



Brussels, 5.2.2013  
SWD(2013) 25 final

**COMMISSION STAFF WORKING DOCUMENT**

**General Report on REACH**

*Accompanying the document*

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE  
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE  
COMMITTEE OF THE REGIONS**

**in accordance with Article 117(4) REACH and Article 46(2) CLP, and a review of  
certain elements of REACH in line with Articles 75(2), 138(3) and 138(6) of REACH**

{COM(2013) 49 final}

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# **Part I.**

## **OPERATION OF REACH**

### **1. GENERAL ISSUES**

#### **1.1. Scope and application**

Article 1(1) of REACH sets out that the aim of the Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. The legal basis for REACH is Article 114 TFEU (Article 95 of the former EC Treaty) relating to the establishment and the functioning of the internal market.

As set out in Article 1(2), REACH applies to substances and mixtures. This Article states further that REACH provisions apply to “the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.”

Article 138(6) sets out that: “By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions.” Article 138(6) further states that “On the basis of that review, the Commission may, if appropriate, present a legislative proposal.”

During this review, in the analysis of the scope, the Commission services focused on practical issues where potential overlaps with other relevant EU legislation may appear. In fulfilling this task, different pieces of EU legislation were considered that may be related to REACH provisions. A number of REACH provisions affect the scope of REACH and its Titles, in particular Articles 2, 14, 15, 56, 58, 60, 61, 62 and 67. Annexes I, II, XIV and XVII are also important in the context of discussions on scope especially as they have points of contact with other pieces of legislation. Overlaps, generally, were understood as situations where two pieces of EU legislation regulate the same situation which may lead to instances of legal uncertainty or where legal requirements lead to unnecessary burdens on dutyholders (e.g. imposing the same or similar regulatory requirements twice or imposing conflicting requirements on the same actors pursuant to two different pieces of legislation). The purpose of Article 138(6) should thus be understood as aiming at avoiding these negative overlaps and ensuring more efficient interactions between pieces of legislation at the EU level.

Incidentally, comparing the scope of other pieces of EU legislation with the REACH scope also permits to identify certain synergies that can serve as inspiration for further work of the Commission and stakeholders.

For the purpose of this review, 155 EU legal acts regulating chemicals, products, environmental protection, workers' protection and food safety have been analysed<sup>1</sup>.

The instances of overlaps or potential overlaps between REACH and other EU legislation identified in the review pertain to REACH registration, information in the supply chain, authorisation or restrictions. Two instances of regulatory gaps identified by the review are also outlined in this section. Some examples of pieces of EU legislation concerned by synergies are listed at the end of this Title.

### **Potential overlaps or overlaps with registration and information in the supply chain**

- Safeners and synergists of plant protection products: a potential overlap regarding safeners and synergists of plant protection products was identified, which – like active substances - are subject to Commission approval under the new Plant Protection Products Regulation (PPPR)<sup>2</sup> and for which a review programme will be established by 14 December 2014, but which are not regarded as registered for the purposes of REACH, as they are not mentioned in Article 15(1) REACH. Similar data requirements as those related to active substances should be defined for safeners and synergists in the PPPR implementing legislation. Since the requisite implementing legislation under the PPPR has not yet been adopted, the degree of potential overlap is difficult to assess at this moment in time.
- Co-formulants in biocidal products: a potential overlap regarding co-formulants in biocidal products was identified. Article 15(2) only regards active substances included in the Annexes of the Biocidal Products Directive (BPD)<sup>3</sup> as being registered but not their co-formulants. As a consequence, these have to be registered under REACH. Annex VI of the BPD requires a risk assessment, equivalent the one carried out for active substances, for co-formulants which are substances of concern present in the biocidal product. Therefore the assessment of co-formulants which are substances of concern under both REACH and the BPD may result in a potential overlap. Duty-holders may have to perform a similar risk assessment twice. It must be noted that the BPD has just been replaced by a new Regulation<sup>4</sup>. Similarly to the BPD, Annex VI point 5 of the Biocidal Products Regulation requires a risk assessment for substances of concern. However, the relevant provision sets out that information submitted in the framework of REACH

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<sup>1</sup> Study “Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps”, Milieu, commissioned by European Commission, March 2012.

<sup>2</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1.

<sup>3</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, p. 1.

<sup>4</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p.1.

should be taken into account where appropriate. The potential overlap concerning co-formulants thus appears to be sufficiently addressed in the BPR.

- Pyrotechnic articles: The Commission services concluded that certain pyrotechnic articles, considered as mixtures under REACH, might be subject to a double regulatory burden, at least as far as communication of the information in the supply chain is concerned. In such a case both obligations under REACH and under the Pyrotechnic Articles Directive<sup>5</sup> would apply at the same time. According to the current ECHA guidance on requirements for substances in articles, a majority of pyrotechnic articles should be regarded as packaged mixtures, whereas they are regarded as articles by the technical experts in the responsible CEN Technical Committee (TC 212) and also by some competent authorities of the Member States. The Commission services will investigate whether this issue requires specific action, including, in particular in the Guidance on requirements for substances in articles.
- Medical devices<sup>6</sup>: Article 2(6)(c) of REACH exempts medical devices which are mixtures, in the finished state and intended for the final user and which are invasive or used in direct physical contact with the human body, from the provisions of Title IV (Information in the Supply Chain), as long as the same level of information provision and protection is ensured for any substances or mixtures classified as dangerous as under Directive 1999/45/EC<sup>7</sup>. The Commission services take the view that the Directives governing medical devices provide such a level of information provision and protection. The exemption however does not apply to medical devices in the form of articles (such as active implantable medical devices governed by Directive 90/385/EEC), nor does it apply to in vitro medical diagnostics governed by Directive 98/79/EC (as these are not used in direct contact with the human body), even though the latter Directive expressly provides for labelling in line with Directives 67/548/EEC<sup>8</sup> and 1999/45/EC. The scope of the exemption therefore appears very limited. Such articles or mixtures, not being subject to the exemption, would thus be potentially subject to an overlap in terms of information requirement.

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<sup>5</sup> Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles, OJ L 154, 14.6.2007, p. 1.

<sup>6</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1.

<sup>7</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999, p. 1.

<sup>8</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1.

Furthermore, the use of a substance in a medical device, and its risks to the safety of patients and medical professionals, is assessed within the context of the Directives on medical devices and the subsequent harmonised standards. Articles 60(2) and 62(6) of REACH recognise this prior assessment in exempting SVHCs used in medical devices from the human health risk assessment in the authorisation process. However, during the REACH registration process, substances used in medical devices are subject to chemical safety assessment for all intended uses. This constitutes a potential overlap as a risk assessment would have to be performed both under REACH and the medical devices legislation.

Under the REACH risk assessment, safe use has to be demonstrated through an exposure assessment, whilst in the Directives on medical devices an exposure assessment is performed and the identified risks then weighed against the benefits. There is thus in addition a potential contradiction in that a substance used in a medical device may not be considered as controlled under Article 14(6) of REACH and Annex I but the risks of the use of the substance may still be accepted under the medical devices legislation.

An overlap was identified for those “Class III” medical devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product and which is liable to act on the human body with action ancillary to that of the devices. Such Class III medical devices are assessed and authorised in accordance with Directive 93/42/EEC<sup>9</sup>, but the quality, safety and usefulness of the substance must be verified *by analogy* with the methods specified in Annex I to Directive 2001/83/EC<sup>10</sup>, which covers human health risks and requires an environmental risk assessment where applicable. The substances concerned do not benefit from the exemption of Article 2(5)(a) of REACH, as Article 1(5)(c) of Directive 93/42/EEC excludes medicinal products covered by Directive 2001/83/EC<sup>11</sup> from its scope, although the assessment they undergo is comparable to that under Directive 2001/83/EC. There is a potential overlap in that the substances used in these medical devices will be subject to REACH Titles II, V, VI and VII provisions as well as an assessment equivalent to the one set out in the medicinal products directive.

- Workplace legislation: There is certain level of confusion between derived no-effect levels (DNELs) under REACH and various occupational exposure limits (OELs) developed under other EU legislation (Chemical Agents Directive<sup>12</sup> or Carcinogens and Mutagens Directive<sup>13</sup>) or national workers protection legislation

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<sup>9</sup> Article 1(4) of Directive 93/42/EEC.

<sup>10</sup> Annex I, section 7.4 of Directive 93/42/EEC.

<sup>11</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

<sup>12</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 131, 5.5.1998, p. 11.

<sup>13</sup> Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth

and how these two potentially different values should be reflected down the supply chain in the SDS to be used by the employer. Because two sets of values have to be derived under the pieces of legislation, there is a potential overlap.

As far as registrant's chemical safety assessment is concerned, guidance on deriving DNELs in cases when the EU or the national OEL are available is provided in the ECHA Guidance on information requirements and the chemical safety assessment (Chapter R 8).

The Commission services are of the view that OELs and DNELs (for both the same duration and the same route of exposure) may co-exist, and in some circumstances may apply simultaneously to some work activities. In certain cases, where the guidance allows the registrant to use OEL instead of deriving DNEL, the problem of two different values would not arise. In other cases, it is the Commission's view that, in principle, the lowest level should be complied with by the employer. The binding OEL needs to be always complied with by the relevant employer. In cases when the DNEL is lower than the OEL, the compliance with DNEL is based on the premise that the registrant could not use OEL instead of deriving DNEL for the same exposure route and duration, as he has obtained new scientific information which indicated that the OEL does not provide the appropriate level of protection.

Annex II to REACH provides for an obligation to list the relevant applicable EU or national OELs in Section 8 of the SDS (exposure controls/personal protection). Therefore the Commission services consider that more guidance on the relationship between the DNEL and different OELs in the ECHA Guidance on the compilation of SDS would be helpful for dutyholders to fulfil properly their obligation to compile a SDS to avoid confusion between the two systems. The SDS itself could contain some explanation how those two values should be considered by the downstream user as an employer.

- The harmonised classification under the CLP Regulation<sup>14</sup>: Although it has been reported to the Commission that the process of harmonised classification under Title V of the CLP Regulation and the REACH process of identification of substances for the candidate list under Article 59 constitutes an overlap with regard to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under CLP, the Commission services do not concur with that view. The objectives of those two procedures are different, same as the legal implications. The harmonised classification and labelling of the substance under CLP is a different risk management measure comparing to the REACH authorisation. Whereas one of the objectives of CLP is to establish a list of substances with their harmonised classifications and labelling elements at EU level, the candidate list is the first step in the authorisation process under REACH. The purpose of

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individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), OJ L 158, 30.4.2004, p. 50.

<sup>14</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1

establishing a candidate list is, according to Article 59, the eventual inclusion of substances in Annex XIV, i.e. identifying substances to be subjected to the authorisation requirement. This is why before considering the inclusion of a substance in the candidate list, an assessment of the best risk management option under REACH is performed (see [Title 7]) and no automatic link is assumed between the classification of a substance as a CMR and its inclusion in the candidate list. There is also a substantial difference in the procedure. Under Article 37 CLP, it is the RAC, composed of members with scientific and technical expertise, assessing in-depth (within 18 months of receipt of the proposal) the proposal for harmonised classification and labelling of a substance. In the process of identification of substances for the candidate list under Article 59 REACH, the Committee that may become involved is the MSC, whose composition and role differs from RAC. The assessment under this process is expected to be lighter, under shorter deadlines, and the work already done under the CLP Regulation is already taken into account, as the Annex XV dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI of the CLP.

- End-of-waste criteria versus recovered substances: Concerns have been reported to the Commission regarding the potential overlap stemming from the fact that recovered substances are subject to REACH registration, unless covered by an exemption. Pursuant to Article 6 of the Waste Framework Directive<sup>15</sup>, in order for a certain specified waste to cease to be waste, it has to fulfil the end-of-waste criteria developed either at EU level or at Member State level. Some perceive a potential overlap in risk assessment in that the derivation of end-of-waste criteria already assesses human health and environmental impact of the material (risk assessment carried out as part of the REACH registration for a recovered substance would amount to an overlap, as the same material would have already been subject to a risk assessment at the waste stage.) The Commission services, however, would like to stress that the assessment for the end-of-waste criteria under Article 6 of the Waste Framework Directive is of a different nature as it is carried out by the Member States authorities and it encompasses different elements. The environment and health impact assessment of the material is considered in determining end-of-waste criteria to the extent whether the material in question merits application of the waste legislation. It is assumed that risks from the product of the recovery will be covered by another appropriate legislation. The Commission services would thus conclude that this does not amount to an overlap and does not jeopardise the policy objectives of the two legislations.
- Cosmetics and animal testing: The fact that Article 18 of the Cosmetics Regulation<sup>16</sup> bans animal testing for finished products and ingredients or combination of ingredients and bans placing on the market of cosmetic products containing ingredients or combinations of ingredients tested on animals has been

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<sup>15</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3.

<sup>16</sup> Regulation No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59.



reported to the Commission as an issue of a potential overlap with REACH. Article 2(4)(b) REACH sets out that REACH applies without prejudice to the cosmetics legislation as regards testing involving vertebrate animals within the scope of that legislation. The Commission services continue reflecting on how this issue should be best addressed. It is important to note, in this respect, that REACH envisages the vertebrate animal testing only as a last resort.

### **Overlaps in restrictions**

A number of pieces of EU sector specific legislation provide for restrictions of certain substances or groups or categories of substances. It has been reported that it would be useful to have a publicly available database that would serve as an inventory of all restrictions laid down in EU legislation for particular individual substances. The Commission services do not consider, in general, as an overlap the situation where the same substance is restricted by different pieces of EU legislation provided different uses are restricted by different pieces of legislation. However, the overlap may arise when the same use is restricted in two different pieces of legislation.

Some double restrictions of the same use have been identified which are not entirely consistent.

- PCB/PCT Directive<sup>17</sup>: The PCB/PCT Directive does not provide restrictions, but rather complements REACH restrictions with the rules on the disposal and decontamination of polychlorinated biphenyls and polychlorinated terphenyls. One minor overlap has been identified. The PCB/PCT Directive by allowing a use of PCBs in transformer equipment if the mixture does not contain more than 0.005%<sup>18</sup> seems to be in contravention to the absolute restriction of the use of substances or in mixtures of entries 24, 25 and 26 in Annex XVII to REACH which do not provide such a threshold.

It has been also reported that there may be an inconsistency with respect to the PCB/PCT Directive allowing transformers in which the fluids contain less than 0.05% PCBs to remain in use<sup>19</sup>, and the restrictions for the use of entries 1, 24, 25 and 26 of Annex XVII. The Commission services are of the view that this is not an inconsistency, as most of the transformers would be considered as articles under REACH and therefore not subject to the restriction of use as a substance or in mixtures in those entries.

- Toys Safety Directive<sup>20</sup>: The Toys Safety Directive makes it clear in recital (21) and in Annex III that REACH restrictions, when they exist for the use in toys, also

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<sup>17</sup> Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT), OJ L 243, 24.9.1996, p. 31.

<sup>18</sup> Article 2a of the Directive

<sup>19</sup> Articles 3 and 9 of the Directive

<sup>20</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p. 1.

apply. However, the Commission services recognise the difficulty for stakeholders to get a clear picture of the regulatory framework and the need to better communicate on it to ensure compliance. The following REACH restrictions are specifically addressed to toys:

- Entries 51 and 52 of Annex XVII to REACH prohibit the use of several phthalates in toys in concentrations greater than 0.1% by weight of the plasticised material, and prohibit the placing on the market of toys containing these phthalates. The Toys Safety Directive does not address phthalates in toys specifically; however, some of the phthalates concerned are classified as toxic to reproduction category 1B and CMRs, in general, cannot be used in toys, components of toys or parts of toys, subject to derogations (Annex II section III to the Toys Safety Directive). The two instruments thus set out a ban with different conditions of applications. The differences in criteria and applicable limits may lead to uncertainty for operators concerned as to their obligations. The Commission services are of the view that the more stringent restriction applies.
- Entry 43 of Annex XVII to REACH prohibits the use of azodyes in, inter alia, textile or leather toys which may come into direct and prolonged contact with the human body, if these azodyes may release certain aromatic amines above 30 mg/kg (0.003% by weight) in the articles or their dyed parts. The placing on the market of non-conforming toys is prohibited. The Toys Safety Directive does not address azodyes. Operators must therefore be aware of relevant restrictions in REACH.
- Entry 5 of Annex XVII to REACH prohibits the use of benzene in toys or parts of toys where its concentration in the free state is greater than 5 mg/kg (0.0005%) of the weight of the toy or part of toy. The placing on the market of non-compliant toys is prohibited. The Toys Safety Directive governs benzene as well: since benzene is classified as a carcinogen category 1A, it cannot be used in toys, components of toys or parts of toys, subject to derogations (Annex II section III to the Toys Safety Directive). The two instruments thus set out a ban with different conditions of applications. The differences in criteria and applicable limits may lead to uncertainty for operators concerned as to their obligations. The Commission services are of the view that the more stringent restriction applies.

The following general REACH restrictions are also relevant for toys:

- Entry 27 of Annex XVII to REACH prohibits the use of nickel in articles (including toys) intended to come into direct and prolonged contact with the skin, if the rate of nickel release from the parts coming into such contact is greater than 0.5  $\mu\text{g}/\text{cm}^2/\text{week}$ . The placing on the market of non-compliant articles is prohibited. The Toys Safety Directive governs nickel as well: since nickel is classified as a carcinogen category 2, it cannot be used in toys, components of toys or parts of toys, subject to derogations (Annex II section III to the Toys Safety Directive); at the same time, and without prejudice to the ban and derogations, specified nickel migration limits from toys or components of toys cannot be exceeded. The differences in criteria and

applicable limits may lead to uncertainty for operators concerned as to their obligations.

- Entry 23 of Annex XVII to REACH prohibits the use of cadmium in articles (including toys) produced from plastic material and prohibits the placing on the market of such articles if the concentration of cadmium is equal to or greater than 0.01% by weight of the plastic material. Painted articles (including toys) cannot be placed on the market if the concentration of cadmium is equal to or greater than 0.1% by weight of the paint on the painted article. The Toys Safety Directive governs cadmium as well: specified cadmium migration limits from toys or components of toys cannot be exceeded. The differences in criteria and applicable limits (especially concentration limits versus migration limits) may lead to uncertainty for operators concerned as to their obligations.
- RoHS Directive<sup>21</sup>: Entry 23 of Annex XVII to REACH prohibits the use of cadmium in cadmium plating metallic articles or components for a certain number of applications but permits it for electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. The RoHS Directive prohibits the placing on the market of electrical and electronic equipment that contain more than 0.01% of cadmium by weight in homogenous materials. However, Annex III of RoHS provides for an exemption from this restriction when cadmium and its compounds is used in electrical contacts. This exemption from restriction is thus broader than REACH as it does not set out a condition of reliability of the apparatus on which these electrical contacts are installed in order to be triggered. The differences in the conditions of application of the two exemptions may lead to uncertainty for operators concerned as to their obligations.

### **Potential overlaps related to future restrictions:**

In the context of consideration of preparations of future restrictions under REACH, the Guidance on the preparation of Annex XV dossiers states that a restriction under REACH may be an appropriate measure in cases where the proper implementation and enforcement of risk management measures under other REACH processes (notably registration) or under other legislation is not possible to achieve<sup>22</sup>. Other risk management options (RMOs) using other sector specific EU legislation should be explored in order to address the identified unacceptable risk in the most appropriate way. It is important to note that if a Member State or ECHA identifies, in the context of the preparation of the Annex XV dossier, that a measure under other EU legislation is more appropriate way of addressing the risk than a REACH restriction, this should be documented in the Annex XV dossier. In some cases, action under other EU

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<sup>21</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88.

<sup>22</sup> See Guidance on Annex XV for restrictions, p. 15.

legislation may be considered as a necessary complementary measure to a proposed REACH restriction. These findings could then be used by the competent authorities and the Commission to determine if action under other EU legislation is appropriate. The Commission services recognize that it is important to avoid any possible future overlaps or inconsistencies with restrictions laid down in EU sector specific legislation.

### **Potential overlaps with REACH authorisation**

The Commission services recognise that there is risk of potential overlap once the substance is included in the REACH authorisation list (Annex XIV) and the exemptions for specific uses from the restrictions in different pieces of EU legislation, such as the RoHS Directive<sup>23</sup>, the End of Life Vehicles Directive<sup>24</sup> and the Packaging Directive<sup>25</sup>. For uses of a substance which is restricted under sectoral legislation and at the same time subject to REACH authorisation, there is a concern that operators would need to go through two separate and independent procedures in order to be able to continue to use the substance, i.e. one under REACH authorisation, and the other for the exemption to apply under the sectoral legislation. Even if the operator already successfully applied to the Commission for a time-limited exemption for a use under the relevant sectoral legislation, there is no guarantee that the authorisation under REACH would be eventually granted by the Commission for the same use. The provisions in Article 58(2) of REACH allow to exempt uses or categories of uses from authorisation provided that there is specific EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks. There is only a limited experience with the use of the Article 58(2) exemption. Three of the current 14 substances in Annex XIV have exemptions from uses based on this provision and in relation to the EU medicinal products legislation. It nonetheless needs to be reviewed how these criteria are currently applied and to what extent they can be used for the exemption of uses covered by exemptions in specific sectoral legislation.

Moreover, the Commission would need to consider how to best use Article 58(2) in order to avoid potential overlaps in other cases, e.g. where the EU workplace legislation sets a binding OEL that applies to a specific use.

The Commission services will explore on a case by case to what extent the Article 58(2) exemption from authorisation may be used in order to exempt from the authorisation requirement the uses that have been already specifically considered in the context of another EU legislation. More generally, the Commission already explores in the risk management options procedure whether it is appropriate to target

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<sup>23</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88.

<sup>24</sup> Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, OJ L 269, 21.10.2000, p. 34.

<sup>25</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10.

by Annex XIV substances that are already restricted in many other pieces of EU legislation.

### **Potential gaps**

Potential gaps were also identified in the process of the review. They are outlined below.

- Animal testing: A potential gap was identified regarding the Animal Testing Directive<sup>26</sup>. This Directive defines live non-human vertebrate animals falling under its scope as including earlier forms of development such as ‘independently feeding larval forms’ and ‘foetal forms of mammals as from the last third of their normal development’. Data sharing is obligatory under REACH for data generated from the testing of vertebrate animals, but REACH does not specify that vertebrate animals include larval and foetal forms. It is therefore unclear whether earlier forms of development of vertebrate animals are provided the same level of protection under REACH as under the Animal Testing Directive. The Commission services would recommend construing the term ‘vertebrate animal’ under REACH in the light of Directive 2010/63/EU so as to include larval and foetal forms.
- Use of cephalopods in animal testing: Another potential gap was identified in that the Animal Testing Directive, unlike REACH, covers live cephalopods. Data-sharing would not be compulsory under REACH if the data is generated through test on non vertebrate animals which includes cephalopods. The Commission services will investigate the possibility to subject cephalopods to the same regime as vertebrates.

### **Synergies in the use of data:**

Potential synergies have been identified that relate to information requirements imposed in the context of REACH and those stemming from regulatory requirements from sector specific legislation. Data collected by dutyholders pursuant to one piece of EU legislation could be useful in the context of REACH and vice-versa. Some examples are listed below in bullet points, this list being not exhaustive:

- Quality of Petrol Directive<sup>27</sup>: metallic fuel additives are, in principle, substances subject to REACH registration, the information generated by the registrant for the CSA (depending on annual volumes) can support the Commission’s risk assessment on fuel additives under the Quality of Petrol Directive.

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<sup>26</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33.

<sup>27</sup> Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC, OJ L 140, 5.6.2009, p. 88.

- Textile Names Regulation<sup>28</sup>: Article 25 of this Regulation requests the Commission to examine possible hazards to human health in relation to allergic reactions and chemicals in textile products. To this end, the Commission is carrying out a scientific study to evaluate whether there is a link between allergic reactions and chemicals used in textile products and propose risk management measures, if appropriate. The findings of this study would support the REACH risk identification and management process; among others, such risk management measures may include labelling to indicate the presence of potentially allergenic chemicals. In order to identify which substances could cause allergic reactions and are used in textiles products, the study will make use of the information produced under REACH for the registration, classification and use of substances.
- Paints Directive<sup>29</sup>: this Directive aims to limit the total content of VOCs in certain paints and varnishes and vehicle refinishing products in order to prevent or reduce air pollution resulting from the contribution of VOCs to the formation of tropospheric ozone. These products are however also mixtures under REACH. The solvents and other substances making up these mixtures are subject to REACH registration which means that chemical safety assessments will have to be carried out for these substances. Information available under REACH may thus be useful for the Commission in order to assess whether further measures to address VOC emissions are needed, while the information collected under the Paints Directive can inform exposure assessment under REACH CSA.
- POPs Regulation<sup>30</sup>: REACH registration requirements could help to identify POP substances that could be candidates for nomination as POPs under the Stockholm Convention.<sup>31</sup> Substances listed in the Annexes to the Convention will subsequently be added to the POPs Regulation.
- ELV<sup>32</sup>, WEEE<sup>33</sup>, Batteries<sup>34</sup> and RoHS<sup>35</sup> Directives: The process of identifying additional substances of concern for management under the End of Life Vehicle,

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<sup>28</sup> Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council, OJ L 272, 18.10.2011, p 1.

<sup>29</sup> Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC, OJ L 143, 30.4.2004, p. 87.

<sup>30</sup> Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, OJ L 158, 30.4.2004, p. 7.

<sup>31</sup> Council Decision of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants, OJ L 209, 31.7.2006, p. 1.

<sup>32</sup> Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, OJ L 269, 21.10.2000, p. 34.

- Waste Electrical and Electronic Equipment, Batteries and Restriction of Hazardous Substances Directives should benefit from the information generated by REACH.
- Water Framework Directive<sup>36</sup>: Data generated through the implementation of the Water Framework Directive and other water-related directives (monitoring, EQS) can be used in carrying out REACH substance evaluations or when considering possible inclusion of a substance on the candidate list or restriction of a substance. Conversely, data from REACH registration dossiers and substance evaluations can be used when implementing the Water Framework Directive.
  - Industrial Emissions Directive<sup>37</sup>: Information on the substance under the registration and authorisation procedures under REACH may be used to support the development of BAT reference documents developed under the Industrial Emissions Directive. The CSA comprises the complete life-cycle of the substance and therefore includes the manufacture and use of these substances in industrial installations covered by this Directive and measures to avoid and control emissions.
  - Construction Products Regulation<sup>38</sup> basic requirements for construction works are defined in Annex I to this Regulation to be the basis for EU standardisation. Accordingly, harmonised standards to be adopted or updated by CEN should reflect basic requirements for health and the environment. Such harmonised standards will not address chemical safety as such, but will provide test methods allowing manufacturers to show compliance with relevant chemicals legislation (e.g. REACH restrictions or the Water Framework Directive). Information provided in accordance with Articles 31 or 33 REACH respectively may allow compliance to be shown and thus obviate the need for testing according to harmonised standards; this is a synergy between REACH and the Construction Products Regulation.

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<sup>33</sup> Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment, OJ L 37, 13.2.2003, p. 24.

<sup>34</sup> Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, OJ L 266, 26.9.2006, p. 1.

<sup>35</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88.

<sup>36</sup> Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1–73

<sup>37</sup> Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), OJ L 334, 17.12.2010, p. 17.

<sup>38</sup> Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5.

For the Commission, it will be particularly important to take into account REACH-generated data, and DNELs in particular, in developing EU lowest concentration of interest (LCI) values<sup>39</sup> in the context of the Commission's EU-LCI harmonised framework for construction products.

<b>Recommendations</b>	
1.1.	All efforts should be made to minimise or avoid potential overlaps through adoption or amendment of implementing legislation of REACH or of other EU sector specific legislation, where possible
1.2.	Whenever the change of the guidance may address overlaps identified ECHA should consider to carry out the necessary changes
1.3.	ECHA should develop a database listing existing restrictions in the EU legislation on a substance base

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<sup>39</sup> EU-LCIs are health-based values used to evaluate emissions after 28 days from a single product during a laboratory test chamber procedure (as defined in the CEN TC 351 horizontal standard) and are applied in product safety assessment with the ultimate goal to avoid health risks from long-term exposure for the general population. JRC ECA report no. 29 "Harmonisation framework for health based evaluation of building products indoor emissions in Europe (EU-LCI)" (Draft, November 2012).



## 1.2. Definitions

*The REACH definitions are a mix of well established notions and some new concepts. Although few of them have been subject to in-depth discussions by stakeholders and Member States it is important to clearly distinguish between issues related to the implementation of those definitions (which can be addressed via guidance documents) and issues related to the definitions themselves.*

The definitions in REACH set out the information necessary to understand and apply REACH correctly. They provide legal clarity in particular in those cases where a term has several meanings in plain language, but must be understood in only one of them in the context of REACH. This sub-title describes the experience acquired with the functioning of the REACH definitions and highlights those definitions which have been subject to extensive discussions or where the Commission observes potential issues of concern. It is also important to mention that the definitions in Regulation (EC) No 1272/2008 (CLP)<sup>40</sup> have been aligned with the REACH definitions.

The definition of **substance** (Article 3(1)) is the cornerstone of REACH, as substances are the main subject of REACH provisions. The current definition has been well-established in EU law for about 20 years. REACH took over the definition from the predecessor chemicals legislation (Directive 67/548/EEC<sup>41</sup> as amended by Directive 92/32/EEC<sup>42</sup>). The definition of substance is closely related to the identification of each specific substance. This is a crucial precondition for the correct application of risk management measures under REACH (registration, authorisation, restrictions). The Commission services note that substance identification is relevant, first, for the identification of the substance for regulatory purposes (e.g. authorisation, restrictions) and, second, for the establishment of sameness of the manufactured or imported substance, mainly in the context of registration (in establishing Substance Information Exchange Forums (SIEFs) among the potential registrants of the same substance, joint submission or in the inquiry procedure)<sup>43</sup>. The Commission services observe some practical problems mainly in the latter area. This is, however, in the Commission services' view not a problem of the definition of substance as such. The issue is rather linked to the rules on the identification of the substance set out in

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<sup>40</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1.

<sup>41</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1.

<sup>42</sup> Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 154, 5.6.1992, p. 1.

<sup>43</sup> Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES commissioned by the European Commission, March 2012.

Annex VI, Section 2 to REACH and in the Guidance on substance identification<sup>44</sup> and to their application in different contexts of REACH (e.g. registration, authorisation). The Commission services notes ECHA's invitation to consider issuing implementing legislation which would ensure that substances of significantly different composition are not merged into single dossiers<sup>45</sup>. It has to be noted that substance identification has been given already considerable attention since the adoption of REACH and has been dealt with within different guidance documents, frequently asked questions, other ECHA support tools, a number of conferences and meetings with different industry stakeholders. The Commission services, ECHA and stakeholders will continue to explore the need for clarifying the existing framework for substance identification. In the registration area, part of the problem may be addressed by Member State enforcement, in cases where it is evident that the provisions related to substance sameness have not been complied with. In summary, the Commission services consider that the efforts in this area (communications, meetings) should be maintained involving stakeholders, Member States, ECHA and the Commission. Additional clarifications will have a direct and positive impact on all REACH processes (registration, evaluation, authorisation and restrictions).

The definition of **mixture** (Article 3(2)), apart from containing a circular reference to the same word "mixture" after its alignment to GHS<sup>46</sup> terminology through the amendment by CLP, is equally well-established in EU law and does not appear to raise problems in practice. Mixtures are formed by intentional mixing or blending of at least two different substances and, contrary to substances, are not the result of a chemical reaction.

The definition of **article** (Article 3(3)) has been subject to many discussions (e.g. on candles, printer cartridges, alcohol testers, glow sticks) addressing borderline cases between substances/mixtures in containers or carrier materials on the one hand, and articles on the other. In order to determine whether or not an object fulfils the definition of an article under REACH, the object's function and its characteristics need to be assessed. This has been clarified to a large extent through the Guidance for substances in articles<sup>47</sup> and its appendices, also on the basis of industry providing specific examples.

Another interpretation issue with respect to the definition of article arose in the context of provisions of Articles 7 and 33 with respect to the 0.1% threshold for substances of very high concern (SVHC) in articles (see [Title 2]). It has been also clarified that the definition of article does not cover buildings as long as they remain fixed to the land on which they stand.

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<sup>44</sup> *Guidance for identification and naming of substances under REACH and CLP*, Version 1.2, European Chemicals Agency, March 2012

<sup>45</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 2

<sup>46</sup> Globally Harmonised System of Classification and Labelling of Chemicals.

<sup>47</sup> *Guidance on requirements for substances in articles - Version 2*, European Chemicals Agency, 2011

The definition of **manufacturer** (Article 3(9)) triggered discussions mainly as far as the concept of toll manufacturing (subcontracting) is concerned, as there may be a large variety of different business arrangements in practice. The Guidance on registration<sup>48</sup> gives the basic elements as to the correct interpretation, while leaving some flexibility for industry in specific cases to determine who should be considered the manufacturer of a substance bearing the corresponding REACH obligations. The Commission services consider this solution adequate.

The definition of **importer** (Article 3(11)), linked with the definition of **import** (Article 3(10)), is, at times, more difficult to apply to the multitude of practical arrangements existing in practice. The definition of importer is linked to the responsibility for the physical introduction into the customs territory of the EU, which is already considered as placing on the market for the purpose of REACH. The Guidance on registration and other ECHA tools provide help on the correct interpretation of the definition. The Commission services consider this solution adequate.

It is important to bear in mind that the REACH definition of **placing on the market** (Article 3(12)) is different from that definition in more recent pieces of EU legislation, where placing on the market means only the first making available of a product on the EU market. Therefore, the concept of placing on the market under REACH applies at every step of the supply chain, unless otherwise specified (e.g. in several instances in Annex XVII).

The definition of **distributor** (Article 3(14)) does not pose problems in the implementation of REACH. However, it should be noted that the reference to a distributor acting for third parties is not interpreted to mean that this definition covers only operators acting on behalf of others. The definition applies to every operator who only stores and places on the market a substance, on its own or in a mixture.

Industry is often contesting the interpretation of the definition of **intermediate** (Article 3(15)), as clarified through the Guidance on intermediates<sup>49</sup> in April 2010. Differing interpretations of this particular definition may have had an impact on registration dossiers submitted before the first registration deadline. ECHA's screening of over 400 registration dossiers submitted before the first registration deadline of 2010<sup>50</sup> suggests that some registrants may have unduly benefited from the reduced registration requirements for intermediates set out in Articles 17 and 18. This may, however, mainly be an issue linked to the application of the criteria of the strictly controlled conditions as set out in Articles 17 or 18, and not necessarily an issue of a broader interpretation of the definition. The lack of agreement with industry on the interpretation of the definition may have an impact when assessing whether a use of a specific substance included in Annex XIV is an intermediate use, and

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<sup>48</sup> *Guidance on registration, Version 1.6*, European Chemicals Agency, 2011

<sup>49</sup> *Guidance on intermediates, Version 2*, European Chemicals Agency, December 2010

<sup>50</sup> *The Operation of REACH and CLP*, European Chemicals Agency 2011, p. 14.

therefore not subject to the authorisation requirement. In that regard the Commission services share ECHA's view on the need to further clarify this issue, in particular to clarify with industry which applications can be considered intermediate uses of a substance in accordance with the interpretation set out in the Guidance on intermediates<sup>51</sup>.

With respect to the definition of **phase-in substance** (Article 3(20)), it is useful to note that the criteria in subparagraphs b) and c) may be met only by certain operators, while for other operators the same substance will be considered as non-phase-in substance. The correct identification of the status of the substance has important implications for the registration obligations. In this respect, the Commission services highlight that a second corrigendum was published in the Official Journal concerning the criteria for so-called "no-longer-polymers" in Article 3(20)(c)<sup>52</sup>.

It is useful to recall that the definition of **use** (Article 3(24)) is broad, i.a. including storage or keeping of a substance. This was taken into account, e.g. when Annex XVII to REACH, as taken over from the repealed Directive 76/769/EEC<sup>53</sup>, was reviewed and amended by Regulation (EC) No 552/2009<sup>54</sup> and some restrictions were redrafted accordingly.

The definition of **exposure scenario** in Article 3(37) is repeated in Annex I, Section 0.7 in analogous, but not identical words, which may be considered as superfluous. A similar issue is noted with respect to the definition of **use and exposure category** (Article 3(38)), which is not consistently used in Annex I. In practice, these issues do not pose any problems.

The scope of the definition of **substances which occur in nature** (Article 3(39)) was further clarified through the Guidance for Annex V<sup>55</sup>, which states, in particular, that living or unprocessed dead organisms, or parts thereof, are not considered substances

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<sup>51</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 35-36.

<sup>52</sup> Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 36, 5.2.2009, p. 84.

<sup>53</sup> Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ L 262, 27.9.1976, p.201.

<sup>54</sup> Commission Regulation (EC) No 552/2009 of 22 June 2009 amending 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 Annex XVII, OJ L 164, 26.6.2009, p. 7.

<sup>55</sup> *Guidance for Annex V Exemptions from the obligation to register - version 1*, European Chemicals Agency, March 2010

under REACH. The definition of **not chemically modified substance** (Article 3(40)) was also further clarified through the Guidance for Annex V.

It is important to note that even if the definition of the term **alloy** (Article 3(41)) does not specifically mention that an alloy is a mixture rather than a substance, recital (31) as well as Annex I, Section 0.11 and the Guidance on substance identification clarify that alloys are special mixtures. Registration obligations related to substances in alloys are explained in the Guidance on registration.

At this juncture, the term **nanomaterial** is not defined in REACH, as it is not specifically mentioned in the REACH text. The term has been recently defined in Recommendation 2011/696/EU<sup>56</sup> and should be also understood to apply in the context of REACH practical application as the Recommendation specifically is addressed to Member States, the Union agencies (including ECHA) and economic operators.

The application of REACH, in particular the delimitation of the REACH scope in Article 2, depends also on the scope of some terms defined in other EU legal acts, which are relied on in the interpretation of exemptions from the scope of REACH (e.g. the terms "food", "waste", "by-product", "temporary storage"). Therefore, it is not necessary to define them in REACH.

### **Conclusions and recommendations**

Overall, the definitions in REACH are fit for their purpose and function well. The problems raised by some stakeholders concerning the definition of "substance" are rather linked to the issue of substance identification than to the definition as such.

The main difficulties related to the application of definitions have been observed in relation to the definitions of "article" and "intermediate", as their interpretation is not universally accepted by all stakeholders. The interpretation of the definition of article in connection with the obligations under Articles 7 and 33 is not accepted by some Member States and stakeholders. The interpretation of the definition of intermediate is not entirely shared by industry. The Commission services are prepared to contribute to the discussions with industry on the implementation of this definition.

