ECHA
EUROPEAN CHEMICALS AGENCY

Mapping the chemical universe to address substances of concern

Integrated Regulatory Strategy
Annual Report

April 2019

Disclaimer

Mapping the chemical universe to address substances of concern - Integrated Regulatory Strategy Annual Report 2019

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List of abbreviations

Abbreviation	Description
ACT	Activities coordination tool
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, toxic for reproduction
CoRAP	Community rolling action plan
COM	European Commission
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
PBT	Persistent, bioaccumulative and toxic
PACT	Public activities coordination tool
PetCo	Petroleum and coal stream substances
POP	Persistent organic pollutant
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
SEv	Substance evaluation
STOT RE	Specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
TP	Testing proposal under dossier evaluation
vPvB	Very persistent and very bioaccumulative

Foreword

This is the first annual report of the Integrated Regulatory Strategy. It combines information previously reported by ECHA in the annual report of the SVHC Roadmap to 2020 and some of the information provided as part of the reporting of progress in evaluation according to Article 54 of REACH. The report offers an overview of the different REACH and CLP processes and activities being carried out on substances and explains how far we are in clarifying the universe of registered substances, or 'chemical universe'.

We plan to publish lists of the substances belonging to the different pools of the chemical universe on our website at the end of the year. We have quite a lot of work ahead of us, as we first address the substances registered at above 100 tonnes per year, and then all other registered substances. We know that for many substances, further hazard data need to be generated as highlighted already in the outcome of the second REACH Review, where the European Commission concluded that even though REACH is fully operational and delivering results towards its objectives, the non-compliance of registration dossiers is hampering progress.

We are working together with the European Commission and Member States in developing an ambitious plan to increase the level of compliance of dossiers, which will accelerate the identification of substances of concern in the years to come. We also urge industry, who is ultimately responsible for ensuring the safe use of their substances, to be proactive and take all necessary steps to ensure that all their dossiers are compliant.

My sincere thanks go to all colleagues in the Member States and the European Commission for working together with us in identifying and addressing substances of concern. I am very pleased to see that, over time, more Member States have become involved. This is to everyone's benefit, and I encourage even more cooperation to achieve our shared goals.

Bjorn Hansen
ECHA Executive Director

Executive summary

ECHA's Integrated Regulatory Strategy aims to ensure the coherent implementation of the REACH and CLP processes and supports authorities in addressing substances of concern as soon as possible. Coherent regulatory processes also contribute to meeting the 2020 goals of the World Summit on Sustainable Development.

Together with Member States and the Commission, ECHA has set up approaches and methods to identify substances of concern and to address them without undue delay. An interim goal for the Agency will be to generate a sufficient understanding of all substances registered above 100 tonnes by 2020 and to assign each substance to one of the following work streams or 'pools': high priority for risk management, high priority for data generation, or currently of low priority for further regulatory action. This approach will be adapted as necessary to allow for similar conclusions to be drawn on lower tonnage substances, with a view of having full clarity on all registered substances by 2027.

The implementation of the strategy builds on progress made over the past 10 years, during which authorities have increasingly focused on the substances of highest concern. Consequently, as documented last year in the SVHC Roadmap to 2020 annual report, authorities have addressed all currently known CMRs, PBT/vPvBs and endocrine disruptors of relevance for regulatory action and progressed them under the appropriate regulatory risk management instruments. This nevertheless still leaves us with the challenge of concluding on the need for regulatory action for a very high number of other substances that have not been the centre of focus so far.

This first report on the implementation of the Integrated Regulatory Strategy presents the state of play of the work and the achievements so far. It sets the baseline for following the progress of authorities in achieving the short-term and long-term policy goals. It combines information previously reported in the annual report of the SVHC Roadmap to 2020 and some of the information in the evaluation progress reporting according to Article 54 of REACH.

In May 2018, ECHA mapped the universe of all registered substances.

- **Around 270 substances are of high priority for risk management.** These are substances with identified concerns, and further regulatory risk management is ongoing or can start based on currently available information. The majority of these substances were identified through screening. Following more in-depth work, authorities will initiate harmonisation of classification, identification as a SVHC, restriction, or actions under other legislation, or conclude that further regulation at Union level is not justified.
- **Around 1 300 substances are of high priority for data generation.** These substances are of potential concern, and either new hazard data need to be generated or existing data need to be assessed in more detail so that authorities can decide whether further regulatory risk management is needed. The majority of these substances were identified through screening. As the testing itself takes time, it is important to keep all process timelines as short as allowed by legislation to ensure that regulatory risk management can be initiated promptly.
- **Around 450 substances are considered of low priority as already sufficiently regulated.** For these substances there is no need for further immediate regulatory action. In 2018, 16 more substances have been identified as SVHCs and included on the Candidate list and 3 restriction proposals have been submitted.

- **Around 500 substances have been concluded to be currently of low priority after assessment.** Authorities have focused on identifying substances of concern, which need further regulatory risk management. However, in carrying out these activities, they have been able to conclude on many other substances, based on available data on hazard and uses, that they can currently be considered of low priority for further work and not needing follow-up action. The conclusions on these substances will be revisited when new information becomes available on hazardous properties or uses.

Currently, the focus is on the 4 700 substances registered at above 100 tonnes per year. We have allocated already more than 40 % of these substances to the above pools of substances. **Around 2 700 substances** have not yet been allocated to any of these pools. What remains in this so-called **'uncertain area'** is what is left after over 10 years of systematically screening for substances of high concern. Therefore, it is expected that in the case of these substances, either there is not enough information in their registration dossiers to enable proper prioritisation, or they are of low priority for further regulatory work. We foresee that a significant number of them will undergo compliance checks or substance evaluation in the coming years. Lists of the substances belonging to the different pools of the chemical universe are not included in this report. ECHA plans to publish them on ECHA's website at the end of the year.

Keeping in mind the sustainability goals, there is a need to speed up the clearing of the uncertain area and to shorten the time between the identification of a concern and when the necessary regulatory risk management measures are in place. To support this, ECHA has moved from a substance-by-substance approach to the grouping of structurally similar substances. This grouping ensures the more effective use of all available information and enhances the coherence and consistency of authorities' work when progressing with similar substances. This in turn supports informed substitution.

To shorten the time between the identification of a concern and regulatory action, Member States need to focus on initiating the regulatory processes. While experience has shown that authorities normally act quickly after good candidates for inclusion in the Candidate List or restriction are identified, there is clearly potential for initiating harmonisation of classification or action under other legislation more swiftly. Where there are valid reasons for not moving forward with regulatory action, authorities should document these conclusions in a transparent manner so that full clarity on all higher tonnage substances in the chemical universe can soon be reached.

MAIN RECOMMENDATIONS

- Further cooperation and coordination between authorities.
- Further optimisation of data generation and assessment to ensure that substances are progressed to regulatory risk management without delay.
- Harmonised classification and labelling should become a priority, as it has a direct impact on company-level risk management and is often the step before restriction, authorisation, or other measures under other pieces of legislation.
- The priority and appropriateness of previously identified but still pending follow-up actions should be reviewed, and those for substances of high priority should be progressed to regulatory risk management
- The quality of registration information needs to be improved, in particular for substances with a high potential for exposure and currently lacking hazard data.

1. Introduction

Since 2015, ECHA has implemented an integrated regulatory strategy which brings together all the REACH and CLP processes and provides support to authorities in addressing substances of concern as soon as possible.

The Integrated Regulatory Strategy aims to:

- Efficiently select substances that raise potential concern, and generate the necessary information for assessing their safety so that any remaining concerns can be addressed through the most suitable regulatory risk management instrument.
- Enable appropriate and timely intervention by all actors – industry, ECHA, Member States and the European Commission – within the different REACH and CLP processes so that chemicals of concern are properly addressed as soon as possible.
- Provide confidence among stakeholders and the public that registrants meet REACH information requirements, followed up by improved communication on safe use in the supply chain.

Objectives and timelines

To have concluded which substances are:

(i) of high priority for regulatory risk management,
(ii) need more data for a judgement to be made
(iii) are currently of low priority for further work.

