances or obliging the Chemical Safety Report for the CMR 1A or 1B substances is being studied further;
- In the light of data-sharing obligations that will continue to apply for registration and evaluation, the consequences of the time limitation of the obligation for SIEFs to stay operational until 1 June 2018, as stated in Article 29 of REACH will be investigated further.

The Commission is also supporting the development of alternative test methods, for example through the Framework Programme for Research and the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM). It has also amended the standard information requirements and so reduced or replaced testing on vertebrate animals, such as the requirement for the extended one-generation reproductive toxicity study (EOGRTS). New (alternative) test methods are included in Regulation (EC) No 440/2008, which provides legal clarity and further effort will be made to speed up the process.

[195] ECHA's REACH 2018 roadmap, European Chemicals Agency (ECHA), January 2015

[196] Report of the SME panel

Communication of information in the supply chain

There is increasingly efficient supply chain communication due to a better communication up and downstream, which is essential for both improving effectiveness and cutting costs in particular through the harmonisation of description of uses and the exposure scenarios. A number of tools have been put in place to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS. These appear to be having a positive effect as highlighted by the work conducted by ECHA and FORUM though specific projects, but could be more fully used. For example, ECHA, Member States and industry actors, including downstream users, supported by their sector organisations are encouraged to:

- Further disseminate and use the tools, templates and guidance provided as a result of ENES and the CSR/ES roadmap,
- Support companies to ensure effective communication in the supply chain
- Make exposure scenario information readily usable on-site, including for SMEs.
- Industry actors are further encouraged to check the content of extended SDS to ensure they contain all the necessary and relevant information
- The products developed by downstream user organisations, such as sector specific use maps should be adopted by the registrants and integrated in their information gathering and assessment processes.
- Collaboration between downstream user associations and ECHA to simplify and harmonise the elaboration of exposure scenarios should be expanded to include new sectors (e.g. building sector).

Further detailed information is provided in Annex 4 part 3.

Actors in the supply chain find it difficult to access information on SVHCs in articles, but more experience is needed to improve this. Likewise, improvements can be seen in the transfer of information to the consumer, and this needs to be better developed reflecting their "right to know".

Another issue that will be further investigated is how to better track chemicals of concern in products, to facilitate recycling and improve the uptake of secondary raw materials, as part of the Circular Economy.

Dossier and substance evaluation

ECHA has been working on improving the efficiency of the processes:

- The Integrated Regulatory Strategy that started in 2014 combines screening for the 'substances that matter' both from an evaluation and a risk management perspective, and focuses the resources on the most relevant information. The development of the Integrated Regulatory Strategy has increased the complementarity and synergy between the REACH processes, as presented in the analysis of the internal coherence of REACH processes below[197]. Its full implementation has only started to deliver in 2016 and cannot be assessed yet, but it is expected to continue to drive efficiency improvements.

[197] See details in the answer to the first coherence question

- The communication with registrants has been improved to facilitate the assessment of the dossiers.
- Decision and commenting templates, as well as manual of procedures have been put in place.
- Streamlining and optimisation of discussion in Member States Committee (MSC) meetings; anda relatively high proportion of draft decisions still receive Proposals for Amendment (PfAs) from Member States, triggering the involvement of the MSC and associated resources. This number should be reduced, thereby freeing Member States' resources from dossier evaluation to risk management, what could bring more added value overall.

Complementarity and relative timing of the two evaluation processes – compliance check and substance evaluation – when performed on the same substance are also identified as important ways of gaining more efficiency. For example, generic decision to performed substance evaluation only on substances for which dossiers have been previously checked for compliance have in 2017 led to the significant (albeit hopefully transient) effect of the reduction of the number of substances evaluated and thereby postponing the assessment of substances identified as having a concern. Dossier and substance evaluation can operate in parallel, which is beneficial for efficiency and time reasons.

Whilst there are already complementary measures in place and helping, there are others that should be further explored to address the difficulties that still exist in achieving a satisfactory level of compliance in registration dossiers. Further consideration could be given to:

- Supporting registrants in the development of compliant adaptations;
- Registration dossier updates: whether amendments to article 22 of REACH in regard to the situations that trigger mandatory updates, and precise deadlines, are needed;
- Additional clarity in terms of the obligations of registrants having ceased manufacturing could be provided;
- Further improvement of the transparency and dissemination of relevant outcomes;
- Addressing related groups of substances and not only individual substances;
- Running evaluation processes in parallel, with the risk management processes;
- Improving the efficiency of the decision-making process by ECHA;
- Improving the feedback from the evaluation processes to the integrated regulatory approach;
- Risk management action potential may be identified during the initial expert assessment of the registration information in the evaluation and the evaluation decision follow-up;
- The common screening tool for selection and prioritisation should be continuously fed with the experience from the processes applied in order to optimise the screening but also provide better indication of the state of the dossiers in general to enable planning and communication;
- The screening results should help to steer complementary measures;

- Assessing if the full examination process of all testing proposals should continue or could be replaced by a less resource intensive pre-notification procedure or enquiry-type ECHA process.

Member States and Member States Committee members agree that a number of the improvements already in place that will further improve the efficiency of the substance evaluation process. Suggestions to improve the meetings include promoting informal communication and consultation among Member States in the finalisation stage of the substance evaluation process, increasing the use of the written procedure, circulating the documents earlier to enable Member States to consult their experts, and increasing the participation of all Member States in substance evaluation.

Authorisation

a) Implementation of the SVHC roadmap, including RMOA and common screening

Before the implementation of the SVHC Roadmap, the authorities were selecting on their own the substances on which to work, based on different approaches, sometimes leading to double work and not entirely coherent conclusions. All this resulted in a sub-optimal use of the available resources. The implementation of the SVHC Roadmap has improved the authorities' coordination, thus increasing the efficiency, thanks to the common screening approach (selection of substances involving a mass screening performed by the ECHA Secretariat complemented by a manual screening by Member States), and the RMO Assessment (consideration of possible regulatory measures in consultation with others). The common screening and the activities conducted as part of the SVHC Roadmap also increase the efficiency of the preparation of dossier or substance evaluation decisions, of the Annex XV dossiers for the identification of SVHC or for restriction proposals due to a better knowledge of the substances and their specific hazard and exposure properties.

b) Applications for authorisation

Authorisation being a new process still at the beginning of the learning curve, the general working procedures still have significant margin for improvement. To improve the efficiency of the process, ECHA and the Commission set up a Task Force on the Workability of the Application for Authorisation process in 2014. The Task Force focused on improving the functioning of the whole process. For instance, it foresaw a simplified application for authorisation for the use of substances in low quantities that is expected to lead to a reduction of the workload for ECHA and its scientific committees. The Task Force also prepared a practical guide addressing the most pressing challenges in the authorisation process[198], and supporting documents with recommendations for the definition of the use description within the applications for authorisation[199] and for the drafting of the report following the end of the review period[200].

In the future, close attention will be paid on whether recent efforts to clarify the required information for applications have led to applications of good quality, especially in cases where the applications are to cover many different operators or their uses serve further

[198] Guidance 'How to apply for authorisation', European Chemicals Agency (ECHA), December 2016

[199] 'How to develop use descriptions in applications for authorisation', European Chemicals Agency (ECHA), June 2017

[200] Note 'Review report of an authorisation', European Chemicals Agency (ECHA), September 2016

businesses in the supply chain. Such a development will be key in making the process work more efficiently and, in turn, will make it less controversial to subject new substances to it in the future.

Restriction

The preparation of Annex XV Dossiers is still perceived as an excessive burden by Member States, due in part as well to the lack of specific expertise, namely on socio-economic assessment, the costs associated to their preparation and the high number of requests for additional information from ECHA committees. To streamline and improve the efficiency of the process, a Restriction Efficiency Task Force was set up in 2014. The Task Force delivered 71 recommendations and these have been implemented by Member States, the Risk Assessment and the Socio-economic Analysis Committees and ECHA. A workshop took place in Helsinki in May 2017 that delivered an additional number of recommendations, still to be put in place. Further details are provided in Annex 4 paragraph 7.4.

Application of the '*simplified*' restriction procedure established by Article 68(2) remains a challenge for consumer articles and, so far, against the initial expectations, it has not been more efficient than the normal procedure under Article 68(1). The ongoing proposal concerning CMRs in textiles may provide the Commission services with additional information to improve the efficiency.

Possible further improvements include:

- ECHA should act more swiftly in accordance with Article 69(2) and consider the preparation of an restriction dossier (Annex XV dossier) before the sunset date in order to avoid possible distortion of the internal market and penalisation of European producers vis-à-vis non-European producers of (consumer) articles containing such substances;
- The Commission services will assess the possibilities to improve efficiency in the implementation of the restriction procedures in accordance with Articles 68 and 69;
- The need for restriction should be considered in all steps of the implementation of the regulatory strategy (screening, follow-up of the evaluation processes, RMOA) to allow initiation of the restriction work as soon as there is sufficient information available to support the use of this instrument;
- More Member States should get involved (either individually or jointly) in the preparation of restriction dossiers (Annex XV dossier).

6.2.4.2. Other efficiency aspects

IT tools facilitate all REACH processes, and allow processing of high numbers of registration dossiers, fee invoicing and dissemination in a timely and cost efficient manner. IUCLID has enabled the preparation of more than 50,000 registrations, while REACH-IT has processed 10 million dossiers[201] since 2008. According to the information gathered through the external evaluation of ECHA[202], stakeholders indicate

[201] Covering classification and labelling notification, pre-registration and registration

[202] Review of the European Chemicals Agency (ECHA) established under Regulation N° 1907/2006, Deloitte, April 2017

overall high levels of user satisfaction with ECHA's scientific IT tools, although improvement possibilities exist (e.g. the complexity and frequency of updates of IT tools is a challenge for duty holders). Nevertheless, the IT investments made over the past years by ECHA are very high and the share of ECHA's expenditure on IT is higher compared to similar agencies such as EMA or EFSA[203] (see further details in Annex 6, part on IT tools).

After a constant investment in IT over 2007 – 2010, the investments made by ECHA in IT progressively increased over the period 2011-2015. In the first years the interface between REACH – IT and IUCLID was changed several times and several of the other IT systems where developed independently. This led ECHA to adopt a multi-annual IT programme to renovate the IT architecture for better maintainability, align IUCLID for stricter control of the quality of submitted data, improve usability and extend automation to cover all regulatory processes not yet served by the IT systems that were in place in 2011, just three years after the start-up of ECHA.

Regarding the development and implementation of the following tools: IUCLID (for dossier preparation), Chesar (for the chemical safety assessment and the generation of CSRs and exposure scenarios for safety data sheets) and REACH IT (bespoke IT systems to perform all the regulatory processes), ECHA spent a total of EUR 18 million for the five years.

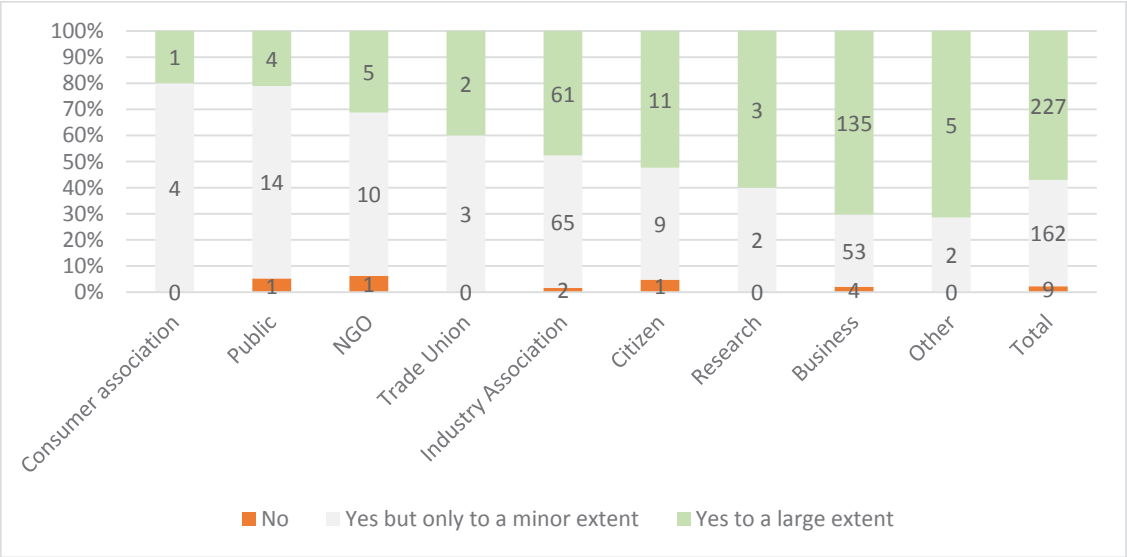
In consideration of the substantial investment sustained thus far, ECHA needs to have a sound business case for future investments in this area as is already foreseen in the ECHA IT governance model.

6.2.4.3. Stakeholder views on simplification and areas for possible burden reduction

The vast majority of respondents to the open public consultation find that there are areas where the REACH Regulation could be simplified to a certain extent and only a very small share find that it could not be simplified at all. There are large differences between the stakeholder groups, with a majority of respondents from consumer associations, public authorities, NGOs and trade unions on the one side finding that the REACH Regulation could be simplified only to a minor extent – and a majority of respondents from businesses, especially SMES, and from academic institutions finding that it could be simplified to a large extent.

Figure 5: Question 19 of the open public consultation: do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?

[203] Analysis of the interface between chemicals, products and waste legislation and identification of policy options http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_116_cpw_en.pdf



Source: Milieu report of the open public consultation in relation to the REACH evaluation, 2017

The main areas suggested for simplification are REACH information requirements and extended SDS, both considered very complex and leading to high administrative burdens, streamlining of the procedure to apply for authorisation and information requirements for substances in articles (Article 33) that should be made more proportionate and easy to understand for companies. Those areas are analysed in further detail in the respective chapter(s) on the implementation state of play, as well as above.

6.2.4.4. Conclusion

Since the 2013 REACH review, mechanisms have been put in place to improve the efficiency of REACH processes as described both above and in more detail in part 6 and Annex 4. This work is ongoing, as experience is gained with the different processes in particular with authorisation and restriction. Overall efficiency of REACH seems to be improving both in terms of improved effectiveness and burden reduction. However, no data is available to quantify those improvements. There is still though room for improvement, for example, to simplify several areas of REACH for duty holders, namely in relation to the information requirements, the extended Safety Data Sheets, the process to apply for authorisation and the requirements for substances in articles.

6.3. Coherence

6.3.1. IS REACH INTERNALLY COHERENT?

Assessment question: "To what extent are the different work processes, including their output, in REACH interacting in a coherent manner?"

In principle, the different actions under REACH link together well, and they provide for a good flow of information between each other. However, weaknesses exist: for example when registration dossiers do not provide sufficient information or when information flows along the supply chain are insufficient. A number of actions have been taken to make sure that these links are operational, such as the integrated regulatory strategy and the associated common screening process and efforts to improve communication in the supply chain and the development of SDS.

What is the issue?

The Intervention Logic sets out a number of actions that together should deliver results on REACH. This internal coherence question considers the degree to which these actions complement each other and work together or whether there are inconsistencies between them.

REACH is based on the principle that industry takes responsibility for ensuring the safe use of chemicals through the generation of the necessary information for hazard and risk assessment, documentation thereof in registration dossiers and communication of relevant information through the supply chain.

6.3.1.1. Internal coherence

A central point for achieving coherence is the proper information flow from registration to evaluation, to authorisation, to restriction, establishing risk management measures down the supply chain. A number of tools have been developed to ensure that information flow. For example, ECHA has improved the exposure scenarios to help downstream users have a better understanding of the information included in the extended SDS, to better communicate this information up and down the supply chain and to improve the risk management measures in particular from the exposure and the risk of chemicals.

Lack of data in registration dossiers can hinder the good functioning of other REACH processes and identification of the appropriate regulatory measures. ECHA and the Member States ensure internal coherence by checking the information in registration dossiers, and concerns about the adequacy of the hazard, exposure and risk management measures in the registration dossiers may trigger the need for further action by Member States, ECHA or the Commission. In addition, substance evaluation should identify the need for more data in order to clarify initial concerns on risk.

Furthermore, incomplete risk assessments or insufficient risk management measures in registration dossiers may raise concerns regarding the level of risks and therefore lead to considering the introduction of additional risk management measures. The 2013 REACH Review highlighted the need to improve the links between the different risk management measures (i.e. authorisation and restrictions) while the SVHC roadmap established the Regulatory Management Option Assessment as a voluntary process to identify the best regulatory option. Discussion of the most suitable regulatory action early in the process aims to ensure that different regulatory options can be taken into account when planning regulatory measures. The Regulatory Management Option Assessment helps in deciding whether substances should be subject to authorisation or restriction as its conclusions trigger further follow up to ensure that the substances are regulated under REACH.

The integrated regulatory strategy developed by ECHA brings REACH processes together to improve the achievement of its objectives. Its most relevant elements include:

- Introduction of an enhanced completeness check, including manual screening of dossiers and retroactive screening of dossiers of substances already registered.

- Enhanced support for data input via IUCLID 6, including substance identity profiles, better reporting formats on use and exposure, assessment entity concept.

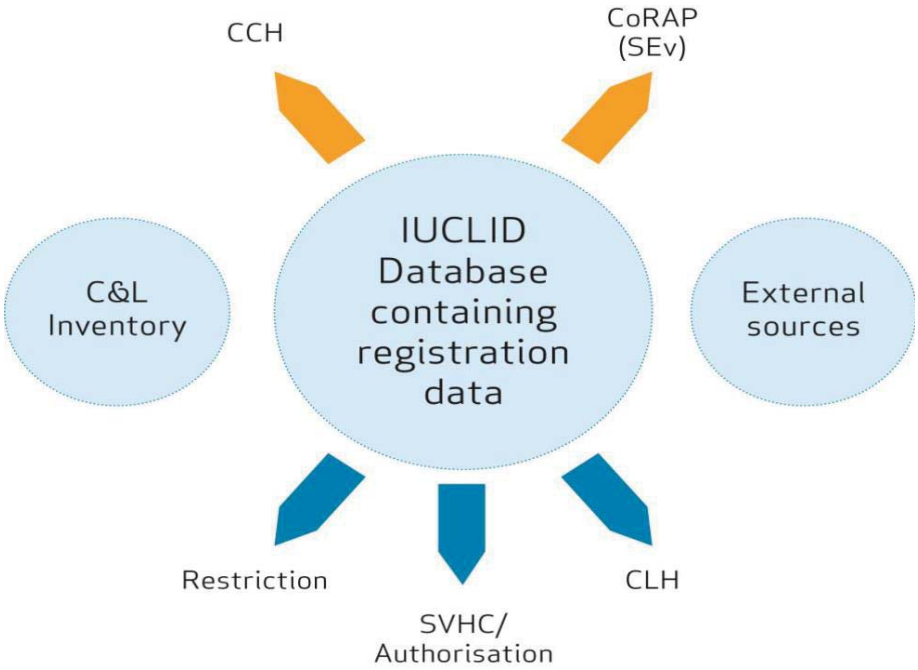
- Grouping approach of substances.

- Improved interplay of dossier and substance evaluation processes, including the possibility of running these in parallel.

In order to support this strategy, ECHA has also developed, in cooperation with Member States, a common screening approach see figure 6 bellow to systematically screen the available information in REACH (and CLP) databases as well as external data sources to identify substances of potential concern and to select these substances for further scrutiny. The common screening approach builds on the experience gained in the implementation of the SVHC roadmap as well as on the early approach to compliance checks, which included the use of algorithms to screen substances for targeted compliance checks. Such screening uses the information concerning hazard properties, exposure and risk management contained in registration dossiers for substances registered above 10 t/y per manufacturer or importer to identify substances for further action.

An example of a group of substances that have undergone the common screening are poly-and perfluoalkyl substances (PFASs). Classification and labelling information for more than 100 PFASs has been notified to ECHA. Among others, PFASs have PBT properties, which made them candidates for regulatory action, e.g. SVHC identification or restriction. As a result of the screening process, two Member States notified their intention to submit a restriction proposal for PFAS poly –and perfluoroalkyl long chain substances.

Figure 6: Screening approach



Regarding information flows along the supply chain, companies are increasingly engaged in the elaboration and transmission of extended safety data sheets (SDSs), resulting in improved communication allowing for safer use of chemicals including complying with the requirements of occupational safety and health legislation. However, information flows do not always work well and in a significant number of cases information is not communicated clearly, leading to inadequate risk management measures. More evidence is reported in Annex 4 paragraph 3.1.2.

6.3.1.2. Stakeholder views

In general, respondents had a fairly positive view of the usefulness of data generated through REACH processes (e.g. registration, evaluation) for public authorities to adopt further risk management measures (e.g. REACH authorisation, REACH restriction). In contrast, and more relevant for the external coherence question, NGO respondents were more critical of the usefulness of data for other legislation (e.g. consumer protection legislation and environmental legislation).

The majority of respondents agreed that the implementation of the SVHC Roadmap, including the Regulatory Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH.

Views were balanced whether the different chapters of REACH are applied in a coherent manner. Some respondents considered that the links between the various REACH processes are not clear and that consistency and integration would have to improve, e.g. to avoid that the same substance is targeted by several parallel processes. Better communication about ongoing processes and coordination among Member States was also called for.

Some noted inconsistencies in the level of evidence required for each procedure and for each topic (identification of the substance, hazards, uses, exposure). Two position papers from NGOs consider that there is a lack of coherence in the way ECHA deals with confidential business information claims: while ECHA checks all such claims as part of the registration process, it is perceived as more lenient with confidentiality claims in applications for authorisation and for information submitted during public consultations..

One respondent states that the SVHC roadmap is adequate to implement authorisation, but is not adequate for restriction, given that much more information on uses and exposure are needed for restriction, that is however not addressed in the SVHC roadmap, which focuses on Carcinogenic, Mutagenic and toxic for Reproduction/Respiratory sensitiser/ Endocrine disruptors/ Persistent, Bioaccumulative and Toxic hazards.

6.3.1.3. Conclusions

In principle, the different actions under REACH link together well, and provide for a good flow of information between each other. There is a clear and logical sequencing between registration and evaluation and then restrictions, authorisations and the flow of information along the supply chain.

It has to be noted that the information available in the registration dossiers is a bottleneck for the whole process. When the dossiers are not compliant, the information is not sufficient for effective priority setting and to identify the need for appropriate regulatory measures. Despite the progress made there still is room for improving coherence, both between the testing proposal, dossier and substance evaluation activities and between evaluation, restrictions and authorisation. In addition, information flows along the supply chain whilst improving are not always allowing for best use to be made of available information by operators down the supply chain.

A number of actions have been taken to make sure that these links are operational, such as the integrated regulatory strategy. Improved compliance of the registration dossiers, effective implementation of the common screening approach (e.g. by applying more broadly grouping approaches), and using evaluation results to better identify substances that need further regulatory action would increase coherence between the different REACH processes.

6.3.2. IS REACH EXTERNALLY COHERENT?

Assessment question: "To what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?"

REACH is generally coherent with the wide range of Union legislation dealing with chemicals, allowing for synergies and a more coherent chemicals policy overall. Inconsistencies with other legislation (POP, RoHS) highlighted in the 2013 review, where mainly addressed by common understanding papers, which proved to be sufficient for clarify the interface with REACH. However, there are some additional specific aspects which need further clarification for example related to recycled materials to ensure coherence. The Commission is currently working on clarifying the interface with the occupational safety and health legislation, in particular in cases where the same chemicals are regulated under two legislative frameworks.

What is the issue?

The coherence of REACH with other legislation related to chemicals was examined in the 2013 REACH review in the context of the review of the scope of the Regulation. While no major overlaps with other Union legislation were identified, potential or minor overlaps, gaps and synergies with specific EU legislation were highlighted. Building on the findings of the 2103 REACH review, the Commission has worked to improve the coherence between REACH and other Union legislation on a case-by-case basis, in order to assess the complementarities, synergies and overlaps.

Further elements will be complemented by the ongoing fitness check of chemical legislation.

6.3.2.1. Interface with POPs and RoHS

In 2014, the interfaces between the REACH Regulation and the RoHS Directive[204] and the 'POPs' Regulation[205] were addressed by the Commission services in two Common Understanding Papers[206]. These documents set out practical advice for industry and competent authorities with a view to avoiding conflict or double regulation, and to provide clarity on the specific provisions in the legislation.

The approach taken in these Papers is to examine three scenarios in relation to authorisation and restriction. The scenarios are:

1. a substance is regulated under the other legislative framework before it becomes liable to be regulated under REACH;
2. a substance is already regulated under REACH when it becomes liable to be regulated under the other legislation; and
3. a substance is not yet regulated under either piece of legislation.

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[204] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**ROHS**)

[205] Regulation (EC) No 850/2004 on persistent organic pollutants (the **'POPs' Regulation**), implementing the obligations of the Union under the Stockholm Convention

[206] http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en

The two Papers have become valuable references in the day-to-day management of the relationship between REACH and these pieces of legislation. They have been well received by industry and Member States as they clarified how a chemical substance could be regulated under one legislation or the other, depending on the rationale for the regulatory action and the time when the regulatory process starts.

The REACH/POPs common understanding paper proved helpful in the implementation of the listing of hexabromocyclododecane (HBCDD) under the Stockholm Convention after considering that the REACH authorisation process revealed that the substance has been phased out in EU; and. It also helped in the preparation of restrictions under REACH for decabromodiphenylether (DecaBDE) and for Perfluorooctanoic acid (PFOA) (and related compounds) when these were already in the early stages of the nomination process under the Stockholm Convention. The latter demonstrated that for a substance that potentially fulfils the POP criteria (mainly a substance having vPvB and T properties and the potential for long range transport), carrying out a restriction procedure under REACH is usually a good first step in order to assess the risk to the environment. After the REACH restriction procedure is initiated or completed, it should be followed by an EU POP nomination in order to ensure harmonised risk management measures at the global level and to contribute to the achievement of the World Summit on Sustainable Development (WSSD) political commitment. The outcome of the EU restriction procedure is normally used as a basis to develop the EU position for Conference of the Parties (COP) negotiations on the listing of the substance in the Convention at the COP. However, experience shows that the extent to which the EU position should be based on the EU restriction depends, i.a. on:

1. The timing of the two procedures, i.e. whether and how long the EU restriction was adopted before the Convention procedure, in particular in relation to the need for possible exemptions;
2. The scope of the EU restriction, in particular if only a limited number of uses were assessed.

The Common Understanding Paper provides guidance in cases where the same substance present in mixtures or articles concerned is potentially regulated in parallel under two different regulatory systems. Assessment of the same information under the two systems can be avoided by using the results of the assessment conducted under one set of legislation under the other legislation according, i.e. an exemption from REACH restrictions or authorisation for substances regulated by RoHS, will avoid double or conflicting rules for the same substance.

The approach set out in the REACH/RoHS common understanding paper proved useful in the restriction on lead and its compounds in consumer articles, excluding electrical and electronic equipment (EEE) already regulated under ROHS. This approach has also been applied in the forthcoming restriction of the phthalates DEHP, BBP, DBP and DIBP, excluding EEE already listed as substances to be restricted under RoHS.

The approach set out in the common understanding paper is expected to provide clarity for the growing market of "smart" objects and the internet of things, when products (e.g. a window, a bag or even clothes) are produced in two versions, one without and one with some added electronic function and thus may fall under two regulatory systems.

The REACH/RoHS paper called for the methodology leading to the inclusion of restricted substances in Annex II to RoHS to be coherent, or even fully aligned, with the methodology set out in Annex I to REACH in particular to cover the manufacturing and

use stages of the lifecycle of EEE. This would provide further justification for re-using assessments conducted under one legislation for the other and for exempting EEE from the REACH authorisation requirement and from restrictions. On the other hand, the more similar the two pieces of legislation become, then the less justification there is for keeping them separate in order to avoid potential duplication.

6.3.2.2. Interface with occupational safety and health (OSH) legislation

The interface between REACH and the OSH legislation covers a range of aspects, inter alia the use of information on chemical substances generated and communicated through the supply chain under REACH (e.g. use of Safety Data Sheets, the generation of exposure scenarios and information on exposure control measures), the authorisation and restrictions processes versus the principles of OSH related to risk assessment and risk management, and the enforcement obligations of REACH and OSH national authorities.

The evaluation of the OSH legislation[207] concluded that there are synergies and complementarity between OSH and REACH. It also confirmed a need to further clarify the interface between the two legislative systems in particular to remove any uncertainties and overlaps in their design and practical application.

A submission via the Commission's REFIT platform[208] (industry and Member States) also sought clarity on the interface between REACH and OSH. The Platform recognised that the two sets of legislation are mutually reinforcing but pointed out that further clarification is needed at their interface.

The Commission shares this analysis and is progressing with work to clarify the interface between REACH and the OSH legislation. This work focuses on the overlap in protecting the health and safety of workers from risks presented by chemicals in the workplace in the context of Derived No Effect Levels (DNEL) under REACH and Occupational Exposure Levels (OEL) under the OSH legislation. A limited number of differences in the methodologies used by the two different scientific Committees (Scientific Committee for Occupational Exposure Levels (SCOEL) and ECHA's Risk Assessment Committee (RAC)) to derive these values have sometimes led to significant divergences, leaving downstream users confused when applying the conditions described in the exposure scenarios attached to the SDS.

In 2015, the Commission, in accordance with Article 95 of REACH (on clarifying conflicts of scientific or technical opinion with other bodies), requested RAC and SCOEL to create a Joint Task Force to analyse and improve the mutual understanding of the different approaches. Both committees were requested to work towards agreed common scientific approaches relating to exposure to chemicals in the workplace, and to prepare a joint report on their scientific evaluation. The Joint Task Force in February 2017 reiterated that differences in the methodologies applied by the two Committees can result in the derivation of different values for the same substance.

In order to avoid discrepancies, the Commission considers that alignment of the two methodologies is required. To reduce potential conflicts of opinion and to ensure at the same time a sound scientific basis to underpin action to improve occupational safety and health, the Commission announced in its Communication on Safer and Healthier Work

[207] Link to COM(2017) 12 and SWD(2017) 10 - Ex-post evaluation of the European Union occupational safety and health Directives

[208] Link to REFIT platform opinion

for All that would request scientific advice from SCOEL or RAC on a case-by-case basis while a more permanent solution was being sought. In March 2017, the Commission services asked RAC to evaluate a number of chemicals in support of the proposals for the 3rd and 4th amendment of the Carcinogens and Mutagens Directive while SCOEL has been so far consulted for the proposal of the 3rd amendment.

The Commission services are considering a Common Understanding Approach clarifying the interface between REACH and the OSH legislation addressing the concerns recognised by the REFIT Platform and proposing concrete steps to remove the overlaps:

- How to use REACH tools (e.g. exposure scenarios, Safety Data Sheets) to enhance the effectiveness of OSH legislation.

- Improve the coordination of national enforcement authorities of REACH and OSH legislation.

- Align methodologies to establish safe levels of exposure to chemicals at the workplace.

- Enhance the role of RAC, involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the Advisory Committee on Health and Safety at Work.

In relation to the exemption of certain uses (or categories of uses) from authorisation in accordance with Article 58(2) of REACH, the Court of Justice of the EU in Case C-651/15 P VECCO vs Commission confirmed that the OSH legislation does not constitute a specific Union legislation under which, by imposing minimum requirements relating to the protection of human health or the environment for the specific use of a substance, the risk is properly controlled.

Stakeholder views

Stakeholders have repeatedly expressed concerns about a lack of coherence in the implementation of REACH and OSH. A large number of respondents from industry in the replies to the online public consultation confirmed the need for further clarity for the interface between REACH and OSH legislation. NGO and Trade Unions stressed the need for a better coherence and harmonisation between OELs developed under the OSH legislation and the DNELs developed under REACH with a preference to have one single numerical value.

Many respondents from industry suggest that if an EU-wide OEL or a Scientific Committee on Occupational Exposure Limits (SCOEL) recommendation exists, the OELs should replace DNELs and this should be recognised by the REACH authorities as it will avoid double work, conflicts of opinion and confusion at the downstream user level[209].

The respondents acknowledged the work already done by the Commission to improve coherence between REACH and OSH, but call for further efforts to reach consistency between OELs and DNELs, including also a better cooperation and alignment of methodologies of RAC and SCOEL, as this would help to overcome problems in practice.

[209] Views expressed through the open public consultation - Stakeholder consultation: report of the open public consultation

Many respondents from industry suggested that OSH legislation should be prioritised during the Risk/Regulatory Management Option Analysis[210] (RMOA) when it is determined that a risk is mainly related to the workplace as this would avoid any possible conflict or overlap with the REACH processes such as authorisation and restriction. Since the OSH legislation also contains a substitution requirement, the OSH legislation was considered by some respondents to be an alternative "risk management option" to REACH authorisation. Respondents from industry also considered that if the workplace legislation or the RMOAs identify risk for workers from exposure to a certain substance, then it would not make sense to spend additional resources on the candidate list or authorisation if no additional impact is expected.

Some consider that information generated under REACH should be better used under OSH legislation and, in particular, for information in the safety data sheets (SDS) although some difficulties were found in the extended SDS, which are considered to be unclear and confusing for straightforward application in the workplace.

6.3.2.3. Interface with the cosmetic products regulation

In 2014, ECHA and the Commission services presented a joint statement on the interface between REACH and the Cosmetic Products Regulation, which clarifies among other an issue with regard to animal testing. While the Cosmetic Products Regulation bans animal testing and marketing and REACH aims to reduce and eventually fully eliminate animal testing, the testing of cosmetic ingredients on animals may be required as a last resort under certain conditions to meet REACH registration requirements. So far, no actual case has been detected where animal testing was conducted for the purposes of REACH registration on a substance used solely as an ingredient in cosmetics. Nevertheless, following a complaint by an animal welfare NGO, the European Ombudsman opened an inquiry into the matter, concluding that the joint statement is not contrary to the Cosmetics Regulation or to EU law more generally[211].

6.3.2.4. Interface with waste legislation

Activities related to the interface between REACH and the Waste Framework Directive (WFD), focused initially on clarifying when recycled materials cease to be waste and become subject to REACH again. This is significant for the implementation of REACH as "waste" is not within its scope. REACH contains a conditional exemption from certain REACH requirements, including registration of substances "which are recovered" in the EU. However, REACH does not set any specific provisions on how the use of this

[210] Originally the RMO stood for risk management options. To avoid confusion with the obligations under Article 69 to prepare an annex XV dossier when a risk has been identified and the obligation in Annex XV to determine the most appropriate Union wide measure to address the identified risk and to better reflect the actual work done, the RMO is now called Regulatory Management Options. Regulatory Management Option (RMO) Assessment is the process for identifying the best regulatory option for a substance. The RMO Analysis is the document presenting the information on the substance, the possible options and the preferred one.

[211] Ombudsman case 1130/2016/JAS, Decision of 21 Jul 2017. In addition, the President of the General Court replied in July 2017 to an individual complaint case that "in so far as the applicant is required by an individual decision from an EU Agency which is addressed to it, in the present case the contested decision, to carry out animal testing, the fact of complying with that requirement cannot result in it incurring liability because of another EU measure of general scope, in the present case the Cosmetics Regulation

exemption for recovered substances is to be monitored and a recovery operator who uses the exemption has no explicit obligation in REACH to notify ECHA or the competent authority of a Member State that he is using the exemption.

To tackle this issue, a practical solution could be that the holder of a recovered substance who wishes to use the registration exemption under Article 2(7)(d) of REACH, being a potential registrant, should be required to notify ECHA and his Member State Competent Authority that he considers that the conditions of this exemption are fulfilled. This would facilitate implementation and enforcement of the exemption, in particular as regards the identity of the recovered substances placed on the market which would also facilitate the implementation of a circular economy. Moreover, the Commission is considering if the wording used in the provisions of Article 2(7)(d) is sufficiently clear to ensure that the obligations are fully implemented and enforced.

The implications of certain REACH requirements for the recycling of materials have been discussed in the context of specific restrictions or applications for authorisation e.g. in the case of the traceability of substances of concern in products and recycled materials or the setting of limits for the presence of the substances in recycled materials. One of the actions under the Circular Economy Action Plan aims to address legal, technical or practical problems at the interface between chemicals, products and waste legislation, including how to reduce the presence and improve the tracking of substances of concern in products and the development of a methodology to determine when a material containing substances of concern can be recycled or should rather be disposed of. A roadmap[212] has been published and a Communication setting out various options to tackle these issues is scheduled for the end of 2017.

Stakeholder views

The responses in the open public consultation confirmed the pertinence of the issues above. One business respondent considers that recovery processes will regularly result in the production of useful, resource efficient, but changed, materials that may have properties that do not easily relate to the registered substances from which they were derived.

Respondents from all stakeholder groups consider recycled materials under REACH, as important for the Circular Economy. Several respondents suggest that recycled materials should comply with REACH, like any other materials. One respondent considers that to achieve a truly sustainable and safe circular economy, it must be accepted that not all materials can be reused or recycled, given that they may contain unwanted substances that should not re-enter the market. When a temporary authorisation has been granted to enable the continued presence of hazardous substances in products made from recycled material, the material should be labelled and specifically marked, and the authorisations must be as limited as possible in scope and time.

On the other hand, one industry position paper suggests that to promote recycling rather than landfilling, longer transition periods and phase-out periods for toxic substances included in recycling materials should be allowed, if the related risk or exposure is low. Several industry respondents call for greater coherence between REACH authorisation and the Circular Economy. They suggest that the substance identity principles established in REACH should be consistently and coherently applied throughout registration and

[212] Analysis of the interface between chemicals, products and waste legislation and identification of policy options

authorisation, in particular: a substance present as an impurity that is not deliberately added in a mixture and does not fulfil any function should not be subject to authorisation and unknown or variable composition, complex reaction products or of biological materials (UVCBs) are to be seen as stand-alone substances and must not be decomposed into individual substances for the assessment under REACH.

One government authority considers that the provisions in REACH, such as restriction, authorisation, registration, and information requirements for substances, mixtures and articles are crucial to boost a circular economy.

6.3.2.5. Interface with other Union legislation

Other aspects of the relationship between the REACH and other Union legislation affecting chemicals, which do not constitute an overlap but cases of synergies and complementarities, are being clarified, as described below:

- In relation to Directive 98/83/EC on the quality of water for human consumption, Regulation (EC) No 1935/2004 on food contact materials (FCM) and Council Regulation (EEC) No 315/93 laying down Union procedures for contaminants in food, REACH is considered not to apply to the extent that measures adopted and allowed under these pieces of legislation relate to the protection of human health. REACH still applies in relation to environmental endpoints.
- Risk assessment under the legislation on Food Contact Material (FCM) may benefit from information made available during the hazard and risk assessment in a REACH Annex XV dossier or performed under the CLP regulation, and vice-versa. The use of substances listed in Annex XIV in FCM is exempt from REACH authorisation for hazards related to human health, while they remain subject to REACH authorisation with respect to occupational or environmental risks as authorisations under the FCM legislation do not consider occupational or environmental exposures. This means that industry has to apply for authorisation under REACH (occupational and environmental risks).
- Work is ongoing to transfer part of the restriction on ammonium nitrate in entry 58 of Annex XVII to REACH into Regulation (EU) No 98/2013 on the marketing and use of explosives precursors to address the potential criminal use of chemical substances.
- For medicinal products (Regulation (EU) No 726/2004), an information gap exists in relation to the environmental risks related to the manufacturing or formulation stages of medicinal products for human and veterinary use as a result of their exemption from REACH in accordance to Article 2(5). The manufacture of medicinal products involving chemical processes of industrial scale is covered by the Industrial Emission Directive 2010/75/EU (IED) but formulations per se would normally not be covered, except particular cases that involve use of large quantities of solvents. Where the activities are covered by the IED, adequate controls have to be put in place to respect conditions in permits granted regarding emissions to the environment, based on Best Available Techniques (BAT). However it has to be emphasised that the environmental risk assessment is not equivalent to that performed under REACH, notably as the IED does not concern the whole life-cycle of the chemicals after production.
- In relation to Regulation (EC) No 765/2008 on market surveillance, the concept of 'serious risk' applied is not aligned with the risk derived applying the risk assessment methodology under REACH and can cause divergent interpretations among market surveillance authorities.

- Liaison with other enforcement networks should be enhanced and collaboration with other policy sectors increased (e.g. AdCo[213], customs).As it concerns the role of customs in the enforcement of the REACH requirements, the roles and tasks of all actors should be defined more clearly in order to enhance legal certainty for both economic operators and customs authorities. To this effect, regulatory measures in addition to non-legislative means (e.g. guidance, training, pilot projects) could be considered
- In relation to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, a need to align REACH information requirements for physical-chemical properties and CLP classification categories has been identified. A further coordination should be ensured between the decision related to testing proposals/substance Evaluation under REACH and the adequacy of such decision for classification under the CLP.
- In relation to the Biocidal Products Regulation EU No 528/2012, legislative proposals on the approval of an active substance, including measures on treated articles with biocides, has to take into account any existing restriction listed in Annex XVII of REACH in order to avoid possible duplication (ex: creosote and treated wood with creosote), and vice-versa.
- In order to improve the consistency on the exchange of information and the risk assessment between REACH and other Union legislations, when an Annex XV dossier for restriction, addresses the cumulative exposure of humans and emissions to the environment from different sources also in areas not covered by REACH, the specific Union legislation could use the information included in the Annex XV dossier as a basis for further regulatory actions. The Annex XV dossier could indeed be used as an important source of information for other Union legislations.

6.3.2.6. Scientific Committees and EU Agencies

ECHA is required to work with other EU agencies and scientific committees in order to avoid potential conflicts of opinion (Art.95 of REACH); similar requirements apply to other EU agencies (e.g. EFSA) or scientific committees (e.g. SCOEL).

A successful example of such collaboration is the joint evaluation of the most recent scientific literature by EFSA and ECHA during the discussion of the restriction proposal on Bisphenol A where they came to an agreed hazard assessment. Collaboration between scientific committees has been more difficult between RAC and SCOEL, when they were mandated by the responsible Commission services to clarify their divergences in the derivation of a safe exposure limit for the substance N-Methyl-Pyrrolidone (NMP). The two Committees did not manage to reach a common opinion, leading to the setting up of a Joint Task Force between them in order to analyse and if possible agree on their general methodologies for deriving safe or acceptable exposure limits. The two scientific committees so far did not reach a common agreement.

The spirit of cooperation to avoid conflicts of opinion with other scientific bodies, as set out in Article 95 should be further reflected in other EU legislations in order to ensure better consistency between different Scientific Committees operating in the assessment of chemicals, for example related to the classification of active substances used in plant

[213] Administrative Cooperation Groups for European cooperation on market surveillance.

protection products, where divergences have been observed between EFSA and ECHA not necessarily linked to the lack of cooperation between the two Agencies.

The data, methodologies and capacity developed under REACH should be used to support the implementation of other legislation, concerning identification and management of the risk of substances that are within the scope of REACH. ECHA should facilitate access to the data it holds for Scientific Committees of other Agencies or Member States authorities conducting assessments, while safeguarding confidentiality and intellectual properties rights. The overall aim is that ECHA's information, knowledge and competences are increasingly used to support the implementation of other legislation and policy areas related to the safe use of chemicals.

6.3.2.7. Implementation of the SVHC roadmap in relation to other legislation

The RMOA is a voluntary procedure not explicitly envisaged by REACH but recommended to be implemented by the Competent Authorities of Member States and ECHA to analyse all the possible regulatory options for a specific substance or group of substances.

In the context of the online public consultation, a great majority of industry respondents supported the RMOA approach as it improves the coherence between REACH and other EU legislations, suggesting that it should be more harmonised and that the RMOA process should become binding under REACH. Some industry respondents even proposed to conduct ex-post RMOA for substances already on the candidate list for which this was not done in the past and that as a result substances might be removed from the candidate list.

Other stakeholders (NGOs, consumer associations, trade union, and one industry association) consider that RMOA is not an adequate procedure and should not be binding. Some call for the RMOAs to be abandoned, as they have introduced too much subjectivity and a loss of coherence. They consider that all SVHC should be added to the candidate list and express concern that since the RMOAs were introduced, the number of substances added to the candidate list has significantly decreased, and the process has become costly and burdensome for Member States. In their view, the RMOA process already includes steps upfront (i.e. consideration of use and exposure information) that legally belongs only to the prioritisation or application for authorisation steps. They consider that RMOAs not only hamper the substitution goal and undermine the precautionary principle, but also deny EU consumers their 'right to know'.

The Commission considers that the implementation of the SVHC roadmap and in particular the RMOA has contributed to a more systematic analysis of the regulatory measures available for public authorities for a specific substance. In addition, it improves coordination of Member States and enhanced transparency and involvement of industry. Member States recognise the added value of the RMOA process in identifying the best regulatory approach, either within REACH or through other Union legislation (e.g. CLP Regulation, OSH legislation, etc.).

6.3.2.8. Conclusions

No major incoherencies between REACH and other Union legislation have been identified. There are however some inconsistencies, some of which have already been addressed in the past years, while others are still requiring attention. Common Understanding Papers and Roadmaps help to better clarify specific implementation aspects of the interface of REACH and other EU legislation, increasing transparency and predictability as well as avoiding duplication. The main inconsistencies are:

- The interfaces between REACH and the RoHS Directive and the 'POPs' Regulation were addressed in two Common Understanding Papers, which have provided clarity and led to synergies between the legislation. On the interface between REACH and RoHS there is still the possibility that the same information has to be assessed under two different regulatory systems, in cases where the same substance in the products concerned are regulated under both pieces of legislation. This aspect should be further explored in order to avoid overlaps.
- There is an issue with when recycled materials cease to be waste and become subject to REACH again, which is being tackled in the context of the Circular Economy and the chemicals-products-waste interface.
- Although some synergies can be considered between REACH and OSH, there is an overlap which request efforts to avoid disparities in the way in which different Scientific Committees are calculating DNEL under REACH and OEL under OSH legislation. Steps have been taken to avoid conflicting results, and in the future to improve consistency of scientific methodologies. This disparity between values is a core element when performing the risk assessment and choosing the appropriate risk management measure from the exposure of chemicals at the workplace. Moreover, if information generated under REACH (e.g. improved risk management measures through authorisation or information in Safety Data Sheets) is better used to comply with the requirements of occupational safety and health legislation, this would ensure a safer use of chemicals at the workplace.
- Where the risk to the safety and health of workers in the workplace is not (or is no longer) adequately controlled by the requirement of the OSH legislation in light of emerging/new scientific information on the severity of the risks arising from occupational exposures or new developments in exposure control technologies, additional regulatory actions such as a restriction or authorisation under REACH may be the appropriate risk management measure.

More generally, efforts are being made to ensure that ECHA's information, knowledge and competences are increasingly used to support the implementation of other legislation related to the safe use of chemicals.

6.3.3. IS REACH INTERNATIONALLY COHERENT?

Assessment question: "To what extent is REACH coherent with international efforts, or chemical legislation in third countries?"

In terms of policy objectives, REACH is coherent with chemicals policy in third countries. REACH has some differences from the actual regulatory regimes to implement these policy objectives, but this does not necessarily mean they are incoherent and in fact there seems to be some signs of harmonisation. A number of the tools used in REACH implementation have been developed at the OECD and are coherent with other countries legislation, when the same tool is being utilised.

What is the issue?

Coherence with international chemicals efforts can be measured on three levels:

- Policy objectives
- Legislative requirements

- Tools used to implement legislative requirements.

6.3.3.1. International Coherence

The 2013 REACH review summarises the Commission cooperation with the OECD (e.g. development of IUCLID, eChemPortal, QSAR Toolbox) and with third countries (e.g. meetings and workshops to inform them about REACH implementation, extended bilateral scientific and technical cooperation). The 2013 review did not include information on coherence and differences between REACH and related international efforts or on chemical legislation in third countries specifically.

6.3.3.2. Policy objectives

REACH was designed as the EUs contribution to meeting the World Summit of Sustainable Development 2020 chemicals goal and its implementation in the EU which aims to achieve that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects to human health and the environment. As mentioned earlier, this goal is now included as target 4 in Sustainable Development Goal 12. There is therefore an overarching, internationally accepted, policy objective regarding chemicals shared by all countries, including the EU and its Member States.

The chemical management cooperation framework set up under the United Nations Strategic Approach to Chemicals Management (SAICM) is actively supported by the EU and its Member States. This approach provides the international platform for achieving the 2020 goal.

The way in which the EU implements this over-arching policy objective is through the objectives of REACH (protection of human health and the environment, ensuring the well-functioning of the internal market, enhancing competitiveness and innovation and promotion of non-animal methods). These policy objectives are shared by some third countries (e.g., Canada, US).

6.3.3.3. Legislative requirements

The EU implements in separate pieces of legislation the Rotterdam and Stockholm conventions through the respective Prior Informed Consent (PIC) which require notification to the Countries importing hazardous chemicals and POP regulations[214]. The international coherence between REACH and the Stockholm convention work at EU level is discussed above concluding that the interaction functions well.

The EU implements almost completely the United Nations Globally Harmonised System (GHS) for classification and labelling of chemicals in the CLP regulation no 1272/2008. Many other countries have implemented GHS too, although not always as comprehensively as the EU. Hence there is an increasing coherence between other countries implementation of the GHS and that of the EU which allow a better exchange on hazard properties of chemicals e.g. in import and export.

The interaction between REACH and chemicals legislation of the main EU trading partners is discussed in the effectiveness section concluding that the legislation is often different, but most have similarities with REACH. For example the new Toxic Substances Control Act (TSCA) of the U.S. has some similarities with REACH

[214] Respectively, Regulation (EU) 649/2012 and Regulation (EC) No 850/2004

Restrictions system although do not cover the wide spectrum of hazardous chemicals as it is mainly based on priority lists of chemicals whereas REACH assess all the registered chemicals. Several third countries have adopted registration systems similar to the EU's REACH; however , in most cases, these regimes are limited to new substances e.g. substances already on the market are not evaluated.

Overall, however, there is world-wide not one single standard which drives the development of chemicals management systems and hence most systems are tailor made to their own context, although harmonisation efforts are taking place on a global scale through e.g. GHS and the WSSD goal. In this picture, REACH is the most advanced and comprehensive chemical legislation.

In spite of the increasing international harmonisation of chemicals legislation, convergence of legal requirements in different jurisdictions is still limited. One of the main difficulties is the lack of mutual recognition of testing results in particular by non-OECD countries that do not adhere to the mutual acceptance of data such as China.

6.3.3.4. Tools used to implement legislative requirements

The EU and its Member States are active in contributing to the technical and scientific harmonisation and standard setting done at OECD. These include:

- Test Guidelines;
- Harmonised templates for reporting data, e.g., from OECD Test Guidelines;
- International Uniform ChemicaL Information Database (IUCLID), for entering, storing and searching data electronically in the format of the OECD harmonised templates;
- eChemPortal, as a one stop portal to access disseminated data in locally stored databases with a direct access to IUCLID databases;
- Guidelines for exposure and hazard assessment
- Guidelines for use of alternative data
- QSAR Toolbox, used to estimate chemical hazards by grouping chemicals and filling gaps in (eco) toxicity data
- Adverse Outcome Pathways

All these tools are used to fulfil REACH requirements. The EU and its Member States contribute to their development directly through the OECD. Thus, the OECD does present a very efficient mechanism for developing the tools the EU needs for the implementation of REACH and CLP, and also ensures immediate international acceptance in all OECD countries. In particular, as testing of chemicals is labour-intensive, expensive and often requires animals, the OECD test guidelines implemented in the EU via the Test method Regulation allow the mutual acceptance of data, i.e. test data generated in any OECD member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.

These tools are also available via the OECD Internet-based Toolbox for Decision Making in Chemicals Management (IOMC) to countries using the tool box to develop chemical management systems.

6.3.3.5. Stakeholder views

There were limited comments received concerning coherence with international efforts specifically. However, some stakeholders responding to the open public consultation indicated that one of the unintended benefits of REACH is that it has become a benchmark for chemicals regulations in the world, either because REACH has inspired the adoption of similar legislation in other countries, or has become a global source of information on chemicals promoting innovation and/or safe use of chemicals worldwide. These stakeholders were mostly industry associations and NGOs. Therefore there are some indications that REACH is inspiring coherence internationally for chemical legislation.

6.3.3.6. Conclusions

In terms of policy objectives, REACH contributes to internationally accepted policy objective regarding chemicals shared by all countries, including the EU and its Member States in the form of target 4 in Sustainable Development Goal 12.

There are a number of different regulatory regimes globally. These all have their differences in terms of principles, approaches and processes but there are indications of harmonisation and certainly they do not appear to be inconsistent.

A number of the tools used in REACH implementation have been developed at the OECD and are coherent with other countries legislation, when the same tool is being utilised. Furthermore, adhering to the WSSD chemical goal in REACH and implementing of GHS in the CLP regulation, which is used for a number of regulatory processes, further strengthens coherence. In addition, the EU and its Member States are active and significant contributors to the international chemicals work, thereby enabling a more consistent approach to chemicals management around the world.

6.4. Relevance

6.4.1. IS REACH TECHNICALLY RELEVANT?

Assessment question: "To what extent is REACH capable of adapting to evolving needs (e.g. through adaptations to technical and scientific progress)?"

REACH has been largely capable of adapting to evolving needs in a context of scientific advances and technical progress. Two issues that will merit further investigation are the review of registration requirements for low tonnage substances and the need to register polymers which were addressed in the REACH review 2013 but not yet clarified. With regards to testing methods, the update mechanisms of REACH are working but the need to manage a complex process means they are judged to be slow. With regards to nanomaterials, there is an ongoing action to improve how to deal with them. Efforts are also ongoing to improve the identification of endocrine disruptors.

What is the issue?

Scientific knowledge on chemical substances and testing methods has been continuously evolving since before the adoption of REACH. In parallel, new substances have been manufactured and registered under REACH, possibly raising new concerns and risks to human health and the environment. Since REACH has to work in this evolving context it is important to ensure that it adapts to this changing environment quickly and efficiently. The REACH review 2013 highlighted a number of specific issues, in particular for

substances between 1 and 10 tonnes per year (especially CMRs); polymers; testing methods; and nanomaterials. The present review identified other emerging issues, such as endocrine disruptors and combination effects of chemicals.

6.4.1.1. Technical relevance

Review of the registration requirements for low tonnage (1-10 tonnes/year) substances

Based on the recommendations from the REACH Review 2013, studies[215] were launched on whether to extend the requirement for chemical safety assessments and chemical safety reports to CMR 1A/1B substances below 10 tonnes[216] and to modify the minimum standard information requirements for substances produced at 1-10 tonnes[217].

With regards to the level of protection of human health and the environment, all the options assessed offer higher levels of protection than the current requirements (as they improve information). The cost analysis of the different options concluded that all of the options would provide an increased benefits/costs ratio and also improve cost-effectiveness compared to the current requirements for registration in 2018. However, there were affordability concerns for the increased information requirements, especially given the number of SMEs who might be affected.

As a follow-up to the recommendation in the *General Report on REACH* 2013, the current 1-10 tonnes requirements will be further examined taking advantage of the experience gained with the last registration deadline of 2018 either to increase the testing requirement for the registrant to update their dossier and/or to increase the information requirements for new registrations.

Review of the need to register polymers

Polymers are exempted from registration under REACH[218] but the Regulation includes a review clause saying that the European Commission may present, as soon as a practicable and cost-efficient way of selecting polymers for registration can be established, a legislative proposal aiming at registering a range of selected polymers[219]. As a follow up of the REACH review 2013, a study on the registration requirements for polymers[220] assessed two strategies: grouping polymers for registration; and, defining a category or categories of polymers of low concern adopted in non-EU jurisdictions (i.e. Australia, USA, Canada, China, Japan, New Zealand, Philippines, South Korea, Taiwan).

This study concluded that a majority of the studied countries have a 'polymers of low concern' categorisation or a grouping approach or both for new polymers in line with the respective OECD definition. Polymers categorised as of low concern are considered less hazardous and benefit from reduced requirements. However, the study did not provide enough information on how to identify polymers of concern for human health and/or

[215] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015. http://ec.europa.eu/environment/chemicals/reach/publications_en.htm

[216] According to Article 138(1)

[217] According to Article 138(3)

[218] Article 2 (3) of REACH, however according to Article 6 (3), the monomer has to be registered under specific conditions.

[219] See Article 138(2) of REACH

[220] Technical assistance related to the review of REACH with regard to the registration requirements on polymer, Bio by Deloitte et al, February 2015

environment and how to group them. The Commission services will further investigate, and details will be set out in a Roadmap.

Testing methods

Timely amendments of the testing methods under the Test Method Regulation[221] , and in particular of the REACH information requirements are important to ensure that scientific development is taken into account under REACH. REACH Annexes VII to X as well as the Test Method Regulation have been amended respectively 3 and 4 times during the reporting period to reflect scientific and technical progress, in particular in relation to alternative methods (see Annex 4, section on testing methods for further details).

Animal welfare NGOs criticised in the public consultation long delays for the update of REACH information requirements and the Test Methods Regulation after the adoption of new OECD test guidelines. However, the implementation of a new method in the information requirements often requires consideration of its role in the overall safety assessment framework and thus additional technical and regulatory discussion with MS and stakeholders, especially where OECD test guidelines give flexibility in the study design or provide results that needs to be integrated with other information to address REACH information requirements. The timely formal recognition of new methods agreed as OECD test guidelines through their inclusion in Test Method Regulation remains a logistic challenge due to the inherent administrative processes and the time required for adaptation to EU standards and translation of the long and highly technical test protocols in all EU languages. The possibility to publish the test protocol in English only should be assessed and discussed with Member States.

It should be noted that the impact of this prolonged process is alleviated by ECHA providing up-to-date information about the availability and possible use of test methods for the purpose of REACH also before their inclusion in the Test Method Regulation.

6.4.1.2. Other issues

Nanomaterials

The amount of specific information about nanomaterials (substances in nanoform) in REACH registration dossiers is insufficient to ensure that registration data is actually relevant and covers the nanoforms of a registered substance. This is to a large degree due to the fact that REACH does not explicitly require registrants to provide separate information for forms of a substance, including bulk form and different nanoform(s).

Furthermore, REACH does not contain a definition of nanomaterial / nanoform.

The ongoing revision of the REACH Annexes for nanoforms is addressing this shortcoming. The changes address the documentation of different nanoforms, the relevance (and where necessary generation) of hazard and exposure information, as well as the assessment of the specificities that might occur through their transformation in the environment or by the modifications made by downstream users for their applications.

One of the characteristics of nanomaterials is the ability to modify function through structure (size, shape, surface chemistry of particles).

Some IT tools, grouping and read-across approach, as well as supporting instruments (e.g. modelling) will have to be extensively applied and require further development and validation in order to cover these additional characteristics.

[221] Regulation (EC) No 440/2008

Substances with endocrine disrupting properties

REACH considers the potential for endocrine disrupting properties to be one of several factors when prioritising substances to be assessed for regulatory risk management[222].

As part of the implementation of the SVHC Roadmap 2020, ECHA and Member States are making a determined effort to identify all relevant endocrine disruptors (EDs) of equivalent level of concern by 2020[223]. REACH provides suitable tools to identify EDs using the WHO/IPCS (2002) definition and to regulate such substances.

However, experience in the SVHC identification process revealed that there are two challenges for the identification of EDs as SVHCs:

1) whether the substance is of equivalent level of concern[224];

2) The availability of relevant scientific data[225] to identify substances using the WHO/IPCS (2002) definition. The REACH standard information requirements have limited capacity for providing data on endocrine disrupting properties: a number of adverse effects related to ED mode of actions (human health and environmental) are specifically identified by the extended one-generation reproduction toxicity study (EOGRTS), as well as by some of the other information requirements

However, the tests required still do not include the endpoints relevant for endocrine disrupting properties or they are only optional. This suggests that a better integration is needed of the latest developments on test methods and screening strategies to better identify endocrine disrupting properties.

The constantly developing scientific comprehension of endocrine disruption stresses the need for continuous knowledge exchange between regulators and the scientific community. The Commission supports this, for instance, by organising a workshop in cooperation with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)[226] on how to assess disruption of the thyroid pathway and on the interpretation of test observations. There is a need for a more systematic exchange of knowledge across disciplines, mainly between regulatory experts and scientists.

Finally, despite the progress under the OECD test guideline programme, gaps remain for an effective identification of endocrine disruptors. For this reason the Commission has stepped up its efforts to support test method development related to endocrine disruption by funding several projects and scoping workshops[227,228,229]. These test methods are also key for the identification of substances with endocrine disrupting properties used in

[222] As referred under the effectiveness section

[223] Seven substances or groups of substances (4-(1,1,3,3-tetramethylbutyl)phenol (also known as 4-tert-octylphenol) and 4-nonylphenol, 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated and 4-nonylphenol ethoxylated) have been identified as SVHCs and placed on the candidate list[223] due to endocrine disrupting properties.

[224] As it refers to article 57 (f) of REACH

[225] Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products. COM (2016) 350 final

[226] Workshop on thyroid disruption

[227] Supporting development of the OECD Detailed Review Paper on the Retinoid System

[228] Review of temporal aspects in the testing of chemicals for endocrine disrupting effects

[229] Workshop on setting priorities for further development and validation of test methods and testing approaches for evaluating endocrine disruptors

biocidal products or plant protection products. The Commission recently adopted a Regulation setting scientific criteria to identify substances with endocrine disrupting properties used in biocidal products. A draft Commission Regulation setting criteria for determining endocrine disrupting properties of substances used in plant protection products is still under scrutiny of the European Parliament and the Council until 9 April 2018 . For the implementation of the criteria two EU agencies, the European Food Safety Agency and the European Chemicals Agency, are developing joint scientific guidance.

Combination effects of chemicals

REACH provides mainly information on substances on its own, however partially addresses combined exposure from a single chemical (i.e. aggregate exposure) since registrants are required to perform risk characterisation for combined routes of exposure (oral, dermal and inhalation). However, a registrant is not obliged to take into account an exposure to the same substance from activities from other producers or importers.

Although REACH does not explicitly cover risk assessment from combined exposure to multiple chemicals, in specific cases (i.e. phthalates and tattoo inks) during the Restriction process and during Substance Evaluation, combined exposure to multiple chemicals from multiple sources can be considered. For instance, restriction proposals may take into account the combined risk arising from several substances with similar mode of action or exposure resulting from different emission sources. This was the case in the Annex XV restriction proposal on four phthalates in articles submitted by ECHA and Denmark [230] on 1 April 2016[231]. The four phthalates have the same modes of action and the overall exposure cause cumulative adverse effects.

According to the study on the EU efforts to meet the WSSD Commitment, the risk assessment under REACH considers the risks of single substances in isolation, and does not consider the effects of substances acting in combination, overlooking the normal situation whereby chemicals interact and present combined exposure to the environment and to humans. This study stresses that the combination effect undermines the traditional risk assessment approach since every similarly acting chemical in a combination contributes to the overall mixture effect, in proportion to its potency and dose. This study quotes a 2010 report[232] which states that REACH does not currently provide a mandate for considering the toxicity of so-called "coincidental" mixtures of industrial chemicals – multicomponent cocktails that are found in the environment or the human body as a result from the concurrent use of different chemicals in a given area

The Commission Communication[233] on the combination effects of chemicals provides a framework to further assess how EU legislation, including REACH, addresses the assessment of combination effects of chemicals.

The progress of this further assessment will be reported separately by the Commission. Further, combination effects are mentioned in the 7th Environment Action Programme and will feed into the Commission's future chemicals strategy for achieving the objective of a non-toxic environment.

[230] In co-operation with Danish EPA.

[231] Available from http://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions/-/substance-rev/13107/term

[232] KEMI (2012) Improved EU rules for a non-toxic environment, KEMI Report 1/12, Gothenburg, Sweden

[233] COM (2012) 252

6.4.1.3. Stakeholder views

While almost all respondents from industry associations think that REACH is the most suitable instrument with which to consider these emerging issues, among business REACH plays a secondary role.

Public authorities consider to a larger extent than other stakeholder groups that REACH is the most suitable instrument to deal with all of the emerging issues mentioned. NGOs are somewhat in between, thinking that REACH is the most suitable instrument concerning the different issues.

6.4.1.4. General Conclusions

Overall REACH appears to be able to adapt to scientific advances.

Two issues that will merit further investigation since 2013 are the review of registration requirements for low tonnage substances and the need to register polymers. Further information is necessary to assess the affordability of additional information requirements for low tonnage substances or to identify relevant polymers that could be subject to registration.

With regards to testing methods, the update mechanisms of REACH allow in principle for its adaptation to evolving scientific knowledge, for example, through updates of technical annexes and guidance. However, in practice, the adaptation of the technical annexes has been hindered by the need to address diverging scientific views (see section 6.4.1.2. Nanomaterials) and deal with administrative procedures applicable to EU legislation (time, resources, translation of technical content).

REACH is addressing emerging issues by increasing knowledge and addressing current gaps. Nonetheless, some challenges have been identified, generating relevant and specific information for nanoforms of substances, ensuring the identification of endocrine disrupting properties and addressing the combination effects of chemicals. Efforts are still needed to reflect on ways to integrate scientific developments into REACH so that it further addresses those emerging issues. With regards to the issue of nanomaterials, the ongoing revision of the REACH annexes[234] should lead to a proportionate response to clarify the registration requirements for nanomaterials.

6.4.2. IS REACH RELEVANT TO EU CITIZENS?

Assessment question: "To what extent is REACH relevant to the EU citizens?"

Europe's citizens are concerned about being exposed to hazardous chemicals in their daily life and REACH responds directly to these concerns. The perception on chemical safety has improved in the last 10 years, although the perceptions of safety vary also considerably between Member States and citizens will need further reassurance.

What is the issue?

What concerns do Europe's citizens have about chemicals and how adequately does REACH respond to this – through provision of information and management of risks.

[234] Currently under Comitology procedure , Article 133 of REACH

6.4.2.1. Citizens' relevance

The EU chemicals acquis, and REACH in particular, is expected to increase confidence in chemicals of consumers, investors, workers and the general public. However, most EU citizens would not be specifically aware of REACH as the overarching chemicals legislation nor would they be able to distinguish between REACH and other chemical related legislation (e.g. CLP, biocides, pesticides, ecolabel, cosmetics, detergents or toys). Therefore, citizens' views and attitudes towards chemical safety and governance of chemicals gathered through a Eurobarometer survey in 2016[235] are most likely related to the overall EU chemicals acquis and not specifically to REACH. According to the Eurobarometer:

- Around two-thirds of EU citizens are concerned about being exposed to hazardous chemicals in their daily life.
- Less than half of the respondents feel well informed about the potential dangers of the chemicals contained in consumer products, with a considerable geographical variation. In northern Europe, especially in the Nordic countries, they tend to feel better informed than in southern Europe.
- Similarly to the pattern identified in 2012[236], citizens consider that product safety has improved in the last 10-15 years.
- EU citizens views are divided over the safety of products containing chemicals and perceptions of safety vary also considerably between Member States. Citizens are inclined to think that products manufactured in the EU contain safer chemicals than those imported from outside the EU, although three in ten say that none of the products are safe. This is very similar to the findings from 2012. It indicates a higher level of confidence in the EU regulatory framework for manufactured products compared to non-EU regulatory regimes.
- Half the respondents say that the current level of regulating chemicals and the current availability of standards in the EU are not high enough to protect human health and the environment and should be increased.
- Two-thirds of citizens stated that retailers are obliged to provide information, upon request, on the presence of particularly hazardous chemicals in products.

REACH can play an important role in helping EU citizens make informed decisions about their use of chemicals. In 2016, ECHA improved the presentation of its dissemination pages[237] which provide information on chemicals in three different levels of detail, tailored to the general public, workers, authorities and other stakeholders.

Table 6: illustrates how the number of visits to ECHA dissemination pages has been increasing over the last years[238].

Number of visits to ECHA	2012	2013	2014	2015	2016

[235] A Eurobarometer survey was carried out at the end of 2016 to get citizens views and attitudes towards chemical safety and governance of chemicals – Link to the Eurobarometer survey on chemical safety

[236] Eurobarometer Flash 361

[237] Information on Chemicals - ECHA

[238] In 2016 ECHA revamped their website and the current number is not comparable to the previous one

dissemination pages					
Visitors	331 000	355 000	650 000	948 000	Over 1 million
Page views	468 000	675 000	757 000	1 816 000	10 281 286

If more and better hazard information is available on substances used in everyday products, this would encourage the use of safer alternatives available on the market. In a few countries, authorities and NGOs have put in place tools[239] to inform citizens about the presence of SVHCs in consumer articles. These are web-based or mobile applications to retrieve available knowledge on substances present in an article (usually by scanning the bar code) and/or to facilitate the submission of a consumer request to article suppliers. Such tools are usually accompanied by awareness raising campaigns and are facilitated by REACH's provision of information.

Taken together, this information suggests that REACH is relevant as it helps tackle real concerns amongst Europe's citizens over their exposure to chemicals. Obviously, chemical legislation has an impact on citizens' health: for example, the reduced prevalence of nickel-sensitisation in some countries since the introduction of restrictions for the use of nickel in 1994 and more recently the restriction on chromium VI in leather articles. Other measures with direct effects on citizens are the ban of carcinogenic, mutagenic and reproductive substances on their own or in mixtures, the restrictions of metals such as cadmium in jewellery or the ban of dichloromethane in paint strippers.

As REACH implementation progresses, and over time, it is expected that similar concrete effects will become more evident, as for example in relation to environmental protection.

According to the replies to the public consultation, stakeholders generally consider that REACH addresses the key issues related to chemical risks. NGOs, trade unions and public authorities are particularly positive about the relevance of REACH, whereas businesses are more critical.

Conclusions

Europe's citizens are concerned about being exposed to hazardous chemicals in their daily life and REACH responds directly to these concerns. The perception on chemical safety has improved in the last 10 years, although the perceptions of safety vary also considerably between Member States and citizens will need further reassurance.

6.4.3. ARE STAKEHOLDERS PROPERLY INVOLVED IN REACH?

Assessment question: "To what extent is REACH capable of taking into account health, consumer concerns, environmental, social and economic consequences that are relevant for citizens and stakeholders (through stakeholder information, consultation or involvement)?

[239] See Annex 4. Section 4.1.3

Stakeholder participation has improved in the different REACH processes, in response to the large number of procedures and tools set up to inform stakeholders early on about ongoing or planned activities and to collect relevant information. Overall, this suggest that REACH is able to take into account relevant concerns, although there is room for improvement concerning the dissemination of public consultations, the transparency about the consideration of the input gathered and the better communication between stakeholders and Member States.

What is the issue?

REACH involves the provision and dissemination of information and the use of this information to better manage chemicals. Stakeholders can make a valuable contribution to the effective and efficient operation of REACH through the provision of relevant information and, from the other side, providing stakeholders with relevant information allows for better and more efficient management of chemicals.

6.4.3.1. Responding to stakeholders

Consultation activities

REACH's operation includes a number of measures to allow stakeholders to be informed, including:

- REACH requires publication of intentions to initiate regulatory actions in relation to restriction of substances well before submission of the respective Annex XV dossier.
- REACH requires that ECHA conducts public consultations when (1) examining testing proposals; (2) examining proposals for the identification of substances as SVHC for the candidate list; (3) preparing recommendations for prioritisation of substances from the candidate list to be included in Annex XIV and (4) assessing applications for authorisation of SVHCs or proposals for restriction.
- ECHA publishes annual draft updates of the Community Rolling Action Plan of substances to become subject to evaluation (covering a three-year period from year N to N+2).
- the Commission launched in 2014, 2015 and 2017 calls for information on socio-economic aspects of the possible inclusion of substances into Annex XIV in parallel with ECHA's calls for information on draft recommendations for prioritisation of substances.

Stakeholders' participation[240] in the public consultations depends largely on the topic sub and the ability to consolidate comments efficiently; for example, public consultations related to testing proposals received over 800 comments[241], mainly from NGOs (over 90% of comments in some cases), public consultations related to SVHC identification received over 500 comments[242] from a wider range of stakeholders (44% industry, 29% Member States, 24% NGOs). The Commission received 490 replies to the first two calls

[240] The number of comments received is presented for illustrative purposes. In recent years, industry has begun to consolidate their comments, e.g. by sending one submission covering all points from e.g. the relevant trade association. This has brought many efficiencies in handling these cases.

[241] Public consultations carried out in relation to testing proposals since 2009

[242] Public consultations carried out in relation to proposals for SVHC identification between 2014 and 2016

for information on socio-economic aspects of inclusion of substances in Annex XIV from industry stakeholders (associations and particular companies).

This shows that public consultations provide a channel for all stakeholders' concerns to be fed into REACH decision-making. However, several categories of stakeholders want to improve the dissemination, timing and duration[243] of the consultations to allow for effective input from stakeholders. ECHA and the Commission publish on their websites, responses-to-comments reflecting how the comments received have been addressed.

In the case of the restriction process, the duration of the public consultation is 8 months, a long time compared to other Union legislation, although ECHA continues to receive comments close and after the deadline. Questions have also been asked during the public consultation in order to attract the attention of stakeholders on the need to receive specific input during the restriction procedure.

Representatives from SME organisations have pointed to difficulties due to the high number of public consultations and the absence of translations into all EU languages of the consultation documents. Some industry stakeholders have also expressed dissatisfaction with the way ECHA and the Commission integrate input from public consultation in their decisions as well as their concern about the possible misuse of public consultations as marketing tools by certain suppliers of alternatives to substances under consideration for authorisation.

Some NGOs have also expressed dissatisfaction on the type of comments submitted by industry during the public consultation and how the ECHA Committees evaluate this information. As regards the authorisation procedure, NGOs consider that the analysis of alternatives should be better assessed by the ECHA Committees and by the Commission.

Public Activities Coordination Tool

Besides the mechanisms envisaged in REACH as legal requirements (registry of intention and public consultations), an important measure to inform and involve stakeholders in planned actions under REACH, is the establishment by ECHA of the Public Activities Coordination Tool (PACT)[244] as part of the implementation of the SVHC Roadmap 2020.

The PACT gives early signals to all stakeholders, and in particular also to industry, by listing substances for which a regulatory management option analysis (RMOA) or an informal hazard assessment for substances with persistent, bioaccumulative and toxic and very persistent and very Bioccumulative (PBT/vPvB) properties or endocrine disruptor properties is either under development or has been completed. Industry uses this warning to ensure that registration dossiers are up-to-date and to be aware of possible actions under the Roadmap.

PACT is an important communication tool in the context of the implementation of SVHC Roadmap to improve transparency and predictability for stakeholders**.** The study *Monitoring the impacts of REACH on innovation, competitiveness and SMEs* states that during the interviews all stakeholders welcomed PACT**.**

The impact of the publication of the PACT and how stakeholders work together with Member States in further regulatory actions under REACH needs to be further explored.

[243] For example public consultations on testing proposals

[244] The PACT went online in September 2014

In addition, ECHA launches a call for evidence allows interested parties to provide input very early on in the restriction process.

Further stakeholder involvement

Stakeholders are also involved in the practical implementation of REACH by participation in the development and amendment of Guidance documents (through the partner expert groups organised by ECHA) and through the meetings of Member State competent authorities for REACH and CLP ("CARACAL"), which advises the European Commission and ECHA on important REACH and CLP interpretation and implementation issues, and include as observers a limited number of key stakeholders including from industry, trade unions, NGO's and trading partners.