It is important to note that REACH definitions differ to a certain extent from the aligned reference provisions for the internal market for goods, as set out in Annex I to Decision No 768/2008/EC<sup>57</sup>. These were designed for EU harmonisation legislation for products (e.g. definitions of "placing on the market", "manufacturer", "importer" and "distributor"). Recital (5) of Decision No 768/2008/EC recognises that specificities of sectoral needs may justify other regulatory solutions and explicitly

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<sup>56</sup> Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, OJ L 275, 20.10.2010, p. 38.

<sup>57</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82.

mentions chemicals. The Commission services therefore do not see a need for reviewing whether alignment to those definitions would be appropriate or not at this point in time.

**Recommendations:**

- 1.2.1. The definitions in Article 3 have been found to be fit for their purpose and function well. However, if at a later stage REACH will need amending for other reasons:
- a. definitions will be reviewed with the view to ensure better coherence between the reference provision in Decision No 768/2008/EC and REACH, if compatible with REACH specific needs and those of Decision No 768/2008/EC.
  - b. consideration should be given to the introduction of the definition of a nanomaterial in line with Recommendation 2011/696/EU
- 1.2.1. Registrants are encouraged to apply the definition of intermediates, as set out in REACH and further explained in the Guidance on intermediates.

## 2. REGISTRATION

*Despite numerous challenges encountered by all actors involved, the first registration deadline should be recognised as a success.*

The "R" in REACH stands for Registration, one of the Regulation's core mechanisms. In general, it requires companies to register all substances manufactured or imported in quantities of one tonne or more per year. Registration shifts the burden from the regulator to the industry to demonstrate how substances can be used safely. The registration obligation seeks to address the concerns detailed in the Commission White Paper<sup>58</sup> regarding the lack of information available on 99% of the volume of chemicals on the market in the EU. Failure to register would result in a manufacturer or importer being unable to legally manufacture or/and import their substance.

A registration dossier should demonstrate that the risks through the lifecycle of a substance are controlled. The amount of information required for registration increases along with the volume of the substance manufactured and/or imported. Manufacturers and importers are required to submit a technical dossier for substances registered in quantities of one tonne or more. The technical dossier contains information on the physicochemical, toxicological and ecotoxicological properties, on the uses and on the classification of a substance as well as guidance on safe use. For substances registered at quantities of 10 tonnes or more per year, a chemical safety assessment (CSA) also needs to be conducted and documented in a chemical safety report (CSR) which accompanies the technical dossier.

For substances in specified hazard classes as well as for all substances that meet the criteria for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) as set out in Annex XIII to REACH, the CSA includes the development of exposure assessment and risk characterisation for manufacture and all the identified uses of the substance.

REACH provides for the phased registration of substances already on the market in the EU prior to REACH by the following deadlines, where the tonnages indicated are per individual manufacturer/importer (Article 23):

- by 30 November 2010:
  - Substances manufactured or imported in quantities of 1 000 tonnes or more per year;
  - Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic to reproduction (CMR) category 1 or 2 (under Directive 67/548/EEC) manufactured or imported in quantities of one tonne or more per year;
  - Substances meeting the criteria for R50/53 (under Directive 67/548/EEC) manufactured or imported in quantities of 100 tonnes or more per year;

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<sup>58</sup> *White Paper - Strategy for a future Chemicals Policy*, European Commission, {COM(2001)88 final}

- by 31 May 2013:
  - Substances manufactured or imported in quantities of 100 tonnes or more per year; and
- by 31 May 2018:
  - Substances manufactured or imported in quantities of one tonne or more per year.

In general, only companies who pre-registered their intention to register a substance at ECHA between 1 June and 1 December 2008 can benefit from these deadlines.

Pre-registration was intended to facilitate the formation of Substance Information Exchange Forums (SIEFs) and thus to increase the efficiency of the registration system, to reduce costs and to avoid duplication of testing, especially testing involving vertebrate animals, to allow downstream users to keep track of whether or not their substances are likely to be registered and also to allow ECHA to anticipate the volumes of registrations to be handled.

Not only due to an unexpectedly high number of pre-registrations but also because registration would involve a large amounts of companies and substances, the Commission followed the process closely during the first years of implementing REACH. Registration contributes to meeting the aims of REACH in a number of ways, directly and indirectly. Through the gathering of data and identification of risk management measures on substances by registrants, better information on risk management can be communicated throughout the supply chain notably on occupational safety, fulfilling one the REACH objectives: to protect human health. Environmental data included in CSRs can also help companies to reduce the environmental impact of their uses of substances, fulfilling another REACH objective: to achieve a high degree of protection of the environment.

REACH introduced a harmonised set of rules for the management of chemicals in the EU. REACH also strives to streamline existing regulatory requirements on chemicals, making the circulation of chemical substances on the internal market easier and seeking to remove national obstacles thereto. Several instruments, e.g. exemptions for research and development or the tiered information requirements, should foster innovation.

### **Pre-registration**

ECHA reports that it received 2.7 million pre-registrations for 146 000 phase-in substances. The number of pre-registrations was 15 times higher than expected<sup>59</sup>. However, as there were no fees for pre-registration it appears likely that many companies pre-registered substances before they were certain whether or not they had

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<sup>59</sup> Originally it was estimated that 130 000 pre-registrations for 70 000 substances and intermediates would be received. The source of this estimate is not specified in ECHA's report on "*The operation of REACH and CLP 2011*".



registration obligations (i.e. may have adopted a “just in case” approach at this stage), e.g. when their substances were re-imported, recycled, covalently bound during polymer reactions or intentionally released from articles. This approach was supported by guidance and information on the ECHA websites (FAQs). Whatever the reason, the high number of pre-registrations led to a temporary overload of the ECHA IT-systems, and communications with industry on the system usability. Nevertheless, ECHA managed to effectively process pre-registrations by reallocating resources<sup>60</sup>.

It was noted that 82% of the pre-registering companies indicated that they were SMEs and 20 000 companies indicated an intention to register before the first deadline (covering approximately 250 000 pre-registrations). However, ECHA reported that only 10% of pre-registrations for the 2010 deadline actually resulted in registrations by that time. The large number of pre-registrations created confusion in the supply chain as to the actual registration intentions and concerns among some downstream users for a discontinuation of a supply of substances. Following the first registration deadline, the Commission has not been presented with any significant evidence in support of these concerns.

Due to the high number of pre-registrations, there were a number of instances where discussions in SIEFs proved very difficult. In some cases, communication within SIEFs broke down altogether. ECHA therefore implemented two additional tools for a smoother functioning: the pre-SIEF, where potential registrants could discuss on the substance identity upfront and find the correct SIEF more easily, and the SIEF Formation Facilitator (SFF), who should initiate the first organisational discussions in the SIEF. Both tools proved to be helpful, although some difficulties were observed, especially with the SFF. The role of the SFF was often abused by certain actors, who had a purely commercial interest in providing their services to other members of the SIEF, or for the purposes of data collection. In some other cases, the SFF did not show signs of activity which meant that other members of the SIEF had to initiate discussions in the SIEF.

ECHA reported that insufficient evidence had been collected about this, making the intervention of Competent Authorities (CAs) impossible in terms of enforcement; The Commission services are nevertheless of the opinion that industry should do its best to eliminate these practices. Within the context of the Directors’ Contact Group (DCG - see below), ECHA also pledged that it would investigate the possibility to improve the REACH-IT pre-SIEF functionality with regards to personal data protection<sup>61</sup>. The Commission services would support further efforts by ECHA to introduce possibilities to screen abuses of REACH-IT for commercial purposes. The Commission services consider that the possibility for a SFF to be replaced by another member of the SIEF could help solving this problem.

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<sup>60</sup> Study “Review of the European Chemicals Agency”, PwC, commissioned by the European Commission, March 2012.

<sup>61</sup> See issue nr. 17 in *"The Summary Paper on 28 issues and solutions"* available on [www.echa.europa.eu](http://www.echa.europa.eu).

The communication in many SIEFs was especially slow in the beginning. A high percentage of members did not respond to any communication at all. The industry organisations reacted to this by establishing a "voluntary code", giving guidance to SIEF members on how and to what extent they needed to get involved in the preparation of a joint submission<sup>62</sup>. This proved to be a helpful tool in supporting an organised and efficient SIEF process.

In order to address i.a. the above challenges, the Commission invited six selected industry organisations and ECHA to become members of the DCG. The DCG monitored progress towards meeting the first registration deadline. It also sought to reduce practical obstacles to SIEF formation and registration of substances and to address foreseeable practical situations not detailed in REACH. The DCG gathered important feedback on the industry's daily work with REACH.

### Registration

By the end of 2011, 27 418 complete registration dossiers had been submitted to ECHA for 3 676 phase-in and 1 670 non-phase-in substances, so in total 5 346 substances.

By June 2011, ECHA checked approximately 400 intermediate registrations and concluded that in 86% of the cases the conditions that allow claiming the provision of reduced information requirements had not been sufficiently demonstrated or justified<sup>63</sup>.

The vast majority of registration dossiers were submitted by large companies (87%). Medium-sized companies had a share of 8%, small 4% and micro-enterprises only 1%. In total, 19% of the registrations were submitted by Only Representatives on behalf of non-EU manufacturers. ECHA assessed the evidence provided for reduced registration fees based on claimed SME status from 66 companies and found that 58% had wrongly identified themselves as SMEs<sup>64</sup>.

Table 1 below outlines the number of registered substances per year and by type of dossier.

**Table 1.** Number of submitted dossiers

Completed dossiers	2008	2009	2010	2011	Total
Registration of on-site isolated intermediates	12	85	1 373	2 394	<b>3 864</b>
Registration of transported isolated intermediates	46	196	3 426	546	<b>4 214</b>
Full registration dossiers	10	217	18 969	144	<b>19 340</b>
<b>Total registrations</b>	<b>68</b>	<b>498</b>	<b>23 768</b>	<b>3 084</b>	<b>27 418</b>

Source: ECHA, The Operation of REACH and CLP, p. 10, Table 1.

<sup>62</sup> *SIEF guidance – updated version*, CEFIC, September 2011, p. 19.

<sup>63</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 14.

<sup>64</sup> *Idem.*

Overall, ECHA evaluates the registration process to date to have been a success, in part thanks to the well-functioning IT-system. For the next deadline, ECHA intends to further streamline the IT processes and to develop additional tools. The work of the DCG showed that the availability of the relevant (parts of the) IT tools in all EU languages may be of importance to ensure access by companies, in particular SMEs, to the tools needed for fulfilling REACH and CLP requirements. In addition, the continuous round-the-clock availability of REACH-IT in the period close to the deadline will give companies additional work time to meet the deadline.

Looking ahead to future registrations, some potential registrants have raised the issue of the capacity of testing laboratories in the run-up to the next phase-in registration deadline<sup>65</sup>.

Industry also reported, notably within the context of the DCG, that stability of guidance documents published by ECHA was an important issue. As guidance is heavily relied on for compliance by industry, the Commission services also considers that it should remain stable in the months preceding any registration deadline. In that respect, ECHA introduced a six-month guidance moratorium on guidance documents ahead of the 2010 registration deadline as part of the DCG solutions. ECHA intends to respect such moratorium also for the next deadlines.

An overview of the work of the DCG was published on ECHA's website<sup>66</sup>. It consists of practical solutions to obstacles to registration encountered by some potential registrants in good faith ahead of the deadline.

## **Inquiry**

ECHA's responsibility in the inquiry process is to bring together previous registrants and new potential registrants of the same substance, to enable most efficient data sharing. To do so, a potential registrant of a non-pre-registered phase-in substance or a non-phase-in substance has to submit an inquiry to ECHA. In 2011 alone ECHA received 1 970 inquiries, and managed to process about 2 100 (reducing the backlog from previous year). With an increasing number of registration dossiers this process is becoming more and more important and it will remain so especially after the last deadline in 2018.

ECHA reported that close to the first registration deadline the number of inquiries related to non-pre-registered phase-in substances suddenly peaked, while the quality of the information on substance identification dropped. This led ECHA to reject many inquiries. ECHA believes that some companies may have been acting under the false impression that a submitted inquiry would remedy the fact that their substances had not been pre-registered in due time<sup>67</sup>.

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<sup>65</sup> Study "Technical assistance to prepare the Commission report on the operation of REACH", RPA and Ökopol, commissioned by European Commission, p.32

<sup>66</sup> See Directors Contact Group webpage on [www.echa.europa.eu]

<sup>67</sup> *The Operation of REACH and CLP 2011*, ECHA, p. 18.

Industry members of the DCG reported that in some cases the inquiry process lasted more than three months, which was considered too long and an obstacle to companies to start the manufacture or import of substances. As a result, ECHA has streamlined its internal processes and further improved the communication with companies about required information, in particular on the substance identity. Inquiries were processed more quickly as a result of the implementation of these changes.

ECHA is responsible for the decision regarding sameness of substances in the inquiry process. In order to fulfil this responsibility ECHA is entitled to request from the inquirer all the information on the identity of the substance as specified in Annex VI, Section 2 to REACH. However, bearing in mind the purpose of the inquiry, all the formal requirements of Annex VI, Section 2 may not always be necessary to establish if the same substance has already been registered. The Commission services recommend that ECHA takes previous registrants' discussions (e.g. in SIEFs) into account when deciding on "sameness" under Article 26. Based on the observations so far, the Commission services invite ECHA to bear this in mind and further monitor, where appropriate and feasible, the efficiency of the inquiry process to avoid long waiting periods for industry upfront.

### **Substances in articles**

The definition of **article** (Article 3(3)) has given rise an interpretation issue in the context of provisions of Articles 7 and 33 with respect to the 0.1% threshold for SVHC in articles. The Commission considers that the definition implies that objects which at a certain step in their life-cycle meet the definition of article under REACH cease to be individual articles once they are assembled into another article and should be considered as components or parts of an article from that moment. The Commission therefore does not consider that the definition allows parts of a more complex article to be articles for the purpose of Articles 7 and 33. This view is reflected in the Guidance on substances in articles.

### **Nanomaterials**

Nanomaterials are a heterogeneous group of materials, with some traditional high volume commodity materials (e.g. carbon black, synthetic amorphous silica), with newly developed medium volume applications such as paints or sunscreens, and with a wide range of new low volume technical and biomedical applications (e.g. catalysts, batteries, solar panels, tumour therapies). The total annual quantity of nanomaterials on the market at the global level is estimated at around 11 million tonnes, with a market value of roughly 20bn €. Furthermore, products underpinned by nanotechnology are forecast to grow from a volume of 200 bn € in 2009 to 2 trn € in 2015<sup>68</sup>. These applications will be essential for the competitiveness of a wide area of EU products in the global market and can provide basis for further innovation in a

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<sup>68</sup> *Ireland's Nanotechnology Commercialisation Framework 2010 – 2014*, Forfas. August 2010. available on [www.forfais.ie](http://www.forfais.ie). The figures refer to the value of products into which nanomaterials are incorporated based on Lux Research.

wide range of other industries<sup>69</sup>. Currently, the direct employment in nanotechnology is estimated at around 300 000 to 400 000 jobs in the EU.<sup>70</sup> There are also many newly founded SMEs and spin-off companies in this high technology area. Nanotechnology has been identified as a key enabling technology (KET) by the High Level Expert Group (HLG) on Key Enabling Technologies.<sup>71</sup>

For a sustainable use of nanomaterials, their safety needs to be ensured in line with the principles of REACH. This raises the question whether some properties of nanomaterials are linked to hazards for human health and the environment not yet addressed by REACH and whether the traditional risk assessment and management approaches underlying the REACH chemical safety assessments are applicable to nanomaterials. This question is analysed in more detail in the Communication on the Second Regulatory Review on Nanomaterials and the attached Staff Working Paper on Nanomaterial Types and Uses, including Safety Aspects [insert quote].

The Regulatory Review concluded that: *“In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required.”*

On that basis, the Second Regulatory Review on Nanomaterials concludes that *“Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013”*. Therefore the Commission services consider that the known hazard and exposure patterns of nanomaterials do not require amendments of the basic REACH rules or new legislation with a similar purpose as REACH.

However, while experience with existing registration dossiers shows that the basic REACH chemical assessment framework is applicable and in principle can be used to demonstrate the safe use of nanomaterials there is a need for more clarity in the

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<sup>69</sup> For a list of effects and property improvements through nanotechnologies see Appendix 4 of Communication From The Commission [...] *Second Regulatory Review on Nanomaterials*, 3.10.2012 {COM(2012)572}.

<sup>70</sup> *Final Report of the High-Level Expert Group on Key Enabling Technologies*, European Commission, June 2011, p. 13.

<sup>71</sup> The High Level Expert Group on Key Enabling Technologies was established on 13 July 2010. It was comprised of 27 members including representatives from EU member states, relevant European industry, downstream industries, the research community and the European Investment Bank. The mandate of the High-Level Group was for one year.

registration dossiers on how the safe use of nanoforms is ensured. As a first step, ECHA has provided further guidance which is now available to companies. Moreover, based on available information on technical progress, including the REACH Implementation Projects on Nanomaterials and experience with the current registration dossiers, there is a need to assess relevant regulatory options in particular possible amendments of REACH Annexes to ensure clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. This should take into account in particular:

- current knowledge about risks of nanomaterials compared to conventional substances and potential risks due to lack of knowledge,
- the potential negative effects of unclear regulatory requirements on environment and health,
- distorting effects on competition between companies resulting from unclear requirements,
- identified information gaps in registration dossiers and impacts of modified requirements, including on SMEs.

For that reason, the Commission services will carry out an impact assessment to identify the most efficient measures to address those issues.

### **Review of Registration requirements for substances in 1 – 10 tonnes**

The Commission has reviewed the current registration requirements for substances registered in quantities greater than or equal to one tonne and less than 10 tonnes per year per manufacturer or importer (1 to 10 tonne substances). These requirements are being assessed for their likely ability to identify hazardous properties of relevance to the protection of human health and the environment bearing in mind the impact on the innovation and competitiveness of the EU market. This assessment includes consideration of the identification of human health or environmental classification endpoints sufficient for classification under CLP, especially for CMR endpoints, plus consideration of the identification of potential PBT/vPvB substances.

Options for the adaptation of the current registration requirements have been developed to reflect both increasing and reducing the registration requirements for 1 to 10 tonnes substances. Reduced requirements include considerations about requirements set out for on-site isolated intermediates, and limiting the generation of Annex VII information to that currently available or capable of estimation by alternative methods (including read-across and (Q)SARs). Increased requirements include the addition of selected Annex VIII endpoints of relevance to the identification of C, M, R, P and B properties, and the adoption of the registration requirements for 10 to 100 tonne substances (Annex VIII with and without CSA/CSR).

## Conclusion and recommendations

The Commission has reviewed the experience gathered during the pre-registration and first registration phases. These processes were new for all stakeholders involved in REACH. Both industry and authorities (in particular ECHA) invested considerably ahead of the deadline by setting up tools and allocating resources to meet the challenge of the first registration deadline. The first registration deadline involved submission of a high number of dossiers and its relative success reflects good cooperation and goodwill from all the involved parties. Particularly the DCG has given important feedback on the industry's daily work with REACH.

In conclusion, REACH registration was a success. Registration dossiers were submitted on time, showing that industry complied with the registration obligation and set up the right tools to prepare for registration. ECHA handled the first registration deadline effectively; a high number of registration dossiers were received and the IT system functioned well on ECHA's side. However, together with industry (e.g. through the DCG) further improvements can be made in preparation of the next registration deadlines.

Recommendations
2.1. Concerning intermediates, as highlighted by ECHA, there is a need for awareness-raising across industry, including a need to encourage updating of registration dossiers.
2.2. The DCG will continue to monitor preparedness of the industry ahead of the next registration deadline. It is recommended that the DCG continues to examine practical issues linked with registration and falling under its mandate.
2.3. Companies should continuously monitor and, where necessary, update their registrations. Equally, any non-compliant dossiers must be brought into compliance.
2.4. Without prejudice to the Commission's legal interpretation of the current legal text on substances in articles in connection to Articles 7 and 33, Member States and stakeholders are invited to provide evidence on what potential environmental or other problems the current REACH provisions on substances in articles.
2.5. Concerning the registration requirements for substances in volumes between 1 to 10 tonnes, there is currently insufficient evidence to justify an alteration of the information requirements. The review has raised a number of issues that call for further investigate in follow up to the Communication on the review of REACH.

### 3. DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

#### 3.1. Data sharing

*Sharing of data served well both the animal welfare and economic objectives, however, joint registration increased the risks of inappropriate use of substance sameness.*

One of the objectives of REACH is to avoid unnecessary testing, especially vertebrate animal testing, whilst generating the necessary information to identify the hazards of substances and manage the resulting risks. In order to avoid animal testing, tests on vertebrate animals shall only be undertaken as a last resort, as per Article 25 of REACH. To meet this objective as well as to increase the efficiency of registration and thus lower costs for enterprises, REACH provides for pre-registered and non-pre-registered substances<sup>72</sup> two similar data sharing mechanisms.

Data must be shared for the same substance in the case of information involving tests on vertebrate animals. Before carrying out tests on vertebrate animals, a potential registrant must make sure that information is not already available from a previous registrant. This is done in a Substance Information Exchange Forum (SIEF) for pre-registered substances or through the inquiry process for non-pre-registered substances. Information not involving tests on vertebrate animals must be shared if requested by a potential registrant of the same substance. The data sharing mechanisms aim to ensure that studies which are already available are shared and that their related costs are agreed and shared amongst potential and previous registrants in a fair, transparent and non-discriminatory way. Importantly, in the case of lacking data, the aim of the sharing mechanism is for potential registrants of the same substance to agree who will undertake the necessary testing to ensure that the test is carried out only once.

In accordance with REACH, ECHA has set up procedures to assist in the resolution of data sharing disputes, as per Article 27(7) for non-pre-registered substances and Article 30(5) for pre-registered substances. They should be initiated as a last resort, i.e. after informal means of resolution have not brought results.

Data sharing plays a crucial role in REACH implementation as it facilitates registration, thereby fulfilling the aims of REACH. The Commission examined several steps of the data sharing process. Registrants of the same substance under REACH ideally have to submit their registration jointly, in line with the so-called "one substance, one registration" (OSOR) principle.

In case of pre-registered substances, the potential registrants first must form a SIEF and then designate a lead registrant. These two activities place a lot of responsibility on the industry as REACH does not prescribe any formal structure for SIEFs. In other words, it is up to the SIEF participants to decide on the sameness of their substance identity and set their internal rules and organisation while respecting EU law

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<sup>72</sup> Non-pre-registered substances can be: 1) phase-in substances which were not pre-registered, and 2) non-phase-in substances.



(especially competition law). As a third step, SIEF participants must ensure efficient sharing of test data for the purposes of registration.

In case of non-pre-registered substances, the new potential registrant has to contact ECHA with an inquiry providing, i.a., relevant information on the identity of his substance, to enable ECHA to identify previous registrants for the purpose of sharing existing data. The potential registrant may use any study summary or robust study summary which has been submitted in the context of a registration at least 12 years previously without financially compensating the previous registrant(s).

### **Substance identity and sameness**

The determination of sameness of substances based on their individual substance identities following the requirements of Annex VI, Section 2 is central in the establishment of SIEFs for phase-in substances and is applied in the inquiry process for non-pre-registered phase-in and non-phase-in substances. Since one of the main objectives of REACH for registration and the inquiry process is data sharing including the reduction of testing costs and avoidance of unnecessary testing in general and especially on vertebrate animals, it follows that enabling effective data sharing is crucial in the process of determining the sameness of substance identity.

Determination of sameness of the identity of two or more substances based solely on the strict comparison of the set of information gathered pursuant to Annex VI, Section 2 often creates inefficiencies as to the transmission of information on substances. Smooth and efficient data sharing should be the main objective of this exercise. However, each registrant needs to carry out an appropriate scientific and technical exercise to ensure that submitted test data covers the hazards and risks of the substance in all the forms he manufactures, imports and places on the market for all his identified uses.

Determining substance identity and sameness has proven to be a complex task strongly based on case-by-case decisions. The Commission services will, together with ECHA and industry, further work on more refined support to further enhance the identification of substances and the efficiency of data sharing.

### **Expectations**

Expectations ahead of the first registration deadline pertained to how efficiently SIEFs were managed by the industry, which can be measured concretely by the actual reduction of tests and costs that SIEFs achieved and by the number of disputes referred to ECHA. Another important area of expectation was the efficiency of SIEFs in nominating lead registrants and the efficiency of their members in the actual sharing of data. On this last point, particular attention is paid below to the ease of availability and use of letters of access.

### **Findings**

It was recognised by all actors that difficulties arose in the designation of lead registrants and that a certain number of registration dossiers had been either subject to

opt-outs or submitted by registrants separately<sup>73</sup>. ECHA noted in particular that there had been difficulties in designating lead registrants because of the high workload involved and a general lack of understanding of the lead registrant's obligations. The late submission of lead dossiers also caused time pressure on other SIEF registrants. Several solutions outlined by the DCG were developed and implemented by ECHA to address these problems.

The Commission services consider that lead registrant issues need to be further monitored. ECHA indicated that it would focus its 2013 communication campaign on the obligation to submit registration dossiers jointly<sup>74</sup>. In addition, ECHA suggested that lead registrants should be legally obliged to make themselves known to ECHA ahead of registration deadlines<sup>75</sup>. The Commission services would support a mechanism to make lead registrants automatically known to ECHA, through e.g. an IT facility.

After pre-registration, industry was required to form SIEFs and 2 176 lead registrants identified themselves voluntarily to ECHA. ECHA reports<sup>76</sup> that in practice SIEFs appear to have suffered due to the large number of (potential) members, making communication and cooperation complex and resource-intensive and causing delays. This assessment of the operation of SIEFs is shared by the DCG, which also indicates that SIEFs present specific additional challenges for SMEs who have fewer resources and, hence, are more vulnerable to unequal treatment and language barriers<sup>77</sup>. Moreover, SMEs generally cannot invest as much time in REACH-related work as bigger companies, which has in certain cases had an impact on the functioning of SIEFs.

Only a small number of data sharing disputes have been forwarded to ECHA and all were resolved within the deadlines. ECHA believes that the existence of the dispute settling mechanism has encouraged data sharing in the SIEFs. However, ECHA notes that penalising breaches of data sharing obligations is difficult due to the different organisation of enforcement authorities in the Member States. Concerns regarding breaches of competition rules and abuse of the dominant position of some companies within SIEFs and in consortia<sup>78</sup> respectively were reported<sup>79</sup>, but could not be substantiated by robust evidence. Often high and opaque costs of letters of access

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<sup>73</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 11-12.

<sup>74</sup> *Ibid.*, p. 13.

<sup>75</sup> *Ibid.*, p. 18.

<sup>76</sup> *Ibid.*, p. 1.

<sup>77</sup> Most SIEFs use English as the working language.

<sup>78</sup> Consortia are legal constructs based on a contractual agreement between the parties involved. REACH does not introduce this concept.

<sup>79</sup> Study "*Functioning of the European chemical market after the introduction of REACH*", CSES, commissioned by the European Commission.

were a particular concern for small firms, which can be mitigated by higher degree of transparency.

It was reported that nearly 90% of all dossiers were submitted jointly, resulting in a total of 2 945 lead dossiers and 19 610 member dossiers (the average ratio of member to lead dossiers was 6.7), leading ECHA to consider the joint submission process to be generally working well.

Opt-outs from joint submission for one or more endpoints were noted in 135 cases across all dossiers. Of all dossiers in the range  $\geq 1000$  tonnes per year considered, 82 dossiers covering 60 substances included opt-outs. Opt-outs related to a total of 1 437 endpoints; typically two opt-outs were included per dossier. Furthermore, ECHA received either multiple joint submissions (of lead and joint dossiers) or more than one individual (lead) dossier, as well as a joint submission for 250 substances and is investigating the reasons for this. On the basis of these outcomes, the Commission services will be working with ECHA to identify measures to eliminate such duplications.

### Conclusions and recommendations

The data sharing provisions fulfilled the expectations with regard to the animal welfare and minimizing costs of data collection for the industry. However, there are particular difficulties in meeting the REACH objectives with regard to demonstrating safe use in cases where results of alternative methods are not sufficiently scientifically argued. The signals of misuse of the position of lead registrants with regard to member applicants – in particular to SMEs are also of particular concern.

The processes so far have shown also that the definition of substance identity and the determination of sameness of substances are some of the most challenging aspects of REACH. The Commission services will keep working on improved practical implementation to further enhance the identification of substances and the efficiency of data sharing.

<b>Recommendations</b>
<p>3.1.1. As to the difficulty in nominating lead registrants in SIEFs, ECHA is invited to consider initiatives to promote early submission of lead dossiers and to raise the awareness of member registrants on the timing of dossier submission.</p> <p>3.1.2. All activities by ECHA and industry are welcome that help to disseminate "best practices" in SIEFs, including developing IT solutions for improving transparency and communication within SIEFs. Specific support to SMEs is crucial and industry is invited to issue targeted guidance for these businesses. Efforts to make guidance available in more languages are also important for SMEs to be able to fully participate to the data sharing process under REACH. This requires involvement of industry as well as of ECHA.</p> <p>3.1.3. Industry should work on best practices concerning the transparency of costs for letters of access and the functioning of consortia. As problems of compliance with competition law rules as well as good practice as to the dissemination of confidential business information within SIEFs have also been identified, it is recommended that industry associations work on raising awareness on these rules and principles to the benefit of their members.</p> <p>3.1.4. ECHA and industry are invited to provide further guidance to companies and authorities for substance identity and the determination of sameness.</p>

### 3.2. Avoidance of unnecessary testing

*Significant amount of data used in the registration exercise did not require additional testing on animals, however, progress achieved in some more elaborate alternative testing methods was slower than expected*

Article 25 provides that testing on vertebrate animals to generate information may only be undertaken as a last resort and that it is necessary to take measures to limit the duplication of other tests. It also provides that sharing and joint submission of data shall concern technical data and in particular information related to the intrinsic properties of substances. Article 40 outlines the process for the examination of testing proposals for provision of information specified in Annexes IX and X for a substance.

In addition, REACH implements the principles of replacement, reduction or refinement (3Rs) as set out in Directive 2010/63/EU<sup>80</sup> in the use of testing and test methods involving vertebrate animals laid down in Regulation (EC) No 440/2008<sup>81</sup>. These tests and test methods are used to provide data to address the information requirements for substances manufactured or imported in quantities of one tonne or more as set out in Annexes VII to X of REACH.

Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods.

Annex XI provides general rules for adaptation of the standard testing regime set out in Annexes VII–X where testing may not be scientifically necessary, including the use of existing data, weight of evidence such as the use of newly developed test methods recognised by the Commission or Agency as being equivalent, (Q)SAR, *in vitro* methods and grouping of substances and read-across approach. There are also specific provisions for adapting information requirements as set out in Annexes VII–X.

#### **Expectations**

The provisions on mandatory data sharing of test data generated on vertebrate animals leading to joint submission of information were expected to make the biggest impact on the avoidance of unnecessary animal testing. Further impact was expected from the use of Annex XI and the submission of testing proposals prior to conducting new test on vertebrate animals.

The use of existing data was expected to provide the most instant impact on the avoidance of unnecessary testing. The major question in relation to existing data is its quality and subsequently its applicability to address information requirements.

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<sup>80</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33.

<sup>81</sup> 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, 31.5.2008, p. 1.

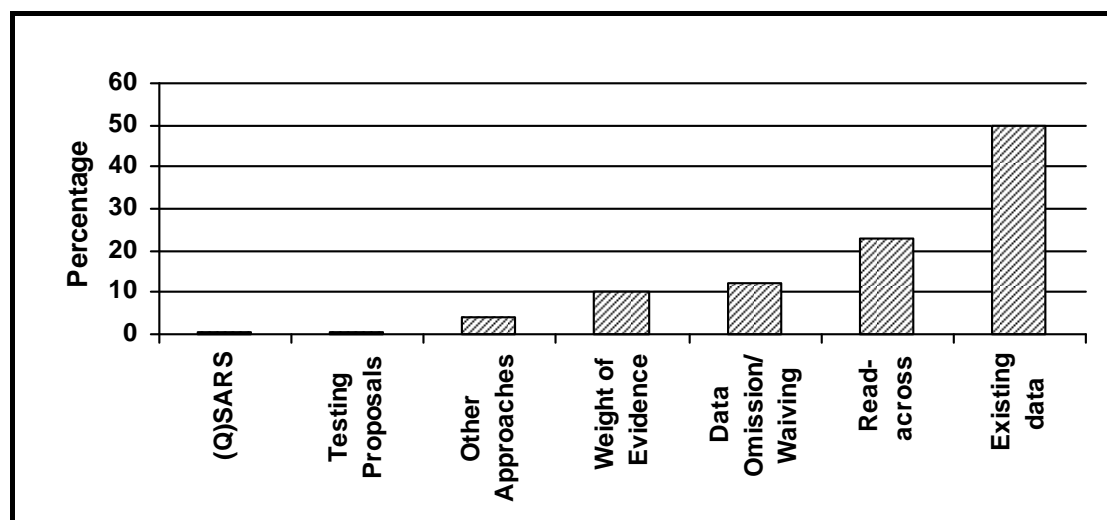
It was expected that the use of weight of evidence, *in vitro* methods and (Q)SAR would need to be developed and improved, and therefore would not make up a high percentage of the alternative methods approaches at this point in time<sup>82</sup>. It was also expected that there would be a need to educate and further develop guidance for registrants and regulators to support the use and preparation of justifications for such approaches and also to promote regulatory acceptance.

## Findings

90% of registration dossiers were submitted jointly. This confirms the success of the data sharing and joint submission schemes.

Of the 14 875 dossiers for phase-in substances registered by end of February 2011 in amounts of 1 000 tonnes or more per year, there were only 19 opt-outs concerning endpoints that would have required animal testing. Endpoint study records show that for substances in volumes of 100 tonnes or more, registrants used data generated prior to the introduction of REACH as their main source of data<sup>83</sup>. The second most used source of information was the application of read-across, especially for endpoints that would otherwise require longer-term animal studies. This indicates that the use of the remaining alternative methods (see figure below) to address endpoints is only a developing area and that mainly existing data is used to fulfil information requirements.

**Figure 1. Data Sources for Registration Dossiers<sup>84</sup>**



Other approaches have been flagged by Registrants as "other information" but this has not been specified in the ECHA report.

<sup>82</sup> Commission Staff Working Paper, [REACH] *Extended Impact Assessment*, COM(2003)644 final, 29.10.2003

<sup>83</sup> The 100 tonnes data was used as a reference point in the *The Use of Alternatives to Testing on Animals for the REACH Regulation* published in 2011 by ECHA [www.echa.europa.eu]

<sup>84</sup> Based on ECHA's Report "The use of alternatives to testing on animal for the REACH regulation"

In total, 574 testing proposals were received covering 1 175 tests, of which 711 related to *in vivo* vertebrate animal studies. The operation of the Member State Committee dealing with testing proposals was successful. ECHA noted that a main issue is information quality and that the quality of justifications for not conducting tests (including animal tests) may be insufficiently robust in some registration dossiers. Furthermore, ECHA indicates that a reduced number of testing proposals were received due to the (inappropriate) use of alternative approaches. ECHA also reports that 107 higher tier animal tests seem to have been conducted without prior submission of a testing proposal<sup>85</sup>.

In 27 public consultations on testing proposals conducted by ECHA as part of its dossier evaluation activities, no information was obtained from third parties that could be used to fulfil the respective data requirements<sup>86</sup>.

The percentage of endpoints that were filled with information from experimental studies (ES), testing proposals (TP) or by use of alternative methods (AM) is provided in Table 2. The column “no data” (ND) applies when information is not required (e.g. because no positive test results triggered the need to conduct further tests).

In summary, registrants have extensively used Annex XI of REACH to waive testing.

**Table 2. Share of information types used to fulfil obligations for the different endpoints**

Endpoint	% ES <sup>87</sup>	% TP	% AM	% ND
Acute Toxicity	85	-	15	-
Skin Irritation	78	-	22	-
Eye Irritation	75	-	25	-
Skin Sensitisation	63	-	37	-
Repeated Dose Toxicity	67	7	26	-
Genetic Toxicity In Vitro	77	-	23	-
Genetic Toxicity In Vivo	41	-	32	26
Toxicity To Reproduction	42	10	48	-
Developmental Toxicity	47	10	43	-
Bioaccumulation Fish	15	-	85 <sup>88</sup>	-
<i>Toxicity to Fish</i>	75	-	25	-
<i>Long-term Toxicity to Fish</i>	16	-	82 <sup>89</sup>	-

<sup>85</sup> *Ibid.*

<sup>86</sup> Study “Technical assistance to prepare the Commission report on the operation of REACH” RPA and Ökopol, commissioned by the European Commission.

<sup>87</sup> Experimental studies include *in vivo* and, where validated, *in vitro* studies.

<sup>88</sup> Experimental studies on invertebrates were counted as alternative methods.

<sup>89</sup> Justification for omission.

<i>Long-term Toxicity to birds</i>	7	-	92 <sup>90</sup>	-
<i>Long-term Toxicity to Mammals</i>	1.8	-	7	91
<i>Toxicity to Other Terrestrial Organisms</i>	4	-	4	92

Source: *The Use of Alternatives to Testing on Animals for the REACH Regulation 2011*, European Chemicals Agency, Section 3, pp. 45 – 47.

### Development and encouragement of alternatives

ECHA is actively supporting the development of alternative methods by contributing to and hosting the OECD QSAR toolbox and by cooperation with the JRC Computational Toxicology Group to promote the use of computer-based prediction methods. The Commission's Joint Research Centre (JRC) compiles the (Q)SAR models and administers the (Q)SAR Model Reporting Format Inventory to promote the use of alternative methods. The database is available at the JRC website and is free of charge. ECHA also disseminates information from the endpoint summary records in order to help future registrants to source information that can be used to predict the properties of their substances by read-across or (Q)SARs.

In September 2010, ECHA organised a workshop to clarify uncertainty with regard to the use of non-test methods and develop a common understanding on the use of these methods in the regulatory context. ECHA did not provide any quantification of its support of the development of alternative methods<sup>91</sup>. ECHA is however conducting an ongoing programme looking at inter alia the evaluation of alternative test methods and participates in the development of test methods and guidance documents in the context of the OECD.

