ECHA
EUROPEAN CHEMICALS AGENCY

Transparent progress in addressing substances of concern

Integrated Regulatory Strategy
Annual Report

April 2021

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Transparent progress in addressing substances of concern - Integrated Regulatory Strategy Annual Report 2021

Reference: ECHA-21-R-04-EN
ISBN: 978-92-9481-859-1
ISSN: 2599-9265
Cat. Number: ED-BD-21-001-EN-N
DOI: 10.2823/506792
Publ.date: April 2021
Language: EN

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LIST OF ABBREVIATIONS

Abbreviation	Description
CCH	Compliance check under dossier evaluation
CLH	Harmonised classification and labelling
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic, and toxic for reproduction
COM	European Commission
CoRAP	Community rolling action plan
DEv	Dossier evaluation
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
MSC	Member State Committee
MSCA	Member State competent authority
NONs	Substance with a recognised notification number under Directive 67/548/EEC
OEL	Occupational exposure limit
PACT	Public activities coordination tool
PBT	Persistent, bioaccumulative and toxic
PetCo	Petroleum and coal stream substances
POP	Persistent organic pollutant
QSAR	Quantitative structure-activity relationship
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals
RMOA	Regulatory management option analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very bioaccumulative

Foreword

This is ECHA's third annual report on our Integrated Regulatory Strategy, where we bring you an update on the progress we have made during 2020 to identify substances of concern and, where necessary, prioritise them for risk management or data generation. Our aim is to do this prioritisation for all registered substances by 2027, and this report outlines how much progress we have made so far.

The integrated approach helps us pool all available information more efficiently which, as a result, contributes to faster and better-informed decision making.

There were two main reasons for rethinking and reframing our approach. The first was a clear observation that working with groups rather than individual substances has become a must. Handling 10 substances in one go is much more resource efficient than dealing with them one by one. It speeds up our assessments, gets risks controlled more quickly and makes it clear which substances carry the same risks, so companies know to avoid them when switching to alternatives.

The second reason was that the integrated approach enables us to look at the totality of our processes under REACH and CLP. Rather than dealing with substances process-by-process, we can connect the dots and find the best routes to control substance risks as quickly as possible. Doing so helps us protect people's health and the environment, contribute to the functioning of the internal market, and support innovation.

The results of these changes to our approach have started to become evident. The report shows that our increased attention on assessing groups has led to a tenfold increase in the number of substances assessed in 2020 compared to our earlier approach. And this has substantially increased the number of substances being considered for regulatory risk management.

It is clear to me, that this is how we should be working in the future. In addition, we need to focus on making sure companies are fully aware of their obligations and that the information they provide meets the legal requirements. And not forgetting how important it is for risk management to become even more consistent. All these measures will enable faster decision making, with – I dare to claim – no less science.

There are clearly some areas where the legislation is working well. But we are also fully aware that some things must be improved. These will be outlined in our upcoming report to the Commission on the operation of REACH and CLP, which you can look out for in June.

But now, I invite you to dive further into this report and see for yourselves the progress we have made.

Bjorn Hansen

Executive Director

Executive summary

ECHA's Integrated Regulatory Strategy aims to accelerate data generation, identification of groups of substances of concern, and regulatory action. It does so by providing a setup where different regulatory processes can be coherently, effectively and efficiently used, and by encouraging collaboration between ECHA, Member States and the European Commission.

The strategy's goal is to clarify by 2027 which registered substances are a high priority for regulatory risk management or data generation, and which are currently a low priority for further regulatory action.

The group approach – where structurally similar substances are addressed together rather than substance by substance – supports these objectives by enhancing the efficiency of authorities' work, helping them focus on substances of potential concern and to identify appropriate regulatory actions. The mapping of the chemical universe increases the transparency of authorities' work.

The results of 2020 show that the strategy has accelerated regulatory action on substances of concern and increased transparency, predictability and efficiency. In particular, by working on groups of substances and pooling all available information together, we have been able to substantially increase the number of substances being considered for regulatory risk management.

The most visible development is the progress made in clearing the 'not yet assigned' pool. The number of substances registered above 100 tonnes per year that were not yet assigned decreased by 26 % compared to August 2019 figures when the first universe mapping was done. Similar trends are also visible for substances registered at lower tonnages.

The group assessment approach together with ECHA's resource investments in this work have led to a nearly tenfold increase in the number of substances assessed per year compared to the previous screening approach. Based on group assessments carried out during 2019 and 2020, EU regulatory risk management actions are expected for 20 % of assessed substances. However, most of these substances require further data generation and confirmation of their hazards before the need for planned actions can be confirmed or actions can be initiated.

Reducing information gaps is integral to the functioning of REACH and needs to be a priority for industry. Compliance checks are a main tool for ECHA to ask companies to submit information needed to bring their registrations into compliance with the relevant information requirements. At the end of 2020, there were around 1 860 substances for which data generation was ongoing or for which it needed to be started. To avoid unnecessarily delaying regulatory actions, it is important for industry to proactively update their registrations and for ECHA to use all available information when assessing structurally similar substances. The available data on structurally similar substances allows coherent risk management actions for similar substances to be planned even before or during data generation.

The group assessments show that after compliance checks, substances can often proceed directly to regulatory risk management without the need for substance evaluation. This can speed up initiating risk management actions substantially.

Authorities have yet to start preparing proposals for harmonised classification and labelling for many substances. This accumulation of candidates for harmonised classification is a bottleneck for the efficient implementation of the strategy, as harmonised classification is often the prerequisite for moving ahead with regulatory measures under REACH, such as authorisation, or under other EU legislation.

To avoid standstills in the flow of substances from assessment to regulatory risk management actions, Member States need to ensure that substances needing further regulatory action are progressed without delay. For this to happen, adequate resources are required.

Progress in implementing the Integrated Regulatory Strategy can be followed through the chemical universe web page[1] and the outcomes of the group assessments of substances that will be published by the end of 2021.

MAIN RECOMMENDATIONS

- The group approach and the mapping of substances placed on the EU market have provided authorities with a more complete picture of the universe of registered substances and how to efficiently address them. ECHA needs to continue refining and optimising the process based on lessons learned during the strategy's implementation.
- Member States need to ensure adequate resources without delay to progress with substances needing further regulatory action and initiate regulatory risk management, where necessary.
- Member States are encouraged to intensify collaboration with each other to maximise the outcome of their work.
- Industry should make use of the programmes developed to help registrants review and update data in REACH registration dossiers. Industry needs to be proactive and not wait until authorities take regulatory action.

[1] https://echa.europa.eu/universe-of-registered-substances

1. Introduction

1.1 Addressing substances of concern efficiently through the Integrated Regulatory Strategy

This is the third annual report of the Integrated Regulatory Strategy and presents the achievements and state of play of its implementation in 2020.

Since 2016, ECHA's Integrated Regulatory Strategy (and its predecessor, the SVHC Roadmap since 2013) has provided a coherent basis for close collaboration between ECHA, Member States, and the European Commission to address substances of concern as quickly as possible.

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 give stakeholders confidence that registrants are meeting REACH information requirements, and to promote improved communication on safe use in the supply chain.

The goal is that by 2027, a conclusion should be made for all registered substances on whether they are a priority for regulatory risk management, currently a low priority for further regulatory action, or a priority for data generation.

The REACH Evaluation Joint Action Plan[2] is in line with the implementation of the Integrated Regulatory Strategy, which in turn contributes to reaching the United Nation's 2030 Sustainable Development Goals concerning chemicals. The Strategy also brings added value to the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment[3], as the sound management of chemicals depends on the ability of the EU and its Member States to make their decisions based on robust, relevant and up-to-date knowledge.

One of ECHA's tasks is to ensure that the information companies submit in their registration dossiers complies with the information requirements set out in REACH. Identifying and managing the risks posed by substances of concern is carried out together with Member States. Industry sectors and companies can proactively contribute to this work by keeping their registration dossiers up-to-date and providing better use and exposure information.

1.2 Integrated processes to achieve the goal

Under ECHA's Integrated Regulatory Strategy several linked regulatory processes are used by authorities to efficiently identify and address substances of concern (Figure 1). By the end of 2020, companies had registered more than 23 000 substances under REACH and submitted information about their physical-chemical, toxicological and ecotoxicological properties, and use and exposure information to ECHA.

Assessing groups of chemically related substances and their regulatory needs (Box 1) helps to identify if further data or assessment is needed, whether further regulatory risk management activities are required and the most appropriate way to address an identified concern.

[2] REACH Evaluation Joint Action Plan - ensuring compliance of REACH registrations
[3] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

The assessment of regulatory needs is an iterative process done under different processes of the Integrated Regulatory Strategy. 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. When an assessment of regulatory needs is revised or an actual proposal for the regulatory measure is prepared, the previous assessments should be used as a basis as much as possible.

Data generation clarifies whether or not a substance has hazardous properties. The main tools for generating missing hazard information are compliance checks, testing proposals and substance evaluation. Additionally, the work carried out by the ED and PBT expert groups supports the identification of persistent, bioaccumulative and toxic or endocrine-disrupting substances.

The **regulatory risk management measures** to confirm hazards under REACH and CLP are harmonised classification (CLH) and identification as a substance of very high concern (SVHC). A substance is normally subject to harmonised classification and labelling if it meets the criteria for carcinogenicity, mutagenicity and toxic for reproduction (CMR) or respiratory sensitisation. Whereas a substance can be identified as an SVHC and placed on the Candidate List if it meets the criteria for a CMR substance, a PBT/vPvB substance, or a substance that gives rise to an equivalent level of concern as such substances, for example, endocrine disruptors. Harmonised classification and inclusion in the Candidate List have important consequences for company-level risk management and they trigger or enable authorities to take further regulatory risk management. Under REACH, authorisation and restriction are the two main further regulatory risk management tools.

Stakeholders are informed about a substance entering regulatory risk management in the registry of intentions until outcome and the public activities coordination tool (PACT)[4].

[4] https://echa.europa.eu/pact

Box 1: Group assessments to identify substances of concern faster

To speed up the identification of chemicals that need regulatory action, ECHA and Member States have shifted from working on individual substances to dealing with groups of chemically related substances. Group work aims to:

- Enable authorities to use all of the available data and cover a bigger share of registered substances, including those lacking hazard and exposure information;
- Improve regulatory consistency when addressing similar substances and increase the predictability of authority actions;
- Support industry to move towards better-informed substitution by considering potential substitutes for known substances of concern; and
- Make the early identification of substances that do not require further action possible.

More information on the group approach is available at: https://echa.europa.eu/working-with-groups

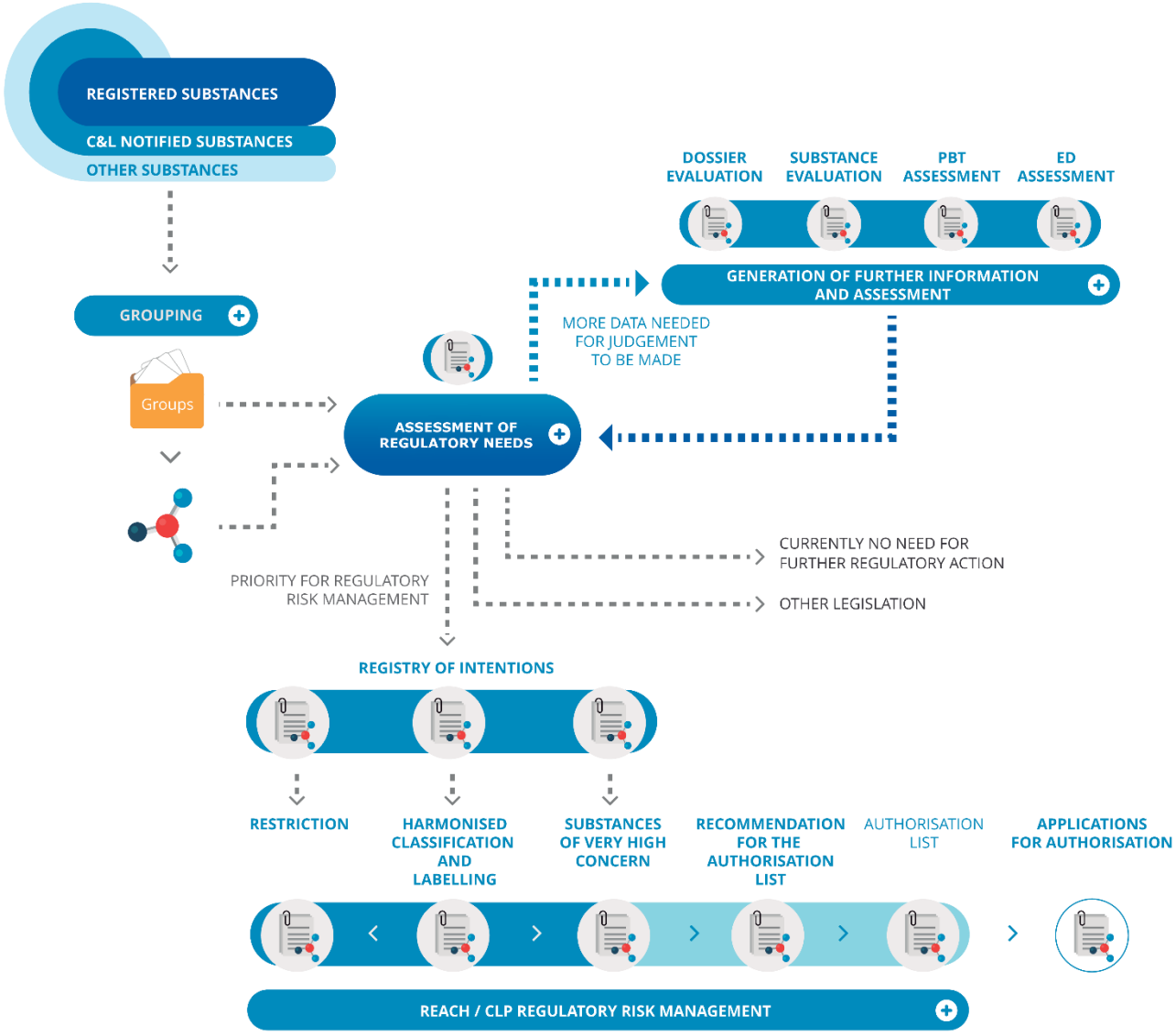
Iterative assessment of regulatory needs throughout the Integrated Regulatory Strategy

Considering regulatory needs early on and iteratively, throughout the processes of the strategy, aims to shorten the time from the identification of a concern until the necessary measures are in place or the concern is refuted. This is achieved by

- Avoiding unnecessary regulatory steps;
- Promoting early discussions and information sharing between authorities and with stakeholders; and
- Supporting better planning of the authorities' work.

As an example of a more complex case, ECHA assesses a group of substances based on the information provided on them in company 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.

Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy[5]



[5] Interactive version available at: https://echa.europa.eu/substances-of-potential-concern

2. The universe of registered substances

2.1 Enhanced transparency on addressing substances of concern

ECHA has created a mapping tool of all registered substances called the **chemical universe** where each substance is assigned to a pool that indicates the regulatory actions already initiated or being considered for that substance. It also shows the substances for which the need for suitable regulatory actions still needs to be determined. At the end of 2020, the universe contained over 23 000 substances[6] (Figure 2 and Table 1).

The chemical universe helps national authorities, ECHA and the Commission monitor the progress made in identifying substances of (potential) concern and appropriate regulatory actions. Being able to monitor these is crucial for authorities as it helps them to achieve the REACH objectives of increased human health and environmental protection.

ECHA publishes the chemical universe to make the actions of authorities more transparent for industry and other stakeholders.

Each substance has been allocated to one[7] of the following pools:

Data generation: This pool contains substances that require additional information or assessment before it is possible to identify whether further regulatory action should be proposed. These include, for example, substances currently under dossier or substance evaluation (excluding testing proposal evaluation and 'targeted' compliance checks that focus only on one or a few aspects, such as only targeting environment endpoints or substance identity), substances being assessed by the PBT and ED expert groups, and substances addressed by the Petroleum and Coal stream working group (PetCo) or under the ECHA-Cefic collaboration on dossier compliance. This pool also includes those substances where authorities have identified the need for further data generation or assessment, but where the action has not yet started. These pending cases may come from substance or dossier evaluation, PBT/ED assessment, or RMOA or group assessment by authorities.

Regulatory risk management under consideration: This pool includes substances that are currently being considered for regulatory risk management. These are, for example, substances for which there is an intention or ongoing proposal to identify a substance of very high concern (SVHC), substances where authorities are preparing or have submitted a proposal for restriction under REACH, and substances under regulatory management option analysis (RMOA). At the latest update of the chemical universe (snapshot from December 2020), this pool also contains substances where authorities are preparing or have submitted a proposal for harmonised classification and labelling under CLP.

This pool also includes substances where authorities have identified that further regulatory risk management might be needed, but where this action has not yet started. These pending cases may come after the outcome of a substance or dossier evaluation, PBT/ED assessment, RMOA, or group assessment by authorities. For example, a Member State may conclude at the end of a

[6] https://echa.europa.eu/universe-of-registered-substances

[7] If there are multiple processes ongoing on the same substance, the mapping is usually based on the latest action, unless there are already stringent regulatory risk management measures in place. For example, if a substance is on the Candidate List but there is further data generation currently under compliance check, the current mapping would be based on the existing Candidate Listing. See more information at: https://echa.europa.eu/how-does-the-chemical-universe-mapping-work

substance evaluation that a substance should be considered for SVHC identification. The substance would be assigned to this pool even if the SVHC identification process has not yet started.

