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

Annex 4

{COM(2018) 116 final}

Annex 4 Implementation state of play

Contents

1 Registration

Conclusions of the 2013 REACH Review

The 2013 REACH review reported that both industry and authorities had invested to meet the challenge of the first registration deadline in 2010, which involved the submission of 27,418 complete registration dossiers for 5,346 substances[1]. The relative success reflected good cooperation from all the involved parties. However, the Commission noted some shortcomings related to the compliance of registration dossiers which could hinder the delivery of the expected benefits from REACH:

– many registration dossiers had been found to be non-compliant, including with regard to substance identity

– insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties.

Impacts on increased market concentration and prices were also reported in relation to the registration costs.

The 2013 REACH review acknowledged the findings of the Commission's Second Regulatory Review on Nanomaterials[2] on the need for more specific requirements in the REACH Annexes to clarify how nanomaterials should be addressed and safety demonstrated in registration dossiers and announced to conduct an impact assessment of relevant regulatory options.

Regarding a possible extension of registration requirements (Article 138), the Commission concluded it had insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages, to extend the requirement to prepare a CSA/CSR for CMR 1A/1B substances registered in low tonnages, and on the need and feasibility, if any, to register certain types of polymers.

1.1 Developments after the 2013 REACH Review

1.1.1 Numbers of Registrations

The number of initial and updated dossiers registered in the years 2013, 2014 and 2015 were 15,380, 9,140 and 8,043 respectively. By April 2016, ECHA had received and disseminated more than 54,000 dossiers for approximately 14,000 unique registered substances since REACH came into operation.

[1] Submitted to ECHA by the end of 2011

[2] COM(2012) 572 final

The deadline for registering substances manufactured or imported in quantities of 100 to 1,000 tonnes per year was 31 May 2013. By 31 August, the deadline set by the REACH Regulation, ECHA performed a completeness checks on all REACH 2013 dossiers. The aim of the completeness check was to ensure that all required elements have been included in the registration dossier. Following the completeness checks, registration numbers were granted to 9,030 submissions.

Registrations were received from 29 EU Member States and EEA countries, with the highest percentage coming from Germany (31 %).

Overall, it seems that the 2013 registration deadline was largely met.

1.1.2 General observations on Registration and Quality of Registration Dossiers

1.1.2.1 The REACH Baseline Study

The so-called "REACH baseline study[3] monitored changes in the Risk Scores and Quality Scores from a subset of registrations. From a set of 237 reference substances across all tonnage levels, the registration dossiers were reviewed as to the toxicity and exposure data. The changes monitored include registrations from the second registration phase (by 31 May 2013) as well as updates from dossiers registered previously[4]. The results of the 10-year update show a clear increase in the quality of the data available compared to 2012 and especially 2007[5], for all the 4 areas assessed (workers, environment, consumers, humans via environment). The improvement in quality in the 10-year update is similar to the one observed in the 5-year update for HPV and BLHC[6] chemicals and is now observed for a larger dataset including also medium production volume (MPV) chemicals[7]. Given that the baseline for the study was the situation before REACH, it suggests that REACH is making available more information to be used for risk assessment and management of chemicals.

The results also show a clear decrease in the Risk Scores – risk values calculated applying the study methodology, when compared with the situation at baseline. The decrease in Risk Scores is similar to the one observed in the 5-year Update for HPV and BLHC chemicals and is now observed for a larger dataset including also MPV chemicals – corresponding broadly to those registered by the 2013 deadlines.

While the Commission services noted in 2013 that many Chemical Safety Reports were deficient in terms of identifying uses of substances as well as related exposure estimates, the 10-year update of the REACH baseline study identified an increased availability of exposure estimates included in Chemical Safety Reports (CSRs). The figure summarises

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[3] REACH Baseline study: 10 years update (2017) - link to final report

[4] In the 10 year update, progress observed refers to the detailed analysis of 94 reference substances (55 HPV chemicals, 23 MPV chemicals, 19 BLHC (Baseline High Concern reference substances)

[5] It is expressed in a reduction of the Quality Score from baseline to the 10 year update (with lower Quality Scores indicating higher quality)

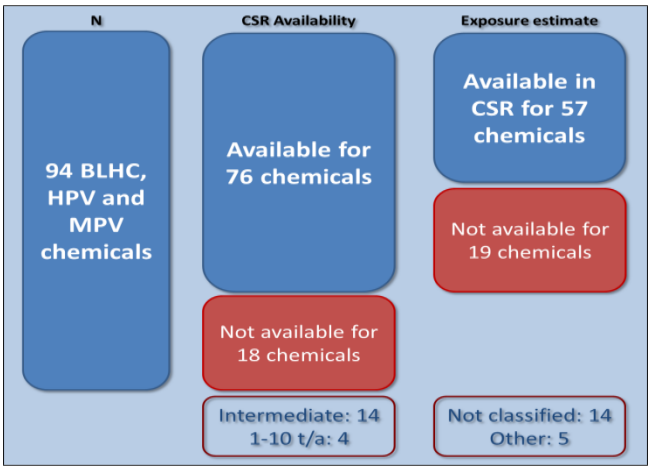
[6] BLHC: Baseline High Concern substances. The term was chosen in the 10 Year Update to avoid confusion with identified SVHC. (SVHC was used in the baseline- and in the 5 Years Update report)

[7] Corresponding largely to those registered in the 2013 registration deadline

the availability of CSRs for 94 chemicals assessed in detail (HPV, MPV and BLHC substances).

- 76 chemicals or 81% had a CSR available and for the remaining 18 chemicals a CSR was not legally required.
- Most of the CSRs (57 of 76 or 75%) contained worker exposure estimates, which is in line with the registration requirements. For the remaining chemicals an exposure assessment was not required because they are not classified.

Figure 4.1 Availability of Chemical Safety Reports in registration dossiers



1.1.2.2 General Observations from ECHA

In its report on the operation of REACH in 2016 [8], ECHA stated that the **quality of information in registration dossiers** has improved. However, ECHA still concluded that:

- the relatively poor quality of some of the data is limiting its usefulness
- the transfer to industry of the burden of proof of demonstrating safety is not completed, as the Agency and Member State competent authorities still need to take action with regard to companies that have not fully complied with their REACH obligations to clearly describe their substance and its effects.

This is illustrated by ECHA's compliance checks in 2016 which focused on higher tier human health and environmental standard information requirements relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB ((very) persistent, bio-accumulative and toxic) substances. 156 dossier evaluations were performed in 2016 on such high-priority substances (85% of all dossier evaluations done in 2016). As a result 805 standard information requests were made in the draft decisions, 550 of which addressed higher-tier human health and environmental endpoints (pre-natal developmental toxicity, mutagenicity/genotoxicity, reproduction toxicity, and long-term aquatic toxicity). These results confirm that there are numerous gaps concerning important data in those dossiers submitted for substances of potential concern. During

[8] ECHA (2016) *Report on the Operation of REACH and CLP 2016.*

2016, ECHA invited Member States to consider enforcement action on 33 cases following a dossier evaluation[9].

ECHA has also identified systematic challenges in the registration of substances with nanoforms and launched an update of its guidance for nanoforms in view of the 2018 registration deadline. ECHA has also called for urgent amendment of REACH annexes to clarify the registration requirements for nanoforms of substances.

ECHA highlighted the insufficient rate of **dossier updates** as the most significant barrier to reaching the objectives of the legislation. Based on a recent ECHA survey:

- only 25% of dossier owners conduct a regular routine review of their REACH data, while 50% check on an ad-hoc basis. 25% of these reviews spark the need for a dossier update.
- Most updates were done because of a direct request from ECHA (50%). Updates because of requests from clients (10%) or inspection by Member States Competent Authorities (10%) were much lower.
- 75% of the respondents do not have a REACH data management system.

ECHA has not determined what the baseline should be, i.e. what the expected update rate is. Article 22 of REACH specifies the situations where a registrant is responsible on his own initiative for updating his registration with relevant new information. Whilst ECHA sees a need for a change in the attitudes and behaviour on the part of companies; ECHA has also suggested considering whether it would be useful to have implementing legislation to further specify obligations under REACH regarding updates[10].

Dossier updates should also update information on the tonnage and ideally tonnage per use, as this information is critical for prioritisation of substances for the development of risk management measures. As reported by ECHA in May 2016[11]:

- About 29,000 dossiers (around 64 % of the registrations) submitted since 2008 have never been updated.
- Of the around 16,000 updates, over 30 % can directly be linked to a letter campaign by ECHA (around 8,000 letters sent since 2011);
- Other updates were prompted by compliance check decisions (8 %) or other actions such as a sector approach (e.g. petroleum streams).
- Another targeted letter campaign in 2016 by ECHA on 270 shortlisted substances invited registrants to improve the dossier quality in advance of any compliance check or other regulatory process. 40 % of the dossiers were updated within four months of the letters being sent[12].

9 ECHA Progress report 2016 on Evaluation under REACH, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

10 ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 14

11 Ibid. Page 39

12 ECHA Progress report 2016 on Evaluation under REACH, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

1.1.2.3 Other observations

The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these. The lack of data on the hazardous properties of chemicals was the driving force behind the development of REACH.

To illustrate the above, REACH lead to more transparency about the number of CMRs on the market. For more than 700 substances[13], REACH registration has led to increased CMR classifications which means that risks from these substances can be better managed. These more stringent classifications seem to be more due to better understanding of hazardous components or impurities rather than experimental tests for CMR properties.

1.1.3 Intermediates

About one third of the overall production of chemicals is used as intermediates[14]. REACH contains lighter registration requirements set out in Articles 17 and 18 for certain types of intermediates that are used under strictly controlled conditions. However, intermediates that are not used under those conditions must be registered in line with the general information requirements in Article 10 of REACH, which is not fully coherent with Article 2(8)(a) of REACH which exempts intermediates by the registration without any reference to the "strictly controlled conditions".

For a number of substances registered as intermediates under Articles 17 and 18 of REACH, ECHA has checked registration dossiers and made use of its powers (based on Article 36) to request detailed descriptions on the synthesis in which registered intermediates are used to ascertain that the substances are indeed used as intermediates. Priority was given to SVHC substances on the candidate list. ECHA started doing this in 2011 when about 95% of dossiers verified did not contain any information on the use of the intermediate requiring ECHA to ask further information from registrants. Even with that, only in 60% of the cases was sufficient information provided by registrants to confirm the intermediate use. Other cases required further actions from ECHA or the involvement of local enforcement authorities. In a few specific cases, registrants claimed that information could be provided only to enforcement inspectors upon request. For the remaining cases, the information provided was sufficient to confirm that the use of the substance fulfils the definition of an intermediate in REACH. Amongst others due to further awareness-raising, the situation improved significantly in the following years, showing that more than 50% of dossiers of intermediates verified by ECHA in 2016 contained sufficient information on intermediate use.

[13] Based on ECHA's 2014 CMR report (section 3.2)

[14] Out of the 330 Million tonnes of chemicals produced in the EU, 117 Million tonnes are used as intermediates. Accenture Study (2017)- Taking the European Chemical Industry into the Circular Economy (commissioned by CEFIC)

The specific registration requirements for intermediates have also given rise to questions regarding the calculation of tonnage of a substance with intermediate as well as non-intermediate uses for the purposes of registration. Recently, a general agreement emerged that the volume of a substance to be used as an intermediate under strictly controlled conditions is not to be taken into account for determining the tonnage band in which the substance is registered.

Furthermore, according to Articles 17(2) and 18(2) of REACH, registrants of intermediates used under strictly controlled conditions are not required to provide information on tonnage in their registration dossiers. However, this has the potential to conflict with other provisions in REACH where information on volumes of intermediates determines the information to be submitted in the registration dossier.[15] As the tonnage information is not communicated in the registration, enforcement authorities can only ascertain via inspections if the information provided in the registration matches the tonnage dependant requirements. Consequently, authorities and the general public do not know accurately the tonnages at which intermediates are manufactured or imported in the EU.

The Forum for Exchange of Information on Enforcement is running a pilot project to address the enforcement approaches to the verification of intermediates and their use under strictly controlled conditions[16].

1.1.4 Data sharing and joint submission

The majority of companies respect the 'one substance, one registration' (OSOR) principle to everyone's benefit. However, in 2016 some 700 existing individual registrations for both standard and intermediate registrations were still in breach of the joint submission obligations under REACH[17]. In addition, breaches of the joint submission obligation were found where registrants had not agreed on forming one joint submission and several joint submissions exist for the same substance.

The Commission addressed concerns about transparency, communication and cost sharing in the SIEF through Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH[18]. The provisions of the Implementing Regulation were based on the central principles of data-sharing in REACH - that the costs of sharing information are determined in a fair, transparent and non-discriminatory way. The Implementing Regulation also tasked ECHA to ensure the respect of the joint submission obligation in cases of disagreement between the registrants. Consequently, ECHA has put in place a process that, in analogy to the data sharing dispute procedure, ensures that potential registrants can register as part of an

[15] See Articles 18(3) or 22(4) of REACH as examples.
[16] ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 138
[17] ECHA (2016) *Report on the Operation of REACH and CLP 2016*, Page 45
[18] COMMISSION IMPLEMENTING REGULATION (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) OJ L 3, 6.1.2016

existing joint submission if they have made every effort in the negotiations with the existing registrants but have been prevented from registering by the latter. In addition, the Commission has also issued a Frequently Asked Question on Competition issues in the context of REACH SIEFs[19].

Given that the Implementing Regulation has only been in force for 1 year at the time of drafting of this evaluation report, the effectiveness of this measure cannot be fully evaluated yet, but indications from industry are that the regulation has helped to increase transparency especially for SMEs. On the other hand, in a few cases, existing registrants have indicated that the obligation to provide a meaningful cost itemisation has created additional work for them.

ECHA has also taken action: since 26 January 2016, it is no longer possible to submit an individual registration in REACH-IT for a substance where a joint submission exists. Letters were sent to 157 priority cases among these 700 individual registrants, to request them to either join the existing joint submission or to submit a data-sharing dispute to ECHA in accordance with the data-sharing provisions of REACH. The registrants must agree on forming a joint submission within six months, and if they do not take action, the registration numbers of those registrants who have not agreed on forming a joint submission will be revoked, which means they would no longer have market access. At the time of drafting this report, the six months deadline had not expired yet, but several data sharing disputes have been filed in response to the letters.

ECHA is of the opinion that the SIEFs set up by industry have worked relatively well. The number of data-sharing disputes remained low even before the 2013 deadline. Since REACH entered into force, ECHA has been notified of 46 data-sharing disputes of which 44 were admissible[20] (less than 1% of joint submissions). By January 2017, the number increased to 61. It should be noted that:

- in some of the disputes the claimants proceeded as a group of over 70 companies
- ahead of the 2013 deadline, the ECHA Helpdesk received almost 1,000 questions on SIEF management and the 2018 registration deadline is also triggering questions. In January 2017 ECHA estimated that it provided advice on SIEF management and data-sharing issues in some cases (range of thousand).
- there has been at least one case, where the claimant considers that access to a joint submission is denied by the lead registrant in order to restrict competition on the EU market for that substance.

A survey carried out with Member States competent authorities[21] indicates that issues most often raised by companies in relation to the operation of SIEFs and consortia included a high or unexpected price demanded for data, communication problems, transparency as well as confidentiality and protection of intellectual property.

[19] http://ec.europa.eu/DocsRoom/documents/14241/attachments/1/translations/

[20] see Figure 4 of ECHA report on the functioning of REACH and CLP 2016

[21] Monitoring the impacts on innovation, competitiveness and SMEs (CSES, RPA, Okopol, 2015), p. 86

ECHA also reported that for approximately 2% of substances with full registrations (244 registration dossiers) and 3 % of substances registered as intermediates (449 registration dossiers), there are registrants that have submitted dossiers totally outside of the joint registration obligations in REACH.

ECHA further recommended in its report submitted in 2016 that Member States should ensure that their national provisions for enforcement include appropriate sanctions for non-compliance with the rules introduced in the Commission Implementing Regulation on data-sharing.

ECHA asked the Commission to consider keeping the SIEFs (or a SIEF like mechanism) mandatory after the 2018 deadline – although the current REACH text requires that the SIEFs be operational until 1 June 2018 only. From the perspective of ECHA and industry feedback, this does not take into account the post-registration activities such as the need for updates, evaluation and the low compliance rate with registration requirements that will require evaluation of chemicals to continue after the last registration deadline for many years leading to the generation of new studies by industry that will have to be shared across all members of joint submissions. The information submitted jointly remains a joint responsibility. Based on ECHA's experience, also existing substances continue to be registered and an appropriate structure is needed to discuss with the new registrants. Without a SIEF, the responsibility falls mostly on the Lead registrant and there is growing reluctance to take the lead registrant role.

1.1.5 Substance Identity (SID)

ECHA noted that industry is facing difficulties in sufficiently identifying certain types of substances (e.g. substances of unknown or variable composition (UVCBs)) with a risk of wrongly assessing substance sameness, preparing inappropriate justifications for read-across and not ensuring that adequate hazard data are submitted for their substance.

The Commission conducted a study that analysed the identity and sameness of 223 complex substances already registered.[22] Results of this study show that some SID elements are the same among all substances (e.g. name, CAS number) but others are very specific to certain groups of substances (e.g. colour, boiling point, granulometry). The main conclusions were that:

1. SID is more consistent where it is systematically addressed by associations/ consortia in a sector approach;

2. Substance sameness criteria can only be developed at a sector or substance-specific level i.e. not in a generic way;

3. A Substance Identity Profile (SIP) is a useful tool for harmonisation of SID information across the joint registration;

[22] Substance Identity in REACH, Study on Substance Identity (SID) in REACH. Analysis of SID and substance sameness of complex substances, final report.

4. Annex VI information requirements for chromatography and spectral data are sufficient usually only to identify organic substances.

In general, it was found that the amount of data provided was enough to identify the substances and to have some evaluation criteria for the sameness of the substances for the members of the SIEF. However, the practical examples also showed the benefit of a structured approach of building and documenting the so-called Substance Identity Profile (SIP), which describes the boundary compositions of complex substances covered by the joint submission and for which the hazard dataset is relevant. ECHA took the initiative to request registrants to provide a SIP for their registered substances and this was taken forward by recent updates to guidance on registration.

Information from ECHA's 2016 Progress report on Evaluation under REACH[23] shows that SID is still among the top three concerns about dossier completeness: 70 % of all 152 ECHA dossier evaluation decisions adopted in 2016 included an information request on SID.

1.1.6 Activities to improve the completeness and compliance of registration dossiers

The previous sections set out specific challenges in terms of the compliance of registration dossiers (dealing with intermediates, data sharing and substance identity), and also some of the specific actions undertaken to respond to them. As well as these actions, more general efforts are being made to improve the compliance of registration dossiers.

After the updates to REACH-IT in 2016, ECHA started to manually verify the completeness of registration dossiers to complement the automated completeness check process. The intention is to identify dossiers with irrelevant content, insufficient information for identifying the substance, insufficient justification of data waivers or missing CSRs in cases that are not possible to detect via the automated process. If submitted registrations are found to be incomplete, ECHA will prescribe a reasonable deadline for the provision of the missing information. If the registrant does not provide the missing information, a registration number will not be issued in case of a new submission. If the failure in completeness concerns an update, this will be rejected and the new information will not be considered. Completeness check is an integral process of registration. Since 2016 it includes additional manual verifications by ECHA staff where completeness cannot be verified automatically, and has been applied also retrospectively. Due to similarity in the objective and implementation, its outcome can be considered as a complementary measure to evaluation.

Since the enhanced completeness checks were put in place in June 2016:

- 42 dossiers newly submitted after that date have been rejected (corresponding to 0.5% of dossiers submitted in that period).

[23] ECHA Progress report 2016 on Evaluation under REACH, Figure 5, February 2017, ECHA-17-R-03-EN, ISBN: 978-92-9495-784-9

- 14 of these 42 were new registrations that have been rejected after the 2nd round of completeness check, meaning no registration number was issued.

- The remaining 28 submissions were dossier updates that have been rejected after the 2nd round of completeness check, meaning that the updated information was not included in ECHA's database.

The corresponding registration numbers were not revoked, but ECHA monitors if the dossiers will be successfully updated in the long-term, if not, they would be followed-up via e.g. retrospective completeness check. As result of retrospective completeness checks of dossiers submitted before 21 June 2016, 3 registration numbers have been revoked so far.

In addition, in line with a recent decision of the Board of Appeal confirming that ECHA can undertake completeness checks for existing dossiers, and in order to ensure a level playing field with registrations submitted before this review of the completeness check process, ECHA has started to carry out retrospective completeness checks on existing registrations. Preliminary results of this enhanced completeness check process show that it is effective in providing the required additional information.

ECHA issued a new version of IUCLID (IUCLID 6 in June 2016) as the main tool to provide the information required in registrations which were designed to alleviate known issues related to Registration. Improvements cover:

Substance Identification: section 1.1 now allows explicit reporting of previous regulatory identifiers of the substance, and section 1.2 allows reporting of the substance identification profile (SIP) as a new composition type as well as the available information on specific parameters on different nanoforms of a substance;

Information on physicochemical and hazardous properties: reporting of data waiving justifications has been structured around the REACH framework, improving the reporting of alternative methods, fields have been added with templates to report the read-across hypothesis, QSAR documentation and the considerations made before proposing animal testing for why the adaptation possibilities could not be used, sections for reporting study summaries on skin and eye irritation and skin sensitisation have been updated according to amendments to REACH Annexes VII and VIII, sections for storing study summary information on physicochemical hazards have been aligned with GHS/CLP;

Information on use and exposure: formats for reporting identified uses were updated to clarify the description of uses and connect them with the corresponding exposure assessment, new fields have been added to allow users to document the REACH registration status or specific regulatory status of the uses, and to better describe uses as an intermediate or why an exposure assessment is not needed; Also, a product category "oil and gas exploration or production products" was added

to the use descriptor system[24] to cover substances typically used for oil and gas exploration and extraction via the so-called hydraulic fracturing techniques. This will improve the search of information on registered substances used for hydraulic fracturing purposes as requested in a Commission Recommendation[25] [26]. Related to this, the possibility to report releases underground has been added in IUCLID.

Hazard and exposure assessment: a DNEL calculator has been developed (January 2017) to help users calculate DNELs based on selected study results; the assessment entity concept has been introduced to support the documentation of complex assessments in the registration dossier;

Low tonnage registrations and decision on full or reduced information requirements according to Annex III: a new data template in section 14 for lead registrants was added to document the reasons why they consider that their substance does not meet the REACH Annex III criteria and can therefore be registered with reduced information requirements.

1.1.7 Preparations for the 2018 registration deadline

ECHA prepared a detailed work plan, the so-called REACH 2018 Roadmap, in close consultation with its stakeholders. This responds to the large number of SMEs that will be involved in this registration, and continuing questions on the topic:

- Questions related to registration are still the main reason for companies to contact the national REACH helpdesks (18% of all enquiries), ahead of questions on safety data sheets (14%) and labelling (9%). In the 11 Member States that keep track of the size of the company enquiring, most enquirers were SMEs[27].

The roadmap describes the different milestones and support services that ECHA will provide to the registrants, including:

- a revamp of the IT tools relevant for registration, IUCLID and Chesar for preparing the registration dossier and the chemical safety report and REACH-IT for submitting the dossiers to ECHA. The modifications improve their usability to cater for SMEs needs and provide an integrated help function.

- ECHA is currently developing an online version of IUCLID (ECHA Cloud Services) to further reduce the IT burden for SMEs.

[24] ECHA (2015): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015

[25] Commission Recommendation of 22 January 2014 - http://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX:32014H0070

[26] European Commission (2016): Report from the Commission to the European Parliament and the Council. COM(2016)794 final

[27] Technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting. Final Report dated 10/05/2016

- ECHA also organised workshops and webinars and participated at information events organised by industry and Member States including hands-on training on the IT tools.

- Specifically for SMEs, ECHA published a registration guide, translated in all EU languages and the REACH2018 toolkit that was shared via the HelpNet and the Communications Network.

- REACH HelpNet has focused on preparing for 2018 over the last two years.

- Complementing activities were carried out by various Member States, ranging from specific guidance on registration (in local language), which is adapted to the needs of SMEs, to workshops or meetings informing about registration obligations for companies having to register by the 2018 deadline.

Moreover, based on the Commission's request, ECHA compiled an inventory of substances[28] likely to meet the criteria of Annex III to the REACH Regulation. The inventory will help registrants to identify whether reduced minimum information on physico-chemical properties only is required or full Annex VII information.

1.2 Review of Information Requirements

1.2.1 Adaptation to Technical Progress

The following adaptations of REACH standard information requirements have been made since 2013 according to Article 13(2) of REACH. More details about their impacts are described in the chapter 'Test Methods'.

- In 2015, the Two-generation reproductive toxicity study, a standard requirement for substances registered at and above 100 tonnes was replaced by the Extended One-Generation Reproductive Toxicity Study (EOGRTS)[29].
- In 2016, *in vitro* rather than *in vivo* studies became the standard requirements for skin and eye irritation, and the requirement for dermal acute toxicity studies for substances that have been shown to be non-toxic via the oral route was deleted[30]. In a second amendment[31] *in vitro* tests for skin sensitisation were introduced as

[28] https://echa.europa.eu/information-on-chemicals/annex-iii-inventory

[29] Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study. OJ L50/1, 21.02.2015

[30] Commission Regulation (EU) 2016/863 of 31 May 2016 amending Annexes VII and VIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity. OJ L 11/27, 01.06.2016

[31] Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation. OJ L 255/14, 21.09.2016

the default information if applicable for the substance under investigation and giving sufficient information for classification and risk assessment.

1.2.2 Low tonnage

In view of the reviews entrusted to the Commission by the legislators in REACH (Article 138(1), (3) concerning low tonnage substances), the Commission conducted a study[32] on the possible extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year. This study evaluated 6 options for increased information requirements only, adding additional information requirements from Annex VIII or changing Annex III to limit the exemptions from full Annex VII testing therein. Key conclusions were that despite a large variation in the magnitude of costs, the benefit/cost ratios suggested that all options would be justified in economic terms, and that the variation between benefit/cost ratios of all options was small. However, the costs of the options might have been underestimated, while the benefits for downstream users might have been overestimated. On the basis of these observations, no firm conclusions could be drawn concerning the 'best' option in economic terms.

The Commission mandated another study[33] to inform on the extension of the obligation to perform a chemical safety assessment and to document it in a chemical safety report for CMR 1A/1B substances manufactured or imported between 1 and 10 tonnes per year. The study concluded that over 100 substances with, as yet, unknown 'CMR 1A/1B' properties would feature in the low tonnage band. The study suggested that if the CSA/CSR requirement for those substances were introduced, there would be sizeable benefits for downstream users based on easier compliance with other legislation on CMRs. Taken together with costs across all actors there would be a total net benefit of around €16.4 million. On the basis of costs alone, extending the CSA obligation to CMRs 1A/1B that are, as yet, unknown and unregistered would likely be justified.

The Commission contracted a third study[34] in 2016 to gather further information to be used in an Impact Assessment of potential options for possible amendments of REACH Annexes, to modify requirements for low tonnage substances (1-10 t/year) and the CSA/CSR requirement for CMR 1A/1B substances. For this study, the Commission selected five options for extending information requirements, plus the option to delete the REACH Annex III criteria (Article 12(1)) and the option to extend CSA/CSR obligations (Article 14(1)) to all 1-10 tonnes substances known or expected to meet criteria for CMR 1A/1B for evaluation alongside the information options. The findings from the refined assessment in the third study confirmed those of the second study; all options assessed provided an increased benefit/cost ratio and increased cost effectiveness over the current registration requirements for low tonnage substances.

[32] Study number ENV.A.3/SER/2013/0057r

[33] Study number 070307/2013/668917/SER/ENV.A.3

[34] Study number 2015 SFRA RPA SI2.724177 low tonnes.
http://ec.europa.eu/environment/chemicals/reach/publications_en.htm

Before deciding which option, if any, it will take forward, the Commission needs to assess the affordability of increased information requirements for SMEs in the lowest tonnage bracket. This assessment should focus on the cost-related impacts on their competitiveness and capacity to innovate. This will have to be further examined, using also the experience from the last registration deadline in 2018.

1.2.3 Polymers

In view of the review entrusted to the Commission by the legislators when adopting REACH (Article 138(2) concerns polymers), the Commission services conducted a study on the obligations on the need, if any, to register certain types of polymers[35]. The study provided insights on registration schemes for new polymers in other countries and how polymers might be grouped into hazard classes. However, given that REACH applies to all substances on the market, not only new ones, the study did not provide enough information on how to identify polymers of concern for human health and/or environment. In order to do so, the Commission services plan to undertake another study after publication of the corresponding roadmap.

1.2.4 Nanomaterials

As indicated in the 2013 Review Report, the Commission services conducted an impact assessment[36] of 6 options comprising 52 measures to assess how to ensure further clarity and demonstrate the safety of nanoforms of substances in registration dossiers. Based on an earlier examination of data contained in the registration dossiers, it had become clear that the present information requirements are insufficient to ensure that the registration data is relevant and covers the nanoforms of a registered substance[37]. The Impact Assessment report[38] provides the analysis of the preferred option on the basis of which the Commission services proposed in mid 2017 changes to Annexes I, III, and VI-XII to the REACH Regulation[39]. The draft Commission Regulation has been notified to the WTO under the TBT agreement and is currently being discussed in the REACH Committee. It includes transitional provisions to allow all registrants and downstream users adequate time to adapt their registration dossiers. After the adoption of the Commission Regulation, ECHA will be asked to update the respective guidance in view of the modifications. Following the review, the proposal for the amendment of the

[35] Study number SI2.671025 2013, final report date 17 February 2015

[36] Complete list and references of all related studies, public consultation etc. is compiled in the Impact Assessment Report (ref after ISC).

[37] JRC Report on NANO SUPPORT Project: Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

[38] And complemented in March 2017 to take into account the Board of Appeal Decision of 2 March 2017 on titanium dioxide that enabled to clarify the baseline for the impact assessment.

[39] To be published

Commission Recommendation on the definition of nanomaterial from 2011 was submitted to a public consultation and is under finalisation. When adopted, the amended definition will, among others, be incorporated in the above mentioned amendments of Annexes to REACH to clarify the registration requirements for nanoforms of substances. The Commission's Joint Research Centre was asked to provide guidance for the implementation of the revised definition.

1.3 Impacts on registrants

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

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

According to the *General Report on REACH 2013*[40], the analysis of the drivers of the registration costs revealed that ECHA's fees in some cases represented 50% or more of the total costs companies are subjected to when registering, especially in the case of simpler registration dossiers and smaller firms. In the case of more complicated dossiers, data collection, costs related to SIEF and consortia (including management and other fees) were the main cost elements. According to ECHA, "*the major cost item in Registration is formed from the costs of compiling and generating the necessary data to fulfil the REACH information requirements*", when registration fees only represent a minor part of the overall cost of registration.

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

1.3.1 Evidence on registration costs

The *Extended Impact Assessment* of the Commission accompanying the proposal on REACH estimated testing and registration costs of REACH to amount to EUR 2.3 billion

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

in 2003 values (EUR 2.6 billion in 2011 values as calculated by Technopolis Group (2016)[41]) over the 11 years planned for completing the registration of all substances. This amount includes registration fees, estimated at EUR 300 million, registration costs, estimated at EUR 500 million, testing costs estimated at EUR 1 250 million (assuming the validation and acceptance of QSARs can be applied within this timeframe), costs linked to safety data sheets, estimated at EUR 250 million, authorisation procedures, estimated at EUR 100 million, and savings of EUR 100 million for new substances below 1 tonne.

For the first registration deadline of 2010, that concerns phase-in substances produced or imported in quantities over 1 000 tonnes[42], the *Extended Impact Assessment* had anticipated a cost of around EUR 1.15 billion for the industry, when recalculated into 2011 prices. According to the *General Report on REACH 2013*, the industry survey of 2011 concluded that the cost incurred by dutyholders had been significantly higher, EUR 2.1 billion (with a broader range of EUR 1.1 - 4.1 billion). Although in 2011 there was a significantly lower use of QSAR compared to what was anticipated in the *Extended Impact Assessment*, this was partially compensated by a higher use of read-across than expected.

The differences between the 2003 estimate and the 2011 survey come thus from:

- the reporting of sums paid by firms for participating in the SIEFs and for accessing data from existing studies, costs[43] which had not been considered in the *Extended Impact Assessment*. This is a cost for some firms in the chemicals sector, but also involves an income for other firms, and so is seemingly no net cost.

- less than predicted use of QSARs, but increased use of read across

- the costs of mandatory data sharing, which was strengthened during the co-decision process compared to the proposal assessed in the *Extended Impact Assessment*

Subsequent studies have also found equal or significantly higher registration costs than those presented in the *Extended Impact Assessment*. CSES et al (2015) focused on the 2013 registration deadline and estimated that the total costs incurred by companies (including registration, testing and safety data sheets) was of the order of EUR 459

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

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

[43] No information is available to quantify these costs

million, for the 2 998 phase-in substances registered in 2013 deadline[44]. These estimations are within the range of the costs anticipated in the *Extended Impact Assessment*. The average cost per substance (covering registration, testing and SDS) from the study surveys is around EUR 153 195 when, for the same cost items, the *Extended Impact Assessment* anticipated a cost per substance of EUR 193 367[45]. CSES found that most companies concerned by the registration costs absorbed them rather than increased the prices to cover the costs and concluded that the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances. Furthermore, the study estimated the costs of registration for the 2018 deadline. The estimates for the 1 to 10 tonnes substances appear to be in the range of the *Extended Impact Assessment* (EUR 228 million compared to the estimate of EUR 295 million), but the total cost of registering 10 to 100 tonnes substances is estimated to be significantly higher than formerly estimated (up to EUR 1 136 million as compared to EUR 581 million). This is partially explained by the fact that this last estimation is based on a worst case scenario with the assumption that validation and acceptance of negative and positive QSAR and read-across does not occur within the time frame envisaged in the earlier *Extended Impact Assessment*.