20 Member States appear to have made contributions from public funds to EU and/or OECD work on the development and validation of alternative test methods with 17 Competent Authorities (CAs) providing quantification, as set out in Table 3<sup>92</sup>. Overall however, due to inconsistencies between information provided by different CAs, it was not possible to establish a robust estimate of the overall funding patterns for 3R research from the Member States reports discussed in [Title 10].

**Table 3. Member State funding for national R&D of alternative testing methodologies<sup>86</sup>**

Level of Funding (Euros per year)	Member state
0 to 10 000	CY, LI, LV, PL, SI and IS
10 001 to 100 000	BE and CZ
100 001 to 1 000 000	BG, DK, ES, FR, NL, SE, UK and NO
More than 1 000 000	DE

<sup>90</sup> Currently the share of information provided by (Q)SARs is only 0.5% of all registration dossiers.

<sup>91</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011.

<sup>92</sup> Study “*Technical assistance to prepare the Commission report on the operation of REACH*”, RPA and Ökopool, commissioned by the European Commission.

Reflecting its strong commitment to alternative methods to animal testing, the Commission made available funding of about € 330 million in the years 2007 to 2011. Research activities account for the biggest part of the total budget with around € 290 million spent on projects through the 6th and 7th Framework Programmes (FP6/FP7) and the LIFE+ Programme. These funds always needed to be complemented by own resources of the funded entities and, in addition, triggered the spending of further € 25 million from industry through a public-private partnership initiative.

**Table 4. Overview of projects on alternative methods/approaches funded by the Framework Programmes (FP6/FP7)**

Name	Total awarded grant [million €]	Period										
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
<b>FP6</b>												
Predictomics	2.3											
CONAM	0.15											
NOMIRACLE	10											
TOXDROP	1.6											
ReProTect	9.1											
ACuteTox	9.0											
MODELKEY	8.4											
Sens-it-iv	11.0											
EXERA	2.2											
CAESAR	1.5											
VITROCELLOMICS	2.9											
MEMTRANS	1.9											
EUPRIM-NET	4.8											
carcinoGENOMICS	10.4											
NANOSH	2.4											
DIPNA	2.8											
NanoInteract	3.3											
Cellnanotox	2.6											
SCARLET	0.11											
InViToPharma	0.58											
INVITROHEARTEART	2.7											
LINTOP	2.9											
ForInViTox	0.29											
ARTEMIS	2.0											
COMICS	2.2											
OSIRIS	10.0											
<b>FP7</b>												
START-UP	0.32											
CONTAMED	3.5											
REEF	2.9											
NANOMMUNE *	3.4											
NanoTEST *	3.0											
OpenTox	3.0											
DEER	3.5											
NEURONANO *	2.5											
NANORETOX *	3.2											
ESNATS	11.9											
PREDICT-IV	11.3											
NANODEVICE *	9.5											
ENFIRO	3.2											
ENNSATOX *	2.8											
ENPRA *	3.7											



INLIVETOX *	2.4																			
NEPHH	2.5																			
HINAMOX *	2.3																			
CADASTER	2.7																			
RISKCYCLE	1.0																			
SYSTEQ	2.7																			
EUROECOTOX	1.0																			
ACROPOLIS	3.0																			
NANOHOUSE *	2.4																			
AXLR8	0.56																			
CHEMSCREEN	3.5																			
SCR&Tox **	4.7																			
HeMiBio **	4.7																			
DETECTIVE **	4.3																			
COSMOS **	3.3																			
NOTOX **	4.9																			
ToxBank **	1.6																			
COACH **	1.5																			
QNANO *	7.0																			
ModNanoTox *	1.0																			
NanoTranskinetics *	1.0																			
Marina *	9.0																			
NanoValid *	9.6																			
Nanoreg *	10.0																			
NanoMile *	9.6																			
NanoSolutions *	10.0																			
Modern *	1.0																			
Mod-ENP-Tox *	1.0																			
NanoPuzzles *	1.0																			
PrenanoTox *	1.0																			
MembraneNanoPart *	1.0																			
<b>Total FP6 + FP7</b>	<b>287.0</b>																			

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 (COLIPA), each having awarded € 25 million. Thus, on top of the sum mentioned above (€ 196.9 million) COLIPA made available additional € 25 million.

The second most important fraction (about € 40 million) was spent for the Commission's European Reference Laboratory (EURL) for Alternative Methods to Animal Testing (ECVAM), hosted by the Commission's JRC. Around a further € 2 million went into various other test methods-related activities of the Commission. Numerous alternative methods have already been developed and many of them have been validated by EURL ECVAM and/or accepted at international level (OECD).

A number of alternative methods have been developed for the different application fields and with the current advancement of toxicological sciences they emerge at an increasing rate. However, the development of non-animal alternative methods represents a considerable scientific challenge.

During the period 2007-2011 EURL ECVAM received 48 test methods for evaluation and finalised the validation of seven alternative methods. At present, 10 methods undergo validation studies for which ECVAM has the lead and additional six methods are validated by other organisations with the support of ECVAM. In the same period the peer review of 15 methods by the ECVAM Scientific Advisory Committee (ESAC) was completed and the peer-review currently is in progress for additional three methods.

The introduction of 3 test methods into Regulation (EC) N°440/2008 was accomplished in period 2007-2011 and the international acceptance of 6 test guidelines by the OECD Test Guidelines Programme was also achieved. They belong to the fields of acute oral toxicology (1), genotoxicity (1), skin sensitisation (1) and skin irritation (1) as well as eye irritation (2). Several other OECD Test Guidelines, e.g. in the fields of eye corrosion/irritation and carcinogenicity, are under development.

In some toxicological areas relevant to REACH, such as skin irritation and corrosion, full replacement has been achieved. However, other more complex toxicological endpoints still lack sufficient alternatives to animal testing as science is not yet advanced as in the other areas. In particular, there are five areas of concern, i.e. toxicokinetics, repeated dose toxicity, carcinogenicity, skin sensitisation and reproductive toxicity, in which further efforts in research are needed. In the context of nanomaterials, further adjustment of the OECD Test Guidelines is currently being discussed by the OECD Working Party on Manufactured Nanomaterials (WPMN). Eight test guidelines have been identified as requiring adaptation. A dedicated working group within WPMN is examining the applicability of alternative testing methods to nanomaterials.

In addition, a gap between the outcome of research projects in terms of developed test methods and the fitness for application of such methods in practice is evident. Many new methods need further optimisation and adaptation to the need of the users. A suitable funding strategy for optimisation activities, however, is lacking, both at EU and Member State level.

At the regulatory level, animal tests have a long history of application leading to much experience in interpreting results. In contrast to this, the majority of *in vitro* and *in silico* methods as well as the read-across approach referred to in Annex XI to REACH have not yet reached this status. It will therefore take further efforts to build up the same level of confidence for alternative methods and, subsequently, improve the acceptance by regulators.

Further gaps may become evident through the AXLR8 project<sup>93</sup> that has the objective to monitor the progress of EU-funded FP6/FP7 research projects aimed at the development of alternative testing methods, to identify gaps in knowledge, to define priority research needs, and to prepare, publish and disseminate progress reports on an annual basis.

Today, toxicology is undergoing a transition towards a more mechanistic, pathway-based, cell- and computer-based approach assessing a substance's toxic mode of action. As current approaches do not always provide the complete mechanistic information on how the chemicals exert toxicity, large uncertainties remain in extrapolating data across dose, species and life stages. It is therefore necessary to

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<sup>93</sup> FP7 project "Accelerating the transition to a toxicity pathway-based paradigm for chemical safety assessment through internationally coordinated research and technology development (AXLR8)", <http://axlr8.eu/>

develop a robust understanding of the networks of biological pathways – many of which are not yet described in full. Although several initiatives already focus on the pathway-based approach (e.g. the SEURAT-1 cluster<sup>94</sup>), much remains to be done in this direction. A strategic, international and cross-sectoral approach would be the most suitable manner of advancement.

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a voluntary collaboration between the European Commission, European trade associations, and companies from seven industry sectors. The aim of the EPAA is to pool knowledge and resources in order to accelerate the development, validation and acceptance of alternative approaches to further the replacement, reduction and refinement (3Rs) of animal use in regulatory testing.

### Conclusions and recommendations

There is good progress on the procedural side of data sharing and with submission of testing proposals. However, there are concerns regarding the robustness of the information and the quality of justifications submitted to address information requirements, which may bring the dossier into non compliance with the information requirements.

Overall, an allocation of € 330 million has been made available by the Commission to develop and evaluate alternative methods in the period 2007-2011. There are still fundamental gaps in providing alternatives for some complex toxicological endpoints. In addition some research outputs are produced which are not suitable for regulatory needs or which require further education of users and regulators to ensure their use and acceptance.

Recommendations
3.2.1. ECHA should 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.
3.2.2. ECHA should 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 <i>in vitro</i> methods.
3.2.3. The effectiveness of research funding for the development of alternative methods will be enhanced by strategic concentration. It is also of value to coordinate internationally and across sectors to avoid the repeat of alternative method-related projects that are ongoing in other jurisdictions and sectors.
3.2.4. Alternative method development will be further targeted to regulatory needs. There is also a need to advance the promotion of the regulatory acceptance and application of alternative methods.

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<sup>94</sup> SEURAT-1 – a cluster funded via a joint venture between the European Commission (in the framework of FP7) and the European Cosmetics Association (COLIPA), each having awarded € 25 million.

#### 4. INFORMATION IN THE SUPPLY CHAIN

*REACH promotes cooperation in the supply chain, at significant cost for companies however. For the moment it is too early to detect and assess the overall benefits of these provisions.*

Communication within the supply chain is a central cross-cutting theme of REACH. In the previous legislation the focus was only on the communication from the supplier down the supply chain. REACH has changed this fundamentally as downstream users (DUs) and distributors have to communicate up the supply chain. This two-way communication aims at ensuring a more transparent 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:

- Safety data sheets (SDSs) were already before REACH a well-accepted and effective method to provide recipients with information on safe storage, handling and disposal of substances and mixtures in the EU. With some adaptations they are also an integral part of REACH. One of the major adaptations is the so-called “extended SDS” (eSDS), which is a SDS with relevant exposure scenarios from the Chemical Safety Report (CSR) attached (Article 31).
- The new obligation to provide information for certain substances and mixtures, which do not require a SDS (Article 32), a concept that was already applied voluntary before REACH in some industrial sectors and has now been extended to all sectors covered by REACH.
- The new duty for all suppliers of articles to communicate information on substances of very high concern (SVHCs) present in articles above a concentration threshold of 0.1 % weight by weight (Article 33) to any recipient, including consumers, who so request.
- The new duty to communicate information on substances and mixtures, e.g. new information about risk and hazard, up the supply chain, which provides the registrant or the DU with a more comprehensive picture of the substances he supplies and underlines the importance of cooperation between different actors in the REACH framework (Article 34).

#### **Safety data sheet and Article 32 information**

REACH requires that a SDS has to be provided not only for all hazardous substances and mixtures, but also for those substances identified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) and/or included as SVHC on the candidate list. For other substances and mixtures, under specific conditions described in Article 32 only very basic safety information must be provided. Although a particular format is not foreseen, in practice the general format of a SDS is also used in these situations. In general, recipients accept this approach, but there is a concern that it may lead to misunderstandings for the recipients and

enforcement authorities. This has been clarified so far in the Guidance on safety data sheets<sup>95</sup>, but should be further monitored.

In contrast to previous legislation, SDSs can now be provided equally in paper or electronically, making IT-solutions, which are increasingly being applied by companies, easier to implement. Although the use of modern IT solutions is highly recommended to streamline efficiently the communication requirements of REACH, the practical implementation of electronic distribution systems is still a challenge.

In general, REACH improved the awareness on communication about substances and especially on the role of the SDS. As a result of increased communication many companies have integrated a chemicals management system into their structures for the first time. A wide range of resources are generally needed to set up such systems. It has been observed however that compared to bigger companies, in general, costs for SMEs are proportionally higher<sup>96</sup>. The Commission services will continue its effort to support SMEs and invites ECHA to continue with the development of relevant tools.

The quality of the information provided has improved compared with the pre-REACH situation. Further improvements in data quality can be expected as a result of the next upcoming registration deadlines, when more data from newly submitted registration dossiers will be available<sup>97</sup>, as well as of the adaptations from CLP and the revision of Annex II<sup>98</sup>, which will require certain important changes of newly supplied SDSs as well as those already circulating.

On average, SDSs have doubled in length and are now 12 to 20 pages long. The information has become more comprehensive and of better quality, especially for registered substances. However, this has resulted in additional workload, as the relevant information has to be extracted. Many companies made the observation that important information is being diluted in purely formal information<sup>99</sup>. The Commission services invite ECHA to continue its work in this field.

Providing the SDS is a clear duty of the supplier. However, due to more complex logistics of imports, specific difficulties were reported in the field of handling mixtures, protecting confidential business information (CBI) and establishing efficient

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<sup>95</sup> *Guidance on the compilation of safety data sheets, Version 1.1*, European Chemicals Agency, December 2011.

<sup>96</sup> Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, funded by the European Commission.

<sup>97</sup> Study “*The (nominal) risk caused by chemicals in 2012 compared to the 2007 baseline*”, DHI and Ökoinstitut, funded by the European Commission, p. 1-4

<sup>98</sup> Commission Regulation (EU) No 453/2010 of 20 May 2010 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 133, 31.5.2010, p. 1.

<sup>99</sup> Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, commissioned by the European Commission, p.90.

communication between Only Representative and the DUs in his supply chain<sup>100</sup>. The Commission services invite ECHA to continue its information work and industry to disseminate good practices.

### **The extended safety data sheet**

The eSDS, a new communication tool, has not yet been widely used. According to the legal obligation to update the SDS without delay, this has been expected however, since exposure scenarios are clearly new information, which may affect risk management measures (Article 37(9)). The following reasons were reported:

- The first registration deadline in 2010, which was very demanding for companies per se and was the only source of the full required information, was given higher priority in matter of time and other resources.
- Many existing IT-systems in companies were not fit for eSDSs and still need fundamental and resource-consuming adaptations. Due to the 2010 registration deadline however, resources were concentrated on the registration.
- Supply chains can be very long and complex, so it can be assumed that in many of them the eSDS has not reached all recipients yet<sup>101</sup>.

Despite limited experience, early evidence points out that eSDSs are too complicated and often too extensive. They are often 30 to 100 pages long and some of them are even up to 1 000 pages. IT-systems could support necessary data handling and reduce costs, but this would require the use of a harmonised format. ECHA, with the full support of the Commission and in cooperation with industry, is already exploring possible technical solutions and guidance, which should allow an efficient exchange of information within supply chains.

The existing use descriptor system<sup>102</sup> has proven to be useful for large companies, but often too demanding for SMEs, who often need external support resulting in higher costs. In this context, significant differences between suppliers of the same substance and their use conditions were reported. This area requires better guidance, especially targeting SMEs and less experienced companies.

In contrast to substances, there is no clear obligation to elaborate and provide a mixture-specific exposure scenario (ES). Several different approaches are being applied for the time being. With the support of industry, ECHA has already started to work on a harmonised approach. This has to be finalised as a priority before the next

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<sup>100</sup> Study “*Impact of the REACH regulation on the innovativeness of EU chemical industry*”, CSES, commissioned by the European Commission; Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, commissioned by the European Commission.

<sup>101</sup> Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, commissioned by the European Commission – Annex, p. 130.

<sup>102</sup> *Guidance on information requirements and chemical safety assessment*, European Chemicals Agency - Chapter R.12: Use descriptor system.

registration deadline and before companies have implemented their own internal standards.

### Language issues

SDSs contain highly specialised information often in a sector-specific jargon. This is why translation costs can be relatively high with typical costs ranging from € 100 to € 300 per SDS and language<sup>103</sup>, while costs for translating an eSDS are assumed to be significantly higher due to their length. These costs certainly are justified, as it is necessary for recipients to have understandable information on the chemicals supplied to them. However, suppliers often refuse to supply the SDSs in the relevant official language despite the clear legal obligation to do so. Further awareness-raising and stricter enforcement in this context is advisable.

Translations are often avoided due to liability concerns. For certain languages there is little experience within the translating sector<sup>104</sup>. In this respect, a wide standardisation of information similar as in the case of the precautionary statements and hazard statements of CLP could be considered. This would also help for the development of future automatic translation systems for (e)SDS, which as of today provide unsatisfactory results.

### Substances in articles

Article 33 provides that suppliers of articles containing a substance included in the candidate list in more than 0.1% weight by weight have to provide recipients of the article with sufficient information to allow safe use of the article. Consumers may also request this information from suppliers of articles, in which case the information must be provided, free of charge, within 45 days of receipt of the request. This provision seems to be a challenge for industry. The following difficulties have been reported:

- Six Member States and one EEA EFTA State disagree with the current interpretation of the 0.1% threshold and requested ECHA to inform industry and other stakeholders about this divergence via the Guidance for articles. As a result, the objective of harmonisation of the internal market has been compromised, which makes communication on the presence of candidate list substances in articles even more complex and confusing for companies and enforcement authorities. The Commission services stress the importance of a harmonised implementation and have taken appropriate steps.
- Difficulties have been observed with regard to the lack of transitional periods after a substance has been identified as SVHC and included in the candidate list. Once a substance is on the candidate list, the information obligation applies immediately.

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<sup>103</sup> Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, commissioned by the European Commission, p. 45.

<sup>104</sup> Study “*Impact of the REACH regulation on the innovativeness of EU chemical industry*”, CSES, commissioned by the European Commission, p. 72; Study “*Functioning of the European chemical market after the introduction of REACH*”, CSES, commissioned by the European Commission, Annex, p. 132.

Although measures such as the introduction of ECHA's Registry of Intentions and fixed dates for inclusion in the candidate list have already been implemented as a support, this should be further monitored.

- Potential shortcomings in some Member States and/or sectors were reported in respect to the requirement to inform consumers on SVHCs included in the candidate list in articles on request. However, retailers and producers of articles have already started to use SVHC-free articles as a marketing tool<sup>105</sup>. The means of communication used seem to be highly varied. This area should be further monitored.

To handle the massive information flow resulting from the information requirements for substances in articles, companies and sector associations have developed (or are developing) sophisticated tools. The most advanced sectors in this respect are the automotive industry and plastics, followed by aerospace and defence<sup>106</sup>. The Commission services urge other sectors to study those examples and explore possible potential applications.

### **Costs and benefits of supply chain communication**

Communication requirements in the supply chain were expected to add important costs to the industry; however, they were also expected to bring a number of business benefits on which companies could capitalise.

E.g., it was envisaged that companies could build a greater customer confidence base by referring to REACH, and although consumers are not (in general) aware about REACH, some companies reported to use "REACH-compliance" as a marketing tool and claim that consumers have more confidence in their products.

With regard to these possible other "marketing advantages" no substantial benefits from intensified communication in the supply chain have been observed yet. With regard to risk management at company level, many companies pointed out that REACH gave them more information about the substances they are using and led to an improvement of their risk management<sup>107</sup>.

These benefits in general are constrained by the complexity of setting up ad-hoc systems in order to comply with REACH information requirements and related administrative complexity and other considerations:

- The longer and more complex a supply chain is, the more negative were the experiences described by the industry. A very high degree of complexity was reported in sectors such as pharmaceuticals, electronics, aerospace, defence and

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<sup>105</sup> Study "*Impact of the REACH regulation on the innovativeness of EU chemical industry*", CSES, commissioned by the European Commission, p. 184.

<sup>106</sup> Study "*Functioning of the European chemical market after the introduction of REACH*", CSES, commissioned by the European Commission - Annex, p. 130.

<sup>107</sup> *Ibid.*, p. 88.



automotive<sup>108</sup>. As a result sectors had to invest in IT systems to support communication activities with the reported cost between several thousands (for very simple databases) up to € 16 million in some cases<sup>109</sup>. The automotive industry with its IT-supported International Material Data System (IMDS) is the most advanced one.

- With more intensified communication, other concerns come to the forefront: EU competition rules, protection of intellectual property and confidential business information. Many companies who are in good faith complying with REACH may have exposed themselves in these areas - this is especially true for smaller ones which need more adequate training. Further guidance and training is highly recommended.
- Non-EU suppliers consider certain information requirements under REACH as breaching their confidentiality policies and often do not share this information - even to their appointed only representatives (ORs). In some cases non-EU-suppliers have withdrawn from the EU market due to the demanding information obligations<sup>110</sup>.

When seen in total, costs arising from communication requirements are seen as the second largest share in REACH compliance after registration costs. The costs for SMEs seem to be relatively higher than for larger companies. Due to less knowledge and expertise, those companies have to rely on external help regularly. A practical example of a company selling 10 substances in five Member States has shown that the total costs for developing and translating SDSs can be in the range of € 3 000 to € 5 000<sup>111</sup>.

At this stage the Commission services consider that numerous ways for costs optimisations are still available. E.g., a significant part of the communication activities was induced by unclear requirements for certain actors. Sometimes it triggered intense flows of e-mails, letters, questionnaires and enquiries etc.<sup>112</sup>. The recurring topics were SVHCs in articles (candidate list) and coverage of uses in the registration dossier. Clarifications with regard to any remaining uncertainties would result in lower communication fatigue.

### Conclusions and recommendations

REACH has promoted cooperation in the supply chain. Companies have implemented more sophisticated IT tools for communication and chemicals management thanks to REACH. In addition, REACH has brought small companies to become part of an

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<sup>108</sup> *Ibid.*, Annex, p. 130.

<sup>109</sup> *Ibid.*, p. 45.

<sup>110</sup> *Ibid.*, p. 65.

<sup>111</sup> *Ibid.*, Annex, p. 114.

<sup>112</sup> *Ibid.*, p. 101 and Annex, p. 132.

overall European chemicals management system. As a consequence, more than 60% of companies involved have established dedicated structures (like units) and, therefore, manage their chemicals in a more structured way than before. However, this has increased costs for companies bearing a significant financial burden<sup>113</sup>.

The SDS remains the central communication instrument, but has been further developed to become a more comprehensive source of data related to substances and mixtures. Due to the emerging complexity more harmonisation is needed on the content so that IT solutions can be more easily implemented. Furthermore there is a need for more clarity on different aspects (e.g. translations, role of ORs, making available in an electronic form, handling of mixtures, confidential business information, competition law). The further development of the eSDS, which is now in its phase-in stage, has to be followed closely.

Information requirements for SVHCs in articles are also a new challenge. Furthermore communication in practical terms needs further support, while lessons learned from different sectors are already available. The retail sector also needs to be more actively involved in the implementation of Article 33.

Methodological assessment, communication and application of risk management measures have been set into motion, but it is too early to detect and assess benefits at a general level. This is the reason why, at the moment, the costs are overshadowing the benefits. This can be expected to change with the next upcoming registration deadlines.

Recommendations:
4.1. Impact on costs of administration will be monitored and technical/legal support especially for SMEs provided. The general effects concerning communication, cooperation in the supply chain and the quality of information will also be monitored.
4.2. ECHA and MSCA should communicate and educate more about legal obligations of suppliers of (e)SDSs concerning language obligations.
4.3. Industry should focus on further knowledge-building within companies concerning REACH in general and especially about issues such as confidential business information, EU competition rules and protection of intellectual property.
4.4. ECHA should <ul style="list-style-type: none"><li>• further promote (e)SDSs as the central risk management tool and inform companies on this topic.</li><li>• promoting better understanding of the role of OR, including by reviewing or developing new guidance if needed and</li><li>• improve guidance and support on the Use Descriptor System in particular for SMEs.</li></ul>
4.5. ECHA together with the industry associations should continue developing REACH-related support such as multilingual databases for SDS-phrases, harmonisation tools for eSDS format, databases about uses of SVHCs and IT tools for the communication in the supply chain. Improve practical usability and readability of (e)SDSs by cooperating with industry stakeholders. In particular monitor development of eSDSs and ES for mixtures.



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<sup>113</sup> *Ibid.*, p. 39.

4.6. ECHA and MSCA should launch support activities to raise awareness on Article 33 in the retail sector and to improve the communication in this respect. In order to help small retailers in complying with Article 33, list relevant non-confidential information on uses and sectors of application for every substance on ECHA's dissemination webpage.

4.7. Action will be taken to ensure a harmonised interpretation of Articles 7 and 33

## 5. DOWNSTREAM USERS

*With REACH, downstream users have a new role in the supply chain which requires a more active involvement in chemical legislation than in the past. Overall, companies are positive that REACH will help to increase knowledge about uses, but this is expected to mainly materialise after the next registration deadlines.*

As a novelty in chemical legislation, REACH made downstream users (DUs) a distinct category of dutyholders 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 operations and processes extending far beyond the chemical industry.

Through rights and obligations introduced by REACH, DUs became active players and a central source of information on different aspects concerning the uses of substances. They are companies spread through a wide range of sectors (e.g. aeronautics, electronics, formulators) and can be very different types of businesses (e.g. internationally or EU-wide active industry, SME, family business). They may have varied levels of awareness of chemical legislation and different chemicals management structures, and due to the wide definition of a DU, they might not always be aware of REACH provisions. For these reasons, it is important to bear in mind that there is no "typical" DU.

DUs have obligations and rights stemming from many REACH titles: registration, evaluation, authorisation, restriction, communication in the supply chain. These elements are discussed in the corresponding titles in more detail. The discussion in this title will mainly concentrate on Title V of REACH concerning downstream users.

### **Role of downstream users**

Before REACH registration, knowledge of uses of substances and mixtures on the EU market was limited and the level of detail was varied between sectors. As described in [Title 2], the registration process requires, i.a., an inclusion of information on identified uses, relevant exposure and risk management measures. This information allows DUs to ensure safe use of the substances and mixtures. However, as parts of relevant information might not be available to the manufacturer or importer, the DUs' role in the registration process can therefore be to support the gathering of all the necessary information. DUs and distributors may provide information to assist in the preparation of a registration and have the right to make a use known to suppliers (Article 37).

In addition, DUs often have new information about different uses and ways of exposure. They are also the ones who apply the risk management measures communicated by the suppliers through the safety data sheet (SDS) or other relevant information according to Article 32. Their practical experience with the substances can provide valuable information up the supply chain, especially about new hazardous properties, the appropriateness of risk management measures and new uses.

One of the main instruments to support DU are national helpdesks established on the basis of Article 124 of REACH in every Member State. They are coordinated by

ECHA in an EU-wide network called HelpNet, with the aim to exchanging information and to giving fast, harmonised answers. Some of these answers are eventually published on the ECHA website FAQ.

### Uses of substances

One of the most important obligations of DUs is set out in Article 37(5). This provision requires a DU to identify, apply and, where suitable, recommend appropriate measures to adequately control risks identified in SDSs supplied to him, in his own chemical safety assessment (CSA) and/or in any other relevant information on risk management measures supplied to him in accordance with Article 32.

Usually it is the task of the registrant of the substance to carry out a CSA, to document it in the chemical safety report (CSR) and to reflect it in relevant exposure scenarios annexed to the SDS (eSDS). However, a DU shall prepare for his substance, on its own or in a mixture, an own CSR for any use outside the conditions described by the supplier or for any use his supplier advises against; alternatively he can report information on a new use up the supply chain in order for it to be assessed against risks for health and environment.

### Chemical safety report

Once a DU decides to carry out a CSA, he has to consider a number of aspects. The requirements are usually not as challenging as for a full registration, but also the expertise of a DU company might not usually be as high as that of a registrant. The same applies for experience in regulatory matters.

If a DU decides to perform his own CSR, he must report certain information to ECHA within six month after receiving a registration number in a SDS. The CSR itself has to be performed within 12 month after receiving a registration number in a SDS.

At the time of publishing this paper only a few notifications by DUs performing their own CSR were submitted to ECHA. One major reason might be that DUs have up to six months to comply with the reporting obligations after receiving the eSDS. Therefore it is still rather early to provide a detailed view on this topic. One has to take into consideration that until now, it is mainly substances in volumes of 1 000 tonnes or more per year that had to be registered. For these substances the knowledge gaps are relatively small and the suppliers have more or less an exhaustive view on the uses. However, this can be expected to change when lower quantity substances will be registered. For these substances the costs related to CSR obligations can be significant for DUs, in particular for SMEs. Depending on the individual case, costs are normally not more than € 25 000, but there are exceptional cases with costs up to € 50 000<sup>114</sup>. These costs were estimated before the adoption of REACH at an average of € 8 963 and a maximum theoretical cost of € 35 850<sup>115</sup>, which is noticeably lower than reported now and should be further monitored.

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<sup>114</sup> *Ibid.*, Annex, p. 122.

<sup>115</sup> Study “Assessment of the Business Impacts of New Regulations in the Chemicals Sector”, RPA, commissioned by the European Commission, June 2003, p. 67.

Fees are not foreseen in this context, so all major costs can be directly attributed to the cost for human resources, data collection and the actual drawing up of CSRs. Another factor is the cost of external consultants, especially for SMEs. The mechanism of drawing up a CSR is nevertheless only applicable for substances registered according to Article 6 and not as intermediates. Once a substance is registered as an intermediate only, it cannot be used in a different way. An extension to non-intermediate uses is only possible, when the registrant agrees to make a registration according to Article 6. This however can be connected to more data requirements and higher fees. In this respect a better and more transparent communication in the supply chain will be important for the upcoming registration deadlines, to prevent a DU from using a substance in a different way. This has been reported in discussions in the Directors' Contact Group discussed in [Title 3].

There are also concerns that registrants are carrying out exposure modelling using default assumptions only and that this is resulting in some cases to unrealistic recommendations on operating conditions and risk management measures for downstream users<sup>116</sup>.

### Registration deadline 2010

ECHA published a list of all pre-registered substances at the end of 2008. One of the aims of the list was to give DUs a possibility to gain an overview whether their substances will be registered. Due to the fact that all EINECS substances were pre-registered, the list was only of limited use. As a consequence, before the first registration deadline in 2010 the Commission together with ECHA and industry took steps to gain an overview of all substances which would be registered for that deadline. Especially DUs needed this information about the future availability of their substances for further planning. This screening was performed within the context of the DCG and proved to be very useful in terms of transparency and further planning for DUs.

Until now there is no indication that relevant substances have been withdrawn from the market because of REACH. Certain changes in portfolios and suppliers have been reported as usual business. Nevertheless, in some cases REACH has facilitated an ongoing phase-out<sup>117</sup>.

It has been also observed that some DUs are willing to contribute to the registration costs for a substance that is critical to them. This is done in different ways, e.g. through direct contributions to the costs of a registration dossier or by agreeing on guaranteed purchasing periods or quantities<sup>118</sup>. Withdrawal of substances could become more relevant for later registration deadlines, making the monitoring work as

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<sup>116</sup> Study "Assessment of the health and environmental benefits of REACH", RPA, commissioned by the European Commission, April 2012.

<sup>117</sup> Study "Functioning of the European chemical market after the introduction of REACH", CSES, commissioned by the European Commission, March 2012, p. 60.

<sup>118</sup> *Ibid.*, p. 60.

performed in the DCG even more relevant, which is also a reason why organisations representing DUs from different stages in the supply chain (e.g. formulators and producers of articles) have joined this group. In general more transparency by registrants concerning their registration strategies would help DUs in further planning their next steps. The Commission services will continue to monitor progress in this area.

### **Current situation and observations**

In general companies are positive that REACH will provide more knowledge about uses, but this can be expected to a larger extent after the next registration deadlines. In addition, studies show that DUs request their suppliers to avoid SVHCs and other hazardous substances, which could be a potential for innovation. Human resources had to be drawn away from manufacturing and R&D to ensure REACH-compliance<sup>119</sup>. Innovation and business opportunities have not been reported yet, but might materialise at a later stage.

The situation regarding information on risks and hazards seems to have slightly improved already after the first registration deadline<sup>120</sup>. However, also here companies expect to gain more information after the next registration deadlines. The same is valid for information on risk management measures, where more details and quality are already being observed. One of the major benefits in this regard is the growing awareness about the necessity of proper chemicals management in general and the role of SDSs as the central communication tool on risk management measures as discussed in the [Title 4] in more detail.

### **Downstream users producing articles**

Producers of articles can be subject to new obligations introduced by REACH. One of these obligations relates to SVHCs included in the candidate list according to Article 59. This can have impacts, e.g. the need to communicate information according to Article 33, which are highly relevant to those DUs who produce and supply articles.

The impact on producers of articles varies strongly between sectors. Some sectors are already familiar with similar communication, such as under the RoHS Directive<sup>121</sup>, where it is common to inform customers on a voluntary basis about the absence of certain substances in articles. Other sectors are only now confronted with such requirements. However, not only communication requirements have an impact. The impact of providing information on the content of SVHC sometimes stretches far

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<sup>119</sup> *Ibid.*, p. 98.

<sup>120</sup> *Ibid.*, p. 88; Study “Assessment of health and environmental benefits of REACH”, RPA, p. 13; Study “The (nominal) risk caused by chemicals in 2012 compared to the 2007 baseline”, DHI and Ökoinstitut, p. 1-4.

<sup>121</sup> Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 37, 13.2.2003, p. 19.

beyond the legal requirements of REACH. E.g., some customers refuse to buy articles containing SVHCs.

As described in more detail in [Title 7], the candidate list or even other, informal lists (e.g. SIN-list<sup>122</sup>) seem to work in certain cases as a blacklist, with the effect that customers are preferring articles free of SVHCs<sup>123</sup>. For the DU producing articles, this implies finding a substitute for the critical substance(s). Moreover, when using substances already included in Annex XIV (i.e. requiring an authorisation), EU producers are at disadvantage compared to the non-EU producers of articles, who are not bound by the authorisation requirement of REACH and often might be subject to less stringent requirement under their national (non-EU) legislation. This effect has been acknowledged, but so far it was not observed in practice, also because the authorisation obligations will become fully functional at a later stage.

Problems have been reported by the industry in the process of identifying SVHCs and listing them in the candidate list. The process was claimed to be too quick and unpredictable, to cause problems with developing substitution plans on time and to demand constant monitoring. These issues have been already taken up and the candidate list is now regularly updated at fixed dates twice a year.

There have been many cases of companies who stated having greater confidence in EU products thanks to the requirements of REACH.

## Conclusions

DUs may have varied levels of awareness of chemicals legislation and different chemicals management structures. It has also been reported that some affected companies might not have knowledge of REACH provisions at all, which is a non-surprising consequence of the wide definition of DUs.

Although REACH has led to additional administrative work in order to comply with its requirements, in general DUs are taking responsibility towards REACH compliance. An important contribution comes e.g. from industry associations and chambers of industry and commerce, where the support is given through a wide variety of tools, starting from general information similar to information obtained from national helpdesks to very sector-specific support, which is often going far beyond what authorities can offer. The Commission services invite industry stakeholders to continue developing tools designed to help DUs.

The guidance provided so far by ECHA is perceived as sufficient, especially after the improvement of translation activities by ECHA. The issue of DU-CSA will become more relevant in the near future and it should be monitored to which extent the existing guidance is sufficient. The Commission services invite ECHA to further develop its DU-targeted tools (e.g. ENES, CHESAR and the tools for SDSs).

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<sup>122</sup> "Substitute It Now", a list published by Swedish NGO ChemSec.

<sup>123</sup> Study "Functioning of the European chemical market after the introduction of REACH", CSES, commissioned by the European Commission, March 2012, p. 66 and 101.



Awareness and knowledge on REACH among smaller DU companies is sometimes very low or even non-existent. This is a matter of concern and should be monitored. Existing channels such as the DCG, the Europe Enterprise Network, industry stakeholders (e.g. UEAPME, CEFIC, DUCC and other sectoral organisations), national helpdesks or HelpNet are useful tools for this task and should be used by the Commission and ECHA, as they have been in the past on different occasions.

<b>Recommendations</b>
<p>5.1. ECHA and Member States are invited to support further awareness-raising and knowledge-building within DU companies. Member State helpdesks and Competent Authorities (CAs) are invited, based on lessons learned from industry examples, to provide sector-specific support. DU organisations and other existing networks in relevant discussions, notably at the level of the DCG will continue to be involved; this is especially relevant for the upcoming registration deadlines in 2013 and 2018.</p> <p>5.2. Impacts on competitiveness, including on producers of articles will be monitored.</p> <p>5.3. Impacts on innovation, especially in respect to possible diversion of resources from R&amp;D to legal compliance, including the resources needed for the development of DU-CSR (Annex XII) will continue to be monitored.</p> <p>5.4. Industry is invited to promote more transparency within the supply chain, especially about registration plans for specific substances and their uses.</p> <p>5.5. Industry is invited to further raise awareness on SDSs and eSDSs being central risk management tools with a view to disseminate good practices within supply chains.</p>

## 6. EVALUATION

*Dossier evaluation is a critical step for ensuring credibility of the registration process and is serving to improve the quality of the registrations dossiers. However, much more was expected with regard of the commitment of Member States to the substance evaluation.*

E in REACH stands for Evaluation. As the safe use of substances under REACH starts with compliant high quality registration dossiers that are industry's responsibility, REACH provides for the follow-up to the registration by the possibility to evaluate these dossiers, assess their compliance and request additional information or order further tests when essential data is required.

Title VI of REACH describes three types of evaluation under REACH: dossier evaluation, comprising compliance check and the examination of testing proposals (Chapter 1: Articles 40 to 43), substance evaluation (Chapter 2: Articles 44 to 48) and the evaluation of intermediates (Chapter 3: Article 49). In Chapter 4: Articles 50 to 54, the common provisions for functioning of evaluations, the adoption of evaluation decisions and the publication of information on evaluation are laid down.

In examination of testing proposals, ECHA examines all testing proposals submitted by the registrants for provision of the information set out in Annex IX or X. In compliance check, ECHA determines whether or not the information submitted in the selected subset of registration dossiers is in compliance with REACH.

There may be grounds for concern that a specific substance represents a risk for human health or the environment but the concern still needs to be clarified before action such as the authorisation or restriction procedure, if required, is considered. ECHA can then in cooperation with the Member States take the necessary steps for a substance to be placed in the Community Rolling Action Plan (CoRAP) and evaluated under substance evaluation.

The general REACH provisions for dossier and substance evaluation do not apply to on-site isolated intermediates. However, where the Competent Authority (CA) of the site's location has concern regarding serious risk to human health or the environment that is not being properly controlled, the CA can require the registrant to provide it with the information needed to assess this concern. Following its evaluation, the CA with concerns must inform ECHA which then informs other CAs and communicates the results.

