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COVER NOTE

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COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 6

{COM(2018) 116 final}

Annex 6 – Review of ECHA

1 Introduction and baseline

The European Chemicals Agency (ECHA) was set up on 1 June 2007 to carry out the technical, the scientific and some administrative aspects of the REACH and CLP Regulations and to ensure for these aspects consistency at the Union level. ECHA draws up opinions so that the Commission can enact Regulations (e.g. restrictions) or take specific Decisions (e.g. granting or refusing authorisations). ECHA has strictly limited decision-making powers allowing it to adopt individual decisions on technical aspects, under clearly and precisely defined conditions. The range of powers given to ECHA is in line with the principles of the EU legal order which imposes constraints on the scope of the powers that can be given to Agencies[1].

Today, ECHA has responsibilities for the implementation of four specific Regulations:

- the REACH Regulation[2] for which the main tasks of ECHA are to manage the registration process of chemical substances, the evaluation of registration dossiers and, in collaboration with the Member States, of substances, and the preparation of opinions on applications for authorisation and proposals for restrictions on the use of chemical substances;
- the Classification, Labelling and Packaging Regulation (CLP)[3], where ECHA manages the technical/scientific work related to the harmonised classification of substances and the European Inventory on the classification and labelling of hazardous substances;
- the Regulation on Biocidal Products[4] where ECHA provides opinions on the approval of active substances and the Union authorisation of biocidal products;
- the Regulation on prior informed consent (PIC)[5], where ECHA handles processes concerning the import and export of certain dangerous chemicals.

This REACH REFIT evaluation assesses the activities undertaken in relation to the obligations stemming from the REACH Regulation and considers also to what extent ECHA has addressed the European Commission's recommendations to ECHA in the 2013 General Report on the Review of REACH[6].

The main recommendations from 2013 can be summarised as follows:

- ECHA should enhance its resource efficiency;
- ECHA Committees need to continue looking for more efficient ways of working and must be able to rely on strong support from the Member States;
- ECHA should increase its SME support and supply chain communication activities;

1 COM(2002)718 final, 11.12.2002, p. 8; COM(2008)135 final, 11.3.2008, p. 5.
2 Regulation (EC) No 1907/2006
3 Regulation (EC) No 1272/2008
4 Regulation (EU) No 528/1272
5 Regulation (EU) No 649/2012
6 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN

- The 2013 review of the Fee Regulation needs to consider suggestions made in the 2011 ECHA report, (see Annex 4, section on Fees and Charges)

2 Operations and processes

2.1 Registration

The tasks of ECHA are to provide a system for the submission and processing of registration dossiers, ensuring that all REACH registration dossiers undergo the required checks, that the respective decisions are taken, and that confidentiality claims are assessed according to the standard procedures within the legal deadlines given by the legislation or in the work programmes. ECHA must ensure that decisions are well justified and are of a high technical and scientific quality. Furthermore, stakeholders and the public must have easy access to non-confidential information from all the dossiers of registered substances, within a reasonable time after their registration.

As stated in its General Reports from 2013 to 2016[7], ECHA has achieved all its own targets for registration activities and even exceeded some of them.

- All registration dossiers – including those submitted by the 2nd registration deadline 31 May 2013 - have been processed within the required deadlines and the non-confidential information from registration dossiers submitted by the registration deadline of 31 May 2013 has been published.
- The percentage of inquiries from potential registrants as to whether a given substance is already registered (Article 26 of REACH) - the internal timeframe of 20 days was exceeded, decreased from 14% in 2013 to 8% in 2015 (against a target of 20%).
- The number of data-sharing disputes decreased year-on-year and all have been processed within the legal timeframe.

Through the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES), ECHA provides industry with scientific and technical support under the Chemical Safety Assessment (CSA) programme to enable successful development of the chemical safety reports (CSRs) and adequate risk management advice through the supply chain in the exposure scenarios. In view of these results, ECHA appears to have been effective in achieving its objectives linked to registration activities, except for some particular aspects examined below.

One issue is that about 2 % of full registrations and 3 % of intermediates registrations submitted by the deadlines in 2010 and 2013[8] did not respect the legal requirement of "one substance, one registration" (OSOR). ECHA has taken measures to enforce the rule**:**

- the latest version of REACH-IT released in 2016 does not allow for the opening of several independent registration dossiers for the same substance (this was possible in the past);
- existing cases are being addressed so that all registrants of the same substance end up in the same joint submission.
- ECHA further promotes data sharing in SIEFs with guidance to increase transparency, non-discrimination and fair cost sharing in the framework of SIEFs (i.e. "*Guidance on*

[7] https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports
[8] ECHA report on REACH & CLP 2016

data sharing", available in 23 languages – which has been updated after the adoption of a specific Regulation on joint submission of data and data-sharing by the Commission[9]) and dedicated workshops on "*practical advice for data sharing negotiations*". This is complemented by hands-on advice on ECHA's website.

Nevertheless, SMEs have flagged that ECHA needs to better tackle data sharing disputes and issues related to lead registrants charging additional fees. Faced with this feedback, the Commission adopted in 2016 an implementing regulation on data sharing and joint submission, which spelled out more clearly the role and responsibilities of ECHA in data sharing disputes. In this respect, it should be noted that ECHA has already undertaken measures to address this issue. Indeed, the access to the dispute settlement mechanism is free of charge and seen as easy to use as only a webform has to be submitted in addition to the copies of the communication (emails, letters) between the parties.

Stakeholders considered in the past that there were shortcomings in ECHA's verification of the completeness of registration information, as the IT-based automatic completeness check led to the acceptance (by giving registration numbers) of registration dossiers that did not contain the required information. ECHA addressed this by introducing in 2016 a manual verification in addition to automatic completeness check for certain data elements that cannot be verified automatically, e.g. substance identity. Improvements also include verification that documentation on SME status is included. ECHA expects that the higher costs of the manual verification of the completeness check will be outweighed by the benefits as improved dossier compliance will result in higher efficiencies in other activities such as compliance checks and identification of substances of potential concern.

According to the surveys conducted in the context of the ECHA evaluation study[10], stakeholders are overall satisfied with the way ECHA has managed the registration deadlines for phase-in substances, providing scientific expertise on chemicals safety, ensuring consistency for disseminating information and guidance to industry and Member States.

Further room for improvement has been noted concerning the guidance material (format and content), which is considered too detailed and too technical for companies and in particular SMEs, thus adding administrative burdens. In response to this feedback, ECHA has prepared the ECHA 2018 webpages[11], in cooperation with all stakeholders. All guidance material has been simplified and translated into all EU languages, with the SMEs in mind. Industry also noted that the complexity and frequent updates of IT tools rendered registration more difficult.

The majority of respondents to the open public consultation consider that in general terms ECHA has handled the registrations of chemical substances effectively. This is not the case for NGO respondents which express more critical views, as they feel that ECHA is too accommodating of industry because it invested too much resources in supporting the industry to comply with their legal obligations under REACH, while REACH registration is meant to shift the burden from the regulator to the industry.

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[9] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing), OJ L 3, 6.1.2016,

[10] Link to the final report of the review of the European Chemicals Agency (ECHA)

[11] https://echa.europa.eu/reach-2018/

Stakeholders are satisfied with ECHA's transparency in the area of "*dissemination of information*" on chemicals. Industry associations tend to agree that ECHA has found the right balance between transparency and openness versus protection of confidentiality of business information. NGOs' responding to the consultation expressed a rather high level of satisfaction with ECHA's transparency.

Some shortcomings were detected in the process for verification of the SME status of registrants. ECHA has to check whether the declaration made by registrants on their size is accurate or not. If not, ECHA rectifies the fee to be paid by registrants (e.g. standard fee instead of reduced fee) and applies an administrative charge that encourages the registrant to be accurate about their actual company size. According to the Commission Internal Audit Service, the Agency accumulated a backlog of SME verifications which constitute a potential loss of income from companies which did not correctly declare their actual size. The Agency has put in place an action plan to deal with this backlog.

2.2 Dossier and Substance evaluation

Dossier evaluation comprises both the examination of testing proposals and compliance checks. In the examination of testing proposals, ECHA assesses whether proposed tests are necessary or not in order to avoid unnecessary animal testing. The purpose of the compliance check is to verify that registration dossiers comply with the information requirements of the REACH Regulation. REACH requires ECHA to select at least 5 % of all the registration dossiers for each tonnage band for a compliance check.

Substance evaluation aims to verify, based on initial concerns, whether a substance constitutes a risk for human health or the environment, and is performed by the Member State's competent authority, with a coordinating role for ECHA. Substances to be evaluated are included in the Community rolling action plan (CoRAP), based on risk-based prioritisation criteria set out in the REACH Regulation.

The tasks of ECHA are to ensure the preparation of scientifically and legally robust draft and final decisions on testing proposals, compliance checks and substance evaluations, as well as to ensure that the decisions are coherent and followed up without delay. In order to put in place effective and efficient processes, ECHA, in cooperation with the Member States' competent authorities and the Commission, developed a variety of approaches to evaluation, in particular:

- In 2011 ECHA introduced the 'Areas of Concern' approach to identify dossiers subject to compliance check;
- In 2014 ECHA developed a new approach to compliance check as set out in the compliance check strategy[12] now referred to as the Integrated Regulatory Strategy[13].