By **2020**, to have all substances registered above 100 tonnes allocated to these pools.

By **2027**, to have all substances registered above one tonne allocated to these pools.

Implementing the Integrated Regulatory Strategy will also contribute to the goals of the World Summit on Sustainable Development[1] and to the UN's 2030 Agenda for Sustainable Development[2].

The further integration of the REACH and CLP processes was initiated through the implementation of the SVHC Roadmap, which set up a system enabling the identification of new substances of concern. In that context, authorities have addressed the substances with confirmed hazards – substances with harmonised classification and labelling or included in the Candidate List – which are of relevance for regulatory action, moving them under the appropriate regulatory risk management instruments[3].

In December 2018, ECHA published its strategic plan for 2019-2023. The first strategic priority is the identification and risk management of substances of concern, with the objectives (i) to accelerate data generation and intensify identification of substances of concern and (ii) to accelerate regulatory action of substances of concern[4]. To support this work, in May 2018 ECHA mapped for the first time the universe of registered substances ('the chemical universe'), assigning each substance to one of the following pools of substances:

- high priority for regulatory risk management;
- high priority for data generation;
- low priority for further regulatory action.

[1] https://www.who.int/wssd/en/
[2] https://sustainabledevelopment.un.org/post2015/transformingourworld
[3] https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_annual_report_2020_en.pdf/9598b52a-776d-8ab8-2e88-dd0b645dac0b
[4] https://echa.europa.eu/documents/10162/13609/echa_brief_strategic_plan_2019-2023_en.pdf/9d0f254d-def8-f77d-daa5-650732780eca

Identification and risk management of substances of concern is carried out together with Member States. Industry sectors and companies can proactively contribute to it by keeping their dossiers up to date and providing better use and exposure information.

This document is the first annual report of its kind and presents the state of play and achievements in implementing the Integrated Regulatory Strategy. It provides an overview of the different processes and activities being carried out on substances (Figure 1) and explains how far we are in clarifying the chemical universe. It combines information previously reported in the annual report of the SVHC Roadmap to 2020 and some of the information provided as part of the reporting of progress in evaluation according to Article 54 of REACH.

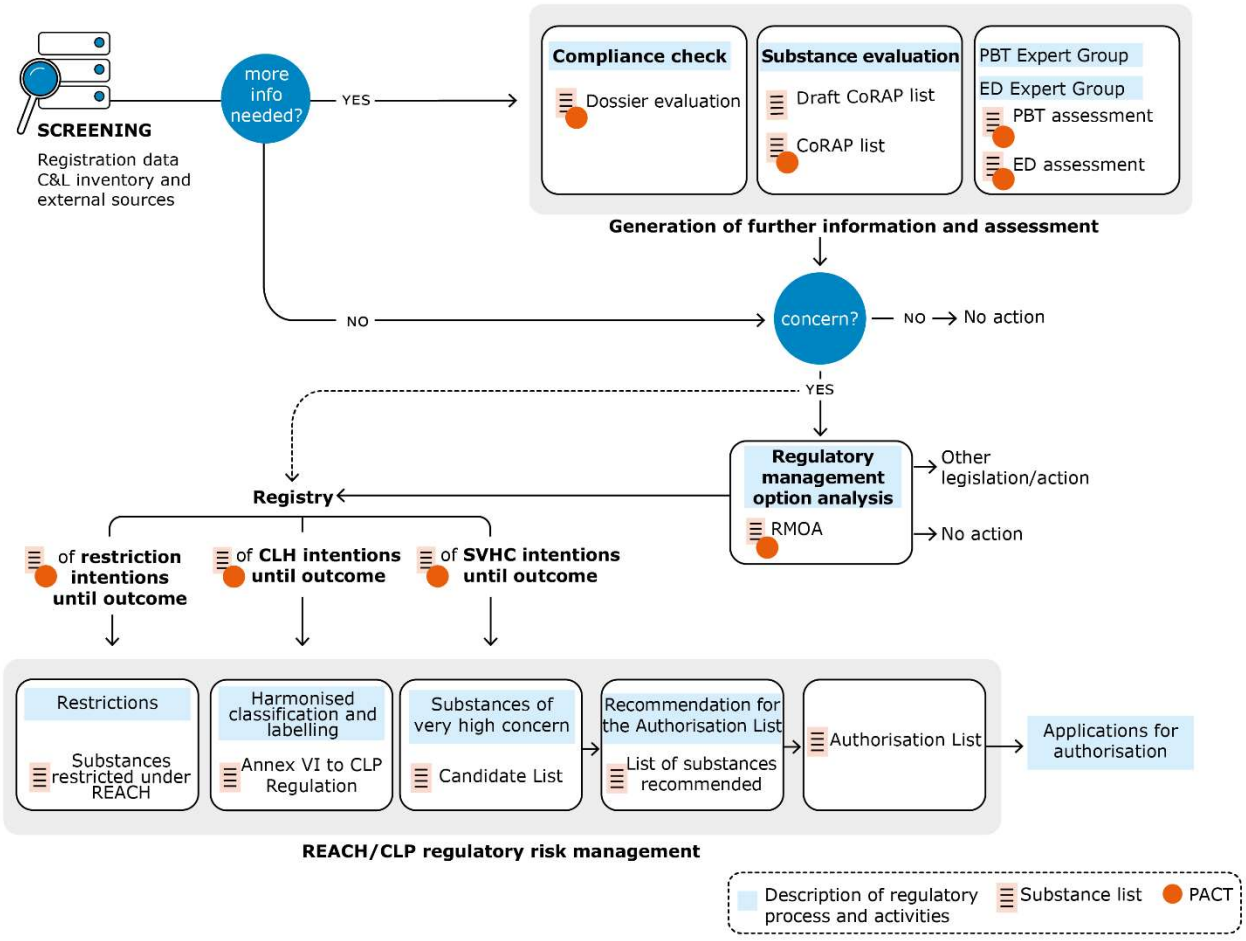


Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy and the SVHC Roadmap[5]

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

This report:

- explains the chemical universe and how authorities are addressing all substances registered in the EU in a proportionate manner;
- provides an overview of the main pools of substances and of the activities being carried out by authorities; and
- provides an overview of the substances in the so called uncertain area and the actions foreseen to address these substances.

This first annual report will serve as a baseline against which the evolution of the work by authorities in addressing substances, especially those in the uncertain area, can be measured in the years to come. The ultimate aim is to have every substance either moved under further regulatory action or concluded as of low priority for further regulatory action because it is sufficiently regulated or of low concern.

Overviews of the preregulatory steps (screening, expert group assessment and regulatory management option analysis), the evaluation processes and the regulatory risk management activities under REACH and CLP are provided in Annex 1, Annex 2 and Annex 3 respectively.

2. The universe of registered substances

A tool to support authorities in planning and in monitoring progress

The chemical universe currently comprises around 19 000 substances. Based on the currently available knowledge, each of these substances have been allocated into one of the following pools:

- high priority for regulatory risk management;
- high priority for data generation and assessment;
- low priority for further regulatory action.

Substances that have not yet been looked at and on which too little information is available are currently placed in the uncertain area.

The chemical universe in numbers

The mapping of registered substances was carried out on a snapshot of the REACH database from May 2018. The database is constantly changing – new substances are registered, changes in uses are indicated, new hazard information is provided, and regulatory actions are concluded – which means that the numbers collected at another time will be different to those provided in this report. What is important to note at this time is the relative size of each pool. Over the coming years, ECHA will periodically repeat this mapping exercise to help monitor and assess the progress of authorities' work as well as to identify and plan further action as needed.

The pools of substances are explained further below and the status of each pool is described in sections 3 to 6 of this report. The numbers of substances handled in the REACH and CLP processes are updated until the end of 2018, are the whereas the numbers for the universe of registered substances are based on a snapshot from May 2018. There may be discrepancies between the numbers in the different explanatory sections and those provided on the chemical universe. As obtaining up-to-date figures on the chemical universe is a complex and resource-intensive exercise, it was not possible to update the snapshot at the end of 2018.