In terms of responsibility for the process, dossiers subjected to dossier evaluation are evaluated by ECHA. In substance evaluation, the evaluation is performed by the CA that has been designated to perform the evaluation in the CoRAP. In both cases the prepared draft decision may be commented by the registrant(s) and the CAs; the latter may propose amendments to the decision. These are discussed in ECHA Member State Committee (MSC) referred to in **[Title 10]**. When the MSC members agree by consensus, the final decision can be adopted by ECHA, otherwise the matter is referred to the Commission. All evaluation procedures run under strict deadlines that importantly determine the organisation and workload of ECHA, MSC as well as CAs.

Examination of testing proposals ensures that the higher tier testing, including testing on vertebrate animals, addresses true information needs of REACH and that tests are not performed when the information is already available or in preparation, addressing prevention of unnecessary animal testing.

Identifying non-compliance in the evaluated dossiers and requiring action by individual registrants through legally binding decisions addresses the deficiency of those evaluated dossiers and enables enforcement, but also more widely promotes compliance and the respective quality of dossiers by all registrants. Substance evaluation also enables the requirement of information that is not part of the REACH standard information requirements, addressing any substance-specific potential limitation in ensuring the provision of an adequate basis for risk assessment. Evaluation is also often the first mechanism within REACH where an implementation issue or the scientific and technical process is identified that may trigger improvement of particular guidance or other activity. Through these features evaluation facilitates a level-playing field implementation of REACH and is an important enhancer of human health and environmental benefits.

### Dossier evaluation

The requirement to perform compliance check on at least 5% of registration dossiers in each tonnage band and ECHA own targets lead to ca. 1 000 dossiers submitted by the first registration deadline to be checked for compliance by the end of 2013, with up to 600 further dossiers annually thereafter for an unspecified length of time. In 2011 only, 158 evaluations were initiated and 146 completed under compliance check<sup>124</sup>. Dossiers to be evaluated are selected by ECHA on the basis of prioritisation criteria outlined in Article 41(5), as well as on the basis of search algorithms that introduce a degree of randomness to substance selection and also allow setting the focus upon specific areas of concern that may be identified.

In its annual reporting under Article 54<sup>124</sup>, ECHA derives some statistics of the evaluation process. The 146 completed compliance checks in 2011 concluded in 105 final decisions and 19 quality observation letters (QOBLs)<sup>125</sup>, with 22 closed without administrative action before or sometimes even after the draft decision was issued. The very high proportion of final decisions within the total number of dossiers evaluated is due to the large number of targeted compliance checks on substance identity that were triggered by concern identified during examinations of testing proposals. For the randomly selected dossiers and the dossiers selected through concern-driven selection, the percentage resulting in final decision was lower (41% and 52%, respectively). Final decisions in general addressed more than one information item to bring the registration into compliance. Main information items requested were on substance identity (Annex VI, Section 2), mutagenicity (Annex VIII, point 8.7.1), prenatal developmental toxicity (Annex IX, point 8.7.2) and predicted no-effect concentration as part of the environmental hazard assessment

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<sup>124</sup> *Evaluation under REACH, Progress Report 2011*, European Chemicals Agency, 2011.

<sup>125</sup> In certain cases ECHA sends a letter to the registrant that includes observation on the identified deficiencies in the dossier that had however not been included in the decision.

(Annex I, point 1.4.1). Main identified shortcomings addressed in the QOBLs<sup>126</sup> include classification and labelling, CSR-related PNEC or DNEL derivation, and substance identity.

The Commission services note that, while the representativeness of the sample to date as to the compliance status of dossiers in general is still limited, the initial analysis of decisions identifies principal compliance shortcomings with respect to substance identity, justification for data waiving and the level of detail within robust study summaries. These identified areas of concern were to an important extent anticipated due to the scope and newness of registration requirements.

As regards the examinations of testing proposals, 80 out of 587 examinations in 2011 were closed or resulted in a final decision, with a further 144 at the draft decision stage. The vast majority (92%) of the examinations addresses the testing proposals for phase-in substances. Roughly three-quarters of all examinations of testing proposals also include third party consultation as they cover testing on vertebrate animals, and in 2011 ECHA received 481 comments from non-governmental organisations, companies, industry or trade organisations and individuals. The majority (13) of the 22 final decisions in 2011 cover the non-phase-in substances for which the deadline for the examination of testing proposals is six months, while the proposals for phase-in substances submitted within the first registration deadline need to be evaluated by 1 December 2012.

Dossier evaluation procedures by all involved actors, and in particular ECHA, are by now well-established and are generating decisions at an accelerated rate. Scrutiny of ECHA work by MSCA is apparent through the fact that, e.g., 11 out of the 22 final decisions adopted in 2011 received at least one proposal for amendment by a CA, triggering discussion in the MSC before adoption, see [Title 10]. To date however, the only issue that has not been resolved unanimously within MSC and for which therefore the related decisions<sup>127</sup> have been passed to the Commission, is on the study protocol to be used for addressing the information requirement of Annexes IX and X, point 8.7.3. "Two generation reproductive toxicity study". Some members were in favour of requesting the OECD TG 443 "EOGRTS" study, whilst others could not agree on imposing the use of the new guideline (also in light of the existing EU method B.35) or could only accept its use within certain specifications. The Commission has until now not concluded its deliberation in these cases, so the dossier evaluation process in this last variation has not yet been tested in full.

Registrants are kept informed about the dossier evaluation process, their rights, their obligations and the possibilities to interact with ECHA at several points in the procedure. When issues are referred to the MSC, representatives of the registrants, and when agreed by the registrant also the stakeholder observers are offered a possibility to be present at the session where their case is addressed, see [Title 10].

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<sup>126</sup> Quality Observation Letters – for definition and further assessment see concluding paragraphs of this chapter.

<sup>127</sup> Four by February 2012.

Nevertheless, it has been reported that registrants often find the procedures complex and may misinterpret the objective or steps in the exercise.

As regards the final decisions, only two had been appealed as of 15 April 2012 by the registrants. Both appeals are still pending.

To date no testing proposal has been rejected on the basis of the third party information.

Dossier evaluation has until now processed all dossiers within the prescribed deadlines. To ensure that the remaining almost 700 compliance checks to be carried out by the end of 2013 and that all examinations of testing proposals are processed in time, dossier evaluation has significantly raised its throughput in 2012, and the potential impact of this additional strain on the process is not yet apparent. Increase in efficiency is clearly required. It is pursued through repeated re-examination of the process within MSC. Efficiency has also been the principal focus of the January 2012 2<sup>nd</sup> Workshop on Dossier Evaluation.

Dossier evaluation will either result in decision or be concluded without any administrative action when a decision is not required or cannot be made at the relevant point in time. An additional tool used in the evaluation context are the QOBLs in which ECHA invites registrants to revise their registration dossiers and address shortcoming not related to formal data gaps. The incentive of these letters is to inform registrants and CAs on quality issues in registration dossiers that raise concern. The letters are sent alongside evaluation decisions or may, in compliance check cases, be the only communicated result.

As the QOBLs require additional administrative effort but are not legally required nor contain legally binding obligations, their added value has been questioned. The initial assessment shows fair response by the addressed registrants, with appreciation of the provided information by the CAs and enforcement authorities. Bearing in mind that the analysis work leading to the drafting of a QOBL is in any event carried out as part of the evaluation process, the Commission services believe that QOBLs provide real added value at little additional work.

The Commission closely monitors the overall impact of the implementation of dossier evaluation on compliance and on the quality of registration dossiers, as this impact is a direct consequence of the application of Article 41(5) (including the >5% requirement) that can be modified in accordance with Article 133(4). At present, no robust conclusions can be drawn due to the still limited number of evaluations and the relatively short time of implementation.

Progress in the compliance check strategy in terms of selection of dossiers and targeting of their evaluation to specific areas of concern, where automated tools can be exploited, can also contribute to the increase in efficiency and the achievement of goals of dossier evaluation. Innovative approaches had already been discussed between ECHA, CAs and the Commission and are now being further developed by ECHA.

## Substance evaluation

In February 2012, the first substance evaluations were launched, following the adoption of the first CoRAP covering a period of three years and published on the ECHA website<sup>128</sup>. The CoRAP will be revised annually.

Exacerbated by the initial uncertainty in the exercise and the eventual intensity of resources required, Member States have been reluctant to pledge their commitment for a significant number of substances for any of the first three years. 36 substances are being evaluated in 2012 by 17 Member States, with 90 substances assigned for the three-year period. This is significantly lower number than the initial expectation of 250 substances (ca. 50 in 2012 and 100 substances annually thereafter). In some cases, two CAs have agreed to evaluate a substance together, with one CA in the lead.

CAs now have 12 months after the publication to evaluate the substance and prepare a draft decision. The substance evaluation provisions of REACH have thus not yet been fully implemented. In contrast to the compliance check, where a single dossier is being evaluated, the CA under substance evaluation evaluates all dossiers in which the substance is covered, and the decision may include, stating reasons, information requirements that go beyond standard information requirements of Annexes VII to X to REACH. There are practical implementation aspects that were already discussed in several workshops.

Following evaluation, CAs are required to inform ECHA of whether and how the results of the evaluation should be used, information that ECHA must then pass on to the registrant, the Commission and other CAs.

During the preparation of the CoRAP, stakeholders had indicated lack of transparency in the identification process of candidates for the CoRAP list. There has even been some misunderstanding that substances put on CoRAP are somehow 'blacklisted', though placing on CoRAP should have no impact *per se* on the substances as the outcome of the evaluation may be a confirmation or the refutation of a risk.

With the first CoRAP, ECHA also provides very limited information on the justification for the selection of substances, as the prepared CA justification documents have not been sufficiently assessed for sensitive information and therefore have to remain confidential.

Experience with the preparation of the 2012 CoRAP indicates that improvements are needed in the selection process, in the access of IT tools by Member States and in the general coordination between ECHA and CAs.

## Evaluation of intermediates

Supporting CAs, ECHA has in 2011, on the basis of its initial screening of dossiers on intermediates conducted in 2010, undertaken a new verification of intermediate status.

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<sup>128</sup> Document "Community Rolling Action Plan (CoRAP)", 29 February 2012 [available on [www.echa.europa.eu](http://www.echa.europa.eu)]

A manual screening of approximately 400 selected dossiers of on-site and transported isolated intermediates identified several cases where the information contained within a dossier is insufficient to check if reduced registration for isolated on-site or transported intermediates was justified according to Article 17 or Article 18, respectively. By the end of 2011, 40 letters related to 17 substances were sent to the registrants, requesting further information in accordance with Article 36. Further action by ECHA may follow as the responses to the letters sent in accordance with Article 36 are assessed in 2012.

### **Conclusions and recommendations**

The Commission services note that dossier evaluation is on track, but acknowledges important challenges ahead. While it is as yet not possible to identify its positive impacts (e.g. downwards trend in the proportion of non-compliance in the evaluated dossiers), decisions as the principal output of the process are being produced at an accelerated pace and with scientifically and legally sound argumentation. The main challenge ahead is to ensure continuous quality of output while having a much higher throughput that is required already at present but also in the foreseeable future.

The Commission services therefore support recommendations that have been brought forward in ECHA Workshop on Dossier and Substance Evaluation 31 Jan - 1 Feb 2012 to increase the efficiency of the process by:

- optimising all underlying technical support such as IT tools, to minimise administrative burden;
- even better interaction between main actors (ECHA, MSC and CAs), in particular in proactively addressing generic issues (e.g. application of new test method) and feedback to CAs on discussions in MSC and the rationale behind the decisions, resulting in streamlined commenting and proposals for amendments;
- optimisation of dossier selection and targeted compliance check, limiting in cases the number of endpoints addressed and focusing on few identified areas of concern, enabling a large number of non-compliant dossiers to be addressed by legally binding decisions thus maximising the regulatory impact.

Some of these recommendations are already being put into practice by ECHA. The Commission services will continue to monitor the overall impact of the implementation of dossier evaluation on compliance and the quality of registration dossiers and may in future propose modification of Article 41(5) if appropriate.

Follow-up to the dossier evaluation decisions is an emerging issue, as for example 42 updates of dossiers following targeted substance identity check decisions have been received and the follow-up procedure initiated by ECHA. There are already situations where the update has not yet been received, although the deadline has expired.

While it is too early to conclude about substance evaluation, it is clear that the number of substances committed to date by Member States is below the initial expectation. The Commission services also note that further work on transparency of the evaluation process is required, between the registrants but also with stakeholders and

general public, probably not as much by modifying the process as by stepping up communication and awareness-raising.

<b>Recommendations</b>
6.1 An assessment by ECHA and CAs of the benefits and resource implications of using QOBL within 2 years is recommended. ECHA is encouraged to continue using QOBL where effective.
6.2. ECHA is invited to re-examine and streamline the third-party consultation process, for example through standardised replies and further guidance to focus these contributions to further increase efficiency of the dossier evaluation.
6.3. ECHA is invited to pay specific attention to the follow-up to the evaluation decisions; taking into account resource implications and coordination with Member State enforcement actions.
6.4. CAs are encouraged to enhance their capacity in relation to substance evaluation. ECHA is also invited to enlarge the number of substances to be considered for inclusion in the CoRAP and provide support to CAs performing substance evaluation.
6.5. ECHA is invited to make future substance evaluation justification documents public while respecting the requirements of Articles 118 and 119 of REACH.



## 7. AUTHORISATION

*The authorisation process is not yet fully operational, but important progress has been made in the preparation of Annex XV dossiers for substance of very high concern (SVHC) identification, in populating the candidate list and in including substances in Annex XIV. Efforts should continue to possibly intensify the SVHC identification process.*

### **Selection of substances for the candidate list and Annex XV dossiers**

The first step of the authorisation process is the preparation of a so-called "Annex XV dossier" for SVHC identification by a Member State or ECHA (the latter on behalf of the Commission).

SVHCs are substances whose intrinsic properties meet one of the following criteria set out in Article 57:

- the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with Annex VI to CLP;
- Substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with the criteria of Annex XIII;
- Substances that give rise to an equivalent level of concern to substances of the previous categories on the basis of scientific evidence of probable serious effects to human health or the environment.

Until now, most Annex XV dossiers include CMRs and mono-constituent substances. In fact, the identification of a substance as SVHC is straightforward in case of mono-constituent CMR substances included in Annex VI to CLP. However, Annex XV dossiers are more complicated for substances with several constituents and substances of unknown or variable composition or biological origin (UVCBs) because of complex substance identity, for PBTs and vPvBs because of the absence of a classification according to CLP, and for substances of equivalent concern according to Article 57(f), which need to be identified on a case-by-case basis.

By 1 June 2012 the candidate list contained:

- 67 CMRs identified according to Article 57(a), (b) and (c);
- four PBTs identified according to Article 57(d);
- one vPvB identified according to Article 57(e);
- one substance of equivalent concern identified according to Article 57(f) (as an endocrine disruptor), added in December 2011.

As far as PBTs and vPvBs are concerned, ECHA established an ad-hoc group composed of Member States, ECHA and Commission experts at the end of 2011 with the view to cover detailed scientific questions and issues related to PBT identification and therefore facilitate their identification.

The procedure foreseen in Article 59 for SVHC identification proved to work in an efficient way for the seven identification exercises conducted from October 2008 to December 2011. During that period the members of the Member State Committee (MSC) were always able to get unanimous agreement on the identification of the substances and the Commission was not asked to prepare a proposal for SVHC identification according to Article 59(9).

As indicated above, REACH foresees a multiple right of initiative in the process of SVHCs identification: any Member State or ECHA (the latter on behalf of the Commission) may submit an Annex XV dossier and no platform for prior coordination is foreseen. This novelty, together with the introduction of the authorisation process as an addition to the pre-existing restriction process, made clear to ECHA, Commission and Competent Authorities (CAs) a need to identify at an early stage which initiatives were taken by which authorities and whether authorisation and/or restriction are an appropriate way to address the potential risk posed by substance, as further explained in [Title 7 and 8]. A workshop organised by ECHA in January 2009<sup>129</sup> recognised the need for close coordination among the different actors, in order to apply a coherent approach and to use resources in an efficient way. At the same workshop, a risk management option (RMO) process was put in place with the full support of Member States, ECHA and the Commission to reach two main objectives:

- Discuss the different regulatory options and their effectiveness as far as possible before proposing a substance for SVHC identification;
- Coordinate the activities of all the actors in charge of the process.

From 2008 onwards, possible candidates for SVHCs have been screened looking mostly at substances classified as CMR category 1A and 1B. The identification exercises will be more and more based on new information (from 2013-2018, registration dossier and evaluation activities) and on new approaches (application of Article 57(f) to substances of equivalent concern and of the amended Annex XIII for PBTs and vPvBs). Information submitted by registrants in the CSR is critical for this exercise. The RMO process now sets the framework to agree on a common and coordinated approach to the future selection of SVHCs.

The Commission services strongly support to continue working in a common framework for the screening of SVHCs in a coordinated way, especially for the identification of substances of equivalent concern. The Commission services believe that identification of SVHCs according to Article 57(f) should take place by preparing Annex XV dossiers for specific cases, and, in parallel, by developing guiding criteria.

The Commission services believe that, in the process of Annex XV preparation, attention should be dedicated to those substances for which the identification as

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<sup>129</sup> See document "Workshop on the Candidate List and Authorisation as Risk Management Instruments, Workshop proceedings" Helsinki, 21-22 January 2009, [available on [www.echa.europa.eu](http://www.echa.europa.eu)]

SVHC is not straightforward (complex substances, PBTs, vPvBs and substances of equivalent concern). A common understanding should be developed to define the information needed for substance identification in order to be able to implement all steps of the authorisation process.

Looking at the activities in the medium term, the Commission services would support a roadmap in the framework of the RMO process, to achieve the objective to include all relevant, currently known SVHCs in the candidate list by 2020. The milestones should include:

- Complete the screening of the classified CMRs to identify the relevant ones for the candidate list;
- Build experience and develop criteria to identify the substances of equivalent concern and include the relevant ones in the candidate list;
- Use the data from 2013 and 2018 registration dossiers and the results of evaluation activities to select relevant SVHCs not identified with the previous screening activities.

### **The candidate list**

Once the MSC has agreed on the identification of a substance as a SVHC, ECHA places it on the candidate list, which is published on its website.

It has been agreed by the Member States, ECHA and the Commission to launch the Article 59 procedure twice a year, in fixed periods. As a consequence, the candidate list is also updated twice a year, normally in June and December.

A process for removing substances from the candidate list (e.g. in case of amendment of a classification) is not specifically foreseen in REACH.

The number of substances on the candidate list has been increasing continuously from 2008 onwards. It is clear that the actors involved gradually gained more experience with the process and the discussions in the RMO framework helped to arrive at the SVHC identification phase with dossiers containing all available information. The rate at which substances are being added to the list is increasing. E.g. in December 2011, 20 entries (the largest increase since the process started) took the number of substances on the candidate list to 73.

It is worthwhile to recall the Commission's aim to have 136 substances on the candidate list by the end of 2012 and to have all relevant, currently known SVHCs on the candidate list by 2020. This objective has had the merit of stimulating an increased activity of Member States in relation with the submission of proposals for SVHC identification. The candidate list currently contains 84 substances and 54 substances are being considered for inclusion by the end 2012 bringing the total number of substances up to 138, corresponding to or even exceeding the political commitment.

The Commission services will continue to encourage Member States to contribute more actively to the process of SVHC identification. ECHA and the Commission

services will continue to contribute by providing assistance, coordination and sharing experiences with the Member States.

Quantitative information on the effects of the candidate list is still scarce, possibly because the process, although started in 2008, has seen a significant increase in the number of substances in the candidate list – including substances with high tonnages and many uses - only from 2010 on.

To date, few cases of a "blacklist effect" of the candidate list were reported<sup>130</sup> but the perception of many downstream users (DUs) is that, as soon as a substance is included in the candidate list, it will be banned from the market in the near future and it has to be substituted in processes and, as a consequence, in articles. Some examples have been reported of governmental public procurement which in the selection criteria excludes articles containing substances on the candidate list. This may be due to a lack of clear information and communication to the parties concerned about the obligations and the effects of the candidate list. In this context, the Commission and ECHA are considering possible information activities to facilitate the understanding of the candidate list and of the authorisation process in general among all actors, including DUs and consumers, and would encourage Member States to do the same.

The candidate list has also been reported as one of the instruments of REACH that could drive innovation, thanks to substitution of SVHCs with safer substances. It is reported<sup>131</sup> that the placing on the candidate list can lead, in some cases, to the launch of initiatives to develop new substances or to the reformulation of existing substances. However, the same study reports also that the substitution of substances that are well tested and well adapted to the process, with substances for which less information is available and which might not have been tested for the specific process, may be a challenge for the companies involved.

The candidate list is not only the first step in the authorisation process. It also triggers obligations for article producers and importers to notify to ECHA, and for suppliers of articles to inform recipients on the presence of SVHCs in the articles, following the provisions of Articles 7(2) and 33 of REACH. These requirements might not be easy to meet, especially for complex articles (see [Title 4] for more details).

As stated in Article 59 of REACH, the candidate list is established for eventual inclusion of SVHCs in Annex XIV. According to the requirements of Articles 7(2) and 33, the candidate list can also provide information on substances in articles. The candidate list has also to be seen as a way to officially identify substances that pose a hazard for which no agreed criteria are available (i.e. endocrine disruptors) or for which no official classification and labelling is available (i.e. PBTs and vPvBs)<sup>132</sup>.

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<sup>130</sup> Study "Impact of the REACH regulation on the innovativeness of EU chemical industry", CSES, commissioned by the European Commission, March 2012.

<sup>131</sup> More in chapter 2.4 on innovation in part II of this paper (page 133).

<sup>132</sup> See document "Workshop on the Candidate List and Authorisation as Risk Management Instruments, Workshop proceedings" Helsinki, 21-22 January 2009, [available on [www.echa.europa.eu](http://www.echa.europa.eu)].

The Commission services believe that there is a need for a common view among Member States, ECHA and the Commission on the use of the candidate list for objectives other than the eventual inclusion of substances in Annex XIV.

Taking into account the relatively short experience in this area, the Commission services believe that it is too early to reach a firm conclusion on the positive and negative effects of inclusion of a substance in the candidate list. The reported results<sup>133</sup> can be considered as early indications of a trend, and they will need to be confirmed once the authorisation process is fully in place. More information will also be needed on the results of the implementation of Articles 7(2) and 33 of REACH.

The Commission services believe that the possibility of a "de-selection" from the candidate list should be considered.

### **Prioritisation of substances for Annex XIV**

The authorisation requirement is laid down in Title VII of REACH. Article 56 prohibits the placing on the market and the use of substances listed in Annex XIV (on their own, in mixtures and the incorporation of substances into articles) unless an authorisation has been granted to the manufacturer, importer or DU for the use(s). Annex XIV currently contains 14 SVHCs, included by two Regulations adopted in 2011 and 2012<sup>134</sup> respectively. Of the 14 substances currently in the Annex, 12 are carcinogenic, mutagenic and/or toxic for reproduction (i.e. meeting the criteria of Article 57(a), (b) and/or (c) of REACH), one is a PBT substance (i.e. meeting the criteria of Article 57(d)), and one is a vPvB substance (i.e. meeting the criteria of Article 57(e)).

Based on the procedure set out in Article 58 of REACH, substances from the candidate list are prioritised for their inclusion in Annex XIV to REACH. Article 58(3) specifies a number of criteria for prioritisation (substances with PBT or vPvB properties, with wide dispersive use or used in high volumes) to which a fourth criterion has been added, namely the regulatory effectiveness of the inclusion of the substance. In addition, REACH requires that the number of substances and the transitional arrangements included in Annex XIV take into account ECHA's capacity to handle applications in the time provided for. Based on ECHA's recommendation, the Commission adopts the decision to include substances in Annex XIV, in accordance with a comitology procedure.

Of the substances currently in Annex XIV, the majority (11 substances) were prioritised based on high volume together with the wide dispersive use criteria, and

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<sup>133</sup> Study *"Impact of the REACH regulation on the innovativeness of EU chemical industry"*, CSES, March 2012; RPA, Study *"Assessment of health and environmental benefits of REACH"*.

<sup>134</sup> Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV 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 44, 18.2.2011, p. 2 and Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV 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 41, 15.2.2012, p. 1.

two substances based on their PBT or vPvB properties together with the high volume and/or wide dispersive use criteria. One substance was prioritised for regulatory effectiveness reasons.

As indicated by ECHA<sup>135</sup>, the public consultations on the draft recommendation on inclusion of substances in Annex XIV has shown a need to improve the quality of the contributions from interested parties. Indeed, contributions are often made concerning aspects which are not relevant for the prioritisation of a substance, such as the availability and feasibility of alternatives, or socio-economic aspects concerning uses of the substance being recommended. The Commission services agree with ECHA in its assessment that there is a need to remind stakeholders of the role of the public consultation at this stage of the procedure, and of the relevant information for the recommendation. With regard to the public consultation, it has also been pointed out in specific cases by stakeholders that the three-month period foreseen in Article 58(4) is not sufficient to be able to provide comments. In that regard it should be pointed out that stakeholders should already be aware, at the stage of the public consultation based on Article 59(4) with a view to the identification of a substance as a SVHC, that the substance may be included in the candidate list (if it meets one of the intrinsic properties listed in Article 57) and thereafter be subject to the process laid down in Article 58. In other words, stakeholders should see the identification of a substance as a SVHC as an “early warning”, to start gathering information with a view to the next stage of the process. Still in relation to public consultation on the draft recommendation, it should be noted that the progressively higher number of submissions by third parties has started to create some challenges to the management of the overall procedure and the capacity of the ECHA Secretariat and of the MSC to assess and digest any additional information provided and to fairly reflect it in the recommendation. The Commission services support ECHA’s commitment to issue a recommendation for inclusion in Annex XIV every year as it increases the predictability of the process. Nevertheless, the Commission services would suggest to ECHA, based on the experience gained, to review its internal procedures to ensure high quality recommendations.

### **Application for authorisation**

An application for authorisation must be submitted to ECHA, whose Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) are required to adopt opinions on the application, and to send them to the Commission for a final decision to grant or refuse authorisation.

An important step in the implementation of Title VII was the adoption of the Guidance on the preparation of an application for authorisation<sup>136</sup> and the Guidance on socio-economic analysis - Authorisation<sup>137</sup>, both aimed at assisting applicants for

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<sup>135</sup> *The Operation of REACH and CLP 2011*, European Chemicals Agency, 2011, p. 35.

<sup>136</sup> *Guidance on the preparation of an application for authorisation, Version 1*, European Chemicals Agency, January 2011.

<sup>137</sup> *Guidance on the preparation of socio-economic analysis as part of an application for authorisation, Version 1*, European Chemicals Agency, January 2011.

authorisation to prepare the application and the socio-economic analysis supporting the application.

A question has arisen with regard to the applicability of the substitution plan requirement laid down in Article 62(4)(f) of REACH to applications for authorisation based on Article 60(4) (the so-called “socio-economic route”). In that regard the Commission services recognise that substitution is the ultimate objective for both routes to authorisation (i.e. the so-called “adequate control route” laid down in Article 60(1) and the “socio-economic route” foreseen in Article 60(4)). The Commission services are currently evaluating the appropriate procedure to reflect this requirement. In the meantime, the Guidance on authorisation application<sup>138</sup> clarifies that the robustness of the analysis of alternatives, and in particular the information provided on research and development activities on alternatives, will be key in determining the length of the review period of the authorisation. The Guidance also recommends that “if there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the “sunset date”) or another operator in the same market has already or will switch in the short future to alternatives, the applicants should explain as part of analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique.”<sup>139</sup>

A question has also been raised, concerning whether an only representative (OR) is legally entitled to apply for authorisation. In the Commission services’ view, even if that possibility has not been expressly foreseen in REACH, based on the principle of non-discrimination, an OR should not be deprived of this right. As a result of this interpretation, ECHA has communicated on its website that applications for authorisation may also be submitted by an OR.

ECHA is preparing the procedures for the handling of applications for authorisation<sup>140</sup>, and the Commission services are setting up its internal procedures for the handling of the ECHA opinions and the decision-making to grant authorisations. In particular, questions concerning the confidentiality of information, the format of the decisions and the internal Commission procedures to handle a potentially high number of application dossiers are being addressed.

### **Interface between authorisation and restrictions**

In accordance with the provisions of Article 58(5) to (7), in principle there is no legal obstacle in REACH preventing the authorisation and restriction processes from being conducted in parallel for the same substance. However, ECHA<sup>141</sup> acknowledges that, even where it is legally possible to launch the two processes in parallel, there may be

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<sup>138</sup> *Guidance on the preparation of an application for authorisation, Version 1*, European Chemicals Agency, January 2011.

<sup>139</sup> *Guidance on the preparation of an application for authorisation, Version 1*, European Chemicals Agency, January 2011, p. 25.

<sup>140</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 32.

<sup>141</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 33.

other reasons not to do so, such as the effective use of resources by authorities and industry, legal clarity and predictability. While sharing this view, the Commission services acknowledge that there may be cases where it is appropriate to launch the two processes in order to target different uses. In particular it is evident that if a substance poses an unacceptable risk that needs to be addressed on an EU-wide basis, the restriction process must be used through an amendment of Annex XVII to REACH. The possibility for both the authorisation and restriction processes to take place in parallel reinforces the need for communication and coordination of the activities of CAs, the Commission and ECHA in preparing proposals for identification of SVHCs and for restrictions, in order to seek a common view early in the process on the most appropriate risk management option for a specific substance.

In view of the above, the Commission services intend to launch a reflection with CAs and ECHA on how to improve the coordination of work in the implementation of the authorisation and restriction processes, with a view to ensuring that legal certainty and predictability of the legal requirements is fully respected.

### **Annex XIII to REACH**

Annex XIII was amended in 2011<sup>142</sup> as a result of the review carried out pursuant to Article 138(5) of REACH. The new Annex XIII has not yet been applied for the purpose of identifying PBT and vPvB substances as SVHCs under Article 59. For the purpose of registration of substances, a two-year transitional period was provided in the Commission Regulation amending Annex XIII<sup>143</sup>, in order to allow registrants sufficient time to update the registration dossiers.

<b>Recommendations</b>
7.1. The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet.
7.2. The Commission services in cooperation with ECHA will in the short term increase its efforts for identifying additional relevant SVHCs and will draft a roadmap in the framework of the RMO process to include all relevant, currently known SVHCs in the candidate list by 2020
7.3. The Commission services and ECHA will consider information activities to facilitate the understanding of the authorisation process among all actors, including DUs and consumers. Member States are encouraged to do the same.
7.4. Discussion should continue in order to obtain a common view on the use of the candidate list for objectives other than the eventual inclusion of substances in Annex XIV.
7.5. ECHA should conduct information activities to improve the quality and the appropriateness of the information submitted during the public consultation on the draft recommendation for inclusion in Annex XIV.

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<sup>142</sup> Commission Regulation (EU) No 253/2011 of 15 March 2011 amending 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 Annex XIII, OJ L 69, 16.3.2011, p. 7.

<sup>143</sup> *Ibid.*



## 8. RESTRICTIONS

*The REACH restriction process establishes clear deadlines for the adoption of EU-wide measures to control and manage unacceptable risks posed to human health and the environment.*

The restriction process (Title VIII) sets up a "safety net" to manage unacceptable risks to human health and the environment which are not adequately controlled by industry and need to be addressed at EU level. The decision-making lies with the Commission, which is empowered to adopt EU-wide restrictions concerning the manufacture, use and/or placing on the market of substances on their own, in mixtures and/or in articles under the comitology procedure, by amending Annex XVII. Restriction measures could take the form of a total ban of a substance, or other measures to control and reduce the exposure and risk from the use of a chemical. They apply equally to all products put on internal market, regardless of their origin, thereby being fair and transparent to both non-EEA and EEA manufacturers.

REACH establishes clear deadlines which, especially when compared with the previous legislative framework, were expected to considerably shorten the time from the moment the risk is identified to the adoption of the EU-wide measure to reduce and control such risk, resulting in a net gain in risk reduction. An EU-wide restriction process was already introduced by Directive 76/769/EEC, in order to address risks at Community level while removing the obstacles to trade created by different national rules concerning the marketing and use of chemicals, which affected the establishment and functioning of the internal market. Regulation (EEC) No 793/93<sup>144</sup> established rules in order to evaluate the risks of existing substances to human health and the environment. However this process had led to very long timelines, stretching over a number of years, from the initial risk evaluation until the adoption of the restriction. REACH addresses those shortcomings by streamlined procedures, in which ECHA plays a central role by coordinating the scientific and technical aspects of the restriction process, as well as by setting strict deadlines in which the different stages have to be accomplished by the different actors.

Moreover, transparency is expected to greatly improve, as the public is informed through ECHA's Registry of Intentions which substances are under scrutiny for potential submission to the REACH restriction process. Once the process has started, public consultation is also required at different stages of the procedure.

Finally the restrictions adopted under the previous legislative framework were taken over in Annex XVII of REACH<sup>145</sup>.

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<sup>144</sup> Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 84, 5.4.1993, p. 1.

<sup>145</sup> Following the adoption of REACH, Regulation (EC) No 552/2009 was adopted with the aim, in particular, to incorporate amendments to the restrictions adopted under Directive 76/769/EEC from 1 June 2007 as well as to adapt the "old" restrictions to the terminology used by REACH.

## **The standard route**

### Initiating the restriction process

Under the REACH restriction process, the Commission (Article 69(1)) or a Member State (Article 69(4)) shall initiate the process leading to the adoption of restriction measures, whenever they consider that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health and/or the environment that is not adequately controlled and needs to be addressed.

In the case of substances on Annex XIV, under certain conditions, after the relevant sunset date ECHA has to initiate the restriction process (Article 69(2)). However, this provision has not been applied so far, as no sunset dates have passed yet.

The specific procedure set up by REACH in which, in addition to the Commission, Member States as well as ECHA are given responsibility in initiating restrictions constitutes a novelty approach. This approach is designed to ensure that, by cooperation between Commission, Member States and ECHA, the identified unacceptable risks to human health and the environment are adequately assessed and addressed at the appropriate level.

The Commission has the responsibility under Article 69(1) to initiate the restriction process, in particular in cases where a specific risk to human health and/or the environment is identified under EU legislations or mechanisms or when an existing restriction needs to be completed or updated.

Member States have similar obligation under Article 69(4). Consideration on risk might be triggered, for instance, by the registration dossier or substance evaluation (Articles 42 and 48 of REACH), as well as by any other concerns identified on a national basis that would indicate the need for restricting the manufacture, placing on the market and/or use of a substance. Once an uncontrolled risk has been identified, Member States have to proceed under Title VIII. The obligation for Member States to inform ECHA and prepare an Annex XV dossier under Article 69(4) ensures that an assessment is done prior to introducing a restriction on the EU or national level, in order to avoid a distortion of the internal market as well as to address the risk at the appropriate level.

Since the entry into effect of Title VIII in June 2009, four Annex XV dossiers have been prepared by Member States<sup>146</sup> and one has been prepared by ECHA upon request of the Commission<sup>147</sup>.

In essence, the factor triggering the restriction process is similar to that under Directive 76/769/EEC, i.e. an assessment of the inadequately controlled risk arising from the use of a substance and of its need to be addressed at EU-wide level. However, there is much more information available to perform such an assessment

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<sup>146</sup> Dimethylfumarate and lead in jewellery (France), five phenylmercury compounds (Norway) and four phthalates (Denmark).

<sup>147</sup> Mercury in measuring devices.

under REACH than within the previous legal framework. In fact, the registration dossiers and chemical safety reports (CSRs) provided by industry have to contain extensive information on substances and their uses, allowing a targeted risk assessment and providing a more extensive set of information as support to the proposed risk management measures.

In addition, further data may be obtained through the stakeholders' involvement in the preparation of an Annex XV. The Guidance on Annex XV for restrictions<sup>148</sup> calls on the involvement of stakeholders as early as possible when preparing the Annex XV dossier, in order to facilitate the collection of the relevant data and improve transparency.

#### The conformity check

The Annex XV dossier is submitted to ECHA and, if declared conform by ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) (both discussed in [Title 10]) in line with Article 69(4), it is published on ECHA website for the public consultation (Article 69(6)).

Regarding the conformity check, based on the experience gained with the five dossiers submitted so far, it has become clear that for some cases this step is not easy to fulfil for the Committees. In fact, in some cases the lack or the insufficient level of information provided in Annex XV dossiers has caused problems to the Committees in concluding on the conformity of the dossiers. ECHA has developed explanations on conformity checks. However, the Commission services note that diverging views still exist in relation to the level of information required for the conformity (or not) of the submitted dossiers and ways to address this issue should be explored.

#### ECHA Committees' opinion-making, interaction of the two Committees

The RAC and SEAC undertake their analysis as described in Articles 70 and 71. The risk assessment is performed by RAC which represents under REACH the risk evaluation body for chemicals, as explained in [Title 10].

REACH expressly requires taking into account the socio-economic impact when adopting a restriction decision under the standard route.

Opinions of RAC and SEAC may diverge from each other or from the original proposal included in the Annex XV dossier. It is important that opinions clearly explain and justify why they present a different conclusion. This should be ensured by more interactions between the committees during the opinion making process.

The socio-economic analysis can be part of the Annex XV dossier prepared by Member States with the potential involvement of stakeholders. In any event, the interested parties have the possibility to submit relevant information or even a socio-economic analysis during the mandatory consultations, as detailed below.

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<sup>148</sup> *Guidance for the preparation of an Annex XV dossier for restrictions*, European Chemicals Agency, June 2007.

### Public consultations

Public consultations are needed at different stages of the process to ensure the involvement of all interested parties as well as greater transparency.

The Annex XV dossier is open to public consultation for a period of six months (Article 69(6)), allowing stakeholders to submit their comments, as well as additional information in particular on risk assessment, availability of alternatives and socio-economic data.

To improve the efficiency of the system, ECHA has suggested shortening the first consultation period from six to three months. However, the Commission services acknowledge that some industrial sectors are fragmented and collecting information can be a long and difficult process for industry associations as well as for other stakeholders. Also, the six-month period can be seen as very short when specific studies would need to be launched by stakeholders. In that context, it appears evident to the Commission services that a time period of six months is the minimum needed to allow stakeholders to gather data and compile them. This has to be seen also in relation to the situation experienced under the previous legislation, when stakeholders were consulted and participated in the Commission working groups where the restriction measures were discussed and that, in most of the case, well beyond a six-month period.

A second public consultation then takes place on the draft SEAC opinion (Article 71(1)).

The consultation under REACH is conducted with full transparency with regard to the comments submitted and the way they are taken into account by the dossier submitter or RAC or SEAC, respectively. In addition, ECHA becomes the central point of contact and coordination for all key players.