The ECHA evaluation study concludes on the basis of an analysis of the General Reports from 2013 to 2016 that throughout the four years, all dossier and substance evaluations have been treated within the legal time limits and in line with the targets set in the annual work programmes. The percentages of compliance checks concluded for the registration dossiers

[12] A new strategy for compliance check to improve the quality of information provided by companies, 26 September 2014, https://echa.europa.eu/documents/10162/17208/echa_cch_strategy_en.pdf/607b157b-a35d-4d1c-8e62-ce8668324b1a

[13] ECHA Report on the operation of REACH and CLP 2016, p. 26-28

submitted by 2010 and by 2013 were in line with the legal requirement of a minimum 5%. The percentage of follow-up evaluations performed within six months after the deadline set in the final dossier evaluation decision slightly exceeded ECHA's own target of 75% for four consecutive years. The percentage of testing proposal examinations, concluded for dossiers received by the 2013 deadline[14], also exceeded ECHA's own target each year[15]. However it was not possible to obtain from ECHA an overview of exactly what information had been requested for how many substances, nor of the cost of an evaluation decision. Hence an assessment of the impact on human health and environment protection of the requested information was not possible. Commission calculations point at a cost of approximately EUR 60,000 for an evaluation decision. This estimate is based on information related to the FTEs allocated to the dossier evaluation activity. The 2003 Extended Impact Assessment did not provide an estimate of the expected cost for this activity.

According to ECHA's Annual Stakeholder Surveys from 2013 to 2015, Member States' competent authorities are satisfied (up to 80% satisfied or very satisfied in 2015) with ECHA's support for dossier and substance evaluation, and with the implementation of the compliance check strategy. However, in 2014, almost 30% were somewhat dissatisfied with ECHA's communication and interaction with competent authorities and national enforcement authorities on the follow-up process to dossier evaluation decisions[16], although the situation was better in 2015. The members of the Member State Committee are satisfied (up to 80% satisfied or very satisfied in 2015) with the scientific and technical support received from ECHA for the opinion-making process in dossier and substance evaluation.

The Commission services acknowledge the improvements under ECHA's new compliance check strategy, which provides more transparency for registrants. However, the Commission, the industry and NGOs see room for improvement and call for the definition of **better quality indicators**. The Commission has called on several occasions in ECHA's Management Board meetings for a better monitoring of the success of the various strategies implemented over the years to enable a proper assessment of the achievements and where improvements are needed. Indeed, most existing indicators are of a quantitative nature and the performance indicators in the Work programme should be further refined to allow for firmer conclusions to be drawn on effectiveness and efficiency targets.

2.2.1 Avoidance of unnecessary animal testing

ECHA should keep the number of animal tests to a minimum through the tools foreseen in REACH, i.e. the enforcement of the data sharing obligation, the promotion of alternative methods and the examination of testing proposals. ECHA publishes the testing proposals involving vertebrate animals on its website[17] to allow third parties to comment on the actual need for the tests. In addition to the dissemination of registration information on its website, and in cooperation with the OECD, ECHA shares the available data on testing through the *eChemPortal* and manages the OECD QSAR Toolbox software application which supports companies in identifying data relevant for assessing the hazards of chemicals and for filling data gaps in the preparation of registration dossiers without conducting tests on animals. Moreover, ECHA works with the Commission's Joint Research Centre (JRC), and in particular it's European Centre for the Validation of Alternative Methods (ECVAM), to both

[14] In order to reach the legal requirement to prepare a draft decision by the 1 June 2016 deadline
[15] 45% in 2014 for a target of 33%, 81% in 2015 for a target of 75% and 100% in 2016.
[16] Article 42(2) notification
[17] https://echa.europa.eu/chemicals-in-our-life/animal-testing-under-reach+&cd=1&hl=it&ct=clnk&gl=be

influence and benefit from the latest scientific developments as regards methods to generate information on chemicals that do not involve animals.

ECHA's implementation of the last resort legal requirement for animal testing has been criticised by the industry and NGOs and has been challenged in two cases by the European Ombudsman.

- The first Ombudsman case, lodged by the Foundation People for the Ethical Treatment of Animals (PETA) and closed on 11 December 2014[18], found that ECHA's interpretation of its obligations on animal testing was too restrictive, particularly in relation to using compliance checks to verify if the last resort legal requirement had been respected. The Ombudsman made a proposal to ECHA concerning its own role as well as the cooperation with Member States competent authorities, which was accepted by ECHA.
- In the second Ombudsman case, lodged by a group of animal welfare NGOs and closed on 11 September 2015[19], the complainants disagreed with ECHA's position that it could not reject testing proposals involving animals on the grounds that the data could be generated by an alternative method not involving animal tests. The Ombudsman reminded ECHA that the avoidance of animal testing is, together with the protection of human health and the environment, one of the objectives of REACH. The Ombudsman proposed that (i) ECHA requires all registrants making testing proposals to document that they have considered alternative testing methods and have found that the information gap cannot reasonably be filled through such methods and (ii) that ECHA provides registrants with all the available information to allow them to avoid animal testing. Both proposals have been accepted and implemented by ECHA since September 2015.

Although the use of waiving statements instead of testing has increased, leading to less animal testing, the industry respondents in the ECHA evaluation study consider that ECHA should be more pragmatic in accepting animal testing proposals, as it is easier, especially for an SME, to carry out an *in vivo* test, rather than using the QSAR tool. On the contrary, animal welfare NGOs deem that ECHA is still too reluctant to accept new testing methods and favours too often animal tests over non-animal tests.

The views expressed by stakeholders through the online public consultation on how ECHA's work has facilitated the implementation of the last resort legal requirement concerning animal testing are generally neutral except for NGOs, which are more critical in this respect.

2.3 Regulatory risk management measures: authorisation and restriction

ECHA's tasks relating to authorisation include the updating of the Candidate List of substances of very high concern (SVHCs) based on proposals by the Member States or its own proposals on request of the Commission. ECHA regularly prepares recommendations to the Commission on the prioritisation of substances from the Candidate List to be subject to authorisation (through inclusion in Annex XIV to REACH) and provides support for companies applying for authorisation. On the request of the Commission, ECHA prepares restriction proposals, either by itself or working together with Member States in the preparation of the required Annex XV dossier. ECHA also conducts public consultations on

[18] http://www.ombudsman.europa.eu/cases/decision.faces/en/58549/html.bookmark
[19] http://www.ombudsman.europa.eu/en/cases/decision.faces

applications for authorisation and restriction proposals and supports the Rapporteurs from the RAC and SEAC during the opinion-making processes on applications for authorisation and on proposals for restrictions.

According to the Annual Stakeholder Surveys from 2013 to 2016, Member States' competent authorities are overall satisfied with ECHA's support, coordination and information sharing for the different risk management activities. The satisfaction with ECHA's support for the prioritisation of substances for inclusion into the Authorisation List improved in 2015 compared to 2013 and 2014. The members of the MSC, RAC and SEAC as well as the involved accredited stakeholders are also satisfied with the ECHA support for their activities related to authorisation and restrictions, although 10% disagreed for SEAC in 2014 and 2015.

The main difficulties signalled by companies in the ECHA evaluation study for the application process for authorisation were, in decreasing order:

- the complexity of the process and lack of user-friendliness of the IT tools (especially IUCLID[20]) leading to the need for support by external consutants,
- the time and costs involved in the procedure,
- the difficulty to liaise and agree with other companies involved.

The Commission services consider that over the last four years, ECHA has improved coordination with Member States, in particular by implementing a common screening approach to identify substances potentially needing risk management measures, and by implementing the SVHC Roadmap, including the promotion of a common understanding of the regulatory management option analysis (RMOA).

Further efforts will be conducted by ECHA to have a more proactive role in the restrictions procedure (instead of waiting for a Commission request) and prepare for the Commission, taking into account the current activities of the RMOA, a list of potential chemicals that could be restricted.

The efficiency of the authorisation and restriction processes has improved through the work of two Task Forces organised with the Commission and some Member States. The Committees have made efforts to achieve greater consistency of the opinions on authorisation (harmonisation of terminology, description of conditions, justification and conclusions as well as the opinion making process thanks to the use of decision trees) although there is still room for further improvement based on the experiences gained so far (e.g. defining the uses applied for according to the analysis of alternatives). ECHA's efforts to support applicants for authorisations (e.g. pre-submission information sessions) are also considered positive by stakeholders including industry. On the other hand, the European Parliament[21] in one instance has been critical of the quality of the Committees' opinions on applications for authorisation.

It should be noted that ECHA has not yet delivered on the Commission recommendation from the 2013 REACH Review to "*increase resource efficiency by developing a database listing existing restrictions in EU legislation*" (a feasibility study to develop such a list was launched only in June 2016). For more details see Annex 4 section on authorisation and restriction.

[20] Although ECHA makes available partially pre-filled IUCLID files for authorisation applicants.
[21] European Parliament non-legislative resolution of 25 November 2015 B8-1228/2015.

2.4 Scientific IT tools

ECHA has developed and manages various scientific tools to implement its activities related to the REACH and CLP Regulations. The role of each IT tool in supporting the implementation of these Regulations is described in Table XX below.

