

Report on the Operation of REACH and CLP 2016



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Report on the Operation of REACH and CLP 2016

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Foreword

This is the second five year report the Agency has produced on the implementation of the REACH and CLP regulations.

It shows that since our previous report in 2011¹ the operations of REACH and CLP have effectively steered companies towards manufacturing, formulating, importing and using industrial chemicals more safely. This constitutes significant progress towards meeting the aims of the Regulations, namely providing a high level of protection for human health and the environment, whilst promoting alternatives to vertebrate animal testing. There are also encouraging signs that this has happened whilst innovation continues and the competitiveness of industry is maintained.

Despite the gains, there are areas that need further effort to ensure they are working as the legislator intended. In our previous report we identified problems with the quality of the information being provided by companies in their registration dossiers. This aspect is critical to the success of REACH and CLP, since adequate and reliable information is the foundation of all of the other REACH and CLP processes. We are pleased to see that the quality of information in registration dossiers has improved, but there is still work to be done, as well as ensuring that information consistently flows along supply chains, ultimately to consumers.

In collecting REACH and CLP-generated information on chemicals, ECHA has moved from a data-gathering organisation to a knowledge management one, in which an integrated regulatory approach is taken to managing the various REACH and CLP processes. This integrated approach is founded on screening all information from the various databases that the Agency manages to trigger risk management measures particularly for 'substances that matter most' for safety. It also puts us in a position to gradually map the 'universe of registered substances' over the years to come.

Looking to the future a lot of efforts are currently being made to ensure that the final 2018 REACH registration deadline is a success. ECHA has put in place its REACH 2018 Roadmap, with a particular emphasis on the needs of small and medium sized companies, which are likely to comprise a large proportion of new registrants. Mobilisation of industry for this deadline has begun, but more needs to be done as many have not yet started their preparations.

Beyond 2018 we must remember this deadline is not the end of the story. As changes occur in the chemicals market companies need to keep their dossiers up-to-date. The most innovative and front-running companies integrate in their business strategies the provision of high quality information on their substances and keep it updated to ensure their substances can be used safely. Industry and authorities will also need to face up to recognised challenges posed by nano-materials, endocrine disrupting chemical properties, or the combination effects of hazardous substances.

Finally, I would like to thank the European Commission, Member State Authorities, our Accredited Stakeholder Organisations and ECHA staff for their contributions to achieving the ambitious objectives of the REACH and CLP legislation.

Geert Dancet
Executive Director

¹ See section entitled 'Reports on the operation of the REACH Regulation' here: <http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports>

Eight years of REACH – the journey so far

INTRODUCTION

REACH was intensively negotiated over a period of five years. It represents a sea change in the way in which chemicals are regulated and managed within Europe. Its objective is the safe manufacture and use of chemicals so as to protect human health and the environment, at the same time as enhancing innovation and the competitiveness of EU industry. Knowing that companies would need to provide data on chemicals, which in turn could require new research, REACH also requires that testing chemicals on vertebrate animals should only be undertaken as a last resort. REACH and CLP are the way in which the European Union is meeting the goals for safer chemicals by 2020, set by the World Summit on Sustainable Development in 2002².

This is the second, five-yearly report on the operation of REACH and CLP and provides a more accurate picture than ever before of the impact, successes and remaining challenges of implementing this ground-breaking legislation. In these first few pages, we give you a sense of the journey so far.

ARE THE MEANS IN PLACE TO ENABLE COMPANIES, MEMBER STATES, THE EUROPEAN COMMISSION AND ECHA TO FULFIL THEIR RESPONSIBILITIES?

The short answer to this is yes. Companies can register their substances, inform ECHA about the classification of their substances and apply for authorisation to use substances of very high concern – all online. There is a wealth of material to help them on ECHA's website – specific online IT tools and support, mostly in 23 languages. Although this support is ECHA branded, it actually results from collaboration with the Member States, Accredited Stakeholder Organisations, the European Commission and the OECD. This collaborative approach has resulted in widely accepted and fit-for-purpose products. Companies can also get one-to-one support from helpdesks at national, sectoral and ECHA level. And, should they disagree with a decision made by ECHA or the European Commission, companies can also challenge them through ECHA's Board of Appeal or the Court of Justice.

Member States play a vital role in REACH – prioritising and preparing proposals for substances for regulatory action, evaluating them, and enforcing the law. Experts from the Member States also participate in the formal opinion and decision-making of ECHA – in the Management Board and ECHA's scientific Committees. In all of these areas, effective working arrangements have been established and tools developed to render efficient cooperation.

Having all the means in place enables us now to see the bigger picture – seeing REACH and CLP as part of the EU landscape for consumer and worker safety, environmental protection, growth, sustainability and, ultimately, better regulation.

ARE COMPANIES RESPONDING?

REACH places the burden of proof on companies, who are now responsible for ensuring and demonstrating the safe use of their substances and mixtures, including their classification. Companies are certainly responding to the legislation in large numbers. So far, over 10 000 have informed ECHA about their substance's classification, almost as many have registered and provided information dossiers on chemicals, almost 3 000 have submitted inquiries to find fellow registrants of their substance and hundreds have

² Outcome of the World Summit on Sustainable Development, Johannesburg 2002: http://www.unesco.org/education/tlsf/mods/theme_a/img/02_WSSDOutcomes.pdf

directly or indirectly applied for authorisation to use a substance of very high concern³ (SVHC) until they can find safer alternatives.

But these impressive numbers only give part of the picture. REACH is about the safe use of chemicals, not simply about giving data to ECHA. The challenge for companies is to collect data on their substance – its hazards, the extent to which workers and consumers are exposed to it, and the uses to which it is put – assess the risks, produce practical advice on how to use it safely, provide all this information to ECHA and then communicate it clearly up and down their supply chain. Much of this initial work is done with fellow registrants of the same substance – very often direct competitors – which in itself has presented challenges. Nevertheless, despite this, an increasing number of companies are providing data of a sufficient quality both to ECHA and to their customers. This gives confidence that these companies understand how to handle their chemical portfolios responsibly.

However, whilst companies are clearly responding to the legislation, it must be said that a significant proportion of registration dossiers are still not of a sufficient quality. The main weaknesses are: a lack of clarity about the identity of complex substances; providing poor justifications for using alternatives to vertebrate animal testing; not providing sufficiently detailed information on the uses of and potential exposure of people to substances; and not having robust risk management (or mitigation) measures for each use.

Fortunately, when companies have been notified of the need to improve their data, the vast majority of companies do it, and provide a sufficient quality to make the dossier compliant with the law.

The importance of good quality data is fundamental. Without it, the safe use of chemicals by all the actors in the supply chain is impossible. Without it, it is impossible to differentiate between the substances that can be used safely and those that cannot. Without it, the Agency and the Member States are unable to prioritise the most hazardous substances for regulatory attention. Without it, time and effort is wasted by both ECHA, the Member States and companies, because poor quality dossiers have to be examined, given the possibility that the substances they describe may be of serious concern. Without it, the risk management of the most hazardous substances is seriously delayed.

Progress is being made on improving the communication about using chemicals safely throughout the supply chain. A programme of initiatives taken by industry, the Member States and ECHA, to support registrants and downstream users have started to bear fruit. Companies increasingly understand the need to improve the quality of information in their safety data sheets.

As noted earlier, over 10 000 companies have informed ECHA of the classification of their substance. Some of these classifications are harmonised at EU level, but most are not. And for a significant number of these non-harmonised substances, there are wide differences between the self-classifications provided by companies. It is actually not surprising that there were differences when the list of these classifications was first created – it was the first time that companies had seen the self-classifications of others. But the fact that different classifications still persist over five years later is of concern. It is not at all helpful – not least to downstream users or consumers. However, thanks to the increasing transparency of the data on ECHA's website – notably its prominence in the new 'info cards' and 'brief profiles' of substances – conflicting classifications are easily seen. This will hopefully prompt companies to make improvements.

One remaining test in terms of companies fulfilling their obligations will be the extent to which smaller and inexperienced companies will successfully register low volume substances in the coming years for the registration deadline in 2018. Many still seem to be unaware of their legal obligations and of the practical effort needed to prepare a registration dossier. ECHA, the Member States and the Accredited Stakeholder

³ Substances of very high concern are defined in Article 57 of the REACH Regulation.

Organisations are working together to reach out to as many of these companies as possible and to make sure that the tools and materials to help them are user-friendly and appropriate – for example, by targeting specific industrial sectors like those developing essential oils.

IS THE LEGISLATION BEING ENFORCED?

The enforcement of REACH and CLP is the responsibility of the Member States, who develop their own enforcement strategies based on their national laws. REACH brings the national authorities together in ECHA's Forum for the exchange of information on enforcement. Through the Forum, Member States are developing their joint practice and expertise by doing joint projects focussing on specific sectors and issues.

Whenever a company has not complied with an ECHA decision, the national authorities are asked to enforce them. In around half of those non-compliant cases so far, companies have taken action to put their dossiers in order without the need for an enforcement action, to the satisfaction of the Member State concerned and the Agency. Consequently, enforcement action has only been required in a small proportion of cases to date.

What is clear though is that a further strengthening and aligning of enforcement is necessary. It is important in terms of: ensuring the safe use of chemicals throughout the EU and achieving the objectives of the legislation; ensuring that animal testing is a last resort; that articles containing SVHCs are notified to ECHA; and achieving a 'level playing field' across Europe.

WHAT HAS BEEN THE IMPACT OF REACH AND CLP?

This remains a complex question to answer – even after eight years of operation. The ultimate impact on human health and the environment will only emerge over time. However, the European Commission is undertaking, for the upcoming review of REACH, a number of studies which will provide a better picture of its impact on human health, the environment and the competitiveness of industry.

Of course there are other impacts which are clearer to see already now, like the immediate impact on the safe use of hazardous chemicals in industry; the phasing out of SVHCs and innovation to find safer alternatives; and the drive to use modern test methodologies and reduce the need for testing on vertebrate animals.

IS THE USE OF CHEMICALS GETTING SAFER?

Yes it is, and that effect will increase and become more embedded over time. The data generated by industry and disseminated by ECHA – despite the shortcomings mentioned earlier – is the bed-rock. Knowing the properties of chemicals and tracking them in the supply chain is leading to improved chemicals management and improved product quality. Companies and sectors of industry increasingly acknowledge this.

The information generated by companies on the effects of chemicals on human health and the environment is now freely available to every authority, citizen and company on ECHA's website. Before REACH, not even the public authorities responsible for chemical safety had access to that level of data. And, through the evaluation processes, more data is being generated every day. Armed with that information, companies can ensure the safe use of substances in their supply chains and make sustainable business choices. Authorities can focus their efforts on identifying and addressing the substances of most concern to provide a high level of protection for human health and the environment and, ultimately, consumers can make safer choices.

However, as mentioned earlier, the relatively poor quality of some of the data is limiting its usefulness. In many ways, it is almost delaying the real transfer of the burden of proof which was a driving principle behind REACH. This is because, in these cases of poor quality, the burden of proof remains with the authorities to show that a company has not taken their responsibility under the law to describe their substance and its effects clearly enough.

More specifically, only a small proportion of safety data sheets have adequate exposure scenarios for all the uses made of the substance, meaning that adequate risk management of chemicals in manufacturing companies is made more difficult. The role of downstream users of chemicals is very important here – by demanding better quality, user-friendly safety data, downstream users can play an active role in helping themselves.

Substituting a hazardous chemical - in advance of a legal requirement - is always a business decision and one over which ECHA has little influence. However, there is also evidence that companies are increasingly taking innovative approaches to finding safer alternatives to the most hazardous substances. More can be done to promote this and to help companies, but again, the upward pressure for safer chemicals from downstream users, retailers and consumers should not be underestimated. So, with increased awareness of SVHCs, consumer demand and the drive towards a circular economy, safer solutions will only become more attractive.

That said, REACH enables companies to apply for authorisation to continue to use an SVHC by demonstrating that the risks of the substance can be controlled until a safer alternative can be found. In fact very few such applications had been made until early 2016, when the first significant wave of applications arrived. Companies have so far successfully met the legal requirements to allow authorisations to be granted under specified conditions and for an appropriate period of time. It clearly requires work on the part of the applicant to make a robust case for their continued use of a substance which is destined to be phased out. At the same time, the arguments made by applicants need to be sufficiently clear and strong so as to enable sound decision-making. This is a new process within REACH, and the procedures and best practice are still evolving as all actors become familiar with it.

Of course the law can require companies to take action to protect people and the environment. Apart from the 31 substances placed on the authorisation list, there is now a reduced risk as a result of the 20 restrictions made under REACH. They have clearly led to positive human health and environmental impacts, encouraged substitution and further contributed to creating a level playing field for companies who place chemicals or articles on the market in the EU. Furthermore, many of the over 200 opinions on harmonised classification trigger significant regulatory risk management actions under REACH and a wide range of other occupational, environmental and product legislation.

A significant concern with regard to the safe use of chemicals by consumers is their exposure to SVHCs in articles – notably those imported into the EU. Companies are required to inform ECHA of such substances in articles, but the number of notifications remains worryingly low. The European Commission recently noted⁴ that the biggest reason for ‘unsafe product alerts’ through the RAPEX system was because of dangerous chemicals. Importers need to take their responsibilities seriously – they are responsible for knowing what they are importing into the EU, what the effects of their products could be on consumers and for notifying ECHA. This, together with the consumer’s right to ask about SVHCs in products they buy, is the most important direct benefit for the citizens of the EU. But these mechanisms are not working well. Additional awareness-raising amongst importers, and ultimately stronger enforcement are the keys to making this happen.

IS INNOVATION FLOURISHING?

Innovation is certainly taking place, but there is room for more. Since REACH has been in force almost 1 500 new substances have been created with an increasing annual trend. Also SVHCs are clearly being phased out and replaced by safer alternatives, often as a result of innovative thinking and developments. This is evident from the relatively low number of applications for authorisation to use them.

4 Annual RAPEX reports here: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/index_en.htm

To encourage further research and development, REACH has built-in safeguards to ensure that chemicals can benefit from reduced requirements – the so called ‘PPORD exemption’⁵. This has been widely used, mainly by larger companies, over the last five years.

IS UNNECESSARY VERTEBRATE ANIMAL TESTING AVOIDED?

Yes, but more can still be done. The basic responsibility for avoiding unnecessary testing on animals lies with individual companies. REACH requires them to share data as part of the process of registering their chemicals and – concerns about fair cost-sharing aside – this works well. Companies also make extensive use of alternatives to testing on animals, such as reading-across from similar chemicals and gathering a weight of evidence to justify their arguments. Unfortunately, this is often poorly justified and documented and can ultimately result in the need to do tests after all. ECHA, the Member States and Accredited Stakeholder Organisations can still do more to help companies to better understand the available alternative tests and approaches and how to make their case more effectively.

On the other hand, where companies propose a test on animals, they need to explain why and to describe the alternatives they have considered. This will also help to improve the information provided in response to public consultations that are designed to gather information to help avoid testing on animals.

However, the wider issue remains that accepted non-animal alternative approaches and tests do not exist for all the endpoints required under REACH. Greater investment of time and money into the identification, development and especially the regulatory acceptance of alternatives would be extremely welcome to all.

WHAT NEEDS TO CHANGE?

On balance, the Agency does not see the urgent need to revise the REACH Regulation. The system as described by the law is fundamentally working and, where improvements need to be made as mentioned above and in the body of this report, they can mostly be done in other ways. Nevertheless, should the European Commission chose to amend the legislation, ECHA can suggest a number of changes to smooth or improve its clarity and effectiveness. The biggest issues are mentioned here.

First of all, the quality of the data (and safety data sheets) on chemicals needs to be improved and updated whenever there is a material change or where new information comes to light. REACH requires companies to do this already, but it is not being done consistently enough. As noted earlier, this is the most significant barrier to be overcome in terms of reaching the objectives of the legislation. It also leads to wasted time and inefficiencies in Member States, the European Commission, ECHA and in companies themselves. So the change needed on the one hand is attitudinal or behavioural on the part of companies, and on the other hand it is for the European Commission to consider the need for implementing legislation to further specify these ongoing obligations.

Secondly, the coverage of nano forms of substances in registration dossiers must improve. Some companies are holding back on providing nano data because there are no explicit information requirements in REACH. But it is only a matter of time before these come, and waiting for that to happen, or resisting requests for information until there is legal clarity, is not helpful. It results in lost time and wasted energy for all involved and may affect human health and the environment. Whilst we await clear information requirements from the European Commission, a constructive approach by industry to providing data on nanos would be welcomed.

Thirdly, the contradictory self-classifications in the classification and labelling inventory need to be resolved. ECHA recommends a change in the CLP legislation to oblige notifiers and registrants to share data and to resolve any unjustified differences.

⁵ Product and process-orientated research and development, see Article 9 of the REACH Regulation.

Fourthly, EU citizens need to have more reliable information on SVHCs in the products they buy. The current legal requirement for information on substances in articles is not working well enough. A fundamental review of these obligations would be helpful and could usefully form part of work on the circular economy and the drive towards a non-toxic environment.

Finally, the interface between REACH and CLP and other pieces of legislation should be optimised – further clarifying the interface where necessary and making more use of the data generated for REACH and CLP to comply with other pieces of EU chemical legislation, thus reducing unnecessary burdens on businesses and providing more clarity and consistency for the consumer. Moreover, when reviewing other EU chemical legislation or introducing new legislation – in line with the Commission's drive for better regulation – the synergies with REACH and CLP should be further explored.

IS THE JOURNEY OVER?

Absolutely not. There are a variety of goals ahead as we work towards the safer use of chemicals and a toxic free environment – 2018 and 2020 are two such. There are also the 2030 world sustainability goals on chemicals that set the direction for further action. But this is a journey whose finishing line stretches much further into the future.

The next step in the journey is the complete, unique picture of chemicals in Europe that we will all have after the 2018 deadline. That information – also on chemicals made in small quantities – will surely reveal further candidates for risk management, as well as safer alternatives for industry to consider.

At the most fundamental level, the materials industry is a dynamic sector, in which new substances are developed and old ones phased out on a regular basis. That implies the need for new chemicals to be registered and their effects described, for the foreseeable future.

At a scientific and analytical level, testing and assessment methods and scientific understanding of the ways in which chemicals affect humans and environment are developing apace. That will presumably never end. Meaning that, as understanding grows, assessments of the need to manage the risks of substances may change.

And at a societal level, change is guaranteed. The health, environmental, economic and resource pressures are leading decision makers to explore ever safer and more efficient ways of maintaining or improving our lives. The European Commission's thinking on the circular economy and the non-toxic environment are examples of that.

The good news is that increasingly, we are all on this journey together. REACH was instrumental in bringing that about and as demonstrated in this report, together, we are making good progress.

List of Commitments and recommendations

RECOMMENDATIONS:

- R1. The last registration deadline of phase-in substances in 2018 will be the most challenging to manage due to the number of registration dossiers expected, and the less experienced companies registering. It is important that sufficient resources are allocated at the Member State level to provide adequate support, especially for SMEs.
- R2. The Commission and industry associations should work together with ECHA to ensure that the rules and mechanism concerning joint registration and data-sharing to support the cooperation among co-registrants are sustained after the last deadline, when the SIEFs formally cease to operate. This is important to avoid any uncertainty among potential registrants, especially for phase-in substances, as it can be anticipated that phase-in substances will continue to be manufactured or brought to the EU market in high volumes and by a variable number of new actors. These registrants need a reliable way to contact the existing registrants to access joint submissions so that the data- and cost-sharing obligations of REACH can be fulfilled. In addition, registration dossiers will need to continue to be updated and co-registrants must be able to react to regulatory actions.
- R3. Industry must take actions to improve the quality of the registration information so that authorities can make informed decisions on whether risk management actions are needed at the EU level. Companies should critically review their existing registrations and take the opportunity of the improved IUCLID 6 format for updating their dossiers, especially substance identity, use, exposure information and justifications for adaptations to information requirements and alternative methods. This may also benefit companies since with better and more transparent information, their substance may be deprioritised from regulatory actions.
- R4. Stronger incentives are needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. An implementing regulation could be considered to ensure mandatory reporting of use and exposure information on a regular basis. In this context clarification of the criteria triggering an update, including a binding timeframe for regular updates should be discussed.
- R5. ECHA considers that amendments of the REACH annexes for information requirements are urgently needed to ensure that sufficient clarity is given to registrants for their registrations of substances with nanoforms and so that their safety can be better assessed.
- R6. ECHA encourages the Commission in the foreseen review of REACH to consider reviewing the information requirements for substances classified as CMRs or other substances of concern in the 1-10 tonnage band. In addition, further consideration should be given to including polymers within the scope of REACH registration.
- R7. 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.
- R8. Member States are encouraged to assist SMEs by providing financial support to them to meet their REACH obligations that is consistent with EU legislation on de minimis aid. The Commission should consider simplifying the Commission Recommendation (2003/361/EC) of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, as it is currently considered too complicated

in the way it includes the enterprise's relationships with other enterprises through control or ownership definitions.

- R9. The Commission, Member States and ECHA should jointly raise awareness to industry managers of the need to keep a sufficient level of regulatory resources, as it is expected that a steady flow of updates will be submitted due to improved and updated information.
- R10. Registrants are urged to proactively improve their dossiers, especially in the areas where deficiencies have been regularly reported by ECHA in its annual evaluation reports and other communications. This also applies to substances, which authorities have identified as candidates for compliance check or other regulatory action. Sectoral and other industry associations should take a leading role in helping their members in this respect. ECHA welcomes a dialogue with industry sectors, which are committed to proactively improve the quality of their registrations to better distinguish between substances of concern and of low priority.
- R11. Registrants should document better and in a more harmonised way their considerations on alternatives before proposing new animal tests in their registration dossiers. Registrants and contract laboratory organisations and consultants advising registrants should keep themselves fully updated on the development and regulatory acceptance of alternatives.
- R12. MSCAs are invited to work more closely with ECHA to allow ECHA to take over the finalisation of substance evaluation decisions and thereby ensure consistency of ECHA decisions.
- R13. MSCAs should strengthen the enforcement of the animal testing related provisions of REACH and other legislation. ECHA is committed to continue facilitating such national enforcement actions by informing national authorities of cases it has identified meriting further examination by them and encouraging exchange of information and best practices through the Forum.
- R14. The Commission should accelerate the inclusion of new alternative test methods and integrated testing strategies in the REACH annexes to avoid unnecessary animal testing. The Commission should also consider provisions for obligatory data-sharing between analogue substances for read-across and category purposes.
- R15. ECHA invites the Commission to consider whether to alter⁶ the percentage of compliance checks required on the dossiers in the two highest tonnage bands and to adjust the percentage required on the dossiers in the lower tonnage band after 2018.
- R16. 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.
- R17. Industry organisations are invited to continue the cooperation with ECHA to exemplify and systematically describe how downstream users can benefit from harmonised and practically useful information communicated down the supply chain. This includes in particular exploring/building the practical interfaces between:
- Information becoming available under REACH (exposure scenarios);
 - Information needs to fulfil company duties under other legislation addressing chemicals; and
 - Information needs for product safety/product stewardship systems.

⁶ According to REACH Regulation (EC) No 1907/2006, Article 41(7)).

- R18. Industry organisations should actively engage in facilitating dialogue along supply chains. The traditional horizontal organisation in sector groups and 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.
- R19. The authorities should improve the interaction at an operational level between REACH and other legislation addressing chemicals, e.g. the Industrial Emissions Directive, the Chemical Agents Directive and waste⁷ legislation and to strengthen the potential links with company quality and environmental, health and safety management systems.
- R20. Exposure assessment tool owners and relevant industry organisations should foresee resources for the maintenance and evolution of IT tools to facilitate chemical safety assessments 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.
- R21. National Enforcement Authorities should target the availability of exposure scenarios in the supply chain to activate the self-regulating mechanisms foreseen under REACH at all levels of industry and commerce.
- R22. The Commission, in consultation with the Agency and Member States is invited to consider how to strengthen supply chain communication. One possibility is to examine ways to check the contents of eSDS to ensure they contain all the necessary and relevant information.
- R23. Industry should improve the information on uses and volumes in their registration dossiers and keep these up-to-date. Without adequate information, authorities are not able to focus their regulatory interventions where these are needed to ensure safe use.
- R24. The Commission should consider whether the ECHA expert groups to support the assessment of PBT and ED properties of substances could also be used for other legislation.
- R25. The information requirements and testing strategies for endocrine disrupting substances should be reviewed to allow for their effective identification.
- R26. MSCAs should make full use of the common screening approach to select substances for further information generation and assessment or directly for the SVHC process.
- R27. NGO stakeholders and third parties providing alternatives are invited to advise ECHA about how the information provided in the public consultation could provide better information on alternatives.
- R28. 'Upstream' applicants should prepare their analysis of alternatives in very close cooperation with downstream users. This would allow an improved description of the uses applied for and 'fit-for-purpose' applications. ECHA is committed to providing further clarifications on the nature and quality of the information that is expected so that it is clear when an application does not conform with the requirements of the REACH Regulation.
- R29. Future applicants should increase their capacity to carry out the analysis of alternatives and SEA. This could be done either by increasing the internal capacity or by using outside expertise. As SEA is closely linked to the technical and economic feasibility of alternatives, it is recommended that such tasks are

⁷ In particular product design, re-use and recycling as elements in a circular economy.

carried out by the same analysts. ECHA is committed to help increase the capability of applicants and their service providers to carry out analysis of alternatives so that they become more pertinent for instance, through the Network of REACH SEA and Analysis of Alternatives Practitioners.

- R30. The Commission is invited to provide further transparency on the follow up of those substances recommended by ECHA for inclusion in the Authorisation List, but not finally included.
- R31. Member States and the Commission are invited to assist ECHA to better understand why the development of restriction proposals is still seen as burdensome and to examine possible further actions to increase the number of suitable candidates for restrictions. ECHA's role in this will be to improve the screening process with regard to restrictions and to further increase the capacity of Member States and ECHA itself to prepare restriction proposals. Any further recommendations for improving the restrictions process should be implemented in consultation with the members of the RETF, when relevant.
- R32. Member States should increase their capacity to carry out the analysis of alternatives and SEA. This could be done either by increasing their internal capability or by using outside expertise. ECHA is committed to facilitating this capacity building. The Network of REACH SEA and Analysis of Alternatives Practitioners will be developed further for this purpose.
- R33. The Commission and Member States are invited to discuss and conclude on a) having restrictions with a wider scope (in terms of the number of substances or activities covered) and b) the key evidence needed to justify a restriction (e.g. hazard, exposure information).
- R34. The Commission is invited to assist ECHA to explore how the obligations for SVHCs would be implemented efficiently under Article 69(2). This also includes situations where it is clear that the SVHC is no longer used in articles and could easily be restricted.
- R35. MSCAs should make full use of the common screening approach to select substances for the CLH process and ensure that the need for CLH is followed up rapidly. This integration of the CLH and REACH processes will increase the number of harmonised classifications of industrial chemicals and the regulatory impact of the CLH.
- R36. The Commission is asked to reflect on whether ECHA's resources should be used to assist Member States to develop CLH proposals for high priority industrial chemicals.
- R37. The Commission services responsible for CLP, Plant Protection Products and the Biocidal Products Regulations should work together with EFSA and ECHA to encourage and support the MSCAs in preparing the CLH dossiers for pesticides and biocides. MSCAs, ECHA and EFSA should further align their processes and tools used for CLH, for the PPP and for the BPR active substance approval processes. MSCAs should more systematically submit CLH dossiers for PPPs that need a (revised) harmonised classification.
- R38. Notifiers and registrants must improve the convergence of their self-classifications of notified substances. All actors (industry associations, MSCAs, NEAs, the Commission and ECHA) should jointly examine ways to raise awareness of the CLP obligations and support industry in reaching agreement on the (self-)classifications. The Commission should consider changing the CLP Regulation to allow the sharing of contact details of notifiers and registrants and to make notifications time-limited.
- R39. ECHA, the MSCAs, the Commission, sector organisations and NGOs should jointly carry out further awareness-raising among importers and producers of articles on the benefits of making informed

choices about substances in articles and on the obligations of importers and producers related to substances in articles.

- R40. ECHA, the Commission and the MSCAs should increase the cooperation with third countries to improve the information flow in supply chains to identify, and where needed, take action on substances of high concern. This could include cooperation in the OECD and UNEP, as well as with exporters to the EU (e.g. China, India) and other importer countries (e.g. Canada).
- R41. Importers and EU producers of articles should improve their knowledge on the substances present in their articles to provide adequate safe use advice to their customers and promote substitution. To this end: a) importers of articles should develop more effective means to communicate in the supply chains outside the EU, b) registrants under REACH should ensure that their CSRs and extended ESs cover the assessment of the service-life of articles, c) industry, MSCAs and ECHA should further develop exposure assessment methods for the service-life and waste stage of articles, and d) The Commission is invited to fundamentally review the current legislative requirements for information on substances in articles and this could usefully form part of work on the circular economy and the drive towards a non-toxic environment.
- R42. All actors involved with substances in articles should become active and allocate more resources for real progress to be achieved in this field. Increased enforcement efforts could activate companies to improve their knowledge on substances in articles and, where relevant, take action to ensure safe use or look for safer alternatives.
- R43. EU and national legislators should make use of the data management capabilities developed in the Agency for supporting other regulations or legislative initiatives on chemicals at EU level for the benefit of industry, citizens, and national authorities.
- R44. The Commission should explore how REACH and CLP information could be used by authorities worldwide and potentially accepted under other jurisdictions to document the safe use of chemicals. This could be linked to the on-going harmonisation work of tools, formats, test methods and information requirements taking place at the OECD level. This would reduce costs for industry and make the assessment of chemicals globally more efficient.
- R45. Member States need to maintain continued support for the work of the ECHA Committees. This will ensure that the core processes of REACH and CLP will continue to deliver and provide independent and fit-for-purpose scientific advice for ECHA and the Commission. The demands of the work as an active Committee member needs to be acknowledged and respected.
- R46. Authorities and stakeholders should continue their dialogue to achieve a better common understanding of the role of SEAC and SEA in REACH.
- R47. To achieve a fair level-playing field throughout the single market, all Member States should take part in all REF projects as well as consistently enforcing ECHA and Commission decisions in their territory.
- R48. The Commission is recommended to review the provisions of Article 8 of the REACH Regulation regarding only representatives. This follows practical shortcomings identified in implementing Article 8 of the REACH Regulation.
- R49. National helpdesks should continue to collaborate closely with national and sector industry associations to spread knowledge, particularly to SMEs, on their obligations under REACH and CLP.

This should be carried out in cooperation with their counterpart EEN advisors in their respective countries.

- R50. Member States need to maintain continued support and resources for the work of national helpdesks and for providing advice and technical guidance, in particular to SMEs. The demands of the work of the helpdesks and the HelpNet need to be fully acknowledged and respected. This is not only important in the run-up to the 2018 REACH registration deadline, but will continue to be essential afterwards.
- R51. Industry associations should support their sectors by providing sector-specific advice where appropriate and by spreading information provided by ECHA and other actors to their members. The communications means that industry associations have at their disposal (newsletters, seminars, etc.), are essential to multiply the support provided by ECHA.
- R52. The Commission is recommended in the forthcoming review of the BoA's Rules of Procedure to consider how: a) to effectively safeguard the efficiency of the appeal proceedings before the BoA and so that the BoA can continue to adopt high-quality decisions within a reasonable time, and b) to allow the BoA to continue to assert its independence from the ECHA secretariat and its stakeholders to ensure that the appeal proceedings continue to be fair and impartial.
- R53. ECHA needs to be guaranteed stable financing for its operations, combined with a capacity to develop new income streams for instance by demanding charges based on real costs for additional services provided to industry.
- R54. The Commission needs to ensure that ECHA is allocated the necessary human resources to fulfil its mandate appropriately under each of the different regulations it is responsible for.
- R55. ECHA's human resource competences should be taken into account when planning for the future of the Agency to create increased synergies and efficiencies.
- R56. The Commission is invited to maintain the current level of financial investment and adequate staffing levels in ECHA's IT tools and services to support ECHA's processes.

COMMITMENTS:

- C1. To give companies certainty on the requirements and to allow adequate time for preparation of the registrations, ECHA is committed to the extent possible to a self-imposed moratorium on publishing new guidance two years ahead of the last deadline. The new generation of IT tools for registration, to be released in mid-2016 will allow companies to start preparing and submitting their dossiers well in advance of the deadline.
- C2. ECHA will continue to stimulate updates to improve the dossier quality through targeted actions, voluntary updating negotiated with specific subsectors and campaigns, as these measures allow for large numbers of dossiers to be scrutinised.
- C3. ECHA will further adapt its practices, enhance its support services and IT tools to simplify the registration process and reduce the burden for companies.
- C4. In advance of the 2018 deadline, ECHA will raise awareness by using multipliers such as the REACH 2018 Communicators' Network and HelpNet. The Commission, MSCAs and industry associations are invited to join ECHA to make every effort to raise awareness of the last registration deadline and act as multipliers for their audiences.

- C5. ECHA will continue to raise awareness of the benefits for innovation of the PPORD exemption over the next years, especially for SMEs.
- C6. In 2016, ECHA will complement the automated completeness check with a manual verification to determine if registrations are incomplete. The Agency will reject the registration, unless a completed dossier is provided within a reasonable time. In addition, ECHA will check registrations submitted (retroactively and in the future) outside of a joint submission and companies will be requested to resubmit their dossier as part of the joint registration. Companies that do not respect the 'one substance, one registration' principle will not receive a registration number or their registration will lose its validity.
- C7. ECHA will continue checking compliance of dossiers of priority substances registered in the highest tonnage bands in line with the regulatory strategy and with the aim of maximising the impact of compliance check on the safe use of chemicals. Furthermore, it will ensure that the evaluation of dossiers and the updates responding to ECHA decisions more readily feed into the other REACH and CLP processes.
- C8. ECHA will promote methods, tools and approaches that are alternatives to vertebrate animal testing and is committed to ensuring that animal testing is only requested when necessary in its own decisions.
- C9. To ensure that increasing workloads can be managed effectively, ECHA will continue improving the effectiveness and efficiency of the dossier evaluation process by reviewing and revising the process and the tools used, streamlining the content and focus of the decisions, and by further improving collaboration with the MSCAs and the MSC.
- C10. ECHA is committed to exploring, together with industry stakeholders, what constitutes a good quality dossier and thereby exemplifying what ECHA regards as sufficient information. Such acknowledgement could also be designed to promote business benefits of preparing compliant dossiers and keeping them up-to-date.
- C11. ECHA will continue its efforts to implement REACH and CLP for nanomaterials. This will include, for example, continued dossier and substance evaluation, guidance development, technical discussions at the OECD and with relevant research projects to work towards further clarifying the technical implementation of the legislation.
- C12. ECHA will - through tools, guidance and the ENES platform - continue to support stakeholders in setting up efficient and effective communication on conditions of use up and down the supply chain with a view to the sectors becoming gradually self-sufficient.
- C13. The common screening approach has laid a foundation for the efficient and effective identification of candidate substances for further information generation. ECHA together with the Member States will ensure that the information generated is used to conclude on the concern and the Member States working with ECHA should further enhance the integration of the CCH and SEv processes with risk management processes to ensure that the objectives of the SVHC Roadmap will be reached. To optimise the management of substances of potential concern and avoid delaying potential further regulatory actions, the MSCAs and ECHA should a) target the generation of further information to aspects necessary for regulatory risk management and b) together with the Commission, reflect on ways to streamline the overall timeframe for REACH processes to work together to ensure that identified regulatory measures are initiated in a timely manner.

- C14. ECHA will continue to invite feedback and suggestions for improvement from its stakeholders to improve the authorisation process. ECHA is committed to further increasing the relevance of the information collected in public consultations and maintain a transparent and trustworthy process.
- C15. ECHA is committed, in close cooperation with the Commission, to carry out further methodological development to establish reference values for health endpoints, quality or disability adjusted life years and, in particular, for the cost of illness.
- C16. As with the previous deadlines, ECHA will provide a dedicated telephone service for registrants in the immediate run-up to the 2018 deadline.
- C17. ECHA will continue to maintain a its focus on efficiency to ensure higher regulatory output per staff members employed and on initiatives to ensure that the Agency can attract, motivate and retain sufficiently qualified and experienced staff.
- C18. ECHA will continue to optimise and automate its IT tools and services to ensure it maximises the cost effectiveness of the investments made.

List of terms

BoA	ECHA Board of Appeal
Ca.	Circa (approximately)
CCH	Compliance check
C & L	Classification and labelling
Chesar	Chemical Safety Assessment and Reporting tool
CL	Candidate List
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic or toxic to reproduction
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DCG	Directors' Contact Group
DEv	Dossier evaluation
DSD	Dangerous Substances Directive
DU	Downstream user
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EOGRTS	Extended one-generation reprotoxicity studies
EINECS	European Inventory of Existing Commercial Chemical Substances
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
FAQ	Frequently asked questions
Forum	The Forum for Exchange of Information on Enforcement
GHS	Globally harmonised system of classification and labelling of chemicals
HelpNet	REACH and CLP Helpdesk Network
HR	Human resources
IT	Information technology
IUCLID	International Uniform Chemical Information Database
MSC	The Member State Committee
MSCA	Member State Competent Authority
NEA	National Enforcement Authority
NeRSAP	The Network of REACH SEA and Analysis of Alternatives Platform
NGO	Non-governmental organisation

OECD	Organisation for Economic Cooperation and Development
OR	Only representative
OSH	Occupation, safety and health
PBT	Persistent, bioaccumulative and toxic
PORD	Process-oriented research and development (in the DSD)
PPORD	Product and process-oriented research and development
(Q)SAR	(Quantitative) structure-activity relationship
RAAF	Read-across assessment framework
RAC	The Committee for Risk Assessment
REACH	Registration, evaluation, authorisation and restriction of chemicals
REACH-IT	The central IT system providing support for REACH
REF	REACH-EN-FORCE
RETF	Restriction Efficiency Task Force
RiME	Risk management experts
RIPE	REACH Information Portal for Enforcement
RMOA	Risk management option analysis
RS	Respiratory sensitiser
(e)SDS	(Extended) safety data sheet
SEAC	The Committee for Socio-Economic Analysis
SEv	Substance evaluation
SIEF	Substance information exchange forum
SIP	Substance identity profile
SME	Small and medium-sized enterprises
SVHC	Substance of very high concern
TP	Testing proposal
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
WSSD	World Summit on Sustainable Development.

List of legislation

Biocidal Products Regulation (BPR)	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
Chemical Agents Directive (CAD)	Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
Dangerous Substances Directive (DSD)	Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
Classification, Labelling and Packaging Regulation (CLP)	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
Industrial Emissions Directive (IED)	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
Prior Informed Consent Regulation (PIC)	Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals

1. Operations

TOWARDS AN INTEGRATED REGULATORY STRATEGY TO ACHIEVE THE MAXIMUM IMPACT FOR THE PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

THE EARLY YEARS: SETTING UP CORE PROCESSES FOR REACH AND CLP

The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH is also designed to promote the development of alternatives to vertebrate animal testing for assessing the hazards of substances. REACH shifts the burden of proof onto industry for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. At the same time, where needed, the European Union can take additional regulatory risk management measures on the most hazardous substances.

In its initial years, ECHA focused on setting up the core processes for REACH and CLP, namely:

1. Registration

Companies are required to document all the information on the substance they manufacture or import in a registration dossier and submit it to ECHA. ECHA manages the registration process through its support to companies, facilitation of data-sharing and arbitration of data-sharing disputes. ECHA verifies the completeness of registration information before assigning a registration number.

2. Evaluation

ECHA and the Member States evaluate the information submitted by companies to examine the compliance of the registration dossiers (compliance check, to verify whether information requirements under the REACH Regulation are met) and the proposals to test on vertebrate animals and, under substance evaluation, to clarify if a given substance constitutes a risk to human health or the environment. After evaluation, registrants may be required to submit further information on the substance.

3. Classification and labelling

The CLP Regulation establishes the rules for the classification, labelling and packaging of chemicals. It aims to determine whether a substance or mixture has properties that lead to a classification as hazardous and manages proposals for the harmonised classification of chemicals.

4. Authorisation

The authorisation procedure aims to ensure that the risks from substances of very high concern (SVHCs) are adequately controlled and that these substances are progressively replaced by suitable alternatives, while maintaining the functioning of the EU's internal market. After being placed on the Candidate List, SVHCs may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

5. Restrictions

Restrictions are designed to manage unacceptable risks to humans or the environment. They limit or ban the manufacture, placing on the market or use of certain substances within the EU.

COMBINING THE REACH AND CLP PROCESSES INTO AN INTEGRATED REGULATORY STRATEGY

Based on the first years of experience in implementing these regulatory processes, ECHA developed an integrated regulatory strategy which coherently brings all the processes together to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development⁸.

Together with the Member States, ECHA developed a common screening process, which identifies substances that have the greatest potential for negative impact on human health and the environment. The common screening allows a conclusion to be reached on which substances need further compliance check and/or substance evaluation and which substances can be directly earmarked for EU risk management measures.

Under the compliance check process, priority is given to full registrations of chemicals produced in volumes over 100 tonnes per year, and with potential concern that may require substance evaluation or risk management measures. The main focus is on the higher tier (Annex IX and X) human health and environment endpoints which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB ((very) persistent, bioaccumulative and toxic) substances.

If the concern is confirmed in the evaluation, a risk management option analysis (RMOA) process will usually follow, firstly to confirm if risk management processes need to be initiated, and secondly, to check which process is the most suitable. Substances which are concluded to be of no, or low concern are also tracked.

ECHA's ambition is by the end of 2018, to gradually map the 'universe of registered substances' above 100 tonnes through a number of actions. These actions are intended to reduce the pool of substances of potential concern and conclude for as many substances as possible the need for specific action or that they are currently of low priority for further work.

The work is being carried out in collaboration with industry sectors, and companies can proactively contribute by updating their dossiers when informed of the results of the common screening and by providing better use and exposure information. This level of coordination will also be instrumental in making sure that all relevant currently known SVHCs are on the Candidate List by 2020 with the best risk management options identified as provided by the SVHC Roadmap.

Integrating REACH and CLP processes is critical as the impact of different regulatory instruments is often only felt after a certain time. For example, it may take a number of years to identify a substance of concern and then apply a risk management process to it.

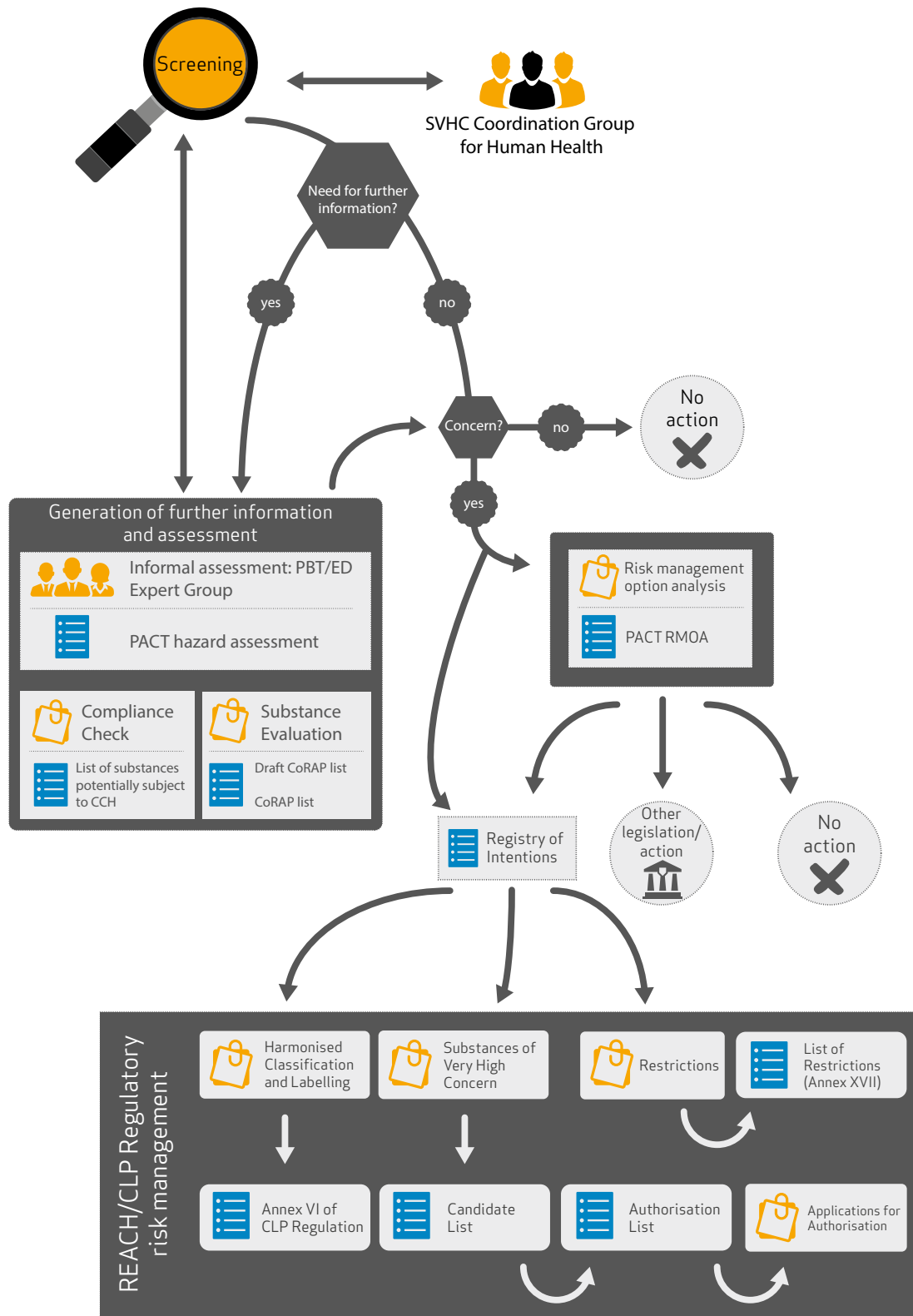
Indeed, information requests generated through a compliance check and/or substance evaluation process may take an additional two to four years before this information has been generated. When subsequent RMOA is carried out and a risk management process is put in place, this could take a further two to four years. This intrinsic time lag can be minimised by ensuring optimal interaction between the various processes (e.g. by running some of them in parallel, reducing the gaps between running each process, or by moving directly to a policy action when justified) and follow-up actions which may be needed by all actors.

⁸ Outcome of the World Summit on Sustainable Development, Johannesburg 2002: http://www.unesco.org/education/tlsf/mods/theme_a/img/02_WSSDOutcomes.pdf

In brief, the integrated strategy ultimately aims to achieve the following impact:

- Providing confidence amongst stakeholders and the public that registrants meet REACH and CLP information requirements, this is followed up by improved communication on safe use in the supply chain;
- Efficiently selecting substances that raise potential concern, generating standard or equivalent information for assessing their safety through a compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable risk management regulatory instrument;
- Improving 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; and
- Ensuring 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.

Figure 1. A schematic overview of the integrated regulatory strategy



- Information on regulatory processes and activities
- Substance lists

1.1 REACH DOSSIER MANAGEMENT AND ASSESSMENT

1.1.1 Registration dossier preparation

THE OBJECTIVES OF THE LEGISLATION

REACH aims to ensure that industry takes responsibility to identify the hazard and uses of a substance and to show that the substance can be used safely. This is achieved by collecting existing data and/or generating new information on substances. The information and the conclusions are documented in the registration dossier which is submitted to the Agency.

Companies registering the same substance are expected to share data and jointly prepare one registration for one substance to avoid unnecessary animal testing and reduce costs.

By the third registration deadline in 2018, the lack of knowledge on properties and uses of existing substances that prevailed before the introduction of the REACH legislation will be closed as the remaining existing substances (the so-called 'phase-in substances') will be registered. The last deadline concerns substances produced or imported in relatively low volumes (1-100 tonnes per year), such as speciality chemicals.

IMPACT OF THE OPERATIONS

REACH & CLP have significantly increased the knowledge about chemicals

By fulfilling their registration obligations, companies have increased the availability of data on chemicals and the knowledge of their chemical portfolios, especially with regard to phase-in substances. Therefore, companies are now in a better position to implement risk management measures at their own work place and provide safety advice to their customers down the supply chain. As a result of the experience and knowledge gained through REACH implementation, both registrants and downstream users have indicated they are better equipped to bring new products and services to the market.

REACH has increased the knowledge of chemicals

'Beyond the authorisation and restriction mechanisms and the pressure on substituting hazardous chemicals, the [REACH] Regulation has enhanced the knowledge of the companies on the properties of the chemicals used: 68 % reported that the Regulation had a positive or very positive impact on the knowledge in relation to the content of chemical substances, their properties and their possible uses. Moreover, around 23 % of the respondents (of which around 34 % were formulators) have indicated they have launched and commercialised products/services as a result of the experience and knowledge gained through compliance with the Regulation.'

European Commission (2015) Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, Final Report, p. 78.