### Restriction decision and comitology

The final restriction decision is taken by the Commission through the comitology procedure. Given that it is based on the SEAC opinion, the performance of an impact assessment is not applicable. Until now, the Commission draft Regulations have not diverged from the opinions of the Committees.

### Simplified procedure for restrictions of CMR substances for consumer uses

Article 68(2) provides for a simplified procedure where the Commission proposes restrictions for a substance on its own, in a mixture or in an article classified as CMR category 1A or 1B which could be used by consumers. In such cases, the standard procedure following Article 69 of REACH (including the involvement of both Committees and preparation of Annex XV dossier) does not apply. The simplified procedure should allow a streamlined process to address risks to human health.

Such an approach is not new for substances and mixtures classified as CMR category 1A and 1B which, since 1994, were not allowed to be sold to the general public. For the case of newly classified substances and mixtures that could be used by consumers, a continuation with the practice of the past is suggested as a general line. This is justified by the potential wide exposure, possible misuse that could result from a

CMR substance or mixture made available to consumers and possible combined exposure from different sources. Also in the case of existing information demonstrating that, for a specific application, the risk is negligible, a time-limited derogation may be considered with the view to provide an incentive for industry to use alternatives. The Commission has already used that legal basis and adopted the Regulation No 109/2012 amending Annex XVII, entries 28 to 30<sup>149</sup>.

The novelty concerns the application of this simplified procedure to CMR substances in consumer articles. At the moment, the Commission services are of the view that the simplified procedure of Article 68(2) as applied so far to CMRs on their own and in mixtures should not be applied in an identical way to CMR in consumer articles. This means that the application of this provision should not result in a systematic prohibition of the sale of all articles containing any newly classified CMR substances to the general public. In addition, the Commission has the sole right of initiative for these cases.

The Commission services are still exploring possible options to define prioritisation criteria that would ensure that Article 68(2) is implemented in a pragmatic and proportionate way, taking in full account the need to preserve a scientific-based decision-making process.

#### Transitional measures

In addition, Article 137 of REACH provided for transitional measures to allow the work initiated under Directive 76/769/EEC to be finalised. This permitted the adoption of two amendments to Annex XVII concerning acrylamide<sup>150</sup> and cadmium<sup>151</sup> in 2011.

#### **Conclusions**

The Commission services have drawn the following conclusions with relation to the experience gathered in the implementation of the restrictions:

- The REACH restrictions enable a faster processing of risk management activities on chemicals that are identified as giving rise to risks requiring action at the EU

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<sup>149</sup> Commission Regulation (EU) No 109/2012 of 9 February 2012 amending 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 Annex XVII (CMR substances), OJ L 37, 10.2.2012, p. 1.

<sup>150</sup> Commission Regulation (EU) No 366/2011 of 14 April 2011 amending 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 Annex XVII (Acrylamide), OJ L 101, 15.4.2011, p. 12.

<sup>151</sup> Commission Regulation (EU) No 494/2011 of 20 May 2011 amending 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 Annex XVII (Cadmium), OJ L 134, 21.5.2011, p. 2.

level than the previous legal framework. It has therefore a high potential to deliver health and environmental benefits.

- Although there is a net gain in risk reduction that can be attributed to REACH restrictions, it is still limited at this stage of the REACH implementation.
- With REACH, transparency has greatly improved; stakeholders are informed of what is going on under the restriction process through ECHA's Registry of Intentions and website. They can also provide input through the public consultations required at different stages of the procedure.
- Diverging views still exist in relation to the information required for the conformity (or not) of the submitted dossiers.
- Coordination between RAC and SEAC opinions should be clarified and improved.
- Implementation of Article 68(2) still needs further work.
- Based on the review findings, the Commission services recommend the following actions or measures to improve the degree to which the restriction process of REACH is delivering its intended benefits:

<b>Recommendations</b>
8.1. The Member States are encouraged to increase their participation in the preparation of restrictions dossiers and further coordinate their activities and ECHA is invited to continue supporting activities for Annex XV dossier submitted by Member States.
8.2. Based on needs also identified in other legislative areas than REACH, the Commission services will enhance efforts to identify and prioritise substance and their uses that should be subject to restrictions under Article 69(1).
8.3. The current timeframe for public consultation to ensure high transparency and stakeholders' involvement will be maintained.
8.4. RAC and SEAC should improve their coordination.
8.5. The criteria for the practical implementation of Article 68(2), in particular in cases of consumer articles containing CMR substances will be considered.

## **9. ECHA**

### **9.1. Process, internal structure and operations**

*ECHA is overall effective. ECHA prioritised effectiveness, i.e. delivering the necessary output. In the Commission services' view this was the right choice for an Agency with a central role in an ambitious new piece of legislation.*

*Due to the focus on delivering output, efficiency was not maximal. In the Commission services' view this reflects a justifiable prioritisation by ECHA. However, the Commission services believe that the time has now come for consolidation and learning from the experience of the start-up period, for ECHA to become more efficient.*

ECHA is a decentralised agency: it draws up opinions so that the Commission can enact legislative proposals (e.g. in the restrictions area) or take specific decisions (e.g. granting or refusing authorisations). It has, in addition, own decision-making powers allowing it to adopt individual decisions needing a defined technical expertise, under clearly and precisely defined conditions and without discretionary power (e.g. in the area of evaluation); however, it is not allowed to adopt legislative measures of general application. The range of powers given to ECHA is in line with the principles of the EU legal order which impose constraints on the scope of the powers that can be given to Agencies<sup>152</sup>.

ECHA was the first Agency to be immediately established in its definitive location; other comparable Agencies had started up at Commission premises in Brussels and moved to their definitive location after some degree of organisational maturity had been reached.

In ECHA's start-up period, the initial team consisted of 38 seconded staff from the Commission selected for their special skills and/or relevant experience; some of them stayed on in the Agency as temporary agents. In addition, while the final stages of the co-decision process on REACH were ongoing, around 30 contract staff and 6 national experts joined the Commission and worked on the so-called REACH Implementation Projects (RIPs) referred to in the recitals of REACH, contributing to such essential preparatory activities as developing the draft guidance which was subsequently made available to ECHA, setting up the IT systems and preparing ECHA's operational structures. A number of these contract agents and national experts joined ECHA afterwards. The overall level of preparedness and ability to transfer relevant experience were some of the key factors contributing to ECHA's speedy and effective start-up.

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<sup>152</sup> COM(2002)718 final, 11.12.2002, p. 8; COM(2008)135 final, 11.3.2008, p. 5.

The study supporting the ECHA review<sup>153</sup> confirms ECHA's *raison d'être*, and accordingly the Commission services recommend to maintain ECHA's current role under REACH and CLP.

The following observations can be made on ECHA's internal structure:

### **The Management Board**

All EU Agencies have a main governing body having a supervisory role, with general responsibility for budgetary and planning matters as well as for reporting the Agency's activities to the EU institutions. ECHA's Management Board appoints the Executive Director, the accounting officer and the members of the Board of Appeal and the Committees and exercises disciplinary authority over the Executive Director. In addition, it adopts the internal rules and procedures as well as the financial rules of ECHA and ECHA's work programmes and general reports. It plays a key role in the budgetary procedures of the Agency, including adoption of the final budget before the beginning of the financial year. Finally, it may approve appropriate co-operation with stakeholders, third countries and international organisations. In this sense it exercises overall authority over the functioning of ECHA and provides strategic direction, but is not called to engage in regulatory chemicals policy.

ECHA's Management Board comprises 27 Member State representatives nominated by the Council, three Commission representatives, three stakeholder representatives appointed by the Commission, two independent persons appointed by the European Parliament and two representatives from EEA EFTA States (Norway and Iceland). Since the signing of the Accession Treaty with Croatia, the Management Board has decided to grant Croatia observer status and to invite a representative of Croatia to attend the meetings of the Management Board and the Committees. After having worked under a more intense meeting schedule in ECHA's start-up period, the Management Board now meets quarterly. It has established a two-level governance structure with six working groups which look into particular issues and meet independently and the plenary meetings of the Management Board. This is consistent with recommendation 10 of the Common Approach on decentralised agencies.

Despite overall performance being satisfactory, several suggestions have been made to increase cost-efficiency of the functioning of the Management Board<sup>154</sup>, such as reducing its size (including by not requiring all Member States to be represented) and focusing on the management of ECHA rather than issues related to the day-to-day running of ECHA or regulatory chemicals policy, as well as more detailed practical suggestions. However, the quality of decision-making was not put into doubt. For most of these suggestions, it is for the Management Board itself to consider their usefulness and to decide whether to act upon them. As for the suggestion to reduce the size, this would necessitate an amendment of Article 79(1) REACH. Although there are examples of EU Agencies with smaller Management Boards (especially

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<sup>153</sup> Study "Review of the European Chemicals Agency", PwC, funded by the European Commission, March 2012, p. 8-9

<sup>154</sup> *Ibid.*, p. 45.



EFSA), the predominant model is that of representation of all Member States which has however been criticised as unnecessary, costly and ineffective<sup>155</sup>.

The Commission services encourage the Management Board and the ECHA Secretariat to explore ways to increase cost-efficiency of the Management Board's functioning, but at this stage sees no need to change the composition of the Management Board through an amendment of REACH.

### **The Executive Director**

All EU Agencies have an Executive Director who acts as their general day-to-day manager. ECHA's Executive Director represents ECHA, supports the Management Board including by submitting to it draft work programmes, draft general reports and draft documents relevant for budgetary procedures, deals with staff matters, manages ECHA's resources, ensures the various parts of ECHA function well and in a timely manner, and where appropriate rectifies ECHA decisions following an appeal. The Executive Director is supported by an Executive Office.

The Management Board appoints the Executive Director on the basis of a list of candidates proposed by the Commission. In the start-up period of ECHA, and in recognition of the fact that a general manager was necessary even before the selection of candidates by the Commission and the Management Board's establishment, which both necessarily took time, the Commission appointed an Interim Executive Director in accordance with Article 134(2)(a) of REACH as part of the Interim Strategy towards ECHA operability. The fact that the Management Board saw this Interim Executive Director as the most suitable candidate and appointed him to the position of Executive Director allowed for a considerable degree of continuity in ECHA's management in the first years of its operation.

A complaint was filed with the Ombudsman regarding the first selection process for candidates for the position of Executive Director conducted by the Commission. The complainant felt that by proposing only two candidates to the Management Board, the Commission did not provide enough choice for the Management Board. After examination, the Ombudsman closed his inquiry with a critical remark, finding an instance of maladministration in that the Commission's failure to document the reasoning underpinning the establishment of the shortlist of candidates made it impossible to verify that the Commission did not unduly and arbitrarily restrict the range of candidates for the post of ECHA Executive Director and did not abuse its discretion in the matter.

The Commission services acknowledge the role of the Executive Director and his staff in the successful start-up and operation of ECHA. The Commission services also acknowledge the central role and active interest of the Executive Director in the establishment and working of the Directors Contact Group<sup>156</sup>. The Commission

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<sup>155</sup> Study "*Evaluation of the EU decentralised agencies in 2009*". Rambóll management, commissioned by the European Commission, December 2009.

<sup>156</sup> See [Sub-Title 3.2].

intends to continue applying the highest standards in any future selection of candidates and encourages the Management Board to do the same in any future appointment process.

### **The Secretariat**

ECHA's Secretariat currently comprises more than 500 staff members under the leadership of the Executive Director and divided over seven Directorates. They deal with REACH tasks related to registration, pre-registration and data sharing, evaluation, authorisation, restrictions, establishment and maintenance of databases, dissemination and communication, provision of technical and scientific guidance, (IT) tools and formats, technical and scientific support to Member State authorities and helpdesks, technical and scientific support to international co-operation (at the request of the Commission) and notification of ECHA decisions. In addition, they also deal with CLP tasks related to classification and labelling and dissemination. The lists of REACH and CLP tasks show that the role of the Secretariat is not purely administrative but goes deeply into technical-scientific issues; in that sense the name "Secretariat" may be a little limitative. The Secretariat also has finance, human resources, corporate services and legal departments. Specific to REACH, the Secretariat also assures the secretariat for the Committees and the Forum.

Currently, the Secretariat's staff is mainly composed of temporary agents on five-year contracts which can be prolonged<sup>157</sup>. There are limited numbers of contract agents (mainly support staff) and seconded national experts<sup>158</sup>.

The location of ECHA in Helsinki is reported to pose a particular challenge for staffing<sup>159</sup>. In spite of considerable, and highly appreciated, efforts of Finland and the City of Helsinki to create a welcoming environment for staff members and their families, promising candidates have been reported to turn down offers of employment for reasons linked to the climatic conditions, the remoteness of the location compared to the rest of the EU, and difficulties for spouses and partners to find attractive employment.

The combination of the high workload and the difficulties to recruit sufficient numbers of highly qualified staff may well require particular attention, and possibly a strategy, from ECHA management to ensure that sufficient resources can be attracted and can be sufficiently motivated to stay.

A continuing factor which has required reallocations of staff from other tasks has been the slower than planned progress in developing and implementing the IT system. This has meant that on the one hand work needed to be done with less IT support than

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<sup>157</sup> The establishment plan of ECHA has 456 temporary agent posts of which 447 were filled as of 31/12/2011.

<sup>158</sup> 92 contract agents and 5 seconded national experts were part of the staff as of 31/12/2011.

<sup>159</sup> Study "*Review of the European Chemicals Agency*", PwC, commissioned by the European Commission, p. 65.

planned and that more resources need to be dedicated to the development and implementation of the IT systems..

The ECHA Secretariat will be entrusted with new responsibilities under the new Biocidal Products Regulation, and under the upcoming recast of the Regulation on export and import of dangerous chemicals. This upcoming extension of the Secretariat's tasks is testimony to the credibility and authority that ECHA built up with the EU Institutions in the short years of its existence.

The Commission services commend the achievements of ECHA which were possible thanks to the dedication and strong commitment of its staff and encourages ECHA's management to continue seeking ways to optimise the allocation of available staff to tasks.

ECHA has identified a need for heightened internal co-ordination within ECHA to ensure coherence in the activities<sup>160</sup>. The Commission services share this analysis and invites ECHA to focus on pragmatic means of co-ordination, avoiding the need for additional structures and horizontal services.

### **The Forum**

No other EU Agency has a body comparable to ECHA's Forum for Exchange of Information on Enforcement. The increased responsibility of operators for the safe use of chemicals, a shift in mindset, that is at the very core of REACH, meant that enforcement of the legislation needed to be strengthened at EU level. In this light it was considered appropriate to provide a more formal framework for the co-operation among enforcement authorities which had emerged under the previous chemicals legislation<sup>161</sup>.

The Forum consists of 27 members, each appointed by their Member State, who have relevant expertise and maintain contacts with their Competent Authorities (CAs). In addition there are three members appointed by Iceland, Liechtenstein and Norway (EEA EFTA States) respectively. All of them are supported by the scientific and technical resources of their CA and ensure appropriate co-ordination with the work of their CA. However, Member States cannot give instructions to Forum members which are incompatible with their individual tasks or the tasks of the Forum. Although the Forum currently has no co-opted members, its expertise is broadened by the advisers that generally accompany members to Forum meetings. The Forum has invited stakeholders' organisations to attend some of its meetings. The secretariat of the Forum is ensured by the ECHA Secretariat. The role of the Forum is discussed in more detail in [**Title 12**].

ECHA has continuously increased the personnel in ECHA Forum Secretariat; the Commission services welcome this and invite ECHA to continue supporting improved cooperation between the CAs and the enforcement authorities.

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<sup>160</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 80-81.

<sup>161</sup> CLEEN – the Chemicals Legislation European Enforcement Network.

## The Board of Appeal

Only decision-making EU Agencies, which are a minority among the total number of EU Agencies, have a Board of Appeal which decides on appeals against the Agency's decisions. ECHA's Board of Appeal has strong similarities with its equivalents in EASA, ACER, CPVO and OHIM. ECHA's Board of Appeal provides a possibility of legal redress which is quicker, less formal and less expensive than an action to the Court of Justice of the European Union. Its composition of three members comprises not only lawyers but also at least one technically qualified member, which allows taking the technical-scientific aspects of each case into account where appropriate. The Board of Appeal is supported by a Registry, which is part of the Secretariat. A party not satisfied with a Board of Appeal decision can seek second tier legal redress by bringing an action to the Court of Justice.

Having a Board of Appeal organisationally within an Agency, and at Agency premises, in charge of dealing with appeals against that same Agency's decisions poses specific challenges: not only must the Board of Appeal, and its Registry, be independent from that Agency in its assessment and decision-making, but it also must be seen to be independent. Both the Board of Appeal itself as well as ECHA have taken organisational measures to guarantee the requisite independence and the ECHA review showed that the Board of Appeal is perceived as a credible, independent organisation.

In accordance with REACH requirements, the Commission has laid down the qualifications for the members<sup>162</sup> and the rules of organisation and procedure<sup>163</sup>. The Board of Appeal currently has one chamber of three members, but its rules of organisation allow the necessary flexibility for it to be able to draw on additional members to cope with any peaks in appeal numbers.

As of 15 April 2012, nine appeals against ECHA decisions had been filed with the Board of Appeal. Two appeals were withdrawn by the appellants; three led to rectifications of the ECHA decision by the Executive Director and were therefore not treated on substance by the Board of Appeal; two led to extensively motivated decisions of the Board of Appeal (one finding for ECHA, one finding for the appellant); two cases are pending. As a measure of good record, it should be noted that no actions against Board of Appeal decisions have been brought to the Court of Justice.

The Board of Appeal assists potential appellants through the publication of practice directions and other useful documents on a special dedicated section of the ECHA website, where appeal announcements and decisions are also published. Appropriate

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<sup>162</sup> Commission Regulation (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency, OJ L 280, 24.10.2007, p. 10.

<sup>163</sup> Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, OJ L 206, 2.8.2008, p. 5.

modalities are in place to ensure the requisite confidentiality of parts of the information. In this way, an open but balanced approach to transparency is ensured.

In the framework of its review of the rules of organisation and procedure, the Commission consulted the Board of Appeal as well as stakeholders represented in CARACAL to identify possible points for improvement. Some suggestions were made, which have been further examined in the review of Regulation (EC) No 771/2008. As for other aspect relating to the Board of Appeal, the very limited experience so far does not allow drawing definitive conclusions. Nevertheless, the Commission services acknowledge the fact that an appropriate framework is in place to ensure the Board of Appeal's independence from the rest of ECHA and shares the reported stakeholders' assessment that it is a credible appeal body<sup>164</sup>.

## 9.2. Committees

*The ECHA Committees have been successfully established with active participation from MS and EEA EFTA State and have provided the expected input to the REACH and CLP processes.*

Risk assessment is a matter for scientific experts, who are called to formulate an independent scientific opinion, based on scientific evidence. The imposition of EU-wide risk management on the other hand is a matter for those bearing political responsibility, as it involves decisions regarding acceptability or non-acceptability of risk. The separation is organically established in most EU legislation designed to address risks, by entrusting the risk assessment role to scientific committees or their equivalents, and the risk management role to a decision-making authority, generally the Commission.

Under pre-REACH chemicals legislation, the idea of separation and independent scientific advice was already applied to some extent: EU risk assessment reports prepared in accordance with Regulation (EEC) No 793/93 were evaluated by a Technical Committee of New and Existing Substances composed of Member State authorities' representatives. Where appropriate, the Commission invited the Scientific Committee on Health and Environmental Risks (SCHER) to give an opinion, not only for chemicals under Regulation (EEC) No 793/93, but also for other questions relating to examination of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment.

ECHA's Committees are today's conceptual equivalents of the Scientific Committees managed by the Commission (e.g. SCHER, SCENIHR, SCCS) or the Committees and Panels operating in the context of comparable Agencies (e.g. EMA's Committee for Medicinal products for Human Use, EFSA's Panel on plant protection products and

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<sup>164</sup> Study "Review of the European Chemicals Agency", PwC, commissioned by the European Commission, p. 40.

their residues). Nevertheless, specific aspects of the REACH system imply that ECHA's Committees present some original features compared to other known committees. As explained below, the Member State Committee (MSC) falls nearly completely outside the classic committee paradigm.

Members of the Committee for Risk Assessment (RAC) and of the Committee for Socio-economic Analysis (SEAC) are appointed by the Management Board, upon nomination of candidates with relevant experience by Member States. At least one, and no more than two members nominated by each Member State can be appointed in this way; the RAC currently has 41 members, the SEAC 30 members. Members of the MSC are appointed directly by the Member States, each appointing one member; also Norway as an EEA EFTA State has appointed one member.

All Committee members are supported by the scientific and technical resources of their Member State, who must provide them with adequate scientific and technical resources. All Committee members ensure appropriate co-ordination with the work of their CA, who facilitate the Committees' activities. However, Member States cannot give instructions to Committee members which are incompatible with their individual tasks or the tasks, responsibilities and independence of ECHA. The secretariat of the Committees is ensured by the ECHA Secretariat.

The close link, embedded in REACH, between Committee members and CAs may appear unusual. The members of Scientific Committees like SCHER, SCENIHR and SCCS or EFSA's Panels are nominated following a call from expressions of interest, without link to Member States. On the other hand, the ECHA model for Committee membership is closely related to that of some of EMA's Committees, whose members are nominated by Member States and supported by the scientific resources of CAs. The ECHA model was chosen deliberately, to ensure the best possible combination between ECHA independence, reliance on experience with the previous chemicals legislation, and avoiding draining national authorities' resources towards ECHA. Nevertheless, it is reported that some of the interventions in RAC and SEAC appear conditioned by the respective national chemicals policies, although this seems to have been somewhat mitigated as the Committees gained maturity<sup>165</sup>.

In addition to the tasks discussed below for RAC and SEAC specifically, REACH envisages the possibility for those two Committees to draw up opinions on any other aspects concerning the safety or use of substances on their own, in mixtures or in articles, at the request of the Executive Director. This possibility was prevailed upon a first time to request RAC to evaluate new scientific evidence regarding the use of boron compounds in photographic applications. Such evaluation was needed in order to justify any derogation from the ban of boron compounds classified as CMR and supplied to the general public. More use of such possibility may be envisaged in the future to support the Commission decision-making process.

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<sup>165</sup> Study "*Review of the European Chemicals Agency*", PwC, commissioned by the European Commission, p. 38.

All ECHA Committees attach great importance to transparency and have invited stakeholders' organisations to attend and intervene in their meetings, although parts of meetings where issues of a confidential nature are discussed are held behind closed doors. Criteria for the identification of relevant stakeholders were laid down by the Management Board in accordance with Article 108 of REACH and are being applied.

### **The Committee for Risk Assessment**

The RAC's core competence and expertise – risk assessment - come closest to those of other Scientific Committees and Panels, although the fact that it plays roles of different nature under different pieces of legislation (REACH and CLP) is unusual. Its main responsibilities include opinions on authorisation applications and on proposals for restrictions as well as for harmonised classification and labelling (the latter under CLP). The RAC's opinions are prepared by a rapporteur, possibly assisted by a co-rapporteur, appointed among its members. CAs are paid for rapporteurs' work (except in the case of harmonised classification and labelling) in accordance with Article 74(4) of REACH and Article 14 of Regulation (EC) No 340/2008<sup>166</sup>. The rapporteur's draft opinion is discussed in a working group and then presented to the plenary meeting and the final opinion adopted, where possible by consensus, otherwise by majority, recording any minority position, and taking into account stakeholders' comments in line with the applicable REACH or CLP provisions.

In ECHA's start-up phase, opinions of RAC were not called for very often and this gave the Committee ample time to discuss its working procedures and approaches, and debate in details all aspects of opinions. With the exception of the authorisation process, other REACH processes where RAC plays a role and the process for delivering opinions on proposals for harmonised classification and labelling under CLP are now more or less at cruising speed. This has meant a continuous increase in the RAC's workload which is anticipated to continue<sup>167</sup>. The workload combined with the legal deadlines for delivery of opinions creates pressure on the RAC which needs to continue looking for more efficient ways of working and must be able to rely on strong support from the Member States towards their RAC members in particular for opinions concerning harmonised classification and labelling under the CLP Regulation. Proposals for improvement are being examined and will need to be implemented in the future.

The procedures and timetables were introduced by REACH with the intention to accelerate the procedures as compared to pre-REACH and pre-CLP experience. Therefore the Commission services believe that at this stage, the most promising way of dealing with the identified workload issues appears to lie in improved working

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<sup>166</sup> Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency 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 107, 17.4.2008, p. 6.

<sup>167</sup> Study "*Review of the European Chemicals Agency*", PwC, commissioned by the European Commission, p. 54.

practices and Member State support, rather than extending the legal deadlines which are already perceived by some stakeholders as excessively long.

Another concern that ECHA is invited to address relates to the need to improve the clarity for industry and other stakeholders on when and how they can provide input into the processes and in what way ECHA reports on how this input is taken into account.

### **The Committee for Socio-economic Analysis**

No other Scientific Committees or Panels in ECHA deal with matters within the competency and expertise of the SEAC – socio-economic analysis. Its main responsibilities include opinions on authorisation applications and on proposals for restrictions. The SEAC's opinions are prepared by a rapporteur, possibly assisted by a co-rapporteur, appointed among its members. CAs are paid for rapporteurs' work in accordance with Article 74(4) of REACH and Article 14 of Regulation (EC) No 340/2008. The rapporteur's draft opinion is discussed in a working groups and then presented to the plenary meeting and the final opinion adopted, where possible by consensus, otherwise by majority, recording any minority position, and taking into account stakeholders' comments in line with the applicable REACH provisions.

Like the RAC, the SEAC had a relatively calm start-up period with time to discuss working procedures and approaches as well as detailed aspects of opinions, but its workload has increased and this trend is expected to continue<sup>168</sup>. The workload combined with the legal deadlines for delivery of opinions and consultations, and especially the interface with the RAC opinions and their timing, creates pressure on the SEAC which needs to continue looking for more efficient ways of working and must be able to rely on strong support from the Member States towards their SEAC members.

Like for the RAC, the Commission services believe that at this stage, the most promising way of dealing with the identified workload issues for the SEAC appears to lie in improved working practices and Member State support. Additional help could come from a better balance of the members' expertise accumulated within the Committee in order to reduce risks of crossing into the domain of Risk Assessment Committee.

### **The Member State Committee**

The MSC's role and nature are not only very different from traditional Scientific Committees and Panels, but also from RAC and SEAC. Its main responsibilities include consensus-building on draft evaluation decisions, proposals for identification of substances of very high concern (SVHCs) to be subjected to authorisation and opinions on the ECHA recommendation for the inclusion of SVHCs in Annex XIV. With regard to evaluation, its role is not limited to providing an opinion; it also brings together in one assembly authorities from the Member States with a view to reaching consensus on a draft decision to be taken by ECHA in case one or more of the CAs

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<sup>168</sup> *Ibid.*, p. 54.



commented on the draft decision, in a field that under previous legislation belonged to the core competences of the CAs. Similarly, with regard to decisions on identification of SVHCs, it is called to reach consensus among the authorities from the Member States, in case one or more of them commented on the proposed identification, allowing ECHA to include substances into the so-called candidate list.

Where the consensus aimed for cannot be achieved, ECHA does not take an evaluation decision, for the first case, nor does it include the substances in the candidate list, in the second case. Instead, the matter is referred to the Commission who takes the decision in accordance with the comitology procedure. This referral to the Commission for decision is another illustration of the extraordinary role and nature of the MSC which leads MSC members to some, perhaps too large, extent to engage in policy discussions rather than scientific-technical discussions. The MSC has so far achieved consensus in nearly all cases; in the future it may need to consider accepting that consensus is sometimes not possible and allowing the matter to be referred to the Commission.

The MSC plays an important role also in the process of recommending SVHCs for inclusion in Annex XIV. Despite the fact that in this case the Committee does not take decisions but gives only an opinion to ECHA, this stage is fundamental to assess the reaction of the Member States to the information provided by the stakeholders during the public consultation, which is discussed in more detail in [Title 8]. The increasing number of comments received and the difficulties encountered to get unanimity within the MSC for supporting ECHA recommendations indicate a need to continue the efforts of working in an efficient way but also possibly the need to increase the dialogue and the early information of the stakeholders to improve the quality and the appropriateness of their involvement into the public consultation process.

Draft evaluation decisions prepared by the ECHA Secretariat are submitted to the CAs for comments; the draft decision only comes to MSC when amendments are proposed, otherwise ECHA takes the decision in accordance with the draft. However, as the evaluation as well as the authorisation process reach cruising speed, following the first registration deadline, the upcoming adoption of the first CoRAP and the fourth round of recommendations for inclusion in Annex XIV, the workload for the MSC can be expected to increase like for the other Committees. Also here there is a need to continue looking for more efficient ways of working, e.g. by communicating in more detail the rationale for decisions to CAs, so that comments are only triggered in truly necessary cases<sup>169</sup>.

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<sup>169</sup> *Ibid.*, p. 54.

### 9.3. Fees and charges

*Since 2010, ECHA is fully financed by fees paid by enterprises. The amounts of the fees to be paid by enterprises should not be prohibitively expensive, especially for SMEs.*

In principle, ECHA activity under REACH and CLP are set up to be largely financed from fees paid to it by operators. An EU subsidy is integral part of its budget, but this is a balancing subsidy essentially meant to cover the start-up, when no or insufficient fees were coming in, as well as any income gaps caused by fee income fluctuations due to no- or low-income periods between registration peaks (although these should largely be mitigated by ECHA's responsible management of the large incomes received during registration peaks). Following this system, ECHA has been self-financed since 2010. The original Legislative Financial Statement published with the Commission's REACH proposal foresaw a very simple fee structure (registration fees for below and above 100 tonnes/year and authorisation fees)<sup>170</sup>. The European Parliament and the Council introduced a number of individual fee items and also important reductions and waivers for specific cases such as SMEs and consortia, leading to a Revised Legislative Financial Statement<sup>171</sup>.

ECHA is expected to receive a balancing subsidy for REACH and CLP as of 2014. The Commission proposal for the Multiannual Financial Framework 2014-2020 foresees rigorous cost savings and maximum efficiency at all levels. This also applies to EU Agencies. Only the global amount per heading of the Multiannual Financial Framework was included in the documents adopted by the Commission on 29 June 2011.

Taking into account the decision on the MFF and the experience gained from the operation of the Regulation, the long-term resource planning as established by the Legislative and Financial Statement of the REACH Regulation may also need to be examined

The principle that ECHA is supposed to be largely self-financing is further laid down in the requirement that the structure and the amount of the fees take account of the work to be carried out by the authorities and be fixed at a level ensuring that the revenue from fees combined with other sources of revenue, covers the cost of services to operators, in accordance with Article 74(3) of REACH.

At the same time, there is a need to ensure that the amounts of the fees to be paid by operators in order to gain or maintain market access do not become prohibitively expensive, notably for SMEs. Another element is that fees can be used to promote certain policy goals, such as in the case of REACH the aim of joint submission of

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<sup>170</sup> Commission Staff Working Paper, [REACH] Extended Impact Assessment, COM(2003)644 final, 29.10.2003, p. 246.

<sup>171</sup> Communication From The Commission To The European Parliament [...] concerning the Common Position of the Council on the adoption of [REACH], 12.7.2006, {SEC(2006)924}, p. 30.

registration information. Both the promotion of SMEs and of joint submission of registration information are equally part of Article 74(3) of REACH.

A balanced approach combining all the above elements was the guiding principle for the Commission in adopting Regulation (EC) No 340/2008 as well as Regulation (EU) No 440/2010<sup>172</sup> (on CLP fees). Both Regulations provide for different fees for different types of submissions and actions, and provide for reductions for medium, small and micro enterprises (who can benefit from reductions of 30%, 60% and 90% respectively), as well as, in the case of REACH fees, for joint submissions of information; moreover, no fees are due for registrations for substances in the 1-10 tonne range where all the information required by Annex VII to REACH is provided. Special guidance has been made available allowing companies to verify if they are eligible for SME reductions<sup>173</sup>. Nevertheless, when special reductions are possible, the risk of abuse or accidental misuse is always present. To ensure that the special facility benefits those and only those for whom it is meant, namely SMEs, through significant reductions, Article 13 of Regulation (EC) No 340/2008 and Article 5 of Regulation (EU) No 440/2010 foresee the possibility for ECHA to demand the full fee as well as an administrative charge in case a company claims SME status but is unable to prove entitlement. The legality of Article 13 of Regulation (EC) No 340/2008 is being contested in the Court of Justice of the European Union.

Registration fees are levied through an invoicing system: operators are only required to pay when they receive an electronic invoice from ECHA. ECHA conducts the invoice process for registrations in parallel to the technical completeness check. First an initial deadline for payment is set – generally 14 days or 30 days for pre-registered substances less than two months before the applicable registration deadline. If no payment is received within the deadline, a second deadline is set. If no payment is received within the second deadline, the process to reject the dossier is initiated, as Article 20(2) of REACH requires payment of the registration fee for a registration dossier to be complete, but a short waiting period for verification is always allowed, to ensure that ECHA does not reject registrations because of delays in bank transactions. If a registration is rejected because missing information was not submitted or because the registration fee was not paid within the deadlines set, the fee is not refunded or credited, in accordance with Article 3(7) of Regulation (EC) No 340/2008.

Late payments of registration fees have been the object of two decisions of ECHA's Board of Appeal. Both decisions concerned cases where the registration fee had been paid after expiry of the second deadline set and, accordingly, the registration rejected. In the first case, the appellant requested that ECHA's decision be annulled, a registration number assigned and the registration fee accepted, arguing that it had

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<sup>172</sup> Commission Regulation (EU) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 126, 22.5.2010, p. 1.

<sup>173</sup> See [Title 3].

fulfilled its obligations but had paid the fee too late due to an internal mistake. The Decision of the Board of Appeal of 7 October 2011 confirmed that ECHA had acted correctly in rejecting the registration. In the second case, the appellant challenged the decision to the extent that ECHA decided not to reimburse the registration fee paid. The Decision of the Board of Appeal of 10 October 2011 found that ECHA had not provided clear enough information to the registrant on the deadline for payment of the fee, and ordered the refund of the registration fee. Meanwhile ECHA has undertaken to carefully review its communications in the light of the latter decision, to make the deadline for payment absolutely clear as well as the consequences of late payment.

REACH fees may be adapted to inflation. The Commission had proceeded to annual reviews to decide whether an amendment of the amounts was due; up until now, no need was identified to adapt amounts to inflation, taking into account the relatively low inflation rate and the policy of the Commission to support economic operators, in particular SMEs in times of economic downturn.

In line with Article 74(4) of REACH and Article 14 of Regulation (EC) No 340/2008, a proportion of the fees collected by ECHA is transferred to CAs for work related to substance evaluation and rapporteurs' work in the RAC and the SEAC. The framework of these transfers is defined by a decision of ECHA's Management Board. The scale of payments is based on Eurostat data using price level index (25%) and gross annual earnings in industry and services (75%). This system is currently under review by the Management Board as the Board has observed a large variation between Member States in the scale of payments and the data used might not reflect correctly the average salary of scientific staff in Member States.

ECHA has provided the following suggestions related to fees<sup>174</sup>: (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. Although the Commission services are still considering these suggestions in detail, it is asserted that changes in the fee regime do not justify a revision of REACH. In any event, the Commission is in the process of reviewing Regulation (EC) No 340/2008 by 1 January 2013, with a view to amend it, if appropriate, taking into account in particular the costs of the Agency and the related costs of the services provided by the competent authorities of the Member States.

The Commission services acknowledge the contribution of SMEs to the EU economy, including in the chemicals fields, and recommends to continue providing them special status through significant fee reductions.

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<sup>174</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 21, 24, 65, 68 and 81.

<b>Recommendations</b>
<p>9.1. ECHA has completed the transition to a mature organization; it now has to enhance its resource efficiency.</p> <p>9.2. The Committees of ECHA need to continue looking for more efficient ways of working and must be able to rely on strong support from the Member States.</p> <p>9.3. The review of the Fee Regulation needs to consider the suggestions made in the ECHA report.</p>

## 10. COMPETENT AUTHORITIES

*Competent Authorities are important players in the implementation of REACH. All Member States have appointed Competent Authorities, and fulfilled their tasks, although concerns have been raised in relation to adequacy of resources committed by MS.*

Article 117(1) of REACH states that “Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127. The first report shall be submitted by 1 June 2010.”

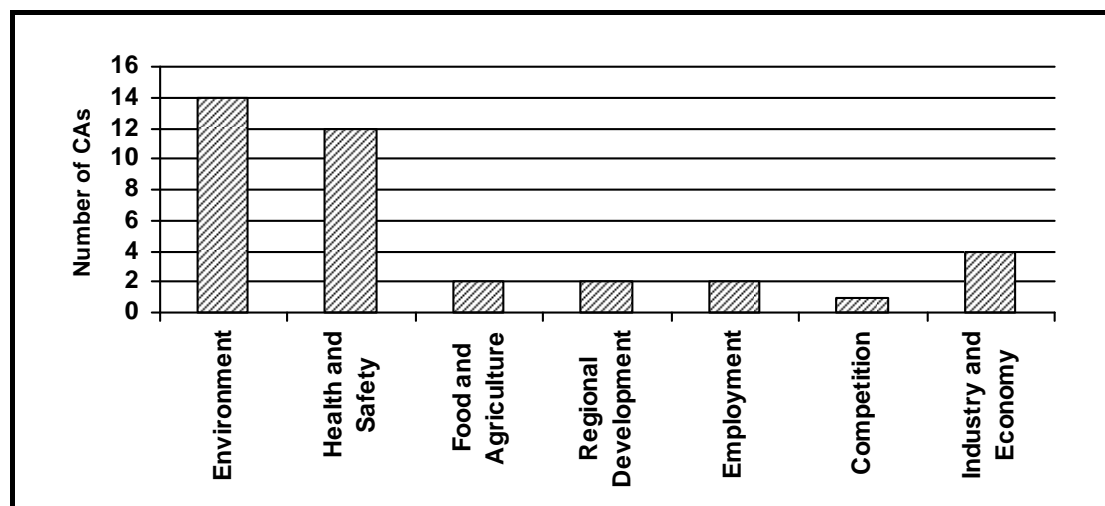
This section summarises the responses received from the Member States and EEA EFTA States by 1 June 2010. However, although several Member States have more than one Competent Authority (CA), the responses received were from one CA per Member State. As a result, in most instances the information related mainly to the activities of the respondent CA, with only limited information on the roles and activities of other CAs within the same Member State.