Table 6.1: ECHA's scientific IT tools for REACH and CLP

IT Tools	Regulations supported	Processes facilitated
REACH IT	REACH	• Submit a registration dossier • Prepare a dossier for a member of a joint submission • Submit an application for authorisation • Submit a PPORD notification • Submit an inquiry • Notify substances on the candidate list • Submit a downstream user notification for substances on the Authorisation (Annex XIV) List • Submit a downstream user report for uses that are not supported by the exposure scenarios or for classification differences
	CLP	• Submit and update a C&L notification • Request an alternative chemical name in mixtures • Submit a CLH dossier
IUCLID	REACH, CLP	• Prepare dossiers, applications and notifications in the IUCLID format • Check dossier completeness; • Verify invoice amount, • Verify level of information to be published on ECHA's website
CHESAR	REACH	Prepare chemical safety assessments (CSAs), chemical safety reports (CSRs) and exposure scenarios (ESs) for communication in the supply chain.

A majority of companies interviewed for the ECHA evaluation study consider the IT tools effective and recognise the efforts of ECHA to manage them, to make them more user-friendly and provide support to applicants via webinars, guidance, and helpdesk.

Nevertheless, the results of the online survey conducted in the framework of the ECHA evaluation study show some shortcomings with ECHA's IT tools. The main difficulties encountered, in decreasing order are:

- the frequent updates (e.g. IUCLID) leading to additional adjustment costs for companies,
- the complexity and lack of user-friendliness of the software (especially IUCLID, but also to a lesser extent CHESAR) leading to time consuming processes (e.g. IUCLID) and the need to the use external consultants for small companies,
- the lengthy and sometimes too complex guidance (e.g. IUCLID, CHESAR),
- the fact that REACH-IT is not accessible on weekends and Finnish public holidays.

In response to industry complaints about the user-friendliness of the scientific IT tools, in particular IUCLID 5 and CHESAR, ECHA has taken actions to improve the functionalities of these tools and provided new versions. However, this led to other complaints from industry about too frequent IUCLID updates entailing high adaptation costs and extra administrative burdens. For example, the new version of IUCLID 6, released in April 2016, requires more information on exposure scenarios and the assessment of PBT properties in highly structured data-entry fields which facilitates the automated screening by ECHA of exposure data. However, this new version will also benefit industry since exposure data can be automatically transferred from CHESAR and easily maintained for updates. While IUCLID 6 contributes to ensuring compliance of registration dossiers, it requires extra resources for companies to fill in the dossiers for the 2018 registration deadline.

Representatives of SMEs also complained that the IT tools were not translated into every EU language, which creates an extra barrier – however, the relevant guidance has now been translated into every EU language in the new released versions of the IT tools.

Lastly, ECHA is developing an 'ECHA Cloud Service', i.e. a cloud version of IUCLID, available to self-declared SMEs, hosted by ECHA on its ICT infrastructure and fully serviced by ECHA. This service has been progressively delivered from the first quarter of 2017 and aims to reduce the technical burden and related costs (financial, labour) for hosting and operating IUCLID locally, to ensure better protection against loss of data and to ensure continuous availability of online IUCLID services over the internet[22].

2.5 Specific attention to SMEs

The 2013 REACH Review specifically identified the need to reduce the impacts of REACH on SMEs. In line with the Commission recommendation from the 2013 REACH Review, ECHA appointed a SMEs Ambassador in 2013. The SME Ambassador is a liaison officer to help the industry and to interact with various bodies at EU level that have a generic interest in SMEs issues, such as the European Union's SMEs Envoy network, formations of the European Parliament or the REFIT platform, and with associations representing SMEs interests. Within ECHA, the SME Ambassador's role is to raise awareness in ECHA about SMEs concerns and act as a catalyst in introducing SMEs-focused considerations into all of ECHA's activities. ECHA has pursued wider communication and awareness-raising of REACH to improve the availability and usability of information available through a dedicated website[23] and a guide for SMEs ("Chemical safety in your business[24]) in 23 EU languages as well as its wide dissemination through the Europe Enterprise Network and national

[22] https://echa.europa.eu/documents/10162/22837330/mb-42_minutes_en.pdf/da130a1b-a03a-48d4-bbda-56c32b726263

[23] https://echa.europa.eu/support/getting-started

[24] https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes

Helpdesks[25]. Furthermore, as explained previously, ECHA has specifically addressed concerns of SMEs related to data-sharing in SIEFs. ECHA has organised and/or participated in numerous events at national level to directly interact with SMEs in their own languages

ECHA has also continued the activities of the so-called Directors' Contact Group (DCG), which provides a platform for the informal exchange of views and information between the Agency, the European Commission and participating Industry Associations and contributed actively in streamlining support and providing orientation to duty-holders.

Stakeholder views on the results of these activities are divided. On the one hand, industry respondents to the online public consultation are rather critical about the way ECHA's work has contributed to reducing the impact of REACH on SMEs. On the other hand, the SME panel shows that information and guidance made available by ECHA is among the most frequently used sources of information on REACH. Respondents from public authorities, NGOs and trade unions have a more positive perception.

3 ECHA bodies

3.1 General consideration on the Committees

Articles 76 and 77 of the REACH Regulation set out the tasks of the three Scientific Committees of ECHA, namely the Member State Committee (MSC), the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC).

In light of the increasing workload, in particular of RAC for which the workload has tripled (i.e. from 34 opinions in 2012 to 102 opinions in 2016), a number of initiatives have been taken to increase the working capacity of the Committees but also to streamline procedures and working methods.

Membership of RAC increased from 39 members in 2012 to 51 members in 2017, while SEAC expanded from 30 to 39 members. In addition to nominations from the Member States, and to cope with the high number of authorisation dossiers, RAC and SEAC co-opted four members each, who were selected in light of the increasing number of applications for authorisation. In fact, while the expertise in RAC for the evaluation of classification and labelling dossier has been solid, the expertise in the other area needed some reinforcement. However, when nominating members for the Committees, there were difficulties to find appropriate experts within and outside national competent authorities and Member States for all relevant areas of expertise which includes human toxicology, ecotoxicology, epidemiology, occupational hygiene, exposure assessment, risk assessment and risk management.

As far as SEAC is concerned, the Commission observed an increase of the relevant expertise required among its members. However, this trend needs to be pursued to ensure that the Committee has the appropriate mix of expertise in particular in the field of socio-economics and the analysis of alternatives.

Based on observations by the Commission, expertise and capacity to deal with the work volume in the Member State Committee is somewhat unevenly distributed and the biggest

[25] Link to the guide for SMEs: Chemical safety in your business

contribution is brought to the meeting and decision making by a small number of only 7 – 8 Member States.

Furthermore, to accommodate the higher workload, the number of Committee meetings was increased and the duration of the Committee sessions was extended. RAC plenary meetings usually take two weeks, four times per year. One week is mainly dedicated to the assessment of classification and labelling dossiers under CLP. The other week is dedicated to the evaluation of applications for authorisation and proposals for restrictions, as well as specific requests for opinion under Article 77(3)(c) of REACH.

Actions have been taken by ECHA to increase the efficiency of the meetings, for instance by organising preparatory meetings and use of written or fast-track procedures. To ensure the cost-effectiveness of meetings, in particular in consideration of travelling costs as well as the limited availability of Committee members, such additional meetings were organised back-to-back to the regular meetings, and where possible, by making systematically use of videoconferencing.

The reduction of debating times in plenary sessions for straight-forward cases, allows for more time for the examination of priority dossiers or complex cases. Informal consultations in between meetings also help to identify contentious points and to facilitate the alignment and the adoption of opinions during the plenary meetings. The streamlining of internal procedures and working practices, such as the recourse to written procedures or fast-track agreements is also perceived as an important timesaver. For example, in the case of the MSC, 90% of dossier evaluation draft decisions are agreed in this way, and 60% of substance evaluation draft decisions. The revision of the internal procedures of RAC and SEAC in June 2015 is perceived by Committee members as facilitating more efficient ways of working and processing dossiers.

The limited availability of individual members translates into higher workload for ECHA staff, in particular for scientific dossier managers assisting the rapporteurs in the preparation of draft opinions, and into more difficult and more time-consuming decision making. This issue has been reported by ECHA to the Management Board in 2014, and the Management Board requested the Member States' competent authorities to make sufficient resources available.

This campaign has been successful in further mobilising current members and increasing the number of members in general (RAC up from 40 to 51 and SEAC up from 30 to 39 (2014-2017). An estimated 60% of members in RAC and SEAC in 2017 now meet or exceed their target.

It should also be noted that the REACH Regulation foresees the possibility that the Committees can make more use of available external experts that can be involved on an ad-hoc basis in the discussions and support the work of the Committees with additional expertise. In fact, dose-response relationships or DNELs for substances recommended for inclusion into Annex XIV are derived by external contractors and validated by RAC, as the time and resources allocation does not give any possibility for RAC member to derive them. However, the Commission services consider that ECHA should reflect on how this work could be performed internally instead of resorting to external contractors in particular as ECHA has the scientific competence to deliver this task. It is important since ECHA's ambition is to become the hub for excellence in regulatory science. In order to have more flexibility, ECHA could

create a list of experts to be continuously updated and use these experts for 'ad hoc' attendance at the meetings of RAC.

