ECHA
EUROPEAN CHEMICALS AGENCY

Report on the operation of REACH and CLP 2021

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Reference: ECHA-21-R-06-EN
ISBN: 978-92-9481-910-9
Cat. Number: ED-02-21-669-EN-N
DOI: 10.2823/041059
Date: June 2021
Language: English

Chief editor: Catherine CORNU

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FOREWORD

In this report, we present for the third time our assessment on the operation of two central tools for managing the safety of chemicals in the EU – the REACH and CLP regulations.

We are able to say that a lot of progress has been made and that we know a lot more today about chemicals on the EU market than we did five years ago. Thanks to this progress, we can identify chemicals that are a concern much quicker than in the past, and in doing so, act faster to reduce risks for human health and the environment. Despite this, more still needs to be done to achieve the protection levels envisaged by the legislator.

REACH aimed to turn the tables and put the responsibility for ensuring chemicals safety back on industry. Looking back, we can't help but conclude that this is still a work in progress. All too often, regulators only get relevant safety information when companies are under pressure to act. We continue to see, for example, significant discrepancies between the data provided on the risks of chemicals submitted in registration dossiers sent to ECHA as a condition for market access, and what companies provide in public consultations once authorities consider specific risk management activities for a chemical. This gap must close.

The impact of ECHA's work is closely linked to efforts by our partners in Member States, the Commission and other stakeholders. Over the years, we have observed a growing imbalance in the flow of REACH and CLP processes, resulting in a situation where the scientific outputs of ECHA are not translated into risk management decisions or enforcement action to address identified concerns quickly enough. The reasons for these delays need to be further assessed, as well as a review of the resourcing and mechanisms needed to channel scientific and socio-economic input into regulatory processes in an efficient and transparent way.

After almost 15 years of managing the core scientific and technical processes of REACH and CLP, we are in a good position to reflect broadly on the shortcomings of the system. Similar to the examples already mentioned, the Agency observes challenges in other areas, such as REACH authorisation, substance evaluation and harmonised classification and labelling.

Our report is fact based and impact focused. It does, however, not attempt to assess all the underlying factors that result in hampered progress at EU level on important issues, such as harmonised classification of CMR substances and development of EU-wide restrictions. This general assessment will be done by the Commission in their third general review of REACH and CLP in 2022.

The timing of the report fits into the discussions on the Commission's Chemicals Strategy for Sustainability, which was published during the course of preparing this report. Where possible we have tried to link our findings with the ambitious goals for the future set out in the strategy. This report is, however, not designed to respond to the strategy and does not replace the technical and scientific input that the Agency is asked to provide to the Commission's implementation work.

I firmly believe ECHA's work will continue to have a central role in managing the evolving challenges linked to chemicals safety. We remain committed to supporting the work of European institutions and Member States in developing the EU's chemicals regulation framework, and will continue to provide both facts and insights, as we believe "to know the future, we need to know the past".

Bjorn HANSEN

Executive Director

1 INTRODUCTION

1.1 The policy context

This is the third five-yearly report on the operation of the REACH and Classification, Labelling and Packaging (CLP) regulations. It looks at how these two regulations have functioned over the years, presenting a detailed picture of the impact, successes and remaining challenges in the operation of the two pieces of legislation. Although ECHA is only required to report on its REACH operations, this report also covers CLP, as they are very much integrated.

Most Europeans remain concerned about the impact that chemicals in everyday products have on the environment and on their health[1]. To address such concerns, the policy context has rapidly evolved in the last five years.

The European Green Deal has set goals to better protect human health and safeguard the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment. This increased ambition can be seen in the new initiatives on zero pollution, climate neutrality, sustainable products, a circular economy action plan, a digital agenda, an industrial strategy for Europe, a plan to beating cancer and the Chemicals Strategy for Sustainability.

ECHA's central role in coordinating the implementation of activities under REACH and CLP places the Agency in a unique position to report on their operation and observed impact, while respecting the technical and scientific role of the Agency. In line with this, ECHA developed this report to assess the progress the EU has made on the respective policy objectives and ECHA's contribution to it. With this report, ECHA aims to provide a fact base to support further policy developments and to identify areas where the functioning of REACH and CLP could be improved.

REACH and CLP:

- *protect human health and the environment;*
- *ensure the free circulation of substances, mixtures and articles on the internal market;*
- *enhance competitiveness and innovation; and*
- *promote alternative methods to animal testing for assessing the hazards of substances.*

1 Regarding chemicals, 90 % of respondents agreed that they are worried about the impact of chemicals on the environment, and 85 % share this concern also for the impact chemicals have on human health – Special Eurobarometer 501 Report on Attitudes of European Citizens towards the Environment, March 2020: https://europa.eu/eurobarometer/surveys/detail/2257

1.2 Summary of key messages

Over the last five years, the operations of REACH and CLP have advanced the protection of worker health, consumer health and the environment in the EU, and positively contributed to innovation, competitiveness and the functioning of the internal market within the EU. There are signs that the obligation on companies to register the chemicals they place on the market under REACH has motivated them to refocus, correct or strengthen the way they manage the risks of their chemicals and ensure safe use.

The completion of the registration of phase-in substances in 2018 marked a major milestone in increasing the data available on the hazards and uses of chemicals on the EU market. We now know more than ever before about the 23 000 chemicals most used in Europe.

However, the information that companies provided in their registrations still needs extensive improvement, as does the use of information in chemical safety reports, safety data sheets (including exposure scenarios), and classification and labelling, which are the main vehicles for communicating safe use. The synergies expected between REACH, CLP and other legislation have often not yet materialised, both in companies and at authority level.

The implementation of a streamlined collaborative approach between ECHA, Member States and the Commission – called the Integrated Regulatory Strategy – has accelerated the screening of registered substances and the assessment of the need to generate more data or for risk management. Working with groups of substances has become the norm in recent years. This has allowed authorities to accelerate obtaining a more complete picture of 'the universe' of registered substances and to take action where needed.

ECHA and Member States have taken action to generate more information. More data has been brought in by enhancing completeness checks of registrations, and the Evaluation Joint Action Plan is improving the compliance of registrations with the information requirements in REACH. 22.5 % of substances registered above 100 tonnes per year have been checked for compliance. However, substance evaluation has not proven efficient to clarify authorities' concerns on priority substances.

In the last five years, authorisation and restrictions under REACH have managed more chemical risks than in the years before. As of December 2020, 211 entries for substances of very high concern are on the Candidate List. Thanks to the grouping approach, these entries correspond to 386 substances. For 54 entries, non-exempted use of the substance requires an authorisation; for 25 of these, all such use has ended. Over 200 applications for authorisation that ECHA has assessed have reported how European companies plan to substitute and reduce health and environmental risks. Authorisation has been successful at reducing risk to workers, consumers and the environment, and there are clear indications that substitution has been achieved. However, it is not efficient, and in general information on available alternatives is lacking.

EU restrictions are working well, resulting in greater protection for workers, consumers and the environment. Thanks to the grouping approach, more substances – covering more uses – have been proposed to be restricted than in earlier years. For example, emissions to the environment from microplastics, siloxanes, and lead in shot are expected to reduce significantly if the proposed restrictions come into force. Industry also generally complies with restrictions; more than 80 % of consumer products inspected by Member State inspectors comply with restriction obligations, with most incompliance in imported products.

The CLP Regulation has demonstrated its value in providing a basis for hazard assessment and provides opportunities for serving as a first step in a 'one substance, one assessment' approach. CLP drives risk management for workers, consumers and the environment directly through the labels communicating risks but also indirectly with much of the EU's chemicals legislation using CLP hazard assessment. A steady increase in

the harmonised classification and labelling of carcinogenic, mutagenic and reprotoxic (CMR) substances (71 between 2016-2020) is assumed to result in employers taking further risk management measures to protect their workers from exposure to these chemicals in the workplace.

The Classification and Labelling Inventory contains information on around 180 000 substances self-classified by companies, but industry compliance is insufficient. There is still divergence in self-classifications for the same substance. Member State inspectors found that one-third of labels for mixtures contain deficiencies – mostly related to incorrect or missing hazard statements.

REACH provides fast access to the EU market and tighter actions by authorities have improved conditions for companies to compete without compromising on chemical safety. The improved transparency on substances, their hazards and uses allows better informed decisions on chemical safety by authorities, companies, workers and consumers. The increased predictability of upcoming regulatory actions encourages greater market trust. ECHA's website is the primary gate for access to such information.

The standard information requirements for skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation were updated in 2016-17, making non-animal testing the default requirement under REACH. As detailed in ECHA's latest report on Alternatives to animal testing[2], these non-animal test methods have clearly been taken up by companies in their registrations.

However, despite the progress made since our previous report in 2016, further efforts are needed to make sure that REACH and CLP operate as intended. For ECHA to continue to successfully perform its tasks under REACH and CLP, it needs a more sustainable financing mechanism. Also, Member States need to step-up their contribution to the work of the ECHA committees and increase their capacity to perform their tasks under REACH and CLP, including enforcement.

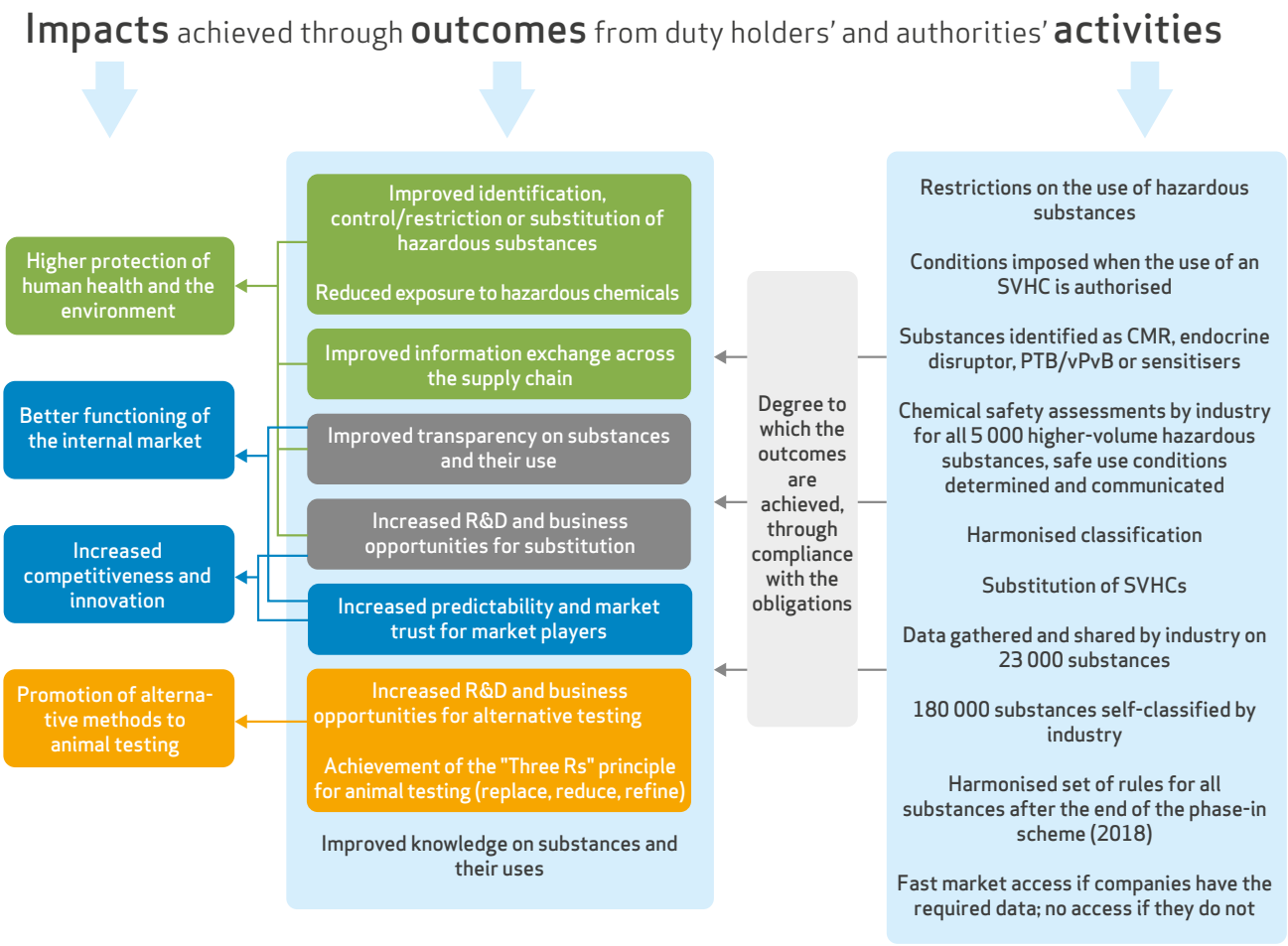
1.3 The REACH and CLP intervention logic

The REACH and CLP intervention logic provides a framework to assess the extent to which objectives set by the legislation have been met. It connects the activities under REACH and CLP to their outcomes and helps to assess in how far these outcomes translate into positive impacts on health, environment, functioning of the internal market, competitiveness and innovation, and promotion of alternatives to animal testing. Together, these impacts represent the ultimate objectives set out by the legislation.

The report starts from the data, and proceeds to pinpoint general trends and emerging issues. The facts are analysed and corresponding insights are generated to identify situations where impact is (or could be assumed to be) achieved. Instances where shortcomings are detected and opportunities for improvement arise in the operation of REACH and CLP are examined. Such shortcomings are indicated in the report with this symbol  .

2 https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf

FIGURE 1: The REACH and CLP intervention logic



To gain EU market access, companies must record this information in a registration dossier and submit it to ECHA. Registrants of the same substance must share their data and submit their registrations jointly, promoting the harmonised interpretation of data and reducing registration costs and testing on animals. If the safety information collected by industry is incomplete or incompliant, or gives rise to a suspected concern, ECHA and the Member State competent authorities will require additional information, or initiate regulatory action if the suspected concern can be clarified without additional information.

REACH authorisation aims for using substances of very high concern safely and progressively replacing them with suitable alternatives and technologies. Substances of very high concern are identified and when the European Commission includes them in the Authorisation List, based on a proposal from ECHA, they are subject to authorisation. These substances cannot be placed on the market (for a specific use) after a given date, unless an authorisation is granted for that use. ECHA's committees assess the scientific and technical aspects of each authorisation application, including the availability of safer alternatives, and based on it, the European Commission takes a decision.

Similarly, under REACH restrictions, if there are risks that need to be addressed on an EU-wide basis, Member States, or ECHA at the request of the European Commission or on its own initiative, can propose to restrict substances. This can entail a wide range of measures, such as a ban, or controlling and limiting their concentration, emissions and exposure. ECHA's committees assess the scientific and technical aspects of the proposals and based on their opinions, the European Commission takes a decision. The European Commission can also restrict the use of CMR substances category 1A/1B in consumer products using a simplified procedure under REACH, not involving ECHA's committees.

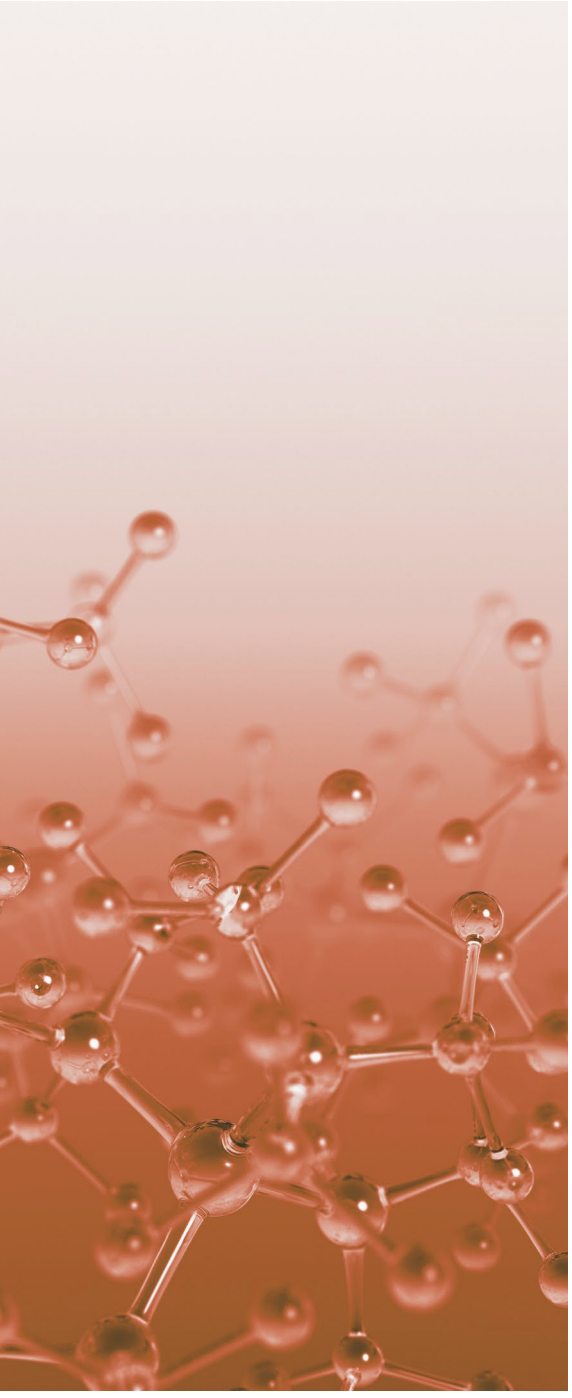
Under CLP, Member States and industry can propose to harmonise the classification and labelling of hazardous substances. This ensures that any risk management decision is based on consistently identified hazards. This is particularly important for hazards that are of the highest concern, such as respiratory sensitisers and substances with CMR properties. For active substances in biocidal and plant protection products, Member States must propose a harmonised classification and labelling.

All companies must assess their substances and mixtures against classification criteria under CLP, and package and label them accordingly. This ensures that safety information (such as 'causes serious eye irritation' or 'keep out of reach of children') is available to workers and consumers. The classifications of substances need to be submitted to ECHA's publicly available Classification and Labelling Inventory.

Companies must also notify hazardous mixtures to authorities for use by national poison centres using a harmonised format. Hazardous mixtures must have a unique formula identifier (UFI) printed on the label. The UFI creates a link between the actual mixture on the market and information that poison centres can retrieve about its composition. This further helps to rapidly find precise information to speed up emergency health responses in poisoning cases.

2

IMPACT OF REACH AND CLP OPERATIONS



2.1 Health and safety for workers

Chemical safety assessment and communication in the supply chain

Throughout the three REACH registration deadlines for phase-in substances, companies performed chemical safety assessments (CSA) for more than 7 000 substances and documented them in the chemical safety reports (CSR) submitted to ECHA with the registration dossiers. Based on the registrants' hazard assessments, more than 5 000 substances were identified that meet the criteria to be classified as hazardous or to be considered as persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT or vPvB), and therefore required registrants to carry out an exposure assessment and risk characterisation.

Following the last registration deadline in 2018, the coverage of chemical safety reports corresponds to almost 100 % of the market volume covered by REACH registrations. The proportion of the market volume not requiring a chemical safety assessment (i.e. market volumes registered in the 1-10 tonnes per year band) is small (less than 0.1%) compared to the total volume, although it can still constitute significant risks to health or the environment.

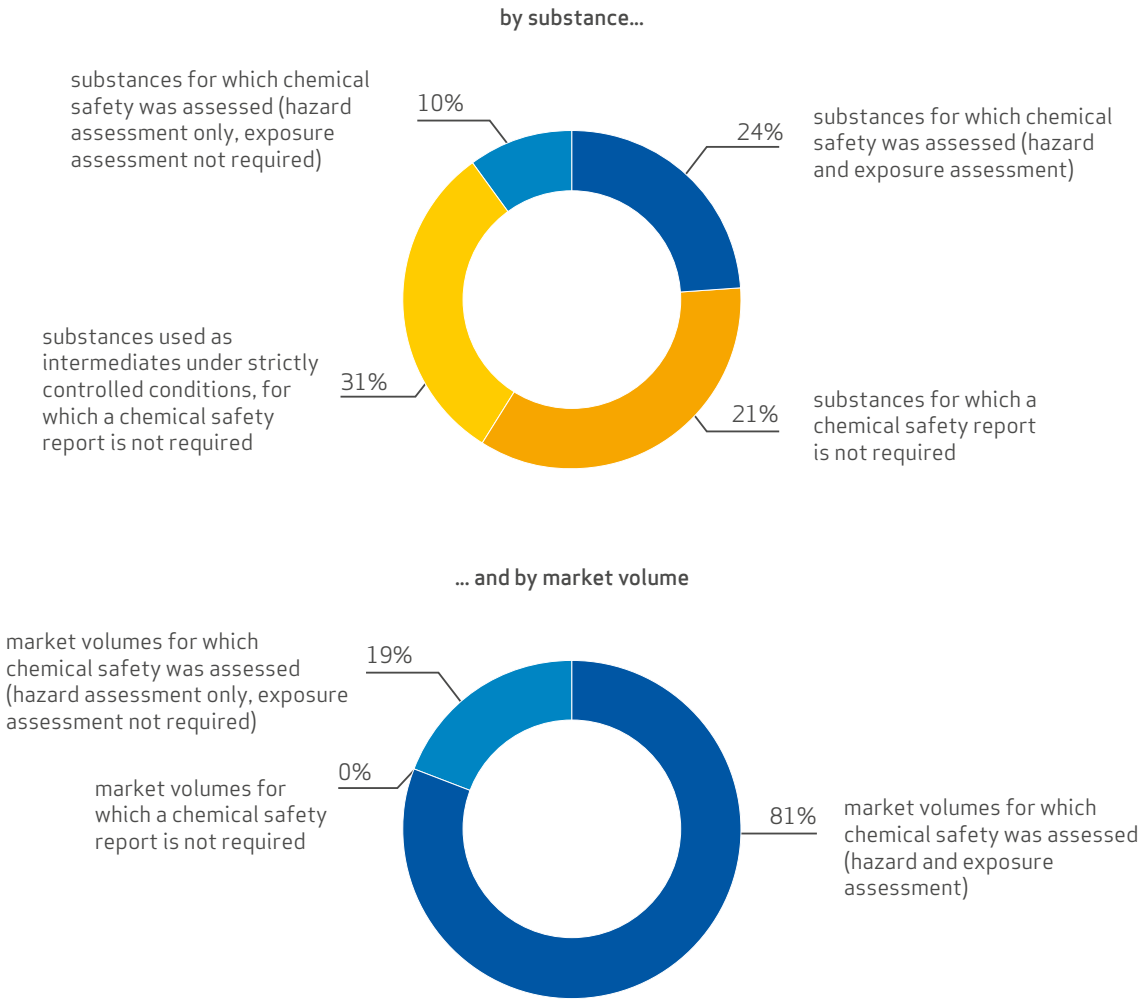
The 6 700 substances only registered as intermediates used under strictly controlled conditions are not considered in the market volume calculation, shown in Figure 2, as we expect exposure to be limited.

When looking at the **impact on company operations** when preparing for registration, there is evidence that the increased transparency of internal information induced by dossier preparation has benefitted companies in improving safety. During April-May 2018, ECHA interviewed 243 registrants on how their preparations for registration had benefitted them – 73 % reported benefits. The biggest benefit was that registration brought more information on substance properties (44 %). Furthermore, the companies indicated improved information to their customers (23 %) and a better visibility of portfolio and volumes (16 %). A number of large companies also saw the necessity to revise their sourcing strategies to be REACH compliant as a benefit (5 % of respondents).

The outcome of registrants' hazard assessments is **self-classification** according to harmonised criteria and the derivation of **no-effect levels** for the routes of human exposure and environmental compartments. Classifications and derived no-effect levels (DNELs) are essential information for generating safety advice and ultimately handling chemicals more safely in the workplace. Figure 4 illustrates, for example, the increasing number of substances that registrants self-classified for carcinogenic, mutagenic and reprotoxic (CMR)

properties between 2010-2017. In addition to the hazard characterisation, registrants have determined the **safe operational conditions** and **risk management** for each identified use of a substance, based on exposure estimates and risk characterisation.

FIGURE 2: Chemical safety assessed, based on chemical safety reports submitted with the registrations



The outcome of the registrants' chemical safety assessments is meant to be communicated to the supply chain through safety data sheets (SDSs). The flow of safety information from the top of the supply chain through extended SDSs was checked by Member State inspectors in 2017[3]. The general conclusion was that many duty holders comply with the provisions of the regulation concerning the compilation, distribution and use of safety information in chemical safety reports and exposure scenarios/extended SDSs **for substances**.

The inspectors found that in 90 % of cases, the chemical safety assessment (CSA) had been performed where needed, and the generated exposure scenarios were communicated as attachments to substance SDSs down the supply chain. Moreover, the report concludes that systems are in place to allow safe use information to be transferred and communicated within the supply chain. For recipients of the information, inspectors also found that 90 % of companies were ready to utilise the safe use advice they receive. As such, companies are committed to generating, receiving, applying and further communicating the information needed for improved health and safety for workers.

3 https://echa.europa.eu/documents/10162/13577/ref-5_report_en.pdf

At the same time, however, **significant deficits** were observed in the chemical safety reports, including missing or outdated harmonised classification of substances, missing or incomplete exposure scenarios, risk management measures that were not clearly specified, exposure models used outside their functional domain and questionable exposure estimates.

More recently, a sample analysis by ECHA found that 50 % of the chemical safety reports sampled from submitted registrations are complete, 40 % are missing some elements, and 10 % were estimated to have more severe deficiencies, such as missing exposure assessments for certain uses or environmental compartments, or missing routes of exposure.

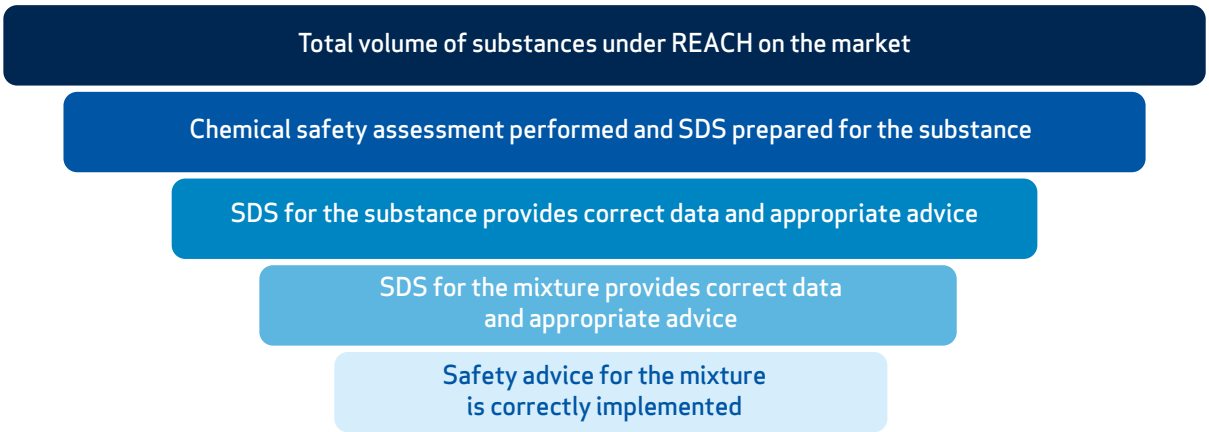
In the majority of cases, these deficits are copied through into the extended SDSs (63 % of communicated exposure scenarios are copies of the chemical safety report's exposure scenarios), meaning that the information transferred through the supply chain via the extended SDSs does not allow employers to control the risks. This is also confirmed by the inspectors' observations during the inspections.

Another factor limiting the impact of REACH generated information on workers' health is that the substance-related REACH information needs to be "translated" into safety data sheets for mixtures, for which – except for the classification and labelling rules – no acknowledged method currently exists.

In a project[4] coordinated by ECHA's Forum in 2018, Member State inspectors conducted over 3 300 controls on safety data sheets for mixtures. Around 33 % of the inspected safety data sheets were found to not be compliant, with deficiencies in particular relating to information on hazard identification and exposure controls. When looking in more depth at the classification of the inspected mixtures, **17 % of the inspected mixtures were found to be classified incorrectly**, leading to unidentified risks.

Figure 3 illustrates the stepwise "loss of impact" of information in the registration to the use of information by downstream users of chemicals. The greatest loss of impact is due to deficits in the substance chemicals safety reports (carried through into the SDSs) and the variability in approach and correctness of mixture assessments. These issues are further elaborated in Section 4.1.

FIGURE 3: Impact flow from substance safety data to downstream implementation of safety advice



4 https://echa.europa.eu/documents/10162/13577/ref-6_project_report_en.pdf

Classification and labelling

Assessing the properties of substances and mixtures and classifying them according to harmonised criteria is a prerequisite for generating safety advice and ultimately handling chemicals more safely in the workplace. Substances that are classified must be labelled accordingly, giving workers information on the hazard. Employers are required to put adequate risk management measures in place to prevent exposure, or where prevention is not technically feasible, protect workers from it.

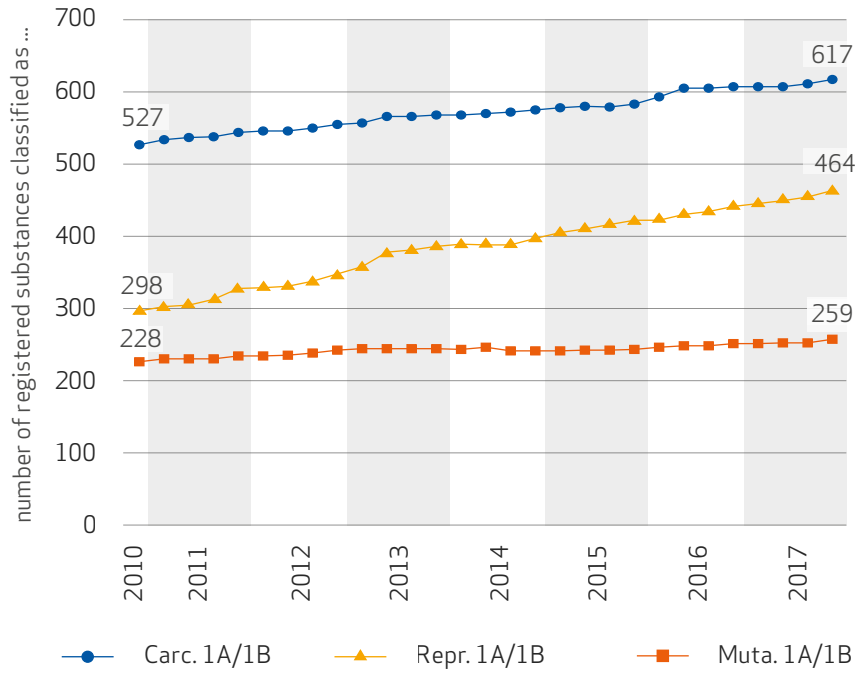
Substances can be classified in two ways: (1) by companies self-classifying their substances based on the information they have available, and (2) by authorities deciding on a harmonised classification for the substance, initiated by a Member State or industry, and involving the evaluation of all information gathered on the substance. Companies must use harmonised classifications when available.