This information on chemicals, especially on existing chemicals, collected for REACH and CLP (see Chapter 1.2.4.) into one central database is now available for the scrutiny of the EU Authorities for assessing whether further EU-wide regulatory measures are needed (see Figure 44 in Chapter 1.3 for increased demand for information held by ECHA).

The knowledge and capacity created through the implementation of REACH information requirements also contributes to the EU's international activities, especially through the OECD. Based upon the information received in registration dossiers and by analysing its regulatory usefulness, ECHA has put forward initiatives at the OECD level for further harmonisation of reporting formats e.g. use and exposure templates, guidance, the identification of oleochemicals or hydrocarbon solvents and testing of nanomaterials.

This international harmonisation will benefit industry by reducing their workload as the information requirements, reporting formats and tools converge globally over time.

REACH knowledge contributes to the EU's international activities

'The implementation of REACH has uncovered many issues relevant for chemical safety experts worldwide and has triggered many collaborative projects at the OECD, led by ECHA or the European Commission. For example, the increased need for non-testing methods has led to impressive collaborative development and exchange of novel tools and data (e.g. on skin sensitisation) that have found their way into the OECD QSAR ((quantitative) structure-activity relationship) Toolbox, thereby making it the worldwide reference tool for data-gap filling. Furthermore, the almost explosive increase of exchange of information between stakeholders has triggered new projects for standardising the way data is captured and stored, including data from novel *in vitro* methods measuring key events along adverse outcome pathways.'

Bob Diderich, Head of Environment, Health and Safety Division, OECD.

The overall success of the phase-in scheme will depend on the last deadline in 2018 where inexperienced and small and medium-sized enterprise (SME) registrants need specific support for dossier preparation

The first two deadlines for phase-in substances took place in 2010 and 2013, and they delivered what was expected, in terms of both the number of registration dossiers and substances registered (see Chapter 1.1.2 for details).

However, for the last deadline in 2018 there will be an estimated 60 000 new registration dossiers, many from SMEs and for substances for which less data is available than for the previous two deadlines. Consequently, a lot of information may need to be generated to fill data gaps. As this is the last deadline for registering phase-in substances, companies can also not postpone their registration decisions by lowering their production volumes. Consequently, the success of the whole phase-in regime for existing chemicals depends on managing the last deadline efficiently.

To ensure that all diligent companies can register by the 2018 deadline, ECHA has reviewed the lessons learnt from the previous two deadlines. This has been done in cooperation with our stakeholders and plans have been put in place in ECHA's REACH 2018 Roadmap⁹, published in January 2015. The roadmap has been drawn up with particular emphasis on the needs of SMEs. It documents ECHA's plans to improve the IT tools for registration, to enhance readability and access to support documents and to produce new, SME-friendly material on how to comply with the registration obligations.

To give companies certainty on the requirements and to allow adequate time for preparation of the registrations, ECHA is committed to the extent possible to a self-imposed moratorium on publishing new guidance, two years ahead of the 2018 deadline.

The new generation of IT tools for registration have been released in 2016, which will allow companies to start preparing and submitting their dossiers well in advance of the deadline.

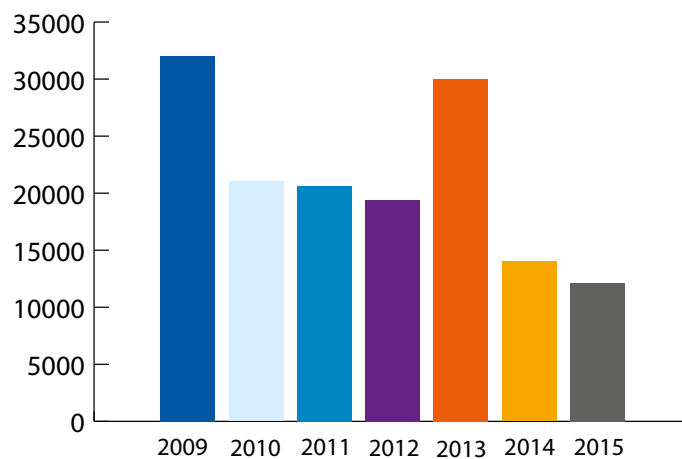
⁹ ECHA (2015) REACH 2018 Roadmap: http://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf

Industry is applying the REACH principles of data-sharing, but SMEs are facing difficulties in substance information exchange forums (SIEFs)

REACH data-sharing provisions have been effective in achieving the dual objectives of avoiding unnecessary testing on animals and reducing aggregate costs of registration. In general, companies appear to share data and prepare their registrations jointly as foreseen in REACH. For new substances or phase-in substances that are new on the EU market, companies are put in contact with existing registrants either through the inquiry process or through 'late' pre-registration.

Late pre-registrations and signing up to SIEFs is continuously at a high level: on average over 19 000 late pre-registrations per year occurred over the period 2011-2015 (see Figure 2), although there has been a decreasing trend since the 2013 deadline.

Figure 2. Pre-registrations received post 2008 deadline ('late' pre-registrations)



The SIEF activities developed by industry around the 2010 deadline seem to have continued to work relatively well for the second deadline in 2013. This was possibly due to similar size companies in both registration periods, where SMEs did not play a major role. This observation is also reflected in the fact that the number of data-sharing disputes remained low even before the 2013 deadline (see Chapter 1.1.2). However, this does not imply a smooth operation of all SIEFs for all actors. For example, SMEs have consistently indicated the need to make data-sharing fair, transparent and non-discriminatory.

The challenges of SIEFs

For the 2010 registration deadline:

'SIEFs present specific additional challenges for SMEs who have fewer resources and, hence, are more vulnerable to unequal treatment and language barriers. Moreover, SMEs generally cannot invest as much time in REACH-related work as bigger companies, which has, in certain cases, had an impact on the functioning of SIEFs'

European Commission (2013) *General Report on REACH*¹⁰

'[T]here is a substantial change in communication within the SIEFs from two years ago. It is not like in 2010 registration, when we had a couple of big companies with enough people to work on REACH inside the company itself. Smaller companies usually have to outsource this work. It is not profitable to train people internally if you have to register only a couple of substances'. He explains that 'usually the lead registrants call on an external consultant and the companies that are members also call on consultants. The dialogue is between the consultants themselves and not between companies, so it is an indirect communication. Moreover, different consultants have different approaches on how to make the gap analysis. This makes it very hard to manage the consortium.'

ECHA Newsletter 5/2012 (article based on interview of Mr. Mariano Alessio Verni from SILC Fertilizzanti Srl, the co-ordinator of the Potassium Phosphites Consortium)

Automated screening methods help registrants to check their dossiers ahead of dossier submission

ECHA's automated screening as well as external studies¹¹ have indicated that there are systematic deficiencies in the registration dossiers that have been submitted (see Chapter 1.1.3). ECHA has developed data screening and analysis tools to survey the entire registration database and the Classification and Labelling (C&L) Inventory. This allows substances to be prioritised for further evaluation or risk management actions, as well as performing targeted actions such as letter campaigns to complement the compliance check process.

These letter campaigns have been used with success to target a large number of dossiers and the response rate from registrants has typically been good, exceeding 90 % in certain cases. They have been used to clarify specific aspects of dossiers such as the identification of the substances or the description of their uses, especially for substances registered as intermediates (see Figure 3). Substance identification observations in screening have led to further activities in the area, as it has become clear that not only substance identification as such, but reliable substance identification in connection with the hazard information provided in registration dossiers are crucial for the further risk management work.

Importantly, apart from the retroactive improvements, the screening process points to areas in the registration dossier which can be included in ECHA's Validation Assistant Tool which is provided with the IUCLID application.

By using the tool registrants can proactively check and correct their dossiers ahead of submission, which saves resources for both companies and authorities. The combined impact of carrying out letter campaigns and enhancing the Validation Assistant Tool has been that registrants have become aware of certain issues in their dossier and have proactively tackled them ahead of submission. This is exemplified in the case of use descriptions in intermediate dossiers. After a letter campaign in 2012, ECHA planned to repeat the exercise

¹⁰ European Commission (2013) *General Report on REACH*, staff working document, final: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013SC0025>.

¹¹ BfR, proceedings of the workshop 'Mind the Gap' (2015): <http://www.bfr.bund.de/cm/349/mind-the-gap-data-availability-in-reach-registrations-abstracts.pdf> and ECHA (2015) *General Report 2014*, p. 16-17: https://echa.europa.eu/documents/10162/13560/mb_04_2015_general_report_en.pdf.

in 2013 and 2014. However, in both years a preliminary screening of the dossiers subsequently showed that the level of potentially problematic cases was very low and a repeat letter campaign was not needed.

Figure 3. Screening results 2010-2015 (percentage of dossiers that pass the automated screening)

	2010	2011	2012	2013	2014	2015
Substance identification (~42 000 dossiers)	55 %	57 %	58 %	62 %	65 %	68 %
Classification (~42 000 dossiers)	97 %	97 %	97 %	97 %	97 %	96 %
Uses in intermediate dossiers (~9 000 dossiers)	58 %	60 %	84 %	88 %	90 %	91 %
Hazard ¹² (~4 500 dossiers)	28 %	29 %	29 %	36 %	37 %	37 %

ACHIEVEMENTS AND CHALLENGES

Reaching out to potential registrants

The last registration deadline of phase-in substances in 2018 will involve many SMEs that have pre-registered in 2008 but have not been affected by REACH since then. It may well be that the previous staff members responsible for REACH no longer work at the company¹³ and the companies remain unaware of their obligations. One major challenge recognised by all stakeholders is, therefore, to reach out to the SMEs to make them aware of the forthcoming deadline and the necessary time they will need to prepare a compliant registration dossier.

ECHA has recognised the issue in the context of the REACH 2018 Roadmap preparations and initiated the REACH 2018 Communicators' Network in spring 2015. Nevertheless, all stakeholders need to make every effort to raise awareness of the 2018 deadline to ensure that all companies are familiar with their obligations and receive relevant support.

Although a share of the registrations received in early 2016 already concern tonnages relevant for the 2018 deadline¹⁴, there are signals from the stakeholders and from ECHA's first surveys that companies have not yet mobilised to the necessary degree and started their preparations for the 2018 registrations.

Therefore, all actors: ECHA, MSCAs, national helpdesks and industry associations need to intensify their awareness-raising efforts in the coming months, e.g. by using multiplication channels such as chambers of commerce, in addition to traditional ones. A good example of efforts at the national level was the UK Competent Authority which managed to include a short message on the approaching 2018 deadline in the official national tax e-Bulletin, which has a much wider coverage of companies than the Competent Authority could normally reach.

12 The methodology used to measure this indicator covered a number of physico-chemical, toxicological and ecotoxicological endpoints, and relied on the compliance check strategy, implemented before 2013. ECHA's strategy is now to focus on the substances and endpoints that matter. In practice, it means that a different set of endpoints are ECHA's regulatory focus and that the quality indicator will be revised.

13 For example, in summer 2015 the German Helpdesk approached ~5900 German pre-registrants to remind them about the REACH 2018 deadline and over 10% of the emails bounced back as invalid.

14 See ECHA (2016, to be published) *General Report 2015*.

SIEFs and data-sharing

Data- and cost-sharing were identified as major obstacles for SMEs in SIEFs in 2013¹⁵. ECHA and the European Commission reacted by providing advice and recommendations, in cooperation with stakeholders, on fair, transparent and non-discriminatory cost-sharing and data-sharing negotiations. The advice is available on ECHA's¹⁶ and industry association websites.

This work was consolidated in a European Commission Implementing Regulation on the Joint Submission of Data and Data-Sharing of 5 January 2016¹⁷. The Regulation provides clearer instructions for potential and existing registrants to interact and a transparent breakdown of the costs and the differentiation between costs related to tests and SIEF administration¹⁸. The Regulation is therefore, expected to help newcomers to negotiate within SIEFs or with established consortia. It also mandates ECHA to ensure that registrants follow the joint submission principle of REACH.

Despite the above, ECHA still faces a number of challenges in the area of data-sharing. Firstly, the Agency does not have a complete picture of the data-sharing reality in SIEFs and therefore has difficulties assessing whether the relatively low number of data-sharing disputes is really a sign of good cooperation or just a result of under-utilisation of the process.

Since REACH entered into force, ECHA has been notified of 46 data-sharing disputes of which 44 were admissible (see Figure 4). This corresponds to less than 1% of joint submissions. However, it should be noted that in some of the disputes the claimants proceeded as a group of over 70 companies, and ahead of the 2013 deadline the ECHA Helpdesk received almost 1 000 questions on SIEF management. ECHA has also observed that in many SIEF agreements, an arbitration body is specified as the first measure to solve any data-sharing disagreements. All these factors reflect that there were issues in SIEFs despite the low number of disputes received by ECHA.

One-third of the data-sharing dispute cases have been closed without decision, mostly due to the fact that parties reached agreements after disputes were notified to ECHA. In the cases where ECHA took a decision, about half were decided in favour of the claimant. All decisions have been published on ECHA's website (see Figure 5) so that potential registrants are aware of the data-sharing dispute mechanism and the criteria used by the Agency in its decision-making process.

Figure 4. Number of data-sharing disputes submitted to ECHA

	2010	2011	2012	2013	2014	2015
Disputes on non-phase-in substances after inquiry	1	3	1	2	1	1
SIEF disputes (phase-in substances)	13	2	0	16	2	4
TOTAL	14	5	1	18	3	5

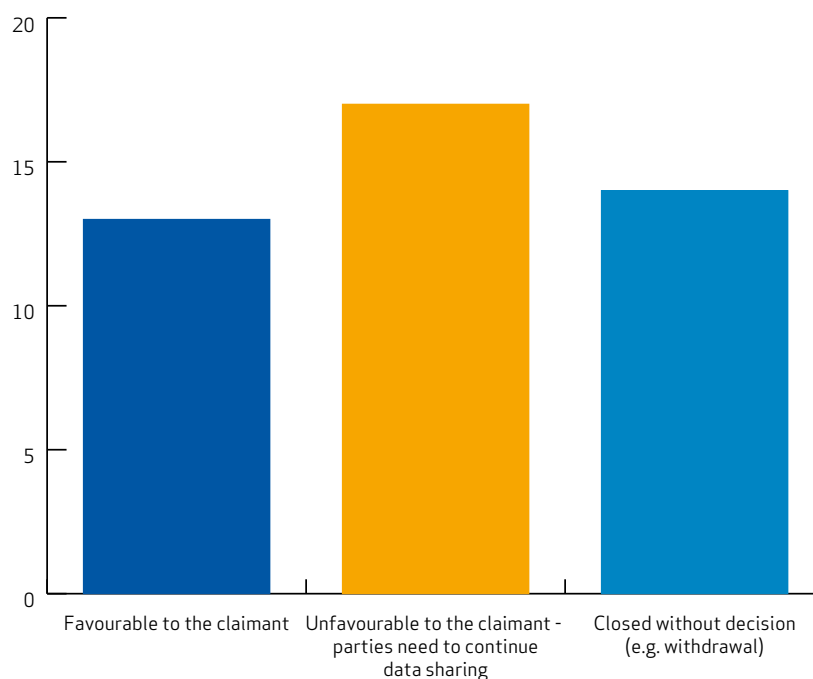
15 See European Commission (2013) *General report on REACH*, final, p. 6: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0049> and European Commission (2012) *Functioning of the European chemical market after the introduction of REACH*, p. 77-80: http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study7.pdf

16 Directors' Contact Group: <http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group>.

17 Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN>

18 Based on the data-sharing disputes that ECHA has received the administrative cost stemming from the required SIEF cooperation can be deduced to be on average around 25 % of the price of the letter of access with a relatively large variance between 5-65 %.

Figure 5. Outcome of the data-sharing disputes



When data-sharing disputes are submitted to ECHA, ECHA's role is to determine if the parties have made every effort to share data. When the decision is unfavourable (second column), it means that claimant has not made every effort. As the data-sharing obligation remains, parties need to continue data-sharing efforts. If the decision is favourable, every effort has been made to reach an agreement and the claimant receives permission to refer to the studies.

Secondly, the Implementing Regulation is expected to lead to an increase in the number of formal data-sharing disputes or a need for the Agency to otherwise support the new registrants because it provides more clarity to newcomers to exercise their rights in negotiations with existing registrants or consortia. As a result of the Regulation, ECHA is adapting its procedure for handling data-sharing disputes, but questions remain regarding the associated workload and timing. This may become an issue for registrants for meeting the deadline if the disputes become so numerous that they cannot be resolved in time to allow registration.

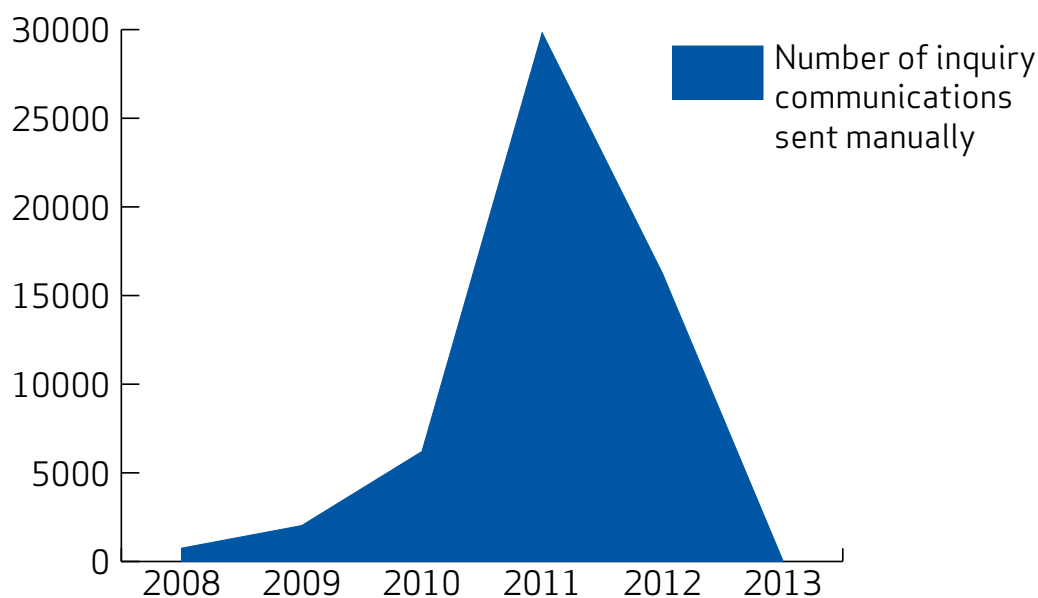
For new substances on the EU market, the inquiry process has been regularly streamlined due to the continuous arrival of inquiry dossiers in high numbers since 2010 (see Figure 6). The aim was to facilitate data-sharing so that newcomers could contact existing registrants in an efficient manner. This has resulted in an improved service to potential registrants. Potential registrants now have real-time information online about other inquirers and registrants such as their contact details.

At the same time, ECHA has reduced the associated administrative tasks, allowing more resources to be allocated to more important matters such as addressing the compliance of substance identity information in registration dossiers (see Figure 7). This has proved to be essential in many cases before starting other regulatory activities on the dossiers or substances (see Chapter 1.1.3).

Figure 6. Number of inquiries received in 2008-2015

	2008	2009	2010	2011	2012	2013	2014	2015
Inquiries received	482	894	1 447	1 763	1 510	1 878	1 488	1 368

Figure 7. Further efficiency increase by sharing contact details in 2012



In 2012, ECHA included contact details of co-registrants in REACH-IT, which allows inquirers to access the details of registrants of the same substance directly in the tool. Therefore, the labour intensive manual sending of communication ceased in Q1/2013.

Another challenge is linked to the closure of the possibility for pre-registration which is foreseen in REACH in May 2017 and the potential impact on the time to market for newcomers. After this date, the only route for contacting previous registrants to share data and register jointly is through the inquiry route and this is likely to put a high pressure on the inquiry process.

In 2011-2015, ECHA received approximately 1 600 inquiries per year. However it is estimated that the closure of late pre-registration may increase the number of inquiries to at least 3 000 inquiries per year, based on the number of new registrations submitted yearly. The actual figure could be much higher, up to 10 000 per year, if all companies that have used the pre-registration route since 2009 now submitted inquiry dossiers.

This is likely to result in longer processing times and prolong the period before companies are legally allowed to manufacture or bring a substance to market. For this reason, ECHA took further steps in 2016 to increase the efficiency of the process by streamlining the way inquiries are handled for well-known and well-defined substances and for which a registration exists.

This allows the Agency to concentrate resources on cases where it is most relevant to scrutinise the substance identification associated with inquiries such as for complex substances and substances for which there is no registration yet.

The other impact of the pre-registration closure is on data-sharing between inquirers and potential registrants that are still preparing their dossiers for the same substance for the 2018 deadline. At the moment, inquirers and pre-registrants are not put into contact with each other automatically. To solve this situation, ECHA is releasing a revamped version of REACH-IT¹⁹ (REACH-IT 3) in mid-2016, which will allow co-registrants (inquirers and registrants) to see the contact details of the pre-SIEF participants (pre-registrants).

It should be noted that while according to REACH, SIEFs only remain operational until June 2018, the data- and cost-sharing obligations will continue to apply. However, as has been demonstrated by the pattern of incoming registrations, there will always be new market players both from within and outside the EU who need to register their substances (see Figure 16 in 1.1.2). It is, therefore, important to ensure that the rules and mechanisms established for the necessary interactions with existing registrants will continue to be applied. Otherwise, there will be uncertainty on the obligations of different parties, which will create inefficiency in the system and may slow down the natural market behaviour of companies.

Information compliance and quality

By submitting a dossier with requisite data, a company provides proof to the regulator that it is taking responsibility for the safe use of its substance. The essence of compliance lies in the company's understanding of the prerequisites of ensuring the safe handling and use of the chemicals it manufactures or imports. In this respect, therefore submitting a dossier is not an end in itself when meeting its legal obligation.

The importance of preparing dossiers of sufficient quality cannot be understated. High quality information in registration dossiers, i.e. meaningful and consistent information reported in a transparent manner, is the starting point for adequate classification and labelling, chemical safety assessment, and communication of correct advice on risk management measures in the supply chain as well as for all the other REACH processes.

This quality is critical to allow the REACH processes to be carried out efficiently and to ensure the safe use of chemicals. Insufficient dossier quality not only undermines the reliability of the safe use in supply chain, but also consumes a lot of effort and time to bring the dossier up to the required high quality standard. This then delays the introduction of any necessary risk management measures. From a competition perspective, companies taking their responsibilities seriously must not be disadvantaged by those which do not.

In the reporting period, ECHA has carried out significant work to improve dossier quality. In addition to evaluation activities, this includes the following actions:

- ECHA carried out several letter campaigns to address deficiencies and inconsistencies observed mainly regarding substance identification and the description of uses, especially for substances registered as intermediates only. For the latter, the guidance was improved and this led to better quality of 2013 registrations;
- Several actions were taken to improve the substance identity information. The format of IUCLID was reviewed so that registrants are better able to report the identification of their substance, explain how it relates to the tested substance, and transparently justify any deviation from the legal requirements. In addition, the substance identity profile (SIP), a concept recommended by industry in preparation for the

¹⁹ The central IT system providing support for REACH.

previous registrations²⁰, was taken on board in the revised IT tools. New fields in REACH-IT and IUCLID enable registrants to transparently report the scope of their registered substance in terms of boundary compositions that their hazard information (Annex VII-XI data) refers to. Finally it was decided that, from 2016 onwards, the completeness check process will include a manual step to verify the relevance of the substance identity when needed (see Chapter 1.1.2);

- A thorough review of the IT tools IUCLID and the Chemical Safety Assessment Reporting Tool (Chesar)²¹, was conducted to enable better reporting of studies in the IUCLID technical dossier (IUCLID 6) and to facilitate the chemical safety assessment and the generation of the CSR (Chesar 3). This was based upon the experience in the first two registration deadlines and through stakeholder consultation and focus groups organised in several countries;
- A Validation Assistant Tool²² was developed to allow companies to check their dossiers not only for completeness but also for 'quality' issues before submission; and
- A thorough review of the ECHA *Guidance on Information Requirements and Chemical Safety Assessment* took place in 2014-2016 to keep companies up-to-date with the lessons learnt from the registration process and scientific developments.

Despite these improvements, adequate reporting on nanoforms of a substance in the registration dossiers still continues to be an unclear issue. There are only a handful of dossiers in ECHA's database where the existence, possible hazard and use information for the nanoform of the substance are reported. The situation is expected to improve with an amendment of the REACH annexes to clarify the information requirements for nanoforms (see text box on 'Nanomaterials' in Chapter 1.1.3).

The screening results also indicate that industry is facing difficulties in identifying certain types of substances (e.g. substances of unknown or variable composition (UVCBs)) with a risk of wrongly assessing substance sameness, preparing appropriate justifications for read-across and ensuring that adequate hazard data are submitted for their substance.

Conversely, they have managed well to classify their substances in accordance with the EU harmonised classification (see Figure 3). It is expected that the introduction of the SIP in the registration tools will alleviate some of the substance identification and sameness issues.

In addition, it is understood that the Commission has started to assess whether to extend the obligation to prepare a safety assessment to substances manufactured or imported in quantities of 1-10 tonnes per year as foreseen in REACH²³. In this context, ECHA encourages the Commission in the foreseen review of REACH²⁴ to consider reviewing the information requirements for substances classified as CMRs or other substances of concern. Similarly, further consideration should also be given to including polymers within the scope of

20 The Cefic substance identification profile (SIP) template was published on 18 August 2009 and is summarised as follows on the Cefic website. The SIP template can be used to support the substance sameness discussions in SIEFs. The intention is to use this template by the SIEF formation facilitator (SFF), consortium or lead registrant to describe the substance to the best of their knowledge. In Cefic's guidance for lead registrants from 23 September 2011, it is advised to use the SIP to establish the coverage of the joint registration (see p. 5 of the document: <http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/>).

21 See Chapter 1.1.4.

22 See the 'Validation Assistant' web page on ECHA's website: <http://echa.europa.eu/en/support/dossier-submission-tools/iuclid/validation-assistant>.

23 REACH Regulation (EC) No 1907/2006, Article 138(1) <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

24 REACH Regulation (EC) No 1907/2006, Article 117(4)

registration; substances that will play an important role in realising the objectives of a circular economy. Clarity would be appreciated as early as possible on these points to facilitate their future implementation.

Overall, further improvement is needed, particularly on the use and exposure information to be able to better prioritise substances for regulatory risk management measures. Although REACH foresees that registrants are responsible for updating their dossiers with relevant new information on their own initiative and establishes criteria for this²⁵, 64 % of the registrations (ca. 29 000 dossiers) submitted since 2008 have never been updated. Of the updates (16 000), over 30 % can directly be linked to a letter campaign by ECHA (ca. 8 000 letters sent since 2011); other updates were provoked by regulatory decisions (8 %) or other actions such as a sector approach (e.g. petroleum streams).

This appears to show that the current system does not provide sufficient incentives to stimulate spontaneous updates by registrants.

All-in-all, companies must live up to the REACH expectation to consider their registration dossier as a living document, and regularly update it for new and improved information. They will need to include continuous REACH compliance into their business strategy and their quality systems, as well as ensure that they have adequate resources for this work. The Agency would like to explore with the Commission and the Member States how to increase the updating of registration dossiers.

Company support

Taking into account the feedback from registrants, ECHA has taken several actions to support companies, especially SMEs, in their registration dossier preparation:

- To facilitate the registrants' path through registration, ECHA has split the process into distinct phases (from knowing your portfolio, to submitting your registration dossier). In line with its REACH 2018 Roadmap, ECHA has established REACH 2018 web pages²⁶ guiding companies through the registration phase-by-phase. The publication of the phases and related support material relevant for preparing and submitting registrations will be completed by the end of 2016;
- ECHA has organised support material for each phase in three layers of complexity creating a structured path to help registrants understand their obligations;
- Provided a practical guide to the information requirements for 1-100 tonne registrations to allow SME managers to devise a registration strategy and decide whether or not to outsource the work;
- Provided an inventory of over 60 000 phase-in substances for which there is an indication that all information specified in Annex VII would be required for phase-in substances as they meet one or both of the Annex III criteria, thus saving industry resources for screening for this information;
- Further developed the OECD QSAR Toolbox to better support non-experts to use it for lower tier endpoints by building automated workflows with pre-programmed selection of relevant databases, profiles and data-gap filling techniques, and by publishing examples²⁷;
- Revised the user interface and help system of IUCLID to make the tool easier to install and use;

²⁵ Article 22 of REACH

²⁶ See the 'REACH 2018' web page on ECHA's website: <http://echa.europa.eu/reach-2018>.

²⁷ See the OECD 'QSAR Toolbox' web page on ECHA's website: <http://echa.europa.eu/support/oecd-qsar-toolbox>.

- Conducted continuous awareness raising and training activities for the national helpdesks to ensure support for registrants in their own languages.

ECHA is exploring the possibilities of providing IUCLID as an online service (through a cloud service) to better serve the needs of companies, in particular SMEs. Under this new approach, ECHA would host the application as well as the data provided by companies, freeing the companies from the need to install, operate, and maintain the IUCLID application in their IT devices. Company submission data would be securely stored by ECHA that would also take care of regularly updating the application. Moreover, this new service would enable multiple users within a company or as members of a SIEF to work collaboratively online. When considering the funding opportunities for this service ECHA will duly consider its legal obligation (Article 111 of REACH) to continue providing formats free of charge for any submissions to the Agency.

ECHA believes that the measures above will enable diligent companies to fulfil their registration requirements by the next deadline by reducing the need to invest resources to understand their obligations.

Furthermore, a constructive dialogue with sectors dealing with UVCB substances has proved effective in supporting them to fulfil their substance identification requirements under REACH.

For essential oils and complex inorganic pigments, sector representatives approached ECHA to initiate a collaborative approach to the development of support material specific to REACH. In the case of oleochemicals and hydrocarbon solvents guidance has been developed within an OECD framework resulting in internationally harmonised guidance documents.

Petroleum and coal stream sectors have been addressed through the PetCo project, where a Working Group of MSCAs, the European Commission, accredited stakeholder organisations and ECHA was set up to agree on a plan to address shortcomings in these registration dossiers.

ECHA has also worked with sectors for which there is not yet a coordinated representation, such as the renewable fuels sector, to ensure a consistent approach to substance identification. The aim is to solve, in a holistic manner, issues that concern a wider group of substances with similar, sector-specific challenges in applying REACH rules.

ECHA has also developed a service to change the main identifiers of a registration if a registered substance has been incorrectly identified. The details of the service are available on ECHA's website.²⁸

In spite of all these efforts, the fulfilment of the duties foreseen in the legislation is considered complex by SMEs, who have less technical and scientific capacity.

²⁸ See the 'How to change your substance identifier' web page on ECHA's website: <http://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier>.

ECHA, the EU Commission and industry jointly work to address REACH registration hurdle of substance identification for essential oils

The 2018 REACH registration deadline was a major concern for producers of essential oils, mostly SMEs, including farmers. They strongly challenged the requirements set by REACH for their sector.

In April 2014, following a dialogue with the European Commission, industry representatives shifted their position and expressed their commitment to comply with the legislation, and provided specific support to take into consideration the specificities of essential oils. In addition, they also requested special attention to help both SMEs and in most cases, single family farmers, to walk the technical and administrative requirements of the REACH registration process.

Working together for about a year, all parties have analysed the regulatory text to identify realistic approaches for registration. It has led to significant progress on understanding the complex issue of characterising essential oils to specifically address the 2018 REACH registrations.

The constant dialogue and mutual respect throughout the process have fostered workable solutions for producers without compromising the very essence of REACH. The guidelines adopted have been subsequently translated and disseminated to be useable for producers across the EU. ECHA and the Commission have used competent authority bodies such as Caracal to multiply support at the national level.

Representatives of the industrial and agricultural sectors have unanimously welcomed the commitment of ECHA and the Commission to find a practical approach for an economic sector often neglected.

'This model of dialogue should become a standard procedure to address other issues involving specific sectors and small businesses in general.' Pierre Sivac, President of the International Fragrances Association.

Essential oils (IFRA website): http://www.ifraorg.org/view_document.aspx?docId=23628
IFRA and EFEO (European federation of Essential Oils).

Developing OECD Guidance on characterising oleochemical substances

ECHA was actively involved in developing OECD guidance for characterising oleochemical substances for assessment purposes²⁹ published in 2014. The aim of the guidance was to present a harmonised method for the characterising this group of UVCB substances. The guidance was developed through an OECD task force that included ECHA and the European Oleochemical Industry (APAG). The active participants of the working group also included OECD member countries: Australia, Canada, Germany, Japan, Sweden, the UK and the US as well as the Business and Industry Advisory Committee to the OECD (BIAC).

The oleochemicals guidance is the first OECD guidance in the field of substance identification. It means that authorities and industry have a common baseline to work from when deciding on how to characterise oleochemical substances. For REACH and CLP processes, this means that dossiers for this type of substance are less likely to have significant issues with their substance identity information. If they do, then communication and discussion can now be based on a common published reference point.

The approach proved to be successful and the work in the field of substance identification has continued in the OECD: for example, the guidance on hydrocarbon solvents was developed in the same manner and published in 2016³⁰.

29 OECD (2014) *OECD Guidance For Characterising Oleochemical Substances For Assessment Purposes*, Series on Testing & Assessment No. 193: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)6&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)6&doclanguage=en)

30 OECD (2016) *OECD Guidance For Characterising Hydrocarbon Solvents For Assessment Purposes*, Series on Testing & Assessment No. 230: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2015\)52&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2015)52&doclanguage=en)

COMMITMENTS AND RECOMMENDATIONS

- C1. To give companies certainty on the requirements and to allow adequate time for preparation of the registrations, ECHA is committed to the extent possible to a self-imposed moratorium on publishing new guidance two years ahead of the last deadline. The new generation of IT tools for registration, to be released in mid-2016 will allow companies to start preparing and submitting their dossiers well in advance of the deadline.
- C2. ECHA will continue to stimulate updates to improve the dossier quality through targeted actions, voluntary updating negotiated with specific subsectors and campaigns, as these measures allow for large numbers of dossiers to be scrutinised.
- C3. ECHA will further adapt its practices, enhance its support services and IT tools to simplify the registration process and reduce the burden for companies.
- C4. In advance of the 2018 deadline, ECHA will raise awareness by using multipliers such as the REACH 2018 Communicators' Network and HelpNet. The Commission, MSCAs and industry associations are invited to join ECHA to make every effort to raise awareness of the last registration deadline and act as multipliers for their audiences.
- R1. The last registration deadline of phase-in substances in 2018 will be the most challenging to manage due to the number of registration dossiers expected, and the less experienced companies registering. It is important that sufficient resources are allocated at the Member State level to provide adequate support, especially for SMEs.
- R2. The Commission and industry associations should work together with ECHA to ensure that the rules and mechanism concerning joint registration and data-sharing to support the cooperation among co-registrants are sustained after the last deadline, when the SIEFs formally cease to operate. This is important to avoid any uncertainty among potential registrants, especially for phase-in substances, as it can be anticipated that phase-in substances will continue to be manufactured or brought to the EU market in high volumes and by a variable number of new actors. These registrants need a reliable way to contact the existing registrants to access joint submissions so that the data- and cost-sharing obligations of REACH can be fulfilled. In addition, registration dossiers will need to continue to be updated and co-registrants must be able to react to regulatory actions.
- R3. Industry must take actions to improve the quality of the registration information so that authorities can make informed decisions on whether risk management actions are needed at the EU level. Companies should critically review their existing registrations and take the opportunity of the improved IUCLID 6 format for updating their dossiers, especially substance identity, use, exposure information and justifications for adaptations to information requirements and alternative methods. This may also benefit companies since with better and more transparent information, their substance may be deprioritised from regulatory actions.
- R4. Stronger incentives are needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. An implementing regulation could be considered to ensure mandatory reporting of use and exposure information on a regular basis. In this context clarification of the criteria triggering an update, including a binding timeframe for regular updates should be discussed.
- R5. ECHA considers that amendments of the REACH annexes for information requirements are urgently needed to ensure that sufficient clarity is given to registrants for their registrations of substances with nanoforms and so that their safety can be better assessed.

- R6. ECHA encourages the Commission in the foreseen review of REACH to consider reviewing the information requirements for substances classified as CMRs or other substances of concern in the 1-10 tonnage band. In addition, further consideration should be given to including polymers within the scope of REACH registration.

1.1.2 Registration and dossier submission

THE OBJECTIVES OF THE LEGISLATION

The principle of registration is that for one substance there is only one registration submitted, which means that registrants of the same substance must register jointly. Registrants are also required to proactively update their dossiers to reflect new knowledge on their substances, as new knowledge may also imply new needs for risk management measures.

Free formats and IT tools are to be provided for companies to submit the required information to ECHA. REACH offers the possibility to be exempt from registration for production scale research and development to enhance the competitiveness of the sector and promote innovation through product and process-orientated research and development (PPORD).

IMPACT OF THE OPERATIONS

Successful registration deadlines have created a firm foundation for advancing the safe use of substances

REACH is incrementally achieving its aims as all actors have taken on their roles in REACH implementation: industry is submitting data and authorities are overseeing risk management measures based upon the information submitted. Overall the provisions concerning manufacturers, importers and only representatives registering on behalf of non-EU companies are functioning well, and companies are successfully submitting their registration dossiers in line with the anticipated schedule (see Figure 8 and 9). By April 2016, ECHA had received and disseminated more than 54 000 dossiers for approximately 14 000 unique registered substances.

REACH harmonises the obligations with regard to manufacturing, importing and using chemicals and thus strongly contributes to meeting the single market objective of the Regulation.³¹ Non-EU companies continue to have access to the EU market, either through their EU-based importers or by the only representatives that they have nominated. By fulfilling their registration obligations, companies demonstrate they are responsible and continue to have access to the market.

ECHA is aware that there were early concerns on the potential withdrawal of substances from the market due to registration, but these fears do not appear to have materialised. However, a clear picture of this will only become apparent after the last registration deadline, where this fear is linked to companies, particularly, small and medium-sized enterprises (SMEs) holding back their decision whether to register a substance until 2017.

The majority of companies respect the 'one substance, one registration' principle (see Figure 10) and hence efficiency is gained for all actors. For industry, duplication of work is minimised and unnecessary animal testing is avoided resulting in less regulatory costs. MSCAs benefit by having all the information on a substance in one place, allowing a holistic view when doing substance evaluation or preparing dossiers proposing regulatory risk management.

³¹ European Commission (2015), Monitoring the impacts of REACH on competitiveness, innovation and SMEs, p. 14-16: <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>

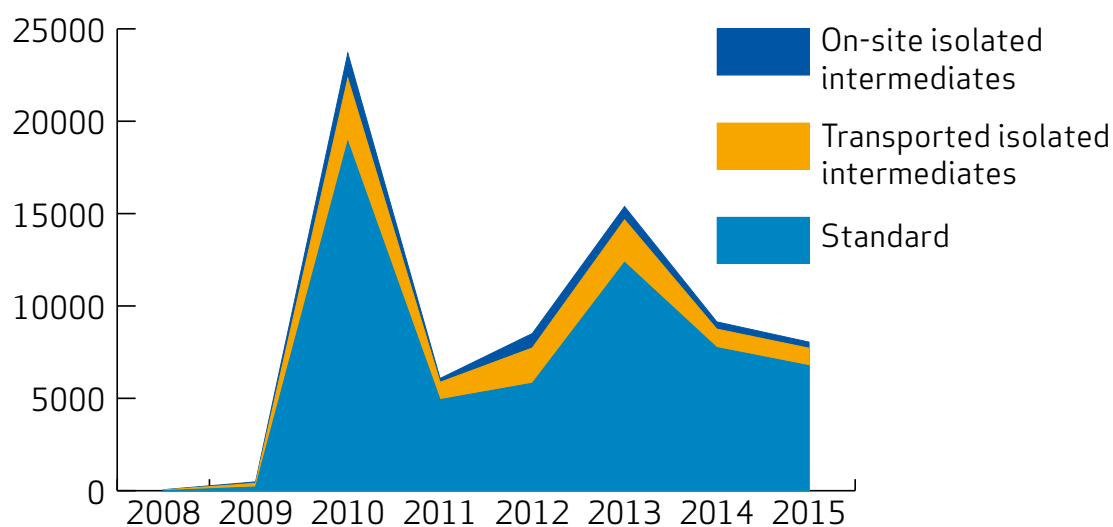
The dossiers ECHA has received for all REACH and CLP processes have been stored in a central database. They have been checked for completeness in terms of information requirements and they can be analysed for further regulatory purposes. This allows compliance checks to focus on substances that raise the highest concern for human health and the environment (see the beginning of chapter 1: 'Towards an integrated strategy'. Companies have used the PPORD exemption to develop new products for their portfolio while ensuring the safe use during the development period.

Figure 8. The two previous registration deadlines have been successful

Number of initial and update dossiers by year (NONS³² included)

Dossier type	2008	2009	2010	2011	2012	2013	2014	2015
Initials	54	429	22 647	3 821	2 788	10 209	2 816	3 304
Updates	0	50	1 042	2 254	5 721	5 171	6 324	4 739
TOTAL	54	479	23 689	6 075	8 509	15 380	9 140	8 043

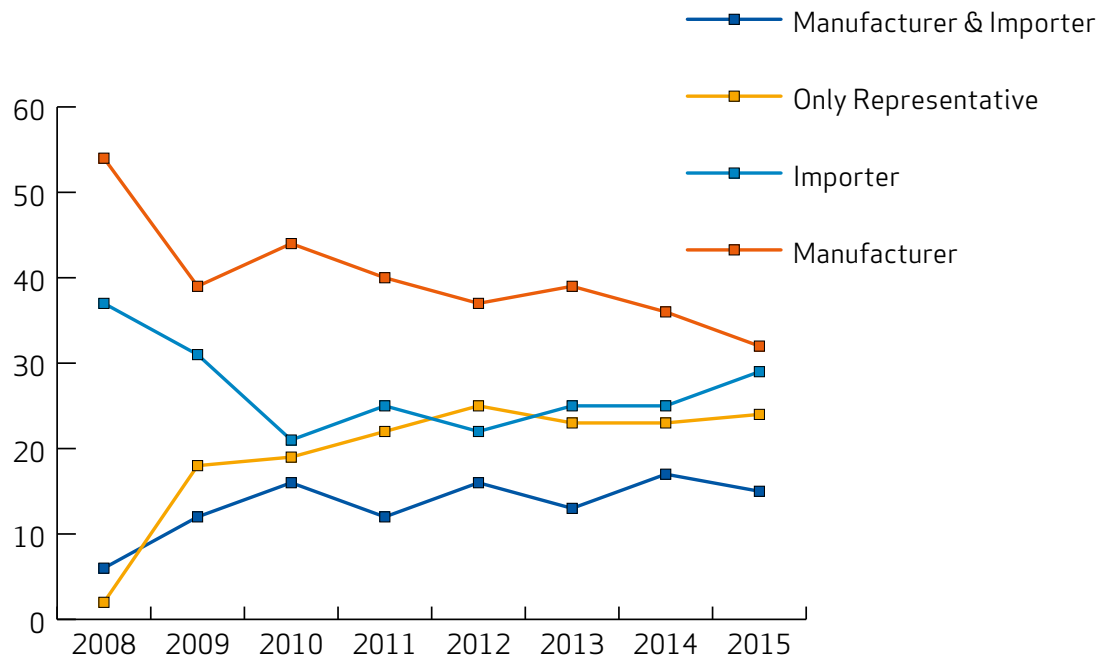
Figure 9. Number of registration dossiers by type and year (NONS included)



Furthermore, what can be observed is a steady flow of registration dossiers for phase-in substances over 100 tonnes/year (see Figure 17) and a growing amount of registrations by importers or only representatives acting on behalf of a non-EU company (see Figure 10 below).

³² A substance notified under the Dangerous Substances Directive (Directive 67/548/EEC).

Figure 10. Registrations by role in the supply chain



Joint submission is a legal obligation to ensure a level playing field of registrants

Despite the encouraging observations concerning registrants taking responsibility for their dossiers, there have been some clear cases of abuse of the registration submission system.

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, in breach of Article 11 (see Figure 11)³³. In some cases, this is combined with low data quality. There are also opt-out that are compliant with REACH (see Figure 14).

Submitting outside of a joint registration can lead to a potential market distortion, because those companies have not invested in data gathering, (substance information exchange forum (SIEF) cooperation and joint registration) which gives them a short-term market advantage over those companies that have diligently invested in complying with REACH requirements. Furthermore, the Forum has found the enforcement of the principle of 'one substance, one registration' varies between Member States and its coordination is challenging due to differences in national provisions that regulate enforcement.

Of the registrations submitted outside the joint submission there was a slightly higher percentage (3%) for substances registered as intermediates only. Furthermore, when inspected by the registrant's role, approximately 29% of the registrations outside joint submission have been made by manufacturers, 34% by importers, 10% by companies with both a manufacturer and importer role and 26% by only representatives. Submission outside a joint registration is rarer for non-phase-in (excluding NONS) than for phase-in substances.

³³ It should be noted that opting out for certain or even all information is possible for the reasons outlined in Article 11(3) of REACH. Importantly, however, the registration must remain as part of the joint submission. in these cases.

ECHA flagged these observations to the Commission in 2014 and, as a result, the legal obligation of joint submission has been clarified in the Commission Implementing Regulation³⁴ on Joint Submission of Data and Data-Sharing. It clarifies that ECHA shall ensure that all registrants of the same substance are part of the same registration, even where a registrant of that substance separately submits some information and justifies it under Article 11(3).

Specifically, the aim is to create a level playing field by ensuring that all registrants of the same substance (for the same registration type) submit jointly and prevent potential registrants from eluding their joint submission by submitting individually instead of participating in data-sharing negotiations and the SIEF process.

ECHA has implemented this in REACH-IT by allowing only one registration for one substance, thereby promoting data-sharing negotiations. Further to the clarification brought by the Board of Appeal decision³⁵ (see Chapter 2.1.4), all dossiers that may be in breach of the 'one substance, one registration principle' submitted outside of a SIEF will be retroactively checked and companies will be requested to resubmit their dossier as part of the joint registration. Member States should also play their role and 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.

However, if a potential registrant cannot reach agreement to share data with existing registrants, it must inform the Agency through ECHA's data dispute resolution mechanism. Based on the assessment of the parties' efforts to reach an agreement, ECHA may give them access to the existing joint submission and a permission to refer to the requested data from existing registrants. Nevertheless, the existing registrants will be entitled to claim financial compensation from the new registrant who uses the shared data for their registration before national courts. ECHA will also consider taking action on clear issues of data quality between existing registrants and newcomers, by e.g. launching a compliance check.

Figure 11. Number of substances registered outside of the joint submission

Phase-in substances	8 679	100 %
Substances registered outside the joint submission		
Substances in full registrations	194	2.24 %
Registered by: <i>Manufacturers</i>		29.45 %
<i>Manuf + Imp</i>		9.89 %
<i>Imp</i>		34.51 %
<i>OR</i>		26.14 %
Substances registered as intermediate	267	3.08 %
Registered by: <i>Manufacturers</i>		34.49 %
<i>Manuf + Imp</i>		9.16 %
<i>Imp</i>		37.54 %
<i>OR</i>		18.82 %

34 Commission Regulation (EU) 2016/9 of 5 January 2016: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN>

35 BoA decision of 15 March 2016 relating to case number A-022-2013: http://echa.europa.eu/documents/10162/13575/a-022-2013_decision_en.pdf

In contrast to submitting a registration totally outside an existing joint submission, REACH gives companies three valid justifications for opting out from some or all parts of the joint submission for the reasons stated in Article 11(3). For the registrations currently in the ECHA database, the various reasons have been used as follows:

Figure 12. Reasons for opting out of the joint submission

Reason	Number of cases	%
Disproportionate costs	213	19.8
Confidentiality reasons	88	8.2
Not agreeing with the information selected by the lead registrant	774	72.0

Many SMEs find the cost of registration burdensome

The major cost item in registration is formed from the costs of compiling and generating the necessary data to fulfil the REACH information requirements.³⁶ Despite the fact that the information requirements have been reduced and lengthy preparations for the 2018 registration deadline, which allows registrants to spread their costs over many years, many SMEs have the impression that registration would be costly for their business.

To a large extent, this is due to the evolution of the surrounding economic environment. Investment decisions – even regulatory investments – are made in a shorter and shorter cycle and, in practice, most companies will decide only in late 2016 or 2017 whether to pursue their 2018 registrations or not. Consequently, the costs will need to be borne over a short period of time, which can be a challenge for companies, especially those with a wide portfolio of low tonnage substances.

It is also typical for joining existing registrations that the newcomers are asked to pay the price for a letter of access in one go.³⁷ In addition, the administrative costs for managing the SIEFs and preparing the joint dossier are higher than anticipated in the impact assessments at a time when joint registration was still voluntary. In the data-sharing disputes brought to the attention of ECHA, the administrative costs were around 30 % of the total cost in 2010 disputes and over 40 % in 2013 disputes on average.

While registration fees represent only a minor fraction of the overall cost of registration, SMEs have welcomed the reductions for SMEs implemented by the European Commission after the first REACH Review in 2013³⁸.