Technopolis Group (2016) aimed at identifying the structure of the cumulative costs incurred by EU chemical companies because of EU legislation during the period 2004-2014. The study breaks down the burden into different legislation packages. The chemicals package includes other pieces of legislation aside REACH, such as CLP, the pesticides or the biocides-related regulations. The study estimated the average annual cost of REACH for the EU chemicals industry to be around 0.8% of companies' added value and less than 0.2% of their turnover for the period 2004-2014. A rough estimation of the average annual cost in monetary terms is approximately EUR 650 million for the EU chemicals industry, although it needs to be noted that this figure is based on a very limited survey (only 31 companies provided figures) and is much more 'top down' and less focused on REACH than other more detailed, bottom-up estimates.

The main reason justifying the divergences from the estimates of the *Extended Impact Assessment* is that the latter excludes the costs paid by companies to participate in SIEFs and to get access to data. The ECHA *Report on the Operation of REACH and CLP 2016* further explains that the administrative costs for managing the SIEFs (additional costs) and preparing the joint dossier are higher than anticipated in the *Extended Impact Assessment* because at that time the joint registration had been considered voluntary as originally proposed by the Commission. The methodologies for the cost assessments also differ. The *Extended Impact Assessment* was carried out in-house based on then available information on how many chemicals were on the EU market in which volumes and a

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

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

detailed analysis of all existing information gaps for substances above 10 tonnes, together with average testing costs based on several testing houses' price lists. The more recent studies based their findings on interviews with Industry representatives and consequent modelling by the study performers.

As Technopolis Group (2016) points out, a limitation of the studies on REACH is that they focus their scope on the regulatory charges and the administrative burdens linked to the registration, excluding capital and operating costs. CSES et al (2015) concluded that compliance costs go beyond what is generally considered as registration costs because REACH has affected the business strategy, the manufacturing processes, the product development, and the supply chain management, leading to further administrative burdens and capital costs. The increase of human resources for compliance purposes may be an indication of an additional administrative burden, as shown by CSES et al (2015). Indeed, the study shows a trend towards a small increase[46] of human resources that companies allocated to compliance over time (2011-2013). This increase was mainly driven by the additional resources allocated by downstream users, article suppliers and end users. However, the studies do not provide a quantification of these costs. Technopolis Group (2016) has included investments into testing facilities and equipment under capital costs, which represent the largest share. It should however be noted that these are costs arising from several pieces of chemical legislation, including REACH, CLP, the POPs Regulation and legislation related to plant protection products and biocides.

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

Given these different information sources, the best estimate probably comes from the bottom-up analyses. Under these, the first two registration periods cost approximately EUR 2.1 billion and EUR 459 million respectively. These figures need adjusting for transfer payments between firms, which gives a cost of around € 2.3 billion in total. It should be noted that part of these costs relate to costs for substances produced outside the EU, which in practice could be borne either by non-EU producers or by EU based companies (importers and EU based subsidiaries).

1.3.2 Registration costs - breakdown

The statistical average cost per substance was calculated as being around EUR 153,000 and the average cost per registrant around EUR 66,000. However, variation around these

[46] From 2011 to 2013, among those enterprises employing 10-25 employees the percentage passed from 2.3% to 3.9%, for those employing 5-10 and 2-5, the share remained very similar, while an increase in those employing 1-2 occurred, from 22.7% to 26.1%

averages is wide as costs depend on a number of complex factors including the numbers of registrants, the identified properties, the further testing required / waived, the amount of test information already available and the numbers and types of uses. The following charts[47] provide a plot of the distribution of costs per substance and per registrant falling between the cost ranges. They show a wide variation of the registration costs across the sample with the vast majority at the lower end of the costs spectrum and a smaller percentage at the higher end.

Figure 4.2: average registration costs per substance

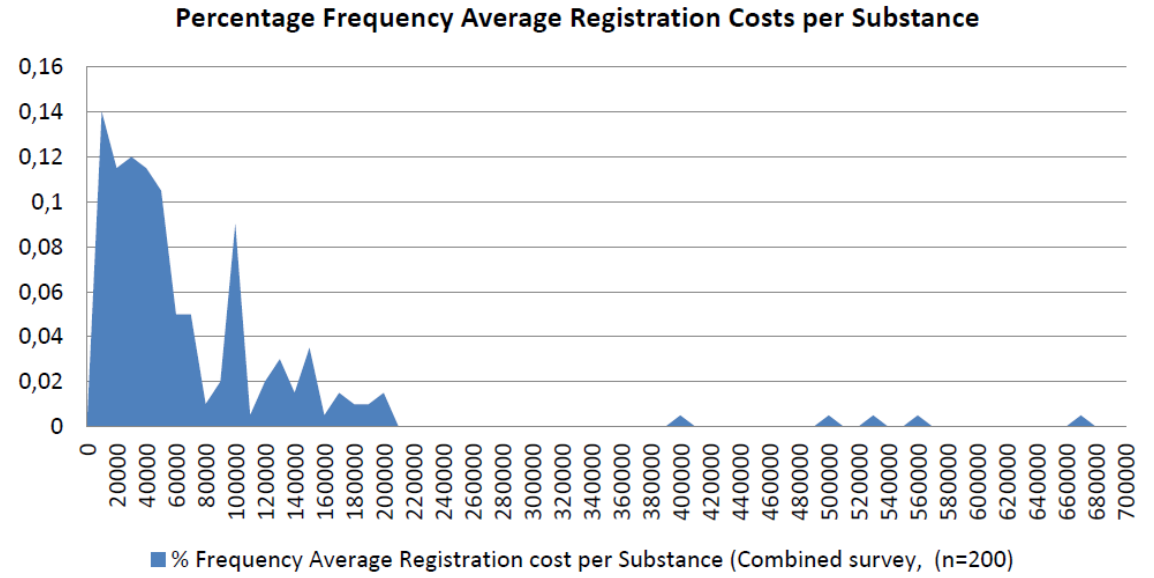
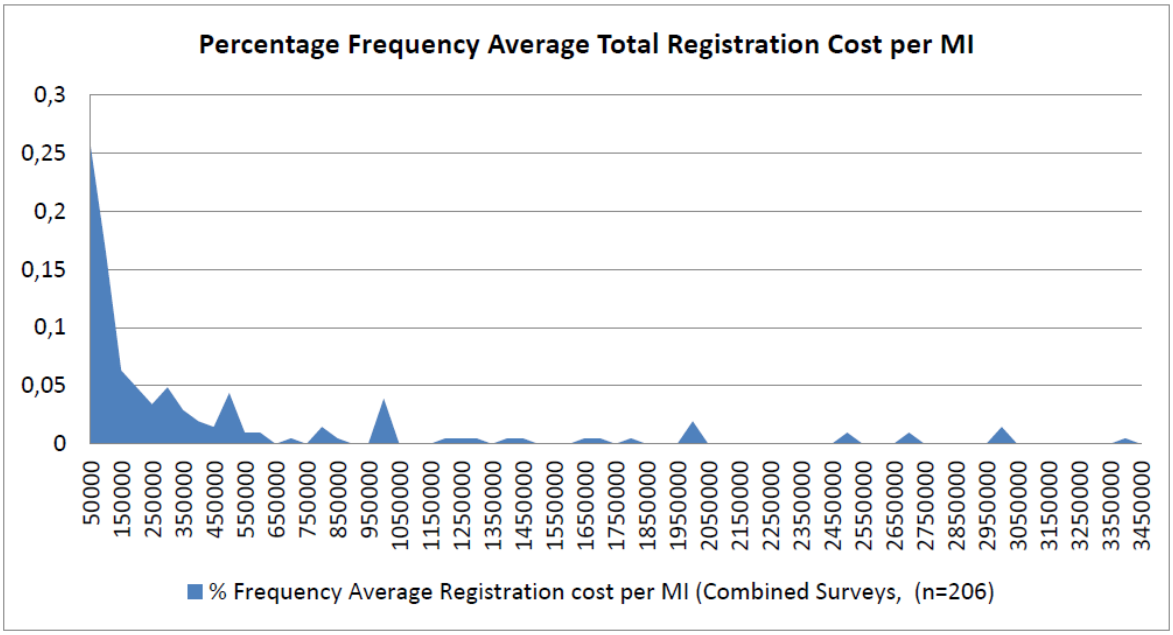


Figure 4.3: average total registration cost per MI



Registration costs affected innovation activity in several ways. Firstly, companies capitalised on information and knowledge generated as part of the registration processes.

47 Monitoring the impacts on innovation, competitiveness and SMEs (CSES, et al. 2015)

Secondly, registration costs have affected the availability of substances on the market. And thirdly, the need of ensuring registration obligations led to re-allocation of resources in the concerned companies from R&D activities to compliance.[48] A detailed assessment of these effects is provided in Annex 5, chapter on Internal Market, Competitiveness and Innovation.

The 2018 registration phase is expected to involve many companies that are new to REACH and that will have to go through the REACH-learning experience from scratch. However, they should be able to benefit from lessons learnt by support institutions during previous registrations.

1.4 Effect of registration on the risks posed by chemicals to humans and the environment

The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these. The lack of data on the hazardous properties of chemicals was the driving force behind the development of REACH.

The results of the 10-year Update of the REACH Baseline study show a clear decrease in the Risk Scores – risk values calculated applying the study methodology[49], when compared with the situation at baseline. The decrease in Risk Scores is similar to the one observed in the 5-year Update for HPV and BLHC chemicals and is now observed for a larger dataset including also MPV chemicals – corresponding broadly to those registered by the 2013 deadlines.

To illustrate the above, REACH lead to more transparency about the number of CMRs on the market. For more than 700 substances[50], REACH registration has led to increased CMR classifications which means that risks from these substances can be better managed. These more stringent classifications seem to be more due to better understanding of hazardous components or impurities rather than experimental tests for CMR properties.

1.5 Comparisons of tests predicted (2003) versus tests conducted since entry into force of REACH (2009)

In spite of the positive developments described above, REACH has however not yet produced the amount of new information on chemicals that was predicted at its conception in 2003.

[48] Monitoring the impacts on innovation, competitiveness and SMEs (CSES, RPA, Okopol, 2015)

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

[50] Based on ECHA's 2014 CMR report (section 3.2).

The JRC study "Assessment of additional testing needs under REACH[51]" from 2003 estimated the testing needs for all substances subject to REACH, taking into account the potential use of (quantitative) structure-activity relationships ((Q)SARs), grouping and read-across instead of testing. The estimates in that study were based on the draft revised Business Impact Study by RPA (July 2003) based on the REACH system as described in the REACH Consultation Document.

The percentage of substances for which the data needs would be either filled by QSARs or waived were estimated for each endpoint, and then the remaining percentage per tonnage category was multiplied by the number of substances predicted for each tonnage band.

The table compares the numbers with data provided by ECHA in the context of the third report under Article 117(3)[52]. ECHA reports the number of studies generated and submitted since 2009, i.e. since REACH entered into force. For a selected number of endpoints a comparison was possible and, for these, it can be seen that for all endpoints that still or until recently required experimental studies in animals, much fewer studies than predicted have been conducted. It has to be noted that these figures do not include studies for which testing proposals were submitted. Until 31 December 2016, ECHA has taken decisions on 953 testing proposals (TP)[53], some of which concerned several studies that are already or will be performed. 467 of the 953 testing proposals concerned prenatal developmental toxicity and 359 concerned repeated dose toxicity. 183 TP decisions on reproductive toxicity are being finalised by the Commission. On the one hand this means that less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted either. Where no new data has been generated, the dossiers either contain data waivers or adaptations.

Table 4.1: Number of testing per study type

Study type	Number of tests expected in 2003	Number of tests submitted between 2008 and March 2016	Number of Testing Proposals
Skin sensitisation	10293 (*in vivo*)	1517 (*in vivo*) + 102 (*in*	NA[54]

[51] Report EUR 20863 EN by the JRC, Assessment of Additional Testing needs under REACH, September 2003.

[52] Third ECHA report under article 117(3) of the REACH regulation, The Use of Alternatives to Testing on Animals for the REACH Regulation, 2017, Appendix 8.

[53] Third ECHA report under article 117(3) of the REACH regulation, The Use of Alternatives to Testing on Animals for the REACH Regulation, 2017, section 3.2.5. Testing proposals submitted to and evaluated by ECHA.

[54] Not applicable (NA) as testing proposals are only required for high tier in vivo tests listed in Annex IX and X.

		vitro)	
Eye irritation	6910 (*in vivo*)	1217 (*in vivo*) + 1064 (*in vitro*)	NA
Skin irritation	3949 (*in vivo*)	741 (*in vivo*) + 1418 (*in vitro*)	NA
In vivo mutagenicity	6580	297	NA
In vitro mutagenicity	2916	3187	NA
In vivo Develop-mental toxicity	2893	369	467
In vivo Reproductive toxicity	2135	73	183
In vivo Repeated dose toxicity	4751	775	359
In vivo Carcinogenicity	121	15	0

The availability of data in 1-10 tpa dossiers appears to be of concern based on the dossiers submitted to ECHA before the 2018 deadline. An analysis of the ECHA database shows that the 1-10 tpa substances for which dossiers have been submitted so far, are statistically less mutagenic than >10 tpa substances. As an illustration, it seems that registrants do not follow the requirement to undertake further studies in case of a positive Ames test. Taken together with the fact that no repeated dose data are required for 1-10 tpa substances, there could be a problem with understanding long term effects of substances in this tonnage range. This appears to be in line with the conclusion from the three studies on 1-10 tpa information requirements conducted for the Commission which calculated in the benefit-cost assessment that the level of human health protection provided by the current requirements is relatively low (at 10% of total health damages that would be caused by 1-10 tpa substances in the absence of any REACH requirements).

1.6 Outcome of the Public Consultation

The majority of respondents considered the chapter Registration and its provisions on data-sharing and avoidance of unnecessary testing clear and of particular EU-added value. However, several respondents (41, of which 71% from companies) also indicated that the registration process, as it currently stands, induces bad practices such as free-riding in the preparation of a joint submission and even more in the updating of registration dossiers. Two respondents commented that registrants do not have a strong incentive to provide high quality data as they risk to be targeted more often by regulatory actions if they do.

Concerns about the availability and quality of information provided by industry in the registration dossiers were found amongst stakeholders: this is the subject of a number of

publications[55,56,57,58], as well as of a position paper submitted by the European Environmental Bureau during public consultation[59].

1.6.1 Information requirements

Three consumer organisations and also one NGO, one public authority and one research institution recommended that stricter information requirements relating to registration of low volume substances (1-10 tonnes) should be introduced. They also suggest to introduce notification requirements for all substances produced >1 kg /y. They flag that some 20,000 low volume chemicals are believed to be on the EU market. At present, companies are not even required to screen these substances for carcinogenicity, reproductive toxicity, endocrine disruption or PBT properties. More comprehensive data requirements should be considered in order to achieve a more complete picture of the properties of the chemicals on the European market.

On the other hand, 40-50% of respondents considered that REACH generates data adequate for risk management measures overall and almost 70% considered that the data generated are adequate for classification & labelling. Public authorities and trade unions have a particularly positive view regarding the use of data for adopting harmonized classification and labelling (over 80% of respondents in each stakeholder groups considers that data is substantially or very useful for that). However, less than 20% of respondents said data generated are sufficient for adopting consumer protection legislation concerning chemicals in articles, environmental legislation, and occupational exposure limits in the context of worker protection legislation.

A Member State Competent Authority highlighted the fact that information requirements for low tonnage substances in Annex VII of REACH should be revised with regard to the information requirements for physical-chemical properties, as for example, some terms used in Annex VII are no longer defined in the CLP Regulation.

On nanomaterials, seven position papers (mostly from industry) consider that the current version of REACH is the adequate framework to regulate nanomaterials and that no additional nanomaterials legislation is necessary. Eight position papers (mostly from NGOs and consumer organisations) consider that nanomaterials should be specifically addressed under REACH and that the current version of REACH does not adequately cover nanomaterials and their specific risks and properties. They provided a long list of recommendations to ensure that REACH adequately covers nanomaterials which includes an update of the REACH Annexes for nanomaterials before 2018.

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[55] G. Stieger, M. Scheringer, C. A. Ng and K. Hungerbühler, Chemosphere, 2014, 116, 118–123. Bundesinstitut für Risikobewertung (BfR), REACH Compliance: Data Availability of REACH Registrations. Part 1: Screening of Chemicals >1000 tpa, 2015.

[56] Client Earth, REACH registrations and endocrine disrupting chemicals, 2013.

[57] E. Westerholm and L. Schenk, Regul. Toxicol. Pharmacol., 2014, 68, 51–58.

[58] L. Schenk, N. Palmen and D. Theodori, Evaluation of worker inhalation DNELs. Part A: quality assessment of a selection of DNELs, 2014.

[59] Position paper by European Environmental Bureau submitted during the online public consultation

Concerning registration requirements for polymers, the views provided were divided: One position paper by industry suggested that the current polymer exemption from REACH registration and evaluation should be maintained as polymers are sufficiently covered under REACH and CLP through existing requirements for monomers, other reactants and additives. Another position paper from an NGO proposes that the exemption for registration of polymers should be re-considered due to potential hazards of the polymers.

1.6.2 Compliance of registration dossiers

Around 20% of all respondents from NGOs, consumer associations, industry associations, public authorities, and research institutions plus 18 position papers commented on the high level of non-compliance of registration dossiers as hindering the objectives of REACH or as impairing the level-playing field between duty-holders. Some considered that the completeness check performed by ECHA should not be limited to an IT check but a first check of the data would be more effective and improve the scrutiny of the files to implement the "no-data-no-market" principle. There was a call for ECHA to refuse to grant or withdraw a registration number when important data are missing from the registration dossiers or when extremely poor data have been provided. Also, ECHA was encouraged to further increase the number of compliance checks.

2 Data sharing, test methods and avoidance of unnecessary animal testing

Conclusions of the 2013 REACH Review

The 2013 REACH Review acknowledged that good progress had been made on the procedural side of data sharing and with submission of testing proposals. However, concerns remained regarding the robustness of the information and the quality of justifications for not submitting test results.

The Commission's report recommended to ECHA (a) to take measures so that registrants improve the quality of the justifications supporting the alternatives to animal testing, so as to improve compliance of registered dossiers with the information requirements; and (b) to continue to provide guidance and training to registrants and regulators to assist in the use, preparation of justifications and regulatory acceptance for approaches such as weight of evidence, grouping of substances and read-across approach and the use of (Q)SAR and in vitro methods.

The report detailed that EUR 330 million in financial support had been made available by the Commission to develop and evaluate alternative methods in the period 2007-2011, but stated that there were still fundamental gaps in providing alternatives for some complex toxicological endpoints. In addition, some research outputs produced were not suitable for regulatory needs or required further education of users and regulators to ensure their use and acceptance.

2.1 Developments after the 2013 REACH Review

2.1.1 Data sharing and joint submissions

During the reporting period for this Review, the Commission reaffirmed and reinforced the "one substance, one registration" principle by adopting a Commission Implementing Regulation on joint submission of data and data-sharing[60] (see also annex 4-part on registration). The ECHA guidance on data-sharing has subsequently been updated to reflect the requirements of the new Regulation[61].

Registrants of the same substance are obliged to share any available data, especially related to vertebrate animals, via the data sharing process. Companies planning to register a new or existing substance that has not been pre-registered need to inquire with ECHA whether a registration has already been submitted for that substance. For the last three years on average ca. 1,500 potential registrants per year used the inquiry process[62].

[60] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

[61] https://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60

[62] ECHA, 2017. The use of alternatives to testing on animals for the REACH Regulation

ECHA improved REACH-IT to put in contact potential registrants (pre-registrants and inquirers) and existing registrants with the lead registrants. Furthermore, ECHA put in place improved tools to prevent submissions outside of an existing joint submission and to ensure that co-registrants discuss the sharing of all relevant data for the substance and avoid duplication of unnecessary animal tests.

The REACH principles of sharing and joint submission of data on intrinsic properties of a substance generally work well (registrants used it to fulfil the information requirements and to avoid unnecessary animal testing in more than 97% of cases) and have a major impact on avoiding unnecessary duplication of animal testing[63].

The recent Implementing Regulation encourages the sharing of the results of animal studies between structurally similar substances to facilitate grouping or read-across approaches and to promote the development and use of alternative methods for the assessment of hazards of substances and to further minimise animal testing. In the same vein, in the report on the Operation of REACH and CLP[64], ECHA pointed out that registrants' possibilities of making full use of scientifically robust read-across or category approaches, as envisaged in Annex XI of REACH,[65] is hampered by the absence of obligatory data-sharing between structurally similar substances in REACH.

2.1.2 Development and use of alternative methods

2.1.2.1 Acceptance and use of new alternative testing methods under REACH

During the reporting period, several amendments to the standard information requirements in REACH Annexes VII to X were made to require the use of test methods that lead to a reduction or replacement of testing on vertebrate animals.

In 2015, the standard information requirement for reproductive toxicity in Annexes IX and X for a two-generation reproductive toxicity study was replaced by a requirement for the Extended one-generation reproductive toxicity study[66] (EOGRTS, OECD TG 443). This test method decreases animal use compared to the two-generation reproductive toxicity study whenever the (conditional) breeding of the second generation is not included in the study. Moreover, this study includes the assessment of additional effects that were not included in the two-generation study. The EOGRTS test guideline provides a flexible study design, with optional modules to assess developmental neurotoxicity and

[63] Report on the Operation of REACH and CLP, ECHA 2016

[64] Report on the Operation of REACH and CLP, ECHA 2016

[65] Annex XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)- 'General Rules for Adaptation of the Standard Testing Regime set out in Annexes VII to X'.

[66] Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study. OJ L50/1, 21.02.2015

developmental immunotoxicity, as well as optional breeding of the second generation. In the data requirements for REACH, these additional modules of the test are triggered depending on exposure and/or indications from the available data for certain effects, e.g. endocrine disruption, knowledge which can change in the future.

Due to the flexible study design of EOGRTS, the implementation of this new study for REACH purposes and the conditions for triggering of the different modules were matters of extended discussions involving scientific and regulatory experts. During these discussions, 216 draft decisions on testing proposals and compliance checks concerning reproductive toxicity were referred from ECHA to the Commission in the period 2011-2014[67], as no unanimous agreement could be found in the MSC on draft decisions proposed by ECHA. The Commission put decision-making on hold in order to resolve the underlying disagreement on how to perform reproductive toxicity testing for the purpose of REACH. Following the change of the information requirements for this endpoint in Annexes IX and X, the Commission is finalising the decision-making process for these cases by requiring registrants to submit new testing proposals for appropriately designed EOGRTS according to the criteria set in the REACH annexes.

In 2016, an amendment[68] to Annexes VII and VIII modified the standard information requirements for skin irritation/corrosion and eye irritation/serious eye damage by removing the standard requirement for an *in vivo* study for substances registered at and above 10 tons per year. Thus, the results of *in vitro* tests are sufficient to fulfil the REACH information requirements at all tonnage levels unless the *in vitro* methods are not applicable or their results not adequate for classification and risk assessment. This amendment also adapted requirements for acute toxicity information, so that for substances shown to be non-toxic via the oral route, dermal acute toxicity studies are no longer required. A second amendment[69] to Annex VII introduced the recently developed AOP-based *in vitro* test battery for skin sensitisation as the default information requirement, if applicable for the substance under investigation and giving sufficient information for classification and risk assessment. While REACH, as a general rule, requires that animal tests are only performed as a last resort and gives priority to available and applicable alternative methods, these amendments clarify the use of the available alternative methods for these endpoints. They also provide increased legal certainty that the data requirements for these endpoints can be fulfilled on the basis of *in vitro* tests as well as increased ease of data submission for registrants, as waiving of in vivo studies is no longer required.

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[67] http://ec.europa.eu/environment/chemicals/reach/implementation_en.htm

[68] Commission Regulation (EU) 2016/863 of 31 May 2016 amending Annexes VII and VIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity. OJ L 11/27, 01.06.2016

[69] Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation. OJ L 255/14, 21.09.2016

Following the modifications of the REACH information requirements, ECHA updated the specific guidance documents for the endpoints affected to provide detailed information on available alternative methods and their use in the context of Integrated Assessment and Testing Approaches (IATAs)[70].

Commission Regulation (EC) No 440/2008[71] on test methods provides an inventory of methods appropriate to generate data for the purpose of REACH, essentially by taking up internationally agreed OECD test guidelines in EU legislation (including translation in all EU languages). It has been amended four times during the reporting period[72] to reflect the scientific progress made in the OECD test guideline programme. These amendments introduced 38 new and 24 updated test methods with potential uses under REACH, including a number of methods with a relevance to replace, reduce or refine animal testing. These comprised four new *in vitro* tests (B.57 H295R cell-based steroidogenesis assay, B.59 Direct Peptide Reactivity Assay, B.60 Keratinosens, B.61 Fluorescein leakage test for ocular corrosion), four updates to existing in vitro tests for genotoxicity and serious eye damage, as well as several new reduction and refinement tests.

The formal recognition of new test methods by amendments to Commission Regulation (EC) No 440/2008 and/or information requirements in REACH Annexes, as well as the adaptation of the detailed information in the endpoint-specific ECHA Guidance documents has frequently been criticised, including in the public consultation for this REFIT evaluation, for taking too long to be completed after test guidelines have been agreed in the OECD, thus creating uncertainties for registrants and hampering the uptake of available alternative test methods for REACH. While the frequency of amendments and the number of included test methods has increased during the reporting period, in particular a timely formal recognition of new testing methods through inclusion in the Annex to Commission Regulation (EC) No 440/2008 remains a challenge due to the inherent administrative processes and the time required for translation of the long and highly technical test protocols in all EU languages. The experience from recent modifications of standard information requirements in Annexes VII-X to REACH have also highlighted a number of challenges for regulatory acceptance of new methods, which can significantly influence the time needed to complete the process, in particular related to concerns raised in relation to assessing the equivalence of information generated via *in vitro* or *in vivo* testing, maintaining the previous level of protection for

[70] Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance. https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

[71] Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 142/1. 31.05.2008

[72] Commission Regulation (EU) No 260/2014 of 24 January 2014. OJ L 81/1, 19.03.2014
Commission Regulation (EU) No 900/2014 of 15 July 2014. OJ L 247/1, 21.08.2014
Commission Regulation (EU) 2016/266 of 7 December 2015. OJ L 54/1, 01.03.2016
Commission Regulation (EU) 2017/735 of 14 February 2017. OJ L 112/1, 28.04.2017

human health and the environment, addressing flexibility in test guidelines as well as testing costs and availability of test laboratories able to perform new tests.

In order to close the gap between the adoption of new OECD test guidelines and the formal recognition in Regulation (EC) No 440/2008 and REACH Annexes VII-X and to give timely information to registrants about the availability of new alternative methods and the possibility to use those methods for the purpose of REACH registrations in advance of changes to legal provisions and guidance documents, ECHA has set up a dedicated web site that can be quickly adapted to new developments[73].

REACH prescribes the use of alternative methods whenever possible and demands that testing on vertebrate animals shall be undertaken only as a last resort. As a follow-up to the 2014 report on the use of alternatives to testing on animals for the REACH Regulation[74], ECHA investigated 295 higher tier studies on vertebrate animals that had been performed without the prior submission of a testing proposal[75]. For the majority of cases, adequate justification was obtained from registrants upon request (e.g. test conducted for other regulatory purposes or by a different legal entity). For the cases where a possible non-compliance was found (no or unsatisfactory response), the information was handed over to Member State Competent Authorities and National Enforcement Authorities for follow-up.

In order to reinforce the avoidance of unnecessary animal testing, and following two European Ombudsman cases on this topic[76], ECHA has modified its practices in the examination of proposals for tests involving vertebrate animals and compliance checks of the registration dossiers. Following the Ombudsman's decision in September 2015, ECHA started to request additional information on the alternative methods considered by registrants who submit new testing proposals for tests involving vertebrate animals[77]. A special field is now available in IUCLID 6 for the documentation of the alternatives considered prior to each proposed study on vertebrate animals[78].The information received is published with the public consultation on the testing proposals so that third parties can comment and it will be considered in the testing proposal examination. Furthermore, ECHA is currently assessing whether compliance check proves to be an effective way of

[73] https://echa.europa.eu/support/oecd-eu-test-guidelines

[74] The Use of Alternatives to Testing on Animals for the REACH Regulation. Second report under Article 117(3) of the REACH Regulation. ECHA, 2014

[75] Survey results - Analysis of higher tier studies submitted without testing proposals. ECHA, 2015

[76] 1606/2013/AN (TP), 1568/2012/(FOR)AN (CCh)

[77] Evaluation under REACH, Progress Report 2015. ECHA, 2016

[78] https://echa.europa.eu/view-article/-/journal_content/title/considerations-for-alternative-methods-need-to-be-included-in-your-testing-proposal

checking that animal testing is conducted only as a last resort[79] on the basis of two test cases.

2.1.2.2 Use of test methods and adaptations in REACH registration dossiers

Analysing the database of registrations available up to 31 March 2016 (6,290 substances included in the assessment), ECHA evaluated the use of available test methods as well as the adaptation possibilities given by Annex XI[80], including information for substance falling in the lower tonnage bands (i.e. 1-100 t/a)[81].

The overall analysis of options used by registrants to cover REACH information requirements at the substance level (see Fig. 4.4) showed that for low tier endpoints (acute rodent toxicity, skin and eye irritation/corrosion, skin sensitisation, genetic toxicity *in vitro* and acute toxicity to fish), the main sources of information are experimental *in vivo* and *in vitro* studies, which are used for 59 to 71% of substances, depending on the endpoint (new experimental studies (NES) and old experimental studies (OES) combined in Fig.4.4). Many of these studies are old experimental studies, i.e. they were carried out before REACH came into force. Read-across and weight of evidence adaptations were frequently used (on average over all endpoints for 14% and 12% of substances, respectively). Data waivers and (Q)SARs were more rarely used (on average for 4% and 2% of the substances, respectively).

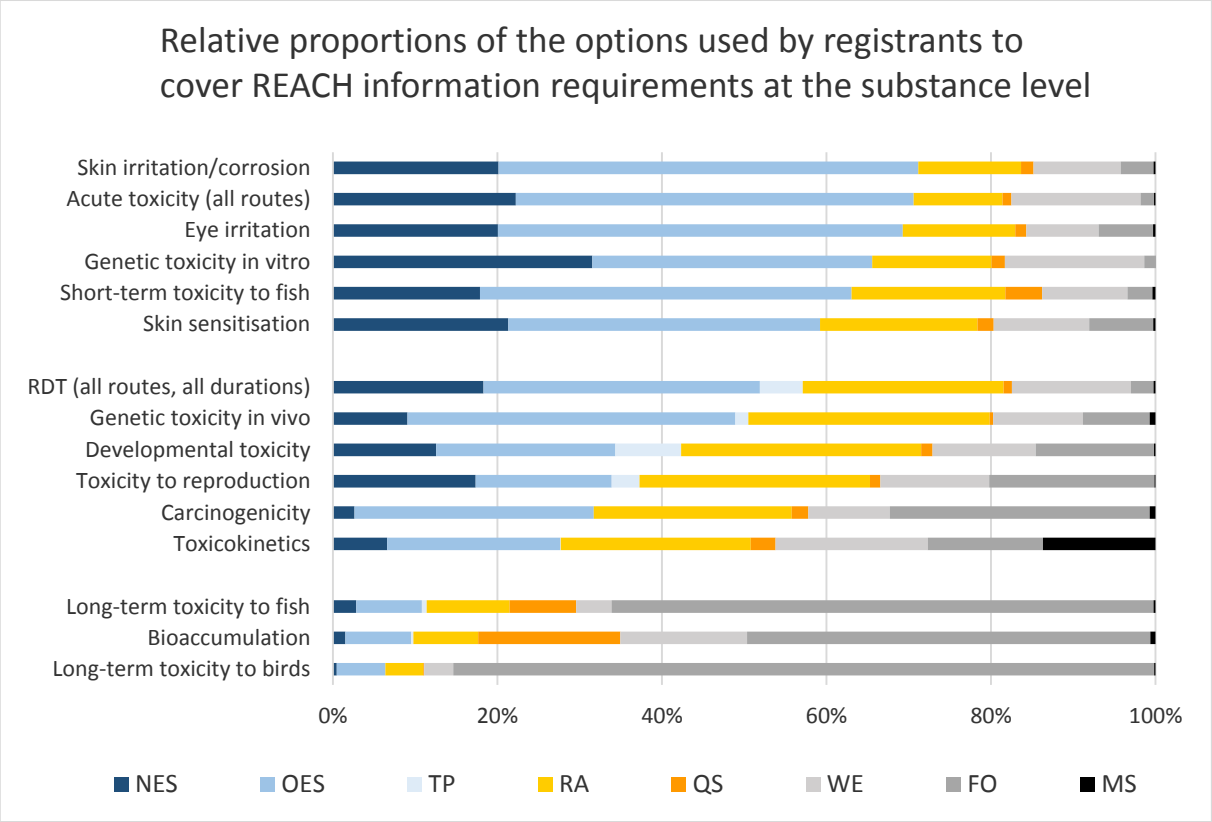
Figure 4.4: Relative proportions of the principal options to fulfil information requirements for human health and environmental endpoints for the substances.