ECHA's stakeholder surveys indicate that the level of satisfaction with the support provided by the ECHA Secretariat to the Committees is generally positive. However, a number of interviewees in the ECHA evaluation study suggested that that the operation of the Committees could be further optimised, e.g. ECHA could be more proactive, meetings could be prepared more efficiently and the workload of Committee members could be reduced by providing more streamlined documents.

Members of ECHA's Committees noted that the strict legal deadlines, in particular for restriction and authorisation dossiers, limit the margin for flexible workload management such as the prioritisation of dossiers. A number of interviewees in the ECHA evaluation study commented that the unanimity rule[26] for adopting MSC opinions creates inefficiencies in the process, especially in politically sensitive or controversial cases. As an example, 216 draft decisions on the Extended One Generation Reproductive Toxicity Study were referred to the Commission due to the lack of unanimity in the MSC.

Members of the MSC as well as the Commission have highlighted that RAC uses for risk assessment and classification & labelling (C&L) dossier the data that has been generated in evaluation with the involvement of the MSC. However, RAC does not always accept in particular when processing C&L dossier the data generated via evaluation – so more interaction between RAC and MSC would be desirable.

The collaboration between RAC and SEAC has improved on the basis of the increasing expertise and thanks to the support of ECHA Secretariat. However the Commission services consider that this dialogue has to continue to improve in particular for complex cases.

During this review period, SEAC has delivered in a timely manner more than 100 opinions on applications for authorisation and over 20 opinions on restriction proposals. According to ECHA's 2015 and 2016 Annual Stakeholder Survey, a majority of SEAC members and accredited stakeholders are satisfied with the transparency of the SEAC processes. According to the ECHA evaluation study, SEAC is considered as an innovative Committee compared to other EU agencies by accredited stakeholder organisations (ASOs) and Member States authorities. The methodology used in the socio-economic assessment related to chemicals risk management is not as developed as risk assessment techniques and some NGOs note that very few SEAC experts have in-depth expertise in socio-economic issues, which may affect the opinions formulated by the Committee.

Many NGOs and some Member States authorities have also criticised that SEAC accepts too easily requests for derogation from restrictions and is not critical enough as to the outcome of the analysis of alternatives in authorisation applications. Nevertheless, the Commission services and stakeholders agree that the quality and value of SEAC opinions has increased but consider that further capacity building to widen the pool of expertise in the area is needed[27]. Further improvement is noted in terms of process, structure, analysis and presentation of the opinions. This work should continue to ensure delivery of opinions of high quality addressing the increasing needs of the decision-making process. The Commission will continue to provide feedback in order to ensure that the opinions it receives are fit for purpose.

[26] Such unanimity rule only applies to MSC
[27] 2016 Report on the operations of REACH and CLP

In a resolution adopted by the European Parliament[28] objecting to a draft decision of the Commission on authorisation, one joint scientific opinion delivered by RAC and SEAC was criticised, and SEAC was reproached with having overstepped its mandate by giving policy-driven opinion. While the Commission dismissed this allegation[29], as policy elements were mentioned but not decisive for this opinion, the Commission services concur that policy is out of the remit of SEAC. A follow-up discussion also took place in the 17-18 March 2016 Management Board where an action plan was agreed.

In view of the above-mentioned perceptions of certain stakeholders, the Commission services and ECHA organised a workshop to clarify the role of socio-economic analysis (SEA) under REACH, and in particular to improve the understanding on what SEA does and what it does not do, how the opinions of SEAC are derived, and how SEA and SEAC opinions are used in the decision-making with regard to restrictions and applications for authorisation. The workshop concluded, among other things, that SEAC supports and is necessary for the decision-making, but does not replace it, that it provides the factual (not necessarily purely quantitative) basis and analysis for the decision-making based on which political judgement is made. It also recognised that SEAC's capacity has increased, underlined the need to improve the understanding between risk assessors and socio-economic analysts, and noted the challenge to properly communicate SEA results to uninvolved stakeholders.

Member State Committee

The Member State Committee (MSC) participates in several REACH processes such as Evaluation and Authorisation. The MSC is responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs). The Committee provides opinions on ECHA's draft recommendations for the authorisation list (Annex XIV) and draft Community Rolling Action Plan (CoRAP) for the substance evaluation process. If an agreement is not reached within the MSC, the matter is referred to the European Commission for decision-making.

The Committee meets 6 times a year, gathering 53 experts (most of the Member States participate with 2 experts), plus the accredited stakeholders (NGOs and Industry), and requires substantial support from a dedicated group of staff from ECHA's Secretariat.

A survey was performed and discussed with stakeholders in 2015 in the framework of ECHA's General report on the operation of REACH and CLP. The survey results showed that Member States and MSC members are generally satisfied with the workload and the current number of substances evaluated per year and believe it should be maintained (65%), while 23% of them called for a reduction. The comments on the workload are in line with the comments made by Member States in their 2015 reports submitted in accordance with Article 117(2). Member States considered that preparing the draft decisions, addressing comments from registrants and preparing responses to the PfAs were resource-intensive, often because of time constraints.

Member States acknowledged the progress achieved over the years to increase the efficiency

[28] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 – 2015/2962(RSP)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0409+0+DOC+PDF+V0//EN

[29] See COM response to EP Resolution B8-1228/2015

of the MSC meetings and the good results of streamlining efforts implemented by the Secretariat. Member States and MSC members agree that a number of the improvements already in place will further improve the efficiency of the substance evaluation process (e.g. new format for conclusion documents, new structure of MSC meetings etc.). Suggestions to improve the MSC meetings include promoting informal communication and consultation among Member States in the finalisation stage of the substance evaluation process, increasing the use of the written procedure, circulating the documents earlier to enable Member States to consult their experts, and increasing the participation of all Member States in substance evaluation.

Usually, the proposals for amendments (PfAs) reflect the different views from the Member States on different scientific and technical or policy issues, rather than corrections of ECHA's assessments. Sometimes these views diverge greatly among the Member States, which may make the PfAs unavoidable. This is partly reflected by the fact that even though the process has matured after almost ten years of experience, the percentage of PfAs remains very high. In 2016, 237 draft decisions were submitted to Member States Competent Authorities (MSCAs), of which 90 received PfAs. The number of PfAs per draft decision varied widely between 1 to 10-12. On average, PfAs were received for about 40 % of the draft decisions referred to MSCAs. The main issues referred to by the PfAs were read-across (different views on acceptance/rejection of read-across), Extended One-Generation Reproductive Toxicity Studies, environmental testing for persistency and mutagenicity testing (test guideline and study design). The interventions of the MSC in the identification of SVHCs and in the definition of the candidate list for the inclusion in Annex XIV have diminished over time due to the progressive standardisation of the process, hence most of its contributions are focused on dossier (testing proposals and compliance checks) and on substance (Community Rolling Action Plan) evaluations.

The PfAs were made by 9 Member States out of the 29 that are represented (the 28 EU countries plus Norway, as Iceland and Liechtenstein have not appointed any delegate), the activity being very strongly led by 4 countries.

According to Deloitte (2017)[30], there is the perception that the MSC performs well in terms of working procedure and expertise. However, as the members of the MSC are appointed by MSCA and represent national interests, some discussions tend to be more politically-oriented than scientifically based. Actually, the nature of the MSC has been the source of confusion and conflict with some Member States. These Member States believe that the MSC is an extension of their national authorities and distinguish between the ECHA decision making power and that emanating from the MSC. Although it has been clarified on multiple occasions that the MSC is a body of ECHA, some Member States believe the MSC is independent from ECHA and hence is not bound by the same rules, for example is not bound by the decisions of ECHA's Board of Appeal.

Risk Assessment Committee[31]

Member's expertise

[30] Link to the final report of the review of the European Chemicals Agency (ECHA)

[31] Further information on the independence of the Risk Assessment Committee (RAC) is available on ECHA's website.

The discussion during the RAC plenary session usually takes two weeks, four time per year.

One week is mainly dedicated to the assessment of the classification and labelling dossier which requires an expertise of toxicology, eco toxicologists, chemistry, biology. Experts have to judge mainly the intrinsic properties of chemicals.

The other week is dedicated to the evaluation of the application for authorisation, the assessment of the Annex XV dossier, requests under Article 77 (3) (c). The expertise requested in this area is mainly on toxicology, eco-toxicology, exposure, epidemiology, industrial hygiene, risk assessment and risk management.

While the expertise on the evaluation of classification and labelling dossier is quite solid in RAC, the expertise in the other area needs some more qualified staff in particular as the workload is increasing mainly due to the increased number of applications for authorisation and other "new" tasks.

The tasks are quite different and having a big pool of experts in each area is complex. However the Committee could benefit from allocating more support ECHA staff in specific areas where this expertise is requested. The allocation could be addressed through permanent or temporary staff depending of the allocation resources which ECHA has to consider for its budget in 2018.

As the experts are nominated by Member States, the selection at national level is fundamental and the different expertise should be addressed by Member States avoiding the focus on only one specific area.