Regulatory risk management ongoing: This pool is for substances where regulatory risk management measures have already been initiated. For most of these substances, additional EU level regulatory actions are not expected. However, for some substances in this pool, there may still be significant work required (for example, prioritisation on the Authorisation List or a restriction proposal for certain PBT/ED substances).

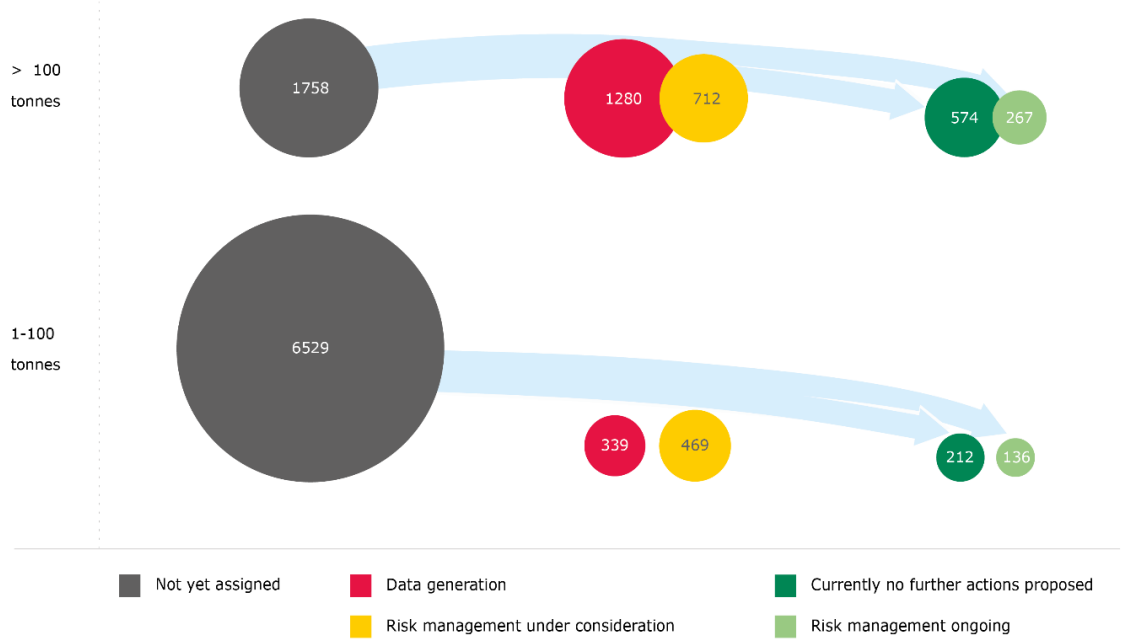
This pool includes, for example, substances on the Candidate List, most substances restricted under REACH (excluding, for example, CMR substances restricted in consumer products), active substances in biocides and pesticides and persistent organic pollutants (POPs). With the latest update of the chemical universe (snapshot from December 2020), this pool also includes substances that have a harmonised classification on Annex VI to CLP as carcinogenic, mutagenic or toxic for reproduction in categories 1A or 1B, or as respiratory sensitisers in any category. These classifications are severe and trigger several downstream consequences and therefore, regulatory risk management can be considered ongoing. However, if there are any additional risk management measures under consideration or further data generation ongoing, the classified substances are mapped in the other pools to highlight this.

Currently no further actions proposed: Authorities review many substances under different regulatory processes and may not identify a need for further regulatory action at that moment. These processes are substance or dossier evaluation, PBT/ED expert group assessment, and RMOA or group assessment by authorities. This could be due to, for example, low hazard or low potential for exposure, considering company-level risk management measures. If the situation changes and, for example, companies report new uses or new data on the substance's hazardous properties or regulatory priorities change, these substances may be subject to further regulatory actions.

At the latest update of the chemical universe (snapshot from December 2020), this pool also includes substances where ECHA has received a proposal for harmonised classification and labelling under CLP, and the Committee for Risk Assessment (RAC) has concluded on a harmonised classification for categories other than carcinogenic, mutagenic or toxic for reproduction in categories 1A or 1B, or as respiratory sensitisers in any category. In doing so, we assume that the authority submitting the CLH proposal has considered whether further regulatory actions are needed and that they will have acted, if necessary. As some entries on Annex VI to CLP are decades-old, we only include those substances in the mapping for which we have received a proposal under CLP and not those that have not been updated since CLP entered into force. Substances addressed under the Existing Substances Regulation, which have not been mapped to other pools, are also included here as they were reviewed by authorities.

Not yet assigned: This pool includes substances registered under REACH that have not yet been assigned to any of the other pools. Substances such as intermediates, unclaimed NONS, and substances for which manufacture has ceased, are usually not prioritised for further assessment and are, therefore, more likely to remain in this pool.

Figure 2: REACH chemical universe at the end of 2020: substances with active registrations above 1 tonne per year



> 100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage above 100 tonnes per year.
1-100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage between 1 and 100 tonnes per year, and for which there are no active registrations registering at a tonnage above 100 tonnes per year under Article 10 of REACH.

Table 1: REACH chemical universe at the end of 2020: all substances

REACH CHEMICAL UNIVERSE. ALL SUBSTANCES					
Registration status and tonnage	**Not yet assigned**	**Data generation**	**Risk management under consideration**	**Currently no further actions proposed**	**Risk management ongoing**
>100 tonnes per year	1 758	1 280	712	574	267
1-100 tonnes per year	6 529	339	469	212	136
Intermediate	6 443	146	159	58	85
NONS - claimed active	1 178	6	17	7	23
Unclaimed NONS	1 591	10	20	11	62
Ceased manufacture - REACH	493	80	31	28	34
Ceased manufacture - claimed NONS	486	2	1	2	23
Total	**18 478**	**1 863**	**1 409**	**892**	**630**

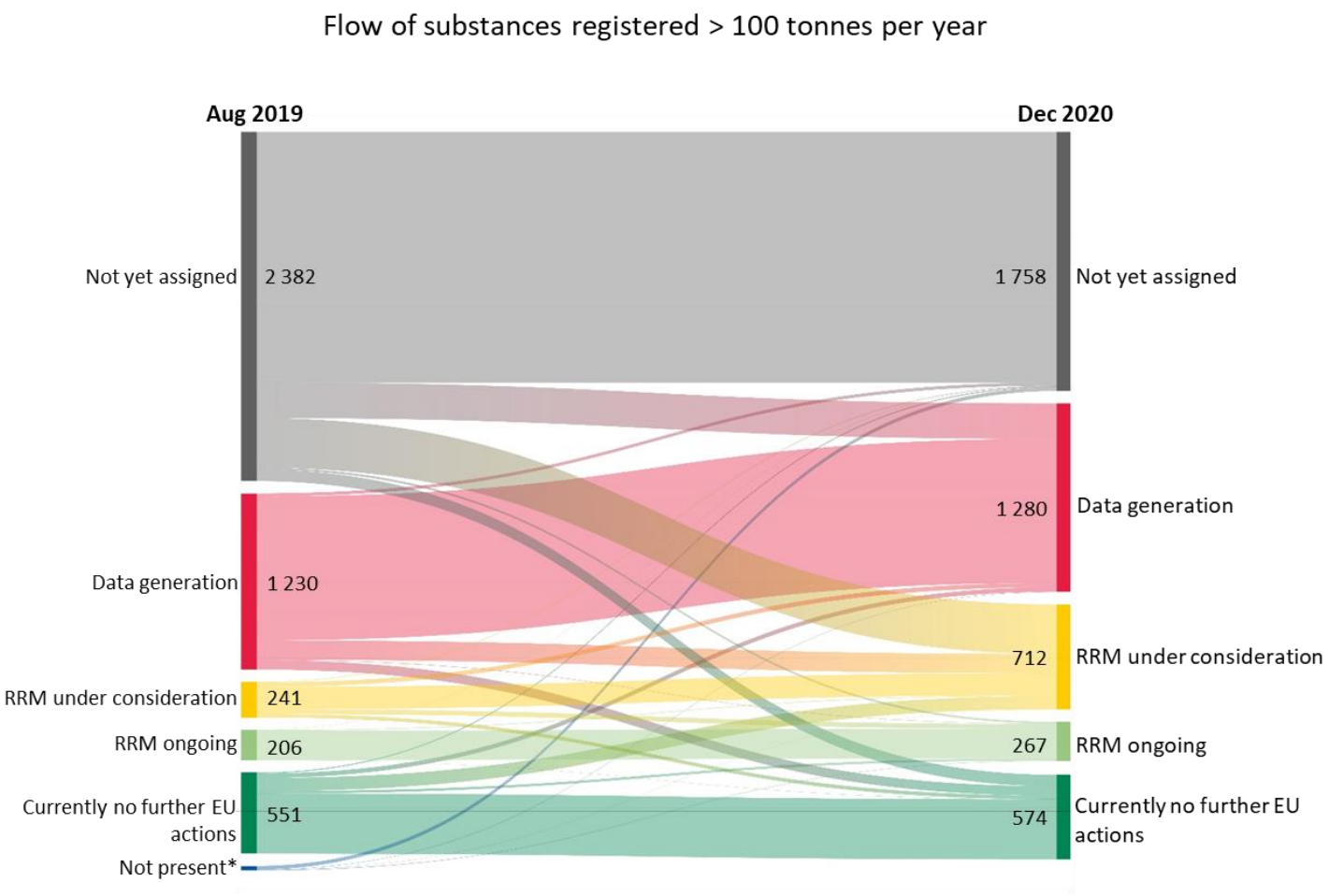
> 100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage above 100 tonnes per year.
1-100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage between 1 and 100 tonnes per year (and which are not covered by the above).
Intermediates: Substances for which there is at last one active registration for intermediate use under Articles 17 or 18 of REACH (and which are not covered by the above).
NONS – claimed active: Former NONS substances for which a registration number has been claimed by a previous notifier, and for which no update has been received under REACH (and which are not covered by the above).
Unclaimed NONS: Former NONS substances for which the registration number has not been claimed (and which are not covered by the above).

2.2 Progress in allocating substances

The first chemical universe mapping in August 2019 provided a snapshot of the allocation of substances to the different pools, whereas the most recent mapping presents the allocation status of substances in December 2020 (Table 1 and Figure 2).

When comparing the allocation of substances registered above 100 tonnes per year, the most visible development between August 2019 and December 2020 is the substantial progress made in clearing the 'not yet assigned' pool (Figure 3). From this pool, around 600 substances were moved to other pools, largely due to ECHA's work on groups of substances.

Figure 3: Flow of substances registered above 100 tonnes per year between August 2019 (the first universe mapping) and December 2020



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

The substances have most commonly moved to the 'data generation' and 'risk management under consideration' pools, where in particular for the latter, there has been a substantial increase in the number of substances due to ECHA's ongoing group assessment work.

Similar trends can be seen for lower tonnage substances in the chemical universe. Through the group assessment work, we have assessed around 10 times as many substances than previously,

and for the first time, have made clear progress in assessing low-tonnage substances (registered at 1-100 tonnes per year).

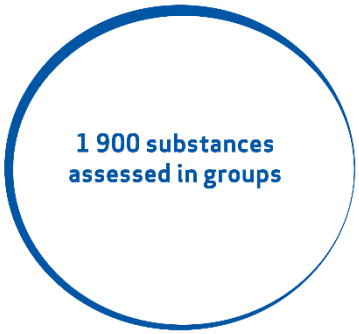
Figure 3 shows the dynamic nature of the mapping as substances move from one pool to another as regulatory processes continue. Some of these movements are explained by certain changes in the latest universe refresh, for example inclusion of the CLH process in the mapping, and improved definitions for POPs, plant protection products and biocides.

Although there are very few instances, we can also see that some substances have moved back to the 'not yet assigned' pool. This is usually because of improved mapping or data quality issues that have been corrected.

Some substances have also moved from the 'currently no further actions proposed' pool to other pools of the universe. This is usually due to the group assessment work, where substances can be reassessed as group members.

It is useful to keep in mind that the mapping is just a snapshot in time and these substances usually move back to the 'currently no further actions proposed' region once the assessment of the group is concluded. This also demonstrates that, as expected, authorities reassess substances that have been allocated to this pool when needed.

3. Working with groups

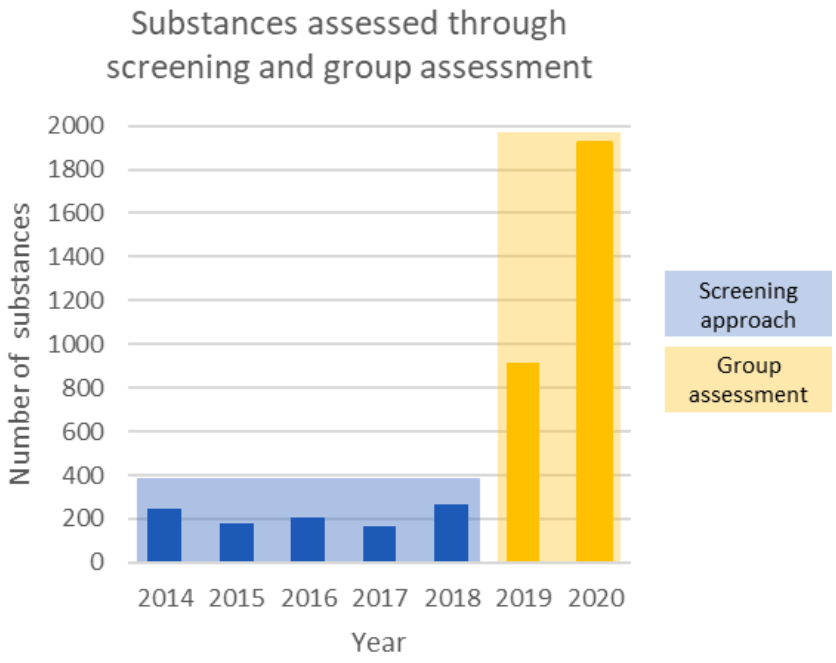


3.1 Accelerated assessment of groups of substances

The year 2019 marked a change from screening to working with groups of substances. The new way of working not only switched the focus to groups of chemically similar substances, but also expanded the scope and depth of the assessment.

Compared with the screening during 2014-2018, there has approximately been a tenfold increase in substances assessed per year using the group approach (Figure 4). In 2020, around 1 900 substances were assessed (this includes concluded and ongoing assessments) as members of groups. Of the assessed substances, around 38 % had been registered above 100 tonnes per year.

Figure 4: Overview of substances screened in 2014-2018 and assessed through the group approach in 2019-2020



The pace of the work was accelerated in 2020 by fully implementing the group approach, enabling twice as many substances to be worked on compared to the previous year.

The considerable increase in the number of substances assessed during the last two years is also attributable to ECHA allocating resources to this work while until 2018 Member States carried out the majority of the screening. Likewise, the fact that the group assessments also include substances with past or ongoing regulatory actions can contribute to the observed increase. This was not the case in the early years of the screening approach, which did not consider and therefore benefit from prior work done on structurally similar substances.

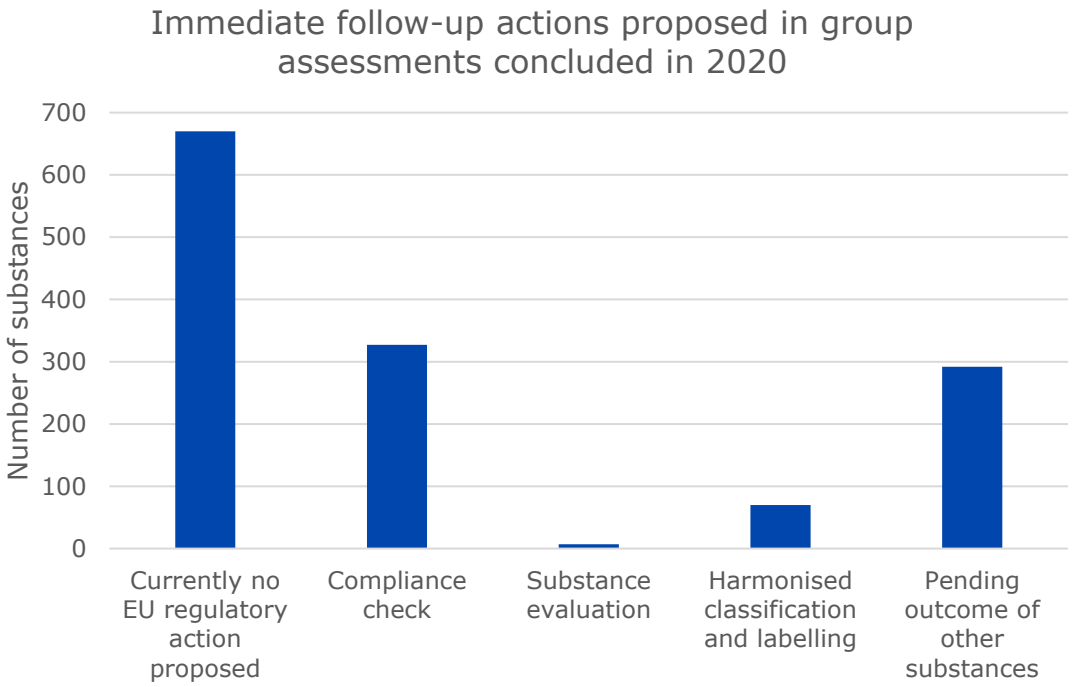
Based on group assessments carried out during 2019 and 2020, EU regulatory risk management actions are planned for approximately 20 % of substances assessed (see also Figure 8). Most of

these substances require further data generation and confirmation of hazard before they can advance to regulatory risk management actions.