Companies **self-classified** around 180 000 substances, of which around 23 000 are registered substances (i.e. manufactured or imported in market volumes above one tonne per year). Despite inconsistencies observed across notifications of the same substance, a wealth of data is available in the Classification and Labelling Inventory.

Through REACH, new information was generated, which was then used in CLP to revise classifications, both for self-classifications and for harmonised classifications.

In 2018, ECHA analysed the evolution of self-classifications in registration dossiers for CMR substances in category 1A/1B[5]. As shown in Figure 4, there was a constant increase during 2010-2017 in the number of substances that are self-classified as CMR by registrants.

FIGURE 4: Evolution of the number of substances self-classified as CMR during 2010-2017



For reference, this dataset contained 14 053 substances on 31 December 2017

This increase is due to
(1) newly registered CMR substances; and
(2) updates of already registered substances to a more stringent classification.

The contributions of both reasons are as follows, expressed in registered CMR substances per year:

	Carc. 1A/1B ●	Repr. 1A/1B ▲	Muta. 1A/1B ■
(1) new	+8	+17	+3
(2) update	+4	+6	+1
total	+12	+23	+4

5 https://doi.org/10.1016/j.yrtph.2019.05.003

Although phase-in substances that were classified as CMR category 1A/1B were already registered before the first registration deadline (November 2010), substances for which new information was derived for the purpose of registration which led to a CMR category 1A/1B classification continued to be registered, as did non-phase-in substances.

Overall, for substances registered under REACH, the self-classifications have strengthened over time in the last 10 years. This is believed to be the combined result of proactive actions by registrants and regulatory actions by authorities, which jointly led to new testing and a critical reassessment of existing studies. The increase in information requirements due to increases in manufactured or imported volumes was not found to be a significant driver for updating the classification.

The impact of newly generated data and regulatory action by authorities is greater for reproductive toxicity than for carcinogenicity or mutagenicity, reflecting the strengthening of the information requirements for reproductive toxicity with the introduction of REACH. The requirements for carcinogenicity testing are triggered at Annex X and only under certain conditions, while testing for reproductive toxicity is already triggered at Annex IX, and sub-acute studies are required at Annex VIII. Few new substances are being self-classified as category 1A/1B mutagens. The reasons for this are under investigation.

The identification of more substances as CMR category 1A/1B by companies is expected to have been matched by an increase in the risk management measures they take for these substances, improving worker safety.

In addition to self-classifications by companies, during 2016-2020, 120 substances received a **harmonised classification and labelling**, through inclusion into Annex VI to CLP in the 9th, 10th, 13th, 14th and 15th adaptations to technical progress (ATPs) of Annex VI. 49 of these 120 substances are registered under REACH. Classification under CLP is also a vital part of the approval process for pesticide and biocidal active substances (40 and 31 substances, respectively). Industry initiated harmonised classification for six substances during 2016-2020; the remainder were initiated by Member States.[6]

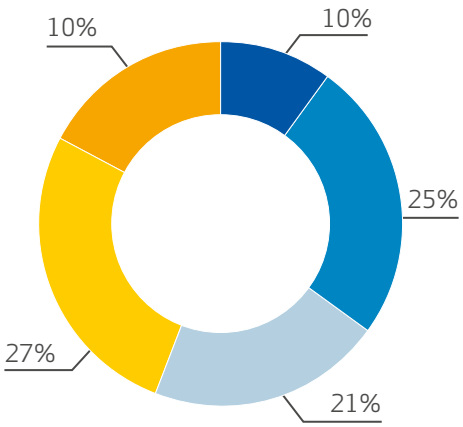
The 51 opinions in 2019 from ECHA's Committee for Risk Assessment (RAC) will be included through the 17th ATP and the 50 opinions adopted in 2020 are in preparation in the draft 18th ATP. The operational issues limiting the rate of harmonising classification and labelling of substances are discussed in Section 3.

FIGURE 5: Number of substances with a harmonised classification and labelling

Hazard class	Number of substances classified under harmonised classification during 2016-2020	Total
Acute toxicity	87	1 777
Skin corrosion / skin irritation	23	954
Skin sensitisation	32	1 181
Serious eye damage / eye irritation	41	1 004
Respiratory sensitisation	1	192
Mutagenicity	21	635
Carcinogenicity	45	1 252
Reproductive toxicity	66	413
Specific target organ toxicity	63	946
Aspiration hazard	0	230
Hazardous to the aquatic environment	91	2 565

6 https://echa.europa.eu/registry-of-clh-intentions-until-outcome

FIGURE 6: Stage in the authorisation process at which substitution starts



- Screening of substances and Risk Management Option Analysis (RMOA)
- Inclusion of substances in Candidate List
- Recommendation for inclusion in Authorisation List (Annex XIV)
- Inclusion of substances in Annex XIV
- Applications for authorisations (AfA)

A number of these classifications also impact workers through other legislation. The Carcinogens and Mutagens Directive (CMD)[7] on the protection of workers from risks related to exposure to carcinogens or mutagens at work, for example, foresees that companies should as a first option consider to phase out carcinogens and mutagens category 1A/1B, and specifies major further requirements for the safe use of these substances.

SVHC identification and Candidate listing

Substances that meet one or more of the criteria in Article 57 of REACH can be identified as substances of very high concern (SVHCs). SVHCs are added to the Candidate List and can be recommended for inclusion in the Authorisation List, after which they are included in Annex XIV to REACH, meaning that companies need to apply for authorisation to continue using the substances after their sunset date.

During 2016-2020, 43 additional entries (substances or groups of substances) were identified as SVHCs. At the end of 2020, the Candidate List contained a total of 393 substances in 211 entries.

Candidate listing, as a pre-requisite for authorisation, can already provide an incentive for companies to start phasing out the substance and eliminate exposure. From its 2020 survey[8], ECHA found that more than half of the 96 respondents started their substitution activities before the substance was included in Annex XIV.

Authorisation

Currently, the Authorisation List (i.e. Annex XIV to REACH) contains 54 substances or groups of substances, of which 43 were added with the purpose of protecting human health – workers and the general population[9]. The authorisation process reduced human exposure to these SVHCs through the different steps of the process, as illustrated in Figure 7. However, the application for authorisation process has efficiency issues, which are expanded on in Section 3.

For 37 substances, the latest application date has passed. For 14 of these substances, ECHA has not received any applications by the latest application date.

In February 2020, the European Commission added 11 substances to the Authorisation List, of which six were added to protect human

7 https://echa.europa.eu/understanding-cad-and-cmd

8 https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf

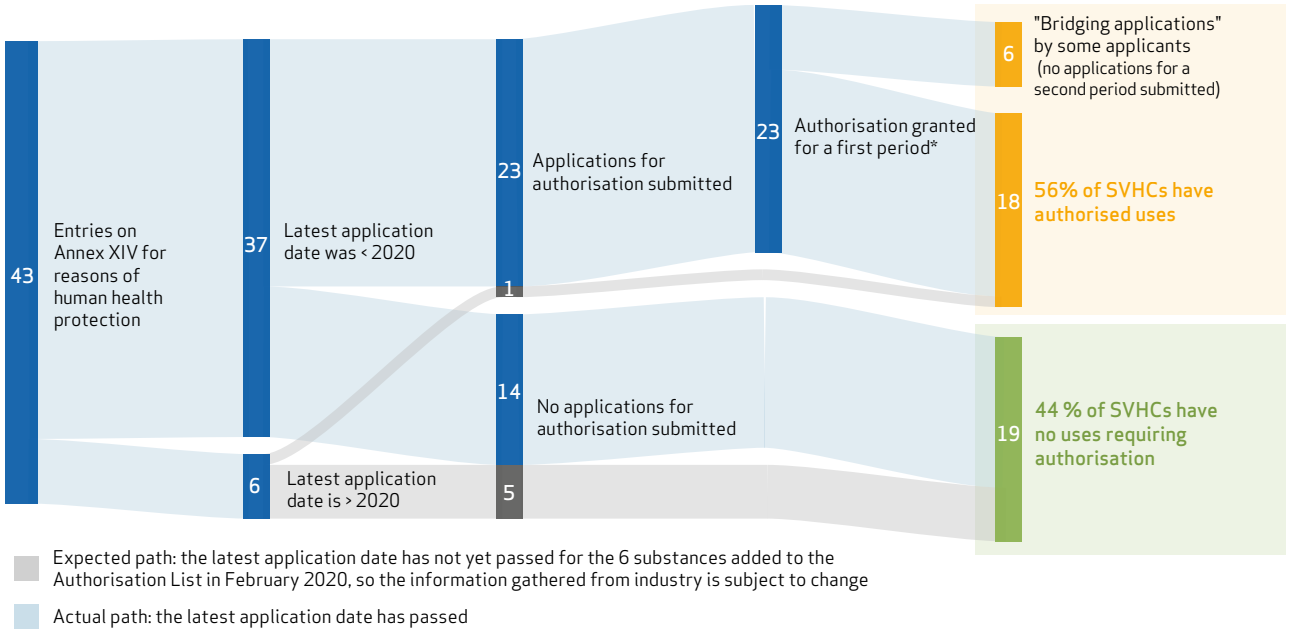
9 To avoid double counting substances and impacts, the two substances (coal tar pitch, high temperature and anthracene oil) on the Candidate List to protect both the environment and human health are not included in this figure. They are included in Figure 13 on environmental protection. Persistent, bioaccumulative and toxic (PBT) substances are also only included in Figure 13.

health. According to ECHA's forecast[10], no applications are expected for five of these substances.

Therefore, overall, for 19 out of 43 (44 %) health-related Annex XIV entries, no applications for authorisation have been or are expected to be submitted, implying that their uses requiring authorisation were phased out, or will be phased out by the latest application date, either as the result of the inclusion of these substances in the Authorisation List or at an earlier stage. Six of the substances for which the latest application date has passed were registered, with volumes totalling around 15 000 tonnes per year before their Annex XIV listing[11]. Registration data for these substances show that the majority of registrants have notified ECHA that they ceased manufacturing and importing the substances, and the registered volumes decreased by about 85 %.

When an authorisation was granted and the use of the substance will continue beyond the period specified in the authorisation, the applicant needs to submit a review report. Out of the 24 authorisations with a first period that had expired by the end of 2020, ECHA received review reports for 8. In these review reports, the updated volumes decreased from 12 000 tonnes to 600 tonnes, i.e. a 95 % reduction. For the remaining 16 authorisations, no review reports were submitted, suggesting that the corresponding volumes (7 000 tonnes per year) are no longer on the EU market.

FIGURE 7: Phasing out of uses requiring authorisation of the 43 entries on the Authorisation List for reasons of human health protection



* In parallel, decision making on the authorisation of some applicants is still ongoing

19 entries having no uses requiring authorisation, but possibly having uses exempt from authorisation: 2, 5, 7, 9, 13, 14, 32-39, 44-46, 48 and 49.
18 entries having authorised uses: 4, 15, 17-31 and 47.
Six entries for which some but not all authorised uses have ended: 6, 8, 10-12 and 16.

Another benefit of the authorisation process is linked to the worker conditions set – in the authorisation opinion – for the authorised uses. During 2017-2020, ECHA's opinions on applications for authorisation contained recommended worker conditions for 56 % of the uses. Furthermore, additional worker conditions were recommended for 69 % of the uses, to be taken into account in case the companies would re-apply for a second authorisation period. While the site-by-site setting of use conditions may lead to improved worker conditions, the specific analysis required as part of the process has an impact on the overall efficiency of authorisation, as further discussed in Section 3.

Overall, there is evidence that the REACH authorisation system, in synergy with occupational safety and health

10 https://echa.europa.eu/documents/10162/13634/applications_for_11_substances_Authorisation_List_February_2020.pdf

11 Volumes under standard registration, not including volumes indicated for use as an intermediate.

(OSH) legislation, has helped to reduce workers' exposure to SVHCs. Perhaps the most pertinent example relates to the use of hexavalent chromium for surface treatment, which is undertaken in hundreds of workplaces across the EU. There is some evidence[12] that the inclusion of hexavalent chromium compounds on the Candidate List in 2010 and the subsequent inclusion in Annex XIV in 2013, together with stricter national occupational exposure limit (OEL) values in various EU Member States, led companies to invest in additional risk management measures or alternative plating techniques, leading to a steady decrease in exposure levels at workplaces. When the European Commission proposed a Union-wide binding OEL (BOEL) for hexavalent chromium of 25 µg/m^3 per 8 hours in 2016, several companies had already applied for REACH authorisation with exposure levels below 5 µg/m^3. As a result, the European Parliament requested to lower the BOEL, leading to a final agreed BOEL for hexavalent chromium of 10 µg/m^3 until 17 January 2025, and 5 µg/m^3 thereafter (Directive (EU) 2017/2398[13]).

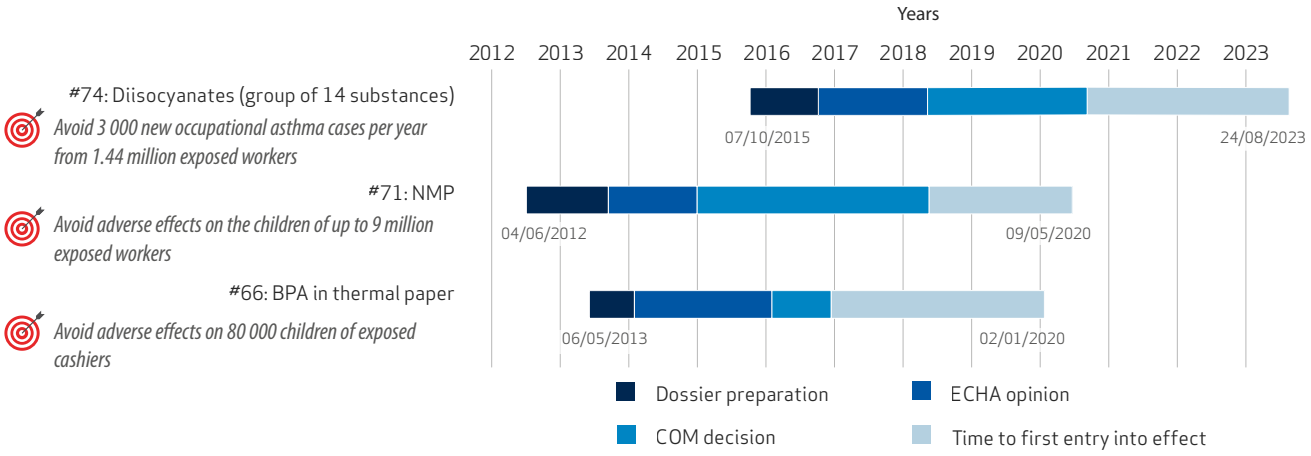
Authorisation is an enforcement priority for Member State inspectors. In 2016, a small-scale inspection campaign ran 800 controls on substances with sunset dates that passed in 2015[14] and found that the authorisation provisions generally work; the substances were mostly phased out. In 9 % of cases, the substance was placed on the market in breach of the authorisation duty.

During 2020, ECHA's Forum conducted preparations to start its ninth major enforcement project, which will cover EU-wide controls of all substances subject to authorisation which are past their sunset date. The controls will focus on safety of workers, addressing conditions of use together with inspectors responsible for checking occupational health and safety conditions.

Restrictions

As summarised in Figure 8, during 2016-2020, two restrictions with the aim of protecting industrial and professional workers and their future children entered into effect and one restriction was decided on, where the transition period is still ongoing. Altogether, these restrictions cover the use of 16 hazardous substances.

FIGURE 8: Reduced exposure of workers to restricted hazardous substances



During the transition time between the restriction decision and the entry into effect, companies adapt their processes, substitute the substance and start to reduce exposures.

Substances for which ECHA prepared an opinion on a restriction to protect workers and sent it to the European Commission during 2016-2020 include N,N-dimethylformamide (DMF) – aiming to protect 1 300-2 500 workers in workplaces that currently have unsafe exposure levels – and five soluble cobalt salts – aiming to reduce exposure to 18 900 workers and avoid 0.24 cancer cases per year. In the latter case, the volumes (and potential

12 https://academic.oup.com/annweh/article/59/1/41/2464399

13 https://eur-lex.europa.eu/eli/dir/2017/2398/oj

14 https://echa.europa.eu/documents/10162/13577/final_report_second_forum_pilot_project_on_authorisation_en.pdf

exposures) are expected to grow due to rapidly increasing demand for rechargeable batteries[15].

2.2 Health and safety for consumers

Classification and labelling

Classification and labelling of substances is an important instrument to ensure that chemicals are used safely in consumer products. The obligation to **label** the substances and mixtures applies to all hazardous substances. The correct classification of chemical products also affects the packaging requirements under CLP, which in turn increases consumer safety. Furthermore, appropriate labelling is intended to provide consumers with information not only on the hazards of substances and mixtures, but also on how to use the products safely. This increases the likelihood for consumers to apply protective measures and make informed choices on the products they buy.

In 2018, Member State inspectors conducted nearly 4 700[16] controls of CLP labels or related duties to ensure that the consumers receive the right information, in a project coordinated by ECHA's Forum. Results of the EU-wide controls reveal that while 67 % of labels are correct, 33 % contain deficiencies – most frequently related to incorrect or missing hazard statements.

Targeted checks by Member State inspectors on a small sample of imported goods in 2019 showed that 71 % of controlled products had incorrect labels, usually due to use of an incorrect language or wrong or missing hazard statements[17]. Controls of online sales reveal that the vast majority of online advertising (83 %) was missing the required information on hazards. In these cases, the breaches were addressed through enforcement action – for example, ordering labels to be corrected or refusing import.

The amendment of CLP in 2017 introduced the requirement to add a unique alphanumeric code on the label of each mixture, called the **'unique formula identifier'** (UFI) and to include this UFI in the harmonised information provided to the relevant national appointed bodies, as of 1 January 2021. These national appointed bodies use this information to advise preventative and curative measures, in particular, in the event of an emergency. Having a UFI on the label is expected to facilitate emergency health response, and reduce unnecessary overtreatment of patients and hospitalisation for precautionary reasons.

Poison information centres were previously experiencing problems with the correct identification of the mixture in up to 40 % of emergency calls they received, which are mostly on accidental exposure to hazardous mixtures by consumers[18]. The harmonisation of the requirements for information to be provided by companies is also expected to reduce the inconsistencies caused by the considerable variation in information previously required across Member States. ECHA is hosting the database where national authorities can find all the information included in the notifications to perform their tasks.

During 2016-2020, of the 120 substances added to Annex VI to CLP with a **harmonised classification and labelling,** 71 were added as CMR category 1A/1B. Those CMR substances are included by the European Commission in the appendices to entries 28-30 of Annex XVII to REACH, restricting their placing on the market and use as substances and in mixtures for supply to the general public.

Exposure of consumers to these substances – and 48 substances classified as CMR category 2 – is also

15 https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf
16 https://echa.europa.eu/documents/10162/13577/ref-6_project_report_en.pdf
17 https://echa.europa.eu/documents/10162/13555/customs2_project_report_en.pdf
18 https://doi.org/10.2769/90437

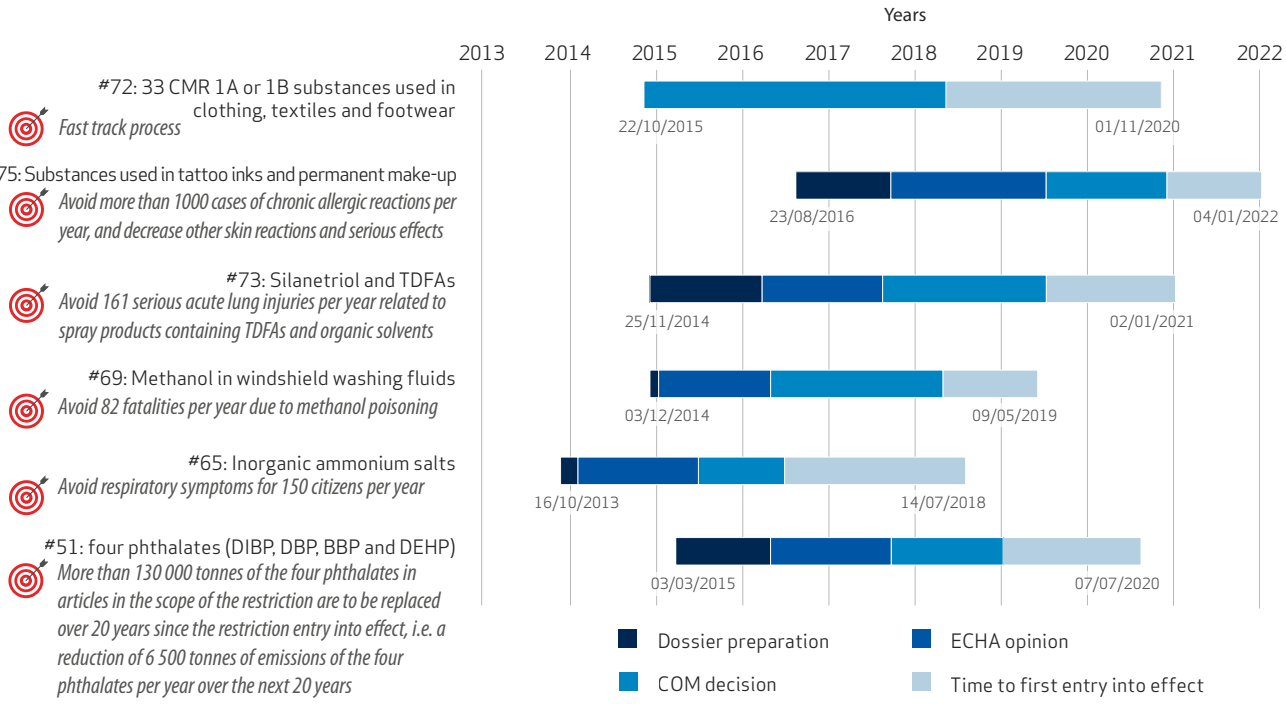
expected to have been reduced through **product-specific EU legislation**. The Cosmetic Products Regulation[19] foresees that category 1A/1B CMR substances cannot be used in cosmetic products without an authorisation by the Scientific Committee on Consumer Safety. The Toy Safety Directive[20] foresees that the presence of category 1A/1B and category 2 CMR substances in toys or components thereof becomes prohibited or that specific concentration limits or specific migration limits will be prescribed. The voluntary scheme according to the EU Ecolabel Regulation[21] foresees that products containing CMR substances of category 1A/1B and 2 do not satisfy the eligibility criteria for the product to be awarded with the ecolabel, although certain motivated derogations are possible.

Harmonised classification in certain hazard categories also leads to substances no longer being allowed to be used in specific products, such as tattoo inks, through restrictions under REACH.

Restrictions

As summarised in Figure 9, during 2016-2020, six restrictions entered into effect that **restrict the use of hazardous substances in consumer products**. One of these restrictions was for a group of 33 CMR substances used in clothing, textiles and footwear which was made by the European Commission using the simplified procedure, without involving ECHA's committees.

FIGURE 9: Reduced exposure of consumers to restricted hazardous substances



Another restriction was on the use of four phthalates in articles and extending an existing restriction on phthalates in childcare articles to include another substance. After the entry into effect date, consumer products placed on the market need to comply with the conditions specified in each particular restriction.

During 2017-18, ECHA, together with Denmark, Italy and Norway, with the contribution of German authorities as well, proposed to restrict the use in tattoo inks and permanent make-up of more than 4 000 substances that have a harmonised classification as carcinogen, reproductive toxicant, germ cell mutagen, skin sensitiser/

19 https://eur-lex.europa.eu/eli/reg/2009/1223/oj
20 https://eur-lex.europa.eu/eli/dir/2009/48/oj
21 https://eur-lex.europa.eu/eli/reg/2010/66/oj

irritant/corrosive, and eye irritant/damaging under CLP[22], or are restricted under the EU's Cosmetic Products Regulation. This restriction was adopted by the European Commission on 14 December 2020 and will avoid more than 1 000 cases of allergic reactions per year. This group approach is expected to help avoiding regrettable substitution by preventing the use of substances with the same hazards replacing the substances currently used.

Additionally, through the synergies between harmonised classification of CMR substances under CLP and Annex XVII entries 28-30, 66 substances, or groups of substances, have been restricted from being used in consumer products during 2016-2020.

During this period, ECHA's committees also adopted opinions on the following restrictions to protect consumers: formaldehyde released from consumer articles, polycyclic-aromatic hydrocarbons (PAHs) in rubber granules and mulches, and perfluorinated carboxylic acids (C9-C14 PFCAs).

In 2020, ECHA's committees adopted an opinion on the restriction of substances with a harmonised classification as skin sensitisers 1/1A/1B in textile, leather, synthetic leather, hide and fur articles. This restriction will reduce the risk of sensitisation via the skin and could help around five million EU citizens who are expected to be sensitised to chemical substances present in these articles. The dynamic relationship with the CLP Regulation means that substances that will be classified as skin sensitisers in the future will also become covered by the restriction.

In 2016, Member State inspectors checked compliance with restrictions imposed on 13 selected substances across Europe, in a project coordinated by ECHA's Forum[23]. Inspectors found that out of 5 625 targeted checks on consumer products, **18 % of consumer products did not comply with the conditions of the restrictions** and contained illegal amounts of restricted chemicals. In particular, 20 % of toys were found to contain restricted phthalates. Most breaches were found in imported products. Similar compliance rates were found by Member State inspectors in 2019, in a small-scale project consisting of 1 225 checks performed in collaboration with Member State customs authorities, which found that 17 % of imported products were in breach of restriction requirements[24]. The issue of imported products is further elaborated in Section 3.8.

Restrictions on articles containing SVHCs after their sunset date

For SVHCs on the Authorisation List, after their sunset date, ECHA has to consider whether their use in articles poses a risk to human health or the environment that is not adequately controlled[25]. In addition to further protecting human health and the environment, the measures can also ensure the functioning of the EU's internal market by preventing articles with SVHCs from being imported, while without an authorisation they are no longer allowed to be manufactured in the EU.

ECHA screens each substance on the Authorisation List to assess if the use of the substance in articles poses a risk to human health or the environment that is not adequately controlled. Risks were identified for four phthalates (bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP)) in consumer articles, and a restriction proposal was prepared, which went into effect in 2020.

Risks were also identified for tris(2-chloroethyl) phosphate (TCEP) in consumer articles, two lead chromate pigments (lead chromate molybdate sulphate red and lead sulfochromate yellow), coal tar pitch, high temperature (in clay pigeons) and 2,4-dinitrotoluene. Restriction proposals for these are being prepared.

22 Excluding any such substances if classified due to effects only following exposure by inhalation.

23 https://echa.europa.eu/documents/10162/13577/ref_4_report_en.pdf

24 https://echa.europa.eu/documents/10162/13555/customs2_project_report_en.pdf

25 Under Article 69(2) of REACH.

No risks were identified following the screening for seven (groups of) substances[26].

Authorisation

As illustrated in Figure 7 and Figure 13, no applications were or are likely to be received for 24 SVHCs out of the 54 currently on the Authorisation List. To the extent that these SVHCs were used in consumer products or articles, the uses have now stopped, preventing consumer exposure.

An example of early substitution impacting consumers is sodium perborate (entry 48). It was one of 11 substances added to the Authorisation List in February 2020 because of its toxicity to reproduction. It was primarily used as a source of oxygen in laundry detergents and peroxide-based bleaches. No applications were estimated[27] to be made due to the availability of technically and economically feasible alternatives, in particular, sodium percarbonate. The substitution of sodium perborate had started before the inclusion of the substance in the Authorisation List, because of its inclusion in entries 28-30 of Annex XVII to REACH.

The authorisation requirement for two plasticisers DEHP (entry 4) and DBP (entry 6) has reduced risks to reproduction. Three companies applied for authorisation in 2013. ECHA proposed a restriction on the use of these substances (as well as DIBP and BBP) in 2016 based on Article 69(2) of REACH, as the risk of their use in articles was considered unacceptable. The restriction entered into effect in July 2020. In the meantime, two of the applicants withdrew their application as they had stopped manufacturing DEHP and DBP. As requested by the Commission, the third applicant provided a substitution plan according to which their use had reduced by over 90 %. This implies that the use of DEHP in the EU has dropped by 97 % from 320 000 tonnes to less than 10 000 tonnes. This reduction has reduced the exposure of consumers to the phthalate in the EU.

This exemplifies how REACH authorisation and restriction requirements can complement each other to improve the health of European consumers, while noting that risks related to use in food contact materials – which are regulated outside of REACH – may remain.

SVHC identification and Candidate listing

Consumers have the right to ask if articles contain SVHCs.

A small-scale inspection campaign by Member State inspectors in 2017 and 2018 checked nearly 700 consumer articles[28]. 12 % of the articles contained Candidate List substances in concentrations above 0.1 % and the requirements regarding notification of these substances to ECHA were fulfilled. However, inspectors found that in **89 % of cases the suppliers did not communicate information down the supply chain** about the presence of Candidate List substances in articles, so the information cannot be passed to consumers when requested.

The poor implementation of these provisions by suppliers has been highlighted before. It is ECHA's hope that the SCIP database for information on SVHCs in products (articles or complex objects), established under the Waste Framework Directive[29], will increase compliance. Companies supplying articles containing SVHCs in a concentration above 0.1 % weight-by-weight on the EU market have had to submit information on these articles to ECHA, from 5 January 2021. The SCIP database ensures that information on articles containing SVHCs is available throughout the whole lifecycle of products and materials. The information in the database will be made available to waste operators and consumers.