Collaboration with the Agencies and Scientific Committee

Article 95 of REACH deals with potential scientific conflicts between the Agency and the other EU agencies or Scientific Committees.

In two specific cases RAC had to discuss with other Scientific Committees their evaluation.

- In the case of Annex XV dossier for restriction on Bisphenol A in thermal paper, RAC discussed together with EFSA the hazard assessment on the substances and the choice of the most relevant scientific studies and publications. The experts from EFSA panel and those from RAC agreed on the scientific assessment taking into account the most recent studies and scientific results.
- In another case, on the substance 1-methyl-2-pyrrolidone, RAC worked together with members of the Scientific Occupational Exposure Committee (SCOEL), and the discussion came to a divergent conclusion highlighting the different approach and methodology followed by the two Committees.

On a general case, RAC and SCOEL also worked together to discuss their methodology in deriving occupational exposure limits (OEL) and Derived No-Effect Level (DNEL) for inhalation route as well as DNEL –skin notation for dermal route, which has been the most fundamental point of discussion on chemicals subject to the regulatory process of adoption of limit values under the OSH legislation and to the authorisation process under REACH.

Following this discussion, the Commission questioned the need to have at EU level two different committees dealing with the evaluation of the same chemicals. Therefore, it was considered necessary to build within RAC the necessary expertise to cover the areas covered by SCOEL in a very short-time period and over a longer time period to replace SCOEL with RAC.

Due to this future change, RAC would definitely need to re-consider its own expertise and the Agency should allocate the necessary resources to deal with these relatively new tasks.

Socio-Economic Analysis Committee

Collaboration with RAC

The collaboration has been good in general, with creation of *ad hoc* groups to address specific issues. This is was in particular the case for impacts of man-via-the environment where, due to the potential high level of uncertainties, a close collaboration between the two committees was necessary and has been ensured.

MS reports according to Article 117

17 CAs commented on their responses. In addition, 4 CAs stated that they did not participate in the SEAC.

With regard to the effectiveness of SEAC, 8 respondents commented either that the Committee is effective or that the effectiveness has increased in recent years. 3 CAs attributed this positive change to improved and streamlined work processes. Two CAs recognised the added value of the support provided by the ECHA Secretariat to rapporteurs in the form of increased competences and expertise, and more experience of members in handling restriction dossiers.

However, 4 CAs indicated that the SEAC lacks members with sufficient expertise in socio-economic analysis. According to two CAs, the nomination of experts in the Committee is not based on adequate peer approval, which reduces the number of rapporteurs available, their effectiveness and the support they can get from the Committee. One CA added that the heterogeneous composition of the technical committee (economists, scientists, engineers) could complicate the work of the SEAC.

The increasing workload of the Committee appeared as a concern to 3 CAs, as it puts pressure on the CAs to find experts for the Committee, potentially compromising the quality of the expertise provided or the regular work of the CAs. In addition, 2 CAs blamed an unequal distribution of the work, placing a greater burden on certain CAs.

Regarding work procedures, one CA indicated that there is no coordinated assessment practice to a number of key substantive tasks of the SEAC – without specifying which ones. Another CA mentioned that some steps of the procedure were still taking too long, such as the conformity check for applications for authorisation, and another one, that the level of details of the assessment goes sometimes beyond what is needed and leads to ineffective work. Finally, one CA indicated that discussions and commenting rounds could be better organised and that communication and cooperation with RAC needed to be improved.

Regarding the assessment of application for authorisation, 2 CAs have mentioned that the poor quality of applications complicates the work of the Committee and forces the Committee to make its own assessment instead of evaluating the proposal. One CA added that the challenge lies in finding the right balance between further streamlining the application for the authorisation procedure, while ensuring a high level of information so that the RAC and the SEAC can do their assessment. Receiving ‘fit for purpose’ applications should be the main goal, and the level of details should be sufficient in all applications, especially concerning exposure.

For the sake of completeness it should be noted that some of the criticisms expressed by CAs have been addressed by the Task Force on the workability of Applications for Authorisation

and in particular the development of a practical guide on how to apply for authorisations[32].

The assessment of the analysis of alternatives is complex: for example, the only way for SEAC to validate the information at its disposal is through the inputs from the public consultations. It may thus be worthwhile to create an ad-hoc group with technical expertise on the assessment of alternatives, with specialisation by industrial sectors or segments, which would provide support for the assessment of the technical and the economic feasibility of alternatives.

Proposals for recommendations

Members

1. Need to ensure that members have sufficient socio-economic expertise, ideally socio-economic expertise applied to chemicals and to human health and the environment, in order to properly fulfil their duties according to Article 76 (1) (d) of REACH.
2. Need to ensure that members dedicate to SEAC at least as much time as they have committed to when accepting the task.
3. Ensure that opinion of the Committee is always technically justified and not driven by political national agenda.
4. ECHA continue to set up training sessions targeted to members dedicated to specific SEAC-related knowledge and processes.

Functioning

Restriction

5. The task force should assess ways to improve the technical and economic feasibility of alternatives and provide some practical guide to SEAC.
6. Continue to improve the approach for assessing the impacts from PBT/vPvB substances.
7. Need to clarify the necessary level of SEA assessment by the dossier submitter (in order not to burden them too much, with unnecessary requests), and of subsequent scrutiny by the Committees as recommend by the Restriction Task Force.

Authorisation

8. The task force should assess ways to improve the technical and economic feasibility of alternatives and provide some practical guide to SEAC.
9. Need to clarify the necessary level of SEA assessment by the applicant (in order not to burden them too much with unnecessary requests), and of subsequent scrutiny by the Committees as foreseen in the practical guide.
10. Need to improve the approach for assessing the impacts from PBT/vPvB substances.
11. Ensure that the opinions are fit for purpose.
12. Need to improve the definition of economic feasibility.

Others

13. ECHA should explore the possibility to have a system of scoring the applications for authorisation according to their level of quality, and categorisation by type of application (e.g. broad use, narrow use, substance, occupational concern related,

[32] https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676

general population concern related, environmental concern related, etc.), what may facilitate the task of applicants when preparing their application for authorisation

14. SEAC being the only expert group of all EU pieces of legislation specialised on SEA-related issues, possibility to use SEAC as a consultation group for other legislation.

Proposals for improvement from MS

To improve the quality of the expertise of the SEAC, 5 CAs proposed to:

- Introduce more stringent vetting procedures for new members to ensure they have sufficient expertise in socio-economic analysis

To improve the general working procedures of the SEAC, respondents proposed to:

- Notify to Committee members, ten days before the meeting, the issues that need to be finalised in the opinion during the next meeting to ensure that CAs are able to give a statement during the meeting
- Further streamline formats and committee-internal processes
- Avoid presenting systematically the conformity check for applications for authorisation during plenaries to speed up the process
- Distribute the work more evenly between Committee members and increase participation of all members in the drafting of opinions
- Make rapporteurs' work more flexible (deadlines, meetings, etc.)
- Establish an expert group on health impact assessment to bridge the gap between the RAC and the SEAC
- Increase the discussions on alternatives associated with the uses of a substance in the evaluation of applications for authorisation To improve the quality of the applications for authorisation and the authorisation process, 3 respondents have suggested that:
- The ECHA Secretariat increases the support to applicants preparing the dossiers
- Communicating to the industry that applications of poor quality hampers the work of the RAC and the SEAC and might have consequences when it comes to the formulation of opinions
- Information requests to applicants and the level of detail of the evaluation is tailored according to the specificities of the application. For instance, if costs and benefits are similarly high, requests for additional information will be necessary and the evaluation will have to be more detailed

3.2 The FORUM for Exchange of Information on Enforcement

The FORUM for Exchange of Information on Enforcement (the FORUM) coordinates a network of Member State authorities responsible for the enforcement of REACH. The aim of the FORUM is to harmonise the enforcement action of these National Enforcement Authorities (NEAs), by sharing good practices, undertaking harmonised enforcement projects and joint inspections, coordinating the exchange of inspectors, equipping them with manuals and tools, liaising with industry as well as examining proposals for restrictions with regards to their enforceability (see Annex 4, section 9 related to enforcement for further details).

According to the Annual Stakeholder Surveys and interviews conducted for the ECHA evaluation study, the members of the FORUM are satisfied with the effectiveness and transparency of the FORUM activities, as well as with the involvement of the accredited

stakeholder organisations (ASOs) in their work (ASOs can attend one of the three annual plenary sessions and contribute to some of the FORUM Working Groups).

A report of ECHA's Internal Audit Capability (IAC) on the FORUM in 2013 identified improvement points for a more efficient organisation of the FORUM's work and suggested how more effective support could be provided by the FORUM Secretariat, e.g. monitoring more systematically the allocation of time to activities to allow for a more efficient management of resources, to reduce the delivery times for working groups, and to engage more effectively its less 'active' members.

Since then, a number of improvements in the FORUM's functioning have been put in place. Compared to the situation in 2013, working practices have been streamlined and more efficient ways of working implemented. In 2015, the rules of procedure of the FORUM were reviewed. In addition, a new procedure for the delivery of the FORUM advice on enforceability of restrictions has been adopted[33]. Efficiency has improved in terms of communication with the ECHA's operational Directorates and NEAs. Some further improvements are still needed in terms of communication of the FORUM with RAC and SEAC to determine the best timing for the FORUM to provide opinions on the enforceability of the restriction proposals.