The group approach has enabled ECHA to speed up identifying substances for further work. As a result of the group assessments concluded in 2020, 290 substances were identified as candidates or potential future candidates for further EU regulatory risk management. These include many likely or potential CMRs, and a few potential EDs, PBTs, and respiratory sensitisers. As stated previously, most, but not all, of these substances require data generation and confirmation of hazard before they can advance to regulatory risk management actions (Figure 5).

The conclusions of the finalised group assessments have been shared with Member States and will be made publicly available on ECHA's website by the end of 2021.

Figure 5: Immediate follow-up actions proposed in group assessments concluded in 2020



In 2020, ECHA also focused on specific groups that merited additional focus, such as phthalates, and bisphenols.

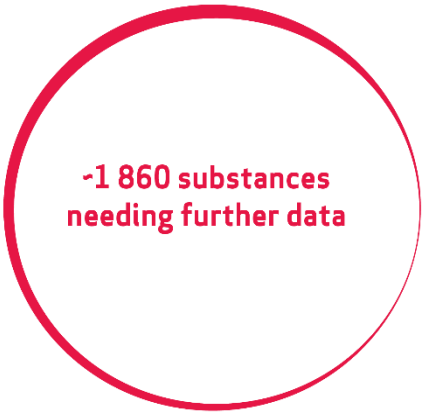
ECHA has also used its grouping and prioritisation approaches to support the European Food Safety Authority (EFSA) to identify plasticisers used in different food contact materials or that could potentially replace current substances in this use.

Stemming from the work on groups of substances, we also identified several cross-cutting generic issues requiring further work from authorities in the coming years, including:

- Skin sensitisers potentially in consumer mixtures;
- Groups of substances which may cause the formation of nitrosamines under certain conditions; and
- Several groups of substances used in fertilisers which may need further hazard data and scrutiny.

4. Substances under data generation

4.1 Robust and relevant information on chemicals is needed



At the end of 2020, there were around 1 860 substances of potential concern needing further data generation. This includes substances for which data generation is ongoing and those for which it needs to be started. The number of substances in this pool increased by approximately 20 % compared to August 2019. The increase is due to the large number of substances assessed under the group approach.

It also shows that the trend observed during the previous years has continued – that is, in many cases, the information available in registration dossiers is not adequate to determine the risks related to a substance and that data fulfilling the information requirements need to be generated. The generation of the data can take anywhere from less than a year up to several years.

4.1.1 Progress in data generation in 2020

Data generation under REACH plays an important role as it contributes to building up, as further outlined in the Commission's Chemicals Strategy[8], '*a comprehensive information base on all substances placed on the market and on their overall environmental footprint, including their impact on climate, and this hinders the proper management of chemicals and products and does not allow for a full sustainability assessment*'.

Compliance checks, testing proposals and substance evaluation are the main tools used to generate missing data. In 2020, ECHA conducted 347 compliance checks (covering over 2 500 dossiers) for 302 substances, of which 271 were full compliance checks for 258 substances and 76 targeted compliance checks[9]. Under substance evaluation, ECHA and Member States adopted 18 decisions requesting further data generation in 2020. Requests for information issued by ECHA under compliance check and substance evaluation in 2020 are outlined in Figure 6 and Table 2 respectively.

An overview of the cumulative outcomes of all concluded compliance checks and substance evaluations (including those leading towards risk management measures) by the end of 2020 is presented in Annex 2.

Companies that are aware of missing information in their registration dossiers, must submit a testing proposal if they intend to perform a new test listed in Annexes IX and X to REACH. Therefore, in contrast to compliance check and substance evaluation, the proposals to test substances come from industry and are not initiated by ECHA. Nevertheless[10], ECHA examines all submitted testing proposals and ensures that each testing proposal addresses the actual

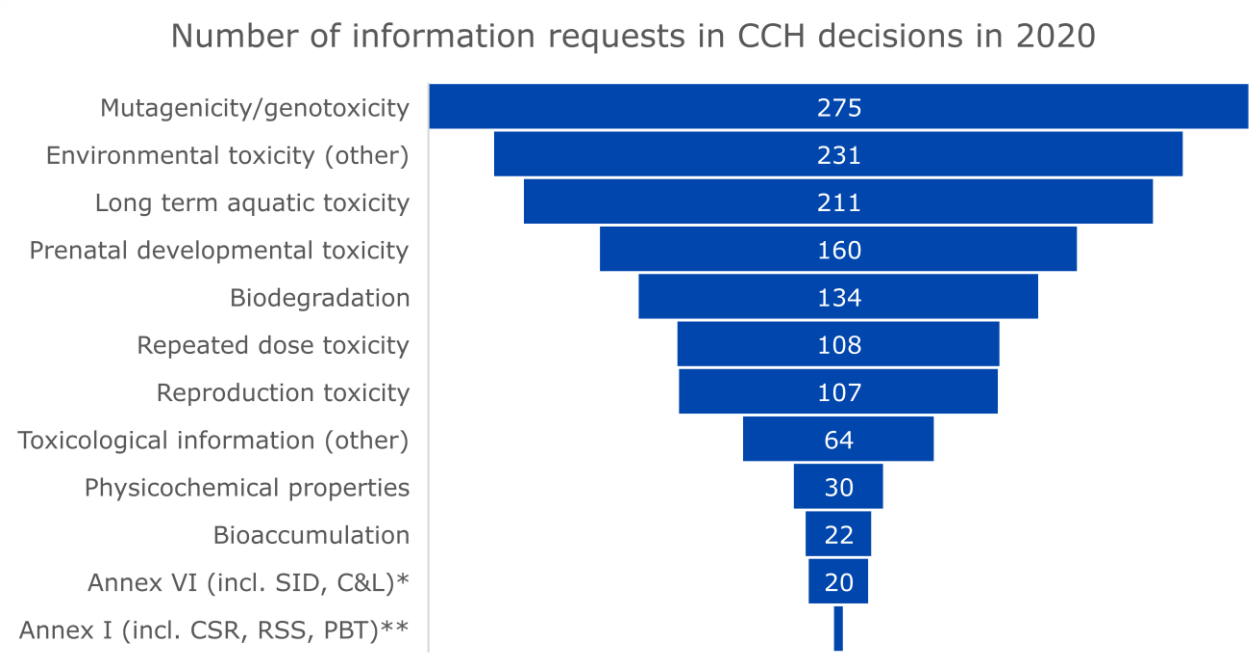
[8] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
[9] In a full compliance check, ECHA performs a systematic evaluation of all information requirements in the registration dossier, including the corresponding elements and conclusions provided in the chemical safety report. In a targeted compliance check, ECHA evaluates only a specific part of the registration dossier based on specified concerns.
[10] According to Article 40 of the REACH Regulation.

information needed and avoids unnecessary testing, particularly when testing involves the use of vertebrate animals.

In 2020, ECHA performed 130 examinations on tests proposed by registrants, issuing 108 draft decisions covering 768 dossiers and terminating (e.g. due to the cease of manufacture or withdrawal of testing proposals) 22 examinations[11] covering 122 dossiers. An overview of testing proposal examinations by the end of 2020 is presented in Annex 2.

For the first time, ECHA also published a list of the substances evaluated in 2020. This list includes full details on the information requests that have been issued to companies as part of ECHA's decisions[12], adopted under dossier evaluation processes. More comprehensive information on ECHA's progress on evaluation is available on ECHA's website[13].

Figure 6: Number of information requests in adopted compliance check decisions[14] in 2020



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

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

[11] https://echa.europa.eu/regulations/reach/evaluation/examination-of-testing-proposals
[12] https://echa.europa.eu/documents/10162/13628/evaluation_report_2020_en.xlsx/a5575c24-4a24-60bc-7194-5e2a7e426f0c
[13] https://echa.europa.eu/overall-progress-in-evaluation
[14] Annex I: General provisions for assessing substances and preparing chemical safety reports; Annex VI: Information requirements referred to in Article 10 (information to be submitted for general registration purposes).

Table 2: Number of information requests[15] in adopted substance evaluation decisions in 2020

INFORMATION REQUESTED UNDER SUBSTANCE EVALUATION IN 2020		
Suspected concern	**Information requested to clarify concern**	**Number of requests**
PBT/vPvB*	Simulation biodegradation test	4
	In vivo mammalian comet assay	1
	In vitro mammalian cell micronucleus assay	1
	Analytical information on composition	1
Reproductive toxicity	Developmental neurotoxicity study	1
	Sub-chronic 90-day toxicity study	1
Endocrine disruption	Amphibian metamorphosis assay	2
	Fish sexual development test	1
	Larval amphibian growth and development assay	1
	In vitro alcohol dehydrogenase inhibition assay	1
Other hazard-based concerns	Sub-chronic 90-day toxicity study	3
	Terrestrial toxicity test	2
	Sediment-water toxicity test	1
	Total	**24**

*PBT: persistent, bioaccumulative and toxic; vPvB: very persistent and very bioaccumulative

4.1.2 Follow-up to dossier evaluation: data generated in 2020

In 2020, hazard data was generated for more than 170 substances in response to compliance checks, substance evaluation and testing proposal decisions. The 'top five' endpoints for which further information was submitted to ECHA under dossier evaluation (CCH and testing proposal examination) were pre-natal developmental toxicity and sub-chronic toxicity (90-day) studies, followed by studies on *in vitro* genotoxicity, long-term toxicity to fish and toxicity to reproduction.

Decisions may contain requests for several studies to be provided. Depending on the complexity of the studies requested, companies may have from six to even 58 months or more to provide them. Then, ECHA checks whether the requested information is in line with the adopted decision. However, the information submitted by registrants further to an evaluation decision is generally in line with the requests and, therefore, higher levels of compliance are expected to be seen in the next years.

As their contributions to the decision-making process and further testing requests, during 2020, the PBT and ED expert groups gave scientific advice[16] on 30 cases concerning PBT properties and 20 cases concerning ED properties of substances[17].

Some substances are under scrutiny in several regulatory processes. An example where risk management measures were implemented earlier than the completion of data generation under

[15] A decision may contain more than one request.
[16] Expert group opinions are informal advice given to Member States that are assessing substances and generally consist of advice on ED/PBT properties, testing strategies or information needs.
[17] These numbers also include some substances discussed in the context of the Biocidal Products Regulation and the Persistent Organic Pollutants Regulation.

substance evaluation, that consequently resulted in a safer use of the chemical, is outlined in Box 2.

Box 2: Classification proposal during substance evaluation

Although it can be time consuming to finalise work on all hazard endpoints considered in substance evaluation, it is not necessary to wait for the whole process to be finished before starting regulatory risk management action. An example of this is with the substance trimethoxy(vinyl)silane, which has a harmonised classification as a skin sensitiser category 1B that was adopted two years before the whole substance evaluation process was finalised.

When concluding on a substance evaluation, the evaluating Member State indicates by when the necessary regulatory risk management proposal (harmonised classification, SVHC identification, restriction, others) will be submitted and, in the majority of cases, a tentative timing and commitment.

For trimethoxy(vinyl)silane, the follow-up action commenced very swiftly. The substance was selected for substance evaluation to clarify its suspected skin sensitising hazards, which were a concern as the substance is widely used and registered at a high tonnage, and can therefore pose a risk to workers. The skin sensitisation hazard was confirmed based on the evaluation of available data. Sweden, as the evaluating Member State, submitted a classification dossier with the skin sensitiser category 1B proposal in May 2017, which was adopted in September 2018 by the Committee for Risk Assessment (RAC). The formal conclusion of the substance evaluation process covering assessment of other concerns was published in October 2020.

4.2 Constant flow of substances to data generation

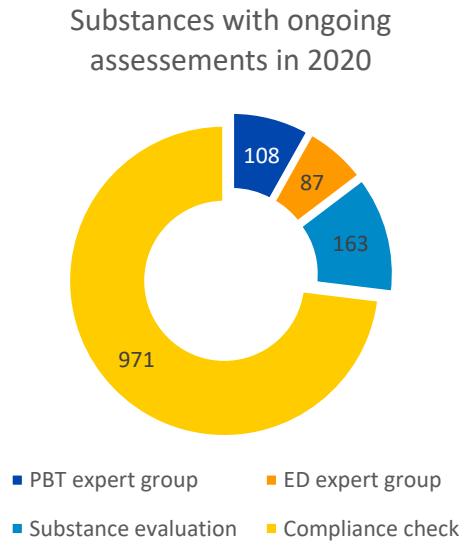


Figure 7: Number of substances with an ongoing assessment in the PBT and ED expert groups, substance evaluation and compliance check at the end of 2020

The number of substances registered above 100 tonnes per year in the 'data generation' pool was nearly the same in August 2019 (1 230 substances) as in 2020 (1 280 substances). Despite these relatively similar figures, there was actually a good flow of both new substances being brought to the pool for data to be generated and substances for which data has been generated, moving to the other pools, as was demonstrated earlier in Figure 3. That said, many REACH registered substances of potential concern have an assessment ongoing. By the end of 2020, many substances were in the process of being assessed under compliance check, substance evaluation or in one of the expert groups (Figure 7). This means that for each of these substances:

- An assessment is under way;
- Missing information is being requested or generated by registrants; or
- Authorities are assessing the information submitted by registrants.

Some substances in Figure 7 are counted more than once. For example, Member States use the expert groups to support their work under substance evaluation and around 82 % of the substances with potential PBT and ED properties listed in the Community rolling action plan (CoRAP) between 2012 and 2020 were discussed in the PBT and ED expert groups.

In addition, a compliance check is usually carried out on substances listed in the CoRAP for substance evaluation, meaning that these are also counted more than once.

In other cases, industry may respond to a compliance check outcome by submitting a testing proposal for other endpoints than those requested. For example, testing proposals for an extended one-generation reproductive toxicity study (EOGRTS) may be submitted based on adverse effects on fertility observed in the sub-chronic 90-day toxicity study, requested at the Annex IX tonnage band under compliance check. Therefore, several dossier evaluation processes may result in more than one verification of generated data. A couple of examples where registrants changed the self-classification of their substances based on new data are presented in Box 3. An overview of the outcome of the work carried out in the PBT and ED expert groups during 2012-2020 is presented in Annex 1. More information on progress in data generation from 2009 until the end of 2020 is available in Annex 2 as well as on ECHA's website[18].

Box 3: Stricter self-classifications applied by registrants based on new data following compliance checks

DIPHENYL(2,4,6-TRIMETHYLBENZOYL)PHOSPHINE OXIDE, TOXICITY TO REPRODUCTION

This substance has a harmonised classification as a *suspected* human reproductive toxicant (Category 2). Under compliance check, the registrant was requested to provide information on an extended one-generation reproduction toxicity study (OECD Test Guideline 443). Instead, the registrant adapted the requirement and conducted a screening study (OECD 421), in which severely impaired male fertility was observed. Based on the findings, the registrant applied a more stringent self-classification of the substance as a *presumed* human reproductive toxicant (Category 1B).

Although the revised self-classification addresses reproductive toxicity appropriately, other potential hazards, such as developmental toxicity, PBT and ED, require further action by authorities. Currently, Sweden is revising the harmonised classification and labelling with a proposal to classify the substance as a skin sensitiser (Category 1B) with a H317 hazard statement *"May cause an allergic skin reaction"* and as a reproductive toxicant (Category 1B) with a H360FD hazard statement "*May damage fertility. May damage the unborn child*".

The substance is also proposed for substance evaluation in 2022 by Sweden to clarify PBT and ED concerns.

[18] https://echa.europa.eu/progress-in-dossier-evaluation

N-[3-(DIMETHYLAMINO)PROPYL]TALL-OIL AMIDES, AQUATIC TOXICITY

This substance is reported to be used in plastic articles, and there is therefore a potential for releases to the environment. Following a compliance check, the registrant submitted results obtained in a freshwater alga and cyanobacteria, growth inhibition test (OECD Test Guideline 201) in which a range of seven concentrations were tested and a concentration dependent inhibition in algae growth rate was observed.

As an outcome, the registrant updated the substance's chemical safety report and increased the M-actor* of the self-classification (Aquatic Acute 1 and Chronic 1, now M=10 for both).

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* *The **M-factor** stands for a multiplying factor for substances that are highly toxic to the aquatic environment. The purpose of applying the M-factor is to give an increased weight to highly toxic components **when classifying a mixture**. The M factor can be 1, 10, 100, 1000 or 10000. The higher the M factor of a component of a mixture, the more weight it has on the overall need to classify the mixture.*

The REACH Evaluation Joint Action Plan[19] calls for industry to review their registrations and update them when necessary, including generating new information. Although dossier compliance is the responsibility of each individual registrant, the obligation to share data and register jointly for the same substance, and the efficiency brought by addressing groups of similar substances, lend support to the idea of reviewing and updating registration dossiers in a more structured and systematic manner.