26 Substances are marked as Article 69(2) reports in the completed restrictions activities: https://echa.europa.eu/completed-activities-on-restriction

27 https://echa.europa.eu/documents/10162/13634/applications_for_11_substances_Authorisation_List_February_2020.pdf

28 https://echa.europa.eu/documents/10162/13577/sia_pilot_project_report_en.pdf

29 https://eur-lex.europa.eu/eli/dir/2008/98/oj

2.3 Environmental protection

Chemical safety assessment

As presented in Section 2.1, the data gathered through registration enables environmental hazard characterisation for nearly 100 % of the market volume of chemicals. The considerations presented in Section 2.1 on the beneficial impact of registration to company operation – such as actions to inform own customers and the revision of own sourcing strategies – apply to environmental hazards in a similar way as for human health hazards. The issues identified regarding information deficits in chemical safety reports and safety data sheets, also apply.

Regarding the nature of communicated information, the key information generated and communicated to the supply chain is self-classification, predicted no-effect concentrations (PNECs), biodegradability and potential for bioaccumulation. For 32 % of the assessed substances, environmental hazards have been identified, triggering exposure and risk assessment by registrants.

Based on the environmental hazard characteristics of the chemicals (as described in the SDSs), industries emitting wastewater to the environment can better identify their key environmental issues and corresponding needs to take pollution prevention measures. Information generated under REACH (such as SDSs and exposure scenarios) can provide practical information on how to address potential environmental emissions and can be used to support the fulfilment of obligations under other legislation, such as the Industrial Emissions Directive[30]. Downstream users, such as producers of mixtures and articles, can make better informed choices on raw materials, to avoid those that may harm the environment.

The impacts on the environment are, however, often largely the result of releases from multiple sources. While the data collected under REACH offers a valuable contribution to improving the assessment of environmental risks, there are limitations. Registrants assess the risks for their production and the use in their supply chain, and do not (need to) determine the overall environmental loading. There are also limitations in available data, such as the tracking of substance volumes channelled through the supply chain into use-areas with specific release conditions. Due to these factors, the impact of the CSR information on the environment is limited up to this point.

30 https://eur-lex.europa.eu/eli/dir/2010/75/oj

Classification and labelling

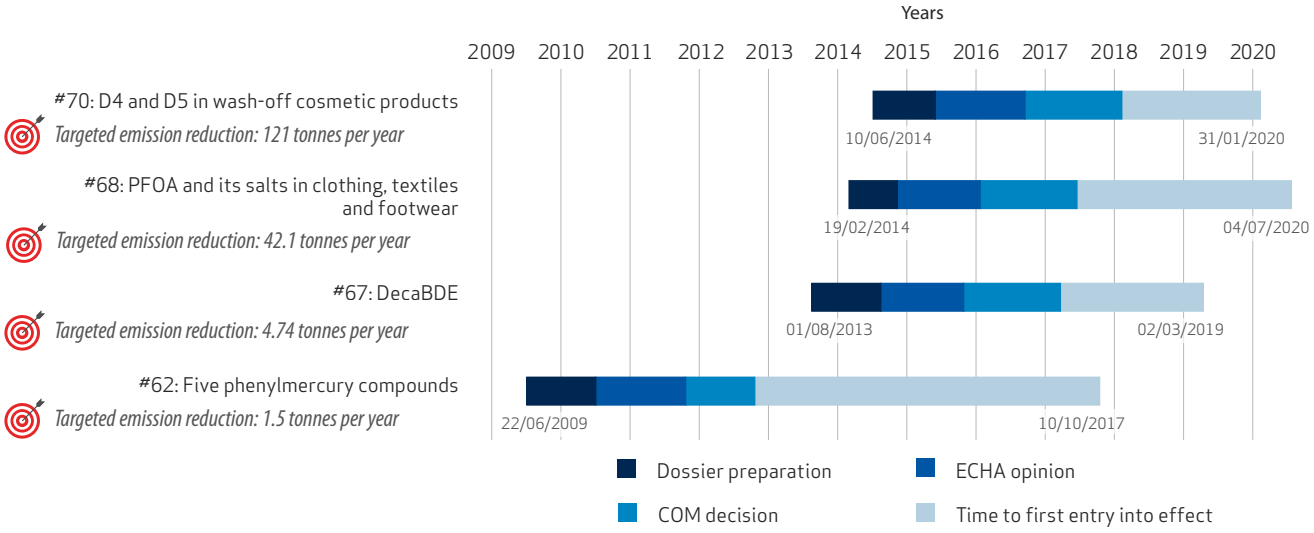
As already described for workers and consumers, classification and labelling of substances is an important instrument to ensure that chemicals are used safely with regard to the environment. During 2016-2020, out of the 120 substances added to Annex VI to CLP, 91 were added with the classification 'hazardous to the aquatic environment'.

The voluntary scheme according to the EU Ecolabel Regulation[31] foresees that products containing substances classified as hazardous to the aquatic environment do not satisfy the eligibility criteria for the product to be awarded with the ecolabel, although certain derogations are possible.

Restrictions

As summarised in Figure 10, during 2016-2020, four restrictions entered into effect that aim to reduce the use of substances hazardous to the environment. These restrictions prevent up to a total of 170 tonnes annually of PBT and vPvB substances from being emitted into the environment. Reduction of the emissions of these substances also creates health benefits for EU citizens, for example, through a cleaner environment and reduced exposure to hazardous chemicals in drinking water, the food chain or the air.

FIGURE 10: Reduced emissions of hazardous substances to the environment due to restrictions



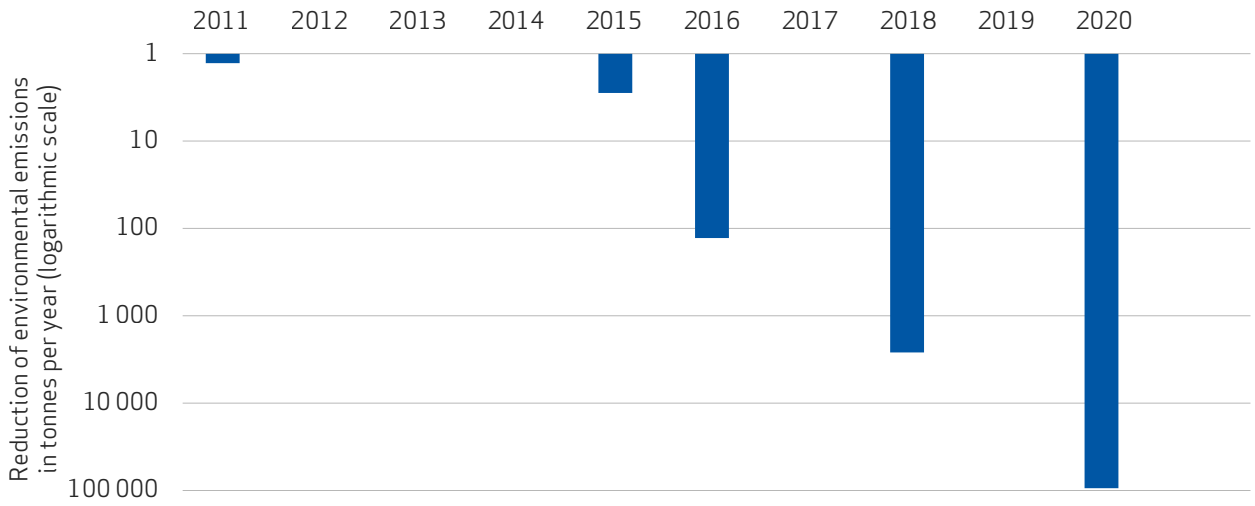
The emissions reduced represent a fraction of the actual volume of the substances used by industry, which needs to be substituted in response to a restriction. For example, the restriction on decabromodiphenyl ether (decaBDE), requires around 4 400 tonnes of PBT and vPvB substances to be replaced in the restricted products in order to achieve the 4.74 tonnes per year reduction in emissions. In this specific example, the emissions covered by the restriction amount to close to 100 % of the total estimated emissions. However, due to the very large stock of decaBDE in the technosphere (and already in environmental sinks such as sediment), the environment will remain at (unquantified) risk from this substance for decades to come.

While the opinions adopted until 2015 indicated a total reduction of about 190 tonnes per year of releases into the environment[32], the last five years from 2016 to 2020 have seen an **acceleration** of the work on restricting substances that pose risks to the environment[33].

31 https://eur-lex.europa.eu/eli/reg/2010/66/oj
32 https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf
33 https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf

As illustrated in Figure 11, ECHA has developed the restriction dossiers for and worked on an increasing number of opinions targeting large emission reductions of substances with PBT and vPvB properties and other substances of environmental concern, which have been addressed where possible in groups, to further increase impact. These include a restriction in the use of the siloxanes D4, D5 and D6 in cosmetics and cleaning products (16 500 tonnes per year), calcium cyanamide as a fertiliser (53 000 tonnes per year), lead in gunshot over wetlands (4 750 tonnes per year), and lead stabilisers in polyvinyl chloride (PVC) (seven tonnes of prevented lead released to the environment).

FIGURE 11: Tonnages of yearly emissions estimated to be reduced – by year of RAC and SEAC opinion adopted



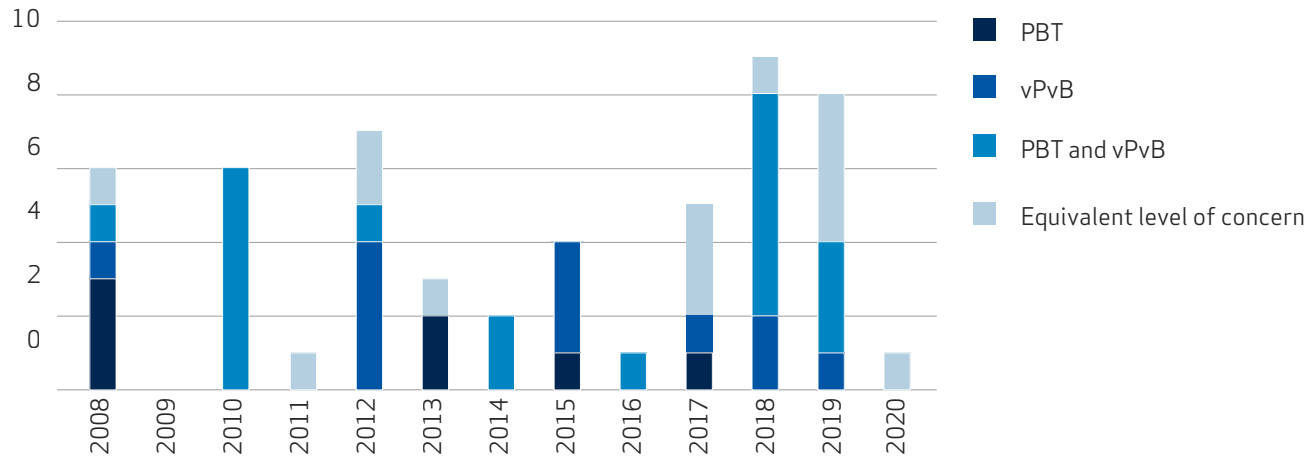
In December 2020, ECHA's Committee for Socio-economic Analysis (SEAC) adopted its opinion on the proposed restriction for intentionally added microplastics, where a reduction of 500 000 tonnes over the 20 years following implementation has been estimated. When all the transition periods have expired, the emissions would be reduced by more than 90 %. This restriction proposal is the most comprehensive of its kind in the world.

ECHA is currently developing restriction dossiers on lead in shooting, hunting and fishing (submitted in January 2021), and per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams, at the request of the European Commission, and on lead chromates in plastic articles and coal tar pitch, high temperature in clay targets, according to Article 69(2) of REACH.

SVHC identification and Candidate listing

During 2016-2020, the number of substances identified as SVHCs because of environmental reasons has continued to grow: 27 substances or groups of substances were added to the Candidate List, bringing the total to 53 substances or groups of substances identified as SVHCs for environmental protection reasons, out of 211 SVHC entries on the Candidate List.

FIGURE 12: Number of SVHCs identified for environmental protection reasons

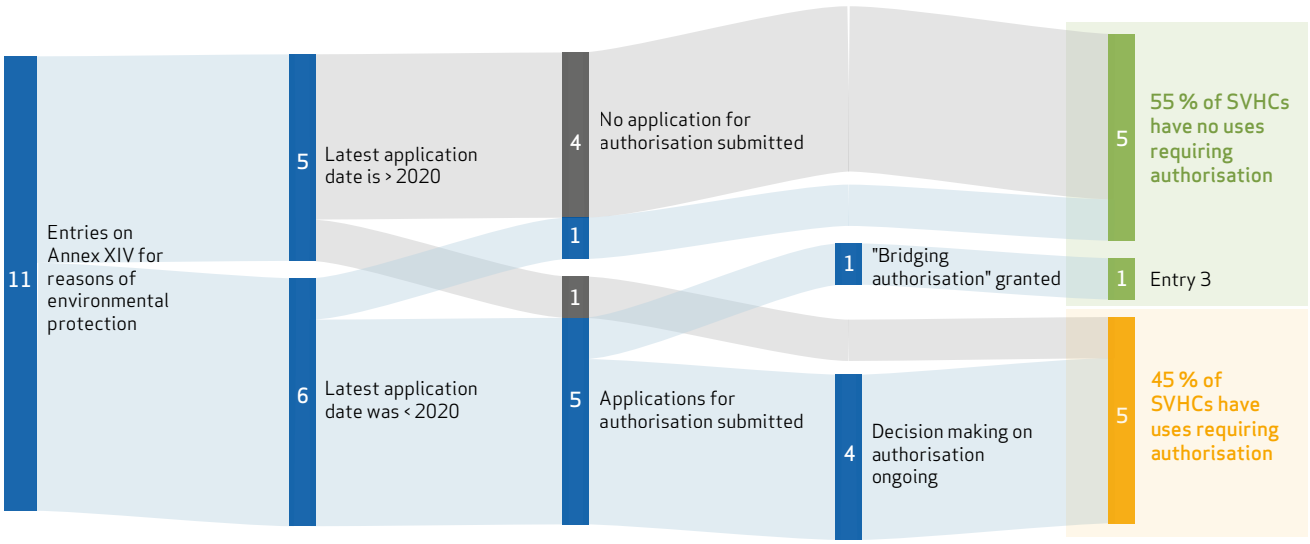


For substances potentially fulfilling Article 57(f), such as endocrine disruptors, an assessment must be conducted on whether the hazards of the substance present an equivalent level of concern to CMR or PBT/vPvB substances. This is different to the approach taken under other legislation such as the Biocidal Products Regulation, where the identification itself of a substance as an endocrine disruptor already has regulatory implications. A closer alignment across legislation would improve consistency in regulating these substances. Similarly, for persistent, mobile and toxic (PMT) substances, the route towards identification as SVHCs – in the absence of specific criteria – remains the assessment of an **equivalent level of concern**, which requires additional time and effort.

Authorisation

The authorisation requirement reduces environmental emissions in a similar manner as for health risks. Figure 13 illustrates the different pathways for the 11 entries that are on the Authorisation List for environmental protection reasons.

FIGURE 13: Phasing out of uses requiring authorisation of the 11 entries on the Authorisation List for environmental protection reasons



Expected path: the latest application date has not yet passed for the 5 substances added to the Authorisation List in February 2020, so the information gathered from industry is subject to change

Actual path: the latest application date has passed

5 entries having no uses requiring authorisation, but possibly having uses exempt from authorisation: 1 and 50-54.
5 entries having authorised uses: 40-43 and 51.

The 1-10 tonnes of substances covered by entry 50 manufactured or imported per year (from registration data) are expected to be phased out by 2023, as no companies have indicated that they will apply for authorisation.

The use of hexabromocyclododecane (HBCDD - entry 3) as a flame retardant was authorised for two years between 2015 and 2017, to allow applicants to finalise their research and development on the identified substitutes, and obtain the necessary approvals for their products using substitutes. Authorisation holders did not submit a review report after 2017. The estimated annual emissions of 0.5 tonnes of HBCDD from the annual use of 8 000 tonnes of HBCDD has been eliminated. Still, 3.2 tonnes were estimated to be released from demolition and disposal at later stages from four years of use of HBCDD.

For the groups of octylphenol and nonylphenol ethoxylates (OPE and NPE - entries 42 and 43), the applicants projected that their emissions would drop by 93 % from roughly 10 tonnes per year in 2020 to 0.7 tonnes per year by 2033.

In December 2020, ECHA's scientific committees issued opinions where they had substantial reservations about the use of coal tar pitch, high temperature (CTPHT - entry 41) as a binder in clay targets for sports shooting, as they considered that suitable alternatives are readily available in the EU. The emissions to the environment associated with this use currently amount to 157 tonnes of polyaromatic hydrocarbons (PAHs) per year.

The authorisation requirement introduced conditions that would also reduce future risks. During 2017-2020, ECHA's opinions on applications for authorisation contained recommended environmental control conditions for 46 % of the uses. Furthermore, additional conditions were recommended for 65 % of the uses, to be taken into account if the companies would re-apply for a second authorisation period.

2.4 Functioning of the internal market

Level playing field for registrants

The completion of the last registration deadline in 2018 marked a major milestone in establishing full visibility of the EU chemicals market, for substances manufactured or imported above one tonne per year. In a project coordinated by ECHA's Forum during 2019[34], Member State inspectors checked if companies across the EU had satisfied the registration obligation. It was found that the **obligation to register** was fulfilled for **93.5 %** of the 1 193 substances inspected and requiring registration. Companies in breach of the registration obligation had to bring themselves into compliance.

The functioning of the internal market is expected to have improved during 2016-2020 thanks to the actions taken by companies in participating to joint submissions for the same substance.

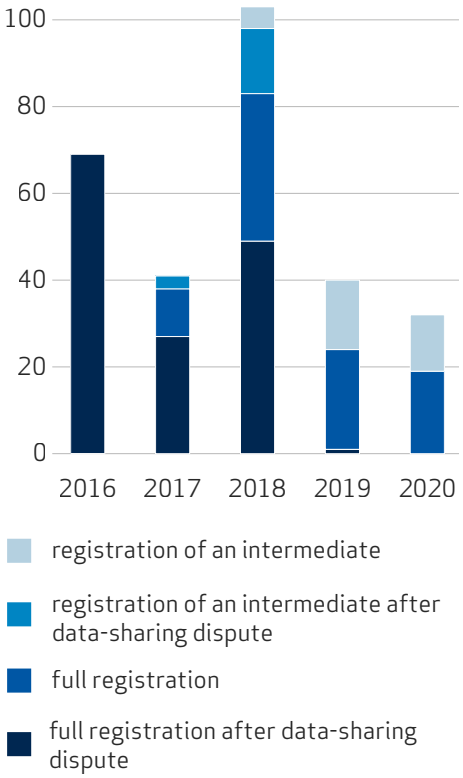
The obligation on companies to register jointly was strengthened by ECHA, to remove opportunities for so-called free riders. Until 2016, ECHA allowed companies to make their own determination on the need to register jointly. During 2010-2015, as reported in the previous five-yearly report on the operation of REACH, 2.5 % of registrants registered individually outside the joint submissions. Following the entry into force of the Commission Implementing Regulation on joint submission of data and data sharing[35], ECHA started to ensure joint submission through its IT submission tools in January 2016. Since then, it is no longer technically possible to register a substance individually outside of a joint submission, if other registrants of the substance already exist[36]. This ensures that companies contact each other to discuss the sharing of data and costs before

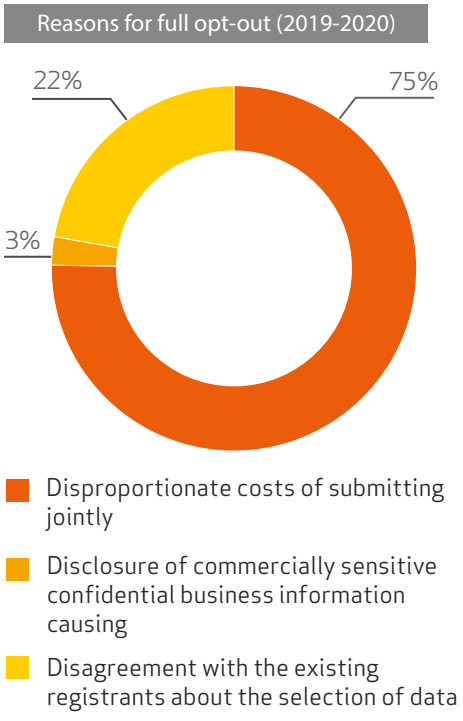
34 https://echa.europa.eu/documents/10162/13577/project_report_ref-7_en.pdf

35 https://eur-lex.europa.eu/eli/reg_impl/2016/9/oj

36 This implementation is in line with decision A-022-2013, REACheck Solutions, Decision of the Board of Appeal of 15 March 2016.

FIGURE 14: Registrations with all data submitted separately within the joint submission (full opt-out) and reasons for opting out





registration. If they disagree and provide a justification according to REACH Article 11(3), registrants can still submit (some or all) information separately within the joint submission.

The number of cases where **registrants separately submit all the data** for their registration ("full opt-out") due to a disagreement with the joint submission has declined in the last three years to **less than 0.6 % of incoming registrations** (285 registrations for 171 substances, of which 86 registrations are for charcoal). At ECHA's request, during 2017-18 most of the registrants who had previously registered individually joined the joint submissions.

With the closure of the phase-in scheme, the focus has shifted from companies finding each other to register jointly, to companies aiming to jointly keep the registrations up to date and to respond to decisions. In line with this objective, ECHA has enhanced its IT submission tools to provide more transparency to co-registrants on who is still active and can be expected to contribute to further dossier updates, and which information requirements currently apply to other registrants of the same substance. This information is intended to support companies to act towards those who do not contribute their fair share of costs.

ECHA initially established the completeness check on registration dossiers as a fully automated check. This automation enabled us to perform the registration activities with the staffing level foreseen in the staffing plan. When analysing the registration data from the first registration deadlines, it became evident that the completeness of some of the required information could not be verified by automated tools. ECHA implemented stronger measures to ensure that the 'no data, no market' objective is met by launching an enhanced completeness check in July 2016, where the **automated completeness check of incoming dossiers was complemented by manual verifications**.

These manual verifications ensure that registrants provide relevant justifications when they adapt the standard information requirements. The approach was supported by a 2016 Board of Appeal decision on the subject[37]. During 2016-2020, ECHA staff verified completeness of elements triggering manual verification in around 30 % of incoming registrations; close to 10 % of registrations were found incomplete and were requested to be completed. The increased scope of the completeness check puts companies in a more equal position when preparing their registrations.

However, the current manual verifications cover only the specific rules for adaptation of the standard information requirements. The general rules for adaptation were found to

37 A-022-2013, REACheck Solutions, Decision of the Board of Appeal of 15 March 2016.

not be sufficiently specific on what the required elements for a complete justification are. Therefore, the justifications for read-across, for example – the most used adaptation – are not verified for their relevance during the completeness check. This leaves room for improving further the implementation of the 'no data, no market' objective.

While all registrations are confirmed to be complete, the subsequent evaluation activity checks their compliance with applicable information requirements. Evaluation processes contribute to the generation of relevant data on chemicals, to ensure a fully functioning internal market with a level playing field and to instil the confidence of the general public in industry taking responsibility to ensure the safety of their chemicals.

As of January 2019, if the registrations for a substance undergo a **compliance check** and further information is requested in a decision, such decision is **addressed to all relevant registrants** – not only to the lead registrant, but also to the member registrants in the relevant tonnage band (with or without separately submitted information) and to individual registrants. Therefore, all co-registrants know which companies have obligations for each information request, and which companies need to cooperate to fulfil these obligations. This approach has reinforced the REACH provisions expecting that all relevant registrants of a substance are equally responsible for generating the requested data, and ensures that the costs of the tests can be shared in a fair and transparent manner between the relevant registrants.

If not all the addressed registrants are willing to participate in the costs for the required testing, a practical approach has been followed to make this clear to ECHA: all the registrants that have contributed to the costs (lead and/or members) update their dossiers and submit the requested information separately within the joint submission, broadening the provisions of Article 11(3). Subsequently, ECHA can issue a decision of non-compliance to the companies not complying with the decision, and work with the Member State enforcement authorities to enforce the decision. However, checking the information submitted under this approach is not efficient, as many registrations need to be compared and evaluated.

ECHA's analysis of the activities performed by national enforcement authorities (NEAs) in enforcing evaluation decision[38] indicates that existing enforcement measures are effective in enforcing evaluation decisions in nearly all cases. There have been few cases where NEA measures have not been effective in bringing the registrant into compliance. These constitute less than 2 % of all compliance check decisions sent for enforcement. These cases involved Only Representatives who are directly supplying downstream users in other EEA countries without importing the substance in their own country.

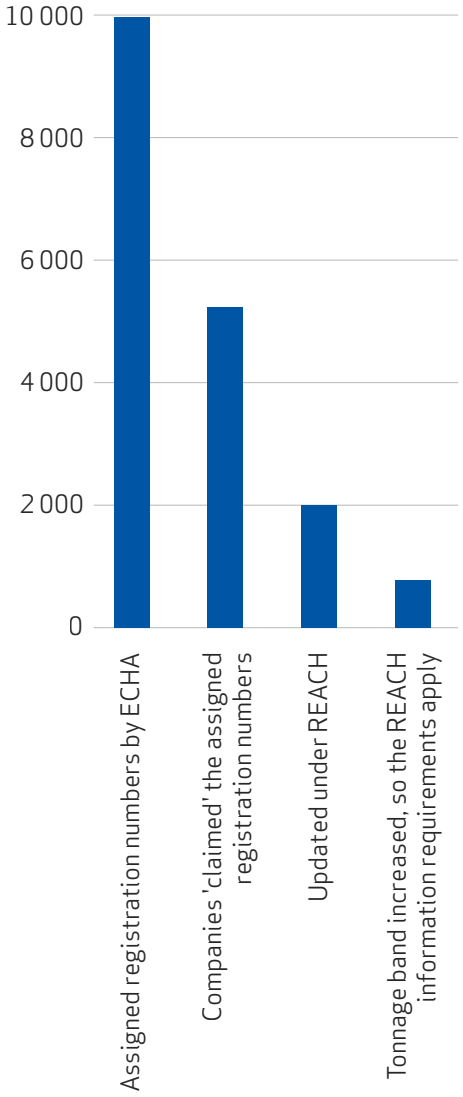
In such cases, having the possibility for ECHA to **revoke the registration** decision would ensure compliance with REACH and strengthen the 'no data, no market' objective. In its Chemical Strategy for Sustainability, the European Commission has foreseen a modification of the REACH Regulation to provide ECHA with the legal competence to revoke registration decisions of non-compliant companies.

Overall, REACH foresaw that the internal market would benefit from **one set of rules** for the registration of substances after the end of the phase-in regime. However, as per Article 24, the substances notified in accordance with the previous Dangerous Substances Directive[39] – the **NONS** – still benefit from different rules. This has resulted in ECHA handling them differently, regarding the completeness check, but also the compliance check, the provision of data older than 12 years, and their dissemination on the ECHA website. This concerns about 5 300 substances in almost 10 000 registrations. Furthermore, no end-date was foreseen for this benefit. REACH requirements start to apply on a case-by-case basis when the tonnage band of the previous notifier's registration is increased, which has happened for 8 % of registrations.

38 Action 12 of the REACH Evaluation Joint Action Plan: https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

39 https://eur-lex.europa.eu/eli/dir/1967/548/oj

FIGURE 15: State-of-play of notifications in accordance with the Dangerous Substances Directive, regarded as registrations under REACH



Therefore, this exemption regime has since its implementation caused many difficulties, including within the joint submission, where co-registrants of the same substance may have different information requirements. This in turn has an impact on the assessment of the safe use of these substances, first in relation to the generation of data (as per the latest development of internationally approved test guidelines), and then in the possible subsequently required regulatory risk management measures.

Also, after the Court judgement in Case C-650/15 P[40], companies are applying different interpretations to "use as an intermediate" of substances. This can bring certain benefits, such as exemption from authorisation, and – if used under strictly controlled conditions – lighter information requirements for registering the substance, and exemption from dossier evaluation. As this could be undermining the level playing field, clarification of the concept of "use as an intermediate" in REACH would be beneficial.

Impacts of restrictions and authorisation on the internal market

While restrictions and the authorisation requirement improve health and the environment, they also incur costs to EU industry and the society as a whole. REACH risk management endeavours for these costs to be reported in a transparent manner and can, therefore, be taken into account when regulatory decisions are made, in line with the objective to enhance competitiveness and innovation.

ECHA estimated[41] that the costs of the restrictions prepared in 2016-2020 to society relating to health risks add up to EUR 0.5 billion per year. Health benefits are equivalent to over EUR 2.1 billion per year. For restrictions related to environmental risks, the total costs amount to EUR 1.2 billion a year. Total benefits amount to a reduction of 95 000 tonnes of environmental emissions of substances of concern per year. Costs related to restrictions are normally incurred as companies need to reduce the exposure, and replace the restricted chemicals with safer substances or alternative technologies.

Benefits of authorisation[42] to SVHC users relate to the continued use of substances, whenever technically feasible and economically viable alternatives are not available. For substances for which an (eco)toxicological threshold could not be determined, applicants for authorisation have to demonstrate that the societal benefit of continuing to use the SVHC outweighs the associated risks to human

40 Judgment of 25 October 2017, PPG and SNF SAS v. ECHA, C-650/15 P, EU:C:2017:802

41 https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf

42 https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf

health and the environment[43].

For carcinogenic and reprotoxic substances, these benefits were estimated to amount to EUR 8.7 billion per year. Annuitisation of the monetised risks assessed by applicants suggests that, on an annual basis, the continued use of the SVHCs applied for results in negative externalities of EUR 470 million.

The ratio of benefits to costs as established by ECHA's committees is around 19:1, meaning that for every euro of health externalities incurred, EUR 19 of economic value are preserved.