From ECHA's stakeholder surveys some administrative improvements could be suggested regarding the support provided by ECHA to the planning of meetings, agenda-setting as well as the preparation of meeting documents.

The set-up of Working Groups is perceived as a more efficient solution to organise the FORUM's work compared to the three plenary meetings, which do not provide sufficient room for discussions. The ten Working Groups, composed of a limited number of NEA officials, focus on specific topics and prepare decisions and manage the workload. However, the workload is perceived as high by the FORUM members as the involvement in Working Groups requires a permanently high level of commitment, which is for some members difficult to combine with their work in the national enforcement authorities. To reduce the impact in terms of travelling time and costs, meetings of working groups are occasionally organised via video conferences. Due to the increased number of projects which could be requested to the FORUM, the workload is not foreseen as decreasing in the future which would imply a possible restructuring of this body (for instance by creating a sub-group for Biocides).

Nevertheless, as for ECHA's Committees, resource constraints and limited availability of members at national level represent a challenge to the efficient and effective working of the FORUM. Moreover, the existence of different competent National Enforcement Authorities (NEAs) in the Member States, which are not always well informed of one another's activities, can lead to inefficiencies.

3.3 The Board of Appeal

The Board of Appeal (BoA) deals with appeals lodged against certain decisions taken by ECHA, both in the context of REACH and the Biocidal Products Regulation. The most

[33] ECHA MB 12/2015: Rules of Procedure for the FORUM for Exchange of Information and Enforcement, 20.03.2015.

common cases of appeal relate to compliance check decisions, registration revocation/rejection, substance evaluation decisions and decisions on data sharing.

The BoA is an independent body from the rest of ECHA and reports directly to ECHA's Management Board - discussions on the organisational structure and composition of the BoA take place within a specific Working Group of the Management Board. ECHA's BoA is a collegial body composed of three permanent members (a Chairman of legal qualifications, a legally qualified member and a technically qualified member) and is assisted by a Registrar. A number of alternate and additional members have been nominated, as each appeal has to be heard by a Board of three members.

The workload of the Board of Appeal has increased since 2012 as more appeals are submitted and more hearings organised. The BoA is now operating effectively with about 20 cases per year received for consideration. The number of decisions appealed in front of the BoA is significantly lower than was expected when REACH entered into force.

Appeal proceedings are open and accessible to stakeholders, ensuring that all relevant interests are heard before a decision is adopted. NGOs active in the fields of health, the environment or animal welfare, concerned companies, industry associations and Member States authorities, under certain conditions, can present their views in a particular case as interveners. Moreover, with all final decisions published online as well as certain procedural decisions related to intervention applications and confidentiality requests, the BoA is achieving its objective of effective communication and transparency.

BoA decisions have had an impact on ECHA, adapting processes towards more relevance and effectiveness[34]. Stakeholders consider that the BoA decisions enhance legal clarity as regards interpretation of the provisions in REACH, in particular on compliance check, testing proposals and substance evaluation.

So far, only two BoA decisions have been challenged at the European Court of Justice, with the focus on the powers of review of the BoA.

Only limited views on the efficient functioning of the Board of Appeal could be collected during the ECHA evaluation study. ECHA's Annual Stakeholder Surveys reveal that only half of REACH registrants are aware that they can appeal to the BoA against certain ECHA decisions. ECHA staff as well as the reports of the Board of Appeal point to a more efficient functioning of the Board of Appeal, given the consolidation of procedures as well as an improved case management. Efficiency gains were associated with the joint submission of appeals on the same decision or joint hearings in similar cases.

However, a number of elements are perceived by BoA staff to limit the optimal operation of the BoA:

- Increase in workload, while the administrative unit within ECHA, providing support to the BoA has decreased in size under the required overall staff reductions;

[34] An example is the adaptation of registration process and IT system due to a case on Charcoal linked to completeness check. As another example, a decision on the use of languages in relation to the ECHA's communications with registrants, in the context of the SME verification process, prompted the ECHA to reassess its processes.

- Increased resource-intensity of the cases due to the higher technical and scientific complexity of appeal cases as well as the specialised expertise required for the Biocides-related appeals which require training of staff;

New procedures were adopted in May 2016, which interviewees in the ECHA evaluation study considered as allowing for a more efficient operation of the BoA as well as a better management of cases.

The reports of the chairman of the Board of Appeal emphasise the need for an adequate level of resources, to ensure that the BoA can continue to deliver high quality work and operate efficiently. Some interviewees in the ECHA evaluation study perceive that the BoA is understaffed and suggested to appoint an additional legally qualified member to accommodate the high workload. The framework of the BoA allows for flexible solutions to appoint alternate members. Alternate members worked on appeal cases when the position of the legally qualitied member was filled ensuring continuity of operations.

Overall, the experience after 10 years of operation of REACH is that the BoA is a vulnerable body, depending on the solid performance of its members as well as their interpersonal relationships, as all BoA members have equal voting rights. Given that, according to REACH, there can only be one technically qualified member in the BoA, it has become clear that the assistance provided by the Registrar to the BoA should be strengthened to cover scientific aspects, and not be limited as it is today to legal research and drafting. Feedback from industry on the operation of the BoA is overall positive[35].

3.4 The Management Board

ECHA activities are overseen at strategic level by the Management Board, while the day-to-day management falls under the responsibility of the Executive Director. The respective roles and areas of responsibilities are defined in the REACH Regulation.

Article 79 (1) of REACH prescribes the composition of the Management Board. The Management Board comprises 36 members: 28 representatives of the Member States selected "on the basis of their relevant experience and expertise in the field of chemical safety or the regulation of chemicals whilst ensuring there is relevant expertise amongst the Board members in the fields of general, financial and legal matters", three Commission officials, and three individuals from interested parties (representing industry, trade unions, consumer and environmental NGOs) are appointed by the Commission and two independent persons by the European Parliament. The representation of the Commission in the Management Board (from the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, the Directorate-General for Environment and the Directorate-General for Health and Food Safety), and in particular in its Working Group 'Planning and Reporting', facilitates the alignment of ECHA's Work Programme with the policy priorities of the Commission.

With regards to the profile of the Management Board members appointed by the national competent authorities, a number of interviewees in the framework of the ECHA evaluation study, including members of the Management Board themselves, pointed to the lack of expertise in financial and legal matters among members of the Management Board. The majority of members of the Management Board are not "managers", rather experts with a

[35] CEFIC presentation at 10 years REACH litigation seminar organised by ECHA, Helsinki May 2017.

scientific profile. This is explained by the fact that national competent authorities, which are in the majority of cases ministries in charge of Health or Environment, send their experts with relevant scientific expertise. Consequently, discussions at the Management Board can sometimes deviate from the consideration of strategic planning, financial and legal matters, and instead focus on scientific and operational aspects. Different priorities on national policy agendas might also come into play. A number of interviewees considered that the efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates for membership.

Members of the Management Board hold generally positive views on the internal organisation, rules of procedures and working practices of the Board have been generally positive, although a number of improvements were suggested:

- The efficiency and effectiveness of the Management Board could be optimised by giving more importance to the managerial qualifications of potential candidates. Member States should appoint members of the boards in light of their knowledge of the agency's core business and taking into account relevant managerial, administrative and budgetary skills and limit their turnover;

- The establishment of an executive board or a similar structure in line with the Common Approach on EU decentralised agencies, reducing the overall number of Management Board sub-groups and using more written procedures could increase the efficiencies of the Management Board;

- Discussions in the Management Board could be more focused on the management issues of the agency and less on scientific aspects.

The Management Board’s decision-making procedure, i.e. two-thirds majority, has not hampered efficiency. The “proxy” system allowing individual members to be replaced in discussions if they are unable to attend a meeting is perceived positively.

The number of meetings of the Management Board (i.e. four two-day meetings per year) is considered to be adequate. The frequency and number of meetings is in line with those of similar EU Agencies, e.g. the European Medicines Agency (EMA) and the European Food Safety Agency (EFSA). However, to increase efficiency, ECHA could resort to written procedures for the adoption of decision not requiring discussion in the Management Board and reduce the length of the meetings from two to one day.

The Management Board has set up a number of specialised Working Groups to plan and organise its work more efficiently, and to focus the quarterly meetings of the Management Board on strategic discussions and the adoption of decisions prepared in the Working Groups. Working Groups have been established on different topics, either related to tasks of the Board or to thematic issues such as ‘Planning and Reporting’, ‘Audit’, etc. The small size of the MB Working Groups, composed of 4 to 9 members, facilitates discussions in preparation for the plenary meetings of the Board. However, whilst this system was chosen at the start-up and consolidation phase of ECHA's operations, the Commission services are of the view that ECHA should investigate the possibility of merging and reducing the numbers of working groups will enhance the efficiency of the Management Board.

Some interviewees in the ECHA evaluation study considered that the size and composition of the Management Board is not optimal to ensure efficient and effective ways of working and

suggested to review its set-up. For example, a number of interviewees suggested either the reduction of the number of members or the creation of a two-level governance structure with a Management Board, in charge of providing strategic direction, assisted by a more professional, small-sized Executive Board, responsible for the monitoring of ECHA's activities and the supervision of administrative and budgetary matters. This latter structure could potentially replace (in part) and/or simplify the system of Working Groups. In fact, this would align the ECHA with the recommendations of the EU's Common Approach for a two-level structure[36].