Legend: OES – old experimental studies (conducted before 2009); NES – new experimental studies (including *in vivo* and *in vitro*, unless specified)); WE – weight of evidence; RA – read-across; QS – QSAR; TP – testing proposal; FO – flags to omit study; MS – miscellaneous

[79] Report on the Operation of REACH and CLP, ECHA 2016

[80] The Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017. DOI 10.2823/023078

[81] Two earlier reports in 2011 and 2014 had focused on substances in tonnage bands 100-1000 tpa and ≥1 000tpa



For higher tier human health endpoints (repeated dose toxicity, genetic toxicity *in vivo*, reproductive and developmental toxicity and carcinogenicity), generally less experimental studies were submitted than for lower tier endpoints (for between 32% and 52% of substances depending on the endpoint). The information requirements are more often covered by adaptations, most prominently by Read-Across (on average over all endpoints for 27% of substances), while Weight of Evidence (WoE) (12%) and waivers were used for 12% and 13% of substances, respectively. (Q)SARs, on the other hand, were very rarely used (1%) as the main option to fulfil information requirements.

For higher tier environmental endpoints (bioaccumulation, long-term toxicity to fish, long term toxicity to birds), relatively few experimental data are available (only for 6-11% of substances, depending on the endpoint). The information requirements are often addressed with data waivers (on average 64%) followed by other adaptations in decreasing order: QSARs (10%), Read-Across (8%) and Weight of Evidence (8%). The low number of experimental studies can be explained by the numerous possibilities to waive the experimental tests for these endpoints.

In the public consultation, 30 respondents addressed the issue of animal testing and alternatives in open questions, and 11 included this topic in position papers. The main message provided by those respondents is that the principle of 'animal testing as a last resort' is not yet fully implemented (80% of them referred to this issue in the open questions and 72% in position papers). Respondents attribute this problem to the strict information requirements, often referring to the low acceptance of read across and QSAR by ECHA, leading to unnecessary animal testing. Many respondents state that the

acceptance of alternative methods is low[82]. Furthermore, a plea was made by some respondents to adopt a systematic, quantitative approach to weight-of evidence.

2.1.2.3 New studies

At the cut-off date for the ECHA report, a total of 15,188 new (e.g. performed from 2009 onward) unique experimental studies across all endpoints had been submitted to ECHA, while the number of submitted existing experimental studies (performed before 2009) was ca. 2.5 times higher.

- Many studies conducted in accordance with the OECD test guidelines/EU test methods after 2009 were for low tier human health endpoints: 5,542 *in vivo* studies; 5,795 *in vitro in chemico* and *ex vivo* studies.
- A total of 2 471 new studies for high tier human health endpoints were reported. The main type of health endpoints are screening studies for reproductive/developmental toxicity and combined studies combining a screening study with a 28-day repeated dose toxicity study (a total of 952), followed by 28-day repeated dose studies, all routes (a total of 442).
- 359 new developmental toxicity studies
- 268 new 90-day repeated dose studies
- 73 new studies on reproductive toxicity

For all endpoints, the main source of experimental data are studies that already existed when REACH came into force, with the exception of reproductive toxicity, due to the significant number of screening studies performed.

Compared to human health endpoints, there are relatively few new studies for environmental endpoints (1,274 studies, of which 1,060 address acute toxicity in fish). These data have a high potential to support new adaptations to be applied for low tonnage substances and new registrations, by QSAR and read-across for example.

From the data available from the registration dossiers, it is currently not possible to deduct how many of the studies have been generated in order to fulfil REACH information requirements or regulatory needs other than REACH and CLP (e.g. the same test might have been required in other jurisdictions). In the case where ECHA requested further justifications for higher tier tests performed without testing proposals and for animal tests for endpoints where alternatives are available, registrants frequently referred to regulatory requirements in other regions. Since the requirement to provide justification for *in vivo* studies in registration dossiers has been strengthened (see above), more information on this aspect should be available in the future.

As the registration process for high volume phase-in substances is now completed, a first comparison of the number of animal tests following requirements in Annex IX and X that have been submitted, and requested in testing proposal (TP) or compliance check (CCh)

[82] 53% of respondents addressing animal testing and alternatives in the open question and 72% in the position papers

decisions, with the estimates made before the adoption of REACH[83] is possible. However, such a comparison, for the time being, has to be seen as very approximate and preliminary, as dossier and substance evaluation processes are still ongoing and in particular additional tests may still be requested in CCh decisions. Double counting of studies is possible, as the current statistics on new tests[84] (performed after 2009) submitted to ECHA does not distinguish between tests that have been performed following TP and CCh decisions, and tests that have been performed for other regulatory purposes. On the other hand, the statistics on tests requested in TP and CCH decisions[85] does not allow a conclusion on how many of the requested studies have already been completed and submitted to ECHA[86]. However, even by adding all new studies submitted to ECHA and requested in evaluation processes, it becomes evident that the number of studies performed for human health high tier endpoints remain well below the minimum estimations initially made (see also table xxx in section registration).

For the endpoints for which *in vitro* test methods are available that can (individually or in combination) fully replace *in vivo* testing for substances in the application domain of these methods, ECHA performed a detailed analysis of the data submitted from 2010 onwards[87]. In the case of skin corrosion/irritation and serious eye damage/eye irritation, a large proportion of registrants relied on existing data or read-across approaches in about 70% of dossiers analysed (substance approach) . An analysis of the experimental studies submitted showed that dossiers for around 20% of substances contained *in vitro* data for skin corrosion/irritation and serious eye damage/eye irritation, either as supporting evidence or as the main source of information. For skin corrosion/irritation, registrants have used *in vitro* information alone to fulfil the information requirements in 10.6% of substance dossiers, and for serious eye damage/eye irritation this was the case for 7.2% of substance dossiers.

From the ECHA report it becomes evident that, while the number of submitted *in vitro* data for both skin corrosion/irritation and serious eye damage/ eye irritation has overall increased in comparison to previous reports, there was still a relatively high number of recent *in vivo* tests submitted, necessitating further exploration by ECHA and, where relevant, the Member States enforcement authorities, of the reasons and justifications for this.

The total number of *in vitro* data submitted for skin sensitisation has grown but is still very low compared to the number of submitted *in vivo* tests (a total of 102 *in vitro* studies in 2016 versus 54 in 2014). This low number may be attributed to the fact that, at the cut-off date for this analysis, OECD test guidelines were not yet available for all methods of

[83] Assessment of Additional Testing Needs under REACH. EC, 2003

[84] Table 2 in: ECHA report on the Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017

[85] Table 3 in above report and aggregated information from ECHA Progress reports on Evaluation 2010-2016 (https://echa.europa.eu/regulations/reach/evaluation)

[86] It should also be noted that not all decisions necessarily lead to testing as registrant may still decide to fill a data gap by using an adaptation

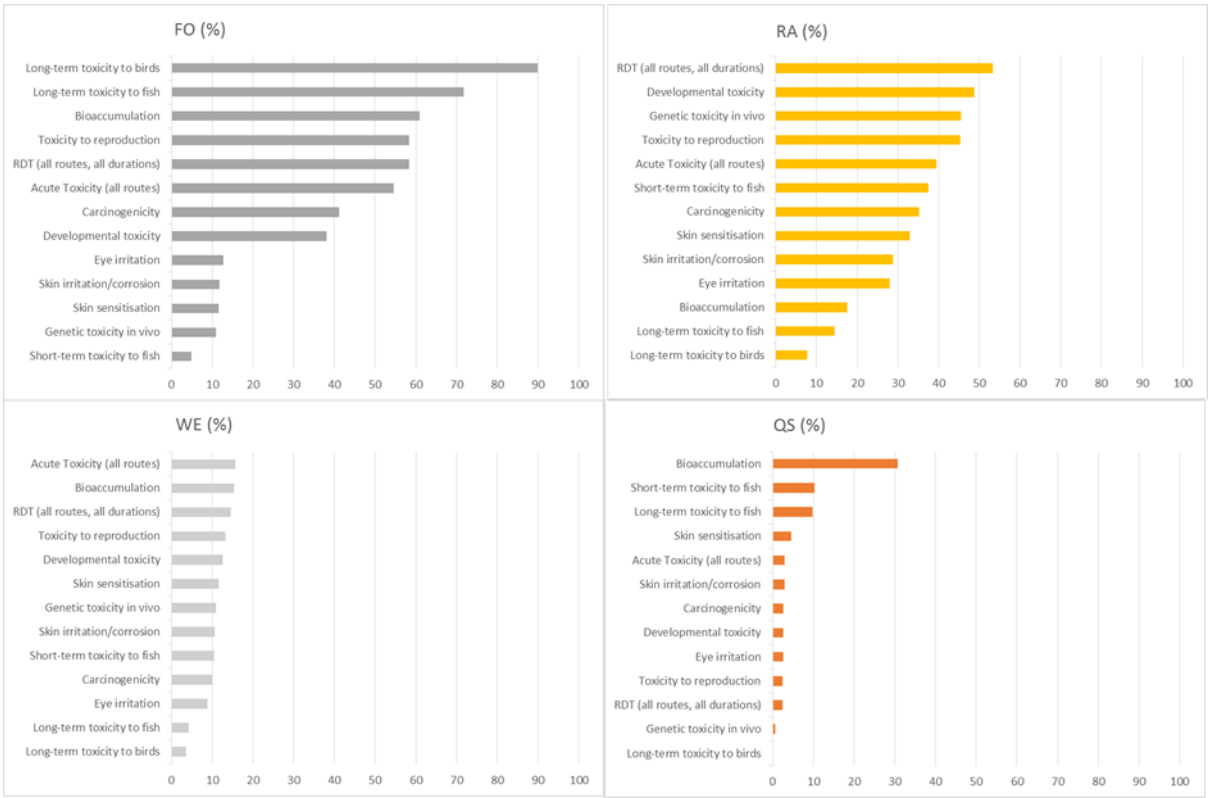
[87] The Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017. DOI 10.2823/023078, Appendices 5-7

the basic test battery, and detailed guidance for their application for regulatory purposes was missing. Their use should increase following the revision of the information requirements in REACH for this endpoint in 2016. However, efficient uptake of these methods will depend on the development of defined approaches to predict sensitisation hazard and potency based on the results of the available tests and/or other available information. A project addressing this is currently ongoing at OECD.

2.1.2.4 Adaptations

The three ECHA reports on the use of alternatives to testing, covering the period from 2009 to 2015, show that the rate of use of adaptations remained similar on Endpoint Study Record (ESR) level. In the 2017 report, there is on average, across all endpoints, a slight increase in the use of Weight of Evidence, and about the same use of read-across and QSAR[88] reported.

Fig. 4.5: The fraction of substances for which an adaptation was used related to the overall number of substances with information for this endpoint**.** The endpoints are sorted in decreasing order of percentages and start with the endpoint where the adaptation was used most. Legend: FO – flags to omit study; RA – read-across; WE – weight of evidence; QS – QSAR



[88] ECHA report on the Use of Alternatives to Testing on Animals for the REACH Regulation. Third report under Article 117(3) of the REACH Regulation. ECHA, 2017

Results from the analysis of adaptations according to Annex XI show that of the dossiers for 6,290 substances 89% contained at least one adaptation (including waivers), 63% contained read-across adaptations, 43% contained weight of evidence arguments, and 34% contained read-across predictions for at least one endpoint concerning vertebrate animals.

Quantitative structure-activity relationships (QSARs) were used mainly for environmental endpoints, particularly for bioaccumulation, short- and long-term toxicity to fish. For health endpoints, QSARs are only rarely used. In weight of evidence (WoE) approaches, the main contributions come from the use of old studies or read-across approaches. QSARs in WoE are used frequently for particular endpoints (i.e. bioaccumulation and short-term toxicity to fish).

Waiving was used frequently for endpoints where endpoint-specific triggering or waiving options exist in the REACH Annexes (e.g. bioaccumulation, long term toxicity for fish or birds, reproductive toxicity, carcinogenicity), or where multiple routes of administration are possible, but not always required (acute rodent toxicity and repeated dose toxicity). The main reasoning provided for waiving was that the given test was scientifically unjustified. Exposure-based justifications were used considerably less and only for particular endpoints like long-term toxicity to fish, long-term toxicity to birds, and for endpoints like acute and repeated dose toxicity, where different routes of exposure are possible.

Read-across was frequently used for the higher tier human health endpoints Repeated Dose Toxicity, developmental and reproductive toxicity. Read-across is considered a viable adaptation for complex health endpoints, presuming that a scientific plausible hypothesis can be proven and used for deriving quantitative result for the targeted substances. For these endpoints *in vitro* alternatives that can replace the results of experimental tests with a similar level of protection to human health do not exist yet.

However, experience from dossier evaluation[89] shows that the majority of adaptations identified in the registration dossiers are found non-compliant, leading to the request for the standard information in the Compliance Check decision[90]. According to ECHA, the main reasons for not accepting adaptations, especially WoE and RA, are poor documentation, insufficient substance identification of both, the substance which is target of the prediction and the source substance(s), deficiencies in the quality of the source study, lack of or low quality of supporting data, lack of qualitative and quantitative data to support predictions based on toxicokinetics, and shortcomings in the toxicological hypothesis. Similar problems were identified by another study[91], which for human health endpoints frequently found insufficient justification for the similarity of source and target substances for read-across and the use of inappropriate waiving justifications. For ecotoxicological endpoints, the absence of read-across justifications, and missing or absent experimental data for the source substance for read-across, as well as the use of

[89] ECHA Evaluation Reports, 2008 – 2015, summarised in Report on the Operation of REACH and CLP, ECHA 2016

[90] However, registrants can still update their dossiers with improved information supporting the original adaptation

[91] Data availability in REACH registrations. BfR, 2015

inappropriate models and insufficient reporting for QSARs were identified as main reasons for non-compliant adaptations.

Although some industry stakeholders and animal welfare organisations commented in the public consultation for this REFIT evaluation that ECHA is too stringent in its assessments of adaptations, there is no objective evidence supporting this. There have been no Board of Appeal decisions overturning a rejection by ECHA of an adaptation statement. On the contrary, the Board of Appeal has several times expressed that ECHA has a wide margin of discretion in making such scientific assessments.

ECHA has undertaken significant efforts in the reporting period to support registrants to improve the quality of adaptations used. This includes revision and expansion of relevant ECHA Guidance documents, the development of a Read-Across Assessment Framework (RAAF) for human health (published 2015), environment (2017) and multi-constituent substances and UVCBs (2017) as well as scientific meetings, workshops and webinars on alternative approaches.

In reaction to the many deficiencies in the read across arguments for higher tier health endpoints in particular, ECHA is actively following and supporting the scientific developments of methods that are promising in either strengthening the use of read-across and grouping or that could limit or replace the need for new studies on animals in the longer term. In addition, ECHA plans in 2017 to conduct a review on the applicability of alternative test methods to fulfil the REACH information requirements.

2.1.2.5 Test method development, validation and OECD test guideline development

During the reporting period, the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) received 32 test methods for evaluation or peer-review as a pre- or/and a full submission. Following a call dedicated to assays in the area of toxicokinetics (liver clearance) another 15 methods were submitted to and evaluated by EURL ECVAM.

In the relevant period, validation studies for 11 *in vitro* methods were completed under the (co-)lead of EURL ECVAM or by ICATM[92] partners with EURL ECVAM's active involvement. Another 9 methods were validated by other organisations or industry. The validation of 18 methods is ongoing or will start in the near future. One validation study trial lead by EURL ECVAM engages for the first time the newly established network of validation laboratories (EUNETVAL[93]), which now has 37 member laboratories. In the same period, the peer review of 15 methods by the EURL ECVAM Scientific Advisory Committee (ESAC) was completed, most of them in the area of skin sensitisation, skin irritation and serious eye damage/eye irritation. ESAC further adopted an Opinion on the use of Performance Standards to evaluate similar test methods.

[92] International Cooperation on Alternative Test Methods

[93] European Union Network of Laboratories for the Validation of Alternative Methods

In the OECD, 11 new OECD test guidelines on alternative methods were adopted between 2012 and 2016, the drafting in 6 cases was led by EURL ECVAM. These 11 methods serve the testing in the fields of skin sensitisation (3), serious eye damage/eye irritation (3), genotoxicity (1), endocrine disruption (3) and acute fish toxicity (1). EURL ECVAM furthermore led or was main contributor to the drafting of 6 OECD guidance documents and 2 performance standards. EURL ECVAM leads 7 ongoing OECD projects for the establishment of new or updated test guidelines or guidance documents, and two new project proposals were submitted to OECD in 2016.

While in the last years progress has been made to develop and refine *in vitro* test methods for some endpoints, and these have the potential to replace animal testing to a large extent, such methods are still missing for higher tier endpoints like systemic or reproductive toxicity, due to the underlying complexity of the physiological mechanisms involved. As one strategy to open new paths to the development of non-animal testing and assessment approaches of complex toxicity endpoints, the OECD launched a new programme on the development of Adverse Outcome Pathways (AOP)[94]in 2012. An AOP describes the sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect, and serve as the central element of a toxicological knowledge framework to support chemical risk assessment based on mechanistic reasoning. The first AOP-based testing approach has entered regulatory application with the set of *in vitro* test methods and the linked IATAs[95] for skin sensitisation.

2.1.3 Research funding

2.1.3.1 Research funding through EU research programmes

The European Commission (EC) has supported research into the development of alternative methods through its successive Framework Programmes for Research and Innovation (FPs), including the current seven-year programme Horizon 2020 (H2020: 2014 to 2020).

Over the last decade, EC funding in the field of research into alternatives has remained stable and significant with, on average, more than EUR 35 million per year to new research projects. During the period 2012-2016, sixty-nine research projects were running at various stages of implementation, with EUR 350 million from EC programmes. As part of this effort, thirteen projects were co-financed within the context of public-private partnerships with Cosmetics Europe (the seven projects from the SEURAT-1 cluster) or the European Federation of Pharmaceutical Industries and Associations (the six projects from the Innovative Medicines Initiative: IMI). The additional resources provided by the industry to these projects were estimated to represent more than EUR 115 million.

[94] http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[95] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)29&doclanguage=en

Research activities supported in the period 2012-2016 were carried out in the context of better and more cost-effective safety and efficacy testing. They included one FP6, fifty-three FP7 and fifteen Horizon 2020 projects covering areas such as toxicity of nanomaterials, chemical products and drugs, as well as quality control of vaccines. Overall, these projects developed a range of various novel *in silico* and *in vitro* approaches from innovative modelling tools to multiple organs-on-a-chip. In addition, for the risk management of nanomaterials, significant international cooperation exists with a number of countries outside the EU through the NANOSAFETY Cluster[96].

The contribution of these projects for the availability of new alternative methods is difficult to assess. The FPs monitoring and evaluation system collects information in a structured and systematic way on publications and IPR (patents, registered designs, trademarks, copyrights) only. There are no data on, for example, the actual policy impact of R&I projects. Moreover, the bibliometric and IPR data is based on projects' reporting and are not fully reliable. Within these limitations, the FP7 projects mentioned in Table 4.2 have so far produced about thousand peer-reviewed publications in scientific journals and have generated around thirty Intellectual Property Rights. Since all Horizon 2020 projects are still in their initial phases, it is premature to report outputs at this stage. There is always a lag in the implementation of new methods from EC funding due to the long time needed between the development of the methods, their validation, and their regulatory acceptance. However, regulatory impact starts to be observed from FP6 projects for less complex toxicological endpoints, such as skin sensitization for instance. Additional regulatory impacts are expected to come out of FP7 and H2020 projects, including in the areas of more complex toxicological endpoints, such as repeated dose systemic toxicity, developmental and reproductive toxicity, and carcinogenesis.

Additional research funding

The Commission is notably providing support through Horizon 2020 for the harmonisation of human biomonitoring in Europe (HBM4EU[97]– started in January 2017). In addition, the Commission has stepped up its efforts to support test method development related to endocrine disruption by calling for proposals for research and innovation actions[98] in order to fill gaps in the identification of endocrine disruptors relevant to the OECD test guideline programme.

The NANOREG[99] project combined EU Member States and industry resources for regulatory testing of nanomaterials. The projects NANOREG and PROSAFE[100], with contribution from other projects summarised the aims, efforts and results in a white paper[101] submitted also to the OECD Working Party of Manufactured Nanomaterials (WPMN) in 2017. Projects were driven by the need to reduce uncertainty in the

[96] https://www.nanosafetycluster.eu/
[97] The European Human Biomonitoring Initiative – HBM4EU
[98] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-bhc-27-2018.htm[l]
[99] http://www.nanoreg.eu/
[100] http://cordis.europa.eu/project/rcn/194431_en.html
[101] http://www.rivm.nl/dsresource?objectid=008c3189-984e-4204-b129-048cecad1743&type=PDF

regulatory assessment of the Environmental Health and Safety aspects of nanomaterials and support a climate where the innovative potential of nanotechnology can be fully exploited.

Table 4.2. Overview of main projects on alternative methods/approaches and nanomaterials funded by the EC Framework Programmes during 2012-2016

Project Name	**Total awarded grant [million €]**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
FP6																	
carcinoGENOMICS	10,44																
FP7																	
CONTAMED	3,49																
DEER	3,50																
ESNATS	11,90																
NanoTEST *	3,00																
PREDICT-IV	11,33																
NANORETOX *	3,19																
CADASTER	2,70																
ENFIRO	3,16																
RISKCYCLE	1,00																
SYSTEQ	2,70																
ENNSATOX *	2,80																
ENPRA *	3,70																
HINAMOX *	2,30																
InLiveTox *	2,40																
NANODEVICE *	9,49																
NEPHH*	2,43																
NEURONANO *	2,50																
SafeSciMET	2,37																
SAFE-T	13,90																
CHEMSCREEN	3,50																
EUROECOTOX	0,96																
AXLR8	0,56																
ACROPOLIS	3,00																
NANOHOUSE	2,40																

*																	
eTOX	6,91																
COACH **	1,50																
COSMOS **	3,34																
DETECTIVE **	4,33																
HeMiBio **	4,70																
NOTOX **	4,85																
SCR&Tox **	4,70																
ToxBank **	1,56																
diXa	2,80																
QNANO *	7,00																
Marina *	9,00																
ModNanoTox *	1,00																
NanoTranskinetics *	0,99																
NanoValid *	9,59																
BOC	1,39																
MIP-DILI	15,33																
STEMBANCC	26,00																
HeCaToS	12,00																
MembraneNanoPart *	1,00																
Mod-ENP-Tox *	1,00																
Modern *	1,00																
NanoMile *	9,62																
NanoPuzzles *	0,98																
NANoREG *	10,00																
NanoSolutions *	10,00																
PreNanoTox *	1,00																
eNanoMapper	4,00																
FutureNanoNeeds *	6,80																
IN TIME	0,19																
H2020																	
EuroMix	8,00																
MolNANOtox	0,19																
NanoCytox	0,16																
F-CCW	0,05																
PROSAFE *	2,51																
BIOTIMA	0,05																

NanoREG II *	10,00																
EDC-MixRisk	6,22																
BioMNP	1,13																
PANDORA	2,81																
NANOGENTOOLS	0,71																
HISENTS *	6,33																
SmartNanoTox *	8,00																
EU-ToxRisk	27,80																
VAC2VAC	7,85																
ACENano *	7,00																
CALIBRATE *	8,00																
EC4SAFENANO *	1,99																
npSCOPE *	6,66																
NANOFASE *	9,95																
GoNano	1,99																
PATROLS	12,71																
GRACIOUS	7,00																

The projects given above and marked with one or two asterisks form part of two research clusters as follows:

* NANOSAFETY cluster

** SEURAT-1 cluster, the funding of which was realized via a joint venture between the European Commission (in the framework of FP7) and the European Cosmetics Association (Cosmetics Europe), who made available additional € 25 million.

2.1.3.2 Investments in alternatives by the Joint Research Center (JRC)

In the period 2012-2016, about EUR 36 million have been spent for the operation of the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), hosted by the JRC. The current annual budget is EUR 6.5 million. About 98% of the expenditure is for staff, the operation of laboratories, the set-up, maintenance and update of IT systems and tools, the management of a number of advisory and consultation bodies, EURL ECVAM's collaboration with various partners in the EU and globally; as well as overhead costs. Around 2% of EURL ECVAM's budget in 2012-2016 have been spent for specific studies conducted by external contractors to speed up deliverables of special policy interest.

The major contributions of ECVAM towards the regulatory use of alternative methods are described above in the section on test method development, validation and OECD test guideline development. Furthermore, EURL ECVAM contributed substantially to the FP7 research initiative SEURAT-1, cosponsored by the European Commission and Cosmetics Europe, which has been completed at the end of 2016. This initiative gathered more than 70 EU partners and aimed at animal-free safety assessment of chemicals for

repeated dose toxicity. Currently, EURL ECVAM is collaborating with the recently started Horizon 2020 funded projects EU-ToxRisk and EuroMix.

2.1.3.3 Other funding

During the reporting period, the Commission has contributed to the development of standardised and internationally agreed test methods through two grants to the OECD test guideline programme. For the periods 2014/2015 and 2016/2017 a contribution of 800,000 Euro was given twice towards the development of guidelines for the testing of chemical, endocrine disruptors and nanomaterials. During these periods, approximately 50 new or updated test guidelines as well as several guidance documents were agreed by OECD. The contribution also benefitted the work on Integrated Approaches to Testing and Assessment (IATA) (including IATAs for skin and eye irritation with high relevance for data generation under REACH) and Adverse Outcome Pathways (AOP), which are expected to play an important role in defining future alternatives testing approaches.

2.1.3.4 Furthering Alternatives through EPAA

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a public-private initiative between services of the European Commission (DG GROW, ENV and SANTE) and European industry stakeholders from eight sectors. All EPAA activities serve the so-called '3Rs principle' to replace, reduce and refine animal testing. The focus of EPAA's core activities through various projects lies in the promotion of regulatory acceptance of alternative methods.

EPAA projects related to the REACH Regulation are:

- *3D skin models to assess the potential for skin sensitisation*

3D skin models better mimic the skin structure and organisation and offer advantages as the substances can be applied to the model skin. However, the utility of these models for the evaluation of hydrophobic or “difficult to test substances” is unclear. The objective of the project is therefore to evaluate the three most advanced 3D skin models for their reliability for skin sensitisation prediction. Qualification of the three 3D skin methods has already begun using a battery of 12 ”difficult to test substances” selected by industry. Preliminary results are expected in early 2017.

- *Acute Toxicity - Identification of clinical signs predictive of mortality*

The REACH standard information requirement for the endpoint of acute toxicity by the oral route is the most common testing requirement and therefore this route has been prioritised by EPAA. This EPAA project has identified opportunities to waive the acute toxicity animal testing requirements completely or, where this is not possible, to refine the decision-making steps or assessment strategies so as to minimise suffering of animals. Recommendations on a 3Rs-based classification & labelling decision framework to include replacement of death as an endpoint have been drafted. Additional evidence is being developed through data mining and analysis of previous acute, oral

toxicity studies in collaboration with the UK National Centre for the 3Rs (NC3Rs) and the UK Chemicals Regulation Directorate.

In 2016, more than 450 previously filed acute toxicity studies have been screened and data from more than 100 of these have been collected. The data are now being analysed statistically to determine their quality and adequacy. The objective is to establish that clinical signs (evident toxicity) are predictive of mortality in acute oral toxicity studies and are an appropriate alternative to death as an endpoint.

3 Communication of information in the supply chain

Baseline

The main tool to pass on information down the supply chain, the safety data sheet (SDS), existed prior to REACH. REACH changed the sequence of certain sections of the SDS to align it to the world-wide SDS standard established in the UN Globally Harmonised System. REACH also introduced the requirement to annex exposure scenarios to the SDS.

The REACH registration process ensures greater availability of data. For instance, REACH introduced the obligation to generate so-called chemical safety reports for substances in volumes above 10 tonnes, which must include information on identified uses and uses advised against. REACH requires that such information must be passed on in the supply chain so that downstream users have adequate knowledge on how to use substances safely. If downstream users want to use them in a manner advised against or for a use outside the conditions described in the exposure scenarios, they need to prepare a chemical safety report themselves for those uses.

It was therefore expected that REACH would improve the content of the SDSs and thereby the management of risks by the users of the SDSs. In addition, REACH requires that exposure scenarios for identified uses are attached to the SDS – turning these into the so-called 'extended SDS'. The extended SDS thereby aims at increasing the amount of information available so that the necessary environmental, occupational safety and health measures can be implemented by downstream users.

Conclusions of the 2013 REACH Review

The 2013 REACH Review identified an increase of information in the supply chain. This was resulting in more appropriate risk management measures and thus contributing to risk reduction. However, the Review also recognised the need to address some shortcomings, particularly by improving the practical usability and readability of exposure scenarios annexed to the SDSs. Thus, a recommendation was made to ECHA and industry to address problems related to the compilation, communication and use of exposure scenarios annexed to the SDSs and thereby promote them as a central risk management tool.

Under REACH, downstream users became active players and a central source of information on different aspects concerning the use of substances. However, the 2013 Review recognised that, due to the wide range of downstream users, levels of awareness and knowledge of chemicals legislation vary and should be raised.

3.1 Developments after the 2013 REACH Review

3.1.1 Information in the supply chain, practical tools and support to downstream users

In November 2011, ECHA created the Exchange Network on Exposure Scenarios (ENES)[102] to share good practice and identify solutions for the generation, communication and implementation of REACH exposure scenarios with the aim to enable the exchange of information up and down the supply chain. ENES participation has to date consisted of individual companies, 28 industry sector associations (manufacturers, formulators and downstream end users of chemicals) themselves representing many thousands of companies at European level, consultants, NGOs and competent authorities from 15 Member States although the participation is open to all. Ten ENES meetings have taken place with a network community of more than 200 contacts[103].

A cross-stakeholder action plan, the Chemical Safety Report/Exposure Scenario Roadmap (CSR/ES Roadmap)[104] was published in July 2013, containing 21 actions in five priority areas designed to improve the quality of information in REACH chemical safety reports and extended safety data sheets. The latest implementation plan was published in July 2015[105].

Industry organisations, including downstream users associations of many relevant sectors have worked intensively with their associates and collaborated with ECHA in developing an extensive set of tools to simplify and harmonise the elaboration of exposure scenarios for the chemical safety report and their incorporation in the SDSs.

To a large extent the work done under the CSR/ES Roadmap and ENES has contributed to raising awareness and knowledge among downstream users of their obligations under REACH.

As illustrated in Figure 4.6, a number of tools intended to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS, including exposure scenarios, have been developed by ECHA and also under the umbrella of ENES and the CSR/ES Roadmap with its stakeholders:

- Templates with a recommended structure for different types of exposure scenarios (i.e. for industrial, professional and consumer uses)[106] and describing the type of information that should be included in each section. The use of templates may help registrants to understand how to structure the exposure

[102] https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

[103] In the last meeting of ENES (ENES 10) in November 2016 it was announced that the ENES programme would be run for an additional 4 years (from 2017 – 2020).

[104] https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

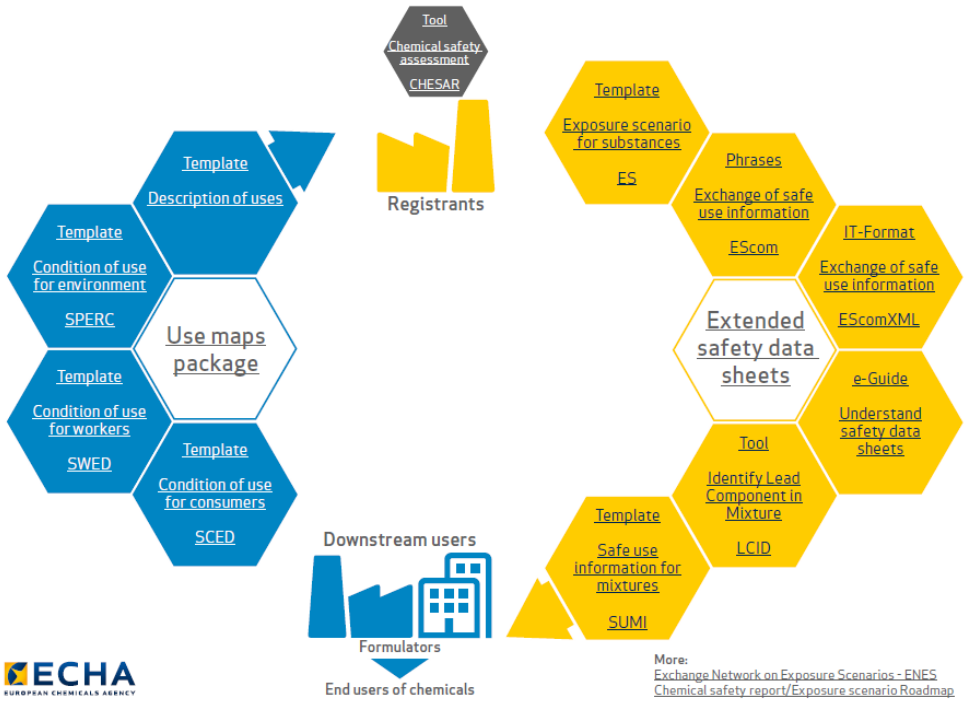
[105] https://echa.europa.eu/documents/10162/15669641/updated_csr_es_second_implementation_plan_en.pdf/3b375df6-df87-4db4-98b7-ec2fc770bca9

[106] http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

scenarios for optimal communication and encourage a move towards a harmonised format within the industry.

- ECHA has developed a specific IT tool – CHESAR (CHEmical Safety Assessment and Reporting) - to enable the elaboration of chemical safety assessments in a systematic way and to achieve and maintain consistency between the information in the registration dossiers and the advice on safe use communicated with the safety data sheets.

Figure 4.6: Improving communication on the safe use of Chemicals [107]



- Guide on safety data sheets and exposure scenarios[108];
- Practical Guide on how downstream users can handle exposure scenarios[109]
- Practical examples of exposure scenarios and of chemical safety reports such as [110,111]:

[107] ECHA website https://echa.europa.eu/documents/10162/15669641/safe_use_chemicals_en.pdf

[108] https://echa.europa.eu/documents/10162/22786913/sds_es_guide_en.pdf/b5e90791-68a0-4ad3-8769-6b3a17e61c36

[109] https://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf/2c3bc624-fb3c-4515-a581-87b79d460d38

[110] https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

[111] https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

- Illustrative examples of exposure scenarios to be annexed to the safety data sheet were developed and published;
- Exposure scenario for CSR. An example of consumer exposure to substances in articles;
- Examples of exposure scenarios for the semiconductor industry, for the professional use of a substance in floor coatings and for consumer use of a substance in cleaning products have been developed and published by ECHA in collaboration with the relevant sector associations which are currently under review.