2.5 Innovation and competitiveness

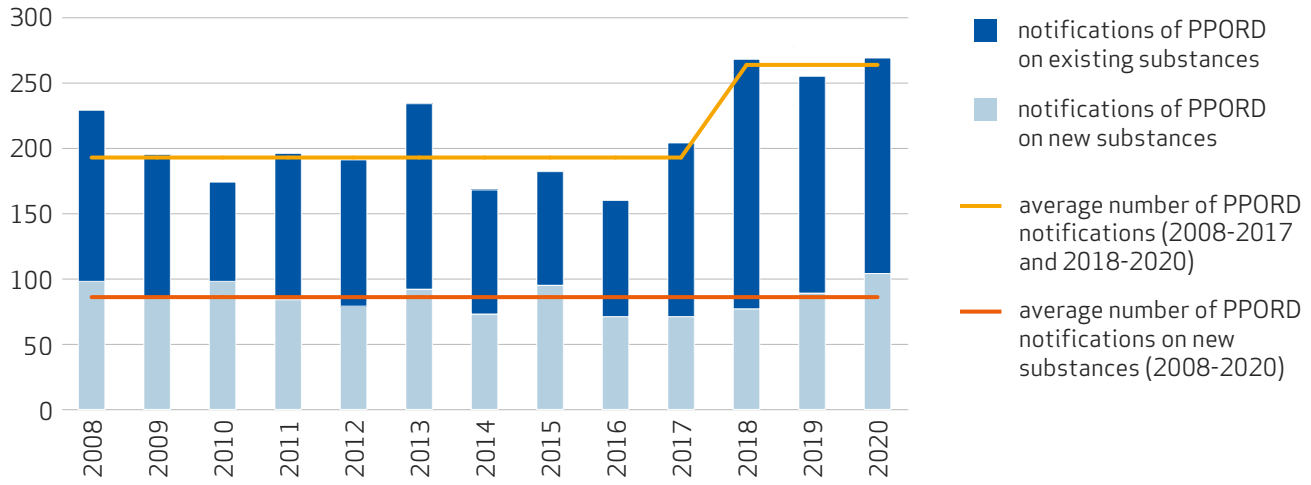
Two long-standing indicators of innovation are the notification of product or process orientated research and development (PPORD) and the registration of new substances. These indicators give a partial view on the wider concept of innovation.

PPORD

The PPORD exemption in REACH gives companies the possibility to forego registration for substances that are used in quantities above one tonne per year in PPORD activities, for a period of five years or, if extended, up to 10 additional years. PPORD activities can relate to the use of new substances, the development of new technologies (e.g. new manufacturing processes) or new uses of existing substances.

As shown in Figure 16, the number of PPORD notifications has been fairly constant between 2008 and 2017. For the last three years, from 2018 to 2020, the number of notifications has been, on average, 35 % higher than the average until 2017. This is mostly because of PPORD notifications on existing substances. One explanation for this step change is that companies proceeded to notify those substances involved in PPORD activities that could no longer be covered by a pre-registration after the end of the transitional period for phase-in substances in June 2018.

FIGURE 16: Number of PPORD notifications

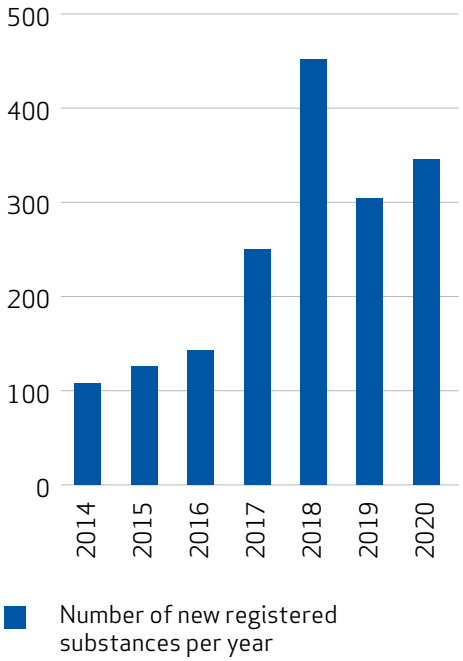


The number of PPORD notifications for new substances[44] has been constant over the last 10 years, at about

43 According to Article 60(2) of REACH, this is not required if the applicant demonstrates "the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled".

44 A substance is considered to be a new substance under the PPORD notification process if it is not part of the EC inventory (covering the European Inventory of Existing Commercial Chemical Substances (EINECS), European List of Notified Chemical Substances (ELINCS) and No-longer Polymers (NLP) List) and if it has not been pre-registered, inquired about according the Article 26 of REACH, or registered before.

FIGURE 17: Number of new registered substances



90 per year. EU manufacturers are responsible for 65 % of PPORD notifications, and for 80 % of PPORD notifications for new substances.

Although the information required in PPORD notifications is insufficient to reliably attribute the PPORD activities to specific industry sectors, it is nevertheless understood that these substances mainly relate to the fine chemicals sector, including biotechnology, pharmaceutical, healthcare and nutrition industries. An increase in research activities related to the recovery of substances, new recycling technologies and renewable substances has been observed in the past two years

Registration of new substances

The registration data shows that the number of new substances[45] has increased overall since the entry into operation of REACH. The peak in 2018 is understood to be an artefact related to the registration of substances that were not explicitly covered by a pre-registration by June 2018.

Aside from this outlier, an increase in the number of new registered substances is still observed for the past two years. In 2020, 346 new substances were registered. Whereas the figures under REACH may not be readily comparable to statistics for the notification of new substances (NONS) under the Dangerous Substances Directive, the 346 new registered substances in 2020 are a notable increase compared with the previous legislation, where about 280 new substances were notified per year, of which ~200 substances exceeding one tonne per year[46].

In 2020, 58 % of the companies that registered a new substance were EU manufacturers, while 27 % of registrations in 2020 were by EU manufacturers. This suggests that the EU remains a key actor in innovation.

Fast market access for newcomers that have all required safety data

ECHA has streamlined the REACH provisions on inquiry and registration, ensuring fast market access for newcomers to the EU market while making sure that their substances are used safely.

Before a company can bring a substance to the EU market in volumes exceeding one tonne per year – a new substance or a substance

45 A substance is considered to be a new substance under the registration process if it is not part of the EC inventory (covering EINECS, ELINCS and the NLP List), it has not been previously pre-registered or registered, and it has not been registered with a pre-registration number.

46 http://web.archive.org/web/20110211062753/http://ecb.jrc.ec.europa.eu/new-chemicals

already registered by other companies – they need to register the substance. Before they register, companies need to submit an inquiry[47] to ECHA to find out if another company has already registered that substance, so they can share data. In the past five years, ECHA has streamlined its **inquiry** process to enable faster contact between new and previous registrants of a substance. For almost 80 % of the substances, new registrants receive access to the contact details immediately. For complex substances and new substances where the substance identity needs to be checked, ECHA provides the contact details of a previous registrant or confirms that the substance has not yet been registered, on average, within **16 days**.

Subsequently, for companies that possess the data required to register the substance or have obtained a letter of access to it from previous registrants, REACH offers fast market access.

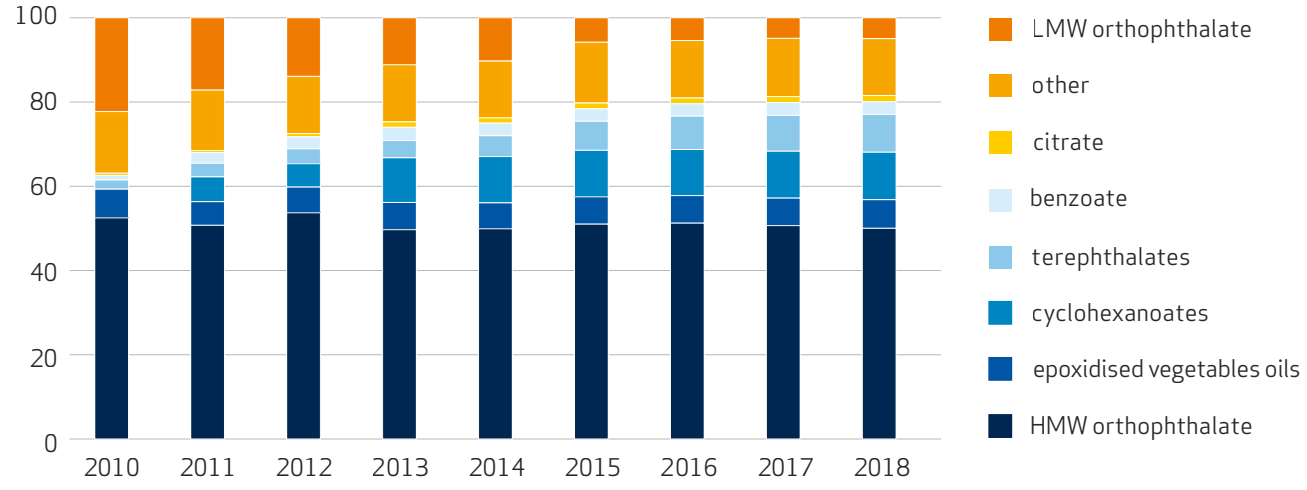
ECHA prepared extensive support material informing companies on how to prepare a successful registration dossier. ECHA's IT systems allow dossiers to be submitted 24/7, and the completeness check performed on each submitted **registration** dossier is performed within the foreseen **three weeks**[48], also for the many registrations that are checked manually. If the registration passes the completeness check, a registration number is issued, granting access to the EU market for the registered tonnage band. If the registration does not pass the completeness check, detailed information is provided on which additional information is needed to be successful.

Substitution

Where regulatory action is taken, or anticipated, it creates a pressure on the market to gradually move to substitutes and phase out substances that may be restricted or require authorisation in the future.

In general, it is difficult to identify from REACH data the extent to which substitution of hazardous substances takes places, though in some cases it is possible to find indications. For example, the market volume of low molecular weight ortho-phthalates has decreased while the volume of some groups of possibly less hazardous substitutes have increased (for instance, cyclohexanoates and terephthalates). The aggregated volumes reported in REACH registrations show the phasing out of low molecular weight (LMW) orthophthalates and increases in market volume of some selected alternatives.

FIGURE 18: Relative tonnages reported in registrations for phthalates and alternatives



47 Since the end of the transitional period for phase-in substances, the duty on registrants to inquire applies for all substances, as clarified in Implementing Regulation 2019/1692: https://eur-lex.europa.eu/eli/reg/2019/1691/oj

48 100 % success rate for initial submissions. During the peak in workload for the 2018 deadline for registration of phase-in substances, the completeness check of the registrations submitted in the course of the two-month period before the deadline was performed within three months of the deadline, as foreseen in Article 20(2).

Predictability on actions by authorities on substances

ECHA has no fact base on which to draw conclusions on the competitiveness of EU industry, but – to support competitiveness – has improved the predictability for companies on the actions to be expected on their registered substances.

The **public activities coordination tool** (PACT) on ECHA's website provides an overview of the planned and ongoing regulatory actions by authorities for each substance. It includes conclusions from the analyses by Member States and ECHA indicating which regulatory actions authorities consider necessary based on the available information. This overview enables industry (and other stakeholders) to plan early actions, such as improving the company-level risk management and communication in supply chains, plan the substitution of hazardous substances, update their dossiers and prepare among registrants and downstream users for the consultations during the regulatory processes.

In addition, in 2019 the **chemical universe**[49] was published for the first time, including all registered substances, and indicating which substances are a priority for further regulatory action, which are currently not a priority, and which will need further data generation before this can be determined. For more information on the chemical universe, see Section 3 of this report. The chemical universe, in combination with PACT, provides industry and stakeholders with information to plan their activities ahead and decide which substances to invest in. Additionally, for substances needing further data generation, ECHA informs companies of the opening of the compliance check, so they can review, update and coordinate during this time. Each year, the **Integrated Regulatory Strategy report** gives an overview of the progress in concluding whether registered substances are a priority for further regulatory risk management, of low priority or where more data is needed.

ECHA also developed a predictable approach to **prioritise which substances from the Candidate List** to recommend for inclusion in the Authorisation List (Annex XIV). This allows companies to assess upfront the relative priority of the substances they are interested in and prepare for authorisation or search for alternatives before the recommendation is made. ECHA updates the list of recommendations regularly with clear timelines and allows for a three-month consultation of interested parties. In parallel, ECHA runs, at the request of the European Commission, a call for information on socio-economic aspects to further support inclusion in Annex XIV. So far, nine recommendations have been submitted, including 92 substances.

2.6 Promotion of alternative methods to animal testing

Companies are responsible for ensuring that the chemicals they place on the market are safe. To prove they are, companies must perform tests, some of which are carried out on animals. Alternative methods to animal testing are promoted in three ways:

Implementing REACH effectively

There are mechanisms in REACH to ensure that animal testing is only done **as a last resort**. ECHA ensures that these obligations are fulfilled:

- **Registration** (giving access to the EU market): incoming data is examined during the completeness check to ensure that alternative methods have been considered before proposing new tests on animals, otherwise the registration is rejected.

49 https://echa.europa.eu/-/mapping-the-chemical-universe-list-of-substances-by-regulatory-action-published

- **Data sharing and inquiry**: ECHA facilitates access to hazard data for new registrants.

- **Evaluation**: if further testing is needed, registrants must agree on who performs the test on behalf of all those that have been requested to provide further data.

Additionally, ECHA grouping activities are continuing with the aim to identify substances or groups of substances which are not a priority for data generation or group level regulatory conclusions, which may also limit the need of animal tests[50]. Furthermore, ECHA provides hands-on support to companies – through collaboration with industry sector associations – to develop testing strategies for groups of substances based on read across, so companies can avoid unnecessary animal testing and costs, as further detailed in Section 3.1.

Data sharing only requires registrants of the same substance to share (vertebrate animal) data to avoid duplicate animal tests. Extending these data-sharing rules could lead to further avoidance of unnecessary testing. This is already a possibility under the Biocidal Products Regulation.

Making information available on alternatives

Every three years, ECHA publishes a **report on the use of alternatives to testing on animals** under Article 117(3) of REACH[51]. This report describes the progress made in developing alternative methods and their regulatory acceptance. The latest report was published in 2020.

One of the main alternatives provided by REACH to fulfil information requirements is the use of grouping and read across. ECHA developed the **Read Across Assessment Framework** to bring consistency to the assessment of read-across approaches encountered when evaluating dossiers. The framework was made publicly available in 2017 to help registrants build reliable adaptations based on read across to ensure regulatory acceptance.

Alternatives to animal testing are used extensively to fulfil obligations under REACH. However, the approaches are often applied incorrectly. Despite the efforts in developing guidance and recommendations for registrants, valid read-across approaches remain low at around 25 %, meaning that registrants will be asked to perform standard tests during compliance checks. However, as also the European Court and ECHA's Board of Appeal have clarified, registrants still have the possibility to use an alternative approach following a compliance check decision, or improve any previously submitted alternative approach[52].

ECHA continues to invest in developing guidance and recommendations for registrants. The Agency has published reports on the applicability of non-animal approaches (ANAA)[53] (2017), and proceedings of a scientific workshop on New Approach Methodologies in Regulatory Science[54]. Moreover, ECHA provides tutorials and training to registrants and the scientific community on the use of alternatives in the regulatory context.

Contributing to international activities to promote alternatives

ECHA fully finances and co-manages the development of the **OECD QSAR Toolbox** – a comprehensive tool for assessing chemical hazards based on mathematical modelling. The Toolbox has been used in over 12 000 registrations and has about 22 000 active users.

50 https://echa.europa.eu/-/grouping-of-chemicals-speeds-up-regulatory-action

51 https://echa.europa.eu/report-archive-specific-reports?panel=animal-testing-reports#animal-testing-reports

52 A-001-2019, *Solvay Fluor*, Decision of the Board of Appeal of 21 October 2020, paragraph 83; A-019-2013, *Solutia Europe*, Decision of the Board of Appeal of 29 July 2015; cf. judgments of 8 May 2018, *Esso Raffinage* v *ECHA*, T-283/15, EU:T:2018:263, and of 21 January 2021, *Germany* v *ESSO Raffinage*, C-471/18 P, EU:C:2021:48

53 https://echa.europa.eu/-/more-progress-needed-to-replace-animal-tests-under-eu-chemicals-laws

54 https://echa.europa.eu/documents/10162/22816069/scientific_ws_proceedings_en.pdf

ECHA is also actively involved in developing **OECD test guidelines**, the development of which adheres to the requirements of refining, reducing and replacing animal tests. ECHA contributed to the adoption of the OECD test guidelines for *in vitro* tests for skin and eye irritation (2016) and skin sensitisation (2017). These test guidelines have been widely used, particularly since their introduction as standard requirements in the REACH annexes.

Further to this, ECHA has joined efforts with the United States Environmental Protection Agency (US EPA) and Health Canada to further investigate the use of **new approach methodologies** for generating exposure and hazard information on chemicals in regulatory processes, mostly through APCRA[55].

Within the frameworks of the Seventh Framework Programme (FP7) and Horizon 2020 , ECHA has been involved in steering research projects (SEURAT[56] and EUToxRisk[57]) with the aim of developing suitable alternatives for regulatory needs. ECHA also contributes to the European Platform for Alternatives to Animal testing (EPAA) and its related activities[58].

55 Accelerating the Pace of Chemical Risk Assessment.

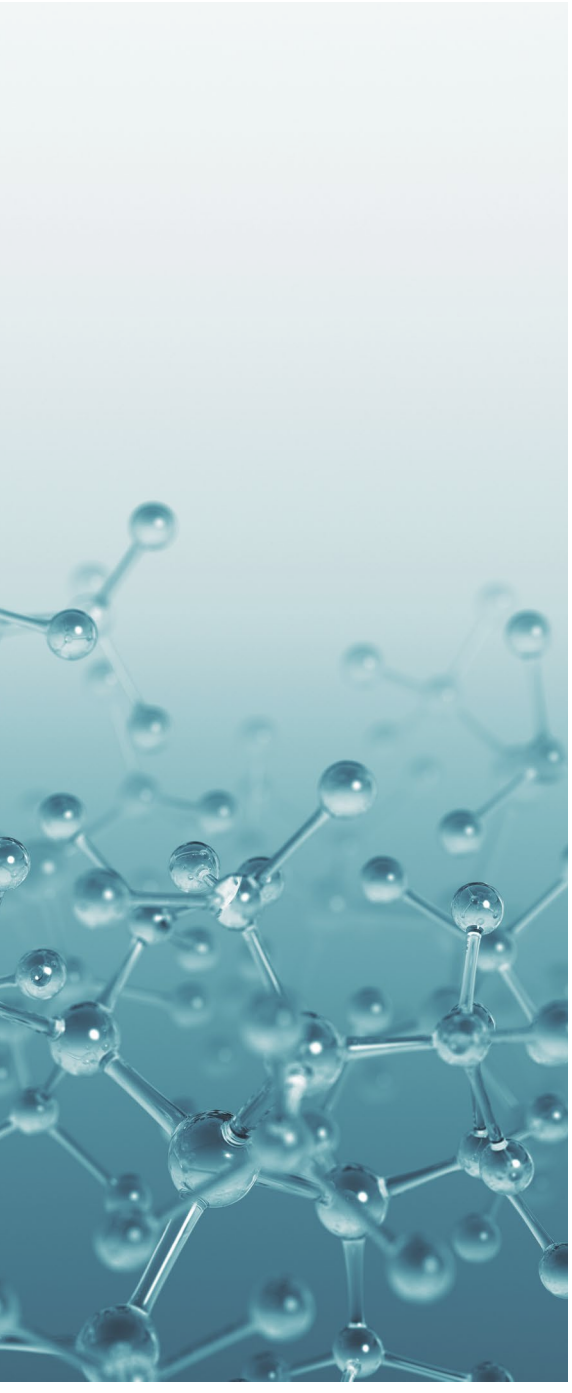
56 Safety Evaluation Ultimately Replacing Animal Testing

57 An EU programme driving mechanism-based toxicity testing and risk assessment.

58 https://ec.europa.eu/growth/sectors/chemicals/epaa_en

3

THE OPERATION OF REACH AND CLP



This section describes the operation of the REACH and CLP regulations from the point of view of the activities performed by industry and authorities. When analysing the activities and their resulting outputs and outcomes, this section aims to highlight achievements, issues and opportunities to improve the operation of the two pieces of legislation.

3.1 Dossier preparation and submission

During the last five years, companies have managed several deadlines under REACH and CLP, such as the third registration deadline for phase-in substances (31 May 2018), the registration deadline for nanoforms of substances (31 December 2019) and the first compliance date for poison centre notifications (1 January 2021).

Registering phase-in substances in the lower tonnage bands

For the 2018 registration deadline, companies registered 11 114 substances in the 1-100 tonnes per year range, of which 6 824 were registered for the first time (i.e. they were not registered before in higher tonnage bands). As of 31 December 2020, the total number of substances registered under REACH stands at about 23 000.

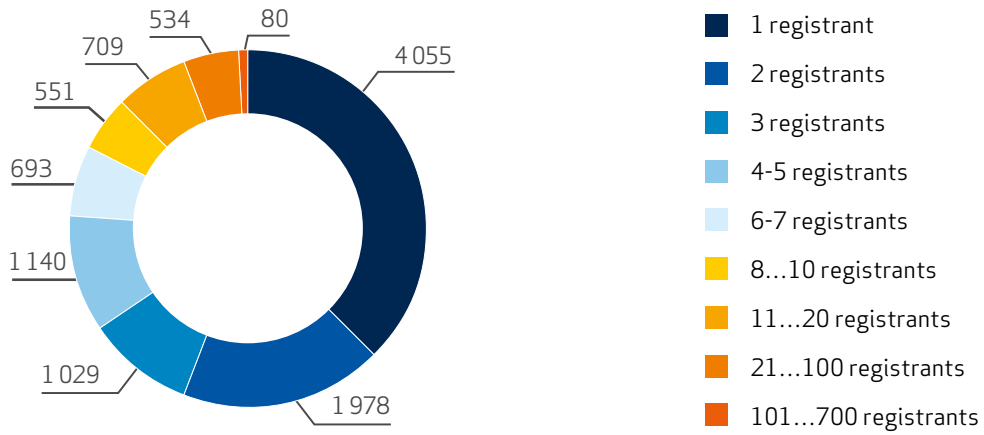
30 % of registered substances are registered only for use as intermediates, under strictly controlled conditions. These registrations are subject to reduced information requirements and data sharing. 70 % of substances are registered in full registrations, also known as standard registrations.

The registration of substances under REACH has required collaboration within industry: substance information exchange fora were set up and joint submissions were prepared and submitted, members were welcomed into the joint submissions throughout the deadlines and afterwards, and information was shared. For full registrations, 6 714 joint submissions were prepared by two or more registrants (63 % of joint submissions for full registration)[59].

12 % of these joint submissions have more than 10 registrants, up to almost 700 registrants for the most registered substance ethanol. 75 % of registrants are in a joint submission with more than 10 registrants.

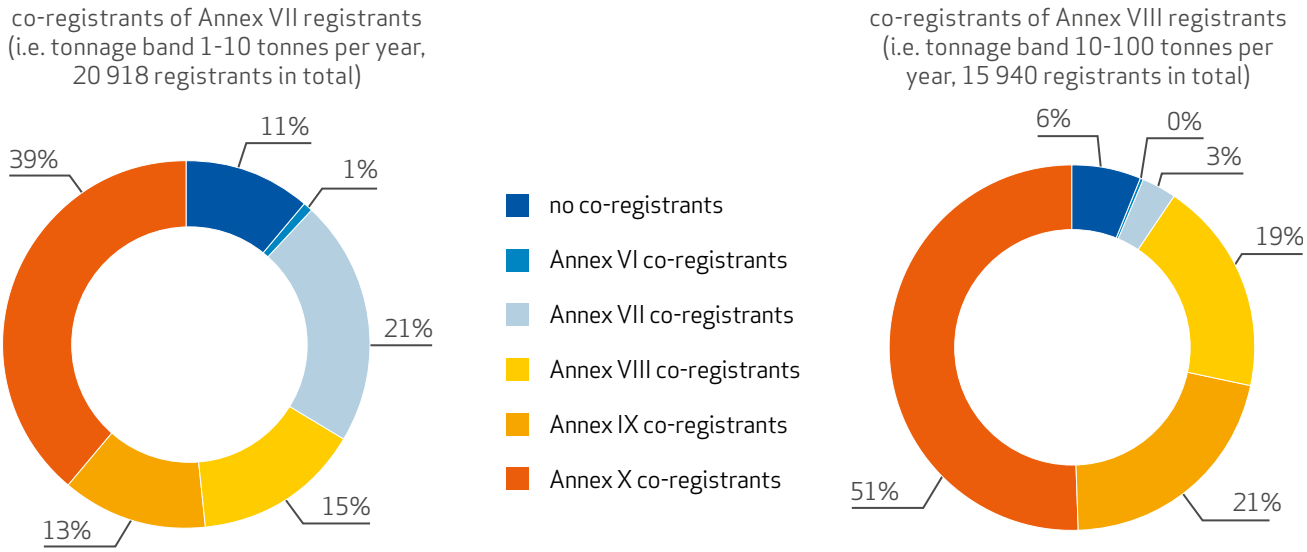
59 Joint submissions can be set up also if there is only one registrant for the substance, which is the case for 37 % of joint submissions for full registration

FIGURE 19: Joint submissions set up by companies (for full registrations), by number of registrants participating



Most joint submissions have members in different tonnage bands. 67 % of registrants in the 1 10 tonnes per year band (Annex VII registrants) and 72 % of registrants in the 10 100 tonnes per year band (Annex VIII registrants) are in a joint submission with co registrants in a higher tonnage band.

FIGURE 20: Co-registrants of registrants in the lower tonnage bands in the joint submissions



Sharing with registrants in the lower tonnage band of data needed for registration in higher tonnage bands and data used for classification and labelling is expected to have increased the safe use of the substance within those companies, and safe use in their supply chains. These collaborations should be the foundation for further work to keep registration information up to date, aligned with the applicable information requirements, and to improve it where needed.

While the data sharing process has generally functioned well, it could benefit from clarifications in certain respects – such as data-sharing obligations by companies that have submitted information on substances in the context of plant protection products or biocides. There are still challenges in dealing with disputes where there are disagreements among parties involved in data-sharing, especially where disagreements do not relate to the transparency requirement as clarified by Commission Implementing Regulation 2016/9[60] and case-law from the Board of Appeal[61]. Certain additions would be helpful such as

60 https://eur-lex.europa.eu/eli/reg_impl/2016/9/oj

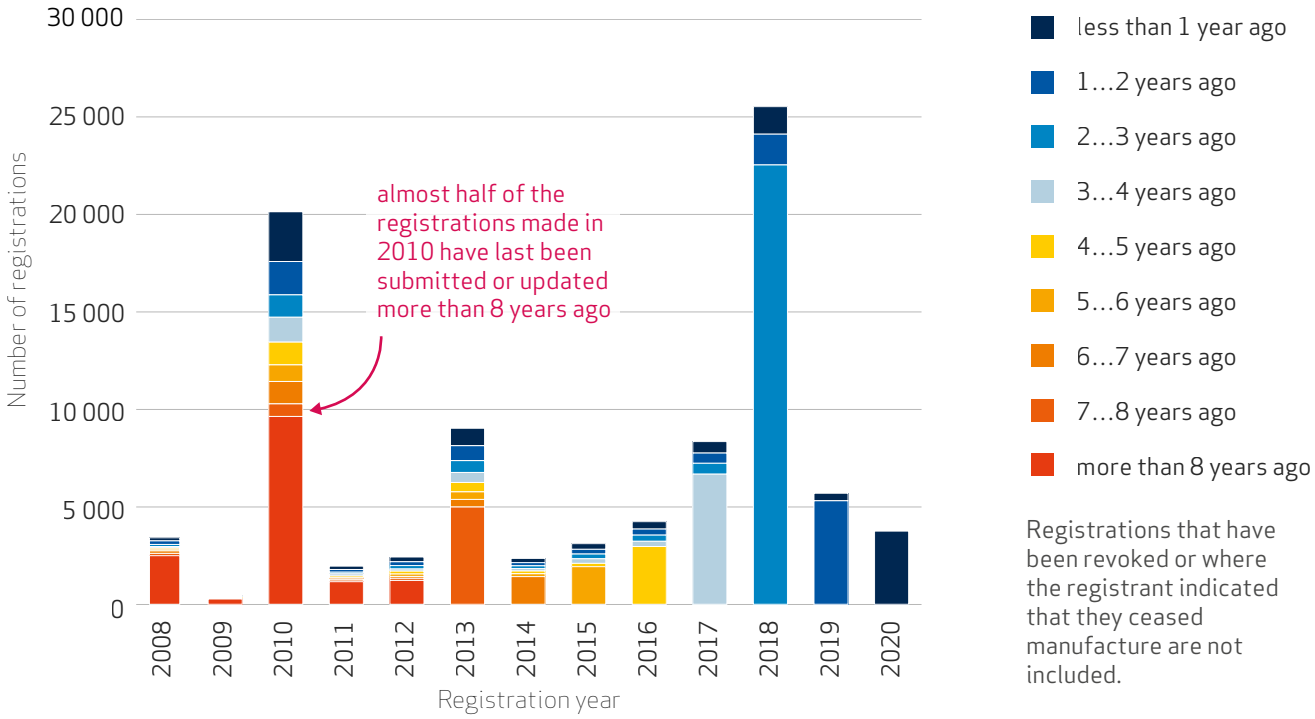
61 For example, A-010-2017, *REACH & Colours and REACH & Colours Italia*, Decision of the Board of Appeal of 15 April 2019; and A-014-2018 to A-021-2018, *Tecnofluid*, Decision of the Board of Appeal of 23 July 2020

stopping the clock in data-sharing disputes while evidence and proof of payment are awaited, benefitting the interests of the parties to the dispute.

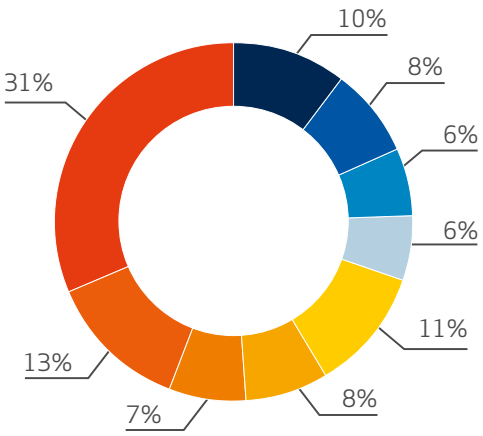
Updating and improving registrations

REACH establishes the obligation for companies to keep their registration up to date. There are currently around 95 000 active registrations to which the obligation to keep the dossier up to date applies (a registration is considered inactive when it has been revoked, or when the registrant indicated that they have ceased manufacture or import).