Given that this was the first reporting activity under this obligation, the Commission will discuss how future reporting can ensure that information on the entirety of activities performed by all CAs within a Member State is captured.

### Competent Authorities: Coordination, cooperation and information exchange

There are 40 REACH CAs operating in the EU Member States and EEA EFTA States (in this title collectively referred to as “Member States”), reflecting that seven of the Member States have more than one CA. This section presents a summary of the analysis of the information from the first set of Article 117(1) reports submitted to the Commission by CAs.

**Figure 2. Areas of responsibilities of national institutions nominated as CAs.**



**Notes:** Up to 3 main areas of responsibilities have been identified per individual CA. Only EU CAs have been taken into account.

The “Competent Authorities for REACH and CLP (CARACAL)” is a Commission expert group that brings together all CAs to facilitate cooperation between CAs, and between CAs and the Commission and ECHA, on the implementation and functioning of REACH and CLP in their respective areas of responsibility.

CARACAL is working effectively. Some Member States provide more resources than others, but this in some cases is simply a reflection of the resources available within Member States for their CA(s).

However, the 15 CAs that provided comments expressed concerns that the resources allocated to them are inadequate or limited due to:

- an insufficient number of employees; and
- inappropriate skill sets (e.g. particular emphasis was placed on the lack of expertise in socio-economic analysis and risk communication and of senior toxicology experts).

The Commission services take note of this finding and intend to explore this further with Member States.

Member States also have obligations in relation to ECHA Committees. In addition, there is a range of other bodies designed to facilitate the coordination, cooperation, and information exchange related to specific functions of REACH (e.g. the Forum<sup>175</sup> and HelpEx<sup>176</sup>).

ECHA, the CAs and the Commission services are positive about the quality of their interactions overall, both formal and informal. According to the reports the work of the Committees was considered by CAs to be above average and ECHA is largely positive regarding their communication with the Commission. CAs in general felt the effectiveness of communication and collaboration to be average or above, between themselves and (number of CAs expressing this opinion):

- CAs of different Member States (28);
- ECHA (28);
- the Commission (30); and
- the ECHA Committees (30).

### **Operation of REACH**

Member States were asked to report their experience in the following areas:

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<sup>175</sup> See [Title 12].

<sup>176</sup> HelpNet Exchange - a secure web-based discussion platform set-up by ECHA which allows members of the helpdesk network to discuss difficult questions, to cooperate and to support one another on a daily basis

- Risk Communication Network: a voluntary body of CAs organised by ECHA to support the cooperation obligation as set in Article 122 of REACH, the Risk Communication Network (RCN) focuses on risk communication to the general public. The six CAs that commented on the RCN felt that this was a well organised body that was an important and valuable venue for sharing expertise/experiences of ‘risk communication’ between Member States, as well as a source of training (information volunteered by CAs and not asked in Member State questionnaire).
- Duty-holders (registrants): 12 CAs provided estimates of the total number of likely duty-holders for each of the years 2007 and 2008 and 15 CAs provided estimates for 2009. The remaining CAs submitted either a blank response or stated that such data were not maintained/collected. However, there are reasons to suppose that the data provided may not relate to a common metric, a view supported by the fact that CAs had not been provided with guidance on how these estimates should be calculated. Hence no sound conclusions could be drawn.
- Information in the supply chain: Member States were not asked to report on the activities of duty-holders regarding the supply and movement of information in the supply chain. However, in their responses regarding helpdesk support provided to industry, it is clear that advice was provided by Member States on downstream user obligations, the operation of SIEFs and safety data sheets.
- Annex XV dossiers (authorisation): The identification of Substances of Very High Concern (SVHCs) is the key requisite for triggering the authorisation provisions of REACH. 21 CAs indicated that their Member State had been involved in some Annex XV dossier-related activity for the identification of SVHCs. Activities range from developing full dossier to commenting on a dossier prepared by another Member State or ECHA.

In general, CAs felt that they did not have the experience to comment on the “reasonableness” of the time spent following up Member State dossiers or acting as co-rapporteur. However, the Danish and Swedish CAs predicted that Annex XV dossier work would not be resource-demanding but stated that the time/resources requirements varied significantly between dossiers. These comments applied to all Annex XV dossiers, not just those for the identification of SVHCs.

Eight CAs indicated that industry was involved in the preparation of Annex XV dossiers for SVHC identification within their Member State. However, the level of industry contribution varied greatly between Member States.

- Effectiveness of RAC and SEAC: The views on the effectiveness of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) were mixed, with respondent CAs commenting on the usefulness of the secretariats and procedures whilst also raising concerns regarding the workload and availability of resources of the Committees.
- Annex XV dossiers (restriction): 13 CAs indicated that their Member State had been involved in some Annex XV dossier-related activity. However, the activity may have only involved commenting on a dossier prepared by another Member State or ECHA.



- Dossier and substance evaluation: Nine CAs reported having been involved in substance evaluation. However, several CAs noted that as substance evaluation has not yet begun, they had not been involved.
- Alternative testing: Responses from all CAs indicate that 20 Member States have made contributions to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees.

17 CAs provided data on overall public funding for national research and the development of alternative testing methodologies, with nine CAs reporting expenditure of more than € 100 000 per year each. However, from comments provided by CAs it is possible that the expenditure reported for some Member States includes not only funding of national research projects but also contributions to EU and/or OECD work.

### **Enforcement**

Administrative structures differ between Member States and often more than one authority plays a role in the enforcement of REACH, which can bring differing challenges. Co-operation between CAs and enforcement authorities also differs between Member States. According to Member States reports five of them have a single CA and a single enforcement authority and nine have several CAs and multiple enforcement authorities (national, regional, local). The rest typically has a single CA and several enforcement authorities.

However, issues related to this area are discussed in [Title 11].

### **Guidance and support**

- Helpdesk organisation and resources: All CAs manage their REACH helpdesks internally, except for the Netherlands, which still, however, retains the control over the Member State helpdesk. A further six CAs indicated that they outsourced at least some helpdesk enquiries. The greatest number of enquiries was received by e-mail and then by telephone with a small minority of Member States not having both of these options available. 22 Member State helpdesks also handle enquiries relating to CLP and 18 helpdesks provide specific advice to small and medium-sized enterprises (SMEs). No helpdesks receive funding outside of Member State governments.
- Member State helpdesk activities: The number of inquiries received by helpdesks varied significantly. However, two-thirds of the Member States receive between 100 and 1 000 inquiries per year. The greatest number of inquiries related to registration or pre-registration, the majority from SMEs. 64% of inquiries were considered to be straightforward with 36% described as complex. On average, straightforward inquiries received a response within one week (and often within a day) while complex inquiries were dealt with within two weeks.
- Cooperation between Member State helpdesks: For the majority of Member States, the level of cooperation within the REACH Helpdesk Correspondents' Network (REHCORN, now renamed Helpnet) was significantly greater than the level of cooperation outside of REHCORN. However, six CAs felt that there was no

difference. 19 of the 30 helpdesks make use of REACH Helpdesk Exchange Platform (RHEP, now renamed HelpEx) at least weekly.

- Awareness-raising activities: In general, CAs employed a wide range of awareness-raising activities, with the greatest level of activity focused on the entry into force of REACH. CAs found speaking events, telephone contact and leaflets most effective at awareness-raising.
- Member State websites: All Member States except Austria and Greece have a REACH-specific website or webpage(s). Ten Member States have single webpages dedicated to REACH and the remaining 18 Member States have multiple such webpages as part of their website. Topics of interest comprised REACH news/updates, company obligations, (pre-)registration, exemptions from registration, authorisation, socio-economic assessment (IT only), classification and labelling and FAQs.
- REACH guidance documents: Effectiveness of Partner Expert Groups (PEGs): The majority of Member States had actively participated in PEGs. A minority of CAs was supportive of the organisation of PEGs although with some reservations.

#### **REACH aims: Protection of human health and environment**

- Article 129 of REACH: No MS indicated that they had made use of the safeguard clause of Article 129 REACH.
- Effectiveness of REACH for the protection of human health and environment: With the exception of Italy, all CAs felt that the effectiveness of REACH in protecting human health and the environment was best assessed at the level of the EU rather than at a national level.

#### **REACH aims: Enhancing competitiveness and innovation and the single market**

All CAs except Italy stated that enhancing competitiveness and innovation should be assessed at the EU, not the national level.

#### **Suggestions for improving Article 117(1) reporting**

Responses from CAs (within and separate from Article 117(1) reports) and the legal requirements for Member States reporting set out in REACH were analysed with the intention of identifying possible improvements to the content and format of future Article 117(1) reports.

On the basis of this first reporting experience and a technical analysis<sup>177</sup> the Commission services see a need to improve the reporting process and will consider how this can be best achieved.

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<sup>177</sup> Study “*Technical assistance to prepare the Commission report on the operation of REACH*”, RPA and Ökopol, commissioned by the European Commission, 2012

## Conclusions and recommendations

The reporting of the Member States provides a first snapshot of the functioning of REACH. Recommendations and conclusions on specific aspects e.g. authorisation, are provided at those corresponding sections of this document.

The Commission services acknowledge the challenges faced in this first reporting round and the efforts made by the CAs to fulfil this obligation.

Recommendations
10.1. The Member States should improve the reporting quality by exploring ways in which more robust information can be provided through the questionnaire. It will be examined how the reporting process (including IT tools used and reporting format) can be made more user-friendly for the Member States.
10.2 The Member States should explore if the resource constraints that appear to be acting on the CAs can be addressed by improved ways of working e.g. wider sharing of best practice across Member States.
10.3. Further assistance to Member States and the CAs will be explored e.g. through development of tools for assessment of competitiveness and innovation.

## 11. ENFORCEMENT

*A strong and harmonised approach towards enforcement in the Member States is vital for delivering objectives of REACH and CLP Regulations. Achieving this is a challenge and Member States are actively cooperating within the Forum to enhance compliance.*

The aim of the national enforcement systems is to ensure the implementation of REACH. A strong and uniform enforcement of REACH throughout the EU members and EEA EFTA States (in this title collectively referred to as “Member States”) is vital for delivering its objectives

REACH places different enforceable obligations on duty-holders. They can be grouped according to the main REACH processes: registration-related duties, supply chain-related duties, authorisation and restrictions.

Related to the obligations prescribed by REACH, CLP imposes additional obligations including the basic obligation of classification and requirements to label and package substances and mixtures according to hazard.

The enforcement of REACH and CLP lies with the Member States. The harmonisation of enforcement amongst Member States was a key issue during the development of REACH. The REACH preamble stresses the importance of strengthening enforcement<sup>178</sup>. The Forum (an ECHA body) was created to coordinate a network of Member State authorities responsible for the enforcement of REACH<sup>179</sup>. It is a unique body and may serve as an example for other legislation.

### Enforcement in Member States

In order to enable REACH to operate effectively in practice, Member States are obliged to establish the necessary arrangements for its implementation. REACH therefore requires the Member States to:

- maintain “a system of official controls” and other activities as appropriate to the circumstances (Article 125);
- lay down the provisions on penalties applicable for infringement of REACH and take all measures necessary to ensure that they are implemented (Article 126);
- regularly report on enforcement (Article 127).

The Commission as the "guardian of the Treaties" oversees the fulfilment of these obligations.

As reported in [Title 10], the administrative structures of enforcement authorities differ from one Member State to another and often more than one national

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<sup>178</sup> Recital (105) of REACH.

<sup>179</sup> Article 76(1)(f) of REACH.

enforcement authority plays a role in the enforcement of REACH. For example in the Czech Republic the Czech Customs Administration checks the duties of importers, focusing on safety data sheets, and the Regional Public Health Authorities checks the duties of manufacturers, importers, downstream users and distributors. However, the enforcement arrangements in many Member States, such as Germany, Spain and the UK, are more complex.

Since CAs have the scientific and political knowledge and national enforcement authorities the necessary practical experience in implementation, a proper cooperation and information exchange between CAs and national enforcement authorities is crucial to ensure the effective implementation of REACH.

### **The Forum**

The Forum coordinates the network of Member States authorities responsible for enforcement of REACH. It is required to spread good practice, identify enforcement strategies, set up harmonised enforcement projects and joined inspections, provide certain types of support to inspectors and liaise with industry and other stakeholders. In addition to these activities which came into play "downstream" for provisions already adopted, the unique expertise of the Forum is called to contribute to the quality of provisions still to be adopted through the Forum's upstream advice on enforceability of restrictions proposals.

The formal structure of the Forum is further described in [Title 9]. While ECHA has no direct enforcement responsibilities, it does have a number of tasks that at first sight appear to be enforcement, and in particular the completeness check and compliance check of the registration dossiers. ECHA may indicate to Forum members issues of concern and stimulate Member States to undertake enforcement actions to ensure compliance with REACH. The Commission services welcome the initiative of ECHA to inform Forum members on enforcement issues of concern (for example in case of QOBL or registration of intermediates). The Commission services encourage ECHA to establish a more systematic and regular information exchange on enforcement issues between the Forum and other parts of ECHA.

The Forum conducts many of its activities through Working Groups addressing particular enforcement issues; until now 14 such working groups have been set up and benefit from the strong commitment of the vast majority of Member State enforcement authorities.

The Forum requires national enforcers, some of whom had no previous experience with coordination work at the EU level, to discuss with their counterparts in other Member States and jointly come to harmonised projects and strategies, thus increasing consistency in REACH implementation across the European Union. So far the Forum's work appears to have had limited influence on the practice in Member States with strong traditions of chemical legislation enforcement, but it appears to be bringing real added value in others. Workload appears an issue for all members, who conduct their Forum work on top of their "day jobs".

Since its formation, the Forum has developed several documents illustrating its approach of enforcement. The main ones are:

- the strategies for enforcement of REACH and CLP;
- the minimum criteria for REACH and CLP inspections;
- the documents related to Forum's EU/EEA EFTA harmonised enforcement projects (REACH-EN-FORCE projects) to check compliance with REACH.

To ensure proper cooperation and information exchange between national CAs and national enforcement authorities, the Forum has established a working group to analyse the interlinks between ECHA, CAs and national enforcement authorities for the different REACH processes. The Commission services welcome and encourage the Forum initiative on this important issue.

The Forum's workload is increasing and its members should receive full scientific, technical and administrative support from Member States. Further prioritisation efforts of enforcement and inspections across the European Union is needed in order to target the limited resources of national enforcement authorities and maximise the benefits from compliance activities.

The work already performed by the Forum is highly appreciated by the Commission and CAs. The Commission services are encouraging the Forum to further strengthen its efforts and focus on delivering its core tasks, which are pursuing harmonised enforcement projects, joined inspections, exchange of inspectors and practical help to local inspectors. The Forum should also consider facilitating exchange programmes between Member States to allow for the dissemination of best practice and increase harmonisation of enforcement activities.

### **Information exchange on enforcement**

The key element of coordination of enforcement activities within and between Member States is the exchange of information. For this the Forum and the Member States have developed different systems. Some examples are:

- The information in REACH-IT databases, e.g. on companies and substances, is needed for enforcement purposes. For this reason, in June 2011 ECHA established a REACH information portal for enforcement authorities (RIPE) containing a selection of the most essential information for the purpose of enforcement. Before RIPE was operational, some enforcement authorities had significant difficulties in the planning and execution of their duties because of lack of a direct access to relevant data. Currently almost all Member States (except two) have access to the REACH-IT system and can use it e.g. for enforcement activities.
- Ten CAs reported receiving enforcement referrals from other Member States. However, in each case these were few in number.
- The most common mechanism used to share information (formal or informal) within Member States is the organisation of meetings between CAs and national enforcement authorities (e.g. Austria holds two per year). Furthermore, many CAs provide oversight to the activities of the enforcement bodies and most CAs provide training. The Commission services recommend sharing these practices among other Member States.

- Information exchange on products posing a serious risk within Member States and between Member States is also ongoing via the notification by the authorities under the Community Rapid Information System for non-food dangerous products (known as “RAPEX”), as required under Regulation (EC) No 765/2008<sup>180</sup>.

## **Enforcement activities**

### Enforcement strategies

A proper enforcement strategy should allow the enforcement activities to be most effective, i.e. providing for the greatest output with regard to compliance by using the same amount of Member States resources. The Forum developed in 2008 a document on enforcement strategy concerning REACH and subsequently updated it (in 2011) to incorporate the CLP requirements as well.

In their Article 117(1) reports, 24 of the 30 Member States indicated that they had (an) enforcement strategy(ies) that were in line with those devised by the Forum. Six national enforcement strategies were not fully in line but two were very close to it and one was reported to be revised to meet the Forum strategy. Each Member State enforcement strategy was unique so as to better fit with different administrative structures and based on their own experience from enforcing chemical legislation.

The Commission services consider the enforcement strategies would become more effective by giving priority to assessing compliance of the exposure scenarios, information in the supply chain (safety data sheets) and substances in articles. This would allow enforcement authorities to assess compliance with registration, authorisation, restriction and classification and labelling requirements.

The information generated by the different REACH requirements can be relevant in the enforcement of other EU legislation, including worker health and safety, industrial pollution control, product requirements, market surveillance and customs. Therefore, to improve efficiency of enforcement, the combination and/or coordination of REACH enforcement activities with those under other EU legislation should be considered. This approach is also confirmed by the recent study on inspection requirements for REACH and CLP<sup>181</sup>.

### Inspections and investigations

For reporting purposes Member States were asked for data on the number of inspections or investigations undertaken during 2007, 2008 and 2009 “*in which REACH was discussed or enforced*”. However, it was clear that Member States use inspections and investigations in very different ways within their overall enforcement strategies and the Member States reports showed a high degree of variation between

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<sup>180</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30.

<sup>181</sup> Study “*Inspection requirements for REACH and CLP*”, Millieu Ltd, commissioned by the European Commission, 2012.

them. Some Member States undertook tens of thousands of such actions per year and others undertook less than ten, regardless of the size of the Member State. It would appear likely that different Member States have different interpretations of the scope of investigations.

Furthermore, a lack of consistency in the answers given to Article 117(1) questionnaires showed that it was not possible, e.g., to carry any type of statistical analysis on the inspection burden to duty-holders of different types and sizes. However, from the most recent data available (2009), the main focus for inspection activities up to that time would appear to have been on small and medium-sized enterprises (SMEs). For all these reasons, the Commission services see as a priority the development of European REACH Enforcement Indicators which would help to better know how REACH is implemented, help the Forum in fulfilling their tasks and help Member States in fulfilling their reporting obligations. For this exercise, the Forum can play an important role.

The REACH-EN-FORCE-1 (REF-1), a Forum harmonised enforcement project, found that approximately 4% of the companies inspected were not complying with their registration requirements. Furthermore, the Forum reported that 9% of companies did not have safety data sheets available for inspection while the safety data sheets provided by 16% of companies did not meet the requirements prescribed for safety data sheets. Overall, the Forum found that 20% of companies were not in full compliance with the obligations checked in REF-1. The ongoing REF-2 harmonised enforcement project is focusing on the obligation of downstream users – formulators of mixtures. The scope of the planned REF-3 project will include the registration obligations for importers, manufacturers and only representatives (ORs) as well as close cooperation with customs and compliance of ORs with their duties. The Commission services are of the view that all Member States should participate in and report to these harmonised enforcement project.

Also with regard to restrictions under REACH, it is to be noted that the enforcement activities varies among Member States, which reflects the different priorities of Member States authorities with regard to certain restrictions over others. In the Commission services' view, Member States should further improve prioritisation of enforcement actions, exchange of information among enforcement authorities and cooperation with customs. These findings are confirmed by the recent Commission study on enforcement of restrictions<sup>182</sup>.

### **Sanctions**

The Article 117(1) reports and the findings of the harmonised enforcement projects of the Forum (REF) describe a wide range of enforcement sanctions that are available to national enforcement bodies. This includes the prohibition to a company to place its products (substances, mixtures or articles) on the market, large fines and/or prison sentences, and the confiscation of illegal goods for those found guilty of breaching

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<sup>182</sup> Study “*Implementation and enforcement of restrictions in Member States*”, Milieu Ltd, commissioned by the European Commission, 2012.



a(some) provision(s). Enforcement actions and possible sanctions are assessed on a case-by-case basis.

The Member State systems typically describe a mixture of administrative and criminal measures available to their enforcement authorities but some enforcement bodies have only administrative measures available. The punitive measures described above are typically preceded by non-punitive measures designed to bring companies into compliance.

### **Stakeholders**

Stakeholders, at a first instance, can approach their Member State enforcement authorities to discuss their concerns. Furthermore, they can regularly attend Forum meetings where they can bring enforcement issues for discussion at the EU level. Duty-holders have the possibility to address, as well, their national REACH and CLP helpdesks which also have their regular meetings in ECHA. Furthermore, the Commission and ECHA regularly organise conferences or ad-hoc meetings for stakeholders where enforcement issues are also discussed (for example, the Commission Conference on REACH and CLP Enforcement held in Brussels on 1 March 2012).

The survey on industry<sup>183</sup> found that 45% of companies had as yet no experience of REACH inspection or enforcement. The remaining companies were positive overall regarding their experience of such activities by regulators.

Stakeholders commented on the significant differences in approach between Member States with regards to inspection requirements, penalties and the role of customs, without specifying the degree and experienced impacts of these differences. The Commission services are closely following these issues and addressing the appropriate issues at the appropriate level. Comments were also received regarding the lack of resources for inspection and/or enforcement available to authorities in some Member States.

### **Conclusions**

A strong and harmonised approach towards enforcement of REACH throughout the EU/EEA EFTA is vital for delivering its objectives. The enforcement of REACH lies with the Member States. In order to enable REACH to operate effectively in practice, Member States are obliged to establish the necessary arrangements for its implementation.

The practical arrangements for enforcement vary between one Member State to another, allowing Member States to operate the system that best fits with their administrative structures or legal cultures. Enforcement authorities typically have a mixture of administrative and criminal measures at their disposal.

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<sup>183</sup> CSES was commissioned by the Commission to conduct an industry survey with the aim to study industry impacts of REACH. More than 1500 companies participated in the survey which ran over the period of July to September 2011.

The coordination of enforcement activities within Member States in order to integrate other EU legislation is considered essential to maximise the effectiveness of the existing resources.

The work already performed by the Forum has shown that the Member States found this network very useful. The Commission services encourage Member States to enhance their support to Forum members by providing full scientific, technical and administrative assistance. Further prioritisation of enforcement and inspections across the EU is needed to focus the limited resources of national enforcement authorities in order to achieve the most benefits as regards compliance and objectives of REACH. The Forum is encouraged to further strengthen its efforts and focus on delivering its core tasks, which are pursuing harmonised enforcement projects, joined inspections, exchange of inspectors and practical help to local inspectors. The Forum should also consider facilitating exchange programmes between Member States to allow for the dissemination of best practice and increase harmonisation of enforcement activities.

Despite the fact that according to the reports available, Member States are undertaking their tasks entirely, and in most of the cases through common strategy(ies), a harmonised enforcement of REACH across Member States continues to be a challenge.

More consistent and comparable data from Member States on implementation of REACH would allow having better overview and assessment of the actions to be taken. The Commission services consider that it will therefore assume a yet stronger overview role in the development, use and analysis of the European enforcement indicators, thus leading to a more in-depth examination of meeting the requirements set up by REACH.

<b>Recommendations</b>
11.1 Member States should further focus their inspection/enforcement activities across the EU to target limited resources where most benefit is to be expected.
11.2 Member States should improve coordination of their inspection and enforcement activities under REACH/CLP and other EU legislation.
11.3 Enforcement indicators will be developed in liaison with the Forum. This will help to a) have better knowledge of the implementation of REACH, b) Forum to better fulfil their activities and c) achieve a more harmonised and systematic approach concerning the collection of information and reporting.
11.4 The Member States should consider the Forum as a single point of discussion, collation and compilation of information on REACH / CLP enforcement activities.
11.5 ECHA is invited to make more systematic use of information from all relevant ECHA activities to better enable targeted enforcement activities by the Member States.

## 12. INFORMATION

*Through ECHA's dissemination activities the world is being transformed into "a world of a lot of knowledge on chemicals." However, it took time for ECHA to get to this stage.*

### **ECHA's dissemination activities**

REACH is designed to lead to an unprecedented level of collection and generation of information on chemical substances. Compiling a registration dossier and sending it to ECHA does not mean that the information is buried in a data cemetery, only to be mined if and when the desire or need of Competent Authorities, ECHA or Commission arises. As explained in [Titles 2 and 6], the information is to lead to better management of chemical risks by registrants and downstream users themselves in the first place. In addition, however, REACH aims to provide EU citizens with free and easy access to basic data on chemicals held in ECHA's database, so as to allow them to make informed decisions about their use of chemicals (recital (117)). Article 119 of REACH lists the information to be published by ECHA; in the case of information listed in Article 119(2), companies can make justified requests for the information not to be published. Information listed in Article 118(2) is not published by ECHA, but can be disclosed when urgent action is essential to protect human health, safety or the environment. PPOD information is not published under Article 9(9).

In the first years of ECHA's operation, its website was not generally perceived to be user-friendly. It was criticised for lacking clarity in the routing, making it sometimes difficult to find documents fast, and for its limited search facilities<sup>184</sup>. The ECHA website was revamped towards the end of 2011<sup>185</sup>, improving its transparency and accessibility.

ECHA's current website ([www.echa.europa.eu](http://www.echa.europa.eu)) has different tools and facilities to search for information on substances. The public database on registered substances was launched in December 2009<sup>186</sup> and allows searching for substance properties and other information from registration dossiers. As per 16 March 2012, information on 4 326 substances could be consulted<sup>187</sup>. The Classification and Labelling Inventory foreseen by Article 42 of CLP took longer to publish than expected, including by ECHA itself<sup>188</sup>, and this raised concerns, but since February 2012 it is available for searching. Data on candidate list substances in articles can be consulted as well, and

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<sup>184</sup> Study "Review of the European Chemicals Agency", PwC, commissioned by the European Commission, p. 25 and 35.

<sup>185</sup> *The Operation of REACH and CLP 2011*, European Chemicals Agency, 2011, p. 24.

<sup>186</sup> *Idem*, p. 22.

<sup>187</sup> Current registration figures are available on ECHA website ([www.echa.europa.eu](http://www.echa.europa.eu))

<sup>188</sup> Study "Review of the European Chemicals Agency", PwC, commissioned by the European Commission, p. 41.

is based on notifications submitted under Article 7(2) of REACH and on registration dossiers.

In addition to the dissemination of basic data on chemicals, there are also publication activities as part of ongoing REACH processes. The list of pre-registered substances was made available at the end of 2008, in accordance with Article 28(4); see also [Title 6]. Consultations through publication of testing proposals according to Article 40(2) are part of the dossier evaluation process; see also [Title 4]. The first CoRAP was published on 29 February 2012 in accordance with Article 44(2), launching the first substance evaluations as further detailed in [Title 7]. Three recommendations for priority substances to be included in Annex XIV were published so far under Article 58(4) and the publication of the candidate list itself is regularly updated in accordance with Article 59(4); see also [Title 8]. Notices regarding the preparation of Annex XV dossiers are published in accordance with Article 59(4) for authorisation, Annex XV dossiers are published in accordance with Article 69(6) for restriction, as are proposals for harmonised classification and labelling under Article 37(4) of CLP<sup>189</sup>.

ECHA also publishes information to assist companies in the fulfilment of their obligations under REACH. The results of the screening highlighted in [Title 6], which aimed at gaining an overview of substances intended to be registered by the 2010 deadline to enable planning of downstream users (DUs), were made available before the 2010 registration deadline. Similarly, a list of substances identified for registration by 31 May 2013, compiled based on responses from individual companies to a survey, is available for consultation so as to allow planning of manufacturers, importers and DUs towards this upcoming deadline. Finally, ECHA also publishes the Registry of Intentions, the role of which is further discussed in [Titles 2, 5 and 9], not only to facilitate timely preparation of interested parties for commenting in the later stages of Annex XV dossier preparations, but also to avoid duplication of work and encourage coordination between Member States.

The Commission services welcome the progress made in ECHA's dissemination activities and encourage ECHA to continue finding new and improved ways to deliver transparency on chemicals information, so as to benefit all stakeholders – consumers, the general public, industry and downstream users alike.

### **Policy about information published on ECHA's website**

Publishing large amounts of information related to chemical substances entails a risk that the publication of some of that information might be detrimental for the submitting company, as it is sensitive from a commercial or intellectual property viewpoint. On the other hand, there is an interest for society as a whole, including many companies that information is made publicly available. The inherent tension between both interests, that of confidentiality and that of transparency, led to discussions during the legislative process and resulted in the wording of Articles 118 and 119, as well as references to them in several other articles of REACH (e.g.,

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<sup>189</sup> Before the adoption of CLP, the format for such proposals was outlined in Annex XV to REACH. Accordingly, these proposals are also commonly referred to as “Annex XV dossiers”.

Articles 64(2), 69(6) and 77(2)(e)). The application of Articles 118 and 119 has raised various issues in practice.

First of all, several interpretation questions have been clarified: (1) The name of the registrant can be published by ECHA, unless a justified confidentiality request has been made and accepted, as the registrant's name is contained in the safety data sheet (SDS) and thus falls within the remit of Article 119(2)(d). (2) ECHA, when dealing with confidentiality requests regarding the registrant's name, must duly take into account any use made of the possibility to omit the part of the registration number referring to the individual registrant in the SDS. (3) If a third party representative was appointed pursuant to Article 4 of REACH, ECHA has no discretion to refuse confidentiality requests regarding the registrant's name. (4) Article 119(2)(b) requires the publication of the sum of the individual tonnages for which registration dossiers have been submitted, expressed as tonnage band. (5) Confidentiality requests regarding tonnage data to be omitted from the publication of the total tonnage band are to be assessed case-by-case, but are likely to succeed when the company requesting confidentiality is the only registrant for a given substance or, depending on the market structure, when there are a limited number of registrants.

Secondly, issues related to confidentiality of and access to information generated an unexpectedly high workload for ECHA<sup>190</sup>. Rules needed to be defined to decide which of the fields in a IUCLID dossier could be made available on the internet, and manual intervention for publication was needed until March 2011, when automated dissemination was achieved<sup>191</sup>. By March 2011, ECHA had received some 1 300 confidentiality requests foreseen by Article 119(2), all of which ECHA aimed to assess by the end of 2012. ECHA's Management Board adopted in 2008 a Decision establishing remedies for reviewing rejections of confidentiality requests pursuant to Article 118(3) of REACH<sup>192</sup>. In addition, a strategy was developed and implemented to ensure that, in cases where the IUPAC name of the substance is kept confidential under Article 119(2)(f) and (g), a suitable "public" name for the substance is provided by the registrant to allow dissemination of substance information and consultation on testing proposals.

Non-industry stakeholders are reported to perceive ECHA as too stringent when it comes to releasing registrants names for dissemination purposes<sup>193</sup>. The Commission services believe that as long as the clarification of the related interpretation questions was pending, the approach taken by ECHA was the correct one under the circumstances, and takes note of the fact that ECHA is now working in accordance with the clarification provided. Non-industry stakeholders moreover are reported to believe that ECHA is too cautious when it comes to confidentiality of company data

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<sup>190</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 78.

<sup>191</sup> *Idem*, p. 22.

<sup>192</sup> Document MB/17/2008, amended by MB/17/2011 [available on [www.echa.europa.eu](http://www.echa.europa.eu)]

<sup>193</sup> Study "*Review of the European Chemicals Agency*", PwC, p. 25 and 42; note that the cut-off for the review period was and 2010, when interpretations questions (1) to (3) were not yet resolved.

and is not evaluating all confidentiality requests made due to resource constraints, but the Commission services found no evidence substantiating this claim<sup>194</sup>. The Commission services note ECHA's intent to assess by the end of 2012 all 1 300 confidentiality requests received by March 2011.

The Commission services note that significant progress has been made and encourages ECHA to continue on its path of dissemination and transparency, while taking due notice of the various interests to be balanced as laid down in Articles 118 and 119 of REACH.

### **Cooperation with OECD and third countries**

International co-operation on REACH remains an important component of the EU's work.

At the multilateral level, the main focus has been on strengthening cooperation with the OECD<sup>195</sup>. The Commission, in association with the OECD, has further developed the International Uniform Chemical Information Database (IUCLID) enabling the exchange of data on intrinsic and hazard properties of chemical substances. IUCLID is the key data exchange tool under the OECD's Cooperative Chemical's Assessment Programme. In addition, ECHA has cooperated closely on two major OECD projects, namely the eChemPortal (Global Portal to Information on Chemical Substances) and the QSAR Toolbox. The Portal now provides free public access to information on chemical substances (including those published on ECHA's website). This is a significant contribution to identify and make information on chemical properties available to citizens. The QSAR Toolbox ensures that (Q)SAR technology is readily accessible, transparent and less demanding in terms of infrastructure costs. It fills gaps in the (eco)toxicity data needed for assessing the hazards of chemicals and provides a common framework for the chemical industry (see also [Title 4]). Cooperation with the OECD extends beyond project development to include also participation in the implementation of the OECD Programme on High Production Volume Chemicals.

At bilateral level, much investment has been made to increase the knowledge and understanding of REACH. Numerous meetings and workshops have been convened within and outside the EU in an effort to ensure that candidate countries, potential candidate countries and countries within the European Neighbourhood as well as third countries are informed about REACH implementation. In addition, several visits are organised annually in Brussels and Helsinki involving third country governments, industry representatives and academia. REACH has also frequently been on the agenda of EU bilateral high-level meetings (Australia, Brazil, Canada, China, Japan, India, Russia and USA), while every effort has also been made to address third country concerns in other fora (notably WTO-TBT meetings).

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<sup>194</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 47.

<sup>195</sup> Organisation for Economic Co-operation and Development.

In recent years ECHA has further extended bilateral scientific and technical cooperation. It signed Statements of Intent with Japan and the United States and Memorandums of Understanding with Canada and Australia.

<b>Recommendations</b>
<p>12.1. ECHA is encouraged to continue finding new and improved ways to deliver transparency in chemicals information to the benefit of all stakeholders, while taking due notice of the various interests to be balanced as laid down in Articles 118 and 119.</p> <p>12.2. ECHA is encouraged to continue its fruitful cooperation with the OECD. ECHA is also invited to assess its general international activities taking into account its broader commitment and the added value of its involvement and the international activities undertaken by the EU. Where justified ECHA should consider reassigning the related resources to other commitments.</p>

## Part II.

# ACHIEVING REACH OBJECTIVES

### 1. HUMAN HEALTH AND ENVIRONMENT

#### 1.1. Background and Introduction

The EU industrial chemicals *acquis* started in 1967 and grew over the decades into a system of Directives and Regulations. In the late 1990s it was recognised that existing chemicals legislation needed to be improved to address the growing concern for the negative impacts chemicals had on human health and the environment. REACH was adopted in 2006 replacing the previous regulatory system where one of the objectives was to ensure a high level of protection of human health and the environment. The appropriate implementation of its provisions are also the key elements of the EU's commitment towards the implementation plan adopted at the 2002 World Summit on Sustainable Development (WSSD) which aims to achieve that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects on human health and the environment.

The REACH objective of *Environment and Health Protection* was to be achieved by identifying suitable risk management measures based on a systematic collection or generation of information on the hazards of chemicals, including testing. For substances at or above 10 tonnes registrants must perform a chemical safety assessment to check if additional risk reduction measures are necessary, beyond those required by the hazard classification. Through registration the registrants confirm the implementation of the necessary risk management measures and document their decisions. This comprehensive approach would not only improve the control where this was needed, it would also identify those substances which needed no further or even less controls. The REACH **restrictions** process was designed to control risks which were not adequately controlled by measures already in place. The cumulative result of industry and authority risk management measures are expected to reduce the risks to the environment and human health, including workers, consumers and the general public via the environment. The **authorisation** process aims at assuring that risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by less dangerous alternative substances or technologies where these are economically and technically viable.

Protection of human health and the environment, including wildlife, should be balanced against the **use of animals in laboratory experiments**. Therefore, REACH provides for promoting the development of alternative methods for the assessment of hazards of substances.

The health and environment objective of REACH is expected to be achieved through (1) better knowledge on the properties and uses of chemicals which results in better safety and control measures, reducing exposure and hence, the negative impacts on human health and the environment; and (2) the use of less dangerous alternatives to those substances of very high concern.



In 2003, the Commission carried out an impact assessment of its REACH proposal, where potential health and environment benefits were assessed<sup>196</sup>.

First, it concluded that the main benefits of REACH arise from the application of appropriate **risk reduction measures** – by industry in the first instance and mandated by authorities in the second - enabled by a systematic generation of information on hazards and uses of chemicals.

Second, the impact assessment provided an illustration of the potential scale of the expected long term health benefits due to these risk reduction measures. It was anticipated that the positive effects of REACH on public health would start to occur 10 years after the start of REACH implementation, i.e. effectively from 2018, and would be fully observed after another 20 years, with total health benefits due to REACH in the order of magnitude of € 50 billion over the 30 years period (after discounting). The long-term benefits of REACH on the environment were estimated by another study to be up to € 50 billion over the 25 years period (after discounting)<sup>197</sup>. Notwithstanding the methodological difficulties the overall conclusion was that the benefits of REACH far outweighed the costs.

The studies launched by the Commission in the framework of this review have confirmed that 5 years after the entry into force of REACH, it is still too early to quantify human health and environment benefits. This review therefore looks at initial trends based on the examination of qualitative information and a representative set of quantitative indicators<sup>198 + 199</sup>.

Assessment of the degree to which the health and environmental objectives of REACH have been achieved started with the identification of the drivers of benefits within REACH, where these are the set of legal provisions which are expected to trigger direct or indirect human health and/or environmental benefits; and the enhancers of these drivers, which are those provisions that help to realise the benefits through support, control and enforcement and thus assist or ensure compliance with the main obligations.

The Commission reviewed those key drivers which are already operational and of particular relevance to the generation of human health and environment benefits, namely registration, requirements concerning information through the supply chain, authorisation and restrictions. The key enhancers of these benefit drivers (dossier

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<sup>196</sup> Commission Staff Working Paper, [REACH] *Extended Impact Assessment*, 29.10.2003 {COM(2003)644 final}.

<sup>197</sup> Study “*The impact of REACH on the environment and human health*”, DHI, commissioned by the European Commission, September 2005.

<sup>198</sup> Indicators reported on by the *REACH Baseline Study: 5 Years Update, Progress Report IV*, Oeko-Institut, FoBiG, DHI and INERIS, commissioned by European Commission - Eurostat, December 2011.