- Guidance to support a harmonised approach for the creation and structuring of exposure scenario short titles ('Structured short titles in exposure scenarios for Communication')[112], including guidelines for implementing this approach in software applications used for compiling and issuing SDS.

- The use of standard phrases, allowing the efficient and consistent creation of harmonised text paragraphs for SDS and exposure scenarios, which will ease electronic data transfer of standardised phrases between suppliers and their customers and also facilitate the translation of documents into other languages. The ESCom package[113] for the exchange of exposure scenarios data between IT systems has been developed to enable consistent communication of exposure scenarios information throughout the supply chain. The package consists of two components: i) ESCom XML standard, the XML format; ii) ESCom standard phrase catalogue, covering the standard phrases for exposure scenario content.

- Use maps[114] describe the uses of chemicals in a harmonised and structured way and are typically generated by downstream users' sector organisations. A use maps package containing four templates was produced: one for the general description of the uses and three for the information needed to carry out exposure assessments. Separate templates exist to report the inputs for the exposure assessment for workers (SWEDs), the environment (SPERCs) and consumers (SCEDs).

- The top-down approach to communicating safe use information for mixtures, known as LCID (lead component identification methodology)[115], and the sector-specific, bottom-up, approach for deriving information towards developing and communicating safe use of mixtures for end-users, known as SUMI (safe use on mixtures information)[116].

[112] http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and Tools/StructuredShortTitles04112014.pdf

[113] http://www.cefic.org/Industry-support/Implementing-reach/escom/

[114] https://echa.europa.eu/csr-es-roadmap/use-maps/

[115] http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/REACH-Practical-Guide-on-Safe-Use-Information-for-Mixtures-under-REACH-The-LCID-Methodology.pdf

[116] http://www.ducc.eu/documents/Sector%20specific%20approaches%20towards%20developing%20and%20communicating%20information%20for%20the%20safe%20use%20of%20mixtures%20FINAL.pdf

The improvement of exposure scenarios through all these different tools should help downstream users to have a more comprehensive understanding of the information included in the SDS, to better communicate this information up and down the supply chain and ultimately to make better use of the information to improve safety.

Additionally, in the first quarter of 2016, ECHA developed and consulted on a Downstream User Communication Strategy for 2016-2018, which aims, among other things, to provide user-friendly, comprehensive information for downstream users on their roles, obligations and the tools that are available to help them. The tools described above are available on ECHA's downstream user website, to motivate downstream users to make best use of information coming down the supply chain and to encourage them to demand good quality.

A Progress Report on the implementation of the chemical safety report/exposure scenario (CSR/ES) Roadmap was published in March 2014[117]. According to an ECHA evaluation in 2016[118], industry views the Roadmap products as being critical in ensuring that the exposure scenarios are relevant and consistent, although many SMEs downstream user (DU) groups consider that further simplification of the communicated Exposure Scenario and extended SDS information would be beneficial. There is also some frustration about ENES tools not being consistently adopted and/or maintained by different industry sectors/companies/consortia. A number of recommendations for future work resulted from that assessment. In summary:

- Implementation and consolidation work should be carried out to maximise the take up and use of ENES products. Attention should be directed to those sectors not engaged in ENES or which are slow adopters of the tools
- Communication - ENES should produce and deliver a Communication Plan to actively promote the work of ENES/CSR Roadmap to Member States and Industry, particularly those currently not involved
- Targeted marketing – there is a need for the currently available products to be marketed to different actors.
- Expanded skills - the skill set of ENES, consistent with the requirements of targeted marketing, needs to be enhanced.

A SDS checklist[119] has been developed by ECHA in cooperation with the Forum for Exchange of Information on Enforcement (Forum). It has been designed from an

[117] https://echa.europa.eu/documents/10162/15669641/csr_es_progress_report_first_en.pdf/0662efa1-6510-4445-8d9d-f53c1d3f19d7

[118] The evaluation reviewed the programme from inception to implementation and included an internal ECHA staff survey and an external survey of industry and Member States (done by an external contractor - https://echa.europa.eu/documents/10162/22771348/external_evaluation_report_en.pdf/9f87dfe6-8670-4a12-b137-85991522955c).

[119] https://echa.europa.eu/regulations/reach/safety-data-sheets/checklist

inspector's point of view, to support the examination of the main body of a SDS compiled under REACH. The checklist was made public to meet the more general objective of improving the quality of safety data sheets in the supply chain.

At the end of 2015, the Forum agreed on launching a REACH Enforcement Project (REF-5) focusing on obligations related to safe use advice in extended SDSs (description of operational conditions and risk management measures). The key element of the project is to investigate how the outcome of the REACH chemical safety assessment – the conditions of use in the exposure scenario – is communicated consistently and clearly along the supply chain from the registrant to the downstream end user of a substance or mixtures. As of January 2017 and throughout the year, REACH inspectors of the EU Member States will check if the extended SDSs contain safety information which matches the information in the chemical safety report. A report on the results of the inspections is expected to be available by the end 2018.

From the perspective of legislative developments, it should also be mentioned that Annex II to REACH was amended by the Commission in May 2015[120] to adapt the requirements for SDSs in accordance with the fifth revision of the GHS rules for SDSs and to rectify inconsistencies due to past amendments.

3.1.2 Additional findings on how to improve communication through SDS

ECHA further recommended[121] that:

- downstream users, supported by their sector organisations, should demand good safe use information as it is the mechanism foreseen under REACH to mobilise actors upstream in the supply chain. This should be combined with efforts to enlarge the communication networks and communication means to reach more companies within supply chains.
- industry organisations should actively engage in facilitating dialogue along the supply chains. The traditional horizontal organisation in sector groups and Substance Information Exchange Forums (SIEFs) should be complemented with dialogue in the supply chain to better address the supply chain specific needs and challenges in generating and communicating safe use information.
- exposure assessment tool owners and relevant industry organisations should foresee resources for the maintenance and evolution of IT tools to facilitate chemicals safety assessment and to communicate information on use and conditions of use up and down the supply chain. The need to update chemical safety assessments and further improve communication in the supply chain will not stop after the last registration deadline in 2018.

[120] Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 132, 29.5.2018, p. 8).

[121] Report on the Operation of REACH and CLP 2016 by European Chemicals Agency, May 2016.

Further evidence was also obtained from two Dutch studies[122] which pointed out difficulties in achieving effective communication in the supply chain as well as in the dissemination and use of SDSs and extended SDSs. It was reported that 25-50% of companies participating in the surveys had no SDSs or those they had were outdated, that 75% of SDSs examined were of poor quality and that, of those, less than 20% had exposure scenarios annexed.

In a Conference organised in 2016 by the then Dutch Presidency of the Council,[123] the following conclusions as regards "Communication in supply chains about substances and mixtures" were drawn:

- The quality and usability of SDS has to improve;
- A more practical approach for SMEs is needed, with automated and tailor-made information per type of user;
- Broader implementation of ENES-tools is needed;
- The establishment of a legally required format for exposure scenarios should be considered;
- Market demand for good SDSs should be reinforced (also in cases without exposure scenarios) and REACH information should be communicated as part of a wider perspective (such as occupational safety and health).

One Member State reported on a national inspection campaign in the metal surface treatment sector[124] where 87% of the companies visited were in possession of the mandatory SDS. However, only 37% of the companies visited had extended SDS. It was mentioned that a reason for this low percentage could be the fact that the majority of the products used in the sector are mixtures for which there is no obligation to draw up an extended SDS. Nevertheless, the information on safe use provided in the exposure scenario of each substance should be converted and used to produce information for the mixture containing specific substances. Although some tools exist for this purpose, the practical transfer of exposure scenario information into the safety data sheets for mixtures is still in a very early stage and requires formulators to have an in-depth knowledge of the substances involved and be highly skilled in the use of the different methodologies. It was also reported that only 1 in 4 employers were aware of the obligations when receiving an extended SDS.

[122] Impact of REACH on SMEs by Panteia and IVAM (2013) analysing the situation of SDSs and a survey performed by the Dutch Workplace Inspectorate (SWZ) in 2014-2015.
[123] REACH forward conference organised by the Dutch presidency on 1 June 2016.
[124] http://www.emploi.belgique.be/defaultNews.aspx?id=44990

3.1.3 Additional finding on the costs of extended SDS

The study on monitoring the impact of REACH on innovation, competitiveness and SMEs[125] provided estimates of the costs of producing and translating extended SDS as part of the 2013 registration activities. The average costs related to SDS (per registered substance) were estimated at EUR 36,358, which is higher than the estimate in the Impact Assessment accompanying the REACH proposal (EUR 19,844).

In order to provide an estimate of the 'typical' costs borne by companies, the study provided median costs per substance and per registrant for substances registered in the 100-1,000 tonnage range. These were EUR 5,763 for producing extended SDS and EUR 4,473 for translation. Furthermore, these figures show that the median costs were somewhat higher for SMEs (EUR 11,899 as the total of producing extended SDS and translation) than for large companies (EUR 8,016).

The business survey conducted for that study revealed that around 50% of companies adopted changes in risk management measures on the basis of information received via extended SDS. This proportion was higher for companies that are primarily manufacturers of chemicals and formulators (respectively 51% and 70%) and relatively lower for companies further down the supply chain (from 48% for distributors to 27% for suppliers of articles[126]). However, these risk management measures' changes usually comprised only the introduction of additional personal protective equipment (20 % of companies) or modified safety instructions (12 %); measures that are low in the hierarchy of measures to be applied under occupational safety legislation[127].

In terms of obligations related to extended SDS, the survey indicates that a significant share of companies, in particular SMEs, were not aware of methods and options that can be used to consolidate information received via extended SDSs for individual substances into their own SDS for mixtures (63.9% among SMEs and 43.6% among large companies). Respondents also flagged gaps in the information flow via the extended SDS, suggesting that especially not all formulators provided information on the safe conditions of use of mixtures.

In summary, the study concluded that the introduction of extended SDS has led to improvements in communication and more transparency in the supply chain. Another benefit identified was that information shared via the SDS helps companies to improve their risk management measures and can also be useful for new product conception, development and commercialisation. On the other hand, especially SMEs appeared to consider (extended) SDSs as a burdensome tool which is too technical to be fully understood.

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

[126] For the purpose of the survey, 'suppliers of articles' is to be understood as comprising manufacturers, importers and distributers of articles.

[127] OSH legislation envisages the use of PPE only if elimination of the hazard or other technical measures are not possible.

The findings are further complemented by the results of the survey on the REACH REFIT evaluation carried out with the SME panel where 40% of respondents considered the obligation to transmit information along the supply chain (which includes management of extended SDS) as a considerable/very important challenge and a further 30% saw it as a slightly/moderately important challenge. Furthermore, 23% of respondents considered the costs incurred in this respect as considerable/very important and a further 37% as slightly/moderately important.

3.2 Stakeholder views

Comments related to information in the supply chain were essentially focused on extended SDS and exposure scenarios. Some of the respondents indicated that information included in SDS was often not targeted enough to the needs of the downstream users, either because the SDS is too lengthy and technical, or not providing enough practical information to adopt risk management measures. A few respondents also stated that the quality and clarity of exposure scenarios was very variable and often did not reflect the practical uses of a substance. One of the reasons provided by respondents is that manufacturers use a variety of templates, which creates difficulties for downstream users. A few respondents called for the establishment of a harmonised template for SDS and exposure scenarios. Some welcomed the work started under the CSR/ES Roadmap and supported its continuation.

A few respondents highlight that information generated under REACH, in particular the information in the SDS, should be better used under occupational safety and health legislation.

4 Information on substances in articles

Conclusions of the 2013 REACH Review

The 2013 REACH review recalled the need for a consistent and harmonised interpretation of the 0.1% concentration threshold of Substances of Very High Concern (SVHCs)[128] in articles[129]. Moreover, it reported shortcomings in the informing of consumers and professional users of articles, as well as difficulties for companies to adapt to the information obligations triggered after inclusion of new substances in the candidate list.

The REACH Review demanded that ECHA and Member State Competent Authorities launch support activities to raise awareness on the requirement to communicate the presence of SVHCs in articles in the retail sector and also to improve the communication.

4.1 Developments after the 2013 REACH Review

4.1.1 Interpretation of the 0.1% threshold

A number of requirements are set by REACH which concern SVHCs when these substances are present in articles above a concentration of 0.1% weight by weight (w/w). The application of these provisions was hindered by a disagreement on how to interpret the concentration threshold for complex products[130], which compromised the harmonisation of the internal market and hampered enforcement activities, and resulted in a referral to the European Court of Justice (ECJ) for a preliminary ruling. The ECJ, in its judgement[131] of 10 September 2015, clarified that the requirements of Article 7(2) (regarding notifications to be submitted to ECHA) and Article 33 (regarding communication in the supply chain and to consumers) of REACH need to be applied to each individual article, even if these articles are components of a more complex product.

This ruling made it necessary to revise the ECHA guidance on requirements for substances in articles. ECHA published a preliminary update, aligning the most relevant sections, in December 2015. A more extensive revision of the Guidance was subsequently undertaken. A draft version of the guidance was consulted with the Partner Expert Group (PEG) for this topic in July 2016 and the guidance has been published in June 2017[132]. Feedback from Industry stakeholders during the PEG consultation as well as during the public consultation for the REACH evaluation have pointed to challenges for manufacturers and importers of very complex products (e.g. airplanes, cars,

[128] i.e. substances that meet the criteria in Article 57 and are identified in accordance with Article 59(1)

[129] Threshold to be applied for the purposes of Articles 7 and 33

[130] The Commission and a majority of MS held the view that the concentration should be calculated on the basis of the total weight of the "complex article", while six Member States and Norway maintained the opinion that the SVHC content should be determined individually for every article contained as a component in such a complex product.

[131] Judgment of the Court (Third Chamber) in Case C-106/14. 10 September 2015, OJ C 363 from 03.11.2015, p.12 http://curia.europa.eu/juris/liste.jsf?&num=C-106/14

[132] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

electronics) in addressing the obligations for the high number of component articles present in these products.

The Commission services are currently assessing the impact of the ruling on the use of the term 'article' in the Annexes of the REACH Regulation, in particular on article-related restrictions in Annex XVII. Where the interpretation of 'article' as put forward in the ECJ judgement creates ambiguities, concerned entries may be clarified.

4.1.2 Information about the presence of substances in articles

Apart from the specific requirements in Articles 7(2), all Registration dossiers should, where relevant, include information on the use of the registered substance in articles, and where a chemical safety assessment is required, such uses, as well as the different stages of the life cycle, should be included in the assessment. The *Report on the Operation of REACH and CLP* 2016, however, states that the amount and adequacy of information in registrations dossiers for the safe use of substance in articles is still very limited. This was attributed to a lack of awareness of those obligations by duty holders, but also to uncertainty on how to correctly describe substance uses in articles and to document the safety of such uses, and how to adequately assess exposure from articles[133].

The obligation to notify SVHCs in articles to ECHA (Article 7(2)-(4)) was introduced to complement the information in registration dossiers, in particular for SVHCs present in imported articles. ECHA has made substantial efforts to facilitate the submission of such notifications by providing easy-to-understand guidance to duty holders[134] as well as by making available a web form[135] for users that are not familiar with the IUCLID format. Despite these efforts, the number of notifications received so far has remained limited. By the end of 2015, 359 notifications related to 38 listed SVHC had been submitted to ECHA[136]. This number had only slightly increased to 365 notifications on 39 SVHCs by 16 December 2016[137].

While it is difficult to estimate how many notifications there should be, this number is likely to indicate a low level of compliance. The reasons for the low number of notification are thought to be:

- a lack of awareness of duty holders
- difficulties to get appropriate information from (third country) suppliers,
- very broad descriptions of uses in articles in registration dossiers, which may (incorrectly) lead duty holders to the conclusion that their articles are exempt from the obligation to notify.

[133] Report on the Operation of REACH and CLP, ECHA 2016
[134] https://echa.europa.eu/documents/10162/22308542/manual_subs_in_art_notif_en.pdf/71b39d03-d140-418c-830e-896f281bb9bb
[135] https://reach-forms.echa.europa.eu/sia/sia.php
[136] Report on the Operation of REACH and CLP, ECHA 2016
[137] https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table

4.1.3 Communication on SVHCs in articles

The obligations in Article 33 to communicate the presence of SVHCs in articles allows operators in the supply chain to implement appropriate risk management measures as well as enabling operators and consumers to make informed purchasing decisions.

There are some signs that actors in the supply chain take the obligations in relation to SVHCs in articles seriously. The study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs reports that, regardless of their role under REACH, about 55 % of firms included in the survey had started to implement IT-systems to monitor SVHC in products. Over 60 % of the firms that received articles validated the information on the SVHC content with chemical analyses for the articles they supply. Companies that receive articles often demand the absence of SVHCs, or they may set via conditions in their purchasing contracts more detailed substance restrictions or information disclosure requirements on the content of hazardous substances in articles supplied to them. This constitutes an incentive to other actors in the supply chain to be REACH compliant and provide an effective co-operation. NGOs and trade unions have stressed the importance of Article 33 in having an effect on the use of substances in supply chains by being an incentive to substitute SVHCs in consumer products.

While the study indicated an improvement in communication on SVHCs, it also pointed to important gaps in implementation. In this context, respondents flagged challenges such as the relatively large administrative burden related to tracking of SVHCs, a lack of awareness about the obligation and limited availability of information from suppliers, difficulties with communicating information in case of complex supply chains (especially when reaching outside the EU) and a lack of confidence in information received, leading to the need of verification information by testing. ECHA also reported similar problems for article suppliers in receiving, generating and monitoring information on SVHC in their articles[138]. Stakeholders had also been raising difficulties and administrative burdens (e.g. requests for so-called "REACH certificates") that Article 33 entails for retailers and SMEs.

A functioning transfer of information in the supply chain is necessary in order for suppliers to be able to respond to consumer requests according to Article 33(2). In the past years, companies and industry associations have developed various systems to facilitate the management and transfer of information on chemicals in articles and enhance compliance with regulatory requirements in Articles 7 and 33 of REACH[139,140]. Such supply chain tools are currently mostly industry-sector specific, but some may have the potential for wider uses. In 2015, ECHA carried out a feasibility study on a Materials Information Platform, aimed as an additional tool to support economic operators in identifying SVHCs potentially present in their articles. Due to difficulties in collecting the necessary input data, the development is presently not further pursued.

[138] ECHA 2016. Report on the Operation of REACH and CLP.

[139] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[140] Interim study " Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH"

Nevertheless, concerned actors, and the retail sector in particular, frequently report that they do not receive adequate information from their suppliers. On the other hand, according to findings of the study on Monitoring the Impacts of REACH on Competitiveness and Innovation, a significant proportion of business operators has been required to communicate information on the presence of SVHCs in articles (45.5 % of all firms), with this proportion broadly increasing when going down the supply chain. Around 57% of respondents had installed specific IT systems in order to monitor SVHC in products and answer to costumer questions in this regard.

However, retailers who make investments to collect and manage such information, often perceive these efforts as superfluous, as they do not experience a high level of interest by consumers for such information[141]. On the other hand, there are indications that the awareness by consumers about their "right to know" may be slowly increasing. In a 2016 Eurobarometer survey[142] 66% of EU citizens said they are aware that “if you ask whether a product contains particularly hazardous chemicals, the seller is required by law to provide you with this information”. In a few countries, authorities and NGOs[143] have put in place tools to inform citizens about the presence of SVHCs in consumer articles. These are web-based or mobile applications to retrieve available knowledge on substances present in an article (usually by scanning the bar code), and/or to facilitate the submission of a consumer request to article suppliers. Such tools are usually accompanied by awareness raising campaigns. However, the scope of Article 33(2), limited to articles and hazardous substances identified as SVHC, seems to be little understood and consumer requests concern issues not covered by the requirements (e.g. mixtures) or outside the scope of REACH (e.g. food products). An EU-wide project to raise awareness and to develop IT-tools to facilitate information transfer between suppliers and consumers is running under the Life+ programme.

One aspect that has been identified as impairing efficient communication is a lack of centralised information flow on SVHCs in articles. The information generated and communicated in the supply chains through Article 33 is not available for national or EU authorities, preventing a comparison and plausibility check with information available from registration and notification. The information communicated following consumer requests is not centrally collected and accessible, thereby potentially increasing the burden for suppliers by repetitive consumer requests.

During the reporting period, only a few Member States (MS) have undertaken enforcement activities in relation to substances in articles[144], likely due to the uncertainties linked to the interpretation of the 0.1% threshold. The information on non-compliance found during these controls is available from the report, is limited and highly variable, making it difficult to draw reliable conclusions. A few projects of limited scale

[141] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[142] Link to the Eurobarometer survey on chemical safety

[143] https://www.bund.net/themen/chemie/toxfox/, http://tjekkemien.dk/hj%C3%A6lp-til-virksomheder/information-english, www.reach-info.de/verbraucheranfrage.htm

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

for which more information is available[145] highlighted a significant proportion of non-compliance with the legal requirements. A study on CMR substances in construction products also reported a high number of irrelevant or lack of responses to requests according to Article 33(2)[146].

A lack of enforcement as regards imported articles (for example articles which contain SVHC), as well as the lack of valid test methods for SVHC contents in articles were identified as important issues to tackle by surveyed companies in the study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs[147].

A pilot project in the context of the ECHA Enforcement Forum planned for 2017/2018 is expected to deliver more information on compliance issues with the requirements of Articles 7(2) and 33(1) as well as indications of which legal provisions and/or economical actors could benefit from further specific support from ECHA, the Commission or Member States.

4.1.4 Other aspects related to substances in articles

The EU 7th Environmental Action Programme (EAP)[148] lists as one of its aims to *safeguard the Union's citizens from environment-related pressures and risks to health and well-being*, to minimise exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances". Likewise, the EU Action Plan for the Circular Economy[149] recognises that better tracking of chemicals of concern in products will facilitate recycling and improve the uptake of secondary raw materials.

The current REACH requirements in Article 33 address only communication of information on the presence of SVHCs included in the candidate list in articles in the supply chain and to consumers. They do not contain provisions for the transfer of information on the chemical content of end-of-life articles to the waste management sector[150]. Waste treatment operators are not considered downstream users under REACH, but rather as manufacturers of substances/mixtures or producers of articles when the result of the waste treatment operation reaches end-of-waste status. Therefore, information on the chemical content of end-of-life articles is not usually available to waste treatment operators, except for some specific cases covered by waste legislation. The presence of substances of concern and the tracking of these substances has been

[145] http://www3.kemi.se/Documents/Publikationer/Trycksaker/Tillsyn/Tillsyn_6_12.pdf; http://kemi.taenk.dk/bliv-groennere/test-plastic-products-contained-unwanted-phthalates

[146] Scoping study for the application of Article 68(2) of REACH to construction articles containing CMR substances with likelihood of consumer exposure. EC, 2016

[147] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES, 2015

[148] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet (OJ L 354, 28.12.2013, p.171).

[149] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Closing the loop - An EU action plan for the Circular Economy. COM(2015) 614, 2.12.2015.

[150] Study for the strategy for a non-toxic environment of the 7th Environment Action Programme, Milieu 2017

identified as an issue that needs to be examined further in the context of the implementation of the Circular Economy Action Plan in order to facilitate clean material cycles and to advance towards a circular economy.

Furthermore, the notion that a better knowledge and communication about substances in articles is an important aspect of chemical management is not limited to the EU but has also gained momentum in other countries and at international level. Under the framework of the **S**trategic **A**pproach to **I**nternational **C**hemicals **M**anagement (SAICM), chemicals in products have been identified as a priority policy issue, and SAICM has set up a "Chemicals in products" programme[151], which aims at developing practical solutions for information transfer on the presence of chemicals in products for several priority product categories (electronics, toys, building products and textiles). In Japan, an industry initiative to expand the utilisation of a communication tool initially developed by the electronics industry to other sectors is supported by the government with the view to make it available also across geographic boundaries[152]. Such work is expected to facilitate the implementation of Article 33 of REACH.

4.2 Stakeholder views

In the public consultation for this evaluation, the topic of substances in articles was frequently addressed, mainly by industry respondents. Overall, respondents agreed that the current provisions on communicating about substances in articles do not work well and that in particular the awareness among consumers about their rights is low.

Many responses from industry commented that the ECJ ruling on the application of the 0.1% threshold to each article in complex products places a disproportionate burden on businesses and called for more guidance to facilitate implementation, frequently stressing that notification obligations should be proportionate and feasible for companies. Several expressed the opinion that requirements for substances in articles should only apply to individual articles within complex assemblies where the information is needed for a safe use. One position paper called for a transition period between the moment a substance is placed on the Candidate list and when the communication requirements of Article 33 become applicable.

On the other hand, NGOs and public authorities, but also some submissions by industry called for improving the information communicated in the supply chain, to enable consumers to make conscious choices, to make the information directly available to consumers, to strengthen awareness raising activities among consumers, to support companies who invest in substituting chemicals of high concern by safer alternatives, and to improve traceability of such substances in recycled materials to ensure that these comply with legal requirements. Some of these respondents also proposed to amend Article 7(2) to introduce notification requirements of all SVHCs substances in articles irrespective of tonnage (from 1 kg/year), or at least to lower the tonnage, or a compulsory content declaration for all consumer goods. Another solution proposed was to label

[151] http://www.saicm.org/index.php?option=com_content&view=article&id=454&Itemid=707
[152] https://chemsherpa.net/chemSHERPA/english/

articles containing SVHC. Further submissions suggested to extend the scope of Article 33 to articles containing any substance that meets SVHC criteria present above 0.1% and to clarify that "sufficient information" should include the background for the substance being an SVHC and the appropriate risk management measures.

5 Dossier and substance evaluation

Conclusions of the 2013 REACH review

At the time of the 2013 REACH review, the dossier evaluation process had started to deliver in accordance with the envisioned aims. ECHA examined all testing proposals for substances registered by 2010 within the legal deadline of 1 December 2012 and issued a number of compliance check decisions as well as quality observation letters[153]. It was however too early to identify its positive impacts, assess the effectiveness of the process or the appropriateness of its drivers e.g. the 5% compliance check target set in Article 41 of REACH. Some recommendations were identified in the area of dossier selection, better targeting of compliance checks and improving efficiency of the processes.

Substance evaluation had only just started at the time of the 2013 review; the first Community Rolling Action Plan was published on February 2012, listing 90 substances on the basis of potential concerns for action in the three-year period 2012-2014. As the number of substances selected for substance evaluation was significantly lower that the initial expectation, Member States competent authorities were encouraged to enhance their capacity in relation to substance evaluation, so that more substances could be evaluated.

5.1 Developments after the 2013 REACH Review

The developments of the evaluation process can be presented in terms of its outputs such as the number of evaluation decisions and the volume of data generated as a consequence of the evaluation activities. The parameters used to assess the efficiency of the process include the time and resources required for the processes to deliver, the performance of individual steps (preparation of the individual evaluation decision, number of appeals, follow-up) as well as the measurement of positive trends, consequence of improvements introduced as experience has been gained in the process.

Effectiveness can be assessed both in terms of the amount of data generated and included in dossiers as well as by determining the contribution of the evaluation process to achieving the objectives of REACH, e.g. does it trigger the risk management measures where needed? All these points are explored in the subchapters below.

5.1.2 Expected and actual effort on dossier and substance evaluation

Evaluation under REACH was designed to be a procedure that responds to the data received under registration. While the main evaluation targets (and therefore the expected

[153] In certain cases ECHA was sending a quality observation letter (QOBL) to the registrant that included observations on the identified deficiencies in the dossier that had however not been included in the decision. The practice has been discontinued in the following years.

evaluation baseline) can be determined from the legal requirements[154], the expectations that it will deliver in terms of follow up to registration were reflected in the assumptions underlying the ECHA staff model[155] developed prior to REACH implementation.

The annual workload on average over 2014-16 was estimated[156] [at the time of adoption of REACH] as:

- for ECHA, 86.2 FTE per year for evaluation (proper) and a further 7.3 FTE in decision making (work of committees and support to Committee work).
- for the Member States, 42 and 44 FTE respectively,
- for the Commission, 7 and 9 FTE.

These estimates were built on the projection that by 2016 (inclusive):

- 1182 **compliance checks** would have been performed, with approximately 250 compliance checks performed annually from 2014 onwards. It was estimated that, in parallel, the chemical safety assessment would be checked for all examined dossiers in tonnage >10 tonnes.
- 4868 **testing proposals**[157] would be examined, peaking with ca. 1500 examined in 2011.
- **Substance evaluation** was expected to start in 2012 with first 50 substances evaluated, and with continuous annual evaluation of further 99 substances, leading to an estimated total of 448 substances by 2016.

Throughout the last five years, dossier evaluation has been a resource-intensive exercise for ECHA, which estimates that annually 59 FTE are used[158] for dossier evaluation

[154] All testing proposals must be examined, compliance check of 5% of registration dossiers, and no specific numerical target for substance evaluation.

[155] Common reference ECHA staff model

[156] These estimates were based on a number of assumptions, for example with regard to the fraction of non-compliant dossiers (30%), fraction of all registered substances that would be expected to be subject to substances evaluation (2%), dossiers under evaluation that would receive comments that would require modification (25%), and fraction of conflicting cases that would be forwarded to the Commission (5%). The 'evaluation (proper)' roughly corresponds to the expert assessment and engagement work required, while the 'further decision work' to the additional administrative resources required. In this estimation substance evaluation work by member States is fully accounted for (in present evaluation actual figures are not available), and the resources required by the Commission when draft decisions are passed to it following Article 51(7) are assumed also for the assessment. In practice, the expertise in these cases is mainly drawn from ECHA by the Commission.

[157] This reported number is unusually high: upon further analysis, the estimation seems not to take sufficiently into account data sharing incl. submission of testing proposals in joint submissions and not individually. For example, 20% of 17.500 dossiers are assumed in the estimate for 2010 deadline (substances >1000 tonnes), which is very accurate, however 82% of these are member registrations; estimate should be closer to 630.

[158] Reference: disaggregated numbers from internal ECHA Annual Workplan 2017, based on ECHA Programming Document 2017-19). It should be noted that in addition to the specifically assigned 'case work', additional 13.5 FTE are required in related evaluated tasks, and that for example HelpDesk and litigation also attribute certain proportion of their resources to evaluation.

across ECHA[159]. The selection and allocation of dossiers is estimated to require 18% of resources, scientific assessment 28%, drafting of the decision 20%, decision making[160] 26% and the follow-up an additional 8%.

Resources required for substance evaluation in the Member States are difficult to assess as no consistent information is available on the time required by the Member State competent authority that performs the assessment. To coordinate the process and the decision making with member states, 13 FTE are required in ECHA alone.

5.2 Dossier evaluation

5.2.1 Main outputs of the Dossier evaluation process

Principal outputs of the evaluation process can be presented by the statistics presented in the Table 4.3.

Table 4.3: Basic evaluation statistics and outputs

	2009	2010	2011	2012	2013	2014	2015	2016	Total	Baseline estimate
Testing proposal examinations										4856
Adopted testing proposal examination decisions	1	4	22	171	111	129	194	116	748	
Terminated examinations (before draft decision)	0	1	51	52	9	24	45	28	211	
Terminated at the draft decision stage	0	2	7	32	32	11	14	17	121	
Compliance checks										1182
Adopted compliance check decisions	0	12	105	66	159	273	144	152	911	

[159] Directorates E,C and B.

[160] Includes interaction with registrant and MSC agreement seeking.

Quality observation letters(a)	7	33	19	1	1	0	0	0	61	
Concluded without administrative action(b)	7	24	18	117	361	111	33	16	691	
Terminated after draft decision(c)	0	1	10	14	121	137	59	35	378	
Substance evaluation	-	-	-	-						448
Adopted substance evaluation decisions					2	24	30	26[(d)]	82	
Concluded without decision									50	

(a) Quality observation letters provided observation on weaknesses of the registration dossier but did not constitute a legally binding request.

(b) Conclusion without administrative action indicates that no further action was considered necessary e.g. as compliance was established.

(c) Termination after draft decision implies that the initial assessment has been performed and draft decision prepared and communicated to the registrant, but the process has not led to a final decision, principally as the registrant has updated the dossier in meantime. The high numbers in 2013-14 indicate the many quick responses to single request draft decisions.

(d) Plus one CoRAP complimentary NONS substance.

The evaluation process has been constantly evolving since its launch, so as to improve its efficiency based on experience[161,162]. In particular, the evaluation process has been integrated into ECHA's Integrated Regulatory strategy[163], which took effect in 2015, and

[161] Improved understanding of the most frequent weaknesses of registration dossiers, the strive for efficiency and effectiveness, increasing body of experience including evaluation related Board of Appeal decisions and the external triggers such as European Ombudsman's enquiries drove continued development of the evaluation strategy and implementation from dossier selection to drafting of the decisions.

[162] ECHA has been organising evaluation workshops on semi-annual basis to discuss the process with member states and stakeholders. Their content and conclusions can be found on ECHA's evaluation website.

[163] ECHA Integrated Regulatory Strategy.

so is cohesive with the processes supporting the development of risk management measures. A common screening process is applied to all substances and registration dossiers. Where potential concern is identified and the case prioritised, an action is determined to either 1) ensure compliance with standard information requirements (via compliance check), 2) clarify/confirm concern via listing on Community Rolling Action Plan (CoRAP) and eventual substance evaluation, or 3) direct initiation of regulatory risk management action (development of dossiers on harmonized classification, listing as substance of very high concern, or restriction).