In addition, REACH requires ECHA to develop appropriate contacts with stakeholders. ECHA has implemented its stakeholder management activities[245] along three main lines: broad communication and events aimed at all stakeholders (such as stakeholders days, website, newsletters and helpdesk), events and communication targeted at specific stakeholder groups (e.g. workshops for industry and Competent Authorities) and specific roles and privileges for its accredited stakeholders (such as the right to attend ECHA Committee meetings). 100 organisations are listed as Accredited Stakeholder Organisations on ECHA's website[246]. Stakeholders (industry, trade unions and NGOs) also have a seat each as observers in ECHA's Management Board.

Regarding the stakeholder involvement at national level, the Analysis of Member States' reporting questionnaire states that involvement of companies during the preparation of Annex XV SVHC identification and restriction dossiers by Member States and ECHA has been limited**.** However, several Member States are actively engaging with stakeholders when conducting RMOAs and others have found difficulties to have industry stakeholders engaged in the discussion in particular during the preparation of the Annex XV dossier for restriction.

Overall the Stakeholders participation has been constructive during the preparation of guidance as well as during the policy discussion in CARACAL.

6.4.3.2. Conclusion

The REACH Regulation includes a number of mechanisms enabling stakeholders to participate in the decision-making processes. Stakeholder participation has improved in the different REACH processes, in response to the large number of procedures and tools – both with and without legal requirements in REACH – that have been set up to inform stakeholders early on about ongoing or planned activities and to collect relevant information early during the implementation of the different REACH processes or to trigger updates of registration dossiers.

It can be concluded that the REACH procedures allow citizens and stakeholders to present their views and relevant information, although there is room for improvement concerning the dissemination of public consultations, the transparency about the consideration of the input gathered and the better communication between stakeholders and Member States.

[245] Link to Stakeholders website - ECHA

[246] December 2016

6.5. EU added value

6.5.1. WHAT IS THE EU ADDED VALUE OF REACH?

Question VA1: What is the additional value of regulating the risk management of chemicals at EU rather than at Member State level?

There is clear EU added value to having REACH and regulating the risk management of chemicals at the EU rather than at the Member State level. The EU approach offers advantages in terms of effectiveness and avoiding a fragmented approach in a market where firms are increasingly cross border in their outlook. There are also synergies reflected in better value for money from cross border legislation of chemicals.

6.5.1.1. Analysis of EU value added

The effectiveness and efficiency sections provide relevant analysis on how REACH contributes to the risk management of chemicals at EU level, cooperation and coordination between Member States as well as international cooperation. The conclusion that REACH is proving to be effective and that it is efficient, in the sense that the costs seem to be justified by the benefits, already suggests that it has EU value added.

Moreover, REACH is the only European legislation which provides a comprehensive risk assessment of chemicals from all the different sources and routes of exposure and can also cover not only individual chemicals but also group of substances. REACH may also complement other legislation where the risk of chemicals is not adequately controlled. For example, a restriction for industrial use can be initiated also for those chemicals which have an occupational exposure limit value set up at Union level if it is demonstrated that the risk is not adequately controlled. The situation has clearly changed since the adoption of REACH. REACH transferred the burden of proof to the industry as regards the safety of chemicals placed on the EU market, with uniform rules that apply across Member States. This has increased the knowledge on properties, uses, emission/exposure and risks of chemicals manufactured and imported in Europe. The increased knowledge about chemicals and enhanced communication in the cross-border supply chain enables all actors (manufacturers, importers and downstream users) to take the necessary measures to ensure safe use and consumers to gather a better knowledge on chemicals used during their daily life.

REACH has helped to avoided fragmentation in the European market. EU level intervention brings consistent rules to create a level-playing field for the economic operators in the EU market, avoiding differences that would clearly have occurred if REACH objectives were pursued by individual Member State actions. Since REACH's adoption, cross-border flows have increased although whether this is because of REACH or simply a reason for REACH is unclear.

The implementation of the REACH Regulation at the EU level also offers better value for money by allowing for resources, expertise and information to be better shared and co-ordinated, in a way that delivers efficiency. For example, REACH requires sharing of the workload (e.g. SVHC identification, restriction proposals) and exchanging knowledge between the public authorities as well as enhancing the coordination of their approaches between the different departments. Different bodies and activities organised to exchange expert opinions and coordinate the views of different national authorities such as the European networks created (e.g. CARACAL, HelpNet, Forum) facilitate the coordination of Member State activities, ensuring coherence between risk assessment practices at national level and avoiding duplication of work. Member States are therefore

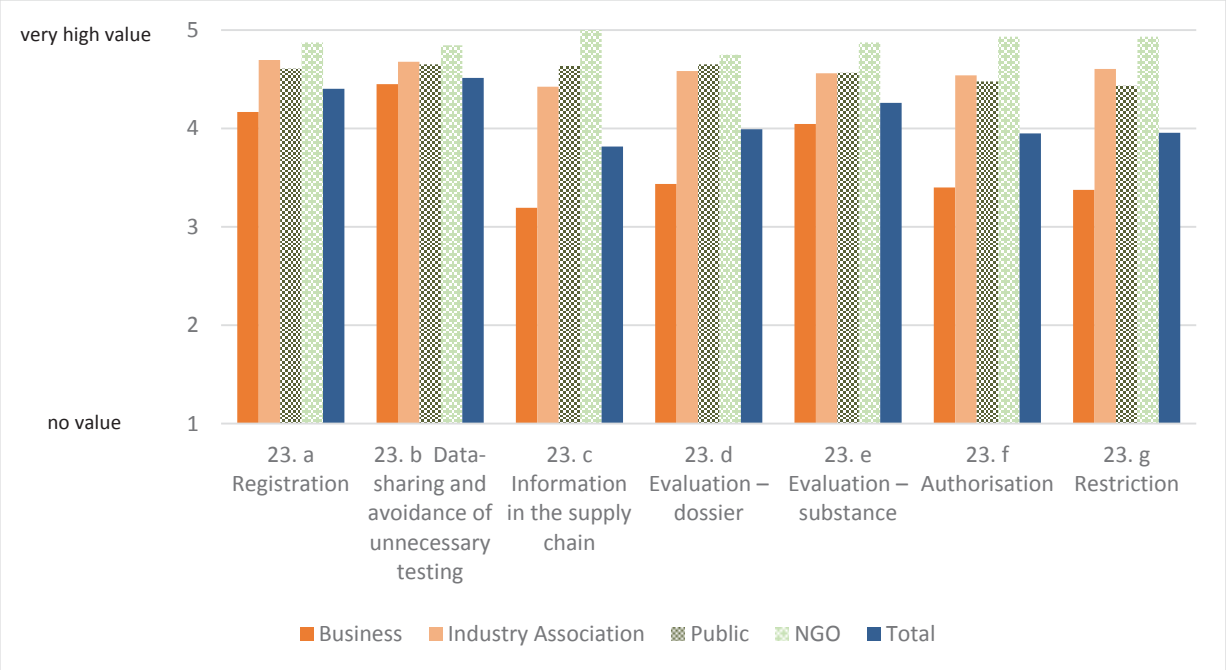
more efficient than if they were working in isolation. Moreover, having an EU central body like ECHA produces cost-savings in terms of the time and resources needed by Member States e.g. as registration is done centrally and not at national level and provides increased visibility of EU activities in international fora (e.g OECD and UN).

Moreover, the objectives of REACH – high level of protection of human health and the environment, the internal market for chemicals and the competitiveness and innovation of industry - remain relevant for the EU and its citizens. This can be shown by the harmonisation effects of the restrictions proposal where Member States consider the protection of human health and the environment a goal for all European citizens and therefore prefer to act under REACH rather than at national level. Impacts both on human health and the environment are often cross border. Similarly, the Commission considers that the risk of chemicals is better addressed if the measures to limit their risks are implemented at EU level as this provides the same level of protection of human health and the environment and allows for consistent control of imports at the EU border.

Some stakeholders have flagged the need for further efforts to make market surveillance and enforcement practices more aligned across the Member States as they perceive differences in the frequency of inspections and resources allocated by different Member States to ensure compliance with REACH. Nonetheless, the Forum is an effective instrument to coordinate and harmonise the national enforcement of REACH across the EU and can further improve the synergies between Enforcement Authorities and REACH Competent Authorities.

Overall, stakeholders from all groups consider that having a harmonised Union-wide approach is appropriate to manage the risks of chemicals in the EU. Respondents to the online public consultation expressed a very high appreciation of the EU added value achieved by the different chapters of REACH, compared to what could have been achieved through action by Member States alone at national level. Registration and data sharing and avoidance of unnecessary testing are considered of highest added value. The biggest difference between stakeholders is that respondents from individual businesses, academic institutions and individual citizens hold less favourable views, while consumer associations, NGOs and industry associations have a particularly positive view concerning the EU added value.

Figure 7: Answers to question on EU added value through the open public consultation: To what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (average values by stakeholder group on a scale from 1=no value to 5=very high value)



Conclusion

There is clear EU added value to having REACH and regulating the risk management of chemicals at the EU rather than at the member State level. The EU approach offers advantages in terms of effectiveness and avoiding a fragmented approach in a market where firms are increasingly cross border in their outlook. There are also synergies reflected in better value for money from cross border legislation of chemicals.

7. CONCLUSIONS

This Staff Working Document presents the findings of the evaluation of the REACH Regulation. It has been carried out on the basis of Member States reports and on the inputs from those involved in implementing the Regulation, including through detailed feedback received as part of the stakeholder consultation process, as well as a result of the continuous dialogue that the Commission maintains with Member States and stakeholders.

REACH is being fully implemented, and all its processes are operational. Key milestones have been met thanks to the effective cooperation between the Commission, ECHA, Member States, duty holders and other stakeholders.

The follow-up to the 2013 REACH review by the Commission, Member States and ECHA led to important improvements; however, there is still a need to improve certain specific REACH processes in order to make the system more workable and efficient, in particular, authorisation evaluation and restriction.

Ten years after entry into force, this REACH evaluation confirms the relevance and achievability of the objectives of REACH: to have a European chemical legislation which protects human health and the environment, promotes alternative methods for the assessment of substances' hazards and strengthens the internal market while promoting competitiveness and innovation.

Effectiveness of REACH

Progress has been made towards achieving the REACH objectives, as evidenced by the outcomes delivered so far. Although this progress is lagging behind the initial expectations of 2006, the progress has steadily improved and expectations recalibrated. The different building processes and actions envisaged in the intervention logic of REACH are being largely implemented, which suggests that REACH is protecting human health and the environment. REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort has been implemented at the expense of hazard information relevant for the protection of human health and the environment. REACH has strengthened the internal market thanks to further harmonisation of its governing rules. The result of several stakeholder surveys did not provide a clear picture if REACH generated an increase of intra-EU trade.

More information on the properties and uses of chemicals is available and being used for the assessment and management of risks, indicating that REACH has improved the protection of human health and the environment. Some specific evidence confirms the progress towards the expected results at this stage (such as in more information provided in the registration dossier, in the improved communication through the supply chain, in the reduction of chemical risk). Evidence also confirms that the benefits are starting to materialise, even if most of them will first occur in the coming years. However, the shortcomings in relation to the high level of non-compliance of the registration dossiers, the insufficient flow of information along the supply chain and the challenges associated

with the evaluation, authorisation and the restriction processes are slowing down the delivery of those benefits. As stated in the legal text, REACH's provisions are underpinned by the precautionary principle, however, since the entry into force of the legislation, the risk management actions proposed by the Commission have been limited. The development and consideration of alternative methods have greatly improved during the last ten years, although at the expense of the hazard information being delivered to Member States and hence at the expense of the protection of human health and the environment.

Regarding the free circulation of substances on the internal market, REACH is delivering further harmonisation of its governing rules and thus seems to be supporting the intra-EU trade. However, whilst the enforcement seems to have improved, further efforts to ensure compliance with REACH are needed at Member State level to better achieve a level-playing field across the EU.

The effects of REACH on competitiveness and innovation are difficult to quantify. There is some limited evidence of increasing innovation, but it is difficult to say whether this is due to REACH or not. It is also hard to clearly distinguish the impact of REACH on competitiveness as, again, competitiveness depends on many other important factors, such as the increasingly global market and the global economic developments.

REACH is leading to some other effects, either expected or unplanned. For example, REACH is increasing the expertise of public authorities and industry on chemicals and it has become a benchmark for third countries in terms of chemical regulation, thus contributing to international harmonisation in the implementation of chemicals policy. REACH provides a comprehensive data generation and assessment of most chemicals, compared to non-EU regimes that focus only on new and/or prioritised chemicals. Hence, REACH has also led to a vast publicly available database on chemicals, unique in the world. Other effects have been reported by industry stakeholders although limited evidence has been produced in this respect: market concentration, withdrawals of substances from the market, competitive advantage for non-EU producers of articles and possible business relocation.

The effective collaboration between the Commission, ECHA and Member States Competent Authorities has been a key factor to enhance the effectiveness of all the REACH processes. This coordination helped improvements in the implementation of the evaluation, authorisation and restriction processes as well as in identifying substances of very high concern by the SVHC Roadmap.

All the above has resulted in considerable progress towards meeting the World Summit Sustainability Development 2020 goal, positioning the EU as the strongest promoter.

Efficiency of REACH

In general, the costs of REACH seem to be justified by the expected benefits that are starting to materialise. The cost for businesses to meet the obligations of the first two registration deadlines (these being the costliest of the processes in REACH so far), was around EUR 2.3 billion, which although higher than expected (EUR 1.7 billion), is in the same order of magnitude expected. On the other hand, even though it is still too early to conclude, the benefits are progressively materialising. For the

time being, whilst the total costs seem justified and the efficiency has improved over time, there is still further scope for improvement, by simplifying and reducing the regulatory burden, whilst enhancing the delivery of benefits.

Benefits have started to materialise, but most of the benefits will first occur in the coming years. The first signal of benefits observed are the effects of the adopted restrictions on chemicals for human health and the environment, the improvement of risk management in the workplace, the better knowledge of chemicals, the substitution of substances of very high concern and the improvement of the communication through the supply chain.

The implementation of REACH brings costs for duty holders and public authorities. The main source of costs for duty holders is the registration process, which resulted in costs higher than originally predicted in the extended Impact Assessment, but in the same order of magnitude. Compulsory data sharing was the main factor increasing the costs compared to the original expectations. The cost of the first two registration deadlines was around EUR 2.3 billion spread over seven years (in the context of a chemicals sector which had sales of more than EUR 3500 billion over seven years). Included in the registration costs for businesses are the fees paid to ECHA, which between 2008 and 2016 were EUR 581 million – of this at least EUR 136 million were paid by representatives of non-EU producers. These costs are higher than the Commission estimates, which can, at least partly, be due to the additional costs of the "one substance, one registration" requirement introduced in REACH by the co-legislator and the lower use of QSARs compared to what was anticipated.

As regards public authorities, the costs at EU level have been slightly below the expectations as a result of the – 14% higher than foreseen – fees and charges revenues collected by ECHA by 2016. However, there has still been an EU balancing subsidy to ECHA totalling EUR 247 million, and EU funding of research on alternative methods of around EUR 40 million per annum. The resources available for Member States' activities vary widely and some REACH processes, namely the evaluation of substances or the restriction proposals, are driven by a relatively small group of Member States.

The registration costs are the largest cost factor for businesses, but there are also costs linked to the communication in the supply chain, evaluation, authorisation process or restrictions put in place: the costs quantified for these processes so far are justified by the positive results observed. The costs of applying for individual authorisations, for example, have halved since 2013 but the overall cost and benefits for implementing the authorisation process remain unknown.

The concerns described in the 2013 REACH review about the impact on SMEs remain, especially in view of the forthcoming registration deadline (2018), where many more SMEs are expected to be involved. On the other hand, the support measures put in place including the further reduction of fees are perceived as useful to assist them in complying with the REACH provisions.

The need to improve the efficiency of the REACH processes had been underlined in the 2013 REACH review and, since then, a number of improvements have been implemented or are being developed to improve the efficiency (e.g. registration) or to simplify the processes (e.g. authorisation and restriction). Further opportunities for improvement and simplification have been identified, namely in relation to the extended Safety Data

Sheets, the process of applying for authorisation, the preparation of restriction dossiers, the evaluation process and the requirements for substances in articles.

Coherence of REACH

The different actions under REACH link well together and largely deliver internal coherence, although the weaknesses identified in registration dossiers and the insufficient flow of information in the supply chain hinder the functioning of the subsequent REACH processes. REACH also seems to be largely consistent with other EU legislation, but some incoherencies affecting recycled materials and occupational safety and health legislation have been observed and need to be addressed.

Whilst the different REACH processes link well together there are weaknesses in registration dossiers and in the subsequent flow of information along the supply chain. This hinders subsequent REACH processes and, for example, the identification of appropriate regulatory measures (authorisation or restriction). However, the flow of information has improved since the REACH Review 2013, and efforts are ongoing to improve it, especially in light of the increasing operational experience. For example, the integrated regulatory strategy and associated common screening developed by ECHA in recent years is a significant contribution to improving the way the REACH processes work together.

When analysing the coherence between REACH and other EU legislation, some critical elements have been identified and addressed in the interface with RoHS and POPs. Further efforts are needed to assess other pieces of EU legislation and analyse their coherence with REACH and their added value. Currently the following actions are being undertaken:

- The interface of REACH and occupational safety and health legislation (OSH), where the overlaps have started to be tackled, such as the different limit values of exposures and the different methodologies for the same chemical substance.
- The interface of REACH with the Waste framework legislation affecting recycled materials, where a roadmap has been published and issues will be tackled in the context of the Circular Economy by the end of 2017.

The general coherence between the different EU agencies and the Scientific Committees needs to be improved to allow for better regulation, including more harmonisation between the different methodologies applied by these bodies.

REACH is coherent with the chemicals policy in third countries, and there are some signs of harmonisation (in terms of objectives or tools). The current international activities with the active contribution of the Commission and Member States ensure a more consistent approach to chemicals management in the world.

Relevance

REACH appears to be generally able to adapt to continuous scientific advances. REACH also responds to citizens' concerns, and is improving public perceptions of

chemicals, with stakeholders involved in the decision-making process.

REACH operates in a context of continuous scientific and technical progress, with new products and testing methods constantly being developed. Generally, the mechanisms of REACH to adapt to this constant change via updates are generally working, although in some specific areas such as the obligation to update registration dossiers, it has been found that they are not delivering.

It can be concluded that REACH responds directly to the concerns of citizens about being exposed to chemicals in their daily life and is contributing to an improved public perception of chemical safety. Stakeholder participation in the REACH processes has improved and their concerns are taken into account by the Commission and ECHA in the decision-making processes, although there is room for increased transparency.

The relevance of the registration requirements for substance in low tonnages (1-10t) and for polymers to ensure environmental safety and human health have been examined in this evaluation. For substances in low tonnages, options improving health and environmental benefits have been identified and will be further examined, considering also the experience gained with the last registration deadline of 2018 and their likely impact on SMEs. The Commission will also further investigate how to identify and group polymers of concern for human health and the environment with a view to establish the need, if any, of a legislative proposal.

EU added value

There is clear EU added value to having REACH and regulating chemicals at the EU level rather than at the Member State level. This is both more effective and efficient.

There is clear EU added value resulting from the implementation of REACH. Addressing chemical risks at EU level rather than at Member State level clearly offers advantages. In terms of effectiveness, it avoids a fragmented approach in a market where activities of firms are increasingly cross border. It also allows public authorities to pool their resources together and share the workload. Thus, there are synergies reflected in better value for money from cross border legislation for chemicals.

REACH provides a comprehensive assessment approach covering all the different sources and routes of exposure. The wider range of risk management measures available (in addition to the restrictions, in particular the authorisation process) are progressively leading to the identification and effective control of more hazardous substances by public authorities, as well as substitution of substances of particular concern for human health and the environment. Moreover, the increased knowledge about chemicals and the extension of responsibility along the supply chain are also leading to improved risk management procedures and responsibility in companies. ECHA has demonstrated the EU added value in the implementation of REACH and CLP.

Overall conclusion and need for improvement

Ten years after the entry into force, the objectives of REACH – high level of protection of human health and the environment, the internal market for chemicals and the

competitiveness and innovation of industry, remain relevant for the EU and its citizens. Moreover, the EU-level intervention is providing a more effective and efficient means to achieve such objectives than action by individual Member States.

The functioning of REACH has improved in response to the conclusions of the REACH Review 2013, with a number of changes being put in practice in response to the experience gathered and the feedback of stakeholders. Further room for simplification, reduction of the regulatory burden by clarifying the incoherencies between REACH and other Union legislations and improvement of the effectiveness have been identified.

The issues requiring most urgent action are:

- Non-compliance of registration dossiers: work is still needed to rectify the important data gaps or the inappropriate adaptations in the registration dossiers. Greater incentives may be needed for companies to update their registration dossiers as required by REACH, especially on the use, exposure and tonnage information.
- Simplification of the authorisation process: ongoing efforts to streamline and simplify the authorisation process should continue with a view to clarifying the requirements and make the process more predictable. The SVHC roadmap provides an effective and efficient system to identify relevant SVHCs and possible regulatory measures. In parallel, efforts must be stepped up to promote substitution of very high concern chemicals, in particular among SMEs.
- Level playing field with non-EU companies: in order to ensure the same level playing field between economic operators in and outside the EU, it is important that ECHA takes all possible preparatory steps in the lead up to the sunset date in order to expedite the assessment of the need for a restriction on imported articles containing substances listed in Annex XIV. Moreover, enforcement activities by Member States, in particular for imported goods, needs to be reinforced.
- Coherence: further activities are needed to clarify the coherence between REACH and other pieces of EU legislation. Work should continue on the coherence between REACH and OSH and waste legislation.

Further issues to be addressed are:

- The review of registration requirements for low tonnage substances and the need to register some polymers merit further investigation.
- The tools put in place to support the downstream users in meeting their obligations as regards the communication in the supply chain and the development of extended Safety Data Sheets should be further disseminated and their use improved.
- There is a need to consider how dossier and substance evaluation can move towards further addressing dossier deficiencies and concerns of high volume substances, but also towards the assessment and improvement of lower tonnage registrations, and eventually to monitoring the continuous compliance of all the dossiers in light of the technological and scientific development and the registration of new substances.
- The number of restrictions has so far not met the original expectations, but the process

has been improved on the basis of the recommendations resulting from of the Task Force (Commission services, ECHA and Member States as well as members of RAC and SEAC) e.g. through common screening and regulatory management option analysis..

- There is room for further improvement in the restriction process, on the basis of the recommendations of the Task Force, which are being implemented but are considered "work in progress". The activities should continue on the basis of the experience gained in the preparation of Annex XV dossiers. ECHA should review the requirements for the conformity check and continue its efforts to obtain a maximum of information through the public consultation. RAC and SEAC should diligently scrutinise the information submitted in the dossier and via the public consultation, including in particular requests for exemptions. Efforts to ensure compliance with the REACH provisions across the EU and achieve an effective level-playing field should be stepped up.
- The further development of enforcement indicators must be pursued to ensure monitoring.

ANNEXES

Annex 1 – Procedural information concerning the process to prepare the evaluation

Annex 2 – Stakeholder consultation

Annex 3 – Methods and analytical models used in preparing the evaluation

Annex 4 – Implementation state of play

Annex 5 – Horizontal issues

Annex 6 – Review of ECHA

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PART 2/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 1

{COM(2018) 116 final}

Annex 1: Procedural information

Lead DGs and internal references

The "REACH REFIT Evaluation (REACH Review 2017)" was co-led by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. It was included as item 2017/ENV/005 in the Agenda Planning (AP) and as Commission's REFIT Initiative item 1 in the Commission Work Programme of 2016[1].

This initiative is linked to other actions, REFIT action 52 of the Commission Work Programme of 2015 the " Fitness Check of the most relevant chemicals legislation not covered by REACH" to be delivered in 2018, the REFIT Ex-post evaluation of the EU occupational safety and health Directives (SWD (2017) 10 final) and the new initiative item 3 of the Commission Work Programme of 2016, the Circular Economy Package with the aim to address economic and environmental concerns by maximizing efficiency in the use of resources, covering the whole value chain (including sustainable consumption, production, waste management).

Organisation and timing

An Inter-service Group to steer and provide input for the REACH report 2017 was set up in September 2015 with representatives from the Directorate Generals for Environment; Internal Market, Industry, Entrepreneurship and SMEs; Budget; Competition; Employment, Social Affairs and Inclusion; Health and Food Safety; Joint Research Centre; Justice and Consumers; Research and Innovation; Taxation and Customs Union; Trade and the Secretariat General. In addition, representatives from the European Chemical Agency (ECHA) were invited to contribute to the meetings as external experts.

The group met seven times during the evaluation process (25 September 2015, 14 April and 8 September 2016, 22 February, 29 March, 20 April and 14 June 2017).

Table 1.1 ISG meeting dates and topics of discussion as well as other consultations

Date	**Topics of discussion**
25.09.2015	Context of the REACH report 2017;Presentation of the roadmap and planning of the work; Main elements of the roadmap; Ongoing and planned studies; the Consultation strategy
14.04.2016	Update on the roadmap; Ongoing studies with regards to the REACH report 2017; Presentation and discussion of the evaluation framework
08.09.2016	Update on the roadmap and consultation strategy; Update on work planning, Key milestones and timelines; Questionnaires for the public consultation and the SME panel
22.02.2017	Update on recent developments and work plan; Preliminary results of the online public consultation and SME consultation; Development of the evaluation report (SWD), Outline and general sections, Section 6: Implementation state of play, Section 7: Answer to evaluation questions

[1] Annex II of COM(2015) 610

29.03.2017	Update on recent developments ; Preliminary results of the online public consultation and SME consultation; Discussion on the draft evaluation report (SWD)
20.04.2017	Update and discussion on the draft evaluation report (SWD)
14.06.2017	Update and discussion on the draft evaluation report (SWD)
18.07.2017	Written consultation on the draft evaluation report (SWD) for submission to the RSB

External Expertise

The analysis underpinning this REFIT was undertaken via several thematic studies commissioned by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. In addition, the evaluation uses the regular reports from Member States Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and their enforcement. A description of those information sources can be found in Annex 3.

Relevant developments of the preparatory work for this REFIT evaluation were discussed at the Commission Expert Group CARACAL (Competent Authorities for REACH and CLP)[2].

In addition, a conference was held:

- Reporting on progress at Commission Conference "Towards phasing out animal testing" (follow-up to the European Citizen's Initiative).

Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present evaluation and issued its positive opinion on 29 September 2017. The Board made several recommendations to further improve the report. Those were addressed in the revised report as follows:

RSB recommendations	Modification of the report
(B) Main considerations	
The Board acknowledges significant efforts to collect evidence on how REACH is functioning and to report on implementation.	
The Board gives a positive opinion and suggests some improvements with respect to the following key aspects:	
(1) The report does not make full use of the evidence to substantiate REACH benefits and effectiveness. It does not conclude either on how higher-than-expected costs and delays in REACH	This recommendation has been addressed by adding relevant data presented in the technical annexes as

[2] Link to CARACAL in the Register of Commission Expert Groups

processes affect effectiveness and competitiveness. A systematic international comparison would improve the evidence base in these respects.	well as providing a comparison of achievements of chemical legislation in other jurisdictions. See sections 6.1.1 and 6.1.2 of the SWD.
(2) The report does not identify the key findings calling for action.	The conclusions have been revised to identify issues requiring most urgent action. See section 7 of the SWD.
(3) The report does not sufficiently address enforcement issues and their consequences for the effectiveness of REACH for the single market objective.	Available evidence on enforcement issues has been added to the main body, specifically section 6.1.3 of the SWD.
(4) The report does not sufficiently explain the outcomes of measures already undertaken to address coherence of REACH with other legislations.	Concrete steps to address overlaps with other legislation, in particular with OSH legislation, have been added in section 6.3.2 of the SWD.
(C) Further considerations and recommendations for improvement	
(1) Effectiveness, benefits and costs	
The report contains a wealth of information on the implementation of REACH and derives many of its findings on its functioning from stakeholders' views and opinions. These should be further corroborated and qualified with data extracted from the Annexes and supporting studies. The report should support the effectiveness assessment by comparing REACH to regulatory approaches in third countries. When assessing effectiveness, the report explains why it is hard to evaluate the overall impacts of REACH on health and the environment (e.g. long latency period before benefits materialise). Nevertheless, the evaluation should elaborate further on whether shifting the burden of proof to businesses to demonstrate the safety of chemicals	The findings have been completed with relevant data collected through thematic studies and presented in the technical annexes. The comparison with regulatory approaches in third countries has been further elaborated. The contribution of several factors (e.g. shifting the burden of proof, comparison of the number of new restrictions, non-compliance of registration dossiers) to the overall effectiveness of the system has been further described, mainly in sections 6.1.1 and 6.1.2 of the SWD. The description of benefits and costs

has been more effective and efficient than continuing with pre-REACH legislation. For instance, the report could address whether the number of actual restrictions put in place under REACH compared to the pre-REACH situation or to initial expectations is an indicator of the overall effectiveness of REACH. In this respect, the report should address aspects such as the value of the enhanced knowledge about chemicals or the deterrent effect of the authorisation process generated by REACH. The report should clarify the trade-offs between the incentives for firms to provide complete and accurate data vs regulators' ability to test and verify claims. It should present the current state of play. In terms of costs, the report should address the reliability of cost estimates (e.g. not only based on business' views). It should further explain why costs were higher than expected. Some may be legitimate (e.g. forced data sharing was not considered in the original impact assessment) while others may require attention to avoid that the situation worsens (e.g. costs associated with delays generated by non-compliance, costs imposed on downstream businesses). The report should also better detail the issue of non-compliance of registration dossiers (e.g. by distinguishing between different types and seriousness of non-compliance). It should indicate the costs in terms of foregone benefits and address how these shortcomings are dealt with. Finally, after weighing its pros and cons, the report should transparently discuss trade-offs of the REACH system. It could do so by comparing REACH more systematically with other approaches	has been further elaborated according to this recommendation. See section 6.2.1 of the SWD.
(2) Conclusions and priorities	
The report should more clearly identify key findings for policymaking and clarify the urgency for action. It should explain the rationale and methodology used to prioritise. Priorities could be laid out with a view to evaluate progress in the future. This implies hypotheses that can be tested	This recommendation has been addressed by amending sections 4 and 7 of the SWD.

and indicators that can deliver useful benchmarks.	
(3) Enforcement and market surveillance	
Given the critical role of enforcement in the overall effectiveness of the system, the report should elaborate on the structures, resources and organisation in place at Member State and EU level to ensure compliance. It should further qualify the functioning of enforcement mechanisms. It should, where relevant, assess to what extent identified flaws and limitations are affecting the effectiveness of REACH in terms of ensuring the smooth functioning of the single market.	This recommendation has been addressed by amending section 6.1.3 of the SWD.
(4) Coherence	
The report should better present the interplay of REACH with relevant EU priorities, strategies and legislation. It should further elaborate on the added value of different parallel initiatives to ensure coherence (e.g. roadmap, common understanding papers). Finally, it should explain the overarching approach undertaken to review and ensure the proper functioning of EU chemical legislation, in which the present evaluation takes place.	This recommendation has been addressed by amending section 6.3.2 of the SWD.

EUROPEAN
COMMISSION

Brussels, 5.3.2018
SWD(2018) 58 final

PART 3/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 2

{COM(2018) 116 final}

Annex 2: Synopsis report of stakeholder consultation

Consultation activities - introduction and approach

The stakeholder consultation for the REACH (REFIT) evaluation took place between 2014 and 2017[1] . As described in the Roadmap of the evaluation[2], the consultation approach aimed to complement regular consultation on the implementation of REACH through existing channels, ensuring stakeholder engagement and a balanced representation of the relevant interest groups.

In particular, it involved collecting input from a wide range of stakeholders on: (1) the effects, costs and benefits of the implementation of REACH, (2) strengths and weaknesses in the functioning of REACH, as well elements for potential burden reduction (3) stakeholder views on the general approach to the REACH evaluation, identifying potentially missing issues, (4) citizens perception of chemical safety in relation to EU legislation.

As part of the 2017 evaluation of the REACH Regulation a specific public consultation took place to present the approach to the REACH Evaluation 2017 and collect views on any potentially missing elements. Furthermore, views on relevant issues were obtained from Small and Medium Enterprise (SME) through the Europe Enterprise Network.

Stakeholder groups covered by the consultation activities

In line with the consultation strategy, input from a wide range of stakeholders was collected:

- Public authorities, notably competent authorities responsible for the implementation and enforcement authorities in EU Member States
- European Chemicals Agency (ECHA)
- Companies in both the chemicals industry and downstream sectors affected by REACH, focusing in particular on Small and Medium-sized Enterprises (SMEs)
- Industry associations covering both the chemicals industry and downstream sectors
- Workers that manufacture or use chemicals within the chemical industry, downstream sectors or as industrial/professional users
- Trade unions representing the above mentioned workers
- Civil society organisations – NGOs (e.g. environmental, health, animal welfare)
- Consumer associations
- Consumers / citizens
- Third countries' stakeholders defined as above (public authorities, companies etc).
- Other interested groups such as academics/researchers.

[1] The cut-off date is June 2017. Stakeholder contributions received by the Commission after that date could not be taken into account in preparing this document.

[2] See Roadmap for the REACH REFIT evaluation published on 18 May 2016 . One Member State provided feedback on the roadmap for the REACH Evaluation, concerning timing of deliverables and involvement of Member States in the process. The concerns were addressed in the context of the regular meetings of the expert group CARACAL (Competent Authorities for REACH and CLP).

The Commission developed a Stakeholder Consultation Strategy[3] providing details on the consultation objectives and activities planned. A 12-week open public consultation was one of the seven consultation tools proposed for the REACH Evaluation. The open public consultation aimed to gather stakeholders' and citizens' views on the general approach to the 2017 REACH Evaluation, strengths and weaknesses of REACH, and any potential missing elements.

Outcome of the consultation activities

1. The open public consultation

The open public consultation ran from 28 October 2016 to 28 January 2017. It was carried out via EU survey, the survey software of the European Commission, and accessible in three languages (English, French and German). The questionnaire[4] contained 25 questions, including on general information on the respondents (Part I), four compulsory general questions (Part II), 14 optional questions related to the five evaluation criteria, intended for respondents more familiar with REACH (Part IIIa), one extensive question on mechanisms and procedures of the REACH Regulation (Part IIIb) and finally one general open question for respondents' comments. Respondents also had the opportunity to submit position papers. The optional questions (Part III) were geared towards the REACH informed stakeholder.

Participants to the public consultation

Businesses and industry associations have an overly large weight (78% of respondents) in the overall results of the public consultation.

In total, 453 respondents replied to the Open Public Consultation. Most respondents decided to also answer the more specific questions indicative of that they were well-informed stakeholders. The largest group of respondents were businesses (47%) and industry associations (31%), totalling 78% of all respondents. The public sector was represented by 6% of respondents, most of them governments or public authorities and one representing the European Defence Agency, an intergovernmental organisation. NGOs were 4% of the respondents and whereas 6% were individual citizens. However, with 20 NGOs responding this is quite a large representation of the REACH relevant NGOs. Few respondents came from research and education, consumer associations and trade unions (together totalling about 4% too).

Among the 208 businesses who replied, 113 were large companies with 250. SMEs were well represented with 82 respondents. 18 responses came from self-employed/micro enterprises.

Representation throughout the EU and beyond

Except for Bulgaria, Cyprus and Latvia all Member States replied. The two largest groups of respondents came from Germany (32%) and those based in Belgium (20%). A large majority of respondents from Belgium (67%) represent industry associations and organisations that operate at EU level (75%). Other fairly large respondent groups were France, the UK, Austria, Sweden and Italy. 17 respondents came from non-EU countries[5], making up a fairly large group when compared to the representation of Member States.

[3] Link to the consultation strategy
[4] Questionnaires for the open public consultation in relation to the REACH REFIT evaluation
[5] Thailand (2), Turkey, United States (9), Japan (2), Canada (2).

Most responses came from organisations that operate at global level, followed by those operating at EU level and then at national level.

Respondents from businesses and industry associations were asked to indicate what their field(s) of interest or activity is/are. A large number of respondents (146) mentioned at least one sector in the group of raw materials, metals and wood as their activity and 101 respondents mentioned at least one sector in the group of base chemicals. Other important groups are the transport and mechanical engineering sectors and consumer products.

Table 2.1, Sectoral activity or interest (multiple replies possible)

	Activity in at least one sector in group
raw materials, metals and wood	146
base chemicals	101
consumer products	65
transport and mechanical engineering	64
polymers	43
specialty chemicals	40
consumer chemicals	37
carriers and retailers	33
professional	28
energy	17
agriculture	12
water and waste	8
construction	4

Main outcomes of the public consultation

It should be noted that the overall replies are heavily influenced by respondents from businesses and industry associations due to lower numbers of respondents from other stakeholder groups, an analysis was done to asses if views of some stakeholder groups deviate significantly from the overall results. Where relevant, this is indicated.

Overall Summary of the Open Public Consultation

Industry associations and companies, including SMEs

Industry acknowledges the positive effects of REACH in terms of making information available to ensure safe use of chemicals and they also encourage the Commission and other stakeholders to communicate more strongly about the benefits and the good functioning of REACH in order to build further trust amongst all stakeholders, including the general public.

For industry stakeholders, legal stability and certainty is a key issue as the regulatory framework is an important driver for predictability and thus business decisions. Therefore, they are not in favour of re-opening the enacting terms of the REACH Regulation.

They stress the need to reduce burden and costs by favouring a risk-based approach and to minimise negative impacts in the innovation capacity and competitive position of EU industry vis-à-vis third countries. They also highlight the need to ensure a level playing field by further harmonising enforcement, including at the EU borders.

The coherence between REACH and other legislation, in particular OSH, is another area of concern for industry stakeholders.

SMEs further emphasise the need to reduce burdens and step up efforts to support compliance, in particular in view of the 2018 registration deadline.

Civil society: non-governmental organisations (NGOs) and consumer organisations

For NGOs, REACH has a high potential to deliver a high level of protection of human health and environment and is a model inspiring legislation in other jurisdictions but its potential has not been fully developed after 10 years of implementation.

They raise concerns about the poor quality of data from registration dossiers and about the insufficient information on safe use of chemicals flowing through the supply chain and reaching consumers and adaptation of legal text could be considered. They consider that the mechanisms to address risks through regulatory measures, namely authorisation and restriction, are excessively burdensome and lengthy, leading to slow progress to substitute and phase-out hazardous chemicals. Moreover, the current operation of the authorisation process disfavours innovative companies investing in alternatives to hazardous chemicals.

Such deficiencies result in general principles underlying REACH such as the "no data, no market", the shift in the burden of proof or the precautionary principle not being applied in practice.

Public authorities: Member State, national and regional authorities

Member States in general find that REACH is delivering on its main objectives as it is bringing improvements in the management of chemical risks but they also raise deficiencies related to its implementation. Most Member States express concerns about the quality of data generated by REACH, which is not sufficient for public authorities to conclude on the need for regulatory risk management measures and thus make the shifting of the burden of proof incomplete. They also express concerns about the flow of information in the supply chain, namely about the extended Safety Data Sheets. Some Member States acknowledge that REACH have created costs for industry and that it is more challenging for SMEs to comply with the requirements. In general, Member States do not favour re-opening the enacting terms of the Regulation but propose improvements to close gaps, increase the speed of regulatory measures and minimise the negative impacts on industry.

Trade unions

Trade unions see REACH as a positive development to make companies better informed about the risks posed by chemicals and to improve risk management, also improving the safety of workers using chemicals beyond the chemical industry.

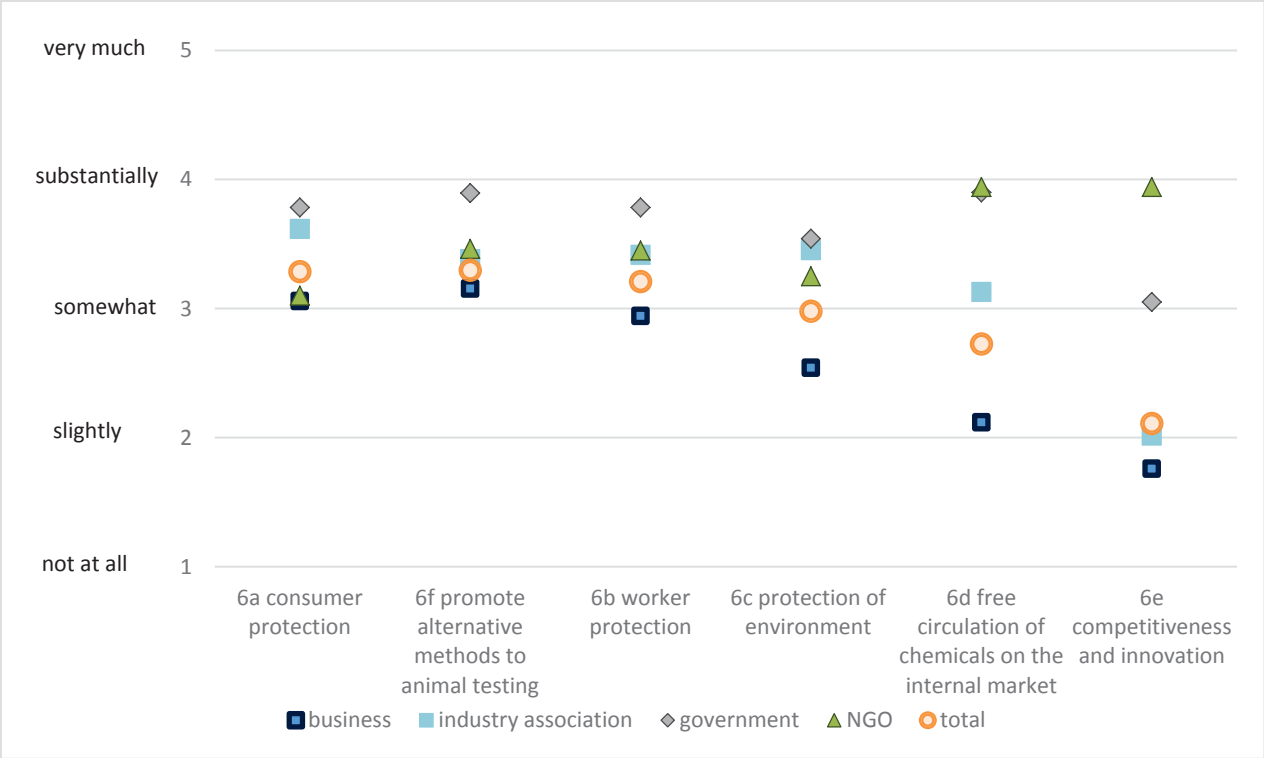
Overall impression

The overall impression from these views is that in general stakeholders believe the REACH legislation is adequate to address most of the different challenges posed to it, but that implementation should be improved.

Overview of the responses to the general and compulsory questions (Part II):

To the question if REACH was reaching its objectives, overall the respondents fairly positive view regarding the improvement of protection of consumers, workers and the environment, as well as promoting alternative methods for animal testing. Respondents believe that REACH is achieving these objectives to some extent. Respondents have more critical views concerning the economic objectives of free circulation of chemicals on the internal market with businesses having an overly large weight in the negative replies as well as on competitiveness and innovation. Figure 1 provides further details.

Figure 2.1: To what extent do you think REACH is achieving the following objectives? (Marker points show average value[6] of responses (mean) by stakeholder group and across all respondents (total))



Respondents' views on the results of REACH are rather positive regarding some deliverables: overall, the vast majority of respondents think that REACH generates data for hazard/risk management and shifts the burden of proof from public authorities to industry. A slimmer majority agrees that REACH increases information on chemicals for risk management and information exchanged in the supply chain. About half of the respondents agreed that REACH improves development and implementation of risk management measures, promotes the development, use, and acceptability of alternatives to animal testing, and implements the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing.

However, more than half of the respondents believe that REACH fosters innovation slightly or not at all. This question was answered mainly negatively by businesses and industry associations, and answered mainly positively by NGOs. On the dissemination of information on chemicals for the general public there were diverging views between industry associations, which had largely positive views on this result, and businesses which hold largely negative views, with half thinking that this result has been delivered slightly at best.

[6] See section 5.1.2 for an explanation of the values presented

Overall respondents had a positive view concerning the usefulness of data generated under REACH, almost half of the respondents said that the data was substantially or very useful for adopting the different risk management measures (REACH authorisation, REACH restriction, consumer protection legislation concerning chemicals in articles, environmental legislation, occupational exposure limits in the context of worker protection legislation). Furthermore, NGO respondents were more critical of the usefulness of data for consumer protection legislation and environmental legislation. Also, consumer associations hold a very different view on the usefulness of data for consumer protection legislation: four out of the five consumer associations think that data generated under REACH is only slightly useful for this measure.

Overall, the majority of respondents agree that ECHA has handled the registrations of chemical substances effectively, except for NGO respondents of which almost 50% disagree to this statement. The majority of respondents also agree or strongly agree that ECHA has established a strong and trustful relationship with its stakeholders. However, when it comes to ECHA's work on reducing the impact of REACH on SMEs and to facilitate and innovation-friendly framework, respondents are more critical, with half of the respondents disagreeing and only low shares agreeing to this. However, this critical view is mainly held by businesses and industry associations, while respondents from public authorities, NGOs and trade unions to a large majority agree or strongly agree to these positive effects.

As regards ECHA's work on facilitating the implementation of the last resort principle concerning animal testing, most respondents are neutral, with NGOs being more critical.

Overview of the responses to the REACH REFIT Evaluation Questions (Part IIIa):

Effectiveness

Overall respondents were positive concerning the implementation of REACH. Chapters that received particularly positive perception are in particular registration, but also data-sharing and avoidance of unnecessary testing, dossier evaluation, and the overall implementation of REACH. Respondents were more critical of substance evaluation, restriction and in particular authorisation.

Consumer associations and NGOs have a much more negative views than most concerning dossier evaluation and restriction, with NGOs in addition being very critical of registration, and consumer associations also being critical of authorisation and the overall REACH implementation. The REACH legal text regarding authorisation is considered as not very clear or predictable by a larger number of respondents. Table 2 summarises the implementation appreciation for the different REACH chapters on average.

Table 2.2: To what extent have the REACH Regulation and its various chapters been implemented successfully?

	5.0	very much
10.a Registration	4.0	substantially

10.b Data-sharing and avoidance of unnecessary testing	3.4	somewhat
10.h Overall implementation of REACH	3.4	
10.d Evaluation – dossier	3.3	
10.e Evaluation – substance	3.2	
10.c Information in the supply chain	3.1	
10.g Restriction	2.9	
10.f Authorisation	2.8	
	2.0	slightly
	1.0	not at all

(sorted by average value of responses (mean) [7], highest to lowest, on a scale from 1=not at all to 5=very much)

As regards REACH enforcement, replies vary depending on the question. Respondents presented negative views on whether REACH is enforced uniformly across the EU (most negative, with almost 70% replying negative). More positive replies were received on the prioritisation of enforcement activities at EU level via the Forum. Concerning the overall REACH enforcement in the EU REACH enforcement at Member State level and communication of enforcement activities from Member States and the Forum, the overall view is slightly negative.

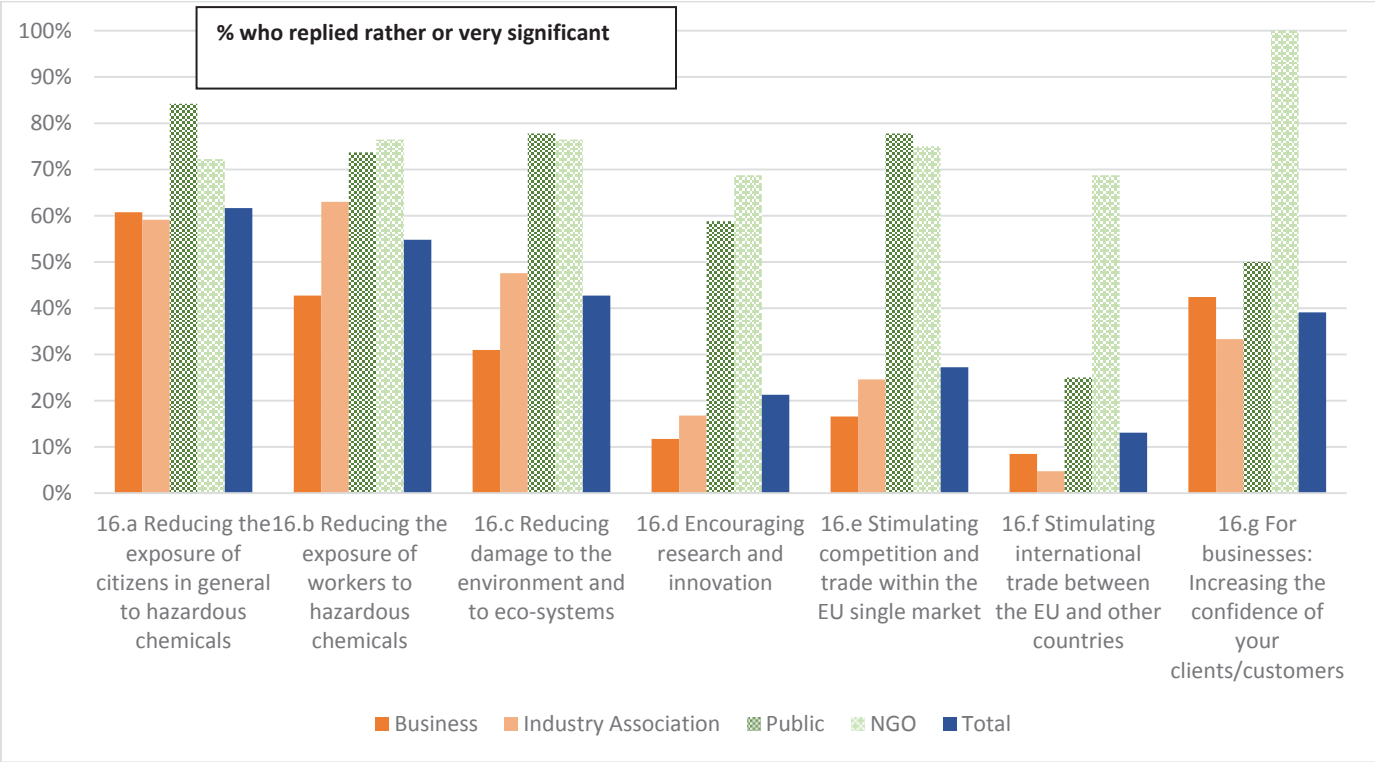
There are consistent differences between stakeholder groups across each of the different aspects of enforcement: NGOs and consumer associations hold much more negative views than other stakeholder groups on the enforcement of all aspects; Businesses also hold more negative views than the average on all aspects. However trade unions, public authorities and – to a slightly lesser extent – industry associations, hold more positive views than the average on all five aspects.

Efficiency

Reducing the exposure of citizens in general to hazardous chemicals, reducing the exposure of workers to hazardous chemicals and reducing damage to the environment and to eco-systems are considered significant benefits. Negative views among businesses and industry associations prevail concerning the benefits of encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry, stimulating competition and trade within the EU single market and stimulating international trade between the EU and other countries. However, NGOs think also these aspects were significant benefits generated by REACH, as do public authorities. Concerning the benefit for businesses of increasing the confidence of clients/customers in products positive views prevail.

Figure 2.2: How significant are the following benefits generated for society by the REACH Regulation?

[7] See section 5.1.2 for an explanation of the values presented



Overall, respondents showed balanced views to the question of proportionality of costs on registration and information in the supply chain. Concerning the costs linked to dossier evaluation and substance evaluation, a larger share thinks that costs are not proportionate (around 40%) compared to those holding positive views (20%). For costs related to the chapter on restriction, positive views are slightly more common than negative ones. Regarding costs related to authorisation and to requirements for substances in articles many think that costs are not proportionate. The overall tendency is heavily biased by replies from businesses and industry associations. Public authorities and NGOs think that the costs are substantially proportionate to the benefits regarding all the REACH chapters.

The majority of respondents, mainly businesses, find that there are areas where the REACH Regulation could be simplified to a large extent. There are large differences between the stakeholder groups, with consumer associations, public authorities, NGOs and trade unions believing that the REACH Regulation could be simplified to a minor extent.

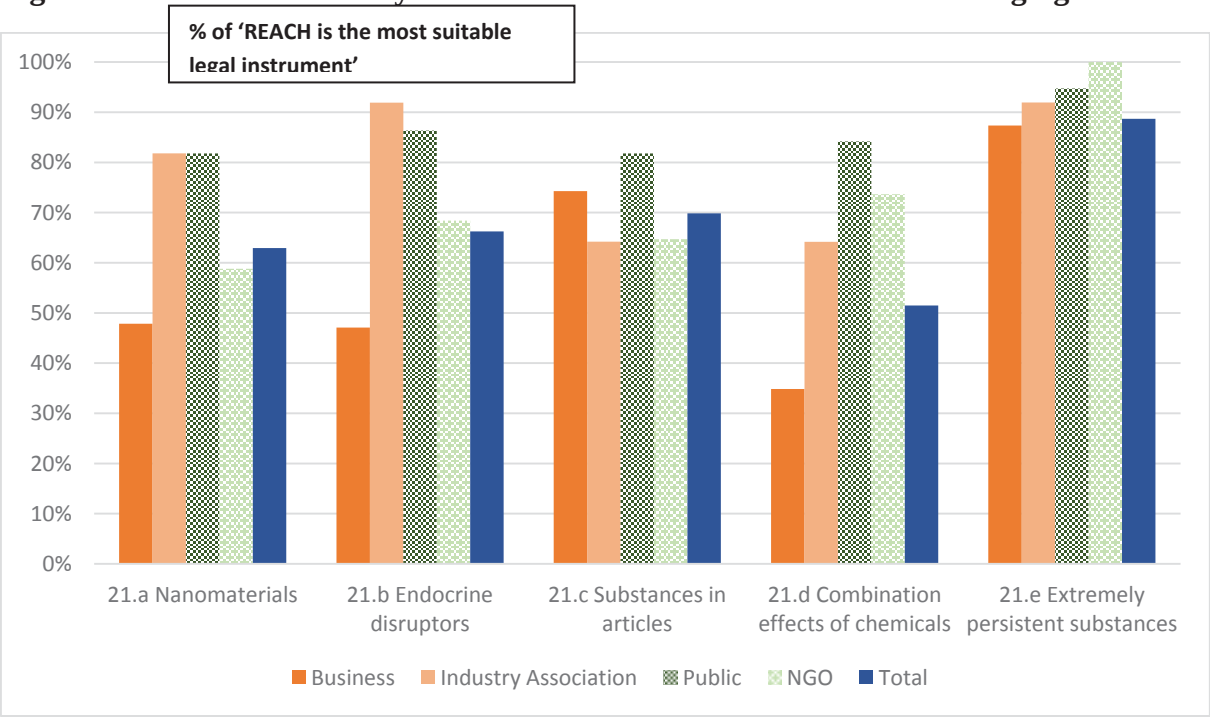
Relevance

Respondents think that the REACH Regulation is relevant for the management of chemicals. Businesses are particularly critical towards the relevance of REACH, whereas NGOS, trade unions and public authorities are particularly positive about it.

For emerging issues most respondents believe that REACH is the most suitable EU legal instrument to address them. The share of these respondents is particularly high concerning the issue of extremely persistent substances and lowest concerning the issue of combination effects of chemicals.

Notably businesses think that REACH should only play a secondary role concerning nanomaterials, endocrine disruptors and combination effects of chemicals. Also some consumer associations and trade unions think REACH should play a secondary role for various emerging issues (further detail in figure 3).

Figure 2.3: How suitable do you consider REACH to be to deal with emerging issues?

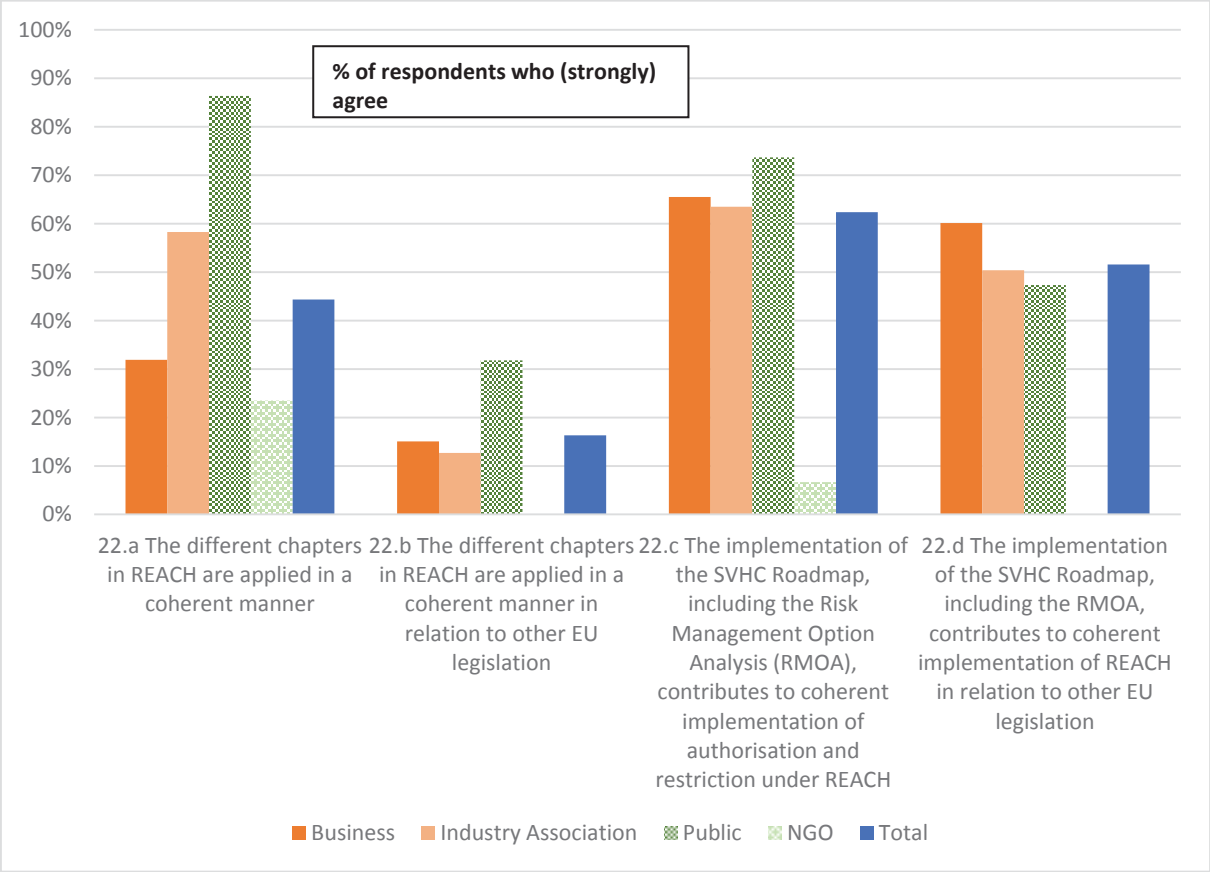


Coherence

Overall views were largely positive on the coherent implementation of authorisation and restriction under REACH' via implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA) also in relation to other EU legislation. Views were more divided regarding if the different chapters of REACH are applied in a coherent manner and the respondents were largely negative concerning the coherence of the application of the different chapters in REACH in relation to other EU legislation (see figure 4 for further details).

Business respondents have a more critical view than industry associations on the coherence of the REACH chapters. Consumer associations and NGOs oppose more strongly than the other stakeholders and all four consumer associations strongly disagree that the different chapters in REACH are applied in a coherent manner with other EU legislation.

Figure 2.4, Coherence: Please tell us to what extent you agree or disagree with the following statements?



EU added Value

Overall, respondents think REACH has significant EU added value. It should be noted that respondents from businesses, academic institutions and individual citizens in particular hold more negative views than allother groups regarding the EU added value. Consumer associations, NGOs and industry associations have a particularly positive view concerning the EU added value.

Summary of the responses to the REACH REFIT Evaluation Open Questions and Position Papers (Part IIIb):

Respondents had the opportunity to submit position papers in addition to the open questions. These papers and responses were systematically summarised via categorisation. Main messages provided by the different categories of stakeholders are summarised below. The stakeholder groups 'business' and 'industry association' have been commonly addressed as 'industry respondents' or 'industry representatives'.

The legal text should not be changed, adaptation through guidance should be sufficient

According to industry respondents, problems with the operation of the REACH Regulation are mostly due to implementation of rather than the legal text, and can be resolved by developing more guidance, rules of practice or templates.

According to some stakeholders, REACH has effectively increased knowledge on chemical substances, communication in the supply chain and has encouraged substitution of SVHC

A number of respondents, mostly industry associations and businesses, stated that REACH performed well in improving the knowledge on chemical substances, increasing the transfer of information through the supply chain and encouraging safe use of chemicals in companies, and supporting the phasing out of hazardous substances from the market. a very small number of industry respondents stated that the REACH Regulation had benefits for the free circulation of chemicals in the single market.

According to industry respondents REACH had negative effects on the competitiveness and innovation of the EU industry

Industry respondents were generally rather negative on the performance of REACH concerning competitiveness and innovation. According to them, compliance costs and risk management measures (e.g. authorisation and restriction) have led to some extent to the relocation of activities outside the EU and the withdrawal of substances from the market, especially those produced in low volumes, forcing market concentration and causing disruption in the supply chains of certain products. Reducing business uncertainty caused by the placing of a substance on the Candidate List has often been mentioned as a necessity to reduce negative impacts on competitiveness.

A large number of respondents also argued that, because they do not have to apply for authorisation, but can export products containing SVHC in the single market, non-EU producers have a competitive advantage, which harms the competitiveness of the EU industry. Respondents also argued that compliance costs had a negative impact on innovation, since, in companies, resources normally dedicated to research and the development of new products have been focused on compliance and substitution.

However, substitution is considered as an important driver for innovation by NGOs

Several environmental NGOs stated, on the contrary, that there is evidence that regulation or the anticipation of regulation efficiently drives innovation and help to bring new products to the market. Some NGOs added that substitution can also have economic benefits for companies, which will be saving on the handling of hazardous chemicals.

According to industry respondents, REACH should be simplified, administrative burdens and costs should be reduced

According to industry respondents, compliance costs and administrative burden have been generally much higher compared to what had been anticipated by duty holders. Most of their comments relate to the registration process, particularly to the preparation and update of registration dossiers, the management of consortia, data collection, testing and data sharing, fees of ECHA, etc. but also to applications for authorisation and substitution. Respondents also frequently stated that SMEs are more affected than large companies and need specific support to comply with the REACH Regulation.

The quality of registration dossiers still needs to be improved

Many respondents from all categories of respondents indicated that the quality of registration dossiers was still not satisfactory, with different perspectives: for industry respondents, all registrants should be treated equally and free-riders punished, for other respondents, the good functioning and objectives of REACH are hindered by the poor quality of some dossiers. This is why NGOs and consumer associations who participated to the consultation, emphasised the need to implement with more severity the ‘no data, no market’ principle and to refuse to grant or withdraw their registration number to non-compliant dossiers.

Reduction in animal testing could be greater

Respondents from almost all stakeholder groups agreed that the principle of 'animal testing as a last resort' is not yet fully implemented. Respondents explain this problem by strict information requirements coupled with a low acceptance of alternative methods.

According to downstream users, extended Safety Data Sheets should be simplified and reflect better conditions of use

Numerous downstream users (or associations of downstream users) stated that the extended safety data sheets they received were too lengthy and technical to be useful for their needs. Many respondents, therefore, called for uniform templates to be used. Respondents also criticised that the exposure scenarios are often not reflecting reality. Some respondents added that, in general, the quality of safety data sheets is poor.

According to industry respondents, information requirements on SVHC in articles should remain manageable for companies

Numerous industry representatives expressed concern over the European Court of Justice ruling on applying the 0.1% threshold for notifying SVHCs in articles, which concluded that the obligation to notify applies to each article included as a component of a complex article. In many position papers, industry representatives called for more guidance on the requirements concerning articles under REACH.

However, according to other respondents, information on SVHC in article should be improved and better communicated

A mix of stakeholder types stressed the importance of improving, and for some respondents extending, the information on substances in articles communicated in the supply chain to enable consumers to make conscious choices, to support companies who invest in substituting hazardous chemicals by safer alternatives, and to improve traceability of recycled materials. Several respondents mentioned that information on SVHC in articles communicated through the supply chain did not reach the recycling industry, which creates problems for fulfilling obligations applying to recycled materials. Stakeholders of several types, including industry and NGOs, stressed the importance of extending the Article 33 requirements to imported articles. Some respondents also proposed to extend the provision of Article 56 on authorisation to articles.

Enforcement efforts at national level need to be increased and harmonised

Respondents generally argued that enforcement at national level needed to be significantly harmonised, both in term of level of activity and interpretation of the rules, industry respondents emphasising that the lack of harmonisation leads to an uneven playing fields for EU companies, other respondents, especially NGOs, that it generally puts at risk the achievement of better health and environmental protection in the EU. In particular, increased controls of imported goods at EU borders are deemed necessary by a significant number of respondents.

Industry respondents favour a risk-based approach to risk management measures

The question of applying a risk-based or hazard-based approach to risk management measures profoundly divided respondents to the consultation. According to industry respondents, data on exposure and socio-economic considerations should be considered much earlier in the

process, to reduce the time between the identification of a substance as an SVHC and the adoption of the risk management measures, avoid unnecessary measures and eventually increase the legal certainty for duty holders. Industry respondents are therefore very much in favour of integrating the RMOA as a compulsory step in the regulatory process.

Non-industry respondents defend and wish to strengthen the current hazard-based approach

Non-industry respondents, in particular environmental NGOs, argued, on the contrary, that the inclusion of substances on the Candidate List should remain an independent step, exclusively hazard-based, to ensure that all potentially hazardous substances are identified according to the objectives of the SVHC Roadmap. They blamed the slowing down of SVHC listing and identification of PBT /vPvB substances, and called for abandoning or at least not give more importance to the RMOA, accused of the burden of proof to authorities.

According to industry respondents, the authorisation procedure should be simplified and more targeted

Industry respondents called for a simplification of the procedure to apply for authorisation, in particular for low volumes or substances used in legacy spare parts, and supported the ongoing initiative from the European Commission on that matter. According to many industry respondents, the inclusion of substances in Annex XIV does not take enough into account that some substances cannot be substituted. These respondents generally argued for better considering other risk management measures before authorisation, in particular restrictions, which have the benefits of prohibiting the most hazardous use of a substance while preserving critical uses of the substance for certain products. Many respondents also called for longer review periods to achieve substitution of substances used in products requiring long development and testing periods or with a very long life-span.

According to other respondents, authorisations should not be granted when alternatives are available

Other respondents, and in particular NGOs, consumer associations, and some public authorities, argued that the practice of granting all authorisations, even when alternatives exist, was disadvantaging companies who have invested in safer alternatives and not incentivising enough the substitution of hazardous substances. They supported a more thorough assessment of alternatives in socio-economic analyses, not only taking into account the applicant's perspective but 'all relevant aspects', including the impact of the authorisation on alternative producers, as required by Article 60(5). In addition, NGOs and consumer associations called for addressing groups of substances rather than individual substances in SVHC listing to avoid regrettable substitution.

Coherence of REACH with other legislation, especially the OSH legislation, needs to be improved

A large number of industry respondents stressed the need for better coherence between REACH and the OSH legislation, and, in particular, the confusion created by the application of both OELs developed under the OSH legislation and DNELs developed under REACH. Some suggested harmonising OELs and DNELs and aligning methodologies used by SCOEL and RAC, to avoid the co-existence of multiple and different values. Others proposed to prioritize OELs over DNELs at the workplace. These respondents also defended the use of the RMOA as a tool to assess which regulation is the most appropriate to address the hazard early in the process and avoid the duplication of risk management measures. The great majority of

this respondents suggested that EU OSH legislation should be prioritized under RMOAs. The other main coherence issues identified concerned the relation between REACH and RoHS, the EU water legislation, or the waste legislation.

REACH should enable the development of the circular economy

The relation between REACH and the objectives of the circular economy received a lot of comments in several questions of the questionnaire. A number of industry respondents indicated as a potential unintended effect the possibility that REACH prevents the development of the recycling sector by including recycled materials in the scope of risk management measures and called for the implementation of a 'repair as produced' principle for recycled materials. Other respondents on the contrary mentioned that REACH should enable the development of the circular economy by ensuring that articles do not contain hazardous substances and that the lifecycle of the product is clean. This should be supported, as mentioned above, by the transfer of sound information on substances in articles, through the whole supply chain, including recyclers.

REACH is the relevant instrument for addressing emerging risks, but information requirements should be strengthened to properly manage these risks, according to some respondents

Most respondents considered that REACH is the suitable instrument to address emerging issues, such as nanomaterials, endocrine disruptor, or combined exposure. However, certain respondents, mainly NGOs, consumer associations, and public authorities, indicated that, among other issues, information and testing requirements should be amended to take better account of the specific risks and properties of nanomaterials and endocrine disruptors or to take account of possible combination effects in their registration dossiers.

Overall impression

The overall impression from these views is that in general all stakeholders believe the REACH legislation is adequate to address most of the different challenges posed to it, but that implementation should be improved.

Stakeholders generally acknowledge the positive effects of REACH so far but they all see considerable room for improvement in different areas. Most stakeholders, mainly industry, have indicated that at this stage, they do not favour reopening the enacting terms of the REACH Regulation but rather improve the implementation through changes in the Annexes, development of guidance and more cooperation between stakeholders and institutions.

Industry stakeholders stress the need to reduce burden and costs to minimise negative impacts in the innovation capacity and competitive position of EU industry. For NGOs, the full potential of REACH to deliver benefits for human health and the environment has not been developed.

Stakeholders do share appreciation for addressing chemical risks at EU level rather than at national level. Most stakeholders also encourage the Commission, ECHA and Member States to communicate more strongly about the benefits and the good functioning of REACH. This will help building further trust amongst all stakeholders, including the general public.

2. Other consultation activities

The implementation of REACH is subject to extensive consultation with the stakeholders involved through existing discussion fora and through public consultation on specific matters.

The implementation of REACH is steered through targeted consultation that takes place in the context of the expert group CARACAL, which meets regularly (three times/year) to discuss matters related to the implementation of REACH. The group is composed of experts from Competent Authorities nominated by Member States as well as observers representing industry associations, trade unions, civil society organisations and third countries. The regular meetings of CARACAL have been used to report progress in the implementation of the recommendations resulting from the REACH review 2013 and has been used to disseminate information regularly concerning the preparation of the REACH report 2017 as well as to collect the views of the stakeholders on the development of this work. Agendas, minutes and documents from CARACAL are publicly available.

In addition, dedicated consultation activities planned in the context of the REACH REFIT evaluation included the following:

- Targeted consultations to gather specific evidence through questionnaires, interviews or case studies in the context of thematic studies[8]

- An SME specific consultation (SME panel) carried out through the Europe Enterprise Network (EEN) between November 2016 and January 2017[9],- A Eurobarometer survey carried out between in the 28 Member States of the European Union between 26 November and 5 December 2016[10].

Another important source of information was the Member States and ECHA reports[11], as well as the documents related to the "REACH forward" conference organised by the Dutch presidency on 1 June 2016, which then informed the Environment Council on 19 December 2016.

Furthermore, public consultations are regularly conducted by the ECHA in the context of the preparatory work for the implementation of regulatory action such as listing substances in the candidate list, prioritising substances to be subject to the authorisation regime, examination of proposals for restrictions and applications for authorisation for substances included in Annex XIV. Evidence available from public consultations made by ECHA has been used where appropriate (e.g. evidence on the socio-economic impacts and benefits expected from restrictions). (http://echa.europa.eu)

2.1 The Eurobarometer survey

28,157 face-to-face interviews were conducted with the aim to understand EU citizens' awareness and perceptions of chemical products, including comparisons (where appropriate) with similar surveys conducted in 2012 and 2010. This survey was carried out in 28 EU Member States. Some 27 929 EU citizens from different social and demographic categories were interviewed face-to-face at home and in their native language according to the methodology established for Commission's Eurobarometer surveys. Two-thirds of citizens are

[8] Annex 3 provides a detailed account of the thematic studies carried out for this review, including the consultation tools
[9] Link to the results of the SME panel
[10] Link to the Eurobarometer survey on chemical safety
[11] Further details about information sources used is extensively described in section 5 and Annex 3 of this SWD.

concerned about exposure to chemicals, and less than half feel well informed about the potential dangers of chemicals. Citizens consider that product safety has improved over the last 10-15 years and they consider products manufactured in the EU safer than those imported from outside the EU, although three in ten say that none of the products are safe. Two-thirds of citizens believe that retailers provide information, upon request, on the presence of particularly hazardous chemicals in products. In addition, half of respondents say that the current level of regulation and standards in the EU are not high enough to protect human health and the environment and should be increased[12]. The results of the Eurobarometer survey were published on 8 June 2017.

2.2 The SME panel

The SME specific consultation carried out through the Europe Enterprise Network (EEN) received 181 replies. The main strength of the consultation is the wide coverage in terms of company size (see figure 5), sector of activity and role under REACH (figure 6). Its main limitation is the geographical coverage, as respondents concentrated in few Member States (Italy 22%, France 14%, Germany 12%, Poland, Belgium, Greece, Cyprus and Latvia around 7- 9% each) and for more than half of the Member almost no responses were obtained.

Figure 2.5: Respondents by size of business

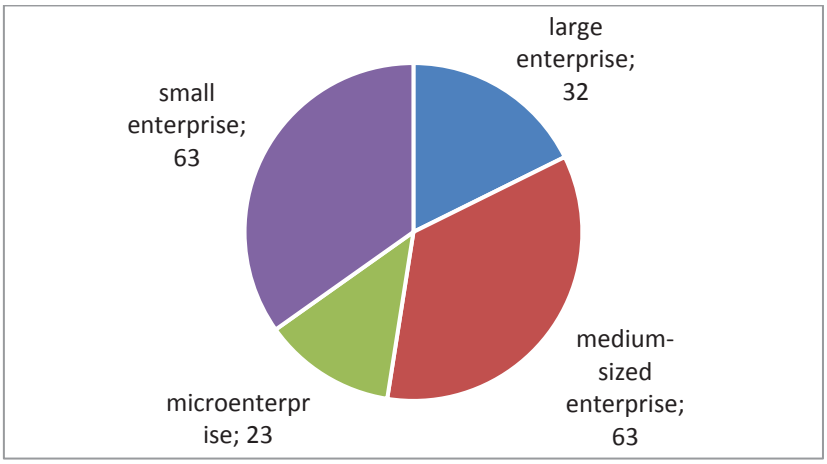
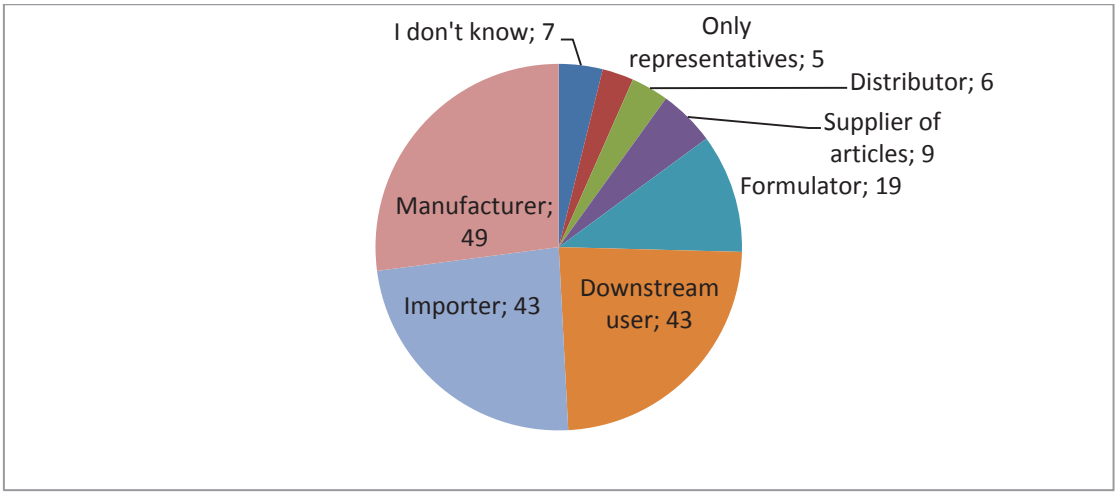


Figure 2.6: Respondents by role under REACH



[12] See section 7 of the main report on Relevance for further details

The SME panel consisted of a specific questionnaire tackling SME related issues in relation to the information sources, existing support mechanisms, effects of REACH and their relation with authorities.