Member States have the possibility to reduce the financial burden of registrants, in particular SMEs, by providing financial support of up to EUR 200,000 per company over a 3-year period provided the conditions of Commission Regulation (EU) No 1407/2013 on de minimis aid are fulfilled. The Commission has clarified such support is in line with EU competition rules.

³⁶ European Commission (2015), Monitoring the impacts of REACH on competitiveness, innovation and SMEs, section 3.3.: <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>

³⁷ A price perceived as 'high' does not necessarily mean that the pricing is excessive. See the European Commission document (2015), Competition issues in the context of REACH SIEFs: https://echa.europa.eu/documents/10162/13631/dg_comp_competition_reach_en.pdf

³⁸ Concretely, the fee reductions have resulted in a total savings of EUR 650 000 for SMEs.

A challenge for companies remains the basis for SME cost-reductions, which are defined in a Commission Recommendation³⁹, where a crucial element of the SME definition is the ownership structure, often ignored by the companies. ECHA verifies the size of the companies that claim to be entitled to reduced fees and which are invoiced accordingly.

By 31 December 2015, the number of registrants identified for verification totalled 2 355 of which 75 % (1 770 registrants) have been verified and completed. The majority of this batch relates to the registrations submitted up to 31 December 2012. Most of the verified cases relate to the first registration deadline but also includes registrations in other tonnage bands.

On the basis of working with the Commission Recommendation over the last five years, it is ECHA's view that it is too complicated in the way it includes the enterprise's relationships with other enterprises through control or ownership definitions and therefore should be simplified. This is shown by a significant proportion of companies that submitted their registrations for the first registration deadline having incorrectly claimed their size despite the support material provided (see Figure 13). In the interim, ECHA will continue to enhance the level of information with respect to the applicable SME definition and will introduce stepwise guidance for company size determination in the next release of the REACH-IT system in June 2016.

Figure 13. SME verification

SME Verification	2011	2012	2013	2014	2015	TOTAL
Number of files verified	245	315	516	271	423	1 770
Number of wrong size cases	197	192	394	88	150	1 021
Rate of wrong size, %	80 %	61 %	76 %	32 %	35 %	58 %

ACHIEVEMENTS AND CHALLENGES

ECHA's IT tools for submission are central in guiding registrants to fulfil their obligations and are being updated to ensure the 'one substance, one registration' principle is observed by registrants and on the basis of user feedback.

Under the framework of the REACH 2018 Roadmap, support to SMEs is being provided to enable all diligent companies to submit their registration dossiers in time. To that end, the submission system, REACH-IT⁴⁰, has been significantly revamped, based on stakeholder's feedback, to simplify its use to cater for SMEs needs.

It now has a new and more intuitive user interface, an integrated help functionality available in 23 EU languages and a reduced number of manuals. Furthermore, members of a joint submission, which are not required to submit the full data package, can now submit their registrations directly online in REACH-IT without using IUCLID. These improvements will facilitate the follow-up of the regulatory processes (e.g. evaluation decisions) affecting the company, which in turn leads to a reduction in costs for companies.

ECHA's approach for completeness check of the registration dossiers has been challenged by some MSCAs and stakeholders on the grounds that the 'one substance, one registration' principle has not been adhered to by some registrants whilst others have provided incomplete dossiers which have not been rejected. This has

39 Commission Recommendation (2003/361/EC) of 6 May 2003: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF>

40 See the 'REACH-IT' web page on ECHA's website: <http://echa.europa.eu/support/dossier-submission-tools/reach-it>

led to a review of the process in 2014-2015 and together with the recent Board of Appeal decision⁴¹, has resulted in several critical changes to the completeness check process.

To complement the automated screening of registration dossiers, after the introduction of the update to REACH-IT in 2016, manual verification will be used in the completeness check process. The intention is to pick up those registrants who add irrelevant content or, for example, provide insufficient information for identifying their substance or fail to provide adequate exposure scenarios. If submitted registrations are found to be incomplete, the Agency will prescribe a reasonable deadline for the provision of the missing information as part of a joint submission. If the registrant does not provide the missing information, a registration may be rejected.

In response to the Implementing Regulation on Joint Submission of Data and Data-Sharing in January 2016⁴² ECHA enhanced the registration process with regard to the 'one substance, one registration' principle and companies that do not respect the principle will not receive a registration number.

If the registrant does not provide the information within the deadline set, the registration will lose its validity and the company will lose market access. In addition, ECHA will retroactively check those registrations that have previously been submitted outside of a joint submission and apply the same approach.

Innovation: the product and process-orientated research and development (PPORD) exemption is well used by large companies and new substances are being steadily registered

ECHA is conscious that many factors – from a company's financial standing, its market conditions, the general economic environment, the availability of qualified scientists for its research and development etc., to the talent of its management in grasping opportunities – determine an enterprise's decisions to innovate. There is no singular direct causal correlation between REACH and innovation, save for the legislation's drive towards substituting hazardous substances. Nonetheless, certain REACH-related indicators provide reliable feedback on innovation occurring in the chemicals industry sector.

PPORD notifications have been submitted in similar numbers as under the previous legislation (PORD⁴³), taking into account that companies only need to use the exemptions for substances manufactured/imported over the threshold of one tonne per annum (see Figure 14). This notification process is now well used (see Figure 15), and allows large- scale research and development without a heavy administrative burden, while ensuring safe use, and in a recent study 26 % of companies responding to the study surveys indicated increased research and development activity.⁴⁴

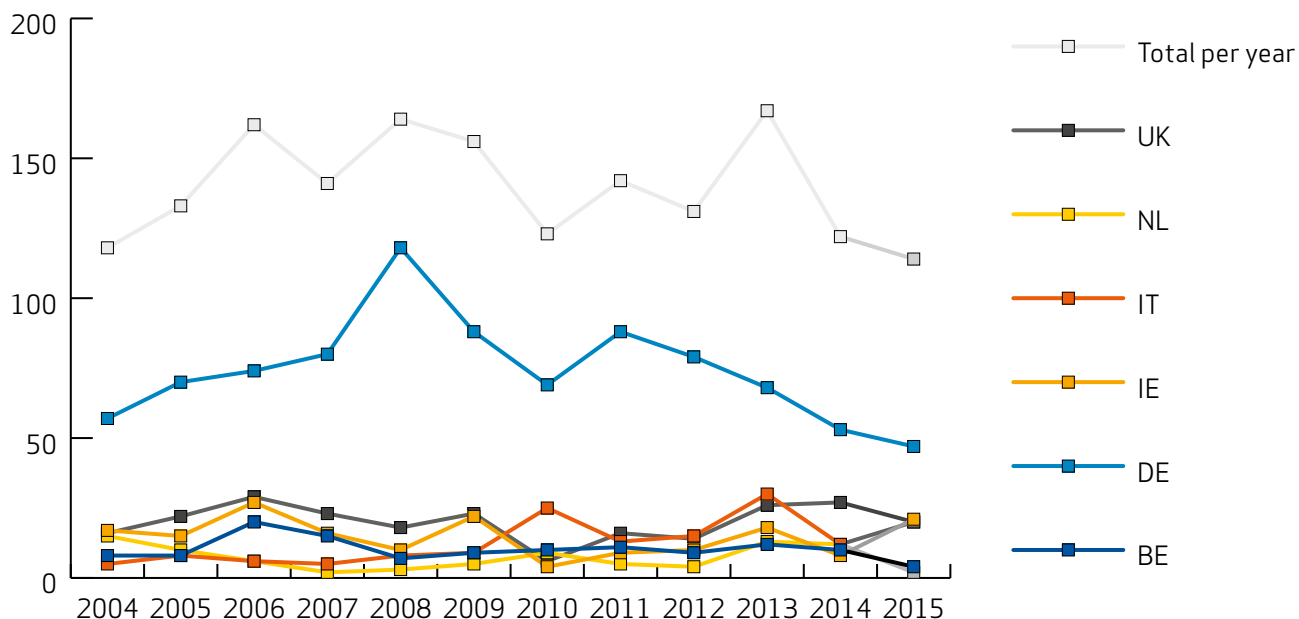
41 BoA decision of 15 March 2016 relating to case number A-022-2013: <http://echa.europa.eu/documents/10162/56569ebe-dc6f-4831-aa72-6cc4819293ee>.

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

43 Process-orientated research and development in the Dangerous Substances Directive (Directive 67/548/EEC.).

44 E. Commission (2015), p.124. Monitoring the impacts of REACH on competitiveness, innovation and SMEs, p. 124.: <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>

Figure 14. Number of substances as PORD and PPORD



In the reporting period, ECHA has noticed that the PPORD exemption is used by a relatively small number of companies in Europe (~350) which are typically large. Therefore, in 2014 ECHA invested in raising awareness about the PPORD exemption and to develop more SME-oriented support material. ECHA anticipates that the PPORD exemption might be increasingly used after the 2018 deadline since until then, in research and development for pre-registered phase-in substances, companies had no legal obligation to register until 100 tonnes per year had been reached – a level often sufficient for product and process-level research and development projects. Awareness raising will continue in the next years.

Fine chemicals represented almost half of the PPORD notifications with substances that are used to manufacture pharmaceuticals and biopharmaceuticals (30 %), and products for plant protection or other special agrochemicals (10 %). Speciality chemicals represented about 40 % of the notifications. The remaining notifications covered petrochemicals, oleochemicals and other energy sectors.

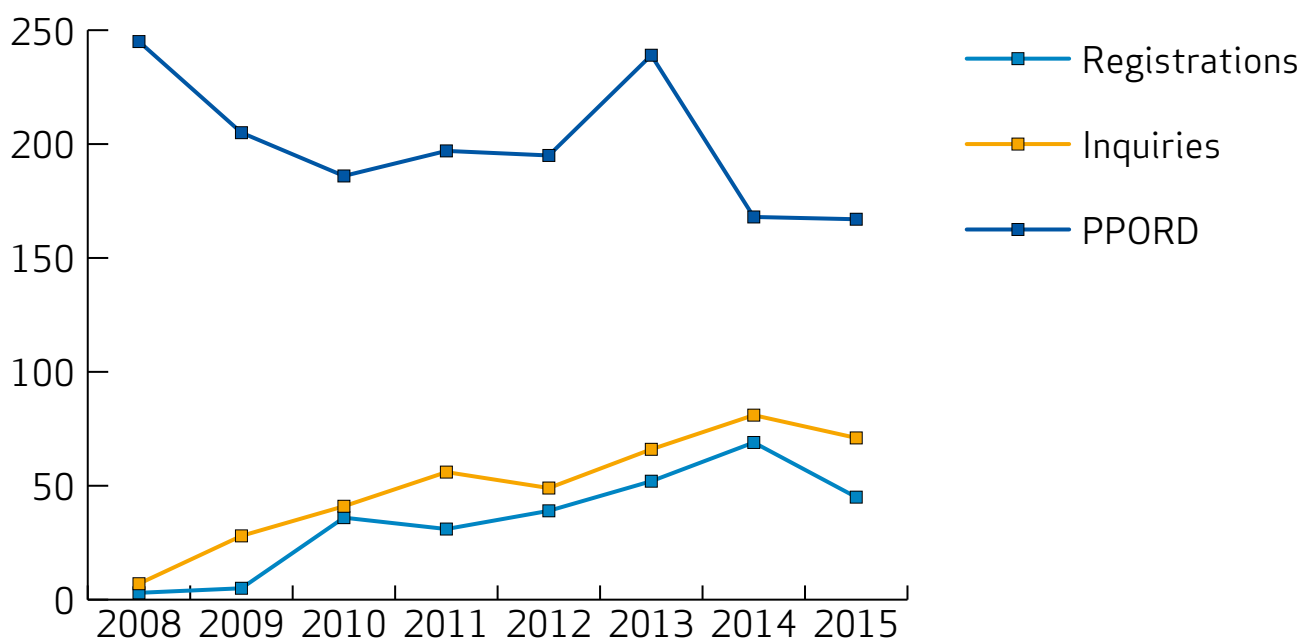
New substances (i.e. substances not listed on the EINECS⁴⁵ or the ELINCS⁴⁶ inventories) are continuously being registered with a steady upward trend (see Figure 16). If the PPORD notifications are scrutinised, it can be observed that so far around 20 % of them have led to registration of the substance, demonstrating that the PPORD notification has the potential to pave the way for new products on the market.

Safeguards to prevent abuse of the system are in place and operating. In several cases, additional conditions were imposed by ECHA to ensure that substances have not been placed on the market and some cases of apparent misuse have been referred to national enforcement authorities.

45 European Inventory of Existing Commercial Chemical Substances.

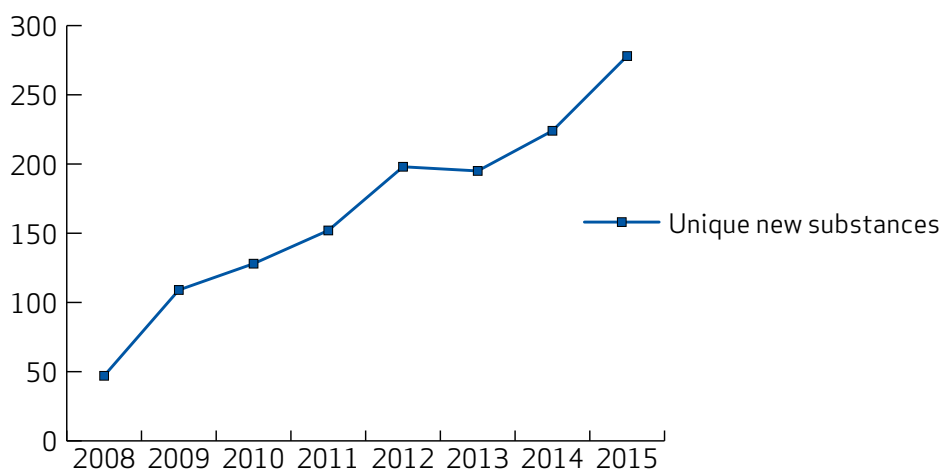
46 European List of Notified Chemical Substances.

Figure 15. The PPORD exemption is well used (PPORDs inquired or registered)



Note: 2008 is an anomaly as there was a possibility in the previous legislation to apply for a one year extension of an existing PORD notification.

Figure 16. New substances registered per annum



	2008	2009	2010	2011	2012	2013	2014	2015
Unique new substances	47	109	128	152	198	195	224	278
Registrations	59	136	154	185	234	242	252	301
>1000	1	3	3	3	9	17	17	15
100-1000	1	4	6	6	4	14	21	10
10-100	5	11	18	22	25	19	19	18
1-10	0	0	0	0	0	0	0	0
Intermediate	41	82	82	112	99	135	117	156

*Note: Here a 'new' substance is defined as not an EINECS, NONS, or NLP (i.e. EC starts with 6, 7, 8 or 9).

Innovation and avoidance of animal testing promoted by REACH can benefit companies

The regulatory pressure on some metals and subsequent questions from the downstream supply chain have triggered the proactive development of new alternative products that combine an improved safety profile with a good technical performance. The integration of toxicology and product safety aspects as an integrated part of the product development created credibility and a high acceptance from customers.

The development of low entry level alternative (non-animal) tests, such as transformation dissolution tests, allow the environmental hazards of mixtures to be addressed in an easy and cost efficient way. This higher level of hazard documentation and communication is perceived as a competitive advantage.

For certain applications, the REACH dossier dataset is being used as a state-of-the-art dataset to address product safety in response to 'popping-up' publications very often reporting one-sided views on certain hazards taken out of context. This helps as an important tool in addressing concerns in the supply chain.

Umicore

Registration should not be considered 'finalised' in 2018

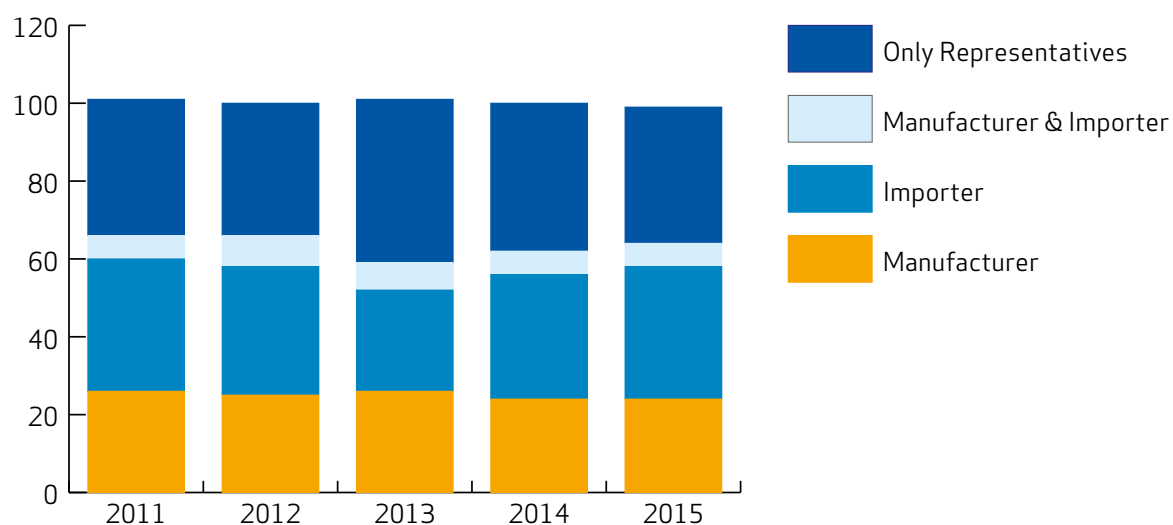
Registration should not be considered 'finalised' in 2018 because the chemicals market is continuously changing. New and existing substances in high tonnages (commodities) are being brought to the market, both from within and from outside the EU (ca. 65 %) (see Figure 17). This is due to the normal turnover of company portfolios and new companies entering the EU market. In the majority of cases, the EU manufacturer is the lead registrant of a joint registration (varying between 40 %-58 %), EU-based importers being the second most common to take this role. Only representatives are lead registrants for about 10 % of the substances (see Figure 18).

A second reason why registration is not complete in 2018 is that registrants also need to keep their dossiers up-to-date. Post 2018, the number of registrations, including updates, is expected to be approximately 20 000 dossiers per year (in a database of ca. 120 000 registrations); hence, the need to maintain a sufficient level of resources within ECHA for processing the dossiers, providing advice and guidance and maintaining the necessary IT tools.

Figure 17. Number of registrations for substances over 100 tonnes per year following previous deadlines

Registrations	2011	2012	2013	2014	2015
Over 1 000	701	379	717	332	311
100-1 000	72	71	958	501	570
TOTAL	773	450	1675	833	881

Figure 18. Registrations over 100 tonnes per year post deadlines by role in the supply chain



While many companies keep their dossiers up-to-date, improvement is needed especially for full registration dossiers. Over one-third of all the dossiers submitted for the 2010 deadline have been updated, and close to one third of the 2013 dossiers also. For intermediate dossiers, the percentage is significantly higher, probably reflecting the impact of ECHA's campaign on uses in intermediate dossiers. Notably, 72 % of the dossiers for full registrations for non-phase-in substances have been updated at least once.

The main reasons for updating the dossier are:

- New or updated CSR (31 %);
- Following a targeted letter campaign (23 %);
- Change in tonnage band (15 %);
- New or updated C&L (8 %);
- Compliance check (7 %); and
- New use (6 %).

The number of confidentiality claims remains low

Registrants can make confidentiality claims on certain information in the dossiers. The assessment of the claims is an established process balancing the needs of the public's right to know and companies' right to protect their confidential business information. The number of claims remains low and this maximises the availability of registration information on ECHA's website.

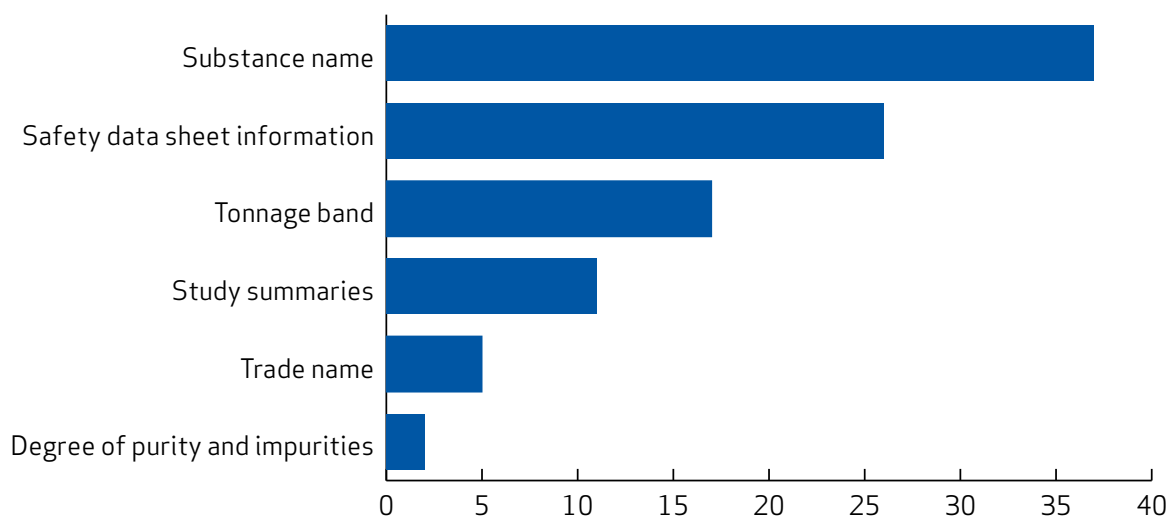
In January 2016, approximately 2 300 confidentiality claims had been made for the close to 50 000 dossiers in the database i.e. approximately 4 %. Confidentiality is requested mostly on the IUPAC name of the substance, on safety data sheet information and on the tonnage band (see Figure 19).

In 2012, the scope of safety data sheet information was expanded from information on the use of the substance to include items such as the name of the registrant, the registration number, and the outcome of the PBT assessment. Since then, the number of confidentiality claims on safety data sheet information has substantially increased, mainly due to confidentiality claims on the name of the registrant, although the overall number still remains low: in only 600 out of more than 50 000 registration dossiers the name of the registrant has been claimed confidential.

Typically, 75 % of confidentiality requests are accepted after the first assessment, while for 25 % of the cases further information is requested before a decision is made. Overall, the acceptance rate is typically 85 %, while 15 % of claims are rejected by ECHA or removed by the registrant after the request for further information.

The main reasons for rejection are that either the information was already available in the public domain, or the justification provided was insufficient. Although a significant number of rejections have been issued, the number of requests for a review of the rejection is low; only three review requests have been received since 2011.

Figure 19. The basis for confidentiality claims



COMMITMENTS AND RECOMMENDATIONS

- C5. ECHA will continue to raise awareness of the benefits for innovation of the PPORD exemption over the next years, especially for SMEs.
- C6. In 2016, ECHA will complement the automated completeness check with a manual verification to determine if registrations are incomplete. The Agency will reject the registration, unless a completed dossier is provided within a reasonable time. In addition, ECHA will check registrations submitted (retroactively and in the future) outside of a joint submission and companies will be requested to resubmit their dossier as part of the joint registration. Companies that do not respect the 'one substance, one registration' principle will not receive a registration number or their registration will lose its validity.
- R7. 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.
- R8. Member States are encouraged to assist SMEs by providing financial support to them to meet their REACH obligations that is consistent with EU legislation on de minimis aid. The Commission should consider simplifying the Commission Recommendation (2003/361/EC) of 6 May 2003 concerning the

definition of micro, small and medium-sized enterprises, as it is currently considered too complicated in the way it includes the enterprise's relationships with other enterprises through control or ownership definitions.

- R9. The Commission, Member States and ECHA should jointly raise awareness to industry managers of the need to keep a sufficient level of regulatory resources, as it is expected that a steady flow of updates will be submitted due to improved and updated information.

SMES AND REACH

The REACH Regulation has only a few provisions that specifically refer to SMEs. Article 77 (2)(g), for instance, stipulates that ECHA's technical and scientific guidance to assist companies in developing chemical safety reports should especially have SMEs in mind. Recital 39 mentions that national helpdesks shall particularly help SMEs to comply with the requirements of the Regulation. This is not surprising as SMEs have the same obligations towards the safe manufacture and use of chemical substances as any other duty holder. The tonnage bands that determine differing levels of information requirements are unrelated to company size, although there is a fee-reduction for those companies that are verified as SMEs.

SMEs subject to the REACH Regulation are numerous, spread across many sectors as well as geographically, and are heterogeneous with respect to the handling of their chemical portfolio and their knowledge of the Regulation. Many benefit from membership of a national or sectoral industry association, but the format and capacities of such associations differ considerably according to national practice and tradition. Overall, manufacturers are better informed than downstream users or only representatives. Nevertheless, some SMEs are still unreachable for receiving information on REACH. SMEs do not have a single voice at EU level⁴⁷.

SMEs are an important constituency for ECHA. REACH aims to increase information on the safe use of chemicals within the supply chain. The 'downstream users' of chemicals are mostly SMEs and as such often struggle with understanding as well as fulfilling their downstream obligations. At the forthcoming registration deadline of 2018 many companies are expected to be registering for the first time. A high proportion of these companies are likely to be SMEs. ECHA's aim has therefore been to support SMEs as REACH duty holders, taking into account their particular needs.

ECHA does not provide specific guidance for SMEs, since they are not exempt from any regulatory duties merely due to their size. Instead, guidance and information, as well as IT tools, are made as user and reader-friendly as possible. Since its establishment in 2007, ECHA has been continuously improving its IT tools and assistance to companies taking into account feedback from their users.

With the experience gained from the first two registration deadlines in 2010 and 2013, the European Commission, ECHA, numerous public bodies as well as think tanks investigated and analysed the concerns and needs of SMEs in the context of REACH. This analysis has provided a valuable basis for ECHA to further develop its support, in particular the REACH Roadmap 2018. ECHA has, therefore, been keen to help managers avoid making costly errors. In this regard, the Agency was instrumental in providing a 'Checklist to choose a good consultant', which was published as a Directors' Contact Group (DCG) document in 2014⁴⁸.

47 There are several trade associations that represent SMEs both at the EU and national level. However, many SMEs do not consider their voice is represented at EU level and have proven to be unreachable.

48 'Checklist to choose a good consultant': http://echa.europa.eu/documents/10162/13559/dcg_consultant_checklist_en.pdf

With SMEs in mind, ECHA has also made information accessible by introducing a new web page structure. These topical web pages (e.g. on REACH 2018 registration, applying for REACH authorisation, or on the duties of downstream users) provide orientation material in a multi-tiered format. The new generation of IT tools released in 2016 were also designed to enhance their ease of use for SMEs.

To help inexperienced SMEs familiarise themselves with the EU chemicals safety regime, ECHA launched a specific 'getting started' web page in 2015 that is structured according to the role of an SME in the regulatory context⁴⁹. This was accompanied by publishing a booklet 'Chemical safety in your business – Introduction for SMEs' that was well received by numerous audiences⁵⁰.

SME-focused topics also figure prominently in ECHA's regular newsletters provided to its nearly 100 Accredited Stakeholder Organisations and to its HelpNet correspondents as well as in the digital 'ECHA Weekly' and the quarterly ECHA Newsletters that are sent to subscribers.

One of the most significant cost factors, in terms of money, time, effort and allocation of human resources, is the expenditure needed for preparing the registration dossier. This includes acquiring the data to meet the legislation's information requirements, which mostly results from expensive tests and applying alternative methods, but also the administrative costs related to data-sharing and consortia management in SIEFs. For this reason, ECHA and the Commission have conceived methods to assist SIEFs and data-sharing (see Chapter 1.1.1) especially with a view of SMEs.

After the first REACH Review in 2013, reductions in the registration fees were implemented for SMEs, but registration fees themselves are only a small fraction of the overall cost of registration. Furthermore, a remaining challenge for companies is the definition of an SME (see Chapter 1.1.1), which serves as the basis for SME reductions. ECHA verifies the size of the companies that claim to be entitled to them, and a significant proportion of companies continue to claim their size incorrectly despite the support material that has been provided.

In an attempt to reach SMEs, the Agency has been cooperating through the European Enterprise Network (EEN) with representatives of business organisations in EU Member States and in various sectors by jointly producing, in 2014, a 'Guide for SME advisors on REACH, CLP and the BPR – EU chemicals management rules and your client's business'. The Agency has presented REACH at numerous EEN events and initiated cooperation between national REACH helpdesk officers and their national EEN counterparts. ECHA initiated a REACH 2018 Communicators' Network in spring 2015 as a platform for disseminating information to help SMEs. As SMEs are known to receive information mainly from their national or sectoral industry associations, an even wider network of multiplier organisations is still needed to familiarise SMEs, particularly downstream users with their REACH obligations as well as the support available to them.

SMEs can and should be assisted in their research and marketing of innovative chemicals that can substitute SVHCs. This can be through promoting existing mechanisms such as the PPORD exemption (see Chapter 1.1.2) and such innovation will be particularly important to include SMEs to realise a circular economy. An obstacle for SMEs in respect of innovation is accessing private (banking or cloud) funds as well as available EU funding, which is often embedded in a complex system of funding mechanisms.

Within ECHA, a senior manager ('SME Ambassador') was tasked to catalyse ECHA's awareness of SME needs and to provide information on relevant actions taken by ECHA to interested stakeholders. For all practical purposes, however, the Agency in its entirety is addressing the particular needs of SMEs.

49 See the 'Getting started' web page on ECHA's website: <http://echa.europa.eu/support/getting-started>

50 http://echa.europa.eu/documents/10162/21332507/guide_chemical_safety_sme_en.pdf.

Overall, ECHA's experience shows that SMEs, whilst they cannot be exempt from their duties, given the overarching goal of protecting human health and the environment from the chemical substances that they handle and use, will profit from any effort undertaken to ease their work. Such support can be provided by many actors, including public administrations and industry associations.

It is also essential to realise that this needs to be done by engaging many multipliers in information platforms. The widest-possible engagement of relevant organisations should be sought in supporting SMEs to comply with the legislation.

1.1.3 Evaluation

THE OBJECTIVES OF THE LEGISLATION

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers, the proposals to test on animals and to clarify if a given substance constitutes a risk to human health or the environment. These processes are fundamental in REACH to instil confidence that registrants meet their legal obligations, to ensure that unnecessary testing on vertebrate animals is avoided and that sufficient information provided to assess and manage risks related to chemicals.

Evaluation under REACH is divided into dossier evaluation and substance evaluation. Dossier evaluation (DEv) focuses on two different areas:

- 1) examination of testing proposals (TPs) submitted by registrants – ECHA examines the TPs and decides whether the tests are necessary or not and if yes, with which modifications or conditions; and
- 2) compliance check (CCH) of the information in the technical dossiers submitted by registrants – ECHA verifies whether the standard information requirements laid down in the Annexes of the REACH Regulation are met.

REACH requires the Agency to select at least 5 % of registration dossiers for each tonnage band for compliance check.

Substance evaluation (SEv) has a different focus: Member States evaluate substances to clarify whether their use poses a risk to human health or the environment. ECHA has a coordinating role in the substance evaluation process.

Once the evaluation is done, registrants may be required to submit further information on the substance. This is done in the form of an ECHA decision, the adoption of which always involves all Member States. Once the deadline given in the decision has passed, ECHA (in DEv) or the evaluating Member State (in SEv) will assess the information submitted and verify if it complies with the decision. If necessary, further information may be requested, or, in the case of non-compliance, national enforcement action initiated.

IMPACT OF THE OPERATIONS

Evaluation processes have improved the quality and compliance of information on chemicals

From 2009 to 2013, ECHA established its CCH process with a view to maximising its early impact on improving the quality and compliance of data in REACH dossiers. In that period, ECHA performed over 1 500 compliance checks which resulted in several hundreds of draft decisions and over 340 final decisions issued by end of 2013.

The selection of the dossiers was based on random selection, IT-screening and more manual prioritisation of substances and dossiers. The majority of these checks were targeted only at certain parts of the dossiers, in particular, to substance identity information and key physico-chemical, environmental and human health endpoints.

This initial approach demonstrated ECHA's capability to perform compliance checks efficiently and led to the successful conclusion of CCHs (targeted to specific endpoints, parts of dossiers or overall) on over 5 % of the dossiers submitted by the 2010 registration deadline, as laid down as a target in ECHA's work programmes.

More importantly, this approach raised awareness of compliance issues among a large number of registrants. As a result, registrants have not only responded to individual ECHA decisions by submitting the requested information but also shared and applied the lessons learnt to successive registrations. At the same time, ECHA was building its understanding of the key compliance issues, its IT-tools and other capabilities that were essential for moving to a more effective use of compliance check and to improve guidance and advice to registrants.

Based on the experience gained from 2009 to 2013, ECHA fundamentally revised its CCH strategy in 2014⁵¹, with the aim of improving the compliance of dossiers of priority substances and significantly increasing the number of substances identified for risk management actions such as restriction, harmonised classification and labelling (C&L) and substance of very high concern (SVHC) identification. Priority substances are those registered in the highest tonnage bands (100-1 000 and >1 000 tonnes per annum) with indications of high exposure and potential concerns with their safe use.

The strategy is based on an integrated approach to enhance the confidence of EU authorities and the public of the quality of available information on chemicals. The implementation plan⁵² developed in 2015 for the strategy further explains ECHA's plans and ambition for the next years, and can be seen as the main regulatory strategy steering not only evaluation, but all REACH and CLP processes (see 'Towards an integrated regulatory strategy' at the beginning of Chapter 1).

As explained in Chapter 1.1.1, the common screening covers the entire pool of registration dossiers and allows ECHA to focus its more in-depth assessments on substances and dossiers selected on the basis that they appear to be of most concern for safety.

The focus of compliance check is on the information that is necessary to identify carcinogenic, mutagenic and reprotoxic (CMR) and persistent, bioaccumulative and toxic (PBT) candidates and decide on the need for regulatory risk management measures. The SEv process has been initiated to clarify concerns that cannot be addressed under dossier evaluation as a more comprehensive assessment of the hazards, exposure and risks of the substance is necessary and where information other than that covered by standard registration information requirements may be needed to conclude the assessment.

In 2014-2015, ECHA concluded over 460 further CCHs and stemming from this and draft decisions issued earlier on, adopted over 400 further final decisions. The actual implementation of the revised compliance check strategy only started fully in 2015 and resulted in more than 100 concluded compliance checks on priority substances and key endpoints. Due to the long process, especially when higher tier studies are requested, the actual impact of the new strategy is not yet fully visible.

51 ECHA (2014), New strategy for compliance check: http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

52 ECHA (2015), Update on the Implementation of the Compliance Check Strategy: http://echa.europa.eu/documents/10162/21961120/mb_59_2015_update_cch_en.pdf

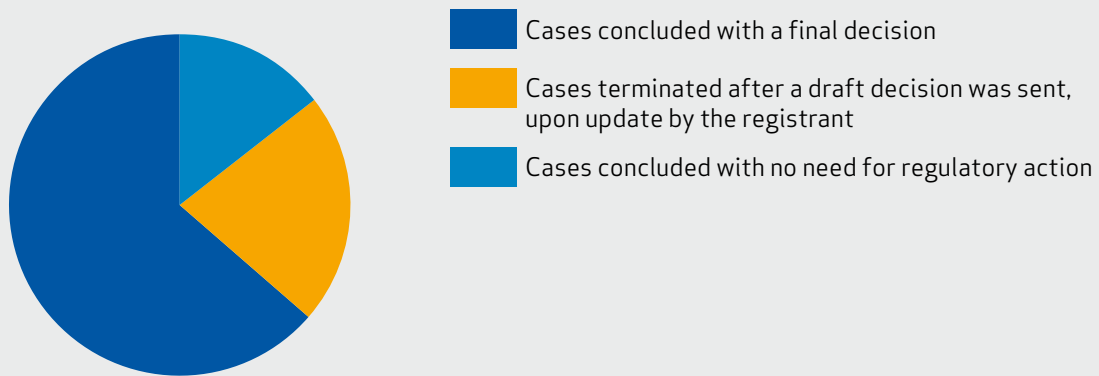
In parallel to compliance checks, the examination of testing proposals (see Figure 20) has ensured the generation of necessary and adequate information to verify the properties that are important for safe chemicals management. Overall, through the evaluation processes considerable new data have been generated for key long-term endpoints for hundreds of substances.

Figure 20. Evaluation processes have improved the quality and compliance of information on chemicals

Overall, all 4 200 substances registered in the range above 100 tonnes per year have been screened for potential concerns. Out of 4 200, compliance check has addressed about 1 500 substances to various degrees of intensity. Testing proposals have been examined for about 600 substances. Substance evaluation has addressed so far over 180 substances. In summary, taking into account overlaps between dossier and substance evaluation, at least 800 - 1 000 substances have been checked to a reasonable extent and missing key information has been requested, representing 19-24% of substances registered above 100 tonnes per year.

Number of compliance checks concluded in 2009-2015:

	Cases concluded with no need for regulatory action	Cases terminated after a draft decision was sent, upon update by the registrant	Cases concluded with a final decision	Total
Overall CCH	167	74	269	510
Targeted CCH	400	173	453	1 026
TOTAL	167	247	722	1 536



Throughout 2009-2015, ECHA has concluded up to the final decision stage 1 536 compliance checks: 510 overall ('full') CCHs and 1 026 targeted. Out of the 510 'full' CCHs, 372 addressed the lead registrant and individual registrations; the remaining 138 addressed members of a joint submission and addressed merely substance identity, opt-outs and chemical safety reports, if submitted separately, not the hazard information.

Instead, in all 372 'full' compliance checks all the eight super endpoints were evaluated; 141 out of the 372 resulted in a decision requesting further information in relation to one or more of the eight super endpoints; another 41 decisions addressed other (lower-tier) endpoints.

Requests in ECHA final decisions for selected endpoints

	No of dossiers checked for the endpoint	No of requests in final decisions for the endpoint	No of compliant cases after the follow-up evaluation	No of non-compliant cases after the follow-up evaluation	No of cases which have not reached the legal deadline yet
Repeated dose toxicity	457	73	31	2	40
Genotoxicity	465	128	55	4	69
Pre-natal developmental toxicity	460	113	42	5	66
Reproductive toxicity	457	17	15	0	2
Carcinogenicity	372	1	0	0	1
Long-term aquatic toxicity	456	36	4	0	32
Biodegradation	452	12	4	0	8
Bioaccumulation	401	3	1	1	1

Notes

1. One decision may contain more than one request
2. Repeated dose toxicity refers to requests for 28-day and 90-day studies;
3. Genotoxicity refers to all types of requests for genotoxicity or mutagenicity, either in vitro or in vivo
4. Reproductive toxicity refers to requests for screening studies for reproductive/developmental studies and 2-generation studies. Owing to the changed legal requirements, for most of these dossiers the decision is pending.
5. Aquatic toxicity refers to the three types of long-term tests, daphnia, fish and plants.

Number of testing proposals for the eight super endpoints (2009-2015)

The total number of dossiers with one or more testing proposals examined (2009-2015): 882

The total number includes terminations (before and after a draft decision) and final decisions; reasons include cease of manufacture, tonnage downgrade, registrant replacing a TP with adaptation, ECHA terminating the process due to ongoing testing etc.

	Termination before draft decision	Termination after draft decision sent	Final decision	Total
2009	0	0	3	3
2010	2	6	7	15
2011	37	9	25	71
2012	66	44	213	323
2013	9	42	167	218
2014	15	15	203	233
2015	45	15	290	350
TOTAL	174	131	908	1 213

	No of requests in a final decision for the endpoint	No of compliant endpoints after the follow-up evaluation	No of non-compliant endpoints after the follow-up evaluation	No of cases which have not reached the legal deadline yet
Long-term aquatic toxicity	134	61	5	68
Biodegradation	26	18	2	6
Bioaccumulation	12	4	1	7
Repeated dose toxicity	302	85	8	209
Mutagenicity	43	17	2	24
Pre-natal developmental toxicity	380	103	18	259
Reproductive toxicity	2			
Carcinogenicity				

Note 1: 9 TPs have been rejected by ECHA without requesting any other study instead

Note 2: One carcinogenicity study has been proposed but was rejected by ECHA

Note 3: 183 testing proposals for reproductive toxicity were examined and draft decisions processed up to the Member State Committee; due to failure to reach unanimous agreement all these draft decisions were referred to the Commission and are not concluded yet.

By requesting better information on chemicals, the evaluation processes have improved their safe use.

Information on substance properties is not useful on its own if it is not used appropriately for ensuring safe use. Adequate information on chemicals allows registrants to properly assess and manage the hazards and risks of their substances.

When requesting new information from registrants, ECHA sets a deadline and then systematically evaluates the submitted information. In these evaluations, the impact of the new information on safe use is sometimes apparent. There are several examples where the information generated has led to improved risk management at company level. For example, the registrant may have more severely self-classified their substance, applied further risk management measures, withdrawn or changed the conditions of use for the substance, or even ceased the manufacture or import of a hazardous chemical. Where the registrant has not taken appropriate action on their own initiative, ECHA has recommended for MSCAs to consider launching substance evaluation or proposing regulatory risk management measures such as harmonised classification.

REACH is pushing for better risk management

'REACH has significantly increased the knowledge on hazard and exposure/workplace conditions, allowing to fulfil data gaps and creating a unique database, which can be used on a worldwide level for exchanges on risk assessment information and data. It has catalysed the development of approaches for complex materials like inorganic UVCBs⁵³, traditionally left aside because of their variability and complexity, and activated the debate and reflection on risk management within industry. From an organisational point of view, it has set up a long-term cooperation within the sector between the different metals (manufacturers and users) and streamlined the role of sectorial stakeholders' associations'.

Eurometaux as a sectoral association

⁵³ Substances of unknown or variable composition.

'REACH has provided a vast amount of important data and risk management information for chemical substances on the EU market. This has meant that nationally the Health and Safety Authority in Ireland, with very limited resources, has been able to target our inspection activities more effectively to those workplaces using chemicals that are of greater concern to human health. In addition, at an EU level, the data generated by REACH has also allowed the Authority to contribute to the screening and assessment of chemical substances to determine what, if any, further risk management is needed.'

Yvonne Mullooly, Health and Safety Authority Ireland

The impact on the safe use of chemicals is expected to further improve following the introduction of the current compliance check strategy described above. Most of the information requests under the strategy have deadlines from 2016 onwards; therefore, it is too early to observe positive impacts on risk management. Similarly, substance evaluation only started in 2012. Out of over 180 substance evaluations, only 29 were concluded by end of 2015. If data needs to be provided by the registrant, it normally takes two to four years from the date of the decision, after which the evaluating MSCA considers the information within 12 months. It is, therefore, too early to appreciate the overall impact of substance evaluation on risk management but a significant impact is anticipated in the coming years.

Evaluation has increased scientific knowledge and understanding of substances and their hazards and risks

In the evaluation of dossiers and substances, ECHA and the Member States have addressed several new and scientifically challenging issues such as new test methods, assessment of read-across and other alternative methods, proper identification and assessment of UVCB substances, characterisation and safety assessment of nanomaterials and the assessment of complex toxicological modes of action such as endocrine disruption. This has increased scientific knowledge and understanding of the issues among EU authorities and the scientific community. Through continually improving guidance and advice, registrants improve their ability to comply with their duties in ensuring safe use.

NANOMATERIALS

Nanomaterials are a group of substances for which rapid scientific development takes place. However, they are not an isolated issue and separated from other categories of substances. In many cases, the impacts of decisions relating to nanomaterials have a direct influence over many other substances e.g. particulate substances, substances with impurities, forms of substances and UVCBs.

ECHA raised concerns about nanomaterials and REACH in the first report on the operations of REACH and CLP in 2011. Since then, ECHA has continued to implement the provisions in REACH for nanomaterials taking into account the Commission Recommendation on the definition of nanomaterial⁵⁴. ECHA's interpretation is that REACH provisions apply to nanomaterials, either as a nanoform of a substance covered by one dossier together with other forms, or a nanoform of a substance in a distinct dossier. This view is shared by the European Commission, Member States and the majority of stakeholders. However, the amount of specific information about nanomaterials in REACH registration dossiers has stayed very low.

To provide clarity in the absence of revision of the REACH annexes but more importantly to aid registrants and Member States, ECHA has been undertaking several activities:

⁵⁴ Commission Recommendation of 18 October 2011 on the definition of nanomaterial: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:en:PDF>

- Providing advice and assistance to registrants, including adapting ECHA guidance, to specifically address nanomaterials. This includes ongoing work to clarify how hazard data can be read-across between different nanoforms;
- Promoting the improvement of data quality for nanomaterials to ensure their safe use, including compliance checks, complemented by letter campaigns and other communication activities;
- Improving mechanisms for identifying and addressing nanomaterials of concern, including continued cooperation with MSCAs under substance evaluation;
- Continued and focused contributions to international activities, especially through the OECD and UN work on GHS, as well as monitoring the main developments in regulatory science;
- Contributing to increased transparency of nanomaterials on the market, their hazards and risks, on ECHA's website;
- Providing an informal Nanomaterials Working Group as a forum for dialogue and cooperation between Member States, the Commission, ECHA and stakeholders.

However, despite the efforts there has been very little progress in increasing nanomaterials-specific information in REACH registration dossiers. An effective implementation of REACH with regard to nanomaterials is hampered by legal uncertainties manifested in several appeals regarding both dossier and substance evaluation decisions on nanomaterials.

The main hurdle is the lack of explicit references to nanomaterials in the REACH annexes to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. Over the past years, the European Commission has been preparing a revision of the REACH annexes.

The delay in this process as well as the ongoing review of the definition of a nanomaterial may have increased the perception of existing legal uncertainties but also the hesitation of registrants to indicate nanoforms in their dossiers without knowing what the requirement may be once an agreement on the annexes has been reached and the review of the nanomaterial definition is completed.

Meanwhile, ECHA will continue its efforts to implement REACH and CLP for nanomaterials in the years to come.

ACHIEVEMENTS AND CHALLENGES

The quality of registration dossiers remains a concern and evaluation will continue to require sustained effort in the future

The findings of ECHA's annual evaluation reports⁵⁵ and the first measurements (see Figure 20) of dossier quality show some improvement in how registrants are meeting the REACH information requirements. A clear majority of companies comply with ECHA's decisions and update their dossiers accordingly in the set timeline. Moreover, there has been an increase in the proportion of cases where requested information was provided after the involvement of MSCAs, indicating that cooperation between ECHA and the enforcement agencies is effective and delivers results.

⁵⁵ ECHA (2016) *Evaluation under REACH: Progress report 2015* (and the earlier reports): <http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>

Nonetheless, since registrants have made extensive use of alternative methods and adaptation possibilities provided in REACH Annexes VII-XI instead of providing data from experimental studies, verification of the compliance of dossiers in the highest tonnage bands will still require sustained effort over the next years. In particular, adaptations based on read-across and weight of evidence are often poorly documented and justified, and are not acceptable. All-in-all, checking the registration dossiers in the highest tonnage bands for compliance and addressing the identified shortcomings has proven to require much more effort than originally foreseen by the legislator, mainly due to the abundance and complexity of the adaptations used by registrants. This may also mean that the registration fees that were meant to cover the evaluation costs throughout the years may not suffice.

The revised compliance check strategy does not aim to maximise the number of compliance checks but instead it puts the emphasis on maximising the impact of this regulatory process. Nevertheless, ECHA is committed to reach the 5 % minimum target set out in the legislation for the tonnage band 100-1 000 tonnes/yr by the end of 2018 and at the same time exceed the minimum target for the highest tonnage band. Hence, ECHA will continue checking the compliance of dossiers of priority substances registered in the highest tonnage bands in line with the regulatory strategy and with the aim of maximising the impact of compliance check on the safe use of chemicals.

Concerning the lower tonnage band dossiers, ECHA recommends that the target for compliance check is reviewed together with the Commission. Should the 60 000 expected dossiers be submitted for the 2018 registration deadline, 5 % would mean 3 000 further compliance checks, which is a significant number.

Due to the significantly lower information requirements for substances registered in 1-10 and 10-100 tonnes per annum in comparison to the higher tonnage band dossiers, the effort required to check their compliance is much smaller. However, the impact of compliance check in terms of the regulatory strategy (including among others, efficient identification of potential CMR and PBT candidates) would also remain very limited. At the same time, the incoming dossiers are expected to be of higher quality, due to improved IT-tools, support to registrants and the reinforced completeness check process.

ECHA would, therefore, invite the Commission to consider whether to alter⁵⁶ the percentage of compliance checks required on the two highest tonnage band dossiers and to adjust the percentage required on the lower tonnage band after 2018. This would enable ECHA to focus its evaluation resources more effectively.

The efficiency and effectiveness of the dossier evaluation processes can be further improved

In the past years, ECHA, the MSCAs and the Member State Committee (MSC) have demonstrated their ability to successfully process a high number of draft decisions on evaluation. The vast majority of the decisions have been unanimously agreed despite the fact that many decisions requiring Committee involvement have dealt with complex scientific, technical and legal issues. Furthermore, all legal timelines set for the decision-making have been met although the 60 days given for the committee to reach agreement causes a very high pressure on the whole system. There has been a noticeable rise in the number of decisions agreed by the MSC through written procedure and in the number of dossier evaluation cases concluded by the Committee each year.