<sup>199</sup> Study “*Assessment of health and environmental benefits of REACH*” RPA, commissioned by the European Commission, April 2012.

evaluation, provision of guidance, inspections and enforcement activities) were also looked at. It is also important to note that a number of key drivers were not considered in this review as they have only just started or are still to come (e.g. registration deadlines of 2013 and 2018, substance evaluation in 2012; first applications for authorisation in 2012).

## 1.2. Registration

Registration under REACH requires collection, generation and assessment of hazard and exposure data, risk assessment and the identification of risk management measures to ensure the safe use of chemicals. In particular, the following elements are the key drivers for the control and reduction of harmful impacts on human health and the environment:

- The preparation of Chemical Safety Assessments (CSAs) for substances which have hazardous properties should create benefits through a reduction in unsafe use.
- The systematic collection of data and, where necessary, the generation of new (test) data should lead to improved information on the properties of chemicals, improved reliability of classifications and thus improved information on safe use and handling. It should also improve the information base for the implementation and enforcement of other legislation.
- The requirement to carry out a PBT assessment<sup>200</sup> as part of the CSA should help ensure that substances are identified as potential SVHC and can be made subject to more detailed evaluation, authorisation or restriction.
- The requirement to register substances will create benefits for human health and the environment where a substance is no longer supported by registrants due to its hazardous properties as well as the availability of suitable alternatives, and is therefore withdrawn from the market.

In addition, the evaluation of dossiers should act as an enhancer of benefits if it helps registrants to learn how to improve their registration dossiers. Guidance should also act as an enhancer by providing tools for assessing safe use. Similarly, inspection and enforcement should act as enhancers by ensuring there is an incentive to comply with the registration provisions.

From work carried out specifically for the REACH benefits study<sup>201</sup> on a sub-set of 71 substances being reviewed as part of the REACH baseline study, it is clear that the information being generated from REACH is resulting in changes in classification, with the majority of these being more restrictive classifications. This is particularly

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<sup>200</sup> Assessment of persistency, bioaccumulation and toxicity of substances.

<sup>201</sup> Study “*Assessment of health and environmental benefits of REACH*”. RPA, commissioned by the European Commission, April 2012.

noticeable for endpoints such as acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity. Overall, the percentages classified after registration increased across all of the endpoints being considered. This suggests that classifications are becoming more reliable as more and improved information on substances properties is generated and as registrants harmonise classifications. These findings are important as classifications drive the need for the development of exposure scenarios within the CSA and, in response to these, for registrants to put forward recommended risk management measures in their extended safety data sheets (eSDS). There are some outstanding issues, such as the continued existence of multiple self-classifications which is giving rise to problems for formulators, but these should reduce over time as more substances go through registration.

With respect to the duty to prepare a CSA, the findings<sup>202</sup> confirm that this should lead to safer use as new or more stringent risk management measures than those currently in place are being recommended by registrants to their downstream supply chains. This should lead to benefits for workers, to the environment (through reduced emissions) and to the general public through reductions in environmental exposures, particularly as the substances produced and/or imported in less than 1000 tonnes per year go through registration.

With regard to substance withdrawal, there is evidence that substances have been “dropped” from the market or otherwise not registered due to their properties (in particular CMRs<sup>203</sup>) and/or the potential costs of supporting them through authorisation as well as registration<sup>204</sup>. It is also clear though that substance withdrawal may be taking place as part of the rationalisation of product portfolios. The exact extent to which substances that have been withdrawn are replaced by a less hazardous alternative is not known at this stage of REACH implementation but it would be worth investigating in future research in order to avoid unwanted withdrawal of substances that would lead to no additional benefits to human health and the environment.

There is a need for all actors to increase efforts to improve the quality of registration dossiers. The quality of information submitted by industry in registration dossiers has indeed been identified by ECHA<sup>205</sup> as being of concern, leading to many dossiers being found non-compliant or whose quality should be improved, as already described in [**Title 6 of Part I**]. An analysis of a sub-set of registered substances also suggests that registrants have not fully responded to the need to provide a clear assessment of PBT and vPvB properties. A preliminary conclusion is that bringing the registration dossiers already submitted into compliance is a priority. An appropriate scrutiny is likely to become even more important in the next registration phases, as in the past the

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<sup>202</sup> *Idem.*

<sup>203</sup> Carcinogenic, mutagenic, toxic for reproduction.

<sup>204</sup> Study “Assessment of health and environmental benefits of REACH”. RPA, commissioned by the European Commission, April 2012, .

<sup>205</sup> *Evaluation Under REACH, Progress Report 2011*, European Chemicals Agency, 2012

lower volume substances had generally less data available on their properties than those registered in the first phase. It is therefore evident that without increasing industry efforts with respect to the fulfilment of the REACH registration requirements, as well as ECHA and Member States not ensuring the compliance with legal requirement through the dossier evaluation and the enforcement inspections, the fulfilment of the health and environmental objectives of REACH will be jeopardised. The Commission services in liaison with ECHA will gather further practical evidence on how to provide the best possible basis for the identification of substances and determination of "sameness". This will take into account experience gained from the current registration dossiers. Once there is a solid evidence basis the Commission may come forward with a proposal which could be legal measures, such as for instance implementing legislation on the identity of substances, in order to improve the compliance with REACH requirements.

Finally, it has to be noticed that the monitoring of REACH performance carried out by Eurostat<sup>206</sup> relating to the quality of the data publically available for chemicals assessment, for the substances already registered, shows a marked increase in the quality of available data if compared with the pre-REACH situation.

### **1.3. Requirements concerning information in the supply chain**

Effective supply chain communication is essential for the functioning of REACH both in terms of registrants relying on information for the assessment of risks and of downstream users relying on good information to implement safe use. Manufacturers and importers of hazardous substances are required to provide hazard, exposure and risk management information to their recipients, primarily via the eSDSs. In addition, suppliers of articles containing chemicals identified as SVHCs have obligations (under Article 33) to provide information down the supply chain and to consumers, to enable the safe use of those articles.

For these provisions, the health and environmental benefits are generated through three main mechanisms:

- The communication of information through SDS and eSDS creates benefits because new information is passed to downstream users enabling them to check their handling and use of chemicals.
- The requirement to communicate information upstream on operating conditions or risk management measures (RMM) creates benefits because new and appropriate RMMs are identified and included in updated safety assessments and the overall quality of SDS is improved.
- The need for article producers to communicate the presence of a SVHC on the candidate list in an article leads to benefits by helping to ensure the safe use of articles, triggering requests from retailers for the phase-out of SVHCs in articles,

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<sup>206</sup> *REACH Baseline Study: 5 years update. Contribution to the Report of the Commission*, European Commission – Eurostat, 2012.

and enabling consumers to take the presence of an SVHC into account in their purchasing decisions.

The findings of the Commission services confirm that the new obligation on registrants to set out safe operating conditions (OCs) and RMMs as well as to provide such information to downstream users have already generated benefits during this first phase but is likely to be even more important for those substances about which there is currently less knowledge.

Additionally, the monitoring activities conducted by Eurostat on reference substances show a marked decrease in the nominal risk associated with those already registered, due largely to REACH<sup>207</sup>.

With respect to the quality and value of SDS and eSDS, the findings are twofold. The quality of SDSs have improved because the information on classification (and hence labelling) contained within them is regarded as more reliable. In addition, the information being provided on DNELs<sup>208</sup> is useful for workplace safety assessments (as a substitute for an OEL<sup>209</sup>) and can contribute to better targeted RMMs. However, there are problems with regard to the content and format of eSDS as currently being provided in supply chains.

Formulators have an essential role in supply chain communication with regard to the information on safe use, because they have to provide their safety data sheet in a way that it gives orientation to the downstream user on what to actually do. It has been reported that both suppliers of substances and formulators of chemical mixtures compile large amounts of information in their eSDS which sometimes leads to confusion. Hence, there is a need for ECHA, in cooperation with industry, to progress their work on CHESAR<sup>210</sup> and derive from that the core information structure for communication on uses in order to facilitate respective supply chain communication. Structures such as CHESAR should be used by industry to develop their software tools to provide safety data sheets. There is also a need for a revised format of the exposure scenario for supply chain communication which should be provided in a standardised IT format.

Industry continues working on standard phrases for conditions of use and RMMs. However, it appears that more commitment is needed. Downstream users should be encouraged to provide information on conditions of use in ECHA information structure in a targeted way.

At the same time, players at the bottom of the supply chain, such as article producers, have still already benefited from an increased level of knowledge on the properties

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<sup>207</sup> *Idem*

<sup>208</sup> Derived No-effect Levels

<sup>209</sup> Occupational Exposure Level

<sup>210</sup> CHEmical Safety Assessment and Reporting tool

and/or the possible uses of chemical substances. This can only have been the result of supply chain communication requirements. The same is true for end-users, who confirmed through the surveys conducted under this review that REACH has increased their level of knowledge on the properties and/or the possible uses of chemicals.

With respect to communication on SVHCs through the supply chain, substitution would be promoted through the “announcement effect” associated with the candidate listing of SVHC and the duty to provide information on SVHCs in articles contained in concentrations above 0.1% to users of articles. Indeed, the candidate listing is leading to an early action towards substitution by formulators and demands for substitution within their supply chains by article producers. Thus, it could be expected that the use of SVHCs will gradually reduce, particularly in consumer goods.

Article producers and retailers are putting in place the necessary information systems to manage the necessary supply chain communication and in particular to undertake the necessary compliance checks through product and supplier inspections. It is important that these efforts are intensified to avoid supply disruptions as the candidate list grows in size.

One of the problems identified relates to the 0.1% concentration threshold for SVHC present in articles. These are addressed in greater details in [Title 5] of Part I.

#### **1.4. Authorisation and restrictions**

The authorisation provisions within REACH are aimed at ensuring that 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 identification of SVHCs is a hazard based concept, although the prioritisation of SVHCs does take into account factors such as production volumes and whether there is wide-dispersive use of the substance as proxies for potential risks.

REACH also includes a separate provision allowing restrictions on the manufacture (or import), placing on the market and/or on specific uses of either a substance, mixtures and/or articles (subject to some exemptions), where these can be shown to pose an unacceptable risk to human health or the environment that should be addressed on an EU-wide basis. The restriction provisions are not dissimilar to those established under the earlier combination of Regulation (EC) No 793/93 and Directive 76/769/EEC. However, the restriction process under REACH is expected to speed up the time taken for measures to be adopted and implemented as well as to allow for more targeted assessments.

At the time of writing, 82 substances had been entered onto the candidate list, with 36 substances prioritised for authorisation. From the information obtained in this review, it is clear that Annex XIV and candidate listings are having their desired effect:

substances placed on the lists are being withdrawn from use and downstream users are moving to substitutes where possible<sup>211</sup>. Thus, this process is beginning to deliver benefits associated with removals of SVHCs from use in the EU. As anticipated, substance withdrawal is taking place because some manufacturers and importers are reluctant to register a substance that may be subject to Authorisation, which would lead to further costs associated with having to make applications for continued use.

Although an important increase in the number of substances included in the candidate list in 2011 and 2012 has been observed, there is still a need for more effort to achieve the target proposed by the Commission. This is that all relevant currently known SVHCs will be included in the candidate list and so contribute to the 2002 WSSD goal that, by 2020, chemicals are produced and used in ways that do not lead to significant adverse effects on human health and the environment. This suggests that inadequate resources are provided to maintain the candidate list process. The Commission is striving to mobilise efforts in Member States to achieve the long-term objective as well as a mid-term target of 136 SVHC on the candidate list by end of 2012.

Achieving these targets should also be seen in the context of the Roadmap to a resource-efficient Europe which was adopted by the Commission on 20 September 2011<sup>212</sup>. The roadmap sets an agenda for competitiveness and growth based on using fewer resources when we produce and consume goods and creating business and job opportunities from activities such as recycling, better product design, materials substitution and eco-engineering. Phasing out and substituting dangerous chemicals with safer alternatives can help protect key resources like soil and water, and make others, like materials, safer, easier and less costly to recycle and reuse.

On the other hand, a need for increased transparency in the judgements underlying the decision-making of Member States and the Commission when deciding which chemicals should have dossiers prepared and then which should be the ones prioritised has been reported. Further explanation and justification could, therefore, help address this issue and build understanding and trust between the regulators and the regulated.

Moreover, there have been concerns reported that potential substitutes to SVHC listed already on the candidate list may not necessarily be better from a human health or environmental perspective. In this respect, groups of substances with similar properties should be considered together when assessing substances for entry onto the candidate list to avoid downstream users of these chemicals shifting to unsuitable alternatives. There may also be a role here for ECHA in undertaking work to help identify substitutes, following listing or for other types of support to be given to smaller companies.

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<sup>211</sup> Study “Assessment of health and environmental benefits of REACH”. RPA, commissioned by the European Commission, April 2012.

<sup>212</sup> *Communication from the Commission [...] Roadmap to a Resource Efficient Europe*, European Commission, 20.9.2011, {SEC(2011) 1067 final},

Under REACH, four dossiers concerning risks to human health and the environment were proposed by Member States, Norway and ECHA (dimethylfumarate, lead in jewellery, mercury in measuring devices and phenylmercury compounds) and the Commission will adopt restriction measures and amend Annex XVII.

Other Annex XV dossier for restriction proposals have been submitted to ECHA, mainly targeting human health concerns. These target the use of chromium (notably an allergic and irritant substance) in leather articles and the use of phthalates in indoor applications and some articles.

Particular attention continues to be paid to substances that are carcinogenic, mutagenic and toxic for reproduction (CMR). As under the previous legal framework, the Commission adopted Regulation (EU) No 109/2012 (under Article 68(2)) which bans the sale to the general public of substances that were newly classified under CLP as CMR category 1A or 1B and of mixtures containing them.

The restriction procedure provides a structured and transparent procedure to tackle unacceptable risks to human health and environment which need to be addressed on an EU-wide basis. The initiation of the process is a shared responsibility among Commission and Member States, and further efforts should be undertaken to encourage initiatives in this area with the view to maximise the potential benefits of this measure.

## 1.5. Conclusions

As detailed in the chapter above, some progress towards meeting the human health and environment objectives of REACH is materialising. This trend is expected to accelerate as the remaining key benefit drivers and their associated enhancers become operational, conditional on the legislation being appropriately applied and adequately enforced.

On that basis, the Commission services conclude that:

- Increased information is resulting in changes in classification, with the majority becoming more restrictive. This is valid across all hazard classes, but particularly noticeable for acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity.
- The overall quality of available data for the chemical assessment of registered substances has generally increased if compared with the pre-REACH situation.
- Increased information passed along the supply chain and the obligation to set out safe operating conditions and risk management measures is resulting in improved SDS, making them better risk management tools.
- Increased information in the supply chain has benefited end-users, such as article producers.
- Increased obligations on SVHCs through the candidate listing and authorisation provisions has in some cases led to their withdrawal.



The Commission services also identified a number of key shortcomings hindering the achievement of the health and environment objectives and in particular the improvements set out above. These can be summarised as follow:

- ECHA identifies the quality of information submitted by industry in registration dossiers as being of concern leading to many dossiers found non-compliant.
- Analysis carried out for the human health and environment study on selected registration dossiers suggests that registrants need to improve their assessment of PBT and vPvB properties.
- Industry indicates problems with regard to the content and format of the eSDS.

Although it is too soon to have a complete picture of the extent of the benefits generated by the first implementation phase of REACH, the data collected so far verifies the general hypothesis that REACH will deliver human health and environmental benefits. Nevertheless, there are areas where improvements should be made if the expected benefits are to materialise. The Commission services have developed the following recommendations on actions or measures that could be taken to improve the degree to which REACH is delivering human health and environmental benefits.

<b>Recommendations</b>	
I.1.	The Industry should improve the quality of dossiers to ensure that the information they submit adequately documents how they ensure the safety of their substances.
I.2.	Based on evidence gathered by ECHA relating to the identification of substances and determination of "sameness", the Commission services will consider options to improve the situation, including legal measures.
I.3.	In order to progress towards achieving the WSSD goal that by 2020 chemicals are produced and used in ways that lead to minimisation of significant adverse effects on human health and the environment, identification and phasing out of SVHCs as well as restrictions should both be encouraged.

## 2. SINGLE MARKET, COMPETITIVENESS AND INNOVATION

REACH regulation affects all sectors of the economy where chemical substances are produced or used. Businesses that manufacture or import (from outside the EU) 1 tonne or more of any given substance each year (with limited exemptions) are subject to registration. Any business using chemicals will have to apply appropriate risk management measures for any use of the substance and respond to other actors on other aspects of REACH. Whilst acknowledging the wide and varied impact across all the economy, the Commission services have decided to focus an analysis on one sector which will be affected first and by all processes of REACH – the chemicals sector as a representative for all roles and types of impacts.

### 2.1. Background

*The EU chemical industry performed well during the past decade, but its global presence decreased from ~30% to ~21% of the world's chemicals market share as a result of very high and continuous growth rates in emerging economies.*

The chemical industry is one of the largest EU industrial sectors and an important source of direct and indirect employment in many regions of the EU. In 2009, the EU chemical industry comprised some 29 000 enterprises that employed around 1.2 million employees representing 4% of the total employment in the EU manufacturing sector. 96% of the companies in the sector are SMEs – 61% with less than nine employees. They account for 28% of sales and 35% of employment of the sector. With a total production value of € 491 billion in 2011, the chemical industry's contribution to the EU gross domestic product amounted to 1.1% representing about 7% of the EU manufacturing sector total.

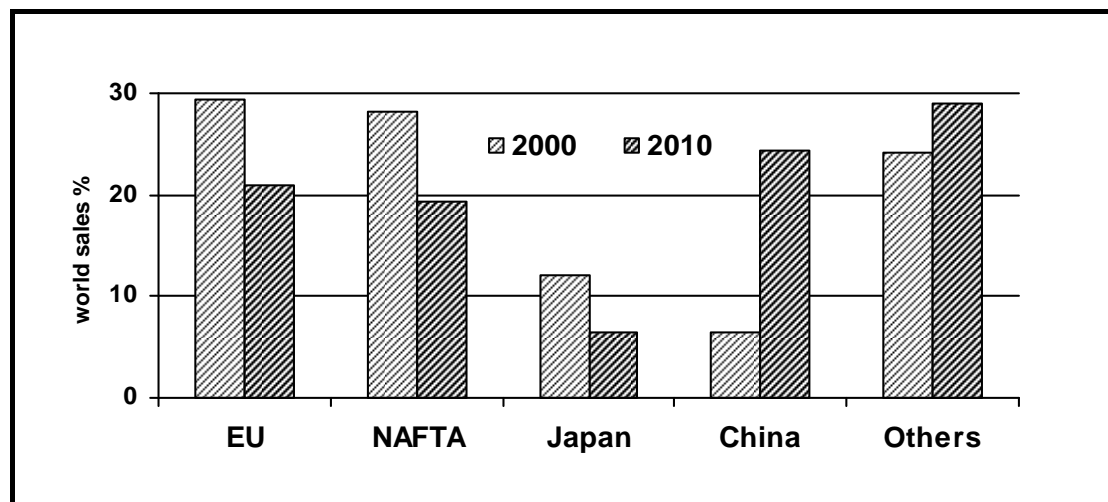
Between 2000 and 2010 the chemical industry production experienced an average growth rate of 0.7% – slightly higher than the 0.2% average growth rate for total EU manufacturing. The economic crisis of 2008 and 2009 has sharply decreased the output to the levels last seen a decade ago but it recovered vastly in 2010 and with a greater pace than the rest of the manufacturing sector.

In 2000 (when the preparation of the White Paper that led to REACH began), the EU was regulating a market of close to 30% of global chemicals production. Together with NAFTA and Japan, where environmental and industrial policies also are closely observed and mirrored – these jurisdictions regulated 70% of global chemicals market sales.

A decade later, the global economic outlook has changed dramatically. The centre of gravity in world manufacturing and chemical industry alike has shifted eastward: in 2010, the Asian market was double that of the EU, which share of global sales decreased to ~20%, despite growth in absolute numbers. REACH as a regulatory model has consequently a somewhat reduced impact worldwide, even though the

generated data and technology changes remain important for chemical safety also outside the EU. Also, some emerging economies were inspired by the REACH approach and are adopting similar regimes<sup>213</sup>.

**Figure 3. World sales of chemicals by dominant markets**



Source: CEFIC: Facts and Figures 2011, [www.cefic.eu](http://www.cefic.eu)

The position of the EU chemical industry seems to be very solid, but when coupled with the changing dynamics of global competitiveness over the course of the past decade, it is important to review how the economic objectives of REACH have been met so far.

## 2.2. Single market

*REACH has increased the harmonisation of the EU chemicals market, and therefore contributed to increased intra-EU trade, but in a rather limited scale at this stage as other important barriers still exist.*

The single market, with 500 million consumers, 220 million workers and 20 million entrepreneurs, is a key instrument in achieving a competitive industrial EU. The single market has been one of the main motors of economic growth in the EU over the last 20 years. It has provided EU industry with considerable reductions in cross-border trading costs, increased competition, and provided considerable economies of scale and scope from the availability of an EU-wide market. However, as the market is constantly evolving, new barriers emerge and add up to the already identified barriers as well as to those yet to be discovered.

<sup>213</sup> The South Korean Ministry of the Environment conducted public consultations on a draft “Act on the Registration and Evaluation of Chemicals”. The new act will overhaul the current *Toxic Chemicals Control Act* and will regulate both new and existing substances. In many dimensions is inspired by REACH and is often referred to as ‘Korea REACH’. The legislation is expected to come into force in 2013.

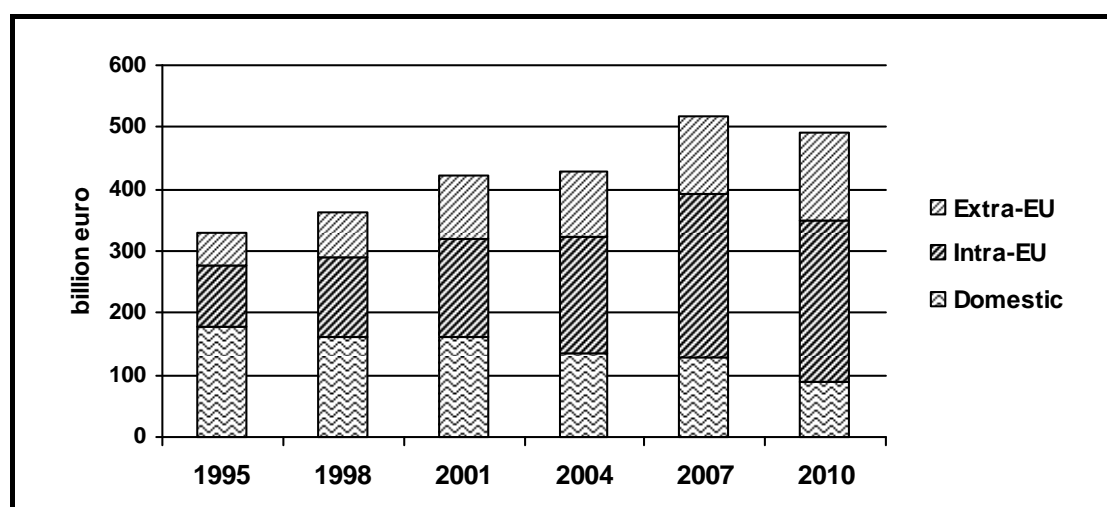
REACH was designed to attempt reducing the number of barriers for intra-EU trade of chemicals and provide the Commission with tools preventing future fragmentation. Recital (2) provides that “[t]he efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State”.

REACH also provides a set of unified tools for EU-wide distribution of chemical products:

- a single registration process with unified guidelines and unified fee structure, implemented by a single authority (ECHA);
- a single and directly applicable list of restrictions on marketing and use; and
- a single list of substances subject to authorisation.

Complying with these administrative requirements (which are necessary for marketing in a company-based market), shall give, in the Commission's intent, an instant administrative green light to distribute EU-wide – therefore being completely transparent with regard to the single market.

**Figure 4. Composition of EU chemical sector sales by destination**



Source: Eurostat and Cefic Chemdata International

This can therefore be seen as a success of REACH. The data on intra-EU trade show an uninterrupted increase of the intra-EU trade as a share of the total EU market size over the past 15 years. Although the *direct* impact of the introduction of REACH cannot be detectable yet, the fact that intra-EU trade has been growing faster than the overall rate of the manufacturing industry already gives a solid reassurance that REACH has met its expectation in preventing regulatory fragmentation.

To verify this claim, companies were asked a question in a survey<sup>214</sup> on their opinion of the role of REACH in entering other markets within the EU. About 10% answered that it already was (or would be in the future) a positive factor – which is a non-trivial share, given the relatively early stage in the implementation of REACH.

However, the exact mechanisms by which REACH impacts intra-EU trade are not evident to companies at this stage. For example, 91.5% of companies' respondents could not identify any particular contribution of REACH in relation to trade. This might be explained by the fact that companies answered this question only on the basis of their direct experience with the registration process and that registration did not unify any pre-existing fragmented process (with regard to phase-in substances<sup>215</sup>), as it rather established a unique and new process. Its contribution should thus be perceived as a measure to prevent market fragmentation in anticipation of possible future similar schemes introduced by various legislations within the EU.

Furthermore, some important harmonisations happened on less visible levels of implementation. Enforcement is key for the credibility of any legal framework. It fosters an equal level playing field for all economic operators and in all EU Member States. Therefore, it enhances the single market and increases the credibility of the responsible industry. The establishment of the Forum has allowed enforcement authorities to intensify their cooperation, as well as exchange best practices and mutual benchmarking. Transparency in their mutual performance via reports and joint projects established a sense of common goal and spurred creative imitation.

In addition, Article 122 obliges Competent Authorities (CAs) to cooperate with each other in the performance of all of their tasks under REACH. This happens, for instance, through the work of the Commission expert groups (e.g. CARACAL<sup>216</sup>) and the ECHA Committees. All of these platforms have facilitated information flow about new concerns in Member States, and helped disseminating best identified approaches to assess risks and select the most appropriate risk measure. In result, the risk of national risk management measures being sought by Member States was greatly reduced, but unfortunately, not completely eliminated<sup>217</sup>.

Finally, some important harmonisation impacts come from the restrictions process – which only recently got operational by having the first case of a substance restriction fully handled under REACH<sup>218</sup>. Restrictions are a known and well-recognised risk

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<sup>214</sup> CSES was commissioned by the Commission to conduct an industry survey with the aim to study industry impacts of REACH. More than 1 500 companies participated in the survey which ran over the period of July to September 2011.

<sup>215</sup> It did establish an improvement for new substances, but the vast majority of the value of the chemicals market constitute phase-in substances.

<sup>216</sup> Competent Authorities for REACH and CLP, see [Title 11] of Part I.

<sup>217</sup> For instance, in the field of unified approach to the enforcement of Article 33.

<sup>218</sup> Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII 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 128/1, 16.5.2012, p.1.

management tool. They provide authorities a great flexibility as they may target substances, specific uses (e.g. in articles), concentration limits, etc. For this reason they were commonly used by the REACH predecessor Directive 76/769/EEC and numerous national measures. Harmonisation potential within this domain was significant. Some solutions were “low hanging fruit” like the direct application of REACH which reduced the timelag resulting from transposition into national law and eliminated the risk of going beyond that which was legally required. Others required more elaboration, like the development of common guidance for identification of risks to ensure that all concerns of Member States’ priorities (which are variable) are addressed homogeneously.

In conclusion, REACH is leading to harmonisation of the internal market. However, harmonisation may be further pursued by removing remaining pre-REACH national measures, differences in administrative cultures, and the enforcement of REACH.

### 2.3. Competitiveness

*There are signs that the functioning of the market is improving, but in the short term, the competitiveness of the EU chemical industry has been affected by the costs of registration which have been higher than expected.*

#### Competitiveness of the single market

The concepts of competitiveness and competitive advantage have traditionally been discussed on a firm- or industry-base. However, it may also be applied to the “market”, in which case it relates to the efficiency of the given market in allocating resources. In the literature<sup>219</sup>, the ideal market is characterised by a very large number of buyers and sellers, equal distribution of information, lack of barriers for entering and exiting the market etc. REACH has affected some of these parameters, which are discussed in more detail below, such as (a) number of market players, (b) distribution of information and (c) barriers to market entry.

With regard to **number of market players**, the Commission has anticipated an effect of concentration and analysed its potential costs in the original impact assessment. It was considered to give rise to more than half of all REACH-related costs (€ 2.8-3.6 billion)<sup>220</sup>. The survey found confirmation of this development. Among suppliers, around 25% of manufacturers and importers of chemicals stated that they decided to remove one or more substances from the market (usually representing a small share of their portfolio). Considering the reasons for the withdrawal of substances, by far the most common reason – according to the survey results – appears to be the registration costs that make the overall trading of the substance unprofitable.

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<sup>219</sup> Stigler J. G. (1987), "competition," The New Palgrave: A Dictionary of Economics, 1st edition, vol. 3, p. 531–46.

<sup>220</sup> J. Canton, CH. Allen, *A Microeconomic Model to Assess the Economic Impacts of the EU's New Chemicals Policy*, DG Enterprise, 2003

The survey suggests a rather wide variation in terms of the average total costs per registration (per substance and per registrant), with the most typical value falling within the range of € 50 000-100 000 and 70% in the broader range of € 25 000-€ 250 000. For complex registration dossiers (for instance for substances with numerous uses or forms) the registration costs may go beyond € 1 million<sup>221</sup>. Analysis of the drivers of the registration costs reveals that ECHA fees often represent 50% or more of the total costs, especially in the case of simpler substances and smaller firms. In the case of more complicated substances, data collection, costs related to SIEF and consortia (including management and other fees) are the main cost elements, often exceeding € 100 000.

In global terms, the original impact assessment, and subsequent more detailed calculations<sup>222</sup>, have tended to anticipate a cost for the first registration deadline (which passed in November 2010) of around € 1.15 billion (when recalculated into 2011 prices) for the industry. The results of the survey provide an estimate of the effective cost of that phase with a total of around € 2.1 billion. A large part of the difference comes from firms reporting also on the sums paid to data holders for access to existing data. These costs were not considered in the impact assessment as they do not represent an additional cost from the perspective of society. Nonetheless, as existing data represented 50% of all data collected in the first registration period (see Figure 1 in **[Sub-Title 3.2] of Part I**) this needs to be considered as an important cost factor from the registrant's perspective. Another main reason behind the difference is significantly lower use of (Q)SAR than anticipated as a mean to lower the cost of acquiring new data.

The Substance Information Exchange Forums (SIEFs) have helped in reducing the costs – as confirmed by 65% of surveyed companies in the survey - even though a variety of problematic aspects affecting the further realisation of cost savings have been identified. E.g., communication and coordination problems were mentioned by 75% of surveyed companies. At the same time, ways of improving communication have also been identified, e.g. by establishing consortia (30% of consortia members have positive view of the SIEF functioning, as compared to only 13% of firms who do not participate in any consortia).

A more crucial point concerns the cost of letters of access<sup>223</sup> that often represent more than 50% of the total costs of the registration and, as revealed by the survey, are often seen by SMEs as a tool used by large firms to push small competitors out of the market. In addition the survey analysis suggests that the main problem is the absence of a transparent approach in presenting the various cost elements and how the price of letters of access is set. It should be also noted that costs of letters are usually fixed and

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<sup>221</sup> Study “*The REACH contribution to the development, commercialization and uptake of products of emerging technologies*”. Gaia, commissioned by the European Commission.

<sup>222</sup> Commission Staff Working Paper, *[REACH] Extended Impact Assessment*, COM(2003)644 final, 29.10.2003.

<sup>223</sup> A letter of access is a document issued by a lead registrant (or consortium) granting a company the right to refer to the registration dossier as a member registrant.

independent of effective volume – in effect causing smaller companies to pay more per unit of trade. This issue was also brought up in the Directors' Contact Group (DCG) and some solutions relating to transparency were already suggested to the industry. Other options relating to the variation of prices of data sharing based on the indicative tonnage band of individual companies remain to be explored.

As for the impact on actors down the supply chain, the analysis of individual comments to the survey suggests that “experience of withdrawal” usually does not mean complete loss of access to the specific substance, but rather only a switch to another supplier – be it within the EU or outside the EU. Such a switch must have had an impact on the costs of supplies because under normal circumstances one has to assume that the previous supplier was the most economic one. For those substances that are no longer offered on the market at all, a number of downstream users (DUs) associations reassured that they had been in the last stages of the substance's economic lifecycle, and had been expected to be withdrawn regardless of REACH. For those substances, REACH has only accelerated a natural trend.

For the complete withdrawals, the most common response of firms was to identify substitutes (53% suggested it as the most common response). Only a small share of DUs (close to 12%) stated that they had decided to register the relevant substance themselves, despite the fact that switching to other suppliers can be troublesome. In the survey, companies referred to substantial resources dedicated to identifying alternative suppliers of substances and to confirming continued supply in the future. For certain downstream industries (like aerospace or defence) alternatives need to pass internal certification procedures to guarantee performance.

Nevertheless, the general picture is that so far the complete withdrawal of substances is not a widespread phenomenon and that there are only limited cases where this has been problematic for firms in terms of their access to essential input substances. Furthermore, as already mentioned, many of these withdrawn substances were towards the end of their economic life-cycle and firms were already preparing for their phase-out. More important consequences relate to partial withdrawal, which results in increased concentration and decreased competition among suppliers.

With regard to the **distribution of information**, the main contribution from REACH is the provision of data from the chemical safety reports (CSR) via the extended (or standard) safety data sheets (eSDS). Another contribution comes from ECHA's public dissemination of information on substances' intrinsic properties, hazard profiles, classification and labelling, safe uses and risk management measures associated with them. On 16 March 2012 ECHA published information on 4'326 substances<sup>224</sup>. It will take some time until all actors in the supply chain learn about this new source of information and take it into account in their market decisions.

However, the flow of information among the chemicals market players has been also affected by the side-effects of formation of SIEFs and of working lists of substances pending assessment of the need for future risk management measures.

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<sup>224</sup> *The Operation of REACH and CLP*, European Chemicals Agency, 2011, p. 22.



Through an abuse of the tools available to pre-registering companies, a certain number of them gained access to previously unavailable platforms to advertise their services by using the functionality of SIEF Formation Facilitators, which in consequence blocked genuine potential lead registrants from taking over the role.

Moreover, the function of the lead registrants has created opportunities to retrieve information from the market about the structure of the competition. This does not relate to systematic breach of intellectual property or confidential information (for which we have found no evidence whatsoever), but to the fact that participation in a SIEF provides important business information about the offer and the volume offered within the supply chain. Especially companies who act as lead registrant for a large number of substances (which constitute their core business) received an unprecedented access to reliable information about the composition and structure of their competition.

Finally, the working lists of substances entering the assessment for possible risk management measures (candidate list, ECHA's Registry of Intentions) have sent multiple signals to the market. The intent was to increase the transparency and predictability of REACH risk management processes, but they have also resulted in a demand to avoid these substances even before their risks have been effectively assessed by the regulators. This goes beyond legal obligations and has already had a tangible impact on the market; it is more a question of psychology rather than assessment of risks by end-users or customers.

Concerning the **barriers for entering the market**, the impacts of REACH can be both positive and negative<sup>225</sup>. Positive: by the harmonisation efforts, the costs of expanding into other EU markets were reduced. Negative: by costs of registration; for new (and existing) supply-side companies, registration will be mandatory as of a 1 tonne of annual manufacturing or import volume, subject to transition deadlines<sup>226</sup>.

However, REACH does not seem to constitute a barrier to enter the market for existing substances. It is rather a potential expansion barrier, since for companies who are close to the threshold, an analysis of the marginal cost of registration has to be considered before companies decide to expand above the threshold<sup>227</sup>. In case of fast expansions, the decision may be obvious. But for slow and gradual expansions in low-margin markets, the registration requirement becomes a trap effectively preventing firms from continuing their gradual growth as they lack capacity to build a new customer base large enough to pass the range of uneconomic volume. The survey

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<sup>225</sup> The expectations for reducing barriers for expanding to other markets have been already discussed above [Sub-Title 2.2].

<sup>226</sup> Where meeting criteria of Art. 3(20) of REACH.

<sup>227</sup> As already mentioned - a typical individual registration through a SIEF membership costs between € 25 000 euro to € 250 000 euro. In addition, other REACH obligations imply additional work for the company staff. For SMEs it usually requires 0.5-1 full time equivalent for REACH related activities. Larger firms have usually established dedicated units with a typical occupancy of 1 to 5 persons.

revealed that companies who have already found themselves close to the registration threshold have opted to downsize rather than expand (which in case of year 2010 could anyway be rather difficult to achieve given the economic crisis) and therefore delay registration expenses<sup>228</sup>.

### **External competitiveness of EU chemical industry**

The EU chemical industry has been performing well in the last decade, especially in comparison to other traditional global competitors. Particularly well-performing are sub-sectors such as specialty chemicals and consumer chemicals which increased their trade surplus with most of the EU's main trading partners<sup>229</sup>. These two sub-sectors in 2010 accounted for 70% of the extra-EU chemicals trade surplus. Basic inorganics experienced a trade deficit of € 1.9 billion – but this is the only sector with a trade deficit since 1994.

However, there are a number of indicators suggesting that the EU chemical sector is under increased pressure. Compared to 1999, the EU's share of world chemical sales has declined by 11 percentage points (from 32.1% in 1999 to 20.9% in 2010). While still in a strong position, the EU has lost its top ranking to Asia, mainly due to the rise of China and of the Middle East.

It appears, therefore, that the EU chemical industry is doing much better in innovation-driven sub-sectors (e.g. specialty products) than in more cost-orientated sub-sectors (e.g. commodity products) or sub-sectors for which important downstream industries have moved a substantial proportion of their activities out of the EU. In consequence, the competitiveness of the chemical industry is very much dependent on its capacity to conduct research and development, commercialise the results and ensure rapid uptake of innovation results<sup>230</sup>, as discussed in more detail in [Sub-Title 2.4].