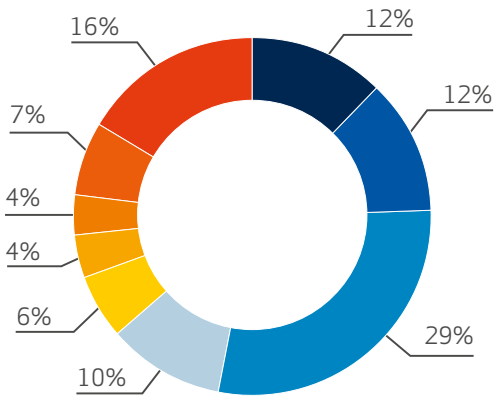
FIGURE 21: Time since last update or submission of registration dossiers



Of the registrations initially submitted more than 4 years ago (i.e. during 2008-2016), 70% have not been updated in the last 4 years (orange colours), and 31% have not been updated in the last 8 years



Overall, 37% of registrations have not been updated in more than 4 years (orange colours). 63% of registrations were submitted or updated in the last 4 years (blue colours), mostly in the context of the 2018 deadline



Each year, around 10 000 registrations are updated – this is around 10 % of the total number of registrations. The reasons for updating the registrations are declared by registrants by selecting from a picklist. In October 2020, ECHA expanded the picklist of update reasons to start collecting more detailed information on the changes made, and if these changes concern the jointly submitted data or the registrant's own data.

When changes occur in items that impact the safety assessment, such as increases in tonnage, new uses, new knowledge on hazards or risks, companies should update their chemical safety assessment and their registrations and propagate this updated information in the safety data sheet. This has been clarified by the European Commission and ECHA's Board of Appeal[62].

Most events that would require registrants to update their registrations are only known to the companies themselves, so ECHA is not in a position to determine if more updates should have happened. However, in a project coordinated by ECHA's Forum[63] in 2019, Member State inspectors probed whether companies have internal provisions in place to detect if their volumes exceed the registered tonnage band or if new uses are alerted in their supply chain, so an update of the registration can be prepared. Inspectors found that 55 % of inspected companies did not have systems in place to ensure dossier updates. 18 % of companies were found to be in breach of the obligation to update their registration.

ECHA finds that only a limited number of chemical safety reports (CSRs) in the registration dossiers have been updated, which raises concerns over whether new or adapted uses, or new hazard information has been reflected in the CSRs. Further analysis could establish if these updates concerned administrative changes or an actual review and update of the safety information.

To increase the update frequency within the current legal framework, the Commission published an Implementing Regulation on 12 October 2020, which clarifies the meaning of updating 'without undue delay', with specific timelines for each item that needs to be updated[64]. This implementing regulation is the result of the previous REACH review, and its impact on dossier updates is expected to become visible in the next years.

One issue that seems to hamper updates of the jointly submitted information for some substances, is that some co-registrants (and occasionally the lead registrant) do not contribute to the costs of dossier maintenance or newly generated data, leaving the costs to be borne by others. Registration numbers 'for life' do not incentivise registrants to update.

Registration of nanoforms

As of 1 January 2020, the updated REACH information requirements for nanoforms of substances started to apply[65]. After this date, companies must have a registration compliant with these requirements to manufacture or import nanoforms of substances that fall within the scope of REACH. Despite ECHA's efforts during 2019 to raise awareness among potential registrants of nanoforms and provide extensive support to ensure a successful registration, low numbers of updates were received.

By 1 January 2020, ECHA had received 86 registrations for 34 substances covering nanoforms. By the end of 2020, the numbers had increased to 190 registrations for 68 substances. The estimated number of substances with nanoforms on the EU market subject to the registration obligation is three- to five-fold this number[66]. Capacity issues in the testing laboratories, challenges to agree within the joint submissions and a lack of

62 A-001-2019, Solvay Fluor, Decision of the Board of Appeal of 21 October 2020, paragraph 71

63 https://echa.europa.eu/documents/10162/13577/project_report_ref-7_en.pdf

64 https://eur-lex.europa.eu/eli/reg_impl/2020/1435/oj

65 https://echa.europa.eu/-/get-ready-for-new-reach-requirements-for-nanomaterials

66 334 unique substances are estimated to be occurring in nanoforms: https://euon.echa.europa.eu/search-for-nanomaterials

clarity on test methods and guidance were some difficulties industry representatives identified as hurdles to registration. ECHA had published a list of recommended methods to compensate the lack of validated methods[67]. Nevertheless, the availability of specific (eco)toxicological data and safety assessments of nanoforms of substances supplied on the EU market remains limited. Five testing proposals on the nanoforms of substances have been submitted.

Updating and improving C&L notifications

The Classification and Labelling (C&L) Inventory, containing information on around 180 000 substances self-classified by companies and all substances with a harmonised classification and labelling, is freely available and heavily consulted, with 14 000 page views per day. It supplements the classification and labelling information that downstream users receive from their suppliers through the safety data sheets (SDSs).

During 2016-2020, 16 000 notifications were updated from the five million notifications received in 2010. There is still divergence in the self-classifications for many substances, despite the obligation on notifiers and registrants to make every effort to agree. To remedy difficulties of notifiers in identifying and contacting each other, it was agreed to publish the names of notifiers when redesigning the C&L Inventory[68].

First compliance date for poison centre notifications

Under Article 45 of CLP, companies placing hazardous mixtures on the market must provide information on the mixtures to relevant national appointed bodies. The national appointed bodies are then responsible for making this information available to poison centres so they can advise citizens or medical personnel in the event of an emergency. In 2017, CLP was amended, introducing Annex VIII on harmonised requirements for poison centre notifications, including a unique formula identifier. ECHA prepared the harmonised format and a central submission portal so companies can submit their notifications to relevant appointed bodies in one place.

The duty to notify hazardous mixtures in the harmonised format began on 1 January 2021 for consumer and professional uses and will apply to industrial uses on 1 January 2024. As of January 2021, ECHA had already received 350 000 notifications with information on hazardous mixtures, that were made available to appointed bodies and poison centres, and the numbers continue to increase steadily.

3.2 Screening and prioritisation

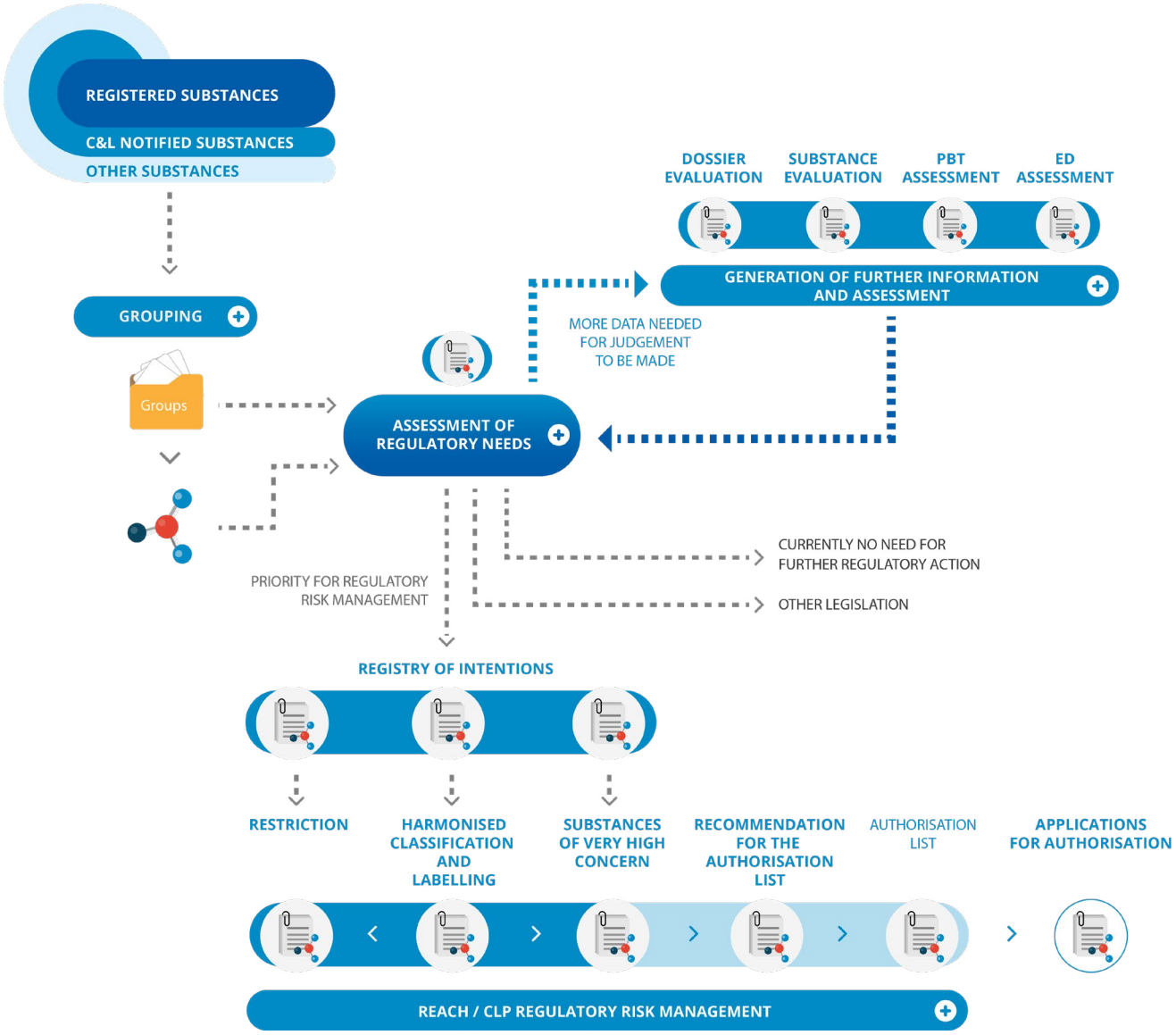
Integrated Regulatory Strategy

ECHA's Integrated Regulatory Strategy provides a coherent basis for close collaboration between ECHA, Member States and the European Commission to address substances of concern. The strategy aims to accelerate data generation, the identification of groups of substances of concern, and regulatory action on them. It strives to ensure appropriate and timely intervention by authorities and industry, to provide confidence among stakeholders that registrants meet REACH information requirements, and to promote improved communication on safe use in the supply chain.

67 https://echa.europa.eu/-/updated-guidance-for-registering-substances-in-nanoform

68 https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/23140aa9-f8eb-46e7-8031-400ce3f445af/details

FIGURE 22: ECHA's Integrated Regulatory Strategy



The annual Integrated Regulatory Strategy reports[69] provide details on the outcomes of the different steps in the strategy.

Grouping and screening

Since 2014, ECHA and Member States have systematically screened the hazard, use and exposure information that companies have provided on registered substances to identify substances of concern and address them with the most appropriate regulatory actions.

Since 2019, authorities shifted to assessing groups of chemically related substances and subsequently addressing groups, where possible. Grouping allows authorities to use all of the available data and cover a bigger share of registered substances, including those lacking hazard and exposure information – increasing the efficiency and effectiveness of regulatory action. This approach also improves regulatory consistency when addressing similar substances and increases the predictability of authorities' actions. It also supports industry in moving towards better-informed substitution, by considering potential substitutes for substances of concern.

69 https://echa.europa.eu/report-archive-specific-reports?panel=irs-reports#irs-reports

FIGURE 23: Number of substances screened in 2014-2018 and assessed through group assessment in 2019-2020

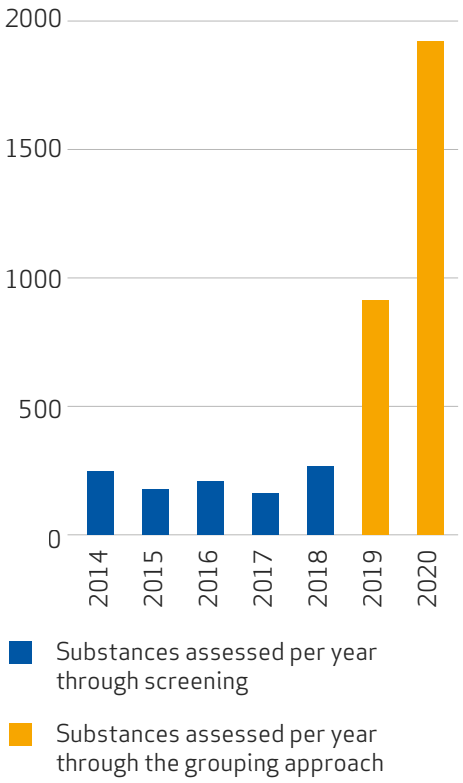
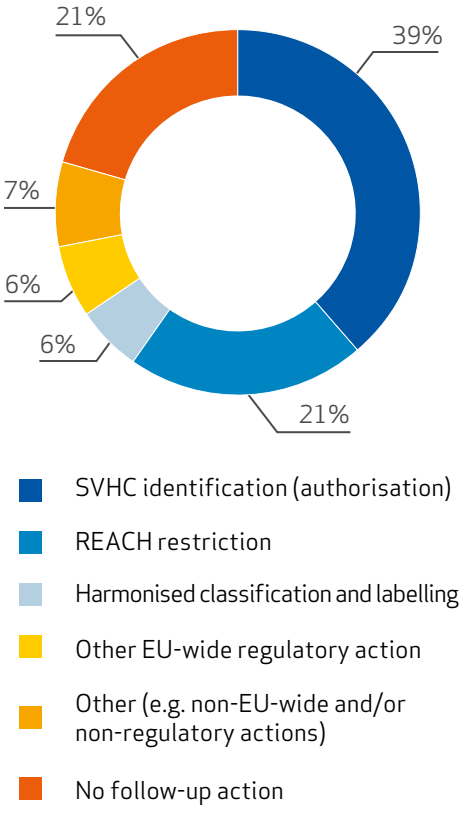


FIGURE 24: Follow-up regulatory actions proposed in concluded RMOAs during 2013-2020



The grouping approach has increased the number of substances assessed in the years following its implementation. Consequently, it speeds up the identification of which substances require further action and which do not.

As of 2019, ECHA and Member States have agreed that ECHA would perform most of the group assessments – and also expanded the scope and depth into an assessment of regulatory needs – allowing Member States to focus on regulatory risk management actions on substances of concern identified during the screening.

Assessment of regulatory needs is an iterative process, done under different processes of the Integrated Regulatory Strategy, aiming to shorten the time from the identification of a concern until the necessary measures are in place or the concern is refuted. In straightforward cases, regulatory action can be initiated based on the first assessment, while in more complex cases, the assessment may need to be revisited and strengthened under subsequent regulatory processes that are part of the strategy.

As an example of a more complex case, ECHA assesses a group of substances based on the information provided in the registration dossiers, considering any ongoing and past regulatory actions. ECHA revises the group assessment as necessary, for example, once new information has become available from a compliance check. This revised group assessment could then be picked up by a Member State and used as a basis for justifying substance evaluation or for further elaborating the need for regulatory actions in a regulatory management option analysis (RMOA). The RMOA can subsequently form the basis for relevant parts of a restriction proposal.

By the end of 2020, Member States had concluded RMOAs covering around 220 substances to identify the most appropriate way to address the identified concern. Further details on the type of conclusions drawn are presented in Figure 24.

The chemical universe

The progress with ECHA's screening work can be monitored through the chemical universe, which is a mapping tool of all registered substances under REACH, in which each substance is assigned to a pool that indicates the regulatory actions already started or under consideration for that substance.

The chemical universe currently comprises over 23 000 registered substances (including intermediates). Based on available knowledge, substances have been allocated into one of the following pools:

1. **Regulatory risk management ongoing:** substances with confirmed hazards for human health and the environment.

2. **Regulatory risk management under consideration:** substances that are currently being considered for regulatory risk management.

3. **Data generation:** substances that require additional information to conclude whether further regulatory action is needed.

4. **Currently no further actions proposed:** substances for which authorities have not proposed further regulatory action at the moment.

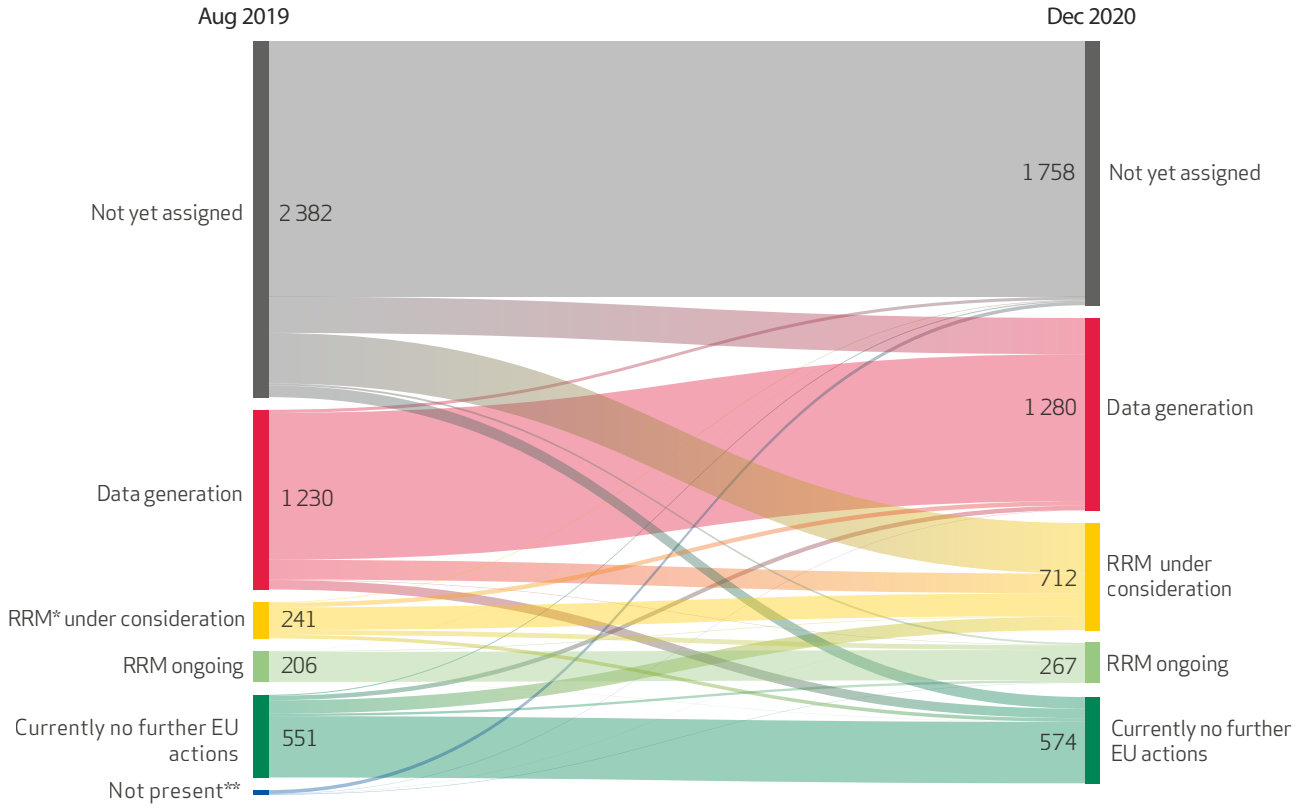
5. **Not yet assigned:** substances currently registered under REACH but not yet assigned to any of the other pools.

The main source of information for the chemical universe are ECHA's REACH and CLP databases, which contain information from the registration and notification processes as well as the ongoing, planned and completed regulatory actions and the outcomes of these actions.

To make sure that the mapping is based on comprehensive information of all substances, sources in addition to REACH and CLP, such as biocides and plant protection products, and persistent organic pollutants (POPs), are also taken into consideration.

Additional details about the planned regulatory actions, i.e. the basis of the pool assignments, can be seen in the public activities coordination tool (PACT).

FIGURE 25: 2019-2020 evolution of the chemical universe of registered substances > 100 tonnes per year



* RRM: regulatory risk management

** Not present refers to substances that had not been registered in 2019

PBT and endocrine disruptor assessment

To address complex questions on hazard assessment and develop common views between ECHA, Member States, stakeholders and the Commission, **expert groups** were established. There are currently two expert groups: on persistence, bioaccumulation and toxicity (**PBT**) and on endocrine disruptors (**ED**), which support decision making and opinion forming on suspected PBT or ED substances and help to identify substances that do not meet the PBT or ED criteria.

During 2016-2020, the expert groups gave over 170 opinions[70] on PBT properties and 95 opinions on ED properties of substances[71].

Expert group consultation has proven to be efficient and enable consistency. This is particularly the case when identifying PBT or ED substances, agreeing on testing strategies to identify them and interpreting study results. The added consistency has reduced the likelihood of legal challenges later in the formal steps of the processes. The great majority of expert group conclusions (over 80 % in general, up to 100 % in cases related to identification of substances of very high concern (SVHCs)) were followed by the committees.

Improvement initiatives by sector associations in collaboration with ECHA

In the last five years, additional data-generation initiatives have been implemented under the umbrella of voluntary agreements of industry sectors with the support of ECHA.

In 2019, the **European Chemical Industry Council** (Cefic) launched a voluntary multi-annual **action plan** for reviewing and improving REACH registrations[72]. ECHA supported this action plan, which aims to get dossiers compliant in a quicker and more effective manner, by building a framework for companies that propose testing strategies for their (groups of) substances. Four cooperative pilot projects under the plan ran from December 2019 until October 2020, with ECHA and a small set of companies working together to pinpoint improvements for a prioritised group of substances.

The participating registrants committed to bring forward the (revised) strategies and testing proposals for formal examination. The general lessons learned from these pilot studies[73] are expected to be applied to future testing strategies in 2021 and the coming years.

The **metals and inorganics sectoral approach** (MISA) is a voluntary programme set up by Eurometaux – the European non-ferrous metals association – and ECHA. The programme aims to address technical and scientific issues faced by the metals and inorganics sectors and to update and improve the registration dossiers in these sectors. 28 consortia, covering about 340 substances, signed the cooperation agreement.

During 2018-2020, issues in hazard and risk assessment were addressed for human health, environment, substances of unknown or variable composition (UVCBs), environmental classification and exposure, resulting in additional guidelines and a commitment of the participating consortia to update their registration dossiers accordingly. A majority of the updates under MISA improved the adaptations to the standard information requirements used in the registrations, generation of new data occurs much less. While for instance read-across is in general justified for data rich metal compounds, more testing would still seem to be needed for the group of data-poor substances.

70 The expert group opinions are informal advice given to Member States assessing a substance and generally consist of advice on substance persistent, bioaccumulative and toxic (PBT) or endocrine-disrupting (ED) properties and/or testing strategies or information needs.

71 These numbers also include some substances discussed in the context of the Biocidal Products Regulation and the Persistent Organic Pollutants Regulation.

72 https://echa.europa.eu/echa-cefic-collaboration-on-dossier-compliance

73 https://cefic.org/app/uploads/2021/04/CEFIC-REACH-IMPLEMENTATION-ACTION-PLAN-Report-April-2021.pdf

In 2015, the **Petroleum and Coal stream Substances** (PetCo) Working Group was established to develop an approach to identifying and addressing PetCo substances. In 2017, the group developed an approach to prioritise and address petroleum and coal stream UVCB substances for further work under the SVHC Roadmap and implementing REACH risk management measures. As a result of the group's work, testing proposals for human health endpoints were submitted for around 120 PetCo substances. These are being examined by ECHA and will support improvements to the registrations of those substances. Currently, the group is developing a strategy to evaluate environmental properties of these complex substances. In parallel, work by authorities to understand which regulatory risk management would be needed to address PetCo substances has progressed and this will, in general, also support the regulation of substances containing constituents of concern.

3.3 Evaluation

Dossier and substance evaluation are essential parts of the Integrated Regulatory Strategy to generate data on substances when the available information is insufficient for making decisions on the need for further risk management at EU level.

Dossier evaluation

Under **compliance check**, currently, priority is given to substances produced in volumes over 100 tonnes per year per manufacturer or importer, and those substances posing a potential concern that may require substance evaluation or regulatory risk management measures by authorities. The focus in evaluation is the information which is relevant to identify SVHCs.

In its second report on the operation of REACH (2018)[73], the European Commission concluded that despite steady progress in implementing the legislation, there were key issues that hampered progress, notably the non-compliance of registration dossiers. This is in line with ECHA's findings throughout 10 years of performing compliance checks and is also confirmed by studies conducted by the German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA)[74] on dossiers submitted for substances in the highest tonnage bands.

Based on these findings, ECHA and the Commission developed the REACH **Evaluation Joint Action Plan**[75] in 2019, outlining 15 actions to increase the efficiency of evaluation. One key recommendation was to increase the minimum number of dossiers ECHA checks for compliance. As a result, the Commission Regulation (EU) 2020/507 **increased the legal requirement for ECHA to check the compliance** of registration dossiers from 5 % to 20 % in each tonnage band.

Further recommendations of the action plan include clarifying some of the information requirements stipulated in REACH annexes, and increasing the efficiency of dossier and substance evaluation by applying both evaluation processes in parallel if needed, but also through enhanced cooperation with the Member State authorities. The plan requires accelerated decision making, increased enforcement efforts, interaction with industry associations to ensure registrants step up their compliance efforts, and the establishment of a transparent and publicly available monitoring system on the progress made.

74 https://ec.europa.eu/commission/presscorner/detail/en/IP_18_1362

75 https://echa.europa.eu/-/data-on-chemicals-needs-to-be-improved

76 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

In the past five years ECHA, has significantly **increased the number of compliance checks**, from approximately 160 substances checked in 2016 to approximately 260 substances checked in 2020.[77] Since most of the data for a substance is submitted jointly by the co registrants of that substance, compliance checks impact many registrants. In 2020, for example, the compliance checks covered more than 2 000 co-registrant dossiers.

FIGURE 26: Substances and registrations checked for compliance at the end of 2020

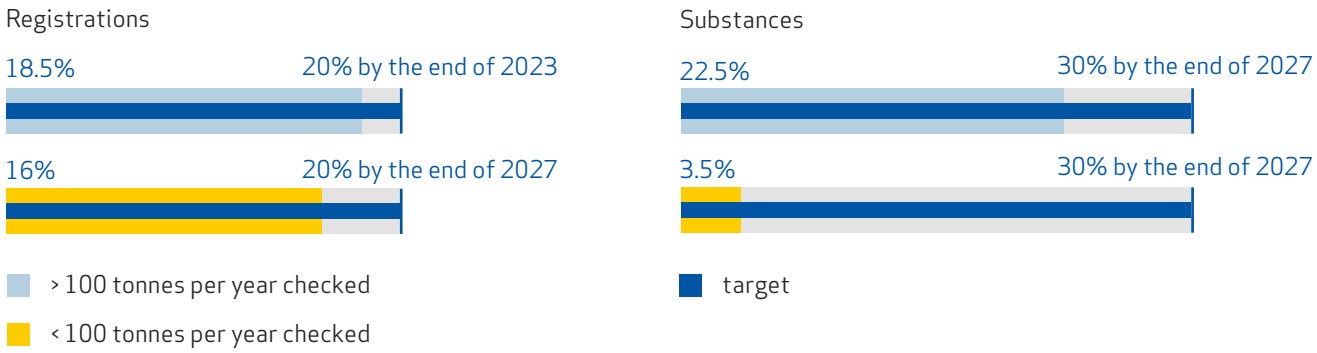
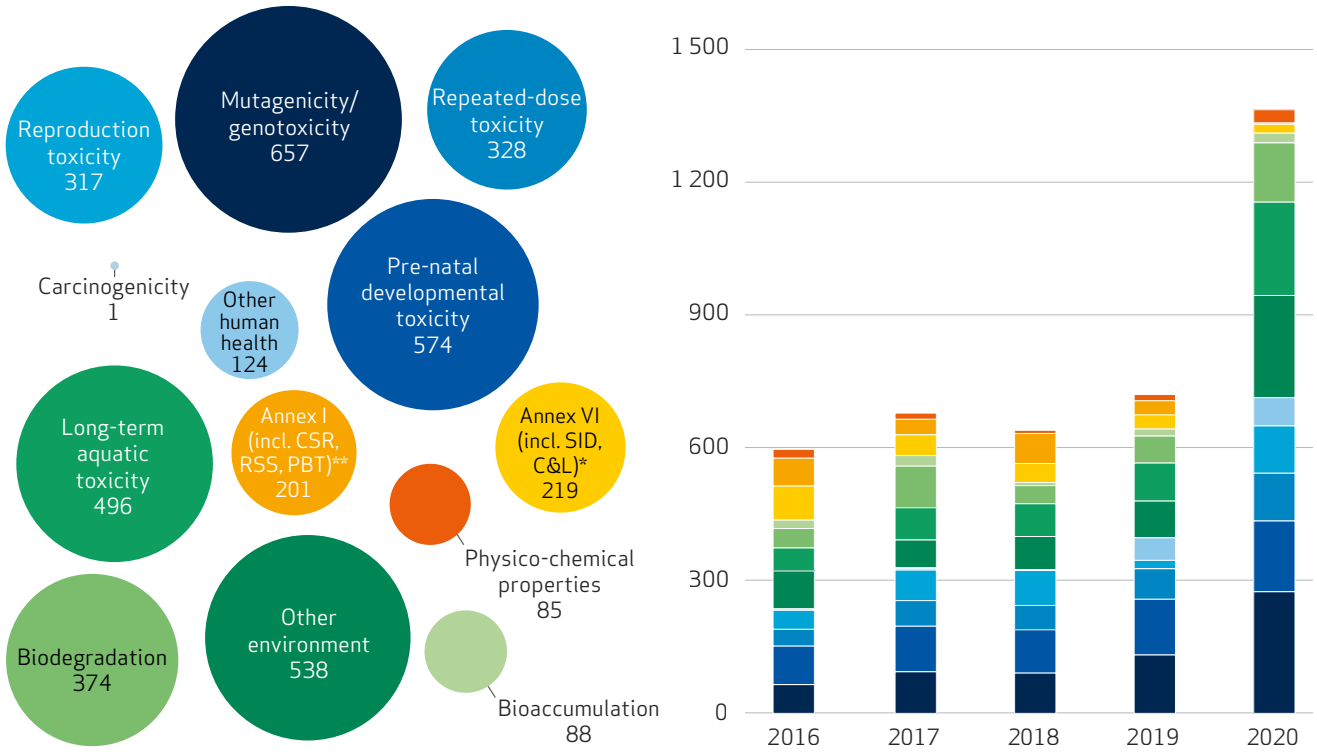


FIGURE 27: Information requested under compliance check during 2016-2020



* SID: substance identification; C&L: classification and labelling

** CSR: chemical safety report; RSS: robust study summary; PBT: persistent, bioaccumulative and toxic

As part of dossier evaluation, ECHA also examined 1 092 **testing proposals** for Annex IX and X studies, and issued 550 draft decisions during 2016-2020. These cover 503 substances, either registered by the 2018 registration deadline or substances for which a 180-day deadline to examine the testing proposal applies (approximately 100 per year).