However, despite having over seven years of experience in dossier evaluation, a relatively high proportion of draft decisions still receive proposals for amendments from the MSCAs, triggering the involvement of the MSC. This means that an important part of ECHA's resources has to be allocated to the decision-making process.

⁵⁶ According to REACH Regulation (EC) No 1907/2006, Article 41(7))

A draft decision requiring the MSC's involvement takes roughly double the amount of ECHA resources and is also costly to the Member States. Hence, although the unique decision-making system for evaluation decisions based on unanimous agreement by all 28 Member States is as such working well, its cost to ECHA and the Member States raises questions on the efficient and effective use of authorities' resources. It should, therefore, be discussed whether reallocating Member States' resources from dossier evaluation to supporting risk management would provide more added value overall.

Furthermore, in one important scientific issue the overall decision-making system has failed to bring results in a reasonable period of time. From 2011–2015, over 200 draft decisions had to be referred to the Commission for decision-making as a result of disagreement among Member States regarding the replacement of the two-generation reproductive toxicity study with an extended one-generation reproductive toxicity study (EOGRTS), a study guideline adopted by the OECD already in July 2011.

The Commission concluded that the amendment of the REACH information requirements was necessary before it could process any of the individual draft decisions through the committee procedure. The amendment entered into force finally in March 2015 and ECHA published the guidance updates in July 2015. Only after that has ECHA been able to start again addressing this endpoint in its (draft) decisions.

In practice, the lack of agreement and delay has meant that only very few requests requiring important standard information on reproduction toxicity have been adopted between 2011 and 2015. Concerning the over 200 draft decisions still pending in the Commission, ECHA is expecting that the Commission will issue decisions requesting the registrants to consider submitting a revised testing proposal, after which ECHA will need to re-examine the cases. In this context, it should be recalled that concerns about (lack of information on) effects on reproduction were among the main arguments leading to REACH.

Concerning its own work, ECHA has substantially streamlined its internal practices to increase the overall efficiency in the reporting period. For example, IT tools now support the whole process saving time and resources in handling cases and in monitoring and reporting on the progress.

In 2015, ECHA decided in its decision-making processes to no longer take into account dossier updates received after a compliance check draft decision is issued. Instead, indicative lists of substances were published that may be picked for compliance check in the future. ECHA continued to provide support to registrants by offering them an opportunity to discuss the process and content-related questions on the draft decision with ECHA experts. Furthermore, the consistency of ECHA decisions has increased through improvements in ECHA's data and knowledge management supported by IT-tools and a more efficient application of previously agreed policies.

To ensure that increasing workloads can be managed effectively, ECHA will continue improving the efficiency of the dossier evaluation process by reviewing and revising the process and the tools used, streamlining the content and focus of the decisions, and by further improving collaboration with the MSCAs and the MSC.

Regarding the effectiveness of dossier evaluation, implementation of the revised compliance check strategy is expected to significantly increase the impact and relevance of the compliance checks. Furthermore, the interplay with substance evaluation can be further developed, with the aim to speed up the generation of critical information to conclude on the possible concerns and need for further measures. At the same time, ECHA is committed to reviewing the length and the way the deadlines are set in its decisions so that missing information is provided without undue delay and conclusions on possible further measures can be promptly taken.

Dossier evaluation findings and follow-up to ECHA decisions need to feed better into other REACH and CLP processes.

In addition to the hundreds of concluded dossier evaluation cases, from 2012-2015 ECHA has also checked over 900 cases to verify whether the registrant has complied with an ECHA decision. This process was established in 2012 in consultation with the Member States with the aim of establishing an efficient and pragmatic process with a strong link to national enforcement.

As mentioned above, the majority of registrants comply with ECHA decisions. Tables presented in Figure 20 show the results of the performed follow-up evaluations for selected key endpoints. More details are available in ECHA's annual evaluation reports⁵⁷.

The revised compliance check strategy calls for improved integration between different processes, which means that follow-up evaluation findings also need to more readily feed into identification of the need for further action by authorities. In a relatively low proportion of cases, ECHA has been concluding whether the information submitted as a response to ECHA's decision necessitates further regulatory action: 33 substances have been flagged for harmonised classification and labelling, and nine substances for substance evaluation. Hence, ECHA is reviewing how it can clarify and strengthen the way follow-up evaluation feeds into the expected regulatory strategy outcomes in 2016, including identification of substances that can be regarded as of low or no concern.

Furthermore, a decision by the ECHA Board of Appeal⁵⁸ issued in 2015 challenged in that specific case the statement of non-compliance and necessitated ECHA to review its follow-up process and initiate consultation of MSCAs at the end of 2015. The process needs to be further developed to ensure efficiency, proper enforcement, registrants' procedural rights and a correct use of new information, which may have become available after the decision was issued.

Compliance check remains important but other measures by ECHA and other actors are necessary

Compliance and consistency⁵⁹ of information in registration dossiers continues to require further effort by registrants. Dossier evaluation plays an important role in ensuring registrants comply with the necessary information requirements. Strong and coordinated national enforcement, and a good interaction with ECHA, are essential to ensure compliance with ECHA's decisions on dossier and substance evaluation. It is also important to follow up indications of potential non-compliance with REACH and CLP that may become apparent during evaluation processes.

Given the number of dossiers requiring improvement, other measures, complementary to compliance check and enforcement, are also needed. These include improved guidance on the correct application of alternative methods to animal testing, information or letter campaigns targeting specific aspects of dossiers or types of dossier and sector-specific approaches. Such other measures are cornerstones of the current compliance check strategy and they have been successfully used so far (see Chapter 1.1.1). The challenge for ECHA is to mobilise all actors to increase their compliance and work together in its implementation. Registrants and industry associations can themselves play a major role by proactively improving and updating the dossiers and responding promptly to ECHA's requests.

57 See the 'Plans and reports' web page on the ECHA's website: <http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>

58 BoA decision of 29 July 2015 referring to case number A-019-2013: <http://echa.europa.eu/documents/10162/916312a2-d237-4fb9-a423-4b78c1d66083>

59 For example, that data reported in the IUCLID part and CSR are the same or that results are taken into account in classification and regulatory risk management measures (RRMMs).

The substance evaluation process has started well and is evolving rapidly

With the first CoRAP substances being evaluated in 2012 and only 29 evaluations having been concluded by the end of 2015, the SEv process is at an early stage of development. The majority of Member States are now actively participating in substance evaluation work. More than 200 SEvs have started and the completion and publication of numerous SEv decisions has markedly increased ECHA's own experience.

A survey on the efficiency, effectiveness, workability and transparency of the SEv process has been performed and discussed at a workshop in 2015 and the related report has been published⁶⁰. Member States, registrants and stakeholders indicated a general appreciation of the process and the improvements already made. A number of suggestions to improve the efficiency and workability for Member States and registrants will be implemented in 2016.

Starting from the development of a common process to screen and identify substances of concern, the SEv process has been targeted to better serve the information needs for regulatory risk management. The synergy with compliance check will be further improved, to allow for integrated approaches and an overall reduction of process time. In addition, ECHA will enhance its support to the evaluating Member States in the decision making and drafting of the decisions.

Being a new process, a significant proportion (ca. 20 %) of initial decisions under SEv have raised questions of interpretation. Recent Board of Appeal (BoA) decisions have either supported current practices or provided important clarification on certain REACH requirements and have improved the predictability of the SEv process. Appeals have also indicated that cost-sharing for information requested under substance evaluation is an area for which further guidance would be useful.

Given the small number of SEv cases concluded so far, it is too early to draw definitive conclusions on the impact of the SEv process on regulatory actions at this stage. However, the progress is promising: from 2012 to 2016, 222 substance evaluations have been started to clarify initial concerns that if confirmed can lead to regulatory actions, for among others carcinogenicity, mutagenicity, reproductive toxicity, sensitisation, PBT, endocrine disruptor properties, normally in combination with indications of relevant exposure (see Figure 20). So far, a high percentage of evaluations (above 80 %) lead to a request for further information, which shows that relevant substances have been selected for assessment (see the type of requests in final decisions in Figure 20).

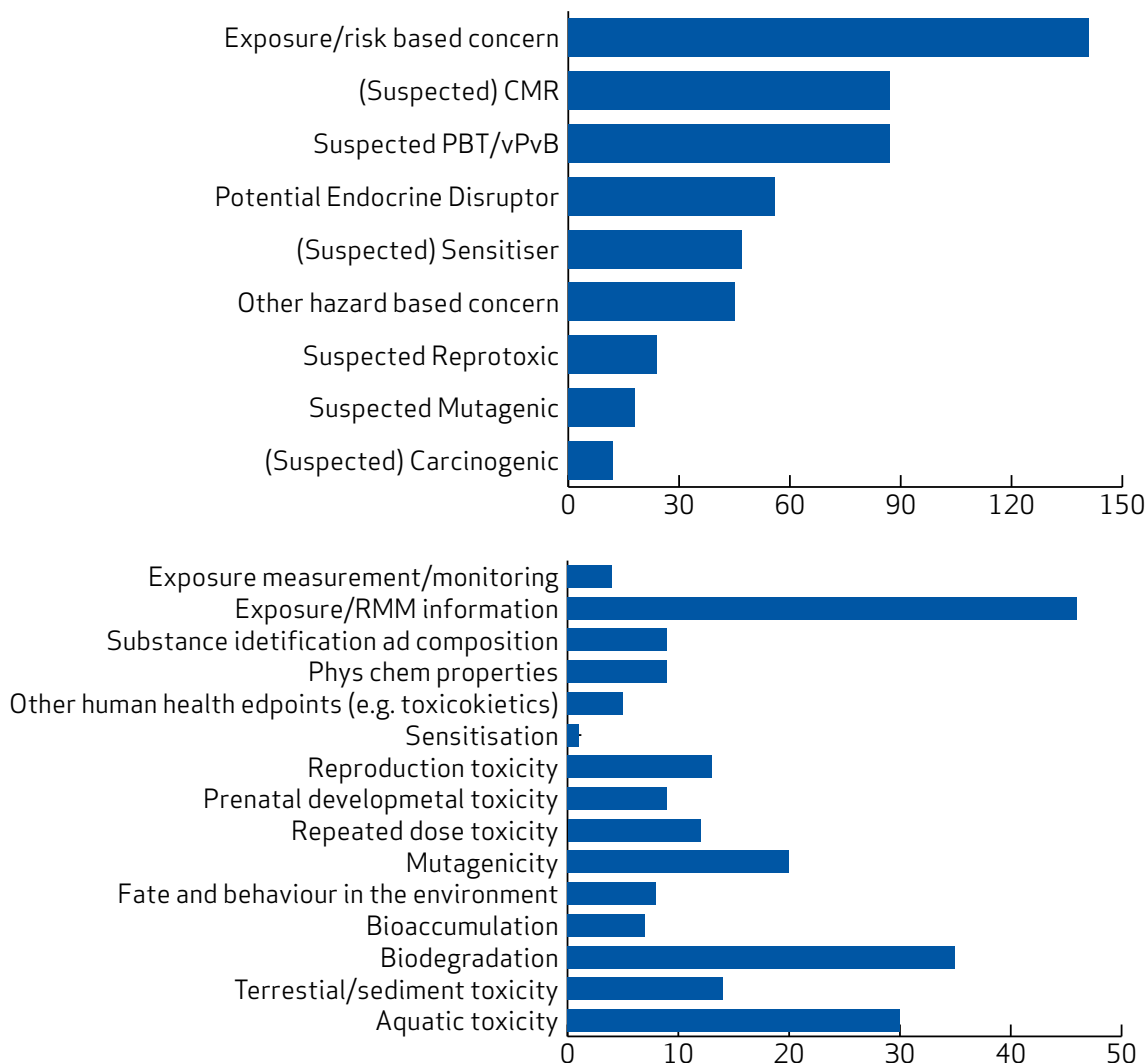
Substance evaluation has an essential role under REACH and will have increasing importance in improving the available information, clarifying the concerns and making the link with the need for regulatory risk management measures. This is particularly important for reaching the 2020 goals of the SVHC Roadmap as, in many cases, missing information prevents proper identification of SVHC candidates. In addition, the optimisation of the interplay of compliance check and substance evaluation, including the possibility of running the two processes in parallel, is expected to play an important role in shortening the time for the identification of SVHCs.

As mentioned above, the importance of substance evaluation will increase even further for the control of low volume substances registered by 2018 because the standard information requirements in REACH Annexes VII and VIII do not alone allow an assessment of CMR and PBT properties and yet cumulative tonnages or exposure can be high. A related challenge is also the effective use of information from sources other than registration and the creation of synergies with other international and national chemical assessment programmes. As more and more cases become subject to follow-up evaluation, the issue of enforcement of

⁶⁰ ECHA (2016) Assessment of the current substance evaluation under REACH, final report: http://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf

substance evaluation decisions with potentially multiple addressees situated in several Member States, will also require coordination and efforts by ECHA and the MSCAs.

Figure 21. Concerns under investigation



The top histogram shows the initial concerns indicated in the CoRAP for the 222 substance evaluations started by 2016. During the evaluation, additional concerns are often identified. The histogram beneath shows the type of information requested in final decisions before the end of 2015.

Efforts undertaken for avoiding unnecessary vertebrate animal testing

Since the start of the evaluation processes, avoidance of unnecessary vertebrate animal testing has been a key consideration in ECHA's scientific assessments and in the decision-making on evaluation cases. ECHA has also invested significantly in improving its own expertise and its advice and guidance to registrants on how to properly use adaptations and alternative methods to animal testing. The issue remains a high priority for the future.

The provisions of REACH to avoid unnecessary animal testing have worked reasonably well. The vast majority of REACH registrants submit data jointly. Nevertheless, ECHA recognises that there is further

scope for registrants to submit their registrations jointly and a Commission Implementing Act adopted in 2016 strengthens ECHA's ability to require joint submissions. Similarly, for the 2013 registration deadline, registrants submitted 701 testing proposals: 81 % of these had been examined by the end of 2015 and the remaining ones are to be evaluated by 1 June 2016.

Most of the proposals involve vertebrate animals and they are also published, and third parties are invited to submit scientifically-valid information and studies. In very few cases, ECHA has rejected the proposal as unnecessary, indicating that registrants do carefully consider before they propose further animal testing. The impact of third party consultations has remained relatively limited, despite the high proportion of cases that received third party comments.

The use of alternative methods and approaches has been reasonably widely used by registrants. By 2014, almost 20 % of analysed registration dossiers contained *in vitro* studies, either alone or combined with other information. The read-across approach was used to fulfil at least one endpoint in 75 % of the dossiers assessed. The fact that there is no obligatory data-sharing between structurally similar substances is hampering registrants' possibilities to make full use of scientifically robust read-across or category approaches.

In the last five years, ECHA, the Commission and the MSCAs re-examined the way in which the provisions of REACH for avoiding animal testing are interpreted and applied. The drivers for this have been the two complaints to the European Ombudsman and to a more limited extent, decisions by ECHA's Board of Appeal.

As a result, a number of modifications to ECHA's operations have been made, mainly in the compliance check process and the examination of testing proposals. For example, appropriate dossiers for compliance check are being identified to verify why animal tests were conducted when non-animal methods seemed possible. On the basis of the first experience of doing this, it will be decided whether compliance check proves to be an effective way of checking that animal testing is conducted only as a last resort.

Despite the above drivers for change, it should be recalled that REACH introduced a paradigm shift, namely that the burden of proof is now on industry to provide information on their substances. Therefore, for example, ECHA does not build or improve a waiving statement on behalf of registrants (e.g. read-across, or weight of evidence) once opening a dossier for compliance check or examining a testing proposal, as ECHA's role is to validate the information submitted by industry. This principle has also been confirmed by the Ombudsman and through decisions of the Board of Appeal. However, ECHA publishes the information to facilitate the registrants' work.

An important element is the timely amendment of the REACH information requirements to scientific development of the test methods, many of which already provide alternatives to vertebrate animal studies. In many cases, recognising a new method requires action by the Commission and amendment of both REACH annexes and the Test Methods Regulation, which may take a considerable time and could be accelerated.

There is very active scientific development taking place on new approach methodologies to replace animal testing. These methods are based on a new paradigm of toxicology, called toxicology of the 21st century that aims to gain a better understanding of the mechanism behind the toxic effect rather than just observing it.

The developments include a wide variety of approaches and techniques such as adverse outcome pathways, modes of action, toxico-dynamics, and various 'omics', part of which may be implemented through high throughput screening techniques. From the regulatory application point of view, it is evident that more and more of (eco)toxicological assessment will require combination and assessment of different strains of evidence, following a weight of evidence approach which will depend a lot on case-by-case expert judgement.

While many of these modern techniques are not yet mature for regulatory application it is important that an integral part of their development is to consider the regulatory applicability, for example, that the results can be used for risk assessment and classification and labelling. The other important aspect is to ensure that one of the main principles created in the OECD Chemicals Programme, the Mutual Acceptance of Data, can be applied for the information generated using the new techniques as otherwise their benefits may not be materialised.

AVOIDING UNNECESSARY VERTEBRATE ANIMAL TESTING

To provide a high level of protection for human health and the environment, REACH requires registrants to collect and provide sufficient data on their substances to ensure they can be safely used and adequately classified and labelled. At the same time, the '3R principle' (reduce, replace and refine vertebrate animal testing) also applies.

Registrants can only carry out new animal tests when they have exhausted all other relevant and available data sources. REACH places obligations on them to generate information by alternative means (particularly for human toxicity) to vertebrate animal testing where possible (testing is a 'last resort').

Companies registering the same substance must work together and share the results of tests on vertebrate animals. Such tests must not be repeated when reliable and adequate studies are available. REACH also has specific mechanisms to allow ECHA to take decisions requiring companies to share animal test data on the same substance.

If companies need to do more higher-tier tests to register their higher tonnage substances, they must present their plans for testing to ECHA. The Agency and the MSCAs need to agree on the testing proposal before tests can be conducted to ensure that they are indeed necessary and are likely to produce reliable and adequate data. Testing proposals involving vertebrate animals are published on ECHA's website to invite third parties to provide scientifically valid information and studies that may help avoid vertebrate animal testing.

For some toxicological endpoints, alternative test methods are available, or will become available in the near future. However, no alternative test methods are available to replace the 28-day and reproductive toxicity screening studies. For higher tier toxicological testing, more scientific development is needed before these can be replaced by alternative test methods. The Commission's Joint Research Centre carried out a review in 2014 of the state-of-the-art of alternative methods, which was co-produced with ECHA.

In addition to alternative test methods, registrants also make use of other alternative approaches. The most widely used approach is 'read-across', or filling data gaps either by reference to a group of substances or substance with properties that are likely to be similar or follow a regular pattern as a result of structural similarity. To assist registrants with the read-across approach, ECHA published a read-across assessment framework (RAAF)⁶¹ in 2015. RAAF is intended to make read-across assessment more transparent and consistent. The published version covers human health and a version covering the environment is under preparation.

In cooperation with the OECD, ECHA has developed the Qualitative/quantitative structural-activity relationship (QSAR) Toolbox, a software application which helps companies to group chemicals into categories and fill data gaps in (eco)toxicity data. The OECD QSAR Toolbox is the most comprehensive,

61 <http://echa.europa.eu/support/grouping-of-substances-and-read-across>

widely recognised and freely available platform for filling data gaps in regulatory hazard assessment. For higher tier human health endpoints however, QSARs cannot alone provide reliable predictions that are fit for the purposes of classification, labelling and risk assessment.

ECHA promotes the use of alternative methods in its publications, its website, guidance, and events. For example, ECHA provides information on substances and the data obtained through testing on its website and through a link to the OECD eChem Portal, which was developed in cooperation with ECHA. ECHA also regularly publishes how new or alternative test methods can be used in the REACH context.

In parallel to the above, ECHA has started two initiatives. Firstly, it is reviewing its operations to determine what further steps may be taken to implement the 3R principle. The review will consider all the relevant operations within ECHA and will be carried out in close collaboration with the Commission and the MSCAs. Secondly, a state-of-the art report is being prepared on the validity and regulatory acceptability of alternative methods and approaches. Both of these activities are planned to be completed by the end of 2017.

ECHA continues promoting methods, tools and approaches that are alternatives to vertebrate animal testing and is committed to ensuring that animal testing is only requested when necessary in its own decisions

COMMITMENTS AND RECOMMENDATIONS

- C7. ECHA will continue checking compliance of dossiers of priority substances registered in the highest tonnage bands in line with the regulatory strategy and with the aim of maximising the impact of compliance check on the safe use of chemicals. Furthermore, it will ensure that the evaluation of dossiers and the updates responding to ECHA decisions more readily feed into the other REACH and CLP processes.
- C8. ECHA will promote methods, tools and approaches that are alternatives to vertebrate animal testing and is committed to ensuring that animal testing is only requested when necessary in its own decisions.
- C9. To ensure that increasing workloads can be managed effectively, ECHA will continue improving the effectiveness and efficiency of the dossier evaluation process by reviewing and revising the process and the tools used, streamlining the content and focus of the decisions, and by further improving collaboration with the MSCAs and the MSC.
- C10. ECHA is committed to exploring, together with industry stakeholders, what constitutes a good quality dossier and thereby exemplifying what ECHA regards as sufficient information. Such acknowledgement could also be designed to promote business benefits of preparing compliant dossiers and keeping them up-to-date.
- C11. ECHA will continue its efforts to implement REACH and CLP for nanomaterials. This will include, for example, continued dossier and substance evaluation, guidance development, technical discussions at the OECD and with relevant research projects to work towards further clarifying the technical implementation of the legislation.
- R10. Registrants are urged to proactively improve their dossiers, especially in the areas where deficiencies have been regularly reported by ECHA in its annual evaluation reports and other communications. This also applies to substances, which authorities have identified as candidates for compliance check or

other regulatory action. Sectoral and other industry associations should take a leading role in helping their members in this respect. ECHA welcomes a dialogue with industry sectors, which are committed to proactively improve the quality of their registrations to better distinguish between substances of concern and of low priority.

- R11. Registrants should document better and in a more harmonised way their considerations on alternatives before proposing new animal tests in their registration dossiers. Registrants and contract laboratory organisations and consultants advising registrants should keep themselves fully updated on the development and regulatory acceptance of alternatives.
- R12. MSCAs are invited to work more closely with ECHA to allow ECHA to take over the finalisation of substance evaluation decisions and thereby ensure consistency of ECHA decisions.
- R13. MSCAs should strengthen the enforcement of the animal testing related provisions of REACH and other legislation. ECHA is committed to continue facilitating such national enforcement actions by informing national authorities of cases it has identified meriting further examination by them and encouraging exchange of information and best practices through the Forum.
- R14. The Commission should accelerate the inclusion of new alternative test methods and integrated testing strategies in the REACH annexes to avoid unnecessary animal testing. The Commission should also consider provisions for obligatory data-sharing between analogue substances for read-across and category purposes.
- R15. ECHA invites the Commission to consider whether to alter⁶² the percentage of compliance checks required on the dossiers in the two highest tonnage bands and to adjust the percentage required on the dossiers in the lower tonnage band after 2018.

1.1.4 Communication of risk management advice through the supply chain

THE OBJECTIVES OF THE LEGISLATION

REACH sets out duties and mechanisms to ensure a proper communication on uses and conditions of use up and down the supply chain. Such communication is necessary to ensure a proper description of the uses and the chemical safety assessment (CSA) at the top of the supply chain and that the end users of chemicals are adequately informed about the risk management measures that they need to take. Supply chain communication is done using safety data sheets (SDSs) that may also include exposure scenarios (extended or eSDS).

IMPACT OF THE OPERATIONS

Downstream users are becoming active but need further support

The importance of the REACH requirement to communicate uses and conditions of use in the supply chain cannot be stressed enough. It is this communication between downstream users and suppliers, between manufacturers and formulators, and essentially between all actors in each supply chain that contributes to rendering REACH more self-regulating. Businesses that interact with each other in the supply chain mutually contribute to the safer handling of the chemicals within their portfolios.

⁶² According to REACH Regulation (EC) No 1907/2006, Article 41(7)).

Meeting this obligation provides considerable challenges, in particular where supply chains are long and transcend the external borders of the EU market or where suppliers are either ill-informed on their substances (for instance, due to imports from abroad or their lack of awareness of their downstream user obligations).

In other cases, suppliers of substances tend to discharge their obligation without due diligence, such as by providing overly lengthy eSDSs (rendering them less useful to their addressees) or failing to adequately translate the safe use information into a language that can be understood by companies not aware of the regulatory terminology.

Overall, it appears that companies are dedicating increasing attention and effort to improving communication in the supply chain, such as when larger companies help their suppliers refine their SDS/eSDS, check the supplied data against in-house databanks or otherwise improve their interaction on safe use with their business partners. This is based on feedback from ECHA's SME visits' programme⁶³ in 2015 and information from individual companies.

Available indications attest to increasing worker awareness of safety requirements, better cooperation of companies with (sectorial) industry associations, and a groundswell of improvements overall in supply chain communication.

Nonetheless, more will need to be done in future to strengthen supply chain communication combined with better use and exposure information (see chapter 1.1.1) being included, firstly in registration dossiers, and then communicated along the supply chain to fully meet the expectations of the REACH Regulation.

ECHA, together with public authorities and industry associations, has undertaken various initiatives to support supply chain communication. As this intensive work has allowed these support measures to mature, ECHA is also making available an increasing volume of downstream user support material in various forms.

Communication in the supply chain benefits companies, authorities and the general public

To support and ensure that the objectives of the legislation are achieved, ECHA in collaboration with stakeholders has taken two initiatives. Firstly, in November 2011, it created a network to share good practice and identify solutions for the generation, communication and implementation of REACH exposure scenarios, the Exchange Network on Exposure Scenarios (ENES). Secondly, a cross-stakeholder action plan was published in July 2013, the Chemical Safety Report/Exposure Scenario Roadmap (CSR/ES Roadmap)⁶⁴ containing 21 actions in five areas of priority designed to improve the quality of the information in REACH chemical safety reports and extended safety data sheets.

Industry groups working on solutions under the CSR/ES Roadmap, expect that suppliers of chemicals will be able to improve their level of information about uses and conditions of use downstream. This would enable them to be in a better position to assess and increase the safety of their substances and provide appropriate use and risk management advice.

Downstream end users receive information relevant to them in a more consistent and useable way for example through extended safety data sheets and they make use of this information for improved risk management. ECHA has organised workshops and collaborated with Member States⁶⁵ and professional

63 ECHA (2015) *Report from the SME Visit Programme*: http://echa.europa.eu/documents/10162/21961120/mb_58_2015_sme_visit_en.pdf

64 The CSR/ES Roadmap: http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf

65 ECHA Newsletter, September 2015, Issue 4, Reaching out to downstream users: http://newsletter.echa.europa.eu/home/-/newsletter/entry/4_15_reaching-out-to-downstream-users

bodies (e.g. the British Occupational Hygiene Society) to educate and encourage downstream users to better integrate this information into their onsite environmental, health and safety processes.

Assuming that the usefulness of exposure scenarios will improve in the future, it is expected that this will support companies to fulfil their obligations under other chemicals legislation more effectively (see Figure 22). However, substantial work is still needed to ensure that the links between REACH and other legislation addressing chemicals can be strengthened at an operational level and aligned better with company quality and environmental, health and safety management systems as this provides ample opportunities for creating synergies and saving resources at company level.

From an MSCA perspective, the process in place improves the available use and exposure information, which in turn provides a firmer basis for them to select and prioritise substances for further regulatory processes. Industries providing transparent information gain benefits as substances are selected and/or prioritised on the basis of actual information and authorities do not need to rely on worst-case assumptions. Information on use and exposure is also available to the general public through ECHA's website.

Figure 22. Making the link between information from REACH/CLP and different onsite legal requirements for chemicals



ACHIEVEMENTS AND CHALLENGES

ECHA has initiated and is managing a stakeholder action programme to make the communication mechanisms under REACH work in practice.

A demand for good quality information on safe use advice has not yet emerged. Only around one-tenth of the expected number of exposure scenarios have been communicated in the supply chain and 20 % of companies in a recent survey have not received any exposure scenarios so far⁶⁶. Improvements are, therefore, still required in the supply chain.

In the framework of the CSR/ES Roadmap, ECHA has been active in developing and promoting transparent and well-organised information on use and exposure information that is largely consistent in expected content and formats across the different ECHA IT tools (e.g. IUCLID, Chemical Safety Assessment and Reporting Tool (Chesar), use maps). This brings benefits to the different REACH actors – registrants, downstream users, authorities – by streamlining the communication.

Through these initiatives, a common understanding among a critical mass of stakeholders has been achieved on how the system could deliver useful risk management advice in practice. ECHA, the Member States and industry have been active in developing solutions (tools, harmonised formats, methods, etc.) to support registrants and downstream users in setting up the necessary communication cycles for safe use information (see Figure 23).

Information on the safe use of chemicals must be generated and communicated in an efficient and effective way. Given the complexity of chemicals' supply chains and supply networks, harmonisation is key to manage the information flows.

ECHA's dedicated tools for registrants carrying out, documenting, processing, maintaining and updating the chemical safety assessment, and generating safe use information at the top of the supply chain (Chesar and IUCLID) are intended to support the harmonisation of information flows. In addition, under the CSR/ES Roadmap, harmonised formats for exposure scenarios in the supply chain, including a system to transfer the information electronically in all the EU languages (the 'ESCom package'⁶⁷), have been developed.

The idea is that the level of information and the structure in which it is provided is consistent across different substance suppliers, thereby making the information more accessible and comparable for downstream users. In this harmonisation process, IT exchange aspects also need to be considered and the means of communication between different systems accounted for. ECHA and stakeholders will continue to work together to facilitate harmonisation to continuously improve the efficiency of the system.

66 http://newsletter.echa.europa.eu/home/-/newsletter/entry/4_15_reaching-out-to-downstream-users.

67 <http://www.cefic.org/Industry-support/Implementing-reach/escom/>

Figure 23. The system set up by the CSR/ES Roadmap to support the development of methods and tools for communication in the supply chain

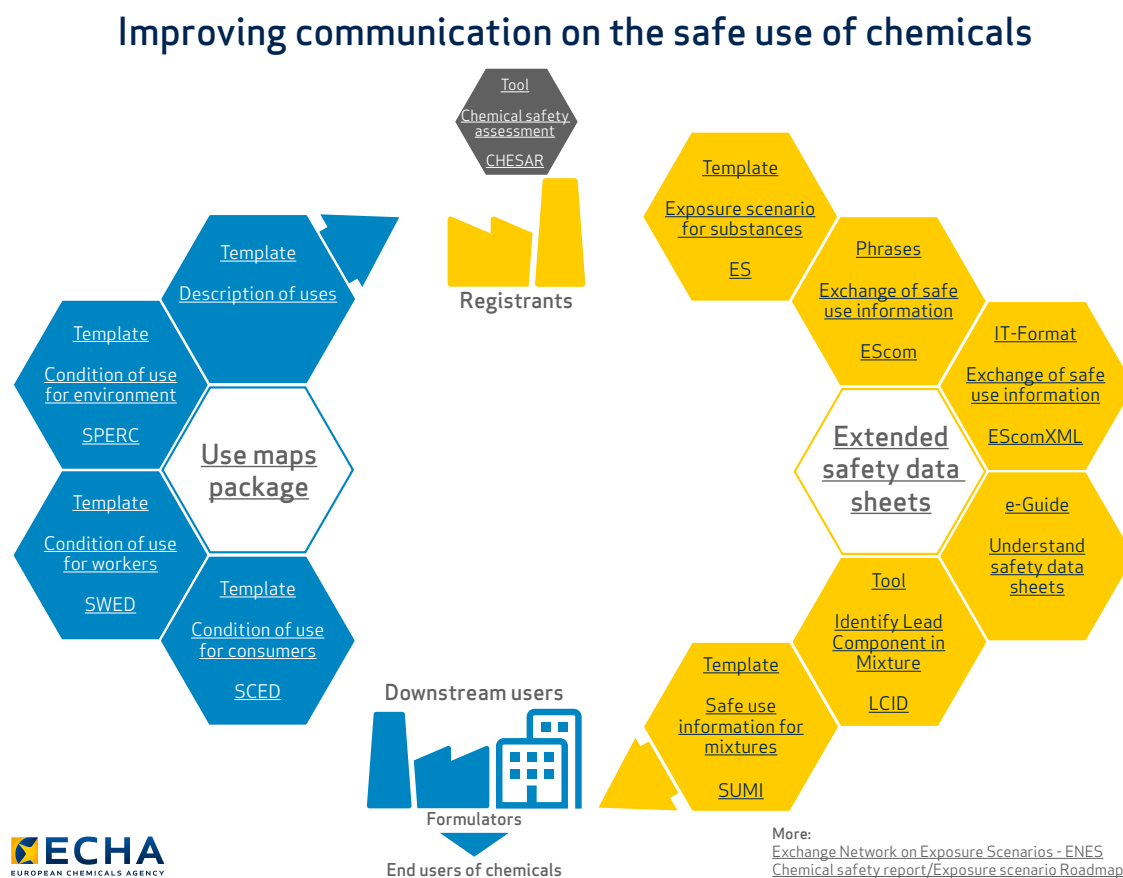


Figure 23 illustrates a circle of communication between downstream users and registrants. On the left hand side, the ‘upstream’ communication of information on conditions of use by downstream user sectors to support the generation of relevant chemical safety assessments by the registrant e.g. Chesar. To support this communication on use and exposure, tools have been or are in development by ECHA and industry such as use maps, sector-specific worker exposure descriptions (SWEDs), specific environmental release categories (SPERCs) and specific consumer exposure determinants (SCEDs). On the right hand side, information on use and exposure from the registrant’s chemical safety report into the exposure scenario for communication (which accompanies the safety data sheet for a substance) is supported by harmonised templates, standard phrases, guidance documents and examples. At the interface between the downstream formulator and end users of their mixtures, further tools have been developed (lead component identification methodology, safe use of mixture information (SUMIs)) to assist companies to convert information from exposure scenarios for substances into information for the safe use of a mixture.

New information generated for REACH has started to positively influence company practice but the communication system needs further incentives and improvements

There are indications that REACH information has started to change risk management in the supply chains⁶⁸ and the work of ECHA to support communication on uses and conditions of use in the supply chain

68 See for instance: Panteia (2013) Impact REACH op MKB (executive summary in English): <http://www.panteia.nl/Expertise/Beleid-en-Bestuur/Nieuwsoverzicht-Beleid-en-Bestuur/-/media/7%20Panteia/Files/rapport-impact-reach-op-mkb.ashx>, p.7.

has contributed to an increasing awareness and level of understanding among companies on the needs to improve.

Various downstream sectors (e.g. CEPE, AISE, EFCC, FEICA, I&P)⁶⁹ which formulate mixtures have committed to generating use maps, i.e. a systematic overview on relevant uses and the related current conditions of use. By summer 2016, these use maps are expected to be available. The information is made available in a form that can be fed into the registrants' chemical safety assessments. This will enable registrants to base their assessments for workers, consumer and the environment on realistic conditions.

Downstream users will also benefit as the resulting safety advice from the registrants will be more meaningful and harmonised. The same sectors have started to publish safe use information for mixtures (SUMIs), a set of easy to understand risk management information consistent with the outcome of chemical safety assessments for substances in a mixture.

At the company level, there are also positive indications. For example, workers having a better understanding of their chemical portfolio and the risk management needs,⁷⁰ changes in safety instructions, application of additional personal protective equipment,⁷¹ or reformulation of mixtures due to new hazard information becoming available from REACH.

However, there are challenges that require further work by all actors:

- Motivating the whole market to invest in the implementation of REACH is still an issue; though the solutions exist, many companies do not see the business case for themselves to change or are even not aware that they have obligations under REACH.
- Awareness of obligations, recommended tools and methods should continue to improve as the solutions are only useful if they are broadly used. The end of the supply chain is more difficult to reach, in particular those sectors buying (including importing) and using articles, as the safety data sheet system does not cover articles.
- The existing exposure estimation methods applied by registrants have not yet been properly connected with the established risk management practice further down the supply chain. It is expected that the increasing availability of use maps and the corresponding information on conditions of use will bring further improvements.
- The quality of information passed through supply chains needs to increase. For example, suppliers need to consistently attach exposure scenarios to their safety data sheets and downstream users need to request them if not supplied. Such improvements are still required so that companies exercise their rights to information and exposure scenarios are seen as an instrument that improves corporate health and environmental practices.

69 Five downstream user sector associations that are members of DUCC: <http://www.ducc.eu/Home.aspx>

70 See Findings from the SME Visits Programme (2015): https://echa.europa.eu/documents/10162/21961120/mb_58_2015_sme_visit_en.pdf

71 European Commission (2015) *Monitoring the impacts of REACH on innovation, Competitiveness and SMEs*, p.117: <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>

COMMITMENTS AND RECOMMENDATIONS

- C12. ECHA will - through tools, guidance and the ENES platform - continue to support stakeholders in setting up efficient and effective communication on conditions of use up and down the supply chain with a view to the sectors becoming gradually self-sufficient.
- R16. 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.
- R17. Industry organisations are invited to continue the cooperation with ECHA to exemplify and systematically describe how downstream users can benefit from harmonised and practically useful information communicated down the supply chain. This includes in particular exploring/building the practical interfaces between:
- a) Information becoming available under REACH (exposure scenarios);
 - b) Information needs to fulfil company duties under other legislation addressing chemicals; and
 - c) Information needs for product safety/product stewardship systems.
- R18. Industry organisations should actively engage in facilitating dialogue along supply chains. The traditional horizontal organisation in sector groups and 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.
- R19. The authorities should improve the interaction at an operational level between REACH and other legislation addressing chemicals, e.g. the Industrial Emissions Directive, the Chemical Agents Directive and waste⁷² legislation and to strengthen the potential links with company quality and environmental, health and safety management systems.
- R20. Exposure assessment tool owners and relevant industry organisations should foresee resources for the maintenance and evolution of IT tools to facilitate chemical safety assessments 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.
- R21. National Enforcement Authorities should target the availability of exposure scenarios in the supply chain to activate the self-regulating mechanisms foreseen under REACH at all levels of industry and commerce.
- R22. The Commission, in consultation with the Agency and Member States is invited to consider how to strengthen supply chain communication. One possibility is to examine ways to check the contents of eSDS to ensure they contain all the necessary and relevant information.

⁷² In particular product design, re-use and recycling as elements in a circular economy.

New information generated for REACH has started to positively influence company practice

Nine Exchange Network on Exposure Scenarios (ENES) meetings have taken place (typically >100 participants), with a network community of more than 200 contacts. ENES consists of individual companies, 28 industry sector associations (manufacturers, formulation and downstream end users of chemicals) themselves representing many thousands of companies at European level, consultants, NGOs, and the involvement of the national authorities from 15 Member States.

Five sectors are engaged in populating use maps and developing safe use information for mixtures.

'The support currently being provided for supply chain communication through various industry organisations such as the DUCC in coordination with ECHA (ENES) is commendable and should be continued and expanded', European Commission (2015) *Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs*, Final Report⁷³

Interview of Erwin Annys, CEFIC ([ECHA Newsletter, December 2013](#)): 'In my view, ENES is very special in the sense that in a non-confrontational way for all players to really contribute to finding solutions for real world problems that we are all confronted with. REACH is the result of a reflection on how the previous legislation could be improved. Many concepts were theoretical, but the ENES community is trying to materialise them in a practical way. The journey is indeed long, but worthwhile continuing if we want to improve.'

Interview of Kao Chemicals Europe ([ECHA Newsletter April 2015](#)): 'As registrants we have used the use maps relevant to our specific sector (such as those developed by, for example, AISE, Cosmetics Europe or IFRA) to make communication easier through the supply chain. Even though the use maps can be too broad for our particular need, we feel that they are very useful when we are trying to harmonise use descriptions.'

Interview of SPG Prints ([ECHA Newsletter June 2015](#)): 'Although the quality of safety data sheets is mixed, Dr Schreurs and Mr Bongers see that it has clearly improved since REACH came into force. This helps SPGPrints also in communicating accurate information to their customers.'

Interview of Brenntag ([ECHA Newsletter April 2013](#)): 'REACH definitely increased the intensity of communication with our customers. Especially with regard to the understanding of exposure scenarios and related obligations, such a dialogue is very important. We took this as an opportunity to provide an additional service and, by this, to increase customer retention.'

Jouni Räisänen, Finnish Chemicals Agency (CW Global Business Briefing September 2015): 'The risk management measures described in exposure scenarios and eSDSs have become more accurate and improved in quality over the past few years.'

Lessons learnt from the [SME visits 2015](#):

- Overall, the companies visited acknowledged the importance of communication in the supply chain. Their experiences with SDSs to date are mixed, with an encouraging groundswell of ongoing improvement;
- Workers' understanding of the chemicals portfolio and of its risk management needs has increased;
- In spite of persistent shortcomings, REACH has triggered better communication in the supply chain;
- Companies have intensified and improved their cooperation with industry associations.

ECHA staff after visiting SMEs

⁷³ European Commission (2015) *Monitoring the impacts of REACH on innovation, Competitiveness and SMEs*, p.206: <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>

THE INTERFACE BETWEEN REACH/CLP AND OTHER CHEMICAL LEGISLATION

The REACH Regulation completely excludes a number of substance groups from the scope of the REACH processes because they are regulated by other EU legislation such as radioactive substances and dangerous substances being transported. For other substances, the REACH processes partially apply such as for plant protection products, cosmetic products and polymers.

Working with REACH over the last eight years, ECHA has perceived two aspects in relation to the interface between REACH and other EU legislation regulating chemical substances:

- 1) sometimes more clarification is needed when applying REACH provisions to substances where other regulatory instruments also apply; and
- 2) there are opportunities to increase synergies between REACH and other chemical legislation.

The first aspect can be exemplified by the relationship between exposure limits established for substances under the Chemical Agents Directive (worker 'occupational exposure limits' - OELs) and those derived from REACH ('derived no effect levels' - DNELs) covering risks in the workplace.

REACH is concerned with authorising substances of very high concern for continued use under certain strict conditions with the specific aim of enabling substitution. This applies to the workplace, where such chemicals are also covered by occupational health and safety (OSH) legislation. These pieces of legislation should work together 'without prejudice' and in a complementary way, covering all essential aspects of workplace chemical safety.

Whilst good progress is being made to clarify the information companies provide in their REACH registrations on occupational exposure and for national inspectors^{74,75}, further efforts are made to clarify the interface with the OSH legislation. REACH has mechanisms to ensure that opinions developed by the ECHA Committees are scientifically consistent with those derived for the same substance elsewhere by EU bodies. Nevertheless, DNELs and OELs are still derived separately using different experts, making different judgements and using different methodologies. The result has been different numerical reference values for exposure limits and risk thresholds being established.

A Joint ECHA Committee for Risk Assessment and SCOEL⁷⁶ Task Force has recently been established which is working towards a common scientific approach in relation to OELs/DNELs. It is aiming to report back in 2016 and its work may provide further opportunities to integrate common scientific activities to determine safe occupational exposure levels to ensure REACH and OSH legislation work more efficiently in the future.

Concerning the second aspect, increasing synergy and integration, ECHA has compiled a powerful database of information on chemical substances. The information includes chemical substance hazard and exposure data as well as other information about how to use substances safely. As such, it also represents a significant investment by industry, regulators and other ECHA stakeholders. The data can be accessed by EU regulators, MSCAs and duty holders under REACH, as well as interested parties inside or outside the EU.

74 See IR & CSA Chapter R14, occupational exposure assessments: <http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach>

75 See Guidance for National Labour Inspectors on the interaction of REACH, CAD and CMD (2014): http://ec.europa.eu/social/main.jsp?catId=148&langId=en&internal_pageId=685&moreDocuments=yes&tableName=INTERNAL_PAGES

76 Health and safety at work - Scientific Committee on Occupational Exposure Limits <http://ec.europa.eu/social/main.jsp?catId=148&intPageId=684&langId=en>

The implementation of REACH and CLP is strongly focused on using the above information to identify substances of concern for humans or the environment. The priority setting mechanisms often rely on use and exposure considerations that are covered by other EU legislation. Thus, there is also an opportunity to use the outcome of the identification of priority chemicals for setting (chemical) priorities in other legislative instruments. This could be done either by making direct references to the Candidate List for SVHCs (e.g. eco-labelling) or by adding chemicals of concern to the relevant lists in other legislation (e.g. the Water Framework Directive).

The Commission is recommended therefore to take the initiative to capitalise on the investments made in the REACH and CLP processes and improve the interaction with other legislation addressing chemicals to ensure optimal efficiency and synergy. This is particularly pertinent when considering a move towards a circular economy in the EU and the Commission's on-going REFIT initiative.

Even more widely, the information may be used by authorities worldwide and potentially accepted under other jurisdictions to document the safe use of chemicals. This could be linked to the on-going harmonisation work of tools, formats, test methods and information requirements taking place at the OECD level. This would reduce costs for industry and facilitate the assessment of chemicals globally.

1.2 RISK MANAGEMENT

1.2.1 Identifying the needs for regulatory risk management

THE OBJECTIVES OF THE LEGISLATION

The information provided by industry through registration and notification processes under REACH and CLP should enable authorities to focus their resources on the substances that matter most for safe use and are candidates for regulatory risk management.

Concerns related to the progress made in the identification of relevant substances and progressing them through the appropriate REACH and CLP processes resulted in an agreement in February 2013 between the Member States, the Commission and ECHA on the 'Roadmap for substance of very high concern (SVHC)⁷⁷ identification and implementation of REACH risk management measures from now to 2020'⁷⁸(the SVHC Roadmap).

The activities necessary for the implementation of the SVHC Roadmap, namely the common screening and risk management option analysis (RMOA) approach, are not prescribed in the REACH and CLP regulations, but are indispensable for the integrated implementation of the evaluation and regulatory risk management processes.

77 Substances of very high concern are CMR category 1A/B, PBT/vPvB as defined in Annex XIII to REACH, and of equivalent concern as defined in REACH Regulation Article 57(f).

78 Available at: <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT>

IMPACT OF THE OPERATIONS

Improved integration of the different REACH and CLP processes increases the efficiency and coherence of the work of the Commission, ECHA and the Member State Competent Authorities.

REACH and CLP processes are designed to complement each other. The level of information and types of concern related to substances varies considerably. Therefore, different substances require different set of actions under REACH/CLP processes to come to a conclusion on whether and what type of regulatory risk management measures are needed. Over the last five years, ECHA has worked on the better integration of the different REACH and CLP processes with the aim of identifying substances that matter most for human health and the environment and then to manage them using the most appropriate (combination of) regulatory actions.

The SVHC Roadmap and its implementation plan have provided direction and set out common priorities for the work of the Commission, ECHA and the MSCAs by consolidating the main tools, common screening and RMOA. It has also provided a framework for co-operation between Member States, ECHA and the Commission.

All this has increased the efficiency and coherence of the authorities' work as further explained below. This is essential to ensure that the limited resources of authorities and industry are focused on the highest concerns, to use an optimal set of REACH/CLP processes (and avoid unnecessary regulatory steps) and to reduce the overall time needed from the identification of concerns until the initiation of the appropriate regulatory process.

To gain full benefit of the work done to identify relevant substances and to clarify the concerns through further information generation and assessment requires that, where needed, regulatory actions are taken and completed. For that, there is a need to further align views and to get a clearer policy steer on the regulatory route to pursue in different cases, in particular, when to use the authorisation process.

The integration of the REACH and CLP processes will be further enhanced by the ongoing inclusion of compliance check into the common screening approach and feeding the evaluation outcomes back to the screening, in line with the ECHA document 'Implementation of the strategy to increase registrant's compliance in the light of the multi-annual strategic objectives and WSSD 2020 goals' (see the beginning of Chapter 1).

Increased cooperation and coordination among Member States, ECHA and the European Commission has resulted in a more streamlined and coherent management of substances of potential concern by reducing overlapping activities on substances and facilitating cooperation on groups of substances.

Identifying and addressing structurally similar substances, including those which are not necessarily yet on the EU market, in a coherent manner aims to avoid cases where industry moves from one substance to another equally problematic one. Such regrettable substitution does not only make substitution meaningless from the protection point of view but also results in unnecessary costs to industry.

Cooperation between the Member States, ECHA and the Commission has also supported less experienced authorities in joining the implementation work and by that increased the number of substances addressed.