The strategy places its main focus on the substances having exposure/release potential and high volumes and, as promoted already early in the development of evaluation process by the Commission, on higher tier (Annex IX and X) human health and environmental endpoints which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic), PBT/vPvB ((very) persistent, bioaccumulative and toxic) substances and substances of specific concern (e.g. respiratory sensitizers). Registrations of substances of highest concern are first examined in compliance check assessing the most important end-points for regulatory risk management.

Beside the changes brought about by the integrated regulatory strategy, the scope of information requested and the drafting of evaluation decisions have evolved with experience, implementing the learnings derived from the ECHA's Board of Appeal decisions and in response to external inputs such as those derived from the European Ombudsman's resolutions requiring a more proactive approach to implement the REACH provision requiring the 'testing on animals as a last resort' in compliance check and test proposal examinations[164].

By the end of 2016, 748 testing proposal examination decisions addressing around 600 substances[165] and 3642 registrants[166] were issued[167], with a further 332 examinations terminated without a decision. The main reasons to conclude without a decision were withdrawals of the testing proposal in subsequent dossier updates, inadmissibility of the testing proposals, identified availability of scientifically-relevant data or important administrative changes. All examinations were performed within the prescribed legal deadlines; 183 cases related to the extended one generation reproductive toxicity study (EOGRTS) required referral to the Commission; changes to the legal text were required before the final decisions could be adopted by the Commission. The remaining decisions are being adopted in 2017.

While fluctuating through the years, as can be seen from the table above, compliance checking had by 2016 achieved a mature stable output in line with ECHA's planned

[164] https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency/ombudsman/cases-animalt

[165] In some cases more than 1 decision is issued per substance.

[166] In large majority of cases, the testing proposal examination decisions are addressed to the lead registrant that includes the data of the joint submission for the substance in its registration dossier.

[167] Five testing proposal examinations were appealed, of which four were later withdrawn. In one case the Board of Appeal required that the procedure is re-launched.

annual output of around 220 compliance checks[168], which is also broadly in line with the Commission's baseline-estimate of ca. 250 compliance checks. Out of roughly 4,200 substances registered in volumes of over 100 tonnes, compliance checks in the period 2009-2016 led to 911 compliance check decisions[169] and addressed, through almost 2,000 compliance checks, over 1,500 substances which were assessed to various degrees of intensity[170]. By 2016 a total 10,918 registrants were directly affected by compliance check decisions.

The figures presented also illustrate ECHA's achievement of the second target set in Article 41(5) of REACH, concluding by the end of 2013 compliance checks on over 5% of the dossiers submitted by the 2010 registration deadline[171].

ECHA can take an evaluation decision only in case of unanimous agreement in its Member State Committee (MSC). Alternatively, the draft decisions are referred to the Commission for adoption. This happened in a total number of 219 cases, with 216 testing proposals and compliance checks jointly referred as 'EOGRTS cases' related to disagreement regarding the test design to address the information requirement on reproductive toxicity testing. Time and effort were required to bring legal clarity on this matter by insertion of EOGRTS in the Test Method Regulation, amendment of the REACH Annexes concerning the information requirements on reproductive toxicity testing, and the adoption of the supporting Guidance.

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[168] Planned output for 2017. The actual numbers vary from year to year also because of the evolving strategy which is steering the scope and selection of dossiers addressed, specific campaigns (e.g. on substance identification) and solutions found (e.g. Areas of Concern approach), and of course the revolving nature of the exercise, as the decisions are usually only finalised in year after the evaluation has been launched. For example, in 2014 ECHA adopted 273 compliance check decisions and closed 137 cases after draft decisions. In 2016, ECHA opened 181 new evaluations while 234 were carried over from the year before. Assessment was concluded in 184 cases (168 cases concluded in draft decision, 16 in no action). In the decision-making stage, 152 decisions were taken, 25 discontinued, and 195 maintaining in the decision making stage for 2017.

[169] Out of 911 decisions 43 were appealed, which led to 13 annulments by the Board of Appeal, while in other cases the appeal was withdrawn or dismissed. Four of the annulled decisions required re-start of the procedure, the 5 decisions related to nanomaterials are currently 'on hold' due to related revision of regulatory provisions, while in other cases the registrants provided further information and follow-up was not required.

[170] Source: ECHA's progress reports on Evaluation 2016 and aggregation with data on previous years. In addition to 911 compliance check decisions, 61 quality observation letter were sent, while 691 checks were concluded without administrative action and 378 terminated after draft decision. In total this would imply over 3000 addressed cases. Some substances were subject to multiple cases, or addressed to more than one registrant per registration number or joint submission.

[171] The legal target of 5% of dossiers per tonnage band checked for compliance does not include a deadline. ECHA set its own 2013 objective for the highest tonnage band. The 19.772 registrations covering approximately 2.700 unique substances provides a target of 989 compliance checks, which was exceeded by the 1130 concluded compliance checks by the end of 2013. These numbers must always be subject to interpretation: testing proposals as well as compliance check decisions were by a vast majority addressing lead registrants, and the number of accompanying member dossiers sharing the joined submission is in fact importantly larger. On the other hand, compliance check decisions varied in the scope/coverage, some being 'full' compliance checks, some only targeting compliance checks addressing a single information requirement.

5.2.2 Follow-up of dossier evaluation decisions

The follow-up to the ECHA dossier evaluation decisions is systematically performed on each decision after the deadline given in the decision to submit the requested information has passed.

Table 4.4: Follow-up of the dossier evaluations, basic statistics.

The numbers apply to decisions for which legal deadline expired in the particular year (not the decisions adopted in that year) and for which the compliance of the update was assessed by ECHA.

Follow-up	**2013[(e)]**	**2014**	**2015**	**2016**	**Total**
Testing proposal examination decisions					
Update compliant with decision (a)	71	88	88	103	350
Update compliant, but only after additional SONC (b)	1	11	23	15	50
Issued statements of non-compliance [SONC]	10	27	17	17	71
Non-compliance, new decision issued (c)	0	0		2	2
Total	82	126	128	137	**473**
Compliance check decisions					
Update compliant with decision(a)	70	117	136	179	502
Update compliant, but only after additional SONC (b)	5	19	11	22	57
Issued statements of non-compliance [SONC]	22	17	25	16	80
Non-compliance, new decision issued (c)	(d)	3		1	4
Total	97	156	172	218	**643**

a) Article 42(2) of REACH. Update considered compliant.
b) SONC – Statement of non-compliance
c) Article 42(1) Non-compliant, but instead of SONC, new compliance check decision is launched
d) In 43 cases requested data was provided but new data needed so 42(2) put on hold.
e) Follow-up evaluation was initiated already in 2011, with no conclusions. In 2012 out of 173 deadlines expired on dossier evaluations, ECHA prioritised 65 cases: 1 was found compliant, in 55 cases on substance identity further information was required, while in 9 other cases information was considered not compliant an passed to Member States for enforcement.

Follow-up now represents an important dimension of ECHA's evaluation activity. In 2016 alone, 612 follow-up evaluations of compliance with individual information requests were performed. In these, most deviations or non-compliances with the request were observed for the high tier pre-natal developmental toxicity study.

In 91% of compliance checks and 83% of testing proposal examination decisions cases to date, the data submitted were compliant[172] with the request set in the evaluation decision.

[172] In 2016 ECHA started to provide also more detailed information on the follow-up: of the 612 individual information requests evaluated in follow-up in 2016, 364 were found fully compliant, 201 compliant with deviations, and 47 non-compliant.

When the data submission was not compliant with the request in the evaluation decision, in the majority of cases a statement of non-compliance was issued which was then followed by the relevant Member State. In the table above 'update compliant, but only after SONC' indicates the ca. two-thirds effectiveness of the additional reminder by a statement of non-compliance and the enforcement[173]. In a very few cases, follow-up compliance check decisions were also issued, but generally ECHA and the Member States have, for reasons of efficiency, shown preference for the informal statements of non-compliance.

5.2.3 Selection of substances and endpoints in dossier evaluation

Statistics of adopted decisions across the years do not provide the full picture of the effectiveness and efficiency of the dossier evaluation process. The selection of substances and the precise scope of the compliance check are also crucially important.

Table 4.5: Requirements in dossier evaluation decisions per endpoint

Endpoint	**Testing Proposal Examination (TPE)**	**Compliance Check (CCH)**	**Total**
Long-term aquatic toxicity	170	126	296
Biodegradation	36	42	78
Bioaccumulation	18	23	41
Repeated dose toxicity	359	124	483
Mutagenicity	55	194	249
Pre-natal developmental toxicity	467	221	688
Reproductive toxicity	6*	65	71
Carcinogenicity	0**	1	1
Substance Identity (SID)	n/a	376	376
CSR / Exposure assessment and risk characterisation	n/a	132	132
DNEL	n/a	56	56

*Note: 183 TPs originating from 2010 pending COM decision.

**Three TPs for carcinogenicity received: One was rejected by ECHA; one TP was withdrawn by the Registrant; for one the process was terminated as the study was already ongoing for biocides directive.

While the number of testing proposals was lower than initially expected in 2006, their spread between different endpoints was roughly as expected. In a number of testing proposals it was considered necessary to first clarify the identity of the substance addressed in order to successfully examine and conclude the testing proposal. On the other hand, as indicated above, a significant number of testing proposal examinations

[173] If enforcement is taken. SONC is submitted to the Member state competent authority but copied also to the registrant. Statistics on actual enforcement based on SONC is not available.

have been terminated prior to decision making (332 terminations compared to 748 decisions). This skews the statistics in terms of endpoints addressed as well as the ability to assess the process efficiency from the decision outcomes. Though the decisions rejected the testing proposal in only a handful of cases, the scrutiny led to numerous early terminations and – in most cases - modifications of the original proposal. This suggests that the testing proposal examination helps.

There was a fluctuating profile of endpoints targeted by compliance checks in the years prior to the integrated regulatory strategy as ECHA developed and learnt from its experience[174] .

As can be seen from the table, ECHA compliance check decisions required improved substance identification in 376 dossiers, and the generation of 796 toxicological and ecotoxicological studies addressing most relevant[175] information requirements. Evolution of these trends is strong: following the 2016 evaluation[176] of over 1,200 higher-tier human health and environmental endpoints, 142 compliance check decisions in 2016 covered in total 805 standard information requests, 550 of which addressed higher-tier human health and environmental endpoints. This is more than a quarter of all such requests since the evaluation process was launched.

In addition, 156 compliance checks in 2016[177] (85% of the 184 compliance checks performed) were performed on the dossiers of high-priority substances identified via the integrated regulatory strategy.

5.2.4 Dossier evaluation and compliance

By 2016, compliance checks generated further information on substance identity for 212 substances[178]. Dossier evaluation also resulted in 1,907 generated toxicological and

[174] ECHA made campaigns to explore the different evaluation aspects: from full compliance checks evaluating compliance with all information requirements to the very targeted compliance checks with IT tools and template decisions on single information requirements across the full registration database (Area of Concern approach),

[175] Also called 'super endpoints', directly related to CMR and respiratory sensitisation effects on human health, and PBT/vPvB effects for the environment. Endocrine disruption is considered a super endpoint for both human health and the environment. Note that further information was also required in the evaluation decisions ot counted in the statistics provided (physical hazards, water solubility etc.)

[176] Source: Evaluation under REACH, Progress Report 2016, https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8

[177] Source: Evaluation under REACH, Progress Report 2016, https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8;

[178] Counting multiple changes by registrants on one substance as one.

ecotoxicological studies on the most relevant information requirements. In over 95% of the compliant updates, the study requested by the evaluation decision was performed[179].

While the number of available studies included in the registration dossiers was generally as estimated, the number of testing proposals put forward to address the remaining information gaps was significantly lower than anticipated (see above). While there may be some marginal reasons to explain discrepancy, the difference is best explained by the extensive submission by registrants of adaptations to standard information requirements in the registrations. Use of adaptations rather than performing an animal test is required by REACH whenever possible; however it requires that a number of conditions are fulfilled to ensure the equivalence of information on which the safety assessment is based. As much as one can deduct from the adaptations cases that were checked for compliance (see below) that was often not the case.

To get a perspective[180] how dossier evaluation contributes to the generation of adequate high tier information on substances under REACH requires comparison of:

- the studies generated due to dossier evaluation, with
- the total number of high tier studies, and
- the number of dossiers with non-compliant information that is potentially expected to be addressed by a compliance check.

Table 4.6: Three illustrative cases regarding the comparison between existing and newly generated data

Endpoint	Total unique studies (a)	Generated pre-REACH	New studies (in parentheses those generated based on dossier evaluation)	Total requested under dossier evaluation	Compliance check	Testing proposal examination
Developmental toxicity	1655	1286	369(278)	688	221	467
Reproductive	1987	970	1017(19)	71[181]	65	6

[179] Adaptations rather than study results were accepted in 51 cases by 2016. Over 40 of them were improved adaptations available (and not accepted) at the time of decision making, with less than 10 adaptations that were genuinely new.

[180] Complete understanding requires also further consideration of the behaviour of the registrants regarding their initial approach to fulfil registration obligations as well as the impact that dossier evaluations (in general or addressed explicitly to them), have on their decisions to generate further information. Unfortunately most such information is anecdotal.

toxicity						
Carcinogenicity (b)	407	392	15(1)	1	1	0

(a) From 2017 ECHA 117(3) report.
(b) Interpretation: Of all registration dossers 744 registration dossiers refer to the 407 unique studies. Other dossiers apply adaptations: 729 omit the study using waiving possibilities, 603 are based on read across, 51 use QSAR and 248 use the weight of evidence.

These three illustrative cases are presented to indicate the complexity of the situation, and the difficulty to draw general conclusions:

- developmental toxicity shows both a strong pre-REACH information base that could be used in dossiers and also extensive generation of data under REACH.
- reproductive toxicity shows an even stronger contribution of new data outside REACH but also delayed decision making due to the new EOGRTS method[183].
- carcinogenicity shows a large number of studies generated in the past, however under REACH the adaptations have been extensively applied in order to avoid performing new tests.

To maximise the impact and efficiency of individual decisions in a scenario where resources are limited, ECHA targets those parts of the registration dossiers that are particularly important for the safe use of a substance. However, such limited assessment does not enable to eventually consider a dossier as compliant, and therefore the approach does not provide individual registrants with certainty about the compliance of their dossiers. It also makes statistics on the level of compliance and assessing the link between the approach and the original targets in Article 41 more difficult.

The level of compliance of registered dossiers can be estimated using different sources.

- ECHA's evaluation progress reports indicate that over the years between ½ and 2/3 of identified dossiers had non-compliance for at least one information requirement
- The high number of studies on 'super-endpoints' requested in 2016 as part of the integrated regulatory strategy on 'substances that matter' confirms important data gaps in more than two third of the cases[182].
- A Member State reviewed[183] the registration dossiers submitted between 2010 and March 2014 for substances > 1000 tonnes / year. Their analysis concluded

[181] Low number is importantly affected by the need for modification of reproductive toxicity information requirements and that also prompted evaluation by the Commission in 216 cases that are still being processed

[182] Any further interpretation is speculative: for example, the increasing trend in the percentage of identified non-compliant dossiers through the years has probably more to do with the improved screening and prioritisation of compliance check cases than either the deterioration of registration dossier quality through the years or the failure of the compliance check strategy itself.

that there is a high proportion of (non-compliant) [184] dossiers for human health endpoints, mainly for developmental and reproductive toxicity, and that for environmental data, 12–59% of the examined endpoints were non-compliant, meaning that significant data gaps still exist for substances that needed to be registered already in 2010.

- Concerns regarding compliance of the dossiers were echoed by most of the 15 Member States responding in the public consultation.

The impact of non-compliance on the actual level of protection achieved by REACH on human health and the environment is difficult to assess. Insufficient or misplaced adaptations applied in place of studies on the registered substance represent an important source of non-compliance and were assessed more closely: a first comparative statistical analysis by ECHA indicates that there is no big difference between the values that define the distribution of no effect levels coming from experimental studies and those coming from adaptations, which may imply that, by using adaptations, registrants are not systematically claiming, that substances are less hazardous. If that is indeed the case, the approach to adaptations, while clearly not applied correctly in a number of cases does not lead to a systematic bias towards a lower level of protection of human health and the environment. On use of adaptations see also Annex 4, part on "Data sharing, test methods and avoidance of unnecessary testing".

5.2.5 Time required to generate the data

An important aspect of the evaluation process as a data-generating tool is the time required for the process to actually deliver data in the registration dossier, thereby allowing further safety assessment and risk management considerations, considering that the substance continues to be placed on the market during this period. The time to commission and run a test can represent a significant part of the evaluation time and is of course very endpoint-dependent. However, the time invested by authorities in the assessment and decision making is also significant: for testing proposal examinations, the average time (with exclusion of the test itself) is 340 days[185], while for compliance checks, including the initial prioritisation step, the average time is 461 days.

The time required importantly depends on the steps required by REACH: as part of the decision making, MSCAs are asked to comment on the ECHA draft decisions. If they submit proposals for amendments , ECHA is required to discuss the decision and the proposals in its Member State Committee (MSC), resolve the issues, and adopt the decision with unanimity within the legal deadline of 65 days. Such proposals for

[183] http://www.bfr.bund.de , Project: Availability of Health and Environmental Data for High Tonnage Chemicals under REACH

[184] http://www.bfr.bund.de , Project: Availability of Health and Environmental Data for High Tonnage Chemicals under REACH. The project screened all the dossiers using formalized and rather conservative procedure using decision trees, with deliberate restriction of the assessment to ca. 60 min/dossier, ranking the dossiers as compliant (no issues identified, very few), non-compliant (with at least one identified issue in any endpoint as non-compliant), and complex (e.g. all dossier using adaptation as validity could not be established fast). As the procedure differs in important ways from the formal compliance check procedure, any comparison of the results from both procedures need to be very careful.

[185] Estimated by ECHA, median information taken.

amendments were triggered in 48% of the testing proposal examinations and in 27% of all compliance checks[186].To reduce workload at the meetings, MSC attempts in many cases to resolve issues in advance and adopt decisions by written procedure.

5.2.6 Issues related to dossier evaluation

The statistics show that the dossier evaluation process performs its principal function to ensure that data required by REACH as standard information is generated. In the 2016 Report on the Operation of REACH and CLP, ECHA states that the evaluation processes have improved the number of compliant registration dossiers. The scale of the problem to be addressed however appears to exceed the REACH legal target (i.e. 5% of dossiers) and the resources available.

Besides being a generator of new data by itself, compliance checks were also expected to deter substandard registration submissions and promote adequate and timely updates and improved risk management measures of substances. While the impacts of ECHA's integrated regulatory strategy in this regard cannot be fully assessed due to its limited time in operation, any analysis to date has not provided any evidence that the compliance check decisions contributed to an improvement of the compliance of registration dossiers beyond the one piece of information specifically requested in the decisions.[187]

The current ECHA compliance check strategy attempts to maximize effectiveness by addressing 'what matters most', in particular in terms of required risk management measures. At the same time, the tool must be used efficiently: an example is to address groups of substances (in selected situations such approach has been applied in testing proposal examination already).

The Commission services note that DNEL derivation (with exception of challenging the undocumented deviations from guidance), self-classification, and identification of adequate risk management measures, cannot be efficiently addressed via dossier evaluation decisions as they require argumentation and not just data generation. Complementary measures including those targeting communication in the supply chain, enforcement and concrete risk management actions (e.g. development of a restriction dossier, request for harmonised classification which would trigger RAC assessment etc.) are likely better suited to address their shortcomings.

Another important consideration is whether ECHA can ask for a germ cell analysis where an *in vivo* mutagenicity test is requested during dossier evaluation to fulfil a standard information requirement. Germ cell analysis may be needed to allow the correct classification conclusion.

The more direct link between dossier evaluation and the regulatory risk management tasks under REACH, envisioned in the integrated regulatory strategy, is still being

[186] Statistics may significantly vary from MSC meeting to meeting as it is dependent on the endpoints addressed.

[187] An ongoing ECHA study on registration updates, including a dedicated survey, might provide some additional knowledge.

developed; for example, there are no available statistics on how often the dossier evaluation has identified a substance which would need a restriction, harmonised classification and labelling or that might be a candidate for identification as a substance of very high concern.

Steps to systematically address such an objective under dossier evaluation (e.g. additional evaluation templates for the experts) were only launched in 2016, as until then such impacts were explored only in the evaluation follow-up.

5.3 Substance evaluation

5.3.1 Main outputs of the Substance evaluation process

Since the 2013 review, all Member States are now participating in substance evaluation coherently with other processes in the Integrated Regulatory Strategy. The numbers of substance evaluations performed every year have not reached the initially projected targets (baseline estimate: 446 until 2016, which assumed about 100 substances would be assessed every year).

In practice, out of 221 substances published in CORAP since 2012, substance evaluation has addressed so far 182 substances while 39 remain in the evaluation process in 2016[188]. Out of the evaluated 182 substances:

- for 50 substances the process concluded with no decision as no further information was required;
- for 132 substances (2 substances with draft decisions suspended; 48 substances with draft decisions in decision-making; 82 substances with decisions taken by 2016, starting with the first decisions adopted in 2010)[189].

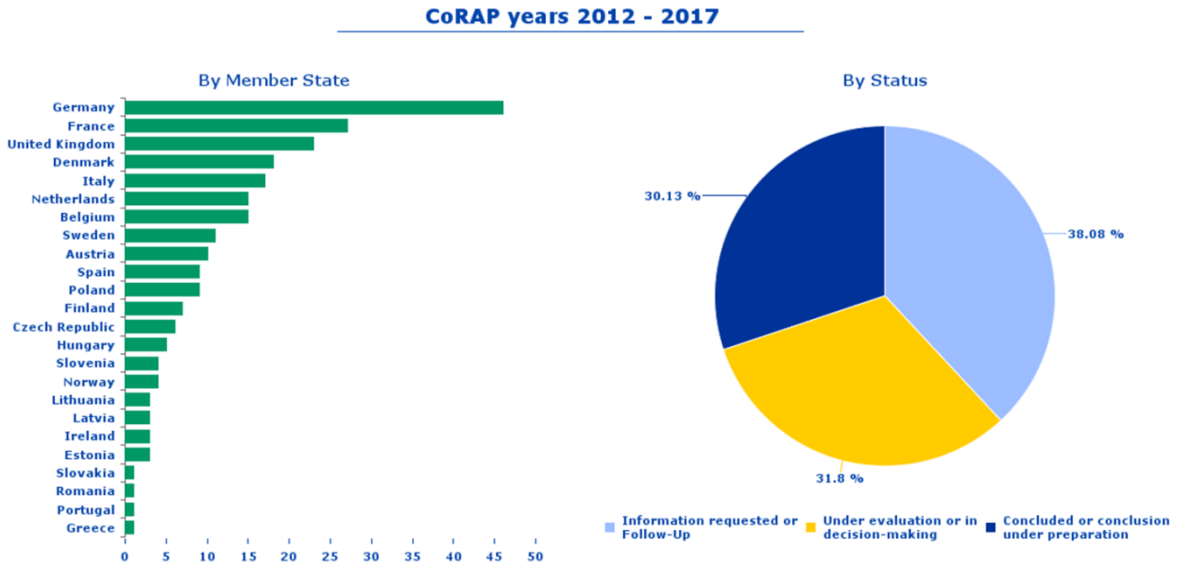
Out of the 48 substances, three draft decisions could not be unanimously agreed and were referred to the Commission.

Figure 4.7: Number of substances evaluated by individual Member States for the period 2012-2017. Also included: status of substance evaluations[190].

[188] ECHA Progress Report on Evaluation 2016

[189] Note that first CORAP was published only in 2012. Substance evaluation however 'picked' also the evaluations still ongoing under regulation preceding REACH.

[190] From presentation to the Member State Committee May 2017.



Statistics on the information requested vary from year to year; for example, in the period between 2014 to 2016 requests regarding exposure represented the majority of requests but with a downward trend (included in 83%, 71% and 54% of decisions in the three successive years). This is likely the result of the identified challenges to request CSA/exposure information, challenges that are confirmed with the experience gained from dossier evaluation. Human health and environment related requests follow closely, each with ca. 30-40%. In 2016, excluding exposure, 39% of requests targeted PBT/vPvB assessment[190].

The 82 ECHA substance evaluation decisions address 800 registrants. It is not yet possible to identify specific challenges or the rate of compliance with individual requests in these decisions[191] to determine their effectiveness. In 2016:

- 66 substance evaluations were waiting for requested information
- 8 were under appeal
- 4 were under follow-up evaluation
- 4 the evaluation has concluded and the conclusion document was either published or being drafted.

The appeal rate (in total 16 out of 82 decisions) is higher than in dossier evaluation; 8 are still ongoing. In the 8 concluded cases, 3 substance evaluation decisions were annulled. The reason for the appeals is that a lot is at stake in substance evaluation. Request may go beyond standard information requests. Substance evaluation decisions are vulnerable because they need to include the concern identified on which the request is built and identifying the information needed to clarify the concern may be difficult as shown also

[191] E.g. standard study requests vs. requests with no standard protocols or related to exposure. It should be noted that in the responses in the survey of competent authorities identified as a key challenge that information delivered was not what was requested.

in the case decided by the Commission[192]. The appeal rate is decreasing in last 2 years as all actors build the experience.

Generating data through substance evaluation requires time: the average time to assess and make a decision is 25 months[193], and this is on top of the time to place the substance on the CORAP (13 months on average) and the variable time required to perform the test.

If any standard information is missing in the dossiers then this makes substance evaluation challenging; this experience prompted ECHA to follow a strategy[194] to preferentially proceed with substance evaluation based only on the information from compliant dossiers. This however further prolongs the time needed and also to the number of substance evaluations proposed in CoRAP in 2016 dropping significantly, as compliance checks were awaited. Steps are being taken to ensure that the two processes can also work in parallel, provided adequate attention is paid to the underlying rationale for the request in each case, and the fact that the addressees of the decisions could differ.

5.3.2 Complementary measures and more indirect impacts

Besides formal compliance check and substance evaluation processes, are taken by ECHA is taking a number of complementary measures to improve the information in registration dossiers. ECHA's annual evaluation progress reports[195] document progress in this area including improved general advice to registrants, based on the experience gained.

An important step towards the common screening of substances for both evaluation and risk management processes as well as to the prioritisation and efficient drafting of the evaluation decisions themselves has been the 'Areas of Concern' approach, where automated tools have been developed by ECHA to screen the dossiers for systemic weaknesses that could also be addressed using template-type compliance check decisions (effective for simple scenarios which are however less common in higher-tier endpoint). This experience enabled further development of the *Registration Validation Tool*, helping registrants to avoid at least some deficiencies in the dossiers prior to submission.

Further complementary measures routinely applied by ECHA include:

1. *Publication of lists of substances to be subjected to compliance check:* in line with the ECHA Programming document 2017-19[196], in order to stimulate updates

[192] In the case of substance polyhaloalkene, used in mobile air conditioners, the MSC could not agree on the specific information request as proposed by the evaluating member State to clarify the concern related to the additional risk of exposure to substance's transformation products in case of very specific exposure scenario: accident with the car on fire. In the Commission decision, the request was eventually not included.

[193] In the decision making to date, proposals for amendments were triggered in practically all substance evaluation cases which therefore all require discussion in the MSC and a time period longer than 25 months

[194] CA_70_2016_Substance_evaluation.doc

[195] https://echa.europa.eu/regulations/reach/evaluation

[196] https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

and in support to the compliance check strategy, ECHA is already since 2016 annually announcing the list of substances likely to be subject to compliance check and addressing individual letters to the potentially affected registrants. Impacts such as an increased updating of dossiers for the announced substances, as well as better preparedness of the registrants[197] once the compliance check is launched, are already observed.

2. *Letter Campaigns*: ECHA periodically runs letter campaigns preceding/complementing the formal evaluation procedures[198], with the intention to promote proactive improvement of registration dossiers. They usually address a single key issue that can be communicated in a short letter. These letter campaigns are importantly intertwined with continuous ECHA communication on evaluation, as well as formal follow-up action from compliance check. As there is no clear metric to assess their impact, their degree of success is yet to be determined. ECHA reports measureable improvement in dossiers and a positive domino effect in the other registration dossiers of the addressee(s) of these letters. Experience with recent 2015 and 2016 letter campaigns on substances short-listed for compliance checks (see measure 2 above) indicate that around 40% of the addressed registrants update after 4 months. Most updates provide improved information on uses and exposure. Improved information on hazard is more limited and there are no additional testing proposals resulting from these campaigns. For the latter, it appears industry prefers to wait for the formal compliance check process.
3. *Sectoral approach:* in addition to addressing substances one-to-one, ECHA has been working, in cooperation with some industry associations, to improve dossiers and clarify hazard as well as uses/exposure for groups of substances either belonging to the same chemical family or sharing the value chain (e.g. UVCB petroleum and coal stream substances). Projects are all still ongoing[199] and their impact cannot be assessed yet.
4. *Article 36 decisions*[200] had been used extensively to verify intermediate status of registrations for substances on-site and transported isolated intermediates. ECHA is considering to expand their use to other types of information such as exposure assessment[201].
5. *Improving Substance ID information:* in 2016 ECHA started addressing substance identification in an informal process; as these issues normally do not

[197] As seen by respectively longer comments to ECHA draft decisions.

[198] For example, retroactive enhanced completeness check or list of substances likely to be subject to compliance check is complemented by a letter campaign to the registrants. In the past, campaigns included the address of intermediate uses (2012, 2014) and substance identification (2014).

[199] ECHA in 2017 launched a further pilot project related to cooperation between ECHA and MS on addressing groups of substances, inviting proactive industry involvement (CARACAL March 2017).

[200] Article 36 enables ECHA and Member States to request submission of existing information that has been used in the preparation of the registration and fulfilment of the duties, when such information is not provided in the dossier.

[201] ECHA Progress Report on Evaluation 2016

require additional testing and are often easy to resolve, the informal process is shorter and more efficient.

These complementary measures are in place and giving results but a number of other actions that should be further explored to address the obstacles to achieving a satisfactory level of compliance of registration dossiers. Therefore, further consideration could be given to:

- use ECHAs competences to support registrants in the development of compliant adaptations, to assist them to implement effective testing strategies for groups of substances where a broader benefit can be obtained, while respecting that the burden of proof lies on industry. This could link to the common efforts by ECHA and the Member States to support (and where necessary force) registrants to apply animal testing only as a last resort.
- Registration dossier updates: whether Article 22 of REACH should be amended to specify further the situations that trigger mandatory updates, as well as to set precise deadlines.
- while the Commission agrees with the general view of responders in the public consultation regarding adequate clarity of the present legal requirements on evaluation[202], additional clarity in terms of the obligations of registrants having ceased manufacturing, as set out in Article 50(4), would contribute to smoother functioning of substance evaluation in specific cases.
- Dissemination: while important improvements have already been made (public dissemination website, list of intent etc.) by ECHA, further improvement of the transparency of relevant outcomes is still possible and some actions are already ongoing[203]. This may for example include further integration of information on substances and (stages of) evaluation and risk management processes including outcomes of common screening, where relevant, with relation to wider objectives such as addressing groups of substances, information on spontaneous updates and the follow-up enforcement. Such transparency should facilitate appropriate and timely intervention from all actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible.
- When substance evaluation is required to clarify a concern, it is preferred for efficiency reasons that it be preceded by compliance checks of the related registration dossiers. However, both processes could also run in parallel to accelerate the generation of missing data.
- The choice to proceed with a specific evaluation process, following the common screening and prioritisation of substances, should be based on the necessity to generate further information before risk management action can be taken. It should also carry the reflection whether the selected process is the right tool to obtain it, by recognizing limits for requests under evaluation (e.g. exposure

[202] Stakeholder consultation: summary report of the open public consultation, question 10,11 under chapter 3.1.1.

[203] For examples, further improvement of the ways how stakeholders are informed on the progress in MSC.

scenarios of downstream users) and identifying in advance the potential to more efficiently obtain information through an informal contact with industry or public call for evidence, in the risk management process from the stakeholders (public consultation during restriction) or by generating some missing data directly (e.g. modelling by the competent authority). The integrated regulatory strategy has taken steps with the aim to ensure this.

- Applying evaluation and risk management steps in sequence should not be a necessity. The processes can be applied in parallel. Where substantial grounds exist to justify concerns about a given substance, the initiation of risk management processes such as restriction or harmonised classification and labelling could be envisaged to partially overlap and complement evaluation, with these processes also prompting generation of the information necessary to determine, shape and justify any subsequent regulatory action. These processes are however also resource intensive and involve multiple actors and should not be applied lightly.
- Further changes to improve the efficiency and effectiveness of evaluation processes could be considered.
    - Addressing related groups of substances and not only individual substances. Related to this, the possibility of running evaluation processes in parallel, either between or with the risk management processes, should be explored.
    - Improving the efficiency of the resource intensive decision development and adoption process by ECHA. Measures may include increased use of shorter and more specific decision templates and automation or further optimization of interaction with registrants, in particular exploitation of the pre-evaluation of dossier updates (e.g. as promoted by annual listing of candidates for compliance check).
    - Better incorporating public consultation under testing proposal examination in the examination to maximise its impact, potentially by launching it together with ECHA's preliminary assessment in particular of the registrants' search for alternatives, to avoid duplication of effort and optimize informed input by third parties.
- The additional opportunities that have already started to be explored by ECHA as part of the implementation of the integrated regulatory strategy include the feedback from the evaluation processes to the integrated regulatory approach:
    - risk management action potential may be identified during the initial expert assessment of the registration information in the evaluation and the evaluation decision follow-up;
    - The common screening tool for selection and prioritisation should be continuously fed with the experience from the processes applied in order to optimise the screening but also provide better indication of the state of the dossiers in general to enable planning and communication;
    - The screening results should help to steer complementary measures.

In the future, modifications of individual steps in the formal evaluation procedure may also be considered to further improve its efficiency and effectiveness, in particular with regard to the third party and double registrant consultation[204], but also the roles of the Member State competent authorities and the Member State Committee (MSC). Specifically for the testing proposal examinations, the Commission should assess if the presently required full examination process of all testing proposals should continue or could be replaced by less resource intensive pre-notification procedure or enquiry-type ECHA process.