The increased number of dossier evaluation decisions has been achieved because of ECHA's continuous development and **streamlining of the dossier evaluation process** by (i) focusing the resources where they are used most effectively and efficiently, (ii) developing standard scenarios to address the most commonly occurring

77 Yearly progress in evaluation: https://echa.europa.eu/overall-progress-in-evaluation

incompliances, (iii) not considering dossier updates during the formal evaluation decision-making processes[78] and (iv) strengthening cooperation with Member State authorities to reduce the number of amendments proposed and allow decisions to be adopted at a faster pace.

In addition, ECHA has proposed several clarifications regarding information requirements and general adaptation possibilities, based on experience gained through the evaluation and appeals processes.

Such developments have led to faster assessment of the dossiers and clearer dossier evaluation decisions, reducing the need to clarify the contents of the decisions in later steps of the process. The percentage of proposals for amendment on dossier evaluation draft decisions by the Member States has dropped from 40-46 % in 2016-2017 to 6 % in 2020. Consequently, ECHA more often formally adopts dossier evaluation decisions without referring the decision to the Member State Committee.

Although efficiency has improved, further changes could be envisaged to speed up the decision making under compliance check and enable ECHA to increase the throughput.

A matter still significantly impacting the time it takes to make decisions requesting data generation, is the broad scope of the **comments submitted by registrants** when their read-across or category approaches are rejected in the draft decision. Despite ECHA's justifications for rejecting the adaptation of the standard information requirements and the request to provide test data, registrants most often provide renewed adaptation strategies in their comments, usually without new data. In other cases, registrants propose elaborate testing strategies to fill the data gaps. However, this information is not new, should have been in the dossier already, and the request to provide test data stays in the decision. Overall, extensive comments not addressing ECHA's assessment are submitted in 80 % of cases.

Reviewing a new read-across or testing strategy requires similar time from the assessors as the initial assessment. On a yearly basis, about 60-65 % of the time is dedicated to new assessments while the remaining is spent on replying to comments and justifying why the information provided does not address the incompliance.

Another matter is the involvement of **multiple authorities**. Considering the maturity of the process achieved in recent years, Member States' capacities could be otherwise utilised for further regulatory processes, and requests for data generation could be sped up if ECHA were the only authority involved. Any policy-related or scientific questions requiring alignment across authorities could be resolved through increased collaboration between ECHA and the Member States, and discussed and agreed in the Member State Committee (MSC). In addition, decision making could be sped up if the discussions on individual evaluation cases in the MSC did not need to try to reach unanimous agreement.

The acceptance of ECHA's dossier evaluation decisions has been high in 2016-2020 as only 2 % of them have been challenged with the Board of Appeal. Moreover, the Board of Appeal has stressed that it is the responsibility of registrants to submit a fully compliant dossier, so that ECHA is not normally required to consider anything other than whether the information contained in a registration dossier satisfies the relevant information requirements[79]. This has simplified compliance checks by focusing the amount of scientific analysis that is required for each case.

Similarly, the Board of Appeal has taken a number of decisions clarifying the requirements for adaptations with

78 The formal decision-making covers Articles 50(1) and 51 of REACH. As of 2019, ECHA does not take into account any changes made to the registration after the notification of the draft decision under Article 50(1).

79 For example, A-005-2014, *Akzo Nobel Industrial Chemicals*, Decision of the Board of Appeal of 23 September 2015, para. 76 and A-011-2018, *Clariant Plastics and Coatings (Deutschland)*, Decision of the Board of Appeal of 4 May 2020, para. 49 *et seq.*

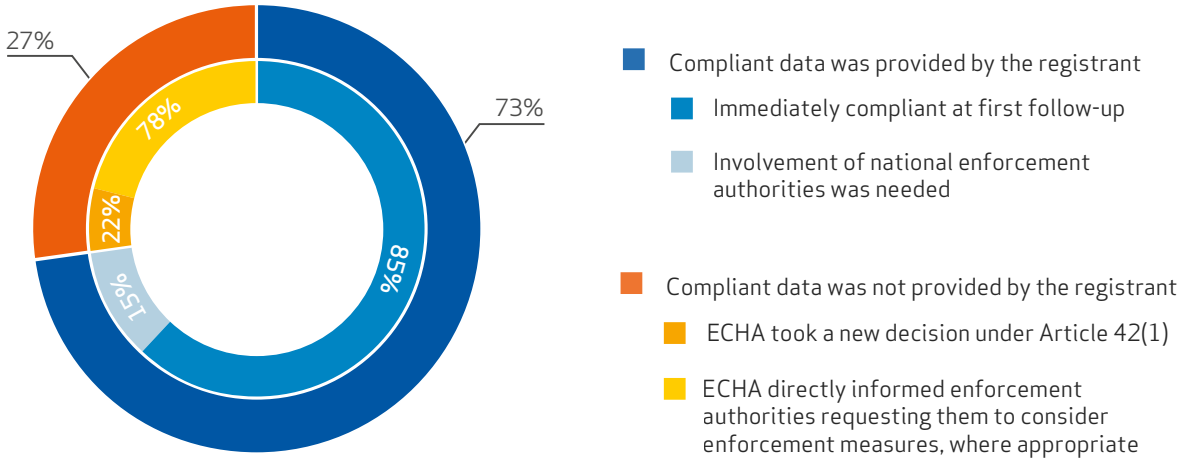
a view to simplifying the assessment and clarifying the applicable rules for all the parties involved in registration and compliance check. Notable examples are the interpretation of the requirements for weight-of-evidence adaptations, and the information requirements for aquatic toxicity testing under Section 9.1. of Annex IX. [80]

A specific controversy has been the generation of information under REACH for **substances used as ingredients in cosmetic products**. The REACH provisions may require registrants of such substances to perform vertebrate animal tests, while the Cosmetics Regulation[81] imposes restrictions on such tests. ECHA has clarified that tests carried out to comply with REACH do not fall under the scope of the restrictions on vertebrate animal testing in the Cosmetics Regulation[82]. Tests on vertebrate animals can be required under REACH for ingredients in cosmetic products for certain endpoints and under certain circumstances, to protect workers or the environment. Such tests do not lead to a marketing ban under the Cosmetics Regulation if the ingredient can be shown to be safe using data not generated by animal testing. But if data generated under REACH show that a cosmetic ingredient may not be safe, then this information should be considered when the ingredient is being assessed.

Another challenge has been related to the information requirements on reproductive toxicity (Annex IX/X, Section 8.7.3, Column 2). The conditions to include the developmental neurotoxicity and/or developmental immunotoxicity cohorts in the **extended one-generation reproductive toxicity study** (EOGRTS) design have been extensively debated by ECHA's Member State Committee. These cohorts must be included if there is a particular concern for these endpoints, based on available data. However, interpretations on how to establish the concern vary, which has led to different opinions on when they should be included in the EOGRTS. This issue, which can delay the decision-making processes, could be clarified in the corresponding REACH annexes.

Due to the time needed for testing, the result of increasing the numbers of data requests is only seen multiple years later. Still, the last five years have seen an **acceleration in data generated** and submitted to ECHA under dossier evaluation. During 2016-2020, ECHA concluded the dossier evaluation of 1 031 substances, which represents a 30 % increase compared to the previous reporting period[83]. Figure 28 gives an overview of the results.

FIGURE 28: Degree of compliance after dossier evaluation follow-up



80 A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, Decision of the Board of Appeal of 4 May 2020.

81 https://eur-lex.europa.eu/eli/reg/2009/1223/oj

82 https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf; see also cases A-009-2018 and A-010-2018, *Symrise*, Decisions of the Board of Appeal of 18 August 2020. Challenged before the General Court in T-655/20 and T-656/20.

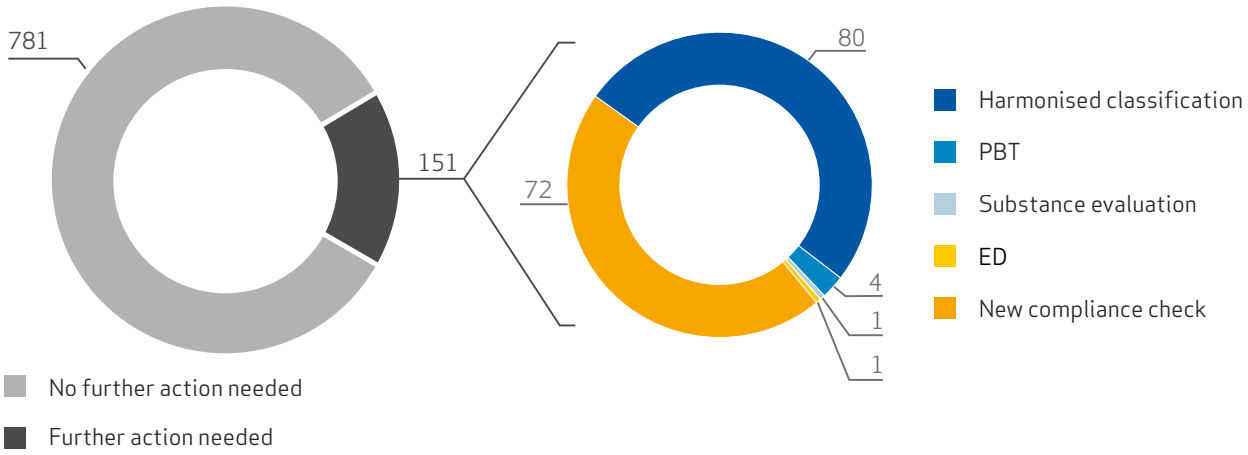
83 The 30 % value has been obtained by applying the relevant corrections to account for the different length of the time intervals (2012-2015 and 2016-2020). The first period is counted as of 2012, because that is the first year when an ECHA decision reached the follow-up stage (first dossier evaluation decisions issued in 2011).

A more detailed breakdown of this information is available in the Annual Evaluation Progress Reports (until 2017), and the Integrated Regulatory Strategy reports (2018-2020).

In a number of cases, registrants provide **dossier updates during the evaluation**, including in the follow-up stage, where they remove uses, downgrade the tonnage band or cease manufacture. Clarifying how such updates should be considered (or not) during the different process steps and how such updates affect the obligation to provide the requested information would contribute to streamlining the process, and may also facilitate the enforcement actions by the Member States where necessary.

Of the substances for which ECHA concluded that the data provided was compliant with the ECHA decisions, four out of five substances did not raise further concern (low hazard) and one out of five was considered as a suitable candidate for further regulatory risk management.

FIGURE 29: Outcomes for substances from concluded dossier evaluation follow up (2016-2020) towards subsequent risk management measures[84]



The two main types of further action proposed to address the concerns are further data generation (a subsequent compliance check) and further risk management measures, such as a harmonised classification of the substance, as a result of the newly generated information.

For 41 substances (corresponding to 78 requests evaluated at follow up), the registrants have updated the self-classification of the substance as a result of the information generated under dossier evaluation.

From the data above, it is concluded that dossier evaluation under REACH is effective in generating new hazard information, and was more efficient in 2016-2020 than in the previous reporting period, although it remains a heavy process. The results from dossier evaluation have a major impact on ECHA's work in mapping the chemical universe, as they support the identification of which substances are of higher or lower concern for further regulatory scrutiny. As the increasing rate of compliance checks and the benefits of grouping start to take effect, the benefit of data generation is expected to grow.

Substance evaluation

Over nine years of substance evaluation (2012-2020), 296 substances have been evaluated. Requests for further information were made for 66 % of substances, while 34 % were concluded without requesting further information[85]. By the end of 2020, 147 evaluations were concluded, out of which 70 resulted in further risk

84 As substances may have been subject to one or more dossier evaluation processes, resulting in potentially multiple outcomes, the number of outcomes exceeds the number of substances requiring further action.

85 The substances that were concluded in 2016-2020 were selected and evaluated before a clear distinction was made between the scopes of compliance check and substance evaluation. The absence of a draft decision meant that the evaluating Member State did not require data to be generated, to clarify the concern or propose further actions.

management measures such as harmonised classification (45), identification of substances of very high concern (11), restrictions (4) or other actions outside the scope of REACH.

FIGURE 30: Outcomes for substances from concluded substance evaluations (2016-2020) towards subsequent risk management measures

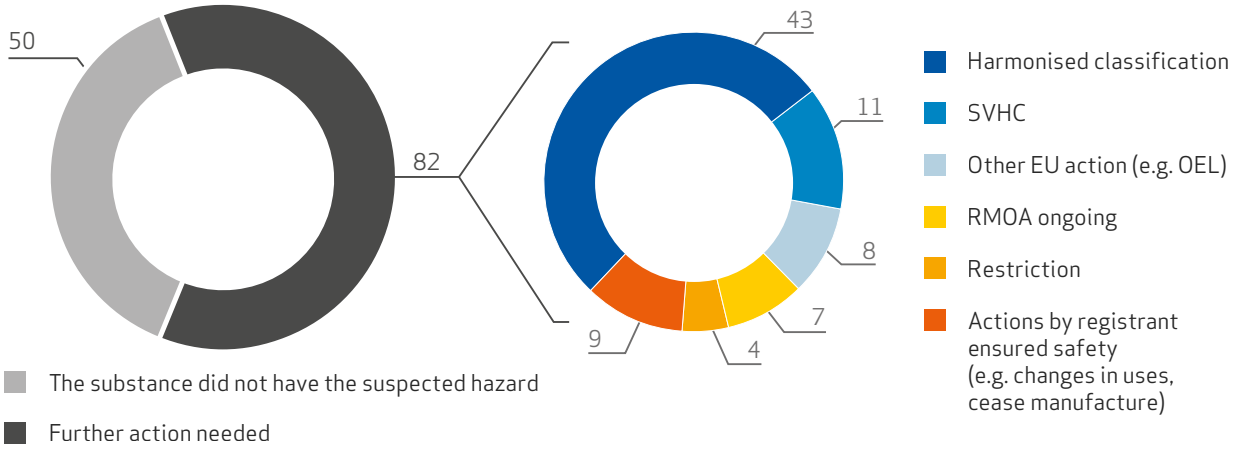
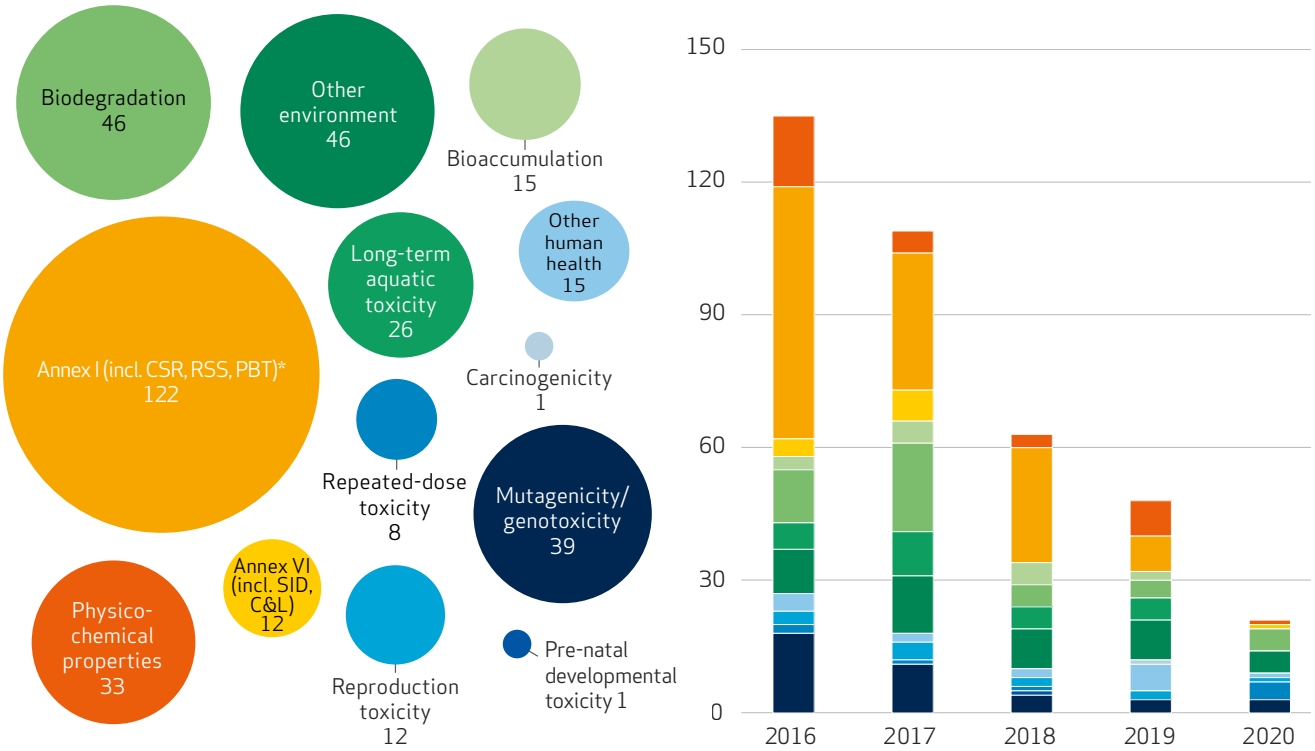


FIGURE 31: Information requested under substance evaluation during 2016-2020



*The majority of requests for Annex I information were related to additional information on exposure.

Between 2016 and 2020, ECHA adopted 115 substance evaluation decisions, including a total of 379 requests for further information, of which 169 were requests to clarify a potential concern on persistent, bioaccumulative and toxic/very persistent, very bioaccumulative (PBT/vPvB) or carcinogenic, mutagenic and reprotoxic (CMR) properties.

The substance evaluation process has been refined based on the experience gained, both from experts in the Member States and in ECHA, and as a result of the clarifications achieved through litigation. The Board of Appeal has developed a set of criteria and prerequisites to follow throughout the substance evaluation process. These were also confirmed by the EU Courts[86]. For example, to request further information under substance evaluation, ECHA must establish that a substance poses a potential risk ('concern') based on existing information, that the risk needs to be clarified, and that the information required has a realistic possibility of leading to improved risk management measures.

However, the need to define a potential risk places the **burden of proof on authorities** for justifying requests made under substance evaluation.

ECHA finds that for **high tonnage substances**, the standard information requirements are generally sufficient for getting all information relevant for classification and labelling and risk assessment. This information can be requested (faster and "cheaper" from the authorities' perspective) under dossier evaluation and enables risk management measures to be initiated at EU level.

Indeed, looking at the types of information requested under substance evaluation, it can be argued that, in most cases, the **requests could have been made under dossier evaluation**. Since the Board of Appeal ruling, the requests have in fact mostly been made under dossier evaluation, and the concerns could be resolved, significantly reducing the number of information requests under substance evaluation. This is also one of the reasons for concluding 30 % of substance evaluations with no requests for further information needing to be made to propose (or not) further risk management measures at EU level.

While significant efforts have been made over the years to conclude more quickly on the existence of a concern, it still takes significant time (on average 5-9 years) to conclude on a substance evaluation. This is mainly due to delays in decision making (as there are no deadlines to address registrants' comments), litigation[87] and the use of a tiered approach in making requests.

Nonetheless, substance evaluation remains the process that allows requests for information beyond the standard information requirements. Therefore, substance evaluation could be more relevant for **substances in lower tonnages**, where information requirements do not allow to conclude on classification and labelling and risk assessment. However, this remains to be explored, as it will be challenging to justify a potential risk with very limited information on a substance. Arguably, **increasing the information requirements for Annex VII and VIII substances** (on a concern-triggered basis) would potentially be a more effective way to reach the same goals. ECHA is developing a strategy for substances registered in lower tonnages, considering how substances of concern can be identified and addressed.

Therefore, the effectiveness of substance evaluation in its current format and with its current criteria is questionable, and dossier evaluation seems to be more effective for generating further information on hazards.

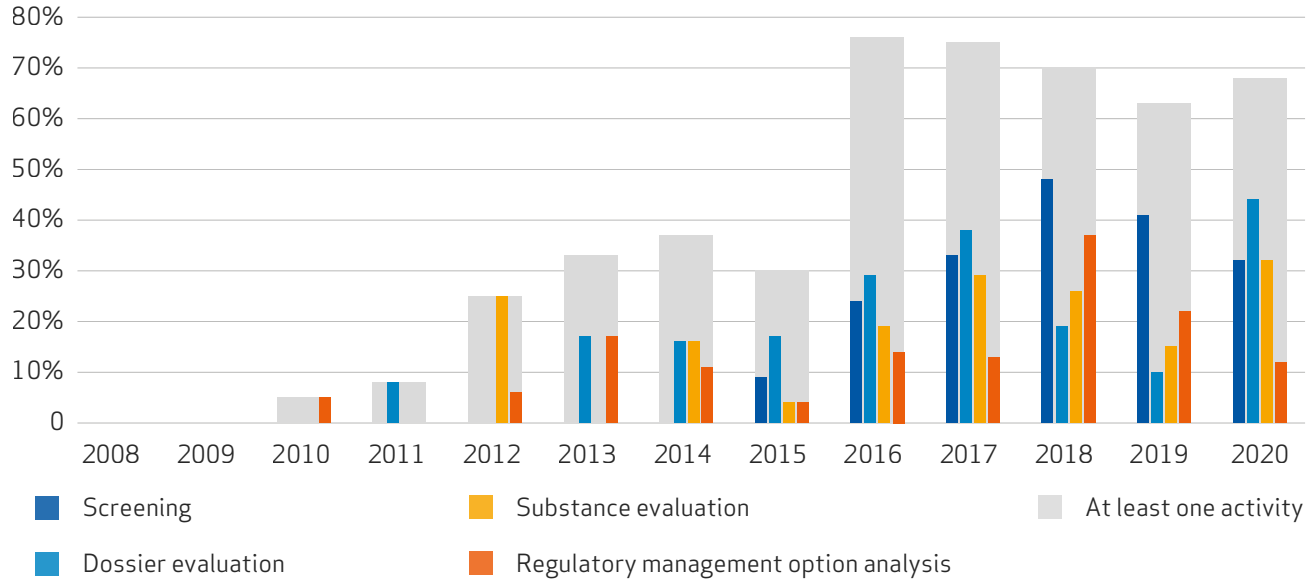
86 For example, A-018-2014, *BASF Grenzach*, Decision of the Board of Appeal of 19 December 2016; confirmed by judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638

87 16 % of substance evaluation decisions have been appealed to the Board of Appeal.

3.4 Harmonised classification and labelling

One of the more visible impacts of the Integrated Regulatory Strategy is on the harmonised classification and labelling (CLH) of substances. More and more substances are being identified – based on screening and also on data received following an evaluation decision – for which CLH is considered the most suitable option for risk management. During the period 2016-2020, an average of 70 % of CLH dossiers resulted from a preceding regulatory activity. This is a significant increase compared to the average of 23 % during the years 2010 2015.

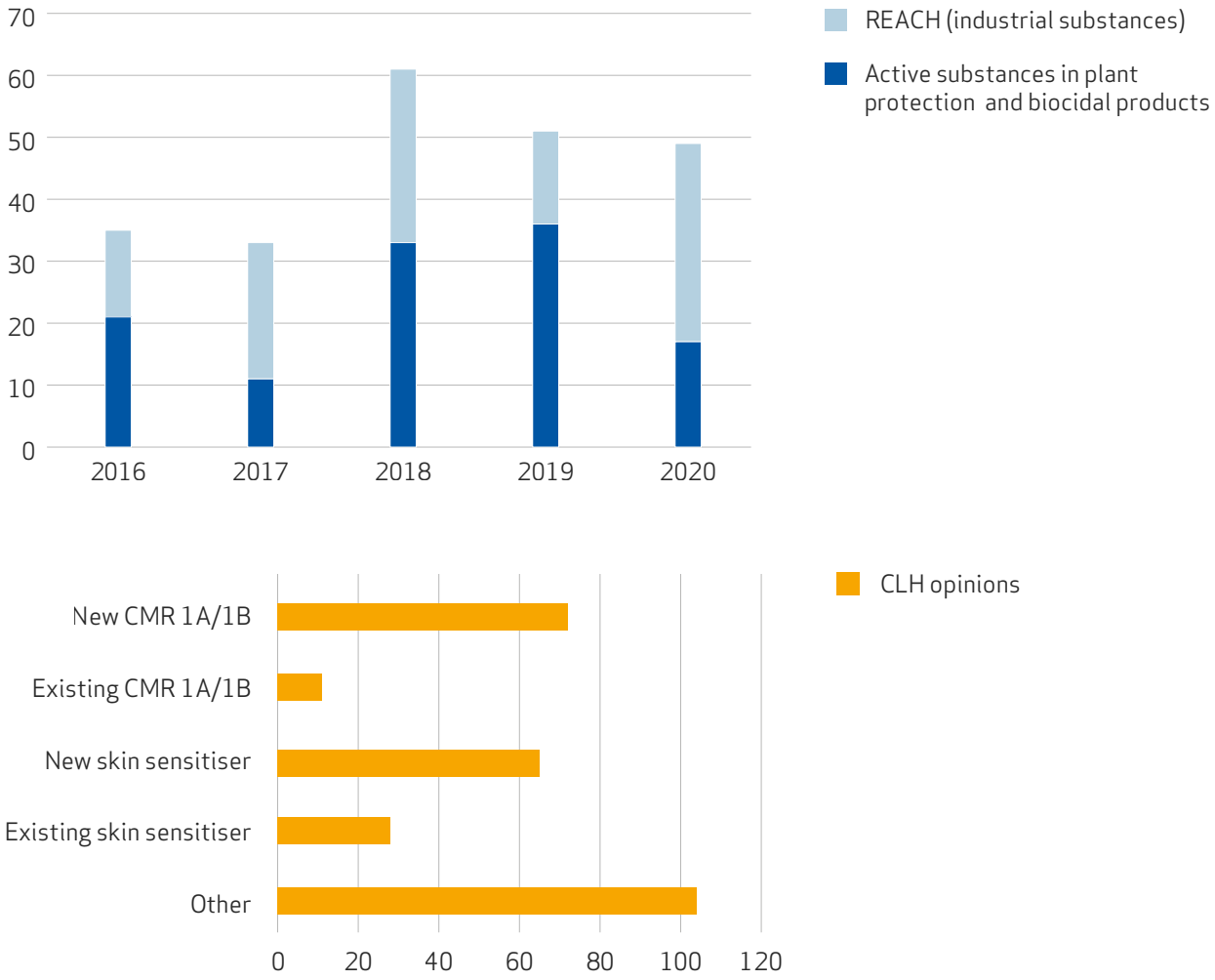
FIGURE 32: Submitted harmonised classification and labelling dossiers with preceding regulatory activity (2008-2020)



Furthermore, the work on groups has enabled authorities to identify recurring issues (for instance, sensitisers in consumer mixtures and the formation of nitrosamines) and consider how substances can be regulated across several groups in an efficient and coherent manner.

At the end of 2020, 110 substances were in the process of being regulated through harmonised classification. However, an even greater number of 125 substances, had been identified through the Integrated Regulatory Strategy as needing harmonised classification, but were not picked up by a Member State. The Registry of Intentions contains another 70 substances for which the Member States intend to initiate CLH. The accumulation of pending harmonised classification candidates demonstrates a bottleneck in the efficient integration of REACH and CLP processes, as CLH is often the prerequisite for moving ahead with Candidate listing and authorisation, or regulatory measures under other EU legislation. Therefore, ECHA welcomes the proposal in the Chemicals Strategy for the Commission to be able to mandate ECHA to prepare dossiers for harmonised classification, which would increase the rate of harmonising classifications, and thereby increase the impact on workers, consumers and the environment.

FIGURE 33: Harmonised classification and labelling opinions adopted by ECHA's Committee for Risk Assessment and the number of substances for which a CMR 1A/1B or sensitiser proposal was included



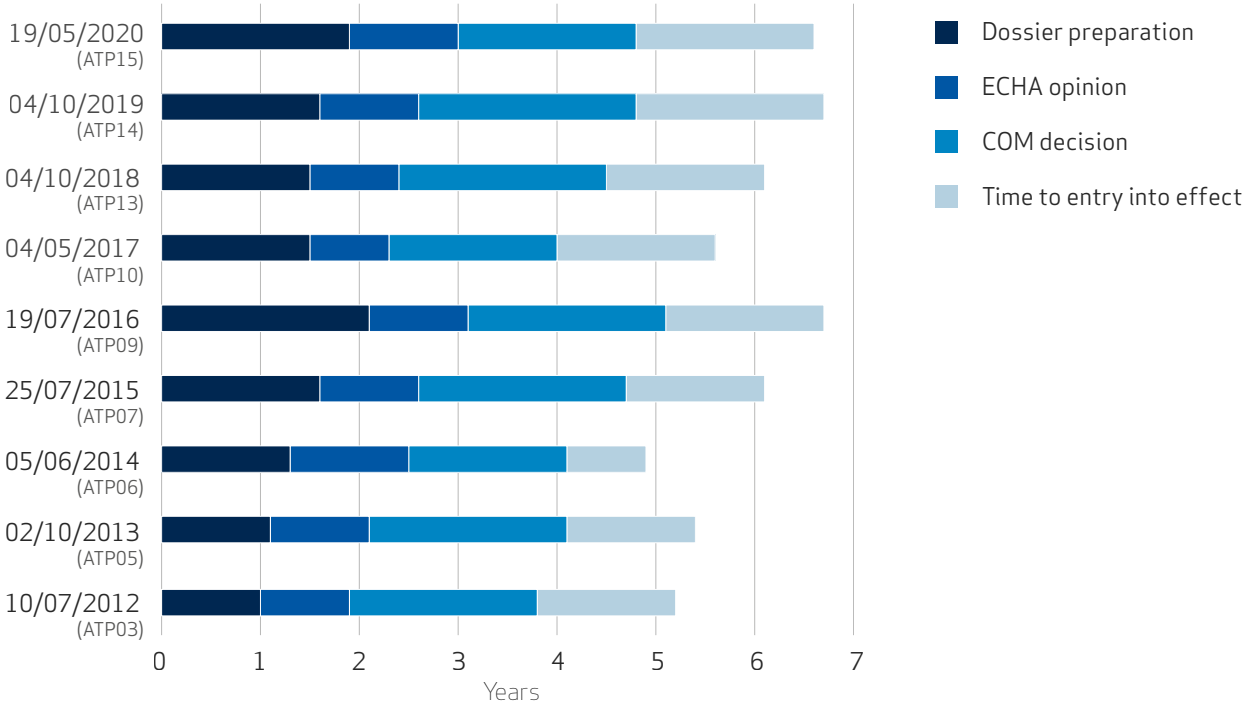
ECHA's opinions continue to provide the European Commission with a solid basis for decision making, with only four[88] legal challenges in 433 opinions adopted since 2009.