THE COMMON SCREENING APPROACH AND RMOA

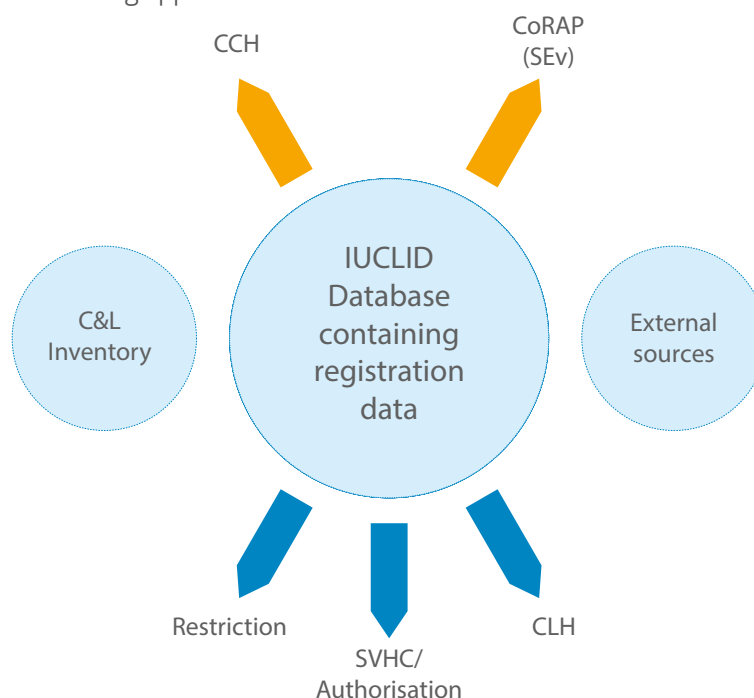
ECHA has developed, in collaboration with the MSCAs, a common screening approach to systematically screen the available information in the REACH/CLP databases and external hazard and exposure data sources to identify substances of potential concern and to select these substances for further scrutiny by the appropriate REACH/CLP processes. Priority is given to substances with (potential) SVHC properties and those with high exposure potential.

The common screening approach includes:

- 1) IT-based mass screening to identify substances with human health and/or environment concerns and indication for potential exposure; and
- 2) manual screening to scrutinise the outcome of the automated IT mass screening and to confirm the appropriate process to be used for each case.

The risk management option analysis (RMOA) framework has supported a better understanding and integration of the different regulatory risk management instruments by ECHA, Member States and the Commission. The Member States and the Commission can initiate REACH/CLP processes on their own. Discussion of the most suitable combination of regulatory actions early in the process aims to ensure that different RMOA views can be taken when planning regulatory measures. This reduces the need to change the course of action later in the process, increases predictability and ensures a smoother regulatory process. An example of a group of substances that are undergoing the common screening and the RMOA process are poly- and perfluorinated substances (PFASs) – see example below.

Figure 24. The common screening approach



The common screening approach systematically screens the available information in the REACH/CLP databases and external data sources to identify substances of potential concern and to select these substances for further scrutiny by the appropriate REACH/CLP processes. CCH is compliance check, SEv is substance evaluation and C&L is classification and labelling.

AN EXAMPLE OF COOPERATION BETWEEN MSCAS AND ECHA

ECHA and a number of Member States are working in close cooperation to regulate poly- and perfluorinated substances (PFASs) that have PBT or other properties which merit SVHC identification and some are known to be released to the environment.

A high number of PFASs have been notified (more than 100) to ECHA and are in the C&L Inventory. Many are also registered and a very high number of related substances and precursors are anticipated to enter the EU in articles.

PFASs are the first large group of substances for which the screening, evaluation, CLH, SVHC and restriction processes are utilised and scheduled in a targeted manner applying the possibilities of grouping and read across to gain efficiency and ensure timely risk management. In 2016, approximately ten further substance-precursor groups are being examined.

Predictability and transparency have increased.

One of the objectives of the SVHC Roadmap is to increase the transparency and predictability of the activities carried out under the roadmap. This is intended to support industry to be proactive in defining their business strategies for substances of potential concern that may be subjected to regulatory action in the future.

To achieve this objective, information on substances undergoing RMOA and informal hazard assessment has been published on ECHA's website since 2014 through a tool referred to as 'PACT' (Public Activities Coordination Tool). As well as supporting industry, PACT also alerts stakeholders to be prepared to provide their contributions during the public consultations, if regulatory processes are initiated.

ACHIEVEMENTS AND CHALLENGES

Most of the substances of concern with sufficient hazard information have been or are being addressed.

The SVHC Roadmap gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020. To achieve this target, a holistic approach is needed to cover all REACH and CLP processes. This includes the screening, information generation and assessment processes preceding the inclusion of substances in the Candidate List and considers other risk management measures.

During 2013, ECHA developed a plan on how to implement the SVHC Roadmap until 2020⁷⁹, together with Member State competent authorities and the Commission. This plan sets out how to identify substances, which have SVHC properties and to determine whether they are relevant according to the criteria set out in the SVHC Roadmap and therefore should be included in the Candidate List. The implementation plan has given direction and set out common priorities for the work of MSCAs on substances of concern.

As a result, the vast majority of the known registered CMRs have been scrutinised and either included in the Candidate List, concluded that inclusion in the Candidate List is not needed or are undergoing RMOA to determine the need for further action. Work done under the previous legislation⁸⁰ has also enabled

⁷⁹ ECHA (2013) *SVHC Roadmap to 2020 Implementation Plan*: http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf

⁸⁰ Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993R0793:EN:HTML>

the identification of substances as SVHCs due to their PBT and ED properties and to include them in the Candidate List (18 and five respectively).⁸¹ This also means that the resources of the MSCAs can be directed to screen and address new CMRs, PBTs, EDs and other SVHCs.

REGISTERED CMRS WITH A HARMONISED CLASSIFICATION

Since 2009, Member States and ECHA have been working on substances with a harmonised classification under CLP as CMR category 1A or 1B to identify which should be included on the Candidate List as substances of very high concern (SVHCs) or addressed by other regulatory means.

According to our most recent analysis, there are over 300 registered substances with a harmonised classification as CMR 1A or 1B and of those over 100 have already been placed on the Candidate List. About one-third of the remaining substances are petroleum and coal derivatives and for these, ECHA is collaborating with Member States, the Commission and industry to address them in a systematic manner. The rest have been examined and found not to warrant identification as an SVHC at this stage. The majority of these substances are used only as intermediates.

ECHA continues to examine the registration database for newly harmonised CMR substances and for changes in the uses of the old ones to identify needs for further regulatory action. Furthermore, work to identify structurally similar non-registered substances continues to inform industry and authorities of substances, which may not be suitable alternatives for registered CMRs.

Work is ongoing to identify and address new substances that matter, but this requires time and resources.

New CMRs are being identified either by proposing new harmonised classification and labelling (based on available data, see Chapter 1.2.4) or, where further information is needed, through compliance check or initiation of substance evaluation and subsequent classification.

In most cases, the identification of new PBT or ED substances requires generation of further information and assessment before final conclusions on their properties can be drawn. For many suspected PBTs and EDs this work is on-going, but this can take substantial time due to the need for higher tier endpoint testing and the related decision-making timelines defined in the regulations. Nevertheless, the common screening approach has laid a foundation for efficient and effective identification of candidate substances for further information generation.

Together with Member States, ECHA needs to ensure that the information generated is used to conclude on the concern and those substances are followed up and processed through the relevant processes. A full picture of the substances under screening, generation of information and assessment is available in the annual report of the SVHC Roadmap.

The main challenge is to develop new means to identify substances of potential concern in particular when hazard information is lacking or scarce, including for substances, which will be registered in 2018. In particular, approaches based on their use profile, presence in articles and exposure potential should be further explored to target generation of further information for substances that matter most. However, this is currently hampered by the lack of adequate use and tonnage data in the registration dossiers. Furthermore, information on substances in articles produced in and imported to the EU is also scarce (see Chapter 1.2.5).

⁸¹ For an overview of the progress in the implementation of the SVHC Roadmap, see Annual Reports: http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

An important option that is being explored is the identification of structurally similar substances and other grouping approaches to address substances in a holistic and coherent manner with the aim of drawing conclusions more quickly on whether regulatory risk management intervention is needed or if they are of lower priority. Cooperation with industry sectors can be used to target and speed up the identification of substances for further work. Good examples have already been demonstrated with the petroleum and coal stream sectors. Information from other sources such as research and biomonitoring programmes or through international cooperation are also being used.

On a wider point, the process from identifying substances of concern to deciding upon the appropriate risk management measure can take as long as five years. This may be perceived as a considerable amount of time to allow a substance of concern to remain on the EU market. The time taken can result from sequentially running the various REACH processes, for example, the need to carry out a higher tier study for one or several end points as a result of a compliance check followed by substance evaluation; an RMOA and then applying the most effective risk management measure.

The integrated strategy described in Chapter 1 is expected to speed up the overall process by shortening time gaps between processes, or performing them in parallel, or skipping steps if not necessary for risk management. Nevertheless, it is sometimes necessary that several processes are performed in sequence. ECHA would like to work with the Commission and the MSCAs to reflect on how best to streamline this sequential approach to optimise the overall timeframe for REACH processes to work together.

RMOA has become the standard approach for MSCAs to determine regulatory action

With the SVHC Roadmap implementation, the RMOA has become a standard approach for MSCAs to assess the need for and type of further regulatory action. Increased cooperation and coordination of the work of the Commission, ECHA and the MSCAs has resulted in a more streamlined and coherent management of substances of potential concern. This has been partly achieved by setting up dedicated groups⁸² to support the coordination and implementation of the roadmap.

Around two-thirds of the Member States are actively involved in the different activities linked to the SVHC Roadmap and this number is increasing. More experienced Member States and ECHA provide training and support to less active Member States to build capacity for the implementation of the roadmap, which should increase the proposals for regulatory action.

Nevertheless, there are still differences in views amongst the Member States on how and when to use the authorisation requirement or when to initiate the restrictions process or advise other community measures. The work done to streamline and support the authorisation application and decision-making phase (see Chapter 1.2.2) is expected to mitigate the concerns related to the proportionality of the authorisation requirement.

⁸² PBT and ED expert groups, CMR and sensitiser coordination groups, exposure network, risk management expert meetings (RiME): <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern>

Figure 25. Participation of MSCAs in SVHC Roadmap-related groups

PARTICIPATION TO SVHC ROADMAP RELATED GROUPS							
	RiME	PBT Expert Group	ED Expert Group	Sensitiser coordination group	CMR coordination group	Exposure expert network	PetCo
AT							
BE							
BG							
CY							
CZ							
DE							
DK							
EE							
EL							
ES							
FI							
FR							
HR							
HU							
IE							
IT							
LT							
LU							
LV							
MT							
NL							
NO							
PL							
PT							
RO							
SE							
SI							
SK							
UK							

Figure 26. Participation of MSCAs in SVHC Roadmap-related activities

PARTICIPATION TO SVHC ROADMAP RELATED ACTIVITIES								
	Screening	PBT	ED	SEv	RMOA	CLH	SVHC	Restriction
AT								
BE								
BG								
CY								
CZ								
DE								
DK								
EE								
EL								
ES								
FI								
FR								
HR								
HU								
IE								
IT								
LT								
LU								
LV								
MT								
NL								
NO								
PL								
PT								
RO								
SE								
SI								
SK								
UK								
ECHA	2014 ->	2012 ->	2014 ->	2012 ->	2013 ->	2009 ->	2008 ->	2009 ->

Expert groups support the assessment of substances with persistence, bioaccumulative and toxic (PBT) and endocrine disruptor (ED) properties to accelerate the processes

The assessment of PBT and ED properties of substances is often complex and requires in-depth expertise to draw conclusions from the available data and identify further information needs. The standard information available in registration dossiers may be insufficient to conclude on the properties of substances and, hence, additional specific tests will be needed. Responding to this need, two expert groups have been set up for the assessment of (potential) PBT and ED substances.

The expert groups provide a forum for MSCAs, stakeholders and the Commission to informally discuss complex questions on the hazard assessment of suspected PBT or ED substances with other authorities and accredited stakeholder organisations (industry and public interest). In this way, they facilitate the formal opinion-forming process by the MSC or RAC in substance evaluation, SVHC identification and restriction processes.

These groups are also used to support work under the Biocidal Products Regulation (BPR). A wider use of the groups to support assessment of PBT and ED properties under other regulatory frameworks, in particular pesticides and pharmaceuticals, could be envisaged to enhance the use of common approaches and consistent opinions on the same substance.

Figure 27. Assessments discussed in the PBT Expert Group 2012–2015

Meetings 1-11	Number of substances
REACH substances discussed	145
• <i>Of these CoRAP substances with PBT/vPvB concern</i>	124
• <i>Of these other PBT/vPvB hazard assessments</i>	21
Outcome:	
According to MSCA's assessment NOT PBT/vPvB	31
According to MSCA's assessment PBT/vPvB	7
Potential PBT/vPvB but further assessment is postponed	10
Authority's assessment under development	97
• <i>cases where further information needs to be generated</i>	64
• <i>cases where refinement of the assessment is required</i>	33

Figure 28. Assessments discussed in the ED Expert Group 2014–2015

Meetings 1-6	Number of substances
REACH substances discussed	33
• <i>of these CoRAP substances with ED concern</i>	21
• <i>of these other ED hazard assessments</i>	12
Outcome:	
According to MSCA's assessment NOT ED	0
According to MSCA's assessment ED according to WHO/IPCS definition	1
Potential ED but further assessment is postponed	1
Authority's assessment under development	31
• <i>cases where further information needs to be generated</i>	18
• <i>cases where refinement of the assessment is required</i>	13

COMMITMENTS AND RECOMMENDATIONS

- C13. The common screening approach has laid a foundation for the efficient and effective identification of candidate substances for further information generation. ECHA together with the Member States will ensure that the information generated is used to conclude on the concern and the Member States working with ECHA should further enhance the integration of the CCH and SEv processes with risk management processes to ensure that the objectives of the SVHC Roadmap will be reached. To optimise the management of substances of potential concern and avoid delaying potential further regulatory actions, the MSCAs and ECHA should a) target the generation of further information to aspects necessary for regulatory risk management and b) together with the Commission, reflect on ways to streamline the overall timeframe for REACH processes to work together to ensure that identified regulatory measures are initiated in a timely manner.
- R23. Industry should improve the information on uses and volumes in their registration dossiers and keep these up-to-date. Without adequate information, authorities are not able to focus their regulatory interventions where these are needed to ensure safe use.
- R24. The Commission should consider whether the ECHA expert groups to support the assessment of PBT and ED properties of substances could also be used for other legislation.
- R25. The information requirements and testing strategies for endocrine disrupting substances should be reviewed to allow for their effective identification.

SCIENTIFIC CHALLENGES TO THE OPERATION OF REACH AND CLP

Several areas of scientific uncertainty have remained over the last five years that have posed difficulties for the operation of REACH and CLP. In particular, for endocrine disruptors (EDs) and considering the combined exposure of several substances.

EDs interfere in some way with natural hormone action, and in doing so can produce adverse effects on humans and the health of wildlife. The endocrine system is a complex network of glands, hormones and receptors that control growth and development during childhood, regulation of bodily functions in adulthood and the reproductive process. The most widely accepted definition for EDs is the one by the International Programme for Chemical Safety (IPCS, 2002): '...exogenous substances that alter the function(s) of the endocrine system and consequently cause adverse health effects in an intact organism or its progeny, or (sub)populations.'

Identifying substances with endocrine-disrupting potential that require regulatory action remains a significant challenge. Under REACH, the potential for ED properties is an important factor in the prioritisation of substances for assessing the need for regulatory risk management in the context of the SVHC Roadmap to 2020 and in particular for inclusion in the Community rolling action plan (CoRAP) for substance evaluation.

Substance evaluation may lead to requests for further information to conclude whether a substance has ED properties. ECHA, as part of its activities under dossier evaluation, also considers ED properties when assessing information in registration dossiers. The possibility to request information specifically on ED properties under dossier evaluation is currently limited to the extended one-generation reproduction toxicity study (EOGRTS), which as a standard information requirement applies to higher tonnage substances.

In relation to REACH regulatory risk management, EDs may be identified on a case-by-case basis as substances of very high concern (SVHCs), where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to CMR or PBT/vPvB substances (REACH Article 57(f)). So far, five (groups of) substances have been identified as SVHCs and EDs of equivalent concern on the basis of the above cited IPCS definition and the provisions set out in REACH Article 57(f). The inclusion of DEHP as an environmental ED based on REACH Article 57(f) is currently challenged before the Court of Justice, which might bring further clarity on this issue.⁸³

An Endocrine Disruptor Expert Group (EDEG), coordinated and hosted by ECHA, was established in February 2014 to provide informal, non-binding scientific advice on questions related to the identification of ED properties of chemicals. This advice does not anticipate or interfere with formal regulatory decision-making, which exclusively remains the responsibility of the competent bodies designated in the REACH and Biocidal Products Regulations.

The European Commission is currently working on a proposal for science-based criteria for endocrine disruptors, as required in the Plant Protection Products Regulation and the Biocidal Products Regulation. ECHA is following developments closely as these will have implications for the approval of biocidal active substances and also, potentially, for identification of substances with ED properties as SVHCs under REACH. In this context, it would be advisable to review and revise the REACH information requirements to enable effective identification of ED properties, based on the latest developments on test methods and screening strategies, and taking into account the forthcoming criteria.

In addition, ECHA contributes to international activities on EDs, e.g. by participating in OECD work and assisting the work of the European Commission, and continues to monitor the main developments in regulatory science. Further information on the EDEG can be found on ECHA's website⁸⁴:

Risks from combined exposure are used to describe one of the following cases:

- Exposure to a single substance by one source of release and/or use through different routes of exposure;
- Exposure to a single substance by multiple sources of release and/or use;
- Exposure to multiple substances by one source of release and/or use; and
- Exposure to multiple substances by different sources of release and/or uses.

The term 'cocktail effects' of chemical mixtures is often used in regulatory settings and would apply to the above cases when exposure occurs through one source if the substance is a UVCB or multi constituent, or through multiple sources to various substances.

REACH already addresses combined exposure from single chemicals since it is a requirement to perform risk characterisation for combined routes of exposure; oral, dermal and inhalation (REACH Annex I, Section 6). The CLP Regulation also has provisions for the classification and labelling of mixtures addressing the hazard that can result from exposure to a mixture.

⁸³ Case T-115/15, *DEZA v. ECHA*.

⁸⁴ See the 'Endocrine Disruptor Expert Group' web page on ECHA's website: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-group>.

Although REACH does not explicitly require risk assessment from combined exposure to multiple chemicals, restriction and substance evaluation processes allow these risks to be considered. For example, a restriction proposal on four phthalates submitted in 2016 was based on the risks from the combined exposure to these four anti-androgenic substances.

The European Commission has initiated work within the area of combination effects of chemicals based on the concerns from the conclusions of the Council of Environmental Ministers. In its conclusions, the Council invited the Commission to assess how and whether existing legislation addresses this problem and to suggest appropriate modifications and guidelines. Concerns were raised that current approaches for the assessment of chemicals does not provide sufficient security and that the combination effects of chemicals should be addressed in a more systematic way.

ECHA has been participating in the activities organised so far by the Commission regarding combined effects of chemicals, at OECD activities dealing with the topic and the development of case studies, and through WHO/IPCS risk assessment network as a member of the Working Group on Combined Exposures.

Adequate methodology to perform risk assessment addressing combined exposure of chemicals has been developed for the purpose of the Biocidal Products Regulation for human health and the environment and is included in the ECHA *Guidance for Biocides*.

ECHA's database of chemicals is essential as a source for future activities in the field of combination effects of chemicals as it provides the (eco)toxicological information on single chemicals and information on uses that can be used to identify the nature and likelihood of exposure from multiple sources of uses. The database is accessible from ECHA's website.

1.2.2 Authorisation

THE OBJECTIVES OF THE LEGISLATION

The authorisation process under REACH aims to ensure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives, where these are economically and technically viable. At the same time, the good functioning of the internal market is to be protected.

Inclusion in the Candidate List is a prerequisite for subjecting a substance to an authorisation requirement. The inclusion in the Candidate List also triggers obligations for article producers, importers and suppliers to generate and communicate information.

ECHA is obligated to regularly prioritise substances in the Candidate List and recommend to the Commission which ones should be included in Annex XIV ('Authorisation List'). Based on this recommendation, the Commission decides on the inclusion in the Authorisation list.

Substances on the Authorisation List cannot be placed on the market for a use or used after the 'sunset date' unless an authorisation is granted or an application has been submitted before the 'latest application date' and the Commission has not yet made its decision. The ECHA Committees, RAC and SEAC, give their opinions on applications for authorisation and provide a recommendation for the review period. The final decision to grant or not grant authorisations is taken by the Commission.

IMPACT OF THE OPERATIONS

The authorisation process is delivering the aim of promoting substitution

The potential impact of the authorisation process can be monitored by the extent to which substitution has taken place and exposure reduced with an accompanying reduction of the impacts to EU workers, citizens and the environment. In addition, it is also important to assess to what extent the authorisation process has increased the costs for EU industry.

Substitution is one of the main aims of authorisation and all three steps of the authorisation process contribute to this aim. When a substance is identified as being of very high concern, companies are given a strong signal that they need to try to find substitutes. At the latest, when a substance is placed on the Authorisation List, companies will need to make a strategic business decision: to substitute or to continue to use the substance and thus apply for an authorisation.

Changes in the uses covered by and in volumes reported in registration dossiers, as well as anecdotal evidence show that substitution happens as a result of the substance being listed on the Candidate List and the Annex XIV recommendation.

It is clear however, that more and more companies, in particular within the retail sector, are developing company strategies that focus on reducing or avoiding the presence of substances on the Candidate List in the products they market⁸⁵. As a result, pressure is placed on their suppliers to provide information on the substances they use and to initiate further analysis of possible alternatives.

Adapting company policies to avoid the presence of SVHCs in products

'The Adidas Group has a long history in chemical management. Already in 1998, we were one of the first companies in the industry to implement a restricted substance list applicable for all our products.

Our programme has constantly evolved based on emerging scientific knowledge and feedback from our stakeholders. For instance, chemical input has become a matter of concern in our industry and as a consequence we have focused on inputting chemical management by nominating chemicals to be used in our production processes.

Additionally, we have started to phase out chemicals of concern such as perfluorinated chemicals (PFCs). We aim to phase out PFCs for 99 % of all of our products by the end of 2017.

For a consumer-oriented, high performance, sporting goods company, this is a very ambitious goal. To achieve it, we drive for innovation and pioneer new methods to make sure that any alternative substances are environmentally-sound and technically feasible - without compromising on the performance and quality of our products.

To further improve our chemical management system, in 2014 we entered a partnership with Bluesign® technologies - a leading chemical evaluation system provider - and implemented their chemical positive database 'Bluefinder' into our apparel material supply chain.

We set targets for the use of Bluesign® approved and therefore environmentally sound chemical formulations. Already in the first year of implementation in 2015, we achieved a high level of adoption. 65 % of dyestuffs and 25 % of auxiliaries are now Bluesign® approved. We will continue to increase these targets on an annual basis.

85 See for instance, 'ChemSec Business Group': <http://chemsec.org/what-we-do/business-dialogue/chemsec-business-group> as well as the report ChemSec (2016) The Bigger Picture Assessing economic aspects of chemicals substitution: http://chemsec.org/images/The_bigger_picture_160217_print.pdf

Our approach to sustainability is driven by collaboration. We are a founding member of the Zero Discharge of Hazardous Chemicals group (ZDHC), an industry group of leading brands with the goal of promoting the adoption of more sustainable chemistry and practices. The ZDHC publically releases voluntary standards and tools such as the first industry-wide Manufacturing Restricted Substance List (MRSL).⁸⁶

Philipp Meister, Director Strategy, Social and Environmental Affairs, adidas Group, for the ECHA Newsletter of February 2016

Substitution takes place at company level and thus, it is not necessarily visible outside. It results from a strategic choice of a company to improve product functionalities or properties. Paradoxically, when substitution is working well, authorities are usually not informed, because companies that have substituted do not need to apply for authorisation. For ECHA, it is difficult to know if a non-application is the result of a decision to substitute, or a 'discontinued use' which may not always be related to the substance being placed on the Authorisation List. Nevertheless, there are some indications of substitutions taken place as a consequence of an authorisation requirement.

Firstly, by March 2016 out of the 31 substances that have been placed on the Authorisation List, ECHA received 90 applications for authorisation relating to only 21 substances (see Figure 30). This is an indication that some substitution may have taken place. Moreover, many⁸⁶ of the submitted applications for authorisation that have been assessed requested the necessary time to substitute the SVHC with a safer alternative. These applications expressed a clear commitment to substitute within given timelines.

Furthermore, National Enforcement Authorities have visited 235 sites in the context of the first Forum enforcement pilot project on authorisation focusing on two substances for which no applications were received (MDA and musk xylene). Inspectors have found that in about only 1 % of these sites, musk xylene was placed on the market or used in breach of Article 56.

Secondly, even if applications for authorisation are received, there are indications that substitution is taking place. For instance, in the case of the plasticiser DEHP, originally 25 companies made a registration⁸⁷. However, only three manufacturers of DEHP applied for an authorisation. During the application process, one company (Arkema, France) discontinued manufacturing DEHP. The EU's production of three phthalates (DBP, DEHP and DIBP) has also reduced by more than 50 % during the period 2010-2015. Other examples are diarsenic trioxide for which Yara France has found a substitute and the complete substitution of the flame retardant HBCDD by a polymeric (brominated) flame retardant, once it is available in sufficient quantities⁸⁸.

Article 69(2) of REACH⁸⁹ provides a further incentive to substitute: ECHA needs to propose a restriction of the substance, should there be a risk from the use of articles containing Annex XIV substances that needs to be addressed at EU-wide level. ECHA is currently investigating this for the four phthalates (DBP, DEHP, DIBP and BBP).

86 About a quarter of the opinions have concerned "bridging" applications, where the applicant has identified its substitution strategy and applied for a specific period identifying when the substitution would take place.

87 Three submitted an intermediate registration. Some registrants have subsequently ceased manufacture or import of DEHP and thus, deactivated their registration.

88 Benzene, ethenyl-, polymer with 1,3-butadiene, brominated (CAS 1195978-93-8).

89 REACH Regulation (EC) No 1907/2006, Article 69(2) states that ECHA shall prepare a restriction dossier if the risk of the substances used in articles is not adequately controlled. This restriction would cover both articles produced in and imported to the EU.

Risks of using SVHCs are reduced

The risks have been reduced through different mechanisms. When a substance is identified as being of very high concern this directly impacts affected companies and stimulates them to review the necessity of using the substance. After a substance is prioritised and placed on the Authorisation List, companies become even more aware of the need to find alternative solutions. In addition, downstream user companies need to notify ECHA that they are using substances in line with the authorisation decision (based on Article 66 of REACH⁹⁰).

If companies decide not to substitute the substance, but continue using it, they often take steps to reduce the risks associated with the use to increase the possibility of a favourable opinion from the ECHA Committees and a favourable decision of the Commission. Such additional risk reduction measures have been introduced in practice, as evidenced by several applications⁹¹.

Three examples where risks have been reduced during the authorisation application process⁹²

When Sasol-Huntsman GmbH & Co. KG (Germany) applied to use dibutyl phthalate (DBP) in the production of maleic anhydride, a monitoring campaign was conducted on the production plant. Sasol-Huntsman found that the exposure of DBP to workers was already safe, but to further reduce potential exposure it benchmarked on Huntsman's production sites in Florida and Louisiana (US). As a result, procedural and equipment changes were implemented in the German plant. A follow-up monitoring campaign showed that exposure and related risks were reduced by about 50 %.

Yara France applied for an authorisation to use diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate in the production of ammonia. During the application process, Yara France identified and adopted new risk management measures for workers. Furthermore, as part of the application process and analysis of alternatives, Yara France found a substitute (potassium vanadate), which it will adopt in March 2017 concurrent with the legally compulsory planned halt of the installation.

Blue Cube Germany Assets GMBH⁹³ (subsidiary of Olin Corporation) applied to use trichloroethylene (TCE) in industrial parts cleaning and degreasing of parts. There are about 600 industrial sites using TCE in the EU. The conditions that Blue Cube required for these users, as a requirement to get the authorisation, were such that the current risks will be considerably reduced, for instance, due to increased monitoring requirements, compulsory training, a mandatory request to conform to risk management measures, as well as substitution activities. TCE will be sold by Blue Cubes business partner SAFECHEM, who will implement these conditions including training on alternatives.

90 REACH Regulation (EC) No 1907/2006, Article 66 states that anyone using a substance the use of which has been authorised needs to notify ECHA about this use.

91 Note that the authorisation holder has an obligation to reduce the exposure to as low a level as technically and practically possible, as stated in REACH Regulation (EC) No 1907/2006, Article 60(10).

92 See the 'Adopted opinions and previous consultations on applications for authorisation' web page on the ECHA website: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>

93 The application was made originally by Dow Deutschland Anlagengesellschaft mbH (Germany). Due to a legal entity change, the application is being transferred to Blue Cube Germany Assets GMBH & Co. KG (Olin Corporation).

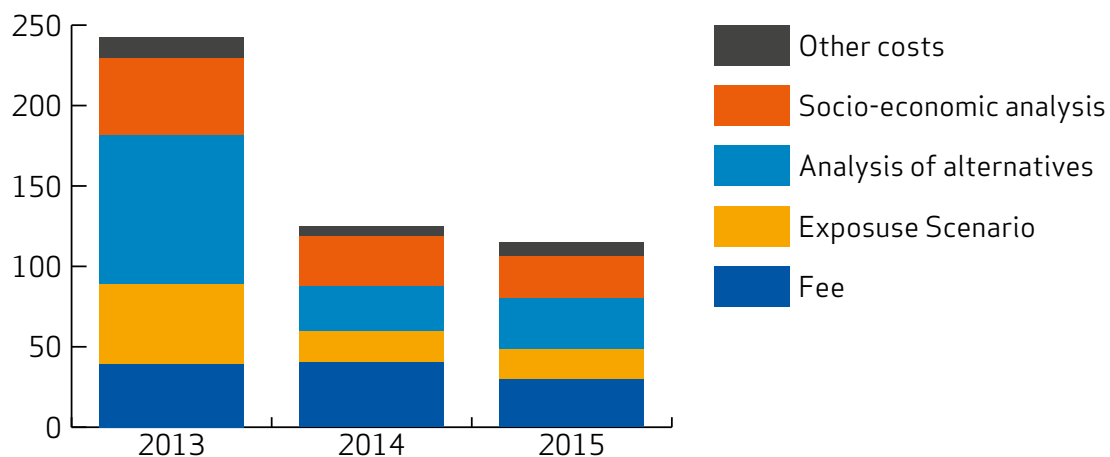
The application costs have reduced

SEAC has discussed how companies approach applications⁹⁴ and concluded that 'as long as any increase in costs from substituting for an alternative is less than the expected costs of applying for authorisation, the firm will switch to the alternative'. In other words, the cost of an application is a good indicator of the impact of the authorisation process on the EU industry.

ECHA has systematically collected the costs of applications. Based on the information for 2013-2015, two findings are evident. Firstly, the application fees have been about 15-20 % of the total application cost and secondly, the total application effort has reduced by about 50 % (Figure 29).

The application effort - measured as the average cost of an application - is currently about EUR 120 000 per use per applicant. This can be compared with the benefit of authorisation, as estimated by the applicants. According to the assessments provided in the SEAs of the applicants for 30 uses, the benefits of the granted authorisation were between EUR 32-38 million per applicant per use⁹⁵. In other words, the application cost has thus far been about 0.2 % of the benefits of granted authorisations, as estimated by the applicants.

Figure 29. Application costs per applicant per use in 2013-2015



Source: Feedback provided by applicants to ECHA after submitting their applications

The costs of the authorisations benefit not only the applicants but also their supply chain. This is in particular the case for 'upstream' applications. For instance, one application for six uses of hexavalent chromium covers the use in a couple of thousand plating companies in the EU. Thus, the impact of the application effort is indirectly shared by the downstream users, for instance, so that the applicant includes the cost of application

94 ECHA (2013) How the Committee for Socio-economic Analysis will evaluate economic feasibility in applications for authorisation: https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf

95 In their applications, applicants have explained what would happen if they were not granted an authorisation and calculated the costs if this took place. In some cases, the consequence would be to use another, more expensive substance and, in other cases, the applicant stated that they would need to close down their operation. Applicants have estimated the costs of these options with different assumptions for a particular number of years. The preliminary numbers in this report are the average of the estimates given by the applicants, per year per applicant and per use. Applicants assess that they would avoid these costs if the authorisation is granted. In other words, these are the benefits of the authorisation, as estimated by the applicants. There is one important caveat; these estimates are evaluated by SEAC. It can have a different view on the estimations made by the applicants. However, at the time of writing of this report, ECHA has not yet had the time to compile these estimates. Neither has it had the time yet to aggregate the health or environmental impacts if the authorisation was granted. ECHA aims to prepare a report of all these elements later in 2016.

in the prices of the substance. Another consideration is that the longer the length of the review period is, the lower the application cost per year. Given that the average length of the review is seven years, the average cost of an application per use and applicant is currently estimated to be about EUR 20 000 per annum.

ACHIEVEMENTS AND CHALLENGES

The authorisation system is functioning and continuously improving.

The Candidate List has been updated twice a year. These regular updates aim to ensure inclusion of new substances without undue delay, whilst avoiding continuous updates which would pose difficulties for industry to adapt their information systems necessary to comply with the obligations for SVHCs in articles (see Chapter 1.2.5).

ECHA has also provided the Commission with an Annex XIV recommendation almost every year since 2009 (see Figure 31). These regular recommendations aim to allow a steady inclusion of substances in the Authorisation List and a more even workload for all parties involved. However, there have been fewer substances added to the Authorisation List than expected, which is likely to result in a correspondingly lower number of applications for authorisation in the future. The Commission is, therefore, invited to provide further transparency on the follow up of those substances recommended for inclusion in the Authorisation List, but not finally included.

In a dedicated conference on applications for authorisation in early 2015⁹⁶, it was concluded that the system functions well. However, as it is a new process there is room for improvement. Therefore, ECHA, together with the Commission, set up a Task Force on the Workability of the Application for Authorisation process in 2014. The purpose is to further streamline and simplify the application for authorisation process based on the lessons learnt in the first years.

Task Force on the Workability of Applications for Authorisation

The Task Force on the Workability of Applications for Authorisation was established in July 2014. It has concluded the first phase of its work on the simplification and streamlining of the application for authorisation process. In 2016-2017, the Task Force will focus on further improving the functioning of the process. With the help of the Task Force, ECHA intends to provide further clarification so that applicants can produce 'fit-for-purpose' applications which can be evaluated in a meaningful manner by ECHA's Committees and to allow the Commission to take decisions with a clear understanding of their impacts. The participants of in the Task Force consist of the Commission, ECHA, the ECHA Committee members and the Member States.

One of the main tasks of the Task Force is to help ECHA prepare a new practical guide to clarify and streamline the application process. This guide will specifically include sections on 'low impact' and 'upstream' applications, which pose the most pressing challenges. The Task Force will also address the scope of the review reports and how ECHA's Committees give opinions on them.

Source: Task Force on the Workability of Applications for Authorisation. Report of activities in 2014-15 and objectives for work for 2016-17⁹⁷

96 Conference on 'Lessons learnt on Applications for Authorisation', February 2015: http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation

97 ECHA (2014) *Report of activities in 2014-15 and objectives for work for 2016-17*: http://echa.europa.eu/documents/10162/13637/afa_task-force_report_en.pdf

One key difficulty that has been identified is how to ensure that when manufacturers, importers or only representatives apply, they have included all the relevant information relating to the downstream users in the supply chain.

A second issue is how to reduce the volume of information in applications prepared by downstream users so that the information is still pertinent and credible.

Both are challenges, which ECHA and its Committees cannot resolve alone, but will need a strong interaction with the key stakeholders: potential applicants, Member States, the Commission and civil society organisations.

Figure 30. The main achievements in applications for authorisation

By March 2016, **90** applications for **154** uses from **171** applicants have been submitted and are at various stages of processing. They have been addressed so far in 11 RAC and 11 SEAC plenary meetings resulting in **62** draft and **59** final opinions adopted and sent to the Commission for decision making.

The processes operate efficiently

ECHA has achieved significant increases in the efficiency of its authorisation operations over the last five years.

To run the authorisation process efficiently, ECHA has designed and implemented a quality management system, which supports the MSCAs, the MSC, RAC and SEAC. A number of other achievements have contributed to increasing the overall efficiency of the authorisation process.

Inclusion of substances in the Candidate List based on PBT/ED properties and equivalent level of concern considerations such as for sensitisers, requires systematically more resources from dossier submitters. The PBT and ED expert groups, which were established in 2012 (see Chapter 2.1.1) and 2014, respectively, have helped the MSCAs to prepare fit-for-purpose SVHC identification dossiers and thereby facilitated a more efficient agreement process in the MSC.

To support the development and assessment of SVHC identification dossiers based on equivalent level of concern considerations (Article 57(f)), ECHA has developed a generic approach document⁹⁸ illustrating the factors to be considered. This has resulted in the SVHC identification and subsequent inclusion in the Candidate List of several substances with endocrine disrupting as well as respiratory sensitising properties.⁹⁹

The European Court of Justice rulings have been helpful in clarifying the scope of ECHA's competences to identify substances as SVHCs and subsequent inclusion in the Candidate List. Indeed, in recent judgments, the European Court of Justice and its General Court have confirmed ECHA decisions identifying certain UVCB

98 Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example: http://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf

99 The identification of two respiratory sensitisers as SVHCSVHCs was supported by the General Court in Cases T-135/13, *Hitachi Chemical Europe GmbH, Polynt SpA and Sitre Srl v European Chemicals Agency (ECHA)*, ECLI:EU:T:2015:253, and T-134/13, *Polynt SpA and Sitre Srl v European Chemicals Agency (ECHA)*, ECLI:EU:T:2015:254 (both judgments currently under appeal). The identification of one environmental endocrine disruptor as an SVHC is currently under review by the General Court; Case T-115/15, *Deza v ECHA*.

substances as PBTs/vPvBs on the basis of the properties of their constituents (Article 57 (d) and (e))¹⁰⁰ and ECHA decisions identifying certain substances as SVHCs on the basis of their respiratory sensitising properties (Article 57(f))¹⁰¹. The Court has also clarified that ECHA can include substances in the Candidate List even if the substance only has intermediate uses¹⁰². The Court is expected to further clarify ECHA's competence to identify substances as SVHCs on the basis of their endocrine-disrupting properties.

ECHA has facilitated the development and more systematic use of the RMOA approach, which in turn should make the discussion of the Annex XIV recommendations more efficient. Based on the experience of the five first Annex XIV recommendations, in 2014 ECHA revised its prioritisation approach to make it more directly based on registration data and information from public consultations. As a result, the substances subsequently prioritised are much less disputed by the MSC or in the comments received during the public consultation on the draft Annex XIV recommendation. Industry stakeholders have given explicit positive feedback on the clarity and predictability of the new prioritisation approach. The European Court of Justice clarified the criteria to be used for including an exemption from authorisation under Annex XIV.¹⁰³

Providing clarity on intermediate use

'A correct interpretation of the boundaries of *intermediate use* and use of a *substance in an article* is critical to ensure a correct application of the authorisation chapter of REACH. Eurometaux and a series of metal downstream users including the battery, frits and inorganic pigments, alloys, and other user sectors set up a programme to clarify those boundaries through the supply chain, for listed and potential SVHC substances. The programme aimed for clarity and uniform understanding and implementation. The ECHA services dealing with intermediates were most supportive and instrumental in providing clarity and support for such an anticipative supply chain exercise.'

Eurometaux and a series of metal downstream users

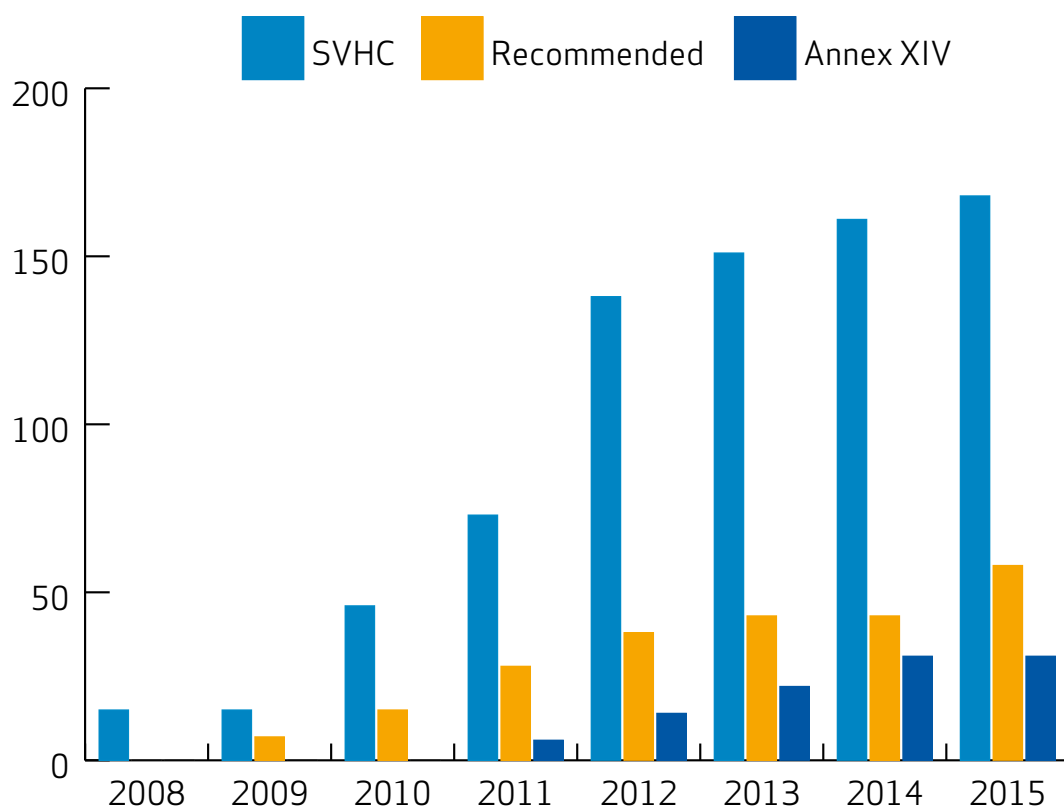
100 See for example the Court's judgment of 7 March 2013, *Bilbaína de Alquitranes and others v ECHA*, T-93/10 ECLI:EU:T:2013:106 as upheld in Case C-287/13 (both judgments currently under appeal).

101 See Judgment of 30 April 2015, *Polynt S.P.A. and Sitre S.R.L. v ECHA*, T-134/13, EU:T:2015:254; judgment of 30 April 2015, *Hitachi Chemical Europe GmbH v ECHA*, T-135/13, EU:T:2015:253.

102 See judgment of 25 September 2015, *PPG and SNF S.A.S. v ECHA*, T-268/10 RENV, EU:T:2015:698, which also confirms ECHA's understanding of the concept of intermediate as defined in REACH Regulation, Article 3(15). This judgment is currently under appeal.

103 Judgment of of 25 September 2015, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) vs European Commission*, T-360/13, ECLI:EU:T:2015:695 (currently under appeal).

Figure 31. Number of substances of very high concern included in the Candidate List, recommended to the Commission for inclusion in the Authorisation List (Annex XIV) and included in Annex XIV



During 2013-2015, the last part of the authorisation requirements, the application for authorisation process started. Before this, ECHA and its Committees started their work to establish and communicate the goals, the requirements, the procedures and practical instructions and formats so that the opinion-making on the applications would work smoothly. According to REACH, the Committees are expected to issue an opinion in about 12 to 14 months¹⁰⁴. On average, the opinions have been adopted in about seven months during 2014-2015.

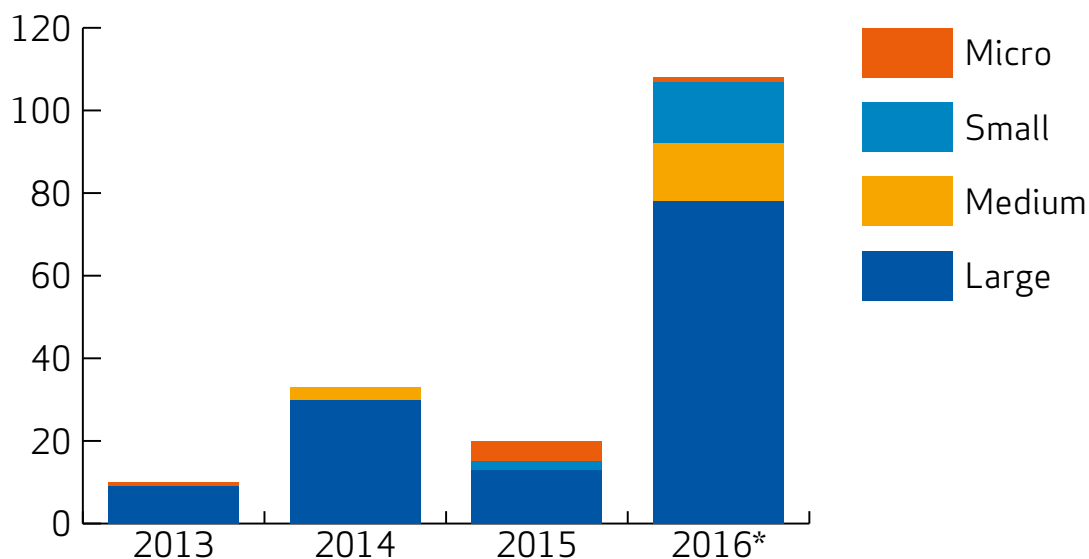
Up to February 2016, 171 companies have submitted applications (see Figures 30 and 32) and it is evident that in 2016-2017, the workload of ECHA's committees will be very high. About a quarter of the applicants have been SMEs and their share has increased in 2016.

RAC and SEAC have recommended a variety of review periods for the 59 completed opinions by March 2016. The average recommended review period has been seven years, with about equal distribution of shorter and longer review periods (see Figure 33).

Approximately a quarter of the uses were 'bridging' cases, i.e. the applicant needed a particular period of time so that it could switch to an alternative. In about half of the cases, RAC and SEAC recommended that the authorisation would include additional conditions and monitoring arrangements, particularly when the recommended review period was long. All-in-all it is clear that RAC and SEAC have carefully scrutinised the applications before concluding on their opinions.

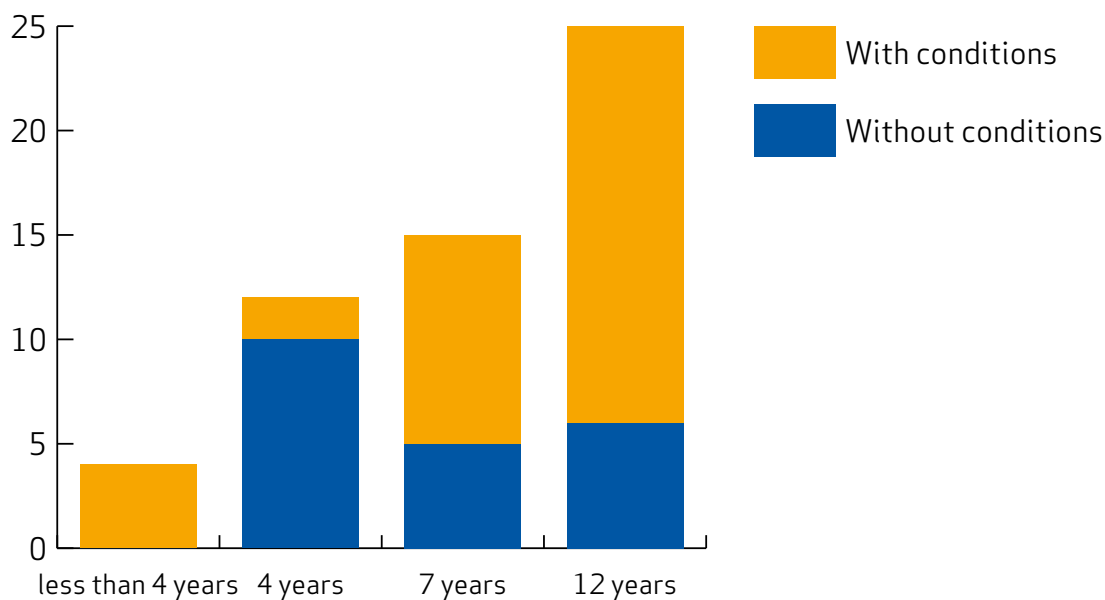
¹⁰⁴ If the applicant chooses not to comment on the draft opinion, the maximum time is about 12 months.

Figure 32. Applicants by size in 2013-16



Note: *This includes 58 applicants that have submitted their application in February 2016.

Figure 33. RAC and SEAC have recommended a variety of review periods – in half of the cases with additional conditions and monitoring arrangements



Source: RAC and SEAC opinions on the applications for authorisation, available at <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>

To further improve the efficiency of the process, ECHA routinely asks applicants for feedback. Based on this feedback, ECHA has been able to introduce several adjustments, contributing to the relatively short throughput time of opinions.

The system operates in an increasingly transparent manner but public consultations warrant additional effort

ECHA has made considerable effort to run the authorisation process in a transparent manner. This is partly as a result of ECHA's values, but also to ensure that all stakeholders are confident that ECHA selects, prioritises and gives opinions in an objective manner. At the same time, ECHA needs to ensure that confidential business information is not released. During 2011-2015, ECHA worked closely with stakeholders and applicants to establish a transparent and trustworthy authorisation process and will continue doing so.