According to the responses received, respondents expressed a wide variation in the satisfaction with the sources of information available on REACH. The main sources of information used by companies are suppliers, helpdesks and guidance provided by ECHA or industry associations.

Companies replies on the effects of REACH suggest that companies were generally not able to pass costs increases on to customers, although there was a wide variation in the cost impact, with registration and testing as well as substitution of SVHCs being the main cost factors indicated by the companies. The replies also indicate that the main challenges are the complexity of the Regulation, the obligation to communicate information in the supply chain as well as the access to data, and the company replies suggest that these requirements have a significant impact on companies, regardless of their type, size or sector. When looking at differences based on the role under REACH, distributors, importers, only representatives and suppliers of articles generally score these challenges higher than other stakeholders.

Regarding company size, micro-enterprises generally consider the challenges to be bigger compared to larger companies. Regarding the differences between the sectors, the respondents perceive the challenges as more or less equally important. The main opportunities and benefits of REACH appear in relation to the reduction of workers risks and environmental risks, as well as the substitution of hazardous substances. The effects on R&D activities of the respondents seem to be limited.

As regards the experience when contacting public authorities in relation to REACH a rather positive feedback was provided on the replies obtained from national helpdesks in terms of content and time needed to get a reply.

A final open question in the SME panel allowed respondents to provide additional comments or suggestions for reducing any burdens while keeping the main objectives of REACH. The most frequent comment was that REACH creates administrative burden and market distortions in favour of larger companies or third country producers. Respondents also demanded more guidance and training tailored for the needs of SMEs, including support by authorities.

2.3 Targeted consultation

Targeted consultations were carried out through questionnaires and interviews in the context of thematic studies[13] used for this evaluation.

The stakeholders provided their input on:

- Structure and magnitude of costs expected or resulting from REACH.

- Views on the factors affecting the implementation of REACH as well as its effects.

- Identification and analysis of relevant case studies.

[13] Annex 3 provides a detailed account of the thematic studies carried out for this review, including the consultation tools

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PART 4/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 3

{COM(2018) 116 final}

Annex 3: Methods and analytical models

The purpose of this Annex is to summarise the main methodologies applied and the information sources used for this evaluation. As described in the methodology section, a number of thematic studies have been carried out by external consultants for the Commission services. In addition, the evaluation uses the regular reports from Member States Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and their enforcement.

Studies on the operation of REACH

A first set of reports provides a detailed account of the implementation and enforcement of REACH at European and national level.

The ***Analysis of the Member States' reporting questionnaire 2015*** provides a comparative analysis of the 2015 Member States reporting questionnaires on the implementation of REACH at national level for the period 2010-2015, and CLP for the period 2011-2014, as per Article 117(1) of the REACH Regulation and Article 46 of the CLP Regulation. The questionnaire covers all activities to be carried out by Member States including the enforcement activities. Reports published by the ECHA and focussing on the implementation of certain REACH processes have also been included in the evidence base.

The ***Report on the Operation of REACH and CLP 2016*** is the second five year report the Agency has published in accordance with Article 117(2). It gives an overview of the implementation of REACH and CLP, the progress to date, impacts, successes and areas needing further work or improvement. It also presents a list of recommendations to the European Commission, Member States and industry.

The third report on the ***Use of Alternatives to Testing on Animals for the REACH Regulation***, published by ECHA as per Article 117(3), describes the implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment. The report is based on the information provided in the registration dossiers held by ECHA on 31 March 2016. Most of the analysis is based on a data pool covering 6 290 substances in 6 911 dossiers. The ***Analysis of higher tier studies submitted without testing proposals*** investigates the reasons why some registrants have submitted new higher-tier studies on vertebrate animals without submitting a testing proposal. These cases have been identified through the research conducted for the second report on the *Use of Alternatives to Testing on Animals*.

In addition, the ***annual reports on evaluation under REACH*** 2012, 2013, 2014 and 2015 describe the progress made in the dossier and substance evaluation activities according to the objectives defined in the Agency's work programme, the compliance check (CCH) strategy and the Community Rolling Action Plan (CoRAP). The 2015 and 2016 ***annual reports on the SVHC Road*****map** monitor the implementation of the SVHC Roadmap to 2020 Implementation Plan. The reports contain a summary of activities carried out in the previous year, an outline of activities planned for the following year, and an overview of related regulatory risk management activities.

The ***Final report on the first Forum pilot project on authorisation***, presents the outcome of the first pilot project undertaken by the Forum on the Authorisation process, which aimed at checking compliance with the REACH Regulation on the marketing and use of MDA and Musk xylene after their sunset date, in order to gather experience and building practice and processes for enforcing the authorisation-related obligations. 18 Member States participated

in the project.

The study on ***Substance Identity in REACH*** analyses approaches applied by the industry in identification of substances for registration under REACH. The study consists of a substance identity screening of 223 complex substances selected as a representative set of substances with different challenges in their identification, with the aim of identifying key challenges in the identification of complex substances and comparing approaches taken by registrants of different groups of substances. The study is based on information contained in registration dossiers reported in the ECHA database of registered substances as of August 2014.

Finally, the ***Study on 'Development of enforcement indicators for REACH and CLP'*** proposed indicators that can be used to monitor and measure the performance of the enforcement of the REACH and CLP regulations. The study defined indicators at the levels of the individual Member States, the Forum and the EU as a whole. Enforcement indicators at Member State level aim at assessing how REACH and CLP enforcement is functioning within the Member States; indicators at Forum level aim at assessing the level of implementation of the activities of the Forum; and indicators at EU level aim at providing an overall insight on how the enforcement of REACH and CLP is functioning within the EU and the European Economic Area (EEA). A total of 50 indicators were developed, including 44 key indicators that were fully developed and six additional indicators, which require further development before they can be implemented. The majority of the indicators developed are outcome indicators.

Studies related to the scope of REACH

A second set of reports examines the relevance of extending registration requirements or more stringent information requirements to certain substances currently excluded from REACH or benefitting from lighter requirements. These reports have mostly been commissioned following the requirements of Article 138 of the REACH Regulation.

Since 2012, four studies have been commissioned to review information requirements for 1 to 10 tonnes substances and the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) for 1 to 10 tonnes CMRs 1A/1B, as required by Article 138(1) and 138(3) of REACH. After the 2012 study that had defined a methodology to address these questions and some first options, the second study (2014) on the extension of the obligation to perform a CSA and to document it in a CSR considered the changes introduced by extending the CSA/CSR requirement to 1 to 10 tonnes CMRs 1A/1B and provided an estimation of the costs and benefits of extending it. A third study (2015) on the extension of registration requirements proposed options for refining information requirements and assessed their costs, business impacts and benefits on a per substance basis. The fourth study (2017) built on the results of these previous studies and updated the evaluation of five selected options taking into consideration the combination of the information options with the CSA/CSR option and also any changes in context and timing since previous studies have been conducted. The options and the baseline are compared by using an Excel based Monte Carlo model and simulation that analyses, for each of the options, the number of substances with hazardous properties that would be detected, the usefulness of the information generated, the cost of registering/updating the registration dossiers, the likely impact of the registration costs at a company level and, to the extent possible, the likely impacts on SMEs, competition and innovation.

Two studies have been conducted since 2012 following the requirement of Article 138(2) to review registration requirements on polymers. The first study from 2012 described the

polymer market and hazards posed by polymers compared with those posed by monomers and other substances, summarised previous impact assessment conclusions on the registration of polymers and assessed some policy options for the future registration of polymers. A second study from 2014 providing ***Technical assistance related to the review of REACH with regard to the registration requirements on polymers*** assessed two potential approaches for the registration of polymers: grouping polymers for registration and defining a category (or categories) of Polymers of Low Concerns (PLCs), and aimed to develop alternative approaches for registering polymers based on this analysis. The study collected information on the approaches for polymers in non-EU jurisdictions and compared them according to the parameters used to identify polymers, type of approaches, and criteria used to define PLCs. Third countries approaches were then assessed in terms of hazard assessment and in terms of cost-effectiveness.

In addition, the ***study to support the 3rd regulatory review on nanomaterials*** compiled information on nanomaterials and advanced materials in the environment and explored further the regulatory implementation challenges. One component of the study was to review the application of environmental and other key legislation to nanomaterials, including the REACH Regulation, to assess the coverage of nanomaterials in EU environmental legislation.

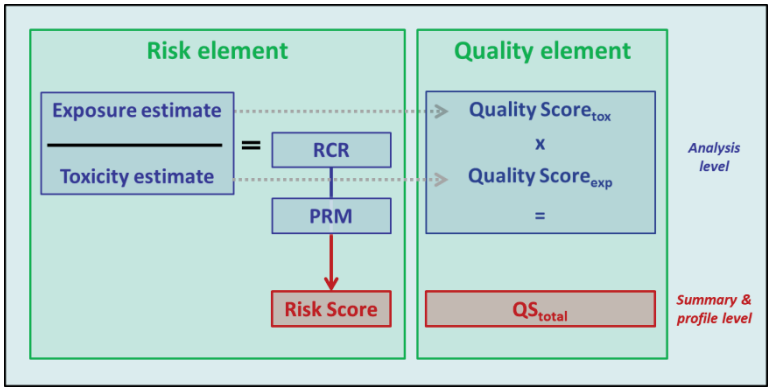
Studies on the impacts of REACH on human health and the environment

The ***Study on the calculation of the benefits of chemicals legislation on human health and the environment*** proposed indicators measuring the links between chemical substances and their impacts on human health and the environment, and measured the role that chemicals legislation, in particular REACH and CLP, has had in reducing such impacts in the period 2004-2013. They defined indicators at three different levels of objectives (operational, specific and general), resulting in output indicators, results indicators and impact indicators. The study also proposed monetary estimates of certain impact indicators. However, the suitability of these estimates was considered by the authors as very limited as they rely on assumptions that are likely to be changed over time.

The ***REACH Baseline study*** aims at monitoring the effectiveness of REACH as regards risk reduction and improvement of the quality of data available for the assessment of chemicals by means of Risk and Quality indicators. The methodology to derive the Risk score (risk posed by a substance) and the Quality score (quality of the data available to assess the risk associated with a substance) was established in 2007[1] and applied for the first time in 2009 to a set of 237 reference substances considered a representative sample of the chemicals available in the EU market before REACH entered into force. The assessment was repeated after five years for the substances which had been registered by August 2011 to feed into the first REACH review. The ***REACH baseline study: 10 years update*** analyses changes in the Risk Scores and Quality Scores based on registrations until September 2015, including registrations from the second registration phase (by May 2013) as well as updates from dossiers registered previously.

The Risk & Quality Indicator system consists of an element assessing the nominal risk and an element assessing the quality of the underlying data.

[1] The REACH baseline study, A tool to monitor the new EU policy on chemicals - REACH (Registration, Evaluation, Authorisation and restriction of Chemicals), Eurostat, June 2009



The Risk Scores and Quality Scores are calculated for four impact areas:

- ✓ workers,
- ✓ environment,
- ✓ consumers and
- ✓ human health via the environment

The study ***Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH*** aims at identifying specific priorities that ECHA and other public authorities could support in the short term to advance substitution programs and practices among Member States and the Commission, including specific needs related to analysis of alternatives capacity. The study is based on a review of applications for authorisation and restrictions proposals, surveys and interviews involving industry, Member State and Commission authorities, and NGOs.

The study on the ***Interpretation of the World Summit on Sustainable Development (WSSD) 2020 Chemical Goal and assessment of EU efforts to meet the WSSD Commitment*** developed a series of 20 indicators to measure EU progress towards achieving that goal from a baseline year of 2002 up until the end of 2012, assessed progress and provided recommendations for future EU actions.

Studies on the impacts of REACH on the internal market, competitiveness and innovation

The study on the ***Cumulative Cost Assessment (CCA) for the EU Chemical Industry*** aims at identifying the structure of the cumulative costs incurred by EU chemical companies because of EU legislation during the period 2004-2014. The study does not aim at providing overall figures of costs or at assess the benefits of EU legislation. Only pieces of legislation incurring high cost directly to chemical companies have been included in the study. These comprise: chemicals, energy, emissions and industrial processes, workers' safety, product-specific, customs and trade, and transport legislation. Chemical legislation is not limited to REACH and includes as well CLP, the Persistent organic pollutants (POPs) Regulation and legislation related to pesticides and biocides. Costs have been calculated only for the subsectors of the NACE classification for which some data were available, e.g. inorganic basic chemicals, organic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, and cleaning and polishing preparations, paints, varnishes and similar coatings and other chemicals products. Data on costs for the past 10 years were collected

from a limited panel of 31 typical companies from different sectors, and an online survey with a sample of 90 companies, from which a cross-sector extrapolation was done to the whole of the European Union. The cost estimates provided, and in particular the conclusions about the change of these costs over time, need to be treated with caution because they are based on the extrapolation of data from a limited number of companies and their recollections of past costs.

The study ***Monitoring the impacts of REACH on innovation, competitiveness and SMEs*** aims at 'evaluating changes to the operational conditions and the structure of the chemicals industry and downstream industries focusing on the implementation of the REACH Regulation' during the 2010 – 2013 period. The study focuses on assessing the impacts on the trade exchanges and the harmonisation of the single market, on the external competitiveness, on business opportunities, on innovation, on small and medium enterprises (SMEs), and evaluates the costs of the 2013 registration deadline on dutyholders and provides an estimation for the costs of the 2018 registration deadline. The information was collected from five sources: a computer aided telephone interview (CATI) business survey, covering 15 Members States with a sample of 1 076 responses (38% large firms, 62% SMEs) - 47% of which are downstream users; an online business survey (OBS), which gathered 566 responses from all 28 EU, EEA and non-EU based firms (45.6% large, 54.4% SME); 104 interviews with stakeholders (Commission, ECHA, industry associations, Member States authorities, Environmental and consumer group and trade unions); 56 in-depth interviews with firms with different roles, sizes and countries of operation (57.1% large, 42.9% SME); and 5 thematic cases studies. Both the OBS and the CATI surveys requested estimates of the cost of the registration 2013. The survey data collected included the number of substances registered, the estimated cost of registering substances in different tonnage bands, as well as different components of the registration costs (fees and costs associated with undertaking the Chemical Safety Assessment, liaising with the downstream users, safety data sheets, etc.). The data from both surveys were presented separately to allow comparison between the results and to check consistency.

The study in the ***Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry*** aims at assessing the impacts on international competitiveness of the general legislation governing the conditions for marketing and use of chemicals in the EU and the following countries: China, Japan, the USA, Canada, and South Korea. The study focuses on the REACH Regulation in the EU, and in the other five countries, on the main legislation dealing with horizontal conditions related to the placing chemical substances on the market to guarantee safe use and protection of human health and the environment. The study is based on collecting secondary data through literature review on the impacts of REACH and corresponding third-country chemicals legislation, particularly with respect to comparisons of similarities and differences; an interview programme with stakeholders (4 European business associations, 4 Business associations of concerned sectors in the third countries); case studies on 12 companies from EU and third countries representing the chemicals sector and three downstream sectors (textile, automotive, rubber and plastics).

The report from ECHA on ***Cost and benefit assessments in the REACH restriction dossiers*** assesses costs and benefits of the restrictions included or proposed to be included in Annex XVII of REACH. It summarises and aggregates the information on costs and human health and environmental benefits provided in the restriction dossiers and opinions of the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC). The analysis covers the 18 restriction proposals on which RAC and SEAC have adopted their

opinions by April 2016. In addition, one case where the RAC opinion and SEAC draft opinion were finalised, although not adopted, is covered in the report. The main cost category assessed in the restriction cases is substitution costs, i.e. investment and recurring costs to switch to alternative substance.

The ***study on the impacts of REACH authorisation*** evaluates the performance of the REACH authorisation process. It is based on evidence to assess if it is working as intended and achieving its objectives in terms of progressive substitution of SVHCs by less hazardous alternatives and control of the risks. The study is focusing on five areas: costs of authorisation, benefits of authorisation, changes in the market structure for SVHCs and alternatives, progress on substitution and affordability of authorisation for SMEs. Finally, the study intends to evaluate the adequacy of current guidance for stakeholders to facilitate the preparation of the authorisation applications while reducing their costs, to search for alternatives and to provide input on alternatives during the process. The study gathers evidence through an initial literature review, followed by an extensive data collection through desk research (Eurostat data), stakeholder surveys (companies, NGOs, Member States, ECHA and Commission) and case studies.

The ***presentation by ECHA at the 9th annual meeting of the Society for Benefit-Cost Analysis in Washington D.C. in March 2017*** provided some figures on the benefits and the costs of authorising the use of Substances of Very High Concern under REACH for the first 60 opinions adopted by ECHA.

The article on '***Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH***' quantifies the benefits and risks (and benefit-risk ratio) of industrial uses of hazardous chemical substances (carcinogens), for which applications for authorisation have been submitted under the REACH Regulation. The article is based on the opinions of SEAC, which were adopted until July 2016, and cover 32 uses of 9 carcinogenic substances. Applications for threshold substances have been excluded from the scope of the article, as well as ancillary uses such as formulation and packaging and one application for a persistent, bioaccumulative and toxic (PBT) substance.

Studies related to other EU legislation

The ***Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States*** assesses the implementation of the OSH directives with a view to evaluating their relevance, effectiveness and coherence and identifying possible improvements to the regulatory framework. The section on the coherence of OSH directives with other measures and/or policies at the European level addresses the coherence with the REACH Regulation, especially regarding occupational exposure limit values (OELs) and derived no-effect levels (DNELs) in CSR and exposure assessments. The evaluation focuses on the 24 OSH directives and their implementation in 27 Member States (Croatia not included) in the period 2007-2012. The evaluation is based on the National Implementation Reports, on an extensive mapping and analysis of transposition and implementation of OSH legislation in each Member State, official statistics at the national and EU levels, scientific literature, existing studies and interviews with national and EU stakeholders.

Other studies

The ***Evaluation of the European Chemicals Agency (ECHA)*** assesses the performance of ECHA, covering the full range of ECHA's operations and processes: REACH, CLP, BPR and PIC. The evaluation of ECHA was conducted based on the intervention logic of the Agency and a comprehensive analytical framework comprising the evaluation questions to assess the effectiveness, efficiency, coherence, relevance and EU added value of ECHA's work and their respective judgement criteria, indicators and information sources. The study maps and compares the obligations stemming from each of the Regulations mentioned above and compares those to the activities implemented. The Agency's organisation, its resource allocation, the use of tools and results achieved were compared to what was expected from the Agency. The data collection tools used to gather the relevant information consisted in document review, stakeholder interviews, an online company survey, a comparative analysis with similar EU Agencies and a limited process analytics exercise. Document review covered ECHA's planning, reporting and monitoring documents, organisational strategies, policies and procedures, as well as internal and external audit reports and other relevant documentation of the Agency's bodies. In addition, the perception of stakeholders was assessed by analysing the results of ECHA's Stakeholder Annual Surveys and staff surveys as well as position papers of external stakeholders. Interviews were conducted with ECHA staff and management, member of the Agency's bodies, Commission officials, EU Agencies, Member States Competent Authorities (MSCAs), peer agencies in third countries, OECD, industry associations and individual companies and NGOs. The online survey covered a representative selection of companies involved in ECHA's activities. A comparative analysis with similar organisations was carried out to compare the functioning of ECHA on specific indicators with practices implemented by other EU Agencies, such as the organisational structure, management and governance as well as on communication resources and activities. The limited process analytics exercise allowed to assess the efficiency of ECHA at process level, by comparing a documented process, as described in the Agency's standard procedure, with the process that occurs in practice.

The ***Eurobarometer survey on chemical safety***, which aims to understand EU citizens' awareness and perceptions of chemical products, including comparisons (where appropriate) with similar surveys conducted in 2012 and 2010. The survey covers public awareness and information about chemicals; public perceptions about the safety of chemicals, whether this has improved in recent years and the relative safety of chemical products manufactured both within and outside of the EU; perceptions of who is currently responsible for the safety of chemicals in the EU and who ought to be responsible for such activity; awareness and understanding of chemical hazard pictograms. This survey was carried out 28 EU Member States. Some 27 929 EU citizens from different social and demographic categories were interviewed face-to-face at home and in their native language according to the methodology established for Commission's Eurobarometer surveys[2].

[2] http://ec.europa.eu/COMMFrontOffice/PublicOpinion/

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PART 5/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 4

{COM(2018) 116 final}

Annex 4 Implementation state of play

Contents

1 Registration

Conclusions of the 2013 REACH Review

The 2013 REACH review reported that both industry and authorities had invested to meet the challenge of the first registration deadline in 2010, which involved the submission of 27,418 complete registration dossiers for 5,346 substances[1]. The relative success reflected good cooperation from all the involved parties. However, the Commission noted some shortcomings related to the compliance of registration dossiers which could hinder the delivery of the expected benefits from REACH:

– many registration dossiers had been found to be non-compliant, including with regard to substance identity

– insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties.

Impacts on increased market concentration and prices were also reported in relation to the registration costs.

The 2013 REACH review acknowledged the findings of the Commission's Second Regulatory Review on Nanomaterials[2] on the need for more specific requirements in the REACH Annexes to clarify how nanomaterials should be addressed and safety demonstrated in registration dossiers and announced to conduct an impact assessment of relevant regulatory options.

Regarding a possible extension of registration requirements (Article 138), the Commission concluded it had insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages, to extend the requirement to prepare a CSA/CSR for CMR 1A/1B substances registered in low tonnages, and on the need and feasibility, if any, to register certain types of polymers.

1.1 Developments after the 2013 REACH Review

1.1.1 Numbers of Registrations

The number of initial and updated dossiers registered in the years 2013, 2014 and 2015 were 15,380, 9,140 and 8,043 respectively. By April 2016, ECHA had received and disseminated more than 54,000 dossiers for approximately 14,000 unique registered substances since REACH came into operation.

[1] Submitted to ECHA by the end of 2011

[2] COM(2012) 572 final

The deadline for registering substances manufactured or imported in quantities of 100 to 1,000 tonnes per year was 31 May 2013. By 31 August, the deadline set by the REACH Regulation, ECHA performed a completeness checks on all REACH 2013 dossiers. The aim of the completeness check was to ensure that all required elements have been included in the registration dossier. Following the completeness checks, registration numbers were granted to 9,030 submissions.

Registrations were received from 29 EU Member States and EEA countries, with the highest percentage coming from Germany (31 %).

Overall, it seems that the 2013 registration deadline was largely met.

1.1.2 General observations on Registration and Quality of Registration Dossiers

1.1.2.1 The REACH Baseline Study

The so-called "REACH baseline study[3] monitored changes in the Risk Scores and Quality Scores from a subset of registrations. From a set of 237 reference substances across all tonnage levels, the registration dossiers were reviewed as to the toxicity and exposure data. The changes monitored include registrations from the second registration phase (by 31 May 2013) as well as updates from dossiers registered previously[4]. The results of the 10-year update show a clear increase in the quality of the data available compared to 2012 and especially 2007[5], for all the 4 areas assessed (workers, environment, consumers, humans via environment). The improvement in quality in the 10-year update is similar to the one observed in the 5-year update for HPV and BLHC[6] chemicals and is now observed for a larger dataset including also medium production volume (MPV) chemicals[7]. Given that the baseline for the study was the situation before REACH, it suggests that REACH is making available more information to be used for risk assessment and management of chemicals.

The results also show a clear decrease in the Risk Scores – risk values calculated applying the study methodology, when compared with the situation at baseline. The decrease in Risk Scores is similar to the one observed in the 5-year Update for HPV and BLHC chemicals and is now observed for a larger dataset including also MPV chemicals – corresponding broadly to those registered by the 2013 deadlines.

While the Commission services noted in 2013 that many Chemical Safety Reports were deficient in terms of identifying uses of substances as well as related exposure estimates, the 10-year update of the REACH baseline study identified an increased availability of exposure estimates included in Chemical Safety Reports (CSRs). The figure summarises

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[3] REACH Baseline study: 10 years update (2017) - link to final report

[4] In the 10 year update, progress observed refers to the detailed analysis of 94 reference substances (55 HPV chemicals, 23 MPV chemicals, 19 BLHC (Baseline High Concern reference substances)

[5] It is expressed in a reduction of the Quality Score from baseline to the 10 year update (with lower Quality Scores indicating higher quality)

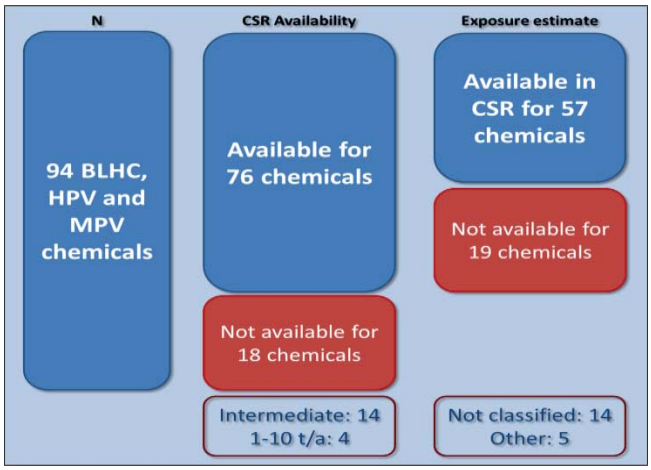
[6] BLHC: Baseline High Concern substances. The term was chosen in the 10 Year Update to avoid confusion with identified SVHC. (SVHC was used in the baseline- and in the 5 Years Update report)

[7] Corresponding largely to those registered in the 2013 registration deadline

the availability of CSRs for 94 chemicals assessed in detail (HPV, MPV and BLHC substances).

- 76 chemicals or 81% had a CSR available and for the remaining 18 chemicals a CSR was not legally required.
- Most of the CSRs (57 of 76 or 75%) contained worker exposure estimates, which is in line with the registration requirements. For the remaining chemicals an exposure assessment was not required because they are not classified.

Figure 4.1 Availability of Chemical Safety Reports in registration dossiers



1.1.2.2 General Observations from ECHA

In its report on the operation of REACH in 2016 [8], ECHA stated that the **quality of information in registration dossiers** has improved. However, ECHA still concluded that:

- the relatively poor quality of some of the data is limiting its usefulness
- the transfer to industry of the burden of proof of demonstrating safety is not completed, as the Agency and Member State competent authorities still need to take action with regard to companies that have not fully complied with their REACH obligations to clearly describe their substance and its effects.

This is illustrated by ECHA's compliance checks in 2016 which focused on higher tier human health and environmental standard information requirements relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB ((very) persistent, bio-accumulative and toxic) substances. 156 dossier evaluations were performed in 2016 on such high-priority substances (85% of all dossier evaluations done in 2016). As a result 805 standard information requests were made in the draft decisions, 550 of which addressed higher-tier human health and environmental endpoints (pre-natal developmental toxicity, mutagenicity/genotoxicity, reproduction toxicity, and long-term aquatic toxicity). These results confirm that there are numerous gaps concerning important data in those dossiers submitted for substances of potential concern. During

[8] ECHA (2016) *Report on the Operation of REACH and CLP 2016.*

2016, ECHA invited Member States to consider enforcement action on 33 cases following a dossier evaluation[9].

ECHA has also identified systematic challenges in the registration of substances with nanoforms and launched an update of its guidance for nanoforms in view of the 2018 registration deadline. ECHA has also called for urgent amendment of REACH annexes to clarify the registration requirements for nanoforms of substances.

ECHA highlighted the insufficient rate of **dossier updates** as the most significant barrier to reaching the objectives of the legislation. Based on a recent ECHA survey:

- only 25% of dossier owners conduct a regular routine review of their REACH data, while 50% check on an ad-hoc basis. 25% of these reviews spark the need for a dossier update.

- Most updates were done because of a direct request from ECHA (50%). Updates because of requests from clients (10%) or inspection by Member States Competent Authorities (10%) were much lower.

- 75% of the respondents do not have a REACH data management system.

ECHA has not determined what the baseline should be, i.e. what the expected update rate is. Article 22 of REACH specifies the situations where a registrant is responsible on his own initiative for updating his registration with relevant new information. Whilst ECHA sees a need for a change in the attitudes and behaviour on the part of companies; ECHA has also suggested considering whether it would be useful to have implementing legislation to further specify obligations under REACH regarding updates[10].

Dossier updates should also update information on the tonnage and ideally tonnage per use, as this information is critical for prioritisation of substances for the development of risk management measures. As reported by ECHA in May 2016[11]:

- About 29,000 dossiers (around 64 % of the registrations) submitted since 2008 have never been updated.

- Of the around 16,000 updates, over 30 % can directly be linked to a letter campaign by ECHA (around 8,000 letters sent since 2011);

- Other updates were prompted by compliance check decisions (8 %) or other actions such as a sector approach (e.g. petroleum streams).

- Another targeted letter campaign in 2016 by ECHA on 270 shortlisted substances invited registrants to improve the dossier quality in advance of any compliance check or other regulatory process. 40 % of the dossiers were updated within four months of the letters being sent[12].

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9 ECHA Progress report 2016 on Evaluation under REACH, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

10 ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 14

11 Ibid. Page 39

12 ECHA Progress report 2016 on Evaluation under REACH, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

1.1.2.3 Other observations

The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these. The lack of data on the hazardous properties of chemicals was the driving force behind the development of REACH.

To illustrate the above, REACH lead to more transparency about the number of CMRs on the market. For more than 700 substances[13], REACH registration has led to increased CMR classifications which means that risks from these substances can be better managed. These more stringent classifications seem to be more due to better understanding of hazardous components or impurities rather than experimental tests for CMR properties.

1.1.3 Intermediates

About one third of the overall production of chemicals is used as intermediates[14]. REACH contains lighter registration requirements set out in Articles 17 and 18 for certain types of intermediates that are used under strictly controlled conditions. However, intermediates that are not used under those conditions must be registered in line with the general information requirements in Article 10 of REACH, which is not fully coherent with Article 2(8)(a) of REACH which exempts intermediates by the registration without any reference to the "strictly controlled conditions".

For a number of substances registered as intermediates under Articles 17 and 18 of REACH, ECHA has checked registration dossiers and made use of its powers (based on Article 36) to request detailed descriptions on the synthesis in which registered intermediates are used to ascertain that the substances are indeed used as intermediates. Priority was given to SVHC substances on the candidate list. ECHA started doing this in 2011 when about 95% of dossiers verified did not contain any information on the use of the intermediate requiring ECHA to ask further information from registrants. Even with that, only in 60% of the cases was sufficient information provided by registrants to confirm the intermediate use. Other cases required further actions from ECHA or the involvement of local enforcement authorities. In a few specific cases, registrants claimed that information could be provided only to enforcement inspectors upon request. For the remaining cases, the information provided was sufficient to confirm that the use of the substance fulfils the definition of an intermediate in REACH. Amongst others due to further awareness-raising, the situation improved significantly in the following years, showing that more than 50% of dossiers of intermediates verified by ECHA in 2016 contained sufficient information on intermediate use.

[13] Based on ECHA's 2014 CMR report (section 3.2)

[14] Out of the 330 Million tonnes of chemicals produced in the EU, 117 Million tonnes are used as intermediates. Accenture Study (2017)- Taking the European Chemical Industry into the Circular Economy (commissioned by CEFIC)

The specific registration requirements for intermediates have also given rise to questions regarding the calculation of tonnage of a substance with intermediate as well as non-intermediate uses for the purposes of registration. Recently, a general agreement emerged that the volume of a substance to be used as an intermediate under strictly controlled conditions is not to be taken into account for determining the tonnage band in which the substance is registered.

Furthermore, according to Articles 17(2) and 18(2) of REACH, registrants of intermediates used under strictly controlled conditions are not required to provide information on tonnage in their registration dossiers. However, this has the potential to conflict with other provisions in REACH where information on volumes of intermediates determines the information to be submitted in the registration dossier.[15] As the tonnage information is not communicated in the registration, enforcement authorities can only ascertain via inspections if the information provided in the registration matches the tonnage dependant requirements. Consequently, authorities and the general public do not know accurately the tonnages at which intermediates are manufactured or imported in the EU.

The Forum for Exchange of Information on Enforcement is running a pilot project to address the enforcement approaches to the verification of intermediates and their use under strictly controlled conditions[16].

1.1.4 Data sharing and joint submission

The majority of companies respect the 'one substance, one registration' (OSOR) principle to everyone's benefit. However, in 2016 some 700 existing individual registrations for both standard and intermediate registrations were still in breach of the joint submission obligations under REACH[17]. In addition, breaches of the joint submission obligation were found where registrants had not agreed on forming one joint submission and several joint submissions exist for the same substance.

The Commission addressed concerns about transparency, communication and cost sharing in the SIEF through Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH[18]. The provisions of the Implementing Regulation were based on the central principles of data-sharing in REACH - that the costs of sharing information are determined in a fair, transparent and non-discriminatory way. The Implementing Regulation also tasked ECHA to ensure the respect of the joint submission obligation in cases of disagreement between the registrants. Consequently, ECHA has put in place a process that, in analogy to the data sharing dispute procedure, ensures that potential registrants can register as part of an

[15] See Articles 18(3) or 22(4) of REACH as examples.
[16] ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 138
[17] ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 45
[18] COMMISSION IMPLEMENTING REGULATION (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) OJ L 3, 6.1.2016

existing joint submission if they have made every effort in the negotiations with the existing registrants but have been prevented from registering by the latter. In addition, the Commission has also issued a Frequently Asked Question on Competition issues in the context of REACH SIEFs[19].

Given that the Implementing Regulation has only been in force for 1 year at the time of drafting of this evaluation report, the effectiveness of this measure cannot be fully evaluated yet, but indications from industry are that the regulation has helped to increase transparency especially for SMEs. On the other hand, in a few cases, existing registrants have indicated that the obligation to provide a meaningful cost itemisation has created additional work for them.

ECHA has also taken action: since 26 January 2016, it is no longer possible to submit an individual registration in REACH-IT for a substance where a joint submission exists. Letters were sent to 157 priority cases among these 700 individual registrants, to request them to either join the existing joint submission or to submit a data-sharing dispute to ECHA in accordance with the data-sharing provisions of REACH. The registrants must agree on forming a joint submission within six months, and if they do not take action, the registration numbers of those registrants who have not agreed on forming a joint submission will be revoked, which means they would no longer have market access. At the time of drafting this report, the six months deadline had not expired yet, but several data sharing disputes have been filed in response to the letters.

ECHA is of the opinion that the SIEFs set up by industry have worked relatively well. The number of data-sharing disputes remained low even before the 2013 deadline. Since REACH entered into force, ECHA has been notified of 46 data-sharing disputes of which 44 were admissible[20] (less than 1% of joint submissions). By January 2017, the number increased to 61. It should be noted that:

- in some of the disputes the claimants proceeded as a group of over 70 companies
- ahead of the 2013 deadline, the ECHA Helpdesk received almost 1,000 questions on SIEF management and the 2018 registration deadline is also triggering questions. In January 2017 ECHA estimated that it provided advice on SIEF management and data-sharing issues in some cases (range of thousand).
- there has been at least one case, where the claimant considers that access to a joint submission is denied by the lead registrant in order to restrict competition on the EU market for that substance.

A survey carried out with Member States competent authorities[21] indicates that issues most often raised by companies in relation to the operation of SIEFs and consortia included a high or unexpected price demanded for data, communication problems, transparency as well as confidentiality and protection of intellectual property.

[19] http://ec.europa.eu/DocsRoom/documents/14241/attachments/1/translations/

[20] see Figure 4 of ECHA report on the functioning of REACH and CLP 2016

[21] Monitoring the impacts on innovation, competitiveness and SMEs (CSES, RPA, Okopol, 2015), p. 86

ECHA also reported that for approximately 2% of substances with full registrations (244 registration dossiers) and 3 % of substances registered as intermediates (449 registration dossiers), there are registrants that have submitted dossiers totally outside of the joint registration obligations in REACH.

ECHA further recommended in its report submitted in 2016 that Member States should ensure that their national provisions for enforcement include appropriate sanctions for non-compliance with the rules introduced in the Commission Implementing Regulation on data-sharing.

ECHA asked the Commission to consider keeping the SIEFs (or a SIEF like mechanism) mandatory after the 2018 deadline – although the current REACH text requires that the SIEFs be operational until 1 June 2018 only. From the perspective of ECHA and industry feedback, this does not take into account the post-registration activities such as the need for updates, evaluation and the low compliance rate with registration requirements that will require evaluation of chemicals to continue after the last registration deadline for many years leading to the generation of new studies by industry that will have to be shared across all members of joint submissions. The information submitted jointly remains a joint responsibility. Based on ECHA's experience, also existing substances continue to be registered and an appropriate structure is needed to discuss with the new registrants. Without a SIEF, the responsibility falls mostly on the Lead registrant and there is growing reluctance to take the lead registrant role.

1.1.5 Substance Identity (SID)

ECHA noted that industry is facing difficulties in sufficiently identifying certain types of substances (e.g. substances of unknown or variable composition (UVCBs)) with a risk of wrongly assessing substance sameness, preparing inappropriate justifications for read-across and not ensuring that adequate hazard data are submitted for their substance.

The Commission conducted a study that analysed the identity and sameness of 223 complex substances already registered.[22] Results of this study show that some SID elements are the same among all substances (e.g. name, CAS number) but others are very specific to certain groups of substances (e.g. colour, boiling point, granulometry). The main conclusions were that:

1. SID is more consistent where it is systematically addressed by associations/ consortia in a sector approach;

2. Substance sameness criteria can only be developed at a sector or substance-specific level i.e. not in a generic way;

3. A Substance Identity Profile (SIP) is a useful tool for harmonisation of SID information across the joint registration;

[22] Substance Identity in REACH, Study on Substance Identity (SID) in REACH. Analysis of SID and substance sameness of complex substances, final report.

4. Annex VI information requirements for chromatography and spectral data are sufficient usually only to identify organic substances.

In general, it was found that the amount of data provided was enough to identify the substances and to have some evaluation criteria for the sameness of the substances for the members of the SIEF. However, the practical examples also showed the benefit of a structured approach of building and documenting the so-called Substance Identity Profile (SIP), which describes the boundary compositions of complex substances covered by the joint submission and for which the hazard dataset is relevant. ECHA took the initiative to request registrants to provide a SIP for their registered substances and this was taken forward by recent updates to guidance on registration.

Information from ECHA's 2016 Progress report on Evaluation under REACH[23] shows that SID is still among the top three concerns about dossier completeness: 70 % of all 152 ECHA dossier evaluation decisions adopted in 2016 included an information request on SID.

1.1.6 Activities to improve the completeness and compliance of registration dossiers

The previous sections set out specific challenges in terms of the compliance of registration dossiers (dealing with intermediates, data sharing and substance identity), and also some of the specific actions undertaken to respond to them. As well as these actions, more general efforts are being made to improve the compliance of registration dossiers.

After the updates to REACH-IT in 2016, ECHA started to manually verify the completeness of registration dossiers to complement the automated completeness check process. The intention is to identify dossiers with irrelevant content, insufficient information for identifying the substance, insufficient justification of data waivers or missing CSRs in cases that are not possible to detect via the automated process. If submitted registrations are found to be incomplete, ECHA will prescribe a reasonable deadline for the provision of the missing information. If the registrant does not provide the missing information, a registration number will not be issued in case of a new submission. If the failure in completeness concerns an update, this will be rejected and the new information will not be considered. Completeness check is an integral process of registration. Since 2016 it includes additional manual verifications by ECHA staff where completeness cannot be verified automatically, and has been applied also retrospectively. Due to similarity in the objective and implementation, its outcome can be considered as a complementary measure to evaluation.

Since the enhanced completeness checks were put in place in June 2016:

- 42 dossiers newly submitted after that date have been rejected (corresponding to 0.5% of dossiers submitted in that period).

[23] ECHA Progress report 2016 on Evaluation under REACH, Figure 5, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

- 14 of these 42 were new registrations that have been rejected after the 2nd round of completeness check, meaning no registration number was issued.

- The remaining 28 submissions were dossier updates that have been rejected after the 2nd round of completeness check, meaning that the updated information was not included in ECHA's database.

The corresponding registration numbers were not revoked, but ECHA monitors if the dossiers will be successfully updated in the long-term, if not, they would be followed-up via e.g. retrospective completeness check. As result of retrospective completeness checks of dossiers submitted before 21 June 2016, 3 registration numbers have been revoked so far.

In addition, in line with a recent decision of the Board of Appeal confirming that ECHA can undertake completeness checks for existing dossiers, and in order to ensure a level playing field with registrations submitted before this review of the completeness check process, ECHA has started to carry out retrospective completeness checks on existing registrations. Preliminary results of this enhanced completeness check process show that it is effective in providing the required additional information.

ECHA issued a new version of IUCLID (IUCLID 6 in June 2016) as the main tool to provide the information required in registrations which were designed to alleviate known issues related to Registration. Improvements cover:

Substance Identification: section 1.1 now allows explicit reporting of previous regulatory identifiers of the substance, and section 1.2 allows reporting of the substance identification profile (SIP) as a new composition type as well as the available information on specific parameters on different nanoforms of a substance;

Information on physicochemical and hazardous properties: reporting of data waiving justifications has been structured around the REACH framework, improving the reporting of alternative methods, fields have been added with templates to report the read-across hypothesis, QSAR documentation and the considerations made before proposing animal testing for why the adaptation possibilities could not be used, sections for reporting study summaries on skin and eye irritation and skin sensitisation have been updated according to amendments to REACH Annexes VII and VIII, sections for storing study summary information on physicochemical hazards have been aligned with GHS/CLP;

Information on use and exposure: formats for reporting identified uses were updated to clarify the description of uses and connect them with the corresponding exposure assessment, new fields have been added to allow users to document the REACH registration status or specific regulatory status of the uses, and to better describe uses as an intermediate or why an exposure assessment is not needed; Also, a product category "oil and gas exploration or production products" was added

to the use descriptor system[24] to cover substances typically used for oil and gas exploration and extraction via the so-called hydraulic fracturing techniques. This will improve the search of information on registered substances used for hydraulic fracturing purposes as requested in a Commission Recommendation[25] [26]. Related to this, the possibility to report releases underground has been added in IUCLID.

Hazard and exposure assessment: a DNEL calculator has been developed (January 2017) to help users calculate DNELs based on selected study results; the assessment entity concept has been introduced to support the documentation of complex assessments in the registration dossier;

Low tonnage registrations and decision on full or reduced information requirements according to Annex III: a new data template in section 14 for lead registrants was added to document the reasons why they consider that their substance does not meet the REACH Annex III criteria and can therefore be registered with reduced information requirements.

1.1.7 Preparations for the 2018 registration deadline

ECHA prepared a detailed work plan, the so-called REACH 2018 Roadmap, in close consultation with its stakeholders. This responds to the large number of SMEs that will be involved in this registration, and continuing questions on the topic:

- Questions related to registration are still the main reason for companies to contact the national REACH helpdesks (18% of all enquiries), ahead of questions on safety data sheets (14%) and labelling (9%). In the 11 Member States that keep track of the size of the company enquiring, most enquirers were SMEs[27].

The roadmap describes the different milestones and support services that ECHA will provide to the registrants, including:

- a revamp of the IT tools relevant for registration, IUCLID and Chesar for preparing the registration dossier and the chemical safety report and REACH-IT for submitting the dossiers to ECHA. The modifications improve their usability to cater for SMEs needs and provide an integrated help function.

- ECHA is currently developing an online version of IUCLID (ECHA Cloud Services) to further reduce the IT burden for SMEs.

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[24] ECHA (2015): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015

[25] Commission Recommendation of 22 January 2014 - http://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX:32014H0070

[26] European Commission (2016): Report from the Commission to the European Parliament and the Council. COM(2016)794 final

[27] Technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting. Final Report dated 10/05/2016

- ECHA also organised workshops and webinars and participated at information events organised by industry and Member States including hands-on training on the IT tools.

- Specifically for SMEs, ECHA published a registration guide, translated in all EU languages and the REACH2018 toolkit that was shared via the HelpNet and the Communications Network.

- REACH HelpNet has focused on preparing for 2018 over the last two years.

- Complementing activities were carried out by various Member States, ranging from specific guidance on registration (in local language), which is adapted to the needs of SMEs, to workshops or meetings informing about registration obligations for companies having to register by the 2018 deadline.

Moreover, based on the Commission's request, ECHA compiled an inventory of substances[28] likely to meet the criteria of Annex III to the REACH Regulation. The inventory will help registrants to identify whether reduced minimum information on physico-chemical properties only is required or full Annex VII information.

1.2 Review of Information Requirements

1.2.1 Adaptation to Technical Progress

The following adaptations of REACH standard information requirements have been made since 2013 according to Article 13(2) of REACH. More details about their impacts are described in the chapter 'Test Methods'.

- In 2015, the Two-generation reproductive toxicity study, a standard requirement for substances registered at and above 100 tonnes was replaced by the Extended One-Generation Reproductive Toxicity Study (EOGRTS)[29].
- In 2016, *in vitro* rather than *in vivo* studies became the standard requirements for skin and eye irritation, and the requirement for dermal acute toxicity studies for substances that have been shown to be non-toxic via the oral route was deleted[30]. In a second amendment[31] *in vitro* tests for skin sensitisation were introduced as

[28] https://echa.europa.eu/information-on-chemicals/annex-iii-inventory

[29] Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study. OJ L50/1, 21.02.2015

[30] Commission Regulation (EU) 2016/863 of 31 May 2016 amending Annexes VII and VIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity. OJ L 11/27, 01.06.2016

[31] Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation. OJ L 255/14, 21.09.2016

the default information if applicable for the substance under investigation and giving sufficient information for classification and risk assessment.

1.2.2 Low tonnage

In view of the reviews entrusted to the Commission by the legislators in REACH (Article 138(1), (3) concerning low tonnage substances), the Commission conducted a study[32] on the possible extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year. This study evaluated 6 options for increased information requirements only, adding additional information requirements from Annex VIII or changing Annex III to limit the exemptions from full Annex VII testing therein. Key conclusions were that despite a large variation in the magnitude of costs, the benefit/cost ratios suggested that all options would be justified in economic terms, and that the variation between benefit/cost ratios of all options was small. However, the costs of the options might have been underestimated, while the benefits for downstream users might have been overestimated. On the basis of these observations, no firm conclusions could be drawn concerning the 'best' option in economic terms.

The Commission mandated another study[33] to inform on the extension of the obligation to perform a chemical safety assessment and to document it in a chemical safety report for CMR 1A/1B substances manufactured or imported between 1 and 10 tonnes per year. The study concluded that over 100 substances with, as yet, unknown 'CMR 1A/1B' properties would feature in the low tonnage band. The study suggested that if the CSA/CSR requirement for those substances were introduced, there would be sizeable benefits for downstream users based on easier compliance with other legislation on CMRs. Taken together with costs across all actors there would be a total net benefit of around €16.4 million. On the basis of costs alone, extending the CSA obligation to CMRs 1A/1B that are, as yet, unknown and unregistered would likely be justified.

The Commission contracted a third study[34] in 2016 to gather further information to be used in an Impact Assessment of potential options for possible amendments of REACH Annexes, to modify requirements for low tonnage substances (1-10 t/year) and the CSA/CSR requirement for CMR 1A/1B substances. For this study, the Commission selected five options for extending information requirements, plus the option to delete the REACH Annex III criteria (Article 12(1)) and the option to extend CSA/CSR obligations (Article 14(1)) to all 1-10 tonnes substances known or expected to meet criteria for CMR 1A/1B for evaluation alongside the information options. The findings from the refined assessment in the third study confirmed those of the second study; all options assessed provided an increased benefit/cost ratio and increased cost effectiveness over the current registration requirements for low tonnage substances.

[32] Study number ENV.A.3/SER/2013/0057r

[33] Study number 070307/2013/668917/SER/ENV.A.3

[34] Study number 2015 SFRA RPA SI2.724177 low tonnes.
http://ec.europa.eu/environment/chemicals/reach/publications_en.htm

Before deciding which option, if any, it will take forward, the Commission needs to assess the affordability of increased information requirements for SMEs in the lowest tonnage bracket. This assessment should focus on the cost-related impacts on their competitiveness and capacity to innovate. This will have to be further examined, using also the experience from the last registration deadline in 2018.

1.2.3 Polymers

In view of the review entrusted to the Commission by the legislators when adopting REACH (Article 138(2) concerns polymers), the Commission services conducted a study on the obligations on the need, if any, to register certain types of polymers[35]. The study provided insights on registration schemes for new polymers in other countries and how polymers might be grouped into hazard classes. However, given that REACH applies to all substances on the market, not only new ones, the study did not provide enough information on how to identify polymers of concern for human health and/or environment. In order to do so, the Commission services plan to undertake another study after publication of the corresponding roadmap.

1.2.4 Nanomaterials

As indicated in the 2013 Review Report, the Commission services conducted an impact assessment[36] of 6 options comprising 52 measures to assess how to ensure further clarity and demonstrate the safety of nanoforms of substances in registration dossiers. Based on an earlier examination of data contained in the registration dossiers, it had become clear that the present information requirements are insufficient to ensure that the registration data is relevant and covers the nanoforms of a registered substance[37]. The Impact Assessment report[38] provides the analysis of the preferred option on the basis of which the Commission services proposed in mid 2017 changes to Annexes I, III, and VI-XII to the REACH Regulation[39]. The draft Commission Regulation has been notified to the WTO under the TBT agreement and is currently being discussed in the REACH Committee. It includes transitional provisions to allow all registrants and downstream users adequate time to adapt their registration dossiers. After the adoption of the Commission Regulation, ECHA will be asked to update the respective guidance in view of the modifications. Following the review, the proposal for the amendment of the

[35] Study number SI2.671025 2013, final report date 17 February 2015

[36] Complete list and references of all related studies, public consultation etc. is compiled in the Impact Assessment Report (ref after ISC).

[37] JRC Report on NANO SUPPORT Project: Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

[38] And complemented in March 2017 to take into account the Board of Appeal Decision of 2 March 2017 on titanium dioxide that enabled to clarify the baseline for the impact assessment.

[39] To be published

Commission Recommendation on the definition of nanomaterial from 2011 was submitted to a public consultation and is under finalisation. When adopted, the amended definition will, among others, be incorporated in the above mentioned amendments of Annexes to REACH to clarify the registration requirements for nanoforms of substances. The Commission's Joint Research Centre was asked to provide guidance for the implementation of the revised definition.

1.3 Impacts on registrants

Among the REACH processes, Registration remains the main cost driver for EU industry, as it has the largest impact on business activity (production, prices, downstream sectors).

The cost drivers in the registration process are associated to the fees, which can vary according to the volume of the substance (the higher the volume, the higher the fee) and the size of the company (as SMEs benefit from lower registration fees), and to the preparation of the registration dossiers, which can vary according to the complexity of the dossier (depending on the intrinsic properties of the substance, the volume placed on the market and the use spectrum of the substance), the level of data sharing between registrants, the complexity of the Substance Information Exchange Forum (SIEF) and the availability of information (e.g. already existing information vs. new tests to be performed).

According to the *General Report on REACH 2013*[40], the analysis of the drivers of the registration costs revealed that ECHA's fees in some cases represented 50% or more of the total costs companies are subjected to when registering, especially in the case of simpler registration dossiers and smaller firms. In the case of more complicated dossiers, data collection, costs related to SIEF and consortia (including management and other fees) were the main cost elements. According to ECHA, "*the major cost item in Registration is formed from the costs of compiling and generating the necessary data to fulfil the REACH information requirements*", when registration fees only represent a minor part of the overall cost of registration.

The results from the Online Business Survey conducted by CSES et al (2015) confirm the views of ECHA, and suggest that the two costliest activities in the registration of substances in the tonnage band 100 to 1 000 tonnes (2013 registration deadline) were those associated with the fulfilment of the information requirements and with the preparation of the registration dossiers, while the registration fees represented 14% of the costs only.

1.3.1 Evidence on registration costs

The *Extended Impact Assessment* of the Commission accompanying the proposal on REACH estimated testing and registration costs of REACH to amount to EUR 2.3 billion

[40] General Report on REACH 2013, European Chemicals Agency (ECHA), April 2014

in 2003 values (EUR 2.6 billion in 2011 values as calculated by Technopolis Group (2016)[41]) over the 11 years planned for completing the registration of all substances. This amount includes registration fees, estimated at EUR 300 million, registration costs, estimated at EUR 500 million, testing costs estimated at EUR 1 250 million (assuming the validation and acceptance of QSARs can be applied within this timeframe), costs linked to safety data sheets, estimated at EUR 250 million, authorisation procedures, estimated at EUR 100 million, and savings of EUR 100 million for new substances below 1 tonne.

For the first registration deadline of 2010, that concerns phase-in substances produced or imported in quantities over 1 000 tonnes[42], the *Extended Impact Assessment* had anticipated a cost of around EUR 1.15 billion for the industry, when recalculated into 2011 prices. According to the *General Report on REACH 2013*, the industry survey of 2011 concluded that the cost incurred by dutyholders had been significantly higher, EUR 2.1 billion (with a broader range of EUR 1.1 - 4.1 billion). Although in 2011 there was a significantly lower use of QSAR compared to what was anticipated in the *Extended Impact Assessment*, this was partially compensated by a higher use of read-across than expected.

The differences between the 2003 estimate and the 2011 survey come thus from:

- the reporting of sums paid by firms for participating in the SIEFs and for accessing data from existing studies, costs[43] which had not been considered in the *Extended Impact Assessment*. This is a cost for some firms in the chemicals sector, but also involves an income for other firms, and so is seemingly no net cost.
- less than predicted use of QSARs, but increased use of read across
- the costs of mandatory data sharing, which was strengthened during the co-decision process compared to the proposal assessed in the *Extended Impact Assessment*

Subsequent studies have also found equal or significantly higher registration costs than those presented in the *Extended Impact Assessment*. CSES et al (2015) focused on the 2013 registration deadline and estimated that the total costs incurred by companies (including registration, testing and safety data sheets) was of the order of EUR 459

[41] Cumulative cost assessment CCA for the EU Chemical Industry, Technopolis Group, commissioned by the European Commission, April 2016

[42] Phase-in substances are substances that have been on the European market for a long time, unlike non-phase-in substances, which are all those newly invented; phase-in substances are subject to three different registration deadlines (2010, 2013 and 2018), depending on the tonnage band (between 1 and 100 tonnes, between 100 and 1 000 tonnes, and over 1 000 tonnes, respectively), whereas non-phase-in substances must be registered at any time before their placing in the market.

[43] No information is available to quantify these costs

million, for the 2 998 phase-in substances registered in 2013 deadline[44]. These estimations are within the range of the costs anticipated in the *Extended Impact Assessment*. The average cost per substance (covering registration, testing and SDS) from the study surveys is around EUR 153 195 when, for the same cost items, the *Extended Impact Assessment* anticipated a cost per substance of EUR 193 367[45]. CSES found that most companies concerned by the registration costs absorbed them rather than increased the prices to cover the costs and concluded that the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances. Furthermore, the study estimated the costs of registration for the 2018 deadline. The estimates for the 1 to 10 tonnes substances appear to be in the range of the *Extended Impact Assessment* (EUR 228 million compared to the estimate of EUR 295 million), but the total cost of registering 10 to 100 tonnes substances is estimated to be significantly higher than formerly estimated (up to EUR 1 136 million as compared to EUR 581 million). This is partially explained by the fact that this last estimation is based on a worst case scenario with the assumption that validation and acceptance of negative and positive QSAR and read-across does not occur within the time frame envisaged in the earlier *Extended Impact Assessment*.

Technopolis Group (2016) aimed at identifying the structure of the cumulative costs incurred by EU chemical companies because of EU legislation during the period 2004-2014. The study breaks down the burden into different legislation packages. The chemicals package includes other pieces of legislation aside REACH, such as CLP, the pesticides or the biocides-related regulations. The study estimated the average annual cost of REACH for the EU chemicals industry to be around 0.8% of companies' added value and less than 0.2% of their turnover for the period 2004-2014. A rough estimation of the average annual cost in monetary terms is approximately EUR 650 million for the EU chemicals industry, although it needs to be noted that this figure is based on a very limited survey (only 31 companies provided figures) and is much more 'top down' and less focused on REACH than other more detailed, bottom-up estimates.

The main reason justifying the divergences from the estimates of the *Extended Impact Assessment* is that the latter excludes the costs paid by companies to participate in SIEFs and to get access to data. The ECHA *Report on the Operation of REACH and CLP 2016* further explains that the administrative costs for managing the SIEFs (additional costs) and preparing the joint dossier are higher than anticipated in the *Extended Impact Assessment* because at that time the joint registration had been considered voluntary as originally proposed by the Commission. The methodologies for the cost assessments also differ. The *Extended Impact Assessment* was carried out in-house based on then available information on how many chemicals were on the EU market in which volumes and a

[44] These estimates have been built from the results of the Open-ended online business survey (OBS) conducted for the study, which gathered 566 responses from all types of dutyholders. The scope for error within this estimate is potentially large given that it is based in a combination of estimates and relatively small proportion of respondents to the survey as a whole (86/566 or 15%).

[45] Own calculation based on the estimates provided in the *Extended Impact Assessment*.

detailed analysis of all existing information gaps for substances above 10 tonnes, together with average testing costs based on several testing houses' price lists. The more recent studies based their findings on interviews with Industry representatives and consequent modelling by the study performers.

As Technopolis Group (2016) points out, a limitation of the studies on REACH is that they focus their scope on the regulatory charges and the administrative burdens linked to the registration, excluding capital and operating costs. CSES et al (2015) concluded that compliance costs go beyond what is generally considered as registration costs because REACH has affected the business strategy, the manufacturing processes, the product development, and the supply chain management, leading to further administrative burdens and capital costs. The increase of human resources for compliance purposes may be an indication of an additional administrative burden, as shown by CSES et al (2015). Indeed, the study shows a trend towards a small increase[46] of human resources that companies allocated to compliance over time (2011-2013). This increase was mainly driven by the additional resources allocated by downstream users, article suppliers and end users. However, the studies do not provide a quantification of these costs. Technopolis Group (2016) has included investments into testing facilities and equipment under capital costs, which represent the largest share. It should however be noted that these are costs arising from several pieces of chemical legislation, including REACH, CLP, the POPs Regulation and legislation related to plant protection products and biocides.

The studies discussed above have mainly considered the costs incurred by the registrants (manufacturers, importers and only representatives). The specific costs incurred by distributors are briefly described in both the Technopolis Group (2016) and CSES et al (2015) studies, but have not been quantified. These costs have been mostly linked to the pre-registration obligation (pursuant to Article 28 of REACH) and the preparation, translation, coordination, update and modification of Safety Data Sheets.

Given these different information sources, the best estimate probably comes from the bottom-up analyses. Under these, the first two registration periods cost approximately EUR 2.1 billion and EUR 459 million respectively. These figures need adjusting for transfer payments between firms, which gives a cost of around € 2.3 billion in total. It should be noted that part of these costs relate to costs for substances produced outside the EU, which in practice could be borne either by non-EU producers or by EU based companies (importers and EU based subsidiaries).

1.3.2 Registration costs - breakdown

The statistical average cost per substance was calculated as being around EUR 153,000 and the average cost per registrant around EUR 66,000. However, variation around these

[46] From 2011 to 2013, among those enterprises employing 10-25 employees the percentage passed from 2.3% to 3.9%, for those employing 5-10 and 2-5, the share remained very similar, while an increase in those employing 1-2 occurred, from 22.7% to 26.1%

averages is wide as costs depend on a number of complex factors including the numbers of registrants, the identified properties, the further testing required / waived, the amount of test information already available and the numbers and types of uses. The following charts[47] provide a plot of the distribution of costs per substance and per registrant falling between the cost ranges. They show a wide variation of the registration costs across the sample with the vast majority at the lower end of the costs spectrum and a smaller percentage at the higher end.

Figure 4.2: average registration costs per substance

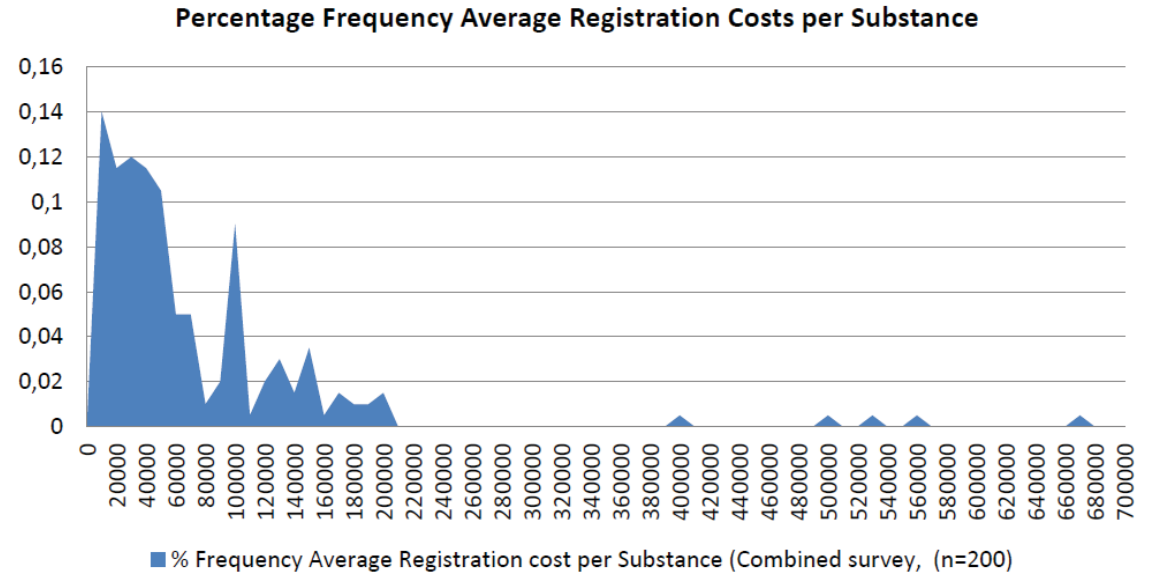
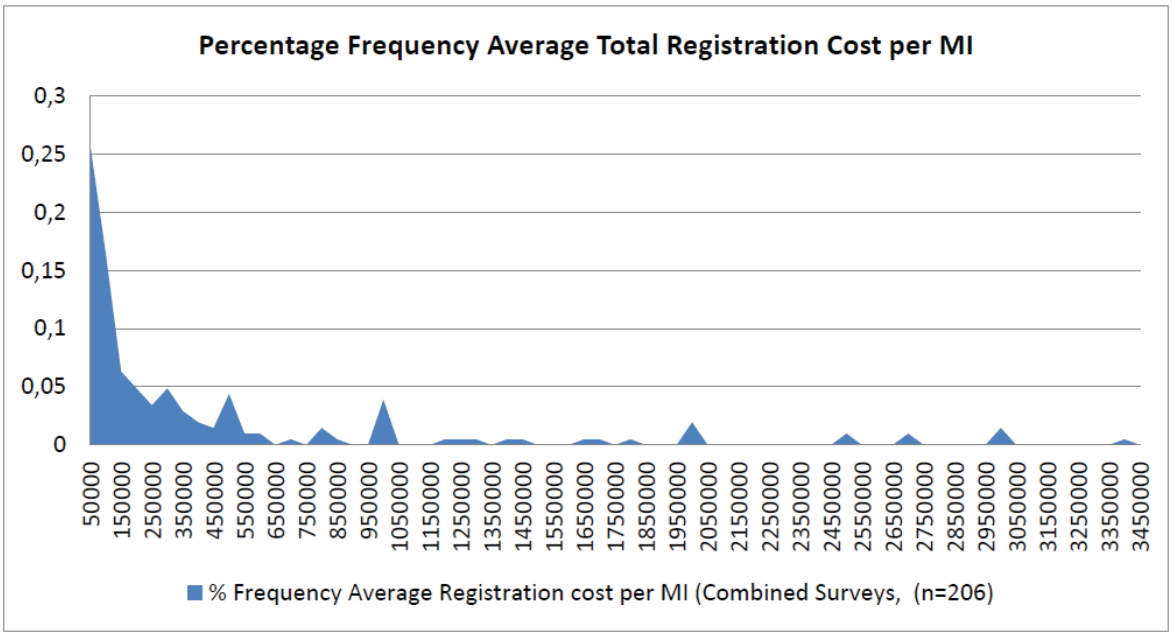


Figure 4.3: average total registration cost per MI



Registration costs affected innovation activity in several ways. Firstly, companies capitalised on information and knowledge generated as part of the registration processes.

47 Monitoring the impacts on innovation, competitiveness and SMEs (CSES, et al. 2015)

Secondly, registration costs have affected the availability of substances on the market. And thirdly, the need of ensuring registration obligations led to re-allocation of resources in the concerned companies from R&D activities to compliance.[48] A detailed assessment of these effects is provided in Annex 5, chapter on Internal Market, Competitiveness and Innovation.

The 2018 registration phase is expected to involve many companies that are new to REACH and that will have to go through the REACH-learning experience from scratch. However, they should be able to benefit from lessons learnt by support institutions during previous registrations.

1.4 Effect of registration on the risks posed by chemicals to humans and the environment

The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these. The lack of data on the hazardous properties of chemicals was the driving force behind the development of REACH.

The results of the 10-year Update of the REACH Baseline study show a clear decrease in the Risk Scores – risk values calculated applying the study methodology[49], when compared with the situation at baseline. The decrease in Risk Scores is similar to the one observed in the 5-year Update for HPV and BLHC chemicals and is now observed for a larger dataset including also MPV chemicals – corresponding broadly to those registered by the 2013 deadlines.

To illustrate the above, REACH lead to more transparency about the number of CMRs on the market. For more than 700 substances[50], REACH registration has led to increased CMR classifications which means that risks from these substances can be better managed. These more stringent classifications seem to be more due to better understanding of hazardous components or impurities rather than experimental tests for CMR properties.

1.5 Comparisons of tests predicted (2003) versus tests conducted since entry into force of REACH (2009)

In spite of the positive developments described above, REACH has however not yet produced the amount of new information on chemicals that was predicted at its conception in 2003.

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[48] Monitoring the impacts on innovation, competitiveness and SMEs (CSES, RPA, Okopol, 2015)

[49] Risk Characterisation Rations and Risk Scores established according to the methodology developed for the Baseline study and calculated at different points in time to monitor risk reduction. See the Report of the REACH baseline study: 10 years update

[50] Based on ECHA's 2014 CMR report (section 3.2).

The JRC study "Assessment of additional testing needs under REACH[51]" from 2003 estimated the testing needs for all substances subject to REACH, taking into account the potential use of (quantitative) structure-activity relationships ((Q)SARs), grouping and read-across instead of testing. The estimates in that study were based on the draft revised Business Impact Study by RPA (July 2003) based on the REACH system as described in the REACH Consultation Document.

The percentage of substances for which the data needs would be either filled by QSARs or waived were estimated for each endpoint, and then the remaining percentage per tonnage category was multiplied by the number of substances predicted for each tonnage band.

The table compares the numbers with data provided by ECHA in the context of the third report under Article 117(3)[52]. ECHA reports the number of studies generated and submitted since 2009, i.e. since REACH entered into force. For a selected number of endpoints a comparison was possible and, for these, it can be seen that for all endpoints that still or until recently required experimental studies in animals, much fewer studies than predicted have been conducted. It has to be noted that these figures do not include studies for which testing proposals were submitted. Until 31 December 2016, ECHA has taken decisions on 953 testing proposals (TP)[53], some of which concerned several studies that are already or will be performed. 467 of the 953 testing proposals concerned prenatal developmental toxicity and 359 concerned repeated dose toxicity. 183 TP decisions on reproductive toxicity are being finalised by the Commission. On the one hand this means that less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted either. Where no new data has been generated, the dossiers either contain data waivers or adaptations.

Table 4.1: Number of testing per study type

Study type	Number of tests expected in 2003	Number of tests submitted between 2008 and March 2016	Number of Testing Proposals
Skin sensitisation	10293 (*in vivo*)	1517 (*in vivo*) + 102 (*in*	NA[54]

[51] Report EUR 20863 EN by the JRC, Assessment of Additional Testing needs under REACH, September 2003.

[52] Third ECHA report under article 117(3) of the REACH regulation, The Use of Alternatives to Testing on Animals for the REACH Regulation, 2017, Appendix 8.

[53] Third ECHA report under article 117(3) of the REACH regulation, The Use of Alternatives to Testing on Animals for the REACH Regulation, 2017, section 3.2.5. Testing proposals submitted to and evaluated by ECHA.

[54] Not applicable (NA) as testing proposals are only required for high tier in vivo tests listed in Annex IX and X.

		vitro)	
Eye irritation	6910 (*in vivo*)	1217 (*in vivo*) + 1064 (*in vitro*)	NA
Skin irritation	3949 (*in vivo*)	741 (*in vivo*) + 1418 (*in vitro*)	NA
In vivo mutagenicity	6580	297	NA
In vitro mutagenicity	2916	3187	NA
In vivo Develop-mental toxicity	2893	369	467
In vivo Reproductive toxicity	2135	73	183
In vivo Repeated dose toxicity	4751	775	359
In vivo Carcinogenicity	121	15	0

The availability of data in 1-10 tpa dossiers appears to be of concern based on the dossiers submitted to ECHA before the 2018 deadline. An analysis of the ECHA database shows that the 1-10 tpa substances for which dossiers have been submitted so far, are statistically less mutagenic than >10 tpa substances. As an illustration, it seems that registrants do not follow the requirement to undertake further studies in case of a positive Ames test. Taken together with the fact that no repeated dose data are required for 1-10 tpa substances, there could be a problem with understanding long term effects of substances in this tonnage range. This appears to be in line with the conclusion from the three studies on 1-10 tpa information requirements conducted for the Commission which calculated in the benefit-cost assessment that the level of human health protection provided by the current requirements is relatively low (at 10% of total health damages that would be caused by 1-10 tpa substances in the absence of any REACH requirements).

1.6 Outcome of the Public Consultation

The majority of respondents considered the chapter Registration and its provisions on data-sharing and avoidance of unnecessary testing clear and of particular EU-added value. However, several respondents (41, of which 71% from companies) also indicated that the registration process, as it currently stands, induces bad practices such as free-riding in the preparation of a joint submission and even more in the updating of registration dossiers. Two respondents commented that registrants do not have a strong incentive to provide high quality data as they risk to be targeted more often by regulatory actions if they do.

Concerns about the availability and quality of information provided by industry in the registration dossiers were found amongst stakeholders: this is the subject of a number of

publications[55,56,57,58], as well as of a position paper submitted by the European Environmental Bureau during public consultation[59].

1.6.1 Information requirements

Three consumer organisations and also one NGO, one public authority and one research institution recommended that stricter information requirements relating to registration of low volume substances (1-10 tonnes) should be introduced. They also suggest to introduce notification requirements for all substances produced >1 kg /y. They flag that some 20,000 low volume chemicals are believed to be on the EU market. At present, companies are not even required to screen these substances for carcinogenicity, reproductive toxicity, endocrine disruption or PBT properties. More comprehensive data requirements should be considered in order to achieve a more complete picture of the properties of the chemicals on the European market.

On the other hand, 40-50% of respondents considered that REACH generates data adequate for risk management measures overall and almost 70% considered that the data generated are adequate for classification & labelling. Public authorities and trade unions have a particularly positive view regarding the use of data for adopting harmonized classification and labelling (over 80% of respondents in each stakeholder groups considers that data is substantially or very useful for that). However, less than 20% of respondents said data generated are sufficient for adopting consumer protection legislation concerning chemicals in articles, environmental legislation, and occupational exposure limits in the context of worker protection legislation.

A Member State Competent Authority highlighted the fact that information requirements for low tonnage substances in Annex VII of REACH should be revised with regard to the information requirements for physical-chemical properties, as for example, some terms used in Annex VII are no longer defined in the CLP Regulation.

On nanomaterials, seven position papers (mostly from industry) consider that the current version of REACH is the adequate framework to regulate nanomaterials and that no additional nanomaterials legislation is necessary. Eight position papers (mostly from NGOs and consumer organisations) consider that nanomaterials should be specifically addressed under REACH and that the current version of REACH does not adequately cover nanomaterials and their specific risks and properties. They provided a long list of recommendations to ensure that REACH adequately covers nanomaterials which includes an update of the REACH Annexes for nanomaterials before 2018.

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[55] G. Stieger, M. Scheringer, C. A. Ng and K. Hungerbühler, Chemosphere, 2014, 116, 118–123. Bundesinstitut für Risikobewertung (BfR), REACH Compliance: Data Availability of REACH Registrations. Part 1: Screening of Chemicals >1000 tpa, 2015.

[56] Client Earth, REACH registrations and endocrine disrupting chemicals, 2013.

[57] E. Westerholm and L. Schenk, Regul. Toxicol. Pharmacol., 2014, 68, 51–58.

[58] L. Schenk, N. Palmen and D. Theodori, Evaluation of worker inhalation DNELs. Part A: quality assessment of a selection of DNELs, 2014.

[59] Position paper by European Environmental Bureau submitted during the online public consultation

Concerning registration requirements for polymers, the views provided were divided: One position paper by industry suggested that the current polymer exemption from REACH registration and evaluation should be maintained as polymers are sufficiently covered under REACH and CLP through existing requirements for monomers, other reactants and additives. Another position paper from an NGO proposes that the exemption for registration of polymers should be re-considered due to potential hazards of the polymers.

1.6.2 Compliance of registration dossiers

Around 20% of all respondents from NGOs, consumer associations, industry associations, public authorities, and research institutions plus 18 position papers commented on the high level of non-compliance of registration dossiers as hindering the objectives of REACH or as impairing the level-playing field between duty-holders. Some considered that the completeness check performed by ECHA should not be limited to an IT check but a first check of the data would be more effective and improve the scrutiny of the files to implement the "no-data-no-market" principle. There was a call for ECHA to refuse to grant or withdraw a registration number when important data are missing from the registration dossiers or when extremely poor data have been provided. Also, ECHA was encouraged to further increase the number of compliance checks.

2 Data sharing, test methods and avoidance of unnecessary animal testing

Conclusions of the 2013 REACH Review

The 2013 REACH Review acknowledged that good progress had been made on the procedural side of data sharing and with submission of testing proposals. However, concerns remained regarding the robustness of the information and the quality of justifications for not submitting test results.

The Commission's report recommended to ECHA (a) to take measures so that registrants improve the quality of the justifications supporting the alternatives to animal testing, so as to improve compliance of registered dossiers with the information requirements; and (b) to continue to provide guidance and training to registrants and regulators to assist in the use, preparation of justifications and regulatory acceptance for approaches such as weight of evidence, grouping of substances and read-across approach and the use of (Q)SAR and in vitro methods.