Figure 2 provides an overview of the chemical universe. The x-axis reflects the level of assessment already carried out and the priority for action. Substances which have not yet been assessed lie in the uncertain area on the left; furthest to the right are the substances for which the assessment has been concluded and the substance that are already sufficiently regulated or have been concluded as of lower priority. In the middle area are the substances of high priority for further work, entailing either data generation and assessment or further regulatory risk management.

Authorities have so far focused their activities on substances registered at above 100 tonnes per year. The aim is to know by 2020 how all substances registered above 100 tonnes per year will be addressed.

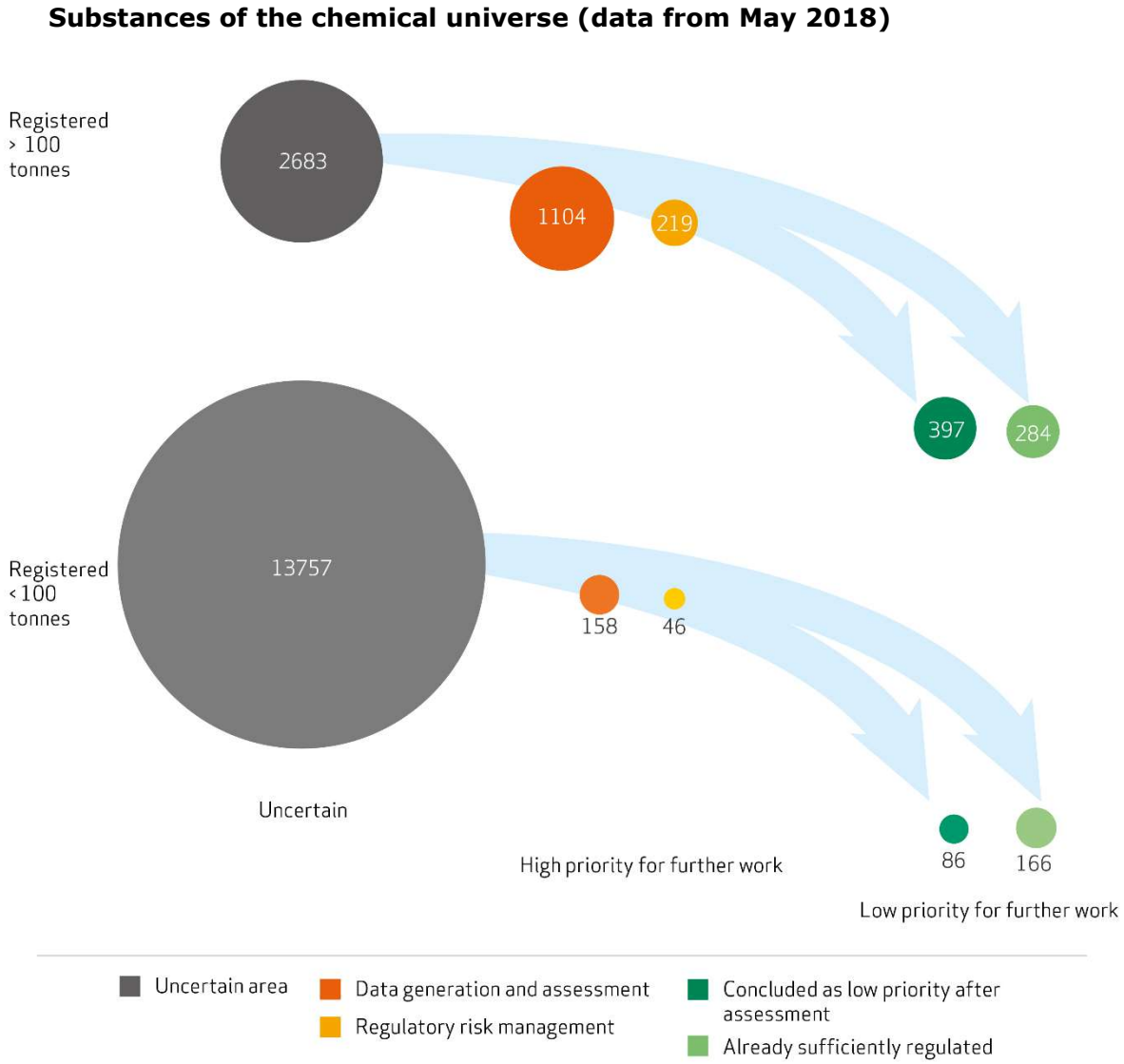


Figure 2: Substances of the chemical universe in their pools of different priority for further work (data from May 2018)

The different pools of substances are the following:

- **Uncertain:** Any substance that is currently registered under REACH and has not yet been assigned to any of the other pools.
- **Currently under data generation and assessment**: Any substance on which more data is needed before a decision on its safe use can be made. This pool includes e.g. all substances currently under dossier or substance evaluation, substances assessed by the PBT and ED Experts Groups, and groups of substances under specific investigations (e.g. petroleum and coal stream substances).
- **Currently under regulatory risk management:** Any substance that has been identified or is currently being considered for regulatory risk management. This pool includes e.g. all substances under regulatory management option analysis (RMOA) or for which there is an intention for identification as a substance of very high concern (SVHC),

and substances that have been manually screened and found to warrant regulatory risk management.

- **Already sufficiently regulated:** Substances for which sufficient regulatory measures have already been put in place. This pool includes e.g. substances on the Candidate List, certain substances restricted under Annex XVII to REACH, active substances in biocides and pesticides, persistent organic pollutants (POPs), and substances subject to prior informed consent (PIC). This represents a very important group of chemicals, but as measures have already been put in place to manage their risks, they are considered of low priority for further regulatory work.
- **Concluded to be of low priority after assessment**: During the course of regulatory work (e.g. manual screening, dossier or substance evaluation, or RMOA), authorities have assessed many substances and concluded that no further action is warranted at the moment. This could be due to low hazard, low potential for exposure, or because sufficient risk management measures are already in place. These conclusions are subject to review if the situation changes, such as if new uses are reported or new insights become available on hazard properties.

This report does not provide lists of the substances belonging to each pool. ECHA intends to make these lists available towards the end of 2019. However, it should be noted that the information used to generate the snapshot of the chemical universe is already largely available on ECHA's website through the public activities coordination tool (PACT). Through this portal, information on the substances which have been or are currently in our processes, such as dossier and substance evaluation, RMOA and SVHC identification, can be easily retrieved.

Public activities coordination tool – information on individual substances

The public activities coordination tool (PACT) offers stakeholders an overview of the substances that are currently on the authorities' radars for potential regulatory risk management. Users can find a summary of each activity per substance, and be directed to process-specific lists providing information on all substances subject to a particular process. The advance notice enables companies to consider their business strategies and gives all stakeholders more time to prepare their contributions to the public consultations that are run during the formal decision-making processes.

PACT covers:

- substances under regulatory management option analysis (RMOA);
- substances under informal hazard assessment for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties or endocrine-disrupting properties;
- dossier evaluation (compliance check and testing proposal examination), indicating the type, scope and status of the assessment undertaken for a given dossier;
- substance evaluation;
- the Registry of CLH intentions until outcome;
- the Registry of restriction intentions until outcome; and
- the Registry of SVHC intentions until outcome.

PACT is available at: https://echa.europa.eu/pact.

Grouping to clarify the chemical universe and ensure efficient assessment

Over several years, authorities have moved to addressing **groups of structurally similar substances** rather than single substances. This approach has been progressively introduced through the common screening, and since 2017, groups of substances of potential concern have been the main starting point for authorities' work.

The work on groups of substances:

- Ensures that authorities make full use of all available hazard data to conclude whether there is a need for further regulatory actions. This in turn helps them to cover a bigger share of all registered substances, including substances on which information on hazard and exposure is lacking. Grouping should also reduce the need to generate hazard data where that is not necessary and would slow down the confirmation of the hazard (via harmonised classification and labelling or placing on the Candidate List) or the initiation of further regulatory risk management (restriction, authorisation, or measures under other legislation).
- Ensures that substances of low priority for further work (e.g. substances currently not registered, substances registered only for intermediate uses) but which could be potential substitutes for known substances of concern are considered. This will support better-informed substitution by industry.
- Enhances the regulatory coherence of authorities' work and the consistency in addressing similar substances.