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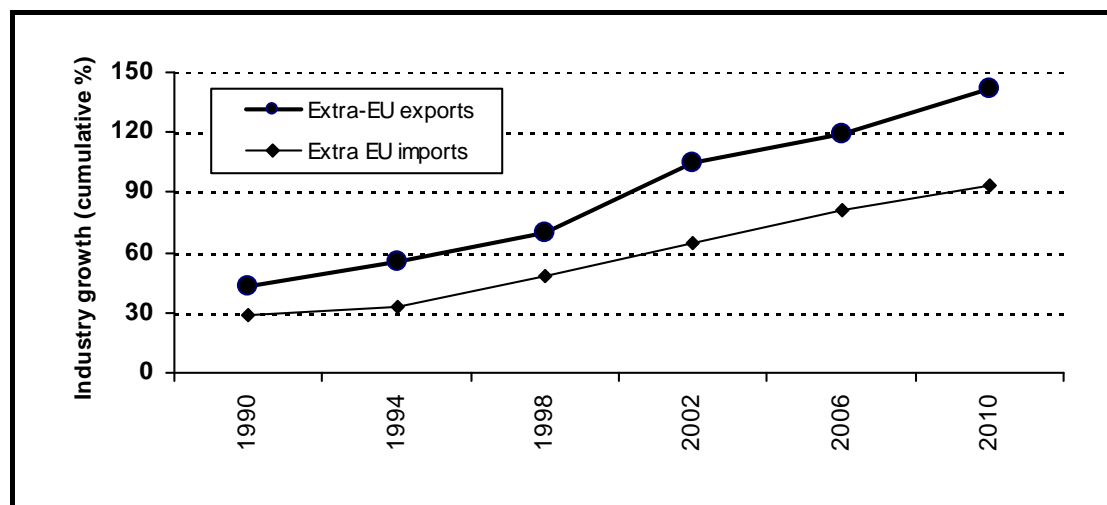
<sup>228</sup> End of November 2010 the registration deadline passed for manufacturers and importers placing on the market 1000 tonnes or more of any substance per year. Those who scaled below 1 000 tonnes will have to undergo the registration process by May 2013 when the deadline passes for all manufacturers who place on the market 100 tonnes or more per year.

The Commission has also learned that companies from countries outside the EU could have set up multiple new legal entities within the EU, each of which can take up less than 1 000 tonnes to circumvent registration requirements.

<sup>229</sup> *Facts and Figures 2011*, CEFIC, [<http://www.cefic.org>]

<sup>230</sup> A. Stajano, *Research, Quality, Competitiveness. EU Technology Policy for the Knowledge-based Society*, 2009.

**Figure 5. Export / import balance of EU chemical industry in the past decade.**



Source: CEFIC, Facts and Figures 2011, [www.cefic.org](http://www.cefic.org)

The positive contribution of REACH to the global position of EU industry lies in various aspects like better information or well-documented sources of supplies. The registration and authorisation requirements, and resulting reallocation of R&D<sup>231</sup> as well as, in some fields, impacts on marginal cost structure<sup>232</sup> can also be seen as a negative factor for some companies.

Further improvement in the information flow within the value chains will expand EU industry's competitive advantage with regard to timely response to changing market needs. The development of more advanced supply chain management practices – including the use of IT tools – has been a response to REACH requirements that can bring important productivity results in the future.

However, at this stage, these benefits are generally outweighed by the costs and challenges of supply chain communication. For the majority of the survey respondents (close to 70%) REACH has increased the costs of managing information exchange along the supply chain. Significant human resources and time are dedicated to the development, handling and extraction of the relevant information included in the SDS or, if applicable, in the eSDS. The typical costs for the preparation of an SDS is around € 200 and over € 500 for an eSDS, but can reach up to € 2 500 in the case of translations in all EU languages. IT systems are also often purchased by firms to support the handling of information with costs ranging from a few thousands to more than a million euro depending on the size of the firm and the extent of integration into overall resources management systems.

Well-documented source of supplies and reliable information on properties may provide a marketing advantage on external markets which require high reliability and

<sup>231</sup> Discussed in detail in [Sub-Title 2.4].

<sup>232</sup> Study “The REACH contribution to the development, commercialisation and uptake of products of emerging technologies”, Gaia, commissioned by the European Commission, 2012.

stability with regard to requested properties. There are already firms declaring business gains by using their compliance with REACH in order to market a product outside the EU. One survey respondent from the Netherlands explained that REACH had made the firm re-position its business in the area of environment and safety and added: “*Now we can show that we want to be a forerunner.*”

However, the survey responses indicate a considerable level of scepticism towards the potential of REACH to lead to improved customer confidence, with almost 80% of respondents disagreeing with the idea that REACH has led to increased customer confidence in chemicals in the EU.

With regards to the negative contribution of REACH, restrictions on uses or the costs associated with registration and authorisation requirements may result in replacing EU-based production or chemical processes by imported articles (either parts or final products) which are outside of scope from many provisions of REACH. Feedback received to the survey revealed already individual cases of such relocation<sup>233</sup>.

REACH treats imported and domestic products in an equal manner, in line with the WTO rules. In all respects, EU legislation ensures that when suppliers of chemical substances are competing on the EU market, they are treated in an equal manner. However, this does not necessarily create an equal basis for competition outside the EU. Despite export being exempted from many provisions of REACH (such as restrictions, when related to placing on the market) very few companies are exclusively trading outside the EU and REACH costs are affecting extra-EU export activities in the same way as any intra-EU sales.

Most firms and associations suggested that it is still too early to identify long-term impacts of REACH on their competitive position. In the short term, the financial situation of most firms was reported to be negatively affected. The severity of this impact depends on the type of product traded. For firms in highly competitive markets – as is the case for basic chemicals and metals that are treated as commodities – already low profit margins appear to have been further squeezed, as there is limited capacity to transfer these costs to customers through price increases. In other markets – such as certain segments of the specialty chemicals – firms appeared more confident of their capacity to increase prices and maintain profit margins without seriously affecting their overall competitive position.

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<sup>233</sup> Study “Functioning of the European chemical market after the introduction of REACH”, CSES, commissioned by the European Commission, March 2012.

## 2.4. Innovation

*REACH fulfilled its objectives with regard to innovation. However, the persisting innovation gap compared to US and Japan and increasing pressure from emerging economies indicate a need for more ambitious objectives in this area.*

Innovation has been placed at the heart of the Europe 2020 strategy for growth and jobs. It has been noted that in order to address the EU's challenges (like an ageing population) with strong competitive pressures from rising economies, the EU's future economic growth and jobs will have to come from innovation in products, services and business models.

Innovation is a specific function of entrepreneurship, in either existing businesses, or new ventures. It is a process of creating new wealth-producing resources or improving existing resources which enhance potential for creating wealth<sup>234</sup>. On a micro level, innovation is focused on a change in an economic or social potential of an enterprise, while on a macro level, this translates into jobs and prosperity. In addition, innovation, with the support of adequate regulation, can also result in reducing impacts on the environment, enhancing resilience to environmental pressures by, e.g., a more efficient and responsible use of natural resources<sup>235</sup>.

In recent studies it has been demonstrated that Member States with a strong innovation baseline have coped with the crisis much better than others<sup>236</sup>. It has also been demonstrated that innovative companies consistently perform better in generating new jobs across all size classes, and are much better in retaining employment during economic downturns<sup>237</sup>. In addition, an often overlooked fact is that young companies generate many more new jobs than established companies. In the period 2002 to 2010 SMEs generated 85% of all new jobs added to the EU economy, but established SMEs (older than 10 years), as a group, lost jobs during that period). This implies that young companies not only added new jobs, but also compensated for the loss of jobs which happened in the group of established companies. This indicates that innovation, which is essential to all new businesses, is the backbone for social prosperity.

### Innovating in chemicals

The chemical industry experienced an innovation boom in the middle of the last century on a scale similar to the current one in the IT sector. From 1930 to the early

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<sup>234</sup> Drucker P. F., *The Discipline of Innovation*, Harvard Business Review, Issue May-June 1985.

<sup>235</sup> *Communication from the Commission [...] Innovaton for a sustainable Future – The Eco-innovaton Action Plan (Eco-AP)*, European Commission, 15.12.2011, {COM(2011) 899 final}, p. 2.

<sup>236</sup> Vroonho P. et al., *Do SMEs create more and better jobs?*, EIM Business & Policy Research, study funded by EU Competitiveness and Innovation Framework Programme.

<sup>237</sup> *Ibid.*

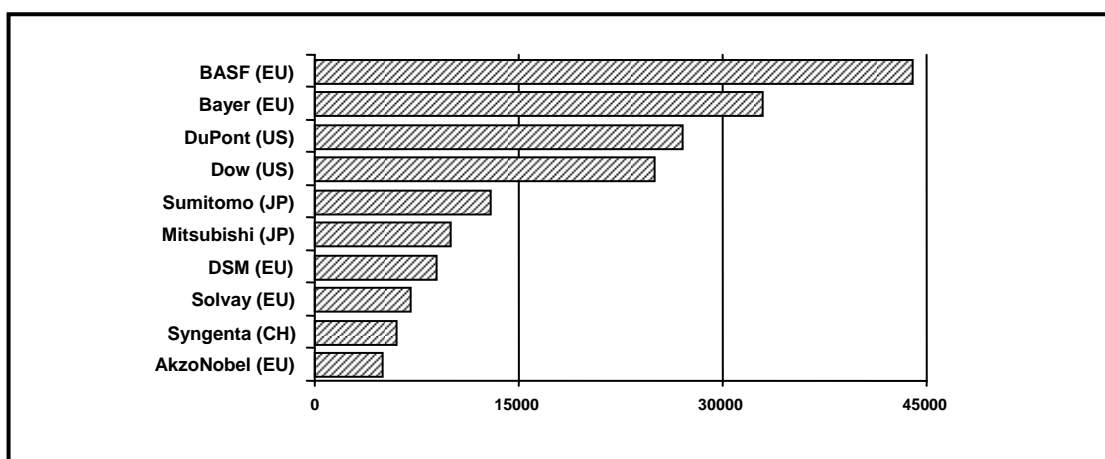
1980s, there were 63 major (or disruptive) innovations in chemical products<sup>238</sup>. In subsequent decades, the pace of innovations gradually declined. Bringing new products to the market became increasingly difficult in terms of time and resource requirements. In addition, as the industry was increasingly regulated, it shifted its focus towards innovating with traditional substances rather than developing disruptive new ones.

More recently however, there are signs that disruptive innovations may return to the chemical industry, for example, due to a necessity attributed to increased scarcity of natural resources and thanks to regulatory changes introduced by REACH.

Efforts to avoid, where possible, use of chemicals that reduce future productivity of key resources such as soil and water, and make waste materials more costly to recycle and reuse may help to reduce pressures from increasingly scarce natural resources. REACH helps to identify opportunities for switching to safer chemicals or technologies whenever economically feasible. These alternatives will improve the quality of waste streams and thereby enhance recycling and reuse of the raw materials contained in these streams. These opportunities will have to come from innovation into new manufacturing processes or chemicals.

The Commission services believe that the EU chemical industry is well-positioned to face these challenges as it has been strong in innovating and was doing better than other EU sectors in many aspects. Indeed, an important benchmark comes from a Patent Asset Index calculated by PatentSight<sup>239</sup> which measures the combined competitive impact of all patents in company portfolios and therefore an overall technology strength. In this ranking, within the top-ten chemical companies five are EU-based.

**Figure 6. Patent Asset Index for leading chemical companies**



Source: PatentSight 2011, [[http:// http://www.patentsight.com](http://www.patentsight.com)]

<sup>238</sup> Bennett, M. J.; Kline, C. H., “*Chemical: An Industry Sheds Its Smokestack Image*”, Technology Review 1987, July Issue, 36-45

<sup>239</sup> Ernst, H., Omland, N., “*The Patent Asset Index - A New Approach to Benchmark Patent Portfolios*”, (forthcoming)

This strong position of EU companies indicates that the climate for innovation in the EU has been favourable.

### **Innovating in REACH**

As has been shown above, innovation in chemicals, in many ways, is different from innovation in other sectors. Its specificity requires particular attention by public policies. REACH, in that respect, plays an important role as it can affect (in positive and negative ways) innovations at all stages of the innovative process. The Commission has analysed the effectiveness of REACH in achieving innovation objective at the following three stages of the innovation process:

- invention (idea generation and evaluation);
- implementation (development/prototype, pilot application, testing); and
- marketing (production and market launch, market uptake).

It is questioned by some that business activities driven by REACH mechanisms such as registration, the candidate list, restriction and authorisation can be considered as drivers of future growth – an attribute of innovation as pursued by the Europe 2020 strategy<sup>240</sup>. In support of that view, it is argued that innovation must respond to market demands, while restriction and authorisation processes are, in effect, a result of lack of adequate market reactions. However, forced innovations may bring economic benefit indirectly via improved quality of waste streams, productivity of natural resources or by minimising external costs assumed by the society.

In addition, it has been brought to the attention of the Commission that 40% of chemical companies observed a shift of R&D or other innovative practices into health, safety and environmental protection areas that would not otherwise have taken place. Even more, a fundamental reappraisal of the research orientation had occurred within 5% of surveyed companies<sup>241</sup>.

### Invention

REACH contains a number of mechanisms which impact on the willingness and determination to innovate. These are mechanisms which (i) mandate or induce substitution (like the candidate list), (ii) increase the costs and administrative burden for companies, (iii) generate new data and help identify customer needs.

Firstly, with regard to the **substitution mechanisms**, the impact of REACH on the invention stage relates to the uncertainty around the candidate list. In the most

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<sup>240</sup> *Communication From The Commission - Europe 2020 - A Strategy For Smart, Sustainable And Inclusive Growth*, European Commission, 3.3.2010, {COM(2010) 2020}, p. 9: "Smart growth means strengthening knowledge and innovation as drivers of our future growth."

<sup>241</sup> Survey commissioned by the European Commission and conducted by CSES Ltd. in September 2011 on 500 chemical companies from EU (including manufacturers, downstream users and other actors in the chemical supply chain) – further in the document referred to as an 'Innovation Survey'.

common response from the industry it is pointed out that the research on substances to substitute identified SVHCs in the candidate list is hindered by uncertainty regarding the status of potential substitutes which may be included into the candidate list themselves later on. It is argued that a greater predictability would certainly help.

Secondly, concerning **costs of complying** with obligations under REACH, the Commission's original Impact Assessment had identified a concern that the requirements of the REACH regulation could divert resources from other research activities. Unfortunately, the Innovation survey<sup>242</sup> revealed that this indeed happened as confirmed by more than 60% of respondents. However, nearly half of them also stated that there was an overall increase in expenditure on R&D to compensate for the compliance-related activities.

Finally, in the domain of **availability of data**, REACH introduced industrial information transfer mechanisms aimed at capturing and disseminating data across industries and throughout the supply chain to support and stimulate the development of safe chemicals and practices. This aspect is of particular interest for this stage of innovative process and will be looked in more detail below.

The main mechanisms for data capture and dissemination are SIEFs and consortia, SDS and eSDS, and CSR and the ECHA dissemination portal.

About a quarter of respondents in the Innovation Survey (including a disproportionately large share of SMEs) indicated that they had found the SDS of value in this regard. Registration dossiers with technical dossiers and CSRs were found useful by one out of six, and SIEFs by one out of ten. This suggests that, although the overwhelming majority did not find any use in innovative processes for the new information, a noticeable share of companies did already benefit from these sources – in particular the SDS which was the most useful tool in this respect. It should also be noted that the first registration period dealt with large volume substances which have been in use for a long period of time and whose properties tended to be well known. More new data are therefore expected to be revealed with the next registration deadlines when substances which are less well known are to be registered.

An explanation why not more companies benefited from these additional information sources may be found in the results of the survey on competitiveness where the experience from communication along the supply chain was reported as negative by 44% of firms. The main problem, in this respect, appeared to be the absence of a standardised format for eSDS and their size of often more than 100 pages.

With regard to the quality of the information over 70% of participants in the Innovation survey considered that there had been an increase in access and scrutiny of the information, and nearly 20% indicated it increased a lot. In addition, nearly a quarter of respondents stated that they had been able to benefit from that increased openness and scrutiny.

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<sup>242</sup> *Ibid.*



An important stimulus for idea generation also came from the better awareness of the application and uses of the substances down the supply chain due to communication requirements. With the complex structure of the supply chains in the chemical sector, manufacturers of substances are often separated by a large number of intermediaries from the final recipient or user of the substance. Specific knowledge on the particular applicability of specific substances may therefore not have reached manufacturers or importers and important market opportunities may therefore have remained uncovered. With the incentive to communicate all uses up the supply chain, the manufacturers got a much better overview of the range of uses for the substances in their offer, and may react with optimised and improved offer. The Innovation Survey found important evidence that this is indeed already taking place. Companies indicated various ways in which they have innovated as a result of these processes: a better dialogue with major customers and learning new information about substances from the (e)SDS. As a result, new applications can be realised in a better and safer way (for the customers).

### Implementation

The implementation stage of the innovation process comes after an invention passes its initial business evaluation. It involves development of prototypes, testing and piloting. REACH introduced some changes aimed at supporting this phase of the innovation process, it: (i) equalised testing requirements for new substances with those already existing, (ii) established various exemptions (volume, product and process oriented research and development, polymers and intermediates) in support of research and development, (iii) allowed read-across of test results that would reduce costs of testing in general and the need to undertake animal testing in particular.

With regard to **equal treatment**, REACH levered conditions for both new and existing (phase-in) substances to undergo testing and safety assessment within the registration process. This requirement equalised the costs of developing new products based on new substances with costs of continued use of existing substances. The Innovation Survey confirmed that this approach is effective: nearly half of the respondents stated that this was a problem and a third agreed that REACH has effectively addressed it. However, interviews with the industry indicated that some barriers for research activity on new substances under REACH still exist. For example, for non-phase-in substances in the low tonnage band (between 1-10 tonnes per year) one has to provide the standard test data of Annex VII while there is no such requirement for phase-in substances (except if they meet one of the criteria from Annex III). But despite these differences, ECHA has received as many registrations<sup>243</sup> for new substances as was estimated in the original Impact Assessment, thereby fully meeting the Commission's projections.

With regard to **exemptions** under REACH, the most important is the exemption for substances used in pilot plant or production trials to test the production process or test the fields of application of the substance (PPORD). It extends to registration,

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<sup>243</sup> By end of 2011, ECHA received 1670 registrations for non-phase-in substances, which gives an average of 477 substances per year (registration obligation under REACH was effective as of 1 June 2008)

authorisation and restrictions. Until January 2012, there have been around 800 notifications for use of that exception from registration submitted to ECHA. This is rather a small number compared to the size of the chemical industry, which may be explained by the fact that currently only high volume substances have to be registered. The Innovation Survey also found that 15% of interviewed companies have recognised this as an opportunity to intensify their R&D activity and applied for PPORD (of which 75% were large enterprises). At the same time, an important share of companies reported that the duration was sufficiently long (5 years) to conduct necessary R&D. Another exemption, from authorisation and restrictions, is available for substances used in scientific experimentation, analysis or chemical research in a volume of less than one tonne per year. Feedback from the survey suggests that the volume exemption may often be too low for the testing required.

As regards exemptions for polymers it should be pointed out that the exemption was intended to *maintain* innovation within this domain, and consequently, the majority of surveyed companies were of the view that this did not contribute to *increased* innovation. A similar response was provided to the exemption which relates to isolated intermediates (on-site or transported)

With regard to **read-across** and animal testing nearly 50% of survey respondents indicated that provisions within REACH for the use of read-across as regards research testing results led to a reduction in the need (and costs) for testing. However, the survey responses also took a view that ECHA has used a very strict (precautionary) interpretation of their testing proposals and results, lowering the impact of this measure on innovation.

### Marketing

This end stage of the innovation process involves the establishment of production, launch of products and market uptake. The following aspects were identified as applicable to this stage: intellectual property protection, patenting, registration costs and market uptake.

The main areas of concern identified with regard the protection of **intellectual property** were: (a) information requirements to downstream users through the (e)SDS (potentially leading to the disclosure of critical know-how related to the formulation technology used); (b) loss of key intellectual property where procedures cannot be (or were not) patented, and (c) concerns in relation to the required data and information sharing among SIEF members. In relation to **patenting**, there were questions as to whether the pre-publication requirements under REACH may result in difficulties in protecting new developments under patent law.

The Innovation Survey found that some 75% of respondents did not think that there were conflicts as regards protecting intellectual property and making information available at registration and throughout the supply chain. Among those that did, conflicts tended to arise mostly in the context of SIEFs, and preparation of the SDS and CSR. Some 18% of surveyed companies asserted that REACH provided for sufficient protection of *intellectual property* to promote innovation, but 40% were of the opposite view (with another 40% having no opinion). A somewhat more positive assessment was given to the provisions intended to protect *confidential business*

*information* – with nearly 20% of the companies stating that they were sufficient to support innovation, versus 35% that had an opposite view.

With regard to **registration costs**, the feedback from industry points out that new innovation projects are more highly scrutinised in terms of costs, risks and returns before it is decided to go ahead with launch and marketing – also further up the pipeline – than it was before the implementation of REACH. This may be linked to the fact that over 40% of firms considered time to market as being increased, while over 10% expected a reduction of this time to market. It seems that some of the larger firms that would have submitted multiple notifications across several Member States prior to REACH have been able to benefit from not having to deal with this requirement at Member State level.

With regard to **market update**, an expected gain has been reported by some 25% of respondents who indicated that compliance has contributed to a better acceptance of their new products and technologies by the market.

## 2.5. Perspective of SMEs

*REACH has increased concentration on the market by various mechanisms. Greater specialisation among chemical suppliers and new compatible business models resulted in a need for restructuring the supply chain. This opens a number of opportunities, but due to financial and organisational constraints, SMEs are less likely to succeed, if not properly supported.*

The population of SMEs is a highly diverse group of firms. They range from micro-firms to mini-multinationals, and could fill one or several of the REACH roles. SMEs also have a different role in the economic structure depending on the economies involved. And while only 14% of dossiers in the first registration deadline were submitted by SMES<sup>244</sup>, many more are expected to participate in the next registration deadline, or are already now concerned by other obligations of REACH.

REACH has taken into account the specificity of SMEs in a number of ways, like reductions in registration fees, testing requirements increasing progressively with tonnage band, different registration deadlines depending on the tonnage, etc. But notwithstanding these measures, the feedback received from SMEs clearly shows that they still tend to be disadvantaged by REACH compared to large firms. The Commission has looked at the effects of REACH on SMES with regards to access to markets, innovation and protection of intellectual property.

As regards **access to supply markets**, the key driver of accessibility is the effect of registration costs, whether as a manufacturer, a formulator or a distributor. The Commission has been informed of SME having problems in financing letters of

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<sup>244</sup> *Dossier Submission Report On 1 December 2010*, ECHA, available at [www.echa.europa.eu](http://www.echa.europa.eu)

access to participate in joint submission, or having to review business relationships with long-standing suppliers pending appointment of an only representative.

When all registration costs are taken into account, a pattern may be observed whereby, despite significant fee reductions, micro- and small firms are paying disproportionately more in relative terms to their sales due to the fixed costs incurred by REACH compliance (e.g. SDS and eSDS, translations, IT systems, legal services, letters of access).

In addition, there may be cases where SMEs, would be more impacted due to their lower abilities to pass on the costs via the increases of the price where dominant market players are larger companies. Furthermore, SMEs may not be so well equipped for the expansion to other customer areas, especially if e.g. safety assessment requirements between respective regulatory areas differ considerably from each other.

As for the situation of “not yet existing SMEs”, it should be recognised that the complexity of REACH, manifested by the existence of thousands of pages of various guidance documents, impacts on entrepreneurship within the chemical sector. Altogether, these factors may discourage SMEs from starting activities implying REACH obligations.

However, with regard to **innovation**, small firms have indicated that they have benefited proportionately more than larger firms in terms of conception of products resulting from increased openness, particularly from the SDS. On the other hand, SMEs reported more often than larger companies that they had experienced a transfer of resources from market-driven innovative projects to compliance-related work. They more often saw this shift as permanent and more often reported concerns with regard to protection of confidential business information or **intellectual property protection** under REACH. As a consequence, SMEs have so far made less use of the research exemptions under REACH than larger firms.

## 2.6. Summary and conclusions

REACH maintains its relevance in relation to both objectives of competitiveness and the contribution to the harmonisation of the single market. Both objectives can be served by the effective and efficient implementation of REACH on the basis of the promotion of innovation in chemicals, the minimisation of the implementation costs, and the pre-emption of the creation of national regulations as regards chemicals that could lead to a fragmentation of the EU market.

REACH as an EU Regulation is considered by the industry as positive in avoiding a possible fragmentation from the potential introduction of separate national legislations. Despite the feedback received pointing to some variation in the way Member States monitor or enforce REACH, the existing coordination structures

(CARACAL, the Forum, enforcement projects and RIPE<sup>245</sup>) are seen as having a positive impact.

The compliance requirements of REACH introduced sizeable costs for almost all firms in the chemicals market. The key drivers of compliance costs are, at this point, the costs of registration – including data collection and ECHA fees – as well as communication and exchange of information along the supply chain. The available data suggest that the costs for the first registration period incurred by suppliers of chemicals – manufacturers and importers of chemicals – were around € 2.1 billion. This figure includes amounts paid for access to existing data which is not considered as a net cost for the industry (and was not accounted for in the Impact Assessment). However, with regard to the use of (Q)SAR as a low cost data collection method, the initial estimations were much more optimistic than the actual use by the industry; this contributed in part to higher overall cost than anticipated.

So far, it can be concluded that the industry seems able to absorb the additional costs with, in general, no significant adverse effects on its overall competitiveness and with a general acceptance of the longer-term objectives. There is no evidence available at this stage indicating sizeable shifts in terms of both imports and exports of chemicals as a result of REACH.

There are significant deviations in terms of expected impacts and certain firms or sectors appear more vulnerable than others in the process. The data analysis provided by the commissioned surveys indicates that small firms, firms in sectors with less integrated supply chains, or firms that rely on the use of chemicals on the candidate list often face greater challenges as a result of REACH. SMEs appear to lose part of their market share either as a result of the costs, or as a result of withdrawals of substances from the market or reduction of production levels. This is because, in relative terms, the costs of compliance with REACH tend to be partially independent from the volume (e.g. supply chain communication, or letters of access costs). In addition, REACH requirements and administrative procedures make their margins lower in comparison to non-EU competitors with a potential longer term impact in their capacity to compete inside and outside the EU.

Fortunately, the analysis also indicates that there is significant scope for reducing the costs of compliance without a detrimental effect on other objectives of REACH. In addition, further addressing differences in monitoring and enforcement of REACH could increase the harmonisation effect of the single market.

With regard to impact on other industries, the implementation of REACH does have a certain impact on the availability of chemical substances used by DUs. The withdrawal of substances is driven primarily by the registration costs, but also, for a smaller number of firms, by the inclusion of substances in the candidate list. There is no evidence at this stage that substance withdrawal has had an impact on final customers in terms of the variety of final products available or their prices. On the basis of the above it can be concluded that REACH caused some reduction in the

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<sup>245</sup> ECHA's REACH Information Portal for Enforcement, see [Title 12].

number of suppliers of chemicals and, in consequence, is leading to a greater concentration of the market.

**Recommendations:**

- II.1. ECHA and industry associations should reinforce their efforts to reduce the overall costs incurred by the industry in complying with REACH. This should be done by:
  - a. simplifying and optimising guidance for businesses (taking into account costs of adaptation and familiarisation),
  - b. facilitating transmission of best practices between companies,
  - c. providing information on the age of data in inquiry process,
  - d. further development of QSAR, read across and other alternative hazard assessment methods, to enable their regulatory acceptability.
- II.2. ECHA and industry associations should reinforce their efforts to ensure protection of IP rights and confidential business information, in particular by simplifying and optimising guidance for businesses, in particular for SMEs, about existing possibilities under REACH to safeguard IP rights and confidential business information
- II.3. Provide additional support to SMEs. In particular the following means should be explored:
  - a. by ECHA - more specific guidance on transparency, non-discrimination and fair cost sharing.
  - b. within the scope of the review of the Fee Regulation<sup>246</sup>, consider further rebalancing the distribution of fees across various company size classes.
  - c. by national helpdesks and/or ECHA – guidance on effective integration of regulatory requirements into product development and commercialisation.
- II.4. The Enterprise Europe Network will be used to increase awareness of REACH along the supply chain and to improve the communication within the supply chain.

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<sup>246</sup> Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency 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 107, 17.4.2008, p.6.

## Part III.

# CLP ENFORCEMENT ACTIVITIES

### Introduction

The CLP Regulation<sup>247</sup> sets the rules for classification, labelling, and packaging of chemical substances and mixtures at EU level. Its main objectives are to determine whether a substance or mixture displays properties that lead to a classification as hazardous and to harmonise the standard symbols, phrases and packaging conditions that should be used to inform users. The Regulation aligns previous EU legislation on classification, labelling and packaging of chemicals<sup>248</sup> to the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It maintains the previously existing level of protection of human health and environment and intends to facilitate EU internal as well as international trade in chemicals.

CLP entered into force on 20 January 2009. The underlying principle of this legislation, which applies to substances from 1 December 2010 and to mixtures from 1 June 2015, is that industry is responsible for classifying and labelling substances and mixtures. For substances with particularly severe hazards, national authorities or industry propose harmonised classifications on which the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) provides opinions. Based on those opinions, the Commission, if found appropriate, includes the harmonised classifications into Annex VI to CLP, through which they become mandatory. When a substance or mixture is classified for one or several hazards, the relevant information is communicated to other actors in the supply chain, including to consumers, via particular elements on the labels of products placed on the market and, where relevant, via safety data sheets.

Manufacturers and importers are also obliged to notify the classification and labelling of the substances placed on the EU market after December 2010 to the classification and labelling inventory (*the C&L Inventory*) managed by ECHA. It contains entries for more than 115 000 substances and a public version is available on ECHA's website<sup>249</sup>.

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<sup>247</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

<sup>248</sup> Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1) and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

<sup>249</sup> <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

## **Enforcement and reporting**

### Enforcement

In general, enforcement of EU legislation lies within the responsibility of Member States. In order to ensure an effective implementation of CLP, Member States are obliged, among others, to:

- take all necessary measures, including maintaining a system of official controls to ensure that CLP is applied;
- introduce penalties for non-compliance with the Regulation and notify them to the Commission;
- regularly report on enforcement.

This chapter is mainly focused on the analysis of the Member States' obligation on regular reporting. Other initiatives that could play a role in CLP enforcement are mentioned solely to provide an overall picture.

The enforcement of CLP is closely related to the enforcement of REACH. The classification and labelling of substances is part of REACH registration dossiers and Safety Data Sheets required under the REACH Regulation also have to contain the correct classification of chemical substances or mixtures. Furthermore, the activities of ECHA's Forum for exchange of information on enforcement also include CLP. Further information on the Forum's work, information exchange and the Commission services' recommendations concerning enforcement of CLP and REACH are therefore to be found in [Title 11 of Part I] of this paper.

In addition, the consequences of the classification of chemical substances under CLP go well beyond the Regulation itself. Classification is often used as a reference to trigger obligations or restrictions under many other pieces of legislation such as the Pressure Equipment Directive<sup>250</sup>, Toys Safety Directive<sup>251</sup>, Seveso Directive<sup>252</sup>, Regulation on the EU Ecolabel<sup>253</sup> and Regulation on Cosmetic Products<sup>254</sup>.

### Member States reporting

Article 46(2) of CLP requires Member States to submit a report to ECHA every five years by 1 July, on the results of official controls and other enforcement measures taken. The first report had to be submitted to ECHA no later than 20 January 2012.

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<sup>250</sup> OJ L 181, 09.07.1997, p. 1.

<sup>251</sup> OJ L 170, 30.06.2009, p. 1.

<sup>252</sup> OJ L 10, 14.01.1997, p.13.

<sup>253</sup> OJ L 27, 30.1.2010, p. 1 .

<sup>254</sup> OJ L 342, 22.12.2009, p. 59.



ECHA shall in turn make the reports available to the Commission, which shall take them into account when preparing its general report under Article 117 of REACH.

With this aim, the Forum mandated a working group to develop a template and a document with common issues on enforcement that should be reported under Article 46(2) of CLP. The reporting template has been the main tool used by Member States to submit consistent and comparable data. ECHA has reviewed the information received from Member States and evaluated its usefulness. The results of those observations has been summarised in a report sent to the Commission in March 2012 together with the national reports.

The reports cover national enforcement strategies, describe the co-ordination and co-operation among national authorities and document enforcement activities during the reporting period, which covers the time between the entry into force of CLP (20 January 2009) and June 2011.

Enforcement activities encompass a range of actions an authority may undertake in order to assess, secure or promote duty holders' compliance with CLP. Activities may be routine or non-routine and include inspections, investigations, monitoring as well as formal enforcement (i.e. issuing warnings, bringing legal proceedings by criminal or civil means).

It should be noted that as a consequence of this having been the first reporting and the template having been made available only rather late in the process, it was difficult for Member States to gather data during the enforcement activities that could then be easily adapted to the level of detail required in the reporting template. It was also complex to differentiate between controls of products classified and labelled according to the Directive on the classification and labelling of dangerous substances (which was still possible until 30 November 2010, meaning for nearly 22 out of 28 months of the reporting period) and the Directive on the classification and labelling of dangerous preparations (which is still applicable until 2015) or according to CLP. Furthermore, CLP-related violations cannot always be distinguished from enforcement of other specific legislation, such as for toys, plant protection products, detergents, cosmetics, REACH, etc. Overall 26 Member States submitted reports and more than a half thereof contained quantified data for the reporting period.

The results of official controls and other measures submitted by the Member States showed that in the short period that was covered in the first reporting exercise, it was not possible to carry out any type of statistical analysis on the results. However, from the data available some trends may be concluded:

- All Member States appointed authority/ies for the enforcement of CLP. The administrative structures of enforcement authorities differ from one Member State to another and, often, more than one authority plays a role in the enforcement of CLP. The level of enforcement differs between Member States but most of the Member States have elaborated specific enforcement strategy/ies that are in line with the strategy developed by the Forum.
- In most of the Member States there are mechanisms in place to ensure cooperation, coordination and exchange of information on enforcement of CLP. This is

achieved via a variety of instruments such as the performance of joint inspections, use of electronic databases (e.g. ICSMS<sup>255</sup>, REACH-IT, HelpEx<sup>256</sup>), participation in coordinated Forum projects, cooperation with national Helpdesks, dedicated workshops, training and meetings.

- The information provided suggests that the total number of official controls on products carried out by enforcement authorities in the EU, as a whole, has increased during the three years covered by the reporting period. From 38.778 in 2009 to 46.815 in 2011, with a total of 127.436 official controls or other enforcement measures during the period 2009-2011. The same increasing trend has been observed in many Member States.
- Accordingly, also the number of duty holders subject to enforcement has increased in that period. Downstream users have the largest share in the number of duty holders subject to enforcement, followed by distributors, importers and finally manufacturers. The size of duty holders subject to enforcement activities differs between Member States. In general, mostly small and medium size duty holders were inspected. Even micro duty holders were the largest targeted group in several Member States
- The official controls addressed the duties concerning the following categories of issues: hazard classification, hazard communication in the form of labelling, packaging, harmonisation of classification and labelling of substances, notification to the C&L Inventory, obligations to maintain information and requests for information, and other CLP obligations. The main areas where cases of non-compliance were found are the hazard classification and hazard communication in the form of labelling and packaging.
- In terms of absolute figures, Bulgaria, Estonia, Finland, Greece, Hungary and Poland were the most active Member States of those who submitted reports with quantified data. The data from Finland have the largest impact on the aggregated data summarising official controls of products for the Member States for the reporting period. The same Member State also reported the highest number of cases of non-compliance for all reference years followed by France for the last two reference years.
- Generally the compliance rates amount to 70%. About 20% of the official controls resulted in verbal or written advice. Less than 8% of the official controls led to formal enforcement measures such as enforcement notices or administrative sanctions. Only less than 1% of controls led to legal proceedings. Out of those, five ended in convictions by a Court.

These figures are the baseline for the future reporting and indicate that there is still substantial room for improvement of compliance. More comparable data from

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<sup>255</sup> Internet-supported information and communication system for the pan-European market surveillance of technical products

<sup>256</sup> Web-based discussion platform for national Helpdesks

Member States are needed in the future. This will be beneficial not only for Member States but also for the Commission, in order to get a solid basis for further development of a more harmonised approach of Member States towards enforcement of CLP.

It should also be noted that the number of official controls on notification to the C&L Inventory, as required by Article 40 of CLP, has played a minor role when compared to the total number of official controls (around 4% of total controls). However, it is to be expected that the Inventory will play a bigger role in the next enforcement report to be received from the Member States in 5 years. The Inventory provides easy access to information on the hazardousness of a given substance, facilitating the task to correctly classify and label substances and mixtures. In case of divergent classifications for the same substance, industry as well as enforcement authorities have the possibility to further check whether the classification and labelling on a given products is correct and companies having notified classification and labelling for the same substances are obliged to undertake all efforts to come to agreed entries or to identify the legitimate reasons for diverging classifications.

### **Conclusions and recommendations**

CLP sets the rules for classification and labelling of chemical substances and mixtures. The processes for its implementation are relatively recent. In order to ensure effective implementation in practice, Member States are obliged to establish the necessary arrangements for enforcement. Especially a strong and harmonised approach towards enforcement of CLP throughout the EU is vital for delivering its objectives. Despite significant efforts of Member States also within the Forum a more harmonised approach towards enforcement of CLP is still a challenge.

The reports submitted by Member States for the first reporting period (2009 - 2011) showed large variations in the level of detail and the issues addressed. Differences were also apparent in results between the years and depending on the Member State. Inconsistencies in the reporting by Member States further complicated the comparative analysis of the data.

However, from the data received, it can be concluded that the total number of inspections has increased over the last three years but that the compliance rate of the duty holders with their obligations could be substantially improved. In the Commission services' view, this can be achieved through, among others, harmonised and targeted enforcement projects focusing on the areas of detected non-compliance as well as further development and implementation of the Forum enforcement strategies regarding CLP. Such projects should always incorporate an element of awareness raising particularly focussed on SMEs, which, in fact, are the vast majority of duty holders under CLP.

Enforcement is a Member States led activity but having a clear picture about enforcement of CLP on the basis of consistent and comparable data would be to the advantage of all. The Commission, alongside with Member States, in the Enforcement Forum, could have a role in developing enforcement indicators for reporting purposes [Title 11 of Part I]

The enforcement of CLP is closely related to the enforcement of REACH. Member States pursue their CLP inspections often jointly with REACH inspections. Therefore the recommendations related to enforcement of REACH in this paper are also relevant to CLP.

This applies especially to the Commission's recommendation addressed to Member States to enhance their support to Forum members by providing full scientific, technical and administrative assistance, as well as the Commission's recommendation encouraging the prioritisation of enforcement and inspections across the EU in order to focus the limited resources of national enforcement authorities to achieve the most benefits as regards compliance.