As already indicated, experience has driven the evolution of the evaluation process itself which have allowed for the improvement of a number of different ECHA processes and of guidance, in particular on registration. It has also supported the development of Commission proposals for modification of REACH annexes on information requirements. Examples include changes to the information requirements regarding skin sensitisation and reproductive toxicity, improvement of the ECHA guidance on how to address registered nanomaterials, development of the implementing act on data sharing and improvements of the IUCLID reporting tool.

5.4 Outcome of the Public Consultation

Stakeholders from industry and NGOs claim that the evaluation process lacks transparency, which industry considers a driver for cost. However, the evaluation process is conceived as a stepwise and transparent mechanism and the overall transparency has been further increased by ECHA with extended dissemination of information on substances on the Community Rolling Action Plan (CoRAP), by the publication of the list of substances potentially subject to compliance check, informing companies when their substances are short-listed for possible regulatory action[205].

The results from the public consultation, as regards dossier evaluation, suggest general satisfaction with the clarity of requirements and level of implementation and that a majority of respondents holds the view that the benefits of the process exceed or are proportional to the costs. In its 2016 Report on Operation of REACH and CLP, ECHA suggests to the Commission to review the existing 5% compliance check target to maximise the impact of compliance checks on the safe use of chemicals. It also recommends further improvement of the transparency of relevant outcomes of the different steps of the compliance check process for the benefit of Member States, accredited stakeholder organisations and registrants. In the public consultation, Member States, NGOs, industry and a consumer association called for more compliance checks. Several responses from industry however indicated that the processes are cumbersome

[204] Registrants are consulted twice: the first time on the basis of draft decision following ECHA assessment and the second time when the modified draft decision taking into account industry comments has received proposals for amendments from the Member States Competent Authorities afterwards.

[205] Stakeholder consultation: summary report of the open public consultation,

and costly for registrants, leading to sometimes disproportionate requests for additional information. One case has been presented through the open public consultation of a company withdrawing a registration because of the costs of additional studies requested by ECHA. Proportionate requests were also called for by an NGO advocating for animal welfare.

The length of the substance evaluation process has been acknowledged as problematic by authorities and stakeholders contributing to the public consultation and the specific survey conducted by ECHA in 2015[206]. In spite of this, some stakeholders continue to believe that substance evaluation is the best tool to deploy before making considerations on risk management measures at EU level.

While the substance evaluation process was generally considered both comprehensive and clear, suggestions were made in the public consultation to better indicate which information has been considered in the evaluation and to outline the potential divergences of risk assessment conclusions with the registrants. One NGO called also for more substances to be put on CORAP and that nanomaterials should be included automatically. Industry indicated that agreements between the registrants on who shall perform the test etc. generally do not pose problems, but the cost-sharing might still be an issue, and that interaction with downstream users, while it has taken place in some instances, can be a complicated and lengthy process. Industry also commented that substance evaluation is managed somewhat differently by Member States and that stronger involvement of ECHA as well as further coordination between evaluating competent authorities when dealing with substances within a same group would be beneficial and should lead to improved efficiency and consistency between the decisions. A best practice document has already been developed addressing these aspects[207].

[206] Assessment of the current substance evaluation process under REACH, AMES Foster Wheeler Environment and Infrastructure UK Limited, January 2016

[207] Developed by ECHA, some Member States and industry association, and discussed in the Workshop: https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf/c5ba2af8-eadc-4830-9dfb-389a4bf8f637

6 Authorisation

Conclusions of the 2013 Reach Review

The authorisation process was not fully operational at the time of the 2013 REACH Review. Nevertheless, the 2013 review addressed specific recommendations to the Commission services, Member States and ECHA to identify SVHCs and to draft a roadmap to include all relevant SVHC substances in the candidate list by 2020.

The 2013 review also recommended continuing the discussion to obtain a common view on the use of the candidate list for objectives other than inclusion in the Authorisation List (hereafter referred to as Annex XIV).

The Commission services also committed, together with ECHA, to improve the understanding of the authorisation process for all actors and underlined the need for better quality of the information submitted during the public consultation on the draft recommendations for priority substances for inclusion in Annex XIV.

Baseline

The pre-REACH legislation did not include an authorisation system for industrial chemicals. There was a mechanism to identify PBTs and vPvBs through the EU PBT working group, while CMRs were identified through the C&L working groups. No comparable system existed for identifying endocrine disruptors or other chemicals of equivalent concern. So, while the original predictions regarding candidate listing had some basis in the experience of the previous legislation, for the authorisation system itself there was no direct experience.

- It was originally expected that 137 substances would be placed on the candidate list by 2010 and 25 per year thereafter. In 2010, the Commission established a new target of 136 substances to be included in the candidate list by 2012.
- The first Annex XIV entries were expected to start in 2011 with 8 substances, then 12 added in 2012 and 25 per year thereafter.
- There was no estimate as to how many applications for authorisation could be expected per substance listed in Annex XIV, but only that approximately 100 downstream users would benefit from an application held higher up the supply-chain.

6.1 Developments since the 2013 Reach Review

6.1.2 The SVHC Roadmap

By the end of 2012, the candidate list did indeed contain 138 substances. To develop on this, and to add all relevant substances on the candidate list and make the process more predictable after 2012, the Commission developed a roadmap up to 2020, in collaboration with Member States and ECHA. The "Roadmap for SVHC identification

and implementation of REACH Risk Management measures from now to 2020" (the SVHC Roadmap), and hereafter the Roadmap) is a process to ensure that all relevant currently known SVHCs are included in the Candidate List by 2020. The SVHC Roadmap outlines a methodology for working towards achieving this objective, with clear deliverables, planning and sharing of responsibilities.

The SVHC Roadmap established four criteria to identify, among the substances fulfilling the criteria in Article 57, those that are relevant for the candidate list. It was endorsed by the Council in February 2013[208]. In the course of 2013, ECHA developed an implementation plan[209] that guided the activities in the field of SVHC identification from 2013 onwards.

During the initial stages of the implementation, the Risk Management Option (RMO) Assessment[210] hereinafter referred to as "regulatory management option" became a key element of the SVHC Roadmap. It is now used to assess if, for substances fulfilling the four criteria of the SVHC Roadmap, another regulatory mechanism under REACH (evaluation or restriction) or outside of REACH (e.g.CLP or OSH) is more appropriate to address substances of particular concern for consumers, workers and the environment.

The ECHA annual reports published in 2015[211], 2016[212] and 2017[213] provide the details of the implementation of the SVHC Roadmap. The main achievements of the SVHC 2020 Roadmap during its first 4 years of implementation are the following:

6.1.2.1 Screening of substances

The key objective of the SVHC Roadmap was to set out priority criteria and a methodology to achieve the inclusion of all relevant SVHC in the Candidate List by 2020. ECHA started screening the information available in the registration dossiers and the CLP classifications notified by industry. It became soon clear that, in addition to finding substances for the Candidate List, such screening could serve also other REACH processes (compliance check and substance evaluation) and CLP (identification of candidates for harmonised classification and labelling). ECHA then

[208] Endorsement by the Council of the European Union of the Roadmap on Substances of Very High Concern, February 2013

[209] SVHC Roadmap to 2020 Implementation Plan, European Chemicals Agency ECHA, December 2013

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

[211] Annual report of the Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures, European Chemicals Agency, March 2015

[212] Annual report of the Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures, European Chemicals Agency, April 2016

[213] Annual report of the Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency, April 2017

developed a common screening approach[214] that provides every year the competent authorities with a list of potential candidates for all REACH and CLP processes. Since 2017, the screening identifies not only individual substances, but also groups of substances, in order to ensure a more consistent and efficient approach to regulatory actions for similar substances.

6.1.2.2 Regulatory Management Option (RMO) Assessment

The RMO Assessment is now fully operational. Before a regulatory action under REACH is proposed on a specific substance, the Member States competent authorities or ECHA (on behalf of the Commission) prepare a RMO Analysis and submit it for comments to the other Member States competent authorities. Albeit voluntary, this approach has increased the exchange of information and communication among the authorities, in particular when deciding about the need for and/or the type of regulatory action and about whether to share the workload in complex cases. An example was the initiative of the Commission to launch a discussion on the links between REACH and occupational health and safety (OSH) legislation in the framework of the RMO Assessment. This has led to a better consideration of information available under OSH and the possibility for substances used mainly in occupational settings to consider as a first regulatory option the OSH legislative framework. It also improved the internal communication of the competent authorities for the two legislations.

At the RMO Assessment stage, it is also possible to consider some socio-economic aspects. However there is a need for a reflection on how socio-economic information, as well as information on exposure, can be taken into account without making the RMO Analysis too cumbersome and without giving the impression that a RMO is conceived as an Annex XV dossier or a risk management measure analysed within the Annex XV dossier for restriction.

In essence, the RMO Assessment serves the purpose of collecting views and information informally from other Member States and Commission/ECHA before a Member State or Commission/ECHA decides or has sufficient evidence to take any action allowed by REACH and which falls fully within the Member State and Commission/ECHA competence to decide. It is therefore important to recognise the difference between the obligations in Articles 69(1) and 69(4), where Member States and the Commission have obligations to act once a risk is identified (at EU level in the case of the Commission) and the RMO Assessment stage, where such risks have not (yet) been identified.

[214] https://echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/screening

The responses in the context of the open public consultation for the REACH REFIT Evaluation[215] indicated that a great majority of industry stakeholders consider that the RMO Assessment enhanced the coherence between different regulatory options within REACH, and between REACH and other EU legislations. Some of the respondents stressed that the RMO Assessment should be binding and more harmonised, to avoid discrepancies on how to manage chemicals by different competent authorities or by different Member States. On the other hand, respondents from consumer associations, a trade union and NGOs are critical of the RMO Assessment process. They consider it has no legal basis in REACH and, in their opinion, it delays the inclusion of SVHCs in the Candidate List and makes this process more burdensome.

6.1.2.3 Cooperation among authorities and expert/coordination groups

Before the SVHC Roadmap, authorities were selecting on their own the substances on which to work, based on different approaches, sometimes leading to duplication of work and not entirely coherent conclusions. The implementation of the SVHC Roadmap has improved authorities' coordination thanks to the common screening approach (selection of substances involving a mass screening performed by the ECHA secretariat complemented by manual screening by Member States), and the RMO Assessment (consideration of possible regulatory measures in consultation with others). In addition, experts are exchanging views and are looking for consensual opinions in the so-called Risk Management Expert (RiME) meetings[216] and several coordination groups, including the meetings of the PBT[217] and Endocrine Disruptor (ED)[218] expert groups for the discussion of the hazard properties not harmonised via the CLP process. A coordination group on human health hazards[219] steers the discussions on sensitisers and substances classified on the basis of Specific Organ Toxicity (STOT) to be potentially identified as SVHCs. An expert group on Petroleum and Coal stream substances (PETCO) is discussing a common approach for this complex group of substances.

Table 4.7 shows that the number of Member States participating in the implementation of the SVHC Roadmap has increased over the years.

6.1.2.4 Transparency, communication with stakeholders and predictability

The SVHC Roadmap also aims to increase transparency and predictability of the process to identify SVHCs. Thanks to the Public Authorities Coordination Table

[215] Report of the open public consultation

[216] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rime

[217] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pbt-expert-group

[218] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-group

[219] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/coordination-groups

(PACT[220]) on ECHA's website, stakeholders are now informed of substances selected for a RMO Assessment or discussed in the PBT and ED expert groups and can ensure that their registration dossiers are up-to-date with all relevant information and provide feedback to the competent authorities or to ECHA. PACT also includes the conclusions of the RMO Analyses. As of 2015, communication has started at an even earlier stage, with letters sent by ECHA to the registrants of the substances selected in the yearly screening. The whole process has thus become more predictable for stakeholders and it is no longer the "black hole" it was claimed to be at the beginning. In the open public consultation for the REACH REFIT Evaluation, industry stakeholders acknowledge that the RMO Assessment is an important instrument allowing them to predict the regulatory fate of a specific substance and to start early actions; however, some NGOs considered the process too slow to meet the final goal of the Roadmap by 2020.

6.1.2.5 Interface authorisation/restriction

The RMO Assessment also helped in deciding whether substances should be subjected to the restrictions and/or authorisation requirement. In some cases, where both authorisation and restriction processes had been initiated prior to the SVHC Roadmap, subjecting substances to the authorisation requirement has been put on hold while waiting for the finalisation of the restriction process (e.g. NMP, DMF), in others the discussion during the RMO Assessment has helped in the choice of one regulatory approach between two EU legislations (e.g. REACH restriction vs OSH legislation on isocyanates).

Cases have emerged where substances where subject to both restriction and authorisation processes (e.g. phthalates, NMP). To better utilise the strengths of the two instruments, being mindful of the objectives of REACH and the need to ensure legal certainty, an assessment is necessary to determine when it is opportune to consider restrictions, when authorisation and when both (sequentially or complementary) for the same substance.

Table 4.7

	2014	2015	2016	total
Number of substances manually screened	247	180	184	611
Number of Member States participating to manual screening	17	21	22	23
Number of RMO Assessments (cumulative numbers)	98	139	159	159

[220] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

Number of RMOAs (cumulative) with REACH as best RMO, of which • Authorisation • Restriction	 5 1	 16 5	 24 6	 24 6
Number of RMOAs (cumulative) with another legislation as best RMO, of which • Harmonised C&L • Other EU legislation (OSH) • Other	 1 1 (+1) 1	 2 1 (+2) 2	 4 1 (+4) 3	 4 1 (+4) 3
Number of RMOAs (cumulative) with conclusion that there is no need for regulatory action for the time being	5	11	15	15
Number of substances discussed in • ED[221] group • PBT group • PETCO group[222]	 14 43	 22 30	 17 29 2	 48[223] 88 2
Number of Member States preparing an RMOA (cumulative)	9	14	15	15

6.2 The Candidate List

Achievements and developments

During the development and initial implementation of the SVHC Roadmap, the authorities discussed the role of the Candidate List, i.e. whether only substances for which authorisation is considered to be the best regulatory option should be included, or whether the list should also be used to officially identify EDs, PBTs and vPvBs, for which no CLP classification criteria are available, and whether the Candidate List also serves other objectives[224]. While no general consensus has been reached on the objectives

[221] Endocrine disruptors

[222] "PETCO" stands for petroleum and coal streams. The PETCO group until now discussed the approach for this complex group of substances and only recently started the discussion on specific cases. Those specific cases were more discussed from a methodology perspective

[223] The total sum does not match, because some substances have been discussed in more than one meeting during more than one year.

[224] In two recent judgments (C-323/15 P and C-324/15 P), the Court of Justice would appear to consider that, once a substance has been included in the candidate list, the decision to include that substance in Annex XIV is no longer a question of whether authorisation is the most appropriate risk management measure to address the risks from the use of that substance, but of when it is most appropriate to include it. The Commission is currently analysing the two judgements.

of the Candidate List, it is now clear that the Candidate List can also include EDs, PBTs and vPvBs for which, in the next step, the best regulatory option is a restriction. Even if ECHA recommends these substances from the Candidate List for inclusion in Annex XIV because they fulfil the prioritisation criteria, the Commission can still decide not to include them in Annex XIV, if the RMO Assessment concludes that a restriction is the preferred option. However, in such cases the substance should be included in the Registry of Intentions for Restrictions (RoI- Restrictions) shortly after the conclusion of the RMO Assessment.

Table 4.8 key figures concerning the inclusion of substances in the candidate list

	2013	2014	2015	2016
Number of Annex XV dossiers for SVHC identification	17	14	9	10
Number of substances included in the Candidate List	13	10	7	5
Number of Member States submitting an Annex XV for SVHC identification	5	4	4	5
Number of cases deferred to COM[225]	0	4 EDs	1 skin sensitiser	3 EDs 1 respiratory sensitiser

From the data presented in Table 4.8, it is clear that the inclusion of substances in the Candidate List has slowed down. The following main reasons could explain this evolution:

- Thanks to the RMO Assessment, the authorities now assess more in depth the different options, choosing, in some cases, other regulatory actions, as reported in the 2017 SVHC Roadmap report[226].

[225] According to Art. 59(9) of REACH, in case the MSC does not REACH an unanimous agreement on a case of SVHC identification, the decision is referred to the Commission.

[226] Annual report of the Roadmap for SVHC identification and implementation of REACH risk management measures, European Chemicals Agency, April 2017. Page 30 : "The number of RMOAs concluding on the need for other EU legislation and/or other measures has also increased, which confirms that the RMOA tool is open and can in practice serve other legislation than regulatory risk management under REACH and CLP"

- The straightforward cases (CMRs – except for the petroleum streams) have all been assessed through the common screening approach and, in selected cases, with an RMO Assessment. The focus has now moved to more complex cases, such as PBTs, vPvBs and Article 57(f) substances, where more detailed RMO dossiers and, in some cases, generation of new data are needed. This is acknowledged in the 2017 SVHC Roadmap report[227].

- As concluded regarding registration and restrictions, the non-compliance of registration dossiers and/or the lack of detail of the registered uses hamper the identification of substances fulfilling Article 57, hence the identification of new SVHCs and prioritisation according to Article 58(3).

- There is only a small number of newly identified CMRs and other CLP hazard classes potentially corresponding to equivalent level of concern (STOT, respiratory sensitisers), due to lack of resources from MS to develop CLH dossiers for REACH related substances.

The Commission is more and more involved in the decision-making for the identification of SVHC since in an increasing number of cases the Member States Committee (MSC) has not reached unanimity. Such cases concern endocrine disruptors (seven cases) and sensitisers (two cases). This is mainly due to the absence of a common interpretation of 'equivalent level of concern' under Art. 57(f) of REACH. Through the decisions taken by the Commission after a vote in the REACH Committee on these disputed cases, the MSC receives feedback on the common interpretation, which should increase the efficiency of the overall process.

Available information from a survey conducted in the study to monitor the impacts of REACH on innovation, competitiveness and SMEs[228] suggests that already the inclusion of substances into the Candidate List or in Annex XIV has worked as a driver for a part of the companies concerned to look at the possibilities of substitution. The most common responses to such inclusion were to launch development of new substances, to find alternative formulations and to request substitution from suppliers. The effects of the Candidate List on the markets and on substitution have been further investigated in a study on the impacts of authorisation[229], which also confirmed those findings. .

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[227] Page 28: " … the number of RMOAs investigating substances with ED and PBT properties has been increasing steadily for two years as more and more substances are progressing under either substance evaluation, compliance check or in the PBT and ED expert groups, it can be expected that the number of RMOAs covering substances with those properties will continue to increase. However, it should be kept in mind that, as the generation and assessment of information takes often substantial time, it will also take more time before the RMOAs can be concluded."

[228] CSES, 2015 - Among respondents to the underlying business survey who were affected by inclusion of a substance in the Candidate List, about 19% launched initiatives to develop new substances, 30% launched initiatives to find an alternative formulation and 24% requested substitution to the supplier. The response of companies to inclusion of substances in the Authorisation List has had a similar pattern.

[229] Study on the impacts of REACH authorisation - final report

The Commission did not need to develop a procedure for de-selection of substances from the Candidate List because there was no need for it. It will be considered if a case of de-classification of a substance already in the candidate list arises in the future, which has not happened so far.

6.3 Prioritisation of substances by ECHA and inclusion in the Authorisation List (Annex XIV)

6.3.1 ECHA recommendations of priority substances for inclusion in Annex XIV

In 2014, ECHA updated the approach for the prioritisation of substances for inclusion into Annex XIV. The way the scores are calculated for the substances is now clearer and, as a consequence, during the public consultation ECHA receives information useful to refine the scoring of the substances. In some cases, this information led ECHA to change the score and modify the list of recommended substances. Still, a lot of information submitted during the public consultation was not related to the prioritisation criteria mentioned in Article 58(3), but rather to socio-economic impacts of subjecting a given substance to the authorisation requirement. ECHA and the MSC agreed that such information is not relevant for the discussion of MSC on ECHA's draft recommendation as it should rather be considered by the Commission and the Member States in the REACH Committee when considering amendments of Annex XIV. The criteria for prioritisation are now well accepted and stable and therefore very limited technical debate is taking place at MSC level and most of the policy debate is now taking place at REACH Committee level.

To better channel such information, and in line with the announcement in the Commission REFIT Communication in 2014[230], since 2015 the Commission has introduced a parallel public consultation to gather socio-economic elements linked to the possible inclusion into Annex XIV of the substances proposed to be prioritised by ECHA. Respondents were also invited to submit information on potential alternatives, on how sectors and individual companies would approach a potential application for authorisation (for example, individual applications or relying on an application from the manufacturer/importer). This consultation thus provides a transparent channel for the collection of such information, which is then considered by the Commission and the Member States in the REACH Committee during the decision-making on proposed amendments of Annex XIV based on ECHA's recommendations.

Such public consultations on socio-economic elements have been conducted during the preparation of ECHA's 6th, 7th and 8th recommendations of priority substances for inclusion into Annex XIV, and have delivered numerous comments, often focusing on a limited number of proposed substances. However, many Member States have questioned the representativeness of the input received for the whole EU, all sectors and all uses of

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

the proposed substances and believe that the analysis of impacts and alternatives for individual uses should be done subsequently on the basis of the individual applications for authorisation. Indeed, the consultation results show that some information is not submitted, in particular on how industry would organise the applications for authorisation within their supply chains. This may be due to the fact that at the time of this consultation the operators may not yet have decided whether they would need to apply for authorisation and if so, who in their supply chains would apply, since applying for an authorisation may be done by the operator placing the substance on the market (e.g. manufacturer, importer) or by the user of the substance. Furthermore, the choice between one or the other requires a focused communication in the supply chain that may not yet be organised at the time ECHA proposes a substance for inclusion in Annex XIV.

From the 6th recommendation (submitted in July 2015) onwards, ECHA has reduced the frequency of its recommendations, from one per year to an 18 months cycle – while the REACH Regulation requires such recommendations to be made at least once every 2nd year. In reducing the frequency, ECHA reacted to the announcement of the Commission in 2014[231] that it would consider reducing the frequency of including substances in Annex XIV to allow time for improvements in the process and simplification in some specific cases. Pending this work, this reduced frequency allowed more time for discussion in the REACH Committee. When the improvements and simplifications as discussed below are in place, the Commission services will reflect on the most appropriate frequency of Annex XIV amendments for the future.

6.4 Inclusion in Annex XIV

As of June 2017, Annex XIV contains 43 substances. While the Commission had included virtually all the substances recommended by ECHA in the first two Recommendations, the decision on inclusion of a number of substances from the 3rd, 4th, 5th and 6th Recommendations (from the years 2011-2015) was postponed. In fact, these four recommendations contained in total 48 substances, while only 29 were included in Annex XIV through three amendments made between 2013 and 2017.

There were several reasons for postponing the decision on the inclusion of some substances into Annex XIV: for example, the initial experience with some complex applications for authorisation, especially those covering a broad range of different industries that are submitted by upstream operators (in particular by manufacturers and importers) on behalf of the downstream users or submitted by multiple downstream users, revealed important challenges for this type of applications that need to be addressed before new substances in comparable complex supply chains are made subject to authorisation. It has also become clear that ECHA underestimated the workload created by the high number of complex applications for such substances (as required by Article 58(3)). This reasoning was the basis for postponing the decisions on diazene-1,2-

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

dicarboxamide (C,C'-azodi(formamide)) (ADCA) and four boron compounds[232]. In other cases, the decision was postponed because it was not clear whether the authorisation was the most relevant regulatory measure for the substances (five cobalt compounds[233], N,N-dimethylacetamide (DMAC), N-methyl-2-pyrrolidone (NMP), N,N-dimethylformamide (DMF) and certain aluminosilicate refractory ceramic fibres (Al-RCF) and zirconia aluminosilicate refractory ceramic fibres (Zr-RCF)).

Article 58(2) provides for the possibility to exempt uses or categories of uses from the authorisation requirement provided that, on the basis of existing specific Union legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. During the public consultation on draft ECHA Recommendations and the Commission's public consultation on the socio-economic elements, a large number of requests are systematically received from industry for exemptions under that Article. So far, , an exemption based on this provision has only been granted to the sue of three phthalates (DEHP, DBP and BBP) in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC. In 2013 an action was brought to the General Court for the partial annulment of Commission Regulation (EC) No 348/2013 amending Annex XIV to REACH because it did not include an exemption under Article 58(2) for the use of chromium trioxide in surface treatment[234]. The General Court judgment, which dismissed the action as unfounded, has been confirmed by the Court of Justice (appeal case C-360/15 P). Although the Court ruling has provided some clarification on the conditions set out in Article 58(2), further policy discussions will probably still be needed on other criteria that would allow granting exemptions from authorisation under this Article.

6.5 Application for authorisation

By 1st June 2017, 123 applications for authorisation related to 23 substances and 194 uses have been submitted, and one withdrawn, of which 23 applications (covering 35 uses) are currently being assessed by RAC and SEAC. The Commission has by that date adopted 35 authorisation Decisions covering 58 uses, all granting the authorisations, and 61 applications were under consideration for adoption of a Decision.

6.5.1 Preparing applications for authorisation

Multiple measures have been put in place to guide and support applicants to prepare an application for authorisation. While at the beginning of the processes two main Guidance documents were available, that information has been gradually complemented by

[232] Boric acid, disodium tetraborate (anhydrous), diboron trioxide, and tetraboron disodium heptaoxide (hydrate)

[233] Cobalt(II) sulphate, cobalt dichloride, cobalt(II) dinitrate, cobalt(II) carbonate and cobalt(II) diacetate

[234] Action for the partial annulment of Commission Regulation [ADD] amending Annex XIV to REACH was brought to the General Court (case T-360/13, VECCO and Others v. Commission).

guidance (e.g. *Readers' guide for preparing an application for authorisation*[235], *How to apply for authorisation*[236]), comprehensive update of *How to develop use descriptions in applications for authorisation*[237]) Q&As and other relevant information available on the ECHA's website. In addition, to ensure that applicants are well-informed about the process and to clarify any specific questions regarding their applications before they are submitted, ECHA has also set up a 'pre-submission information session' with potential applicants. Once the opinion-making has started in ECHA, the latter also organises (when considered necessary) so-called 'trialogues' with relevant members of the ECHA Committees, the applicant(s) and interested parties who submitted comments during the public consultation, in order to clarify specific points in the application in particular related to the analysis of alternatives. More generally, ECHA has been organising annual workshops on applications for authorisation in order to help future applicants to become familiar with the system.

In addition, clarification has been provided on specific elements of applications. In particular since 2013 the RAC has been publishing on the ECHA website reference derived no-effect levels (DNELs) and reference dose-response relationships for the substances listed in Annex XIV, so that the applicants may use those values when making the risk assessment for their applications for authorisation. In that regard it has also been clarified that, where applicants use those reference values, the chemical safety report only needs to include part A, the exposure assessment (Section 9) and the risk characterisation (Section 10) for each of the uses applied for, as well as the physico-chemical properties of the substance that are relevant to any exposure modelling performed. This is of particular benefit to downstream users who may not have access to the full chemical safety report in the registration dossier.

For non-threshold substances applicants should in their applications describe the remaining risk (after application of proposed operational conditions (OCs) and Risk Management Measures (RMMs)) quantitatively/semi-quantitatively based on information on dose-response, or qualitatively if dose-response information is not available. RAC is then expected to give an opinion on the appropriateness of the proposed OCs and RMMs and whether these are effective for attaining the exposure levels in the applicant's exposure assessment and assure that the exposure levels are as low as technically and practically possible. This information on the remaining risk is an input to the socio-economic analysis, which SEAC will use when developing its view on the health and environmental impacts and its subsequent opinion on whether these are outweighed by the benefits of continued use.

[235] Readers' guide for preparing an application for authorisation, European Chemicals Agency, December 2015

[236] How to apply for authorisation, European Chemicals Agency, December 2016

[237] https://echa.europa.eu/applying-for-authorisation/start-preparing-your-application

6.5.2 The ECHA Scientific Committees' opinion-making process on applications for authorisation

ECHA has published 'opinion-trees' guiding the different steps of the assessment of applications by RAC and SEAC, in order to ensure consistent opinions and increase predictability. The Commission has worked closely with ECHA and its Scientific Committees to ensure a common understanding of the legal requirements and provide clarifications where needed (e.g. on defining criteria for setting the review periods in authorisation decisions), to adjust and improve the latter's internal procedures (e.g. the Committees' timing for declaring whether the application is in conformity), and to ensure that the Committees' opinions are a suitable basis for the Commission to adopt a decision.

Regarding applications for authorisation in general, concerns have been raised by several Member States, NGO stakeholders and the European Parliament as to the quality of specific applications covering a large number of companies, which hampers the ability of the Committees to assess them. This in particular concerns:

- the representativeness of the data provided to support the exposure assessment in the chemical safety report (namely the representativeness of exposure scenarios for all the companies covered) leading to significant uncertainties in the determination of the level of risk for workers exposed to chemicals at the workplace; and

- the broad description of the uses applied for in cases where the substance is used in many different types of articles (for example where it is used as a plasticiser in polymers or as pigment in paints, which are then used in the production of many different types of articles) thereby rendering the analysis of alternatives for the entire scope of the uses applied for more challenging.

The European Parliament expressed particular criticism about one particular application[238], considering that the ECHA Committees had not correctly assessed the application, in particular with regard to the socio-economic aspects as compared to the costs for human health and the environment.

More generally, some NGOs see an imbalance in the evaluation of the interest of applicants and that of third parties in the public consultation, in particular of suppliers of alternatives, and have expressed concerns about the ECHA Committees giving more weight to the applicants' perspective. In their view this discourages substitution and causes disadvantage to companies that have already substituted and did not need to apply for authorisation at all. On the other hand, many applicants consider that during the opinion-forming process the ECHA Committees request considerable additional information, which creates further burdens, while – in their view – not being necessary.

The Commission services note that the ECHA Committees make their assessment on the basis of the information provided both by the applicants and by third parties in the public

[238] European Parliament non-legislative resolution of 25 November 2015.

consultation. While in some past applications the ECHA Committees have pointed to a number of uncertainties arising from the dossier, so far in none of those cases have the applications been considered by the Commission as non-conforming with the REACH requirements. However those uncertainties have led to the imposition of specific conditions and monitoring arrangements on the applicant or downstream users or to short review periods in the authorisation decision.

In order to have opinions that better suit the needs for decision-making, the Commission services have asked the ECHA Committees to clearly specify, where possible:

- which concrete risk management measures can be applied or improved to reduce risks;

- the details of the monitoring programmes recommended, the results of which can be used by the RAC when reviewing authorisations.

6.5.3 Streamlining and simplifying applications for authorisation

The authorisation system creates a step-wise increasing pressure starting from the SVHC identification, through prioritisation and then inclusion into Annex XIV so that these substances are substituted when and where there are suitable alternative substances or technologies. Exercising this substitution pressure dissuades the continued, albeit controlled, use of these substances. A certain pressure is therefore naturally and intentionally built into the authorisation system and awareness of it has been evolving with the entry into operation of the authorisation provisions.

The authorisation requirement is still in its early stages of implementation and naturally, in the beginning it has triggered concerns with stakeholders regarding the predictability of the process and the cost for applicants, while NGOs have raised concerns and called upon authorities to implement the authorisation processes more rigorously.

This led the Commission to start a debate in 2014 with Member States and ECHA, followed by debates with past and future applicants and stakeholders to take stock of the early experience gained and identify challenges and possible solutions for all parties concerned.

Those discussions have shown that, although the process of applying for authorisation is working, there is room for improvement with regard to the administrative burden for applicants and in particular for SMEs, who account to date for one-fourth of all applications. The Commission in 2014[239] acknowledged the need to lower the administrative burden by increasing the predictability of the process, implement a general streamlining of the process, and simplifying it in specific cases where possible. To assist the Commission and ECHA in developing those actions, a Task Force for improving the workability of the applications for authorisation process ('AfA Task Force') was set up. In

[239] *Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook*, 18.6.2014 (COM(2014) 368 final)

addition, the Commission considered modifying the authorisation fees and their structure in order to better align them to the actual cost for their handling by ECHA[240].

Simplification in certain specific cases

The Commission identified two cases where it considered a simplification of the requirements was clearly justified, namely for uses of a substance in low quantities and for uses in spare parts of articles that are no longer produced, as well as in the repair of such articles.

- in the case of uses in low quantities the simplification is justified by the relatively high burden of preparing a standard application as compared to the likely risk for human health or the environment from the use in low quantities;
- in the case of uses in legacy spare parts the main purpose is to avoid the premature obsolescence of articles, where they cannot function as intended without those spare parts, as well as where a particular Annex XIV substance is necessary for the repair of such articles.

In all cases, simplification is envisaged within the framework of the requirements laid down in the REACH Regulation, by specifying as far as possible the particular information to be provided within that framework. Work on these initiatives is progressing slowly due to considerations on the extent of the Commission's empowerment by the REACH Regulation to propose such measures.

Other possible specific cases for simplification have been discussed, such as for uses of substances as biologically essential nutrients, uses of recycled substances and uses in products subject to type-approval or certification requirements. While the latter case was abandoned (since type-approval or certification requirements were considered rather as elements for consideration in the application for authorisation itself, in particular in the analysis of alternatives and for setting the length of the review period), conclusions on the two first cases have not yet been reached.

General streamlining

The Commission, together with ECHA and the AfA Task Force, reflected in 2016 on possible ways to improve the predictability of the application process in general, and to better inform applicants, with specific instructions and practical examples based on previous applications, Committee opinions and authorisation decisions, on how to prepare a fit-for purpose application. This work was conducted in the AfA Task Force and was concluded with the publication by ECHA of the step-by-step guide *How to apply for authorisation*[241]. This guide notably clarifies the type of data required regarding in particular the chemical safety report (exposure assessment) in order to be representative, the elements to consider for describing the uses applied for and the level of detail needed in the socio-economic analysis in cases with minimal expected health impacts. This guide

[240] See Fee chapter

[241] Link to ECHA guide on "How to apply for authorisation"

should help in particular applications that cover many companies to prepare good quality dossiers and to avoid spending resources in gathering and submitting unnecessary information. This should benefit in particular SMEs, in cases where specific uses of a substance are similar across a sector of activity and no feasible alternatives exist. How effective the guide will be in improving predictability for applicants will have to be assessed in the coming years, on the basis of the quality of future applications.