The report detailed that EUR 330 million in financial support had been made available by the Commission to develop and evaluate alternative methods in the period 2007-2011, but stated that there were still fundamental gaps in providing alternatives for some complex toxicological endpoints. In addition, some research outputs produced were not suitable for regulatory needs or required further education of users and regulators to ensure their use and acceptance.

2.1 Developments after the 2013 REACH Review

2.1.1 Data sharing and joint submissions

During the reporting period for this Review, the Commission reaffirmed and reinforced the "one substance, one registration" principle by adopting a Commission Implementing Regulation on joint submission of data and data-sharing[60] (see also annex 4-part on registration). The ECHA guidance on data-sharing has subsequently been updated to reflect the requirements of the new Regulation[61].

Registrants of the same substance are obliged to share any available data, especially related to vertebrate animals, via the data sharing process. Companies planning to register a new or existing substance that has not been pre-registered need to inquire with ECHA whether a registration has already been submitted for that substance. For the last three years on average ca. 1,500 potential registrants per year used the inquiry process[62].

[60] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

[61] https://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60

[62] ECHA, 2017. The use of alternatives to testing on animals for the REACH Regulation

ECHA improved REACH-IT to put in contact potential registrants (pre-registrants and inquirers) and existing registrants with the lead registrants. Furthermore, ECHA put in place improved tools to prevent submissions outside of an existing joint submission and to ensure that co-registrants discuss the sharing of all relevant data for the substance and avoid duplication of unnecessary animal tests.

The REACH principles of sharing and joint submission of data on intrinsic properties of a substance generally work well (registrants used it to fulfil the information requirements and to avoid unnecessary animal testing in more than 97% of cases) and have a major impact on avoiding unnecessary duplication of animal testing[63].

The recent Implementing Regulation encourages the sharing of the results of animal studies between structurally similar substances to facilitate grouping or read-across approaches and to promote the development and use of alternative methods for the assessment of hazards of substances and to further minimise animal testing. In the same vein, in the report on the Operation of REACH and CLP[64], ECHA pointed out that registrants' possibilities of making full use of scientifically robust read-across or category approaches, as envisaged in Annex XI of REACH,[65] is hampered by the absence of obligatory data-sharing between structurally similar substances in REACH.

2.1.2 Development and use of alternative methods

2.1.2.1 Acceptance and use of new alternative testing methods under REACH

During the reporting period, several amendments to the standard information requirements in REACH Annexes VII to X were made to require the use of test methods that lead to a reduction or replacement of testing on vertebrate animals.

In 2015, the standard information requirement for reproductive toxicity in Annexes IX and X for a two-generation reproductive toxicity study was replaced by a requirement for the Extended one-generation reproductive toxicity study[66] (EOGRTS, OECD TG 443). This test method decreases animal use compared to the two-generation reproductive toxicity study whenever the (conditional) breeding of the second generation is not included in the study. Moreover, this study includes the assessment of additional effects that were not included in the two-generation study. The EOGRTS test guideline provides a flexible study design, with optional modules to assess developmental neurotoxicity and

[63] Report on the Operation of REACH and CLP, ECHA 2016

[64] Report on the Operation of REACH and CLP, ECHA 2016

[65] Annex XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)- 'General Rules for Adaptation of the Standard Testing Regime set out in Annexes VII to X'.

[66] Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study. OJ L50/1, 21.02.2015

developmental immunotoxicity, as well as optional breeding of the second generation. In the data requirements for REACH, these additional modules of the test are triggered depending on exposure and/or indications from the available data for certain effects, e.g. endocrine disruption, knowledge which can change in the future.

Due to the flexible study design of EOGRTS, the implementation of this new study for REACH purposes and the conditions for triggering of the different modules were matters of extended discussions involving scientific and regulatory experts. During these discussions, 216 draft decisions on testing proposals and compliance checks concerning reproductive toxicity were referred from ECHA to the Commission in the period 2011-2014[67], as no unanimous agreement could be found in the MSC on draft decisions proposed by ECHA. The Commission put decision-making on hold in order to resolve the underlying disagreement on how to perform reproductive toxicity testing for the purpose of REACH. Following the change of the information requirements for this endpoint in Annexes IX and X, the Commission is finalising the decision-making process for these cases by requiring registrants to submit new testing proposals for appropriately designed EOGRTS according to the criteria set in the REACH annexes.

In 2016, an amendment[68] to Annexes VII and VIII modified the standard information requirements for skin irritation/corrosion and eye irritation/serious eye damage by removing the standard requirement for an *in vivo* study for substances registered at and above 10 tons per year. Thus, the results of *in vitro* tests are sufficient to fulfil the REACH information requirements at all tonnage levels unless the *in vitro* methods are not applicable or their results not adequate for classification and risk assessment. This amendment also adapted requirements for acute toxicity information, so that for substances shown to be non-toxic via the oral route, dermal acute toxicity studies are no longer required. A second amendment[69] to Annex VII introduced the recently developed AOP-based *in vitro* test battery for skin sensitisation as the default information requirement, if applicable for the substance under investigation and giving sufficient information for classification and risk assessment. While REACH, as a general rule, requires that animal tests are only performed as a last resort and gives priority to available and applicable alternative methods, these amendments clarify the use of the available alternative methods for these endpoints. They also provide increased legal certainty that the data requirements for these endpoints can be fulfilled on the basis of *in vitro* tests as well as increased ease of data submission for registrants, as waiving of in vivo studies is no longer required.

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[67] http://ec.europa.eu/environment/chemicals/reach/implementation_en.htm

[68] Commission Regulation (EU) 2016/863 of 31 May 2016 amending Annexes VII and VIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity. OJ L 11/27, 01.06.2016

[69] Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation. OJ L 255/14, 21.09.2016

Following the modifications of the REACH information requirements, ECHA updated the specific guidance documents for the endpoints affected to provide detailed information on available alternative methods and their use in the context of Integrated Assessment and Testing Approaches (IATAs)[70].

Commission Regulation (EC) No 440/2008[71] on test methods provides an inventory of methods appropriate to generate data for the purpose of REACH, essentially by taking up internationally agreed OECD test guidelines in EU legislation (including translation in all EU languages). It has been amended four times during the reporting period[72] to reflect the scientific progress made in the OECD test guideline programme. These amendments introduced 38 new and 24 updated test methods with potential uses under REACH, including a number of methods with a relevance to replace, reduce or refine animal testing. These comprised four new *in vitro* tests (B.57 H295R cell-based steroidogenesis assay, B.59 Direct Peptide Reactivity Assay, B.60 Keratinosens, B.61 Fluorescein leakage test for ocular corrosion), four updates to existing in vitro tests for genotoxicity and serious eye damage, as well as several new reduction and refinement tests.

The formal recognition of new test methods by amendments to Commission Regulation (EC) No 440/2008 and/or information requirements in REACH Annexes, as well as the adaptation of the detailed information in the endpoint-specific ECHA Guidance documents has frequently been criticised, including in the public consultation for this REFIT evaluation, for taking too long to be completed after test guidelines have been agreed in the OECD, thus creating uncertainties for registrants and hampering the uptake of available alternative test methods for REACH. While the frequency of amendments and the number of included test methods has increased during the reporting period, in particular a timely formal recognition of new testing methods through inclusion in the Annex to Commission Regulation (EC) No 440/2008 remains a challenge due to the inherent administrative processes and the time required for translation of the long and highly technical test protocols in all EU languages. The experience from recent modifications of standard information requirements in Annexes VII-X to REACH have also highlighted a number of challenges for regulatory acceptance of new methods, which can significantly influence the time needed to complete the process, in particular related to concerns raised in relation to assessing the equivalence of information generated via *in vitro* or *in vivo* testing, maintaining the previous level of protection for

[70] Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance. https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

[71] Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 142/1. 31.05.2008

[72] Commission Regulation (EU) No 260/2014 of 24 January 2014. OJ L 81/1, 19.03.2014
Commission Regulation (EU) No 900/2014 of 15 July 2014. OJ L 247/1, 21.08.2014
Commission Regulation (EU) 2016/266 of 7 December 2015. OJ L 54/1, 01.03.2016
Commission Regulation (EU) 2017/735 of 14 February 2017. OJ L 112/1, 28.04.2017

human health and the environment, addressing flexibility in test guidelines as well as testing costs and availability of test laboratories able to perform new tests.

In order to close the gap between the adoption of new OECD test guidelines and the formal recognition in Regulation (EC) No 440/2008 and REACH Annexes VII-X and to give timely information to registrants about the availability of new alternative methods and the possibility to use those methods for the purpose of REACH registrations in advance of changes to legal provisions and guidance documents, ECHA has set up a dedicated web site that can be quickly adapted to new developments[73].

REACH prescribes the use of alternative methods whenever possible and demands that testing on vertebrate animals shall be undertaken only as a last resort. As a follow-up to the 2014 report on the use of alternatives to testing on animals for the REACH Regulation[74], ECHA investigated 295 higher tier studies on vertebrate animals that had been performed without the prior submission of a testing proposal[75]. For the majority of cases, adequate justification was obtained from registrants upon request (e.g. test conducted for other regulatory purposes or by a different legal entity). For the cases where a possible non-compliance was found (no or unsatisfactory response), the information was handed over to Member State Competent Authorities and National Enforcement Authorities for follow-up.

In order to reinforce the avoidance of unnecessary animal testing, and following two European Ombudsman cases on this topic[76], ECHA has modified its practices in the examination of proposals for tests involving vertebrate animals and compliance checks of the registration dossiers. Following the Ombudsman's decision in September 2015, ECHA started to request additional information on the alternative methods considered by registrants who submit new testing proposals for tests involving vertebrate animals[77]. A special field is now available in IUCLID 6 for the documentation of the alternatives considered prior to each proposed study on vertebrate animals[78].The information received is published with the public consultation on the testing proposals so that third parties can comment and it will be considered in the testing proposal examination. Furthermore, ECHA is currently assessing whether compliance check proves to be an effective way of

[73] https://echa.europa.eu/support/oecd-eu-test-guidelines

[74] The Use of Alternatives to Testing on Animals for the REACH Regulation. Second report under Article 117(3) of the REACH Regulation. ECHA, 2014

[75] Survey results - Analysis of higher tier studies submitted without testing proposals. ECHA, 2015

[76] 1606/2013/AN (TP), 1568/2012/(FOR)AN (CCh)

[77] Evaluation under REACH, Progress Report 2015. ECHA, 2016

[78] https://echa.europa.eu/view-article/-/journal_content/title/considerations-for-alternative-methods-need-to-be-included-in-your-testing-proposal

checking that animal testing is conducted only as a last resort[79] on the basis of two test cases.

2.1.2.2 Use of test methods and adaptations in REACH registration dossiers

Analysing the database of registrations available up to 31 March 2016 (6,290 substances included in the assessment), ECHA evaluated the use of available test methods as well as the adaptation possibilities given by Annex XI[80], including information for substance falling in the lower tonnage bands (i.e. 1-100 t/a)[81].

The overall analysis of options used by registrants to cover REACH information requirements at the substance level (see Fig. 4.4) showed that for low tier endpoints (acute rodent toxicity, skin and eye irritation/corrosion, skin sensitisation, genetic toxicity *in vitro* and acute toxicity to fish), the main sources of information are experimental *in vivo* and *in vitro* studies, which are used for 59 to 71% of substances, depending on the endpoint (new experimental studies (NES) and old experimental studies (OES) combined in Fig.4.4). Many of these studies are old experimental studies, i.e. they were carried out before REACH came into force. Read-across and weight of evidence adaptations were frequently used (on average over all endpoints for 14% and 12% of substances, respectively). Data waivers and (Q)SARs were more rarely used (on average for 4% and 2% of the substances, respectively).

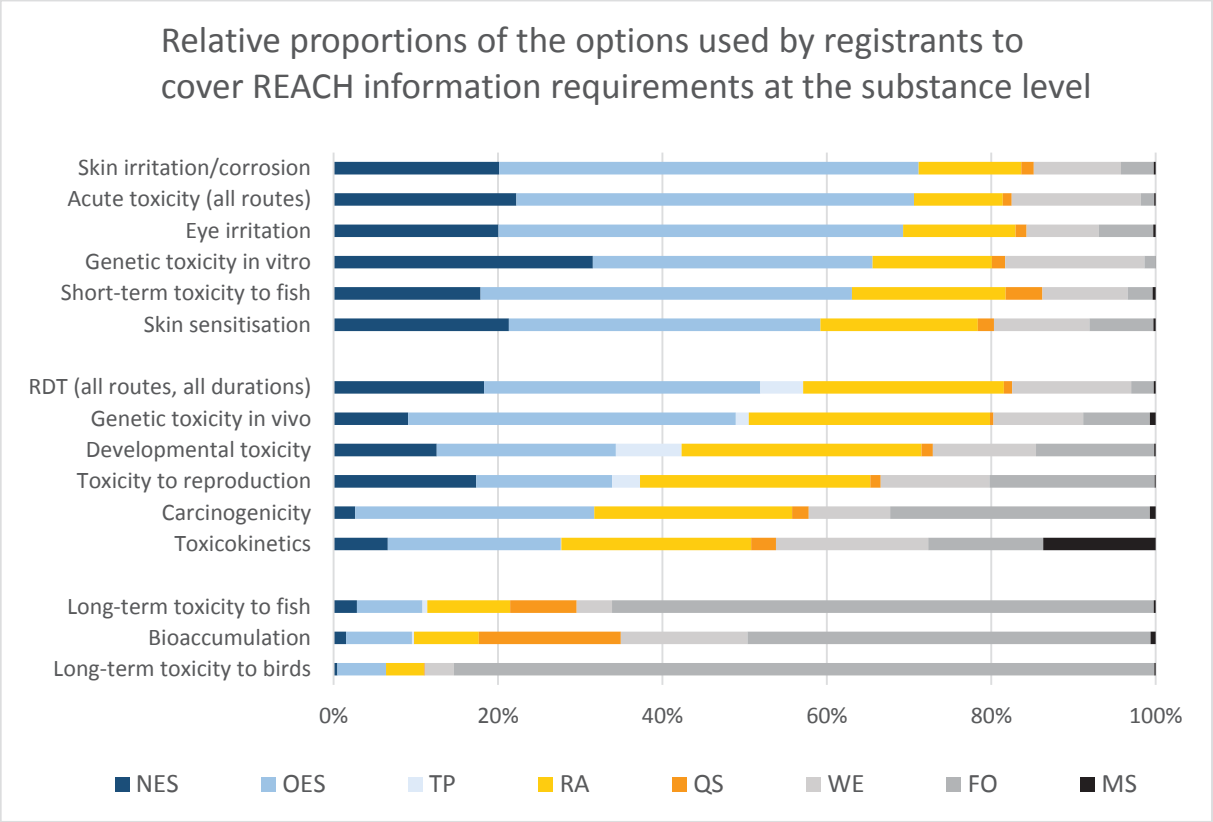
Figure 4.4: Relative proportions of the principal options to fulfil information requirements for human health and environmental endpoints for the substances.

Legend: OES – old experimental studies (conducted before 2009); NES – new experimental studies (including *in vivo* and *in vitro*, unless specified)); WE – weight of evidence; RA – read-across; QS – QSAR; TP – testing proposal; FO – flags to omit study; MS – miscellaneous

[79] Report on the Operation of REACH and CLP, ECHA 2016

[80] The Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017. DOI 10.2823/023078

[81] Two earlier reports in 2011 and 2014 had focused on substances in tonnage bands 100-1000 tpa and ≥1 000tpa



For higher tier human health endpoints (repeated dose toxicity, genetic toxicity *in vivo*, reproductive and developmental toxicity and carcinogenicity), generally less experimental studies were submitted than for lower tier endpoints (for between 32% and 52% of substances depending on the endpoint). The information requirements are more often covered by adaptations, most prominently by Read-Across (on average over all endpoints for 27% of substances), while Weight of Evidence (WoE) (12%) and waivers were used for 12% and 13% of substances, respectively. (Q)SARs, on the other hand, were very rarely used (1%) as the main option to fulfil information requirements.

For higher tier environmental endpoints (bioaccumulation, long-term toxicity to fish, long term toxicity to birds), relatively few experimental data are available (only for 6-11% of substances, depending on the endpoint). The information requirements are often addressed with data waivers (on average 64%) followed by other adaptations in decreasing order: QSARs (10%), Read-Across (8%) and Weight of Evidence (8%). The low number of experimental studies can be explained by the numerous possibilities to waive the experimental tests for these endpoints.

In the public consultation, 30 respondents addressed the issue of animal testing and alternatives in open questions, and 11 included this topic in position papers. The main message provided by those respondents is that the principle of 'animal testing as a last resort' is not yet fully implemented (80% of them referred to this issue in the open questions and 72% in position papers). Respondents attribute this problem to the strict information requirements, often referring to the low acceptance of read across and QSAR by ECHA, leading to unnecessary animal testing. Many respondents state that the

acceptance of alternative methods is low[82]. Furthermore, a plea was made by some respondents to adopt a systematic, quantitative approach to weight-of evidence.

2.1.2.3 New studies

At the cut-off date for the ECHA report, a total of 15,188 new (e.g. performed from 2009 onward) unique experimental studies across all endpoints had been submitted to ECHA, while the number of submitted existing experimental studies (performed before 2009) was ca. 2.5 times higher.

- Many studies conducted in accordance with the OECD test guidelines/EU test methods after 2009 were for low tier human health endpoints: 5,542 *in vivo* studies; 5,795 *in vitro in chemico* and *ex vivo* studies.
- A total of 2 471 new studies for high tier human health endpoints were reported. The main type of health endpoints are screening studies for reproductive/developmental toxicity and combined studies combining a screening study with a 28-day repeated dose toxicity study (a total of 952), followed by 28-day repeated dose studies, all routes (a total of 442).
- 359 new developmental toxicity studies
- 268 new 90-day repeated dose studies
- 73 new studies on reproductive toxicity

For all endpoints, the main source of experimental data are studies that already existed when REACH came into force, with the exception of reproductive toxicity, due to the significant number of screening studies performed.

Compared to human health endpoints, there are relatively few new studies for environmental endpoints (1,274 studies, of which 1,060 address acute toxicity in fish). These data have a high potential to support new adaptations to be applied for low tonnage substances and new registrations, by QSAR and read-across for example.

From the data available from the registration dossiers, it is currently not possible to deduct how many of the studies have been generated in order to fulfil REACH information requirements or regulatory needs other than REACH and CLP (e.g. the same test might have been required in other jurisdictions). In the case where ECHA requested further justifications for higher tier tests performed without testing proposals and for animal tests for endpoints where alternatives are available, registrants frequently referred to regulatory requirements in other regions. Since the requirement to provide justification for *in vivo* studies in registration dossiers has been strengthened (see above), more information on this aspect should be available in the future.

As the registration process for high volume phase-in substances is now completed, a first comparison of the number of animal tests following requirements in Annex IX and X that have been submitted, and requested in testing proposal (TP) or compliance check (CCh)

[82] 53% of respondents addressing animal testing and alternatives in the open question and 72% in the position papers

decisions, with the estimates made before the adoption of REACH[83] is possible. However, such a comparison, for the time being, has to be seen as very approximate and preliminary, as dossier and substance evaluation processes are still ongoing and in particular additional tests may still be requested in CCh decisions. Double counting of studies is possible, as the current statistics on new tests[84] (performed after 2009) submitted to ECHA does not distinguish between tests that have been performed following TP and CCh decisions, and tests that have been performed for other regulatory purposes. On the other hand, the statistics on tests requested in TP and CCH decisions[85] does not allow a conclusion on how many of the requested studies have already been completed and submitted to ECHA[86]. However, even by adding all new studies submitted to ECHA and requested in evaluation processes, it becomes evident that the number of studies performed for human health high tier endpoints remain well below the minimum estimations initially made (see also table xxx in section registration).

For the endpoints for which *in vitro* test methods are available that can (individually or in combination) fully replace *in vivo* testing for substances in the application domain of these methods, ECHA performed a detailed analysis of the data submitted from 2010 onwards[87]. In the case of skin corrosion/irritation and serious eye damage/eye irritation, a large proportion of registrants relied on existing data or read-across approaches in about 70% of dossiers analysed (substance approach) . An analysis of the experimental studies submitted showed that dossiers for around 20% of substances contained *in vitro* data for skin corrosion/irritation and serious eye damage/eye irritation, either as supporting evidence or as the main source of information. For skin corrosion/irritation, registrants have used *in vitro* information alone to fulfil the information requirements in 10.6% of substance dossiers, and for serious eye damage/eye irritation this was the case for 7.2% of substance dossiers.

From the ECHA report it becomes evident that, while the number of submitted *in vitro* data for both skin corrosion/irritation and serious eye damage/ eye irritation has overall increased in comparison to previous reports, there was still a relatively high number of recent *in vivo* tests submitted, necessitating further exploration by ECHA and, where relevant, the Member States enforcement authorities, of the reasons and justifications for this.

The total number of *in vitro* data submitted for skin sensitisation has grown but is still very low compared to the number of submitted *in vivo* tests (a total of 102 *in vitro* studies in 2016 versus 54 in 2014). This low number may be attributed to the fact that, at the cut-off date for this analysis, OECD test guidelines were not yet available for all methods of

[83] Assessment of Additional Testing Needs under REACH. EC, 2003

[84] Table 2 in: ECHA report on the Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017

[85] Table 3 in above report and aggregated information from ECHA Progress reports on Evaluation 2010-2016 (https://echa.europa.eu/regulations/reach/evaluation)

[86] It should also be noted that not all decisions necessarily lead to testing as registrant may still decide to fill a data gap by using an adaptation

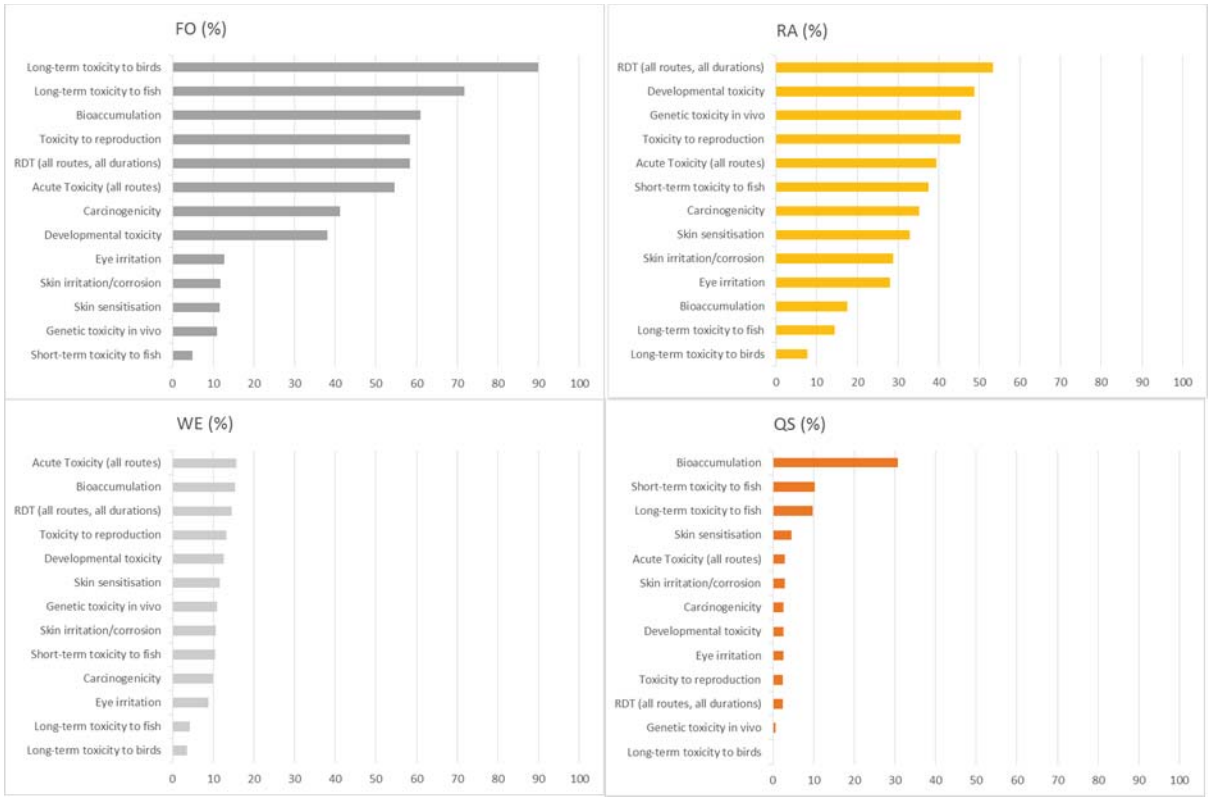
[87] The Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017. DOI 10.2823/023078, Appendices 5-7

the basic test battery, and detailed guidance for their application for regulatory purposes was missing. Their use should increase following the revision of the information requirements in REACH for this endpoint in 2016. However, efficient uptake of these methods will depend on the development of defined approaches to predict sensitisation hazard and potency based on the results of the available tests and/or other available information. A project addressing this is currently ongoing at OECD.

2.1.2.4 Adaptations

The three ECHA reports on the use of alternatives to testing, covering the period from 2009 to 2015, show that the rate of use of adaptations remained similar on Endpoint Study Record (ESR) level. In the 2017 report, there is on average, across all endpoints, a slight increase in the use of Weight of Evidence, and about the same use of read-across and QSAR[88] reported.

Fig. 4.5: The fraction of substances for which an adaptation was used related to the overall number of substances with information for this endpoint**.** The endpoints are sorted in decreasing order of percentages and start with the endpoint where the adaptation was used most. Legend: FO – flags to omit study; RA – read-across; WE – weight of evidence; QS – QSAR



[88] ECHA report on the Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017

Results from the analysis of adaptations according to Annex XI show that of the dossiers for 6,290 substances 89% contained at least one adaptation (including waivers), 63% contained read-across adaptations, 43% contained weight of evidence arguments, and 34% contained read-across predictions for at least one endpoint concerning vertebrate animals.

Quantitative structure-activity relationships (QSARs) were used mainly for environmental endpoints, particularly for bioaccumulation, short- and long-term toxicity to fish. For health endpoints, QSARs are only rarely used. In weight of evidence (WoE) approaches, the main contributions come from the use of old studies or read-across approaches. QSARs in WoE are used frequently for particular endpoints (i.e. bioaccumulation and short-term toxicity to fish).

Waiving was used frequently for endpoints where endpoint-specific triggering or waiving options exist in the REACH Annexes (e.g. bioaccumulation, long term toxicity for fish or birds, reproductive toxicity, carcinogenicity), or where multiple routes of administration are possible, but not always required (acute rodent toxicity and repeated dose toxicity). The main reasoning provided for waiving was that the given test was scientifically unjustified. Exposure-based justifications were used considerably less and only for particular endpoints like long-term toxicity to fish, long-term toxicity to birds, and for endpoints like acute and repeated dose toxicity, where different routes of exposure are possible.

Read-across was frequently used for the higher tier human health endpoints Repeated Dose Toxicity, developmental and reproductive toxicity. Read-across is considered a viable adaptation for complex health endpoints, presuming that a scientific plausible hypothesis can be proven and used for deriving quantitative result for the targeted substances. For these endpoints *in vitro* alternatives that can replace the results of experimental tests with a similar level of protection to human health do not exist yet.

However, experience from dossier evaluation[89] shows that the majority of adaptations identified in the registration dossiers are found non-compliant, leading to the request for the standard information in the Compliance Check decision[90]. According to ECHA, the main reasons for not accepting adaptations, especially WoE and RA, are poor documentation, insufficient substance identification of both, the substance which is target of the prediction and the source substance(s), deficiencies in the quality of the source study, lack of or low quality of supporting data, lack of qualitative and quantitative data to support predictions based on toxicokinetics, and shortcomings in the toxicological hypothesis. Similar problems were identified by another study[91], which for human health endpoints frequently found insufficient justification for the similarity of source and target substances for read-across and the use of inappropriate waiving justifications. For ecotoxicological endpoints, the absence of read-across justifications, and missing or absent experimental data for the source substance for read-across, as well as the use of

[89] ECHA Evaluation Reports, 2008 – 2015, summarised in Report on the Operation of REACH and CLP, ECHA 2016

[90] However, registrants can still update their dossiers with improved information supporting the original adaptation

[91] Data availability in REACH registrations. BfR, 2015

inappropriate models and insufficient reporting for QSARs were identified as main reasons for non-compliant adaptations.

Although some industry stakeholders and animal welfare organisations commented in the public consultation for this REFIT evaluation that ECHA is too stringent in its assessments of adaptations, there is no objective evidence supporting this. There have been no Board of Appeal decisions overturning a rejection by ECHA of an adaptation statement. On the contrary, the Board of Appeal has several times expressed that ECHA has a wide margin of discretion in making such scientific assessments.

ECHA has undertaken significant efforts in the reporting period to support registrants to improve the quality of adaptations used. This includes revision and expansion of relevant ECHA Guidance documents, the development of a Read-Across Assessment Framework (RAAF) for human health (published 2015), environment (2017) and multi-constituent substances and UVCBs (2017) as well as scientific meetings, workshops and webinars on alternative approaches.

In reaction to the many deficiencies in the read across arguments for higher tier health endpoints in particular, ECHA is actively following and supporting the scientific developments of methods that are promising in either strengthening the use of read-across and grouping or that could limit or replace the need for new studies on animals in the longer term. In addition, ECHA plans in 2017 to conduct a review on the applicability of alternative test methods to fulfil the REACH information requirements.

2.1.2.5 Test method development, validation and OECD test guideline development

During the reporting period, the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) received 32 test methods for evaluation or peer-review as a pre- or/and a full submission. Following a call dedicated to assays in the area of toxicokinetics (liver clearance) another 15 methods were submitted to and evaluated by EURL ECVAM.

In the relevant period, validation studies for 11 *in vitro* methods were completed under the (co-)lead of EURL ECVAM or by ICATM[92] partners with EURL ECVAM's active involvement. Another 9 methods were validated by other organisations or industry. The validation of 18 methods is ongoing or will start in the near future. One validation study trial lead by EURL ECVAM engages for the first time the newly established network of validation laboratories (EUNETVAL[93]), which now has 37 member laboratories. In the same period, the peer review of 15 methods by the EURL ECVAM Scientific Advisory Committee (ESAC) was completed, most of them in the area of skin sensitisation, skin irritation and serious eye damage/eye irritation. ESAC further adopted an Opinion on the use of Performance Standards to evaluate similar test methods.

[92] International Cooperation on Alternative Test Methods

[93] European Union Network of Laboratories for the Validation of Alternative Methods

In the OECD, 11 new OECD test guidelines on alternative methods were adopted between 2012 and 2016, the drafting in 6 cases was led by EURL ECVAM. These 11 methods serve the testing in the fields of skin sensitisation (3), serious eye damage/eye irritation (3), genotoxicity (1), endocrine disruption (3) and acute fish toxicity (1). EURL ECVAM furthermore led or was main contributor to the drafting of 6 OECD guidance documents and 2 performance standards. EURL ECVAM leads 7 ongoing OECD projects for the establishment of new or updated test guidelines or guidance documents, and two new project proposals were submitted to OECD in 2016.

While in the last years progress has been made to develop and refine *in vitro* test methods for some endpoints, and these have the potential to replace animal testing to a large extent, such methods are still missing for higher tier endpoints like systemic or reproductive toxicity, due to the underlying complexity of the physiological mechanisms involved. As one strategy to open new paths to the development of non-animal testing and assessment approaches of complex toxicity endpoints, the OECD launched a new programme on the development of Adverse Outcome Pathways (AOP)[94]in 2012. An AOP describes the sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect, and serve as the central element of a toxicological knowledge framework to support chemical risk assessment based on mechanistic reasoning. The first AOP-based testing approach has entered regulatory application with the set of *in vitro* test methods and the linked IATAs[95] for skin sensitisation.

2.1.3 Research funding

2.1.3.1 Research funding through EU research programmes

The European Commission (EC) has supported research into the development of alternative methods through its successive Framework Programmes for Research and Innovation (FPs), including the current seven-year programme Horizon 2020 (H2020: 2014 to 2020).

Over the last decade, EC funding in the field of research into alternatives has remained stable and significant with, on average, more than EUR 35 million per year to new research projects. During the period 2012-2016, sixty-nine research projects were running at various stages of implementation, with EUR 350 million from EC programmes. As part of this effort, thirteen projects were co-financed within the context of public-private partnerships with Cosmetics Europe (the seven projects from the SEURAT-1 cluster) or the European Federation of Pharmaceutical Industries and Associations (the six projects from the Innovative Medicines Initiative: IMI). The additional resources provided by the industry to these projects were estimated to represent more than EUR 115 million.

[94] http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[95] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)29&doclanguage=en

Research activities supported in the period 2012-2016 were carried out in the context of better and more cost-effective safety and efficacy testing. They included one FP6, fifty-three FP7 and fifteen Horizon 2020 projects covering areas such as toxicity of nanomaterials, chemical products and drugs, as well as quality control of vaccines. Overall, these projects developed a range of various novel *in silico* and *in vitro* approaches from innovative modelling tools to multiple organs-on-a-chip. In addition, for the risk management of nanomaterials, significant international cooperation exists with a number of countries outside the EU through the NANOSAFETY Cluster[96].

The contribution of these projects for the availability of new alternative methods is difficult to assess. The FPs monitoring and evaluation system collects information in a structured and systematic way on publications and IPR (patents, registered designs, trademarks, copyrights) only. There are no data on, for example, the actual policy impact of R&I projects. Moreover, the bibliometric and IPR data is based on projects' reporting and are not fully reliable. Within these limitations, the FP7 projects mentioned in Table 4.2 have so far produced about thousand peer-reviewed publications in scientific journals and have generated around thirty Intellectual Property Rights. Since all Horizon 2020 projects are still in their initial phases, it is premature to report outputs at this stage. There is always a lag in the implementation of new methods from EC funding due to the long time needed between the development of the methods, their validation, and their regulatory acceptance. However, regulatory impact starts to be observed from FP6 projects for less complex toxicological endpoints, such as skin sensitization for instance. Additional regulatory impacts are expected to come out of FP7 and H2020 projects, including in the areas of more complex toxicological endpoints, such as repeated dose systemic toxicity, developmental and reproductive toxicity, and carcinogenesis.

Additional research funding

The Commission is notably providing support through Horizon 2020 for the harmonisation of human biomonitoring in Europe (HBM4EU[97]– started in January 2017). In addition, the Commission has stepped up its efforts to support test method development related to endocrine disruption by calling for proposals for research and innovation actions[98] in order to fill gaps in the identification of endocrine disruptors relevant to the OECD test guideline programme.

The NANOREG[99] project combined EU Member States and industry resources for regulatory testing of nanomaterials. The projects NANOREG and PROSAFE[100], with contribution from other projects summarised the aims, efforts and results in a white paper[101] submitted also to the OECD Working Party of Manufactured Nanomaterials (WPMN) in 2017. Projects were driven by the need to reduce uncertainty in the

[96] https://www.nanosafetycluster.eu/
[97] The European Human Biomonitoring Initiative – HBM4EU
[98] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-bhc-27-2018.htm[l]
[99] http://www.nanoreg.eu/
[100] http://cordis.europa.eu/project/rcn/194431_en.html
[101] http://www.rivm.nl/dsresource?objectid=008c3189-984e-4204-b129-048cecad1743&type=PDF

regulatory assessment of the Environmental Health and Safety aspects of nanomaterials and support a climate where the innovative potential of nanotechnology can be fully exploited.

Table 4.2. Overview of main projects on alternative methods/approaches and nanomaterials funded by the EC Framework Programmes during 2012-2016

Project Name	**Total awarded grant [million €]**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
FP6																	
carcinoGENOMICS	10,44																
FP7																	
CONTAMED	3,49																
DEER	3,50																
ESNATS	11,90																
NanoTEST *	3,00																
PREDICT-IV	11,33																
NANORETOX *	3,19																
CADASTER	2,70																
ENFIRO	3,16																
RISKCYCLE	1,00																
SYSTEQ	2,70																
ENNSATOX *	2,80																
ENPRA *	3,70																
HINAMOX *	2,30																
InLiveTox *	2,40																
NANODEVICE *	9,49																
NEPHH*	2,43																
NEURONANO *	2,50																
SafeSciMET	2,37																
SAFE-T	13,90																
CHEMSCREEN	3,50																
EUROECOTOX	0,96																
AXLR8	0,56																
ACROPOLIS	3,00																
NANOHOUSE	2,40																

*																	
eTOX	6,91																
COACH **	1,50																
COSMOS **	3,34																
DETECTIVE **	4,33																
HeMiBio **	4,70																
NOTOX **	4,85																
SCR&Tox **	4,70																
ToxBank **	1,56																
diXa	2,80																
QNANO *	7,00																
Marina *	9,00																
ModNanoTox *	1,00																
NanoTranskinetics *	0,99																
NanoValid *	9,59																
BOC	1,39																
MIP-DILI	15,33																
STEMBANCC	26,00																
HeCaToS	12,00																
MembraneNanoPart *	1,00																
Mod-ENP-Tox *	1,00																
Modern *	1,00																
NanoMile *	9,62																
NanoPuzzles *	0,98																
NANoREG *	10,00																
NanoSolutions *	10,00																
PreNanoTox *	1,00																
eNanoMapper	4,00																
FutureNanoNeeds *	6,80																
IN TIME	0,19																
H2020																	
EuroMix	8,00																
MolNANOtox	0,19																
NanoCytox	0,16																
F-CCW	0,05																
PROSAFE *	2,51																
BIOTIMA	0,05																

NanoREG II *	10,00																
EDC-MixRisk	6,22																
BioMNP	1,13																
PANDORA	2,81																
NANOGENTOOLS	0,71																
HISENTS *	6,33																
SmartNanoTox *	8,00																
EU-ToxRisk	27,80																
VAC2VAC	7,85																
ACENano *	7,00																
CALIBRATE *	8,00																
EC4SAFENANO *	1,99																
npSCOPE *	6,66																
NANOFASE *	9,95																
GoNano	1,99																
PATROLS	12,71																
GRACIOUS	7,00																

The projects given above and marked with one or two asterisks form part of two research clusters as follows:

* NANOSAFETY cluster

** SEURAT-1 cluster, the funding of which was realized via a joint venture between the European Commission (in the framework of FP7) and the European Cosmetics Association (Cosmetics Europe), who made available additional € 25 million.

2.1.3.2 Investments in alternatives by the Joint Research Center (JRC)

In the period 2012-2016, about EUR 36 million have been spent for the operation of the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), hosted by the JRC. The current annual budget is EUR 6.5 million. About 98% of the expenditure is for staff, the operation of laboratories, the set-up, maintenance and update of IT systems and tools, the management of a number of advisory and consultation bodies, EURL ECVAM's collaboration with various partners in the EU and globally; as well as overhead costs. Around 2% of EURL ECVAM's budget in 2012-2016 have been spent for specific studies conducted by external contractors to speed up deliverables of special policy interest.

The major contributions of ECVAM towards the regulatory use of alternative methods are described above in the section on test method development, validation and OECD test guideline development. Furthermore, EURL ECVAM contributed substantially to the FP7 research initiative SEURAT-1, cosponsored by the European Commission and Cosmetics Europe, which has been completed at the end of 2016. This initiative gathered more than 70 EU partners and aimed at animal-free safety assessment of chemicals for

repeated dose toxicity. Currently, EURL ECVAM is collaborating with the recently started Horizon 2020 funded projects EU-ToxRisk and EuroMix.

2.1.3.3 Other funding

During the reporting period, the Commission has contributed to the development of standardised and internationally agreed test methods through two grants to the OECD test guideline programme. For the periods 2014/2015 and 2016/2017 a contribution of 800,000 Euro was given twice towards the development of guidelines for the testing of chemical, endocrine disruptors and nanomaterials. During these periods, approximately 50 new or updated test guidelines as well as several guidance documents were agreed by OECD. The contribution also benefitted the work on Integrated Approaches to Testing and Assessment (IATA) (including IATAs for skin and eye irritation with high relevance for data generation under REACH) and Adverse Outcome Pathways (AOP), which are expected to play an important role in defining future alternatives testing approaches.

2.1.3.4 Furthering Alternatives through EPAA

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a public-private initiative between services of the European Commission (DG GROW, ENV and SANTE) and European industry stakeholders from eight sectors. All EPAA activities serve the so-called '3Rs principle' to replace, reduce and refine animal testing. The focus of EPAA's core activities through various projects lies in the promotion of regulatory acceptance of alternative methods.

EPAA projects related to the REACH Regulation are:

- *3D skin models to assess the potential for skin sensitisation*

3D skin models better mimic the skin structure and organisation and offer advantages as the substances can be applied to the model skin. However, the utility of these models for the evaluation of hydrophobic or “difficult to test substances” is unclear. The objective of the project is therefore to evaluate the three most advanced 3D skin models for their reliability for skin sensitisation prediction. Qualification of the three 3D skin methods has already begun using a battery of 12 ”difficult to test substances” selected by industry. Preliminary results are expected in early 2017.

- *Acute Toxicity - Identification of clinical signs predictive of mortality*

The REACH standard information requirement for the endpoint of acute toxicity by the oral route is the most common testing requirement and therefore this route has been prioritised by EPAA. This EPAA project has identified opportunities to waive the acute toxicity animal testing requirements completely or, where this is not possible, to refine the decision-making steps or assessment strategies so as to minimise suffering of animals. Recommendations on a 3Rs-based classification & labelling decision framework to include replacement of death as an endpoint have been drafted. Additional evidence is being developed through data mining and analysis of previous acute, oral

toxicity studies in collaboration with the UK National Centre for the 3Rs (NC3Rs) and the UK Chemicals Regulation Directorate.

In 2016, more than 450 previously filed acute toxicity studies have been screened and data from more than 100 of these have been collected. The data are now being analysed statistically to determine their quality and adequacy. The objective is to establish that clinical signs (evident toxicity) are predictive of mortality in acute oral toxicity studies and are an appropriate alternative to death as an endpoint.

3 Communication of information in the supply chain

Baseline

The main tool to pass on information down the supply chain, the safety data sheet (SDS), existed prior to REACH. REACH changed the sequence of certain sections of the SDS to align it to the world-wide SDS standard established in the UN Globally Harmonised System. REACH also introduced the requirement to annex exposure scenarios to the SDS.

The REACH registration process ensures greater availability of data. For instance, REACH introduced the obligation to generate so-called chemical safety reports for substances in volumes above 10 tonnes, which must include information on identified uses and uses advised against. REACH requires that such information must be passed on in the supply chain so that downstream users have adequate knowledge on how to use substances safely. If downstream users want to use them in a manner advised against or for a use outside the conditions described in the exposure scenarios, they need to prepare a chemical safety report themselves for those uses.

It was therefore expected that REACH would improve the content of the SDSs and thereby the management of risks by the users of the SDSs. In addition, REACH requires that exposure scenarios for identified uses are attached to the SDS – turning these into the so-called 'extended SDS'. The extended SDS thereby aims at increasing the amount of information available so that the necessary environmental, occupational safety and health measures can be implemented by downstream users.

Conclusions of the 2013 REACH Review

The 2013 REACH Review identified an increase of information in the supply chain. This was resulting in more appropriate risk management measures and thus contributing to risk reduction. However, the Review also recognised the need to address some shortcomings, particularly by improving the practical usability and readability of exposure scenarios annexed to the SDSs. Thus, a recommendation was made to ECHA and industry to address problems related to the compilation, communication and use of exposure scenarios annexed to the SDSs and thereby promote them as a central risk management tool.

Under REACH, downstream users became active players and a central source of information on different aspects concerning the use of substances. However, the 2013 Review recognised that, due to the wide range of downstream users, levels of awareness and knowledge of chemicals legislation vary and should be raised.

3.1 Developments after the 2013 REACH Review

3.1.1 Information in the supply chain, practical tools and support to downstream users

In November 2011, ECHA created the Exchange Network on Exposure Scenarios (ENES)[102] to share good practice and identify solutions for the generation, communication and implementation of REACH exposure scenarios with the aim to enable the exchange of information up and down the supply chain. ENES participation has to date consisted of individual companies, 28 industry sector associations (manufacturers, formulators and downstream end users of chemicals) themselves representing many thousands of companies at European level, consultants, NGOs and competent authorities from 15 Member States although the participation is open to all. Ten ENES meetings have taken place with a network community of more than 200 contacts[103].

A cross-stakeholder action plan, the Chemical Safety Report/Exposure Scenario Roadmap (CSR/ES Roadmap)[104] was published in July 2013, containing 21 actions in five priority areas designed to improve the quality of information in REACH chemical safety reports and extended safety data sheets. The latest implementation plan was published in July 2015[105].

Industry organisations, including downstream users associations of many relevant sectors have worked intensively with their associates and collaborated with ECHA in developing an extensive set of tools to simplify and harmonise the elaboration of exposure scenarios for the chemical safety report and their incorporation in the SDSs.

To a large extent the work done under the CSR/ES Roadmap and ENES has contributed to raising awareness and knowledge among downstream users of their obligations under REACH.

As illustrated in Figure 4.6, a number of tools intended to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS, including exposure scenarios, have been developed by ECHA and also under the umbrella of ENES and the CSR/ES Roadmap with its stakeholders:

- Templates with a recommended structure for different types of exposure scenarios (i.e. for industrial, professional and consumer uses)[106] and describing the type of information that should be included in each section. The use of templates may help registrants to understand how to structure the exposure

[102] https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

[103] In the last meeting of ENES (ENES 10) in November 2016 it was announced that the ENES programme would be run for an additional 4 years (from 2017 – 2020).

[104] https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

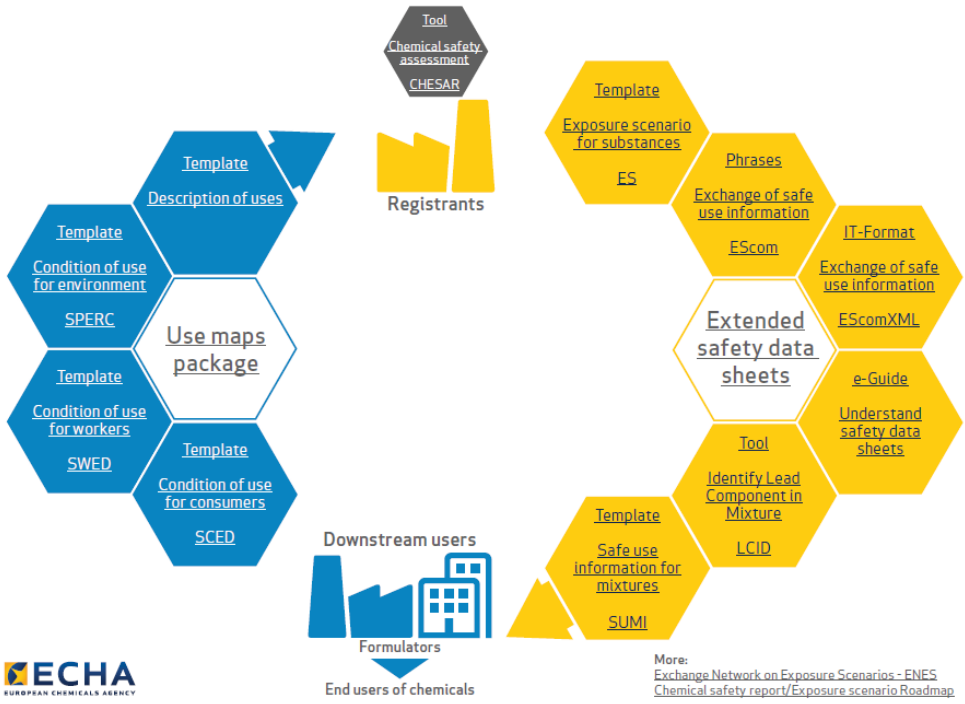
[105] https://echa.europa.eu/documents/10162/15669641/updated_csr_es_second_implementation_plan_en.pdf/3b375df6-df87-4db4-98b7-ec2fc770bca9

[106] http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

scenarios for optimal communication and encourage a move towards a harmonised format within the industry.

- ECHA has developed a specific IT tool – CHESAR (CHEmical Safety Assessment and Reporting) - to enable the elaboration of chemical safety assessments in a systematic way and to achieve and maintain consistency between the information in the registration dossiers and the advice on safe use communicated with the safety data sheets.

Figure 4.6: Improving communication on the safe use of Chemicals [107]



- Guide on safety data sheets and exposure scenarios[108];
- Practical Guide on how downstream users can handle exposure scenarios[109]
- Practical examples of exposure scenarios and of chemical safety reports such as [110,111]:

[107] ECHA website https://echa.europa.eu/documents/10162/15669641/safe_use_chemicals_en.pdf

[108] https://echa.europa.eu/documents/10162/22786913/sds_es_guide_en.pdf/b5e90791-68a0-4ad3-8769-6b3a17e61c36

[109] https://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf/2c3bc624-fb3c-4515-a581-87b79d460d38

[110] https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

[111] https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

- Illustrative examples of exposure scenarios to be annexed to the safety data sheet were developed and published;
- Exposure scenario for CSR. An example of consumer exposure to substances in articles;
- Examples of exposure scenarios for the semiconductor industry, for the professional use of a substance in floor coatings and for consumer use of a substance in cleaning products have been developed and published by ECHA in collaboration with the relevant sector associations which are currently under review.

- Guidance to support a harmonised approach for the creation and structuring of exposure scenario short titles ('Structured short titles in exposure scenarios for Communication')[112], including guidelines for implementing this approach in software applications used for compiling and issuing SDS.

- The use of standard phrases, allowing the efficient and consistent creation of harmonised text paragraphs for SDS and exposure scenarios, which will ease electronic data transfer of standardised phrases between suppliers and their customers and also facilitate the translation of documents into other languages. The ESCom package[113] for the exchange of exposure scenarios data between IT systems has been developed to enable consistent communication of exposure scenarios information throughout the supply chain. The package consists of two components: i) ESCom XML standard, the XML format; ii) ESCom standard phrase catalogue, covering the standard phrases for exposure scenario content.

- Use maps[114] describe the uses of chemicals in a harmonised and structured way and are typically generated by downstream users' sector organisations. A use maps package containing four templates was produced: one for the general description of the uses and three for the information needed to carry out exposure assessments. Separate templates exist to report the inputs for the exposure assessment for workers (SWEDs), the environment (SPERCs) and consumers (SCEDs).

- The top-down approach to communicating safe use information for mixtures, known as LCID (lead component identification methodology)[115], and the sector-specific, bottom-up, approach for deriving information towards developing and communicating safe use of mixtures for end-users, known as SUMI (safe use on mixtures information)[116].

[112] http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and Tools/StructuredShortTitles04112014.pdf

[113] http://www.cefic.org/Industry-support/Implementing-reach/escom/

[114] https://echa.europa.eu/csr-es-roadmap/use-maps/

[115] http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/REACH-Practical-Guide-on-Safe-Use-Information-for-Mixtures-under-REACH-The-LCID-Methodology.pdf

[116] http://www.ducc.eu/documents/Sector%20specific%20approaches%20towards%20developing%20and%20communicating%20information%20for%20the%20safe%20use%20of%20mixtures%20FINAL.pdf

The improvement of exposure scenarios through all these different tools should help downstream users to have a more comprehensive understanding of the information included in the SDS, to better communicate this information up and down the supply chain and ultimately to make better use of the information to improve safety.

Additionally, in the first quarter of 2016, ECHA developed and consulted on a Downstream User Communication Strategy for 2016-2018, which aims, among other things, to provide user-friendly, comprehensive information for downstream users on their roles, obligations and the tools that are available to help them. The tools described above are available on ECHA's downstream user website, to motivate downstream users to make best use of information coming down the supply chain and to encourage them to demand good quality.

A Progress Report on the implementation of the chemical safety report/exposure scenario (CSR/ES) Roadmap was published in March 2014[117]. According to an ECHA evaluation in 2016[118], industry views the Roadmap products as being critical in ensuring that the exposure scenarios are relevant and consistent, although many SMEs downstream user (DU) groups consider that further simplification of the communicated Exposure Scenario and extended SDS information would be beneficial. There is also some frustration about ENES tools not being consistently adopted and/or maintained by different industry sectors/companies/consortia. A number of recommendations for future work resulted from that assessment. In summary:

- Implementation and consolidation work should be carried out to maximise the take up and use of ENES products. Attention should be directed to those sectors not engaged in ENES or which are slow adopters of the tools
- Communication - ENES should produce and deliver a Communication Plan to actively promote the work of ENES/CSR Roadmap to Member States and Industry, particularly those currently not involved
- Targeted marketing – there is a need for the currently available products to be marketed to different actors.
- Expanded skills - the skill set of ENES, consistent with the requirements of targeted marketing, needs to be enhanced.

A SDS checklist[119] has been developed by ECHA in cooperation with the Forum for Exchange of Information on Enforcement (Forum). It has been designed from an

[117] https://echa.europa.eu/documents/10162/15669641/csr_es_progress_report_first_en.pdf/0662efa1-6510-4445-8d9d-f53c1d3f19d7

[118] The evaluation reviewed the programme from inception to implementation and included an internal ECHA staff survey and an external survey of industry and Member States (done by an external contractor - https://echa.europa.eu/documents/10162/22771348/external_evaluation_report_en.pdf/9f87dfe6-8670-4a12-b137-85991522955c).

[119] https://echa.europa.eu/regulations/reach/safety-data-sheets/checklist

inspector's point of view, to support the examination of the main body of a SDS compiled under REACH. The checklist was made public to meet the more general objective of improving the quality of safety data sheets in the supply chain.

At the end of 2015, the Forum agreed on launching a REACH Enforcement Project (REF-5) focusing on obligations related to safe use advice in extended SDSs (description of operational conditions and risk management measures). The key element of the project is to investigate how the outcome of the REACH chemical safety assessment – the conditions of use in the exposure scenario – is communicated consistently and clearly along the supply chain from the registrant to the downstream end user of a substance or mixtures. As of January 2017 and throughout the year, REACH inspectors of the EU Member States will check if the extended SDSs contain safety information which matches the information in the chemical safety report. A report on the results of the inspections is expected to be available by the end 2018.

From the perspective of legislative developments, it should also be mentioned that Annex II to REACH was amended by the Commission in May 2015[120] to adapt the requirements for SDSs in accordance with the fifth revision of the GHS rules for SDSs and to rectify inconsistencies due to past amendments.

3.1.2 Additional findings on how to improve communication through SDS

ECHA further recommended[121] that:

- downstream users, supported by their sector organisations, should demand good safe use information as it is the mechanism foreseen under REACH to mobilise actors upstream in the supply chain. This should be combined with efforts to enlarge the communication networks and communication means to reach more companies within supply chains.
- industry organisations should actively engage in facilitating dialogue along the supply chains. The traditional horizontal organisation in sector groups and Substance Information Exchange Forums (SIEFs) should be complemented with dialogue in the supply chain to better address the supply chain specific needs and challenges in generating and communicating safe use information.
- exposure assessment tool owners and relevant industry organisations should foresee resources for the maintenance and evolution of IT tools to facilitate chemicals safety assessment and to communicate information on use and conditions of use up and down the supply chain. The need to update chemical safety assessments and further improve communication in the supply chain will not stop after the last registration deadline in 2018.

[120] Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 132, 29.5.2018, p. 8).

[121] Report on the Operation of REACH and CLP 2016 by European Chemicals Agency, May 2016.

Further evidence was also obtained from two Dutch studies[122] which pointed out difficulties in achieving effective communication in the supply chain as well as in the dissemination and use of SDSs and extended SDSs. It was reported that 25-50% of companies participating in the surveys had no SDSs or those they had were outdated, that 75% of SDSs examined were of poor quality and that, of those, less than 20% had exposure scenarios annexed.

In a Conference organised in 2016 by the then Dutch Presidency of the Council,[123] the following conclusions as regards "Communication in supply chains about substances and mixtures" were drawn:

- The quality and usability of SDS has to improve;
- A more practical approach for SMEs is needed, with automated and tailor-made information per type of user;
- Broader implementation of ENES-tools is needed;
- The establishment of a legally required format for exposure scenarios should be considered;
- Market demand for good SDSs should be reinforced (also in cases without exposure scenarios) and REACH information should be communicated as part of a wider perspective (such as occupational safety and health).

One Member State reported on a national inspection campaign in the metal surface treatment sector[124] where 87% of the companies visited were in possession of the mandatory SDS. However, only 37% of the companies visited had extended SDS. It was mentioned that a reason for this low percentage could be the fact that the majority of the products used in the sector are mixtures for which there is no obligation to draw up an extended SDS. Nevertheless, the information on safe use provided in the exposure scenario of each substance should be converted and used to produce information for the mixture containing specific substances. Although some tools exist for this purpose, the practical transfer of exposure scenario information into the safety data sheets for mixtures is still in a very early stage and requires formulators to have an in-depth knowledge of the substances involved and be highly skilled in the use of the different methodologies. It was also reported that only 1 in 4 employers were aware of the obligations when receiving an extended SDS.

[122] Impact of REACH on SMEs by Panteia and IVAM (2013) analysing the situation of SDSs and a survey performed by the Dutch Workplace Inspectorate (SWZ) in 2014-2015.
[123] REACH forward conference organised by the Dutch presidency on 1 June 2016.
[124] http://www.emploi.belgique.be/defaultNews.aspx?id=44990

3.1.3 Additional finding on the costs of extended SDS

The study on monitoring the impact of REACH on innovation, competitiveness and SMEs[125] provided estimates of the costs of producing and translating extended SDS as part of the 2013 registration activities. The average costs related to SDS (per registered substance) were estimated at EUR 36,358, which is higher than the estimate in the Impact Assessment accompanying the REACH proposal (EUR 19,844).

In order to provide an estimate of the 'typical' costs borne by companies, the study provided median costs per substance and per registrant for substances registered in the 100-1,000 tonnage range. These were EUR 5,763 for producing extended SDS and EUR 4,473 for translation. Furthermore, these figures show that the median costs were somewhat higher for SMEs (EUR 11,899 as the total of producing extended SDS and translation) than for large companies (EUR 8,016).

The business survey conducted for that study revealed that around 50% of companies adopted changes in risk management measures on the basis of information received via extended SDS. This proportion was higher for companies that are primarily manufacturers of chemicals and formulators (respectively 51% and 70%) and relatively lower for companies further down the supply chain (from 48% for distributors to 27% for suppliers of articles[126]). However, these risk management measures' changes usually comprised only the introduction of additional personal protective equipment (20 % of companies) or modified safety instructions (12 %); measures that are low in the hierarchy of measures to be applied under occupational safety legislation[127].

In terms of obligations related to extended SDS, the survey indicates that a significant share of companies, in particular SMEs, were not aware of methods and options that can be used to consolidate information received via extended SDSs for individual substances into their own SDS for mixtures (63.9% among SMEs and 43.6% among large companies). Respondents also flagged gaps in the information flow via the extended SDS, suggesting that especially not all formulators provided information on the safe conditions of use of mixtures.

In summary, the study concluded that the introduction of extended SDS has led to improvements in communication and more transparency in the supply chain. Another benefit identified was that information shared via the SDS helps companies to improve their risk management measures and can also be useful for new product conception, development and commercialisation. On the other hand, especially SMEs appeared to consider (extended) SDSs as a burdensome tool which is too technical to be fully understood.

[125] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (CSES, RPA, Okopol 2015) http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations

[126] For the purpose of the survey, 'suppliers of articles' is to be understood as comprising manufacturers, importers and distributers of articles.

[127] OSH legislation envisages the use of PPE only if elimination of the hazard or other technical measures are not possible.

The findings are further complemented by the results of the survey on the REACH REFIT evaluation carried out with the SME panel where 40% of respondents considered the obligation to transmit information along the supply chain (which includes management of extended SDS) as a considerable/very important challenge and a further 30% saw it as a slightly/moderately important challenge. Furthermore, 23% of respondents considered the costs incurred in this respect as considerable/very important and a further 37% as slightly/moderately important.

3.2 Stakeholder views

Comments related to information in the supply chain were essentially focused on extended SDS and exposure scenarios. Some of the respondents indicated that information included in SDS was often not targeted enough to the needs of the downstream users, either because the SDS is too lengthy and technical, or not providing enough practical information to adopt risk management measures. A few respondents also stated that the quality and clarity of exposure scenarios was very variable and often did not reflect the practical uses of a substance. One of the reasons provided by respondents is that manufacturers use a variety of templates, which creates difficulties for downstream users. A few respondents called for the establishment of a harmonised template for SDS and exposure scenarios. Some welcomed the work started under the CSR/ES Roadmap and supported its continuation.

A few respondents highlight that information generated under REACH, in particular the information in the SDS, should be better used under occupational safety and health legislation.

4 Information on substances in articles

Conclusions of the 2013 REACH Review

The 2013 REACH review recalled the need for a consistent and harmonised interpretation of the 0.1% concentration threshold of Substances of Very High Concern (SVHCs)[128] in articles[129]. Moreover, it reported shortcomings in the informing of consumers and professional users of articles, as well as difficulties for companies to adapt to the information obligations triggered after inclusion of new substances in the candidate list.

The REACH Review demanded that ECHA and Member State Competent Authorities launch support activities to raise awareness on the requirement to communicate the presence of SVHCs in articles in the retail sector and also to improve the communication.

4.1 Developments after the 2013 REACH Review

4.1.1 Interpretation of the 0.1% threshold

A number of requirements are set by REACH which concern SVHCs when these substances are present in articles above a concentration of 0.1% weight by weight (w/w). The application of these provisions was hindered by a disagreement on how to interpret the concentration threshold for complex products[130], which compromised the harmonisation of the internal market and hampered enforcement activities, and resulted in a referral to the European Court of Justice (ECJ) for a preliminary ruling. The ECJ, in its judgement[131] of 10 September 2015, clarified that the requirements of Article 7(2) (regarding notifications to be submitted to ECHA) and Article 33 (regarding communication in the supply chain and to consumers) of REACH need to be applied to each individual article, even if these articles are components of a more complex product.

This ruling made it necessary to revise the ECHA guidance on requirements for substances in articles. ECHA published a preliminary update, aligning the most relevant sections, in December 2015. A more extensive revision of the Guidance was subsequently undertaken. A draft version of the guidance was consulted with the Partner Expert Group (PEG) for this topic in July 2016 and the guidance has been published in June 2017[132]. Feedback from Industry stakeholders during the PEG consultation as well as during the public consultation for the REACH evaluation have pointed to challenges for manufacturers and importers of very complex products (e.g. airplanes, cars,

[128] i.e. substances that meet the criteria in Article 57 and are identified in accordance with Article 59(1)

[129] Threshold to be applied for the purposes of Articles 7 and 33

[130] The Commission and a majority of MS held the view that the concentration should be calculated on the basis of the total weight of the "complex article", while six Member States and Norway maintained the opinion that the SVHC content should be determined individually for every article contained as a component in such a complex product.

[131] Judgment of the Court (Third Chamber) in Case C-106/14. 10 September 2015, OJ C 363 from 03.11.2015, p.12 http://curia.europa.eu/juris/liste.jsf?&num=C-106/14

[132] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

electronics) in addressing the obligations for the high number of component articles present in these products.

The Commission services are currently assessing the impact of the ruling on the use of the term 'article' in the Annexes of the REACH Regulation, in particular on article-related restrictions in Annex XVII. Where the interpretation of 'article' as put forward in the ECJ judgement creates ambiguities, concerned entries may be clarified.

4.1.2 Information about the presence of substances in articles

Apart from the specific requirements in Articles 7(2), all Registration dossiers should, where relevant, include information on the use of the registered substance in articles, and where a chemical safety assessment is required, such uses, as well as the different stages of the life cycle, should be included in the assessment. The *Report on the Operation of REACH and CLP* 2016, however, states that the amount and adequacy of information in registrations dossiers for the safe use of substance in articles is still very limited. This was attributed to a lack of awareness of those obligations by duty holders, but also to uncertainty on how to correctly describe substance uses in articles and to document the safety of such uses, and how to adequately assess exposure from articles[133].

The obligation to notify SVHCs in articles to ECHA (Article 7(2)-(4)) was introduced to complement the information in registration dossiers, in particular for SVHCs present in imported articles. ECHA has made substantial efforts to facilitate the submission of such notifications by providing easy-to-understand guidance to duty holders[134] as well as by making available a web form[135] for users that are not familiar with the IUCLID format. Despite these efforts, the number of notifications received so far has remained limited. By the end of 2015, 359 notifications related to 38 listed SVHC had been submitted to ECHA[136]. This number had only slightly increased to 365 notifications on 39 SVHCs by 16 December 2016[137].

While it is difficult to estimate how many notifications there should be, this number is likely to indicate a low level of compliance. The reasons for the low number of notification are thought to be:

- a lack of awareness of duty holders
- difficulties to get appropriate information from (third country) suppliers,
- very broad descriptions of uses in articles in registration dossiers, which may (incorrectly) lead duty holders to the conclusion that their articles are exempt from the obligation to notify.

[133] Report on the Operation of REACH and CLP, ECHA 2016
[134] https://echa.europa.eu/documents/10162/22308542/manual_subs_in_art_notif_en.pdf/71b39d03-d140-418c-830e-896f281bb9bb
[135] https://reach-forms.echa.europa.eu/sia/sia.php
[136] Report on the Operation of REACH and CLP, ECHA 2016
[137] https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table

4.1.3 Communication on SVHCs in articles

The obligations in Article 33 to communicate the presence of SVHCs in articles allows operators in the supply chain to implement appropriate risk management measures as well as enabling operators and consumers to make informed purchasing decisions.

There are some signs that actors in the supply chain take the obligations in relation to SVHCs in articles seriously. The study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs reports that, regardless of their role under REACH, about 55 % of firms included in the survey had started to implement IT-systems to monitor SVHC in products. Over 60 % of the firms that received articles validated the information on the SVHC content with chemical analyses for the articles they supply. Companies that receive articles often demand the absence of SVHCs, or they may set via conditions in their purchasing contracts more detailed substance restrictions or information disclosure requirements on the content of hazardous substances in articles supplied to them. This constitutes an incentive to other actors in the supply chain to be REACH compliant and provide an effective co-operation. NGOs and trade unions have stressed the importance of Article 33 in having an effect on the use of substances in supply chains by being an incentive to substitute SVHCs in consumer products.

While the study indicated an improvement in communication on SVHCs, it also pointed to important gaps in implementation. In this context, respondents flagged challenges such as the relatively large administrative burden related to tracking of SVHCs, a lack of awareness about the obligation and limited availability of information from suppliers, difficulties with communicating information in case of complex supply chains (especially when reaching outside the EU) and a lack of confidence in information received, leading to the need of verification information by testing. ECHA also reported similar problems for article suppliers in receiving, generating and monitoring information on SVHC in their articles[138]. Stakeholders had also been raising difficulties and administrative burdens (e.g. requests for so-called "REACH certificates") that Article 33 entails for retailers and SMEs.

A functioning transfer of information in the supply chain is necessary in order for suppliers to be able to respond to consumer requests according to Article 33(2). In the past years, companies and industry associations have developed various systems to facilitate the management and transfer of information on chemicals in articles and enhance compliance with regulatory requirements in Articles 7 and 33 of REACH[139,140]. Such supply chain tools are currently mostly industry-sector specific, but some may have the potential for wider uses. In 2015, ECHA carried out a feasibility study on a Materials Information Platform, aimed as an additional tool to support economic operators in identifying SVHCs potentially present in their articles. Due to difficulties in collecting the necessary input data, the development is presently not further pursued.

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[138] ECHA 2016. Report on the Operation of REACH and CLP.

[139] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[140] Interim study " Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH"

Nevertheless, concerned actors, and the retail sector in particular, frequently report that they do not receive adequate information from their suppliers. On the other hand, according to findings of the study on Monitoring the Impacts of REACH on Competitiveness and Innovation, a significant proportion of business operators has been required to communicate information on the presence of SVHCs in articles (45.5 % of all firms), with this proportion broadly increasing when going down the supply chain. Around 57% of respondents had installed specific IT systems in order to monitor SVHC in products and answer to costumer questions in this regard.

However, retailers who make investments to collect and manage such information, often perceive these efforts as superfluous, as they do not experience a high level of interest by consumers for such information[141]. On the other hand, there are indications that the awareness by consumers about their "right to know" may be slowly increasing. In a 2016 Eurobarometer survey[142] 66% of EU citizens said they are aware that "if you ask whether a product contains particularly hazardous chemicals, the seller is required by law to provide you with this information". In a few countries, authorities and NGOs[143] have put in place tools to inform citizens about the presence of SVHCs in consumer articles. These are web-based or mobile applications to retrieve available knowledge on substances present in an article (usually by scanning the bar code), and/or to facilitate the submission of a consumer request to article suppliers. Such tools are usually accompanied by awareness raising campaigns. However, the scope of Article 33(2), limited to articles and hazardous substances identified as SVHC, seems to be little understood and consumer requests concern issues not covered by the requirements (e.g. mixtures) or outside the scope of REACH (e.g. food products). An EU-wide project to raise awareness and to develop IT-tools to facilitate information transfer between suppliers and consumers is running under the Life+ programme.

One aspect that has been identified as impairing efficient communication is a lack of centralised information flow on SVHCs in articles. The information generated and communicated in the supply chains through Article 33 is not available for national or EU authorities, preventing a comparison and plausibility check with information available from registration and notification. The information communicated following consumer requests is not centrally collected and accessible, thereby potentially increasing the burden for suppliers by repetitive consumer requests.

During the reporting period, only a few Member States (MS) have undertaken enforcement activities in relation to substances in articles[144], likely due to the uncertainties linked to the interpretation of the 0.1% threshold. The information on non-compliance found during these controls is available from the report, is limited and highly variable, making it difficult to draw reliable conclusions. A few projects of limited scale

[141] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[142] Link to the Eurobarometer survey on chemical safety

[143] https://www.bund.net/themen/chemie/toxfox/, http://tjekkemien.dk/hj%C3%A6lp-til-virksomheder/information-english, www.reach-info.de/verbraucheranfrage.htm

[144] Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting , Milieu 2016

for which more information is available[145] highlighted a significant proportion of non-compliance with the legal requirements. A study on CMR substances in construction products also reported a high number of irrelevant or lack of responses to requests according to Article 33(2)[146].

A lack of enforcement as regards imported articles (for example articles which contain SVHC), as well as the lack of valid test methods for SVHC contents in articles were identified as important issues to tackle by surveyed companies in the study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs[147].

A pilot project in the context of the ECHA Enforcement Forum planned for 2017/2018 is expected to deliver more information on compliance issues with the requirements of Articles 7(2) and 33(1) as well as indications of which legal provisions and/or economical actors could benefit from further specific support from ECHA, the Commission or Member States.

4.1.4 Other aspects related to substances in articles

The EU 7th Environmental Action Programme (EAP)[148] lists as one of its aims to *safeguard the Union's citizens from environment-related pressures and risks to health and well-being*, to minimise exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances". Likewise, the EU Action Plan for the Circular Economy[149] recognises that better tracking of chemicals of concern in products will facilitate recycling and improve the uptake of secondary raw materials.

The current REACH requirements in Article 33 address only communication of information on the presence of SVHCs included in the candidate list in articles in the supply chain and to consumers. They do not contain provisions for the transfer of information on the chemical content of end-of-life articles to the waste management sector[150]. Waste treatment operators are not considered downstream users under REACH, but rather as manufacturers of substances/mixtures or producers of articles when the result of the waste treatment operation reaches end-of-waste status. Therefore, information on the chemical content of end-of-life articles is not usually available to waste treatment operators, except for some specific cases covered by waste legislation. The presence of substances of concern and the tracking of these substances has been

[145] http://www3.kemi.se/Documents/Publikationer/Trycksaker/Tillsyn/Tillsyn_6_12.pdf; http://kemi.taenk.dk/bliv-groennere/test-plastic-products-contained-unwanted-phthalates

[146] Scoping study for the application of Article 68(2) of REACH to construction articles containing CMR substances with likelihood of consumer exposure. EC, 2016

[147] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[148] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet (OJ L 354, 28.12.2013, p.171).

[149] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Closing the loop - An EU action plan for the Circular Economy. COM(2015) 614, 2.12.2015.

[150] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme, Milieu 2017

identified as an issue that needs to be examined further in the context of the implementation of the Circular Economy Action Plan in order to facilitate clean material cycles and to advance towards a circular economy.

Furthermore, the notion that a better knowledge and communication about substances in articles is an important aspect of chemical management is not limited to the EU but has also gained momentum in other countries and at international level. Under the framework of the **S**trategic **A**pproach to **I**nternational **C**hemicals **M**anagement (SAICM), chemicals in products have been identified as a priority policy issue, and SAICM has set up a "Chemicals in products" programme[151], which aims at developing practical solutions for information transfer on the presence of chemicals in products for several priority product categories (electronics, toys, building products and textiles). In Japan, an industry initiative to expand the utilisation of a communication tool initially developed by the electronics industry to other sectors is supported by the government with the view to make it available also across geographic boundaries[152]. Such work is expected to facilitate the implementation of Article 33 of REACH.

4.2 Stakeholder views

In the public consultation for this evaluation, the topic of substances in articles was frequently addressed, mainly by industry respondents. Overall, respondents agreed that the current provisions on communicating about substances in articles do not work well and that in particular the awareness among consumers about their rights is low.

Many responses from industry commented that the ECJ ruling on the application of the 0.1% threshold to each article in complex products places a disproportionate burden on businesses and called for more guidance to facilitate implementation, frequently stressing that notification obligations should be proportionate and feasible for companies. Several expressed the opinion that requirements for substances in articles should only apply to individual articles within complex assemblies where the information is needed for a safe use. One position paper called for a transition period between the moment a substance is placed on the Candidate list and when the communication requirements of Article 33 become applicable.

On the other hand, NGOs and public authorities, but also some submissions by industry called for improving the information communicated in the supply chain, to enable consumers to make conscious choices, to make the information directly available to consumers, to strengthen awareness raising activities among consumers, to support companies who invest in substituting chemicals of high concern by safer alternatives, and to improve traceability of such substances in recycled materials to ensure that these comply with legal requirements. Some of these respondents also proposed to amend Article 7(2) to introduce notification requirements of all SVHCs substances in articles irrespective of tonnage (from 1 kg/year), or at least to lower the tonnage, or a compulsory content declaration for all consumer goods. Another solution proposed was to label

[151] http://www.saicm.org/index.php?option=com_content&view=article&id=454&Itemid=707
[152] https://chemsherpa.net/chemSHERPA/english/

articles containing SVHC. Further submissions suggested to extend the scope of Article 33 to articles containing any substance that meets SVHC criteria present above 0.1% and to clarify that "sufficient information" should include the background for the substance being an SVHC and the appropriate risk management measures.

5 Dossier and substance evaluation

Conclusions of the 2013 REACH review

At the time of the 2013 REACH review, the dossier evaluation process had started to deliver in accordance with the envisioned aims. ECHA examined all testing proposals for substances registered by 2010 within the legal deadline of 1 December 2012 and issued a number of compliance check decisions as well as quality observation letters[153]. It was however too early to identify its positive impacts, assess the effectiveness of the process or the appropriateness of its drivers e.g. the 5% compliance check target set in Article 41 of REACH. Some recommendations were identified in the area of dossier selection, better targeting of compliance checks and improving efficiency of the processes.