The methods used to group substances based on structural similarity is further explained below.

In brief: Grouping structurally similar substances

Grouping is done primarily using IT-based algorithms and following two broad complementary methods:

(i) structural similarity, which uses the substance identity information in registration dossiers and C&L notifications; and

(ii) read-across and categories, which uses the test material and category information in registration dossiers and read-across and category information in external sources.

These methods do not constitute validated read-across and category information. Nevertheless, they are both useful tools for grouping substances that will be subject to further manual work by authorities.

Structurally similar substances are identified within the universe of registered substances around preselected substances also known as 'seeds'. Examples of seeds are substances in Annex VI to the CLP Regulation, in the Candidate List, or listed in the CoRAP for which there is already an identified or potential hazard. Another starting point for grouping could be a substance that has a certain type of use or function with a potential for exposure.

ECHA is now in the process of grouping substances in the uncertain area:

(i) together with substances belonging to the other pools of the chemical universe; and

(ii) among themselves.

This work is primarily done using IT algorithms. Following this structural grouping, the assessment of the groups can start and will result in substances belonging to the group being allocated to the appropriate pools and later to different REACH and CLP processes.

Figure 3 shows the current map of the chemical universe and how grouping supports the clarification of the uncertain area and the optimal use of REACH and CLP processes to generate missing hazard data and to progress with regulatory risk management. The figure also illustrates the foreseen status of the mapping in 2020.

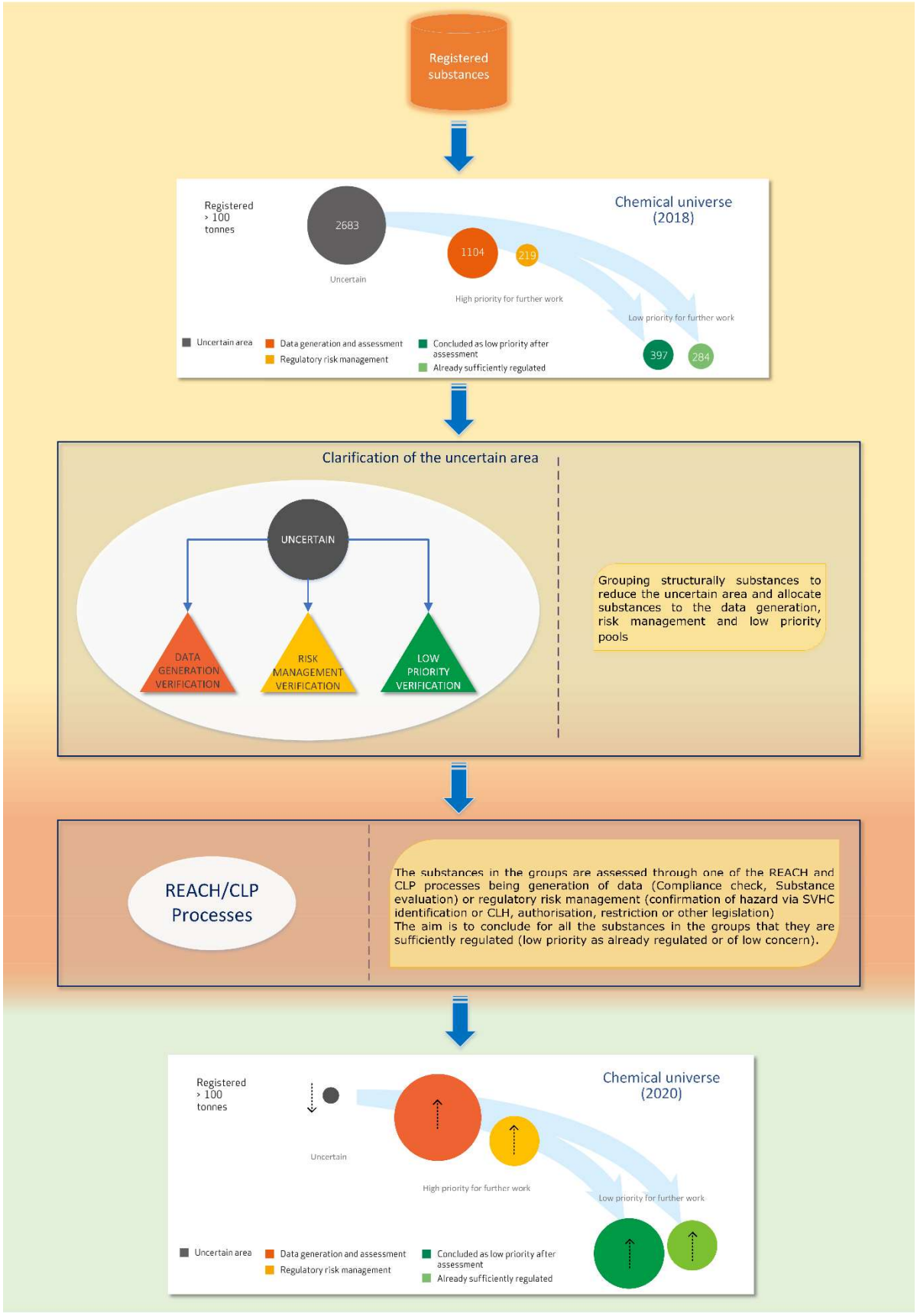


Figure 3: Clarification of the uncertain area through grouping and further processing of substances by authorities

3. Substances of high priority for data generation and assessment

Many substances are of potential concern and need hazard data to be generated

Substances of high priority for data generation and assessment are substances that:

- are being evaluated either under compliance check or substance evaluation for further data generation;
- are being assessed, e.g. substances for which the assessment is ongoing in the PBT/ED Expert Groups, or all petroleum and coal stream (PetCo) substances for which an approach is being developed; or
- have been identified for further data generation but action has not yet been initiated by authorities, e.g. screening has concluded that there is a need for compliance check or substance evaluation, the follow-up evaluation of a compliance check has concluded on the need to generate more information.

Compliance check and substance evaluation as the tools for generating missing hazard data

By the end of 2018, around 700 substances were in the process of being assessed under compliance check, under substance evaluation or in one of the expert groups. This means that for each of these substances, (i) an assessment is under way, (ii) the missing information is in the process of being requested or generated by the registrants, or (iii) authorities are assessing the information submitted by registrants. An overview of the number of substances covered by different processes is provided in Table 1.

Table 1: Number of substances with an ongoing assessment in the PBT and ED Expert Groups, substance evaluation and compliance check (2012-2018)

	Ongoing assessment	Postponed assessment[6]
PBT Expert Group	98	17
ED Expert Group	52	3
Substance evaluation	169	-
Compliance check (priority compliance checks)	321	-

[6] The assessment has been postponed for some substances where it was considered that the substance was not of priority for the time being (e.g. in the case of a substance for which there would be only intermediate uses).

Some substances in Table 1 are counted more than once as they are, for instance, under substance evaluation but also being looked at by the PBT and ED Expert Groups before entering the formal process. In addition, a compliance check is usually carried out on substances listed in the Community rolling action plan (CoRAP) for substance evaluation, meaning that these substances are also counted twice.

The Member States use the expert groups mainly to support their work under substance evaluation or in the preparation of dossier for SVHC identification. Around 70 % of the substances with potential PBT and ED properties listed in the CoRAP between 2012 and 2018 were discussed in the PBT and ED Expert Groups.

In 2015, with the implementation of the Integrated Regulatory Strategy, ECHA started to select substances for compliance check based on hazard and exposure priority criteria. Only these priority compliance checks are reported in Table 1.

More information on progress in evaluation and data generation from 2009 until the end of 2018 is available in Annex 2.

In addition to the substances covered in Table 1, the pool of substances of high priority for data generation also contains substances which have been identified as requiring further data generation but are not yet included to any process. These are substances identified by Member States during manual screening as being, for instance, candidates for compliance check or for inclusion in the CoRAP. Their number changes quickly as they are usually progressed promptly under the indicated process. At the time of mapping of the chemical universe, around 250 new substances were identified for further data generation; by the end of 2018, the number of substances in this group was closer to 120.