Companies with large portfolios and business associations have launched programmes that capture many substances to update the registration information appropriately, introduce new knowledge and propose optimised testing strategies, where necessary. These voluntary industry programmes should, in the future, bring necessary dossier improvements and additional information instead of ECHA issuing compliance check decisions.

ECHA supports the development of voluntary testing strategies by industry, where companies can avoid unnecessary animal testing and costs, and achieve compliance of their registration dossiers without the need to test each substance individually. Such approaches include voluntary generation of lower tier (Annex VII/VIII) information and testing proposals to avoid compliance checks on each individual substance.

An example of such collaboration is a pilot project carried out as part of a voluntary multi-annual action plan to review and improve REACH dossiers[20] that the European Chemical Industry Council (Cefic) launched in 2019[21]. The pilot project was carried out with a small set of companies from December 2019 until October 2020 to pinpoint improvements for a prioritised group of substances and found that the areas that need improvement in developing the testing strategies were: clarity on the substance compositions, development of a scientifically sound read-across hypotheses substantiated with existing data or generation of further data, and selection of candidate substances for higher tier testing.

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19 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

20 https://cefic.org/our-industry/reach-dossier-improvement-action-plan/

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

The registrants committed to bring forward the (revised) strategies and testing proposals for formal examination. The general lessons learnt from these pilot studies have been published in January 2021[22] and are expected to be applied to future testing strategies in 2021 and the coming years.

Support has also been given to the non-ferrous industry with the Metals and Inorganics Sectoral Approach. This approach aims to improve the compliance of the metals and inorganics large volume registration dossiers. The work has resulted in a number of dossier updates for human health and environmental endpoints and to continue the progress made, the programme has been extended to run until the end of 2021.

[22] https://cefic.org/app/uploads/2021/01/Pilot-project-report_-Dec-2020_summary.pdf

5. Substances under consideration for regulatory risk management

5.1 Visible impacts of the Integrated Regulatory Strategy

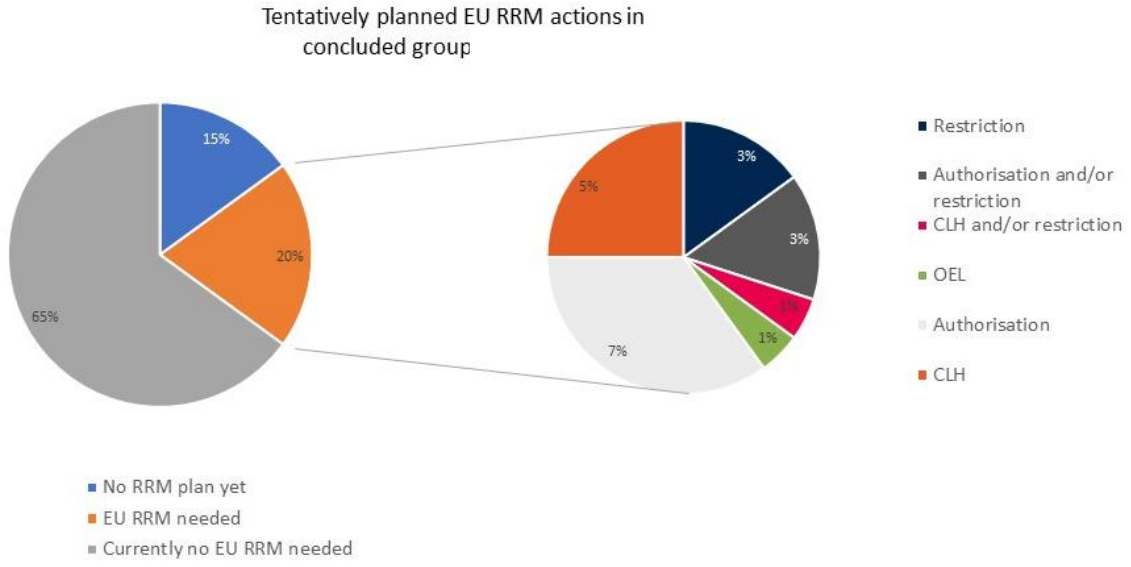
-1 400 substances under consideration for regulatory risk management

By the end of 2020, almost 1 400 substances were under consideration for regulatory risk management. In August 2019, around 330 substances had been allocated to this pool.

The four-fold increase from 2019 to 2020 is mostly due to the rise in substances being assessed in groups, which makes up over 80 % of the substances in this pool. Even though this work is ongoing, for many groups the assessments have been carried out and follow-up actions, where necessary, have been identified but not yet implemented.

Figure 8 gives an overview of the outcomes of group assessments carried out during 2019 and 2020. EU regulatory risk management actions are foreseen for roughly 20 % of substances assessed in the groups. The most common regulatory risk management actions planned are authorisation, restriction, and harmonised classification. However, for most of the substances, data generation and confirmation of hazard are needed before regulatory risk management can be considered in more detail and, where needed, initiated under the relevant process.

Figure 8: Tentatively planned EU regulatory risk management actions for substances based on group assessments carried out during 2019-2020



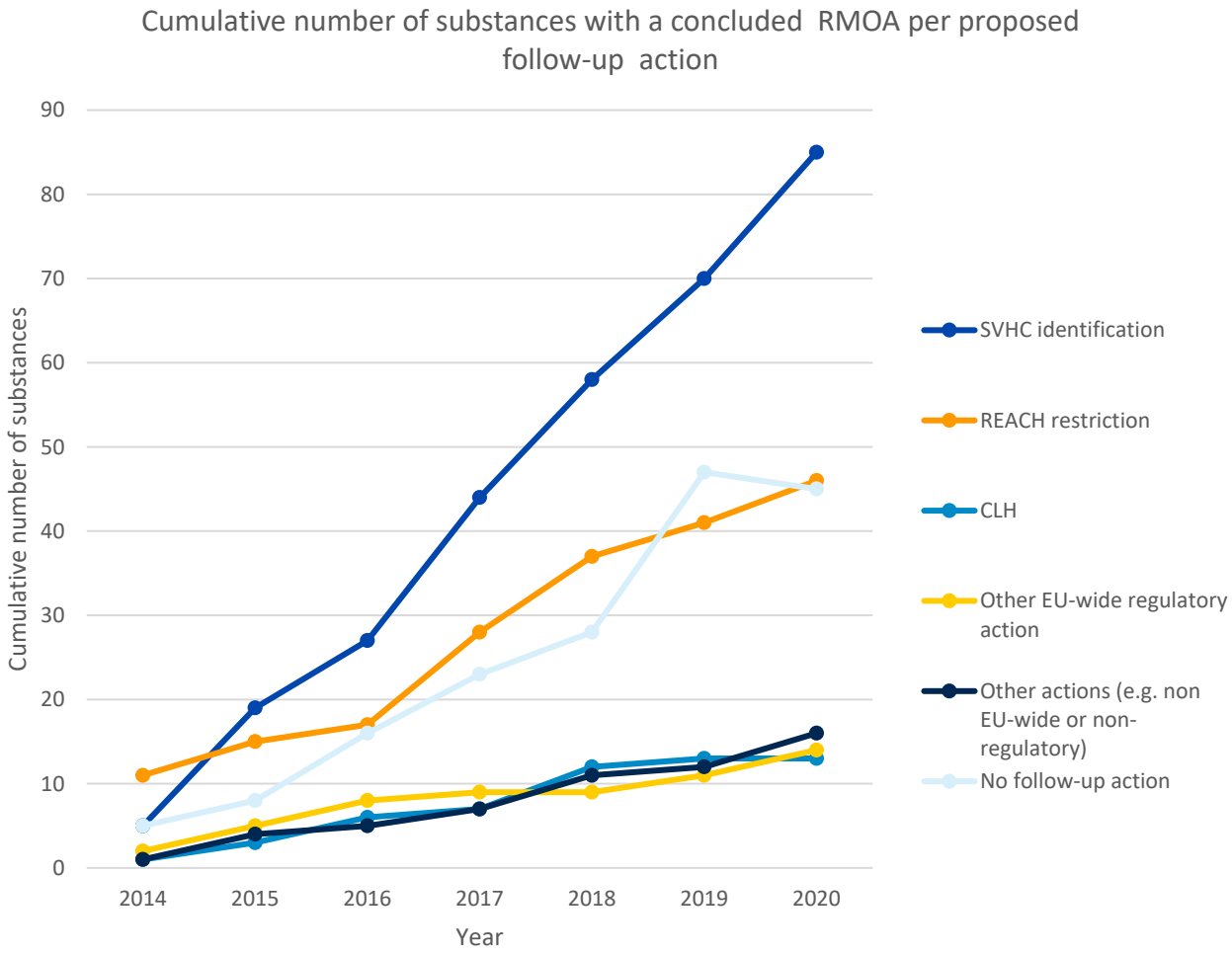
To identify the most appropriate regulatory actions to address a concern, Member States continued to carry out RMOAs. By the end of 2020, the cumulative number of substances

(individually or as part of a group) for which an RMOA had been concluded was around 220 – an increase of 13 % compared to the previous year.

A breakdown of the follow-up actions proposed in the RMOA conclusions is presented in Figure 9. The figure shows that SVHC identification is the most common follow-up action and that their number has increased at a steady pace from 2017 onwards.

In the RMOAs concluded in 2020, 27 new substances were identified as needing further EU regulatory risk management (under REACH, CLP, or other EU legislation) or another action (Figure 9). The number of substances for which an intention to prepare an RMOA has been made has increased from 22 in 2019 to 45 in 2020. The extent to which concluded RMOAs resulted in regulatory follow-up increased from 83 % in 2019 to 92 % in 2020. More information on RMOAs carried out by the Member States is available in Annex 1.

Figure 9: Cumulative number of substances for which Member States had concluded an RMOA per proposed follow-up regulatory action (February 2013-December 2020)



As in 2019, it is clearly visible from the proportion of CLH dossiers that were submitted as a follow-up to previous activities that the Integrated Regulatory Strategy has had an impact on connecting REACH and CLP processes. During 2016-2020, an average of 70 % of CLH dossiers concerning substances registered under REACH resulted from a preceding regulatory activity, compared to an average of 23 % during 2010-2015. In 2020, the majority of the submitted CLH dossiers were proceeded by dossier evaluation, followed by substance evaluation and assessment of groups of substances (Table 3).

Table 3. Sources of harmonised classification and labelling dossiers concerning substances registered under REACH in 2020

SOURCES OF CLH DOSSIERS IN 2020	
Activity	**Proportion**
Compliance check	44 %
Substance evaluation	32 %
RMOA	12 %
Group assessment	32 %
At least one activity	68 %

EXAMPLE OF GROUP ASSESSMENT AROUND SUBSTANCES INCLUDED ON THE CANDIDATE LIST

In 2020, ECHA assessed phthalic anhydrides and their derivatives. Three phthalic anhydrides, **TMA** (EC 209-008-0), **HHPA** (EC 201-604-9) and **4-MHHPA** (EC 243-072-0), are on the Candidate List and have been recommended for inclusion in the Authorisation List due to their respiratory sensitising properties.

With grouping, we were interested in finding similar substances that may share this hazard property and have similar uses, and therefore be used as substitutes. With this approach, we also wanted to ensure consistency with previous regulatory actions.

Phthalic anhydrides are substances that are mainly used in industrial settings to produce polymeric resins, which brings concerns related to worker exposure and risks to their health to the forefront.

In the group assessment, more than 30 substances were identified from the chemical universe that resemble the three phthalic anhydrides on the Candidate List. As the group consists of substances that have similar uses and similar chemical structures, we consider that there is potential for substitution within the group for at least some of their uses, for example, as epoxy resin hardeners. For this reason, these substances could be used as regrettable substitutes for the substances on the Candidate List.

Assessing the substances holistically has enabled us to consider what could be the most appropriate regulatory risk management measures to control the risks arising from the uses of a large group of substances with potentially similar risks.

Currently, a group harmonised classification for skin sensitisation (Category 1) and respiratory sensitisation (Category 1), and the need for further regulatory risk management action is being considered.

The proposed actions are not set in stone but will be considered in detail throughout the integrated regulatory processes. The conclusions of the finalised group assessments have been shared with Member States and will be published on ECHA's website by the end of 2021.

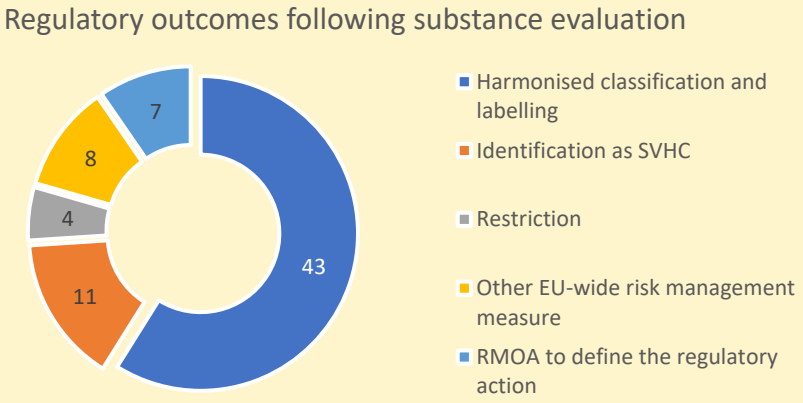
5.2 Investments required to progress with substances needing regulatory action

By the end of 2020, Member States and the Commission had started timely follow-up action for substances proposed for identification as an SVHC or restriction under REACH. Similarly, Member States had progressed well in initiating RMOAs for around 125 substances, leaving 20 substances pending an RMOA to be started. For a substantial amount (100 substances) a hazard confirmation through harmonised classification and labelling had also been initiated. Regardless of this, there was an even higher number (125 substances) pending CLH to be initiated.

During the year, ECHA concluded follow-up assessments for 129 substances that were subject to either compliance checks or testing proposal examinations. From these substances, 16 were proposed for CLH, one requires further clarification on endocrine-disrupting properties and two were proposed for further assessment of persistent, bioaccumulative and toxic properties. An overview of the cumulative outcomes of all concluded substance evaluations (including those leading towards risk managements measures) by the end of 2020 is presented in Box 4.

Box 4: Substances from data generation and assessment are progressed to regulatory risk management

By the end of 2020, substance evaluation had been concluded for 118 substances. For half of the substances, a need for further EU regulatory risk management was concluded. The proposed follow-up actions are shown in the figure below. A substance can have more than one proposed action.



For the remaining half of the substances, currently no further EU regulatory risk management is warranted. 50 substances were concluded as not hazardous or not demonstrating a potential for exposure, and 9 substances did not require further regulatory action at EU level due to actions by registrants to ensure safety (e.g. changes to supported uses, applied risk management measures, reduction of the aggregated tonnage, cease of manufacture).

To facilitate the follow-up of agreed regulatory risk management actions, a working group of Member States and ECHA was set up in December 2019. During the past year, Member States reviewed over 200 pending cases for which they had proposed regulatory actions but had not yet started them.

As an outcome of the review, Member States committed to progress around one third of the substances to regulatory risk management over the next two years. For another third of the

substances, Member States no longer considered the previously identified action necessary because appropriate risk management action had in the meanwhile been put in place or was no longer needed. The Member States indicated that a lack of resources was one of the main reasons preventing them from acting.

The responses from Member States enable ECHA to identify further needs for improvement of its tracking systems for substances pending regulatory action. In parallel, ECHA is analysing the remaining pending actions that were not yet reviewed by the Member States, and will propose a plan on how to effectively proceed with them and enhance the timely follow-up of identified actions in the future. An overview of RRM activities under REACH and CLP since 2008 is available in Annex 3. Additional information on regulatory activities is provided each year in ECHA's Annual Report[1].

[1] https://echa.europa.eu/plans-and-reports

6. Substances with regulatory risk management ongoing

6.1 Increasing number of new substances of concern identified and regulated every year

By the end of 2020, 630 registered substances, of which around 40 % were substances registered above 100 tonnes per year, had regulatory risk management already ongoing and did not require additional regulatory action at EU level.

The regulatory risk management actions include:

- Harmonised classification on Annex VI to CLP as carcinogenic, mutagenic or reprotoxic substances (CMRs) in categories 1A or 1B, or as respiratory sensitisers;
- Inclusion on the Candidate List of substances of very high concern (SVHCs);
- Substances covered by certain restrictions under REACH;
- Regulated through the POPs Regulation; and
- Approval as pesticidal or biocidal active substances.

The size of this pool increased by around 60 % compared to August 2019. The difference is largely explained by the high number of new substances brought to regulatory risk management from the group work and by the inclusion of substances with a harmonised classification as CMRs in categories 1A or 1B, or as respiratory sensitisers in any category. While there are more substances in each of the previously mentioned lists, only those registered under REACH are considered.

In 2020, the Candidate List was updated with six new entries[2] of which five were due to their reproductive toxicity and one due to its endocrine-disrupting properties (Table 4).