REFIT platform

The European Environmental Bureau (EEB) submitted a paper to the REFIT Platform on the Authorisation process, making the case that the process is not working properly and is too slow. The underlines the main flaws of the process and sets out a clear path for reform showing how the Authorisation procedure can be made fully fit for purpose to achieve not only its main goal, namely health and environmental protection, but also its goal of free circulation of substances on the internal market while enhancing competitiveness and innovation[242].

6.6 Other issues

It is worth noting that most applications for authorisation submitted so far are from downstream users and for their own use, and the quality of those applications tends to be better than that of applications covering a large number of different operators. In this context, certain applications covering many downstream users still trigger many questions for clarification by ECHA' Committees in order for them to fully understand the scope and content of the applications and need to involve consultants and consortia managers. In some cases, the cost to apply can indeed be regarded, in absolute terms, as substantial, if referring to applications with a very broad scope and covering complex supply chains. For instance, Lanxess Deutschland GmbH estimates that the cost of their joint application for the use of chromium trioxide was around 4 million, half of which approximately was spent on managing the consortium and the other half on the application itself[243]. This cost needs nonetheless to be significantly nuanced if considered in terms of per applicant and per use, since the application was submitted by 7 different applicants, for 6 different uses of the substance. Thus, if looking at the cost per applicant per use, more affected are those that apply on their own and that rely on a consultant to develop most parts of their application. In the other end, the case of applications from individual downstream users for very specific uses (e.g. Biotech for the use of EDC), where there are no consortium-related expenses and no consultant needs to be involved, or to a very little extent, the main financial cost is ECHA's administrative charge.

It is clear that the centralised authorisation process created by REACH were intended by the legislator to allow actors at the top of the supply chain to apply for the uses of their downstream users, and for actors to submit joint applications. Therefore the authorisation process must be practical for this type of applications for it to be fully implemented as

[242] Link to the opinion by the REFIT platform
[243] ECHA's Newsletter n°2, April 2015

originally intended. Ensuring that applications for authorisation covering a large number of operators are of good quality is one of the main challenges in the implementation of REACH authorisation.

There are differing views as to the minimum level of detail in the information that such applications should contain in order to consider them as sufficiently documented. In that regard, the Commission has received two requests for internal review of two authorisation Decisions[244] under Article 10 of Regulation (EC) 1367/2006[245]. The Commission has dismissed the two requests for internal review as it considered them unfounded. Furthermore, the Commission has been challenged before the General Court concerning the Implementing Decision granting an authorisation for uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red[246] as well as concerning its response to the request for internal review of the Implementing Decision granting an authorisation for uses of DEHP in recycled PVC[247].

Moreover, some Member States have suggested that the Commission should clarify details of the content of applications for authorisation in a legally binding form through an Implementing Regulation. The Commission services consider that the impacts of the renewed guidance mentioned above should be awaited first.

Industry stakeholders have raised concerns regarding the impacts of authorisation on competitiveness of EU industry in terms of uncertainty, competitive advantage for non-EU producers of articles and potential relocation of activities outside the EU[248].

Experience in dealing with applications for authorisation for non-threshold substances has triggered the discussion on whether it would be appropriate to identify acceptable levels of risks[249]. Discussions have taken place regarding carcinogens in the context of authorisation, focusing on workplace exposure, and in the context of restrictions, focusing on consumer exposure. These reflections should continue with a view to the determination of acceptable levels of risks for all non-threshold substances.

6.7 Achievement of the objectives of authorisation

The assessment of the applications for authorisation submitted so far shows some positive developments towards improving risk management of Annex XIV substances

[244] Request for an internal review by ClientEarth of Commission Implementing Decision C(2016)3549 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) and Request for an internal review by ClientEarth, EEB, ChemSec and IPEN of Commission Implementing Decision C(2016)5644 granting an authorisation for uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red:http://ec.europa.eu/environment/aarhus/requests.htm

[245] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies

[246] Case T-837, Sweden v. Commission

[247] Case T-108/17, ClientEarth v. Commission

[248] Please see section on competitiveness for further details

[249] Workshop on "Acceptable level of risk to workers and consumers exposed to carcinogenic substances"

and efforts towards substitution. As concluded by the ECHA Report on the Operation of REACH and CLP 2016[250], there is evidence that substitution is happening as a result of substances being listed on the Candidate List and the Annex XIV recommendation. The following achievements can be noted:

- By March 2016, ECHA received applications for authorisation relating to only 21 substances out of the 31 substances included in Annex XIV by then, which may be an indication that substitution is taking place for all or at least part of the remaining 10 substances.

- Even if applications for authorisation are received, there are indications that substitution is taking place. DEHP was registered by 25 companies, however only three manufacturers of DEHP applied for an authorisation, out of which one withdrew the application subsequently. The EU's production and consumption of dibutyl and dioctyl orthophthalates (which includes DBP, DEHP and DIBP primarily) have also reduced during the period 2007-2013, from circa 376k tonnes to 89k (-76%) and from circa 326k tonnes to 94k (-71%), respectively, the imports not having compensated the decreases (from 4k tonnes up to 8k only during the same period)[251]. Other examples are diarsenic trioxide for which a company has found a substitute and HBCDD completely substituted by another polymeric (brominated) flame retardant.

- Not enough information is yet available on whether the production reduction is accompanied by a reduction of imports of SVHCs (e.g. phthalates) in articles[252].

- About a quarter of the applications were for "bridging", i.e. the applicant has identified a substitution strategy and applied for a specific period until the substitution would take place.

- The costs of applying for authorisation remain high for individual companies, even though they have significantly decreased over time (i.e. from EUR 230,000 on average per substance, use and applicant for the first applications to EUR 120,000 in 2016, of which 15-20% are attributable to the fees)[253, 254].

- The costs of applying for authorisation can be considered as relatively low when compared to the overall benefits from the authorised uses.

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

[251] Annexes to the Annex XV restriction report for four phthalates DEHP, DBP, DIBP and BBP, April 2016

[252] Article 69(2) envisages a restriction procedure for Annex XIV substances in articles

[253] Report on the Operation of REACH and CLP 2016, European Chemicals Agency, May 2016

[254] This reflects a partial picture of the costs and the benefits. Additional data will become available from an ongoing study.

- It is acknowledged that "regrettable substitution"[255] might happen, however its share in the overall substitution picture is not known.

- Furthermore, when preparing an application for authorisation, many applicants have revised and improved their risk management measures and operational conditions, which in practice improved workers protection. Companies are actively seeking to substitute and investing in substitution related activities[256].

Based on the applications for 32 uses of 9 carcinogenic substances ECHA estimated that the cumulative socio-economic benefits of the authorised continued use of the substances, derived from the direct and the indirect compliance costs, are at least EUR 368 million per year, for the use of 8,400 tonnes of the substances per year. On the other side, the monetised risks, calculated from the modelling via dose-response function of the statistical cancer cases on workers and on the general population for each substance, were estimated to amount to EUR 7.4 million per year.

[255] Substances that are replaced by other substances of similar concern

[256] Study on the impacts of REACH authorisation - final report

7 Restrictions

Conclusions of 2013 REACH Review

In the 2013 REACH Review the Commission services concluded that, under the REACH procedure it is possible to adopt new restrictions faster and more transparently than under pre-REACH legislation. The implementation of Title VIII of REACH was still in the early stages; nonetheless it was suggested to streamline and improve the efficiency of the whole process (Annex XV dossier preparation and subsequent steps) under the standard restriction procedure of Article 68(1), to better coordinate Member States' and ECHA's activities and improve the identification of substances for restriction.

It was also suggested to consider criteria for use of the restriction procedure for CMR substances in consumer articles – Article 68(2).

7.1 Developments after the 2013 REACH Review

During the period between January 2011 and December 2016, the Commission adopted 13 restrictions under Article 68(1) (i.e. initiated under either Article 69(1) or Article 69(4)):

- 11 of these were new restrictions,
- 2 were reviews of existing restrictions,
- 2 restriction procedures were finalised without adopting a restriction,
- 3 existing restrictions were reviewed with the conclusion that there was no need to amend the existing restrictions,
- 5 are in the opinion-making phase of ECHA or the decision-making phase of the Commission.
- 3 restrictions were proposed and adopted in accordance with Article 68(2), while 1 other is currently being prepared.
- 1 restriction was proposed in accordance with Article 69(2) and is currently in the decision-making phase.

Table 4.9 presents the information related to the restriction procedures that began during that period (i.e. submission of the Annex XV dossier, where applicable), as well as related to reviews of existing restrictions.

Based on a study conducted by ECHA[257] it is estimated that 9 of the restrictions submitted and adopted in this period under Article 68(1) produce health benefits of more

[257] Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016. Please note that these figures include only the quantified and monetised benefits and costs, and thus do not represent the absolute value of the benefits and costs of the adopted restrictions. The benefits and costs figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns, and costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the

than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, positive health impacts or removed risk for thousands of consumers and workers, at an estimated cost of about EUR 170 million per year.

Table 4.9: Overview of restriction proposals and reviews of existing restrictions considered under REACH between 2011 and 2016

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Four phthalates (DEHP, DBP, BBP, DIBP) in articles	Article 69(4)	Denmark	14/4/2011	No vote	Restriction process finalised without amendment of Annex XVII[258]
Chromium VI in leather articles	Article 69(4)	Denmark	20/1/2012	4/11/2013	
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	Article 69(1)	ECHA	19/4/2012	17/12/2013	
Lead and its compounds in consumer articles	Article 69(4)	Sweden	18/1/2013	3/12/2014	
Nonylphenol ethoxylates (NPE) in textile	Article 69(4)	Sweden	3/8/2012 and 29/7/2013	7/7/2015	
1-Methyl-2-pyrrolidone (NMP)	Article 69(4)	Nether-lands	9/8/2013		Pending Commission decision
Cadmium and its compounds in paints	Article 69(1)	ECHA	17/10/2013	22/9/2015	Review of an existing restriction

reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[258] Pursuant to Article 73(1) of REACH, the Commission considered that the conditions laid down in Article 68 are not fulfilled and did therefore not prepare a draft amendment to Annex XVII of REACH - OJ C 260, 9.8.2014, p. 1–4

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Phthalates in Point 52 of Annex XVII	Article 69(1)	ECHA	NA	No vote	Review of an exisiting restriction with conclusion of no need for further action[259]
Phthalates in Point 51 of Annex XVII	Article 69(1)	ECHA	NA	No vote	Review of an existing restriction with conclusion of no need for further action[260]
Ammonium salts in in cellulose wadding insulation materials	Article 129(3)	France	15/1/2014	3/2/2016	First use of the safeguard clause
Cadmium and its compounds in artist paints	Article 69(4)	Sweden	17/1/2014	No vote	Restriction process finalised without amendment of Annex XVII[261]
Bisphenol A in thermal paper	Article 69(4)	France	17/1/2014	6/7/2016	
Asbestos	Article 69(1)	ECHA	17/1/2014	3/2/2016	Review of an existing restriction
Decabromodiphenyl ether (DecaBDE)	Article 69(1)	ECHA	1/8/2014	20/9/2016	
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	Article 69(4)	Germany	17/10/2014	7/12/2016	

[259] ECHA completed its review in August 2013. The Commission services' conclusions are published at: http://ec.europa.eu/DocsRoom/documents/13172/attachments/1/translations

[260] ECHA completed its review on 13/11/2013. The Commission services' conclusions are published at: http://ec.europa.eu/DocsRoom/documents/5765/attachments/1/translations

[261] Pursuant to Article 73(1) of REACH, the Commission considered that the conditions laid down in Article 68 are not fulfilled and did therefore not prepare a draft amendment to Annex XVII of REACH - OJ C 356, 28.10.2015, p. 1–3

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
Methanol in windshield washing and de-frosting fluids	Article 69(4)	Poland	16/1/2015		
Siloxanes D4 and D5 in personal care products	Article 69(4)	UK	17/4/2015		
Lamp oils and grill lighter fluids	Article 69(1)	ECHA	8/7/2015	NA	Review of an existing restriction with conclusion of no need for further action[262]
TDFA and derivatives	Article 69(4)	Denmark	2/10/2015		
Four phthalates (DEHP, DBP, BBP, DIBP) in certain articles	Article 69(2)	ECHA	1/4/2016		
N,N-Dimethylformamide	Article 69(4)	Italy	17/6/2016		Possible resubmission of Annex XV dossier pending
Diisocyanates	Article 69(4)	Germany	7/10/2016		
PAHs in rubber and plastic articles	Article 68(2)	Com-mission	4/6/2010[263]	18/6/2013	
Newly classified CMR substances and mixtures for supply to the general public	Article 68(2)	Com-mission	NA	4/11/2013	
Newly classified CMR substances and mixtures for supply to the general public	Article 68(2)	Com-mission	NA	16/3/2017	

[262] Published at: http://ec.europa.eu/DocsRoom/documents/11463/attachments/1/translations

[263] Date of submission of technical dossier by Germany to the Commission

Substance(s)	Article used for initiation	Dossier submitter	Date of Annex XV dossier submission	Date of REACH Committee vote	Remarks
CMR in textile articles	Article 68(2)	Com-mission	NA		Public consultation on the initial proposal from 22/10/2015 to 22 March 2016[264]. A technical workshop to discuss a refined approach was then organised on 7 February 2017[265].

7.2 Comparison with the Baseline

The documentation required to support a restriction under REACH has many similarities with those needed in the pre-REACH system. A comprehensive risk assessment was conducted and where it concluded that a risk needed to be managed then a risk reduction strategy was also required, which could result in a recommendation for establishing a restriction. These two elements were included in Annex XV to REACH, though the risk assessment under REACH can be targeted. In the pre-REACH system, the restriction proposal itself as well as the socio-economic analysis was developed by the Commission whereas under REACH the Member States can submit restriction proposal and the socio-economic analysis is no longer mandatory.

Overall, the number of restrictions initiated per year is about the same as in the final years of the pre-REACH system, the latter being based on the outcome of evaluations conducted under the Existing Chemicals Regulation[266] (see Table Y for details), while the numbers are becoming more stable from one year to the other.

Table 4.10: Comparison of number of restriction procedures initiated under REACH and amendments of Directive 76/769/EEC

Number of restrictions initiated under REACH		Number of amendments of Directive 76/769/EEC	
2011	1	2003	6
2012	2	2004	3
2013	4	2005	3
2014	6	2006	2
2015	3	2007	1
2016	3	2008	1

[264] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299
[265] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9088
[266] Regulation (EEC) No 793/93

Nevertheless, the numbers fall short of what was expected from REACH at the time of adoption, when the Commission estimated that Member States would prepare 11[267] Annex XV dossiers for restriction per year, reflecting in particular that more information would be available.

7.3 Implementation of Articles 69(1) and 69(4)

Today, ECHA is the major contributor to the preparation of Annex XV dossiers due to requests from the Commission. In fact, ECHA has initiated 5 restriction procedures and conducted reviews for an additional 3 restrictions. Even though the REACH Regulation conferred the right to initiate the EU-wide restriction process on the Member States, a right that the Member States did not enjoy in the pre-REACH system, only 8 Member States have so far made use of this prerogative (and only 4 have done it more than once). This is particularly noteworthy because a higher share of Member States prepared comprehensive risk assessments in the context of the Existing Substances Regulation in the pre-REACH system as described in section 2.1: the high workload and technical expertise required where identified as the main reasons.

Collaboration among Member States and between Member States and ECHA has improved and several joint Annex XV dossiers have been prepared (e.g. DecaBDE, PFOA and phthalates). 4 Member States and ECHA are working together on the Annex XV dossier on tattoo inks, completed in 2017.

Nonetheless, most Member States perceive the development of restriction proposals as too burdensome in particular the preparation of the socio-economic analysis, which results in few Member States becoming actively involved. Although the socio-economic analysis is not obligatory to conform with Annex XV, the SEAC considers such information necessary for their work and the Commission needs it for its decision making. This has resulted in fewer restriction proposals being submitted, thus potentially slowing down substitution of hazardous chemicals that pose unacceptable risks.

Several Member States also considered that it is difficult to identify good candidate substances for proposing restrictions as compared to other risk management options. This is due to:

1. limited data has been generated for the chemical inherent properties in the registration dossiers, with industry submitting adaptations to fill the majority of data gaps. The

[267] Estimation made by the Commission services during the drafting of the proposal for the REACH Regulation and discussed with Member States in the so-called Commission Working Group to prepare for REACH (2005-2006). These estimation formed the basis of the financial Fiche accompanying the Commission Proposal and the Extended Impact Assessment. The assumption for restrictions was that better information in the registration dossiers, more information on the hazard properties of substances (e.g. through substance evaluation), the ability to target the risk assessment and strict deadlines would significantly increase both efficiency and the ability to identify substances needing restrictions.

majority of the adaptations conclude no concern for the substances[268]. There is therefore limited new information available to identify new problematic substances;

2. the fact that the substance evaluation process, which could lead to the identification of candidate substances, takes longer and produces fewer results that expected, in particular obtaining the desired exposure information as proven difficult[12];

3. it could be an indication that the requirements of REACH related to registration and communication of information in the supply chain have led to better risk management decisions by industry, thus reducing the occurrence of unacceptable risks that need to be addressed via a restriction.

As described in section 6 on authorisation, ECHA has in the meantime developed a common screening approach[269] that provides the Competent Authorities every year with a list of potential candidates for all REACH and CLP processes, which, together with the risk management option analysis, has the potential to identify more substances as candidates for restriction. By June 2017, 6 restriction proposals have been submitted as result of the common screening activity and one proposal is still at the RMOA stage.

During the public consultation, several Member States and NGO stakeholders commented that ECHA's Committees are too strict when checking the conformity of restriction proposals or when asking for additional information during opinion-making, which requires dossier submitters to invest further resources to get the dossiers accepted and processed. They consider, therefore, that the implementation of the REACH provisions requires too high a level of evidence compared to what the legal text stipulates. The public consultations conducted by ECHA were also criticised, with some considering that they are not sufficiently publicised and the information received on alternatives is disappointing, while SMEs in particular highlighted the impossibility to contribute to the high number of consultations, which is further hampered by the fact that most consultation documents are only available in English. Lastly, the final decision-making step is hampered by the fact that some Member States and NGO stakeholders consider that the SEAC does not scrutinise sufficiently requests for exemptions/derogation from proposed restrictions, accepting them as they come, and recommends too long transition periods. The information submitted by industry during public consultation for claiming an additional derogation or longer transitional period is considered not comprehensive enough for a scientific and technical assessment by RAC and SEAC in comparison to the information requested for an application for authorisation.

According to data provided by ECHA, the Agency invested the equivalent of 1 full-time person per year to prepare each Annex XV dossier plus the costs of a consultant of around EUR 60,000, depending on the difficulty of the dossier. It should be noted that

[268] See Evaluation Chapter for a comprehensive analysis of this.

[269] https://echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/screening

comparable costs were incurred in the pre-REACH system by the Commission when preparing restriction proposals, which required the preparation of an impact assessment to accompany a proposal submitted to Council and Parliament in the legislative procedure, in particular for the substances which were not evaluated in the context of the Existing Substances Regulation. One Member State reported costs, in relation to the complicated Annex XV dossier for PFOA and related compounds, of up to 2.5 persons per year and up to EUR 635,000 for consultancy. Another Member State[270] considered that the costs of preparing proposals for restrictions under REACH to be between EUR 0.5 -1 million).

On the other hand, the substances for several proposals have also been under scrutiny in the international domain such as the Stockholm Convention on Persistent Organic Pollutants (e.g. DecaBDE and PFOA). Therefore, the investment made in preparing a restriction proposal under REACH has also supported the EU nomination of the substances under the Stockholm Convention.

Furthermore, in anticipation of possible restrictions, respondents to the information gathering for the study *Monitoring the impacts of REACH on innovation, competitiveness and SME*s, confirmed that between 17.2% (SMEs) and 5.4% (large firms) of respondents withdrew substances from the market when these were entered into the registry of intentions to restrict substances.

Under the Existing Substances Regulation, the precautionary principle, according to the Commission Communication[271], was applied to 4 substances – twice leading to severe restrictions and twice leading to the request for additional information. Since the entry into force of REACH, the precautionary principle has not been invoked to justify the restriction of a substance. The available evidence in all cases allowed the RAC to conclude on the existence, or absence of an unacceptable risk or that additional information was needed to concluded. The principle could be invoked by ECHA where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question. In such cases, ECHA should highlight to the Commission which information is needed to clarify the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction.

Lastly, the principle of "internal market" harmonisation by virtue of Annex XVII entries and the availability of the restriction procedure in Title VIII has been generally accepted by Member States although some have still adopted (or attempted to adopt) national measures without following the procedures foreseen under REACH and without developing proposals for EU-level restrictions. Where such cases were notified to the Commission in accordance with Directive (EU) 2015/1535, the Commission issued detailed opinions or comments to the Member States concerned, setting out its

[270] KEMi (2015) Sub-study a report on The strategy for a non-toxic environment of the 7th Environment Action Programme

[271] COM (2000) 1 final

interpretation of the harmonising effect of Title VIII. In 2016 the EFTA surveillance authority, supported by the Commission, brought Norway before the EFTA Court when Norway adopted national restrictions on PFOA and related compounds, even though a EU-wide restriction was being developed and has since been enacted.

7.4 Actions taken to improve the efficiency of the restriction procedure

7.4.1 Task Force on the efficiency of the restriction procedure

In 2013, a Task Force (Commission, ECHA, RAC and SEAC members, and Member States as Dossier Submitters) was set up to improve the efficiency of the restriction procedure. Within a year, the Task force agreed on 71 recommendations in relation to the role of the dossier submitter and the Committees, the involvement of stakeholders in the two public consultations[272], the opinion making process and deliverables, and the required extent of the analysis.

Implementation of those recommendations has delivered the following positive results:

- clarification of the role of the dossier submitter in the preparation of the Annex XV dossier and the opinion-making process;
- streamlined structure and reduced length of Annex XV dossiers, without undermining their quality;
- better coordination during the scientific/technical assessment of the dossiers by RAC and SEAC;
- improved public consultations;
- clarification of the scope of restriction proposals as regards the risk assessment underpinning the proposal and the substances identified, which includes the grouping approach;
- clarification of the necessary socio-economic information and analysis in context of the proportionality assessment.

The implementation of the recommendations is "work in progress" as the Task Force continues its work, based on experience gained with new restriction dossiers. For example, a paper has been developed on second hand articles and stocks in order to contribute to the efficiency of restriction procedures. Other aspects under continued analysis are the conformity check, the grouping approach, the analysis of alternatives, the better use of the international assessments and the information submitted during the ECHA public consultation.

Regular workshops are held with Member States (normally once per year) to discuss how to make further improvements in the process. This will be supplemented by occasional

[272] The complete list of recommendations can be consulted on the ECHA website https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

joint workshops also with Committee members and the Forum to obtain a holistic overview of progress.

7.4.2 Further action by the Commission and ECHA

As Member States had in particular referred to lack of experience/capacity and the high burdens related to the preparation of the socio-economic analysis for an Annex XV Dossier as a reason for not submitting restriction proposals, the Commission and ECHA have provided support to Member States for preparing socio-economic analyses for restriction proposals. In particular, ECHA has set up a Network for Socio-economic Analysis and Analysis of Alternatives Practitioners (NeRSAP), which provides peer-to-peer discussions and capacity building. Several Member States have participated in these network meetings that have been held five times in 2011-16. In 2016, ECHA organised together with the Commission a workshop on how to carry out socio-economic analysis. ECHA has also provided hands on assistance to Member States when they carried out socio-economic analysis as part of their preparation of restriction dossiers. The Commission developed a 'SEA Toolkit' to facilitate data gathering, mapping of the supply chain, and the assessment of competitiveness, innovation and the impacts on SMEs. However, so far it has not been used extensively.

7.5 Implementation of Article 68(2)

Article 68(2) of REACH sets out what is often referred to as a fast-track procedure based on a generic risk assessment approach for the restriction of CMRs (categories 1A and 1B), as substances, in mixtures or in articles which could be used by consumers.

The routine restriction of CMR substances and mixtures for supply to the general public following harmonised classification under the CLP Regulation[273] is well established, and was already implemented in the pre-REACH system under Directive 76/769/EEC. Such restrictions were adopted under REACH in March 2014 and March 2017 to restrict 33 additional substances newly classified as CMR under the CLP Regulation.

The situation is less clear as regards the newly introduced possibility to use Article 68(2) to restrict CMR substances in consumer articles. The first restriction was adopted in December 2013[274], supported by evidence submitted by a Member State to the Commission already in 2010. The complexity of this case, mainly in terms of conditions (e.g. direct, prolonged or short-term repetitive contact with the human skin or oral cavity, the proposed limits of concentration) and identification of the articles concerned slowed down the whole process, making it no shorter than the standard restriction procedure. Therefore, the Commission services together with Member States and ECHA developed a systematic approach on when to apply this fast-track procedure to the restriction of consumer articles containing CMRs (categories 1A and 1B).

[273] Regulation (EC) No 1272/2008

[274] Annex XVII - Entry 50, paragraphs 5 and 6, on PAHs in rubber and plastic components of articles. https://echa.europa.eu/documents/10162/176064a8-0896-4124-87e1-75cdf2008d59

In this context, the Commission services commissioned a study in 2012 to analyse the potential impacts of restricting different CMRs in articles using Article 68(2). The Commission used the results of the study to develop a general approach and criteria, explained in a paper[275] that was discussed with the Competent Authorities and stakeholders and considered aspects such as the level of risk assessment required to underpin the proposal, the need for socio-economic data, or when and how to consult experts, stakeholders and Member States. Textile articles and clothing were proposed as a first case study, because of the potential for long-term dermal exposure to chemicals contained in textiles. The preparation of this restriction is almost complete[276] and, on the basis of this example, the Commission will reflect on how to proceed with future restrictions under the Article 68(2) procedure.

7.6 Implementation of Article 69(2)

ECHA has already finalised 6 dossiers examining the need for restrictions for substances subject to authorisation when present in articles, once the sunset date has passed (MDA, musk xylene, HBCDD, diarsenic trioxide, diarsenic pentoxide and the phthalates DEHP, DBP, BBP, DIBP). According to information from the authorisation applications, and the calls for evidence[277] carried out by ECHA, the first five substances were not used in consumer articles produced in the EU and ECHA found no evidence that they were present in imported articles[278].

The situation is different for the phthalates and ECHA in cooperation with one Member State prepared and submitted a restriction dossier, which is currently being assessed by RAC and SEAC.

During the period between the sunset date and the adoption of a restriction under Article 69(2), imports of articles containing a substance listed in Annex XIV (if indeed the substance is present in articles) may continue unabated while the production of the same articles in the EU is prohibited or subject to the conditions of authorisations granted. With a view to minimising the length of this period, in which EU citizens' health or the environment may be at risk, and economic operators in the EU may be at a competitive disadvantage, the Commission services and ECHA have agreed on the importance of taking all possible preparatory steps in the lead up to the sunset date in order to expedite analysis of the need for a restriction.

It has to be noted that it is possible to introduce a restriction for consumer articles via Article 68 (2) for CMR (categories 1A and 1B) substances listed in Annex XIV. When these substances are no longer used in the EU in the production of articles, such a

[275] http://ec.europa.eu/DocsRoom/documents/10045/attachments/1/translations

[276] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299

[277] ECHA systematically launches calls for evidence to gather as much as possible information on imported articles

[278] ECHA systematically launches calls for evidence to gather as much as possible information on imported articles

restriction would prevent the re-introduction of articles containing these substances in the EU market, in particular due to potential 'new' investments of non-European companies to produce articles containing them. On the other hand, if the substances are already phased-out from all articles placed on the EU market, enacting such a restriction would not have any effect other than preventing such a potential reintroduction.

It also has to be noted that the majority of substances subject to authorisation to date are process chemicals that are not present in finished articles. While this means that there are no risks from the (non)-presence of the substances in articles placed on the market in the EU, it also means that the disadvantage for EU producers of such articles from the authorisation procedure cannot be addressed via a restriction.

8 Member States activities

Conclusions of the 2013 REACH Review

Member States are required under Article 117(1) of the REACH Regulation to submit to the European Commission every five years a report on the operation of the REACH Regulation in their respective territories, including sections on evaluation and enforcement.

8.1 Developments after the 2013 Reach Review

8.1.1 Key issues from Member State reports

Acknowledging that collecting the necessary information poses challenges to Member States, the questionnaire that was the basis for reporting due by 1 June 2010 was improved, both for content and format. All Member States submitted their reports in 2015[279], according to the improved template developed for that purpose.

8.1.1.1 Competent Authorities

There are 45 REACH Competent Authorities (CAs) operating in the 28 EU Member States and the 3 EEA countries. 6 Member States have more than one CA. Out of the 45 CAs, 28 deal with all REACH processes (i.e. registration, evaluation, restriction and authorisation). 44 CAs indicated they are involved in other chemical legislation as well. A large majority of them have responsibilities under CLP (39), Biocides (30) and PIC (30).

CAs are generally satisfied with their technical expertise, while some consider their financial and human resources too limited to achieve all activities required under REACH.

8.1.1.2 Cooperation and communication between CAs, and with ECHA and the Commission

CAs generally expressed a high level of satisfaction with the cooperation between CAs at EU and national levels and with ECHA and the Commission.

CAs expressed a high level of satisfaction over the functioning of the Forum, the REACH Committee, the Member States Committee (MSC), the Risk Assessment Committee (RAC) and the HelpNet network. The Socio-Economic Assessment Committee (SEAC), CARACAL and the Risk Communication Network (RCN) gathered less positive feedback. Frequent comments, on all groups, address organisational issues, working methods, workload, availability of experts and resources.

CAs also made proposals for improvement, regarding for instance the decision-making at

[279] Member States Reports on the operation of REACH (Art. 117)

the Forum, the REACH Committee or the MSC (such as an increased use of the written procedure for finding agreement on certain issues or voting), the duration, frequency and functioning of the CARACAL, or the opinion-making of RAC and SEAC (such as the need to improve the conformity check of submitted restriction dossiers and authorisation applications, or comments regarding the type and level of expertise of the respective members).

8.1.1.3 National helpdesks

In 25 Member States, the REACH helpdesk is part of the REACH CA. In the 6 other cases, the helpdesk is part of another Ministry, a public Agency or a public research institute. Helpdesks provide a combination of services ranging from online guidance, advice services, newsletters and/or training. The majority of helpdesks receive between 100 and 1000 enquiries per year. Most enquiries related to registration, safety data sheets and CLP labelling. Few countries keep track of the size of enquirers, but in the 11 Member States that have reported data, most enquirers were SMEs. As for the coordination network HelpNet, although a number of concerns were pointed out by respondents (among which the slow average speed to provide a reply to the more horizontal questions concerning several national helpdesks or necessitating the involvement of the Commission), over two-thirds of them considered it to be effective or highly effective.

The SME consultation carried out in the context of the REACH REFIT evaluation indicates that the overall experience with the public authorities seems to be rather neutral without a significant indication of either positive or negative experiences[280]. The number of respondents per Member State is relatively small and reveals no conclusive differences among Member States.

8.1.1.4 Awareness raising activities

Apart from the Czech Republic and Luxembourg, all other Member States indicated that they had carried out awareness raising activities during the reporting period. Most tend to target a broad audience in their activities (consumers, companies in chemicals and downstream sectors). Two-thirds of Member States have targeted SMEs as a specific group. Most common awareness raising activities include the production of easily accessible information content (e.g. leaflets and newsletter) and the organisation of

[280] A quarter of the respondents state that they have a neutral experience as regards the content of the reply they get when they contact national helpdesks concerning REACH (24%) and concerning the time needed to get a reply (25%). A similar number state their experience has been positive regarding the same aspects (28% for content of the reply and 25% for time needed to get a response).

36% of the respondents seem to be satisfied with the overall consistency of public authorities, whereas 23% say they have come across several inconsistencies. However, 41% state they never had any contact with the authorities, which can be considered quite high.

speaking events (including seminars), the development of websites and the use of social media.

8.1.1.5 Alternative test methods

17 Member States indicated that they had contributed in the past five years to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees. 11 Member States provided data on the overall public funding on national research and development of alternative testing, with six reporting expenditure of more than EUR 100,000 per year, and two Member States (Germany and the Netherlands) of more than EUR 1,000,000. The rest of the Member States did not report this information.

8.1.1.6 Involvement in dossier and substance evaluation

15 CAs reported having been involved in dossier evaluation during the reporting period. Most of them considered that the dossier evaluation process had achieved its objectives, although some concerns have been raised on the poor quality of registration dossiers impeding the evaluation process.

23 CAs have been involved in substance evaluation. 36 substances have been evaluated in 2012, 47 in 2013 and 51 in 2014. The most frequent issues reported by CAs regarding the substance evaluation process relate to the lack of expertise, capacity and financial resources, and updates of dossiers by registrants during the 12-month evaluation period, leading to changes in the evaluation process.

8.1.1.7 Preparation of restriction and SVHC dossiers

9 CAs indicated having been involved in the preparation of Annex XV Restriction Dossiers during the reporting period, sometimes in cooperation with other CAs or with ECHA. 7 of them have consulted or involved Industry in the preparation of restriction dossiers.

11 CAs reported having been involved in the preparation of Annex XV SVHC dossiers, sometimes in cooperation with other CAs or with ECHA. 7 of them have consulted Industry or involved them in the preparation of the dossiers. Most CAs (26) considered that there is enough coordination between ECHA and CAs in the implementation of the SVHC Roadmap.