3.5 The Executive Director (ED)

The Executive Director is appointed by the Management Board for a five-year mandate, renewable once for another five-year period. He is in charge of ECHA's day-to-day administration (Article 83 of REACH).

The Executive Director is assisted in the day-to-day administration by a Deputy Executive Director. Unlike other decentralised Agencies, this function is not foreseen in the founding Regulation of ECHA, the REACH Regulation.

The Executive Director is assisted in planning, monitoring and reporting activities and the management of inter-institutional relations (e.g. with the European Commission, the European Parliament, the Council, etc.) by an Executive Office. Again, an Executive Office is not foreseen in the REACH Regulation, but is a deliberate organisational choice made by the Executive Director. The Executive Office centralises certain horizontal functions[37]. The size of the Executive Office has increased between 2012 and 2016 from 17 to 20 staff, who are not assigned to a specific function, but have multiple roles and various responsibilities. For example, the function of a Data Protection Officer (DPO), which is a legal requirement but does not fill a full-time position, is combined with other horizontal tasks.

Interviews in the context of the ECHA evaluation study with ECHA management and the Management Board confirmed that the Executive Office facilitates internal coordination with relevant operational units and transversal views on the functioning of the organisation. The Executive Office is also perceived to provide governance support and input to the work of the Management Board.

A comparison with similar EU Agencies such as EMA and EFSA, shows that ECHA's Executive Office is relatively big and that these Agencies have implemented a decentralised solution to organise the support functions to the Executive Director. Only advisory functions for strategy and policy support are independently organised.

[36] https://europa.eu/european-union/sites/europaeu/files/docs/body/2012-12-18_roadmap_on_the_follow_up_to_the_common_approach_on_eu_decentralised_agencies_en.pdf

[37] Functions within the Executive Office are: Information Security Officer, Data Protection Officer, Secretary to the Management Board and Inter-Institutional Relations, Internal Control Officer, Strategic Planning Officer, Quality Manager, Business Process Improvement Officer and Analyst, Stakeholder Relationships Officer.

4 Horizontal and administrative issues

4.1 Relationship with stakeholders

In the context of Article 108 of the REACH Regulation, ECHA has developed an accreditation scheme to respond to the legal requirement to develop appropriate contacts with stakeholder organisations. The number of accredited stakeholder organisations (ASO) has increased from 64 in 2012 to 100 in 2016. 71% of the ASOs represent industry associations, 12% environmental NGOs, 6% animal welfare NGOs, 5% academic associations, 3% consumer associations and 3% trade unions[38]. Every year the list of ASOs is reviewed.

The status of ASO allows stakeholders to be invited to meetings of RAC, SEAC, and MSC with an observer status and to receive meeting documentation[39]. In 2015, participation of ASOs with an observer status in ECHA's committees was as follows:

- SEAC[40]: 7 regular observers, 45 occasional observers;
- RAC[41]: 7 regular observers, 56 occasional observers;
- MSC[42]: 20 regular observers, 35 occasional observers;

According to ECHA staff, only some ASOs are very active and come regularly, namely industry representative and animal welfare groups. Case owners (i.e. registrants of substances that are discussed) are invited to participate in the MSC discussions for dossier or substance evaluation. The case-owners participated in the Committees' discussions in 71% of cases in 2014[43] and in 70% of the cases in 2015[44].

In addition, ASOs can be involved in Partner Expert Groups for Guidance (PEGs), the Communicator's Network, the Endocrine Disruptors Expert Group (EDEG), the PBT expert group, the nanomaterials working group and the NGO-ECHA discussion platform. Some ASOs are also observers of ECHA's Helpnet Steering Group, and other ASOs, mainly from industry, have an active role in the Exchange Network on Exposure Scenarios, sharing knowledge, techniques and approaches to building and applying exposure scenarios. ECHA also organises annually a specific ASO workshop in Brussels where ECHA seeks their feedback on issues of strategic importance.

The majority of respondents to the online public consultation consider that ECHA has established a strong and trustful relationship with its stakeholders. From the interviews performed for the ECHA evaluation study, stakeholders consider that ECHA provides more opportunities for interaction and is more open and transparent with external stakeholders than other EU agencies. However, some stakeholders report that with the variety of networks and FORUMs it can be difficult to identify in which ones an issue could be best positioned.

[38] https://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations

[39] See the "*General Approach on the Admission of Observers from ECHA's Accredited Stakeholder Organisation to the work of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis* https://echa.europa.eu/documents/10162/13580/admission_of_stakeholder_organisations_as_observers_en.pdf and the "*General Approach on the Admission of Observers from ECHA's Accredited Stakeholder Organisation to the work of the Member States Committee*" https://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf

[40] ECHA figures from 11 September 2015

[41] ECHA figures from 11 September 2015

[42] ECHA figures from 15 September 2016

[43] General Report 2014

[44] General Report 2015

Participating at all the events and committees can become costly for smaller organisations, and in particular for SMEs, which regret that such activities seem more oriented towards larger organisations with more resources.

The 2015 Annual Stakeholders Survey shows improvement in the stakeholders' satisfaction in most of the areas, with one of the highest improvements in the level of stakeholders' satisfaction towards the information received from ECHA and ECHA's commitment to stakeholders. According to the successive Annual Stakeholder Surveys, half of the ASOs would like to be more involved in ECHA's activities and an increasing number[45] consider that their opinion is not taken enough into account.

Lastly, ECHA frequently surveys its staff and stakeholders. As response rates of stakeholder surveys are declining, the Agency could reconsider its strategy in response (e.g. by sending shorter surveys or survey at different time periods or provide translations). Moreover, the Agency could refine its methodology of calculation of the satisfaction levels, to capture a more realistic picture and meaningful results.

4.2 The use of resources

4.2.1 Revenues and Budget Execution

ECHA is a partially self-financed agency. Its resources derive from both fees and charges payable by the industry and a balancing subsidy from the EU budget. ECHA was self-financed from 2010 to 2015 thanks to the reserve accumulated from the first two registration deadlines in 2010 and 2013, respectively. The reserve was exhausted in 2015 and a balancing subsidy was needed in 2016 and will be required for the subsequent years till 2020, the last year of the current Multiannual Financial Framework (2014-2020).

Due to unforeseeable fluctuations in registrations submitted by industry, ECHA's forecasts have almost systematically underestimated fees and charges income from 2012-16 (having overestimated them in 2010), causing discrepancies between the forecasted and actual revenue (see Table XX). Whilst the overall difference in fees and charges collected was around 14% so far (ie not that significant), it was very significant for individal years (see Annex 4 section of fees and charges)

Table 6.2: Number of registration dossiers (including updates) and related fees

	Expected No. of Dossier	Actual No. of Dossiers	Actual in %	Fees and charges forecast (in 000 Euros)	Fees and charges collected (in 000 Euros)
2012	5 100	9 773	192%	17 208	26 612
2013	15 200	14 839	98%	38 372	85 800
2014	5 800	9 001	155%	20 078	25 951
2015	5 700	8 243	145%	14 417	23 785
2016	10 000	11 357	114%	24 056	33 377

Source: ECHA

ECHA has been working on mitigating this challenge by putting in place an action plan following the recommendations from the Commission auditors to enhance the process of fees

[45] 13% of ASOs in the 2014 Annual Stakeholder Survey and 20% in the 2015 Stakeholder Annual Survey

and charges income forecasting and revenue budgeting and to further refine its accuracy and reliability. The auditors also recommended to enhance the effectiveness of the verification process for the SME status of registrants (see also point 2.1 above) to ensure that all registrants pay the correct fees that are due.

In the Work Programme 2015[46] ECHA recognised the necessity to "…*significantly invest on forecasting and modelling*…", considering the high uncertainty on the level of industry driven fee income and consequently "…*to balance its volatile income and expenditure without some form of balancing mechanism*…". However, ECHA's Work Programme 2016 does not mention any improvement and still signals the necessity to improve forecasting.

ECHA is consistently not implementing / consuming the budget allowed by the budget authority (commitment appropriations and payment appropriations) and adopted by the Management Board. Therefore, the Agency could set more ambitious financial Key Performance Indicators and could budget more carefully and realistically in the future.

While the commitment rates remain at an acceptable level, the payment appropriations consumption needs to be improved. The carry-overs of committed appropriations are relatively high namely under Title 3 (operational expenditure). The agency carried over in 2015: EUR 7,3 million, i.e. 32 % and in 2016 the carry over amounted to EUR 11,6 million i.e. 40 %.

4.2.2 Output versus input

ECHA has developed a composite indicator 'Decisions and opinions equivalent' that divides the total weighted decisions by the maximum annual staff capacity.[47] The total weighted decisions represent the number of decisions and opinions produced per annum, weighted with the time required to process an average case. The maximum annual staff capacity includes both operational and supporting personnel as well as consultants and interim personnel. The correlation between the weighted output and the annual staff capacity gives an indication on whether the ECHA produced more weighted outputs with the same or less resources.