The last group of substances included in this pool are the petroleum and coal stream (PetCo) substances. Around 480 substances are under assessment in the PetCo Working Group.

Petroleum and coal stream substances

There are currently around 480 petroleum and coal stream (PetCo) substances in the chemical universe. These include petroleum substances (supported by Concawe), coal stream substances, hydrocarbon solvents, lower olefins and aromatics (LOAs), higher olefins and polyalphaolefins (HOPAs) – with each of these groups supported by a consortium – as well as several so-called orphan substances.

The work is currently focused on assessing the environmental and human health hazard properties of these substances, the aim being to identify what data needs to be generated to confirm these hazards through harmonised classification and labelling or inclusion in the Candidate List. At the same time, authorities are discussing how to best regulate these substances from a regulatory risk management perspective (e.g. restriction, authorisation).

The work carried out so far confirms that this is a typical group of substances needing to be looked at in a holistic manner due to the structure and hazard similarities between substances. The main goal of assessing these types of substances together is to avoid duplication of work, unnecessary testing and regrettable substitution.

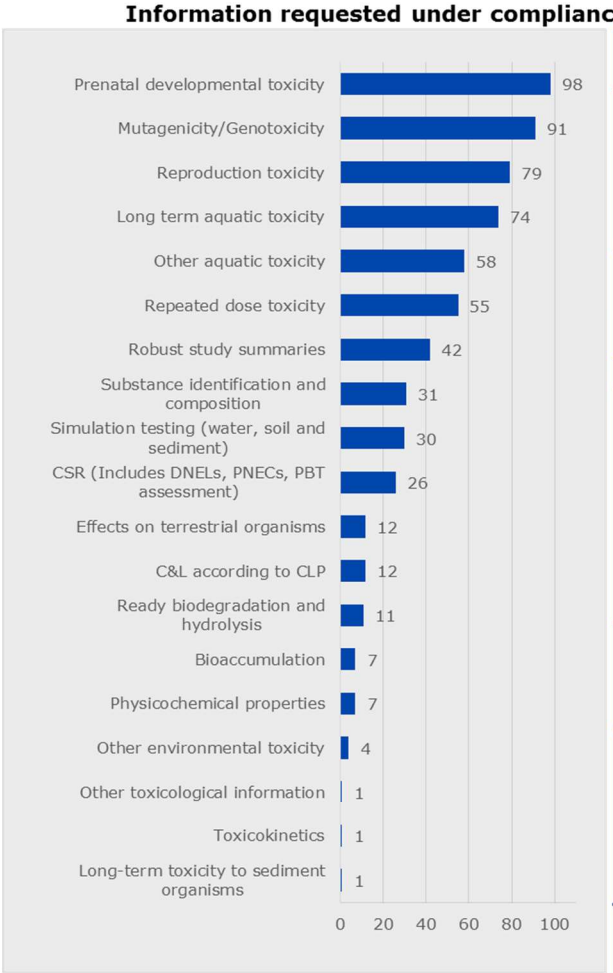
The work will also support more generally how to address substances of unknown or variable composition, complex reaction products or biological materials (UVCBs) in hazard assessment and regulatory risk management.

More information is available on ECHA's website at: https://echa.europa.eu/petco-working-group.

Every year a high number of hazard data is generated and authorities should ensure their follow up

Compliance check and substance evaluation are the tools for generating missing hazard data. Figure 4 shows that the information requested in 2018 under both compliance check and substance evaluation is mainly information needed to clarify a potential concern. This includes information on chronic aquatic toxicity, biodegradation and bioaccumulation to clarify the potential PBT/vPvB properties of a substance, or information on pre-natal developmental toxicity, reproductive toxicity, genotoxicity and mutagenicity to clarify the CMR properties. Exposure requests are not further discussed in this report.

Information requested under compliance check and substance evaluation in 2018



Suspected concern	Information requested to clarify the concern	requests*
Mutagenicity	Transgenic rodent somatic and germ cell gene mutation assay	2
	In vivo mammalian bone marrow chromosomal aberration test	1
	Combined mammalian erythrocyte micronucleus test and mammalian alkaline comet assay	1
Reproductive toxicity	Combined developmental neurotoxicity study and neurotoxicity study	1
	Developmental neurotoxicity study	1
	Prenatal developmental toxicity study	1
Sensitisation	Skin sensitisation local lymph node assay	1
PBT/vPvB**	Bioaccumulation in fish: aqueous and dietary exposure	5
	Simulation biodegradation test	4
	Physico-chemical test	3
	Fish, early-life stage (FELS) toxicity test	2
	Daphnia magna reproduction test	2
	Algae growth inhibition test	2
	Enhanced ready biodegradation test	1
Endocrine disruption	Fish sexual development test	3
	Amphibian metamorphosis assay	2
	Larval amphibian growth and development assay	2
Other hazard-based concern	*Daphnia magna* reproduction test	1
	Sub-chronic 90-day toxicity study	1
	Short time exposure method for identifying chemicals inducing serious eye damage and chemicals not requiring classification for eye irritation/serious eye damage	1
	Further information on exposure and/or risk assessment	26
	Total	**63**

* A decision may contain more than one request.

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

Figure 4: Information requested under compliance check (left) and substance evaluation (right) in 2018

Another source of hazard information are testing proposals made by registrants in their dossiers. An overview of the information requested by ECHA in 2018 under testing proposal examination is available on ECHA's website[7]. For CMR properties, testing proposals follow a similar pattern as observed for compliance check and substance evaluation requests. However, this is not true for

[7] https://echa.europa.eu/further-information-requests-2018

other requests. For instance, registrants have not submitted many requests to clarify the PBT properties of their substances.

In 2018, hazard data was generated for around 140 substances in response to compliance check, substance evaluation and testing proposal decisions.

Figure 5 provides an overview of the number of substances on which new information has been requested and is expected to be submitted per year. Requests for information started to be made in 2013 under substance evaluation, in 2015 for the priority compliance checks. The requested data started to be delivered in 2014 for substance evaluation and in 2017 for priority compliance checks. It is assumed that after 2020, the generation of information will follow a similar pattern.

Non-priority compliance checks are not included in Figure 5, as they were done before the Integrated Regulatory Strategy started to be implemented. The overall number of registration dossiers that underwent compliance checks between 2009 and 2018 can be found on ECHA's website[8].