Table 4: SVHC proposals discussed in 2020 and their reasons for inclusion

SUBSTANCES ADDED TO THE CANDIDATE LIST IN 2020 AND THEIR REASONS FOR INCLUSION	
Dibutylbis(pentane-2,4-dionato-O,O')tin	Toxic for reproduction (Article 57c)
Butyl 4-hydroxybenzoate	Endocrine disrupting properties (Article 57(f) - human health)
2-methylimidazole	Toxic for reproduction (Article 57c)
1-vinylimidazole	Toxic for reproduction (Article 57c)
Bis(2-(2-methoxyethoxy)ethyl) ether	Toxic for reproduction (Article 57c)
Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	Toxic for reproduction (Article 57c)

[2] Published in June 2020 and January 2021

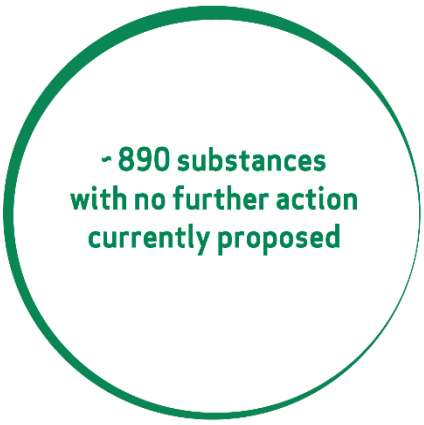
Altogether, three restriction proposals on (groups of) substances were adopted in 2020 and five were going through the restriction process. A restriction intention for certain substances in single-use baby diapers was submitted in October 2020. None of these proposals followed from group assessments carried out by ECHA. Instead, they were initiated based on other activities by the Member States or the European Commission (COM). However, as reported in section 3 of this report, candidates for restriction have been identified as an outcome of the group assessments carried out in 2020.

After the sunset date has passed for a substance included on the Authorisation List, ECHA considers if the use of the substance in articles causes risks to human health or to the environment which are not adequately controlled. This is done by gathering information on all the uses of the substances in articles from various sources and by screening the uses for potential risks. If there is a potential for a risk, ECHA is required to prepare a restriction proposal. Based on the screening work carried out in 2020, few restriction proposals are expected to be initiated. When it is confirmed that a restriction proposal is the way to go ahead, the intentions to submit restriction proposals will be placed in the registry of restriction intentions[3] on ECHA's website.

More information on substances on the Candidate List, on the Authorisation List, or restriction proposals adopted, going through the restriction process, or going through the Article 69(2) screening from 2009 until December 2020, is available in Annex 3.

[3] https://echa.europa.eu/registry-of-restriction-intentions

7. Substances with no further EU RRM action currently proposed



7.1 Assigning substances to this pool allows focusing on substances that matter

By the end of 2020, around 890 registered substances were concluded not to currently need further EU regulatory risk management action based on assessments carried out during compliance check, substance evaluation, RMOA, or group assessments (Table 5).

This figure increased by 27 % compared to August 2019, when the pool contained 700 substances. As in 2019, the majority of the substances in this pool stem from RMOA / group assessment activities.

Table 5: The source activity where the outcome of currently no need for further EU regulatory risk management was proposed

SUBSTANCES WITH NO FURTHER REGULATORY ACTION CURRENTLY PROPOSED AFTER REVIEW IN DIFFERENT ACTIVITIES	
Activity	**Proportion**
RMOA / group assessment	53 %
Compliance check	37 %
Substance evaluation	3 %
PBT/ED expert group assessment	2 %
Other	6 %

The hazards and uses of substances in this pool do not raise enough concern for EU level actions to currently be considered. The two main reasons for allocating a substance to this pool are:

- Low hazard – based on available information, the substance is likely to be non-hazardous; and
- Low exposure potential – based on available information, the substance has low potential for exposure to humans or releases to the environment.

In 2020, substances with a harmonised classification under CLP other than CMR (categories 1A/1B) or respiratory sensitisation were also included in this pool based on the assumption that the authority submitting the CLH proposal has considered whether further regulatory actions are needed and would have taken action, if necessary.

Differentiating between substances needing and not needing further EU regulatory risk management is crucial for addressing substances of concern efficiently as it allows authorities to focus their resources on substances that matter. Systematic and transparent tracking of substances that currently do not need regulatory action enables them to be reassessed when new information on hazards or uses becomes available or when the regulatory interest or political priorities change. Also, identifying and assessing groups of substances around low hazard substances speeds up the clearing of the 'not yet assigned' pool.

As was depicted in Figure 3, substances can be reallocated from the 'no need for further EU RRM' pool back to other pools, for example, based on new information that indicates a need to initiate

further regulatory risk management. This is particularly true for substances where no need for action has been decided based on low exposure. A good example is a substance with CMR properties currently used only as an intermediate. While such a substance would normally be concluded to not need immediate regulatory risk management, it could be moved to the pool of substances for risk management together with structurally similar substances to give a clear signal that it is likely not a suitable substitute.

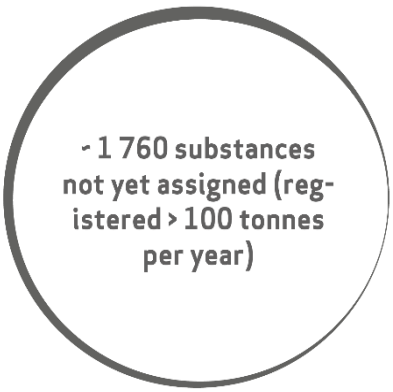
ALCOHOL ETHOXYLATE SULFATES: GROUP ASSESSMENT, LEADING TO THE CONCLUSION OF CURRENTLY NO NEED FOR FURTHER EU REGULATORY RISK MANAGEMENT

Alcohol ethoxylate sulfates (36 substances as group members) function as surfactants, foaming agents, processing aids and process regulators. They have a large variety of uses by professional workers and consumers, including in washing and cleaning products, textile coating, cosmetics and body care products. These uses have a potential for exposure to humans and releases to the environment and, therefore, ECHA assessed whether the substances could be of concern.

Based on available information, all substances appeared to have low human health and environmental hazards. However, the dossiers of these substances were generally data-poor and the proposed read-across adaptations within the group or category were not sufficiently substantiated by data. Therefore, compliance check was opened to confirm the low hazard for human health and the environment. ECHA adopted decisions requesting nearly 100 studies for 11 substances on several endpoints addressing both human health (*in vitro* mutagenicity, sub-chronic and pre-natal developmental toxicity) and environmental (short and long-term toxicity to aquatic invertebrates, plants and fish) toxicity. Updated dossiers including new studies are expected to come by spring 2023.

8. Substances in the 'not yet assigned' area

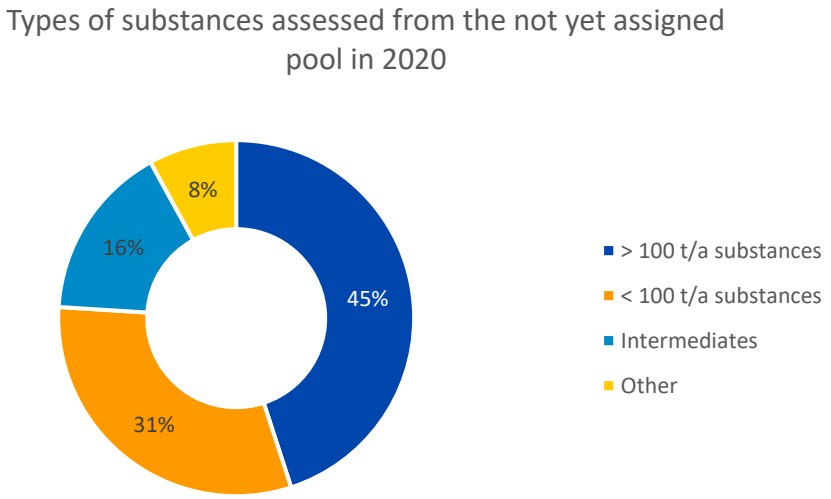
8.1 Progress in mapping and grouping the not yet assigned pool



At the end of 2020, there were around 1 760 substances registered above 100 tonnes per year that had not yet been assigned to any other pool, and approximately 6 530 substances registered between 1-100 tonnes.

In 2020, around 1 025 substances from the 'not yet assigned' pool were assessed as members of groups. Of these, 45 % were substances registered above 100 tonnes per year (Figure 11). Compared to August 2019, the pool of not yet assigned substances registered above 100 tonnes per year decreased by 26 % as a result of the group work.

Figure 11: Overview of the types of substances assessed from the not yet assigned pool in 2020



Of the assessments concluded in 2020, 43 % of substances registered above 100 tonnes per year were proposed for further data generation under compliance check, followed by 36 % of substances being concluded as currently not needing further EU regulatory action (Table 6).

For substances registered at 1-100 tonnes per year, the latter type of substances were the most common (44 %), whereas compliance check was the second most frequent common outcome (29 %).

For a subset of substances, it was possible to propose further regulatory risk management based on the available data: altogether 36 substances for harmonised classification and two substances for inclusion in the Candidate List.

Table 6. Number of substances from the not yet assigned pool for which a group assessment was concluded in 2020 and the concluded proposal

NUMBER OF SUBSTANCES FROM THE NOT YET ASSIGNED POOL FOR WHICH A GROUP ASSESSMENT WAS CONCLUDED IN 2020 AND THE CONCLUDED PROPOSAL				
Group assessment proposal	**Registered above 100 t/y**	**Registered below 100 t/y**	**Intermediates**	**Total**
Need for CCH	124	80	0	204
ED assessment	0	1	0	1
Need for CLH	16	17	3	36
Inclusion in Candidate List	1	0	1	2
Currently no need for action	103	122	63	288
Pending the outcome of other substances	46	59	30	135

By the end of 2020, around 20 % of substances contained in this pool had been assigned to groups to be assessed. Of the grouped substances, up to 50 % are substances registered above 100 tonnes per year, which supports the goal of having assessed all high tonnage substances by the end of 2023.

Although the speed at which substances were assessed increased significantly during 2019 and 2020, with its current capacity, ECHA was unable to reach its interim target of having all substances registered above 100 tonnes per year assessed by the end of 2020. However, with the group approach we not only concentrated on higher tonnage substances, but also assessed a substantial number of structurally related, lower tonnage substances. If the group assessment work continues as is, we expect to have mapped over 80 % of the substances above 100 tonnes per year by the end of 2021. ECHA will continue refining and optimising the process based on the learnings gained during its full implementation.

The remaining 1 760 substances registered above 100 tonnes per year in the 'not yet assigned pool' are expected to mostly be substances that have less severe hazards, for which group assessments have been delayed due to many ongoing clarifications on substance identity or data generation, or that are complex, such as slags and residues, and for which additional elements need to be considered before deciding on further action. On the other hand, the remaining 6 530 substances registered between 1-100 tonnes are expected to be those for which there is not enough information in the registration dossiers and other data sources to form a view on their potential hazardous properties or uses.

To ensure that the substances that have not yet been assigned to groups will be managed in the most impactful way, ECHA has carried out an initial, stepwise mapping to find substances that are unlikely to have properties of concern. This filtering has been based on use considerations and a suite of QSAR models and other alternative methods to identify potential hazards. Based on the outcome, we expect that further scrutiny will be required for approximately two thirds of the substances to conclude whether further data generation and potential further regulatory action is needed. The remaining third of substances will likely not require further EU level regulatory action.

9. Conclusions

The work carried out in 2020 shows that authorities have successfully used the group approach to accelerate the identification of new substances of potential concern. As a result of the group assessments concluded in 2020, 290 substances were identified as candidates or potential candidates for further EU regulatory risk management.

Compared to the screening carried out in 2014-2018, a nearly tenfold increase in substances assessed per year has been achieved. In the coming years, ECHA can use the lessons learned during the Integrated Regulatory Strategy's full implementation to further refine and optimise the group approach, including collaboration with Member States so that actions are initiated, where relevant.

Based on group assessments carried out during 2019 and 2020, EU regulatory risk management actions are expected for 20 % of assessed substances, while there is currently no need for EU regulatory action for about two-thirds of the substances assessed. However, further data generation is often required before the need for planned actions can be confirmed or actions can be initiated. Therefore, effective and impactful compliance checks remain a priority for ECHA in the coming years.

It is important for ECHA to use all available information when assessing structurally similar substances. This will avoid the need for new data to be generated for substances where data on similar substances is available.

The ECHA-Cefic collaboration to improve registration dossiers for four prioritised groups of substances has helped companies understand how to review and improve the content of their registration dossiers, with a focus on read-across approaches and how to implement them successfully. As such, industry is recommended to make use of this, and other programmes developed to help registrants review and update their registration data. Industry needs to be proactive and not wait until authorities take regulatory action.

The group assessment work has shown that after compliance checks, substances can often proceed directly to regulatory risk management without substance evaluation. This can speed up initiating risk management actions substantially.

The fourfold increase from August 2019 to December 2020 of substances under consideration for regulatory risk management is largely explained by the group assessments, which make up over 80 % of the substances in this pool. However, not all of these substances will require further EU regulatory risk management.

Substantial amounts of substances have been identified as needing regulatory risk management but have not yet been picked up by authorities. The majority of these substances require harmonised classification and labelling. To prioritise the pending substances, Member States reviewed many of the pending cases in 2020 and indicated that around 30 % would progress to regulatory risk management over the next two years. While reasons were provided why they do not intend to work further at this point in time for 35 %. An important reason preventing Member States from acting was their lack of resources.

The accumulation of pending CLH candidates is a bottleneck in efficiently implementing the strategy, as a harmonised classification is often the prerequisite for moving ahead with regulatory measures under REACH, such as authorisation, or under other EU legislation. As we can see from the group assessments concluded in 2020, the number of CLH candidates is expected to rise even further.

To shorten the time between the identification of a concern and regulatory action being taken, Member States need to ensure that such substances are progressed without delay so that regulatory risk management can be initiated, where necessary. Member States are encouraged to ensure sufficient resources for regulatory risk management and intensify collaboration with each other to maximise the outcome of their work.

Most new substances brought to regulatory risk management have resulted from work on groups of substances, demonstrating that the impacts of the group approach are starting to be visible. The impact of group work on the number of substances for which regulatory risk management is ongoing is expected to increase in the coming years as information needed to conclude on their hazards becomes available through data generation.

Annex 1. Overview of pre-regulatory steps (2008-2020)

PBT and ED expert groups

The PBT and ED expert groups support Member States in assessing substances with persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB) or endocrine-disrupting properties (EDs). Their main goal is to ensure that the process goes smoothly later on for both substance evaluation and identification of substances of very high concern (SVHCs).

Table 1 gives an overview of the number of substances that have been considered by the PBT and ED expert groups during 2012-2020. In 2020, the PBT and ED expert groups advised on 30 PBT cases[1] and 20 ED cases[2].

Expert group consultation has proven particularly useful in discussing appropriate ways to move forward with assessment and testing strategies, evaluation of study results, and justifying conclusions on substance properties or information needs. All of this has contributed to improving the quality of assessments and documentation, which in turn has reduced challenges later in the formal steps of the processes, for example, evaluation or identification of SVHCs.

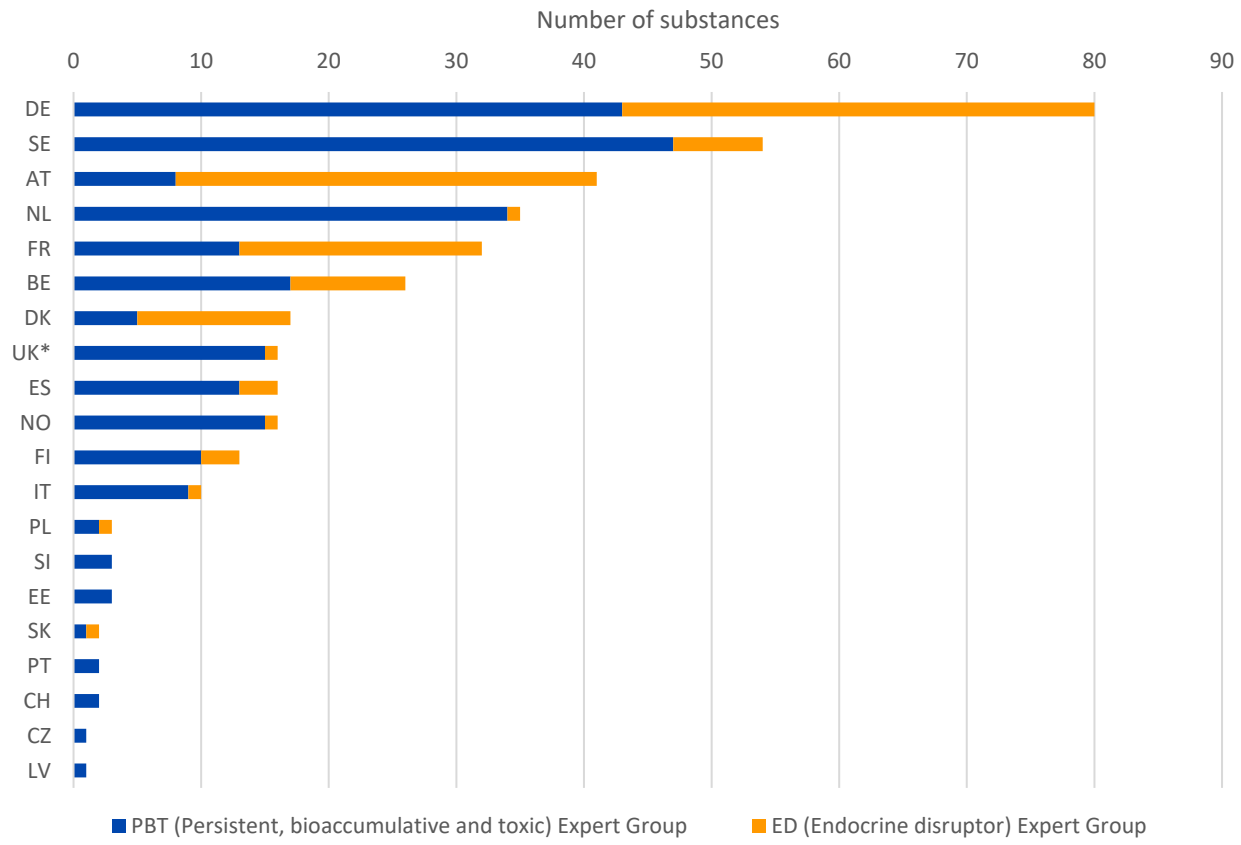
Table 1: Number and outcome of substances considered by the PBT and ED expert groups (2012-2020)

OVERVIEW OF SUBSTANCES CONSIDERED BY THE PBT AND ED EXPERT GROUPS				
Property	**Substances concluded on**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties**	**Substances ongoing or postponed**
PBT	137	81	45	124
ED	39	34	4	91

Since 2012, 20 Member States have been active in the PBT Expert Group and 14 in the ED Expert Group (Figure 1).