Currently, most opinions on harmonised classification concern active substances in biocidal or plant protection products. As presented in Section 2, the benefit of harmonised classification is multiplied through the impact that this has on other legislation. When it comes to the operational link between the harmonised classification process and regulatory processes under other legislation, ECHA has observed that – for biocides and plant protection products legislation – the parallel execution of such processes may lead to the risk of inconsistencies and duplications. Within the overall review of the role of harmonised classification in other legislation, the operational aspects could also be considered, for example, by mandating harmonised classification in advance of Biocical Products Regulation and Plant Protection Product processes, as is already done in several cases, so that the harmonised classification output can be fully utilised for subsequent assessments.

The overall time needed for harmonised classifications to enter into force is presented in Figure 34. The dossier preparation step is highly variable, as listing in the Registry of intentions – which is taken as the starting point – is not mandatory, and is sometimes done when dossier preparation is already quite advanced.

88 https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency/cases-where-echa-is-a-party/clh. One case was upheld, and two cases are still ongoing.

FIGURE 34: Timelines for harmonised classifications (in years) by year of Commission decision



For a number of substances, there are no or insufficient classifications because of a lack of data. As can be seen from Figure 4 and Figure 5, fewer new substances are being classified for mutagenicity and carcinogenicity, compared to reproductive toxicity. As presented in Section 2.1, this reflects the relative focus on information requirements introduced with REACH. The testing for **carcinogenicity** is currently triggered at Annex X and only under certain conditions, however, this could be reviewed, including the conditions, to assess the testing that could be triggered at Annexes IX and VIII. The CLP criteria for **mutagenicity** are under review by a Working Group on Germ Cell Mutagenicity under the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to consider changing the criteria to facilitate classification of category 1B mutagens. Mutagenicity is a strong indication of carcinogenicity in the absence of carcinogenicity data and, therefore, the classification of category 1B mutagens is essential to identify potential carcinogens and prevent the exposure of EU citizens.

3.5 Restrictions

Overall, REACH restrictions are working well. Since 2010, ECHA's scientific committees have processed 36 restriction proposals – 22 prepared by Member States and 14 by ECHA alone or in collaboration with Member States. On 22 of these proposals, the European Commission has taken a decision. These restrictions address different groups of substances, controlling the risks using different types and levels of measures, thereby protecting workers, consumers and the environment. Managing the risks to workers in restrictions is complicated by the separate regimes of Occupational Safety and Health (OSH) and REACH.

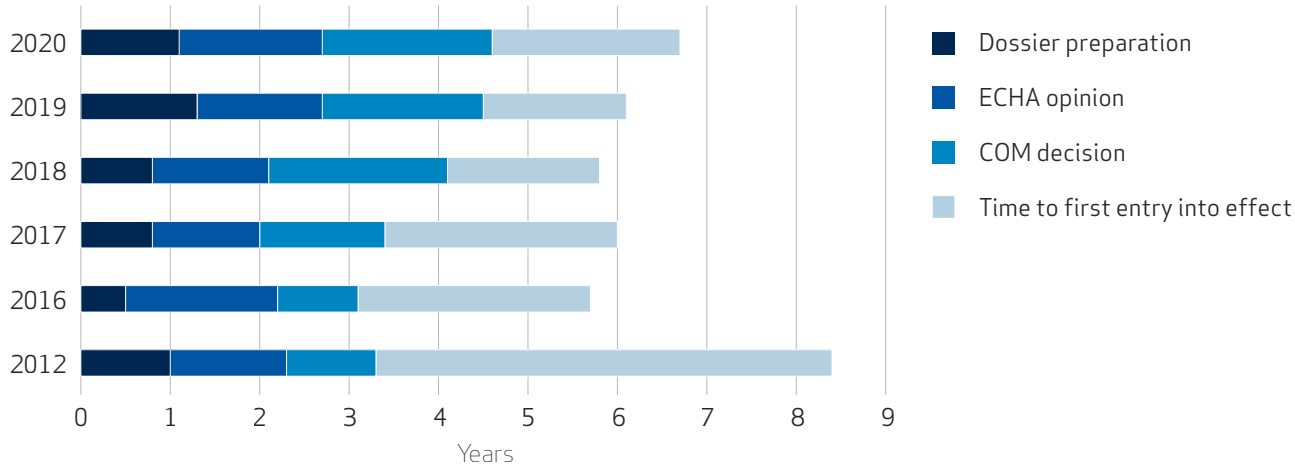
With the systematic assessment of groups of substances, a number of potential candidates for restriction have been found and work is continuing to refine the assessments. This is addressing one of the key questions in the second REACH review on how to find more candidates for restrictions. Processing restrictions for groups of substances also **increases efficiency** per substance (the effort per dossier increases, however, it is distributed across more substances) and **speed** per substance (multiple substances are addressed at the same time in one dossier).

The **participation of Member States** in the preparation of restrictions dossiers and to the functioning of the ECHA committees needs to be encouraged. Member States and European Economic Area (EEA) countries have produced fewer restrictions proposals than originally foreseen, with six countries producing nearly 90 % of these dossiers. As such, the European Commission has made more requests to ECHA to prepare restriction proposals than initially foreseen.

The work of the restriction task force has enabled the restrictions process to become more streamlined, to better be able to deal with higher numbers of restrictions and broader restrictions. In parallel, as can be seen in Figure 8, Figure 9 and Figure 10, the tendency has been to move from single substance restrictions to group restrictions, also including life-cycle aspects, where relevant. Reversal of the burden of proof, as applied for example in the preparations for the restriction on microplastics, putting the responsibility on industry to demonstrate safe uses of the substances, was determined to be a good approach, applicable also to future restrictions.

The increased breadth of restrictions, in moving to groups of substances and broad uses, has increased their impact but has also led to an increase in stakeholder contributions, making the **dossier development and opinion making more resource consuming**.

Figure 35. Timelines for restrictions (in years) by year of Commission decision



3.6 Authorisation

As explained in Section 2, Candidate listing, Authorisation listing and applications for authorisation all contribute to substitution and risk reduction.

During 2016-2020, 43 additional substances or groups of substances were identified as substances of very high concern (SVHCs), bringing the total number of **Candidate List** entries to 211. The goal of the 2020 SVHC Roadmap has been achieved[89], as all currently known carcinogenic, mutagenic and reprotoxic (CMRs), PBT/vPvBs and endocrine disruptors have either been included in the Candidate List, identified for other regulatory risk management measures (e.g. restriction), or considered as not requiring further regulatory risk management action. 11 SVHC identification decisions have been challenged in court[90] during 2016-2020 and, so far, the European Courts have found all of ECHA's SVHC decisions to be sound.

As new data emerges, further substances continue to be scrutinised under the Integrated Regulatory Strategy and proposed as SVHCs (or other risk management measures), particularly those with PBT/vPvB or endocrine disrupting properties.

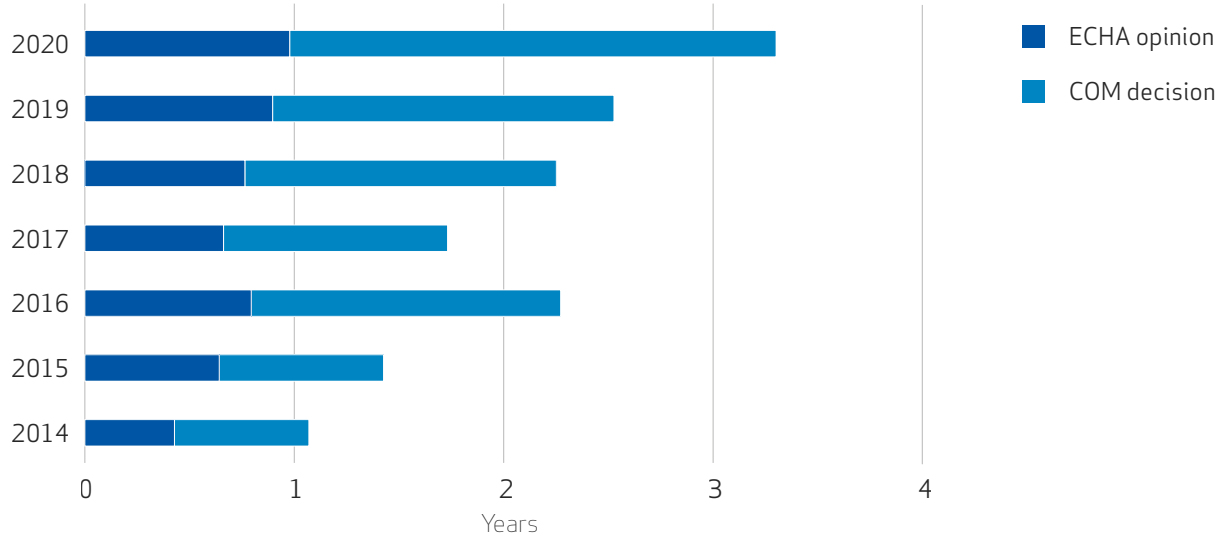
89 https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2020_achievements_en.pdf

90 https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency/cases-where-echa-is-a-party/candidate-list

Currently, 54 substances are included in the **Authorisation List**. For 24 substances, ECHA has not received any applications for authorisation, indicating substitution or cessation of the uses requiring authorisation. For the remaining substances, 346 applicants have submitted 213 applications for authorisation covering 340 distinct uses.

ECHA's **application for authorisation process** has been streamlined to deliver opinions in 10 months instead of the maximum 14 months set out in REACH. Further process improvements are believed to be possible, for example with the introduction of a formal conformity check, and a differentiation of the requirements and committee assessment of applications which have risks below a specified threshold. At the same time, the overall duration of the authorisation process is increasing.

FIGURE 36: Timelines for authorisations (in years) by year of Commission decision



Overall, the process of dealing with applications for authorisation is not efficient. With the current approach, ECHA's committees and the Commission have often assessed conditions of use for each site. An approach for authorising many sites – through an 'upstream' application by the supplier to the sites – was found to not be sufficiently specific in describing how risks are controlled. With the current, site-specific 'downstream' approach, the number of applications is difficult to predict and has been highly fluctuating, leading to peaks of work in ECHA and the Commission.

Given the efficiency issues in assessing the conditions of use of SVHCs site-by-site, a different approach – preserving the substitution effects and risk control – could be envisaged whereby the burden of proof to demonstrate that risks are controlled is shifted more towards the applicants.

Court cases[91] have also highlighted that the provision of information on alternatives would benefit from changes, as there is **insufficient information on alternatives for the substances and their use** in the EU market to challenge applicants. A review of the system, putting more responsibility on industry and users, incentivising market functioning to progressively replace substances of very high concern with suitable alternatives, with less need for authorities' case-by-case intervention would be needed.

ECHA's **Committee for Risk Assessment (RAC)** provides opinions on proposals for harmonised classification, restrictions, applications for authorisation, and proposals under other legislation. Since 2008, RAC has operated as a single Committee with only occasional use of ad hoc working groups for specific dossiers. The increase

91 Judgments of 7 March 2019, *Sweden* v. *European Commission*, T-837/16, EU:T:2019:144, and of 25 February 2021, *European Commission* v. *Sweden*, C-389/19 P, EU:C:2021:131

in workload since 2014 has been continuous and reached the point in 2018 where a standing working group for evaluating applications for authorisation was set up under the RAC Rules of Procedure in order to reduce the pressure on plenary. This enabled RAC to expand the number of opinions substantially but has reached its maximum effectiveness.

With further increases in **overall workload of the RAC**, considering the current processes (authorisation, restriction, harmonised classification and occupational exposure limits), as well as upcoming workload from other legislation (for example, the Drinking Water Directive[92]) the RAC is reorganising, by increasing the use of working groups, starting in 2021-22. Further improvements could be achieved by Member States stepping up support to the committee and by increasing the use of co-opted members.

3.7 Safe and sustainable use of chemicals

During 2019-2020, a joint analysis conducted by ECHA, the Commission services and the stakeholder Exchange Network for Exposure Scenarios (ENES), under the umbrella of REACH Review Action 3 has clarified that significant further work in this area is needed by industry. The areas for further work to improve the system for supply chain communication have been documented in a development plan, which received support from the European Commission's advisory body on REACH and CLP.[93] [94] In addition, industry agreed to define and organise a proof of concept for the main system elements or changes to determine the corresponding value (cost, benefit) and workability to the supply chain.

As part of the work, ECHA identified that a **harmonised standard**[95] for conveying relevant safety data **electronically** along the supply chain, together with more clarity on the safe use advice to be communicated (the content of the exposure scenario) and a merging of the REACH and other legislative requirements, would be key to enabling the policy objectives. To be workable, this would require further investment by authorities to:

- Develop and endorse a common exchange format for safety data sheet (SDS) information.
- Clarify, through legislation, the minimum requirements for the content of the exposure scenario.
- Develop a method for mixture assessment, which integrates the principles of REACH annexes I and XII with the classification rules for mixtures according to CLP.
- Modify the legal obligations across legislation to clarify certain roles and duties of registrants and downstream users in this context.

Both industry and Member States acknowledge that improving the workability of the (extended) safety data sheets through the outlined actions needs to be accompanied by improvements in the chemical safety report (CSR) content (as the source of information expected to travel through the supply chain):

- Ensure that chemical safety assessments (CSAs) are based on representative conditions of use and updated dossiers with information becoming increasingly available from downstream sector organisations.

92 https://echa.europa.eu/understanding-dwd

93 https://echa.europa.eu/documents/10162/13563/caracal_202011_rra3_dev_plan_annex_en.pdf

94 Following a review of priorities for ECHA, ECHA's Management Board decided in December 2020 to pause ECHA's support to communication in the supply chain, including REACH Review Action 3.

95 For example, in Extensible Markup Language (XML).

- Apply higher tier exposure estimation methods to avoid determining unrealistic safe use conditions.
- Review and ensure that the hazard assessment (derived no-effect levels (DNELs) and self-classification) is up to date and consistent so that meaningful risk management advice can be derived.
- Ensure that CSAs are identical with the requirements for similar assessment under other chemicals legislation.

3.8 Support to enforcement via Forum

ECHA's Forum for enforcement is delivering on its legislative targets and is promoting a harmonised approach for enforcement. The Forum has successfully mobilised Member State national enforcement authorities (NEAs) to participate in harmonised enforcement projects with a participation rate of 92 % during 2016-2020. The Forum's pilot projects are also successful in their objective of testing new enforcement practice and gauging compliance levels, and had a participation rate of 48 %[96]. There is, however, a limited number of active members that take the lead on Forum projects. With a view of the need to further strengthen the enforcement of REACH and CLP, it would be necessary to find ways to ensure that all Forum members have enough time allocated to contribute to Forum activities, and sufficient levels of support from their Member States, as required by REACH. The scarcity of Member State resources at Forum level indicates that enforcement at Member State level could benefit from better resourcing.

For the content of the Forum work, the priority setting of the harmonised projects is currently working very well and the projects are providing added value also from ECHA's strategic point of view. Along with the implementation of the Commission's Chemical Strategy for Sustainability, more focus will be given to integrated and holistic enforcement approaches across legislation, including their interfaces. This includes, but is not limited to, occupational health and safety and waste legislation, where enforcement interactions exist but need further development. As the harmonised enforcement projects and pilot projects take several years to be completed, it would be useful to complement these formal projects with a more agile way of working – 'concerted action' – to **enable NEAs to react more quickly** and with very light governance to any emerging issues.

A pilot exercise on annual reporting of national enforcement activities has been agreed to be started, on a voluntary basis, as a follow-up to the Commission's REACH review 2018. The absence of such data on an annual basis is hampering the creation of a full continuous picture of what enforcement is taking place in the EU, and thereby also not providing the best **information base** for Forum itself to focus its harmonisation efforts where they could add most value. Depending on how the audit capability mentioned in the Commission's Chemical Strategy for Sustainability is implemented, it could potentially help to address that need.

A strategically important goal for strengthening enforcement would be to achieve more chemical **controls** at the level of customs **before goods enter the EU market**. Forum's effort to improve cooperation between customs and chemicals enforcement, through its pilot projects and harmonised enforcement projects have been well placed and strengthened the inspections of imports. However, customs only actively controls ~2 % of all shipments and 98 % is processed automatically. A strong impact could be achieved if some simple checks of chemical legislation duties can be automated and done by customs IT systems or support enforcers in targeting the shipments for control.

One possibility for further harmonisation of enforcement, and for more impact, would be to give the Forum powers that allow its members mutual recognition of national enforcement decisions. This would help with issues related, for example, with joint submissions with members in various Member States, or to avoid the transfer of the non-compliant actors or actions from one Member State to another.

96 https://echa.europa.eu/documents/10162/13577/forum_indicators_report_2018_en.pdf

3.9 ICT

ECHA is largely an IT-based agency, viewing digitalisation as a key enabler for the regulatory work it carries out. The availability of all data in a digital format ensures systematic accessibility, streamlining and automation in the processing of that data. The design of ECHA's regulatory processes, by default, includes a high level of digitalisation and automation. Specifically, in 2020 the high level of digitalisation has been one of the key enablers that allowed ECHA to seamlessly switch its operations to remote working, while facing mobility restrictions during the COVID 19 pandemic.

Thanks to digitalisation and automation, ECHA is able to execute its processes efficiently, consistently and transparently. Examples of automation are the automated checks on incoming dossiers and automated dissemination of the data. ECHA is also able to digitally link and integrate with external parties, such as duty holders and other authorities.

Initially, as a small agency, ECHA had its own IT infrastructure at its premises. This provided flexibility, with required expertise incorporated as part of the initial ECHA staff. This model has evolved and deeply transformed as the needs of ECHA grew along with the variety of implemented tasks.

In the last five years, ECHA has driven important changes in its digital operations:

- Implementation of an asset-light operating model, by which ECHA does not own devices and infrastructure, but sources them "as a service", as an operational cost. This enables ECHA to respond timely to challenges of the fast-evolving IT market e.g. by easily replacing devices and improving services.

- Increased outsourcing, which allows increased flexibility in adapting to needs, as well as access to specialist expertise.

- Modularisation of ECHA's IT tool landscape, redesigning functionalities into IT modules that can be reused in multiple processes and pieces of legislation.

- Convergence of core scientific data around the IUCLID platform – with its cloud delivery model – ensuring greater expandability and scalability.

These investments have positioned ECHA at a high level of IT efficiency, as measured by a third-party benchmark performed in 2019[97]. With this progression, a number of new challenges have arrived. The scope of work has substantially grown and with it the financial means in an appropriate manner. The amount of outsourced IT work has also grown appropriately to cover these needs. At the same time, the number of ECHA staff available to ensure 'value for money' when working with contractors has been decreasing to a point which is at a minimal viable level. This means that for possible new tasks for the Agency which would include IT aspects, the availability of not only budget but also staff starts to be of critical importance.

An additional challenge is managing the extensive outsourcing itself. Within the financial rules in which ECHA operates, contract opportunities are open to EU parties and need to be re-opened at regular intervals, usually every 4-8 years. With the very specific IT landscape ECHA has, introducing a new contractor decreases efficiency and at times increases project risks significantly. At the same time, vendor 'lock in' would generate risks in terms of complying with financial rules. In a recent call for a Framework Contract for ECHA's bespoke applications[98], ECHA has further developed the sourcing model, to increase stability of the contractors used, while minimising the risk of being 'locked in'. Given the breadth of the portfolio, the quest for more stability within the context of

97 https://echa.europa.eu/documents/10162/13612/gartner_echa_benchmark_en.pdf

98 https://echa.europa.eu/-/framework-contract-for-it-services-covering-echa-s-bespoke-applications-sourcing-tiers

our financial rules will remain a topic for further improvement.

About half of the total budget for IT is invested in maintaining tools and operations, supporting not only ECHA, but also industry and authorities. Without these tools and the support to end users, the work would simply stop. The other half is invested in enhancing existing IT and implementing new services and capabilities.

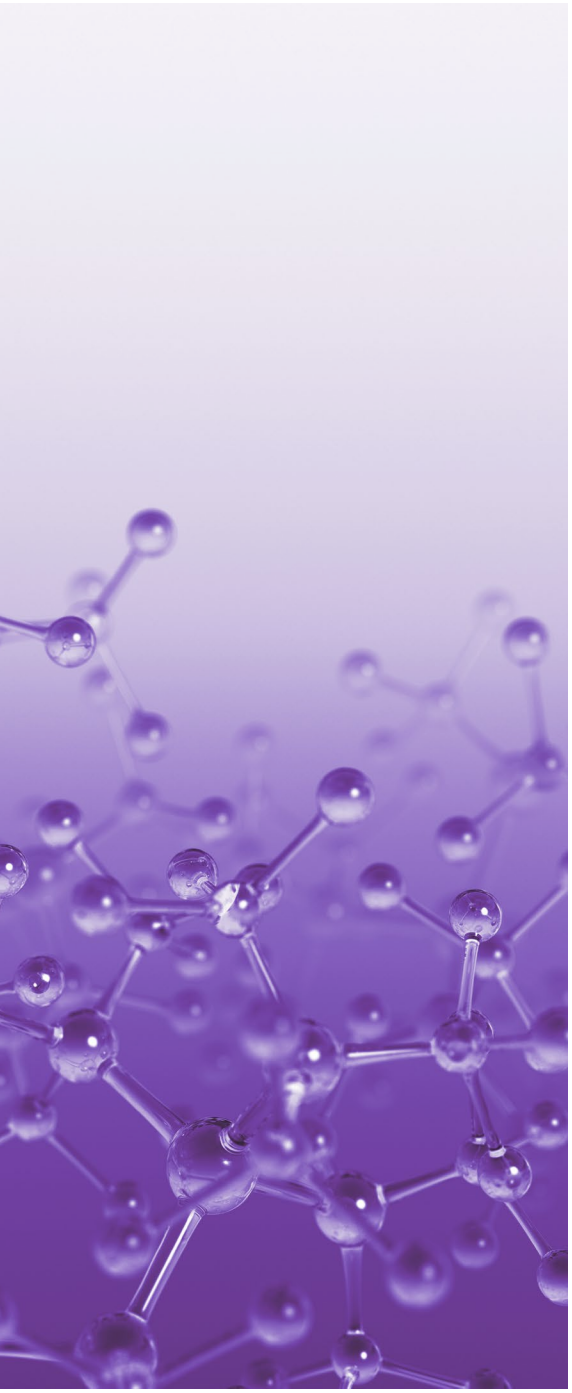
Over the next few years, ECHA's development is expected to focus on supporting the Agency's immediate priorities – notably the Integrated Regulatory Strategy. Further digitalisation of internal processes, as well as improvements to IT support for interaction and collaboration with Member States and the Commission will be a priority. In addition, onboarding of new tasks – for instance, possible tasks stemming from the Chemicals Strategy for Sustainability – will be in focus.

At the same time, ECHA will seek to further develop collaboration with other EU institutions. ECHA, for instance, uses sourcing and other opportunities offered by DG DIGIT to increase efficiency and avoid duplication at Union level. One example is the introduction of EU Login for ECHA's users, avoiding the distribution of security tokens and reusing functionality offered by DG DIGIT. Another example is ECHA's collaboration with EFSA to support the use of IUCLID for the Pesticides Regulation.

These types of cross institution activities are beneficial when processes and approaches overlap. ECHA, nevertheless, has a very operational focus in executing the (scientific) tasks and a specific IT landscape that follows that. Because of this, opportunities for collaboration are limited to specific areas.

4

DATA AND KNOWLEDGE ON CHEMICAL SAFETY



4.1 The knowledgebase on chemicals safety

Overview

Over its years of REACH and CLP operation, ECHA has accumulated much data on chemicals safety. As chemicals safety data from industry becomes organised, assessed, enriched and embedded into regulatory outcomes, it turns into knowledge, which underpins regulatory action. ECHA's knowledgebase is consulted and used by the Agency, other authorities, industry, researchers, NGOs and consumers, in the EU, and also internationally.

From a data perspective, the implementation of REACH and CLP can be seen as a progressive accumulation, updating and utilisation of the following data types:

Scientific data:

- Data collected from chemical companies on identity, intrinsic properties, use/exposure collected through various regulatory submissions by the companies themselves.[99]
- Data on chemicals and their properties collected from authorities and academia which are in the public domain (for example, through public consultations).

Assessment data:

- Assessment data from industry, such as chemical safety reports and documented risk management measures applied by companies.
- Assessment data from authorities, such as opinions from the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), identification of data deficiencies (for example through evaluation), the clustering of substances into groups and the identification of concerns, documents and opinions such as expert group analyses that support regulatory outcomes.

Regulatory outcomes:

- Produced by the EU and Member State authorities such as REACH evaluation decisions, harmonised classification decisions and restriction decisions, inclusion in REACH annexes, etc.
- Produced by regulatory bodies worldwide.

99 Information from certain dossiers, such as PPORD notifications or inquiries falls under the confidentiality protection in its entirety and only aggregated data (statistics, trends) can be made publicly available.

Additionally, ECHA hosts **market data**, such as legal entity, country of origin, status of companies a small or medium enterprise, tonnage bands for substances, as well as **transactional data**, such as submission dates, invoicing data for fees, etc.

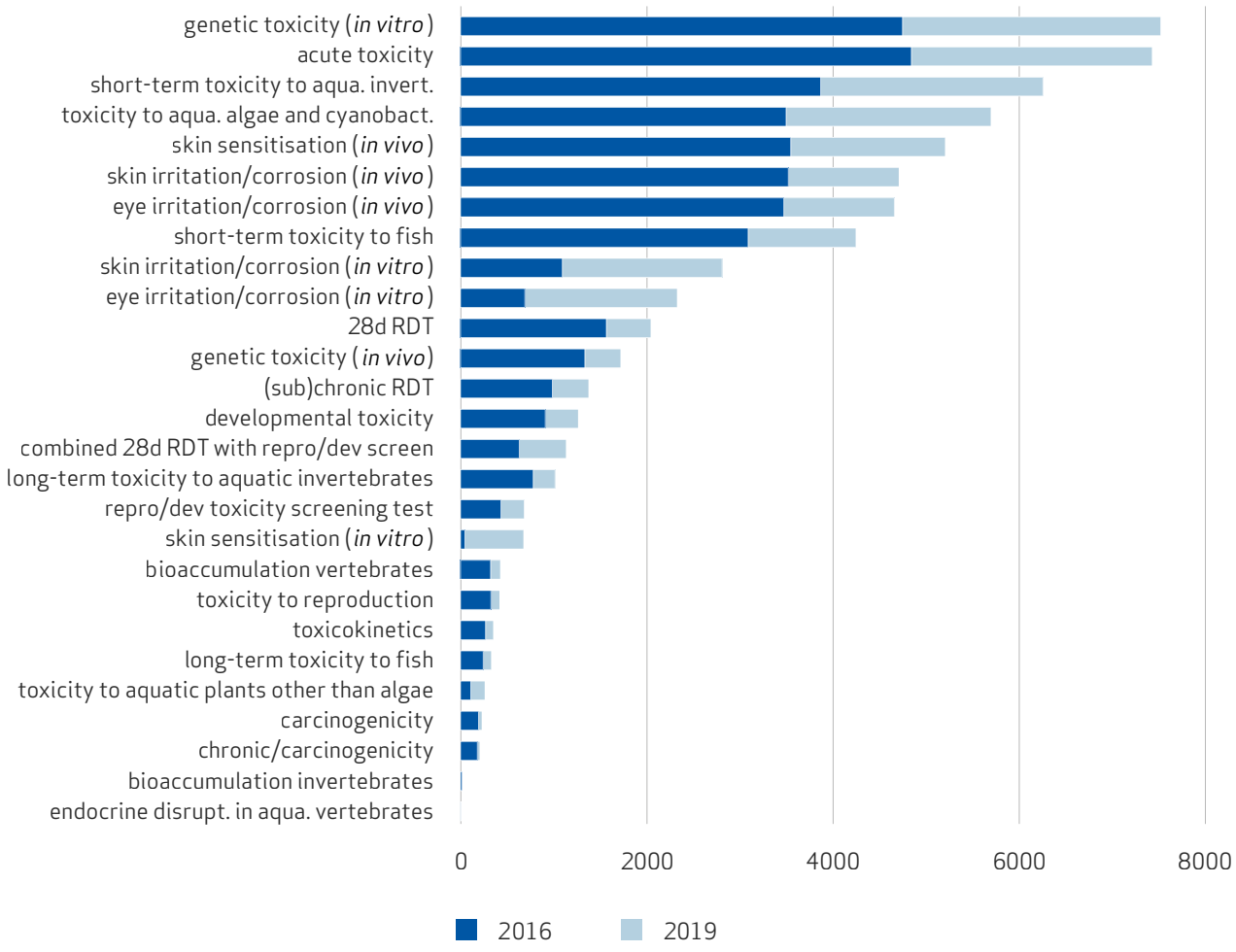
Information on chemical hazard

The increase in available chemical hazard information can be observed through the trends in registration data, which are discussed in more detail in ECHA's report on the use of alternatives to animal testing under Article 117(3) of REACH[100]. The analysis of study data in registration dossiers shows that REACH has brought transparency to an enormous collection of pre-existing studies, as well as stimulating additional testing – where no other options were available – by revealing the existence of information gaps needed to ensure safe use. The comparison between data generated before and after REACH is further presented in the above-mentioned report.

An example are the studies combining 28-day repeated dose and reproductive toxicity screening. By 2016, 623 substances were registered using such studies (of which most were performed in or after 2009). By 2019, the number of substances registered with such studies had grown to 1 129 (of which most were also performed in or after 2009). This suggests that REACH, with most provisions starting to apply in 2008 and with the last registration deadline for phase-in substances in 2018, has been the driver for most of the new studies.

An overview of the data density of industry data from guideline studies is presented in Figure 37.

FIGURE 37: Number of substances registered with guideline studies



100 https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf

REACH has driven the use of *in vitro* skin corrosion/irritation, serious eye damage/eye irritation and sensitisation tests. A striking example is the change for *in vitro* serious eye damage/eye irritation studies, where the number of substances registered with such studies tripled between 2016 and 2019. Similarly, for *in vitro* skin corrosion/irritation tests, the number of substances more than doubled.