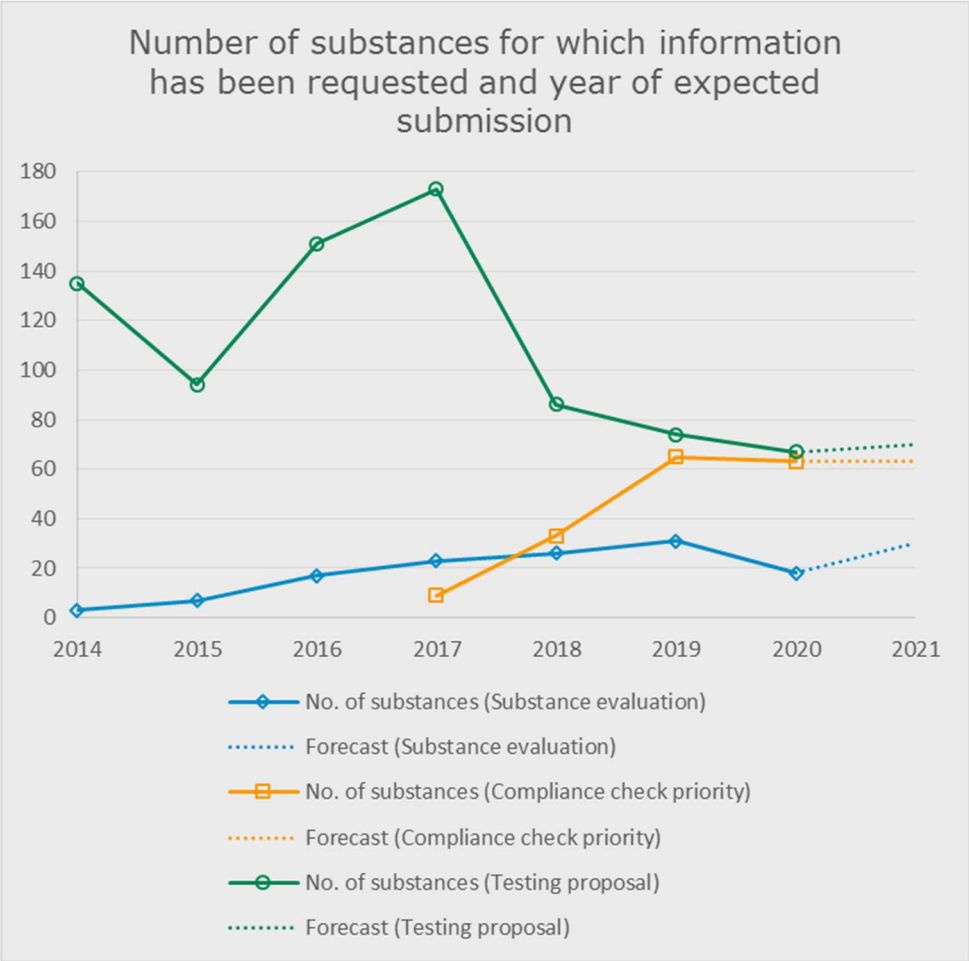


Figure 5: Number of substances on which information requested under substance evaluation, compliance check and testing proposal examination is expected (by year)

As shown in Figure 6, most of the hazard data requested aim at clarifying the potential CMR properties of substances. The pattern is similar for 2018, 2019 and 2020. For 2021 and the years that follow, the number is lower, as all decisions that will influence the amount of incoming data

[8] https://echa.europa.eu/overall-progress-in-evaluation

for those years have not been taken yet. However, Figure 6 provides a good picture of the amount and type of workload that can be expected, and an indication to authorities on the endpoints for which follow-up regulatory actions may be needed. CMR properties are clearly the main focus, and among these, toxicity to reproduction is the most represented endpoint of concern.

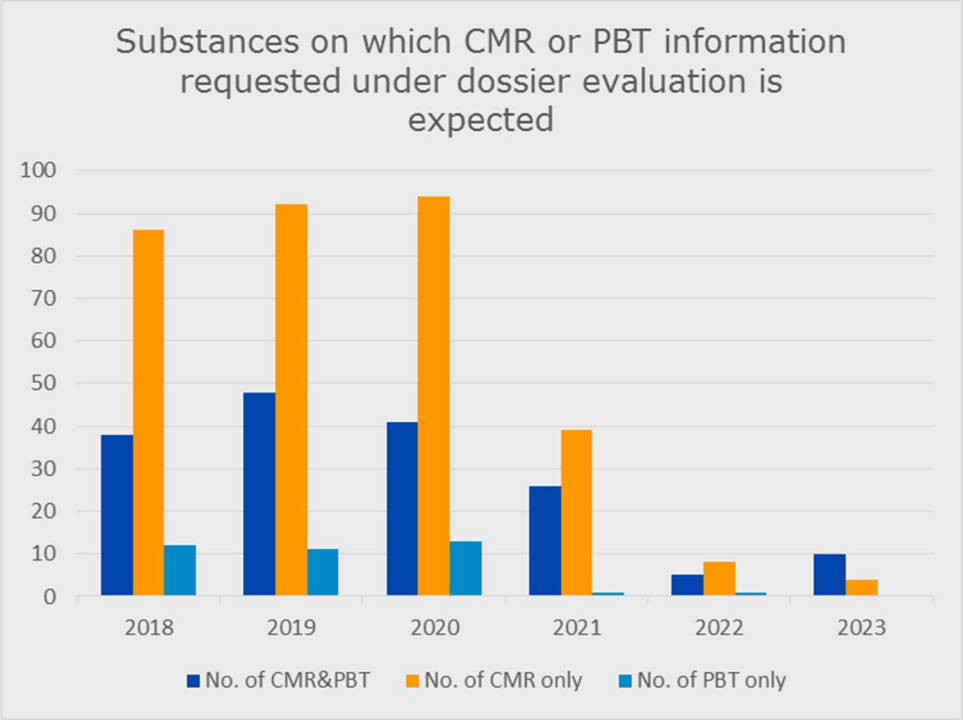


Figure 6: Overview of number of substances on which CMR or PBT information requested under dossier evaluation is expected (by year)

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

By the end of 2018, **substance evaluation** was concluded for 95 substances.

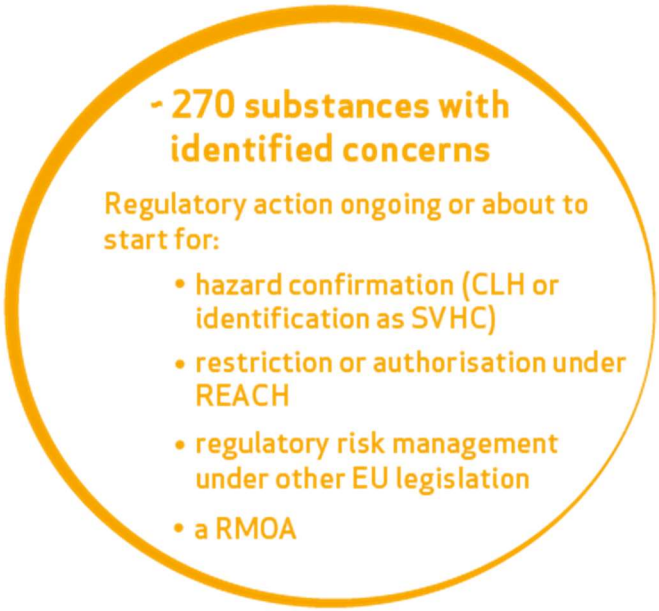
For 47 substances, the Member State considered further regulatory risk management to be needed:

- **21 substances have been followed up**: Regulatory risk management (harmonised classification, identification as a substance of very high concern (SVHC), restriction) was initiated, is ongoing or was concluded for 12 substances. For two substances, an RMOA concluded no need for further regulatory action. For 7 substances, an intention for RMOA or harmonised classification was submitted or an RMOA concluded that further regulatory risk management is needed.
- **20 substances are yet to be followed up**: Harmonised classification and labelling has been identified as the necessary regulatory risk management measure. For 6 substances, the proposal would relate to CMR properties. For 10 substances, substance evaluation was concluded in 2018 and therefore there may have not been enough time to initiate the CLH proposal.
- For 4 substances, the identified regulatory risk management measure was outside the scope of REACH and CLP, with proposals including occupational exposure limits (OELs) and enforcement. ECHA has no information on whether these cases have been followed up. In addition, for 2 substances, substance evaluation concluded that further regulatory risk management may be needed. However, identification of the appropriate measure is pending other actions (e.g. the outcome of the substance evaluation of a constituent of the substance, results of a monitoring programme).

All substances on which there was sufficient information on PBT/vPvB or ED properties – based on further information generated under substance evaluation, or based on an assessment of available information by the PBT/ED Expert Groups – have been followed up. For two PBT substances, the assessment was concluded at the end of 2018, and SVHC dossiers are expected for 2019; for two ED substances, an RMOA is ongoing. These substances have all been discussed in the PBT/ED Expert Groups. From this it is clear that in case of PBT/vPvB properties, once the hazard properties have been confirmed, Member States normally follow up quickly with regulatory action.

So far, 52 substances coming from **compliance check** or **testing proposal examination** have been identified as needing follow-up regulatory risk management action. All these substances need harmonised classification; however, for most, no follow-up action has been initiated yet.

4. Substances of high priority for further regulatory risk management



There are many candidates for further regulatory risk management and authorities need to ensure follow-up action

Substances of high priority for further regulatory risk management are substances:

- in the process of being regulated (e.g. an intention for restriction or for identification as a substance of very high concern (SVHC) is available);
- identified for action but for which the regulatory process has not yet been initiated by authorities (e.g. a substance evaluation has concluded on the need for harmonised classification and labelling, a regulatory management option analysis (RMOA) has concluded on the need for restriction); or
- for which a RMOA is ongoing.