[1] Expert group opinions are informal advice given to Member States that are assessing substances and generally consist of advice on ED/PBT properties, testing strategies or information needs.
[2] These numbers also include some substances discussed in the context of the Biocidal Products Regulation and the Persistent Organic Pollutants Regulation.

Figure 1: Number of substances under assessment in the ED Expert Group, the PBT Expert Group per Member State 2013-2020



*Member State until 31 January 2020

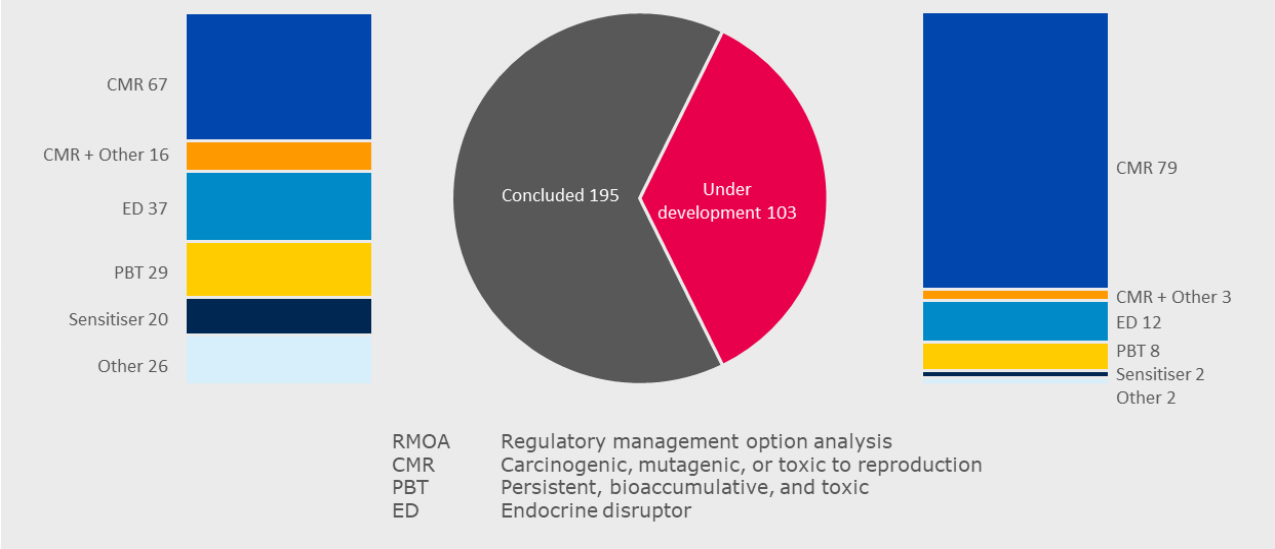
Regulatory management option analysis

Regulatory management option analysis (RMOA) helps authorities decide whether further regulatory risk management activities are required for a substance and, if so, to identify the most appropriate (combination of) instruments to address a concern. The RMOA approach promotes early discussions and sharing of information between authorities and stakeholders.

By the end of 2020, an RMOA has been concluded or is under development for around 300 substances.

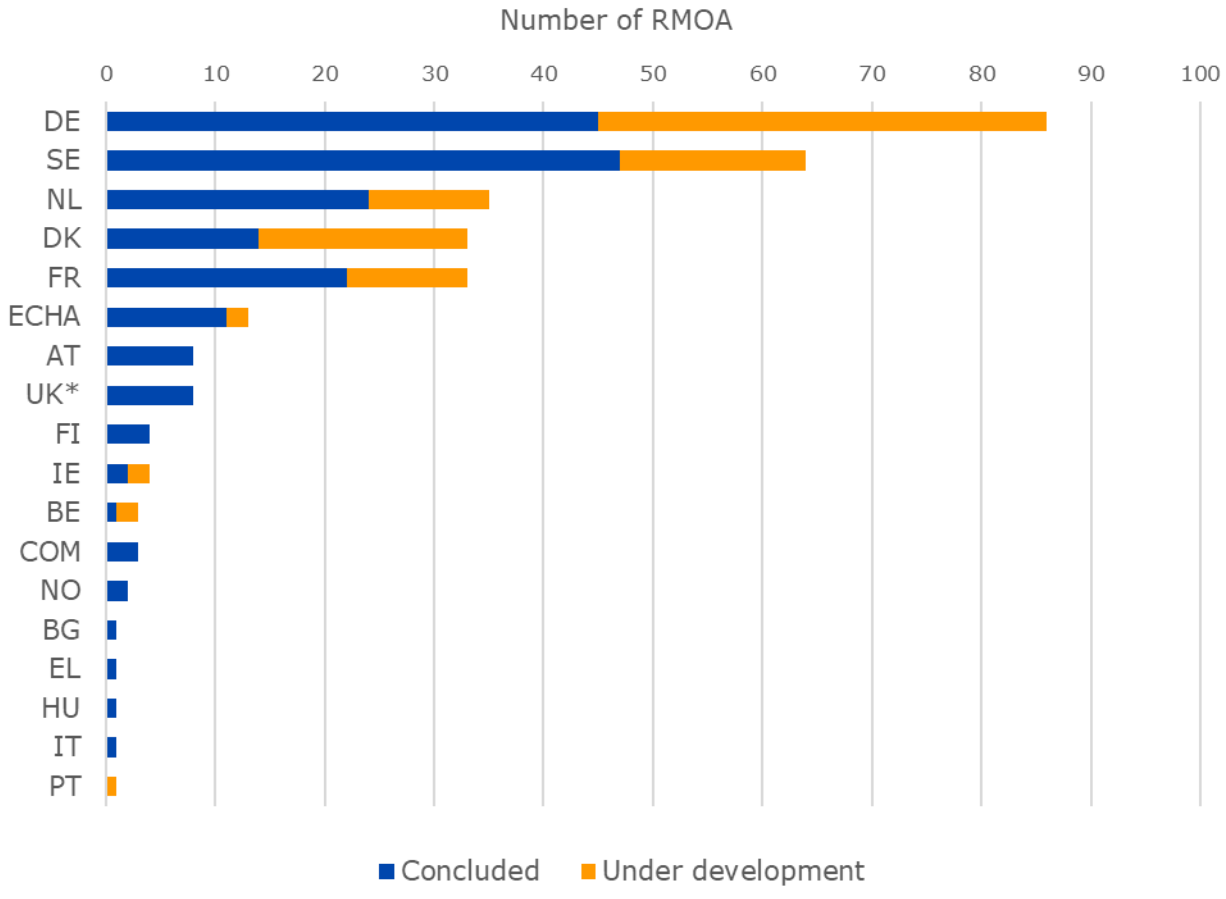
Figure 2 gives the number of RMOAs concluded or under development from the implementation of the SVHC Roadmap in 2013 to the end of 2020, subdivided according to hazard property.

Figure 2: Number of substances under RMOAs per status and property (2013-2020)



Member States have been developing RMOAs since 2013, when the work on the implementation of the SVHC Roadmap started. In some cases, RMOAs have been developed in cooperation between Member States (Figure 3).

Figure 3: Number of RMOAs concluded or under development per authority (2013-2020)



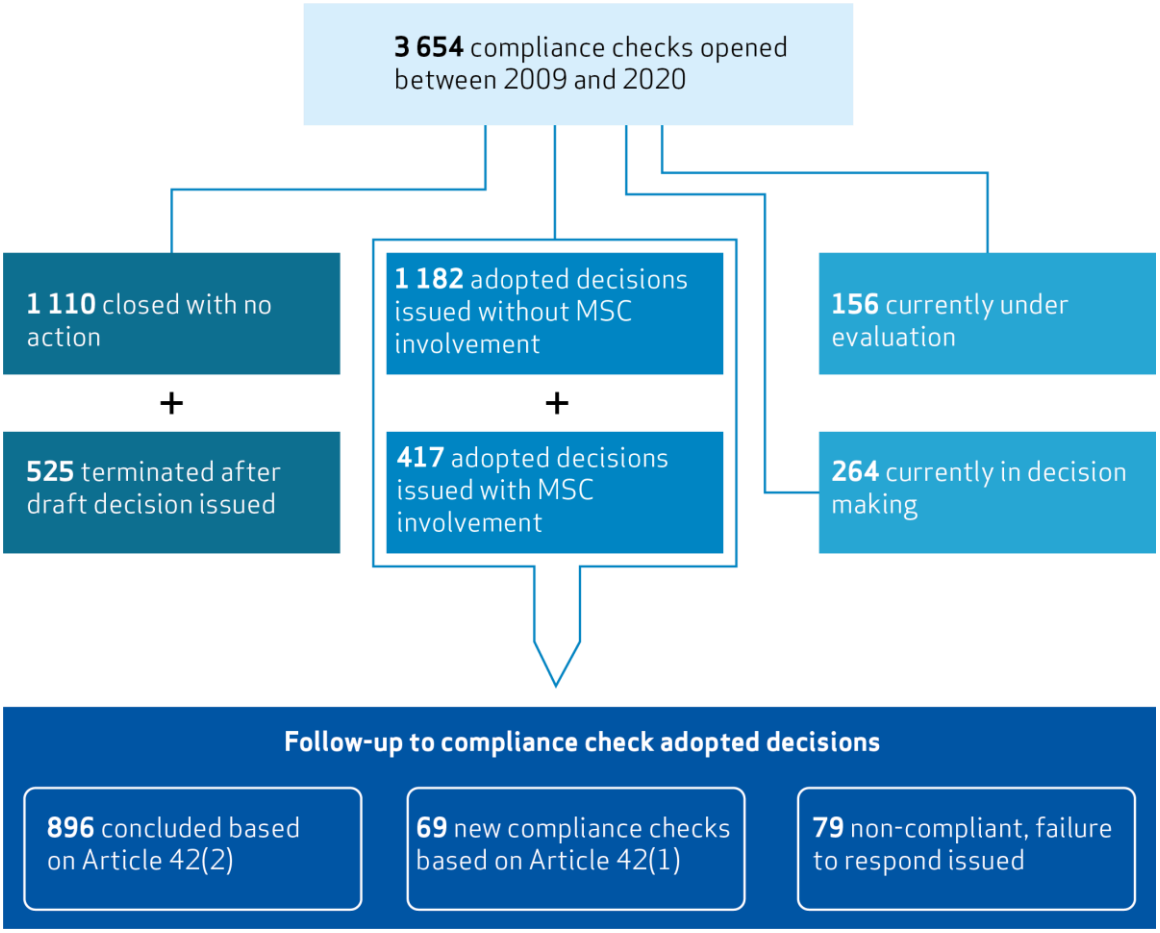
*Member State until 31 January 2020

Annex 2. Overview of evaluation activities (2009-2020)

Compliance check and substance evaluation

Dossier and substance evaluation have been established as key processes for generating further information on substances. Figure 1 provides an overview of the number of compliance checks carried out between 2009 and 2020 and their outcome[1], and Figure 2 shows the status of substance evaluations at the end of 2020. Table 1 gives an overview of the properties of substances evaluated between 2012 and 2020. For more detailed statistics on the progress in evaluation[2] and recommendations to registrants[3] resulting from evaluation work, consult ECHA's website.

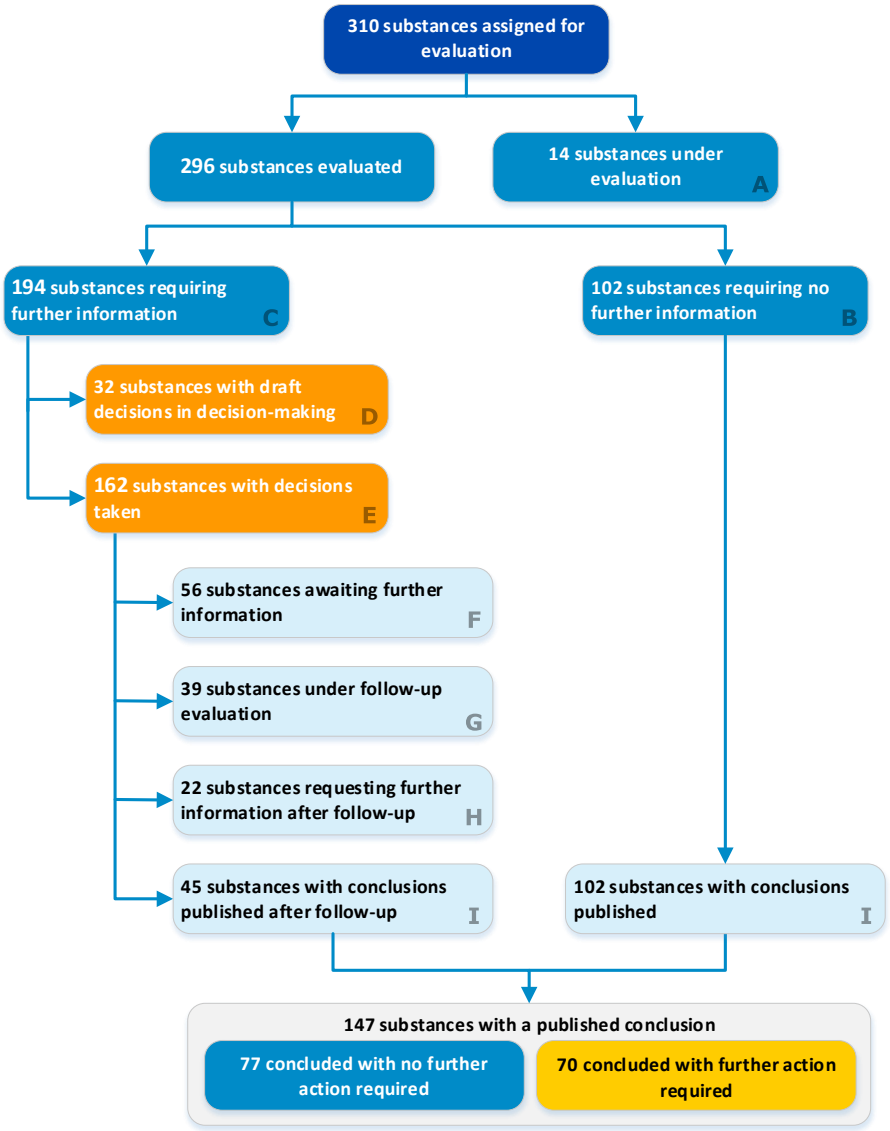
Figure 1: Number of compliance checks between 2009 and 2020



[1] Case concluded based on Article 42(2) of REACH: that the registrant has submitted sufficient information in a dossier update as a response to an evaluation decision. Member States and the European Commission are informed about the completion of the dossier evaluation and any conclusions thereof. A new compliance check based on Article 42(1) of REACH: the registrant has updated dossier with relevant information which not yet compliant with ECHA's decision. In this case, a new decision is drafted and sent to the registrant according to Article 42(1).

[2] https://echa.europa.eu/overall-progress-in-evaluation
[3] https://echa.europa.eu/recommendations-to-registrants

Figure 2: Status of all substance evaluations at the end of 2020



[A] Substance under evaluation by Member State competent authority (MSCA).

[B] Evaluating MSCA can conclude on suspected risk based on available information.

[C] Draft decision requesting further information is deemed necessary.

[D] Stages of draft decision processing: 23 substances currently in decision-making stage. Nine substances currently suspended pending the outcome of an ongoing compliance check.

[E] ECHA evaluation decision taken. Note: a substance may have more than one adopted SEv decision (Overall, 175 SEv decisions adopted, requesting further information for 162 substances).

[F] Registrants to submit requested information within timelines specified in decision. For three substances, decisions are appealed before the Board of Appeal of ECHA.

[G] Evaluating MSCA is examining all new information in updated registration. For 22 substances, draft conclusion documents are being prepared.

[H] Draft decision requesting further information deemed necessary after follow-up assessment: 13 substances have draft decisions in decision-making, 8 substances are awaiting further information according to the timelines specified in the decisions taken, and for 1 substance the evaluating MSCA is examining all new information in updated registration.