At the start of the authorisation process, registrants and notifiers are systematically informed of public consultations that involve their substances. Subsequently, the prioritisation results of all substances in the Candidate List are published on ECHA's website. These actions allow applicants and stakeholders to prepare for further regulatory processes and facilitate their business planning by providing a longer-term view of when substances can be expected to be included in ECHA's Annex XIV recommendation.

The public consultation instructions on draft recommendations for inclusion into Annex XIV have been updated based on feedback from previous rounds and based on the new prioritisation approach. Furthermore, the responses to comments were reformatted to provide a more holistic overview and increase readability. This has helped industry in particular to understand what information and comments are needed to impact the recommendation discussions. ECHA also supports the Commission in hosting calls for information on socio-economic consequences of the potential inclusion of substances in Annex XIV.

In the applications for authorisation process, ECHA has set up a public consultation system which – after initial difficulties¹⁰⁵ – ensures that all essential information provided in applications (including the analysis of alternatives and SEA) is publicly available on ECHA's website as part of the public consultation. ECHA also published the comments received during the consultation and the responses by the applicants to those comments. This has proved important for third parties to see the rationale for making the application and the applicants' analysis of possible alternatives. It also allows third parties to provide pertinent information during the public consultation. The RAC and SEAC opinions and their justifications are also made public.

ECHA has received feedback from stakeholder representatives that it should strive to better alert third parties that do not have direct obligations under the legislation but may be able to provide relevant information during the public consultation. It is a challenge for ECHA to contact such third parties and we are working closely with NGOs, industry organisations and various European networks to further improve¹⁰⁶ possibilities for companies to provide pertinent comments.

ECHA will continue to invite for feedback and suggestions for improvement from its stakeholders whilst noting that the challenges of reaching the right audiences are different and, hence, need specific targeted actions. Nonetheless, ECHA is committed to further increase a) the relevance of information received in public consultations and b) the capability of applicants and their service providers to carry out analysis of alternatives so that they become more pertinent.

RAC and SEAC have also agreed how they will evaluate applications for authorisation and these working procedures have been published on ECHA's website, as well as questions and answers on different aspects

105 Deza took ECHA to the General Court (Case T-189/14, *Deza v ECHA*) as it objected to ECHA wanting to publish exposure information on a substance of very high concern.

106 On 10 February 2016, ECHA launched its largest public consultation so far. This concerned the consultation for 40 uses. To launch this, ECHA organised a webinar together with four NGO and industry experts on how to further improve the relevance of the consultation and to better reach out to third parties. Over 200 viewers followed this webinar, which is available at: http://echa.europa.eu/view-webinar/-journal_content/56_INSTANCE_DdN5/title/applications-for-authorisation-how-to-respond-during-public-consultation.

of applications. ECHA has set up a system on how to handle confidential information. This has allowed stakeholders to observe the deliberations of RAC and SEAC. The system is set up so that applicants are reassured that their confidential information is protected while a full information set is provided to allow the Committees to make their evaluation.

Support has been given to industry but challenges remain

Despite the efforts of industry associations and ECHA¹⁰⁷ to support and inform industry, there are still some who believe in 'myths' about authorisation. For instance, there is a misconception that if a substance is listed in Annex XIV this constitutes a 'ban'. Another fallacy has been that an applicant needs to have an alternative to be granted an authorisation. ECHA, the Commission, MSCAs as well as NGOs and industry organisations will continue to improve communication on the objectives of authorisation and so that companies, where needed, can decide in a timely manner on their business strategy¹⁰⁸.

'RAC reference values' for DNELs and dose-response functions for substances included in the Authorisation List have been established by ECHA to support the RAC evaluation of applications. These have been appreciated by applicants as they have allowed applicants to better predict the way RAC will evaluate their applications. This has also proven useful to downstream user applicants which do not usually have access to registration dossiers and do not have to provide hazard data if these 'RAC reference values' are used. These values have been a major achievement helping to reduce the time to prepare applications and the time RAC spends evaluating applications.

Pre-submission information sessions have been organised by ECHA with industry so that industry can make focused applications and provide a better understanding of the key information requirements for RAC and SEAC. In addition, 'dialogues' are organised with applicants, Committee rapporteurs and interested parties during the opinion-making process. These activities have been appreciated by applicants as they have ensured that information is exchanged during the process in an efficient manner. Well-attended seminars and workshops have added to the support for applicants, in addition to the guidance and more formal documents that ECHA has published.

Upstream applications are posing difficulties.

Experience from the first years of running this process has demonstrated that the development as well as opinion-forming on so-called 'upstream' applications are challenging. Here a manufacturer or importer of a substance makes an application and covers the uses of the customers further down the supply-chain.

These types of applications are beneficial since it is possible to cover the same use of the substance by many downstream companies in one application. However, it has turned out to be a challenge for applicants to describe the use conditions, benefits and risks related to the authorisation for the entire supply chain.

107 See e.g. 'Unauthorised myths' of applications for authorisation, 29-30 June 2015 available at: https://echa.europa.eu/documents/10162/21933566/afa20150623_10_unauthorised_myths_cefic_annys_en.pdf

108 ECHA will continue to discuss with industry and NGO stakeholders to further clarify the overall aims of authorisation, the aim for applications, how the process works, how to document applications in a 'fit-for-purpose' manner, how to reach the relevant third parties to provide meaningful comments during public consultations, how RAC and SEAC evaluate the applications during opinion making and how the implementation (e.g. notifications from downstream users) and review of the authorisations will work in practice. This will be carried out through various ways, e.g. seminars, workshops, webinars, publications, questions and answers, revisions of guidelines as well as in the pre-submission information sessions and dialogues with the applicants.

Options for obtaining this information have also been addressed by the Task Force on the Workability of Applications for Authorisation and a specific workshop on this theme was jointly organised by the Commission and ECHA in November 2015¹⁰⁹.

With the help of the task force, ECHA is doing its part to meet this challenge so that applicants can write 'fit-for-purpose' applications which allow efficient evaluation by the Committees and Commission decisions to be taken with a clear understanding of their impact.

COMMITMENTS AND RECOMMENDATIONS

- C14. ECHA will continue to invite feedback and suggestions for improvement from its stakeholders to improve the authorisation process. ECHA is committed to further increasing the relevance of the information collected in public consultations and maintain a transparent and trustworthy process.
- R26. MSCAs should make full use of the common screening approach to select substances for further information generation and assessment or directly for the SVHC process.
- R27. NGO stakeholders and third parties providing alternatives are invited to advise ECHA about how the information provided in the public consultation could provide better information on alternatives.
- R28. 'Upstream' applicants should prepare their analysis of alternatives in very close cooperation with downstream users. This would allow an improved description of the uses applied for and 'fit-for-purpose' applications. ECHA is committed to providing further clarifications on the nature and quality of the information that is expected so that it is clear when an application does not conform with the requirements of the REACH Regulation.
- R29. Future applicants should increase their capacity to carry out the analysis of alternatives and SEA. This could be done either by increasing the internal capacity or by using outside expertise. As SEA is closely linked to the technical and economic feasibility of alternatives, it is recommended that such tasks are carried out by the same analysts. ECHA is committed to help increase the capability of applicants and their service providers to carry out analysis of alternatives so that they become more pertinent for instance, through the Network of REACH SEA and Analysis of Alternatives Practitioners.
- R30. The Commission is invited to provide further transparency on the follow up of those substances recommended by ECHA for inclusion in the Authorisation List, but not finally included.

SOCIO-ECONOMIC ANALYSIS

Under REACH, ECHA's Committee for Socio-economic Analysis (SEAC) aims to apply SEA in a balanced manner during the opinion-forming process for restriction proposals and applications for authorisation. When preparing restriction reports, ECHA also applies SEA in a 'fit-for-purpose' manner, namely, impacts are quantified only when this is possible and when it adds value to the decision-making process.

In the context of REACH, the objective of SEA is to consider the likely health, environmental, economic and social consequences when regulatory action is taken on chemical substances. The economic consequences are closely tied to the cost of using alternative substances or technologies, i.e. the costs of substitution. Thus, SEA is closely linked with the analysis of the technical and economic feasibility of alternatives.

¹⁰⁹ More information on the Workshop on 'Streamlining applications for authorisation' can be found here: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8399

To facilitate the application of SEA, ECHA provides tools for applicants and MSCAs and is fostering the capacity of its own staff and others to apply SEA in practice. For example, ECHA publishes reference values, such as willingness-to-pay (WTP) values for monetising health risks to chemicals exposure, and quality or disability-adjusted life years (QALYs/DALYs) related to specific health endpoints. It also publishes the reference DNELs and dose-response functions for substances of very high concern as agreed by the Committee for Risk Assessment (RAC).

These tools have been complemented by capacity-building workshops organised by ECHA for the MSCAs and applicants, a SEAC working group on how to assess SEA-related issues on PBTs and through the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP). ECHA has also carried out a preliminary analysis of the costs of using alternative substances and of the overall cost of enforcing restrictions (see Chapter 1.2.3)

As a result of these activities, the evaluation of restriction proposals and applications for authorisation has become increasingly efficient and the costs and benefits of restrictions have been reported more transparently. The restriction and authorisation opinions are therefore increasingly based upon clear evidence and the capacity of industry to prepare comprehensive, but targeted applications has improved. Despite these gains, there are still opportunities for improvement and it is apparent that the analysis of alternatives and SEA are too often carried out by different analysts, thus making their preparation burdensome and leading to possible inconsistencies.

In the future, this work will be continued based on the demand for such services in close collaboration with industry, including ECHA's accredited stakeholder organisations, MSCAs and the Commission. Internationally, ECHA will become more active this year by organising a workshop with the OECD on applying socio-economic analysis on health impacts.

Another promising area of SEA work is to see how ECHA, the MSCAs and industry could carry out the analysis of alternatives better. To this end, ECHA has started to collaborate with the University of Massachusetts Lowell in the USA. Preliminary findings of this work will be published in 2016.

Feedback on the use of SEA is also needed. Therefore, ECHA will carry out an aggregate assessment of the costs and benefits of restricting and authorising the substances in 2016. These assessments should facilitate the analysis of socio-economic impacts in the future. While there is a continuous need to establish reference values for certain health endpoints (e.g. neurological development) and environmental impacts, ECHA has a particular challenge to establish reference values for the cost of illness linked to the exposure by substances of concern. ECHA will carry out this work in close cooperation with the Commission, on account of the close relationship with the Commission's Impact Assessment Guidelines and SEA under REACH.

ECHA commits to further develop the capability to carry out fit-for-purpose analysis of alternatives and SEA in ECHA, the Member States and industry through capacity building and carrying out applied research to establish additional reference values for willingness-to-pay and cost of illness. The Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) will be developed further for this purpose.

1.2.3 Restrictions

THE OBJECTIVES OF THE LEGISLATION

An EU-wide restriction under REACH can be established to limit the manufacture, use and placing on the market of a substance on its own, in a mixture or in an article where there is an unacceptable risk to human health or the environment. Member States or ECHA (at the request of the Commission or under Article 69(2) on their own initiative) can propose restrictions¹¹⁰.

Proposals are evaluated by ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), which give their opinions on the proposal.

Public consultations are conducted as part of the restriction process. The European Commission decides whether to amend Annex XVII of REACH by adopting a Commission Regulation.

IMPACT OF THE OPERATIONS

Health and environmental benefits of restrictions have outweighed the impact on business in the EU.

ECHA has carried out an overall assessment of the health and environmental benefits of restrictions¹¹¹ (see Figures 34 and 35). The reductions in risk as a result of the restrictions that have been introduced have led to positive human health and environmental impacts.

In addition, EU-wide restrictions have the advantage that they are harmonisation measures that create a level playing field for all EU and non-EU actors who place chemicals or articles on the market in the EU. Evaluating these impacts is challenging and different approaches and methods have been used. Figure 34 gives more details of the benefits of recent restrictions.

Figure 34. Health and environmental benefits linked to restrictions adopted since 2009

The annual human health related benefits from restrictions processed under REACH since 2009, were estimated at over EUR 700 million per annum. In addition, the adopted restrictions were estimated to reduce emissions of PBTs, vPvBs and other substances of concern by about 190 tonnes per annum. Furthermore, there were other positive impacts from the restrictions for at least 81 000 consumers and workers, the value of which could not be estimated. In specific cases, additional benefits, such as the avoidance of legal costs or re-insulation costs¹¹² were evident.

110 See the 'Restriction' web page of ECHA's website: <http://echa.europa.eu/addressing-chemicals-of-concern/restriction>

111 ECHA (2016) *Cost and benefit assessments in the REACH restriction dossiers*: http://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf

112 C.f. inorganic ammonium salts in cellulose restriction where the (product liability related) costs of replacing insulation containing ammonium salts would not be necessary if a restriction was in place. For details, see: <http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1895/term>.

Figure 35. Human health (HH) and Environmental (ENV) benefits in the EU

Case	Indicator of benefits
Monetised benefits	Health benefits equivalent to over EUR 700 million per year
Lead and its compounds in jewellery	EUR 15.7* million per year based on reduced IQ loss.
Chromium VI in leather articles	EUR 354.6 million per year based on reduced chromium allergies and resulting symptoms.
Lead and its compounds in consumer articles	Over EUR 26.9 million per year based on reduced IQ loss.
Methanol in windshield washing fluids	EUR 323 million based on avoided fatalities
Quantified benefits	Reduction of up to 190 tonnes of releases of substances of concern per year
Mercury in measuring devices	Reduction of three tonnes of mercury placed on the market per year.
Phenylmercury used e.g. in the production of polyurethane coatings	Reduction of 1.5 tonnes of mercury released per year.
Nonylphenol (NP) and its ethoxylates (NPE) in textiles	Reduction of 15 tonnes of NP/NPE released to surface water per year.
Decabromodiphenyl ether (DecaBDE) as a flame retardant in plastics and textiles ¹¹³	Reduction of 4.74 tonnes of decaBDE released per year.
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA ¹¹⁴	Reduction of 5.7 tonnes of PFOA and 36.4 tonnes of PFOA-related substances released per year.
Siloxanes D4/D5 in personal care products ¹¹⁵	Reduction of 121 tonnes of siloxanes D4 and D5 released per year.
Qualitatively assessed benefits	Positive health impacts or removed risk for at least 81 000 consumers and workers
Dimethylfumarate (DMF) in treated articles	No additional health impacts. Renewable ban made permanent under REACH.
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	80 850 male users and 140 toilet attendants not exposed above the DNEL.
1-Methyl-2-pyrrolidone (NMP) in industrial applications	The number of exposed pregnant workers at risk is not known.
Cadmium and its compounds in antifouling paints	No additional health or environmental impacts. Existing restriction entry clarified.
Use of asbestos fibres in electrolysis diaphragms	Very small health impacts. An end date added to the specific derogation under the existing restriction.
Ammonium salts in cellulose as insulating material	Avoided respiratory symptoms and odour nuisance for 150 persons per year.

As part of its assessment of the effectiveness, practicality and monitorability of the restriction, ECHA's SEAC Committee carries out an evaluation of the socio-economic costs and compares these with the socio-economic benefits to be able to recommend to the Commission whether the restriction is the most appropriate EU-wide measure.

¹¹³ Restriction has not yet been adopted in Annex XVII to REACH.

¹¹⁴ Restriction has not yet been adopted in Annex XVII to REACH.

¹¹⁵ Restriction has not yet been adopted in Annex XVII to REACH.

ECHA has carried out an overall analysis of the additional costs resulting from these restrictions (See Figure 36). The costs usually comprise substitution costs consisting of investment costs and costs of using alternative substances or techniques. In some cases, the analysis is based on the lost consumer surplus¹¹⁶. Enforcement and compliance control costs to industry have sometimes been quantified as well. In some cases, the costs have been negligible and thus not quantified.

Figure 36. Benefit-cost comparison of the restriction process

The estimated annual cost of all restrictions for which ECHA's committees gave favourable opinions during 2011-15 is approximately EUR 300 million¹¹⁷. The five most expensive restrictions represent around 88% of the total costs. The monetised (over EUR 700 million per annum) as well as the quantified and qualitatively assessed benefits of these restrictions clearly outweigh these costs.

There were two restriction proposals during 2011-15 where the Committees did not recommend to the Commission that a restriction be introduced: phthalates and cadmium in artists' paints. In these cases, the main reason was that the risk reduction for human health or the environment (benefits) was lower than the costs related to the restriction.

Substitution is one of the key impacts of restrictions as a restriction leads to the adoption of alternative substances or techniques by industry affected by the measure. In all cases where the opinions supported the proposed restriction, an analysis of suitable alternatives was carried out.

If RAC considered that an alternative seemed to be as hazardous as the substances subject to the restriction, it has been the practice for RAC or SEAC or both to caution industry not to adopt alternatives where the risk is equal, or expected to be so. This was the case, for instance, for the opinion on the flame retardant DecaBDE and BPA¹¹⁸. Member States or ECHA, if requested by the Commission, can take regulatory action on such alternatives in the future, if a risk is found.

ACHIEVEMENTS AND CHALLENGES

The restriction process in REACH is mature and the ECHA committees have adopted, or are formulating, opinions on 20 restriction proposals in the past five years

Restrictions have been an effective EU-wide risk management measure since 1976, although there is an overall perception that current restriction activity is too low. Before REACH, about two restrictions were adopted per year on average and since the operation of the REACH processes this average has increased by 50 %. However, the number of new restrictions proposed per year is lower than expected before REACH entered into force and is considered by many as disappointing¹¹⁹.

116 Consumer surplus is the monetary gain obtained by consumers because they are able to purchase a product for a price that is less than the highest price that they would be willing to pay. See e.g. https://en.wikipedia.org/wiki/Economic_surplus

117 ECHA (2016) *Cost and benefit assessments in the REACH restriction dossiers*: http://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf

118 See environmental and human health hazards of alternatives for DecaBDE: <http://echa.europa.eu/documents/10162/b5ac0c91-e110-4afb-a68d-08a923b53275> and BPA <http://echa.europa.eu/documents/10162/9ce0977b-3540-4de0-af6d-16ad6e78ff20>

119 In any comparison of number of restrictions pre- and post-REACH, it should be remembered that SVHCs identified and added to the Authorisation List are also part of REACH risk reduction measures that previously would have been addressed under restrictions.

Overall, Member States have indicated that they have found it difficult to find suitable candidates for restrictions and considered that the staff and external resources needed for preparing dossiers is substantial. Action was taken during 2011-2015 to address this lower number of proposals by making the restriction process more 'fit-for-purpose' and efficient. ECHA has also provided questions and answers, and various guidelines on restrictions to facilitate the preparation and in particular the implementation of restrictions.

Figure 37. Main output during 2011-15 from the restriction process

In total, ECHA's Risk Assessment and Socio-economic Analysis Committees adopted 17 opinions¹²⁰ resulting from their evaluation of ECHA and Member State restriction proposals. In addition, one opinion was produced by RAC at the request of the Executive Director¹²¹. An amendment in Annex XVII has been made by the Commission in response to this opinion.

ECHA produced eight review reports and guidelines during 2011-15 on diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), cadmium in coloured articles, cadmium in brazing fillers, cadmium in spectacle frames, nickel – prolonged contact with the skin and an update of the guideline on placing in the mouth of articles containing phthalates.

During 2011-15, ECHA prepared seven restriction reports (new proposals and revisions of existing restriction). Two reports concluded that restriction was not needed (cadmium in plastics and lamp oils). The other five resulted in restriction proposals, all of which received opinions from ECHA's Committees that supported the proposed restriction (mercury in measuring devices, 1,4-Dichlorobenzene (DCB), decabromodiphenyl ether (DecaBDE), asbestos and cadmium in paints). At the time of writing, the Commission has adopted three restrictions in Annex XVII as a result (mercury in measuring devices, DCB, cadmium in paints); the two remaining are awaiting a decision from the Commission (DecaBDE and chrysotile).

ECHA also produced two reports (4,4'-Diaminodiphenylmethane (MDA) and musk xylene) concluding that a restriction of substances of very high concern in articles would not be warranted (based on Article 69(2) of REACH)¹²². ECHA is currently preparing a restriction report for submission in 2016 for four phthalates used in articles: bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), and benzyl butyl phthalate (BBP)).

In 2011-15, ECHA's committees adopted 12 opinions on restriction reports submitted by Member States; nine of these opinions supported the restriction proposed, mostly with some adaptations. The Commission has adopted six restrictions in Annex XVII as a result of these opinions (DMFu, Pb in Jewellery, phenylmercury, chromium VI, Pb in consumer articles and NPE) and two communications where no restriction was proposed (phthalates and cadmium in artists' paints). The remaining four (ammonium salts, PFOA, BPA and NMP) opinions are awaiting a decision from the Commission.

120 In addition, the committee is still discussing opinions on methanol and D4/D5 at the time of the report.

121 Article 77(3)(b) opinion on the increased concentration limit in benzene in natural gas in entry 5 of Annex XVII

122 See 'ECHA's activities on restrictions' web page on ECHA's website: <http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions>

Work continues on the efficiency of the restrictions process

Some Member States have criticised the restrictions process due to the large number of requests for additional information from ECHA's committees. To streamline and improve the effectiveness of preparing restrictions and developing opinions, a Restriction Efficiency Task Force (RETF) was set up in 2014. The RETF which included the MSCAs, the ECHA committees and secretariat, and the Commission made a number of recommendations.

The majority of the recommendations were implemented in 2015 and, as a result the preparation of Annex XV restriction dossiers, is now expected to be simpler, the information received from the public consultation will be improved and the discussion in ECHA's Committees has already become more focused.

The resulting opinions from ECHA's Committees, since the recommendations were implemented, are now clearer and more robust, and should better serve Commission decision-making. Nevertheless, ECHA will continue working with the Member States and the Commission to better understand why the development of restriction proposals is still seen as burdensome and to examine possible further actions to increase the number of meaningful restriction proposals.

This will involve finding ways to further simplify the required documentation, providing assistance during the preparatory phase and ensuring that the information requests during the opinion making are reasonable¹²³.

Throughout 2011-15, ECHA has been working with Member States to assist them in preparing restriction dossiers and this work has intensified as a result of the recommendations of the RETF. Furthermore, ECHA worked with Member States, to better identify and develop EU-wide restrictions, to further explore possibilities for widening the scope of restrictions proposals (e.g. to include more groupings or alternatives not yet in use) and to increase capacity to monitor efficiency gains from the implemented recommendations. These have been carried out in dedicated restriction workshops as well as in the meetings of the risk management experts (RiME) and the Network of REACH SEA and Analysis of Alternatives Platform (NeRSAP)¹²⁴.

Article 69(2) requires ECHA to assess substances included in Annex XIV for their use in articles, and if there is an identified risk, to propose a restriction.

ECHA and the Commission have agreed on how to implement this requirement and ECHA has assessed, or started to assess, six substances during 2014-2015.

For two substances, a restriction was not proposed because the substances were not used in articles. One Annex XV restriction report is due to be submitted on another substance in 2016 and the remaining three substances are under review at the time of writing this report.

The challenge is to ensure that the way the obligations under Article 69(2) are implemented in restrictions contributes to the ultimate aim of authorisation, which is to ensure that those SVHCs included in Annex XIV to REACH 'are progressively replaced by suitable alternative substances or technologies where these are technically and economically viable.' Several substances included in Annex XIV are not present in finished

123 Amongst others, ECHA plans to organise a specific meeting on socio-economic analysis in June 2016 where the aspect of dossier requirements for restriction dossiers can be placed on the agenda.

124 NeRSAP has been set up to exchange information on advances and review of concepts, methods and experiences focused on practical concepts for socio-economic analysis (SEA) and analysis of alternatives (AoA) on EU-wide or national chemicals management implementation. It is set up in collaboration between ECHA, Member States and stakeholders from industry and NGOs. For details, see: <http://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners>

articles because they are transformed during production processes or are process-chemicals (such as solvents), which are not likely to be present in articles. Restrictions under Article 69 (2) can therefore not be used for these substances.

Support to Member States and industry

ECHA provides replies to questions arising in relation to restriction entries. This also assists the enforcement of restrictions by Member States and compliance by industry. During 2011-15, ECHA provided answers to 286 questions. Specific questions of wider interest are published as questions and answers on ECHA's website. During 2011-15, nine such Q&As were published.

As requested by the Commission, ECHA has published Q&As on some restriction entries to help clarify, for example, in which cases the derogations in restricting cadmium and its compounds apply to coloured articles and brazing fillers for safety reasons (entries 23(3) and (9)). ECHA also helped explain the term 'prolonged contact with the skin' in relation to the restriction on nickel and its compounds (entry 27(1)(b)).

In 2013, ECHA produced an evaluation of new scientific evidence concluding that the risk from the mouthing of toys and childcare articles with DINP and DIDP (see Figure 37) could not be excluded if the restriction in entry 52 was lifted. This evaluation was carried out due to a review clause in the existing restriction. The Commission followed this conclusion.

COMMITMENTS AND RECOMMENDATIONS

- C15. ECHA is committed, in close cooperation with the Commission, to carry out further methodological development to establish reference values for health endpoints, quality or disability adjusted life years and, in particular, for the cost of illness.
- R31. Member States and the Commission are invited to assist ECHA to better understand why the development of restriction proposals is still seen as burdensome and to examine possible further actions to increase the number of suitable candidates for restrictions. ECHA's role in this will be to improve the screening process with regard to restrictions and to further increase the capacity of Member States and ECHA itself to prepare restriction proposals. Any further recommendations for improving the restrictions process should be implemented in consultation with the members of the RETF, when relevant.
- R32. Member States should increase their capacity to carry out the analysis of alternatives and SEA. This could be done either by increasing their internal capability or by using outside expertise. ECHA is committed to facilitating this capacity building. The Network of REACH SEA and Analysis of Alternatives Practitioners will be developed further for this purpose.
- R33. The Commission and Member States are invited to discuss and conclude on a) having restrictions with a wider scope (in terms of the number of substances or activities covered) and b) the key evidence needed to justify a restriction (e.g. hazard, exposure information).
- R34. The Commission is invited to assist ECHA to explore how the obligations for SVHCs would be implemented efficiently under Article 69(2). This also includes situations where it is clear that the SVHC is no longer used in articles and could easily be restricted.

ECHA'S INTERNATIONAL ACTIVITIES

ECHA's activities attract global attention as chemicals are traded globally. The Agency's international work includes cooperation with the OECD, technical support to the Commission in contributing to the UN Globally Harmonised System of classification and labelling (GHS), formal contacts with peer agencies in Australia, Canada, Japan, and the United States as well as sharing experience with authorities and industry in third countries for which the EU chemicals regime is relevant.

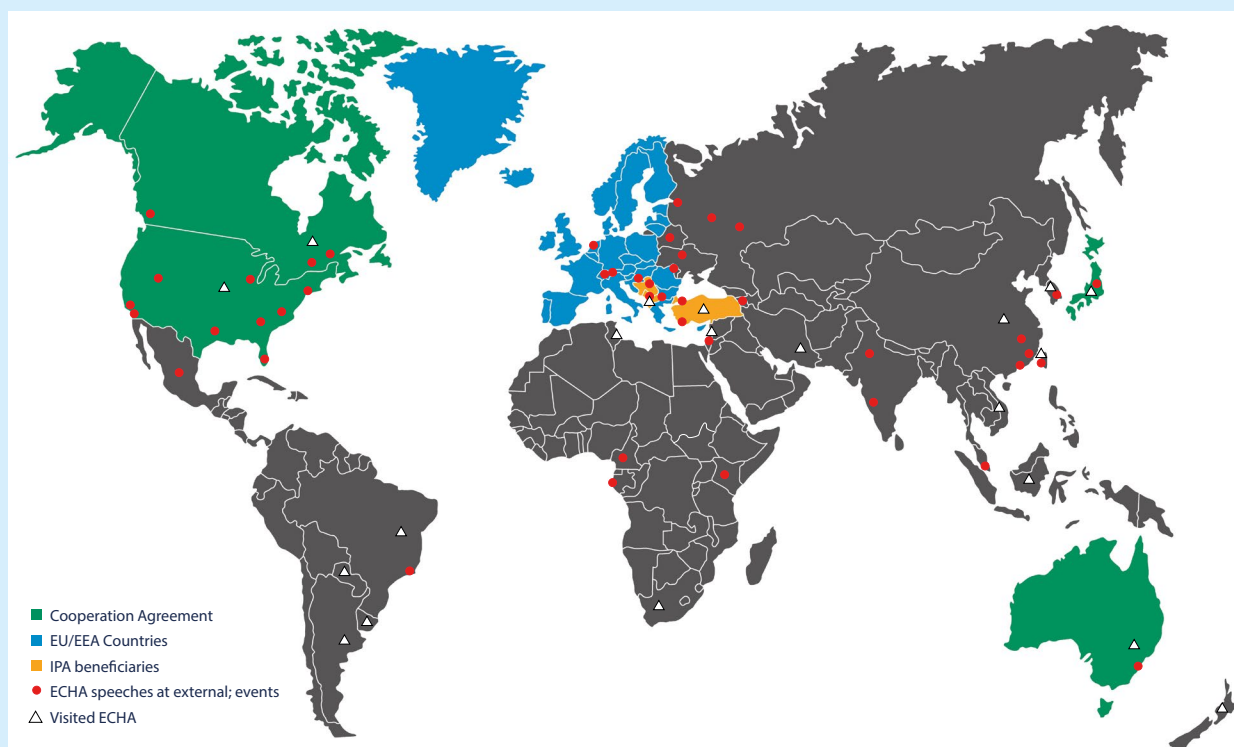
Examples of collaboration include developing the IUCLID submission format and the QSAR tool, which are becoming more widely used in a global market place for chemicals and facilitating the interoperability of IT platforms and the exchange of information between industry and regulatory actors worldwide. This increases the synergies between different regulatory areas at a time in which they modernise their chemicals management, for example, countries in Asia as well as Australia and New Zealand. In addition, ECHA has the most developed public knowledgebase of chemical substances in the world.

Peer cooperation is mutually beneficial for sharing experience in assessing substances as well as identifying emerging issues. Industry benefits from the harmonisation of data collection and IT tools, reducing the aggregate cost of compliance throughout international supply chains. The Agency, with the assistance of the Commission, has also started to consult contacts in relation to international agreements and technical barriers to trade when the potential restrictions are included in the Registry of Intentions to avoid problems at a later stage. In December 2014, working arrangements were established with the European Commission on handling international relations activities, in line with the Common Approach on EU Decentralised Agencies.

In addition, ECHA supports candidate countries aiming for accession to the EU and potential candidates building their capacities for applying the EU chemicals *acquis* with which they align their domestic legislation. These activities are funded from the European Union's Instrument for Pre-accession Assistance, benefiting in particular Serbia as well as other Western Balkan countries and Turkey. The benefits of such training were well demonstrated in Croatia, which gathered experience from ECHA's capacity building projects in 2011-2014 to be fully operational from the date of its accession to the EU.

Finally, ECHA presents the EU chemicals safety regime at events organised by industry or authorities in key EU trading partners. Such explanatory activities ultimately contribute to the quality of dossiers submitted by only representatives or importers as they enable overseas suppliers to become adequately aware of the information requirements for REACH compliance.

Figure 38. A map of countries in contact with ECHA in 2011-15



The international impact of REACH

'For a small new Member State, it is very important to see how other countries have organised their activities. As a beneficiary of the IPA project, we had the opportunity to make study visits to EU Member States, to see how their competent authorities and national enforcement authorities work, and in addition to practical advice, we also received good ideas and were able to create something of our own based on examples we saw during the visits.'

Ms Dubravka Kreković, the Senior State Sanitary Inspector at the Ministry of Health in Croatia.

'The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) finds cooperation with ECHA highly productive and a valuable mechanism for sharing information on regulatory science and operational experiences. Under the existing bilateral agreement, mechanisms for information exchange (such as teleconferences) have been established on topics of mutual interest. Activities are guided by a rolling work plan that is reviewed and updated regularly. NICNAS considers this approach to international cooperation to be efficient, effective and valuable. This collaborative arrangement will continue to facilitate international harmonisation of regulatory approaches and methodologies into the future.'

Dr Brian Richard, Director of NICNAS Australia

'In the recent pursuit of Taiwan's regulatory reform, our interagency cooperation of workplace safety and environmental protection among stakeholders enjoyed exchanges with ECHA on enhancing sound chemical management. Specifically, the experience and implementation of REACH and CLP provide us with unprecedented benchmarks in developing supporting measures and performance indicators. IUCLID, with the harmonised OECD templates and user-friendly driven functions, provides us practical tips and inspiration for developing tools. Furthermore, ECHA's communication strategy covering all stakeholders on a transparent and proactive basis is definitely enlightening.'

Dr Jowitt Li, Safety and Health Technology Center, Taiwan

1.2.4 Classification and labelling

THE OBJECTIVES OF THE LEGISLATION

The CLP Regulation sets out the criteria and procedures for EU-wide harmonised classification and labelling (CLH) and for self-classification by industry. It implements the internationally agreed GHS¹²⁵ into EU law and aims for the hazards presented by chemicals, i.e. their intrinsic hazardous properties, to be identified and clearly communicated to the users (and in certain cases consumers) through safety data sheets (SDSs) and labelling on packaging.

Establishing a CLH involves a process (with timelines defined in the CLP Regulation) which begins with the submission of a proposal to ECHA by a dossier submitter, which is usually an MSCA, but can in certain circumstances be a company. This leads to an opinion on the proposal by ECHA's Committee for Risk Assessment (RAC) with the final decision on classification being made by the Commission. Regulations (which are 'adaptations to technical progress') modify Annex VI to the CLP Regulation by inserting new substances with harmonised classifications and deleting or modifying existing classifications as the case may be.

To focus the efforts of all actors in the CLH process on substances with the highest concern, CLH should normally be applied to substances with carcinogenic, mutagenic, reproductive toxic (CMR) or respiratory sensitisation properties. The classification of substances in other hazard classes may be harmonised, if there is a need for this at Union level¹²⁶.

The CLP Regulation requires that manufacturers and importers use available hazard data to self-classify their substances using the criteria in the CLP Regulation and to notify these self-classifications to ECHA. Notifiers and registrants need to make every effort to agree on their self-classifications. To facilitate the convergence of self-classification and to ensure that information on classifications is widely available, ECHA disseminates the notified hazard information through the C&L Inventory, which also includes information submitted as part of registrations under REACH.

Mixtures are subject to self-classification according to the criteria in the CLP Regulation but unlike for substances, the classifications are not recorded in the C&L Inventory. The CLP Regulation allows companies to apply for alternative chemical names to keep the precise name of certain substances in mixtures confidential under specified conditions. ECHA handles such requests and decides if the use of an alternative chemical name can be granted¹²⁷.

Classification triggers obligations on registrants to identify and communicate hazard information down the supply chain and on downstream users to implement company risk management measures. Furthermore, harmonised classification triggers or enables regulatory risk management actions under REACH and a wide range of other EU legislation. CLP also sets general packaging requirements, to ensure the safe supply and use of hazardous substances and mixtures. Through these mechanisms, CLP contributes significantly to a high level of protection of human health and environment as well as the free movement of substances.

125 Globally Harmonised System of Classification and Labelling of Chemicals.

126 Biocidal and plant protection active substances are also normally subject to harmonised classification and labelling; CLP Regulation (EC) No 1272/2008, Article 36(2).

127 CLP Regulation (EC) No 1272/2008, Article 24: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>

IMPACT OF THE OPERATIONS

Harmonised and self-classification are powerful and effective tools to enhance the safe use of chemicals

A classification of a substance or mixture as hazardous triggers in many instances company-level risk assessment and risk management obligations under REACH. The obligation to label the substances and mixtures and to provide customers with an SDS applies to all hazardous substances. There is no minimum tonnage threshold but there is an obligation to attach an exposure scenario to the SDS for substances manufactured above 10 tonnes per year (see Chapter 1.1.2). Furthermore, labelling provides consumers with information on the hazards of substances and mixtures and also the possibility to make informed choices on the products they buy and when to apply protective measures.

Harmonised classification triggers and enables regulatory risk management actions under REACH and a wide range of other occupational, environmental and product legislation. For example, the consumer uses of substances classified as carcinogenic, mutagenic or toxic to reproduction (CMRs) (cat 1A/B) are normally banned¹²⁸.

Classification also promotes substitution through regulatory measures and by providing information which allows and encourages industry themselves to take action. In particular, the authorisation requirement can be applied to industrial substances with a harmonised classification as CMRs and to active substances in biocidal and plant protection products with CMR (cat 1A/B) classifications, which meet the criteria as candidates for substitution.

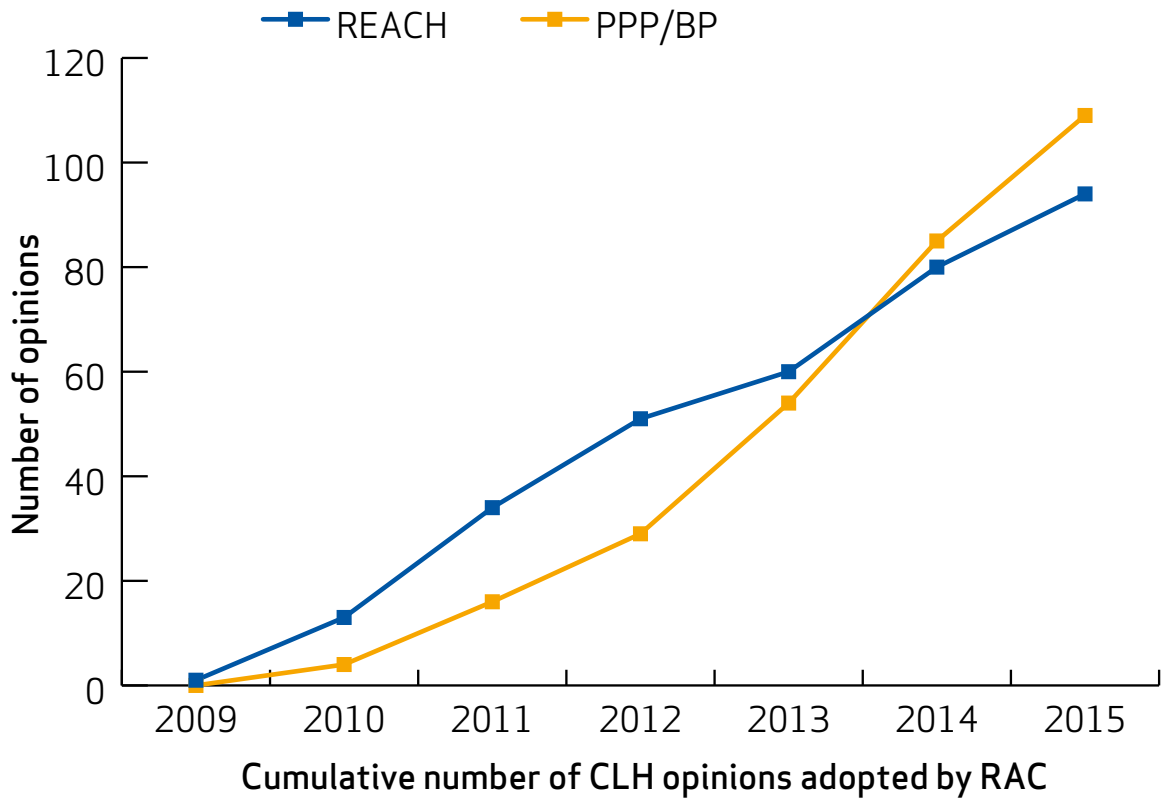
Furthermore, in the absence of adopted criteria for endocrine disruptors (EDs), active substances in biocidal and plant protection products classified as carcinogenic and toxic to reproduction category 2 are considered as EDs. The role of harmonised classification is further emphasised by the fact that the adherence of industry to harmonised classification is highly based on the ECHA study on CMRs¹²⁹.

While not all the direct and indirect consequences of classification are readily quantifiable, it is evident that it is an important instrument for achieving safe use and enhancing substitution.

128 Entries 28 to 30 of Annex XVII to REACH.

129 '2014 CMR Report', January 2015, section 3.1: http://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf

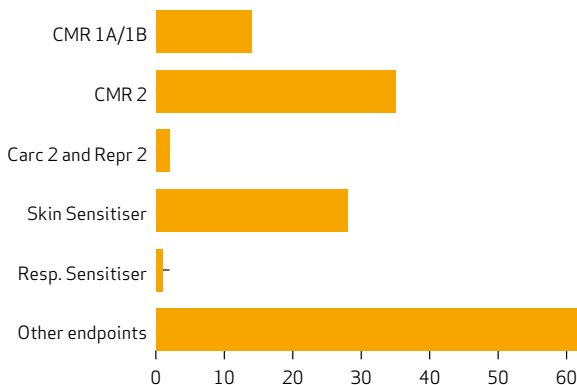
Figure 39. C&L outcome per type of chemicals processed by RAC



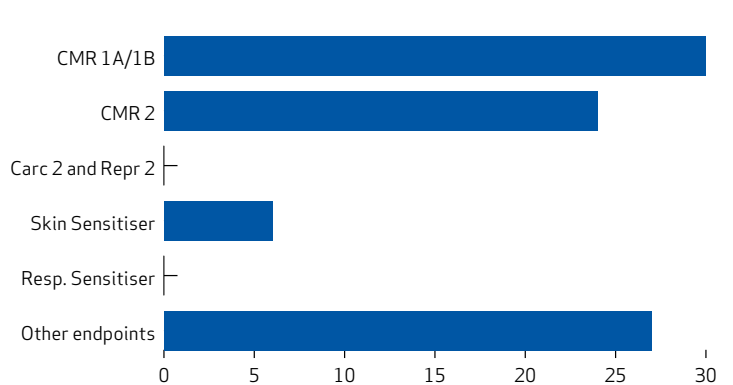
PPP/BP: active substances in plant protection products (PPPs) and biocidal products (BPs)
 REACH: industrial substances

Number of classified endpoints, most substances are classified for several endpoints.

For PPP/BP:



For other:



The Classification and Labelling Inventory provides hazard information on many substances.

The C&L Inventory includes over 130 000 substances and 6.5 million notifications and is accessible from ECHA's website.

It is therefore a very large database of substances, available worldwide. Based on the visits to ECHA's website (around 50 000 views per month), the C&L Inventory is a widely used source of information. The information is also used by MSCAs for identifying substances of potential concern and when assessing the cases for further actions (see Chapter 1.2.1). On the other hand, its usefulness is hampered by obsolete notifications and the level of divergence in the self-classifications, which raises concerns related to the correctness of the self-classification.

The process for alternative chemical name requests under Article 24 of CLP provides an opportunity for companies to protect their commercial interests without compromising safety

The process for requesting alternative chemical names has worked smoothly within the six-week deadline set out in the legislation. There has been a slight increase in the number of alternative name requests received over the last five years. However, the numbers are still low and have not increased significantly after 1 June 2015 when the possibility for national approvals stopped. This may indicate that company concerns relating to confidential business information are lower than expected or that they applied for alternative names with the Member States before 1 June 2015 to avoid paying fees.

ACHIEVEMENTS AND CHALLENGES

The CLH process has improved over the last five years

The transparency and efficiency of the CLH opinion-forming process has significantly improved over the last five years. The number of opinions adopted each year has increased from around 30 to around 50 per year.

In July 2012, the CARACAL meeting endorsed the framework for RAC opinion development, which laid down the roles for the different parties involved, the structure of the opinion, the input to the CLH process and the possibilities to tailor the process to specific circumstances. The starting points were to ensure an adequate and proportional investment of resources and a fully transparent procedure with fair and equal opportunities to provide information and comments. Following the adoption of the framework by RAC, the ECHA Secretariat has improved the approach and procedures for several aspects of the CLH process.

To increase the quality of the CLH proposals and by that the whole opinion-forming and decision process, ECHA has provided extensive case-specific support to dossier submitters, improved the templates for dossier submission and organised workshops on specific items.

The opinion-forming process has been further improved to reduce both the time spent on each dossier and the throughput time of the dossier in RAC while ensuring the scientific robustness of the opinions. These actions have resulted in the majority of the RAC opinions being adopted in one meeting.

The CLH opinions have provided the Commission with a solid basis for decision making, as evidenced by the very low number of legal challenges or the need for additional RAC opinions. Since 2009, over 200 opinions for harmonised classifications have been adopted by RAC. Out of these, one RAC opinion has been challenged before the European Court of Justice¹³⁰. In six cases, there has been a need for an additional RAC opinion under the specific Executive Director request procedure (Article 77(3)(c) of REACH). However, a future

¹³⁰ Judgment of the General Court, Case T 689/13, Classification of pitch, coal tar, high-temperature, in the categories of acute aquatic toxicity and chronic aquatic toxicity, under appeal before the Court of Justice (Case C 691/15)).

challenge will be to provide sufficient support to dossier submitters and RAC to maintain the current good situation as RAC handles more complex scientific cases e.g. new modes of action, new types of *in vitro/in vivo* studies, nanoforms, fibres, UVCBs, etc.

The overall communication with stakeholders has also improved through better web page structure and instructions for the submission of CLH dossiers. The objective is to make sure that the CLH process is transparent and legally robust.

ECHA has actively supported the Commission in the work at the UN subcommittee on GHS, in particular related to the development or revision of the GHS criteria. The guidance on the application of the CLP criteria has been revised to follow the adaptations of CLP to GHS.

One of the main challenges is to ensure that the information generated by registrants is adequate for a conclusion on classification. To this end, classification needs to be a primary consideration when further developing testing, information requirement annexes of REACH and guidance for the registrants on how to fulfil their information requirements. Further alignment of evaluation and classification processes will increasingly support robust classification conclusions.

The number of CLH proposals is low compared to the need for and importance of harmonised classification

For industrial chemicals, the number of dossiers submitted annually is approximately 10–15. In line with the intention of the legislator to focus the work of the authorities on CMRs and respiratory sensitisers, the vast majority of the dossiers have proposed harmonised classification for CMR endpoints.

The challenge for industrial chemicals is twofold: to increase the number of proposals for CLH and to prioritise for CLH substances that matter, i.e. substances which benefit most from the harmonised classification due to the resulting communication obligations and risk management consequences. ECHA supports the former by providing further technical and scientific assistance as well as grouping similar cases and supporting collaboration between the Member States. The latter is supported by the common screening approach (see Chapter 1.2.1) and the further overall integration of the CLP and REACH processes.

Classification is a vital part of the approval process for pesticide and biocidal active substances. The proper functioning of these approval systems requires a clear conclusion on the classification of these substances. This is best achieved through the CLH process, as reflected in Article 36(2) of the CLP which states that they shall 'normally be subject to CLH'.

However, currently only about one-third of the plant protection products (PPPs) peer-reviewed by EFSA, have a corresponding CLH dossier submitted by an MSCA¹³¹. The main challenge is to ensure that the MSCAs prepare CLH dossiers for all PPPs which are not 'low-risk' substances. To support this ECHA has, in collaboration with EFSA and the MSCAs, developed a new common template covering both CLH and active substance assessment needs. Similar activity to align the processes, to reduce the workload for preparing the CLH dossiers and to ensure that MSs submit their dossiers in a timely way applies to biocide active substances. The Commission services responsible for CLP, PPP and BPR Regulations should work together with EFSA and ECHA to encourage and support the MSCAs in preparing the CLH dossiers for pesticides and biocides.

¹³¹ Based on an analysis of the 39 PPPs that have been peer-reviewed by EFSA and for which a peer-review report has been published in the EFSA journal between mid-2014 and October 2015 (CARACAL doc CA/92/2015).

Dissemination of the information in the C&L Inventory has improved, but there is a need to increase the level of agreement on self-classifications.

The C&L Inventory is available on ECHA's website. To facilitate its use, several improvements have been made on how the information is displayed. The new ECHA dissemination site also displays the information from C&L notifications and registrations in an integrated and user-friendly way.

Although there is a clear legal obligation on notifiers and registrants to make every effort to agree on the (non-harmonised) classification of a particular substance, there is still considerable divergence in the self-classifications for many substances. ECHA has been working with the Commission and industry associations to find ways of enhancing the convergence of self-classifications. One of the constraints is that registrants and notifiers have difficulties in identifying and contacting each other.

Even though the CLP Regulation does not allow ECHA to provide the contact details to those interested in seeking agreement, ECHA has put in place a platform to enable the notifiers that have substances in common to get into contact with each other. The platform has been in place for several years, but has only been used to a very limited extent by industry.

Furthermore, notifications are not actively updated sufficiently. As a result, there are notifications in the inventory that do not necessarily reflect the current market situation, for instance, as the notifier does not exist anymore or does not place the substance on the market. Due to the volume of the database, ECHA or the enforcement authorities do not have the possibility to identify such cases and take action.