Substance evaluation had only just started at the time of the 2013 review; the first Community Rolling Action Plan was published on February 2012, listing 90 substances on the basis of potential concerns for action in the three-year period 2012-2014. As the number of substances selected for substance evaluation was significantly lower that the initial expectation, Member States competent authorities were encouraged to enhance their capacity in relation to substance evaluation, so that more substances could be evaluated.

5.1 Developments after the 2013 REACH Review

The developments of the evaluation process can be presented in terms of its outputs such as the number of evaluation decisions and the volume of data generated as a consequence of the evaluation activities. The parameters used to assess the efficiency of the process include the time and resources required for the processes to deliver, the performance of individual steps (preparation of the individual evaluation decision, number of appeals, follow-up) as well as the measurement of positive trends, consequence of improvements introduced as experience has been gained in the process.

Effectiveness can be assessed both in terms of the amount of data generated and included in dossiers as well as by determining the contribution of the evaluation process to achieving the objectives of REACH, e.g. does it trigger the risk management measures where needed? All these points are explored in the subchapters below.

5.1.2 Expected and actual effort on dossier and substance evaluation

Evaluation under REACH was designed to be a procedure that responds to the data received under registration. While the main evaluation targets (and therefore the expected

[153] In certain cases ECHA was sending a quality observation letter (QOBL) to the registrant that included observations on the identified deficiencies in the dossier that had however not been included in the decision. The practice has been discontinued in the following years.

evaluation baseline) can be determined from the legal requirements[154], the expectations that it will deliver in terms of follow up to registration were reflected in the assumptions underlying the ECHA staff model[155] developed prior to REACH implementation.

The annual workload on average over 2014-16 was estimated[156] [at the time of adoption of REACH] as:

- for ECHA, 86.2 FTE per year for evaluation (proper) and a further 7.3 FTE in decision making (work of committees and support to Committee work).
- for the Member States, 42 and 44 FTE respectively,
- for the Commission, 7 and 9 FTE.

These estimates were built on the projection that by 2016 (inclusive):

- 1182 **compliance checks** would have been performed, with approximately 250 compliance checks performed annually from 2014 onwards. It was estimated that, in parallel, the chemical safety assessment would be checked for all examined dossiers in tonnage >10 tonnes.
- 4868 **testing proposals**[157] would be examined, peaking with ca. 1500 examined in 2011.
- **Substance evaluation** was expected to start in 2012 with first 50 substances evaluated, and with continuous annual evaluation of further 99 substances, leading to an estimated total of 448 substances by 2016.

Throughout the last five years, dossier evaluation has been a resource-intensive exercise for ECHA, which estimates that annually 59 FTE are used[158] for dossier evaluation

[154] All testing proposals must be examined, compliance check of 5% of registration dossiers, and no specific numerical target for substance evaluation.

[155] Common reference ECHA staff model

[156] These estimates were based on a number of assumptions, for example with regard to the fraction of non-compliant dossiers (30%), fraction of all registered substances that would be expected to be subject to substances evaluation (2%), dossiers under evaluation that would receive comments that would require modification (25%), and fraction of conflicting cases that would be forwarded to the Commission (5%). The 'evaluation (proper)' roughly corresponds to the expert assessment and engagement work required, while the 'further decision work' to the additional administrative resources required. In this estimation substance evaluation work by member States is fully accounted for (in present evaluation actual figures are not available), and the resources required by the Commission when draft decisions are passed to it following Article 51(7) are assumed also for the assessment. In practice, the expertise in these cases is mainly drawn from ECHA by the Commission.

[157] This reported number is unusually high: upon further analysis, the estimation seems not to take sufficiently into account data sharing incl. submission of testing proposals in joint submissions and not individually. For example, 20% of 17.500 dossiers are assumed in the estimate for 2010 deadline (substances >1000 tonnes), which is very accurate, however 82% of these are member registrations; estimate should be closer to 630.

[158] Reference: disaggregated numbers from internal ECHA Annual Workplan 2017, based on ECHA Programming Document 2017-19). It should be noted that in addition to the specifically assigned 'case work', additional 13.5 FTE are required in related evaluated tasks, and that for example HelpDesk and litigation also attribute certain proportion of their resources to evaluation.

across ECHA[159]. The selection and allocation of dossiers is estimated to require 18% of resources, scientific assessment 28%, drafting of the decision 20%, decision making[160] 26% and the follow-up an additional 8%.

Resources required for substance evaluation in the Member States are difficult to assess as no consistent information is available on the time required by the Member State competent authority that performs the assessment. To coordinate the process and the decision making with member states, 13 FTE are required in ECHA alone.

5.2 Dossier evaluation

5.2.1 Main outputs of the Dossier evaluation process

Principal outputs of the evaluation process can be presented by the statistics presented in the Table 4.3.

Table 4.3: Basic evaluation statistics and outputs

	2009	2010	2011	2012	2013	2014	2015	2016	Total	Baseline estimate
Testing proposal examinations										4856
Adopted testing proposal examination decisions	1	4	22	171	111	129	194	116	748	
Terminated examinations (before draft decision)	0	1	51	52	9	24	45	28	211	
Terminated at the draft decision stage	0	2	7	32	32	11	14	17	121	
Compliance checks										1182
Adopted compliance check decisions	0	12	105	66	159	273	144	152	911	

[159] Directorates E,C and B.

[160] Includes interaction with registrant and MSC agreement seeking.

Quality observation letters(a)	7	33	19	1	1	0	0	0	61	
Concluded without administrative action(b)	7	24	18	117	361	111	33	16	691	
Terminated after draft decision(c)	0	1	10	14	121	137	59	35	378	
Substance evaluation	-	-	-	-						448
Adopted substance evaluation decisions					2	24	30	26[(d)]	82	
Concluded without decision									50	

(a) Quality observation letters provided observation on weaknesses of the registration dossier but did not constitute a legally binding request.
(b) Conclusion without administrative action indicates that no further action was considered necessary e.g. as compliance was established.
(c) Termination after draft decision implies that the initial assessment has been performed and draft decision prepared and communicated to the registrant, but the process has not led to a final decision, principally as the registrant has updated the dossier in meantime. The high numbers in 2013-14 indicate the many quick responses to single request draft decisions.
(d) Plus one CoRAP complimentary NONS substance.

The evaluation process has been constantly evolving since its launch, so as to improve its efficiency based on experience[161,162]. In particular, the evaluation process has been integrated into ECHA's Integrated Regulatory strategy[163], which took effect in 2015, and

[161] Improved understanding of the most frequent weaknesses of registration dossiers, the strive for efficiency and effectiveness, increasing body of experience including evaluation related Board of Appeal decisions and the external triggers such as European Ombudsman's enquiries drove continued development of the evaluation strategy and implementation from dossier selection to drafting of the decisions.

[162] ECHA has been organising evaluation workshops on semi-annual basis to discuss the process with member states and stakeholders. Their content and conclusions can be found on ECHA's evaluation website.

[163] ECHA Integrated Regulatory Strategy.

so is cohesive with the processes supporting the development of risk management measures. A common screening process is applied to all substances and registration dossiers. Where potential concern is identified and the case prioritised, an action is determined to either 1) ensure compliance with standard information requirements (via compliance check), 2) clarify/confirm concern via listing on Community Rolling Action Plan (CoRAP) and eventual substance evaluation, or 3) direct initiation of regulatory risk management action (development of dossiers on harmonized classification, listing as substance of very high concern, or restriction).

The strategy places its main focus on the substances having exposure/release potential and high volumes and, as promoted already early in the development of evaluation process by the Commission, on higher tier (Annex IX and X) human health and environmental endpoints which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic), PBT/vPvB ((very) persistent, bioaccumulative and toxic) substances and substances of specific concern (e.g. respiratory sensitizers). Registrations of substances of highest concern are first examined in compliance check assessing the most important end-points for regulatory risk management.

Beside the changes brought about by the integrated regulatory strategy, the scope of information requested and the drafting of evaluation decisions have evolved with experience, implementing the learnings derived from the ECHA's Board of Appeal decisions and in response to external inputs such as those derived from the European Ombudsman's resolutions requiring a more proactive approach to implement the REACH provision requiring the 'testing on animals as a last resort' in compliance check and test proposal examinations[164].

By the end of 2016, 748 testing proposal examination decisions addressing around 600 substances[165] and 3642 registrants[166] were issued[167], with a further 332 examinations terminated without a decision. The main reasons to conclude without a decision were withdrawals of the testing proposal in subsequent dossier updates, inadmissibility of the testing proposals, identified availability of scientifically-relevant data or important administrative changes. All examinations were performed within the prescribed legal deadlines; 183 cases related to the extended one generation reproductive toxicity study (EOGRTS) required referral to the Commission; changes to the legal text were required before the final decisions could be adopted by the Commission. The remaining decisions are being adopted in 2017.

While fluctuating through the years, as can be seen from the table above, compliance checking had by 2016 achieved a mature stable output in line with ECHA's planned

[164] https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency/ombudsman/cases-animalt

[165] In some cases more than 1 decision is issued per substance.

[166] In large majority of cases, the testing proposal examination decisions are addressed to the lead registrant that includes the data of the joint submission for the substance in its registration dossier.

[167] Five testing proposal examinations were appealed, of which four were later withdrawn. In one case the Board of Appeal required that the procedure is re-launched.

annual output of around 220 compliance checks[168], which is also broadly in line with the Commission's baseline-estimate of ca. 250 compliance checks. Out of roughly 4,200 substances registered in volumes of over 100 tonnes, compliance checks in the period 2009-2016 led to 911 compliance check decisions[169] and addressed, through almost 2,000 compliance checks, over 1,500 substances which were assessed to various degrees of intensity[170]. By 2016 a total 10,918 registrants were directly affected by compliance check decisions.

The figures presented also illustrate ECHA's achievement of the second target set in Article 41(5) of REACH, concluding by the end of 2013 compliance checks on over 5% of the dossiers submitted by the 2010 registration deadline[171].

ECHA can take an evaluation decision only in case of unanimous agreement in its Member State Committee (MSC). Alternatively, the draft decisions are referred to the Commission for adoption. This happened in a total number of 219 cases, with 216 testing proposals and compliance checks jointly referred as 'EOGRTS cases' related to disagreement regarding the test design to address the information requirement on reproductive toxicity testing. Time and effort were required to bring legal clarity on this matter by insertion of EOGRTS in the Test Method Regulation, amendment of the REACH Annexes concerning the information requirements on reproductive toxicity testing, and the adoption of the supporting Guidance.

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[168] Planned output for 2017. The actual numbers vary from year to year also because of the evolving strategy which is steering the scope and selection of dossiers addressed, specific campaigns (e.g. on substance identification) and solutions found (e.g. Areas of Concern approach), and of course the revolving nature of the exercise, as the decisions are usually only finalised in year after the evaluation has been launched. For example, in 2014 ECHA adopted 273 compliance check decisions and closed 137 cases after draft decisions. In 2016, ECHA opened 181 new evaluations while 234 were carried over from the year before. Assessment was concluded in 184 cases (168 cases concluded in draft decision, 16 in no action). In the decision-making stage, 152 decisions were taken, 25 discontinued, and 195 maintaining in the decision making stage for 2017.

[169] Out of 911 decisions 43 were appealed, which led to 13 annulments by the Board of Appeal, while in other cases the appeal was withdrawn or dismissed. Four of the annulled decisions required re-start of the procedure, the 5 decisions related to nanomaterials are currently 'on hold' due to related revision of regulatory provisions, while in other cases the registrants provided further information and follow-up was not required.

[170] Source: ECHA's progress reports on Evaluation 2016 and aggregation with data on previous years. In addition to 911 compliance check decisions, 61 quality observation letter were sent, while 691 checks were concluded without administrative action and 378 terminated after draft decision. In total this would imply over 3000 addressed cases. Some substances were subject to multiple cases, or addressed to more than one registrant per registration number or joint submission.

[171] The legal target of 5% of dossiers per tonnage band checked for compliance does not include a deadline. ECHA set its own 2013 objective for the highest tonnage band. The 19.772 registrations covering approximately 2.700 unique substances provides a target of 989 compliance checks, which was exceeded by the 1130 concluded compliance checks by the end of 2013. These numbers must always be subject to interpretation: testing proposals as well as compliance check decisions were by a vast majority addressing lead registrants, and the number of accompanying member dossiers sharing the joined submission is in fact importantly larger. On the other hand, compliance check decisions varied in the scope/coverage, some being 'full' compliance checks, some only targeting compliance checks addressing a single information requirement.

5.2.2 Follow-up of dossier evaluation decisions

The follow-up to the ECHA dossier evaluation decisions is systematically performed on each decision after the deadline given in the decision to submit the requested information has passed.

Table 4.4: Follow-up of the dossier evaluations, basic statistics.

The numbers apply to decisions for which legal deadline expired in the particular year (not the decisions adopted in that year) and for which the compliance of the update was assessed by ECHA.

Follow-up	**2013[(e)]**	**2014**	**2015**	**2016**	**Total**
Testing proposal examination decisions					
Update compliant with decision (a)	71	88	88	103	350
Update compliant, but only after additional SONC (b)	1	11	23	15	50
Issued statements of non-compliance [SONC]	10	27	17	17	71
Non-compliance, new decision issued (c)	0	0		2	2
Total	82	126	128	137	**473**
Compliance check decisions					
Update compliant with decision(a)	70	117	136	179	502
Update compliant, but only after additional SONC (b)	5	19	11	22	57
Issued statements of non-compliance [SONC]	22	17	25	16	80
Non-compliance, new decision issued (c)	(d)	3		1	4
Total	97	156	172	218	**643**

a) Article 42(2) of REACH. Update considered compliant.
b) SONC – Statement of non-compliance
c) Article 42(1) Non-compliant, but instead of SONC, new compliance check decision is launched
d) In 43 cases requested data was provided but new data needed so 42(2) put on hold.
e) Follow-up evaluation was initiated already in 2011, with no conclusions. In 2012 out of 173 deadlines expired on dossier evaluations, ECHA prioritised 65 cases: 1 was found compliant, in 55 cases on substance identity further information was required, while in 9 other cases information was considered not compliant an passed to Member States for enforcement.

Follow-up now represents an important dimension of ECHA's evaluation activity. In 2016 alone, 612 follow-up evaluations of compliance with individual information requests were performed. In these, most deviations or non-compliances with the request were observed for the high tier pre-natal developmental toxicity study.

In 91% of compliance checks and 83% of testing proposal examination decisions cases to date, the data submitted were compliant[172] with the request set in the evaluation decision.

[172] In 2016 ECHA started to provide also more detailed information on the follow-up: of the 612 individual information requests evaluated in follow-up in 2016, 364 were found fully compliant, 201 compliant with deviations, and 47 non-compliant.

When the data submission was not compliant with the request in the evaluation decision, in the majority of cases a statement of non-compliance was issued which was then followed by the relevant Member State. In the table above 'update compliant, but only after SONC' indicates the ca. two-thirds effectiveness of the additional reminder by a statement of non-compliance and the enforcement[173]. In a very few cases, follow-up compliance check decisions were also issued, but generally ECHA and the Member States have, for reasons of efficiency, shown preference for the informal statements of non-compliance.

5.2.3 Selection of substances and endpoints in dossier evaluation

Statistics of adopted decisions across the years do not provide the full picture of the effectiveness and efficiency of the dossier evaluation process. The selection of substances and the precise scope of the compliance check are also crucially important.

Table 4.5: Requirements in dossier evaluation decisions per endpoint

Endpoint	**Testing Proposal Examination (TPE)**	**Compliance Check (CCH)**	**Total**
Long-term aquatic toxicity	170	126	296
Biodegradation	36	42	78
Bioaccumulation	18	23	41
Repeated dose toxicity	359	124	483
Mutagenicity	55	194	249
Pre-natal developmental toxicity	467	221	688
Reproductive toxicity	6*	65	71
Carcinogenicity	0**	1	1
Substance Identity (SID)	n/a	376	376
CSR / Exposure assessment and risk characterisation	n/a	132	132
DNEL	n/a	56	56

*Note: 183 TPs originating from 2010 pending COM decision.

**Three TPs for carcinogenicity received: One was rejected by ECHA; one TP was withdrawn by the Registrant; for one the process was terminated as the study was already ongoing for biocides directive.

While the number of testing proposals was lower than initially expected in 2006, their spread between different endpoints was roughly as expected. In a number of testing proposals it was considered necessary to first clarify the identity of the substance addressed in order to successfully examine and conclude the testing proposal. On the other hand, as indicated above, a significant number of testing proposal examinations

[173] If enforcement is taken. SONC is submitted to the Member state competent authority but copied also to the registrant. Statistics on actual enforcement based on SONC is not available.

have been terminated prior to decision making (332 terminations compared to 748 decisions). This skews the statistics in terms of endpoints addressed as well as the ability to assess the process efficiency from the decision outcomes. Though the decisions rejected the testing proposal in only a handful of cases, the scrutiny led to numerous early terminations and – in most cases - modifications of the original proposal. This suggests that the testing proposal examination helps.

There was a fluctuating profile of endpoints targeted by compliance checks in the years prior to the integrated regulatory strategy as ECHA developed and learnt from its experience[174] .

As can be seen from the table, ECHA compliance check decisions required improved substance identification in 376 dossiers, and the generation of 796 toxicological and ecotoxicological studies addressing most relevant[175] information requirements. Evolution of these trends is strong: following the 2016 evaluation[176] of over 1,200 higher-tier human health and environmental endpoints, 142 compliance check decisions in 2016 covered in total 805 standard information requests, 550 of which addressed higher-tier human health and environmental endpoints. This is more than a quarter of all such requests since the evaluation process was launched.

In addition, 156 compliance checks in 2016[177] (85% of the 184 compliance checks performed) were performed on the dossiers of high-priority substances identified via the integrated regulatory strategy.

5.2.4 Dossier evaluation and compliance

By 2016, compliance checks generated further information on substance identity for 212 substances[178]. Dossier evaluation also resulted in 1,907 generated toxicological and

[174] ECHA made campaigns to explore the different evaluation aspects: from full compliance checks evaluating compliance with all information requirements to the very targeted compliance checks with IT tools and template decisions on single information requirements across the full registration database (Area of Concern approach),

[175] Also called 'super endpoints', directly related to CMR and respiratory sensitisation effects on human health, and PBT/vPvB effects for the environment. Endocrine disruption is considered a super endpoint for both human health and the environment. Note that further information was also required in the evaluation decisions ot counted in the statistics provided (physical hazards, water solubility etc.)

[176] Source: Evaluation under REACH, Progress Report 2016, https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8

[177] Source: Evaluation under REACH, Progress Report 2016, https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8;

[178] Counting multiple changes by registrants on one substance as one.

ecotoxicological studies on the most relevant information requirements. In over 95% of the compliant updates, the study requested by the evaluation decision was performed[179].

While the number of available studies included in the registration dossiers was generally as estimated, the number of testing proposals put forward to address the remaining information gaps was significantly lower than anticipated (see above). While there may be some marginal reasons to explain discrepancy, the difference is best explained by the extensive submission by registrants of adaptations to standard information requirements in the registrations. Use of adaptations rather than performing an animal test is required by REACH whenever possible; however it requires that a number of conditions are fulfilled to ensure the equivalence of information on which the safety assessment is based. As much as one can deduct from the adaptations cases that were checked for compliance (see below) that was often not the case.

To get a perspective[180] how dossier evaluation contributes to the generation of adequate high tier information on substances under REACH requires comparison of:

- the studies generated due to dossier evaluation, with
- the total number of high tier studies, and
- the number of dossiers with non-compliant information that is potentially expected to be addressed by a compliance check.

Table 4.6: Three illustrative cases regarding the comparison between existing and newly generated data

Endpoint	Total unique studies (a)	Generated pre-REACH	New studies (in parentheses those generated based on dossier evaluation)	Total requested under dossier evaluation	Compliance check	Testing proposal examination
Developmental toxicity	1655	1286	369(278)	688	221	467
Reproductive	1987	970	1017(19)	71[181]	65	6

[179] Adaptations rather than study results were accepted in 51 cases by 2016. Over 40 of them were improved adaptations available (and not accepted) at the time of decision making, with less than 10 adaptations that were genuinely new.

[180] Complete understanding requires also further consideration of the behaviour of the registrants regarding their initial approach to fulfil registration obligations as well as the impact that dossier evaluations (in general or addressed explicitly to them), have on their decisions to generate further information. Unfortunately most such information is anecdotal.

toxicity						
Carcinogenicity (b)	407	392	15(1)	1	1	0

(a) From 2017 ECHA 117(3) report.
(b) Interpretation: Of all registration dossers 744 registration dossiers refer to the 407 unique studies. Other dossiers apply adaptations: 729 omit the study using waiving possibilities, 603 are based on read across, 51 use QSAR and 248 use the weight of evidence.

These three illustrative cases are presented to indicate the complexity of the situation, and the difficulty to draw general conclusions:

- developmental toxicity shows both a strong pre-REACH information base that could be used in dossiers and also extensive generation of data under REACH.
- reproductive toxicity shows an even stronger contribution of new data outside REACH but also delayed decision making due to the new EOGRTS method[183].
- carcinogenicity shows a large number of studies generated in the past, however under REACH the adaptations have been extensively applied in order to avoid performing new tests.

To maximise the impact and efficiency of individual decisions in a scenario where resources are limited, ECHA targets those parts of the registration dossiers that are particularly important for the safe use of a substance. However, such limited assessment does not enable to eventually consider a dossier as compliant, and therefore the approach does not provide individual registrants with certainty about the compliance of their dossiers. It also makes statistics on the level of compliance and assessing the link between the approach and the original targets in Article 41 more difficult.

The level of compliance of registered dossiers can be estimated using different sources.

- ECHA's evaluation progress reports indicate that over the years between ½ and 2/3 of identified dossiers had non-compliance for at least one information requirement
- The high number of studies on 'super-endpoints' requested in 2016 as part of the integrated regulatory strategy on 'substances that matter' confirms important data gaps in more than two third of the cases[182].
- A Member State reviewed[183] the registration dossiers submitted between 2010 and March 2014 for substances > 1000 tonnes / year. Their analysis concluded

[181] Low number is importantly affected by the need for modification of reproductive toxicity information requirements and that also prompted evaluation by the Commission in 216 cases that are still being processed

[182] Any further interpretation is speculative: for example, the increasing trend in the percentage of identified non-compliant dossiers through the years has probably more to do with the improved screening and prioritisation of compliance check cases than either the deterioration of registration dossier quality through the years or the failure of the compliance check strategy itself.

that there is a high proportion of (non-compliant) [184] dossiers for human health endpoints, mainly for developmental and reproductive toxicity, and that for environmental data, 12–59% of the examined endpoints were non-compliant, meaning that significant data gaps still exist for substances that needed to be registered already in 2010.

- Concerns regarding compliance of the dossiers were echoed by most of the 15 Member States responding in the public consultation.

The impact of non-compliance on the actual level of protection achieved by REACH on human health and the environment is difficult to assess. Insufficient or misplaced adaptations applied in place of studies on the registered substance represent an important source of non-compliance and were assessed more closely: a first comparative statistical analysis by ECHA indicates that there is no big difference between the values that define the distribution of no effect levels coming from experimental studies and those coming from adaptations, which may imply that, by using adaptations, registrants are not systematically claiming, that substances are less hazardous. If that is indeed the case, the approach to adaptations, while clearly not applied correctly in a number of cases does not lead to a systematic bias towards a lower level of protection of human health and the environment. On use of adaptations see also Annex 4, part on "Data sharing, test methods and avoidance of unnecessary testing".

5.2.5 Time required to generate the data

An important aspect of the evaluation process as a data-generating tool is the time required for the process to actually deliver data in the registration dossier, thereby allowing further safety assessment and risk management considerations, considering that the substance continues to be placed on the market during this period. The time to commission and run a test can represent a significant part of the evaluation time and is of course very endpoint-dependent. However, the time invested by authorities in the assessment and decision making is also significant: for testing proposal examinations, the average time (with exclusion of the test itself) is 340 days[185], while for compliance checks, including the initial prioritisation step, the average time is 461 days.

The time required importantly depends on the steps required by REACH: as part of the decision making, MSCAs are asked to comment on the ECHA draft decisions. If they submit proposals for amendments , ECHA is required to discuss the decision and the proposals in its Member State Committee (MSC), resolve the issues, and adopt the decision with unanimity within the legal deadline of 65 days. Such proposals for

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[183] http://www.bfr.bund.de , Project: Availability of Health and Environmental Data for High Tonnage Chemicals under REACH

[184] http://www.bfr.bund.de , Project: Availability of Health and Environmental Data for High Tonnage Chemicals under REACH. The project screened all the dossiers using formalized and rather conservative procedure using decision trees, with deliberate restriction of the assessment to ca. 60 min/dossier, ranking the dossiers as compliant (no issues identified, very few), non-compliant (with at least one identified issue in any endpoint as non-compliant), and complex (e.g. all dossier using adaptation as validity could not be established fast). As the procedure differs in important ways from the formal compliance check procedure, any comparison of the results from both procedures need to be very careful.

[185] Estimated by ECHA, median information taken.

amendments were triggered in 48% of the testing proposal examinations and in 27% of all compliance checks[186].To reduce workload at the meetings, MSC attempts in many cases to resolve issues in advance and adopt decisions by written procedure.

5.2.6 Issues related to dossier evaluation

The statistics show that the dossier evaluation process performs its principal function to ensure that data required by REACH as standard information is generated. In the 2016 Report on the Operation of REACH and CLP, ECHA states that the evaluation processes have improved the number of compliant registration dossiers. The scale of the problem to be addressed however appears to exceed the REACH legal target (i.e. 5% of dossiers) and the resources available.

Besides being a generator of new data by itself, compliance checks were also expected to deter substandard registration submissions and promote adequate and timely updates and improved risk management measures of substances. While the impacts of ECHA's integrated regulatory strategy in this regard cannot be fully assessed due to its limited time in operation, any analysis to date has not provided any evidence that the compliance check decisions contributed to an improvement of the compliance of registration dossiers beyond the one piece of information specifically requested in the decisions.[187]

The current ECHA compliance check strategy attempts to maximize effectiveness by addressing 'what matters most', in particular in terms of required risk management measures. At the same time, the tool must be used efficiently: an example is to address groups of substances (in selected situations such approach has been applied in testing proposal examination already).

The Commission services note that DNEL derivation (with exception of challenging the undocumented deviations from guidance), self-classification, and identification of adequate risk management measures, cannot be efficiently addressed via dossier evaluation decisions as they require argumentation and not just data generation. Complementary measures including those targeting communication in the supply chain, enforcement and concrete risk management actions (e.g. development of a restriction dossier, request for harmonised classification which would trigger RAC assessment etc.) are likely better suited to address their shortcomings.

Another important consideration is whether ECHA can ask for a germ cell analysis where an *in vivo* mutagenicity test is requested during dossier evaluation to fulfil a standard information requirement. Germ cell analysis may be needed to allow the correct classification conclusion.

The more direct link between dossier evaluation and the regulatory risk management tasks under REACH, envisioned in the integrated regulatory strategy, is still being

[186] Statistics may significantly vary from MSC meeting to meeting as it is dependent on the endpoints addressed.

[187] An ongoing ECHA study on registration updates, including a dedicated survey, might provide some additional knowledge.

developed; for example, there are no available statistics on how often the dossier evaluation has identified a substance which would need a restriction, harmonised classification and labelling or that might be a candidate for identification as a substance of very high concern.

Steps to systematically address such an objective under dossier evaluation (e.g. additional evaluation templates for the experts) were only launched in 2016, as until then such impacts were explored only in the evaluation follow-up.

5.3 Substance evaluation

5.3.1 Main outputs of the Substance evaluation process

Since the 2013 review, all Member States are now participating in substance evaluation coherently with other processes in the Integrated Regulatory Strategy. The numbers of substance evaluations performed every year have not reached the initially projected targets (baseline estimate: 446 until 2016, which assumed about 100 substances would be assessed every year).

In practice, out of 221 substances published in CORAP since 2012, substance evaluation has addressed so far 182 substances while 39 remain in the evaluation process in 2016[188]. Out of the evaluated 182 substances:

- for 50 substances the process concluded with no decision as no further information was required;
- for 132 substances (2 substances with draft decisions suspended; 48 substances with draft decisions in decision-making; 82 substances with decisions taken by 2016, starting with the first decisions adopted in 2010)[189].

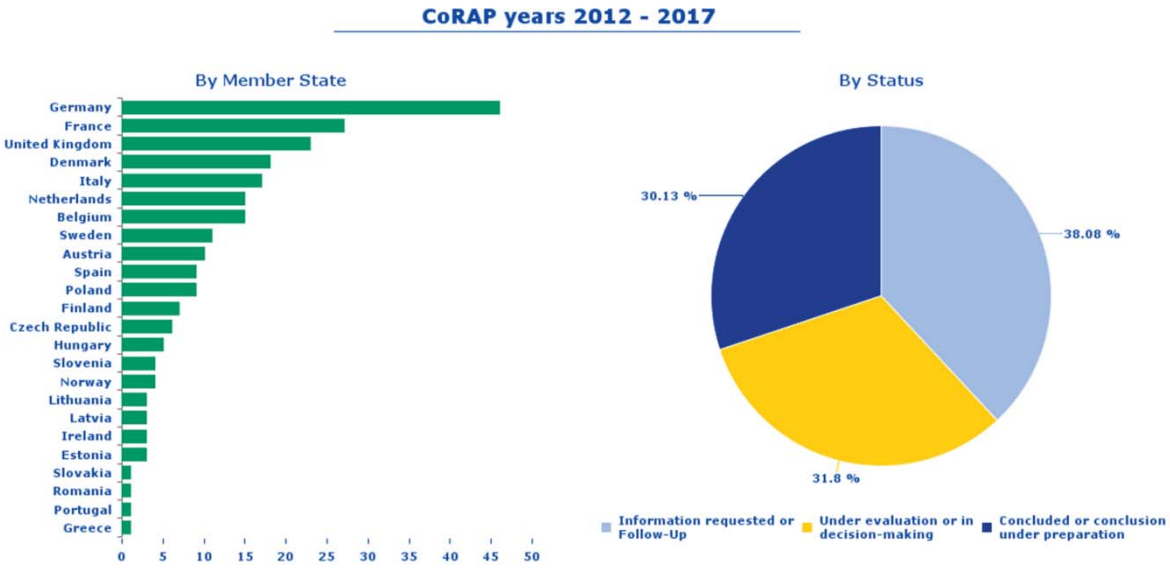
Out of the 48 substances, three draft decisions could not be unanimously agreed and were referred to the Commission.

Figure 4.7: Number of substances evaluated by individual Member States for the period 2012-2017. Also included: status of substance evaluations[190].

[188] ECHA Progress Report on Evaluation 2016

[189] Note that first CORAP was published only in 2012. Substance evaluation however 'picked' also the evaluations still ongoing under regulation preceding REACH.

[190] From presentation to the Member State Committee May 2017.



Statistics on the information requested vary from year to year; for example, in the period between 2014 to 2016 requests regarding exposure represented the majority of requests but with a downward trend (included in 83%, 71% and 54% of decisions in the three successive years). This is likely the result of the identified challenges to request CSA/exposure information, challenges that are confirmed with the experience gained from dossier evaluation. Human health and environment related requests follow closely, each with ca. 30-40%. In 2016, excluding exposure, 39% of requests targeted PBT/vPvB assessment[190].

The 82 ECHA substance evaluation decisions address 800 registrants. It is not yet possible to identify specific challenges or the rate of compliance with individual requests in these decisions[191] to determine their effectiveness. In 2016:

- 66 substance evaluations were waiting for requested information
- 8 were under appeal
- 4 were under follow-up evaluation
- 4 the evaluation has concluded and the conclusion document was either published or being drafted.

The appeal rate (in total 16 out of 82 decisions) is higher than in dossier evaluation; 8 are still ongoing. In the 8 concluded cases, 3 substance evaluation decisions were annulled. The reason for the appeals is that a lot is at stake in substance evaluation. Request may go beyond standard information requests. Substance evaluation decisions are vulnerable because they need to include the concern identified on which the request is built and identifying the information needed to clarify the concern may be difficult as shown also

[191] E.g. standard study requests vs. requests with no standard protocols or related to exposure. It should be noted that in the responses in the survey of competent authorities identified as a key challenge that information delivered was not what was requested.

in the case decided by the Commission[192]. The appeal rate is decreasing in last 2 years as all actors build the experience.

Generating data through substance evaluation requires time: the average time to assess and make a decision is 25 months[193], and this is on top of the time to place the substance on the CORAP (13 months on average) and the variable time required to perform the test.

If any standard information is missing in the dossiers then this makes substance evaluation challenging; this experience prompted ECHA to follow a strategy[194] to preferentially proceed with substance evaluation based only on the information from compliant dossiers. This however further prolongs the time needed and also to the number of substance evaluations proposed in CoRAP in 2016 dropping significantly, as compliance checks were awaited. Steps are being taken to ensure that the two processes can also work in parallel, provided adequate attention is paid to the underlying rationale for the request in each case, and the fact that the addressees of the decisions could differ.

5.3.2 Complementary measures and more indirect impacts

Besides formal compliance check and substance evaluation processes, are taken by ECHA is taking a number of complementary measures to improve the information in registration dossiers. ECHA's annual evaluation progress reports[195] document progress in this area including improved general advice to registrants, based on the experience gained.

An important step towards the common screening of substances for both evaluation and risk management processes as well as to the prioritisation and efficient drafting of the evaluation decisions themselves has been the 'Areas of Concern' approach, where automated tools have been developed by ECHA to screen the dossiers for systemic weaknesses that could also be addressed using template-type compliance check decisions (effective for simple scenarios which are however less common in higher-tier endpoint). This experience enabled further development of the *Registration Validation Tool*, helping registrants to avoid at least some deficiencies in the dossiers prior to submission.

Further complementary measures routinely applied by ECHA include:

1. *Publication of lists of substances to be subjected to compliance check:* in line with the ECHA Programming document 2017-19[196], in order to stimulate updates

[192] In the case of substance polyhaloalkene, used in mobile air conditioners, the MSC could not agree on the specific information request as proposed by the evaluating member State to clarify the concern related to the additional risk of exposure to substance's transformation products in case of very specific exposure scenario: accident with the car on fire. In the Commission decision, the request was eventually not included.

[193] In the decision making to date, proposals for amendments were triggered in practically all substance evaluation cases which therefore all require discussion in the MSC and a time period longer than 25 months

[194] CA_70_2016_Substance_evaluation.doc

[195] https://echa.europa.eu/regulations/reach/evaluation

[196] https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

and in support to the compliance check strategy, ECHA is already since 2016 annually announcing the list of substances likely to be subject to compliance check and addressing individual letters to the potentially affected registrants. Impacts such as an increased updating of dossiers for the announced substances, as well as better preparedness of the registrants[197] once the compliance check is launched, are already observed.

2. *Letter Campaigns*: ECHA periodically runs letter campaigns preceding/complementing the formal evaluation procedures[198], with the intention to promote proactive improvement of registration dossiers. They usually address a single key issue that can be communicated in a short letter. These letter campaigns are importantly intertwined with continuous ECHA communication on evaluation, as well as formal follow-up action from compliance check. As there is no clear metric to assess their impact, their degree of success is yet to be determined. ECHA reports measureable improvement in dossiers and a positive domino effect in the other registration dossiers of the addressee(s) of these letters. Experience with recent 2015 and 2016 letter campaigns on substances short-listed for compliance checks (see measure 2 above) indicate that around 40% of the addressed registrants update after 4 months. Most updates provide improved information on uses and exposure. Improved information on hazard is more limited and there are no additional testing proposals resulting from these campaigns. For the latter, it appears industry prefers to wait for the formal compliance check process.
3. *Sectoral approach:* in addition to addressing substances one-to-one, ECHA has been working, in cooperation with some industry associations, to improve dossiers and clarify hazard as well as uses/exposure for groups of substances either belonging to the same chemical family or sharing the value chain (e.g. UVCB petroleum and coal stream substances). Projects are all still ongoing[199] and their impact cannot be assessed yet.
4. *Article 36 decisions*[200] had been used extensively to verify intermediate status of registrations for substances on-site and transported isolated intermediates. ECHA is considering to expand their use to other types of information such as exposure assessment[201].
5. *Improving Substance ID information:* in 2016 ECHA started addressing substance identification in an informal process; as these issues normally do not

[197] As seen by respectively longer comments to ECHA draft decisions.

[198] For example, retroactive enhanced completeness check or list of substances likely to be subject to compliance check is complemented by a letter campaign to the registrants. In the past, campaigns included the address of intermediate uses (2012, 2014) and substance identification (2014).

[199] ECHA in 2017 launched a further pilot project related to cooperation between ECHA and MS on addressing groups of substances, inviting proactive industry involvement (CARACAL March 2017).

[200] Article 36 enables ECHA and Member States to request submission of existing information that has been used in the preparation of the registration and fulfilment of the duties, when such information is not provided in the dossier.

[201] ECHA Progress Report on Evaluation 2016

require additional testing and are often easy to resolve, the informal process is shorter and more efficient.

These complementary measures are in place and giving results but a number of other actions that should be further explored to address the obstacles to achieving a satisfactory level of compliance of registration dossiers. Therefore, further consideration could be given to:

- use ECHAs competences to support registrants in the development of compliant adaptations, to assist them to implement effective testing strategies for groups of substances where a broader benefit can be obtained, while respecting that the burden of proof lies on industry. This could link to the common efforts by ECHA and the Member States to support (and where necessary force) registrants to apply animal testing only as a last resort.
- Registration dossier updates: whether Article 22 of REACH should be amended to specify further the situations that trigger mandatory updates, as well as to set precise deadlines.
- while the Commission agrees with the general view of responders in the public consultation regarding adequate clarity of the present legal requirements on evaluation[202], additional clarity in terms of the obligations of registrants having ceased manufacturing, as set out in Article 50(4), would contribute to smoother functioning of substance evaluation in specific cases.
- Dissemination: while important improvements have already been made (public dissemination website, list of intent etc.) by ECHA, further improvement of the transparency of relevant outcomes is still possible and some actions are already ongoing[203]. This may for example include further integration of information on substances and (stages of) evaluation and risk management processes including outcomes of common screening, where relevant, with relation to wider objectives such as addressing groups of substances, information on spontaneous updates and the follow-up enforcement. Such transparency should facilitate appropriate and timely intervention from all actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible.
- When substance evaluation is required to clarify a concern, it is preferred for efficiency reasons that it be preceded by compliance checks of the related registration dossiers. However, both processes could also run in parallel to accelerate the generation of missing data.
- The choice to proceed with a specific evaluation process, following the common screening and prioritisation of substances, should be based on the necessity to generate further information before risk management action can be taken. It should also carry the reflection whether the selected process is the right tool to obtain it, by recognizing limits for requests under evaluation (e.g. exposure

[202] Stakeholder consultation: summary report of the open public consultation, question 10,11 under chapter 3.1.1.

[203] For examples, further improvement of the ways how stakeholders are informed on the progress in MSC.

scenarios of downstream users) and identifying in advance the potential to more efficiently obtain information through an informal contact with industry or public call for evidence, in the risk management process from the stakeholders (public consultation during restriction) or by generating some missing data directly (e.g. modelling by the competent authority). The integrated regulatory strategy has taken steps with the aim to ensure this.

- Applying evaluation and risk management steps in sequence should not be a necessity. The processes can be applied in parallel. Where substantial grounds exist to justify concerns about a given substance, the initiation of risk management processes such as restriction or harmonised classification and labelling could be envisaged to partially overlap and complement evaluation, with these processes also prompting generation of the information necessary to determine, shape and justify any subsequent regulatory action. These processes are however also resource intensive and involve multiple actors and should not be applied lightly.
- Further changes to improve the efficiency and effectiveness of evaluation processes could be considered.
    - Addressing related groups of substances and not only individual substances. Related to this, the possibility of running evaluation processes in parallel, either between or with the risk management processes, should be explored.
    - Improving the efficiency of the resource intensive decision development and adoption process by ECHA. Measures may include increased use of shorter and more specific decision templates and automation or further optimization of interaction with registrants, in particular exploitation of the pre-evaluation of dossier updates (e.g. as promoted by annual listing of candidates for compliance check).
    - Better incorporating public consultation under testing proposal examination in the examination to maximise its impact, potentially by launching it together with ECHA's preliminary assessment in particular of the registrants' search for alternatives, to avoid duplication of effort and optimize informed input by third parties.
- The additional opportunities that have already started to be explored by ECHA as part of the implementation of the integrated regulatory strategy include the feedback from the evaluation processes to the integrated regulatory approach:
    - risk management action potential may be identified during the initial expert assessment of the registration information in the evaluation and the evaluation decision follow-up;
    - The common screening tool for selection and prioritisation should be continuously fed with the experience from the processes applied in order to optimise the screening but also provide better indication of the state of the dossiers in general to enable planning and communication;
    - The screening results should help to steer complementary measures.

In the future, modifications of individual steps in the formal evaluation procedure may also be considered to further improve its efficiency and effectiveness, in particular with regard to the third party and double registrant consultation[204], but also the roles of the Member State competent authorities and the Member State Committee (MSC). Specifically for the testing proposal examinations, the Commission should assess if the presently required full examination process of all testing proposals should continue or could be replaced by less resource intensive pre-notification procedure or enquiry-type ECHA process.

As already indicated, experience has driven the evolution of the evaluation process itself which have allowed for the improvement of a number of different ECHA processes and of guidance, in particular on registration. It has also supported the development of Commission proposals for modification of REACH annexes on information requirements. Examples include changes to the information requirements regarding skin sensitisation and reproductive toxicity, improvement of the ECHA guidance on how to address registered nanomaterials, development of the implementing act on data sharing and improvements of the IUCLID reporting tool.

5.4 Outcome of the Public Consultation

Stakeholders from industry and NGOs claim that the evaluation process lacks transparency, which industry considers a driver for cost. However, the evaluation process is conceived as a stepwise and transparent mechanism and the overall transparency has been further increased by ECHA with extended dissemination of information on substances on the Community Rolling Action Plan (CoRAP), by the publication of the list of substances potentially subject to compliance check, informing companies when their substances are short-listed for possible regulatory action[205].

The results from the public consultation, as regards dossier evaluation, suggest general satisfaction with the clarity of requirements and level of implementation and that a majority of respondents holds the view that the benefits of the process exceed or are proportional to the costs. In its 2016 Report on Operation of REACH and CLP, ECHA suggests to the Commission to review the existing 5% compliance check target to maximise the impact of compliance checks on the safe use of chemicals. It also recommends further improvement of the transparency of relevant outcomes of the different steps of the compliance check process for the benefit of Member States, accredited stakeholder organisations and registrants. In the public consultation, Member States, NGOs, industry and a consumer association called for more compliance checks. Several responses from industry however indicated that the processes are cumbersome

[204] Registrants are consulted twice: the first time on the basis of draft decision following ECHA assessment and the second time when the modified draft decision taking into account industry comments has received proposals for amendments from the Member States Competent Authorities afterwards.

[205] Stakeholder consultation: summary report of the open public consultation,

and costly for registrants, leading to sometimes disproportionate requests for additional information. One case has been presented through the open public consultation of a company withdrawing a registration because of the costs of additional studies requested by ECHA. Proportionate requests were also called for by an NGO advocating for animal welfare.

The length of the substance evaluation process has been acknowledged as problematic by authorities and stakeholders contributing to the public consultation and the specific survey conducted by ECHA in 2015[206]. In spite of this, some stakeholders continue to believe that substance evaluation is the best tool to deploy before making considerations on risk management measures at EU level.

While the substance evaluation process was generally considered both comprehensive and clear, suggestions were made in the public consultation to better indicate which information has been considered in the evaluation and to outline the potential divergences of risk assessment conclusions with the registrants. One NGO called also for more substances to be put on CORAP and that nanomaterials should be included automatically. Industry indicated that agreements between the registrants on who shall perform the test etc. generally do not pose problems, but the cost-sharing might still be an issue, and that interaction with downstream users, while it has taken place in some instances, can be a complicated and lengthy process. Industry also commented that substance evaluation is managed somewhat differently by Member States and that stronger involvement of ECHA as well as further coordination between evaluating competent authorities when dealing with substances within a same group would be beneficial and should lead to improved efficiency and consistency between the decisions. A best practice document has already been developed addressing these aspects[207].

[206] Assessment of the current substance evaluation process under REACH, AMES Foster Wheeler Environment and Infrastructure UK Limited, January 2016

[207] Developed by ECHA, some Member States and industry association, and discussed in the Workshop: https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf/c5ba2af8-eadc-4830-9dfb-389a4bf8f637

6 Authorisation

Conclusions of the 2013 Reach Review

The authorisation process was not fully operational at the time of the 2013 REACH Review. Nevertheless, the 2013 review addressed specific recommendations to the Commission services, Member States and ECHA to identify SVHCs and to draft a roadmap to include all relevant SVHC substances in the candidate list by 2020.

The 2013 review also recommended continuing the discussion to obtain a common view on the use of the candidate list for objectives other than inclusion in the Authorisation List (hereafter referred to as Annex XIV).

The Commission services also committed, together with ECHA, to improve the understanding of the authorisation process for all actors and underlined the need for better quality of the information submitted during the public consultation on the draft recommendations for priority substances for inclusion in Annex XIV.

Baseline

The pre-REACH legislation did not include an authorisation system for industrial chemicals. There was a mechanism to identify PBTs and vPvBs through the EU PBT working group, while CMRs were identified through the C&L working groups. No comparable system existed for identifying endocrine disruptors or other chemicals of equivalent concern. So, while the original predictions regarding candidate listing had some basis in the experience of the previous legislation, for the authorisation system itself there was no direct experience.

- It was originally expected that 137 substances would be placed on the candidate list by 2010 and 25 per year thereafter. In 2010, the Commission established a new target of 136 substances to be included in the candidate list by 2012.
- The first Annex XIV entries were expected to start in 2011 with 8 substances, then 12 added in 2012 and 25 per year thereafter.
- There was no estimate as to how many applications for authorisation could be expected per substance listed in Annex XIV, but only that approximately 100 downstream users would benefit from an application held higher up the supply-chain.

6.1 Developments since the 2013 Reach Review

6.1.2 The SVHC Roadmap

By the end of 2012, the candidate list did indeed contain 138 substances. To develop on this, and to add all relevant substances on the candidate list and make the process more predictable after 2012, the Commission developed a roadmap up to 2020, in collaboration with Member States and ECHA. The "Roadmap for SVHC identification

and implementation of REACH Risk Management measures from now to 2020" (the SVHC Roadmap), and hereafter the Roadmap) is a process to ensure that all relevant currently known SVHCs are included in the Candidate List by 2020. The SVHC Roadmap outlines a methodology for working towards achieving this objective, with clear deliverables, planning and sharing of responsibilities.

The SVHC Roadmap established four criteria to identify, among the substances fulfilling the criteria in Article 57, those that are relevant for the candidate list. It was endorsed by the Council in February 2013[208]. In the course of 2013, ECHA developed an implementation plan[209] that guided the activities in the field of SVHC identification from 2013 onwards.

During the initial stages of the implementation, the Risk Management Option (RMO) Assessment[210] hereinafter referred to as "regulatory management option" became a key element of the SVHC Roadmap. It is now used to assess if, for substances fulfilling the four criteria of the SVHC Roadmap, another regulatory mechanism under REACH (evaluation or restriction) or outside of REACH (e.g.CLP or OSH) is more appropriate to address substances of particular concern for consumers, workers and the environment.

The ECHA annual reports published in 2015[211], 2016[212] and 2017[213] provide the details of the implementation of the SVHC Roadmap. The main achievements of the SVHC 2020 Roadmap during its first 4 years of implementation are the following:

6.1.2.1 Screening of substances

The key objective of the SVHC Roadmap was to set out priority criteria and a methodology to achieve the inclusion of all relevant SVHC in the Candidate List by 2020. ECHA started screening the information available in the registration dossiers and the CLP classifications notified by industry. It became soon clear that, in addition to finding substances for the Candidate List, such screening could serve also other REACH processes (compliance check and substance evaluation) and CLP (identification of candidates for harmonised classification and labelling). ECHA then

[208] Endorsement by the Council of the European Union of the Roadmap on Substances of Very High Concern, February 2013

[209] SVHC Roadmap to 2020 Implementation Plan, European Chemicals Agency ECHA, December 2013

[210] Originally the RMO stood for risk management options. To avoid confusion with the obligations under Article 69 to prepare an annex XV dossier when a risk has been identified and the obligation in Annex XV to determine the most appropriate Union wide measure to address the identified risk and to better reflect the actual work done, the RMO is now called Regulatory Management Options. Regulatory Management Option (RMO) Assessment is the process for identifying the best regulatory option for a substance. The RMO Analysis is the document presenting the information on the substance, the possible options and the preferred one.

[211] Annual report of the Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures, European Chemicals Agency, March 2015

[212] Annual report of the Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures, European Chemicals Agency, April 2016

[213] Annual report of the Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency, April 2017

developed a common screening approach[214] that provides every year the competent authorities with a list of potential candidates for all REACH and CLP processes. Since 2017, the screening identifies not only individual substances, but also groups of substances, in order to ensure a more consistent and efficient approach to regulatory actions for similar substances.

6.1.2.2 Regulatory Management Option (RMO) Assessment

The RMO Assessment is now fully operational. Before a regulatory action under REACH is proposed on a specific substance, the Member States competent authorities or ECHA (on behalf of the Commission) prepare a RMO Analysis and submit it for comments to the other Member States competent authorities. Albeit voluntary, this approach has increased the exchange of information and communication among the authorities, in particular when deciding about the need for and/or the type of regulatory action and about whether to share the workload in complex cases. An example was the initiative of the Commission to launch a discussion on the links between REACH and occupational health and safety (OSH) legislation in the framework of the RMO Assessment. This has led to a better consideration of information available under OSH and the possibility for substances used mainly in occupational settings to consider as a first regulatory option the OSH legislative framework. It also improved the internal communication of the competent authorities for the two legislations.

At the RMO Assessment stage, it is also possible to consider some socio-economic aspects. However there is a need for a reflection on how socio-economic information, as well as information on exposure, can be taken into account without making the RMO Analysis too cumbersome and without giving the impression that a RMO is conceived as an Annex XV dossier or a risk management measure analysed within the Annex XV dossier for restriction.

In essence, the RMO Assessment serves the purpose of collecting views and information informally from other Member States and Commission/ECHA before a Member State or Commission/ECHA decides or has sufficient evidence to take any action allowed by REACH and which falls fully within the Member State and Commission/ECHA competence to decide. It is therefore important to recognise the difference between the obligations in Articles 69(1) and 69(4), where Member States and the Commission have obligations to act once a risk is identified (at EU level in the case of the Commission) and the RMO Assessment stage, where such risks have not (yet) been identified.

[214] https://echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/screening

The responses in the context of the open public consultation for the REACH REFIT Evaluation[215] indicated that a great majority of industry stakeholders consider that the RMO Assessment enhanced the coherence between different regulatory options within REACH, and between REACH and other EU legislations. Some of the respondents stressed that the RMO Assessment should be binding and more harmonised, to avoid discrepancies on how to manage chemicals by different competent authorities or by different Member States. On the other hand, respondents from consumer associations, a trade union and NGOs are critical of the RMO Assessment process. They consider it has no legal basis in REACH and, in their opinion, it delays the inclusion of SVHCs in the Candidate List and makes this process more burdensome.

6.1.2.3 Cooperation among authorities and expert/coordination groups

Before the SVHC Roadmap, authorities were selecting on their own the substances on which to work, based on different approaches, sometimes leading to duplication of work and not entirely coherent conclusions. The implementation of the SVHC Roadmap has improved authorities' coordination thanks to the common screening approach (selection of substances involving a mass screening performed by the ECHA secretariat complemented by manual screening by Member States), and the RMO Assessment (consideration of possible regulatory measures in consultation with others). In addition, experts are exchanging views and are looking for consensual opinions in the so-called Risk Management Expert (RiME) meetings[216] and several coordination groups, including the meetings of the PBT[217] and Endocrine Disruptor (ED)[218] expert groups for the discussion of the hazard properties not harmonised via the CLP process. A coordination group on human health hazards[219] steers the discussions on sensitisers and substances classified on the basis of Specific Organ Toxicity (STOT) to be potentially identified as SVHCs. An expert group on Petroleum and Coal stream substances (PETCO) is discussing a common approach for this complex group of substances.

Table 4.7 shows that the number of Member States participating in the implementation of the SVHC Roadmap has increased over the years.

6.1.2.4 Transparency, communication with stakeholders and predictability

The SVHC Roadmap also aims to increase transparency and predictability of the process to identify SVHCs. Thanks to the Public Authorities Coordination Table

[215] Report of the open public consultation

[216] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rime

[217] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pbt-expert-group

[218] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-group

[219] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/coordination-groups

(PACT[220]) on ECHA's website, stakeholders are now informed of substances selected for a RMO Assessment or discussed in the PBT and ED expert groups and can ensure that their registration dossiers are up-to-date with all relevant information and provide feedback to the competent authorities or to ECHA. PACT also includes the conclusions of the RMO Analyses. As of 2015, communication has started at an even earlier stage, with letters sent by ECHA to the registrants of the substances selected in the yearly screening. The whole process has thus become more predictable for stakeholders and it is no longer the "black hole" it was claimed to be at the beginning. In the open public consultation for the REACH REFIT Evaluation, industry stakeholders acknowledge that the RMO Assessment is an important instrument allowing them to predict the regulatory fate of a specific substance and to start early actions; however, some NGOs considered the process too slow to meet the final goal of the Roadmap by 2020.

6.1.2.5 Interface authorisation/restriction

The RMO Assessment also helped in deciding whether substances should be subjected to the restrictions and/or authorisation requirement. In some cases, where both authorisation and restriction processes had been initiated prior to the SVHC Roadmap, subjecting substances to the authorisation requirement has been put on hold while waiting for the finalisation of the restriction process (e.g. NMP, DMF), in others the discussion during the RMO Assessment has helped in the choice of one regulatory approach between two EU legislations (e.g. REACH restriction vs OSH legislation on isocyanates).

Cases have emerged where substances where subject to both restriction and authorisation processes (e.g. phthalates, NMP). To better utilise the strengths of the two instruments, being mindful of the objectives of REACH and the need to ensure legal certainty, an assessment is necessary to determine when it is opportune to consider restrictions, when authorisation and when both (sequentially or complementary) for the same substance.

Table 4.7

	2014	2015	2016	total
Number of substances manually screened	247	180	184	611
Number of Member States participating to manual screening	17	21	22	23
Number of RMO Assessments (cumulative numbers)	98	139	159	159

[220] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

Number of RMOAs (cumulative) with REACH as best RMO, of which • Authorisation • Restriction	 5 1	 16 5	 24 6	 24 6
Number of RMOAs (cumulative) with another legislation as best RMO, of which • Harmonised C&L • Other EU legislation (OSH) • Other	 1 1 (+1) 1	 2 1 (+2) 2	 4 1 (+4) 3	 4 1 (+4) 3
Number of RMOAs (cumulative) with conclusion that there is no need for regulatory action for the time being	5	11	15	15
Number of substances discussed in • ED[221] group • PBT group • PETCO group[222]	 14 43	 22 30	 17 29 2	 48[223] 88 2
Number of Member States preparing an RMOA (cumulative)	9	14	15	15

6.2 The Candidate List

Achievements and developments

During the development and initial implementation of the SVHC Roadmap, the authorities discussed the role of the Candidate List, i.e. whether only substances for which authorisation is considered to be the best regulatory option should be included, or whether the list should also be used to officially identify EDs, PBTs and vPvBs, for which no CLP classification criteria are available, and whether the Candidate List also serves other objectives[224]. While no general consensus has been reached on the objectives

[221] Endocrine disruptors

[222] "PETCO" stands for petroleum and coal streams. The PETCO group until now discussed the approach for this complex group of substances and only recently started the discussion on specific cases. Those specific cases were more discussed from a methodology perspective

[223] The total sum does not match, because some substances have been discussed in more than one meeting during more than one year.

[224] In two recent judgments (C-323/15 P and C-324/15 P), the Court of Justice would appear to consider that, once a substance has been included in the candidate list, the decision to include that substance in Annex XIV is no longer a question of whether authorisation is the most appropriate risk management measure to address the risks from the use of that substance, but of when it is most appropriate to include it. The Commission is currently analysing the two judgements.

of the Candidate List, it is now clear that the Candidate List can also include EDs, PBTs and vPvBs for which, in the next step, the best regulatory option is a restriction. Even if ECHA recommends these substances from the Candidate List for inclusion in Annex XIV because they fulfil the prioritisation criteria, the Commission can still decide not to include them in Annex XIV, if the RMO Assessment concludes that a restriction is the preferred option. However, in such cases the substance should be included in the Registry of Intentions for Restrictions (RoI- Restrictions) shortly after the conclusion of the RMO Assessment.

Table 4.8 key figures concerning the inclusion of substances in the candidate list

	2013	2014	2015	2016
Number of Annex XV dossiers for SVHC identification	17	14	9	10
Number of substances included in the Candidate List	13	10	7	5
Number of Member States submitting an Annex XV for SVHC identification	5	4	4	5
Number of cases deferred to COM[225]	0	4 EDs	1 skin sensitiser	3 EDs 1 respiratory sensitiser

From the data presented in Table 4.8, it is clear that the inclusion of substances in the Candidate List has slowed down. The following main reasons could explain this evolution:

- Thanks to the RMO Assessment, the authorities now assess more in depth the different options, choosing, in some cases, other regulatory actions, as reported in the 2017 SVHC Roadmap report[226].

[225] According to Art. 59(9) of REACH, in case the MSC does not REACH an unanimous agreement on a case of SVHC identification, the decision is referred to the Commission.

[226] Annual report of the Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency, April 2017. Page 30 : "The number of RMOAs concluding on the need for other EU legislation and/or other measures has also increased, which confirms that the RMOA tool is open and can in practice serve other legislation than regulatory risk management under REACH and CLP"

- The straightforward cases (CMRs – except for the petroleum streams) have all been assessed through the common screening approach and, in selected cases, with an RMO Assessment. The focus has now moved to more complex cases, such as PBTs, vPvBs and Article 57(f) substances, where more detailed RMO dossiers and, in some cases, generation of new data are needed. This is acknowledged in the 2017 SVHC Roadmap report[227].

- As concluded regarding registration and restrictions, the non-compliance of registration dossiers and/or the lack of detail of the registered uses hamper the identification of substances fulfilling Article 57, hence the identification of new SVHCs and prioritisation according to Article 58(3).

- There is only a small number of newly identified CMRs and other CLP hazard classes potentially corresponding to equivalent level of concern (STOT, respiratory sensitisers), due to lack of resources from MS to develop CLH dossiers for REACH related substances.

The Commission is more and more involved in the decision-making for the identification of SVHC since in an increasing number of cases the Member States Committee (MSC) has not reached unanimity. Such cases concern endocrine disruptors (seven cases) and sensitisers (two cases). This is mainly due to the absence of a common interpretation of 'equivalent level of concern' under Art. 57(f) of REACH. Through the decisions taken by the Commission after a vote in the REACH Committee on these disputed cases, the MSC receives feedback on the common interpretation, which should increase the efficiency of the overall process.

Available information from a survey conducted in the study to monitor the impacts of REACH on innovation, competitiveness and SMEs[228] suggests that already the inclusion of substances into the Candidate List or in Annex XIV has worked as a driver for a part of the companies concerned to look at the possibilities of substitution. The most common responses to such inclusion were to launch development of new substances, to find alternative formulations and to request substitution from suppliers. The effects of the Candidate List on the markets and on substitution have been further investigated in a study on the impacts of authorisation[229], which also confirmed those findings. .

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[227] Page 28: " … the number of RMOAs investigating substances with ED and PBT properties has been increasing steadily for two years as more and more substances are progressing under either substance evaluation, compliance check or in the PBT and ED expert groups, it can be expected that the number of RMOAs covering substances with those properties will continue to increase. However, it should be kept in mind that, as the generation and assessment of information takes often substantial time, it will also take more time before the RMOAs can be concluded."

[228] CSES, 2015 - Among respondents to the underlying business survey who were affected by inclusion of a substance in the Candidate List, about 19% launched initiatives to develop new substances, 30% launched initiatives to find an alternative formulation and 24% requested substitution to the supplier. The response of companies to inclusion of substances in the Authorisation List has had a similar pattern.

[229] Study on the impacts of REACH authorisation - final report

The Commission did not need to develop a procedure for de-selection of substances from the Candidate List because there was no need for it. It will be considered if a case of de-classification of a substance already in the candidate list arises in the future, which has not happened so far.

6.3 Prioritisation of substances by ECHA and inclusion in the Authorisation List (Annex XIV)

6.3.1 ECHA recommendations of priority substances for inclusion in Annex XIV

In 2014, ECHA updated the approach for the prioritisation of substances for inclusion into Annex XIV. The way the scores are calculated for the substances is now clearer and, as a consequence, during the public consultation ECHA receives information useful to refine the scoring of the substances. In some cases, this information led ECHA to change the score and modify the list of recommended substances. Still, a lot of information submitted during the public consultation was not related to the prioritisation criteria mentioned in Article 58(3), but rather to socio-economic impacts of subjecting a given substance to the authorisation requirement. ECHA and the MSC agreed that such information is not relevant for the discussion of MSC on ECHA's draft recommendation as it should rather be considered by the Commission and the Member States in the REACH Committee when considering amendments of Annex XIV. The criteria for prioritisation are now well accepted and stable and therefore very limited technical debate is taking place at MSC level and most of the policy debate is now taking place at REACH Committee level.

To better channel such information, and in line with the announcement in the Commission REFIT Communication in 2014[230], since 2015 the Commission has introduced a parallel public consultation to gather socio-economic elements linked to the possible inclusion into Annex XIV of the substances proposed to be prioritised by ECHA. Respondents were also invited to submit information on potential alternatives, on how sectors and individual companies would approach a potential application for authorisation (for example, individual applications or relying on an application from the manufacturer/importer). This consultation thus provides a transparent channel for the collection of such information, which is then considered by the Commission and the Member States in the REACH Committee during the decision-making on proposed amendments of Annex XIV based on ECHA's recommendations.

Such public consultations on socio-economic elements have been conducted during the preparation of ECHA's 6th, 7th and 8th recommendations of priority substances for inclusion into Annex XIV, and have delivered numerous comments, often focusing on a limited number of proposed substances. However, many Member States have questioned the representativeness of the input received for the whole EU, all sectors and all uses of

[230] COM (2014) 368 " Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook"

the proposed substances and believe that the analysis of impacts and alternatives for individual uses should be done subsequently on the basis of the individual applications for authorisation. Indeed, the consultation results show that some information is not submitted, in particular on how industry would organise the applications for authorisation within their supply chains. This may be due to the fact that at the time of this consultation the operators may not yet have decided whether they would need to apply for authorisation and if so, who in their supply chains would apply, since applying for an authorisation may be done by the operator placing the substance on the market (e.g. manufacturer, importer) or by the user of the substance. Furthermore, the choice between one or the other requires a focused communication in the supply chain that may not yet be organised at the time ECHA proposes a substance for inclusion in Annex XIV.

From the 6th recommendation (submitted in July 2015) onwards, ECHA has reduced the frequency of its recommendations, from one per year to an 18 months cycle – while the REACH Regulation requires such recommendations to be made at least once every 2nd year. In reducing the frequency, ECHA reacted to the announcement of the Commission in 2014[231] that it would consider reducing the frequency of including substances in Annex XIV to allow time for improvements in the process and simplification in some specific cases. Pending this work, this reduced frequency allowed more time for discussion in the REACH Committee. When the improvements and simplifications as discussed below are in place, the Commission services will reflect on the most appropriate frequency of Annex XIV amendments for the future.

6.4 Inclusion in Annex XIV

As of June 2017, Annex XIV contains 43 substances. While the Commission had included virtually all the substances recommended by ECHA in the first two Recommendations, the decision on inclusion of a number of substances from the 3rd, 4th, 5th and 6th Recommendations (from the years 2011-2015) was postponed. In fact, these four recommendations contained in total 48 substances, while only 29 were included in Annex XIV through three amendments made between 2013 and 2017.

There were several reasons for postponing the decision on the inclusion of some substances into Annex XIV: for example, the initial experience with some complex applications for authorisation, especially those covering a broad range of different industries that are submitted by upstream operators (in particular by manufacturers and importers) on behalf of the downstream users or submitted by multiple downstream users, revealed important challenges for this type of applications that need to be addressed before new substances in comparable complex supply chains are made subject to authorisation. It has also become clear that ECHA underestimated the workload created by the high number of complex applications for such substances (as required by Article 58(3)). This reasoning was the basis for postponing the decisions on diazene-1,2-

[231] COM (2014) 368 " Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook"

dicarboxamide (C,C'-azodi(formamide)) (ADCA) and four boron compounds[232]. In other cases, the decision was postponed because it was not clear whether the authorisation was the most relevant regulatory measure for the substances (five cobalt compounds[233], N,N-dimethylacetamide (DMAC), N-methyl-2-pyrrolidone (NMP), N,N-dimethylformamide (DMF) and certain aluminosilicate refractory ceramic fibres (Al-RCF) and zirconia aluminosilicate refractory ceramic fibres (Zr-RCF)).

Article 58(2) provides for the possibility to exempt uses or categories of uses from the authorisation requirement provided that, on the basis of existing specific Union legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. During the public consultation on draft ECHA Recommendations and the Commission's public consultation on the socio-economic elements, a large number of requests are systematically received from industry for exemptions under that Article. So far, , an exemption based on this provision has only been granted to the sue of three phthalates (DEHP, DBP and BBP) in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC. In 2013 an action was brought to the General Court for the partial annulment of Commission Regulation (EC) No 348/2013 amending Annex XIV to REACH because it did not include an exemption under Article 58(2) for the use of chromium trioxide in surface treatment[234]. The General Court judgment, which dismissed the action as unfounded, has been confirmed by the Court of Justice (appeal case C-360/15 P). Although the Court ruling has provided some clarification on the conditions set out in Article 58(2), further policy discussions will probably still be needed on other criteria that would allow granting exemptions from authorisation under this Article.

6.5 Application for authorisation

By 1st June 2017, 123 applications for authorisation related to 23 substances and 194 uses have been submitted, and one withdrawn, of which 23 applications (covering 35 uses) are currently being assessed by RAC and SEAC. The Commission has by that date adopted 35 authorisation Decisions covering 58 uses, all granting the authorisations, and 61 applications were under consideration for adoption of a Decision.

6.5.1 Preparing applications for authorisation

Multiple measures have been put in place to guide and support applicants to prepare an application for authorisation. While at the beginning of the processes two main Guidance documents were available, that information has been gradually complemented by

[232] Boric acid, disodium tetraborate (anhydrous), diboron trioxide, and tetraboron disodium heptaoxide (hydrate)

[233] Cobalt(II) sulphate, cobalt dichloride, cobalt(II) dinitrate, cobalt(II) carbonate and cobalt(II) diacetate

[234] Action for the partial annulment of Commission Regulation [ADD] amending Annex XIV to REACH was brought to the General Court (case T-360/13, VECCO and Others v. Commission).

guidance (e.g. *Readers' guide for preparing an application for authorisation*[235], *How to apply for authorisation*[236]), comprehensive update of *How to develop use descriptions in applications for authorisation*[237]) Q&As and other relevant information available on the ECHA's website. In addition, to ensure that applicants are well-informed about the process and to clarify any specific questions regarding their applications before they are submitted, ECHA has also set up a 'pre-submission information session' with potential applicants. Once the opinion-making has started in ECHA, the latter also organises (when considered necessary) so-called 'trialogues' with relevant members of the ECHA Committees, the applicant(s) and interested parties who submitted comments during the public consultation, in order to clarify specific points in the application in particular related to the analysis of alternatives. More generally, ECHA has been organising annual workshops on applications for authorisation in order to help future applicants to become familiar with the system.

In addition, clarification has been provided on specific elements of applications. In particular since 2013 the RAC has been publishing on the ECHA website reference derived no-effect levels (DNELs) and reference dose-response relationships for the substances listed in Annex XIV, so that the applicants may use those values when making the risk assessment for their applications for authorisation. In that regard it has also been clarified that, where applicants use those reference values, the chemical safety report only needs to include part A, the exposure assessment (Section 9) and the risk characterisation (Section 10) for each of the uses applied for, as well as the physico-chemical properties of the substance that are relevant to any exposure modelling performed. This is of particular benefit to downstream users who may not have access to the full chemical safety report in the registration dossier.

For non-threshold substances applicants should in their applications describe the remaining risk (after application of proposed operational conditions (OCs) and Risk Management Measures (RMMs)) quantitatively/semi-quantitatively based on information on dose-response, or qualitatively if dose-response information is not available. RAC is then expected to give an opinion on the appropriateness of the proposed OCs and RMMs and whether these are effective for attaining the exposure levels in the applicant’s exposure assessment and assure that the exposure levels are as low as technically and practically possible. This information on the remaining risk is an input to the socio-economic analysis, which SEAC will use when developing its view on the health and environmental impacts and its subsequent opinion on whether these are outweighed by the benefits of continued use.

[235] Readers' guide for preparing an application for authorisation, European Chemicals Agency, December 2015

[236] How to apply for authorisation, European Chemicals Agency, December 2016

[237] https://echa.europa.eu/applying-for-authorisation/start-preparing-your-application

6.5.2 The ECHA Scientific Committees' opinion-making process on applications for authorisation

ECHA has published 'opinion-trees' guiding the different steps of the assessment of applications by RAC and SEAC, in order to ensure consistent opinions and increase predictability. The Commission has worked closely with ECHA and its Scientific Committees to ensure a common understanding of the legal requirements and provide clarifications where needed (e.g. on defining criteria for setting the review periods in authorisation decisions), to adjust and improve the latter's internal procedures (e.g. the Committees' timing for declaring whether the application is in conformity), and to ensure that the Committees' opinions are a suitable basis for the Commission to adopt a decision.

Regarding applications for authorisation in general, concerns have been raised by several Member States, NGO stakeholders and the European Parliament as to the quality of specific applications covering a large number of companies, which hampers the ability of the Committees to assess them. This in particular concerns:

- the representativeness of the data provided to support the exposure assessment in the chemical safety report (namely the representativeness of exposure scenarios for all the companies covered) leading to significant uncertainties in the determination of the level of risk for workers exposed to chemicals at the workplace; and

- the broad description of the uses applied for in cases where the substance is used in many different types of articles (for example where it is used as a plasticiser in polymers or as pigment in paints, which are then used in the production of many different types of articles) thereby rendering the analysis of alternatives for the entire scope of the uses applied for more challenging.

The European Parliament expressed particular criticism about one particular application[238], considering that the ECHA Committees had not correctly assessed the application, in particular with regard to the socio-economic aspects as compared to the costs for human health and the environment.

More generally, some NGOs see an imbalance in the evaluation of the interest of applicants and that of third parties in the public consultation, in particular of suppliers of alternatives, and have expressed concerns about the ECHA Committees giving more weight to the applicants' perspective. In their view this discourages substitution and causes disadvantage to companies that have already substituted and did not need to apply for authorisation at all. On the other hand, many applicants consider that during the opinion-forming process the ECHA Committees request considerable additional information, which creates further burdens, while – in their view – not being necessary.

The Commission services note that the ECHA Committees make their assessment on the basis of the information provided both by the applicants and by third parties in the public

[238] European Parliament non-legislative resolution of 25 November 2015.

consultation. While in some past applications the ECHA Committees have pointed to a number of uncertainties arising from the dossier, so far in none of those cases have the applications been considered by the Commission as non-conforming with the REACH requirements. However those uncertainties have led to the imposition of specific conditions and monitoring arrangements on the applicant or downstream users or to short review periods in the authorisation decision.

In order to have opinions that better suit the needs for decision-making, the Commission services have asked the ECHA Committees to clearly specify, where possible:

- which concrete risk management measures can be applied or improved to reduce risks;

- the details of the monitoring programmes recommended, the results of which can be used by the RAC when reviewing authorisations.

6.5.3 Streamlining and simplifying applications for authorisation

The authorisation system creates a step-wise increasing pressure starting from the SVHC identification, through prioritisation and then inclusion into Annex XIV so that these substances are substituted when and where there are suitable alternative substances or technologies. Exercising this substitution pressure dissuades the continued, albeit controlled, use of these substances. A certain pressure is therefore naturally and intentionally built into the authorisation system and awareness of it has been evolving with the entry into operation of the authorisation provisions.

The authorisation requirement is still in its early stages of implementation and naturally, in the beginning it has triggered concerns with stakeholders regarding the predictability of the process and the cost for applicants, while NGOs have raised concerns and called upon authorities to implement the authorisation processes more rigorously.

This led the Commission to start a debate in 2014 with Member States and ECHA, followed by debates with past and future applicants and stakeholders to take stock of the early experience gained and identify challenges and possible solutions for all parties concerned.

Those discussions have shown that, although the process of applying for authorisation is working, there is room for improvement with regard to the administrative burden for applicants and in particular for SMEs, who account to date for one-fourth of all applications. The Commission in 2014[239] acknowledged the need to lower the administrative burden by increasing the predictability of the process, implement a general streamlining of the process, and simplifying it in specific cases where possible. To assist the Commission and ECHA in developing those actions, a Task Force for improving the workability of the applications for authorisation process ('AfA Task Force') was set up. In

[239] *Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook*, 18.6.2014 (COM(2014) 368 final)

addition, the Commission considered modifying the authorisation fees and their structure in order to better align them to the actual cost for their handling by ECHA[240].

Simplification in certain specific cases

The Commission identified two cases where it considered a simplification of the requirements was clearly justified, namely for uses of a substance in low quantities and for uses in spare parts of articles that are no longer produced, as well as in the repair of such articles.

- in the case of uses in low quantities the simplification is justified by the relatively high burden of preparing a standard application as compared to the likely risk for human health or the environment from the use in low quantities;
- in the case of uses in legacy spare parts the main purpose is to avoid the premature obsolescence of articles, where they cannot function as intended without those spare parts, as well as where a particular Annex XIV substance is necessary for the repair of such articles.

In all cases, simplification is envisaged within the framework of the requirements laid down in the REACH Regulation, by specifying as far as possible the particular information to be provided within that framework. Work on these initiatives is progressing slowly due to considerations on the extent of the Commission's empowerment by the REACH Regulation to propose such measures.

Other possible specific cases for simplification have been discussed, such as for uses of substances as biologically essential nutrients, uses of recycled substances and uses in products subject to type-approval or certification requirements. While the latter case was abandoned (since type-approval or certification requirements were considered rather as elements for consideration in the application for authorisation itself, in particular in the analysis of alternatives and for setting the length of the review period), conclusions on the two first cases have not yet been reached.

General streamlining

The Commission, together with ECHA and the AfA Task Force, reflected in 2016 on possible ways to improve the predictability of the application process in general, and to better inform applicants, with specific instructions and practical examples based on previous applications, Committee opinions and authorisation decisions, on how to prepare a fit-for purpose application. This work was conducted in the AfA Task Force and was concluded with the publication by ECHA of the step-by-step guide *How to apply for authorisation*[241]. This guide notably clarifies the type of data required regarding in particular the chemical safety report (exposure assessment) in order to be representative, the elements to consider for describing the uses applied for and the level of detail needed in the socio-economic analysis in cases with minimal expected health impacts. This guide

[240] See Fee chapter

[241] Link to ECHA guide on "How to apply for authorisation"

should help in particular applications that cover many companies to prepare good quality dossiers and to avoid spending resources in gathering and submitting unnecessary information. This should benefit in particular SMEs, in cases where specific uses of a substance are similar across a sector of activity and no feasible alternatives exist. How effective the guide will be in improving predictability for applicants will have to be assessed in the coming years, on the basis of the quality of future applications.