[I] Conclusion documents published on ECHA's web pages.

Table 1: Number of substances for which an assessment under substance evaluation has been concluded or is ongoing per property (2012-2020)

CONCLUDED AND ONGOING SUBSTANCE EVALUATIONS PER PROPERTY (2012-2020)				
Property	**Substances concluded on**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties***	**Substances ongoing**
PBT	47	41	8	81
ED	26	18	8	60
CMR	96	54	42**	81
Sensitiser	47	11	36	26

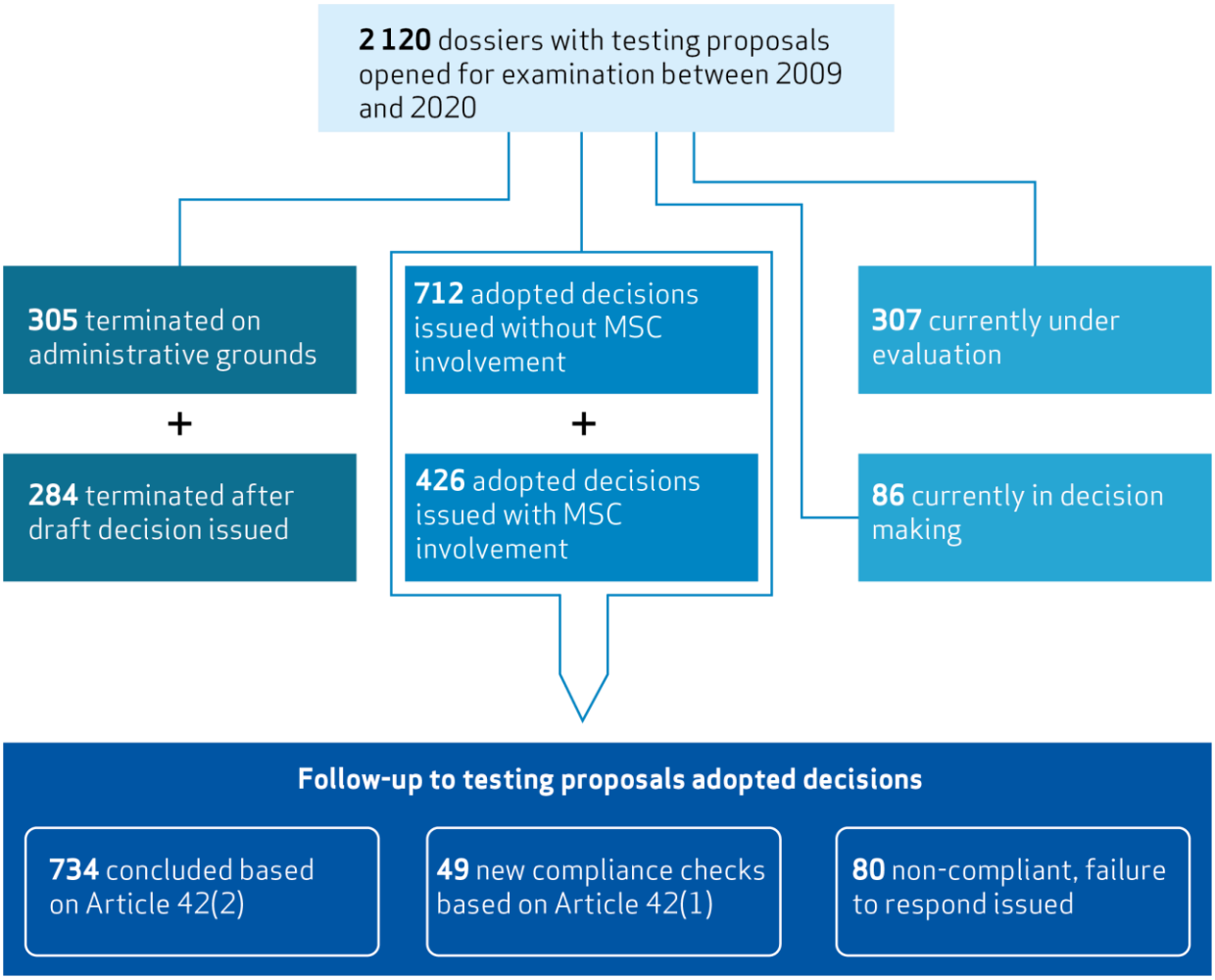
* A few substances have been concluded on with no clarification of the hazard properties, due to low potential for exposure, for instance. These substances have been included under the heading 'considered not to fulfil the hazard properties'.

** Substances already with a harmonised classification and labelling are included here even though they were not necessarily included in substance evaluation to clarify this concern. There are 17 CMRs that have either been newly classified or had their classification as CMR upgraded.

Testing proposal examination

ECHA examines each testing proposal to make sure they address the actual information needed and avoid unnecessary testing, particularly when testing involves the use of vertebrate animals.

Figure 3: Number of testing proposal examinations between 2009 and 2020



Annex 3. Overview of regulatory risk management activities (2008-2020)

Harmonised classification and labelling

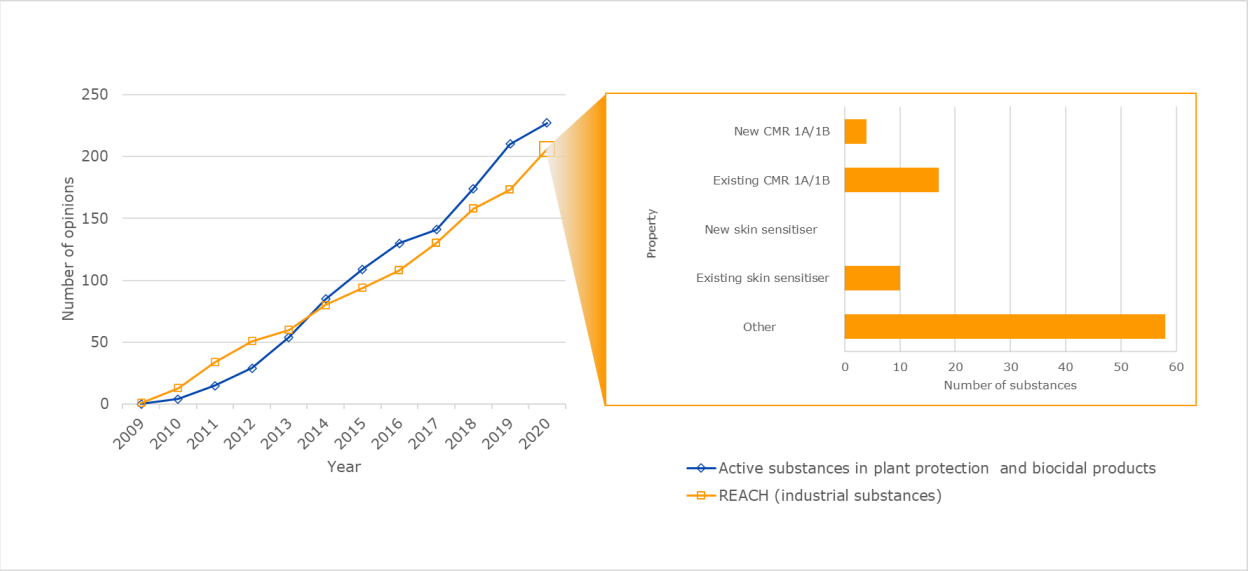
Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity, or respiratory sensitisation in any category, are normally subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal products or plant protection products should also be harmonised.

For all other hazardous substances, a harmonised classification and labelling can be sought, if a justification is provided that shows such an action is required at EU level[1].

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2020, and Figure 2 shows the number of proposals submitted during the same time period. The numbers are further broken down into proposals for active substances in biocidal and plant protection products as well as other substances, mainly those subject to REACH registration.

About half of the substances subject to CLH are active substances in biocidal and plant protection products. The number of REACH substances for which a classification for new[2] and existing CMRs[3] was adopted is also reported.

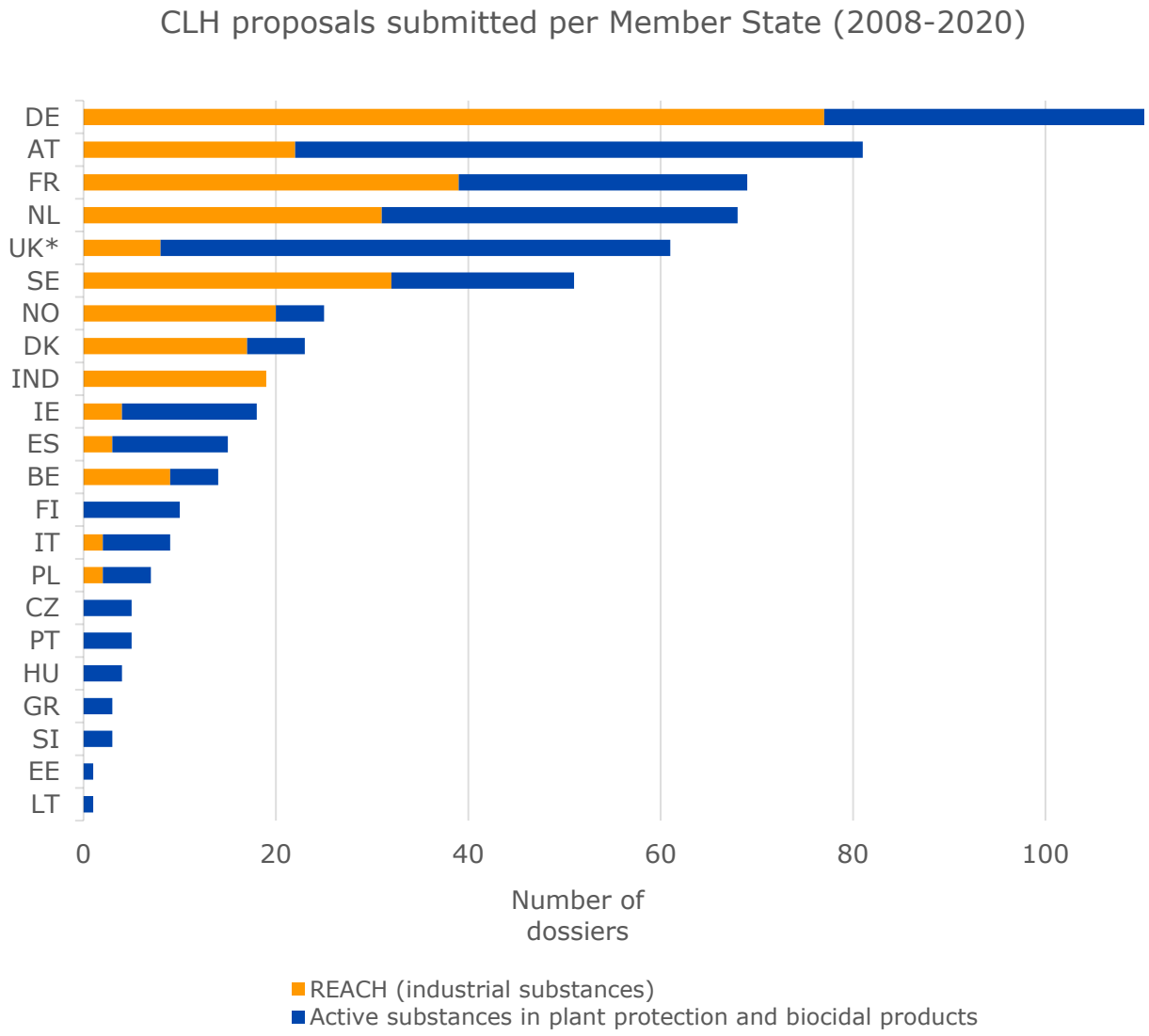
Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2020 and a breakdown of REACH substances for which a CMR 1A/1B or sensitiser proposal was included



[1] https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling
[2] A new CMR is a substance that was not classified as a CMR before.
[3] An existing CMR is a substance that was already classified as a CMR and the proposal was to amend something other than the CMR classification.

Figure 2 gives an overview of Annex VI CLH dossiers submitted by each country.

Figure 2: Number of CLH proposals submitted per Member State (2008–2020)



* Member State until 31 January 2020

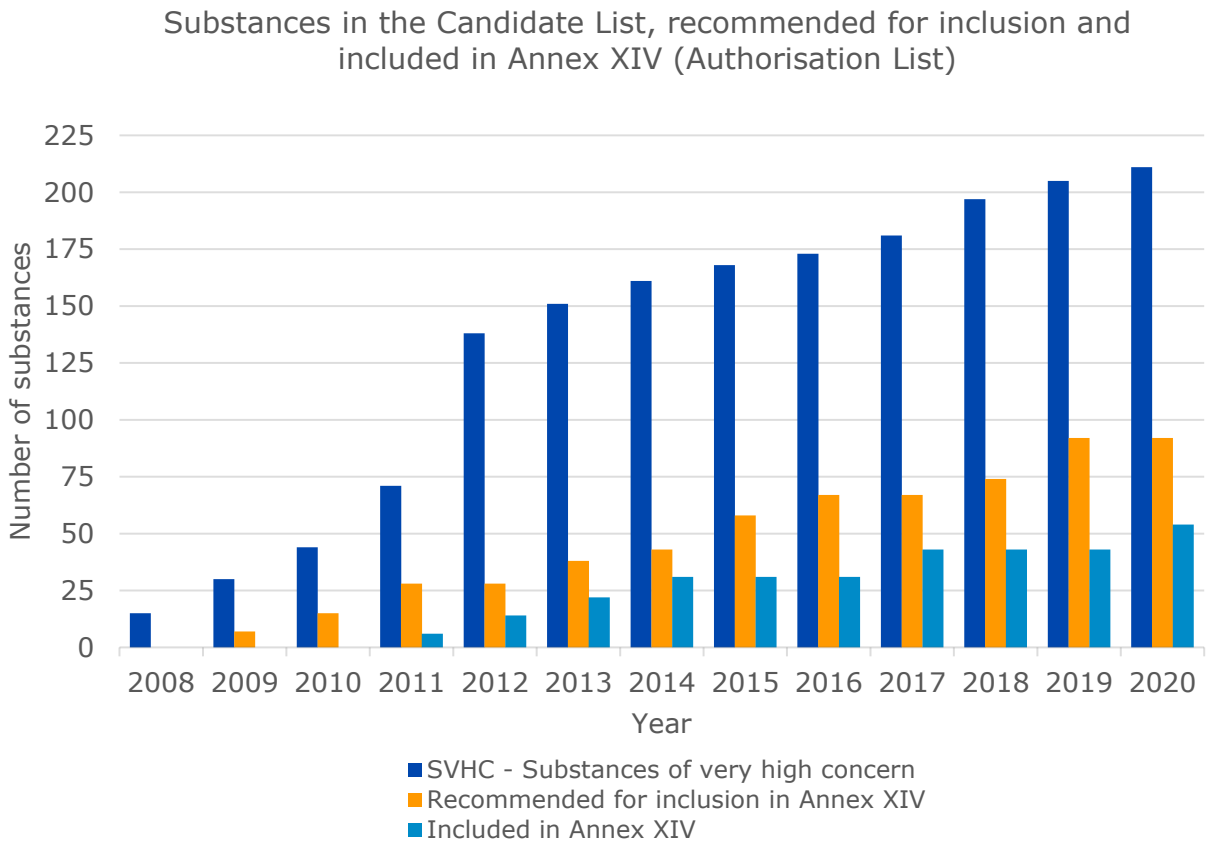
Authorisation

In 2008, the first substances of very high concern (SVHCs) under REACH were identified, marking the start of the REACH authorisation process[4].

Figure 3 gives an overview of the number of substances identified as SVHCs, substances recommended for inclusion in the Authorisation List (Annex XIV), and substances included in the Authorisation List during the period from 2008 to the end of 2020. These numbers are further explained in their respective sections.

[4] http://echa.europa.eu/regulations/reach/authorisation

Figure 3: General overview of the number of substances on the Candidate List, recommended for inclusion in the Authorisation List (Annex XIV), and included in Annex XIV



SVHC identification

A Member State or ECHA, at the request of the European Commission, can propose substances to be identified as substances of very high concern (SVHCs) if:

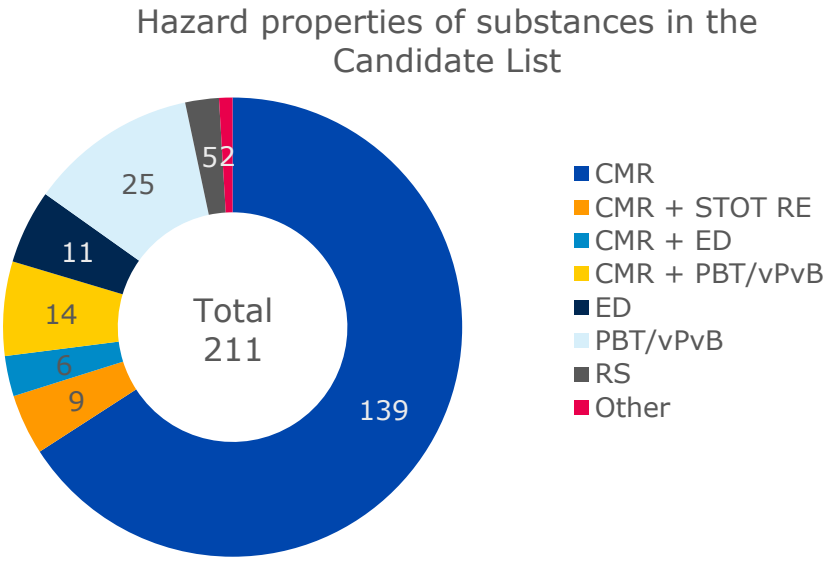
- they meet the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction (CMR) (Category 1A or 1B),
- are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- are identified on a case-by-case basis for which there is scientific evidence of probable serious effects that cause an equivalent level of concern to CMR or PBT/vPvB substances.