8.1.1.8 Enforcement

All Member States have reported on their activities related to enforcement in the context of the 2015 reporting, including information to apply the system of enforcement indicators developed to monitor progress. The results are presented in the enforcement section of this report.

8.1.1.9 Evaluating the impacts of REACH on the environment, human health, competitiveness and innovation

With the exceptions of the CAs of Latvia and Slovenia, CAs stated that the effects of REACH would be better evaluated at EU level. 3 CAs felt that evaluating effects was necessary both at EU and national level.

9 Enforcement

Conclusions of the 2013 REACH Review

The enforcement of REACH[281] was addressed in the 2013 REACH Review but at that time little experience was available. Among other issues, it was highlighted that the Forum contributes to the harmonisation of enforcement action, which is instrumental in avoiding fragmentation of the single market and distortion of competition, and in ensuring high quality enforcement throughout the EU.

The 2013 Review concluded that:

- the Member States need to improve the coordination of their inspection and enforcement activities and to focus them across the EU to target limited resources where most benefit is to be expected.
- The Forum should provide a more systematic support to Member States.
- The Commission, with the support of the Forum, would develop enforcement indicators to monitor the implementation of REACH and achieve a more harmonised and systematic approach for the collection of information and reporting.

9.1 Developments after the 2013 REACH Review

Enforcement activities have both evolved since the 2013 Review as the different actors benefit from experience. The Member States have developed their systems and enforcement capabilities. At the same time, the Forum has developed methodologies, and tools[282] supporting enforcement. Also ECHA's increased experience has improved enforcement of parts of the Regulation (e.g. compliance check decisions after dossier evaluation or verification of SME status of registrants). Furthermore, synergies with the enforcement of other EU legislation have been developed (e.g. market surveillance, product safety, customs, occupational safety and health legislation).

9.1.1 Enforcement indicators

In response to the 2013 REACH Review, the Commission developed enforcement indicators in cooperation with Forum members. 50 enforcement indicators were proposed at three levels (EU, Forum and Member States)[283]. This is the first time that such an approach has been developed in the field of enforcement of chemicals legislation in the EU. A system of uniform EU, Forum and Member State level indicators allows for enforcement challenges to be identified and support targeted. The system also contributes

[281] REACH national enforcement authorities are very often also responsible for CLP Regulation..

[282] Templates, databases, guidance documents

[283] Study on enforcement indicators for REACH and CLP link to final report

to transparency for stakeholders and helps ensure that a certain degree of harmonisation of enforcement is performed, resulting in a more level playing field on the EU market.

Overall, it is still premature to draw final conclusions on the reliability of the first quantitative results of the indicator. Indeed, this indicator covers both REACH and CLP together. In addition, reporting from Member States would need to be further harmonised.

The average level of REACH compliance[284] reported by the Member States and ECHA has varied from 79 % to 89 % in the period from 2007 to 2014[285]. In this period, the areas with lower level of compliance are the ones related to control of imports and supply chain obligations (e.g. 52% non-compliance for safety data sheets). There are some differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end).

9.1.2 Enforcement in the Member States

The architecture of enforcement capabilities continues to be complex in most EU and EEA Countries where, in 25 out of 31 Countries[286], several authorities are responsible for enforcing different parts of REACH (e.g. health and/or consumer protection authorities, national chemical agencies, labour inspectorates, environmental authorities or customs authorities). Such complexity requires enhanced coordination at national level (e.g. via regular meetings, memoranda of understanding or development of legislation to define responsibilities among authorities). Some activities of the Forum support such coordination (e.g. prioritisation and implementation of enforcement projects), as they involve different national authorities, who then have to coordinate among themselves at national level.

All Member States have adopted national legislation on penalties applicable to infringements of REACH[287]. In the last reporting exercise three Member States informed about modifications of their legal provisions on penalties. The penalty laws in the Member States can include enforcement notices, injunctions, withdrawal of products from the market, administrative fines and criminal sanctions.

Substantial differences in enforcement exist mainly due to differences in enforcement culture. Some national enforcement authorities are understaffed, in part due to cuts because of the economic crisis. Most Member States also reported[288] that the majority of infringements of REACH are resolved without applying penalties (with the exception of

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

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

[286] The EU 28 plus Norway, Iceland and Liechtenstein

[287] In accordance with Article 126 of REACH on penalties for non-compliance

[288] In accordance with Article 117.1 of REACH on Member States reporting obligations

some administrative fees in some Member States). This means they are resolved by means of verbal or written advice.

Member States have reported close to 100 000[289], controls per year in the last two years and the number has been steadily increasing since 2007[290]. The controls concerned manufacturers, importers/only representatives, distributors and downstream users, with each group accounting for more or less one quarter of the controls carried out. Data show that efforts were made to prioritise controls according to the risk profile of duty holders. Proactive controls, i.e. those conducted on the own initiative of the authorities in the context of planned monitoring and inspection activities, are the most frequent, rather than those prompted by incidents and complaints, and that these are complemented by reactive controls triggered by complaints. Controls of obligations and duties related to registration, communication in the supply chain and restrictions were the most common over the period.

It is important to highlight that apart from carrying out controls within the framework of Forum activities, the majority of Member States report additional enforcement activities (such as tackling specific local issues, investigating certain groups of duty holders, gathering intelligence on certain REACH duties) or carrying out the so-called 'regular checks' (e.g. Safety Data Sheets are commonly checked in most of the inspections).

An indication of the effectiveness of the enforcement at EU level can be estimated using data reported by the Member States[291, 292]. For this reporting period, 0.6% of enforcement decisions were appealed. For only 2% of these appeals, were decisions by enforcement authorities found inadequate[293].

The majority of Member States (21) had implemented an enforcement strategy at the end of 2014 (compared to 18 in 2010), and another 4 had devised strategies. Of the 6 Member States that had not yet developed a strategy, 3 were planning to do it. All 25 Member States that have either devised or implemented a strategy have indicated that it is, or will be, in line with the strategy of the Forum[10].

The general REACH provisions for dossier and substance evaluation do not apply to on-site isolated intermediates. However, where the National Enforcement Authority (NEA) of the site's location has concerns regarding a serious risk to human health or the

[289] The number of controls reported by the Member States is though not consistent, as some report controls several orders of magnitude higher than others. The main reason for this is that some Member States report the numbers of controls per dutyholder, whereas others report the numbers of controls per product or duty. In some cases, some Member States report fewer controls because they have not received information from all regions/provinces of their country.

[290] As informed by Member States in accordance with Article 117.1 of REACH on their reporting obligations

[291] Link to Member State reports

[292] In the period 2010-2014, Member States reported 26,296 non-compliance cases on a total of 344,546 REACH controls. The number of appeals on those non-compliances is 152 and 3 of them resulted in overturned decisions

[293] Values of the percentages based on the data provided by 19 Member States. The rest did not provide data on appeals against enforcement decisions.

environment that is not being properly controlled, the NEA can require the registrant to provide the information needed to assess this concern.

9.1.3 The Forum and enforcement within ECHA

The Forum for the exchange of information on enforcement (the Forum) contributes to the harmonisation of enforcement at EU level because, for example, the enforcement projects designed and managed by Forum entail that the same type of control is carried out all over Europe at the same time, following the same procedure as laid down in a manual[294]. ECHA provides support to the Forum through its secretariat. These EU projects have proven to be effective tools.

Initial Forum activities addressed registration and a few restrictions, whereas in recent years they have also covered evaluation, authorisation and more restrictions. Enforcement activities have been carried out relating to all tasks given to the Forum under Article 77(4) of REACH. Some examples are given in the table below.

Table 4.11. Some examples of Forum activities related to its legal mandate

Art 77.4	REACH legal text	Examples of some enforcement activities carried out in this period
a	Spreading good practices	Development of 8 project manuals to support the Forum enforcement projects and the Manual of Conclusions
a	Highlight problems at Union level	After the Forum finalises a coordinated enforcement project, they underline [295] identified challenges
b	Proposing, coordinating and evaluating harmonised enforcement projects and joint inspections	3 one-year EU enforcement projects and 5 small projects were performed[296]
c	Coordinating exchanges of inspectors	Pilot ECHA programme in 2012-2013
d	Identify enforcement strategies, as well as best practice in enforcement	Development of two strategic documents that are publicly available[297]
e	Developing working methods and tools of use to local inspectors	Forum project manuals and Manual of Conclusions

[294] Some of these manuals are in the annexes of some of the Forum enforcement projects - link to ECHA website

[295] Recommendations to the Commission can be found towards the end of the Forum enforcement projects reports https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects. For example, the Forum requests clarification on the enforceability of Article 8 of REACH

[296] Link to ECHA website - Forum enforcement projects

[297] 'Strategies for Enforcement of REACH and CLP' and 'Minimum Criteria for REACH and CLP Inspections' documents can be found at ECHA website on Forum

f	Developing an electronic information exchange procedure	A dedicated REACH-IT[298] system for enforcement authorities was developed by ECHA and is fully functional. From this year, the Commission's ICSMS[299] system linked to the Accreditation and Market Surveillance Regulation will also be used for REACH enforcement purposes.
g	Liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary	Annual open sessions of Forum meetings
h	Examining proposals for restrictions with a view to advising on enforceability	On average 4 examinations of enforceability of restrictions per year.

The vast majority of Member States (83 - 94%) participate in major enforcement projects developed by the Forum. These projects are an important tool for achieving harmonised enforcement as the same types of obligations are enforced in the EU and EEA on the basis of the same questionnaires following common priorities. In addition, between 16 and 58 % of Member States participated in small/pilot enforcement projects conceived, developed and reported by the Forum.

ECHA continues to reinforce support to Member States, for example by providing analyses of risks of non-compliance and identifying matters of severe concern. However, ECHA should take Member States' administrative capacity into account by, for example, clearly prioritising its tasks to be carried out.

In around half of the cases where an ECHA decision concluded on non-compliance (e.g. compliance check decision after dossier evaluation), companies updated their registration dossiers without the need of further action. When companies did not update after several reminders, ECHA forwarded the information to national enforcement authorities via ECHA's statement of non-compliance, for Member States to act appropriately. To date, such enforcement action has only been required in a small number of cases.

While public consultation respondents generally acknowledged the positive impact of the Forum on the harmonisation of national enforcement practices, room for improvement was identified, in particular to make the Forum's work more visible for companies. The most prominent claims from stakeholders were to build a more harmonised enforcement system and to carry out more enforcement actions.

[298] PD-NEA is the IT system used by enforcement authorities to access to REACH-IT data

[299] ICSMS system. https://webgate.ec.europa.eu/icsms/?locale=en

9.1.4 Contribution of the European Commission

The European Commission contributes to Forum's work and supports Member States in their activities and has, for example:

- Improved the template of the questionnaire used by Member States to report on the implementation and enforcement of REACH. The questionnaire now includes some information necessary to calculate EU level enforcement indicators.
- As it concerns the role of customs in the enforcement of the REACH requirements, the roles and tasks of all actors should be defined more clearly in order to enhance legal certainty for both economic operators and customs authorities. To this effect, the Commission may consider regulatory measures in addition to non-legislative means (eg guidance, training, pilot projects).
- Encouraged REACH enforcement authorities to use the ICSMS (Information and Communication System for Market Surveillance)[14]. The system will improve the exchange of information among national authorities and with authorities from other Member States. This will increase interaction among authorities and sensitise other authorities for enforcement action.

9.2 Stakeholder consultation

The responses to the public consultation about enforcement in the context of the REACH review were distinctly less than positive. The overall enforcement provided by Member States and Forum activities is considered not at all satisfactory or rather unsatisfactory by 40% of the respondents but 30% say it is rather or very satisfactory. The prioritisation of enforcement at EU level is viewed favourably. However, the most negative perception came when respondents were asked if REACH is uniformly enforced across the EU as 70% of the respondents said that REACH is not uniformly enforced. Such negative views were predominantly expressed by businesses (most of the respondents), but also by NGOs and consumer organisations.

The Accreditation and Market Surveillance Regulation (Regulation (EC) No. 765/2008[300]) contributes to providing legal certainty for authorities when enforcing product-related obligations (e.g. those related to articles in the context of REACH). The results of a public consultation conducted in that framework in 2016 show that 68% of stakeholders perceive that most or some products are affected by non-compliance. However, when asked for an approximate proportion of non-compliant products, most respondents considered that less than 20% of products are affected by non-compliance and close to half were unable to make an estimate.

In their responses to the REACH open consultation, stakeholders asked in general for more national enforcement and some suggested targets for enforcement. Stakeholders identified particular shortcomings with regard to imported goods. Mostly businesses and industry organisations stated that Member States should significantly increase controls in

[300] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF

this area. This was seen of such importance because the lack of controls puts at risk Member States' enterprises competitiveness in a globalised trade system. The lack of level playing field was seen by many as a serious risk for businesses but also for consumer safety.

The public consultation also revealed that there might be room for improvement for prioritization of inspections over a 5 year period. It was felt that currently micro businesses and small business are controlled very little, around 10% to 25% within 5 years, while controls concentrate before all on large companies, around 60% of all controls. According to certain stakeholders, this practice may lead to adverse results, since micro- and small enterprises might find it more difficult than large enterprises to fulfil REACH obligations. This perception should however be nuanced, since available data[301] show that the majority of controls concerns SMEs. It is however true that the rate of non-compliance is usually higher for SMEs than for large companies.

Regarding enforcement at the Member State level the majority of respondents, industry and businesses deplored the lack of harmonised enforcement across the EU. The introduction of standard rules for enforcement was recommended by some of them. Different practices applied by national inspectors and differing national penalty systems are considered as accountable for the lack of a level playing field in REACH enforcement. Mostly businesses and industry organisations asked for more harmonised enforcement practices. As a matter of particular concern it was highlighted by mostly industry associations that national enforcement authorities were not always aware of the latest developments concerning the REACH Regulation at EU level.

These findings provide evidence for a need to develop a common understanding of what harmonisation of enforcement entails and how the level playing field can be achieved.

[301] In the REF2 enforcement project 86% of controls targeted SMEs. This proportion was of 72% in the REF3 enforcement project.

10 Fees and charges

Overview

The revenues from fees and charges are to cover part of the costs of the services rendered to companies[302]. For the period 2011-2015, however, ECHA revenues from fees and charges were sufficient to finance ECHA's budget without the need of an EU balancing subsidy. This was possible due to higher than expected fees and charges revenues from the 2010 and 2013 registration deadlines. The excess from these revenues was accumulated in a reserve, which was exhausted in 2016, when an EU balancing subsidy again became necessary.

It is foreseen that this subsidy will be needed in the future. In 2016, it amounted to EUR 60,544,763 and is forecasted to amount to EUR 69,489,500 in 2017 and circa EUR 31 million in 2018[303]. ECHA's budget must be in balance and in line with the Multiannual Financial Framework 2014-2020 for EU agencies, as set out in Communication COM(2013)519.

Commission Regulation (EC) No 340/2008 (hereafter the Fees and Charges Regulation) sets the fees and charges payable to ECHA pursuant to Regulation (EC) No 1907/2006 (REACH). The basic approach followed for registration and authorisation fees was to set a base fee and have reductions for SMEs and additional fees for joint submissions. The appeal fee is levied for appeals lodged against certain decisions of the Agency in the field of registration and evaluation. The amount of the fee takes into account workload for the Board of Appeal. In accordance with Article 22(2) of that Regulation the Commission must keep the Fees and Charges Regulation under continual review in the light of significant information becoming available in relation to underlying assumptions for anticipated income and expenditure of the Agency.

The Commission was also to review the Fees and Charges Regulation by 31 January 2015 with a view to amending it, if appropriate. However, since the information on the revenues deriving from authorisation applications was limited at that date, that review takes place in the wider context of this REFIT Evaluation.

Evolution of fees and charges revenue

In the 2006 REACH legislative financial statement[304], the fees and charges revenue was foreseen to amount to EUR 510 million over the period 2007 - 2016 and the total ECHA

[302] Fees for registrations (including updates), confidentiality claims, authorisations applications (including updates), notification of Process Orientated Research and Development (PPORD) applications, appeals to the Board of Appeal, and administrative charges, e.g. for the verification of SME status.

[303] Statement of estimates of the European Commission for the financial year 2017 (Preparation of the 2017 Draft Budget). Financial Programming 2018-2020, SEC(2016)280 - June 2016

[304] SEC(2006)924

budget over the same period to EUR 757 million (implying a balancing subsidy of around EUR 247 million).

As shown in the table below, the revenue has been 14% higher than expected, which has had an impact on the level of the EU subsidy. In practice, the fees and charges revenue over the period 2007-2016 was EUR 581 million and the EU balancing subsidy was EUR 225 million.

Of the EUR 581 million, EUR 136 million comes from representatives (ie an entity that represents a non-EU producer). However, the split between EU and non-EU produced substances is not as simple as this as other non-EU producers will have registered through an EU based subsidiary (Manufacturer and importer) or an importer.

Of the EUR 581 million total; Germany, the United Kingdom and the Netherlands are the biggest countries of origin accounting respectively for 23%, 12% and 10% of the fees. From Germany, around a fifth relates to representatives, whilst for the United Kingdom it is more than half.

Indeed, the incomes from fees and charges are highly volatile depending on the various registration deadlines and on the number of applications for authorisation, which, it needs to be noted, are market driven, making them hard to predict.

In particular, ECHA continued to receive, in contrast with the 2006 estimates, registrations for phase-in substances in the two highest tonnage bands (over 1,000 tpa and 100-1,000 tpa) after the respective deadlines of 2010 and 2013 (see table below). It is also difficult to know how much ahead of a deadline the companies will send their dossiers. For example, many more dossiers relevant to the 2013 deadline were submitted in 2011 and 2012 than predicted. The 2006 financial statement also assumed that no registration would be submitted until 2016 for substances in the lowest tonnage bands, while dossiers for these tonnage bands started to be received in 2008. Moreover, a significant share of registrations corresponds to substances produced outside the EU (50% over the 2008-2016 period, 40% in 2016). This makes the income predictions even more difficult to anticipate, due to the lack of information on registration intentions from the non-EU companies. Overall, the numbers reflect the dynamism of the chemical market and the changes in portfolios constantly made by operators.

The uncertainty and volatility of the fees and charges income (see tables 4.12/4.13 and figure 4.8 on the Evolution of ECHA budget and source of revenues for the period 2008-2016 below) led ECHA to take a conservative approach in its estimates because of the financial impact that it may have had in case these registrations had not materialised. This conservative approach means that the needs for the EU balancing subsidy have been overestimated, as compared to a more accurate fee forecasting.

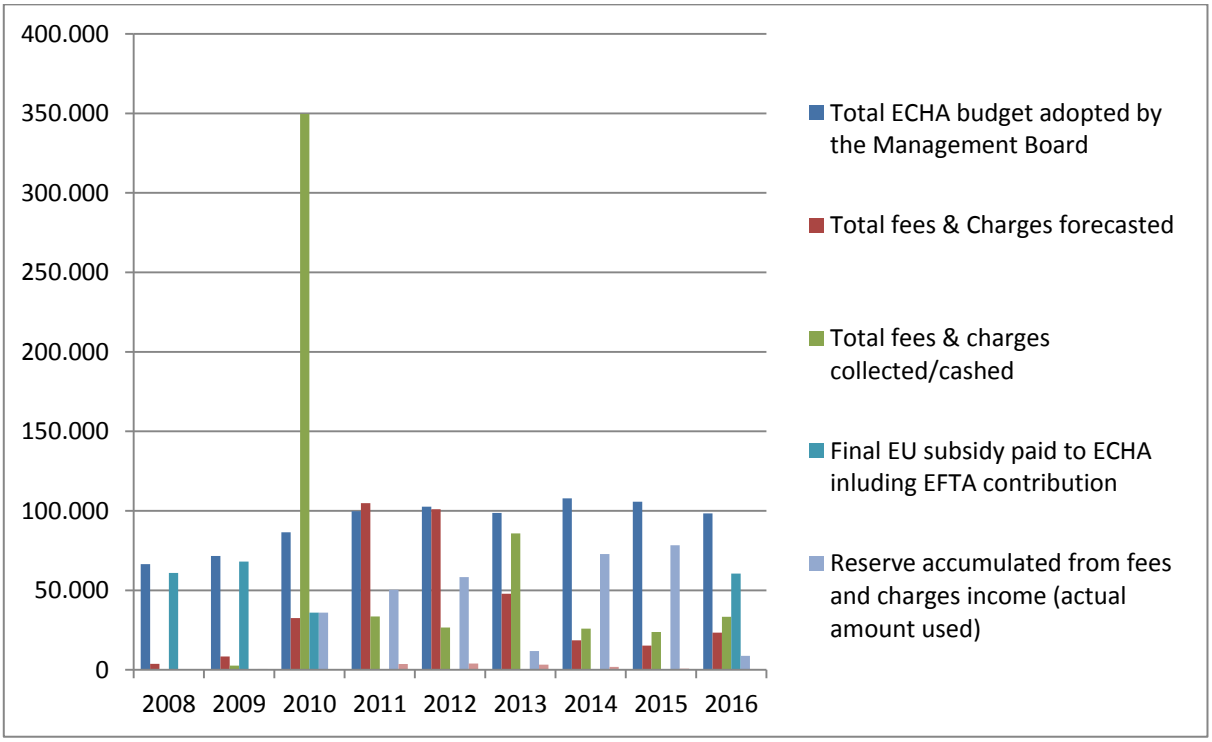
Table 4.12 Comparison of the forecast and the actual number of registrations at ECHA for substances in the two highest tonnages bands for the period 2011-2016 (source ECHA)

Number of registrations	2011	2012	2013	2014	2015	2016
> 1000 tpa						
2006 Forecasts	0	0	0	0	0	0
Actual numbers	815	422	730	369	371	384
100-1000 tpa						
2006 forecasts	93	932	8295	0	0	0
Actual numbers	437	885	6301	575	618	534

Table 4.13 Evolution of ECHA budget and source of revenues for the period 2008-2016 (source ECHA).

REACH revenues 2008-2016									(EUR 000)
	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total ECHA budget adopted by the Management Board	66,425	71,636	86,482	99,800	102,666	98,686	107,890	105,748	98,351
Total fees & Charges forecasted	3,806	8,395	32,500	104,800	100,971	47,900	18,595	15,267	23,384
Total fees & charges collected/cashed	365	2,659	349,652	33,522	26,612	85,800	25,951	23,785	33,377
Final EU subsidy paid to ECHA inluding EFTA contribution	60,934	68,051	36,000	0	0	0	0	0	60,545
Actual amount used from the reserve accumulated from fees and charges income	0	0	36,000	50,367	58,306	11,847	72,855	78,350	8,839
Other income (mainly Interest generated by the reserve) - cashed	2	503	213	3,621	3,913	3,280	1,866	740	517

Figure 4.8: Evolution of ECHA budget and source of revenues for the period 2008-2016 (source ECHA).



Conclusions of the 2013 REACH Review

The Commission considered that changes in the fee regime did not justify a revision of REACH and indicated it would address possible amendments, including those submitted by ECHA in its report, in the context of reviewing the Fees and Charges Regulation.

In the framework of the 2013 REACH Review, ECHA made some suggestions related to the fees[305]: (1) Establishing a specific inquiry fee to avoid inquiry free riding; (2) Requiring separate payments for different confidentiality claims; (3) Ensuring remuneration under CLP for rapporteurs for harmonised classification and labelling proposals that are based on registration dossiers; (4) Achieving a desired degree of self-financing for the Board of Appeal through appeal fee revenue; and (5) Ensuring sufficient coverage of all regulatory resources needed for processes for which no subsidy is assumed to arrive.

The Commission has not seen the need to consider any of the above suggested changes to the fees regime. As a matter of fact, ECHA was self-financed until 2015 (instead of 2014 as initially foreseen) and since then the EU subsidies paid to ECHA have been systematically lower than the estimate budgeted by ECHA. In addition, aiming for partial self-financing for the Board of Appeal through appeal fee revenue is not appropriate as access to the Board of Appeal for potential appellants needs to be safeguarded.

[305] The operation of REACH and CLP, European Chemicals Agency (ECHA), 2011

10.1 Developments after the 2013 Review

10.1.1 Commission actions and follow up

Since the last review of the Fees and Charges Regulation[306], the level of the fees and charges has been adapted only once to the inflation rate as measured by means of the European Index of Consumer Prices as published by Eurostat to reflect the 2013 1.5% inflation rate[307]. At that occasion, the Commission indicated that it would take account of the Agency's efforts to achieve efficiency gains when reviewing the Agency's fees and charges level.

In line with the conclusions of the 2013 REACH Review, the Commission introduced in March 2013 further reductions in favour of small and medium enterprises (SMEs) for both registration and authorisation. As far as registration is concerned, over the period 2013-2016 the additional total fee reduction for SMEs represented a total amount of EUR 1.7 million. It is to be noted though that, according to a Commission study[308], the fees represent only a small proportion of the total cost to companies. For example, for the registration of a substance, the fee would represent only 14% of the total costs, the rest corresponding to the letter of access and the administrative costs. Therefore, any further changes to the fees would only have a minor impact on the overall burden to companies.

The Commission also committed to consider further proposals by certain Member States aiming at further reducing the financial burden for companies, SMEs in particular. In addition, the Commission also enquired whether the structure and the amount of the fees had taken account of the work carried out by the Agency and the competent authorities, in line with Article 74(3) of REACH. Accordingly, the Commission assessed in detail the following potential measures:

- Measure 1: Registration fee reductions for autonomous companies with a headcount between 250 and 499 employees (so called 'Mid-Caps');
- Measure 2: Additional fee reductions for SMEs registering two or more substances in the low tonnage band (1 to 10 tonnes), i.e. multiple registrations made by the same SME;
- Measure 3: 10% reduction to the fee payable when a company registers more than 10 substances. The reduction would be applicable from the 11th registration onwards and would be applicable to all companies (not just SMEs);
- Measure 4: Payment of registration fees in instalments;
- Measure 5: Alignment of the SME reductions for authorisation (i.e. 25%, 55% and 90%) to the ones for registration (i.e. 35%, 65% and 95%).

[306] Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013. OJ L 79, 21.3.2013, p 7–18

[307] Commission Implementing Regulation (EU) No 2015/864 of 5 June 2015. OJ L 139, 5.6.2015, p 1-11

[308] Monitoring the Impacts of REACH on Innovation, Competitiveness and SME, CSES, commissioned by the European Commission, December 2015

The Commission assessed whether such measures would be compatible with the existing legal provisions in REACH. Regarding the proposal to establish a new company category (measure 1), REACH (and, consequently, the Fees and Charges Regulation) only foresee a reduced fee for SMEs and refer to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises. No other category of companies, such as Mid-Caps is mentioned. Since Commission Recommendation 2003/361/EC is binding for all EU institutions, there is no possibility to change the SME status for REACH purposes only.

As regards the opportunity to introduce further reduction on registration fees, such as reduced fees for multiple registrations by the same registrant (Measures 2 and 3), these reductions are not feasible without amending the enacting terms of the REACH Regulation since the reductions foreseen by Article 74 of REACH are exhaustive. Consequently, no reduction for multiple registrations by a same registrant, regardless of its size, can be considered under the existing REACH provisions.

The payment of registration fees in instalments (Measure 4) would be contrary to Article 20(2) of REACH, which provides that, when undertaking the completeness check, the Agency must check each registration in order to ascertain that all elements required for the REACH registration (in accordance with Articles 10, 12, 17 or 18), as well as the registration fee, have been provided. Consequently, the completeness check of each registration performed by ECHA includes the verification of whether the registration fee has been paid in full. A registration for which the fee would not have been paid in full is incomplete and no registration number could be issued. Therefore, the payment of the fee in instalments is not possible without amending the enacting terms of REACH.

Finally, with regard to the alignment of the SME reductions for authorisation to the ones in force for registration (Measure 5), so far only 21% of the applications for authorisation have been submitted by SMEs. Based on the information gathered by ECHA, the average application cost per use has been about EUR 200,000 in 2013-15. The share of the fee represents on average 19% of the total application costs. Given the level of the already existing fee reductions for SMEs, additional rebates would not have a significant effect on the total application costs, but on the contrary could have negative consequences on the finances of the Agency. For this reason, the Commission also investigated whether the current fees accurately reflected the Agency workload.

Regarding the authorisation fees, ECHA currently charges a fee for each additional applicant in a joint authorisation application (25% lower than the base fee) and another one for each additional use of a substance (80% lower than the base fee). On the basis of ECHA's experience, this does not reflect adequately the workload involved. Indeed, the workload is driven by the number of uses, not by the number of applicants that has almost no bearing on the actual work carried out. For this reason, the Commission services is considering the possibility to abolish the additional fee per applicant in a joint application and increase the fee (to 90% of the base fee) for each additional use of a substance. This should contribute to reduce significantly the authorisation costs since companies will have an incentive to introduce joint applications.

10.2 Stakeholders views

In the context of the online public consultation in relation to this REFIT Evaluation[309], the adequacy of the level of fees and charges paid to ECHA for registrations, applications for authorisation and appeals was investigated. A relative majority of respondents (38%) considered that overall the fees and charges for the registration of substances are adequate and 23% considered that they are not[310]. As far as authorisation fees are concerned, a clear majority of respondents (56%) considered them too high. As regards the fees for appeals, while the majority of respondents (55%) did not have an opinion on the matter, 22% of respondents found the level too high and 13% found it adequate. In summary, while registration fees and charges are perceived as adequate, this is not the case for authorisation. As far as appeal fees are concerned, it is difficult to draw conclusions: given the number of appeals lodged over the period 2013-2016 (72)[311], it cannot be said that the level of fees had a deterring effect.

10.3 Part of ECHA's workload financed by fees and charges

Under REACH Registration activities, fees are collected for the registration of substances and intermediates, dossier updates and PPORD notifications (exemption requests for R&D activities). For the Agency's workload calculation, the main driver for ECHA is the overall number of dossiers received - not only those generating a fee, but also the processing time and work needed for their assessment, such as the completeness check process. According to ECHA, fees finance around 70% of the workload in average during the reporting period, the rest (30%) being covered by the EU subsidy.

ECHA may also levy administrative charges. In the registration field, this is the case in the framework of the SME status verification. Indeed, ECHA checks whether the declaration made by registrants over their size is accurate or not. Should it not be the case, ECHA rectifies the fee to be paid by registrants (e.g. standard fee instead of medium-sized enterprise reduced fee) and applies an administrative charge that aims at discouraging the submission of false information. The level of this charge, EUR 20,700, was found excessive by a registrant that appealed to the EU General Court ECHA's Decision to impose this charge[312]. The Court found that in the case at hand, indeed, the level of that charge was disproportionate with regard to the savings (EUR 720) derived from the false declaration as SME. Following that judgement, ECHA revised the administrative charge for the SME verification by capping it to a maximum of 2.5 times the financial gain derived from the false declaration on the size status[313].

On the Evaluation activities, ECHA considers that, on the basis of its experience in the compliance check of dossiers the legal drafting of the decisions requires more work than

[309] Stakeholder consultation: summary report of the open public consultation

[310] The rest of respondents seem not to be concerned by the registration fees as they answered that they did not know

[311] The number of appeals per year was as follows: 22 in 2013; 18 in 2014; 22 in 2015; 10 in 2016

[312] Judgement of the General Court of 2.10.2014 in the case T-177/12 Spraylat GmbH v European Chemicals Agency (ECHA)

[313] ECHA Management Board Decision 14/2015 of 4 June 2015

foreseen by the original financial statement, especially concerning registration dossiers for substances over 1,000 tpa. Further assessment of this matter is provided in the Evaluation chapter where the general issue of efficiency gains is also addressed.

As regards substance evaluation, ECHA transfers to Member States a proportion of the incomes from the fees, so that they can carry out their evaluation work. According to ECHA, the experience shows so far that the workload per case is also higher than anticipated also due to the legal drafting of the decisions requiring more work. The transfer of fees to Member States also occurs in the work carried out in the area of restrictions and authorisations. Over the period 2015-2017, it is estimated that a total of EUR 4.4 million will be transferred to Member States. 2.1% of the registration fees will be transferred for evaluation and restriction purposes, 14.9% of the application fees for authorisation ones.

During the reporting period, the ECHA's implementing rules for the transfer of fees have been revised[314]. Indeed, in a context of declining fees revenues, it was important to ensure that on one hand Member States would receive a compensation for the work done and on the other that ECHA would have available sufficient financial resources to undertake its tasks, having regard to its existing budgetary appropriations and multi-annual estimates of income, including the planned European Union subsidy, as laid down in the Communication from the Commission on the programming of human and financial resources for decentralised agencies for the period 2014-2020[315]. For this reason, an overall ceiling of EUR 12,5 million has been set for the 2015-2017 period.

Compared to the previous period, ECHA estimates that the amount of fees transferred is going to increase. This can be explained by the increasing number of substance evaluations notified by the Member States.

10.4 Ongoing activities

In addition, the Commission is considering to review the authorisation fees as a result of the ongoing work on the streamlining and simplification of the authorisation procedure. The foreseen adoption of a simplified procedure for authorisation applications for the use of substances in low quantities applications will lead to a reduction of the workload for ECHA and its scientific committees since the information to be submitted by the applicant will be reduced in comparison to the ‘standard’ procedure. For this reason, a reduced fee proportionate for this type of application could be considered.

Further fee reductions as suggested for the registration of substances are not feasible under the existing legal framework. The Commission has proposed several measures that will contribute to reduce the burden for companies associated to the applications for authorisation, either through the adjustment of the fees level in order to better reflect the agency workload, or through the streamlining of the authorisation procedure. It needs to be born in mind though that a balance must be kept between alleviating financial burden

[314] ECHA Management Board Decision MB 45/2014
[315] COM(2013)519

on industry and ensuring that ECHA has sufficient resources to perform its tasks having regard to existing budgetary appropriations and financial programming.