COMMITMENTS AND RECOMMENDATIONS

- R35. MSCAs should make full use of the common screening approach to select substances for the CLH process and ensure that the need for CLH is followed up rapidly. This integration of the CLH and REACH processes will increase the number of harmonised classifications of industrial chemicals and the regulatory impact of the CLH.
- R36. The Commission is asked to reflect on whether ECHA's resources should be used to assist Member States to develop CLH proposals for high priority industrial chemicals.
- R37. The Commission services responsible for CLP, Plant Protection Products and the Biocidal Products Regulations should work together with EFSA and ECHA to encourage and support the MSCAs in preparing the CLH dossiers for pesticides and biocides. MSCAs, ECHA and EFSA should further align their processes and tools used for CLH, for the PPP and for the BPR active substance approval processes. MSCAs should more systematically submit CLH dossiers for PPPs that need a (revised) harmonised classification.
- R38. Notifiers and registrants must improve the convergence of their self-classifications of notified substances. All actors (industry associations, MSCAs, NEAs, the Commission and ECHA) should jointly examine ways to raise awareness of the CLP obligations and support industry in reaching agreement on the (self-)classifications. The Commission should consider changing the CLP Regulation to allow the sharing of contact details of notifiers and registrants and to make notifications time-limited.

1.2.5 Substances in articles

THE OBJECTIVES OF THE LEGISLATION

The substance in articles (SiA)-related provisions of REACH aim for the safe use of chemicals in articles, throughout their life cycle, i.e. from their incorporation into an article until its waste stage.

Under REACH, it is primarily the responsibility of industry to ensure the safe use of articles.

In their registration dossiers, registrants must describe the uses of the registered substance in articles and, if the substance is classified as dangerous or is considered to be persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB), such uses have to be covered by a safety assessment and conditions of safe use included in the various exposure scenarios envisaged (see Chapter 1.1.4).

Additional obligations apply to producers and importers of articles containing substances of very high concern (SVHCs) listed in the Candidate List above a certain threshold. Firstly, a specific obligation to communicate the presence of Candidate List substances in articles down the supply chain¹³² aims to:

- Enable all operators in the supply chain to identify, communicate further and implement sufficient risk management measures to ensure the safe use of the articles;
- Allow operators and consumers to make an informed choice when buying and using articles containing SVHCs.

Furthermore, a notification obligation¹³³ aims to complete the information received from registration dossiers for Candidate List substances, and hence was meant to allow authorities (ECHA, Commission, MSCAs, NEAs) to take regulatory actions when necessary.

Finally, the restriction procedure under REACH (see Chapter 1.2.3) applies also to SiA. In addition, REACH has introduced specific procedures for restricting SiAs, which are CMRs that can be used by consumers¹³⁴ and an obligation to consider initiating the restriction process for SVHC substances that are listed on the Authorisation List¹³⁵.

IMPACT OF THE OPERATIONS

Companies have started to document and communicate their use of substances in articles. However the information on substances in articles remains very limited

REACH has introduced obligations and mechanisms for companies to identify, report and communicate on the presence and safe use conditions of the substances contained or imported in articles. This information on SiA is important for ensuring the safe use of chemicals, to facilitate substitution and to support the realisation of a circular economy.

The information that can be made public is published on ECHA's website. This information from the notifications and registrations also allows third parties to know which consumer articles contain Candidate List substances and take appropriate action.

¹³² REACH Regulation (EC) No 1907/2006, Article 33.

¹³³ REACH Regulation (EC) No 1907/2006, Article 7(2)).

¹³⁴ REACH Regulation (EC) No 1907/2006, Article 68(2)).

¹³⁵ REACH Regulation (EC) No 1907/2006, Article 69(2)).

However, the amount and adequacy of information in registrations dossiers for the safe use of SiA is still very limited. The number of notifications received so far has also therefore remained (very) limited. By the end of 2015, 359 notifications of the presence of Candidate List substances in articles for a total of 38 Candidate List substances had been submitted to ECHA. While it is difficult to estimate how many notifications there should be, the low figure is likely to illustrate a low level of compliance. To make submitting the notification easier, ECHA has provided a web form to companies that do not wish to use IUCLID/REACH-IT (e.g. SMEs).

There seems to also be a lack of awareness of the SiA-related registration obligations and of understanding how in practice to describe the uses in articles, assess the exposure and risks and document the safe use advice.

There are clear indications that the information on substances is not adequately communicated in the article supply chains. In this context, it is important to note that in 2015 'chemical risk' was the most reported safety concern under the EU's rapid alert system, accounting for a quarter of notifications, with 62 % of all flagged products originating from China¹³⁶. In addition, there are clear indications that the possibility for consumers to ask information about the presence of SVHCs in articles¹³⁷ is not generally known and therefore only sparsely used.

ACHIEVEMENTS AND CHALLENGES

Tools to allow companies to generate and communicate information on substances in articles are available and support has been provided. However, these need to be further developed and better used

The uses of substances in articles - including the use of the article by its end users and its disposal - must be reported in registration dossiers. ECHA has developed tools aimed at helping registrants provide the required information on the presence of substances in articles and possible exposure during the service life stages of articles. However, the information on the use of substances in articles is still scarce in the registration dossiers.

The foreseen further development of the tools for registrants should help companies to better comply with their obligations, in particular, by allowing a more adequate reporting of the uses of SiA through the new IUCLID 6 release (see Chapter 1.3). Examples on how to develop an exposure assessment for the service-life of articles have been made available on ECHA's website. However, the tools and approaches to better assess the releases and exposure resulting from articles at their service-life and the waste stages still need further development to ensure that appropriate safety advice for these stages can be included in the SDSs and exposure scenarios.

There seems to be a lack of awareness of the SiA-related notification and communication obligations and awareness raising has proven to be challenging due to the very large number of duty holders that have SiA notification and communication obligations.

Furthermore, many companies seem to not acknowledge the added value of knowing better and communicating more on substances in articles. Most of these duty holders do not have other REACH/CLP obligations.

136 European Commission (2016) *Protecting European consumers: toys and clothing top the list of dangerous products detected in 2015*: http://europa.eu/rapid/press-release_IP-16-1507_en.htm

137 REACH Regulation (EC) No 1907/2006, Article 33(2)).

ECHA has initiated various activities to support duty holders in getting more information and ensuring proper communication on substances in articles, for instance, exploring together with trade and sector associations possibilities for awareness-raising and carrying out a feasibility study for a 'materials information platform'¹³⁸. However, considering the current level of compliance with the registration, notification and communication obligations and the lack of information at different levels of article supply chains (illustrated by difficulties authorities face when trying to gather information on SiA) there is still considerable need and possibilities to improve the situation through the joint efforts of different actors.

Some companies - either individually or in the context of voluntary programmes - have recently demonstrated that they have improved the information and management of substances in articles. However, ECHA has so far faced difficulty in identifying sectors/supply chains, which are ready to actively collaborate with the Agency in the implementation of practical means and tools to support duty holders in knowing and communicating the presence of SiAs.

The Commission's review foreseen in Article 138(8) on whether to extend the scope of Article 33 from the Candidate List substances to cover other dangerous substances should pay due attention to the practical implementation of these communication duties.

To enable retailers to reply to consumers' requests on SiAs in the time provided (45 days, Article 33(2)) requires that the full supply chain from the EU article producers and article importers until the final retailers comply with the communication obligation as set out in Article 33(1).

A prerequisite for proper functioning of these communication obligations is that there is adequate technical means to communicate within the supply chains as well as proper awareness and sufficient enforcement of the obligations. It should be noted that the information generated and communicated in the article supply chains through Article 33 is not available for national or EU authorities.

The recent ruling from the European Court of Justice should clarify the obligations in relation to substances in articles

The dispute between MSCAs as to when the duties under Articles 7(2) and 33 for notifying and communicating information on Candidate List substances in articles apply has recently been clarified through the ruling of the European Court of Justice¹³⁹.

The clarity that these obligations apply to any article placed on the market (regardless of whether they are on their own or as a part of another article) should assist companies in implementing their duties and NEAs in their enforcement activities. As a result of this clarification, it is anticipated that the number of SiA notifications will significantly rise.

To assist companies, the related guidance document¹⁴⁰ has been revised to bring it in line with the Court ruling. ECHA is currently improving the advice provided in the guidance and preparing examples in cooperation with stakeholders and the MSCAs.

138 ECHA's conclusions on the workshop on the 'Materials' Information Platform' feasibility study, March 2016: http://echa.europa.eu/documents/10162/13563/echa_conclusions_mip_workshop_en.pdf

139 Case C-106/14, *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'Écologie, du Développement durable et de l'Énergie*, ECLI:EU:C:2015:576.

140 ECHA (2015) Guidance on requirements for substances in articles: http://echa.europa.eu/documents/10162/13632/articles_en.pdf

ECHA has provided support to authorities in addressing the risks related to substances in articles, but further efforts are needed by authorities.

Some Member States have engaged in activities varying from enforcement campaigns on SiA obligations (Sweden¹⁴¹) to the development of online tools and mobile applications for consumers to use their 'right to ask'¹⁴² about the presence of SVHCs in articles they buy (Denmark¹⁴³, Germany¹⁴⁴). However, in general the activities of MSCAs to communicate to the duty holders and to enforce the SiA-related objectives and legal obligations of REACH have been modest. This was confirmed by a survey launched by ECHA among MSCAs in 2013 on their plans and willingness to cooperate with ECHA in this field.

In 2013, ECHA made a proposal to the MSCAs to have a joint action plan on SiA-related activities, including awareness raising actions. This proposal has so far not been supported. Nevertheless, the Forum for Exchange of Information on Enforcement has recently agreed to run a pilot project on this topic in 2017.

ECHA has provided support to the Commission in developing restriction proposals according to the specific restriction procedure in REACH for articles containing CMR substances and which can be used by consumers¹⁴⁵ (e.g. for polycyclic aromatic hydrocarbons in consumer products and CMRs in textiles). ECHA has also supported the MSCAs through discussions at risk management expert (RiME) meetings and by providing data (REACH registration, SiA notifications¹⁴⁶ as well as other data sources on substances in articles). However, it appears that further discussion is needed amongst MSCAs and the Commission on which types of articles should be considered as candidates for further regulatory action.

There are currently no mechanisms to collect and generate information on substances in imported articles other than for substances on the Candidate List. This makes it difficult to identify substances of potential concern in imported articles and to initiate action in a proactive manner. This is particularly challenging for substances not registered in the EU. One possibility would be to consider extending the scope of Article 7(2) to cover all hazardous substances. However, before such an extension can be effective, the current lack of compliance with the requirements should also be solved (e.g. by changing the legal provisions, creating better tools, and improving awareness and adequate enforcement).

To get a better understanding on which substances are present in articles and, therefore, may also enter the waste and recycling processes, MSCAs, NEAs, the Commission and ECHA should become more active and allocate further resources for real progress to be achieved in this field.

Such information is important for ensuring the safe use of chemicals and to support the realisation of a circular economy. Increased enforcement efforts could activate companies to improve their knowledge on substances in (imported) articles and, where relevant, take action to ensure safe use or look for safer alternatives.

141 Kemi (2014) Analyses by the Swedish Chemicals Agency in connection with enforcement 2008-2013: <http://www.kemi.se/en/global/tillsyns-pm/2014/tillsyn-6-14-analyses-2008-2013.pdf>

142 REACH Regulation (EC) No 1907/2006, Article 33(2).;

143 <http://tjekkemien.dk/hj%C3%A6lp-til-virksomheder/information-english>

144 http://www.bund.net/themen_und_projekte/chemie/stell_die_giftfrage/anfrage_generator/

145 REACH Regulation (EC) No 1907/2006, Article 68(2).

146 REACH Regulation (EC) No 1907/2006, Article 7(2).

COMMITMENTS AND RECOMMENDATIONS

- R39. ECHA, the MSCAs, the Commission, sector organisations and NGOs should jointly carry out further awareness-raising among importers and producers of articles on the benefits of making informed choices about substances in articles and on the obligations of importers and producers related to substances in articles.
- R40. ECHA, the Commission and the MSCAs should increase the cooperation with third countries to improve the information flow in supply chains to identify, and where needed, take action on substances of high concern. This could include cooperation in the OECD and UNEP, as well as with exporters to the EU (e.g. China, India) and other importer countries (e.g. Canada).
- R41. Importers and EU producers of articles should improve their knowledge on the substances present in their articles to provide adequate safe use advice to their customers and promote substitution. To this end: a) importers of articles should develop more effective means to communicate in the supply chains outside the EU, b) registrants under REACH should ensure that their CSRs and extended ESs cover the assessment of the service-life of articles, c) industry, MSCAs and ECHA should further develop exposure assessment methods for the service-life and waste stage of articles, and d) The Commission is invited to fundamentally review the current legislative requirements for information on substances in articles and this could usefully form part of work on the circular economy and the drive towards a non-toxic environment.
- R42. All actors involved with substances in articles should become active and allocate more resources for real progress to be achieved in this field. Increased enforcement efforts could activate companies to improve their knowledge on substances in articles and, where relevant, take action to ensure safe use or look for safer alternatives.

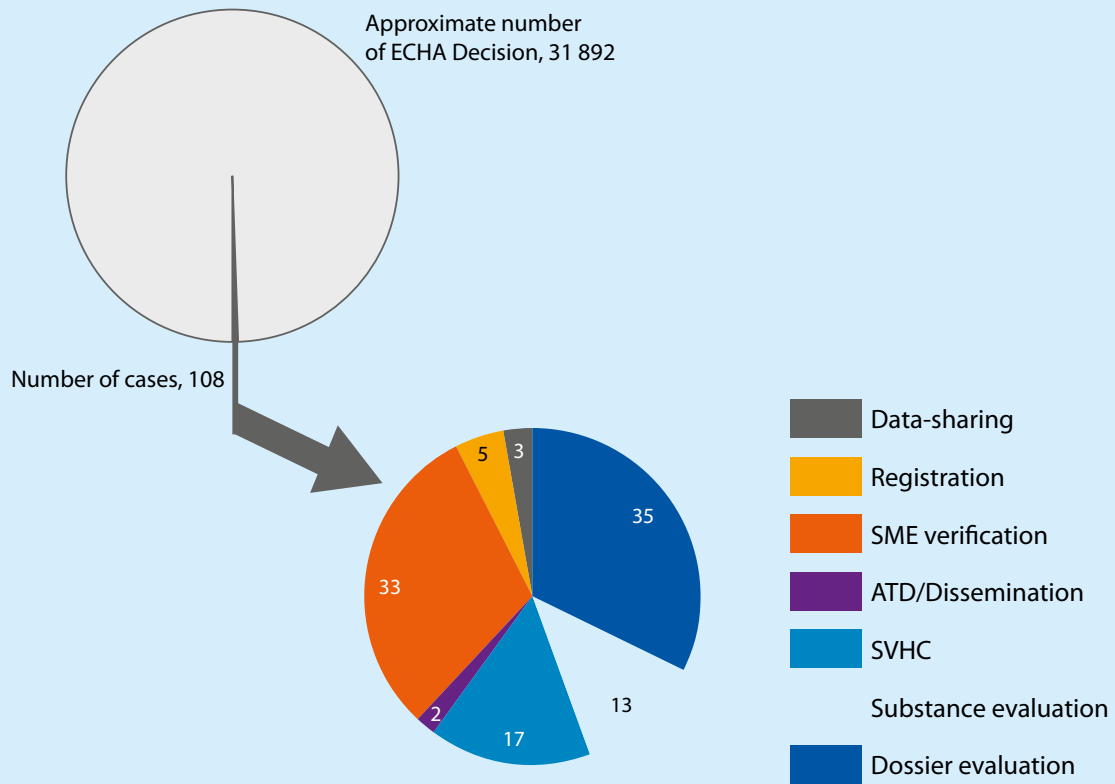
CLARITY AND PREDICTABILITY OF THE REACH PROCESSES

Considering the intricacies of the REACH Regulation and the high number of decisions to be issued every year, ECHA aims to carry out the activities discussed in this report in an efficient and transparent way and to increase the predictability of these processes, with particular attention paid to SMEs. These efforts have resulted in a high level of acceptability of ECHA's decision making (see Figures 40-42 below). The Court of Justice and the Board of Appeal have further increased the predictability of ECHA's processes through various rulings on new issues.

The level of litigation¹⁴⁷ is, however, constantly growing and puts some constraints on the work of ECHA. Current legal challenges, in particular resource-intensive cases on dossier and substance evaluation, require ECHA to reallocate a significant amount of resources to its defence, including key resources from its operational units that could otherwise be dedicated to its core activities. This results in less output in terms of the number and/or quality in these core activities.

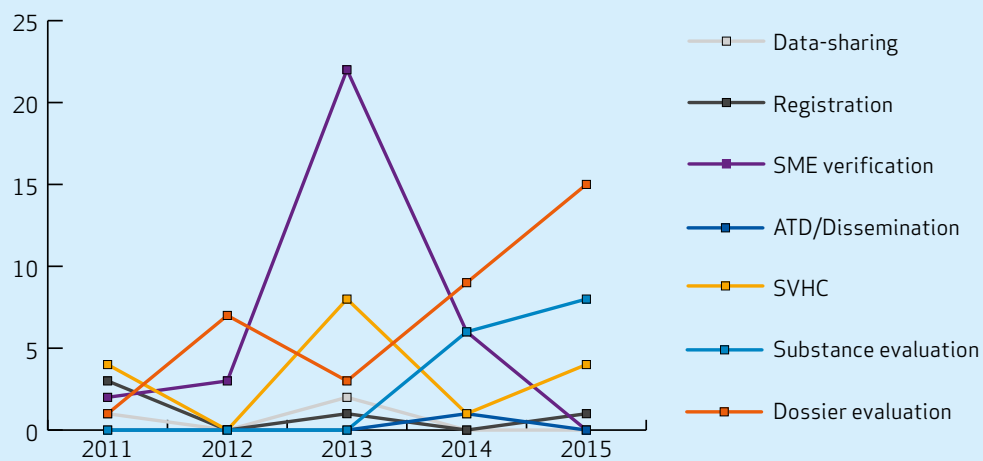
¹⁴⁷ In addition to legal challenges against ECHA decisions, ECHA also intervenes in support of the Commission in authorisation and HCL cases before the Court of Justice of the European Union.

Figure 40. Comparison between the number of decisions made by ECHA with the number of legal challenges and type of legal challenge



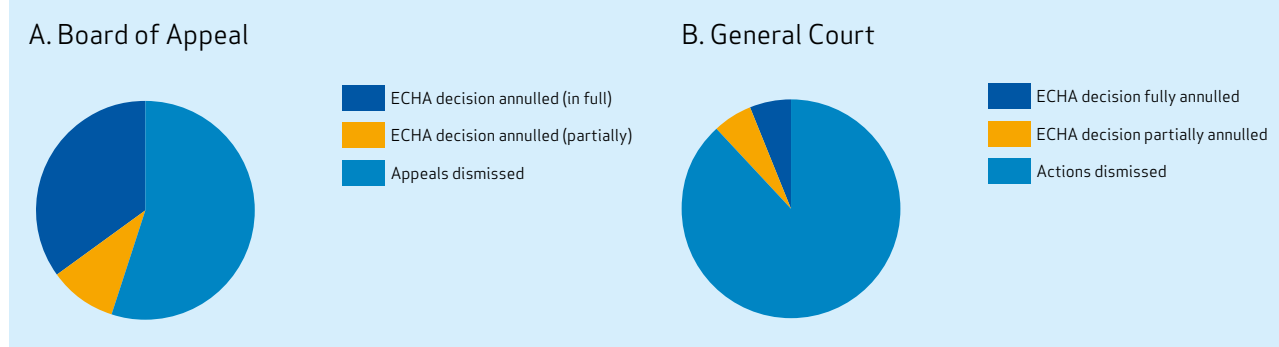
Note: The number of SME verification cases includes situations where one applicant filed the same legal challenges multiple times (e.g. before the Board of Appeal and the Court of Justice) or the same legal challenge was filed separately by more than one applicant. The actual number of legal challenges is, therefore, less than indicated in this figure.

Figure 41. Trend of litigation per activity (2011-2015)



Note: These litigation trends mirror the launch or the increase in the activities of the Agency. As mentioned under the previous figure, the actual number of SME verification challenges is lower than indicated in this figure.

Figure 42. Outcome of decisions of the Board of Appeal and judgments of the General Court (excluding decisions and judgments limited to procedural issues, such as confirmation of an appeal withdrawal)



1.3 DATA MANAGEMENT AND DISSEMINATION

THE OBJECTIVES OF THE LEGISLATION

REACH requires that information on the properties and uses of substances, as well as regulatory management measures associated with them, must be freely accessible to the general public to be able to make informed decisions about their use of chemicals. However, the intellectual property rights and other proprietary rights of companies must be respected by the users of that information.

Furthermore, the commercial interests of companies must be respected so that certain information can be claimed confidential. The dissemination of information is balanced against the right of companies to protect their confidential business information. The Agency may disclose this information if there is overriding public interest in disclosure.

Information submitted to ECHA must also be securely accessible to MSCAs so that they can undertake their regulatory tasks under REACH and CLP and also initiate risk management procedures under other EU legislation if appropriate. Finally, ECHA's database on information on chemicals provides the starting point for identifying and tackling issues related to the safety of substances in a wider context.

IMPACT OF THE OPERATIONS

The risk management of chemicals in the EU has been enhanced by the integration of chemical data held by ECHA

From 2011 onwards, ECHA has invested in the implementation of data models and IT platforms to integrate and process data submitted by industry or generated in the regulatory processes. ECHA's database now integrates the information on the intrinsic properties and uses of substances from REACH registrations and information from the C&L Inventory with the outcome of substance evaluations and regulatory risk management processes, such as harmonised classification and labelling, authorisation and restriction.

This integrated data source is utilised by ECHA, the MSCAs, and the Commission through ECHA's secure IT systems to perform their day-to-day regulatory activities, as well as interact with ECHA in an efficient manner. Access to such data is also used by other EU institutions such as EU agencies dealing with chemicals and at the national level in the management of the risk of chemicals.

The IT platforms are substance-centric and designed to facilitate the integration of additional data sources on chemical substances. In this regard, they are a key enabler for mapping and including state-of-the-art

regulatory knowledge on the risk of chemicals developed in the operations of REACH and CLP, as well as from other legislation on chemicals for example information received by ECHA under the Biocidal Products Regulation and the Prior Informed Consent Regulation.

The new dissemination portal released in 2016 (see Figure 45) automates not only the dissemination of the industry data (IUCLID dossiers, C&L notifications), but also the substance-related content created by the regulatory processes, significantly enhancing the accessibility of the published data.

The ECHA chemical substances database has become one of the most extensive regulatory databases on chemicals in the world. The database supports the EU in fulfilling its WSSD objective of making information on chemicals available

The vast majority of the data contained in ECHA's integrated database on chemical substances can be viewed through ECHA's website by all stakeholders and parties worldwide (see Figure 43). Industry and NGOs can benefit from the disseminated information in different ways. For example, companies can view it and NGOs can monitor the information provided on the substances that they are interested in.

The use of ECHA's data by regulatory authorities outside the EU has also become apparent. For example, authorities in Canada and Australia are using the data in the context of their own regulatory regimes and information is feeding into the OECD eChemPortal¹⁴⁸ thus contributing to the EU's international commitments. Results of studies are also feeding into the OECD QSAR Toolbox¹⁴⁹ helping to fill data gaps through trend analysis, QSAR estimates or justifications for read-across.

Figure 43. Data made available through the website's dissemination pages

Data from the dissemination website

- Over 14 000 substances registered, 52 000 dossiers
- 120 000 substances in the C&L Inventory
- Over 2 million study summaries on properties and effects of chemicals
- 168 substances of very high concern identified
- 64 restrictions of substances
- 31 substances requiring authorisation

Number of visits to the dissemination pages

	2012	2013	2014	2015
Visitors	331 000	355 000	650 000	948 000
Page views	468 000	675 000	757 000	1 816 000

148 Global Portal on Information on Chemical Substances: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en

149 OECD QSAR Toolbox: <http://www.oecd.org/chemicalsafety/risk-assessment/theoecdqsartoolbox.htm>

Use of the dissemination pages in the EU and beyond

ECHA Newsletter, Issue 5, November 2015¹⁵⁰

'Eight years after the introduction of REACH, ECHA possesses one of the most extensive databases of European chemicals. Industry and NGOs can benefit from it in different ways – for registration purposes, searching for specific information and so on. Now, the information is even more accessible through the info cards and brief profiles.

Through these, REACH will strengthen its role in giving information on the handling of chemicals in the workplace. Trade unions have always been demanding short and understandable information about the properties of substances. Extended safety data sheets are difficult to understand and not fit for purpose.

The new functionalities of the dissemination portal completely fill the gap on providing meaningful and reliable information on substances. Thus, in practical terms, REACH is contributing to better health and workplace protection. My hope is that the link to the Brief Profile is given a prominent place in the database, so that workers who do not use ECHA's website very often can benefit from this.'

Gertraud Lauber, German trade union IG Bergbau, Chemie, Energie (IG BCE)

'The EEB welcomes ECHA's new dissemination features since it makes this information more easily accessible to the public, providing clearer, more organised and more concise information about the potential health and environmental risks caused by chemicals. The new portal is an important step towards closing the knowledge gap on the chemicals present in the EU market.'

Tatiana Santos, Senior Policy Officer at the European Environmental Bureau (EEB)

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) uses information from international initiatives such as REACH, to ensure efficiency and reduce duplication of assessment effort. REACH data is an important public source of hazard information for NICNAS chemical risk assessments as it helps inform assessment findings and risk management recommendations. The outcomes of human health and environmental risk assessments are published on the NICNAS website and may be accessed by industry, local and international governments and the public, making an important contribution to regulatory decisions for promoting the safe use of chemicals in Australia.

'We consider ECHA to be a key source of information during our substance assessment work. The ease of access, quality of information, and reliability of the source makes ECHA a favourite choice when searching for substance information and tools.'

Don Cooper, Health Canada / Government of Canada

ECHA has developed a set of tools for data mining, analysis and know-how to interpret REACH and CLP data.

ECHA has developed data mining algorithms and tools to be able to efficiently analyse the vast amount of data received under REACH and CLP. This activity has evolved over time and is now one of the key activities supporting ECHA's regulatory strategy to increase registrants' compliance. It also supports MSCAs in their work to prioritise the substances that matter the most for the protection of people and the environment and make proposals for EU-wide risk management measures as appropriate.

150 ECHA Newsletter, November 2015, Issue 5 *New substance infocards - more useful and transparent information on chemicals*: http://newsletter.echa.europa.eu/home/-/newsletter/entry/5_15_new-substance-infocards-more-useful-and-transparent-information-on-chemicals

In addition, ECHA is now well equipped to support the Commission and the Member States in their policy development by being able to respond to various *ad hoc* data mining and data analysis requests (see Figure 44). In recent years, the number of requests for data has steadily grown to over 200 per year. Between 20 % to 30 % of the requests received are from external entities such as Commission services, including the Joint Research Centre and MSCAs. Figure 44 indicates the trend (in grey the prediction for 2016).

ECHA supports MSCAs work by providing data and IT support

'In 2015, the NL-CA, together with five other MSCAs, initiated the development of a grouped approach to increase efficiency in the context of assessing possible SVHCs under the SVHC Roadmap. This work involved extensive screening of the registration database in which the NL-CA made use of the expertise and IT-technical possibilities of the ACROSS unit of ECHA. The work of the ACROSS¹⁵¹ unit was of special added value where it assisted the NL-CA in the numerical assessment of structure similarity of all substances meeting the scope of the work. This tailor-made service is essential to make optimum use of the knowledge and resources of both ECHA and the MSCAs in meeting the SVHC Roadmap target.'

Fleur van Broekhuizen, Dutch Competent Authority

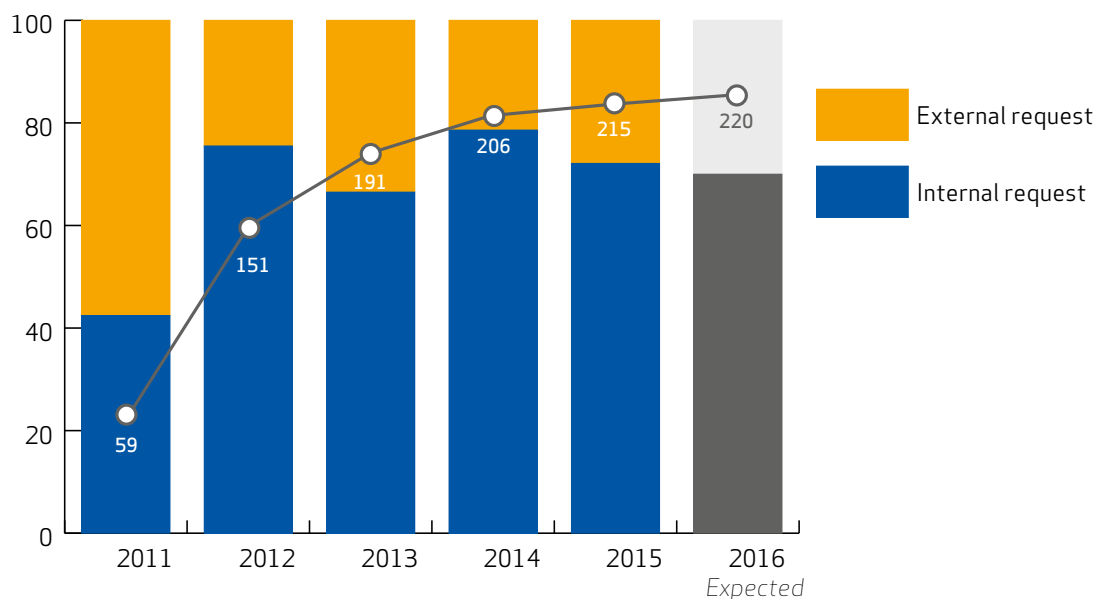
'In my role as Security Officer for the Italian Competent Authority and at the same time as a user administrator, I have started to familiarise myself since the early days (2009) with the applications developed by ECHA. Getting started wasn't an easy road: the configuration of the network and the connectivity have demanded quite some effort and dedication. But after this first step, a fantastic new world unfolded: information is available in real time, you can connect to various organisations; navigate through the myriad of chemical substances and dossiers. All these possibilities have had a tremendous positive effect for the work in our organisation. With ECHA's IT tools, many colleagues can work and study dossiers simultaneously and share the knowledge or the information they have gained.

For many of my colleagues who were used to working by accessing online tools, ECHA's applications have demanded a change in their way of working e.g. getting acquainted with access management and navigating through the pages. The Portal Dashboards made available to authorities in February 2016 are yet a new world to be discovered. They ask for a change in the way authorities go about their work to comply with the European chemical regulations. Another important aspect in the work of authorities looking at the availability of data with the new tools is data security.'

Paolo Izzo - Italian Competent Authority

151 Preparation for risk management (ACROSS) aims to contribute to identifying substances of potential concern by systematically screening available information for substances in the REACH registration dossiers and other databases. Part of the activity is to take care of the technical processing of screening results and communicate them to Member State Competent Authorities.

Figure 44. Increase in the number of data requests 2011-16



ACHIEVEMENTS AND CHALLENGES

Dissemination of chemical information to various audiences: from layman to experts

As announced in the first report on REACH and CLP operations in 2011, ECHA has improved the dissemination of information by several means in the past five years. Following extensive stakeholder consultation, ECHA launched the new dissemination portal which changes the way the information is presented to the public in January 2016. Information on up to 120 000 chemicals is now tailored to the needs of various audiences and structured in three layers: the infocard, brief profile and detailed source data.




The most accessible feature is the infocard, which offers a summary of the key information on a substance in plain language, giving users the possibility to quickly view the key properties of a substance e.g. how it is classified, whether it is hazardous or not and, if it is, how the substance is being scrutinised by ECHA or the MSCAs. The brief profile gives a more extensive view of these aspects and the detailed source data provides information as it is reported by industry in their submissions to ECHA.

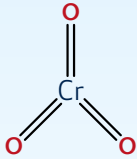

By providing essential and understandable data on the properties of the substances, the dissemination portal can now reach out to a broader audience, for example, workers as illustrated in the 'Use of the dissemination pages in the EU and beyond' text box above. Moreover, the summary data provided in the brief profile can be downloaded by all parties for their own use. For example, academics can use the information to validate QSAR predictions.

Figure 45. Example of an infocard in the new dissemination portal

Substance Infocard

Chromium trioxide

↓ Other names: [IUPAC names \[18\]](#) [Regulatory processes names \[3\]](#) [Trade names \[5\]](#) ↓ Groups:   

<h4>Substance identity</h4> <p>EC no: 215-607-8 CAS no: 1333-82-0 Mol. formula: CrO₃</p> 	<h4>Hazard classification & labelling</h4>  <p>Danger! According to the Harmonised Classification and Labelling approved by the European Union, this is fatal if inhaled, is very toxic to aquatic life with long lasting effects, causes damage to organs through prolonged or repeated exposure, is very toxic to aquatic life, may cause cancer, causes severe skin burns and eye damage, may cause genetic defects, is toxic if swallowed, is toxic in contact with skin, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility, may cause allergy or asthma symptoms or breathing difficulties if inhaled and may cause an allergic skin reaction.</p> <p>Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is fatal in contact with skin and is very toxic to aquatic life.</p>	<h4>Properties of Concern</h4> <p>C M S</p> <h4>Important to know</h4> <ul style="list-style-type: none"> Substance of very high concern (SVHC) and included in the candidate list for authorisation. Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).
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<h4>About this substance</h4> <p>This substance is manufactured and/or imported in the European Economic Area in 10 000 - 100 000 tonnes per year.</p> <p>This substance is used in the following products: metal surface treatment products, non-metal-surface treatment products, pH regulators and water treatment products, adsorbents and laboratory chemicals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).</p> <p>This substance is used for the manufacture of: chemicals, plastic products and fabricated metal products.</p> <p>Release to the environment of this substance is likely to occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, formulation in materials, as processing aid, manufacturing of the substance and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use as reactive substance.</p> <p>ECHA has no registered data indicating the type of article into which the substance has been processed.</p>	<h4>How to use it safely</h4> <ul style="list-style-type: none"> Precautionary measures suggested by manufacturers and importers of this substance. <p>Guidance on the safe use of the substance provided by manufacturers and importers.</p> <p>INFOCARD - last updated: 10/02/2016</p>
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Finally, there is increased transparency of the regulatory processes performed by ECHA and the MSCAs as their outcome is publicly available. Non-confidential versions of evaluation decisions and decisions on data-sharing disputes are published on ECHA's website and also made accessible through the brief profiles. The same applies to ECHA committee opinions and conclusion documents under substance evaluation.

A remaining challenge is that ECHA disseminates the information on substances as it is reported in the registration dossiers or the C&L Inventory by the companies themselves. The revamp of the dissemination portal makes the information more understandable by the public at large and there is the risk that the readers do not fully appreciate that the information has been peer reviewed only in a limited number of cases e.g. where a compliance check has been carried out.

On the other hand, as the information is now integrated and presented more clearly on the ECHA website, the discrepancies in the data across dossiers submitted for the same substance are made more visible e.g. in the C&L Inventory. This may stimulate further updates as registrants and notifiers under REACH/CLP act to ensure their published data is consistent.

COMMITMENTS AND RECOMMENDATIONS

- R43. EU and national legislators should make use of the data management capabilities developed in the Agency for supporting other regulations or legislative initiatives on chemicals at EU level for the benefit of industry, citizens, and national authorities.
- R44. The Commission should explore how REACH and CLP information could be used by authorities worldwide and potentially accepted under other jurisdictions to document the safe use of chemicals. This could be linked to the on-going harmonisation work of tools, formats, test methods and information requirements taking place at the OECD level. This would reduce costs for industry and make the assessment of chemicals globally more efficient.

ECHA'S COMMUNICATION IS SUPPORTING THE IMPLEMENTATION OF REACH AND CLP

The REACH Regulation requires ECHA to communicate in a number of ways to enable the legislation to function: providing guidance and tools to help companies to comply, launching public consultations to gather information from third parties, and making information from its databases freely available on the internet. It also requires the Agency to make use of the Translation Centre of the Bodies of the European Union for its multilingual needs. In practice, to make REACH and CLP work for all relevant audiences, ECHA as the EU regulatory Agency must make a much wider scope of information available more comprehensively than outlined in these exemplary references of the law.

For companies to comply, they need to be aware of their responsibilities, they need to be alerted when things change, they need examples of good practice to follow, and they need to be heard so that their concerns and difficulties can be taken into account. Above all, they need to be reached, so that all of this can take place.

Consequently, the Agency's communications effort over the years has focused both on the basics as required by the law, but also on outreach, stakeholder engagement and developing a range of communication vehicles to complement the website – newsletters, weekly news products, audio-visuals, webinars, print products and social media. All of these products have been developed and evolved in line with the Agency's corporate identity, which was developed with stakeholders in 2011.

The main corporate platform is the ECHA website. All the other communication vehicles serve to drive users to the website. It is the single source of all information, allowing its readers to access explanatory documents, guidance, practical guides and manuals as well as links to IT tools that include the ability to self-calculate or check their submissions to ECHA before sending them off. The various chapters of this report highlight this more specifically.

Visitors to the ECHA website come from almost all countries of the globe. The heaviest traffic within the EU comes from Germany, but equally large numbers visit from Japan and the United States.

The website has grown from a simple static platform in 2007, and was completely rebuilt based on stakeholder input in 2011. Since then, it has gone through a series of incremental improvements. Significant improvements have been made to the searchability of data and its presentation; the look and feel; the layering of content to make it easier for the user to navigate and digest; the proportion of translated material; to the more recent introduction of interactivity (for example, enabling commenting and rating features). The website will be further improved during 2016 in response to some customer research at the end of 2015.

ECHA produces press releases where the news is of wider interest; news alerts to inform companies of changes that may affect them; 'ECHA Weekly' which is an e-news bulletin which brings together the news from the week; and the quarterly Newsletter which gives in-depth coverage of issues of interest, regulatory developments, good practice from companies, stakeholders' perspectives and scientific insight. To enable ECHA accredited stakeholders and national helpdesks to help with the outreach, bimonthly 'updates' are provided for them to give them advance warning of things to come.

Building working relationships with the media has been instrumental in reaching out to companies and citizens to make them aware of their responsibilities and rights under the law. The Agency has provided media briefings ahead of significant news events and during Stakeholder Days and explains its work to journalists, as well as responding quickly to their enquiries. Consequently, monitoring shows that the Agency's media coverage is overwhelmingly accurate and factual – exactly what is required for an independent EU Agency.

The Agency has adopted a translation practice that lays emphasis on translating material destined for the use of SMEs and of the general public. Time-bound news releases are not translated; neither are very technical guidance documents. ECHA has been spending nearly EUR3 million each year for translations.

Over the last five years, ECHA has undertaken dedicated awareness-raising campaigns, often in close collaboration with the Member States and Accredited Stakeholders. These have included, for example, the various legal deadlines such as the 2010 and 2013 registration deadlines or the deadline for classifying mixtures in 2015. Given the need for this information to reach companies across the entire EU/EEA area and beyond, ECHA relies on stakeholders' support to spread the word. This approach is practical from a communications perspective – stakeholders are able to tailor the content to best suit their readers – but it is also highly efficient and cost effective.

Despite all the above, a considerable, but ultimately unknown segment of smaller downstream users, remain either unaware of REACH or have only a very rudimentary understanding of EU chemicals legislation. Therefore, it is of paramount importance to prioritise the outreach to them in the coming years.

Looking ahead, ECHA expects general interest in its work to grow. As REACH becomes more and more established and companies are increasingly familiar with their duties, their needs for information will gradually diminish and will be re-balanced by a growing audience, which is the general public and civil society. This audience has an interest in information on chemicals, but also in providing information in response to public consultations. They have the 'right to ask' about hazardous chemicals in the products they consume and are increasingly interested in the issue.

2. Governance

2.1 ECHA BODIES AND NETWORKS

2.1.1 Committees

THE OBJECTIVES OF THE LEGISLATION

The REACH Regulation establishes three Committees as part of ECHA: the Member State Committee (MSC), the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC). The role of the Committees is to provide independent scientific advice to enable ECHA to take certain decisions and for the European Commission to conclude on restrictions, authorisations and harmonised classification and labelling. The Committees are thus an integral part of the operation of REACH and CLP.

The MSC is responsible for resolving divergences of opinions among Member States on draft decisions on dossier and substance evaluation and on proposals for the identification of substances of very high concern (SVHCs). The Committee provides opinions on ECHA's draft recommendation for the Authorisation List (Annex XIV) and on the draft Community rolling action plan (CoRAP) in the substance evaluation process. If an agreement is not reached by unanimity within the MSC, the matter is referred to the European Commission to take a decision.

RAC prepares the opinions of ECHA related to the risks of substances to human health and the environment on the proposals for restrictions and on applications for authorisation. SEAC prepares the opinions of ECHA related to the socio-economic impact of the same proposals and applications in the REACH processes. RAC also examines and gives its opinion on proposals for harmonised classification and labelling. The final decisions are taken by the European Commission.

IMPACT OF THE OPERATIONS

ECHA Committees are fulfilling their mandate and are continuously improving to deliver fit-for-purpose advice

The workload of the committees has been steadily increasing and now they are all working at full speed and at their maximum capacity.

Stakeholders have provided continuous feedback and worked in the Committees to review both the working methods and the content of the work. As a result of this significant investment, the quality of the Committee opinions has been optimised - quality meaning that opinions are fit-for-purpose in the regulatory context and that they provide the appropriate level of scientific and technical justification in a transparent manner for the Commission to take decisions on risk management (see Figure 46). This optimisation is, however, an on-going and continuous process. This work is described under the evaluation and risk management chapters of this report.

Figure 46. Percentage of stakeholders satisfied with the level of transparency in the ECHA Committees (MSC, RAC and SEAC)

2011	2012	2013	2015 ¹⁵²
77 %	82 %	87 %	87 %

¹⁵² A survey did not take place in 2014.

Most of the work of the Committee is open to public scrutiny, through participation of ECHA Accredited Stakeholder Organisations in the work of the Committees and by making many of the proposals sent to Committees public. The Committee opinions are also published, along with the Committee rules of procedure and working methods. This strengthens the work of the Committee and together with a strong policy on managing conflicts of interest, has resulted in high levels of stakeholder satisfaction of the transparency of the Committee's work (see Figure 47).

The MSC has been able to achieve unanimous agreement in a high number of cases, thereby avoiding the need for referral to the Commission to take a decision and improving the efficiency of decision making.

The biggest group of cases (about 200) referred to the Commission in 2012-13 was related to the interpretation and subsequent change in the information requirements concerning toxicity to reproduction. RAC and SEAC have also agreed on their opinions by consensus in the overwhelming majority of cases. All three Committees are thus meeting the specific expectation of reaching consensus as expressed in REACH.

Figure 47. Outputs of the work of the RAC and SEAC Committees

Statistics of the annual amount of agreements/opinions per committee.

	2009	2010	2011	2012	2013	2014	2015
RAC opinions	1	16	36	34	40	88	68
SEAC opinions	0	0	4	1	3	34	31
MSC opinions/agreements	16	27	71	180	158	150	114
TOTAL	17	43	111	215	201	272	213

Statistics of the number of agreements/opinions concluded per meeting.

	2009	2010	2011	2012	2013	2014	2015
Meetings	11	15	15	14	14	16	16
Opinions/agreements	17	43	111	215	201	272	213
<i>Average per meeting</i>	1.55	2.87	7.4	15.4	14.4	17	13.3

ACHIEVEMENTS AND CHALLENGES

Member States need to continue supporting the Committees through Committee membership and by supporting their Committee members

The capacity of the ECHA Committees to deliver depends on the members appointed or nominated by the Member States, in addition to the support provided by the secretariat. This is reflected both in terms of the number of members and their expertise in carrying out the required tasks. In the first years of REACH implementation, it was not always recognised by MSCAs that being an active member of an ECHA Committee takes at least 50 % of their working time. Additionally, members also need, and are entitled according to REACH, to adequate support by their Authorities for their work.

The above situation started to impair the ability of the Committees to respond to the increasing workload, especially in RAC and SEAC with the increasing number of dossiers starting from 2013. ECHA raised the issue repeatedly at various levels and as a result, real improvements have been observed.

Figure 48. RAC and SEAC members and co-opted members

	2009	2010	2011	2012	2013	2014	2015
SEAC members	16	30	30	30	33	37	40
SEAC co-opted members							3
RAC members	21	36	41	39	42	45	47
RAC co-opted members							5

Nevertheless, it needs to be recognised that this remains a continuous challenge. While all Committees are improving their efficiency and streamlining their working methods, the workload will remain high, and in many areas the scientific complexity of the issues to be evaluated, is increasing.

The role of SEAC is a novelty under REACH, and it is also a unique body under EU legislation dealing with safety. In addition, the methodology used in the socio-economic assessment related to chemicals risk management is not as well developed as risk assessment techniques and the pool of specific in-depth expertise in the EU (and indeed worldwide) is limited. Whilst the quality and value of SEAC opinions is widely recognised, further capacity building to widen the pool of expertise in the area is needed.

In addition, the role of SEAC and of socio-economic assessment under REACH continues to raise criticisms and confusion. This has been reflected, for example, in the resolution adopted by the European Parliament on 25 November 2015 in which it objected to a Commission draft decision under the REACH Regulation.

The contested draft decision concerned the authorisation of a specific use of the substance bis(2-ethylhexyl) phthalate (DEHP). The resolution made critical remarks on the scientific opinions delivered by SEAC and RAC, which formed the basis of the Commission draft decision. In relation to the opinion of SEAC, the European Parliament in particular considered that SEAC overstepped its mandate by giving policy-driven opinions. This resolution has been duly analysed both by the ECHA secretariat and its Management Board, and it has resulted in lessons learnt from one of the very first SEAC opinions, including how to ensure that any statements in the opinions clearly reflect the role of the Committee which is strictly scientific and technical. The case has also initiated a wider discussion on the role of socio-economic assessment under REACH, which is likely to be helpful in creating a better common understanding on this sensitive aspect.

COMMITMENTS AND RECOMMENDATIONS

- R45. Member States need to maintain continued support for the work of the ECHA Committees. This will ensure that the core processes of REACH and CLP will continue to deliver and provide independent and fit-for-purpose scientific advice for ECHA and the Commission. The demands of the work as an active Committee member needs to be acknowledged and respected.
- R46. Authorities and stakeholders should continue their dialogue to achieve a better common understanding of the role of SEAC and SEA in REACH.

TRANSPARENCY AND MANAGING CONFLICTS OF INTEREST

Independence is one of the core values of the Agency and it is of the utmost importance that ECHA's decisions are strictly science-based and independent from any external interests. While ECHA still received criticism from the Court of Auditors in 2012 for its management of potential conflicts of interest¹⁵³, it has since strengthened the measures in place to avoid and detect potential conflicts of interest. These measures include amongst others an assessment against eligibility criteria before appointing committee members, the submission of annual declarations of interest once appointed, oral declarations at the start of each meeting, breach of trust procedures and the establishment of a Conflict of Interest Advisory Committee, which advises ECHA management on matters related to potential conflicts of interest.

Similar provisions also apply to all staff of the Agency, who are assessed for potential conflicts of interest before recruitment, obliged to submit an annual declaration of interest, assessed for impartiality before important tasks are assigned and subject to strict post-employment duties.

As ECHA's decision making must not only be independent, but must also be seen to be independent, the Agency has made a lot of efforts to be fully transparent about the interests that any collaborator of the Agency (staff or external experts) may have by publishing the annual declarations of all external experts and of the ECHA managers on its website for public scrutiny. Furthermore, ECHA allows stakeholder observers to attend and contribute to the meetings of the Committees (unless, in exceptional cases, confidential business information is discussed) and the agendas, minutes, membership including interests declared, opinions and minority views expressed and conclusions drawn by the Committees, are always publicly available.

The Conflict of Interest Advisory Committee had its constituent meeting 24 August 2012. It is available to the Management Board, the Committees and the Forum as well as to the Executive Director for advice on matters related to (potential) conflicts of interest of individuals staffing the Agency or members of its bodies. It has so far advised on the eligibility criteria for RAC and SEAC, on concurrent employment in the competent national authority of RAC/SEAC members, on secondment in the interest of the service and on the eligibility of the co-opted members for RAC/SEAC. It has also discussed conflict of interest management together with RAC and SEAC at their plenary meetings. Most of its discussions and advice have been about the *perception* of a possible conflict of interest, which is according to the policy (and OECD Guidelines) to be regarded like a conflict and thus to be avoided. This obviously raises matters for interpretation and a steady practice is emerging from the Conflict of Interest Advisory Committee whose advice has been well received.

Other improvements to the openness of ECHA's decision making in recent years include the publication of information on the intentions of ECHA and the Member States – for example, to look into substances or create dossiers which can lead to regulation – so that companies can take informed business decisions. Public consultations are conducted in most regulatory processes of the Agency and the comments received are addressed. In some of the processes, individual case owners are consulted during the decision making. When conclusions are drawn, the Agency communicates clearly to the affected parties. Conclusions on a substance level are also widely communicated towards the public at large, except those elements covered by business confidentiality.

153 See European Court of Auditors (Special Report number 15//2012) *Management of Conflict of Interest in Selected EU Agencies*: http://www.eca.europa.eu/Lists/News/NEWS1210_11/NEWS1210_11_EN.PDF

2.1.2 The Forum for Exchange of Information on Enforcement

THE OBJECTIVES OF THE LEGISLATION

REACH requires the Agency to provide a Forum for Exchange of Information on Enforcement (the Forum) that coordinates a network of Member State authorities responsible for the enforcement of the REACH and CLP chemicals legislation.