For all endpoints where animal testing is or was the standard requirement, in practice, other means to fulfil these requirements are more frequently used. This is with the exception of acute toxicity, where for just over 50 % of the substances, an *in vivo* testing approach was used, mostly based on studies conducted before 2009. For the more complex, higher tier endpoints, read-across is the preferred option to meet the information requirements.

For low tonnage substances, the earlier registrations (2016) had more additional information provided beyond the standard minimum requirements, than those submitted more recently (2019). For substances in the lower tonnage bands that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR) categories 1A/1B or 2, an earlier deadline applied (2009). It can be understood that these older dossiers contain more information at a higher level than presently required by the tonnage band, and that this led to their classification in the past.

Under REACH, the evaluation processes play a key role in bringing about further hazard data generation, by identifying data gaps, issuing decisions and following-up on the data that was generated.

An overview of the degree of compliance of the dossiers having gone through dossier evaluation is provided in Figure 28. However, the closing of a dossier evaluation decision does not in itself imply that the whole dossier has been brought to full compliance, since the dossier evaluation policies aim to focus the data generation on the most impactful data gaps and have evolved over the years. For testing proposals, the data gaps are, by definition, targeted. A more detailed breakdown of this information is available in the annual evaluation progress reports (until 2017), and more recently in the Integrated Regulatory Strategy reports (2018-2020).

Information from use descriptions and chemical safety reports

Most registered substances have multiple uses reported in the registration dossier. Some uses have a specific 'regulatory status', for example, being out of scope of certain regulatory instruments (for example, intermediates being exempt from authorisation), or being addressed by another regulation (Plant Protection Products (PPP), Biocidal Products (BPR)). Some uses may raise more concerns than others, for instance widespread uses that lead to exposure of consumers or to the general public through a wide range of articles compared to uses that are limited to a few industrial sites and handled by trained dedicated workers.

For hazardous substances manufactured or imported above 10 tonnes per year, all uses reported in the registration dossier are to be assessed in the chemical safety reports (CSRs) attached to the dossier. The CSRs include self-classification according to CLP, no-effect limits (doses) for human health, no-effect concentrations for the various environmental compartments, substance properties driving the exposure, operational conditions and risk management measures ensuring safe use (per identified use of the substances), corresponding exposure estimates and related risk characterisation. Part of the information, such as exposure-driving substance properties, self-classifications and reference values for toxicological and eco-toxicological effects are available in structured format in IUCLID and are published on ECHA's website. Information on the breakdown of the total market volume into certain use areas can be retrieved from some of the CSRs, at least for those substances where an environmental exposure assessment is required.

Authorities, including ECHA, utilise this information to better understand the conditions under which a substance is meant to be used in the market. This can support authorities in screening and priority setting, determining where regulatory risk management needs to be initiated and what the most optimal risk management strategy should be.

The added value of the CSR information for both companies and authorities is limited by the following obstacles:

- **Conditions of use:** the conditions of use described in the CSR mostly resulted from exposure modelling for generic use-scenarios. REACH foresees that registrants adapt these to real-life conditions, based on detailed information that they should receive from their downstream users. In some market areas (e.g. paints and coating, cleaning products, adhesives, construction chemicals), downstream sector organisations have published use maps[101] from which registrants can retrieve the relevant types of uses for certain mixture types, and the related conditions of use.

- **Volumes and use:** as REACH does not require registrants to provide a mass-flow break-down into the different uses, information regarding the extent of the assessed uses in the market is scattered.

- **Format:** the CSR information on use, exposure and risk characterisation is documented in variable text formats that can extend to 100 pages or more. Hence, the information cannot be read quickly or processed in an automated way for screening purposes (by authorities) or transferred into safety data sheets (SDSs) (by registrants). It is, therefore, a major achievement that registrants – despite the fact that there is no legal obligation to use a specific format – have increasingly switched to Chesar, ECHA's tool to generate safety assessments in a standardised structured format. Overall, more than 70 % of CSRs submitted to ECHA are generated by Chesar. A mandatory structured data format for CSRs would further accelerate this trend.

- **Up-to-date information:** CSRs may get outdated over time, for example in the cases when they were generated as a one-off exercise, at the time of first registration.

Registration data can directly be used for the safety assessment for only about 25 % of hazardous substances[102]. This is because registrants frequently do not determine the suitable datapoints (among the various study results reported) to use in exposure modelling and risk characterisation. One of the reasons is that many substances have a complex composition or behaviour, and that registrants do not yet routinely identify the risk-driving constituent or reaction products for their substance.

Additionally, in many sectors, uses are missing from the registration and the CSR. Missing uses are often added at the time risk management measures are being prepared, for instance, when ECHA recommends a substance to be included in the Authorisation List or suggests a specific restriction. It would be more efficient for authorities to have information on use and volume per use available at an earlier time, or to have the possibility to request it, to avoid timing and efficiency issues in the risk management processes.

Various industry sectors have started to improve their CSRs (see Section 3). This also includes the collection of mass-flow data to be able to target areas of the market where in-depth assessment is more needed than in other areas. Systematic gathering of use volumes (i.e. volumes of substance per use) would require actors in supply chains to agree on a harmonised way of describing the uses, so that aggregate use volumes can be mapped to these uses. This would enable registrants to better assess risks and communicate applicable safe use advice through the supply chain.

In March 2021[103], ECHA launched a manual technical completeness check of the CSRs it receives with dossier updates

101 https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library

102 This number was determined in work aiming to model risk characterisation ratios by combining information on substance properties with the uses contained in the registration database. For such screening assessments all values to be fed into the models must be available in the defined data fields. This was the case for about 25 % of the registered substances requiring exposure assessment.

103 The initial launch in 2019 was postponed because of the COVID-19 pandemic: https://echa.europa.eu/-/completeness-check-of-chemical-safety-reports-postponed-until-october-2020

or new registrations. Over time, this will increase the number of complete CSRs, improving the knowledge of authorities on uses and the risk management information in the SDSs. However, the value of the CSRs for the authorities' work and for the SDSs will remain limited unless the supply chain communication obligations are adhered to.

Additionally, for hazardous substances requiring exposure assessment, regular updates of the annual tonnages[104] and information on use volumes would allow authorities to better assess the impact of specific regulatory interventions (e.g. Candidate listing, Authorisation listing) on the use of the substance.

4.2 Knowledge and data management

Structuring chemicals information in IUCLID

Over the past decade, a considerable amount of information on chemicals on the EU market has been submitted by companies to ECHA. The data has been collected using the **IUCLID platform**, which allows users to record, store, submit and exchange data on chemicals in an internationally agreed format. IUCLID is considered essential for managing scientific data on chemicals in a regulatory context and is recognised as a global standard for managing data on chemicals for regulatory processes.

A harmonised format for collecting, storing and exchanging information on chemicals is key to expanding the knowledgebase as well as implementing (new) legislation efficiently and effectively. An increase in the use of IUCLID by regulatory authorities[105] around the world could pave the way for increased collaboration and the exchange of valuable data across regions – further enhancing progress at global level. Switzerland, Australia and the US, have started to use the IUCLID format for some parts of their chemical legislation, enabling submission and exchange of data with others for assessment purposes. Other countries, such as New Zealand are expecting to start using IUCLID once the tool is fully configured to fit their regulatory contexts. ECHA is also providing support to authorities in third countries such as the United States Environmental Protection Agency (US EPA) and Health Canada through projects aiming to exchange comprehensive information and knowledge on certain chemicals.

Looking beyond the IT and data domain, the last five years have also seen an overall increase in requests for **exchange of knowledge and expertise** between ECHA and non-EU authorities. As a result, ECHA has hosted interactions with delegations and institutes from third countries on topics related to the design and implementation of chemicals legislation, as well as specific exchanges, on areas such as endocrine disruptors (EDs), persistent, bioaccumulative and toxic (PBT) substances and persistent organic pollutants (POPs). In this regard, it is worth noting that interest from non-EU authorities goes beyond data per se and includes assessments done, for instance, when preparing an opinion on a restriction proposal. Such assessments may also be useful for risk management efforts in third countries after adapting them to national conditions such as uses.

Thanks to IUCLID's modularity, expandability and the scalability brought by the ECHA Cloud Services, the platform has also been the way forward for implementing additional pieces of legislation, for example, substances of concern in products (SCIP) under the Waste Framework Directive, notifications to poison centres and more recently plant protection products in collaboration with the European Food Safety Authority (EFSA). IUCLID integration capabilities have enabled an 'ecosystem' of tools around IUCLID to be developed that allows powerful processing of the data, such as automatic validation or filtering. Consequently, the impact of IUCLID on ECHA's IT architecture has facilitated the harmonisation of underlying conventions for data management and increased the data interoperability. Further synergies are being planned, including in the area of the Biocidal Products

104 Under REACH, registrants are required to provide information on the (estimated) volume of a substance they manufacture or import in the year of the registration. The Prodcom Regulation (EU) 2019/193 foresees aggregated reporting of volumes of hazardous substances.

105 https://iuclid6.echa.europa.eu/project-iuclid-6

Regulation, which is already supported by IUCLID but will further be integrated with Chesar and the EU System for Evaluation of Substances (EUSES). This initiative is predicted to provide greater value from the aggregated data.

Over the last five years, ECHA has continued to invest in data integration, reporting capabilities and **advanced analytics** to work with data. This investment is a key enabler in the progress of ECHA's Integrated Regulatory Strategy, such as the screening of information to identify substances of interest, including the generation of groups. These developments also result in the distribution of tools, also used by external parties, such as the **text analytics search engine** for IUCLID and the **OECD QSAR Toolbox**.

Several obstacles still need to be overcome to implement ECHA's ambitions in the field of data management. Moving to an enhanced, structured data management requires an initial effort to adapt own processes and related IT systems, to upgrade the internal competencies required and deal with legacy data that may need to be reformatted to make it fit for ongoing processes. These obstacles can be significant especially given the different situations in various authorities.

Examples are the increased cooperation with EFSA on endocrine disruptors and the classification of pesticides, cooperation with the Commission in planning the implementation of adjacent legislation, such as POPs and SCIP, but also the harmonisation of inspection guidance with national enforcement authorities, and support to national helpdesks.

Collaborating with authorities

The last five years have seen progress in the automation of information exchange and collaboration among authorities.

Under the umbrella of the Interact Portal, the Activities Coordination Tool (ACT) is a one-stop shop for substance activity coordination, helping authorities get a user-friendly overview and better coordinate their work. It provides data across various processes: screening, dossier evaluation, substance evaluation, hazard assessment, regulatory management option analysis, harmonised classification and labelling, authorisation and restrictions. Specific features of the Interact Portal allow for co-authoring of documents and consultations among authorities. However, such features are not consistently opened or used across all the processes. In addition, these features require acceptance and use of our colleagues in the Member States.

Making data publicly available

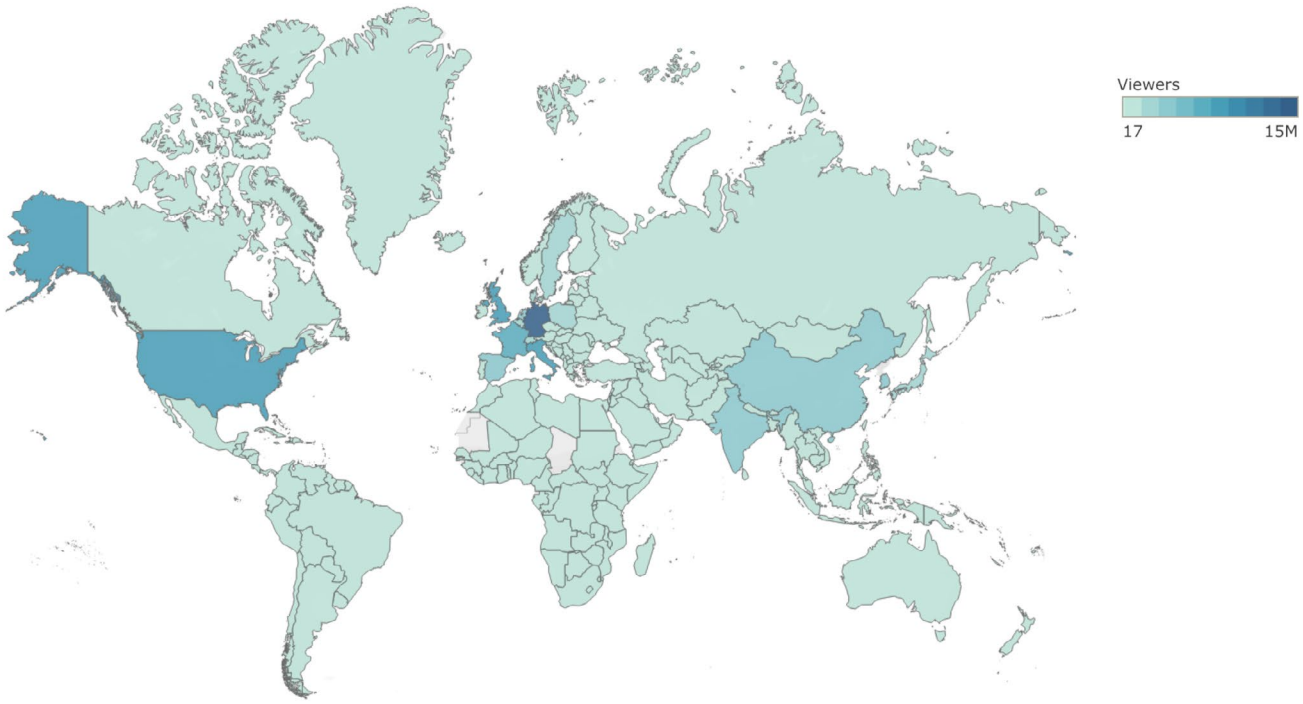
ECHA's **dissemination portal** is the world's largest public database on the properties of industrial chemicals and its use is about to pass the 50 million mark of page views per year. The portal is embedded in ECHA's website.

Dissemination improves the transparency on chemicals and their hazards and uses, which allows better informed decisions on chemical safety by authorities, companies, workers and consumers. Since 2016, the information is presented in a layered format. The first layer is the Infocard, which summarises the main properties of the substance, including properties that might be of concern to consumers, such as skin sensitisation or carcinogenicity. From the Infocards, users can access subsequent layers of the website, providing more detailed information on the substances, including legislation-specific information from the legislation under ECHA's remit.

Additional information is disseminated through the public activities coordination tool (PACT), which provides an overview of the planned and ongoing regulatory actions for each substance by ECHA and the Member States.

In 2020, the **EU Chemicals Legislation Finder** (EUCLEF) was launched[106], to further extend the substance data with references to 40 pieces of EU legislation applying to chemicals. This was extended in early 2021 to 56 pieces of legislation.

FIGURE 38: Location of viewers of ECHA's dissemination portal



In addition to the information published on the ECHA website, ECHA makes REACH study results files available, in a downloadable IUCLID format. The file is a collection of non-confidential substance data that was submitted during registration. Making these data downloadable aims to further increase the possibilities, for third parties, to analyse and reuse the data in bulk, and consequently improve the safe use of chemicals, for example, through improved safety data sheets, or the development and use of alternative methods.

In general, the data on substances are not only useful for the purposes of the legislation under which they were generated (such as REACH and CLP), but their value is multiplied when the **data can be exchanged and reused under other regulatory schemes**. In some cases, the reuse and exchange are clearly enabled by the legislation, such as the revised Waste Framework Directive, Water Framework Directive and Battery Directive. In other cases, there are legal obstacles for the data to be reused, such as for the poison centres notification data, which cannot be directly reused to support screening and priority setting at EU level.

ECHA is keen to continue making data available in ways that maximise its use. In this context, the work under the Chemicals Strategy for Sustainability, to establish a **common open data platform on chemicals**, presents an opportunity to address both technical and legal issues that need to be overcome to achieve that goal.

106 EUCLEF is a specific task carried out based on a contribution agreement with the European Commission.

5 ECHA FINANCING

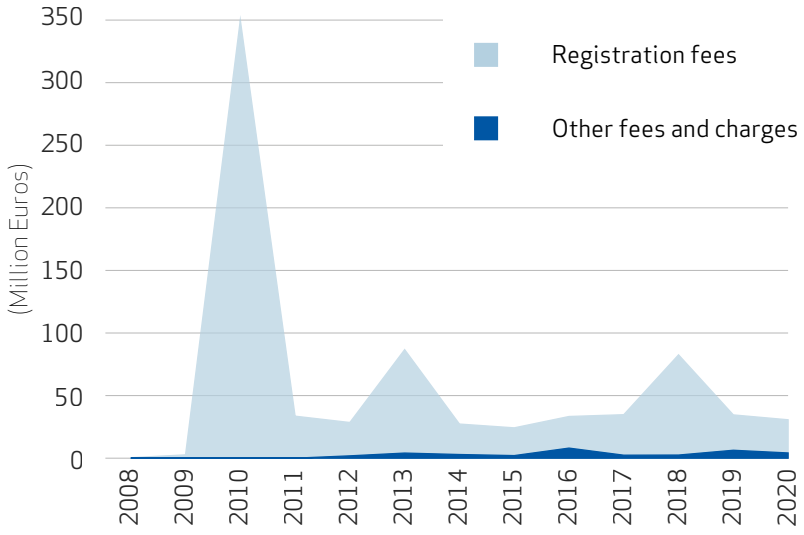
5.1 ECHA's financing structure

ECHA's REACH operations are financed through fee income and an annual EU contribution. Under REACH and CLP, ECHA receives fees from companies, mainly for the registration and authorisation of chemicals. During 2008–2020, ECHA's funding for REACH came mostly from fee income (69 %), while the remaining income came from the EU balancing contribution (31 %).

The main fee income has traditionally come from registration fees, which accounted for 95 % of ECHA's fee income during 2008-2020. Following the last registration deadline in 2018, ECHA's REACH fee income has declined significantly, and the Agency is increasingly relying on the EU balancing contribution to finance its operations. In 2020, 32 % of income came from fees and 68 % from the EU contribution.

Figure 39 presents ECHA's fee income for 2008-2020, illustrating that there has been significant volatility in annual income due to the three REACH registration deadlines (in 2010, 2013 and 2018).

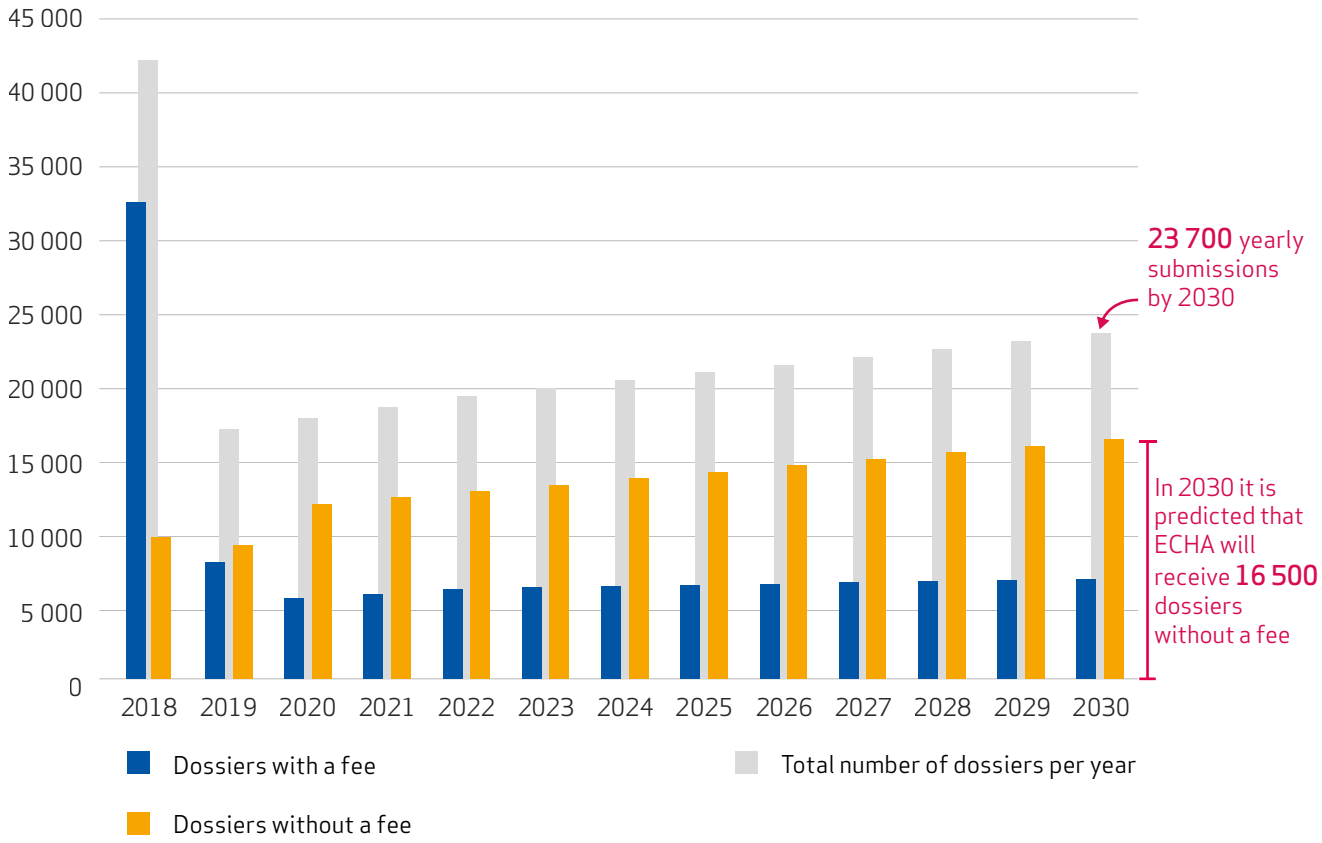
FIGURE 39: REACH fee income over the period 2008-2020



In 2019, an external consultancy study examined ECHA's processes for estimating fee income. The study concluded that even the use of most advanced statistical techniques does not facilitate accurate estimation of future fee income, due to the lack of information on the drivers of demand (that is, the behaviour of companies on the market).

Figure 40 illustrates the projected evolution of fee-generating REACH submissions. The forecast shows that a declining percentage of dossier submissions will generate a fee. The projected gap between dossiers that incur a fee, and those that do not, is anticipated to increase over time. It is estimated that, by 2030, only 30 % of submissions will incur a fee.

FIGURE 40: Forecast of dossier submissions until 2030



The levels of EU contribution indicated in the Multiannual Financial Framework (MFF) 2021-2027 imply that fee income would continue to be a significant part of the future REACH budget financing. As the income stream from the present fee types is projected to decline, it is important to assess the available options to secure sustainable financing for ECHA for the future.

ECHA's revenue, both fees and EU contribution, is considered as general revenue in accordance with ECHA's Financial Regulation[107] and, therefore, fees are not earmarked to a particular task or activity. In the current fee structure for registration of substances, the fees are dependent on the size of the company and the tonnage band registered. The fee structure for REACH authorisation is dependent on the number of uses and the company size of the applicants. Over the past years, the Fee Regulation[108] has been amended with a view to better reflect the workload in the context of applications for authorisation, by incorporating the number of uses to the fees.[109]

5.2 Transfer of fees to Member States

A proportion of the fees and charges collected by ECHA are transferred to the relevant Member States for the work done in the context of substance evaluation and for rapporteur work in the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC).

The amounts are determined by the Management Board, following a favourable opinion from the Commission.

107 https://echa.europa.eu/documents/10162/13611/echa_financial_regulation_en.pdf
108 https://eur-lex.europa.eu/eli/reg/2008/340/oj
109 https://eur-lex.europa.eu/eli/reg_impl/2018/895/oj and https://eur-lex.europa.eu/eli/reg_impl/2013/254/oj

The amounts are fixed in compliance with the principles of economy, efficiency and effectiveness and at a level that ensures that the Agency continues to have sufficient financial resources available to undertake its tasks and take into account the workload and related costs of the Member States. The amounts transferred, however, are not in all cases foreseen to compensate for the entire costs incurred by the Member State. The annual amounts transferred depend on the number of substances on the Community rolling action plan (CORAP), applications for authorisations received and the number restriction dossiers.

The average amounts transferred per year during the period 2012-2020 were c. EUR 1 million for substance evaluation, EUR 250 000 for applications for authorisation and EUR 85 000 for restrictions.

5.3 Addressing the challenges

The European Commission has recognised the challenges in ECHA's financing model. The REACH Review (March 2018) indicated the need to '*explore ways of guaranteeing ECHA's mission and independence and to assess all possible options for financing in a context of projected reduced fee income*.'

The Special Report of the European Court of Auditors (ECA) on the 'Future of EU agencies: Potential for more flexibility and cooperation' (October 2020) noted that '*ECHA faces particular challenges because it has no recurrent revenue and its fee income is difficult to forecast*' and that '*the financial and administrative framework in which ECHA operates is more complex than for other agencies, as ECHA has three separate budgets (and staffing plans) under three different regulations, each with a different partner DG. This further limits ECHA's flexibility to deal with fluctuations in workload*.'[110]

ECHA needs to have long-term financial and human resources stability to fulfil its evolving mandate and to retain and develop its specialist competences and IT applications.

From the operational perspective, ECHA has achieved synergies and efficiencies across legislation by investing in common IT tools and services (such as chemical safety databases, workflow and collaboration services for authorities), common scientific and technical services (such as substance identification and helpdesk activities), and common governance and enabler services. These services require coherent investment planning, management and maintenance to achieve the expected efficiencies when serving all relevant legislation.

Since the completion of the last REACH registration deadline in 2018, ECHA has reorganised its operations and reallocated a significant number of full-time equivalents (45 FTEs) to priority activities within the organisation. ECHA's focus for redeployment has been on strategic priority 1 ("Identification and risk management of chemicals of concern") and, specifically, on evaluation, classification and labelling, restrictions and authorisation activities, together with the implementation of priority work areas under biocides.

The mismatch between relatively stable expenditure and volatile, unpredictable fee income impacts negatively on the implementation of ECHA's Work Programme and creates significant complications in terms of annual budget management. An additional challenge is the fact that ECHA is required to maintain a strict separation of funding between the regulations that it implements, resulting in inflexibility in budget management and inefficient administrative practices. There have been years when ECHA has developed a surplus in one budget area while experiencing a shortfall in fees in another area. On such occasions, as an internal balancing mechanism is not available to ECHA and the required balancing can only be achieved through the EU Budget, the Agency had to seek approval from the Council and the European Parliament to transfer funds, resulting in a disproportionate administrative burden.

110 https://eca.europa.eu/en/Pages/DocItem.aspx?did=54740

If the current hybrid financing model with strict separation of funding continues, the challenges outlined would remain. Therefore, one workable option could be to have ECHA's annual resource requirements determined in collaboration with the European Commission, the Management Board and the budgetary authority and receive a corresponding EU contribution to implement the agreed Work Programme. Under such a proposal, ECHA would continue collecting fee income from industry, as defined in an updated fee regulation, and pass the corresponding income to the Commission for its treasury and budget management, as the Commission would be in a better position to accommodate this, due to the size of its budget.

The Chemicals Strategy for Sustainability, published in 2020 by the Commission, foresees a new '*founding regulation' for ECHA (2023), as well as proposals to strengthen its governance and increase the sustainability of its financing model*[111]. As requested by the Commission in September 2020, ECHA has analysed scenarios to revise the current fee system and submitted these scenarios to the Commission in March 2021 for its consideration. As the three REACH registration deadlines have passed, ECHA considers it important to consider the introduction of new fee types.

111 https://ec.europa.eu/environment/strategy/chemicals-strategy_en

REFERENCES

Integrated Regulatory Strategy 2020 Annual Report, April 2021
https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2020_en.pdf

Archive of Integrated Regulatory Strategy reports
https://echa.europa.eu/report-archive-specific-reports?panel=irs-reports#irs-reports

The use of alternatives to testing on animals for the REACH Regulation, Fourth report under Article 117(3) of the REACH Regulation, June 2020
https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf

New Approach Methodologies in Regulatory Science, scientific workshops proceedings, 2016
https://echa.europa.eu/documents/10162/22816069/scientific_ws_proceedings_en.pdf

ECHA's report on regulatory applicability of non-animal approaches under the REACH, CLP and Biocidal Products regulations
https://echa.europa.eu/-/more-progress-needed-to-replace-animal-tests-under-eu-chemicals-laws

Progress in evaluation according to Article 54 of REACH
https://echa.europa.eu/overall-progress-in-evaluation

Forum REF-4 Project report on restrictions
https://echa.europa.eu/documents/10162/13577/ref_4_report_en.pdf

Forum REF-5 Project report on extended data sheets, exposure scenarios, risk management measures and operating conditions
https://echa.europa.eu/documents/10162/13577/ref-5_report_en.pdf

Forum REF-6 Project report on classification and labelling of mixtures
https://echa.europa.eu/documents/10162/13577/ref-6_project_report_en.pdf

Forum REF-7 Project report on registration duties
https://echa.europa.eu/documents/10162/13577/project_report_ref-7_en.pdf

Forum report on the pilot project on cooperation with customs in enforcement of REACH restrictions and CLP labelling
https://echa.europa.eu/documents/10162/13555/customs2_project_report_en.pdf

Forum report on the second pilot project on authorisation
https://echa.europa.eu/documents/10162/13577/final_report_second_forum_pilot_project_on_authorisation_en.pdf

Forum report on the substances in articles pilot project
https://echa.europa.eu/documents/10162/13577/sia_pilot_project_report_en.pdf

Forum report on the improvement of quality of safety data sheets
https://echa.europa.eu/documents/10162/22749747/echa_sds_report_en.pdf

Estimating the number and types of applications for 11 substances added to the Authorisation List in February 2020
https://echa.europa.eu/documents/10162/13634/applications_for_11_substances_Authorisation_List_February_2020.pdf

Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA. February 2021
https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf

Impacts of REACH restrictions and authorisation on substitution in the EU, July 2020
https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf

REACH Evaluation Joint Action Plan
https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

"SVHC Roadmap 2020 – achievements and extended aims" - Brochure on the closing of the SVHC roadmap
https://echa.europa.eu/-/roadmap-to-address-substances-of-very-high-concern-complete

Strategy to promote substitution to safer chemicals through innovation
https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf

ECHA IT benchmark 2019
https://echa.europa.eu/documents/10162/13612/gartner_echa_benchmark_en.pdf

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