REFIT platform

The European Environmental Bureau (EEB) submitted a paper to the REFIT Platform on the Authorisation process, making the case that the process is not working properly and is too slow. The underlines the main flaws of the process and sets out a clear path for reform showing how the Authorisation procedure can be made fully fit for purpose to achieve not only its main goal, namely health and environmental protection, but also its goal of free circulation of substances on the internal market while enhancing competitiveness and innovation[242].

6.6 Other issues

It is worth noting that most applications for authorisation submitted so far are from downstream users and for their own use, and the quality of those applications tends to be better than that of applications covering a large number of different operators. In this context, certain applications covering many downstream users still trigger many questions for clarification by ECHA' Committees in order for them to fully understand the scope and content of the applications and need to involve consultants and consortia managers. In some cases, the cost to apply can indeed be regarded, in absolute terms, as substantial, if referring to applications with a very broad scope and covering complex supply chains. For instance, Lanxess Deutschland GmbH estimates that the cost of their joint application for the use of chromium trioxide was around 4 million, half of which approximately was spent on managing the consortium and the other half on the application itself[243]. This cost needs nonetheless to be significantly nuanced if considered in terms of per applicant and per use, since the application was submitted by 7 different applicants, for 6 different uses of the substance. Thus, if looking at the cost per applicant per use, more affected are those that apply on their own and that rely on a consultant to develop most parts of their application. In the other end, the case of applications from individual downstream users for very specific uses (e.g. Biotech for the use of EDC), where there are no consortium-related expenses and no consultant needs to be involved, or to a very little extent, the main financial cost is ECHA's administrative charge.

It is clear that the centralised authorisation process created by REACH were intended by the legislator to allow actors at the top of the supply chain to apply for the uses of their downstream users, and for actors to submit joint applications. Therefore the authorisation process must be practical for this type of applications for it to be fully implemented as

[242] Link to the opinion by the REFIT platform

[243] ECHA's Newsletter n°2, April 2015

originally intended. Ensuring that applications for authorisation covering a large number of operators are of good quality is one of the main challenges in the implementation of REACH authorisation.

There are differing views as to the minimum level of detail in the information that such applications should contain in order to consider them as sufficiently documented. In that regard, the Commission has received two requests for internal review of two authorisation Decisions[244] under Article 10 of Regulation (EC) 1367/2006[245]. The Commission has dismissed the two requests for internal review as it considered them unfounded. Furthermore, the Commission has been challenged before the General Court concerning the Implementing Decision granting an authorisation for uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red[246] as well as concerning its response to the request for internal review of the Implementing Decision granting an authorisation for uses of DEHP in recycled PVC[247].

Moreover, some Member States have suggested that the Commission should clarify details of the content of applications for authorisation in a legally binding form through an Implementing Regulation. The Commission services consider that the impacts of the renewed guidance mentioned above should be awaited first.

Industry stakeholders have raised concerns regarding the impacts of authorisation on competitiveness of EU industry in terms of uncertainty, competitive advantage for non-EU producers of articles and potential relocation of activities outside the EU[248].

Experience in dealing with applications for authorisation for non-threshold substances has triggered the discussion on whether it would be appropriate to identify acceptable levels of risks[249]. Discussions have taken place regarding carcinogens in the context of authorisation, focusing on workplace exposure, and in the context of restrictions, focusing on consumer exposure. These reflections should continue with a view to the determination of acceptable levels of risks for all non-threshold substances.

6.7 Achievement of the objectives of authorisation

The assessment of the applications for authorisation submitted so far shows some positive developments towards improving risk management of Annex XIV substances

[244] Request for an internal review by ClientEarth of Commission Implementing Decision C(2016)3549 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) and Request for an internal review by ClientEarth, EEB, ChemSec and IPEN of Commission Implementing Decision C(2016)5644 granting an authorisation for uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red:http://ec.europa.eu/environment/aarhus/requests.htm

[245] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies

[246] Case T-837, Sweden v. Commission

[247] Case T-108/17, ClientEarth v. Commission

[248] Please see section on competitiveness for further details

[249] Workshop on "Acceptable level of risk to workers and consumers exposed to carcinogenic substances"

and efforts towards substitution. As concluded by the ECHA Report on the Operation of REACH and CLP 2016[250], there is evidence that substitution is happening as a result of substances being listed on the Candidate List and the Annex XIV recommendation. The following achievements can be noted:

- By March 2016, ECHA received applications for authorisation relating to only 21 substances out of the 31 substances included in Annex XIV by then, which may be an indication that substitution is taking place for all or at least part of the remaining 10 substances.

- Even if applications for authorisation are received, there are indications that substitution is taking place. DEHP was registered by 25 companies, however only three manufacturers of DEHP applied for an authorisation, out of which one withdrew the application subsequently. The EU's production and consumption of dibutyl and dioctyl orthophthalates (which includes DBP, DEHP and DIBP primarily) have also reduced during the period 2007-2013, from circa 376k tonnes to 89k (-76%) and from circa 326k tonnes to 94k (-71%), respectively, the imports not having compensated the decreases (from 4k tonnes up to 8k only during the same period)[251]. Other examples are diarsenic trioxide for which a company has found a substitute and HBCDD completely substituted by another polymeric (brominated) flame retardant.

- Not enough information is yet available on whether the production reduction is accompanied by a reduction of imports of SVHCs (e.g. phthalates) in articles[252].

- About a quarter of the applications were for "bridging", i.e. the applicant has identified a substitution strategy and applied for a specific period until the substitution would take place.

- The costs of applying for authorisation remain high for individual companies, even though they have significantly decreased over time (i.e. from EUR 230,000 on average per substance, use and applicant for the first applications to EUR 120,000 in 2016, of which 15-20% are attributable to the fees)[253, 254].

- The costs of applying for authorisation can be considered as relatively low when compared to the overall benefits from the authorised uses.

[250] Report on the operation of REACH and CLP, European Chemicals Agency ECHA, May 2016
[251] Annexes to the Annex XV restriction report for four phthalates DEHP, DBP, DIBP and BBP, April 2016
[252] Article 69(2) envisages a restriction procedure for Annex XIV substances in articles
[253] Report on the Operation of REACH and CLP 2016, European Chemicals Agency, May 2016
[254] This reflects a partial picture of the costs and the benefits. Additional data will become available from an ongoing study.

- It is acknowledged that "regrettable substitution"[255] might happen, however its share in the overall substitution picture is not known.

- Furthermore, when preparing an application for authorisation, many applicants have revised and improved their risk management measures and operational conditions, which in practice improved workers protection. Companies are actively seeking to substitute and investing in substitution related activities[256].

Based on the applications for 32 uses of 9 carcinogenic substances ECHA estimated that the cumulative socio-economic benefits of the authorised continued use of the substances, derived from the direct and the indirect compliance costs, are at least EUR 368 million per year, for the use of 8,400 tonnes of the substances per year. On the other side, the monetised risks, calculated from the modelling via dose-response function of the statistical cancer cases on workers and on the general population for each substance, were estimated to amount to EUR 7.4 million per year.

[255] Substances that are replaced by other substances of similar concern

[256] Study on the impacts of REACH authorisation - final report

7 Restrictions

Conclusions of 2013 REACH Review

In the 2013 REACH Review the Commission services concluded that, under the REACH procedure it is possible to adopt new restrictions faster and more transparently than under pre-REACH legislation. The implementation of Title VIII of REACH was still in the early stages; nonetheless it was suggested to streamline and improve the efficiency of the whole process (Annex XV dossier preparation and subsequent steps) under the standard restriction procedure of Article 68(1), to better coordinate Member States' and ECHA's activities and improve the identification of substances for restriction.

It was also suggested to consider criteria for use of the restriction procedure for CMR substances in consumer articles – Article 68(2).

7.1 Developments after the 2013 REACH Review

During the period between January 2011 and December 2016, the Commission adopted 13 restrictions under Article 68(1) (i.e. initiated under either Article 69(1) or Article 69(4)):

- 11 of these were new restrictions,
- 2 were reviews of existing restrictions,
- 2 restriction procedures were finalised without adopting a restriction,
- 3 existing restrictions were reviewed with the conclusion that there was no need to amend the existing restrictions,
- 5 are in the opinion-making phase of ECHA or the decision-making phase of the Commission.
- 3 restrictions were proposed and adopted in accordance with Article 68(2), while 1 other is currently being prepared.
- 1 restriction was proposed in accordance with Article 69(2) and is currently in the decision-making phase.

Table 4.9 presents the information related to the restriction procedures that began during that period (i.e. submission of the Annex XV dossier, where applicable), as well as related to reviews of existing restrictions.

Based on a study conducted by ECHA[257] it is estimated that 9 of the restrictions submitted and adopted in this period under Article 68(1) produce health benefits of more

[257] Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016. Please note that these figures include only the quantified and monetised benefits and costs, and thus do not represent the absolute value of the benefits and costs of the adopted restrictions. The benefits and costs figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns, and costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the

than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, positive health impacts or removed risk for thousands of consumers and workers, at an estimated cost of about EUR 170 million per year.

Table 4.9: Overview of restriction proposals and reviews of existing restrictions considered under REACH between 2011 and 2016

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Four phthalates (DEHP, DBP, BBP, DIBP) in articles	Article 69(4)	Denmark	14/4/2011	No vote	Restriction process finalised without amendment of Annex XVII[258]
Chromium VI in leather articles	Article 69(4)	Denmark	20/1/2012	4/11/2013	
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	Article 69(1)	ECHA	19/4/2012	17/12/2013	
Lead and its compounds in consumer articles	Article 69(4)	Sweden	18/1/2013	3/12/2014	
Nonylphenol ethoxylates (NPE) in textile	Article 69(4)	Sweden	3/8/2012 and 29/7/2013	7/7/2015	
1-Methyl-2-pyrrolidone (NMP)	Article 69(4)	Nether-lands	9/8/2013		Pending Commission decision
Cadmium and its compounds in paints	Article 69(1)	ECHA	17/10/2013	22/9/2015	Review of an existing restriction

reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[258] Pursuant to Article 73(1) of REACH, the Commission considered that the conditions laid down in Article 68 are not fulfilled and did therefore not prepare a draft amendment to Annex XVII of REACH - OJ C 260, 9.8.2014, p. 1–4

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Phthalates in Point 52 of Annex XVII	Article 69(1)	ECHA	NA	No vote	Review of an exisiting restriction with conclusion of no need for further action[259]
Phthalates in Point 51 of Annex XVII	Article 69(1)	ECHA	NA	No vote	Review of an existing restriction with conclusion of no need for further action[260]
Ammonium salts in in cellulose wadding insulation materials	Article 129(3)	France	15/1/2014	3/2/2016	First use of the safeguard clause
Cadmium and its compounds in artist paints	Article 69(4)	Sweden	17/1/2014	No vote	Restriction process finalised without amendment of Annex XVII[261]
Bisphenol A in thermal paper	Article 69(4)	France	17/1/2014	6/7/2016	
Asbestos	Article 69(1)	ECHA	17/1/2014	3/2/2016	Review of an existing restriction
Decabromodiphenyl ether (DecaBDE)	Article 69(1)	ECHA	1/8/2014	20/9/2016	
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	Article 69(4)	Germany	17/10/2014	7/12/2016	

[259] ECHA completed its review in August 2013. The Commission services' conclusions are published at: http://ec.europa.eu/DocsRoom/documents/13172/attachments/1/translations

[260] ECHA completed its review on 13/11/2013. The Commission services' conclusions are published at: http://ec.europa.eu/DocsRoom/documents/5765/attachments/1/translations

[261] Pursuant to Article 73(1) of REACH, the Commission considered that the conditions laid down in Article 68 are not fulfilled and did therefore not prepare a draft amendment to Annex XVII of REACH - OJ C 356, 28.10.2015, p. 1–3

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Methanol in windshield washing and de-frosting fluids	Article 69(4)	Poland	16/1/2015		
Siloxanes D4 and D5 in personal care products	Article 69(4)	UK	17/4/2015		
Lamp oils and grill lighter fluids	Article 69(1)	ECHA	8/7/2015	NA	Review of an existing restriction with conclusion of no need for further action[262]
TDFA and derivatives	Article 69(4)	Denmark	2/10/2015		
Four phthalates (DEHP, DBP, BBP, DIBP) in certain articles	Article 69(2)	ECHA	1/4/2016		
N,N-Dimethylformamide	Article 69(4)	Italy	17/6/2016		Possible resubmission of Annex XV dossier pending
Diisocyanates	Article 69(4)	Germany	7/10/2016		
PAHs in rubber and plastic articles	Article 68(2)	Com-mission	4/6/2010[263]	18/6/2013	
Newly classified CMR substances and mixtures for supply to the general public	Article 68(2)	Com-mission	NA	4/11/2013	
Newly classified CMR substances and mixtures for supply to the general public	Article 68(2)	Com-mission	NA	16/3/2017	

[262] Published at: http://ec.europa.eu/DocsRoom/documents/11463/attachments/1/translations

[263] Date of submission of technical dossier by Germany to the Commission

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
CMR in textile articles	Article 68(2)	Com-mission	NA		Public consultation on the initial proposal from 22/10/2015 to 22 March 2016[264]. A technical workshop to discuss a refined approach was then organised on 7 February 2017[265].

7.2 Comparison with the Baseline

The documentation required to support a restriction under REACH has many similarities with those needed in the pre-REACH system. A comprehensive risk assessment was conducted and where it concluded that a risk needed to be managed then a risk reduction strategy was also required, which could result in a recommendation for establishing a restriction. These two elements were included in Annex XV to REACH, though the risk assessment under REACH can be targeted. In the pre-REACH system, the restriction proposal itself as well as the socio-economic analysis was developed by the Commission whereas under REACH the Member States can submit restriction proposal and the socio-economic analysis is no longer mandatory.

Overall, the number of restrictions initiated per year is about the same as in the final years of the pre-REACH system, the latter being based on the outcome of evaluations conducted under the Existing Chemicals Regulation[266] (see Table Y for details), while the numbers are becoming more stable from one year to the other.

Table 4.10: Comparison of number of restriction procedures initiated under REACH and amendments of Directive 76/769/EEC

Number of restrictions initiated under REACH		Number of amendments of Directive 76/769/EEC	
2011	1	2003	6
2012	2	2004	3
2013	4	2005	3
2014	6	2006	2
2015	3	2007	1
2016	3	2008	1

[264] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299
[265] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9088
[266] Regulation (EEC) No 793/93

Nevertheless, the numbers fall short of what was expected from REACH at the time of adoption, when the Commission estimated that Member States would prepare 11[267] Annex XV dossiers for restriction per year, reflecting in particular that more information would be available.

7.3 Implementation of Articles 69(1) and 69(4)

Today, ECHA is the major contributor to the preparation of Annex XV dossiers due to requests from the Commission. In fact, ECHA has initiated 5 restriction procedures and conducted reviews for an additional 3 restrictions. Even though the REACH Regulation conferred the right to initiate the EU-wide restriction process on the Member States, a right that the Member States did not enjoy in the pre-REACH system, only 8 Member States have so far made use of this prerogative (and only 4 have done it more than once). This is particularly noteworthy because a higher share of Member States prepared comprehensive risk assessments in the context of the Existing Substances Regulation in the pre-REACH system as described in section 2.1: the high workload and technical expertise required where identified as the main reasons.

Collaboration among Member States and between Member States and ECHA has improved and several joint Annex XV dossiers have been prepared (e.g. DecaBDE, PFOA and phthalates). 4 Member States and ECHA are working together on the Annex XV dossier on tattoo inks, completed in 2017.

Nonetheless, most Member States perceive the development of restriction proposals as too burdensome in particular the preparation of the socio-economic analysis, which results in few Member States becoming actively involved. Although the socio-economic analysis is not obligatory to conform with Annex XV, the SEAC considers such information necessary for their work and the Commission needs it for its decision making. This has resulted in fewer restriction proposals being submitted, thus potentially slowing down substitution of hazardous chemicals that pose unacceptable risks.

Several Member States also considered that it is difficult to identify good candidate substances for proposing restrictions as compared to other risk management options. This is due to:

1. limited data has been generated for the chemical inherent properties in the registration dossiers, with industry submitting adaptations to fill the majority of data gaps. The

[267] Estimation made by the Commission services during the drafting of the proposal for the REACH Regulation and discussed with Member States in the so-called Commission Working Group to prepare for REACH (2005-2006). These estimation formed the basis of the financial Fiche accompanying the Commission Proposal and the Extended Impact Assessment. The assumption for restrictions was that better information in the registration dossiers, more information on the hazard properties of substances (e.g. through substance evaluation), the ability to target the risk assessment and strict deadlines would significantly increase both efficiency and the ability to identify substances needing restrictions.

majority of the adaptations conclude no concern for the substances[268]. There is therefore limited new information available to identify new problematic substances;

2. the fact that the substance evaluation process, which could lead to the identification of candidate substances, takes longer and produces fewer results that expected, in particular obtaining the desired exposure information as proven difficult[12];

3. it could be an indication that the requirements of REACH related to registration and communication of information in the supply chain have led to better risk management decisions by industry, thus reducing the occurrence of unacceptable risks that need to be addressed via a restriction.

As described in section 6 on authorisation, ECHA has in the meantime developed a common screening approach[269] that provides the Competent Authorities every year with a list of potential candidates for all REACH and CLP processes, which, together with the risk management option analysis, has the potential to identify more substances as candidates for restriction. By June 2017, 6 restriction proposals have been submitted as result of the common screening activity and one proposal is still at the RMOA stage.

During the public consultation, several Member States and NGO stakeholders commented that ECHA's Committees are too strict when checking the conformity of restriction proposals or when asking for additional information during opinion-making, which requires dossier submitters to invest further resources to get the dossiers accepted and processed. They consider, therefore, that the implementation of the REACH provisions requires too high a level of evidence compared to what the legal text stipulates. The public consultations conducted by ECHA were also criticised, with some considering that they are not sufficiently publicised and the information received on alternatives is disappointing, while SMEs in particular highlighted the impossibility to contribute to the high number of consultations, which is further hampered by the fact that most consultation documents are only available in English. Lastly, the final decision-making step is hampered by the fact that some Member States and NGO stakeholders consider that the SEAC does not scrutinise sufficiently requests for exemptions/derogation from proposed restrictions, accepting them as they come, and recommends too long transition periods. The information submitted by industry during public consultation for claiming an additional derogation or longer transitional period is considered not comprehensive enough for a scientific and technical assessment by RAC and SEAC in comparison to the information requested for an application for authorisation.

According to data provided by ECHA, the Agency invested the equivalent of 1 full-time person per year to prepare each Annex XV dossier plus the costs of a consultant of around EUR 60,000, depending on the difficulty of the dossier. It should be noted that

[268] See Evaluation Chapter for a comprehensive analysis of this.

[269] https://echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/screening

comparable costs were incurred in the pre-REACH system by the Commission when preparing restriction proposals, which required the preparation of an impact assessment to accompany a proposal submitted to Council and Parliament in the legislative procedure, in particular for the substances which were not evaluated in the context of the Existing Substances Regulation. One Member State reported costs, in relation to the complicated Annex XV dossier for PFOA and related compounds, of up to 2.5 persons per year and up to EUR 635,000 for consultancy. Another Member State[270] considered that the costs of preparing proposals for restrictions under REACH to be between EUR 0.5 -1 million).

On the other hand, the substances for several proposals have also been under scrutiny in the international domain such as the Stockholm Convention on Persistent Organic Pollutants (e.g. DecaBDE and PFOA). Therefore, the investment made in preparing a restriction proposal under REACH has also supported the EU nomination of the substances under the Stockholm Convention.

Furthermore, in anticipation of possible restrictions, respondents to the information gathering for the study *Monitoring the impacts of REACH on innovation, competitiveness and SME*s, confirmed that between 17.2% (SMEs) and 5.4% (large firms) of respondents withdrew substances from the market when these were entered into the registry of intentions to restrict substances.

Under the Existing Substances Regulation, the precautionary principle, according to the Commission Communication[271], was applied to 4 substances – twice leading to severe restrictions and twice leading to the request for additional information. Since the entry into force of REACH, the precautionary principle has not been invoked to justify the restriction of a substance. The available evidence in all cases allowed the RAC to conclude on the existence, or absence of an unacceptable risk or that additional information was needed to concluded. The principle could be invoked by ECHA where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question. In such cases, ECHA should highlight to the Commission which information is needed to clarify the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction.

Lastly, the principle of "internal market" harmonisation by virtue of Annex XVII entries and the availability of the restriction procedure in Title VIII has been generally accepted by Member States although some have still adopted (or attempted to adopt) national measures without following the procedures foreseen under REACH and without developing proposals for EU-level restrictions. Where such cases were notified to the Commission in accordance with Directive (EU) 2015/1535, the Commission issued detailed opinions or comments to the Member States concerned, setting out its

[270] KEMi (2015) Sub-study a report on The strategy for a non-toxic environment of the 7th Environment Action Programme

[271] COM (2000) 1 final

interpretation of the harmonising effect of Title VIII. In 2016 the EFTA surveillance authority, supported by the Commission, brought Norway before the EFTA Court when Norway adopted national restrictions on PFOA and related compounds, even though a EU-wide restriction was being developed and has since been enacted.

7.4 Actions taken to improve the efficiency of the restriction procedure

7.4.1 Task Force on the efficiency of the restriction procedure

In 2013, a Task Force (Commission, ECHA, RAC and SEAC members, and Member States as Dossier Submitters) was set up to improve the efficiency of the restriction procedure. Within a year, the Task force agreed on 71 recommendations in relation to the role of the dossier submitter and the Committees, the involvement of stakeholders in the two public consultations[272], the opinion making process and deliverables, and the required extent of the analysis.

Implementation of those recommendations has delivered the following positive results:

- clarification of the role of the dossier submitter in the preparation of the Annex XV dossier and the opinion-making process;
- streamlined structure and reduced length of Annex XV dossiers, without undermining their quality;
- better coordination during the scientific/technical assessment of the dossiers by RAC and SEAC;
- improved public consultations;
- clarification of the scope of restriction proposals as regards the risk assessment underpinning the proposal and the substances identified, which includes the grouping approach;
- clarification of the necessary socio-economic information and analysis in context of the proportionality assessment.

The implementation of the recommendations is "work in progress" as the Task Force continues its work, based on experience gained with new restriction dossiers. For example, a paper has been developed on second hand articles and stocks in order to contribute to the efficiency of restriction procedures. Other aspects under continued analysis are the conformity check, the grouping approach, the analysis of alternatives, the better use of the international assessments and the information submitted during the ECHA public consultation.

Regular workshops are held with Member States (normally once per year) to discuss how to make further improvements in the process. This will be supplemented by occasional

[272] The complete list of recommendations can be consulted on the ECHA website https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

joint workshops also with Committee members and the Forum to obtain a holistic overview of progress.

7.4.2 Further action by the Commission and ECHA

As Member States had in particular referred to lack of experience/capacity and the high burdens related to the preparation of the socio-economic analysis for an Annex XV Dossier as a reason for not submitting restriction proposals, the Commission and ECHA have provided support to Member States for preparing socio-economic analyses for restriction proposals. In particular, ECHA has set up a Network for Socio-economic Analysis and Analysis of Alternatives Practitioners (NeRSAP), which provides peer-to-peer discussions and capacity building. Several Member States have participated in these network meetings that have been held five times in 2011-16. In 2016, ECHA organised together with the Commission a workshop on how to carry out socio-economic analysis. ECHA has also provided hands on assistance to Member States when they carried out socio-economic analysis as part of their preparation of restriction dossiers. The Commission developed a 'SEA Toolkit' to facilitate data gathering, mapping of the supply chain, and the assessment of competitiveness, innovation and the impacts on SMEs. However, so far it has not been used extensively.

7.5 Implementation of Article 68(2)

Article 68(2) of REACH sets out what is often referred to as a fast-track procedure based on a generic risk assessment approach for the restriction of CMRs (categories 1A and 1B), as substances, in mixtures or in articles which could be used by consumers.

The routine restriction of CMR substances and mixtures for supply to the general public following harmonised classification under the CLP Regulation[273] is well established, and was already implemented in the pre-REACH system under Directive 76/769/EEC. Such restrictions were adopted under REACH in March 2014 and March 2017 to restrict 33 additional substances newly classified as CMR under the CLP Regulation.

The situation is less clear as regards the newly introduced possibility to use Article 68(2) to restrict CMR substances in consumer articles. The first restriction was adopted in December 2013[274], supported by evidence submitted by a Member State to the Commission already in 2010. The complexity of this case, mainly in terms of conditions (e.g. direct, prolonged or short-term repetitive contact with the human skin or oral cavity, the proposed limits of concentration) and identification of the articles concerned slowed down the whole process, making it no shorter than the standard restriction procedure. Therefore, the Commission services together with Member States and ECHA developed a systematic approach on when to apply this fast-track procedure to the restriction of consumer articles containing CMRs (categories 1A and 1B).

[273] Regulation (EC) No 1272/2008

[274] Annex XVII - Entry 50, paragraphs 5 and 6, on PAHs in rubber and plastic components of articles. https://echa.europa.eu/documents/10162/176064a8-0896-4124-87e1-75cdf2008d59

In this context, the Commission services commissioned a study in 2012 to analyse the potential impacts of restricting different CMRs in articles using Article 68(2). The Commission used the results of the study to develop a general approach and criteria, explained in a paper[275] that was discussed with the Competent Authorities and stakeholders and considered aspects such as the level of risk assessment required to underpin the proposal, the need for socio-economic data, or when and how to consult experts, stakeholders and Member States. Textile articles and clothing were proposed as a first case study, because of the potential for long-term dermal exposure to chemicals contained in textiles. The preparation of this restriction is almost complete[276] and, on the basis of this example, the Commission will reflect on how to proceed with future restrictions under the Article 68(2) procedure.

7.6 Implementation of Article 69(2)

ECHA has already finalised 6 dossiers examining the need for restrictions for substances subject to authorisation when present in articles, once the sunset date has passed (MDA, musk xylene, HBCDD, diarsenic trioxide, diarsenic pentoxide and the phthalates DEHP, DBP, BBP, DIBP). According to information from the authorisation applications, and the calls for evidence[277] carried out by ECHA, the first five substances were not used in consumer articles produced in the EU and ECHA found no evidence that they were present in imported articles[278].

The situation is different for the phthalates and ECHA in cooperation with one Member State prepared and submitted a restriction dossier, which is currently being assessed by RAC and SEAC.

During the period between the sunset date and the adoption of a restriction under Article 69(2), imports of articles containing a substance listed in Annex XIV (if indeed the substance is present in articles) may continue unabated while the production of the same articles in the EU is prohibited or subject to the conditions of authorisations granted. With a view to minimising the length of this period, in which EU citizens' health or the environment may be at risk, and economic operators in the EU may be at a competitive disadvantage, the Commission services and ECHA have agreed on the importance of taking all possible preparatory steps in the lead up to the sunset date in order to expedite analysis of the need for a restriction.

It has to be noted that it is possible to introduce a restriction for consumer articles via Article 68 (2) for CMR (categories 1A and 1B) substances listed in Annex XIV. When these substances are no longer used in the EU in the production of articles, such a

[275] http://ec.europa.eu/DocsRoom/documents/10045/attachments/1/translations

[276] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299

[277] ECHA systematically launches calls for evidence to gather as much as possible information on imported articles

[278] ECHA systematically launches calls for evidence to gather as much as possible information on imported articles

restriction would prevent the re-introduction of articles containing these substances in the EU market, in particular due to potential 'new' investments of non-European companies to produce articles containing them. On the other hand, if the substances are already phased-out from all articles placed on the EU market, enacting such a restriction would not have any effect other than preventing such a potential reintroduction.

It also has to be noted that the majority of substances subject to authorisation to date are process chemicals that are not present in finished articles. While this means that there are no risks from the (non)-presence of the substances in articles placed on the market in the EU, it also means that the disadvantage for EU producers of such articles from the authorisation procedure cannot be addressed via a restriction.

8 Member States activities

Conclusions of the 2013 REACH Review

Member States are required under Article 117(1) of the REACH Regulation to submit to the European Commission every five years a report on the operation of the REACH Regulation in their respective territories, including sections on evaluation and enforcement.

8.1 Developments after the 2013 Reach Review

8.1.1 Key issues from Member State reports

Acknowledging that collecting the necessary information poses challenges to Member States, the questionnaire that was the basis for reporting due by 1 June 2010 was improved, both for content and format. All Member States submitted their reports in 2015[279], according to the improved template developed for that purpose.

8.1.1.1 Competent Authorities

There are 45 REACH Competent Authorities (CAs) operating in the 28 EU Member States and the 3 EEA countries. 6 Member States have more than one CA. Out of the 45 CAs, 28 deal with all REACH processes (i.e. registration, evaluation, restriction and authorisation). 44 CAs indicated they are involved in other chemical legislation as well. A large majority of them have responsibilities under CLP (39), Biocides (30) and PIC (30).

CAs are generally satisfied with their technical expertise, while some consider their financial and human resources too limited to achieve all activities required under REACH.

8.1.1.2 Cooperation and communication between CAs, and with ECHA and the Commission

CAs generally expressed a high level of satisfaction with the cooperation between CAs at EU and national levels and with ECHA and the Commission.

CAs expressed a high level of satisfaction over the functioning of the Forum, the REACH Committee, the Member States Committee (MSC), the Risk Assessment Committee (RAC) and the HelpNet network. The Socio-Economic Assessment Committee (SEAC), CARACAL and the Risk Communication Network (RCN) gathered less positive feedback. Frequent comments, on all groups, address organisational issues, working methods, workload, availability of experts and resources.

CAs also made proposals for improvement, regarding for instance the decision-making at

[279] Member States Reports on the operation of REACH (Art. 117)

the Forum, the REACH Committee or the MSC (such as an increased use of the written procedure for finding agreement on certain issues or voting), the duration, frequency and functioning of the CARACAL, or the opinion-making of RAC and SEAC (such as the need to improve the conformity check of submitted restriction dossiers and authorisation applications, or comments regarding the type and level of expertise of the respective members).

8.1.1.3 National helpdesks

In 25 Member States, the REACH helpdesk is part of the REACH CA. In the 6 other cases, the helpdesk is part of another Ministry, a public Agency or a public research institute. Helpdesks provide a combination of services ranging from online guidance, advice services, newsletters and/or training. The majority of helpdesks receive between 100 and 1000 enquiries per year. Most enquiries related to registration, safety data sheets and CLP labelling. Few countries keep track of the size of enquirers, but in the 11 Member States that have reported data, most enquirers were SMEs. As for the coordination network HelpNet, although a number of concerns were pointed out by respondents (among which the slow average speed to provide a reply to the more horizontal questions concerning several national helpdesks or necessitating the involvement of the Commission), over two-thirds of them considered it to be effective or highly effective.

The SME consultation carried out in the context of the REACH REFIT evaluation indicates that the overall experience with the public authorities seems to be rather neutral without a significant indication of either positive or negative experiences[280]. The number of respondents per Member State is relatively small and reveals no conclusive differences among Member States.

8.1.1.4 Awareness raising activities

Apart from the Czech Republic and Luxembourg, all other Member States indicated that they had carried out awareness raising activities during the reporting period. Most tend to target a broad audience in their activities (consumers, companies in chemicals and downstream sectors). Two-thirds of Member States have targeted SMEs as a specific group. Most common awareness raising activities include the production of easily accessible information content (e.g. leaflets and newsletter) and the organisation of

[280] A quarter of the respondents state that they have a neutral experience as regards the content of the reply they get when they contact national helpdesks concerning REACH (24%) and concerning the time needed to get a reply (25%). A similar number state their experience has been positive regarding the same aspects (28% for content of the reply and 25% for time needed to get a response).

36% of the respondents seem to be satisfied with the overall consistency of public authorities, whereas 23% say they have come across several inconsistencies. However, 41% state they never had any contact with the authorities, which can be considered quite high.

speaking events (including seminars), the development of websites and the use of social media.

8.1.1.5 Alternative test methods

17 Member States indicated that they had contributed in the past five years to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees. 11 Member States provided data on the overall public funding on national research and development of alternative testing, with six reporting expenditure of more than EUR 100,000 per year, and two Member States (Germany and the Netherlands) of more than EUR 1,000,000. The rest of the Member States did not report this information.

8.1.1.6 Involvement in dossier and substance evaluation

15 CAs reported having been involved in dossier evaluation during the reporting period. Most of them considered that the dossier evaluation process had achieved its objectives, although some concerns have been raised on the poor quality of registration dossiers impeding the evaluation process.

23 CAs have been involved in substance evaluation. 36 substances have been evaluated in 2012, 47 in 2013 and 51 in 2014. The most frequent issues reported by CAs regarding the substance evaluation process relate to the lack of expertise, capacity and financial resources, and updates of dossiers by registrants during the 12-month evaluation period, leading to changes in the evaluation process.

8.1.1.7 Preparation of restriction and SVHC dossiers

9 CAs indicated having been involved in the preparation of Annex XV Restriction Dossiers during the reporting period, sometimes in cooperation with other CAs or with ECHA. 7 of them have consulted or involved Industry in the preparation of restriction dossiers.

11 CAs reported having been involved in the preparation of Annex XV SVHC dossiers, sometimes in cooperation with other CAs or with ECHA. 7 of them have consulted Industry or involved them in the preparation of the dossiers. Most CAs (26) considered that there is enough coordination between ECHA and CAs in the implementation of the SVHC Roadmap.

8.1.1.8 Enforcement

All Member States have reported on their activities related to enforcement in the context of the 2015 reporting, including information to apply the system of enforcement indicators developed to monitor progress. The results are presented in the enforcement section of this report.

8.1.1.9 Evaluating the impacts of REACH on the environment, human health, competitiveness and innovation

With the exceptions of the CAs of Latvia and Slovenia, CAs stated that the effects of REACH would be better evaluated at EU level. 3 CAs felt that evaluating effects was necessary both at EU and national level.

9 Enforcement

Conclusions of the 2013 REACH Review

The enforcement of REACH[281] was addressed in the 2013 REACH Review but at that time little experience was available. Among other issues, it was highlighted that the Forum contributes to the harmonisation of enforcement action, which is instrumental in avoiding fragmentation of the single market and distortion of competition, and in ensuring high quality enforcement throughout the EU.

The 2013 Review concluded that:

- the Member States need to improve the coordination of their inspection and enforcement activities and to focus them across the EU to target limited resources where most benefit is to be expected.
- The Forum should provide a more systematic support to Member States.
- The Commission, with the support of the Forum, would develop enforcement indicators to monitor the implementation of REACH and achieve a more harmonised and systematic approach for the collection of information and reporting.

9.1 Developments after the 2013 REACH Review

Enforcement activities have both evolved since the 2013 Review as the different actors benefit from experience. The Member States have developed their systems and enforcement capabilities. At the same time, the Forum has developed methodologies, and tools[282] supporting enforcement. Also ECHA's increased experience has improved enforcement of parts of the Regulation (e.g. compliance check decisions after dossier evaluation or verification of SME status of registrants). Furthermore, synergies with the enforcement of other EU legislation have been developed (e.g. market surveillance, product safety, customs, occupational safety and health legislation).

9.1.1 Enforcement indicators

In response to the 2013 REACH Review, the Commission developed enforcement indicators in cooperation with Forum members. 50 enforcement indicators were proposed at three levels (EU, Forum and Member States)[283]. This is the first time that such an approach has been developed in the field of enforcement of chemicals legislation in the EU. A system of uniform EU, Forum and Member State level indicators allows for enforcement challenges to be identified and support targeted. The system also contributes

[281] REACH national enforcement authorities are very often also responsible for CLP Regulation..

[282] Templates, databases, guidance documents

[283] Study on enforcement indicators for REACH and CLP link to final report

to transparency for stakeholders and helps ensure that a certain degree of harmonisation of enforcement is performed, resulting in a more level playing field on the EU market.

Overall, it is still premature to draw final conclusions on the reliability of the first quantitative results of the indicator. Indeed, this indicator covers both REACH and CLP together. In addition, reporting from Member States would need to be further harmonised.

The average level of REACH compliance[284] reported by the Member States and ECHA has varied from 79 % to 89 % in the period from 2007 to 2014[285]. In this period, the areas with lower level of compliance are the ones related to control of imports and supply chain obligations (e.g. 52% non-compliance for safety data sheets). There are some differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end).

9.1.2 Enforcement in the Member States

The architecture of enforcement capabilities continues to be complex in most EU and EEA Countries where, in 25 out of 31 Countries[286], several authorities are responsible for enforcing different parts of REACH (e.g. health and/or consumer protection authorities, national chemical agencies, labour inspectorates, environmental authorities or customs authorities). Such complexity requires enhanced coordination at national level (e.g. via regular meetings, memoranda of understanding or development of legislation to define responsibilities among authorities). Some activities of the Forum support such coordination (e.g. prioritisation and implementation of enforcement projects), as they involve different national authorities, who then have to coordinate among themselves at national level.

All Member States have adopted national legislation on penalties applicable to infringements of REACH[287]. In the last reporting exercise three Member States informed about modifications of their legal provisions on penalties. The penalty laws in the Member States can include enforcement notices, injunctions, withdrawal of products from the market, administrative fines and criminal sanctions.

Substantial differences in enforcement exist mainly due to differences in enforcement culture. Some national enforcement authorities are understaffed, in part due to cuts because of the economic crisis. Most Member States also reported[288] that the majority of infringements of REACH are resolved without applying penalties (with the exception of

[284] The average level of compliance is calculated annually as the median value of the average levels of compliance reported by Member States. The average level of compliance experienced at MS levels take into account all controls carried out to REACH duties holders specific year.

[285] Information provided in accordance with Article 117.1 of REACH on Member States reporting obligations

[286] The EU 28 plus Norway, Iceland and Liechtenstein

[287] In accordance with Article 126 of REACH on penalties for non-compliance

[288] In accordance with Article 117.1 of REACH on Member States reporting obligations

some administrative fees in some Member States). This means they are resolved by means of verbal or written advice.

Member States have reported close to 100 000[289], controls per year in the last two years and the number has been steadily increasing since 2007[290]. The controls concerned manufacturers, importers/only representatives, distributors and downstream users, with each group accounting for more or less one quarter of the controls carried out. Data show that efforts were made to prioritise controls according to the risk profile of duty holders. Proactive controls, i.e. those conducted on the own initiative of the authorities in the context of planned monitoring and inspection activities, are the most frequent, rather than those prompted by incidents and complaints, and that these are complemented by reactive controls triggered by complaints. Controls of obligations and duties related to registration, communication in the supply chain and restrictions were the most common over the period.

It is important to highlight that apart from carrying out controls within the framework of Forum activities, the majority of Member States report additional enforcement activities (such as tackling specific local issues, investigating certain groups of duty holders, gathering intelligence on certain REACH duties) or carrying out the so-called 'regular checks' (e.g. Safety Data Sheets are commonly checked in most of the inspections).

An indication of the effectiveness of the enforcement at EU level can be estimated using data reported by the Member States[291, 292]. For this reporting period, 0.6% of enforcement decisions were appealed. For only 2% of these appeals, were decisions by enforcement authorities found inadequate[293].

The majority of Member States (21) had implemented an enforcement strategy at the end of 2014 (compared to 18 in 2010), and another 4 had devised strategies. Of the 6 Member States that had not yet developed a strategy, 3 were planning to do it. All 25 Member States that have either devised or implemented a strategy have indicated that it is, or will be, in line with the strategy of the Forum[10].

The general REACH provisions for dossier and substance evaluation do not apply to on-site isolated intermediates. However, where the National Enforcement Authority (NEA) of the site's location has concerns regarding a serious risk to human health or the

[289] The number of controls reported by the Member States is though not consistent, as some report controls several orders of magnitude higher than others. The main reason for this is that some Member States report the numbers of controls per dutyholder, whereas others report the numbers of controls per product or duty. In some cases, some Member States report fewer controls because they have not received information from all regions/provinces of their country.

[290] As informed by Member States in accordance with Article 117.1 of REACH on their reporting obligations

[291] Link to Member State reports

[292] In the period 2010-2014, Member States reported 26,296 non-compliance cases on a total of 344,546 REACH controls. The number of appeals on those non-compliances is 152 and 3 of them resulted in overturned decisions

[293] Values of the percentages based on the data provided by 19 Member States. The rest did not provide data on appeals against enforcement decisions.

environment that is not being properly controlled, the NEA can require the registrant to provide the information needed to assess this concern.

9.1.3 The Forum and enforcement within ECHA

The Forum for the exchange of information on enforcement (the Forum) contributes to the harmonisation of enforcement at EU level because, for example, the enforcement projects designed and managed by Forum entail that the same type of control is carried out all over Europe at the same time, following the same procedure as laid down in a manual[294]. ECHA provides support to the Forum through its secretariat. These EU projects have proven to be effective tools.

Initial Forum activities addressed registration and a few restrictions, whereas in recent years they have also covered evaluation, authorisation and more restrictions. Enforcement activities have been carried out relating to all tasks given to the Forum under Article 77(4) of REACH. Some examples are given in the table below.

Table 4.11. Some examples of Forum activities related to its legal mandate

Art 77.4	REACH legal text	Examples of some enforcement activities carried out in this period
a	Spreading good practices	Development of 8 project manuals to support the Forum enforcement projects and the Manual of Conclusions
a	Highlight problems at Union level	After the Forum finalises a coordinated enforcement project, they underline [295] identified challenges
b	Proposing, coordinating and evaluating harmonised enforcement projects and joint inspections	3 one-year EU enforcement projects and 5 small projects were performed[296]
c	Coordinating exchanges of inspectors	Pilot ECHA programme in 2012-2013
d	Identify enforcement strategies, as well as best practice in enforcement	Development of two strategic documents that are publicly available[297]
e	Developing working methods and tools of use to local inspectors	Forum project manuals and Manual of Conclusions

[294] Some of these manuals are in the annexes of some of the Forum enforcement projects - link to ECHA website

[295] Recommendations to the Commission can be found towards the end of the Forum enforcement projects reports https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects. For example, the Forum requests clarification on the enforceability of Article 8 of REACH

[296] Link to ECHA website - Forum enforcement projects

[297] 'Strategies for Enforcement of REACH and CLP' and 'Minimum Criteria for REACH and CLP Inspections' documents can be found at ECHA website on Forum

f	Developing an electronic information exchange procedure	A dedicated REACH-IT[298] system for enforcement authorities was developed by ECHA and is fully functional. From this year, the Commission's ICSMS[299] system linked to the Accreditation and Market Surveillance Regulation will also be used for REACH enforcement purposes.
g	Liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary	Annual open sessions of Forum meetings
h	Examining proposals for restrictions with a view to advising on enforceability	On average 4 examinations of enforceability of restrictions per year.

The vast majority of Member States (83 - 94%) participate in major enforcement projects developed by the Forum. These projects are an important tool for achieving harmonised enforcement as the same types of obligations are enforced in the EU and EEA on the basis of the same questionnaires following common priorities. In addition, between 16 and 58 % of Member States participated in small/pilot enforcement projects conceived, developed and reported by the Forum.

ECHA continues to reinforce support to Member States, for example by providing analyses of risks of non-compliance and identifying matters of severe concern. However, ECHA should take Member States' administrative capacity into account by, for example, clearly prioritising its tasks to be carried out.

In around half of the cases where an ECHA decision concluded on non-compliance (e.g. compliance check decision after dossier evaluation), companies updated their registration dossiers without the need of further action. When companies did not update after several reminders, ECHA forwarded the information to national enforcement authorities via ECHA's statement of non-compliance, for Member States to act appropriately. To date, such enforcement action has only been required in a small number of cases.

While public consultation respondents generally acknowledged the positive impact of the Forum on the harmonisation of national enforcement practices, room for improvement was identified, in particular to make the Forum's work more visible for companies. The most prominent claims from stakeholders were to build a more harmonised enforcement system and to carry out more enforcement actions.

[298] PD-NEA is the IT system used by enforcement authorities to access to REACH-IT data

[299] ICSMS system. https://webgate.ec.europa.eu/icsms/?locale=en

9.1.4 Contribution of the European Commission

The European Commission contributes to Forum's work and supports Member States in their activities and has, for example:

- Improved the template of the questionnaire used by Member States to report on the implementation and enforcement of REACH. The questionnaire now includes some information necessary to calculate EU level enforcement indicators.
- As it concerns the role of customs in the enforcement of the REACH requirements, the roles and tasks of all actors should be defined more clearly in order to enhance legal certainty for both economic operators and customs authorities. To this effect, the Commission may consider regulatory measures in addition to non-legislative means (eg guidance, training, pilot projects).
- Encouraged REACH enforcement authorities to use the ICSMS (Information and Communication System for Market Surveillance)[14]. The system will improve the exchange of information among national authorities and with authorities from other Member States. This will increase interaction among authorities and sensitise other authorities for enforcement action.

9.2 Stakeholder consultation

The responses to the public consultation about enforcement in the context of the REACH review were distinctly less than positive. The overall enforcement provided by Member States and Forum activities is considered not at all satisfactory or rather unsatisfactory by 40% of the respondents but 30% say it is rather or very satisfactory. The prioritisation of enforcement at EU level is viewed favourably. However, the most negative perception came when respondents were asked if REACH is uniformly enforced across the EU as 70% of the respondents said that REACH is not uniformly enforced. Such negative views were predominantly expressed by businesses (most of the respondents), but also by NGOs and consumer organisations.

The Accreditation and Market Surveillance Regulation (Regulation (EC) No. 765/2008[300]) contributes to providing legal certainty for authorities when enforcing product-related obligations (e.g. those related to articles in the context of REACH). The results of a public consultation conducted in that framework in 2016 show that 68% of stakeholders perceive that most or some products are affected by non-compliance. However, when asked for an approximate proportion of non-compliant products, most respondents considered that less than 20% of products are affected by non-compliance and close to half were unable to make an estimate.

In their responses to the REACH open consultation, stakeholders asked in general for more national enforcement and some suggested targets for enforcement. Stakeholders identified particular shortcomings with regard to imported goods. Mostly businesses and industry organisations stated that Member States should significantly increase controls in

[300] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF

this area. This was seen of such importance because the lack of controls puts at risk Member States' enterprises competitiveness in a globalised trade system. The lack of level playing field was seen by many as a serious risk for businesses but also for consumer safety.

The public consultation also revealed that there might be room for improvement for prioritization of inspections over a 5 year period. It was felt that currently micro businesses and small business are controlled very little, around 10% to 25% within 5 years, while controls concentrate before all on large companies, around 60% of all controls. According to certain stakeholders, this practice may lead to adverse results, since micro- and small enterprises might find it more difficult than large enterprises to fulfil REACH obligations. This perception should however be nuanced, since available data[301] show that the majority of controls concerns SMEs. It is however true that the rate of non-compliance is usually higher for SMEs than for large companies.

Regarding enforcement at the Member State level the majority of respondents, industry and businesses deplored the lack of harmonised enforcement across the EU. The introduction of standard rules for enforcement was recommended by some of them. Different practices applied by national inspectors and differing national penalty systems are considered as accountable for the lack of a level playing field in REACH enforcement. Mostly businesses and industry organisations asked for more harmonised enforcement practices. As a matter of particular concern it was highlighted by mostly industry associations that national enforcement authorities were not always aware of the latest developments concerning the REACH Regulation at EU level.

These findings provide evidence for a need to develop a common understanding of what harmonisation of enforcement entails and how the level playing field can be achieved.

[301] In the REF2 enforcement project 86% of controls targeted SMEs. This proportion was of 72% in the REF3 enforcement project.

10 Fees and charges

Overview

The revenues from fees and charges are to cover part of the costs of the services rendered to companies[302]. For the period 2011-2015, however, ECHA revenues from fees and charges were sufficient to finance ECHA's budget without the need of an EU balancing subsidy. This was possible due to higher than expected fees and charges revenues from the 2010 and 2013 registration deadlines. The excess from these revenues was accumulated in a reserve, which was exhausted in 2016, when an EU balancing subsidy again became necessary.

It is foreseen that this subsidy will be needed in the future. In 2016, it amounted to EUR 60,544,763 and is forecasted to amount to EUR 69,489,500 in 2017 and circa EUR 31 million in 2018[303]. ECHA's budget must be in balance and in line with the Multiannual Financial Framework 2014-2020 for EU agencies, as set out in Communication COM(2013)519.

Commission Regulation (EC) No 340/2008 (hereafter the Fees and Charges Regulation) sets the fees and charges payable to ECHA pursuant to Regulation (EC) No 1907/2006 (REACH). The basic approach followed for registration and authorisation fees was to set a base fee and have reductions for SMEs and additional fees for joint submissions. The appeal fee is levied for appeals lodged against certain decisions of the Agency in the field of registration and evaluation. The amount of the fee takes into account workload for the Board of Appeal. In accordance with Article 22(2) of that Regulation the Commission must keep the Fees and Charges Regulation under continual review in the light of significant information becoming available in relation to underlying assumptions for anticipated income and expenditure of the Agency.

The Commission was also to review the Fees and Charges Regulation by 31 January 2015 with a view to amending it, if appropriate. However, since the information on the revenues deriving from authorisation applications was limited at that date, that review takes place in the wider context of this REFIT Evaluation.

Evolution of fees and charges revenue

In the 2006 REACH legislative financial statement[304], the fees and charges revenue was foreseen to amount to EUR 510 million over the period 2007 - 2016 and the total ECHA

[302] Fees for registrations (including updates), confidentiality claims, authorisations applications (including updates), notification of Process Orientated Research and Development (PPORD) applications, appeals to the Board of Appeal, and administrative charges, e.g. for the verification of SME status.

[303] Statement of estimates of the European Commission for the financial year 2017 (Preparation of the 2017 Draft Budget). Financial Programming 2018-2020, SEC(2016)280 - June 2016

[304] SEC(2006)924

budget over the same period to EUR 757 million (implying a balancing subsidy of around EUR 247 million).

As shown in the table below, the revenue has been 14% higher than expected, which has had an impact on the level of the EU subsidy. In practice, the fees and charges revenue over the period 2007-2016 was EUR 581 million and the EU balancing subsidy was EUR 225 million.

Of the EUR 581 million, EUR 136 million comes from representatives (ie an entity that represents a non-EU producer). However, the split between EU and non-EU produced substances is not as simple as this as other non-EU producers will have registered through an EU based subsidiary (Manufacturer and importer) or an importer.

Of the EUR 581 million total; Germany, the United Kingdom and the Netherlands are the biggest countries of origin accounting respectively for 23%, 12% and 10% of the fees. From Germany, around a fifth relates to representatives, whilst for the United Kingdom it is more than half.

Indeed, the incomes from fees and charges are highly volatile depending on the various registration deadlines and on the number of applications for authorisation, which, it needs to be noted, are market driven, making them hard to predict.

In particular, ECHA continued to receive, in contrast with the 2006 estimates, registrations for phase-in substances in the two highest tonnage bands (over 1,000 tpa and 100-1,000 tpa) after the respective deadlines of 2010 and 2013 (see table below). It is also difficult to know how much ahead of a deadline the companies will send their dossiers. For example, many more dossiers relevant to the 2013 deadline were submitted in 2011 and 2012 than predicted. The 2006 financial statement also assumed that no registration would be submitted until 2016 for substances in the lowest tonnage bands, while dossiers for these tonnage bands started to be received in 2008. Moreover, a significant share of registrations corresponds to substances produced outside the EU (50% over the 2008-2016 period, 40% in 2016). This makes the income predictions even more difficult to anticipate, due to the lack of information on registration intentions from the non-EU companies. Overall, the numbers reflect the dynamism of the chemical market and the changes in portfolios constantly made by operators.

The uncertainty and volatility of the fees and charges income (see tables 4.12/4.13 and figure 4.8 on the Evolution of ECHA budget and source of revenues for the period 2008-2016 below) led ECHA to take a conservative approach in its estimates because of the financial impact that it may have had in case these registrations had not materialised. This conservative approach means that the needs for the EU balancing subsidy have been overestimated, as compared to a more accurate fee forecasting.

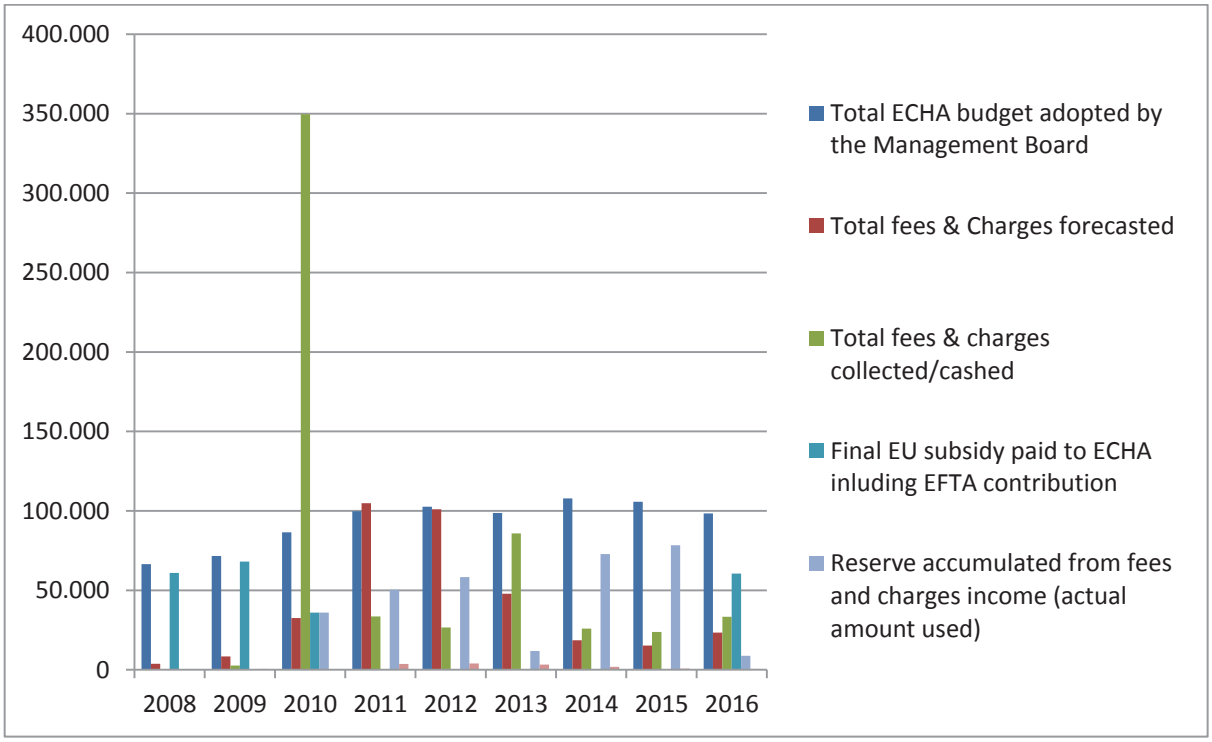
Table 4.12 Comparison of the forecast and the actual number of registrations at ECHA for substances in the two highest tonnages bands for the period 2011-2016 (source ECHA)

Number of registrations	2011	2012	2013	2014	2015	2016
> 1000 tpa						
2006 Forecasts	0	0	0	0	0	0
Actual numbers	815	422	730	369	371	384
100-1000 tpa						
2006 forecasts	93	932	8295	0	0	0
Actual numbers	437	885	6301	575	618	534

Table 4.13 Evolution of ECHA budget and source of revenues for the period 2008-2016 (source ECHA).

REACH revenues 2008-2016									(EUR 000)
	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total ECHA budget adopted by the Management Board	66,425	71,636	86,482	99,800	102,666	98,686	107,890	105,748	98,351
Total fees & Charges forecasted	3,806	8,395	32,500	104,800	100,971	47,900	18,595	15,267	23,384
Total fees & charges collected/cashed	365	2,659	349,652	33,522	26,612	85,800	25,951	23,785	33,377
Final EU subsidy paid to ECHA inluding EFTA contribution	60,934	68,051	36,000	0	0	0	0	0	60,545
Actual amount used from the reserve accumulated from fees and charges income	0	0	36,000	50,367	58,306	11,847	72,855	78,350	8,839
Other income (mainly Interest generated by the reserve) - cashed	2	503	213	3,621	3,913	3,280	1,866	740	517

Figure 4.8: Evolution of ECHA budget and source of revenues for the period 2008-2016 (source ECHA).



Conclusions of the 2013 REACH Review

The Commission considered that changes in the fee regime did not justify a revision of REACH and indicated it would address possible amendments, including those submitted by ECHA in its report, in the context of reviewing the Fees and Charges Regulation.

In the framework of the 2013 REACH Review, ECHA made some suggestions related to the fees[305]: (1) Establishing a specific inquiry fee to avoid inquiry free riding; (2) Requiring separate payments for different confidentiality claims; (3) Ensuring remuneration under CLP for rapporteurs for harmonised classification and labelling proposals that are based on registration dossiers; (4) Achieving a desired degree of self-financing for the Board of Appeal through appeal fee revenue; and (5) Ensuring sufficient coverage of all regulatory resources needed for processes for which no subsidy is assumed to arrive.

The Commission has not seen the need to consider any of the above suggested changes to the fees regime. As a matter of fact, ECHA was self-financed until 2015 (instead of 2014 as initially foreseen) and since then the EU subsidies paid to ECHA have been systematically lower than the estimate budgeted by ECHA. In addition, aiming for partial self-financing for the Board of Appeal through appeal fee revenue is not appropriate as access to the Board of Appeal for potential appellants needs to be safeguarded.

[305] The operation of REACH and CLP, European Chemicals Agency (ECHA), 2011

10.1 Developments after the 2013 Review

10.1.1 Commission actions and follow up

Since the last review of the Fees and Charges Regulation[306], the level of the fees and charges has been adapted only once to the inflation rate as measured by means of the European Index of Consumer Prices as published by Eurostat to reflect the 2013 1.5% inflation rate[307]. At that occasion, the Commission indicated that it would take account of the Agency's efforts to achieve efficiency gains when reviewing the Agency's fees and charges level.

In line with the conclusions of the 2013 REACH Review, the Commission introduced in March 2013 further reductions in favour of small and medium enterprises (SMEs) for both registration and authorisation. As far as registration is concerned, over the period 2013-2016 the additional total fee reduction for SMEs represented a total amount of EUR 1.7 million. It is to be noted though that, according to a Commission study[308], the fees represent only a small proportion of the total cost to companies. For example, for the registration of a substance, the fee would represent only 14% of the total costs, the rest corresponding to the letter of access and the administrative costs. Therefore, any further changes to the fees would only have a minor impact on the overall burden to companies.

The Commission also committed to consider further proposals by certain Member States aiming at further reducing the financial burden for companies, SMEs in particular. In addition, the Commission also enquired whether the structure and the amount of the fees had taken account of the work carried out by the Agency and the competent authorities, in line with Article 74(3) of REACH. Accordingly, the Commission assessed in detail the following potential measures:

- Measure 1: Registration fee reductions for autonomous companies with a headcount between 250 and 499 employees (so called 'Mid-Caps');
- Measure 2: Additional fee reductions for SMEs registering two or more substances in the low tonnage band (1 to 10 tonnes), i.e. multiple registrations made by the same SME;
- Measure 3: 10% reduction to the fee payable when a company registers more than 10 substances. The reduction would be applicable from the 11th registration onwards and would be applicable to all companies (not just SMEs);
- Measure 4: Payment of registration fees in instalments;
- Measure 5: Alignment of the SME reductions for authorisation (i.e. 25%, 55% and 90%) to the ones for registration (i.e. 35%, 65% and 95%).

[306] Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013. OJ L 79, 21.3.2013, p 7–18

[307] Commission Implementing Regulation (EU) No 2015/864 of 5 June 2015. OJ L 139, 5.6.2015, p 1-11

[308] Monitoring the Impacts of REACH on Innovation, Competitiveness and SME, CSES, commissioned by the European Commission, December 2015

The Commission assessed whether such measures would be compatible with the existing legal provisions in REACH. Regarding the proposal to establish a new company category (measure 1), REACH (and, consequently, the Fees and Charges Regulation) only foresee a reduced fee for SMEs and refer to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises. No other category of companies, such as Mid-Caps is mentioned. Since Commission Recommendation 2003/361/EC is binding for all EU institutions, there is no possibility to change the SME status for REACH purposes only.

As regards the opportunity to introduce further reduction on registration fees, such as reduced fees for multiple registrations by the same registrant (Measures 2 and 3), these reductions are not feasible without amending the enacting terms of the REACH Regulation since the reductions foreseen by Article 74 of REACH are exhaustive. Consequently, no reduction for multiple registrations by a same registrant, regardless of its size, can be considered under the existing REACH provisions.

The payment of registration fees in instalments (Measure 4) would be contrary to Article 20(2) of REACH, which provides that, when undertaking the completeness check, the Agency must check each registration in order to ascertain that all elements required for the REACH registration (in accordance with Articles 10, 12, 17 or 18), as well as the registration fee, have been provided. Consequently, the completeness check of each registration performed by ECHA includes the verification of whether the registration fee has been paid in full. A registration for which the fee would not have been paid in full is incomplete and no registration number could be issued. Therefore, the payment of the fee in instalments is not possible without amending the enacting terms of REACH.

Finally, with regard to the alignment of the SME reductions for authorisation to the ones in force for registration (Measure 5), so far only 21% of the applications for authorisation have been submitted by SMEs. Based on the information gathered by ECHA, the average application cost per use has been about EUR 200,000 in 2013-15. The share of the fee represents on average 19% of the total application costs. Given the level of the already existing fee reductions for SMEs, additional rebates would not have a significant effect on the total application costs, but on the contrary could have negative consequences on the finances of the Agency. For this reason, the Commission also investigated whether the current fees accurately reflected the Agency workload.

Regarding the authorisation fees, ECHA currently charges a fee for each additional applicant in a joint authorisation application (25% lower than the base fee) and another one for each additional use of a substance (80% lower than the base fee). On the basis of ECHA's experience, this does not reflect adequately the workload involved. Indeed, the workload is driven by the number of uses, not by the number of applicants that has almost no bearing on the actual work carried out. For this reason, the Commission services is considering the possibility to abolish the additional fee per applicant in a joint application and increase the fee (to 90% of the base fee) for each additional use of a substance. This should contribute to reduce significantly the authorisation costs since companies will have an incentive to introduce joint applications.

10.2 Stakeholders views

In the context of the online public consultation in relation to this REFIT Evaluation[309], the adequacy of the level of fees and charges paid to ECHA for registrations, applications for authorisation and appeals was investigated. A relative majority of respondents (38%) considered that overall the fees and charges for the registration of substances are adequate and 23% considered that they are not[310]. As far as authorisation fees are concerned, a clear majority of respondents (56%) considered them too high. As regards the fees for appeals, while the majority of respondents (55%) did not have an opinion on the matter, 22% of respondents found the level too high and 13% found it adequate. In summary, while registration fees and charges are perceived as adequate, this is not the case for authorisation. As far as appeal fees are concerned, it is difficult to draw conclusions: given the number of appeals lodged over the period 2013-2016 (72)[311], it cannot be said that the level of fees had a deterring effect.

10.3 Part of ECHA's workload financed by fees and charges

Under REACH Registration activities, fees are collected for the registration of substances and intermediates, dossier updates and PPORD notifications (exemption requests for R&D activities). For the Agency's workload calculation, the main driver for ECHA is the overall number of dossiers received - not only those generating a fee, but also the processing time and work needed for their assessment, such as the completeness check process. According to ECHA, fees finance around 70% of the workload in average during the reporting period, the rest (30%) being covered by the EU subsidy.

ECHA may also levy administrative charges. In the registration field, this is the case in the framework of the SME status verification. Indeed, ECHA checks whether the declaration made by registrants over their size is accurate or not. Should it not be the case, ECHA rectifies the fee to be paid by registrants (e.g. standard fee instead of medium-sized enterprise reduced fee) and applies an administrative charge that aims at discouraging the submission of false information. The level of this charge, EUR 20,700, was found excessive by a registrant that appealed to the EU General Court ECHA's Decision to impose this charge[312]. The Court found that in the case at hand, indeed, the level of that charge was disproportionate with regard to the savings (EUR 720) derived from the false declaration as SME. Following that judgement, ECHA revised the administrative charge for the SME verification by capping it to a maximum of 2.5 times the financial gain derived from the false declaration on the size status[313].

On the Evaluation activities, ECHA considers that, on the basis of its experience in the compliance check of dossiers the legal drafting of the decisions requires more work than

[309] Stakeholder consultation: summary report of the open public consultation

[310] The rest of respondents seem not to be concerned by the registration fees as they answered that they did not know

[311] The number of appeals per year was as follows: 22 in 2013; 18 in 2014; 22 in 2015; 10 in 2016

[312] Judgement of the General Court of 2.10.2014 in the case T-177/12 Spraylat GmbH v European Chemicals Agency (ECHA)

[313] ECHA Management Board Decision 14/2015 of 4 June 2015

foreseen by the original financial statement, especially concerning registration dossiers for substances over 1,000 tpa. Further assessment of this matter is provided in the Evaluation chapter where the general issue of efficiency gains is also addressed.

As regards substance evaluation, ECHA transfers to Member States a proportion of the incomes from the fees, so that they can carry out their evaluation work. According to ECHA, the experience shows so far that the workload per case is also higher than anticipated also due to the legal drafting of the decisions requiring more work. The transfer of fees to Member States also occurs in the work carried out in the area of restrictions and authorisations. Over the period 2015-2017, it is estimated that a total of EUR 4.4 million will be transferred to Member States. 2.1% of the registration fees will be transferred for evaluation and restriction purposes, 14.9% of the application fees for authorisation ones.

During the reporting period, the ECHA's implementing rules for the transfer of fees have been revised[314]. Indeed, in a context of declining fees revenues, it was important to ensure that on one hand Member States would receive a compensation for the work done and on the other that ECHA would have available sufficient financial resources to undertake its tasks, having regard to its existing budgetary appropriations and multi-annual estimates of income, including the planned European Union subsidy, as laid down in the Communication from the Commission on the programming of human and financial resources for decentralised agencies for the period 2014-2020[315]. For this reason, an overall ceiling of EUR 12,5 million has been set for the 2015-2017 period.

Compared to the previous period, ECHA estimates that the amount of fees transferred is going to increase. This can be explained by the increasing number of substance evaluations notified by the Member States.

10.4 Ongoing activities

In addition, the Commission is considering to review the authorisation fees as a result of the ongoing work on the streamlining and simplification of the authorisation procedure. The foreseen adoption of a simplified procedure for authorisation applications for the use of substances in low quantities applications will lead to a reduction of the workload for ECHA and its scientific committees since the information to be submitted by the applicant will be reduced in comparison to the ‘standard’ procedure. For this reason, a reduced fee proportionate for this type of application could be considered.

Further fee reductions as suggested for the registration of substances are not feasible under the existing legal framework. The Commission has proposed several measures that will contribute to reduce the burden for companies associated to the applications for authorisation, either through the adjustment of the fees level in order to better reflect the agency workload, or through the streamlining of the authorisation procedure. It needs to be born in mind though that a balance must be kept between alleviating financial burden

[314] ECHA Management Board Decision MB 45/2014

[315] COM(2013)519

on industry and ensuring that ECHA has sufficient resources to perform its tasks having regard to existing budgetary appropriations and financial programming.

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PART 6/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 5

{COM(2018) 116 final}

Annex 5 – Horizontal issues

Contents

1 Human health and environmental benefits

1.1. Scope of this chapter

The intervention logic sets out the way in which the different actions can lead to impacts on the protection of human health and environment. Whilst those actions are part of the process that leads to impacts, the impacts themselves are difficult to quantify for a variety of reasons, such: latency periods, absence of a clear counterfactual, the challenges of analysing in a situation of risk and uncertainty and where the precautionary principle underpins REACH's provisions.

This chapter looks at all of these aspects in turn to identify the human health and environmental impacts associated with REACH.

1.2. Expectations before REACH adoption and conclusions of the 2013 REACH Review

The Extended Impact Assessment the Commission published with its proposal on REACH in October 2003[1] estimated the total implementation costs to be between EUR 2.8 and 5.2 billion over 11 and 15 years respectively and the human health benefits to be in the order of magnitude of EUR 50 billion over the following 30 years (both in net present value terms). This health benefit estimate was based on an illustrative scenario developed with the support of the World Bank and World Health Organisation. A series of further analyses and a Commission funded study[2] broadly confirmed these results.

In 2013, the additional benefits to the environment were expected to be significant but were not quantified[3]. In the same vein, the Commission launched a study to assess the impact of current chemical releases to the environment and the chemicals exposure to humans via the environment[4]. The long-term benefits of REACH were estimated to be up to EUR 50 billion over the following 25 years.

No quantification of the overall benefits of REACH in terms of protection of human health and the environment has been done since. Although the 2013 REACH Review contained partial conclusions on the stocktaking of the achievements of the Regulation until then, it was acknowledged that it was still too early to quantify the benefits and the report did not provide any general estimate, other than references to some of the observed initial trends, such as the improvement of the quality of the information, the implementation of more appropriate risk management measures or the observation that some first moves towards the substitution of SVHC through the supply chain had been undertaken.

[1] REACH Extended Impact Assessment, European Commission, October 2003
[2] Assessment of the impacts of the New Chemicals Policy on Occupational Health, RPA, March 2003
[3] The impact of the New Chemicals Policy on Health and the Environment, RPA and BRE Environment, June 2003
[4] The impact of REACH on the environment and human health, DHI, September 2005

1.3. Developments after the 2013 REACH Review

Singling out the health and environmental benefits that can specifically be attributed to REACH is challenging because REACH acts in concert with a whole suite of other Union chemical legislation in order to reduce human and environmental exposures from hazardous chemicals that are manufactured, placed on the market and used. For example, reductions in workplace exposures to carcinogenic substances are driven by a combination of CLP, REACH, and OSH-related legislations. Furthermore, assigning a particular attribution factor for a particular human disease outcome to chemical exposure remains challenging, as multiple causes can be attributed and the hazardous chemical exposure being one of these. Aside a number of data gaps and uncertainties, it is still very difficult to assess what portion of a particular health or environmental improvement can be attributed specifically to REACH, as opposed to other causes.

The main environmental and health benefit of REACH is that through data generation and industry self-regulation (i.e. through the introduction of risk management measures, information to downstream users on uses advised against), as documented in the registration dossiers, as well as through the actions taken by authorities in REACH, negative impacts are avoided. It is therefore inherently difficult, even with time, to collect direct measurements concerning these benefits – data is therefore at best indirectly measurable and must often be inferred. For example, the increased information on chemicals is measurable, as is the changes in classification and labelling that this causes. However, the accidents and avoided health impacts can only be inferred from the fact that knowing that a substance is hazardous triggers a behaviour which avoids or reduces the risk of damage.

As mentioned above, the 2013 REACH Review confirmed the original expectations that the health and environmental benefits of REACH implementation would take time to materialise. The Member States reports submitted in 2015 in accordance with Article 117(1) confirm that Member States share this view. Only 5 years have passed since the last Review and it is still less than 10 years since the entry into force of the Regulation. Overall, data gathering regarding quantification of health and environmental benefits of REACH has so far been limited but progress can be assessed on the basis of the outcomes so far, as described below.

1.4. Monitoring data availability and risk reduction resulting from REACH implementation

The so-called REACH Baseline study established a set of indicators to monitor the performance of REACH, in particular regarding risk reduction and improvement of the quality of data available for the assessment of chemicals, based on a methodology established in 2007 that calculates Risk and Quality indicators. Because of the accuracy of the methodology and the availability of data it is based on, the REACH Baseline study provides a robust indicator system to monitor progress towards the achievement of the REACH benefits.

The Risk & Quality Indicator system consists of an element assessing the nominal risk and an element assessing the quality of the underlying data. The resulting Risk Scores and Quality Scores are calculated for four impact areas: workers, environment, consumers and human health via the environment.

The risk score for a substance is a nominal value that indicates to what extent a risk could be associated with the use of the substance. In order to determine the risk score, an exposure assessment and a toxicity assessment have to be made. Both steps use data regarding the hazardous properties, the toxicological potency and the exposures. The quality of both of these data sets is characterised by the quality score.

The first baseline study was published in 2009 based on data available in 2007 before REACH entered into force, a five-year update study was completed in 2012 and a ten-year update study was concluded early 2017.

According to the 10-years' update of the REACH Baseline Study[5], the aggregated Risk scores show a clear decrease compared to the baseline. The decline in risk scores and the improvement in quality are evident in all four impact areas. The decrease in risk scores is similar to the one observed in the five-year update for High Production Volume (HPV) and Baseline High Concern Chemicals (BLHC), those correspond mainly to substances registered by the 2010 deadline, and is now observed for a larger dataset including HPV, BLHC chemicals and Medium Production Volumes (MPV), the latter corresponding mainly to substances registered by the 2013 deadline.

1.5. Overall benefits of REACH for human health and the environment

A number of illustrative pieces of information can be referred to when discussing the general benefits of chemicals and environmental legislation; some of these refer more generally to the benefits of broad environmental and/or chemicals legislation, others to specific REACH processes:

- A study compared the costs and the benefits of environmental regulation in the UK[6]. The environment ministry quantified the costs and benefits of 428 of its regulations affecting UK businesses, just over half of which were derived from EU or international legislation. Overall the study estimated that with every £1 spent on compliance and enforcement returned £3 to society through economic, environmental and health benefits. This study has limited direct applicability to the benefits attributable to REACH, but it is relevant to the extent that it concludes that, referring more specifically to the UK chemicals legislation, which is almost exclusively based on EU regulation, a cost benefit ratio of almost 1 to 20 is achieved.
- Amec et al[7] found that the EU chemical legislation avoided significant costs to human health and the environment. Restrictions of certain uses of hazardous substances and the application of binding and indicative occupational exposure limits have resulted in significant reductions in exposure to carcinogens: when considering exposure to a group of 13 carcinogens since 1995, the authors estimate a total number of cancer deaths avoided (now and in the future) that may be in the order of 1.4 million deaths across Europe. The value of the reduction of the exposure to chemicals that may damage the development of children's brains has been estimated to be in the order of EUR 450 billion of avoided damage per year (in terms of higher life earnings potential).
- Another study by CSES[8] shows that around 53% of companies have improved their risk management measures because of REACH, with personal protection equipment and new safety instruction indicated with more frequency. This is an important finding and certainly constitutes a positive economic effect: various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and

[5] REACH Baseline study, 10 years update, Öko Institut et al, commissioned by the European Commission, November 2016

[6] The costs and benefits of Defra's regulations, Defra, 2015

[7] Cumulative health and environmental benefits of chemical legislation, Summary of provisional findings from the stakeholder workshop, Amec et al, 2017

[8] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, December 2015

calculated the Return on Prevention (ROP) to be 2.2[9] and the Benefit-Cost Ratio to be between 1.04 and 2.70[10].