REACH and CLP machinery identifies substances for further regulatory risk management

The purpose of a regulatory management option analysis (RMOA) is to help 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.

A RMOA is a voluntary step performed by authorities that has become common practice. For all substances progressed to regulatory risk management, a RMOA has been developed by authorities. This has been highlighted in discussions with Member States and the Commission during the SVHC Roadmap review as well as in the wider REACH Review[9]. Today, there is consensus among authorities that the RMOA approach serves its purpose as a preparatory step on the journey towards potential regulatory risk management for (groups of) substances.

At the end of 2018, a RMOA had been concluded or was under development for 248 substances (individually or as part of a group). Conclusions are available on 172 substances. Further details on the type of conclusions drawn are presented in Table 2. The results confirm the trend already observed in 2017 last year that most RMOAs concluding on a need for follow-up regulatory actions under REACH and CLP are being followed up. Substances for which the follow up

[9] Commission's communication on the REACH Review: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN.

regulatory action identified is SVHC have not yet been followed up however intentions are available for the remaining ones and the dossier has been submitted beginning of 2019.

Table 2: Cumulative number of substances for which a RMOA has been concluded per proposed follow-up regulatory action (February 2013 - December 2018), together with the progress monitoring indicator (RMOA2) per year.

	By the end of 2014	By the end of 2015	By the end of 2016	By the end of 2017	By the end of 2018	Follow-up regulatory action initiated under REACH/CLP
SVHC identification (authorisation)	5	19	27	44	58	50
REACH restriction	11	15	17	28	37	37
CLH	1	3	6	7	12	7
Other EU-wide regulatory action	2	5	8	9	9	-
Other (e.g. non-EU-wide and/or non-regulatory actions)	1	4	5	7	11	-
No follow-up action	5	8	16	23	28	-
RMOA2: Extent to which RMOA concluded with action resulted in regulatory follow-up (%)	17 %	68 %	84.8 %	94 %	88%	NA

15 Member States have been developing RMOAs since 2013, when the work on the implementation of the SVHC Roadmap started (see also Annex 1). In some cases, RMOAs have been developed in cooperation between Member States. Through the SVHC Roadmap, which was further strengthened by the Integrated Regulatory Strategy, authorities have a strong foundation on which to work together on the assessment and identification of SVHCs beyond 2020, as well as ensure progress in other areas of REACH (e.g. restriction) and in other legislation (e.g. occupational health and safety). A detailed overview of all relevant regulatory risk management activities under REACH and CLP since REACH entered into force in 2008 is available in Annex 3. Additional information on regulatory activities is provided on a yearly basis in ECHA's General Report[10].

The impact of the Integrated Regulatory Strategy is visible through, for instance, the harmonised classification and labelling (CLH) dossiers between 2015 and 2018. These came mainly from screening, substance evaluation, and, in particular, dossier evaluation. Figure 7 shows that since 2016, for almost 80 % of substances for which a CLH dossier has been submitted, there were previous activities (screening, substance or dossier evaluation, or RMOA).

[10] Available at: http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports.

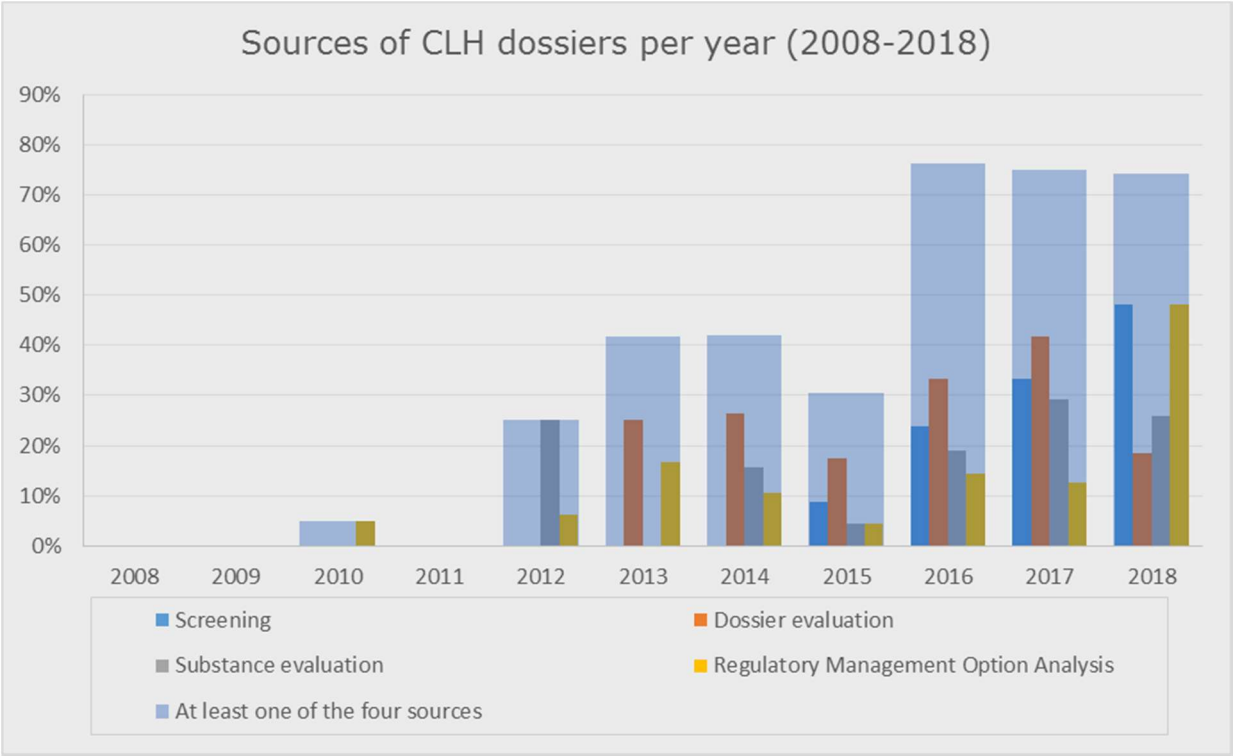


Figure 7: Sources of harmonised classification and labelling dossiers (2008-2018)

Since 2012 submitted dossiers for restriction and for SVHC identification all had an RMOA or equivalent. When relevant, the PBT/ED Expert Groups have been consulted.

When hazard data are available, substances are identified directly for further regulatory action

Member States have screened more than 960 substances in five years. For around 150 substances, data has been sufficient to conclude on the need for further regulatory risk management, in particular the need for a harmonised classification and labelling and regulatory management option analysis (RMOA).

Furthermore ECHA, Member States and ECHA's Member State Committee and Committee for Risk Assessment work together to ensure that when possible, further regulatory action is initiated based on available information.

For instance, in the case of the substance **ethanol, 2,2'- iminobis-, N-(C13-15-branched and linear alkyl) derivs**, a proposal by the registrant to test the substance to fulfil the REACH information requirements was rejected as there were already strong indications that the substance would meet the criteria for classification as toxic to reproduction, category 1B. A proposal for harmonised classification has subsequently been submitted by Member States, and RAC has agreed to the classification of the substance as a category 1B reprotoxicant.

A few of the cases brought forward under restriction or SVHC identification are the result of joint work by ECHA, the Member States and the Commission. Examples of joint efforts by the authorities include the per- and polyfluorinated alkyl substances (PFASs) substances discussed

under the PFAS task force, and the polycyclic aromatic hydrocarbons (PAHs) discussed under the PetCo Working Group.

Screening and substance evaluation have resulted in the identification of potential SVHCs. However these have not been useful as originally expected in identifying candidates for restriction.. However, ECHA has identified potential restriction needs through its recent experiences with groups of substances. This shows that the previous approach that focused on single substances was good for identifying substances for which the hazard properties needed to be confirmed (through inclusion in Annex VI to the CLP Regulation or inclusion in the Candidate List). However, a wider and more holistic understanding gained through the assessment of groups of structurally similar substances enables authorities to identify needs for further regulatory risk management. An example of such a group assessment is that carried out for ethylene glycol ethers (see below). Identification of candidates for restriction is a priority for authorities. In addition to the screening and grouping of substances in the REACH and CLP database, authorities have started to use new ways of identifying emerging risk chemicals, looking at external information sources (e.g. scientific literature, news sites, websites, electronic databases, stakeholder networks) to help identify likely candidates for restriction.