An analysis of the 2015 measurement shows that the "Decisions and opinions equivalent" continues to increase thus showing a positive trend in efficiency. However, the Commission services are of the view that this indicator is not sufficient to measure efficiency. It has a built in bias towards showing efficiency gains and does not consider the quality or impact of the outputs (e.g., a compliance check decision requesting a boiling point test has the same weight as one which requests boiling point plus all of the so-called super end-points). As an example and focusing only on the efficiency of ECHA compliance check decisions, a measure calculating the average cost of a compliance check decision and comparing it to the actual information being requested would give more weight to decisions with more impactful outcomes.

As mentioned in point 2.4, the overall levels of user satisfaction with ECHA's scientific IT tools are high, although improvement areas still exist. Nevertheless, as shown in Table YY, The share of ECHA's expenditure on IT is very high compared to similar agencies such as EMA or EFSA.

[46] https://echa.europa.eu/documents/10162/13608/final_mb_31_2014_wp_2015_en.pdf, p. 73
[47] ECHA General Report 2015

ECHA has from its start focused on developing IT tools which could also serve as standards both for other EU legislation but also for international activities. For example IUCLID, eChemPortal and the QSAR Toolbox are all tools implementing OECD standards and used worldwide and ICLID is used in the EU for implementing both REACH and Biocides. However, over the 10 years of operation of REACH there have been significant changes in the IT infrastructure adding to the costs. For example, the Commission's work on IUCLID prior to 2006 focused on the development of two independent systems of IUCLID and REACH-IT. However, in the first year of operation IUCLID was maintained as a separate software but was also copied into REACH – IT. Later REACH – IT was redesigned to rather interface with IUCLID and finally in 2015 ECHA returned to a design of two separate programmes. In addition, an assessment of the updating of the software and of how industry and users saw it would have been useful to better set priorities. The Commission services have urged ECHA to put in place an ECHA IT master plan to provide a sound and transparent business model for its IT investments.

Table 6.3: Comparison of ECHA's IT budget with similar EU Agencies

	2012		2013		2014		2015	
IT expenditure	Total mio €	% of budget	Total mio €	% of budget	Total mio €	% of budget	Total mio €	% of budget
ECHA	17.6	18.5	18.7	17.6	19.4	17.5	23.8	21.2
EMA	20.5	9	23.7	10	19.8	7	30.6	10
EFSA	10.5	13.4	9.7	12.4	8.8	11.1	8.8	11.1

Sources: ECHA, EMA, EFSA

Given the overall high IT costs of the Agencies, discussions between the agencies as to where software can be reused by other agencies seem opportune. For example the use of IUCLID by EFSA should be investigated.

4.2.3 Administrative organisation and optimal use of resources

While ECHA initially was only responsible for managing the technical, scientific and administrative aspects of the REACH and CLP Regulations, other activities were entrusted to ECHA later by the Biocidal Products and PIC Regulations.

Despite the ring-fencing between the budgets of REACH/CLP, Biocides and PIC, which ECHA has to observe, ECHA has put in place actions to increase synergies and an optimal use of the combined resources. For instance, to mitigate the workload peaks caused by the REACH registration deadlines, human resources are transferred across the different work areas of ECHA. This re-allocation of staff is an established practice in Directorate C (Registration). Within this Directorate, the processing of REACH registration dossiers, PIC notifications and Biocides applications are combined. These tasks can be performed by similar staff profiles. In addition, to increase its staff resources during high peaks of workload before registration deadlines, ECHA recruits external interim staff. As the ECHA's multi-annual staff policy plans show, interims are mainly recruited for REACH and CLP-related tasks. Some of the registration-related tasks do not require a specific scientific or technical expertise or highly experienced profiles, and can therefore be given to interim staff.

The staff of the ECHA Helpdesk provides advice on REACH, CLP, BPR and PIC obligations, and gives support for the various IT tools. Also, synergies and coordination efforts between the REACH/CLP work area and the Biocides work area, in terms of streamlined procedures, can be noted. For the assessment of whether an active substance is a candidate for substitution, the ECHA secretariat ensures cooperation between the Biocidal Products Committee and the Risk Assessment Committee (RAC). Similarly, the PBT properties of an active substance for Biocidal Products also need to be assessed when deciding whether an active substance is a candidate for substitution. Therefore, ECHA aims to ensure cooperation among the BPC and the PBT expert group.

All the ECHA IT systems used for the different business processes are shared across the different legislations, likewise for dissemination. For instance, the IUCLID tool was adapted to processes for Biocidal Products. In addition to dossier creation for REACH, IUCLID data can be (re-)used for other purposes, as the data model also features Biocides elements. A dataset prepared for a substance under REACH can therefore be quickly complemented with data about possible biocidal properties and be re-used for data submission obligations under the Biocides Regulation.

ECHA management interviewed in the context of the ECHA Evaluation study pointed to a number of disadvantages linked to employing interim staff, including costs related to selection and recruitment procedures, as well as the training, integration and familiarisation of interim staff with the organisational procedures and working culture of the ECHA. Therefore, the internal redeployment of staff is considered to be a more efficient and cost-effective solution than recruiting staff externally.

The technical and scientific expertise of ECHA needs constant updating. It is essential that ECHA maps out the competences and identifies the needs for capacity building on a regular basis. The Commission services welcomes the implementation plan for capacity building through the training of staff so that ECHA is able to provide the best scientific and technical advice relating to chemicals legislation falling under its remit. The Commission services also consider that more flexibility to make resources more easily available and be more responsive to changes in workload or ad hoc requests, could still be achieved within ECHA.

The ECHA evaluation study noted that although ECHA does have an Activity Based Costing system in place, is not using it to the fullest extent, e.g. staff timesheets are not used to provide more clarity on precise resource allocation although this could be instrumental for allowing for more cross-department and cross-unit cooperation and expertise-sharing while adhering to the ring-fencing principle of the resources deriving from the various Regulations.

According to the ECHA evaluation study the performance indicators suggests that the link between strategic and operational objectives and performance indicators is not fully established. The Agency does not have in place a holistic integrated performance management system, in which the vision, mission and strategic objectives are directly linked with the more operational objectives of the Agency and where the reporting on performance indicators enables to monitor whether both the operational objectives and the more strategic objectives and goals of the Agency are being met.

5 **Conclusions and recommendations**

Overall, ECHA has been effective in executing the tasks allocated to it by the REACH Regulation according the annual work plans adopted by the management board in all its work areas. ECHA has however not delivered the outputs expected in 2006. Efficiency has improved over time both within ECHA and in how ECHA works with member States and

other stakeholders. There is still though room for improvement to increase efficiency by reducing costs and speeding up processes. Pursuing these efforts is key against the backdrop of resource constraints of the Multiannual Financial Framework for the years 2014-2020[48].

Key findings include:

- The processes could be improved for deriving dose curve response for non-threshold substances, and for preparing scientific guidance when needed to implement restriction proposal (case of Nickel, PAH, Lead). Also, there is scope for improving the guidance documents and IT tools.
- The effectiveness of the reinforced completeness check for registration still needs to be demonstrated and not all recommendations from the 2013 REACH Review relevant to this have been fully implemented.
- Forecasts for revenues from fees and charges, and the process for verification of the SME status of registrants can be further upgraded, as well as for execution of the budget. Therefore, the Agency should budget more carefully and realistically in the future. Whilst ECHA has recently implemented an Activity Based Budgeting/Activity Based Management system, the Agency needs to further improve integrated budget planning, linking the workforce planning to the overall budget planning, and to put in place a clear audit trail between changes in the workforce planning and the overall budget planning of the Agency. This would be instrumental in keeping track of the ring-fencing principle of revenues related to the various Regulations entrusted to the Agency.
- ECHA has improved efficiency in line with the recommendations in the 2013 REACH review. However, there is still room for improvement in particular for dossier and substance evaluation where the output is not proportionate to the resources invested, and also for restrictions and authorisation and for expenditure on IT Tools. Internal collaboration and re-allocation of resources to respond to peaks in workload in the different areas of activity can be reinforced.
- The efficiency of the Management Board could be improved through flexible working methods and through the creation of a two-level governance structure in line with the EU's Common Approach for Agencies as is the case in many EU decentralised agencies.
- Pursuing these efforts is key against the backdrop of resources constraints of the Multiannual Financial Framework for the years 2014-2020[49].
- The creation of a two-level governance structure with a Management Board in charge of providing strategic direction, assisted by one enlarged working group was considered an alternative model by some members of the Management Board and European Commission staff and could be also conducive to more effectiveness and efficiency. The enlarged working group will group members of the Management board with experience in budgetary, financial, audit and human resources matters.
- On the Committees and its members, the Commission considers that for SEAC there is a need to ensure that members have sufficient socio-economic expertise, ideally socio-economic expertise applied to chemicals and to human health and the environment, in order to properly fulfil their duties according to Article 76 (1) (d) of REACH. The two

[48] OJ L 347 p 884, 20.12.2013.

ECHA Committees, RAC and SEAC may face increased workloads in the future due to the number of application for authorisations received; therefore the members should really commit to dedicate 50% of their time to this work.

- ECHA should set up training sessions targeted to members dedicated to specific SEAC-related knowledge and processes.