In the absence of a clear quantification of the benefits directly attributable to REACH, a number of assumptions and intermediate results linked to the effects of the REACH processes (see intervention logic) can be drawn:

- The REACH Registration requirement leads to new and better physicochemical and (eco)toxicological information for the classification of substances, as well as to the introduction of risk reduction measures, the withdrawal of substances for which no appropriate data were available and the identification of safer alternatives
- The progressive Restriction of substances and groups of substances contributes to lowering human and environmental exposure
- The Authorisation mechanism leads to Substances of Very High Concern being progressively replaced by suitable alternatives and eventually phased-out and, while these are being used, the Authorisation process assures that the risks from them are identified, assessed and properly controlled
- The Evaluation processes (dossier and substance evaluation) are, in conjunction with the risk management option analysis (RMOA) by Member States, an essential part of the system, which allow to ensure its consistency and thus contribute to the achievement of the overall benefits of REACH

A study funded by the Commission provided indications on how harmonised classification and labelling (CLH) and self-classifications according to the Classification, Labelling and Packaging (CLP) Regulation have increased for substances and groups of substances across all the different hazard classes[11]:

[9] Calculating the international return on prevention for companies. Costs and benefits of investments on occupational safety and health, DGUV, 2013
[10] Socio-economic costs of accidents at work and work-related ill health, DG EMPL, European Commission, November 2011
[11] Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment – Development of a system of indicators, RPA, April 2016

Table 5.1: Number of substances and groups of substances addressed by harmonised classification and labelling (CLH) and self-classifications

Hazard class – PBT/vPvB – Endocrine activity	Number of substances classified under harmonised classification (June 2008 – April 2016)	Changes in self-classifications (January 2005 – February 2016)[12]
Acute toxicity	80	1 077 *(+32%)*
Skin corrosion / skin irritation	30	2 196 *(+51%)*
Skin Sensitisation	37	1 192 *(+132%)*
Serious eye damage / eye irritation	30	3 340 *(+110%)*
Respiratory Sensitisation	1	1 118 *(+538%)*
Mutagenicity	13	1 731 *(+3 329%)*
Carcinogenicity	41	2 043 *(+284%)*
Reproductive toxicity	47	384 *(+229%)*
Specific Target Organ Toxicity	72	1 692 *(over 4 000%)*
Aspiration hazard	9	419 *(+251%)*
Hazardous to the aquatic environment	90	1 547 *(+40%)*
Hazardous for the ozone layer	0	12 *(+80%)*
PBT/vPvB profile	-	-
Endocrine activity	-	-

The number of substances in this table with harmonised classification and labelling and the changes of self-classifications provide an indication of how many hazards linked to substances have been identified, hence of how much the available level of knowledge on chemical substances, fundamentally from the information generated by REACH, is evolving (among public authorities, industry and the general public). It is particularly noteworthy the significant increase of self-classifications during the REACH period for all hazard classes. The table also shows that there has been a total of 450 harmonised classifications of substances in a legally binding way since the entry into force of REACH until April 2016, which means an average of circa 56 per year, to be compared to the 7 900 substances classified by Directive 67/548[13] during the 41 years previous to REACH, that is an average of 190 per year, hence today at a slower pace than before. It is worth noting that several reasons, not strictly related to REACH only, affect the trend observed, namely the fact that under CLP the focus is (by law) on CMRs and respiratory sensitisers (and pesticides and biocides), the higher level of scrutiny today for adopting harmonised classification (notably with the introduction with REACH of the Risk Assessment Committee) and the level of resources available for Member States in this field.

However, REACH (together with the plant protection products and the biocidal products regulations) seems to be enabling the generation of new and better information, which is resulting in a swelling number of classifications, in absolute numbers and per year, with RAC delivering approximately 30 opinions in 2012, up to around 50 at present (one opinion may

[12] The list of substances with self-classifications for human health and environmental hazard (around 98 000 substances at February 2016) was retrieved from the Classification and Labelling Inventory and compared with a list of substances with self-classifications retrieved from a 2005 extract of the IUCLID system, part of the European chemical Substances Information System (ESIS). The comparison resulted in the identification of 7 709 substances which appeared to be listed on both the IUCLID and CLI lists. The Risk-phrases from the IUCLID list have been translated into Hazard-phrases according to Annex VII of the CLP Regulation. The number of substances having self-classifications for one or more H-phrases has been counted and the distribution of H-phrases has been noted for all the 7 709 substances included in both lists.

[13] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

conclude on several classifications). It can therefore be assumed that REACH is still to attain its full potential in terms of resulting classifications per year, compared to the situation previous to 2008.

This same study[14] also made an estimation of the benefits of REACH referring specifically to two different endpoints. According to these estimations, the progressive reduction in the occurrence of occupational skin diseases and occupational asthma attributed to the exposure to chemical substances has resulted in total cost savings of, respectively, around EUR 1.59-1.87 billion and EUR 250 million for the period 2004-2013. Although these values, derived from two EU Member States only (Germany and the UK), have a limited representativeness for the whole of the EU, they provide an indication of the order of magnitude of the benefits. The accrued benefits are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some skin and respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes. Nevertheless, the chemicals legislation is a determinant of many of these aspects and should be considered as having played a major role in reducing the number of cases of occupational skin diseases and occupational asthma. As a matter of fact, according to CSES et al (2015), because of REACH 53% of companies have improved their risk management procedures, with personal protection equipment and new safety instructions indicated with more frequency, and 39% have improved their management of environmental emissions and waste.

1.6. The benefits of the Registration process

REACH sets out duties and mechanisms to ensure a proper communication on uses and conditions of use up and down the supply chain. Such communication is necessary to ensure a proper description of the uses and the chemical safety assessment (CSA) at the top of the supply chain and that the end users of chemicals are adequately informed about the risk management measures that they need to take. Supply chain communication is done using safety data sheets (SDSs) that may also include exposure scenarios (extended or eSDS). Therefore, companies are now in a better position to implement risk management measures at their own work place and provide safety advice to their customers down the supply chain. The information generated in the registration process has in this manner contributed to building knowledge about chemical substances. There are indeed indications that REACH information has started to change risk management in the supply chains[15]. It has provided as well transparency about what knowledge is still missing and better awareness of the needs of the upstream and downstream value chains.

A report by RPA and CSES on the potential extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year[16] assesses the costs and the benefits of different options for the modification of the information requirements for substances registered in the 1-10 tonnes band. The study assesses the benefits, expressed in terms of damage costs avoided, on the basis of the avoidance of one incidence of 'disease' per year per substance identified with a human health classification and improvement in 1 km of waterbody for every substance identified with a classification for aquatic toxicity. The

[14] NEED TO SAY WHICH STUDY – not clear

[15] See for instance Impact REACH op MKB, Panteia, June 2013

[16] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015

study concludes that the baseline scenario provides EUR 10.02 benefits for every EUR 1 of cost and that by increasing the information requirements, there is a roughly proportionate increase in benefit in terms of damage costs avoided.

1.7 The benefits of the Evaluation processes (dossier and substance)

By requesting better information on chemicals, the evaluation processes have improved their safe use. The European Chemicals Agency (ECHA) quotes in its report on the operation of REACH and CLP (2016)[17] several cases where the information generated has led to improved risk management at company level. For example, the registrant may have more severely self-classified their substance, applied further risk management measures, withdrawn or changed the conditions of use for the substance, or even ceased the manufacture or import of a hazardous chemical. Where the registrant has not taken appropriate action on their own initiative, ECHA has recommended for Member States to consider launching substance evaluation or proposing regulatory risk management measures such as harmonised classification. Evaluation has also increased the scientific knowledge and the understanding of substances and their hazards and risks.

1.8. The benefits of the Candidate list and the Authorisation process

The general report on the operation of REACH and CLP by ECHA points out that over 100 registered substances with a harmonised classification as CMR Categories 1A or 1B out of 300 have already been placed on the Candidate List. About one-third of the remaining substances are petroleum and coal derivatives and for these, ECHA is collaborating with Member States, the Commission and industry to address them in a systematic manner. The rest have been examined and found not to warrant identification as an SVHC at this stage. For many suspected PBTs and EDs work is on-going, but this can take substantial time due to the need for higher tier endpoint testing and the related decision-making timelines defined in REACH. Nevertheless, the common screening approach developed by ECHA has laid a foundation for efficient and effective identification of candidate substances for further information generation and assessment. The report also stresses that an increasing number of companies, in particular within the retail sector, are embedding within their strategies the need to reduce or avoid the presence of substances on the Candidate List in their products, what is resulting in an accrued pressure on their suppliers to provide information on the substances they use and to initiate further analysis of possible alternatives. As a matter of fact, Milieu et al found that 72% of industry stakeholders consider REACH as the main driver to substitute hazardous chemicals[18].

The Annual Report in 2017 on the implementation of the SVHC 2020 Roadmap[19] notes that all substances for which there was sufficient information on the hazard properties have already been addressed. Since the start of the implementation of the SVHC Roadmap in February 2013, 67 Regulatory Management Option Analyses (RMOAs) have been concluded and 92 are ongoing. Around half of the RMOAs concluded propose as a follow-up to identify the substance as being an SVHC. The other half of the RMOAs identifies either the need for other REACH regulatory risk management (e.g. restriction), the need for other regulatory risk management, such as the use of other regulations than REACH (e.g. CLP), or no action. This demonstrates that the SVHC Roadmap not only triggers the identification of substances to be

[17] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016
[18] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme
[19] Progressing together to identify substances of concern - Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency (ECHA), April 2017

included in the Candidate List but allows also identifying where there is need for restrictions or other regulatory action outside of REACH/CLP processes. Even though many RMOAs cover CMR properties, there is a clear increase of other properties (e.g. ED) compared to previous years. More substances with PBT and ED properties are being identified as SVHCs, indicating that the effects of the SVHC Roadmap implementation start to be more visible. This is a demonstration that in the light of more knowledge, there are greater reasons for concern, hence the need to further investigate.

According to ECHA's 2016 report on REACH and CLP, there is evidence that substitution is already happening as a result of a substance being listed on the Candidate List and the recommendation on priority substances for inclusion into Annex XIV:

- By March 2016, ECHA had received 90 applications for authorisation relating to only 21 substances out of the 31 substances that have been placed in Annex XIV (i.e. the Authorisation List), which may be an indication that substitution has taken place for at least some of the remaining 10 substances. For instance, originally 25 companies made a registration of DEHP, but only 3 manufacturers have applied for an authorisation; the EU's production of three phthalates (DBP, DEHP and DIBP) has also reduced by more than 50 % during the period 2010-2015. Other examples are diarsenic trioxide for which a substitute has been identified and the complete substitution of the flame retardant HBCDD by a polymeric (brominated) flame retardant, once it is available in sufficient quantities. ChemSec provides in the report *The bigger picture* a number of illustrative examples of companies that have decided to anticipate regulatory pressure and to undertake substitution[20], although not in direct relation with REACH.
- A big share of the submitted applications for authorisation that have been assessed requested the necessary time to substitute the SVHC with a safer alternative. These applications expressed a clear commitment to substitute within given timelines. Indeed, about a quarter of the opinions have concerned "bridging" applications, where the applicant has identified its substitution strategy and applied for a specific period identifying when the substitution would possibly take place.
- Although suspected, it is not known whether such substances are replaced by others of similar concern, what is often referred to as regrettable substitution. Indeed, Milieu et al found that 35% of companies have substituted at least one substance with a chemical alternative that was subsequently concluded to be of concern and therefore subject to regulatory and non-regulatory pressures. These cases of regrettable substitution, which result in an attenuation of the benefits, are often related to groups of substances with similar chemical structure, such as phthalates, bisphenols, brominated flame retardants and highly fluorinated substances.

Until the end of 2016, 111 applications were submitted by Industry, for which 60 ECHA had adopted an opinion. The socio-economic benefits of the continued use associated to those 60 applications amount to EUR 4.6 – 6.4 billion per year for an annual use of up to 366 metric tonnes of 17 different substances, to be compared to monetised health impacts in the range of EUR 230 – 340 million per year[21]. Even though the specific benefits and risks figures can vary substantially between substances and between uses of the same substance, which led to the case-specific approach as established by REACH, it seems obvious that the socio-

[20] The bigger picture, assessing economic aspects of chemicals substitution, ChemSec, 2016

[21] Socio-economic impacts of REACH authorisations – a meta-analysis of the first 100 applications for authorisation, European Chemicals Agency (ECHA), September 2017

economic benefits of continued use of the substances authorised so far clearly outweighs the monetised risks (i.e. by a factor of circa 14:1).

Whilst it is too early to quantify the overall benefits of the Authorisation process as a risk management option, a good estimate is given by the benefits associated to reducing the exposure to carcinogenic substances at work since occupational cancer concerns 91% of the 60 first applications received by ECHA (Arsenic oxides, Chromium (VI), dichloroethane, Lead Chromates and trichloroethylene). From a broad perspective, a report by the RIVM estimates the direct costs of work-related cancer to be at least EUR 4 – 7 billion per year in terms of healthcare and productivity losses, and the indirect costs as much as EUR 334 billion[22]. The 2017 Commission Communication "Safer and Healthier Work for All"[23] announcing the results of the REFIT Evaluation exercise of the OSH legislation concludes that occupational cancer caused by the exposure to carcinogenic substances is the first cause of work-related deaths in the EU, with 91 500 – 150 500 people exposed to carcinogenic substances at work having being diagnosed with cancer in 2012, and 57 700 – 106 500 cancer deaths attributed to work-related exposure to carcinogenic substances in that same year.

The Commission impact assessment accompanying the first and second amendments to the Directive on carcinogens or mutagens at work[24] provides quantified figures associated to specific carcinogenic substances. Accordingly, about 91 700 workers in the EU were exposed to Chromium VI compounds in 2006. The Commission proposal of an occupational exposure limit value of 0.025 mg/m^3 for all chromium compounds, which was expected to avoid 1 810 work-related cancer cases during the period 2010-2069, will provide estimated benefits in the range of EUR 591 million – 1.7 billion.

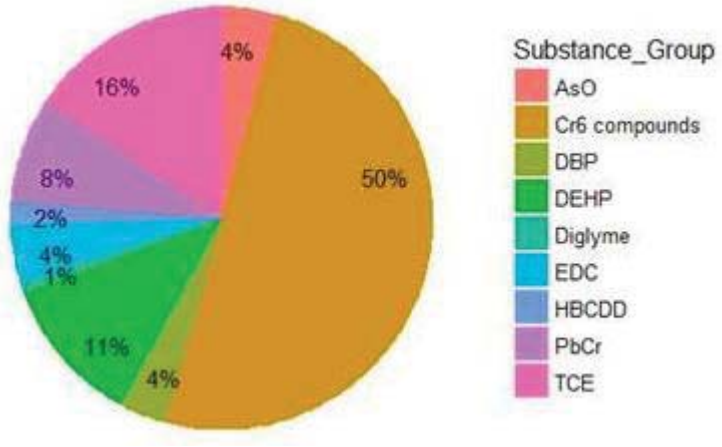
- Chromium VI compounds are listed in Annex XIV of REACH and manifold applications have been received for its use. As a matter of fact, 50% of the 60 first applications received by ECHA concern Chromium VI compounds, with an estimation of circa 186 000 workers and 60 000 locals exposed, and 73 excess cancer cases per year. The exposure limit values for the authorisation decisions adopted so far for Chromium VI compounds are set between 0.001 and 0.002 mg/m^3, 13-25-fold stricter than the occupational exposure limit value by the OSH regulation.
- For trichloroethylene (TCE), the occupational exposure limit value set by OSH legislation is 54.7 mg/m^3, with associated health cost savings expected to be EUR 118 – 430 million for the period 2010-2069. The exposure limit values for the authorisation decisions adopted so far for TCE, the second most numerous substance applied for, with 16% of all applications received so far, are set between 0.2-33 mg/m^3.

[22] Work-related cancer in the European Union: size, impact and options for further prevention, RIVM, Jongeneel W.P. et al, May 2016

[23] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final, January 2017

[24] Link to Directive 2004/37/EC

Figure 5.1: Distribution of the substances applied for (until March 2017)



Source: ECHA, 2016

These two substances alone account for 66% of the 60 first applications received by ECHA. It can thus be reasonably assumed that the more stringent limit values provided for by the REACH authorisation decisions will allow additional benefits in terms of protection of workers[25], through the reduction of occupational cancer cases alone. Also, some of the substances with carcinogenic classification are classified as well under other hazard classes (e.g. Chromium VI compounds are also classified as mutagenic 1B), so there may be further benefits.

The limit values set out in the individual authorisation applications, concern only those companies that have applied for and have been granted with an authorisation. It can be assumed that the rest of the companies (i.e. those not having applied or having been rejected the authorisation) have either ceased the use of the substances and/or replaced them by (non-classified or safer) alternatives, which would presumably signify further benefits.

There is also evidence that companies are improving their risk management measures as a result of the authorisation process, which is a clear direct indicator of the benefits of the Authorisation process.

1.9. The benefits of the Restriction process

On the basis of the calculations by ECHA, it can be concluded that the health and environmental benefits of the restrictions adopted during the reporting period for this review[26] have outweighed the costs of their implementation, with human health and environmental benefits of more than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, positive health impacts or removed risk for

[25] To consider that intermediate use is not covered by REACH authorisation but limit values are attributed under OSH

[26] This number includes restrictions submitted and adopted during the reference period (January 2011 - December 2016): Chromium VI in leather articles, Dichlorobenzene (DCB) in toilet blocks, lead in consumer articles, Nonyphenol ethoxylates (NPE) in textiles, cadmium in paints, ammonium salts in cellulose insulation materials, Bisphenol A (BPA) in thermal paper, DecaBromoDiphenylEther (DecaBDE) , PefluoroOctanoic Acid (PFOA) and its related substances

thousands of consumers and workers (compared to an estimated cost of about EUR 170 million per year) [27].

The two restrictions on the use of DecaBDE and PFOA and PFOA-related substances adopted in 2017 are of particular interest given their broad scope and their large environmental implications (the two substances are PBT). The Socio-Economic Assessment Committee (SEAC) assessed the proportionality of both restrictions based on the volumes of emissions they would avoid (4.74 and 40.9 tonnes per year respectively) and of their cost-effectiveness (the cost of avoiding the emission of one kilo was assessed to be of, respectively, EUR 464 and EUR 1 649), supplemented with a number of additional qualitative arguments, and concluded it was similar to that of previous restricted substances (e.g. Hg, Phenyl-Hg compounds), hence that they could both be considered as proportionate to the risk.

Another relevant example, given its direct effects on consumers, is the restriction of chromium (VI) in leather articles that applies since May 2015, which has been estimated to enable approximately 1.3 million people with chromium allergy to use leather articles without fear of symptoms and to avoid approximately 10 800 new cases of chromium allergy in the Union each year. The benefits, in terms of avoided healthcare costs, productivity losses (due to lost working hours) and avoided suffering (the willingness to pay for avoided allergy and symptom days) amounts to an estimated EUR 350 million per year.

Finally, the restriction of polycyclic aromatic hydrocarbons (PAHs) on articles for the supply to the general public, which was adopted in 2013 following the "simplified procedure" for restrictions (article 68(2) of REACH), is of especial significance for its main purpose was to prevent the exposure of children to these carcinogens.

1.10. Regulatory risk management measures for chemicals

In REACH, the restrictions adopted according to Article 68(2) are 'generic risk' based management decisions[28]. Based on the hazard assessment leading to the classification of a substance as a CMR category 1, Article 68(2) allows the Commission to propose restrictions addressing the use by consumers of the substance as such or in a mixture or in an article. The justification for such a restriction is based on the generic considerations that:

- in the EU there are 500 million consumers whose use of a substance is impossible to control and therefore gives rise to significant uncertainties about the level of exposure and the consequent risk;
- the CMR category 1 properties are the most severe concerning human health;

[27] Based on ECHA's Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016, the figures herein are adjusted to the nine adopted measures only. These figures include only the quantified and monetised benefits and costs, and thus do not represent the absolute value of the benefits and costs of the adopted restrictions. The benefits and costs figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns, and costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the four restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products).

[28] The concept 'generic risk' was first introduced in the roadmap announcing the initiative to carry out an Evaluation and Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, European Commission, May 2016

- the function of the consumer product containing a CMR will have alternative products without the CMR.

All the other individual risk management decisions are based on 'specific risk'[29], i.e. the chemical safety assessments in the registration, restrictions according to Article 69 and authorisations. The various priority setting mechanisms leading up to individual risk management decisions are either simultaneously combining hazard and exposure (e.g. ECHA's combined screening or the development of the Community Rolling Action Plan according to Article 44) or sequentially (e.g. Article 57 first establishes the hazard and Article 58 combines with exposure for Annex XIV listing).

The hazards of a chemical identified in the REACH registration dossiers are the starting point for all the regulatory work, both evaluation and the risk management action. In the light of the numbers regarding the actual tests conducted against the expectations in 2003, as presented in the Registration part of Annex 4, there is a significant number of chemicals where compliant hazard information may not be available, hence resulting in many situations where reporting on hazard does not enable adequate risk management. As a matter of fact, ECHA's 2017 annual report on the roadmap for the identification of SVHC notes that 540 substances are subject to further scrutiny (substance evaluation, compliance check and/or one of the PBT/ED expert groups) due to questions caused by shortage of related data and that, out of these, ECHA still needs to clarify whether 311 have PBT, ED and/or CMR properties.

Where there is sufficient data to establish the hazards, the risk management work under restrictions and authorisation works, though with the issues identified in the sections on restrictions and authorisation.

The outcome of the public consultation shows that the views are divided on whether the regulatory action should be generic or specific risk-based:

- **Industry respondents favour a risk-based (or specific risk-based) approach to risk management measures**

According to industry respondents, data on exposure and socio-economic considerations should be considered much earlier in the process, to reduce the time between the identification of a substance as an SVHC and the adoption of the risk management measures, avoid unnecessary measures and eventually increase the legal certainty for duty holders. Industry respondents are therefore very much in favour of integrating the RMOA as a compulsory step in the regulatory process.

- **Most non-industry respondents defend and wish to strengthen the current hazard-based (or generic-based) approach**

Non-industry respondents, in particular environmental NGOs, argued, on the contrary, that the inclusion of substances on the Candidate List should remain an independent step, exclusively hazard based, to ensure that all potentially hazardous substances are identified according to the objectives of the SVHC Roadmap. They oppose the RMOA process as they find it shifts the burden of proof back to authorities, and they blame this for the slowing down of SVHC listing and of the identification of PBT/vPvB substances, and called for abandoning

[29] The concept 'specific risk' was also introduced in the above-mentioned roadmap

it or at least not giving it more prominence. Member States did not provide any comment on this issue.

In conclusion, as all individual risk management decisions, except article 68(2), are based on a specific risk assessment and on the consideration of the socio-economic impacts, based on the current assessment there is no need to alter the present system of implementation. The action in the restrictions section concerning efficiencies between the application of Articles 68 and 69 will assess this allocation in detail.

1.11. The application of the precautionary principle

The application of the precautionary principle (PP)[30] in REACH can speed up the achievement of human health and environmental benefits. The PP enables the legislator to adopt a decision, in a faster manner than the standard practices would allow, in order to ensure the protection of human health and the environment when a potential risk has been identified, but cannot be assessed with the normal level of scientific certainty.

The study on the EU efforts to meet the World Summit of Sustainable Development (WSSD) Commitment[31], argues that the application of the precautionary approach under chemicals management needs to be tested in the way the EU currently deals with emerging risks, such as nanomaterials, EDCs and cocktail effects. The outcome of the decision-making process in these areas will indicate to what extent the EU is listening to "early warnings" and adopting precautionary measures. The study also considers that the extent of substitution of hazardous substances is an important element of testing the application of the PP in the context of REACH.

There are a number of different views on the application of PP, in particular:

- Based on a number of case studies the European Environmental Agency (EEA)[32] concluded that the application of the PP has been opposed by strong vested interests in the EU. The EEA calls for stronger public engagement in interpreting risk from emerging issues and greater humility in the face of uncertainty.
- There is no evidence of the PP currently being applied for emerging risks such as nanomaterials, EDCs and combined effects of chemicals. This view is shared by an article looking at the SVHC Candidate List, which considered that precaution plays a limited role in the implementation of REACH[33].

The PP does set out that the initial step, leading to a policy decision applying the precautionary principle, is one of a scientific assessment of the uncertainties in determining a risk. Within REACH, this scientific judgment is made by ECHA and the policy decision by the Commission, in consultation with the Member States in the REACH Committee. The scientific judgment of uncertainties is therefore part of the scientific assessments done at ECHA under:

[30] The PP is enshrined in the Treaty on the Functioning of the EU and its definition and scope are set out in the Commission communication (COM(2000) 1final)

[31] Interpretation of the WSSD 2020 Chemicals, Goal and assessment of EU efforts to meet the WSSD Commitment, European Commission, June 2013

[32] Late lessons from early warning: science precaution and innovation, European Environmental Agency EEA, 2013

[33] Risk and the Precautionary Principle in the Implementation of REACH: The Inclusion of Substances of Very High Concern in the Candidate List, Cristoph Klika, 2015

- Testing Proposal Evaluation
- Compliance Check Evaluation
- Substance Evaluation
- Authorisation
- Restriction

Under the first three, a consideration should be made as to whether there is a concern for the substance and, if so, whether addressing the concern can await the generation of the requested information. For authorisations and restrictions, in the absence of information, a similar consideration of weighing the concern, with the time it would reasonably take to obtain the information and the potential consequences of inaction, would be needed.

Although in the large majority of cases it would be expected that the uncertainties are limited, even though in authorisations and restrictions the risk and the socio-economic committees (RAC and SEAC) pay attention to identify them, there is no evidence that ECHA considers such uncertainties in all processes on a routine basis. In particular, the annual allocation of substances in the Community Rolling Action Plan (CoRAP) for substance evaluation is not ranked according to the level of concern.. It is therefore important to be able to communicate clearly and transparently the considerations given to the level of concern and the time needed to dispel it. Further to this, authorities will be able to make a decision on whether to apply the precautionary principle or not. .

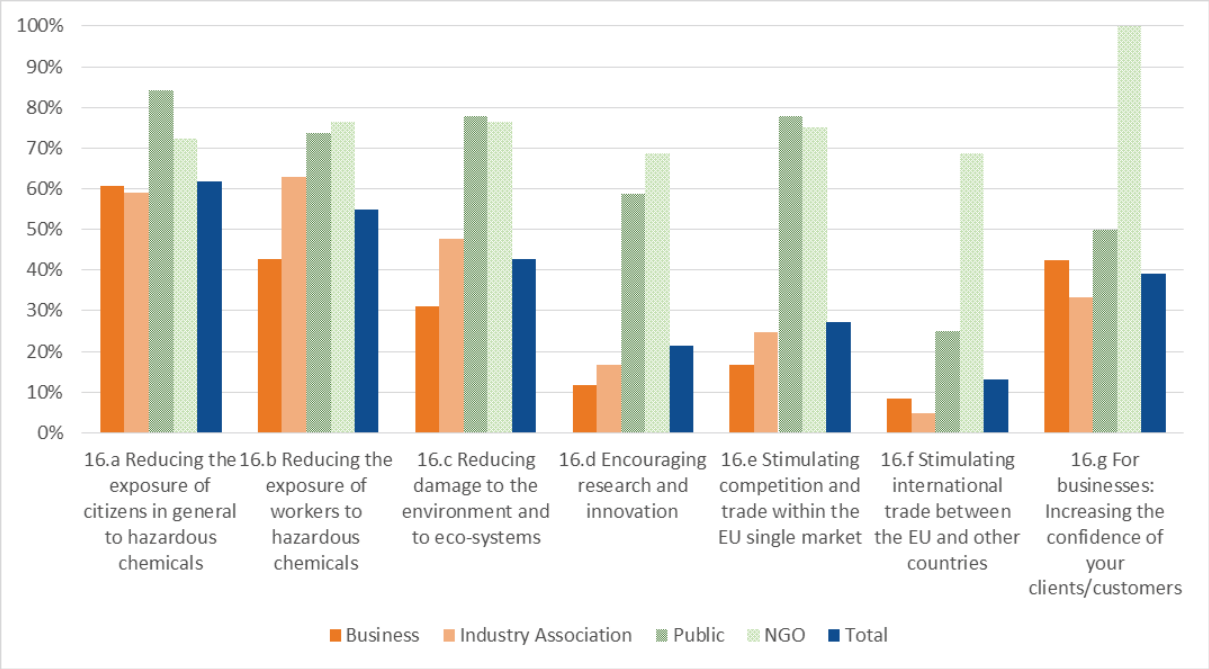
1.12. Results from the Public Consultation

The benefits of REACH are frequently mentioned in the position papers and comments of respondents to the open public consultation by stakeholders from all groups (i.e. industry, public authorities, NGOs, trade unions and other).

The increased knowledge about chemicals properties (i.e. hazards) and uses is the benefit most frequently mentioned. The increased communication in the supply chain is also seen as a benefit. The combination of both leads to increased awareness about chemicals in companies, more accurate choice of products and the adoption of risk management measures. Increased transparency and the dissemination of information on chemicals to the general public is also considered as a benefit of REACH, although mainly for substances as consumer associations and NGOs see a need to improve information to consumers on the safety of articles. Another benefit mentioned by several groups of stakeholders is how REACH has pushed companies to substitute substances of concern and therefore phase out SVHC from the market. Overall, this results in increased protection of human health and the environment, although stakeholders consider it is too early to draw firm conclusions, as evidence of concrete impacts is still not available.

Reducing the exposure of citizens in general to hazardous chemicals, reducing the exposure of workers to hazardous chemicals and reducing the damage to the environment and to the eco-systems are seen as significant benefits by most respondents. In general, trade unions, consumer associations, NGOs and public authorities are more positive than businesses and industry associations in the consideration of benefits generated by REACH.

Figure 5.2: answers to question 16: In your view, how significant are the following benefits generated for society by the REACH Regulation? (percentage of respondents ticking each of the options)



Source: Milieu, 2017

1.13. Conclusions

As foreseen in the Impact Assessment that accompanied the proposal for the REACH Regulation, and reiterated in the 2013 REACH Review, quantifiable benefits of legislation to human health and the environment are difficult to measure.

However, looking at the observable trends so far and extrapolating from current implementation of specific processes and measures (e.g. data availability from the Registration process, dossier and substance evaluations, identification of SVHC on the candidate list, individual restriction dossiers or authorisation applications) leads to the conclusion that the expected outcomes (e.g. generation of new information, introduction of risk management measures) leading towards those benefits are materialising, they are significant and, where quantification was possible, that the aggregated benefits of the legislation offset the costs by a significant margin.

The available evidence at present on the positive trend of classifications and change in self-classifications of substances, the observed gaps in the generation of hazard information, and the current lack of application of the precautionary principle, lead to the conclusion that the benefits of REACH could be further increased.

2 Internal market, competitiveness and innovation

2.1. Scope of this chapter

The changes in the internal market, competitiveness and innovation are all linked, and can be especially felt by SMEs. Strengthening the internal market through harmonisation allows for a more level playing field, lowers costs for businesses and allows for greater economies of scale. A stronger internal market is one of the positive factors for competitiveness, but REACH can also hinder competitiveness, for example, through increased costs for businesses. At the same time, REACH can affect the incentives to innovate, which in the long term underpins the chemical sector's competitiveness.

This chapter looks at all of these aspects in turn but also with an awareness of their interlinkages.

2.2. Conclusions of the 2013 REACH Review

The REACH Review 2013 acknowledged the need for a reduction of the overall costs related to REACH and their impact on SMEs, although industry recognised the positive economic effects for their business.

REACH harmonisation of the internal market was considered a driver for growth and competitiveness of the chemical industry. The 2013 REACH Review acknowledged the vulnerability and insufficient awareness of SMEs, recommending a reduction of the financial and administrative burden on SMEs in order to ensure the proportionality of legislation and to assist them to fulfil their obligations.

Increased communication in the supply chain and substitution of SVHCs were considered drivers of innovation, while the reorientation of R&D expenditure towards regulatory compliance was also noted.

2.3 Developments after the 2013 REACH Review

The REACH Regulation has among its purposes to ensure the harmonisation of the internal market and hereby to reduce the barriers for intra-EU trade. The following section aims to assess the degree of regulatory harmonisation achieved within the chemicals sector due to REACH and the contribution to intra-EU trade.

2.4. Internal market and competitiveness

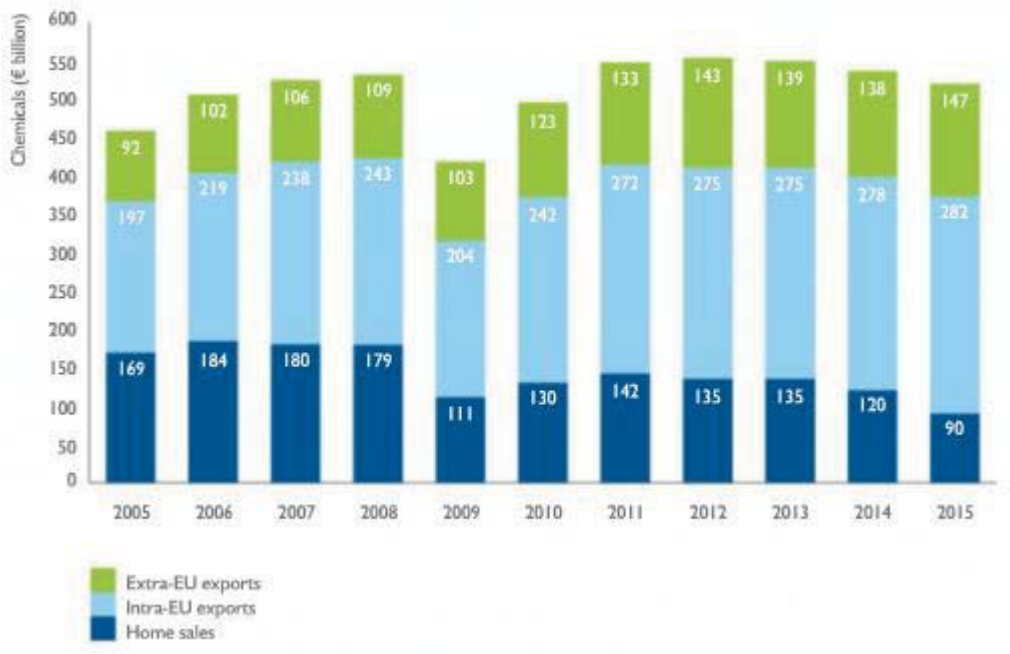
General observations

Europe has a large and integrated market with a customer base of over 500 million consumers. The importance of the internal market is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports'[34]. The data show a continuous increase in the intra-EU trade of chemicals over the last decade, strengthened by the removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007. Total EU chemicals sales were worth EUR 519 billion in 2015[35]. Over time, domestic (home) sales have decreased but a growth in total sales has come with increased exports to non-EU countries. Intra-EU sales (marked as "intra-EU exports" in the graph

[34] European Chemical Industry Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017
[35] CEFIC, chemdata international, 2015

below) increased from EUR 197.2 in 2005 to EUR 282.3 in 2015 – a 43.2 % increase during the last 10 years. How much of this increase can be attributed to REACH or rather to a possible consolidation and diversification of the supply chain is not certain. However, the figures at least suggest that REACH is not hampering the internal market.

Figure 5.3. EU Chemicals Industry Sales



Source: Cefic, chemdata international, 2015

A large majority (80-85%) of respondents to a business survey conducted by CSES with companies from the chemical sector, as well as with their downstream users[36], report no effects (neither negative, nor positive) on the trade of chemical substances within the EU/EEA due to the implementation of the REACH Regulation. While no discernible impact of REACH was reported, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European chemicals legislation / integration of the single market and important benefits could be gained from further harmonisation. The industry representatives also flagged in this business survey the need for further efforts to make market surveillance and enforcement practices more aligned across Member States. One of the main reasons for the perception of not fully effective enforcement, as identified by respondents, was a difference in approaches followed by Member States' enforcement authorities in terms of inspections and the relative resources (quantity and quality) allocated to ensuring compliance with REACH.

Effects from specific REACH processes

The Impact Assessment of the REACH Regulation anticipated concentration as manufacturers/importers removed some of their substances from their portfolios. Although 38% of respondents to the public consultation for the REACH REFIT 2017 Evaluation considered that the fees and charges for the registration of substances are adequate, according to the replies provided to the business survey (CSES et al, 2015), the overall registration costs

[36] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, commissioned by the European Commission, 2015

appear to be the main driver for withdrawals: almost one third of companies (including downstream users) reported being affected by a withdrawal of a substance from the market due to registration costs.

Inevitably, this situation has an influence on the R&D priorities and on the operational patterns of the concerned firms. Out of those companies that had faced a substance withdrawal, two thirds indicated that as a result they carried out research to identify an alternative substance, while a third of those companies changed their manufacturing process to substitute the withdrawn substance. The study (CSES et al, 2015) indicated a lower rate of withdrawal – approximately 16% of companies with downstream users' role have experienced withdrawal of substances from their suppliers. There are clear differences in answers depending on the position of companies in the supply chain and their role under REACH. The respective shares were 32% among formulators and much less among suppliers of articles (8.4%) and end users (5%). The most common response to a substance withdrawal was the identification of an alternative supplier, the identification of alternative substances (with the help of the supplier of that substance) or the change of design of the own products.

These results show that, as part of the registration process in 2013, companies may have revised their portfolios by withdrawing substances based on economic considerations (after factoring in under their profitability the costs of registration, but also because of their undesirable hazard profile). The CSES study found that the substances withdrawn due to economic reasons were mainly specialty chemicals produced in small tonnages and with low profit margin. Although the surveys of industry show that individual companies may have been affected to some extent by the withdrawal of substances, there is no evidence of any major negative impact at EU scale resulting from the non-availability of substances.

The estimate of the total registration costs for the 2,998 phase-in substances registered in 2013 is EUR 459 million (CSES et al, 2015)[37], which is within the range predicted by the Extended Impact Assessment (ExIA) accompanying the REACH proposal[38]:

Table 5.2: Estimation of the total costs for the 2013 registration deadline

Concept	Cost (€ million)
Registration	248
Safety Data Sheets (SDS)	109
Testing / information	101
Total Costs	459

Source: CSES et al, 2015

The statistical average cost (per substance) of registering, testing and preparing the SDS was estimated to be around EUR 153,000 and the average per registrant around EUR 69,000.

[37] Registration costs include external costs such as ECHA fees, costs of participation in SIEFs/consortia, letters of access, consultants paid and any internal costs (e.g. wages and other human resources, travelling) directly linked with the registration process

[38] The impact of REACH on the environment and human health, DHI, commissioned by the European Commission, September 2005

However, the variation around these averages is wide[39], as costs depend on a number of complex factors, including the number of registrants, the properties identified, the additional testing required/waived, the amount of test information already available, the number and types of uses, etc.

The study by CSES found that most companies absorbed registration costs rather than increasing the prices to cover the costs. Altering the production (i.e. lowering the volumes rather than separating in smaller business entities) was also a minority response. Around 20% of companies increased their prices in order to recuperate their costs, which suggests that, overall, the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances as other factors, such as oil and gas prices, play a more important role.

As far as the downstream users are concerned, several stakeholders reported that the availability of data on substances has much improved and that the classifications are regarded as more trustworthy. However, the business survey (CSES et al, 2015) indicates that an important share of enterprises remains unaware of their current/impending roles, obligations and tasks under REACH, specifically with regards to the requirements concerning the communication throughout the supply chain[40]. Several gaps in information flow were identified, particularly compliance with the requirements for the Safety Data Sheets, the core communication tool under REACH.

The inclusions of SVHC in the candidate list or into Annex XIV are other important factors that trigger communication at all supply chain levels. About 39% of companies (21% of manufacturers, 42% of downstream users and 54% of formulators) (CSES et al, 2015) received a request from their clients to remove such SVHC from their products.

The Authorisation process is perceived by companies as having a marked impact on competitiveness, innovation and investment decisions. More specifically, the continuous process of including substances into Annex XIV creates regulatory uncertainty for the use of substances, what could be critical to some industrial processes or applications. The costs implied by the necessity to reformulate or implement an alternative could be associated with high costs. (see further details and key figures on direct costs in Annex 4, part on authorisation).

Finally, evidence of a tendency to move commercial activities outside of the EU as a result of listing a substance as SVHCs is rather limited. In the framework of the survey by CSES et al (2015), about 4 % of the suppliers of products with SVHC indicated they moved away from EU-production and a slightly higher share ceased the use of the substance in commercial activities (9%). According to CSES et al, a potential loss of business to the EU economy could be observed for 13 % of the concerned businesses, although it is likely that at least part of this was compensated by the use of alternatives or by moving resources to new business development. Furthermore, industry provided examples during the public consultation that denote their concerns related to the uncertainty and the recurring costs associated with the Authorisation process:

[39] Ranging from EUR 543 to EUR 666 000 (CSES, 2015)
[40] 28 % of industry associations said that the majority of companies are not aware of their REACH related responsibilities

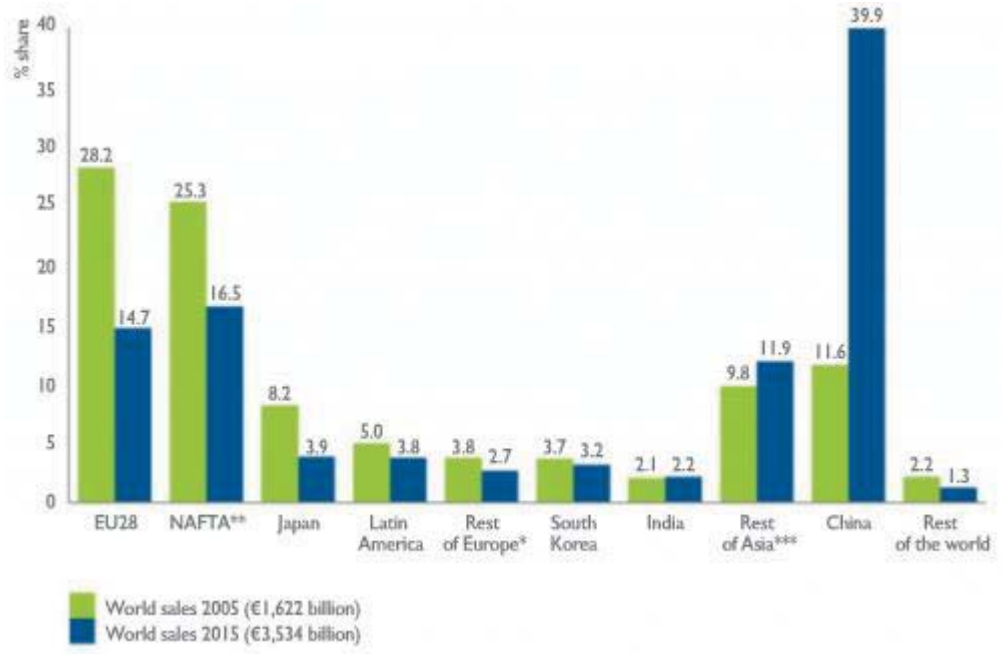
- Examples showing that it may be an important factor behind potential business decisions to relocate affected production activities outside the EU or behind the reluctance from international clients to source such products from the EU.
- In one example provided by industry, the lack of predictability associated with the Authorisation process was an important dissuasive factor for decisions of enterprises to invest in production locations within the EU.

2.5 External competitiveness

General observations

In 2015, China accounted for the largest share in global chemicals sales (40%), followed by the EU28 (28%) and the NAFTA (17%). Global chemicals sales are forecasted to reach EUR 6,300 billion by 2030. According to Milieu et al[41], this expansion will not be evenly distributed across geographical regions; instead, it will be primarily driven by emerging economies, such as China, India and Korea. In these emerging economies, the consumption and production of chemicals is growing faster than the global average.

Figure 5.4: Global chemicals sales: geographical background (2015)



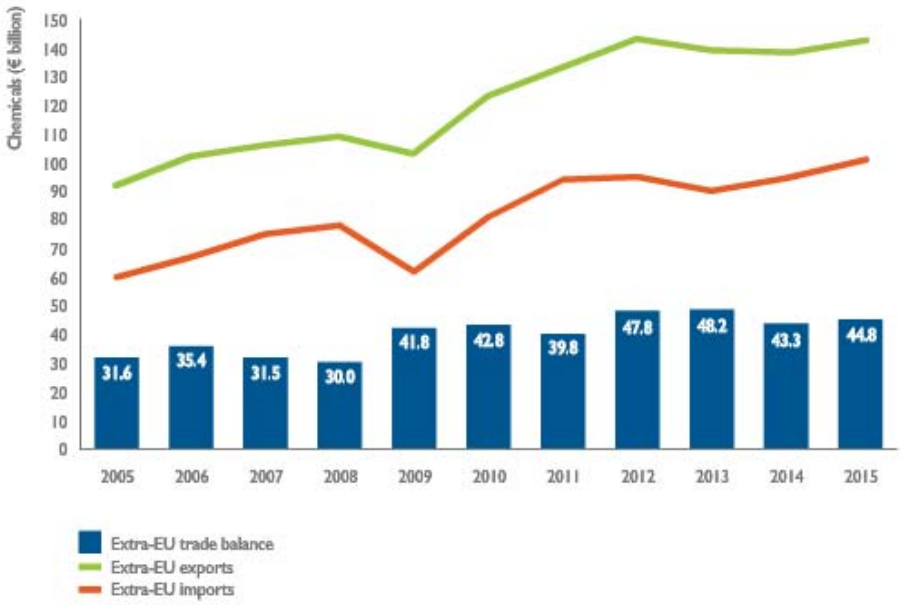
* Rest of Europe covers Switzerland, Norway, Turkey, Russia and Ukraine
** North American Free Trade Agreement
*** Asia excluding China, India, Japan, and South Korea
Source: Cefic, Facts & Figures of the European Chemicals industry, 2016

Over the last ten years, the EU chemicals industry has maintained a significant surplus in its extra-EU trade balance in chemicals. As a result of a solid recovery in the aftermath of the economic crisis in 2008, the trade balance showed clear signs of recovery, reaching over EUR

[41] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme

40 billion in 2015. A sectoral breakdown indicates that the largest part of the surplus came from specialty chemicals (58.2% in 2015), followed by consumer chemicals and polymers[42].

Figure 5.5: Extra-EU trade balance with chemicals

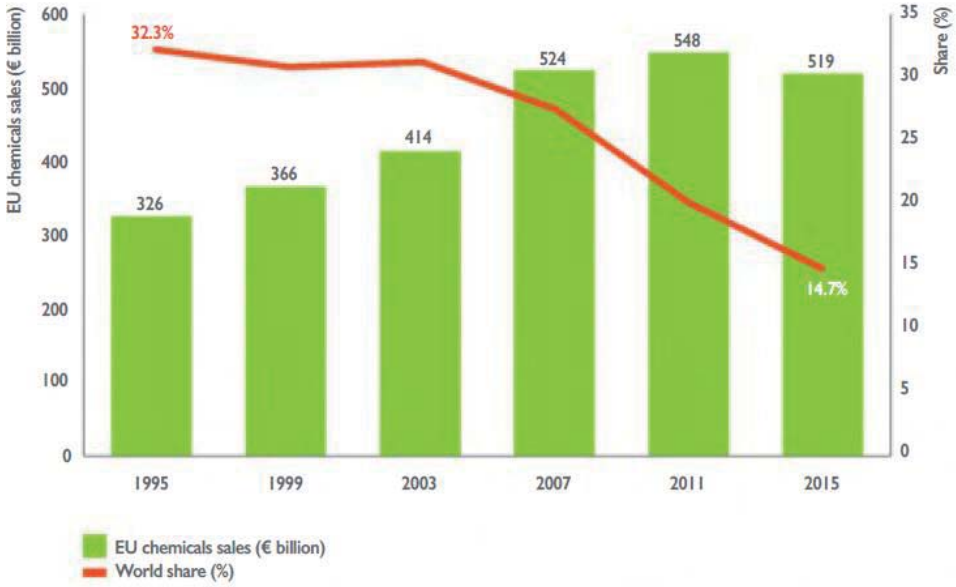


Source: Cefic, Chemdata international, January 2016

At the same time, the share of the EU on the global market has been decreasing over the past 20 years, as a consequence lower average production growth in comparison to other regions. Using a constant-market share analysis of chemical exports at the aggregate and subsector level for the EU and several other large countries that are significant chemical producers, a report by Oxford Economics[43] concludes that, until 2012, the extra-EU export market share has been decreasing over the past 20 years (i.e. including also 10 years before REACH) and that this is due to a declining overall competitiveness. No fundamental changes are expected since 2012 compared to today. The report however acknowledges that quantitative indicators measuring specifically the impacts of chemicals regulation and consistent across countries are not available. The evolution of EU share of global chemicals market over the period 2005-2015 (% of global sales) is illustrated in the chart below.

[42] Cefic, Chemdata international, 2016
[43] Evolution of competitiveness in the European chemical industry – historical trends and future prospects, Oxford Economics, commissioned by CEFIC, October 2014

Figure 5.6. EU share of the global chemicals sales



Source: Cefic, Chemdata international, January 2016

It is to be noted in this respect that the chemical industry is the most energy-intensive manufacturing sector in the EU, accounting for 12% of the total EU energy demand. Oil and gas are vital inputs for the chemical industry, not just as energy sources, but also as principle raw materials for final products. Therefore, raw material and energy costs put the EU at a disadvantage compared with the USA and the Middle East, while it is high labour costs, capital costs and other fixed costs that have the biggest impact on competitiveness in relation to China.

Looking closer at the global export competitiveness, it can be observed that the slow-down in exports may be due to the petrochemicals sector. Indeed, according to McKinsey & Company[44], changes in oil prices have immediate and significant impact on the cost structures of key chemical building blocks. The decline is thus closely linked to the oil refining industry, which has suffered hugely recently due to energy prices being driven by the supply of shale oil and gas in the US[45] and, more recently, by decisions taken by Middle Eastern producers to maintain very low prices in response to the growing shale oil and gas sector in the US.

Effects from specific REACH processes

The business survey (CSES et al, 2015) provides an indication of how companies perceive the broader impacts of costs associated with REACH on factors influencing their competitiveness vis-à-vis their non-EU competitors. Out of the sample of respondents, 56% reported a negative impact on their operating cost; somewhat lower shares saw a negative impact on the access to raw materials (39%), on the access to markets (28%) or on the availability of human resources (31%). On the other hand, the shares of respondents who identified a positive

[44] Oil-price shocks and the chemical industry: preparing for a volatile environment, McKinsey & Company, 2015
[45] "Will Europe's petrochemical industry follow the fate of oil refining?", by Nandita Lal, 10 January 2014

impact were significantly lower (less than 1-5% in all these categories). There were, however, substantial differences in perception depending on the role of the respondents under REACH. Examining the responses by role, distributors tended to have the most negative view, while article suppliers considered REACH more often as either not relevant or not having any particular effect. For example, with regards to the impact of REACH on external competitiveness, nearly three quarters of manufacturers and exporters of chemicals were of the view that the effects were negative, while 59% of the article suppliers considered them as (rather) positive.

These results should be interpreted in the context of the differences or similarities between regulatory regimes of the EU and its main trading partners. While the corresponding pieces of legislation in third countries (e.g. South Korea or China) have partly followed the EU pattern, REACH is considered (one of) the most advanced regulations in a global perspective and it tends to set the highest standards globally. A comparison with respect to the costs of registering new chemicals in different countries was provided in a thematic study comparing the impacts of REACH and corresponding legislation (ECSIP, 2016)[46]. The available evidence from this study shows that the costs of putting a new chemical on the market under REACH is somewhere in the middle of the cost range in the other assessed countries (i.e. South Korea, China, USA, Canada and Japan).

Apart from the Registration costs, the business survey (CSES et al, 2015) conducted among downstream sectors revealed that the biggest concern about external position relates to the control of SVHCs. The Authorisation mechanism often requires adopting costly changes in the production processes in order to allow for the use of alternative chemicals. This is perceived by EU Industry as a clear competitive disadvantage vis-a-vis the companies from third countries non-subjected to Authorisation obligations.

Another conclusion of the study comparing the impacts of REACH and the corresponding legislation in third countries is that European companies do not see compliance with REACH as a competitive advantage in global markets. Being compliant generally does not imply that less effort is required in other jurisdictions, since the standards and requirements are different (e.g. requirements for testing). This conclusion concurs with the results of the business survey (CSES et al, 2015), where only a minor share (3%) of firms indicated a positive impact of REACH in relation to the opening of new markets outside the EU, while in most cases REACH was not considered as having a particular impact.

With regards to the link between REACH and international trade, a quantitative modelling applied in the study of ECSIP indicates that the registration costs of REACH might have had some impact on the external competitiveness of the chemicals industry, most notably by potentially inducing a negligible decline of the EU exports of chemicals (-0.01% of the value of the sector's total exports), if compared to a situation where REACH would not have existed. However, due to the limitations of the quantitative modelling (difficulties to establish counter-factual scenarios), no firm conclusion could be drawn on the extent to which the recent development of external trade could be attributed to REACH. One of the reasons for difficulties with such an assessment is that the trade flows between chemical and downstream chemical user companies are driven by a wide range of factors other than REACH.

[46] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry, ECSIP, 2016

Furthermore, there might be significant differences between sectors in terms of the impact on the operational patterns due to the REACH legislation[47].

On the other hand, the survey among downstream users[48] provides an indication that REACH, especially in connection with the uncertainty associated with the listing of SVHC in the candidate list and Annex XIV, might have been among the factors affecting investment decisions of competitors from third countries, both for the chemicals sector and for the three downstream sectors (rubber and plastics, textiles and motor vehicles) included in the study. However, the observed relocation and investment trends could not be attributed directly or exclusively to REACH because, as the survey showed, the costs related to chemicals regulation were only one among many considerations.

2.6. Innovation

General observations

One of the key objectives of the European Commission is to ensure that 20% of the EU total GDP comes from industry by 2020[49]. The chemicals industry is one of the most R&D-intensive manufacturing sectors in advanced economies. As an input provider for other industries, it is indeed considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges.

The effects of the REACH processes on innovation are complex. On the one hand, Regulation may have a negative impact on the resources that companies make available for R&D and innovation activities as illustrated below. For example, the business survey (CSES et al, 2015) shows that, from the specific viewpoint of companies, REACH would not provide an incentive for innovation, in the sense of improving their competitiveness in comparison to non-EU competitors. This can be illustrated by the finding that 35% of respondents perceive a negative impact of REACH on their capacity to innovate, compared to only 11% who perceive a positive impact.

On the other hand, according to the 'Porter hypothesis', stricter environmental legislative requirements may encourage companies to redirect their priorities to an increased allocation of resources to their research programmes, thus acting as a trigger for innovation towards sustainability, what may provide first movers with competitive advantages to the EU industry[50]. Indeed, although not directly attributable to REACH, the Danish industrial association Dansk Miljøteknologi claims that "the EU legislation is a driver for the countries' willingness to invest in new technology", thanks to which Danish companies are able to export between DKR 15-20 billions (circa EUR 2-3 billions) of environmental technology every year[51]. As a matter of fact, for about a quarter of respondents to the business survey (CSES et al, 2015), the implementation of REACH would have led to an increase in R&D activity and, for the industry stakeholders consulted in the framework of the study for a non-

[47] Operational patterns include e.g. decisions on localisation of production and on entering new markets

[48] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry', ECSIP, commissioned by the European Commission, 2016

[49] A Stronger European Industry for Growth and Economic Recovery Industrial Policy Communication, European Commission, 2012

[50] As acknowledged by Innovation in the chemicals sector and the new European Chemicals Regulation, World Wide Fund (WWF), 2003; Driving Innovation – How stronger laws help bring safer chemicals to market, Centre for International Environmental Law (CIEL), 2013; and Policy Brief on Green growth, Organisation for Economic Co-operation and Development (OECD), 2014

[51] "Dansk Miljøteknologi: Grønt diplomati kan øge eksporten", Jonas Fredsted Villadsen, 21 March 2017

toxic environment strategy (Milieu et al)[52]. The improved and increased communication in the supply chain required by REACH would have provided for the potential for more innovation, as it provides companies with new information on customer needs, on business development opportunities and more efficient and effective supply chain management practices in the longer term. In a similar vein, CIEL (2013) notes that the implementation of stricter measures with REACH has enabled significantly increased patenting of alternatives by major chemical manufacturers. Furthermore, the improved availability of information and transparency helps downstream users to make better informed choices when developing new or applying existing products, hence can contribute to their ability to innovate.

Effects from specific REACH processes

Among the REACH mechanisms, the Registration process can be assumed to affect the innovation activity in several ways. Firstly, companies may capitalise on the information and knowledge generated as part of the registration process. Secondly, the registration costs (in particular in terms of data generation and sharing) may affect the availability of substances on the market. And thirdly, the need of ensuring compliance with the registration obligations may lead to a re-allocation of resources in the concerned companies from R&D activities to compliance. These assumptions were largely confirmed by the results of the business survey (CSES et al, 2015).

- First, the information generated in the registration process contributed to building knowledge of chemical substances and it contributed to better awareness of the needs of the upstream and downstream value chains. As a result, a conceivable share of respondents (23% overall, with differences according to the role of the company ranging from 16% for manufacturers to 33% for formulators) reported having launched new products or services thanks to the knowledge gained through the compliance process.
- Second, about 54% of the companies that experienced a withdrawal from the market conducted R&D to identify alternative substances. On the other hand, several stakeholders also expressed concerns about the registration costs creating barriers to the entry of new innovative mixtures / substances and low volume research substances into the EU from non-EU / EEA sources due to registration costs.
- Third, the last effect of registration on innovation worked through the reallocation of R&D resources to the registration process. Nearly a third of the respondents reported having reallocated their R&D staff to ensure compliance with REACH, either on a permanent or on a temporary basis, which can be assumed to have reduced their capacity to innovate.

Another mechanism of REACH which affects the scope and focus of R&D activities is the Authorisation process. The results of the business survey (CSES et al, 2015) suggest that already the inclusion of substances into the candidate list and the Authorisation list (steps preceding the requirement to apply for an authorisation to be able to use a substance) work as a driver for research to find alternative substances or technologies. From the sample of respondents affected by the inclusion of a substance in the candidate list, about 9% launched initiatives to develop new substances and 30% launched initiatives to find an alternative formulation[53]. The response of companies to the inclusion of substances in the Annex XIV (Authorisation list) was broadly similar. Milieu et al concluded in the survey of member state

[52] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme
[53] For the remaining 61%, no information is available

competent authorities, industry stakeholders and external consultants within the framework of the study for the setting of a non-toxic environment strategy that the legislative requirements are seen as the main driver of substitution, with respondents indicating that placing a substance on the candidate list for authorisation is the key mechanism that initiates the search for safer alternatives.

The industry stakeholders' survey by Milieu et all found however that, for 85% of the companies obstacles to substitution come from the lack of information on hazards and risks of some of the alternatives as well as the uncertainty concerning the regulatory requirements applicable to those alternatives. Also, some of the interviewed industry stakeholders (CSES et al, 2015) highlighted that the Authorisation process is slowing down the development of products and diverting resources from innovation, which otherwise would contribute to improving the competitiveness, towards the preparation and submission of applications for authorisation. Furthermore, during the workshop organised in June 2016 in the framework of the definition of a strategy for a non-toxic environment, it was highlighted that because the Authorisation process does not cover imported articles, it penalises European companies versus extra-EU, and that once the regulatory action has started, there may be insufficient time to identify and develop suitable alternatives. More generally, NGOs and some Member States pointed to unsatisfactory synergies between chemical legislative acts and to the lack of ambition and speed in the Authorisation process.

Nevertheless, there was consensus that a better enforcement of the legislation would ensure sufficient regulatory signals to investments in innovation and research of safer alternatives by reducing the chances of free-riders to continue operating in breach of legislation. In the same vein, the study of CSES collected some views that the candidate list and other communication instruments (PACT and CORAP list) are increasing the transparency and providing guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.

As described in further details in Annex 4, part on authorisation, the European Commission and ECHA are aware of industry concerns and have started to reflect on how to streamline and simplify the Authorisation process for specific areas where the Authorisation requirement might impose a disproportionate administrative burden on operators[54].

For instance, CSES et al mentions that substitution is also encouraged by the development of initiatives such as the Substitution Support Portal (SUBSPORT) [55], a project realised in the framework of the European Union's Life programme[56]. The portal aims to provide guidelines to compare and assess alternatives in order to promote substitution. There are also other initiatives focusing on providing assistance to companies (and especially SMEs) in exploring the possibility of substituting hazardous chemicals in products, for example:

- The Eco-innovation observatory[57] funded by the European Commission;
- Norden[58] – Nordic Innovation funded by the Nordic Council of Ministers;

[54] See the Authorisation chapter for further detail

[55] SUBSPORT is a free-of-charge, multilingual platform for information exchange on alternative substances and technologies, as well as tools and guidance for substance evaluation and substitution management

[56] LIFE is the EU's financial instrument supporting environmental, nature conservation and climate action projects throughout the EU

[57] The Eco-innovation observatory of the European Environmental Agency functions as a platform for the structured collection and analysis of an extensive range of eco-innovation information, gathered from across the European Union

- Substitu tion-cmr by Anses[59], the French Agency for Environmental and Occupational Health Safety.

The impacts of those projects have not been quantified.

This raises the question whether the REACH Regulation actually led to creation of new business opportunities. The business survey (CSES et al 2015), as well as a follow-up inquiry among the participating companies, suggested that up to now very few opportunities for business have been created thanks to REACH. Some business opportunities may however arise from increasing awareness of customers and business leaders of product safety. A survey carried out by TÜV Süd in China, India, Germany and the U.S. analysed the perception of product safety among consumers and business decision makers and outlined the trends between 2012 and 2016. The results show that consumers were placing increasing importance on safety when buying different products (children's products, consumer electronics, food and footwear). At the same time, the survey found an increase in awareness within the business community, as well as increasing confidence of business decisions makers that consumers were willing to pay more for a higher level of product safety. The businesses also reported decreasing costs to ensure product safety over time, but this comparison is however only available for the non-EU countries. This, when coupled with the confidence in consumers' willingness to pay a premium for safe products, points to possible creation of business opportunities.

2.7. Product and Process Oriented Research and Development notifications and registration of new substances

Apart from costs and incentives, the length of time it takes from a product since it is conceived until it is available for sale (time-to-market - TTM) can be another critical aspect of the overall innovation process, particularly in creative sectors such as fashion, design, and Information and communications technology (ICT). About half of the respondents indicated that there were not any effects of REACH on the time to bring their products or services to the market, close to 20% found that it had increased TTM by up to six months and 15% reported that the TTM had increased by six months or more.

Another indication of innovation activity is provided by the number of new substances registered and the number of Product and Process Oriented Research and Development (PPORD) notifications.

Data from the report on the operation of REACH and CLP (ECHA, 2016)[60] show that there was an increasing trend for the overall number of PPORDs. The PPORD exemption is well used by large companies and allows large-scale research and development without a heavy administrative burden, while ensuring safe use.

Further data from ECHA[61] show that between 5 and 20 new substances are notified every month under the PPORD process and that their number has overall remained constant over the period 2008-2016 (see chart 5.7). The share of PPORD submitted by SMEs is around

[58] Nordic Co-operation funds Nordic projects that boost innovation and competitiveness in the Nordic business sector and lead to commercial and sustainable development

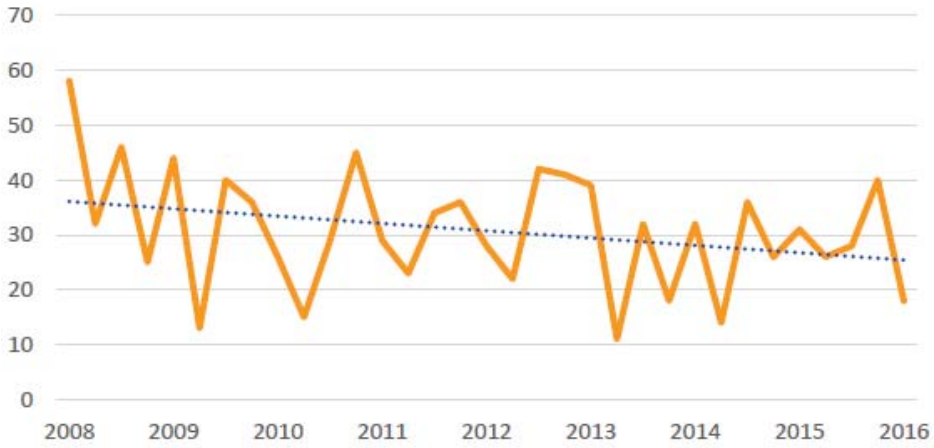
[59] Substitution-cmr website for the diffusion of initiatives, ongoing works and the status of research in the field of substitution

[60] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016

[61] Monitoring innovation under REACH, European Chemicals Agency (ECHA), 2017

16%, which is comparable to the share of SMEs observed in the registration process, the majority are thus large companies. It should also be noted that, according to the results of the SME panel[62], PPORD is perceived as useful or very useful by nearly half of participating companies, while nearly a third was not aware of this mechanism.

Figure 5.7. PPORD notifications for new substances



Source: ECHA, 2017

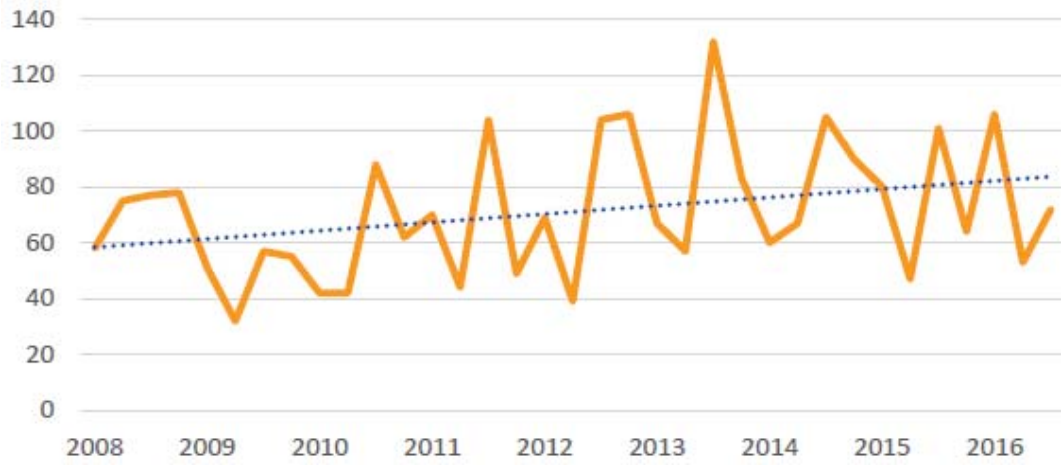
With regards to new substances placed on the market (i.e. substances not listed on the EINECS[63] or the ELINCS[64] inventories), data of ECHA indicate that those are continuously being registered with a steady upward trend. According to the registration statistics provided by ECHA, since the registration of non-phase-in substances under REACH came into force, 1745 non-phase-in substances were registered[65].This amounts to approximately 195 new substances brought to the market every year in quantities above 1 ton per company per year.
Data from ECHA (2017) show that 100 to 150 "new substances" in average have been notified in the C&L Inventory[66] every month during the period 2011-2016, representing about 20% of the total number of notifications. At the same time, data on the number of inquiries according to Article 26[67] suggest a gradual increase in the number of new substances over time (see chart 5.8 below). ECHA concludes that, in comparison with the flow of new substances notified under the previous Directive 67/548/EEC, there is no indication that REACH has negatively changed the previous trend[68].

It is important to note that the majority of PPORD notifications or inquiries for new substances are made by manufacturers (71% and 54% respectively). The proportion of manufacturers inquiring about any substance (whether new or existing) is lower (around

[62] https://ec.europa.eu/eusurvey/publication/REACHrefit
[63] European Inventory of Existing Commercial Chemical Substances
[64] European List of Notified Chemical Substances
[65] ECHA registration statistics (https://echa.europa.eu/regulations/reach/registration/registration-statistics), viewed March 2017. This number includes actually new substances, as well as "existing" substances, which have not been pre-registered. However, it is likely that the latter case is infrequent.
[66] This database contains classification and labelling information on notified and registered substances received from manufacturers and importers
[67] Duty of potential registrant, who have not pre-registered, to enquire from the Agency whether registration has already been submitted for the same substance
[68] ECHA notes however that these figures cannot be easily correlated (taking into account the differences in the tonnage band and in the process)

40%, clearly below the 54%), which would support the idea that manufacturing of new substances mainly takes place within the EU.

Figure 5.8. Article 26 inquiries for new substances



Source: ECHA, 2017

2.8. Perspective of Businesses/Perspective of SMEs

General observations

The main conclusion of the 2013 review concerning SMEs was that 'a significant number of SMEs were unaware about their role and obligations related to REACH, what implied the need for further action to support and guide these companies'. The past review also aimed to discern the impacts REACH registration had on downstream users, the majority of which are SMEs.

It is widely recognised that SMEs face a range of issues as compared to large firms in several fields: access to finance, access to skills and capabilities, access to markets, innovation, etc. The survey and interview conducted with SMEs by CSES et al suggests that there are some areas where SMEs might be differently impacted than larger firms by the requirements of REACH.

Effects from specific REACH processes

The registration costs[69] were estimated to be EUR 459 million for the 2013 deadline (CSES et al, 2015). When referring specifically to SMEs, these estimates show that their registration costs in 2013 (per substance per registrant) were somewhat higher than for large companies[70]. The breakdown also provided an overview of the average costs of the different components of registration. It follows from this analysis that the cost of liaising with downstream users and the costs of producing eSDS were moderately higher for SMEs compared to larger enterprises. This result seems consistent with other findings from the business survey (CSES et al, 2015) in respect of good practice tools and methods for gathering information (for

[69] Registration costs include external costs such as ECHA fees, costs of participation in SIEFs/consortia, letters of access, consultants paid and any internal costs (e.g. wages and other human resources, travelling) directly linked with the registration process

[70] In fact, the costs for SMEs were 5-25% higher than for large companies, depending on the tonnage band

example, it is known that some larger enterprises have developed and applied IT tools to facilitate the communication with their downstream users) and with respect to learning and getting familiarised with the production of extended safety data sheets (eSDS), where it is likely that larger enterprises gained more experience as part of the 2010 registration compared with the SMEs.

The work of companies towards the last registration deadline in 2018 (which will concern substances placed on the market in low tonnages) has started and is expected to involve many small enterprises, many of which will need to go through the learning experience, assuming that they did not yet have to submit registrations at the earlier deadlines. The most recent estimates of registration costs for 2018 for 1 to 10 tonnes substances appear to be in the range of the extended Impact assessment accompanying the REACH proposal (EUR 228 million, compared to the estimate of EUR 295 million). However, the total cost of registering 10 to 100 tonnes substances has been estimated to be significantly higher (up to EUR 1 136 million as compared to EUR 581 million). This may be partially explained by the fact that the estimation is a worst case scenario derived from the assumption that validation and acceptance of negative and positive QSARs[71], grouping and read-across[72] do not occur within the time frame first envisaged. Nevertheless, the registration costs, along with the related uncertainties about the supply and the withdrawal of substances, remain challenges for SMEs. In this context, the sub-sectors where SMEs are largely represented have been voicing concerns that due to their industrial structure (the large share of SMEs and the dependence on imports of low cost low volume substances), such enterprises are particularly vulnerable to REACH compliance costs. Such an example is the one of dyes for the textile and leather industry, where the industry signalled that the costs of registration (the price of the letter of access) are beyond what is affordable for small and micro firms[73]. For this reason, ECHA provided support to the sector on development of scientific methods (read-across and QSAR) that would help to reduce the registration costs. Furthermore, the Commission and ECHA supported development of industry-specific guidance documents for the sector of essential oils in order to clarify the registration requirements.

As regards the effects of the authorisation process, there has not been enough experience yet with regard to SMEs applying for authorisations to allow for a full assessment. The results of the SME panel indicate that some concerns are present among approximately one quarter to one third of SMEs. The preparation of an application for authorisation was seen as a slightly or moderately important challenge by 13% of participants and as a considerable/very important challenge by 19%, while the rest either had no view or did not see the Authorisation process as a challenge. In relation to the costs associated with the application, those are slightly or moderately important for 10% of respondents and considerably or very important for further 15%, while the rest had no view or did not see this aspect as a challenge. Also the business survey (CSES et al, 2015) suggests comparatively less experience of SMEs

[71] Quantitative structure-activity relationship are mathematical models that can be used to predict the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure

[72] Grouping of substances and read-across is one of the most commonly used alternative approaches for filling data gaps in registrations submitted under REACH. This approach uses relevant information from analogous (‘source') substances to predict the properties of ‘target' substances. If the grouping and read-across approach is applied correctly, experimental testing can be reduced as there is no need to test every target substance

[73] This is supported by a 2014 study made by Dye-Staff, a group of (mainly Italian) SME dye manufacturers. The study voices concerns that SME dye manufacturers will need to register a very large number (sometimes hundreds per company) of small-volume dye chemicals for the 2018 registration deadline, and that may reduce their substance portfolio and/or put at risk their business viability. Source: Study on the socio-economic impact of registration of the dyes according to REACH Regulation for small and medium-sized Italian companies, Dye-Staff, 2014

with the process given that a bigger share of SMEs than large firms indicated that they had not been affected by the placing of substances on the candidate list.

Like in the case of registration costs, the question can be raised if and to which extent the Authorisation process could affect decisions of companies on their investment decisions or in their decision to relocate or shift part of their production of articles. While relocating and importing the articles without having to comply with the Authorisation requirements could be an option for some companies (specifically for those with manufacturing facilities outside Europe), there is no available evidence that would enable to fully assess the possible relocation of activities by SMEs outside the EU. However, there are examples indicating that the costs and uncertainty associated with the Authorisation requirements were an important factor for some SMEs active in international value chains in deciding to move the sourcing, manufacture or maintenance of specific components outside the EU.

As regards the restriction process, the feedback from the SME panel shows that it is a matter of concern for about half of the respondents (a slightly/moderately important challenge for 27% of the respondents and a considerable/very important challenge for further 23%). The costs (e.g. of replacing a restricted substance) incurred in relation to the Restriction process are slightly or moderately important for 20% of the respondents and considerably/very important for further 17% while the rest had no view or did not see this aspect as a challenge.

Concerning the impact on innovation, the survey identified no significant differences between large firms and SMEs, except for the situation of substances that enter the registry of intentions (RoI), which triggers the restriction procedure, where more SMEs than large firms stated to have withdrawn the substance in question. Similarly, with regard to business opportunities created by REACH, the results are similar as for larger companies, indicating that very few SMEs perceive such benefits for now.

The findings of the study of CSES however suggest that there are some other differences between SMEs and large companies, for example in terms of their perception of the broader impacts of REACH on competitiveness. SMEs tend to see the effects of REACH on the single market in a less favourable light than large firms, but are less concerned than larger firms about the effects of REACH on their competitive position vis-à-vis firms outside the EU. One possible explanation is that SMEs are on average less involved in international trade. Some smaller firms on the other hand might have benefited from REACH when EU-based downstream users switch their purchasing to EU-based REACH compliant suppliers.

Another difference identified is that more SMEs than large firms have very limited experience with eSDS and tend also to be less proactive as regards upstream communications on use mapping, which can be assumed to be due to limited resources.

Lastly, in terms of human resources, smaller firms tend to rely more on external training and external consultants to ensure compliance with REACH. At the same time, more SMEs consider it very difficult to find consultants with the right level of skills and experience (23% of SMEs compared to 13% of large firms).

2.9. Measures adopted to support SMEs

Since the REACH Review 2013, several support measures have been introduced to alleviate the burden on SMEs. Among those, the registration fees were revised and reduced for SMEs (an additional 5% compared to the earlier situation and applicable already for the 2013 registration deadline). Furthermore, an Implementing Regulation on data-sharing was adopted

and entered into force on 25 January 2016; SMEs were expected to benefit considerably from a more fair and transparent framework, as the actual costs of studies are requested to be itemised and disclosed to any potential registrant, and must be clearly separated from administrative and operational costs of a substance information exchange forum (SIEF). The data from the SME panel survey show that the reduction in fees of 2013 is perceived as useful or very useful by nearly half of the respondents (46 %), whereas a quarter was not aware of this measure. Similar feedback was given for the Regulation on data sharing.