If identified as SVHCs, the substances are added to the Candidate List.

The Candidate List includes candidate substances for eventual inclusion in the Authorisation List (Annex XIV). Furthermore, inclusion of a substance in the Candidate List creates legal obligations for companies manufacturing, importing, or using such substances, whether on their own, in mixtures or in articles.

Since 2008, 211 substances or groups of substances have been identified as SVHCs and included in the Candidate List. The properties leading to inclusion in the Candidate List are listed in Figure 4. Some substances are identified based on more than one hazardous property, as illustrated in Figure 4 and Table 2.

Figure 4: Substances or groups on the Candidate List and overview of their hazard properties



CMR	Carcinogenic, mutagenic or toxic to reproduction
ED	Endocrine disruptor
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent, very bioaccumulative
RS	Respiratory sensitisation
STOT RE	Specific target organ toxicity - repeated exposure
Other	Other environmental and/or human health hazards

In 2020, six more substances were identified and included in the Candidate List.

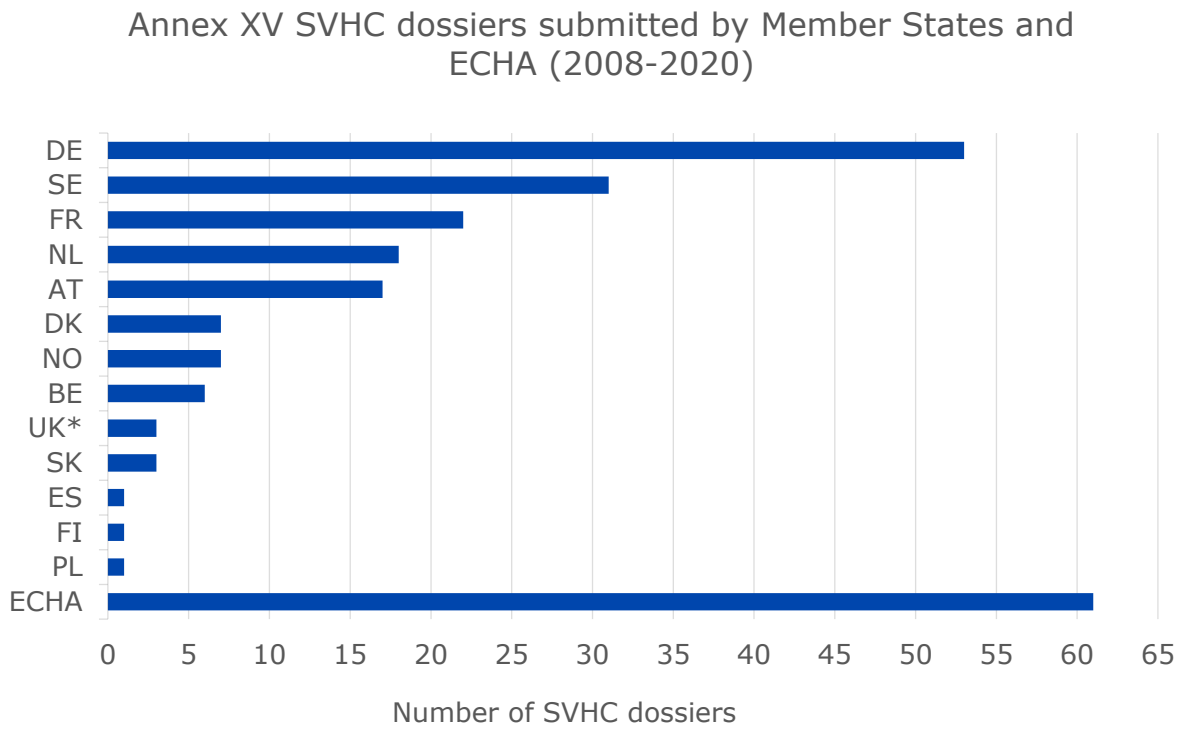
Table 1 gives an overview of the number of substances added to the Candidate List for each property since 2008.

Table 1: Overview of the number of substances included in the Candidate List by property (2008-2020)

NUMBER OF SUBSTANCES INCLUDED IN THE CANDIDATE LIST BY PROPERTY (2008-2020)										
Property	**2008 - 2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**Total**
CMR	122	13	8	4	3	5	6	5	5	171
PBT/vPvB	16	2	2	4	2	4	9	-	-	39
ED	7	1	-	-	3	1	2	1	1	16
STOT RE	-	3	3	-	-	3	-	-	-	9
Equivalent level of concern	-	-	-	-	-	-	-	2	-	2
Respiratory sensitisation	3	-	-	-	-	-	2	-	-	5

Figure 5 gives an overview of Annex XV SVHC dossiers submitted by each Member State and ECHA.

Figure 5: Number of Annex XV SVHC dossiers submitted by Member States and ECHA (2008-2020)



*Member State until 31 January 2021

Recommendation for inclusion and inclusion in the Authorisation List

Substances identified as meeting the SVHC criteria are included in the Candidate List for eventual inclusion in the Authorisation List (Annex XIV to REACH). ECHA prioritises substances from the Candidate List to determine the order in which the substances should be included in Annex XIV.

The substances which are the highest priority are recommended for inclusion first. All substances not recommended, as well as newly added Candidate List substances, are considered in future rounds.

Under Article 58(3), priority is normally given to substances with PBT or vPvB properties, wide dispersive use, or high volumes[5]. Prioritisation is carried out based mainly on information in the registration dossiers. However, information from the consultation on the SVHC identification as well as other REACH information is also considered.

Figure 6 gives an overview of the substances recommended by ECHA to be included in Annex XIV[6] until the ninth recommendation as well as the substances included in the Authorisation List (Annex XIV)[7] by the end of 2020. Substances recommended within the ninth recommendation have not yet been considered by the Commission for amending Annex XIV.

[5] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf
[6] https://echa.europa.eu/previous-recommendations
[7] Substances included in Annex XIV can be found at: https://echa.europa.eu/authorisation-list

Figure 6: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008-2020)[8]

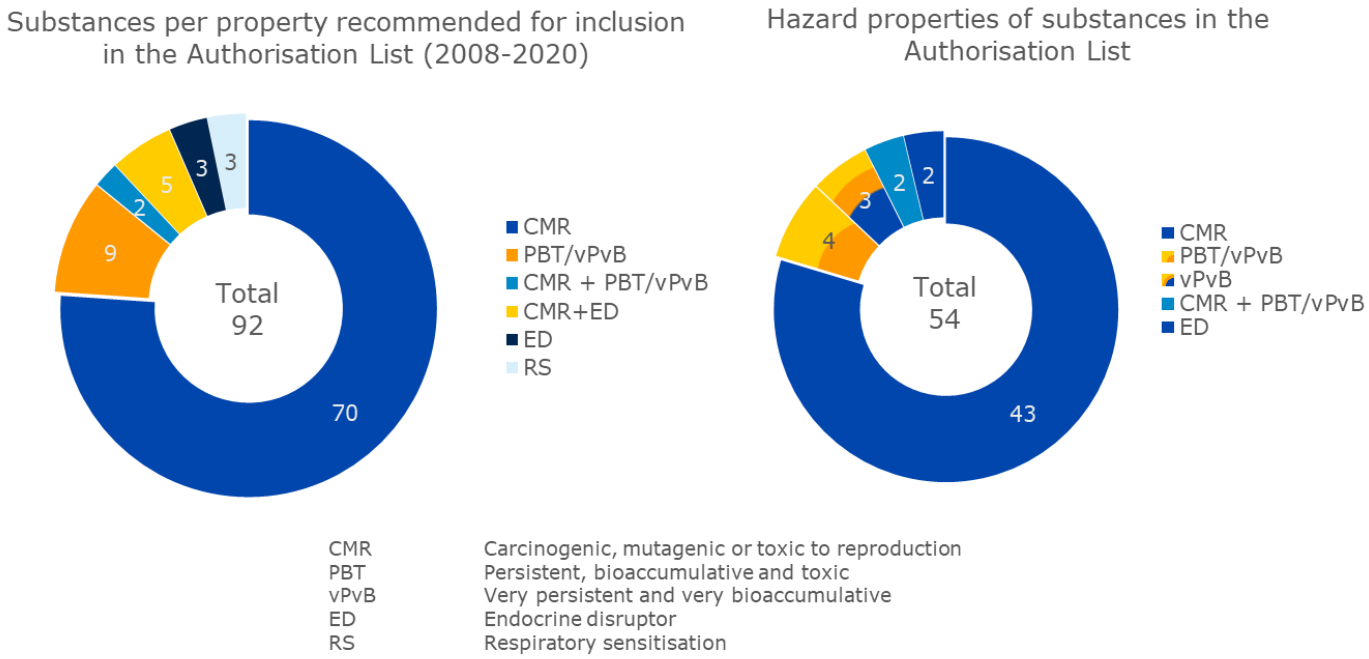


Table 2 gives an overview of the number of substances recommended by ECHA to be included in Annex XIV until the ninth recommendation. It also lists those substances which have been included in the Authorisation List (Annex XIV) and which have not. The Commission has indicated in the preambles of each amendment to Annex XIV the reasons for not taking forward the substances that were recommended by ECHA within that specific amendment.

[8] Four substances are listed in Annex XIV with CMR properties only, while they also have ED properties. This has not yet been updated in Annex XIV and, as a consequence, is not reported here.

Table 2: Overview of (groups of) substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2020)

OVERVIEW OF SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV AND SUBSTANCES INCLUDED IN ANNEX XIV (2008-2020)							
Date and number of recommended substances			**Amendment of Annex XIV**		**Number of substances included in Annex XIV**	**(Groups of) substances included in Annex XIV**	**(Groups of) substances not included in Annex XIV amendment**
1st	1/06/ 2009	7	1st	17/02/ 2011	6	Musk xylene, MDA, HBCDD, 3 phthalates	SCCP*
2nd	17/12/ 2010	8	2nd	14/02/ 2012	8	1 phthalate, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd	20/12/ 2011	13	3rd	17/04/ 2013	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) substances
4th	17/01/ 2013	10	4th	14/08/ 2014	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th	6/02/ 2014	5	5th	13/06/ 2017	1	4-tert-OPnEO	DMF, ADCA, Al-RCF and Zr-RCF
6th	01/07/ 2015	15	5th	13/06/ 2017	11	1-bromopropane, 7 phthalates, anthracine oil, CTPHT, 4-NPnEO	4 borate substances
7th	10/11/ 2016	9	6th	06/02/ 2020	5	2 borates, 2 phthalates, trixylyl phosphate	4 lead substances
8th	05/02/ 2018	7	6th	06/02/ 2020	6	Karanal, UV-328, UV-327,UV-350, UV-320,1 phthalate	NMP
9th	01/10/ 2019	18		[n/a]	[n/a]	[n/a]	**
	Total	**92**			**54**		**20**

* SCCP was recommended but not included as the substance was included in the POPs Regulation

** Substances from ninth recommendation (18) have not yet been considered for amending Annex XIV

Applications for authorisation and decisions on authorisation

Once a substance is included in the Authorisation List (Annex XIV), companies must not place it on the market or use it themselves after the sunset date unless an authorisation has been granted for a particular use.

Companies who want to continue to use a substance after the sunset date need to submit their applications for authorisation to ECHA.

The opinions of ECHA's committees contribute to the decision-making process of the European Commission, which decides whether or not to grant an authorisation for the uses applied for.

The number of applications for authorisation received between January 2013 and the end of December 2020, as well as the number of Committee for Risk Assessment (RAC) opinions, Committee for Socio-economic Analysis (SEAC) opinions and Commission decisions are available online and regularly updated[9].

Restrictions

Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health or to the environment.

A Member State or ECHA, at the request of the European Commission or on its own initiative, can propose restrictions if it assesses that there is a risk that is not adequately controlled and there is a need for action at EU level.

Table 4: Overview of restriction proposals on substances adopted or going through the restriction process from 2009 to December 2020. Some cover groups of substances.

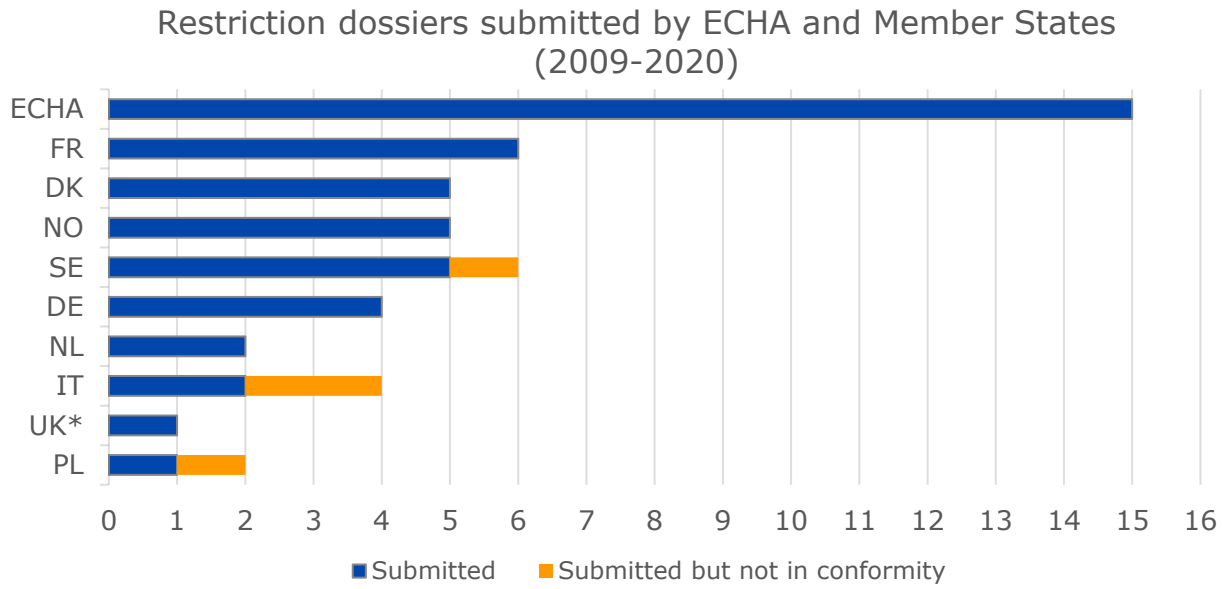
NUMBER OF RESTRICTION PROPOSALS ON (GROUPS OF) SUBSTANCES ADOPTED OR GOING THROUGH THE RESTRICTION PROCES					
Step in restriction process	PBT	ED	CMR	Sensitiser	Other
Included in Annex XVII	Octamethyl-cyclotetrasiloxane (D4), decamethyl-cyclopentasiloxane (D5), PFOA, decaBDE	NPE	4 phthalates, NMP, phenyl mercury, lead in jewellery, lead in articles, mercury, BPA, chrysotile, DCB, lead in shot	Chromium VI*, DMFu, isocyanates	Ammonium salts, methanol, TDFA
Process ongoing	PFHxA	-	Formaldehyde and formaldehyde releasers, single-use baby diapers, lead in SHF	Skin sensitisers in textiles	Microplastics, calcium cyanamide
Sent to Commission, but not yet in Annex XVII	C9-C14 (plus supplementary opinion), D4/D5/D6, PFHxS	-	DMF, PAH in rubber granules, soluble cobalt salts, lead in PVC		

* Chromium VI is also a CMR substance, but is here only considered a sensitiser, as this is the scope of the restriction in question ("Chromium VI in leather articles")

Figure 7 gives an overview of Annex XV restriction dossiers submitted per Member State and ECHA.

[9] https://echa.europa.eu/received-applications

Figure 7: Number of restriction dossiers submitted by ECHA and Member States (2009–2020)



*Member State until 31 January 2021

ECHA is required to investigate whether substances on the Authorisation List, when used in articles, cause risks to the environment or to human health (Article 69(2)). Table 5 provides the number of entries on the Authorisation List screened so far, including the status of the screening.

Table 5: Number of entries on the Authorisation List screened or work ongoing according to Article 69(2) since the first sunset date of 21 August 2014

NUMBER OF SUBSTANCES (ENTRIES) ON THE AUTHORISATION LIST SCREENED OR WORK ONGOING ACCORDING TO ARTICLE 69(2) SINCE THE FIRST SUNSET DATE OF 21 AUGUST 2014				
Status of the screening	Total	No of restrictions proposed	Restriction under preparation	Restriction decided
Screening finalised	14	5	5	4*
Screening ongoing	22	-	-	-
Screening planned to start in 2021	13	-	-	-
Sunset date not passed/screening to start later	5	-	-	-

* Four phthalates

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