The tasks of the Forum, listed in REACH and referred to in CLP, aim at harmonising enforcement action taken by National Enforcement Authorities (NEAs) under their own sovereign responsibility. The legislation tasks the Forum to share best practice, undertake harmonised enforcement projects and joint inspections, coordinate the exchange of inspectors, equip them with manuals and tools, liaise with industry as well as examine proposals for restrictions with a view to their enforceability (see Article 77(4) of the REACH Regulation).

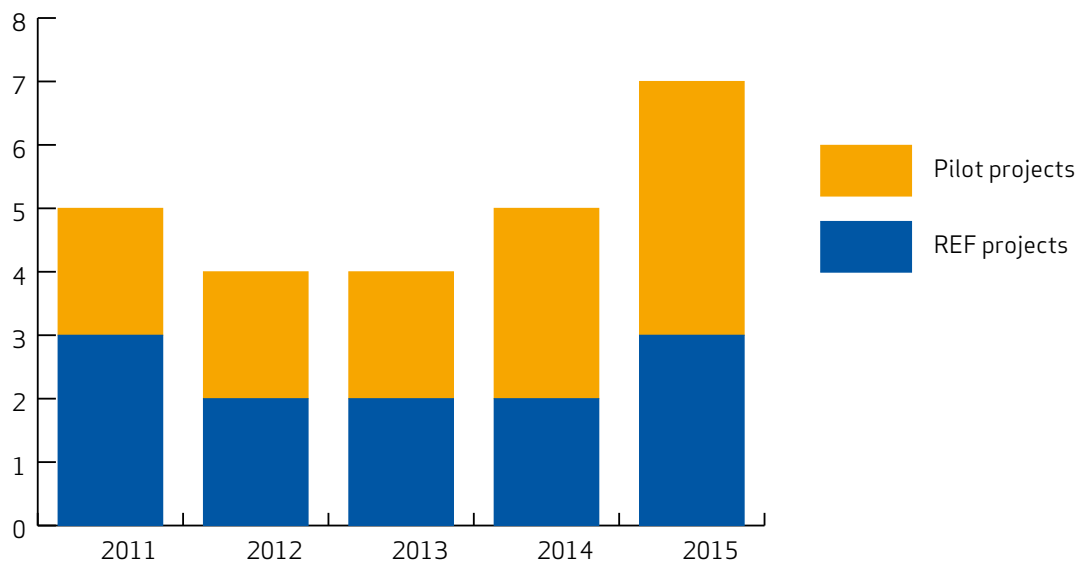
IMPACT OF THE OPERATIONS

The enforcement by Member States of core REACH and CLP provisions is increasingly coordinated

The Forum is a key player in the enforcement of REACH and CLP. Member States undertake enforcement at national level according to their own priorities independently of the Forum. However, coordinated enforcement undertaken by the Forum forms an integral part of the national enforcement plans. The scope, pace and depth of the coordinated enforcement activities is increasing with the number of enforcement projects coordinated by the Forum gradually rising over the years 2011-2015 (see Figure 49).

For any given year, the Forum has established a practice to have one major coordinated REACH-EN-FORCE (REF) project being selected, one being prepared, one being executed and one being reported on. On top these major REF projects, the Forum also runs small-scale pilot projects.

Figure 49. Numbers of active Forum projects 2011-2015



Even with the ambition of achieving a level playing field, differences persist due to the variety in national enforcement strategies and capacities, differences in legal traditions as well as penal sanctions, geographically dispersed concentrations and differing structures of the chemical industry, as well as actors in the supply chain. All aspects considered, against this background and its mandate, the Forum has established an impressive track record and considerable dynamics in designing and implementing joint enforcement action, as reflected below.

Most REACH instruments for coordinating enforcement work well but further resources are needed to boost the exchange of inspectors

REACH provides instruments for coordinating enforcement of REACH and CLP through the tasks given to the Forum by the REACH and CLP Regulations¹⁵⁴. These include spreading good practice, organising projects and building tools for inspectors. All of these tasks have been successfully implemented by the Forum on an annual basis. However, the exchange of inspectors has not been continuously implemented due to a lack of resources in the Member States.

ECHA financed pilot exchanges of inspectors between Member States in 2012 and 2013 and these have been highly appreciated by participating NEAs as they have allowed direct exchange of enforcement practice between the involved countries. In the long term, financing of these exchanges should be ensured by Member States. The Forum and the Member States have made two attempts to obtain funding from the European Commission, but the projects proposals were not successful. Recommendations on how this situation could be remedied can be found below.

The Forum has participated in the European Commission's study to define enforcement indicators for REACH. As a result, a set of Forum enforcement indicators that reflect its key tasks under Article 77(4) are expected to be derived in 2017.

ACHIEVEMENTS AND CHALLENGES

Focus on coordination of enforcement through practical activities

Throughout 2011-2015, the Forum has shifted its focus from defining high level best practice, towards the practical harmonisation of enforcement by coordinating enforcement projects (see Figure 49).

There are two types of Forum projects. Major REF projects focus on the fundamental obligations of REACH and have a broad scope and involve nearly all Member States. In contrast, pilot projects address specific new enforcement challenges such as authorisation obligations or verification of intermediates to test enforcement approaches.

These pilots are also small scale as they involve fewer countries and cover fewer obligations than the REFs. Both types of projects have helped to test the enforcement approaches used in the different Member States with the aim of harmonising enforcement practices throughout the EU.

The scope, pace and depth of the coordinated enforcement activities have been increasing throughout 2011-2015. Since 2011, the Forum projects covered all the key areas of REACH that have become operational. The first REF project focused on pre-registration and availability of SDSs. The second focused on downstream user obligations and the flow of information in the supply chain, including checking safety data sheets (SDSs). The third REF project, coinciding with the second registration deadline again focused on registration-related duties. In parallel to these major REF projects, the Forum has also explored new obligations such

¹⁵⁴ Specified in REACH Regulation (EC) No 1907/2006, Article 77(4) and CLP Regulation (EC) No 1272/2008, Article 46(3).

as the use of intermediates under strictly controlled conditions or duties related to authorisation through smaller pilot projects. Project activities also addressed restrictions and the main areas of CLP. As a result of the integration of ECHA's regulatory operations with that of the Agency's Forum, the enforcement of ECHA decisions since 2012 has been gradually increasing.

It is encouraging that on average, 27 of the overall eligible 31 EU/EEA countries participated in the REF projects that were active in the period 2011-2015. However, full participation of Member States should be the objective to ensure a level playing field.

The practical coordination through projects has been accompanied by a growing harmonisation of enforcement approaches. Since 2012, the Forum has recorded all its adopted conclusions on practical enforcement issues in its Manual of Conclusions (MoC). This manual is intended to ensure a harmonised enforcement approach among the inspectors throughout the EU/EEA.

Efficient operation of the Forum processes

In this reporting period, efforts were undertaken to increase the efficiency of key Forum processes. For example, the process for delivering advice on the enforceability of restrictions, the operation of Forum working groups, cooperation with ECHA's Accredited Stakeholder Organisations and drawing up a harmonised methodology for coordinated enforcement projects.

Key IT tools have been developed to support enforcement by the NEAs

Support has been provided by ECHA to the NEAs and their enforcement activities by building IT tools for national REACH, CLP and PIC inspectors according to the specifications defined with the help of the members of the Forum. The tools allow inspectors to access and examine the files (e.g. registrations or C&L notifications) submitted by industry to ECHA.

The first such tool was RIPE (the REACH Information Portal for Enforcement) released in 2011. Its successor – the Portal Dashboard for National Enforcement Authorities (PD-NEA) – was released in early 2016. At the same time, the ePIC application was made available to the national enforcement authorities. These tools have enabled effective enforcement, as easy access to the files submitted to ECHA is critical for checking fundamental REACH and CLP obligations, such as the obligation to register.

Enforcement experience indicates that some REACH provisions need further clarification or review to ensure that they can be implemented in a practical way

Enforcement experience and the work of the Forum indicate that some legal provisions of REACH would benefit from a review to facilitate enforcement.

The Forum's third coordinated enforcement project (REF-3) focused on checking registration duties. Inspectors observed frequent problems with the flow of information in the supply chain, particularly between only representatives (ORs) and importing downstream users (DUs¹⁵⁵). Two regularly occurring issues were that these actors are often not aware of each other and inspectors were not able to obtain information on the supply chain (see Chapter 1.1.4).

¹⁵⁵ The Forum's third coordinated enforcement project (REF-3) focused on checking registration duties. Inspectors observed frequent problems with the flow of information in the supply chain, particularly between only representatives (ORs) and importers, which should be covered by these ORs. Two regularly occurring issues were that these actors are often not aware of each other and inspectors were not able to obtain information on the supply chain.

Enforcement experience indicates that Article 8 of REACH, concerned with ORs has proven difficult to enforce in its current format as it only places duties on the ORs for keeping information about imported substances and tonnages but not on importing DUs. This results in a situation where DUs are often not sufficiently aware of who is representing them. The Forum recommends that Article 8 is revisited to explicitly define the duties for documenting contact or exchange of information between the importing DU and the OR. In addition, enforceability of OR duties would improve if an OR were obliged to submit the information on the DUs they supply to in their registration dossier. Further details of the Forum recommendation are available in the final report of the REF-3 project¹⁵⁶.

Following the recent ruling of the Court of Justice on the interpretation of Articles 7(2) and 33 of REACH, the Forum decided unanimously that a coordinated enforcement project of the substances in articles provisions will be a priority in 2017. ECHA will start preparing a project proposal in close cooperation with the Forum in the course of 2016 with a view to adopt it shortly thereafter. Inspections are foreseen to take place in 2017 and the reporting phase is planned for 2018.

The Forum also noted challenges in coordinating the enforcement of joint submission obligations due to differences in national provisions that regulate enforcement. This discussion contributed to ECHA's revision of its IT tools for dossier submission such as to prohibit multiple registrations for the same substance (see Chapter 1.1.2).

Enforcement experience indicates that the compliance level with registration obligations should be improved. Even more efforts are needed to improve compliance with obligations related to the communication of information in the supply chain (e.g. SDSs)

Registration and related duties are a fundamental part of REACH. The Forum focused on checking registration-related obligations in project REF-1 (2008-2010) and in REF-3 (2013-2014). In the first project, 7 % of inspected companies were found to be non-compliant with registration-related duties. This increased to 13 % in the second project. While the Forum did not find systematic breaches, most companies were in breach for one of their substances¹⁵⁷. The increased level of non-compliance is significant, especially taking into account that the years of practical experience and information since the entry into force of REACH increased.

REACH duties related to communication of information in the supply chain, in particular the provision and quality of the SDSs, were checked in REF-2 (2011-2012). Inspectors found that SDSs were almost always (97 %) available, but over half of them (52 %) had deficiencies in quality. Issues were most frequently found with information on exposure controls, personal protection and the composition of the substance. The high rate of deficiencies with SDSs means that their quality has not improved since the time before REACH, since enforcement projects in the past¹⁵⁸ found a similar level of non-compliance.

These findings confirm the continued need for strong and coordinated enforcement. In addition, further efforts are needed from the industry and industry stakeholder organisations to increase compliance among companies.

156 ECHA (2015) *Forum REACH-EN-FORCE 3*, Final Report: http://echa.europa.eu/documents/10162/13577/ref_3_report_en.pdf

157 The number of actors who do not register any of their substances (free riders) is low: 2 %.

158 Carried out by the Chemicals Legislation European Enforcement Network – CLEEN.

COMMITMENTS AND RECOMMENDATIONS

- R47. To achieve a fair level-playing field throughout the single market, all Member States should take part in all REF projects as well as consistently enforcing ECHA and Commission decisions in their territory.
- R48. The Commission is recommended to review the provisions of Article 8 of the REACH Regulation regarding only representatives. This follows practical shortcomings identified in implementing Article 8 of the REACH Regulation.

2.1.3 ECHA Helpdesk and the HelpNet

THE OBJECTIVES OF THE LEGISLATION

REACH requires the Agency to provide advice and assistance to manufacturers and importers registering a substance as well as to provide technical and scientific guidance to duty holders more widely. At the time of its establishment, the Agency chose to deliver this, *inter alia*, by dedicating some of its staff to providing helpdesk services to industry customers.

REACH requires ECHA to provide support to the REACH and CLP helpdesks established by Member States¹⁵⁹.

The Agency fulfils this task by managing a network entitled the 'HelpNet' (the network of national BPR, CLP and REACH helpdesks). Under its previous name, 'REHCORN' (the REACH Helpdesk Coordination Network) was the first network that the Agency founded during the early days of its own establishment. The legislation foresees that national REACH helpdesks provide the 'first stop' for companies seeking advice on complying with their obligations.

The legislator thereby foresaw that SMEs in particular would benefit from receiving advice in their own national languages and from a public body with insight into domestic circumstances. Having tasked ECHA with managing the implementation of REACH, the HelpNet provides a forum for the Agency to share information with the national helpdesks.

IMPACT OF THE OPERATIONS

The ECHA Helpdesk constitutes one of the key interfaces between the Agency and duty holders.

REACH has clearly allocated the responsibility for the safe manufacture and use of chemicals to industry. However, duty holding companies may need assistance on how to fulfil their obligations. This has been particularly important during the phase-in period of implementing REACH and the build-up of ECHA during which regulatory processes evolved rapidly. In this period, IT tools were frequently upgraded, guidance was developed on many aspects and numerous legal deadlines drove the pace of events.

With thousands of companies seeking support from ECHA, the impact of its helpdesk services can best be measured by the manner in which companies fulfilled their duties, for example, in meeting the 2010 and 2013 REACH registration deadlines, which were considered successful (see Chapter 1.1.2).

¹⁵⁹ REACH Regulation (EC) no 1907/2006, Article 77(h) and CLP Regulation (EC) No 1272/2008, Article 50(2)b.

Apart from enabling companies to seek support directly from ECHA, the Helpdesk interface also allows the Agency to benefit from real-life feedback, which contributes to the continuous improvement of its guidance and communications efforts as well as to ECHA's REACH and CLP processes.

ECHA's support is essentially twofold: it almost exclusively helps companies to use the Agency's IT tools (such as IUCLID, REACH-IT or Chesar) by providing IT-related advice or direct support. Secondly, it assists companies with the queries related to regulatory issues, although national REACH helpdesks are the first line of response for EU companies. ECHA provides a second line of response for EU companies, and a first line of response for non-EU companies.

The coordination of the national CLP and REACH helpdesks through the HelpNet ensures consistent responses to companies.

The work of the HelpNet has assisted the national REACH and CLP helpdesks in EU/EEA countries to operate, but also to promote a common understanding of REACH and CLP obligations and harmonise the answers given to companies across the EU/EEA. This has been achieved *inter alia* through the provision of FAQs, harmonised replies and common approaches in responding to questions.

With time, many difficult questions related to the implementation of CLP and REACH have been harmonised. In 2015, the focus has been to revise the FAQs related to the first phases of the REACH 2018 Roadmap and to simplify their content to be more SME friendly. The achievements of companies fulfilling their legal obligations under REACH and CLP are also partly due to the availability of national helpdesks to address their questions in a consistent way.

The HelpNet is a key player in supporting REACH and CLP companies

ECHA has been able to draw on the expertise of the HelpNet correspondents to establish specific support products and training sessions to ensure companies complying with REACH and CLP have the most up-to-date information. For example, in 2013, HelpNet correspondents contributed to producing simpler guidelines for mixture classifications, which are published on the ECHA website to help companies in this particularly demanding task.

With a view to reaching out to industry associations, the HelpNet Secretariat, also in 2013, brought all national REACH helpdesk correspondents together with their national counterparts from the European Enterprise Network (EEN). This not only magnified their potential to support SMEs, but also resulted in a joint ECHA-EEN publication on 'EU Chemical Management Rules and Your Client's Business' – a guide for SME advisors on REACH and CLP which the EEN distributed to all its members (see the text box on 'SMEs and REACH' in Chapter 1.1.2). However, further work on enhancing the collaboration of national authorities on REACH matters in a given Member State and among national helpdesks of different countries, could be done in this respect, particularly in advance of the forthcoming 2018 registration deadline.

The speed and intensity of developments of which national helpdesks need to be aware, resulted a regular newsletter being produced and circulated within the HelpNet from the start of 2015 ('The HelpNet Update').

Since its inception, the HelpNet has been supported by HelpEx, an online exchange platform on which national HelpNet correspondents can discuss the most appropriate answers to selected and difficult questions from industry. ECHA and the European Commission help to formulate the answers. On the basis of demand, ECHA moved to continuously publishing FAQs generated on this platform in 2015, after previously having done so only in annual intervals. Thus, targeted advice is now being 'brought to market' more swiftly, for the benefit of companies.

Figure 50. National helpdesks have promoted harmonised advice

- Four dedicated trainings on ECHA's scientific IT tools and submissions
- Eight HelpNet Steering Group meetings
- Four HelpNet REACH workshops
- Three HelpNet CLP workshops
- One training on mixture classification

ACHIEVEMENTS AND CHALLENGES

National REACH and CLP helpdesks actively participate in coordination meetings, training and workshops organised by the HelpNet, increasing their capacity to support companies

During the reporting period, the work of HelpNet has evolved over time, with regard to its format as well as to its content. Specifically, instead of convening in plenary twice per year, from 2014 all correspondents were invited to a single annual HelpNet Steering Group meeting to coordinate activities. More tailored workshops have also been held during each year to tackle specific topics and to assist national helpdesks to broaden their capacity. Examples include: hands-on IT tool training for HelpNet correspondents, discussion of case studies from national helpdesks arising from national awareness campaigns and feedback on how specific questions from duty holders have been handled.

Throughout the period, the particular responsibility of national helpdesks towards SMEs has also figured prominently in many workshops from exchanging best practice on reaching SMEs, to highlighting the needs of SMES in understanding downstream user obligations.

The national helpdesks need to have sufficient resources in the run-up of the forthcoming registration deadline in 2018

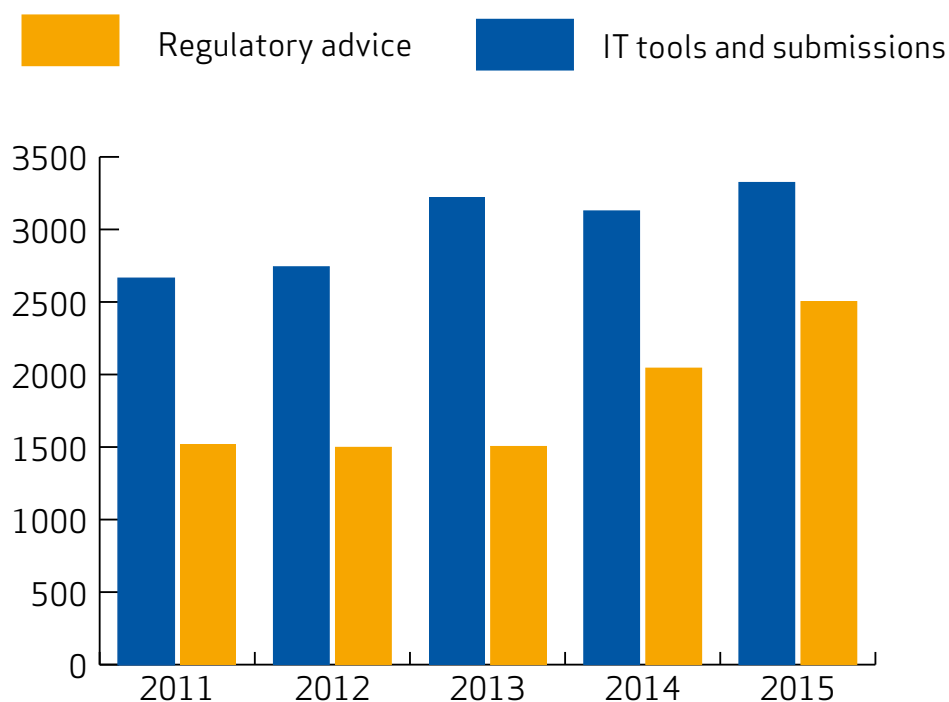
Whilst HelpNet correspondents actively participate in the work of the HelpNet, they depend on the individual and varying capacities of their own administrations to operate effectively. In particular, as well as running their own helpdesks, correspondents convey the knowledge provided by the HelpNet to the appropriate individuals in their own administrations and bring case studies and examples of best practice forward to the HelpNet.

In light of the oncoming 2018 REACH registration deadline, ECHA is concerned that some national helpdesks will not be equipped with sufficient resources to meet the demands that will be posed by a large number of new companies registering for the first time, many of which may be SMEs (see Chapter 1.1.2). Member States need to maintain continued support for the work of national helpdesks. The demands of the work of the helpdesks and the HelpNet need to be fully acknowledged and respected.

The ECHA Helpdesk has responded to customer needs

Over the past years, IT and regulatory support have followed different patterns. ECHA's activity in providing IT support has fluctuated over time, with the number of IT tool-related questions to the Agency peaking with the two registration deadlines as well as around the new release of updates to ECHA's digital submission and scientific tools. Every time such a release occurred, enquiries surged to differing degrees until the REACH managers of companies familiarised themselves sufficiently with the new functionalities. Technical difficulties relating to unblocking accounts (i.e. problems to access passwords) remained fairly constant.

Figure 51. Number of resolved helpdesk questions from 2012-15



In 2014, recognising that MSCAs need support for utilising ECHA's IT tools when conducting their REACH duties, ECHA launched a dedicated MSCA-IT project which provides hands-on responses to officials of the MSCAs as well as keeping them abreast of relevant IT developments through a regular newsletter.

On the other hand, providing regulatory support by answering questions from companies on their obligations or on more specific aspects of various regulatory processes, remained rather constant (see Figure 51). However, as the means for implementing the regulatory regime has developed, along with the experience of companies, the questions received have become more complex. This has required ECHA staff to respond accordingly. Nonetheless, 'newcomers are still contacting the national and ECHA helpdesks on basic matters in the understanding of REACH'.

As the complexity of responses has grown, a challenge that ECHA had to meet was to formulate replies in understandable language. Another inherent tension has been that ECHA can provide companies with a generic approach to fulfilling a legal obligation, whereas some companies have sought tailored support for specific scenarios they face, something more readily provided by consultancies. Perhaps as a result, consultants have also regularly sought assistance from the ECHA Helpdesk.

Typically, ECHA refers companies to documents published on ECHA's website e.g. guidance, practical guides or IT user manuals, or audio-visual material. This implies that such material must be easily accessible and provided in a reader-friendly manner, including translation. Since 2015, ECHA has re-arranged parts of its website to guide companies through such information material in a stepwise and tiered approach.

Subject to available resources, ECHA may support industry in developing user-specific guidance e.g. through ECHA staff attending dedicated workshops organised by industry or giving feedback on specific issues. Evidently, helpdesk work will need to rely on all material being similarly accessible, including sector-specific advice provided by industry associations.

Companies should start their preparations for the 2018 registration deadline now

At the time of this report, the expected high number of potential registrants for the 2018 REACH registration deadline, the variety of sectors they represent, combined with the expectation that they will largely be inexperienced SMEs, represents a challenge for all national REACH helpdesks, and not least also for ECHA.

As with the previous deadlines, ECHA will provide a dedicated telephone service for registrants in the immediate run-up to the deadline. The release of a new generation of IUCLID and REACH-IT tools will undoubtedly lead to an increased need for IT support for companies, which have not yet been exposed to REACH. Companies should therefore be encouraged to start their dossier preparations now to avoid last minute difficulties.

Looking beyond the next registration deadline, companies will continue requiring support from the ECHA Helpdesk. However, the support will shift in emphasis from providing advice on registration, to other areas such as updating existing dossiers, downstream user obligations (including compliance with CLP classifications) and applications for authorisation will continue to be submitted. Registrants for new substances will also still require support.

COMMITMENTS AND RECOMMENDATIONS

- C16. As with the previous deadlines, ECHA will provide a dedicated telephone service for registrants in the immediate run-up to the 2018 deadline.
- R49. National helpdesks should continue to collaborate closely with national and sector industry associations to spread knowledge, particularly to SMEs, on their obligations under REACH and CLP. This should be carried out in cooperation with their counterpart EEN advisors in their respective countries.
- R50. Member States need to maintain continued support and resources for the work of national helpdesks and for providing advice and technical guidance, in particular to SMEs. The demands of the work of the helpdesks and the HelpNet need to be fully acknowledged and respected. This is not only important in the run-up to the 2018 REACH registration deadline, but will continue to be essential afterwards.
- R51. Industry associations should support their sectors by providing sector-specific advice where appropriate and by spreading information provided by ECHA and other actors to their members. The communications means that industry associations have at their disposal (newsletters, seminars, etc.), are essential to multiply the support provided by ECHA.

2.1.4 Board of Appeal

THE OBJECTIVES OF THE LEGISLATION

The REACH Regulation establishes the ECHA Board of Appeal (BoA) as an important component of the regulatory framework for chemicals and as an integral part of the Agency. It is composed of three members, two of whom are legally qualified and one technically qualified.

BoA decides on appeals brought against certain decisions adopted by the Agency as a result of applying the processes under the REACH Regulation, most importantly registration, dossier evaluation (compliance checks of registration dossiers and testing proposals) and substance evaluation. BoA carries out an

independent review of contested decisions to determine if they are legally sound i.e. whether they comply with the REACH Regulation and EU law in general. BoA decisions are decisions of the Agency.

An appeal before BoA has suspensive effect, meaning that the addressee of the contested decision does not have to comply with it until BoA decides on the appeal. After an appeal is received, ECHA's Executive Director may also rectify the contested decision.

When deciding in appeal proceedings, BoA can confirm, amend or annul appealed decisions, exercising any power which lies within the competence of the Agency. If BoA rejects an appellant's claims, the latter can challenge the BoA decision before the EU Courts. However, if BoA finds in favour of the appellant, the case is usually remitted to the Agency for further action, taking into account the outcome of the appeal. BoA decisions consequently have a considerable impact on ECHA's processes.

IMPACT OF THE OPERATIONS

BoA is one of the driving forces behind continuous improvement of the Agency's implementation of REACH and a wider understanding of the responsibilities under REACH.

The aim of BoA is to provide an effective and resource-efficient administrative review of certain Agency decisions. The legitimate interests of registrants can be safeguarded by contested decisions being annulled by BoA or rectified and even withdrawn by ECHA in cases where the parties reach a mutually acceptable solution.

Through its decisions BoA, taking into account the case-law of the Court of Justice of the EU, clarifies the interpretation of the REACH Regulation and helps the Agency to implement the Regulation effectively. Appeals therefore function as a 'safety net', allowing the Agency to ensure that its decisions are of a consistently high standard.

BoA decisions provide guidance both to ECHA and to REACH registrants how a given process should be carried out and how REACH is interpreted in a manner that respects both the objectives of the Regulation and the rights of the registrants. As a result of the issues raised in an appeal, following a BoA decision, the Agency regularly amends its processes. Even when a BoA decision finds in favour of the Agency, the decision often provides useful indications of how processes could be further improved.

Examples of the approach described above include clarifying the requirements that the Agency has to fulfil when requesting further information during substance evaluation (SEv) (Case A-005-2014). Firstly, the Agency must be able to demonstrate that there is a potential risk to human health and the environment. It must also show, secondly, that the potential risk identified needs to be clarified. Thirdly, it must be able to demonstrate that the information requested has a realistic possibility of leading to improved risk management measures.

In the compliance check (CCH) process, if a registrant proposes a read-across for a standard information requirement, the Agency needs to check not only that the registrant observed the adaptation rules but also whether the uncertainty linked to the read-across proposal is acceptable or not (Case A-001-2012). When the Agency imposes a non-standard test requirement, it must ensure that vertebrate animal testing is performed only as a last resort (Case A-005-2011). Another example is a substance evaluation case in which BoA found that a compliance check of the relevant registration dossiers for a substance should normally take place before that substance is evaluated. If, under SEv, the Agency requests information which would usually be requested during the course of a compliance check, such a request must be duly justified, in light of the objectives of the REACH Regulation and substance evaluation and in particular the protection of human health and the environment (Case A-005-2014).

With regard to registration, BoA has clarified that all registrants of the same substance must be part of the same joint submission (the principle of 'one substance, one registration'). When performing the completeness check of a registration, the Agency must verify whether that requirement is observed. It must also ensure that the information provided is not meaningless text. As the submitted registration was not complete, the Board of Appeal considered that the Agency must prescribe a reasonable deadline for the provision of the missing information and may reject the registration (Case A-022-2013).

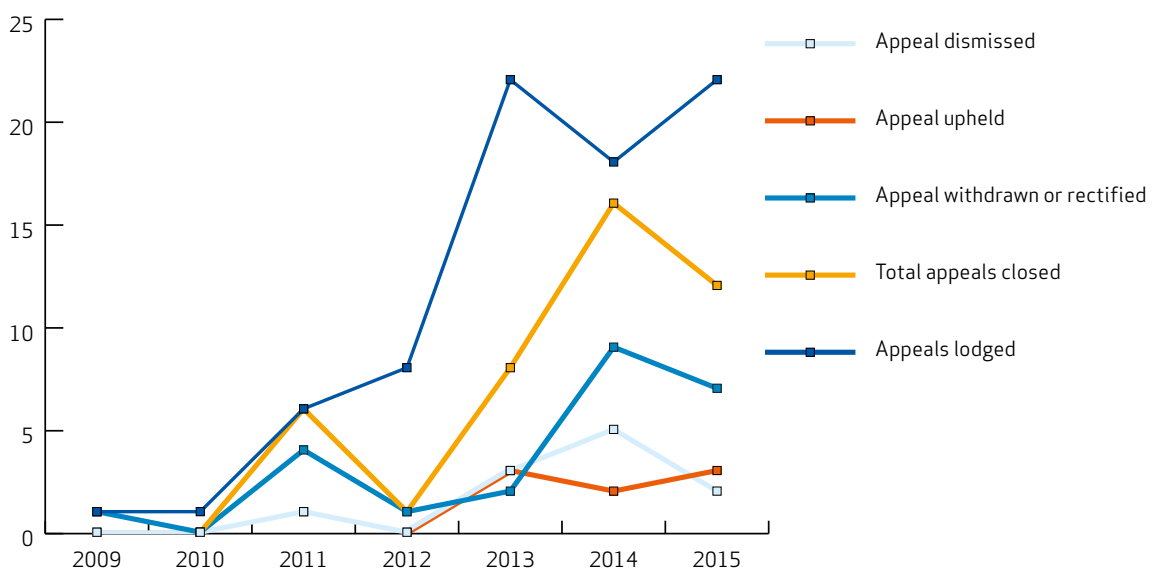
In relation to the Agency's communication with registrants, a registrant who was made aware that it had a right to correspond with the Agency in the language of its own Member State and also the right to receive all documents from the Agency in that language, may explicitly agree to receive the Agency's communications in a language that is not the language of its own Member State, for example, in English (Case A-002-2013).

Appeal proceedings are open and accessible to stakeholders, ensuring that all relevant interests are adequately heard before a decision is adopted. NGOs active in the fields of health, the environment or animal welfare, concerned companies, industry associations and MSCAs may, under certain conditions, present their views in a particular case as interveners.

Overall, the appeals process in general and the BoA decisions in particular have helped to maintain and increase the high level of trust that the stakeholders have in the REACH regulatory system and in the Agency.

Finally, BoA decisions help to provide legal certainty to all registrants as to how the Agency should interpret and implement the REACH Regulation. The appeal process therefore benefits European citizens, the companies concerned and the Agency itself.

Figure 52. Appeals dealt with by BoA since 2009



BoA carries out its functions effectively and its decisions have a positive impact

The impact of BoA decisions often goes well beyond the resolution of the cases concerned. For example, BoA has helped the Agency to refine its operations, clarifying grey areas in the legislation as well as the roles and responsibilities of the various actors in the REACH processes. BoA thus importantly contributes directly to achieving the aims of REACH.

The success of BoA is also shown by the impact of its decisions and of the appeals process as a whole. Clear, sound and thoroughly reasoned decisions often prevent the need for further appeals on similar issues. For example, a decision on the use of languages in relation to the Agency's communications with registrants, in the context of the SME verification process, prompted the Agency to reassess its processes. As a result, the number of appeals on this subject has dropped dramatically and several pending appeals were settled by the Agency. Moreover, BoA decisions may highlight potential areas for further consideration and shed light on regulatory gaps. This contributes to further improvements of the regulatory framework by the Agency, the EU institutions and Member States.

Views on the work of BoA

'[The detailed decisions of BoA] are very useful because the BoA delivers guidance to registrants in regard to whether their practices may be considered as lawful in the future. ECHA has also considerably changed its administrative practice as a follow-up to BoA decisions'

Ursula Schliessner, Jones Day LLP, qt. in New phase for ECHA Board of Appeal, Chemical Watch Global Business Briefing, October 2015.

'BoA's approach [to read-across] has been too deferential to ECHA. Also, [the Lanxess decision on animal welfare issues] was very poorly reasoned and did violence to the clear language of REACH. In other cases, BoA has, where appropriate, taken a robust line against ECHA'

Katy Taylor, Cruelty Free International (NGO), ut supra.

'We believe that BoA has demonstrated its impartiality which is unquestionable.'

Vincent Navez, CEFIC, ut supra.

'Over the years, BoA has emerged as an independent and effective means of controlling and sometime redressing practices of the Agency and for ensuring the implementation of the REACH regulation in line with all of its objectives. By fully seizing the role it is attributed by REACH, and sometimes even quite extensively, the board is raising the standard of administration that ECHA must respect. This is good news for industry, on which the REACH Regulation has put a great burden. However, this does not mean the board is always an ally of industry. In the same vein, many decisions by the board sanction poor industry practices and force industry to raise its own standards of practices.'

Jean-Philippe Montfort and Thomas Delille, Lessons Learned and Prospects on the European Chemicals Agency's Board of Appeal Rulings on REACH Processes, Bloomberg BNA, 7 January 2015.

ACHIEVEMENTS AND CHALLENGES

BoA's work has increased as the Agency's workload has grown

During the reporting period, the BoA has received an increasing number of appeals (see Figure 52), coupled with a considerable increase of procedural communications that is exchanged with the parties. The appeals are handled efficiently and the BoA decisions are still given within a reasonable timeframe.

As a result of these decisions, the Agency has refined a number of its processes in the areas in which BoA can act. These include the registration process, in particular with regards to SMEs and the use of languages other than English as well as clarifying the conditions of use for REACH-IT. Concerning evaluation, the BoA decisions have contributed to the improvement of the quality of the Agency's decisions. For example, BoA has highlighted the need for decisions to be well reasoned when a test on vertebrate animals is requested.

BoA decisions have clarified the information that the Agency must provide to demonstrate that requests for information are proportionate.

The technical and scientific aspects of appeal cases are continuously evolving, advancing in terms of both scientific and legal complexity. Currently, issues which are the subject of appeals include the definition of intermediates for the purposes of registration, the scope of exposure assessment and the identification and information requirements for nanomaterials relating to registration and substance evaluation. By resolving these issues, the BoA will make a further contribution to making REACH work in practice. This trend is expected to continue in the future as the Agency's takes an increasing number of decisions on dossier and substance evaluation.

COMMITMENTS AND RECOMMENDATIONS

R52. The Commission is recommended in the forthcoming review of the BoA's Rules of Procedure to consider how: a) to effectively safeguard the efficiency of the appeal proceedings before the BoA and so that the BoA can continue to adopt high-quality decisions within a reasonable time, and b) to allow the BoA to continue to assert its independence from the ECHA secretariat and its stakeholders to ensure that the appeal proceedings continue to be fair and impartial.

2.2 RESOURCES

2.2.1 Financial and human resources

THE OBJECTIVES OF THE LEGISLATION

To ensure effective and efficient implementation of the legislation, the structure of the Agency should be suitable for its required tasks and the Agency needs to have the means to perform all the tasks required to carry out its role.

2.2.1.1 Financial resources

IMPACT OF THE OPERATIONS

ECHA's budget planning and implementation has been effective and ECHA has a proven track record in sound financial management

ECHA's finance function is responsible for financial management in the Agency, specifically in the areas of budget planning and implementation, procurement and accounting.

ECHA's budgetary and management procedures and systems performed effectively in the reporting period, as evidenced by various audit reports, despite the uncertainty and volatility in its operating environment. Budget implementation has been effective, with variations due primarily to differences between forecasted and actual incoming registration dossiers and authorisation applications.

Despite the challenges, ECHA has a proven track record in sound financial management, including management of its reserve fund. This is shown by the European Court of Auditor's consistent confirmation that ECHA's financial transactions are performed in a correct manner and financial statements are reliable and in accordance with the EU's financial reporting framework.

ACHIEVEMENTS AND CHALLENGES

ECHA's funding structure contains fundamental risks and is a key challenge for the Agency

ECHA's funding structure, based on industry fees and an EU subsidy, contains fundamental risks. The principal financial risk derives from the uncertainty of baseline figures (that is, the estimated number of dossiers and authorisation applications to be processed) on which the associated workload and fee revenues are forecast, while a large proportion of ECHA's expenditure is fixed (for example, employment contracts and building lease contract).

In addition, as an EU Agency, ECHA is obliged to plan its funding arrangements on an annual basis, thereby reducing its flexibility to respond to changes in its environment (for example, in the event that the forecast registration or authorisation application fee levels do not materialise). Not having appropriate stability and predictability of Agency resources can pose a risk that negatively affects the implementation of the legislation.

ECHA's funding structure presents several challenges to its planning and financing functions as the income from industry fees will remain, to a large extent, unpredictable. In addition, as ECHA becomes increasingly dependent on the EU subsidy (and the related financial framework), the flexibility provided by its reserve will no longer exist, while the volatility and uncertainty of fee income will continue. This places an increased demand for continuous budget monitoring and amendments, as necessary, and a guarantee of stable financing to address anticipated cash flow shortages, in close collaboration with the partner Directorate Generals in the European Commission.

It is desirable to reduce the uncertainty related to the annual income available to finance the Agency's operations. This uncertainty could be reduced by, for example, introducing annual or periodic fees to achieve increased stability in income streams or, alternatively, ensuring that ECHA has the capacity to develop new income streams and/or impose fees for providing or updating certain services. In this respect, it has been ECHA's experience that industry is willing to pay fees for services that it values.

RECOMMENDATIONS

R53. ECHA needs to be guaranteed stable financing for its operations, combined with a capacity to develop new income streams for instance by demanding charges based on real costs for additional services provided to industry.

2.2.1.2 Human resources

IMPACT OF THE OPERATIONS

ECHA is dependent on the competence and commitment of its staff. Therefore, the management of the Agency's human resources, specifically in the areas of recruitment and selection, performance management, managing staff contracts and benefits, implementing HR policies and ensuring a positive working environment are among the success factors for how ECHA can fulfil its mission.

ECHA has been successful in attracting staff

ECHA has consistently achieved a low vacancy rate during the review period (see Figures 53 and 54).

Figure 53. Number of REACH/CLP staff working at the Agency (2011-15)

	Temporary agents	Contract agents	Seconded national experts	Total
2011	441	62	3	506
2012	434	77	8	519
2013	430	75	7	512
2014	425	94	11	530
2015	419	90	7	516

Figure 54. Percentage of REACH/CLP establishment plan posts filled (2011-15)

	Temporary agents
2011	98 %
2012	96 %
2013	97 %
2014	98 %
2015	98 %

ECHA has been successful in retaining and motivating staff

ECHA has experienced a relatively low turnover rate during the reporting period as a result of its investment in such pivotal retention and motivation factors as providing challenging and interesting work; motivational leadership; positive working climate; positive work-life balance and successful integration (of self, spouse and family) into Helsinki (see Figure 55).

Figure 55. REACH/CLP staff turnover as a percentage of establishment plan posts filled (2011-15)

	Temporary agents
2011	3 %
2012	5 %
2013	3 %
2014	4 %
2015	5 %

ECHA conducts an annual staff engagement survey – through an independent service provider – to measure staff engagement, demonstrating an average 9 % increase (see Figure 56).

Figure 56. ECHA's staff survey index (2011-15)

	Staff survey index	Increase
2011	505	-
2012	550	9 %
2013	599	10 %
2014	No survey	-
2015	654	9 %

ECHA has managed the imposed staff reductions effectively

ECHA has, since 2013, fully implemented the reductions in authorised staff numbers (that is, temporary agents), in accordance with the Commission communication COM (2013) 519 dated 10 July 2013 (see Figure 57).

Figure 57. ECHA's REACH/CLP authorised establishment plan posts (2011-15)

Authorised temporary agent posts	
2011	456
2012	456
2013	451
2014	441
2015	430

As the Agency's workload has not decreased during the review period, ECHA achieved the imposed reductions through a sharper focus on workload prioritisation (and related staff allocation), efficiency gains and the implementation of performance management and contract renewal processes that are based on clearly defined and transparent criteria (see Figure 58).

Figure 58. REACH/CLP staff contracts renewed as a percentage of eligible contracts (2011-15)

Temporary agents	
2011	100 %
2012	93 %
2013	92 %
2014	92 %
2015	92 %

ACHIEVEMENTS AND CHALLENGES

The continued attraction, motivation and retention of sufficiently qualified and experienced staff is a key challenge for the Agency

ECHA will continue to maintain a focus on initiatives to ensure that the Agency can attract, motivate and retain sufficiently qualified and experienced staff. As an EU Agency, however, many of the 'working conditions' of staff are set within the specialised legal framework of the Staff Regulations (over which ECHA has limited discretion).

ECHA retains flexibility in a number of important areas (for example, designation of core hours and implementation of flexi-time) and it needs to ensure that this discretion around workplace flexibility is used pragmatically to positively impact on staff attraction, motivation and retention.

The Commission needs to ensure that ECHA is allocated the necessary human resources to fulfil its mandate in all areas of its operations (including scientific capacity, IT infrastructure and services, administrative services and the Board of Appeal).

The knowledge and experience of its human resources are a core competence of ECHA and, since 2013, ECHA has fully implemented the imposed reductions in authorised staff numbers through a sharper focus on workload prioritisation (and related staff allocation), efficiency gains and the implementation of performance management. The continued attraction, motivation and retention of sufficiently qualified and experienced staff in the Agency, however, should be a key concern of the Commission to ensure that ECHA delivers on its demanding mandate in the interests of all its stakeholders.

The human resource competences of ECHA are a result of a significant investment since 2008 and they create an asset that provides a solid basis for the future of the Agency, including potential additional tasks. In this respect, ECHA supports the pilot project that is presently being undertaken in another Agency regarding flexibility in the annual number of fee-financed posts to respond to fluctuations in workload from industry. In addition, ECHA recommends that the Commission supports the ongoing work of the EU Agencies Network on sharing services and capabilities between Agencies with the aim of creating increased synergies and efficiencies.

COMMITMENTS AND RECOMMENDATIONS

- C17. ECHA will continue to maintain its focus on efficiency to ensure higher regulatory output per staff members employed and on initiatives to ensure that the Agency can attract, motivate and retain sufficiently qualified and experienced staff.
- R54. The Commission needs to ensure that ECHA is allocated the necessary human resources to fulfil its mandate appropriately under each of the different regulations it is responsible for.
- R55. ECHA's human resource competences should be taken into account when planning for the future of the Agency to create increased synergies and efficiencies.

2.2.2 Information technology (IT)

THE OBJECTIVES OF THE LEGISLATION

ECHA's operations in REACH and CLP are IT-based. Industry, the MSCAs, ECHA's committee members and the Commission interact with ECHA primarily by electronic means. ECHA's internal business and administrative processes are fully supported by IT.

Some of the IT applications offered to stakeholders are explicitly foreseen in the legislation. In this regard, their functionality and availability is mission critical for ECHA. Other duties, foreseen in the legislation, e.g. dissemination, can only be fulfilled through IT processing and automation, given the high volume of data to be processed.

The legislation requires ECHA to support industry and to grant access for MSCAs to the REACH and CLP data. In this regard, developing and servicing adequate and securely accessible IT tools can be seen as one of the key enablers to meeting the objectives of the legislation.

IMPACT OF THE OPERATIONS

ECHA's IT services play a crucial role in ensuring an efficient operation of the REACH and CLP Regulations

IT tools for industry implement the mandatory formats required by the legislation (the 'IUCLID format') and agreed at OECD level. Non-mandatory, yet very helpful tools, are provided to guide and facilitate highly complex scientific assessments. ECHA's continuous investment in enhancing such formats and in improving the usability of the tools provides key enablers for fulfilling industry's obligations under REACH and CLP.

ECHA has delivered a set of tools for industry – IUCLID for dossier preparation, Chesar for the chemical safety assessment, the QSAR Toolbox for read-across support and an impressive list of bespoke IT systems to perform all the regulatory processes.

Most of these IT systems are also used by industry to interact with ECHA or by the MSCAs and NEAs to access data and collaborate with ECHA as foreseen in the legislation. High volume processing of dossiers in registration, fee invoicing and dissemination are possible in a timely and cost efficient manner thanks to automation. In a nutshell, none of this intense network collaboration could happen without the IT systems provided by ECHA.

The crucial role of IT in all ECHA's processes, for internal users and external stakeholders, puts high performance and availability requirements on ECHA's IT services: the IT tools and services must be reliable, performant and foster efficiency.

The large IT portfolio of ECHA requires a substantial ICT capacity, adequate support for business continuity and high quality end-user services.

Figure 59. IT Industry Tools capitalised 2011 to 2015

IT DESCRIPTION	2011 EUR '000	2012 EUR '000	2013 EUR '000	2014 EUR '000	2015 EUR '000	TOTAL EUR '000
IUCLID	0	0	1 104	1 857	1 473	4 434
Chesar	0	1 604	497	540	670	3 311
QSAR	519	618	0	0	472	1 609
REACH-IT	1 143	2 109	1 248	2 032	2 146	8 678
Total by Year	1 662	4 331	2 849	4 429	4 761	18 032

ACHIEVEMENTS AND CHALLENGES

ECHA's IT infrastructure has continuously grown to support operations

ECHA has been able to constantly support intensive growth of its ICT infrastructure and IT services, without sizeable outages or downtime. This has been particularly evident during the registration deadlines successfully managed by the Agency.

Modern ways of working are better supported by IT in ECHA, through regular technology upgrades and the design of secure yet flexible solutions. The number of bespoke software applications is such and so dynamic, that ECHA's expenditure can be qualified as mostly 'grow and transform IT'. In fact, less than 50 % of the annual IT expenditure on average is allocated to running existing, very stable, services.

Every year, a large proportion of the IT budget of the Agency is spent on enhancements to bring more automation or in projects to transform the way some processes are performed through IT deployment. In this context, the footprint of ECHA's ICT infrastructure in terms of servers and storage has been constantly growing at a fast speed and requires relatively frequent upgrade cycles, i.e. every two to three years.

Premium IT security management at ECHA is the baseline

As ECHA handles confidential business information and is mandated to share it with the MSCAs and the European Commission, solid IT security management is a baseline for ECHA.

ECHA has been able to protect confidential business information, as evidenced by no impactful events having occurred and the Agency's responsiveness to threats or incidents being effective and immediate. Over the years, ECHA has implemented IT security management processes – including access management – which have been in scope for the ISO 9000 certification. ECHA has also established a security model for accessing ECHA's databases through the internet under controlled conditions. This model is also deployed for internal staff working offsite, the MSCAs and contractors.

Despite these achievements, continuous investment in security is needed to upgrade the security measures in front of ever changing threats and the evolution of technology. In fact, the evolution of the techniques used to hack IT systems or to jeopardise their functionality require not only constant patching but occasionally also new technological components or different development practices.

(Out)sourcing has become a strategic lever in managing IT

To balance the needs of a growing portfolio and the constraints on staffing, as well as the requirements posed by business continuity, since 2010, ECHA has chosen the path of progressively expanding the scope of outsourced services and refocusing the internal resources.

Thanks to outsourcing, ECHA has been able to offer a manifold increase of its IT services without additional recruitment, but rather reducing the IT staff. In the past five years, ECHA has put in place and constantly honed, a solid outsourcing practice, securing: support to business continuity, availability of external flexible external capacity to sustain growth and cost-effective contract management.

Outsourcing, at the extent practiced in ECHA, requires proficient procurement, contract management, financial and service integration capabilities, which have been honed in ECHA to a large extent but have to be maintained over time. Nevertheless, as less and less technical tasks are performed by ECHA IT staff and entire projects are procured externally, outsourcing of knowledge-intensive services creates a certain dependency on contractors and an intrinsic risk exposure to the bad performance of contractors.

To mitigate this risk, ECHA has significantly developed its sourcing and supplier management capabilities, particularly in the areas of service provider integration and hand-over, and knowledge transfer approaches, particularly useful when changing contractors.

COMMITMENTS AND RECOMMENDATIONS

- C18. ECHA will continue to optimise and automate its IT tools and services to ensure it maximises the cost effectiveness of the investments made.
- R56. The Commission is invited to maintain the current level of financial investment and adequate staffing levels in ECHA's IT tools and services to support ECHA's processes.

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