Several studies that have been prepared for the Commission, ECHA and Member State authorities looked at the availability and usefulness of diverse support tools. In the run up to the last registration deadline, implementation of support initiatives continued via the implementation of the ECHA's 2018 registration roadmap. A dedicated website[74] with a toolkit to guide companies in the process towards the 2018 registration and a guide for SMEs ("Chemical safety in your business"[75]) have been developed in all EU languages, in order to provide readily accessible information and more user-focus guidance to companies, especially SMEs, about their role and obligations in relation to REACH. Furthermore, support in view of the 2018 registration has been provided to some sectors that are made up mostly by SMEs. Also, for the natural essential oils sector, ECHA and the Commission provided support to the development of two industry guidance documents that clarify registration requirements[76] and will thus help to prevent unnecessary costs and burdens. All those actions have received positive feedback from stakeholders (e.g. through the SME panel) although the impact cannot be assessed at this moment.

Furthermore, ECHA is developing its "Cloud Services", in order to deliver IUCLID functionalities from an ECHA-hosted and managed infrastructure. This will save SMEs resources, who will not have to install the software, organise backups and migrate their data in case of new releases. Moreover, it will enable the ECHA to provide integrated support and help functionalities to companies when preparing registration dossiers. ECHA has estimated that this measure may save over EUR 11 million per year across the industry.

The available support mechanisms have been widely disseminated**,** in cooperation with the Communicators network (Member State representatives) and the Enterprise Europe Network (EEN)[77]. The cooperation between the EEN and national Helpdesks has been reinforced with a view to make use of EEN direct contacts with companies in order to disseminate information about REACH and facilitate companies' access to the services of Helpdesks.

As regards availability and quality of information, the SME Panel shows that a majority of respondents are satisfied or very satisfied with the availability of information about REACH and how that affects their company (56%). However, a considerable share (40%) is not satisfied and only a very small share (3%) is very satisfied without providing further explanations.

The guidance published by ECHA is seen by SMEs as useful (33%) or very useful (49%). Concerning national helpdesks, the respondents were satisfied (42%) or neutral (39%) with the content of obtained replies without providing further details.

[74] https://echa.europa.eu/support/getting-started
[75] https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes
[76] https://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/essential-oils
[77] The Enterprise Europe Network helps small and medium-sized enterprises (SMEs) by providing them business expertise in and outside the EU

2.10. Conclusions

REACH has contributed to the harmonisation of the chemicals legislation in the EU, while at the same time is likely to have had only limited impact on the intra and the extra-EU trade.

The number of registrations by the 2013 deadline for substances above 100 tonnes, as well as the associated costs, appears to be broadly in line with the estimates included in the Extended Impact Assessment accompanying the REACH proposal. However, concerns about the vulnerability of SMEs to the registration costs remain, as well as concerns about the competitiveness of specific sub-sectors (with prevailing high numbers of SMEs) in view of the continuing withdrawal of chemicals from the market. Specific support by ECHA, the Commission and Member States has been assisting some sectors to mitigate those concerns and prepare for the next registration deadline.

SMEs are more vulnerable due to their limited resources available and therefore the registration obligations and the costs, along with substance withdrawals, remained the main issue for them. At the same time, benefits in terms of business opportunities / incentives to innovate may have not been created.

Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on R&D and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and the higher transparency enable the users of chemicals to make better choices in the design of products and in their use.

The listing of SVHC in the candidate list or in Annex XIV triggers communication across the supply chain, initiates substitution activities at all supply chain levels, and triggers considerations of reformulation for some products and of withdrawal for some others. The continuous inclusion of new substances in the candidate list and in Annex XIV is however associated with uncertainty and perceived as a challenge for international competitiveness. On the other hand, data confirm that, since the entry of REACH into force, there have been a continuous flow of new substances on the EU market.

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Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 6

{COM(2018) 116 final}

Annex 6 – Review of ECHA

1 Introduction and baseline

The European Chemicals Agency (ECHA) was set up on 1 June 2007 to carry out the technical, the scientific and some administrative aspects of the REACH and CLP Regulations and to ensure for these aspects consistency at the Union level. ECHA draws up opinions so that the Commission can enact Regulations (e.g. restrictions) or take specific Decisions (e.g. granting or refusing authorisations). ECHA has strictly limited decision-making powers allowing it to adopt individual decisions on technical aspects, under clearly and precisely defined conditions. The range of powers given to ECHA is in line with the principles of the EU legal order which imposes constraints on the scope of the powers that can be given to Agencies[1].

Today, ECHA has responsibilities for the implementation of four specific Regulations:

- the REACH Regulation[2] for which the main tasks of ECHA are to manage the registration process of chemical substances, the evaluation of registration dossiers and, in collaboration with the Member States, of substances, and the preparation of opinions on applications for authorisation and proposals for restrictions on the use of chemical substances;
- the Classification, Labelling and Packaging Regulation (CLP)[3], where ECHA manages the technical/scientific work related to the harmonised classification of substances and the European Inventory on the classification and labelling of hazardous substances;
- the Regulation on Biocidal Products[4] where ECHA provides opinions on the approval of active substances and the Union authorisation of biocidal products;
- the Regulation on prior informed consent (PIC)[5], where ECHA handles processes concerning the import and export of certain dangerous chemicals.

This REACH REFIT evaluation assesses the activities undertaken in relation to the obligations stemming from the REACH Regulation and considers also to what extent ECHA has addressed the European Commission's recommendations to ECHA in the 2013 General Report on the Review of REACH[6].

The main recommendations from 2013 can be summarised as follows:

- ECHA should enhance its resource efficiency;
- ECHA Committees need to continue looking for more efficient ways of working and must be able to rely on strong support from the Member States;
- ECHA should increase its SME support and supply chain communication activities;

1 COM(2002)718 final, 11.12.2002, p. 8; COM(2008)135 final, 11.3.2008, p. 5.
2 Regulation (EC) No 1907/2006
3 Regulation (EC) No 1272/2008
4 Regulation (EU) No 528/1272
5 Regulation (EU) No 649/2012
6 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN

- The 2013 review of the Fee Regulation needs to consider suggestions made in the 2011 ECHA report, (see Annex 4, section on Fees and Charges)

2 Operations and processes

2.1 Registration

The tasks of ECHA are to provide a system for the submission and processing of registration dossiers, ensuring that all REACH registration dossiers undergo the required checks, that the respective decisions are taken, and that confidentiality claims are assessed according to the standard procedures within the legal deadlines given by the legislation or in the work programmes. ECHA must ensure that decisions are well justified and are of a high technical and scientific quality. Furthermore, stakeholders and the public must have easy access to non-confidential information from all the dossiers of registered substances, within a reasonable time after their registration.

As stated in its General Reports from 2013 to 2016[7], ECHA has achieved all its own targets for registration activities and even exceeded some of them.

- All registration dossiers – including those submitted by the 2nd registration deadline 31 May 2013 - have been processed within the required deadlines and the non-confidential information from registration dossiers submitted by the registration deadline of 31 May 2013 has been published.
- The percentage of inquiries from potential registrants as to whether a given substance is already registered (Article 26 of REACH) - the internal timeframe of 20 days was exceeded, decreased from 14% in 2013 to 8% in 2015 (against a target of 20%).
- The number of data-sharing disputes decreased year-on-year and all have been processed within the legal timeframe.

Through the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES), ECHA provides industry with scientific and technical support under the Chemical Safety Assessment (CSA) programme to enable successful development of the chemical safety reports (CSRs) and adequate risk management advice through the supply chain in the exposure scenarios. In view of these results, ECHA appears to have been effective in achieving its objectives linked to registration activities, except for some particular aspects examined below.

One issue is that about 2 % of full registrations and 3 % of intermediates registrations submitted by the deadlines in 2010 and 2013[8] did not respect the legal requirement of "one substance, one registration" (OSOR). ECHA has taken measures to enforce the rule**:**

- the latest version of REACH-IT released in 2016 does not allow for the opening of several independent registration dossiers for the same substance (this was possible in the past);
- existing cases are being addressed so that all registrants of the same substance end up in the same joint submission.
- ECHA further promotes data sharing in SIEFs with guidance to increase transparency, non-discrimination and fair cost sharing in the framework of SIEFs (i.e. "*Guidance on*

[7] https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports
[8] ECHA report on REACH & CLP 2016

data sharing", available in 23 languages – which has been updated after the adoption of a specific Regulation on joint submission of data and data-sharing by the Commission[9]) and dedicated workshops on "*practical advice for data sharing negotiations*". This is complemented by hands-on advice on ECHA's website.

Nevertheless, SMEs have flagged that ECHA needs to better tackle data sharing disputes and issues related to lead registrants charging additional fees. Faced with this feedback, the Commission adopted in 2016 an implementing regulation on data sharing and joint submission, which spelled out more clearly the role and responsibilities of ECHA in data sharing disputes. In this respect, it should be noted that ECHA has already undertaken measures to address this issue. Indeed, the access to the dispute settlement mechanism is free of charge and seen as easy to use as only a webform has to be submitted in addition to the copies of the communication (emails, letters) between the parties.

Stakeholders considered in the past that there were shortcomings in ECHA's verification of the completeness of registration information, as the IT-based automatic completeness check led to the acceptance (by giving registration numbers) of registration dossiers that did not contain the required information. ECHA addressed this by introducing in 2016 a manual verification in addition to automatic completeness check for certain data elements that cannot be verified automatically, e.g. substance identity. Improvements also include verification that documentation on SME status is included. ECHA expects that the higher costs of the manual verification of the completeness check will be outweighed by the benefits as improved dossier compliance will result in higher efficiencies in other activities such as compliance checks and identification of substances of potential concern.

According to the surveys conducted in the context of the ECHA evaluation study[10], stakeholders are overall satisfied with the way ECHA has managed the registration deadlines for phase-in substances, providing scientific expertise on chemicals safety, ensuring consistency for disseminating information and guidance to industry and Member States.

Further room for improvement has been noted concerning the guidance material (format and content), which is considered too detailed and too technical for companies and in particular SMEs, thus adding administrative burdens. In response to this feedback, ECHA has prepared the ECHA 2018 webpages[11], in cooperation with all stakeholders. All guidance material has been simplified and translated into all EU languages, with the SMEs in mind. Industry also noted that the complexity and frequent updates of IT tools rendered registration more difficult.

The majority of respondents to the open public consultation consider that in general terms ECHA has handled the registrations of chemical substances effectively. This is not the case for NGO respondents which express more critical views, as they feel that ECHA is too accommodating of industry because it invested too much resources in supporting the industry to comply with their legal obligations under REACH, while REACH registration is meant to shift the burden from the regulator to the industry.

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[9] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing), OJ L 3, 6.1.2016,

[10] Link to the final report of the review of the European Chemicals Agency (ECHA)

[11] https://echa.europa.eu/reach-2018/

Stakeholders are satisfied with ECHA's transparency in the area of "*dissemination of information*" on chemicals. Industry associations tend to agree that ECHA has found the right balance between transparency and openness versus protection of confidentiality of business information. NGOs' responding to the consultation expressed a rather high level of satisfaction with ECHA's transparency.

Some shortcomings were detected in the process for verification of the SME status of registrants. ECHA has to check whether the declaration made by registrants on their size is accurate or not. If not, ECHA rectifies the fee to be paid by registrants (e.g. standard fee instead of reduced fee) and applies an administrative charge that encourages the registrant to be accurate about their actual company size. According to the Commission Internal Audit Service, the Agency accumulated a backlog of SME verifications which constitute a potential loss of income from companies which did not correctly declare their actual size. The Agency has put in place an action plan to deal with this backlog.

2.2 Dossier and Substance evaluation

Dossier evaluation comprises both the examination of testing proposals and compliance checks. In the examination of testing proposals, ECHA assesses whether proposed tests are necessary or not in order to avoid unnecessary animal testing. The purpose of the compliance check is to verify that registration dossiers comply with the information requirements of the REACH Regulation. REACH requires ECHA to select at least 5 % of all the registration dossiers for each tonnage band for a compliance check.

Substance evaluation aims to verify, based on initial concerns, whether a substance constitutes a risk for human health or the environment, and is performed by the Member State's competent authority, with a coordinating role for ECHA. Substances to be evaluated are included in the Community rolling action plan (CoRAP), based on risk-based prioritisation criteria set out in the REACH Regulation.

The tasks of ECHA are to ensure the preparation of scientifically and legally robust draft and final decisions on testing proposals, compliance checks and substance evaluations, as well as to ensure that the decisions are coherent and followed up without delay. In order to put in place effective and efficient processes, ECHA, in cooperation with the Member States' competent authorities and the Commission, developed a variety of approaches to evaluation, in particular:

- In 2011 ECHA introduced the 'Areas of Concern' approach to identify dossiers subject to compliance check;
- In 2014 ECHA developed a new approach to compliance check as set out in the compliance check strategy[12] now referred to as the Integrated Regulatory Strategy[13].

The ECHA evaluation study concludes on the basis of an analysis of the General Reports from 2013 to 2016 that throughout the four years, all dossier and substance evaluations have been treated within the legal time limits and in line with the targets set in the annual work programmes. The percentages of compliance checks concluded for the registration dossiers

[12] A new strategy for compliance check to improve the quality of information provided by companies, 26 September 2014, https://echa.europa.eu/documents/10162/17208/echa_cch_strategy_en.pdf/607b157b-a35d-4d1c-8e62-ce8668324b1a

[13] ECHA Report on the operation of REACH and CLP 2016, p. 26-28

submitted by 2010 and by 2013 were in line with the legal requirement of a minimum 5%. The percentage of follow-up evaluations performed within six months after the deadline set in the final dossier evaluation decision slightly exceeded ECHA's own target of 75% for four consecutive years. The percentage of testing proposal examinations, concluded for dossiers received by the 2013 deadline[14], also exceeded ECHA's own target each year[15]. However it was not possible to obtain from ECHA an overview of exactly what information had been requested for how many substances, nor of the cost of an evaluation decision. Hence an assessment of the impact on human health and environment protection of the requested information was not possible. Commission calculations point at a cost of approximately EUR 60,000 for an evaluation decision. This estimate is based on information related to the FTEs allocated to the dossier evaluation activity. The 2003 Extended Impact Assessment did not provide an estimate of the expected cost for this activity.

According to ECHA's Annual Stakeholder Surveys from 2013 to 2015, Member States' competent authorities are satisfied (up to 80% satisfied or very satisfied in 2015) with ECHA's support for dossier and substance evaluation, and with the implementation of the compliance check strategy. However, in 2014, almost 30% were somewhat dissatisfied with ECHA's communication and interaction with competent authorities and national enforcement authorities on the follow-up process to dossier evaluation decisions[16], although the situation was better in 2015. The members of the Member State Committee are satisfied (up to 80% satisfied or very satisfied in 2015) with the scientific and technical support received from ECHA for the opinion-making process in dossier and substance evaluation.

The Commission services acknowledge the improvements under ECHA's new compliance check strategy, which provides more transparency for registrants. However, the Commission, the industry and NGOs see room for improvement and call for the definition of **better quality indicators**. The Commission has called on several occasions in ECHA's Management Board meetings for a better monitoring of the success of the various strategies implemented over the years to enable a proper assessment of the achievements and where improvements are needed. Indeed, most existing indicators are of a quantitative nature and the performance indicators in the Work programme should be further refined to allow for firmer conclusions to be drawn on effectiveness and efficiency targets.

2.2.1 Avoidance of unnecessary animal testing

ECHA should keep the number of animal tests to a minimum through the tools foreseen in REACH, i.e. the enforcement of the data sharing obligation, the promotion of alternative methods and the examination of testing proposals. ECHA publishes the testing proposals involving vertebrate animals on its website[17] to allow third parties to comment on the actual need for the tests. In addition to the dissemination of registration information on its website, and in cooperation with the OECD, ECHA shares the available data on testing through the *eChemPortal* and manages the OECD QSAR Toolbox software application which supports companies in identifying data relevant for assessing the hazards of chemicals and for filling data gaps in the preparation of registration dossiers without conducting tests on animals. Moreover, ECHA works with the Commission's Joint Research Centre (JRC), and in particular it's European Centre for the Validation of Alternative Methods (ECVAM), to both

[14] In order to reach the legal requirement to prepare a draft decision by the 1 June 2016 deadline
[15] 45% in 2014 for a target of 33%, 81% in 2015 for a target of 75% and 100% in 2016.
[16] Article 42(2) notification
[17] https://echa.europa.eu/chemicals-in-our-life/animal-testing-under-reach+&cd=1&hl=it&ct=clnk&gl=be

influence and benefit from the latest scientific developments as regards methods to generate information on chemicals that do not involve animals.

ECHA's implementation of the last resort legal requirement for animal testing has been criticised by the industry and NGOs and has been challenged in two cases by the European Ombudsman.

- The first Ombudsman case, lodged by the Foundation People for the Ethical Treatment of Animals (PETA) and closed on 11 December 2014[18], found that ECHA's interpretation of its obligations on animal testing was too restrictive, particularly in relation to using compliance checks to verify if the last resort legal requirement had been respected. The Ombudsman made a proposal to ECHA concerning its own role as well as the cooperation with Member States competent authorities, which was accepted by ECHA.
- In the second Ombudsman case, lodged by a group of animal welfare NGOs and closed on 11 September 2015[19], the complainants disagreed with ECHA's position that it could not reject testing proposals involving animals on the grounds that the data could be generated by an alternative method not involving animal tests. The Ombudsman reminded ECHA that the avoidance of animal testing is, together with the protection of human health and the environment, one of the objectives of REACH. The Ombudsman proposed that (i) ECHA requires all registrants making testing proposals to document that they have considered alternative testing methods and have found that the information gap cannot reasonably be filled through such methods and (ii) that ECHA provides registrants with all the available information to allow them to avoid animal testing. Both proposals have been accepted and implemented by ECHA since September 2015.

Although the use of waiving statements instead of testing has increased, leading to less animal testing, the industry respondents in the ECHA evaluation study consider that ECHA should be more pragmatic in accepting animal testing proposals, as it is easier, especially for an SME, to carry out an *in vivo* test, rather than using the QSAR tool. On the contrary, animal welfare NGOs deem that ECHA is still too reluctant to accept new testing methods and favours too often animal tests over non-animal tests.

The views expressed by stakeholders through the online public consultation on how ECHA's work has facilitated the implementation of the last resort legal requirement concerning animal testing are generally neutral except for NGOs, which are more critical in this respect.

2.3 Regulatory risk management measures: authorisation and restriction

ECHA's tasks relating to authorisation include the updating of the Candidate List of substances of very high concern (SVHCs) based on proposals by the Member States or its own proposals on request of the Commission. ECHA regularly prepares recommendations to the Commission on the prioritisation of substances from the Candidate List to be subject to authorisation (through inclusion in Annex XIV to REACH) and provides support for companies applying for authorisation. On the request of the Commission, ECHA prepares restriction proposals, either by itself or working together with Member States in the preparation of the required Annex XV dossier. ECHA also conducts public consultations on

[18] http://www.ombudsman.europa.eu/cases/decision.faces/en/58549/html.bookmark
[19] http://www.ombudsman.europa.eu/en/cases/decision.faces

applications for authorisation and restriction proposals and supports the Rapporteurs from the RAC and SEAC during the opinion-making processes on applications for authorisation and on proposals for restrictions.

According to the Annual Stakeholder Surveys from 2013 to 2016, Member States' competent authorities are overall satisfied with ECHA's support, coordination and information sharing for the different risk management activities. The satisfaction with ECHA's support for the prioritisation of substances for inclusion into the Authorisation List improved in 2015 compared to 2013 and 2014. The members of the MSC, RAC and SEAC as well as the involved accredited stakeholders are also satisfied with the ECHA support for their activities related to authorisation and restrictions, although 10% disagreed for SEAC in 2014 and 2015.

The main difficulties signalled by companies in the ECHA evaluation study for the application process for authorisation were, in decreasing order:

- the complexity of the process and lack of user-friendliness of the IT tools (especially IUCLID[20]) leading to the need for support by external consutants,
- the time and costs involved in the procedure,
- the difficulty to liaise and agree with other companies involved.

The Commission services consider that over the last four years, ECHA has improved coordination with Member States, in particular by implementing a common screening approach to identify substances potentially needing risk management measures, and by implementing the SVHC Roadmap, including the promotion of a common understanding of the regulatory management option analysis (RMOA).

Further efforts will be conducted by ECHA to have a more proactive role in the restrictions procedure (instead of waiting for a Commission request) and prepare for the Commission, taking into account the current activities of the RMOA, a list of potential chemicals that could be restricted.

The efficiency of the authorisation and restriction processes has improved through the work of two Task Forces organised with the Commission and some Member States. The Committees have made efforts to achieve greater consistency of the opinions on authorisation (harmonisation of terminology, description of conditions, justification and conclusions as well as the opinion making process thanks to the use of decision trees) although there is still room for further improvement based on the experiences gained so far (e.g. defining the uses applied for according to the analysis of alternatives). ECHA's efforts to support applicants for authorisations (e.g. pre-submission information sessions) are also considered positive by stakeholders including industry. On the other hand, the European Parliament[21] in one instance has been critical of the quality of the Committees' opinions on applications for authorisation.

It should be noted that ECHA has not yet delivered on the Commission recommendation from the 2013 REACH Review to "*increase resource efficiency by developing a database listing existing restrictions in EU legislation*" (a feasibility study to develop such a list was launched only in June 2016). For more details see Annex 4 section on authorisation and restriction.

[20] Although ECHA makes available partially pre-filled IUCLID files for authorisation applicants.
[21] European Parliament non-legislative resolution of 25 November 2015 B8-1228/2015.

2.4 Scientific IT tools

ECHA has developed and manages various scientific tools to implement its activities related to the REACH and CLP Regulations. The role of each IT tool in supporting the implementation of these Regulations is described in Table XX below.

Table 6.1: ECHA's scientific IT tools for REACH and CLP

IT Tools	Regulations supported	Processes facilitated
REACH IT	REACH	• Submit a registration dossier • Prepare a dossier for a member of a joint submission • Submit an application for authorisation • Submit a PPORD notification • Submit an inquiry • Notify substances on the candidate list • Submit a downstream user notification for substances on the Authorisation (Annex XIV) List • Submit a downstream user report for uses that are not supported by the exposure scenarios or for classification differences
	CLP	• Submit and update a C&L notification • Request an alternative chemical name in mixtures • Submit a CLH dossier
IUCLID	REACH, CLP	• Prepare dossiers, applications and notifications in the IUCLID format • Check dossier completeness; • Verify invoice amount, • Verify level of information to be published on ECHA's website
CHESAR	REACH	Prepare chemical safety assessments (CSAs), chemical safety reports (CSRs) and exposure scenarios (ESs) for communication in the supply chain.

A majority of companies interviewed for the ECHA evaluation study consider the IT tools effective and recognise the efforts of ECHA to manage them, to make them more user-friendly and provide support to applicants via webinars, guidance, and helpdesk.

Nevertheless, the results of the online survey conducted in the framework of the ECHA evaluation study show some shortcomings with ECHA's IT tools. The main difficulties encountered, in decreasing order are:

- the frequent updates (e.g. IUCLID) leading to additional adjustment costs for companies,
- the complexity and lack of user-friendliness of the software (especially IUCLID, but also to a lesser extent CHESAR) leading to time consuming processes (e.g. IUCLID) and the need to the use external consultants for small companies,
- the lengthy and sometimes too complex guidance (e.g. IUCLID, CHESAR),
- the fact that REACH-IT is not accessible on weekends and Finnish public holidays.

In response to industry complaints about the user-friendliness of the scientific IT tools, in particular IUCLID 5 and CHESAR, ECHA has taken actions to improve the functionalities of these tools and provided new versions. However, this led to other complaints from industry about too frequent IUCLID updates entailing high adaptation costs and extra administrative burdens. For example, the new version of IUCLID 6, released in April 2016, requires more information on exposure scenarios and the assessment of PBT properties in highly structured data-entry fields which facilitates the automated screening by ECHA of exposure data. However, this new version will also benefit industry since exposure data can be automatically transferred from CHESAR and easily maintained for updates. While IUCLID 6 contributes to ensuring compliance of registration dossiers, it requires extra resources for companies to fill in the dossiers for the 2018 registration deadline.

Representatives of SMEs also complained that the IT tools were not translated into every EU language, which creates an extra barrier – however, the relevant guidance has now been translated into every EU language in the new released versions of the IT tools.

Lastly, ECHA is developing an 'ECHA Cloud Service', i.e. a cloud version of IUCLID, available to self-declared SMEs, hosted by ECHA on its ICT infrastructure and fully serviced by ECHA. This service has been progressively delivered from the first quarter of 2017 and aims to reduce the technical burden and related costs (financial, labour) for hosting and operating IUCLID locally, to ensure better protection against loss of data and to ensure continuous availability of online IUCLID services over the internet[22].

2.5 Specific attention to SMEs

The 2013 REACH Review specifically identified the need to reduce the impacts of REACH on SMEs. In line with the Commission recommendation from the 2013 REACH Review, ECHA appointed a SMEs Ambassador in 2013. The SME Ambassador is a liaison officer to help the industry and to interact with various bodies at EU level that have a generic interest in SMEs issues, such as the European Union's SMEs Envoy network, formations of the European Parliament or the REFIT platform, and with associations representing SMEs interests. Within ECHA, the SME Ambassador's role is to raise awareness in ECHA about SMEs concerns and act as a catalyst in introducing SMEs-focused considerations into all of ECHA's activities. ECHA has pursued wider communication and awareness-raising of REACH to improve the availability and usability of information available through a dedicated website[23] and a guide for SMEs ("Chemical safety in your business[24]) in 23 EU languages as well as its wide dissemination through the Europe Enterprise Network and national

[22] https://echa.europa.eu/documents/10162/22837330/mb-42_minutes_en.pdf/da130a1b-a03a-48d4-bbda-56c32b726263
[23] https://echa.europa.eu/support/getting-started
[24] https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes

Helpdesks[25]. Furthermore, as explained previously, ECHA has specifically addressed concerns of SMEs related to data-sharing in SIEFs. ECHA has organised and/or participated in numerous events at national level to directly interact with SMEs in their own languages

ECHA has also continued the activities of the so-called Directors' Contact Group (DCG), which provides a platform for the informal exchange of views and information between the Agency, the European Commission and participating Industry Associations and contributed actively in streamlining support and providing orientation to duty-holders.

Stakeholder views on the results of these activities are divided. On the one hand, industry respondents to the online public consultation are rather critical about the way ECHA's work has contributed to reducing the impact of REACH on SMEs. On the other hand, the SME panel shows that information and guidance made available by ECHA is among the most frequently used sources of information on REACH. Respondents from public authorities, NGOs and trade unions have a more positive perception.

3 ECHA bodies

3.1 General consideration on the Committees

Articles 76 and 77 of the REACH Regulation set out the tasks of the three Scientific Committees of ECHA, namely the Member State Committee (MSC), the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC).

In light of the increasing workload, in particular of RAC for which the workload has tripled (i.e. from 34 opinions in 2012 to 102 opinions in 2016), a number of initiatives have been taken to increase the working capacity of the Committees but also to streamline procedures and working methods.

Membership of RAC increased from 39 members in 2012 to 51 members in 2017, while SEAC expanded from 30 to 39 members. In addition to nominations from the Member States, and to cope with the high number of authorisation dossiers, RAC and SEAC co-opted four members each, who were selected in light of the increasing number of applications for authorisation. In fact, while the expertise in RAC for the evaluation of classification and labelling dossier has been solid, the expertise in the other area needed some reinforcement. However, when nominating members for the Committees, there were difficulties to find appropriate experts within and outside national competent authorities and Member States for all relevant areas of expertise which includes human toxicology, ecotoxicology, epidemiology, occupational hygiene, exposure assessment, risk assessment and risk management.

As far as SEAC is concerned, the Commission observed an increase of the relevant expertise required among its members. However, this trend needs to be pursued to ensure that the Committee has the appropriate mix of expertise in particular in the field of socio-economics and the analysis of alternatives.

Based on observations by the Commission, expertise and capacity to deal with the work volume in the Member State Committee is somewhat unevenly distributed and the biggest

[25] Link to the guide for SMEs: Chemical safety in your business

contribution is brought to the meeting and decision making by a small number of only 7 – 8 Member States.

Furthermore, to accommodate the higher workload, the number of Committee meetings was increased and the duration of the Committee sessions was extended. RAC plenary meetings usually take two weeks, four times per year. One week is mainly dedicated to the assessment of classification and labelling dossiers under CLP. The other week is dedicated to the evaluation of applications for authorisation and proposals for restrictions, as well as specific requests for opinion under Article 77(3)(c) of REACH.

Actions have been taken by ECHA to increase the efficiency of the meetings, for instance by organising preparatory meetings and use of written or fast-track procedures. To ensure the cost-effectiveness of meetings, in particular in consideration of travelling costs as well as the limited availability of Committee members, such additional meetings were organised back-to-back to the regular meetings, and where possible, by making systematically use of videoconferencing.

The reduction of debating times in plenary sessions for straight-forward cases, allows for more time for the examination of priority dossiers or complex cases. Informal consultations in between meetings also help to identify contentious points and to facilitate the alignment and the adoption of opinions during the plenary meetings. The streamlining of internal procedures and working practices, such as the recourse to written procedures or fast-track agreements is also perceived as an important timesaver. For example, in the case of the MSC, 90% of dossier evaluation draft decisions are agreed in this way, and 60% of substance evaluation draft decisions. The revision of the internal procedures of RAC and SEAC in June 2015 is perceived by Committee members as facilitating more efficient ways of working and processing dossiers.

The limited availability of individual members translates into higher workload for ECHA staff, in particular for scientific dossier managers assisting the rapporteurs in the preparation of draft opinions, and into more difficult and more time-consuming decision making. This issue has been reported by ECHA to the Management Board in 2014, and the Management Board requested the Member States' competent authorities to make sufficient resources available.

This campaign has been successful in further mobilising current members and increasing the number of members in general (RAC up from 40 to 51 and SEAC up from 30 to 39 (2014-2017). An estimated 60% of members in RAC and SEAC in 2017 now meet or exceed their target.

It should also be noted that the REACH Regulation foresees the possibility that the Committees can make more use of available external experts that can be involved on an ad-hoc basis in the discussions and support the work of the Committees with additional expertise. In fact, dose-response relationships or DNELs for substances recommended for inclusion into Annex XIV are derived by external contractors and validated by RAC, as the time and resources allocation does not give any possibility for RAC member to derive them. However, the Commission services consider that ECHA should reflect on how this work could be performed internally instead of resorting to external contractors in particular as ECHA has the scientific competence to deliver this task. It is important since ECHA's ambition is to become the hub for excellence in regulatory science. In order to have more flexibility, ECHA could

create a list of experts to be continuously updated and use these experts for 'ad hoc' attendance at the meetings of RAC.

ECHA's stakeholder surveys indicate that the level of satisfaction with the support provided by the ECHA Secretariat to the Committees is generally positive. However, a number of interviewees in the ECHA evaluation study suggested that that the operation of the Committees could be further optimised, e.g. ECHA could be more proactive, meetings could be prepared more efficiently and the workload of Committee members could be reduced by providing more streamlined documents.

Members of ECHA's Committees noted that the strict legal deadlines, in particular for restriction and authorisation dossiers, limit the margin for flexible workload management such as the prioritisation of dossiers. A number of interviewees in the ECHA evaluation study commented that the unanimity rule[26] for adopting MSC opinions creates inefficiencies in the process, especially in politically sensitive or controversial cases. As an example, 216 draft decisions on the Extended One Generation Reproductive Toxicity Study were referred to the Commission due to the lack of unanimity in the MSC.

Members of the MSC as well as the Commission have highlighted that RAC uses for risk assessment and classification & labelling (C&L) dossier the data that has been generated in evaluation with the involvement of the MSC. However, RAC does not always accept in particular when processing C&L dossier the data generated via evaluation – so more interaction between RAC and MSC would be desirable.

The collaboration between RAC and SEAC has improved on the basis of the increasing expertise and thanks to the support of ECHA Secretariat. However the Commission services consider that this dialogue has to continue to improve in particular for complex cases.

During this review period, SEAC has delivered in a timely manner more than 100 opinions on applications for authorisation and over 20 opinions on restriction proposals. According to ECHA's 2015 and 2016 Annual Stakeholder Survey, a majority of SEAC members and accredited stakeholders are satisfied with the transparency of the SEAC processes. According to the ECHA evaluation study, SEAC is considered as an innovative Committee compared to other EU agencies by accredited stakeholder organisations (ASOs) and Member States authorities. The methodology used in the socio-economic assessment related to chemicals risk management is not as developed as risk assessment techniques and some NGOs note that very few SEAC experts have in-depth expertise in socio-economic issues, which may affect the opinions formulated by the Committee.

Many NGOs and some Member States authorities have also criticised that SEAC accepts too easily requests for derogation from restrictions and is not critical enough as to the outcome of the analysis of alternatives in authorisation applications. Nevertheless, the Commission services and stakeholders agree that the quality and value of SEAC opinions has increased but consider that further capacity building to widen the pool of expertise in the area is needed[27]. Further improvement is noted in terms of process, structure, analysis and presentation of the opinions. This work should continue to ensure delivery of opinions of high quality addressing the increasing needs of the decision-making process. The Commission will continue to provide feedback in order to ensure that the opinions it receives are fit for purpose.

[26] Such unanimity rule only applies to MSC
[27] 2016 Report on the operations of REACH and CLP

In a resolution adopted by the European Parliament[28] objecting to a draft decision of the Commission on authorisation, one joint scientific opinion delivered by RAC and SEAC was criticised, and SEAC was reproached with having overstepped its mandate by giving policy-driven opinion. While the Commission dismissed this allegation[29], as policy elements were mentioned but not decisive for this opinion, the Commission services concur that policy is out of the remit of SEAC. A follow-up discussion also took place in the 17-18 March 2016 Management Board where an action plan was agreed.

In view of the above-mentioned perceptions of certain stakeholders, the Commission services and ECHA organised a workshop to clarify the role of socio-economic analysis (SEA) under REACH, and in particular to improve the understanding on what SEA does and what it does not do, how the opinions of SEAC are derived, and how SEA and SEAC opinions are used in the decision-making with regard to restrictions and applications for authorisation. The workshop concluded, among other things, that SEAC supports and is necessary for the decision-making, but does not replace it, that it provides the factual (not necessarily purely quantitative) basis and analysis for the decision-making based on which political judgement is made. It also recognised that SEAC's capacity has increased, underlined the need to improve the understanding between risk assessors and socio-economic analysts, and noted the challenge to properly communicate SEA results to uninvolved stakeholders.

Member State Committee

The Member State Committee (MSC) participates in several REACH processes such as Evaluation and Authorisation. The MSC is responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs). The Committee provides opinions on ECHA's draft recommendations for the authorisation list (Annex XIV) and draft Community Rolling Action Plan (CoRAP) for the substance evaluation process. If an agreement is not reached within the MSC, the matter is referred to the European Commission for decision-making.

The Committee meets 6 times a year, gathering 53 experts (most of the Member States participate with 2 experts), plus the accredited stakeholders (NGOs and Industry), and requires substantial support from a dedicated group of staff from ECHA's Secretariat.

A survey was performed and discussed with stakeholders in 2015 in the framework of ECHA's General report on the operation of REACH and CLP. The survey results showed that Member States and MSC members are generally satisfied with the workload and the current number of substances evaluated per year and believe it should be maintained (65%), while 23% of them called for a reduction. The comments on the workload are in line with the comments made by Member States in their 2015 reports submitted in accordance with Article 117(2). Member States considered that preparing the draft decisions, addressing comments from registrants and preparing responses to the PfAs were resource-intensive, often because of time constraints.

Member States acknowledged the progress achieved over the years to increase the efficiency

[28] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 – 2015/2962(RSP)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0409+0+DOC+PDF+V0//EN

[29] See COM response to EP Resolution B8-1228/2015

of the MSC meetings and the good results of streamlining efforts implemented by the Secretariat. Member States and MSC members agree that a number of the improvements already in place will further improve the efficiency of the substance evaluation process (e.g. new format for conclusion documents, new structure of MSC meetings etc.). Suggestions to improve the MSC meetings include promoting informal communication and consultation among Member States in the finalisation stage of the substance evaluation process, increasing the use of the written procedure, circulating the documents earlier to enable Member States to consult their experts, and increasing the participation of all Member States in substance evaluation.

Usually, the proposals for amendments (PfAs) reflect the different views from the Member States on different scientific and technical or policy issues, rather than corrections of ECHA's assessments. Sometimes these views diverge greatly among the Member States, which may make the PfAs unavoidable. This is partly reflected by the fact that even though the process has matured after almost ten years of experience, the percentage of PfAs remains very high. In 2016, 237 draft decisions were submitted to Member States Competent Authorities (MSCAs), of which 90 received PfAs. The number of PfAs per draft decision varied widely between 1 to 10-12. On average, PfAs were received for about 40 % of the draft decisions referred to MSCAs. The main issues referred to by the PfAs were read-across (different views on acceptance/rejection of read-across), Extended One-Generation Reproductive Toxicity Studies, environmental testing for persistency and mutagenicity testing (test guideline and study design). The interventions of the MSC in the identification of SVHCs and in the definition of the candidate list for the inclusion in Annex XIV have diminished over time due to the progressive standardisation of the process, hence most of its contributions are focused on dossier (testing proposals and compliance checks) and on substance (Community Rolling Action Plan) evaluations.

The PfAs were made by 9 Member States out of the 29 that are represented (the 28 EU countries plus Norway, as Iceland and Liechtenstein have not appointed any delegate), the activity being very strongly led by 4 countries.

According to Deloitte (2017)[30], there is the perception that the MSC performs well in terms of working procedure and expertise. However, as the members of the MSC are appointed by MSCA and represent national interests, some discussions tend to be more politically-oriented than scientifically based. Actually, the nature of the MSC has been the source of confusion and conflict with some Member States. These Member States believe that the MSC is an extension of their national authorities and distinguish between the ECHA decision making power and that emanating from the MSC. Although it has been clarified on multiple occasions that the MSC is a body of ECHA, some Member States believe the MSC is independent from ECHA and hence is not bound by the same rules, for example is not bound by the decisions of ECHA's Board of Appeal.

Risk Assessment Committee[31]

Member's expertise

[30] Link to the final report of the review of the European Chemicals Agency (ECHA)

[31] Further information on the independence of the Risk Assessment Committee (RAC) is available on ECHA's website.

The discussion during the RAC plenary session usually takes two weeks, four time per year.

One week is mainly dedicated to the assessment of the classification and labelling dossier which requires an expertise of toxicology, eco toxicologists, chemistry, biology. Experts have to judge mainly the intrinsic properties of chemicals.

The other week is dedicated to the evaluation of the application for authorisation, the assessment of the Annex XV dossier, requests under Article 77 (3) (c). The expertise requested in this area is mainly on toxicology, eco-toxicology, exposure, epidemiology, industrial hygiene, risk assessment and risk management.

While the expertise on the evaluation of classification and labelling dossier is quite solid in RAC, the expertise in the other area needs some more qualified staff in particular as the workload is increasing mainly due to the increased number of applications for authorisation and other "new" tasks.

The tasks are quite different and having a big pool of experts in each area is complex. However the Committee could benefit from allocating more support ECHA staff in specific areas where this expertise is requested. The allocation could be addressed through permanent or temporary staff depending of the allocation resources which ECHA has to consider for its budget in 2018.

As the experts are nominated by Member States, the selection at national level is fundamental and the different expertise should be addressed by Member States avoiding the focus on only one specific area.

Collaboration with the Agencies and Scientific Committee

Article 95 of REACH deals with potential scientific conflicts between the Agency and the other EU agencies or Scientific Committees.

In two specific cases RAC had to discuss with other Scientific Committees their evaluation.

- In the case of Annex XV dossier for restriction on Bisphenol A in thermal paper, RAC discussed together with EFSA the hazard assessment on the substances and the choice of the most relevant scientific studies and publications. The experts from EFSA panel and those from RAC agreed on the scientific assessment taking into account the most recent studies and scientific results.
- In another case, on the substance 1-methyl-2-pyrrolidone, RAC worked together with members of the Scientific Occupational Exposure Committee (SCOEL), and the discussion came to a divergent conclusion highlighting the different approach and methodology followed by the two Committees.

On a general case, RAC and SCOEL also worked together to discuss their methodology in deriving occupational exposure limits (OEL) and Derived No-Effect Level (DNEL) for inhalation route as well as DNEL –skin notation for dermal route, which has been the most fundamental point of discussion on chemicals subject to the regulatory process of adoption of limit values under the OSH legislation and to the authorisation process under REACH.

Following this discussion, the Commission questioned the need to have at EU level two different committees dealing with the evaluation of the same chemicals. Therefore, it was considered necessary to build within RAC the necessary expertise to cover the areas covered by SCOEL in a very short-time period and over a longer time period to replace SCOEL with RAC.

Due to this future change, RAC would definitely need to re-consider its own expertise and the Agency should allocate the necessary resources to deal with these relatively new tasks.

Socio-Economic Analysis Committee

Collaboration with RAC

The collaboration has been good in general, with creation of *ad hoc* groups to address specific issues. This is was in particular the case for impacts of man-via-the environment where, due to the potential high level of uncertainties, a close collaboration between the two committees was necessary and has been ensured.

MS reports according to Article 117

17 CAs commented on their responses. In addition, 4 CAs stated that they did not participate in the SEAC.

With regard to the effectiveness of SEAC, 8 respondents commented either that the Committee is effective or that the effectiveness has increased in recent years. 3 CAs attributed this positive change to improved and streamlined work processes. Two CAs recognised the added value of the support provided by the ECHA Secretariat to rapporteurs in the form of increased competences and expertise, and more experience of members in handling restriction dossiers.

However, 4 CAs indicated that the SEAC lacks members with sufficient expertise in socio-economic analysis. According to two CAs, the nomination of experts in the Committee is not based on adequate peer approval, which reduces the number of rapporteurs available, their effectiveness and the support they can get from the Committee. One CA added that the heterogeneous composition of the technical committee (economists, scientists, engineers) could complicate the work of the SEAC.

The increasing workload of the Committee appeared as a concern to 3 CAs, as it puts pressure on the CAs to find experts for the Committee, potentially compromising the quality of the expertise provided or the regular work of the CAs. In addition, 2 CAs blamed an unequal distribution of the work, placing a greater burden on certain CAs.

Regarding work procedures, one CA indicated that there is no coordinated assessment practice to a number of key substantive tasks of the SEAC – without specifying which ones. Another CA mentioned that some steps of the procedure were still taking too long, such as the conformity check for applications for authorisation, and another one, that the level of details of the assessment goes sometimes beyond what is needed and leads to ineffective work. Finally, one CA indicated that discussions and commenting rounds could be better organised and that communication and cooperation with RAC needed to be improved.

Regarding the assessment of application for authorisation, 2 CAs have mentioned that the poor quality of applications complicates the work of the Committee and forces the Committee to make its own assessment instead of evaluating the proposal. One CA added that the challenge lies in finding the right balance between further streamlining the application for the authorisation procedure, while ensuring a high level of information so that the RAC and the SEAC can do their assessment. Receiving ‘fit for purpose’ applications should be the main goal, and the level of details should be sufficient in all applications, especially concerning exposure.

For the sake of completeness it should be noted that some of the criticisms expressed by CAs have been addressed by the Task Force on the workability of Applications for Authorisation

and in particular the development of a practical guide on how to apply for authorisations[32].

The assessment of the analysis of alternatives is complex: for example, the only way for SEAC to validate the information at its disposal is through the inputs from the public consultations. It may thus be worthwhile to create an ad-hoc group with technical expertise on the assessment of alternatives, with specialisation by industrial sectors or segments, which would provide support for the assessment of the technical and the economic feasibility of alternatives.

Proposals for recommendations

Members

1. Need to ensure that members have sufficient socio-economic expertise, ideally socio-economic expertise applied to chemicals and to human health and the environment, in order to properly fulfil their duties according to Article 76 (1) (d) of REACH.
2. Need to ensure that members dedicate to SEAC at least as much time as they have committed to when accepting the task.
3. Ensure that opinion of the Committee is always technically justified and not driven by political national agenda.
4. ECHA continue to set up training sessions targeted to members dedicated to specific SEAC-related knowledge and processes.

Functioning

Restriction

5. The task force should assess ways to improve the technical and economic feasibility of alternatives and provide some practical guide to SEAC.
6. Continue to improve the approach for assessing the impacts from PBT/vPvB substances.
7. Need to clarify the necessary level of SEA assessment by the dossier submitter (in order not to burden them too much, with unnecessary requests), and of subsequent scrutiny by the Committees as recommend by the Restriction Task Force.

Authorisation

8. The task force should assess ways to improve the technical and economic feasibility of alternatives and provide some practical guide to SEAC.
9. Need to clarify the necessary level of SEA assessment by the applicant (in order not to burden them too much with unnecessary requests), and of subsequent scrutiny by the Committees as foreseen in the practical guide.
10. Need to improve the approach for assessing the impacts from PBT/vPvB substances.
11. Ensure that the opinions are fit for purpose.
12. Need to improve the definition of economic feasibility.

Others

13. ECHA should explore the possibility to have a system of scoring the applications for authorisation according to their level of quality, and categorisation by type of application (e.g. broad use, narrow use, substance, occupational concern related,

[32] https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676

general population concern related, environmental concern related, etc.), what may facilitate the task of applicants when preparing their application for authorisation

14. SEAC being the only expert group of all EU pieces of legislation specialised on SEA-related issues, possibility to use SEAC as a consultation group for other legislation.

Proposals for improvement from MS

To improve the quality of the expertise of the SEAC, 5 CAs proposed to:

- Introduce more stringent vetting procedures for new members to ensure they have sufficient expertise in socio-economic analysis

To improve the general working procedures of the SEAC, respondents proposed to:

- Notify to Committee members, ten days before the meeting, the issues that need to be finalised in the opinion during the next meeting to ensure that CAs are able to give a statement during the meeting
- Further streamline formats and committee-internal processes
- Avoid presenting systematically the conformity check for applications for authorisation during plenaries to speed up the process
- Distribute the work more evenly between Committee members and increase participation of all members in the drafting of opinions
- Make rapporteurs' work more flexible (deadlines, meetings, etc.)
- Establish an expert group on health impact assessment to bridge the gap between the RAC and the SEAC
- Increase the discussions on alternatives associated with the uses of a substance in the evaluation of applications for authorisation To improve the quality of the applications for authorisation and the authorisation process, 3 respondents have suggested that:
- The ECHA Secretariat increases the support to applicants preparing the dossiers
- Communicating to the industry that applications of poor quality hampers the work of the RAC and the SEAC and might have consequences when it comes to the formulation of opinions
- Information requests to applicants and the level of detail of the evaluation is tailored according to the specificities of the application. For instance, if costs and benefits are similarly high, requests for additional information will be necessary and the evaluation will have to be more detailed

3.2 The FORUM for Exchange of Information on Enforcement

The FORUM for Exchange of Information on Enforcement (the FORUM) coordinates a network of Member State authorities responsible for the enforcement of REACH. The aim of the FORUM is to harmonise the enforcement action of these National Enforcement Authorities (NEAs), by sharing good practices, undertaking harmonised enforcement projects and joint inspections, coordinating the exchange of inspectors, equipping them with manuals and tools, liaising with industry as well as examining proposals for restrictions with regards to their enforceability (see Annex 4, section 9 related to enforcement for further details).

According to the Annual Stakeholder Surveys and interviews conducted for the ECHA evaluation study, the members of the FORUM are satisfied with the effectiveness and transparency of the FORUM activities, as well as with the involvement of the accredited

stakeholder organisations (ASOs) in their work (ASOs can attend one of the three annual plenary sessions and contribute to some of the FORUM Working Groups).

A report of ECHA's Internal Audit Capability (IAC) on the FORUM in 2013 identified improvement points for a more efficient organisation of the FORUM's work and suggested how more effective support could be provided by the FORUM Secretariat, e.g. monitoring more systematically the allocation of time to activities to allow for a more efficient management of resources, to reduce the delivery times for working groups, and to engage more effectively its less 'active' members.

Since then, a number of improvements in the FORUM's functioning have been put in place. Compared to the situation in 2013, working practices have been streamlined and more efficient ways of working implemented. In 2015, the rules of procedure of the FORUM were reviewed. In addition, a new procedure for the delivery of the FORUM advice on enforceability of restrictions has been adopted[33]. Efficiency has improved in terms of communication with the ECHA's operational Directorates and NEAs. Some further improvements are still needed in terms of communication of the FORUM with RAC and SEAC to determine the best timing for the FORUM to provide opinions on the enforceability of the restriction proposals.

From ECHA's stakeholder surveys some administrative improvements could be suggested regarding the support provided by ECHA to the planning of meetings, agenda-setting as well as the preparation of meeting documents.

The set-up of Working Groups is perceived as a more efficient solution to organise the FORUM's work compared to the three plenary meetings, which do not provide sufficient room for discussions. The ten Working Groups, composed of a limited number of NEA officials, focus on specific topics and prepare decisions and manage the workload. However, the workload is perceived as high by the FORUM members as the involvement in Working Groups requires a permanently high level of commitment, which is for some members difficult to combine with their work in the national enforcement authorities. To reduce the impact in terms of travelling time and costs, meetings of working groups are occasionally organised via video conferences. Due to the increased number of projects which could be requested to the FORUM, the workload is not foreseen as decreasing in the future which would imply a possible restructuring of this body (for instance by creating a sub-group for Biocides).

Nevertheless, as for ECHA's Committees, resource constraints and limited availability of members at national level represent a challenge to the efficient and effective working of the FORUM. Moreover, the existence of different competent National Enforcement Authorities (NEAs) in the Member States, which are not always well informed of one another's activities, can lead to inefficiencies.

3.3 The Board of Appeal

The Board of Appeal (BoA) deals with appeals lodged against certain decisions taken by ECHA, both in the context of REACH and the Biocidal Products Regulation. The most

[33] ECHA MB 12/2015: Rules of Procedure for the FORUM for Exchange of Information and Enforcement, 20.03.2015.

common cases of appeal relate to compliance check decisions, registration revocation/rejection, substance evaluation decisions and decisions on data sharing.

The BoA is an independent body from the rest of ECHA and reports directly to ECHA's Management Board - discussions on the organisational structure and composition of the BoA take place within a specific Working Group of the Management Board. ECHA's BoA is a collegial body composed of three permanent members (a Chairman of legal qualifications, a legally qualified member and a technically qualified member) and is assisted by a Registrar. A number of alternate and additional members have been nominated, as each appeal has to be heard by a Board of three members.

The workload of the Board of Appeal has increased since 2012 as more appeals are submitted and more hearings organised. The BoA is now operating effectively with about 20 cases per year received for consideration. The number of decisions appealed in front of the BoA is significantly lower than was expected when REACH entered into force.

Appeal proceedings are open and accessible to stakeholders, ensuring that all relevant interests are heard before a decision is adopted. NGOs active in the fields of health, the environment or animal welfare, concerned companies, industry associations and Member States authorities, under certain conditions, can present their views in a particular case as interveners. Moreover, with all final decisions published online as well as certain procedural decisions related to intervention applications and confidentiality requests, the BoA is achieving its objective of effective communication and transparency.

BoA decisions have had an impact on ECHA, adapting processes towards more relevance and effectiveness[34]. Stakeholders consider that the BoA decisions enhance legal clarity as regards interpretation of the provisions in REACH, in particular on compliance check, testing proposals and substance evaluation.

So far, only two BoA decisions have been challenged at the European Court of Justice, with the focus on the powers of review of the BoA.

Only limited views on the efficient functioning of the Board of Appeal could be collected during the ECHA evaluation study. ECHA's Annual Stakeholder Surveys reveal that only half of REACH registrants are aware that they can appeal to the BoA against certain ECHA decisions. ECHA staff as well as the reports of the Board of Appeal point to a more efficient functioning of the Board of Appeal, given the consolidation of procedures as well as an improved case management. Efficiency gains were associated with the joint submission of appeals on the same decision or joint hearings in similar cases.

However, a number of elements are perceived by BoA staff to limit the optimal operation of the BoA:

- Increase in workload, while the administrative unit within ECHA, providing support to the BoA has decreased in size under the required overall staff reductions;

[34] An example is the adaptation of registration process and IT system due to a case on Charcoal linked to completeness check. As another example, a decision on the use of languages in relation to the ECHA's communications with registrants, in the context of the SME verification process, prompted the ECHA to reassess its processes.

- Increased resource-intensity of the cases due to the higher technical and scientific complexity of appeal cases as well as the specialised expertise required for the Biocides-related appeals which require training of staff;

New procedures were adopted in May 2016, which interviewees in the ECHA evaluation study considered as allowing for a more efficient operation of the BoA as well as a better management of cases.

The reports of the chairman of the Board of Appeal emphasise the need for an adequate level of resources, to ensure that the BoA can continue to deliver high quality work and operate efficiently. Some interviewees in the ECHA evaluation study perceive that the BoA is understaffed and suggested to appoint an additional legally qualified member to accommodate the high workload. The framework of the BoA allows for flexible solutions to appoint alternate members. Alternate members worked on appeal cases when the position of the legally qualitied member was filled ensuring continuity of operations.

Overall, the experience after 10 years of operation of REACH is that the BoA is a vulnerable body, depending on the solid performance of its members as well as their interpersonal relationships, as all BoA members have equal voting rights. Given that, according to REACH, there can only be one technically qualified member in the BoA, it has become clear that the assistance provided by the Registrar to the BoA should be strengthened to cover scientific aspects, and not be limited as it is today to legal research and drafting. Feedback from industry on the operation of the BoA is overall positive[35].

3.4 The Management Board

ECHA activities are overseen at strategic level by the Management Board, while the day-to-day management falls under the responsibility of the Executive Director. The respective roles and areas of responsibilities are defined in the REACH Regulation.

Article 79 (1) of REACH prescribes the composition of the Management Board. The Management Board comprises 36 members: 28 representatives of the Member States selected "on the basis of their relevant experience and expertise in the field of chemical safety or the regulation of chemicals whilst ensuring there is relevant expertise amongst the Board members in the fields of general, financial and legal matters", three Commission officials, and three individuals from interested parties (representing industry, trade unions, consumer and environmental NGOs) are appointed by the Commission and two independent persons by the European Parliament. The representation of the Commission in the Management Board (from the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, the Directorate-General for Environment and the Directorate-General for Health and Food Safety), and in particular in its Working Group 'Planning and Reporting', facilitates the alignment of ECHA's Work Programme with the policy priorities of the Commission.

With regards to the profile of the Management Board members appointed by the national competent authorities, a number of interviewees in the framework of the ECHA evaluation study, including members of the Management Board themselves, pointed to the lack of expertise in financial and legal matters among members of the Management Board. The majority of members of the Management Board are not "managers", rather experts with a

[35] CEFIC presentation at 10 years REACH litigation seminar organised by ECHA, Helsinki May 2017.

scientific profile. This is explained by the fact that national competent authorities, which are in the majority of cases ministries in charge of Health or Environment, send their experts with relevant scientific expertise. Consequently, discussions at the Management Board can sometimes deviate from the consideration of strategic planning, financial and legal matters, and instead focus on scientific and operational aspects. Different priorities on national policy agendas might also come into play. A number of interviewees considered that the efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates for membership.

Members of the Management Board hold generally positive views on the internal organisation, rules of procedures and working practices of the Board have been generally positive, although a number of improvements were suggested:

- The efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates. Member States should appoint members of the boards in light of their knowledge of the agency's core business and taking into account relevant managerial, administrative and budgetary skills and limit their turnover;

- The establishment of an executive board or a similar structure in line with the Common Approach on EU decentralised agencies, reducing the overall number of Management Board sub-groups and using more written procedures could increase the efficiencies of the Management Board;

- Discussions in the Management Board could be more focused on the management issues of the agency and less on scientific aspects.

The Management Board's decision-making procedure, i.e. two-thirds majority, has not hampered efficiency. The "proxy" system allowing individual members to be replaced in discussions if they are unable to attend a meeting is perceived positively.

The number of meetings of the Management Board (i.e. four two-day meetings per year) is considered to be adequate. The frequency and number of meetings is in line with those of similar EU Agencies, e.g. the European Medicines Agency (EMA) and the European Food Safety Agency (EFSA). However, to increase efficiency, ECHA could resort to written procedures for the adoption of decision not requiring discussion in the Management Board and reduce the length of the meetings from two to one day.

The Management Board has set up a number of specialised Working Groups to plan and organise its work more efficiently, and to focus the quarterly meetings of the Management Board on strategic discussions and the adoption of decisions prepared in the Working Groups. Working Groups have been established on different topics, either related to tasks of the Board or to thematic issues such as 'Planning and Reporting', 'Audit', etc. The small size of the MB Working Groups, composed of 4 to 9 members, facilitates discussions in preparation for the plenary meetings of the Board. However, whilst this system was chosen at the start-up and consolidation phase of ECHA's operations, the Commission services are of the view that ECHA should investigate the possibility of merging and reducing the numbers of working groups will enhance the efficiency of the Management Board.

Some interviewees in the ECHA evaluation study considered that the size and composition of the Management Board is not optimal to ensure efficient and effective ways of working and

suggested to review its set-up. For example, a number of interviewees suggested either the reduction of the number of members or the creation of a two-level governance structure with a Management Board, in charge of providing strategic direction, assisted by a more professional, small-sized Executive Board, responsible for the monitoring of ECHA's activities and the supervision of administrative and budgetary matters. This latter structure could potentially replace (in part) and/or simplify the system of Working Groups. In fact, this would align the ECHA with the recommendations of the EU's Common Approach for a two-level structure[36].

3.5 The Executive Director (ED)

The Executive Director is appointed by the Management Board for a five-year mandate, renewable once for another five-year period. He is in charge of ECHA's day-to-day administration (Article 83 of REACH).

The Executive Director is assisted in the day-to-day administration by a Deputy Executive Director. Unlike other decentralised Agencies, this function is not foreseen in the founding Regulation of ECHA, the REACH Regulation.

The Executive Director is assisted in planning, monitoring and reporting activities and the management of inter-institutional relations (e.g. with the European Commission, the European Parliament, the Council, etc.) by an Executive Office. Again, an Executive Office is not foreseen in the REACH Regulation, but is a deliberate organisational choice made by the Executive Director. The Executive Office centralises certain horizontal functions[37]. The size of the Executive Office has increased between 2012 and 2016 from 17 to 20 staff, who are not assigned to a specific function, but have multiple roles and various responsibilities. For example, the function of a Data Protection Officer (DPO), which is a legal requirement but does not fill a full-time position, is combined with other horizontal tasks.

Interviews in the context of the ECHA evaluation study with ECHA management and the Management Board confirmed that the Executive Office facilitates internal coordination with relevant operational units and transversal views on the functioning of the organisation. The Executive Office is also perceived to provide governance support and input to the work of the Management Board.

A comparison with similar EU Agencies such as EMA and EFSA, shows that ECHA's Executive Office is relatively big and that these Agencies have implemented a decentralised solution to organise the support functions to the Executive Director. Only advisory functions for strategy and policy support are independently organised.

[36] https://europa.eu/european-union/sites/europaeu/files/docs/body/2012-12-18_roadmap_on_the_follow_up_to_the_common_approach_on_eu_decentralised_agencies_en.pdf

[37] Functions within the Executive Office are: Information Security Officer, Data Protection Officer, Secretary to the Management Board and Inter-Institutional Relations, Internal Control Officer, Strategic Planning Officer, Quality Manager, Business Process Improvement Officer and Analyst, Stakeholder Relationships Officer.

4 Horizontal and administrative issues

4.1 Relationship with stakeholders

In the context of Article 108 of the REACH Regulation, ECHA has developed an accreditation scheme to respond to the legal requirement to develop appropriate contacts with stakeholder organisations. The number of accredited stakeholder organisations (ASO) has increased from 64 in 2012 to 100 in 2016. 71% of the ASOs represent industry associations, 12% environmental NGOs, 6% animal welfare NGOs, 5% academic associations, 3% consumer associations and 3% trade unions[38]. Every year the list of ASOs is reviewed.

The status of ASO allows stakeholders to be invited to meetings of RAC, SEAC, and MSC with an observer status and to receive meeting documentation[39]. In 2015, participation of ASOs with an observer status in ECHA's committees was as follows:

- SEAC[40]: 7 regular observers, 45 occasional observers;
- RAC[41]: 7 regular observers, 56 occasional observers;
- MSC[42]: 20 regular observers, 35 occasional observers;

According to ECHA staff, only some ASOs are very active and come regularly, namely industry representative and animal welfare groups. Case owners (i.e. registrants of substances that are discussed) are invited to participate in the MSC discussions for dossier or substance evaluation. The case-owners participated in the Committees' discussions in 71% of cases in 2014[43] and in 70% of the cases in 2015[44].

In addition, ASOs can be involved in Partner Expert Groups for Guidance (PEGs), the Communicator's Network, the Endocrine Disruptors Expert Group (EDEG), the PBT expert group, the nanomaterials working group and the NGO-ECHA discussion platform. Some ASOs are also observers of ECHA's Helpnet Steering Group, and other ASOs, mainly from industry, have an active role in the Exchange Network on Exposure Scenarios, sharing knowledge, techniques and approaches to building and applying exposure scenarios. ECHA also organises annually a specific ASO workshop in Brussels where ECHA seeks their feedback on issues of strategic importance.

The majority of respondents to the online public consultation consider that ECHA has established a strong and trustful relationship with its stakeholders. From the interviews performed for the ECHA evaluation study, stakeholders consider that ECHA provides more opportunities for interaction and is more open and transparent with external stakeholders than other EU agencies. However, some stakeholders report that with the variety of networks and FORUMs it can be difficult to identify in which ones an issue could be best positioned.

[38] https://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations

[39] See the "*General Approach on the Admission of Observers from ECHA's Accredited Stakeholder Organisation to the work of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis* https://echa.europa.eu/documents/10162/13580/admission_of_stakeholder_organisations_as_observers_en.pdf and the "*General Approach on the Admission of Observers from ECHA's Accredited Stakeholder Organisation to the work of the Member States Committee*" https://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf

[40] ECHA figures from 11 September 2015

[41] ECHA figures from 11 September 2015

[42] ECHA figures from 15 September 2016

[43] General Report 2014

[44] General Report 2015

Participating at all the events and committees can become costly for smaller organisations, and in particular for SMEs, which regret that such activities seem more oriented towards larger organisations with more resources.

The 2015 Annual Stakeholders Survey shows improvement in the stakeholders' satisfaction in most of the areas, with one of the highest improvements in the level of stakeholders' satisfaction towards the information received from ECHA and ECHA's commitment to stakeholders. According to the successive Annual Stakeholder Surveys, half of the ASOs would like to be more involved in ECHA's activities and an increasing number[45] consider that their opinion is not taken enough into account.

Lastly, ECHA frequently surveys its staff and stakeholders. As response rates of stakeholder surveys are declining, the Agency could reconsider its strategy in response (e.g. by sending shorter surveys or survey at different time periods or provide translations). Moreover, the Agency could refine its methodology of calculation of the satisfaction levels, to capture a more realistic picture and meaningful results.

4.2 The use of resources

4.2.1 Revenues and Budget Execution

ECHA is a partially self-financed agency. Its resources derive from both fees and charges payable by the industry and a balancing subsidy from the EU budget. ECHA was self-financed from 2010 to 2015 thanks to the reserve accumulated from the first two registration deadlines in 2010 and 2013, respectively. The reserve was exhausted in 2015 and a balancing subsidy was needed in 2016 and will be required for the subsequent years till 2020, the last year of the current Multiannual Financial Framework (2014-2020).

Due to unforeseeable fluctuations in registrations submitted by industry, ECHA's forecasts have almost systematically underestimated fees and charges income from 2012-16 (having overestimated them in 2010), causing discrepancies between the forecasted and actual revenue (see Table XX). Whilst the overall difference in fees and charges collected was around 14% so far (ie not that significant), it was very significant for individal years (see Annex 4 section of fees and charges)

Table 6.2: Number of registration dossiers (including updates) and related fees

	Expected No. of Dossier	Actual No. of Dossiers	Actual in %	Fees and charges forecast (in 000 Euros)	Fees and charges collected (in 000 Euros)
2012	5 100	9 773	192%	17 208	26 612
2013	15 200	14 839	98%	38 372	85 800
2014	5 800	9 001	155%	20 078	25 951
2015	5 700	8 243	145%	14 417	23 785
2016	10 000	11 357	114%	24 056	33 377

Source: ECHA

ECHA has been working on mitigating this challenge by putting in place an action plan following the recommendations from the Commission auditors to enhance the process of fees

[45] 13% of ASOs in the 2014 Annual Stakeholder Survey and 20% in the 2015 Stakeholder Annual Survey

and charges income forecasting and revenue budgeting and to further refine its accuracy and reliability. The auditors also recommended to enhance the effectiveness of the verification process for the SME status of registrants (see also point 2.1 above) to ensure that all registrants pay the correct fees that are due.

In the Work Programme 2015[46] ECHA recognised the necessity to "…*significantly invest on forecasting and modelling*…", considering the high uncertainty on the level of industry driven fee income and consequently "…*to balance its volatile income and expenditure without some form of balancing mechanism*…". However, ECHA's Work Programme 2016 does not mention any improvement and still signals the necessity to improve forecasting.

ECHA is consistently not implementing / consuming the budget allowed by the budget authority (commitment appropriations and payment appropriations) and adopted by the Management Board. Therefore, the Agency could set more ambitious financial Key Performance Indicators and could budget more carefully and realistically in the future.

While the commitment rates remain at an acceptable level, the payment appropriations consumption needs to be improved. The carry-overs of committed appropriations are relatively high namely under Title 3 (operational expenditure). The agency carried over in 2015: EUR 7,3 million, i.e. 32 % and in 2016 the carry over amounted to EUR 11,6 million i.e. 40 %.

4.2.2 Output versus input

ECHA has developed a composite indicator 'Decisions and opinions equivalent' that divides the total weighted decisions by the maximum annual staff capacity.[47] The total weighted decisions represent the number of decisions and opinions produced per annum, weighted with the time required to process an average case. The maximum annual staff capacity includes both operational and supporting personnel as well as consultants and interim personnel. The correlation between the weighted output and the annual staff capacity gives an indication on whether the ECHA produced more weighted outputs with the same or less resources.

An analysis of the 2015 measurement shows that the "Decisions and opinions equivalent" continues to increase thus showing a positive trend in efficiency. However, the Commission services are of the view that this indicator is not sufficient to measure efficiency. It has a built in bias towards showing efficiency gains and does not consider the quality or impact of the outputs (e.g., a compliance check decision requesting a boiling point test has the same weight as one which requests boiling point plus all of the so-called super end-points). As an example and focusing only on the efficiency of ECHA compliance check decisions, a measure calculating the average cost of a compliance check decision and comparing it to the actual information being requested would give more weight to decisions with more impactful outcomes.

As mentioned in point 2.4, the overall levels of user satisfaction with ECHA's scientific IT tools are high, although improvement areas still exist. Nevertheless, as shown in Table YY, The share of ECHA's expenditure on IT is very high compared to similar agencies such as EMA or EFSA.

[46] https://echa.europa.eu/documents/10162/13608/final_mb_31_2014_wp_2015_en.pdf, p. 73
[47] ECHA General Report 2015

ECHA has from its start focused on developing IT tools which could also serve as standards both for other EU legislation but also for international activities. For example IUCLID, eChemPortal and the QSAR Toolbox are all tools implementing OECD standards and used worldwide and ICLID is used in the EU for implementing both REACH and Biocides. However, over the 10 years of operation of REACH there have been significant changes in the IT infrastructure adding to the costs. For example, the Commission's work on IUCLID prior to 2006 focused on the development of two independent systems of IUCLID and REACH-IT. However, in the first year of operation IUCLID was maintained as a separate software but was also copied into REACH – IT. Later REACH – IT was redesigned to rather interface with IUCLID and finally in 2015 ECHA returned to a design of two separate programmes. In addition, an assessment of the updating of the software and of how industry and users saw it would have been useful to better set priorities. The Commission services have urged ECHA to put in place an ECHA IT master plan to provide a sound and transparent business model for its IT investments.

Table 6.3: Comparison of ECHA's IT budget with similar EU Agencies

	2012		**2013**		**2014**		**2015**	
IT expenditure	Total mio €	% of budget	Total mio €	% of budget	Total mio €	% of budget	Total mio €	% of budget
ECHA	17.6	18.5	18.7	17.6	19.4	17.5	23.8	21.2
EMA	20.5	9	23.7	10	19.8	7	30.6	10
EFSA	10.5	13.4	9.7	12.4	8.8	11.1	8.8	11.1

Sources: ECHA, EMA, EFSA

Given the overall high IT costs of the Agencies, discussions between the agencies as to where software can be reused by other agencies seem opportune. For example the use of IUCLID by EFSA should be investigated.

4.2.3 Administrative organisation and optimal use of resources

While ECHA initially was only responsible for managing the technical, scientific and administrative aspects of the REACH and CLP Regulations, other activities were entrusted to ECHA later by the Biocidal Products and PIC Regulations.

Despite the ring-fencing between the budgets of REACH/CLP, Biocides and PIC, which ECHA has to observe, ECHA has put in place actions to increase synergies and an optimal use of the combined resources. For instance, to mitigate the workload peaks caused by the REACH registration deadlines, human resources are transferred across the different work areas of ECHA. This re-allocation of staff is an established practice in Directorate C (Registration). Within this Directorate, the processing of REACH registration dossiers, PIC notifications and Biocides applications are combined. These tasks can be performed by similar staff profiles. In addition, to increase its staff resources during high peaks of workload before registration deadlines, ECHA recruits external interim staff. As the ECHA's multi-annual staff policy plans show, interims are mainly recruited for REACH and CLP-related tasks. Some of the registration-related tasks do not require a specific scientific or technical expertise or highly experienced profiles, and can therefore be given to interim staff.

The staff of the ECHA Helpdesk provides advice on REACH, CLP, BPR and PIC obligations, and gives support for the various IT tools. Also, synergies and coordination efforts between the REACH/CLP work area and the Biocides work area, in terms of streamlined procedures, can be noted. For the assessment of whether an active substance is a candidate for substitution, the ECHA secretariat ensures cooperation between the Biocidal Products Committee and the Risk Assessment Committee (RAC). Similarly, the PBT properties of an active substance for Biocidal Products also need to be assessed when deciding whether an active substance is a candidate for substitution. Therefore, ECHA aims to ensure cooperation among the BPC and the PBT expert group.

All the ECHA IT systems used for the different business processes are shared across the different legislations, likewise for dissemination. For instance, the IUCLID tool was adapted to processes for Biocidal Products. In addition to dossier creation for REACH, IUCLID data can be (re-)used for other purposes, as the data model also features Biocides elements. A dataset prepared for a substance under REACH can therefore be quickly complemented with data about possible biocidal properties and be re-used for data submission obligations under the Biocides Regulation.

ECHA management interviewed in the context of the ECHA Evaluation study pointed to a number of disadvantages linked to employing interim staff, including costs related to selection and recruitment procedures, as well as the training, integration and familiarisation of interim staff with the organisational procedures and working culture of the ECHA. Therefore, the internal redeployment of staff is considered to be a more efficient and cost-effective solution than recruiting staff externally.

The technical and scientific expertise of ECHA needs constant updating. It is essential that ECHA maps out the competences and identifies the needs for capacity building on a regular basis. The Commission services welcomes the implementation plan for capacity building through the training of staff so that ECHA is able to provide the best scientific and technical advice relating to chemicals legislation falling under its remit. The Commission services also consider that more flexibility to make resources more easily available and be more responsive to changes in workload or ad hoc requests, could still be achieved within ECHA.

The ECHA evaluation study noted that although ECHA does have an Activity Based Costing system in place, is not using it to the fullest extent, e.g. staff timesheets are not used to provide more clarity on precise resource allocation although this could be instrumental for allowing for more cross-department and cross-unit cooperation and expertise-sharing while adhering to the ring-fencing principle of the resources deriving from the various Regulations.

According to the ECHA evaluation study the performance indicators suggests that the link between strategic and operational objectives and performance indicators is not fully established. The Agency does not have in place a holistic integrated performance management system, in which the vision, mission and strategic objectives are directly linked with the more operational objectives of the Agency and where the reporting on performance indicators enables to monitor whether both the operational objectives and the more strategic objectives and goals of the Agency are being met.

5 **Conclusions and recommendations**

Overall, ECHA has been effective in executing the tasks allocated to it by the REACH Regulation according the annual work plans adopted by the management board in all its work areas. ECHA has however not delivered the outputs expected in 2006. Efficiency has improved over time both within ECHA and in how ECHA works with member States and

other stakeholders. There is still though room for improvement to increase efficiency by reducing costs and speeding up processes. Pursuing these efforts is key against the backdrop of resource constraints of the Multiannual Financial Framework for the years 2014-2020[48].

Key findings include:

- The processes could be improved for deriving dose curve response for non-threshold substances, and for preparing scientific guidance when needed to implement restriction proposal (case of Nickel, PAH, Lead). Also, there is scope for improving the guidance documents and IT tools.
- The effectiveness of the reinforced completeness check for registration still needs to be demonstrated and not all recommendations from the 2013 REACH Review relevant to this have been fully implemented.
- Forecasts for revenues from fees and charges, and the process for verification of the SME status of registrants can be further upgraded, as well as for execution of the budget. Therefore, the Agency should budget more carefully and realistically in the future. Whilst ECHA has recently implemented an Activity Based Budgeting/Activity Based Management system, the Agency needs to further improve integrated budget planning, linking the workforce planning to the overall budget planning, and to put in place a clear audit trail between changes in the workforce planning and the overall budget planning of the Agency. This would be instrumental in keeping track of the ring-fencing principle of revenues related to the various Regulations entrusted to the Agency.
- ECHA has improved efficiency in line with the recommendations in the 2013 REACH review. However, there is still room for improvement in particular for dossier and substance evaluation where the output is not proportionate to the resources invested, and also for restrictions and authorisation and for expenditure on IT Tools. Internal collaboration and re-allocation of resources to respond to peaks in workload in the different areas of activity can be reinforced.
- The efficiency of the Management Board could be improved through flexible working methods and through the creation of a two-level governance structure in line with the EU's Common Approach for Agencies as is the case in many EU decentralised agencies.
- Pursuing these efforts is key against the backdrop of resources constraints of the Multiannual Financial Framework for the years 2014-2020[49].
- The creation of a two-level governance structure with a Management Board in charge of providing strategic direction, assisted by one enlarged working group was considered an alternative model by some members of the Management Board and European Commission staff and could be also conducive to more effectiveness and efficiency. The enlarged working group will group members of the Management board with experience in budgetary, financial, audit and human resources matters.
- On the Committees and its members, the Commission considers that for SEAC there is a need to ensure that members have sufficient socio-economic expertise, ideally socio-economic expertise applied to chemicals and to human health and the environment, in order to properly fulfil their duties according to Article 76 (1) (d) of REACH. The two

[48] OJ L 347 p 884, 20.12.2013.

ECHA Committees, RAC and SEAC may face increased workloads in the future due to the number of application for authorisations received; therefore the members should really commit to dedicate 50% of their time to this work.

- ECHA should set up training sessions targeted to members dedicated to specific SEAC-related knowledge and processes.