Assessment of a group of substances: ethylene glycol ethers

A large group of around 50 ethylene glycol ethers was screened by ECHA. These substances were grouped based on structural similarity, read-across and category information available in the registration dossiers. The ethylene glycol ethers were divided into five subgroups based on metabolite formation. All registered substances have widespread uses with high potential for exposure. Some ethylene glycol ethers metabolise into reprotoxic substances and are already subject to authorisation. The analysis identified a handful of other substances that may need to be regulated in the same way.

In addition, the majority of the substances have irritation or corrosion properties according to both their harmonised classification and self-classification. The use of these substances in spraying applications may result in respiratory irritation. For one substance in the group, 2-(2-butoxy ethoxy)ethanol, there is already a restriction on its use in spray painting applications and spray cleaners supplied to the general public (entry 55 of Annex XVII to REACH).

ECHA concluded that it should be considered to expand the restriction under entry 55 to any linear glycol ether not already covered by a restriction (e.g. substances with reprotoxic properties under entry 54) that has irritation or corrosion properties. Given the uncertainly in the information provided in the registration dossiers on uses, the restriction should not be limited to those substances that have reported uses in paints and/or cleaners.

Authorities need to mobilise resources to ensure follow-up of regulatory risk management actions

In the chemical universe, 265 substances have been identified as being of high priority for further regulatory risk management. Table 3 provides a more detailed overview of these substances. The substances come from different sources – screening, substance evaluation, compliance check, testing proposal examination and RMOA. Member States may also bring further candidates from their national priorities.

Table 3: Substances of high priority for further regulatory risk management (at the end of 2018)

	Ongoing or in the process of being regulated	Identified but action pending	Total
RMOA	28 %	16%	44 %
CLH	6 %	42 %	48 %
SVHC	2.6 %	0.4%	3 %
Restriction	4 %	1%	5 %

Around half of the substances of high priority for further regulatory risk management are either waiting for a Member State to start a RMOA or the RMOA is ongoing. Currently, 28 % of substances (as single substances or as part of a group) have a RMOA ongoing, while 16 % have been identified through screening and are waiting for a Member State to initiate the work.

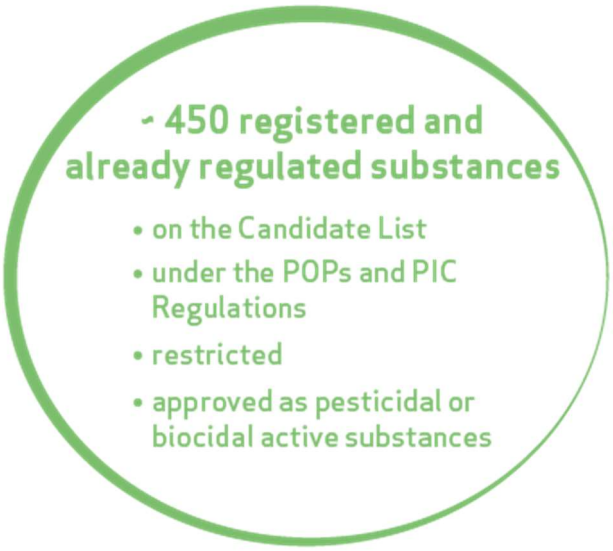
The other half are substances with a potential need for harmonised classification. For only 6 % of these there is already an intention from authorities to prepare a CLH proposal; for the other substances, actions need to be initiated by Member States as soon as possible. Most of these substances are identified as an outcome of screening or are a follow-up of substance evaluation, compliance check or testing proposal examination.

As can be seen from the table there are very few pending substances for which either identification as a substance of very high concern or restriction needs to be initiated. There are intentions to initiate action already in 2019 for all those substances.

The number of RMOAs being concluded per year has been steady, with 28 substances being concluded on in 2018. However, the number of substances for which an intention to prepare a RMOA has been made has clearly diminished, from 31 in 2017 to 13 in 2018. Member States should invest resources and ensure that pending RMOAs are initiated and ongoing ones are concluded. Whether or not the pending RMOAs are relevant for further regulatory risk management needs to be investigated in order to ensure that those substances in need of risk management are progressed further.

In the case of some substances, the need for further action (RMOA, harmonised classification and labelling) has been known already for several years without any action being taken. While there may be valid reasons for not initiating actions, Member State competent authorities should allocate sufficient resources to ensure that these substances are either progressed further or that their priority for action and the appropriateness of the previously identified action is revisited. One possibility would be to use RMOA to review and update the need and priority for further work.

5. Substances of low priority for further regulatory risk management as already regulated



New substances of concern are identified and regulated every year

Substances are considered of low priority for further regulatory risk management because they are already regulated and there is no need for further immediate regulatory action. The following substances are included in this pool:

- substances included on the Candidate List;
- substances under the POPs Regulation and the PIC Regulation;
- substances covered by certain restrictions; and
- approved pesticide and biocidal active substances.

Currently, 450 registered substances are considered to belong to this pool. While there are more substances in each of the above lists, only those for which a registration dossier is available in our database are considered. Information on substances on the Candidate List, on the Authorisation List, or proposed for restriction is available in Annex 3. Biocidal and pesticidal active substances have been added, as these substances have been through a thorough hazard assessment and an exhaustive set of hazard information is already available.

In 2018, 16 more substances were identified and included in the Candidate List (see Table 4). The following three restrictions were initiated:

- The restriction of the placing on the market of certain chemicals and use of professional and industrial use of the five cobalt salts where adequate control cannot be demonstrated. The restriction may also be implemented by imposing operational conditions and risk management measures.
- The restriction of the placing on the market of plastic, rubber and other granules containing polycyclic aromatic hydrocarbons (PAHs) above a set concentration limit for use as infill material on synthetic turf pitches or for use as loose granules or mulch on playgrounds and sport applications.
- The restriction of the manufacturing and industrial use of N,N dimethylformamide.

Table 4: SVHC proposals discussed in 2018 and their outcomes

Substances added to the Candidate List in 2018	
2,2-bis(4'-hydroxyphenyl)-4-methylpentane	Toxic for reproduction
PAHs	
Benzo[k]fluoranthene	Carcinogenic, PBT, vPvB
Fluoranthene	PBT, vPvB
Phenanthrene	vPvB
Pyrene	PBT, vPvB
Benzo[ghi]perylene	PBT, vPvB
Decamethylcyclopentasiloxane (D5)[1]	PBT, vPvB
Dodecamethylcyclohexasiloxane (D6)[2]	PBT, vPvB
Octamethylcyclotetrasiloxane (D4)	PBT, vPvB
Disodium octaborate	Toxic for reproduction
Ethylenediamine	Respiratory sensitising properties
Lead	Toxic for reproduction
Terphenyl hydrogenated	vPvB
1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one 3-benzylidene camphor; 3-BC	Endocrine disrupting properties - environment
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride trimellitic anhydride; TMA	Respiratory sensitising properties
Dicyclohexyl phthalate DCHP	Toxic for reproduction Endocrine disrupting properties - human health
Withdrawn after submission	
Undecafluorohexanoic acid and its ammonium salt	Equivalent level of concern having probable serious effects to human health and environment

1: Decamethylcyclopentasiloxane (D5) meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) as a substance which is persistent, bioaccumulative and toxic when it contains ≥ 0.1 % w/w octamethylcyclotetrasiloxane (D4) (EC 209-136-7).
2: Dodecamethylcyclohexasiloxane (D6) meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) as a substance which is persistent, bioaccumulative and toxic when it contains ≥ 0.1 % w/w octamethylcyclotetrasiloxane (D4) (EC 209-136-7). In addition to its intrinsic properties, it also meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB) when it contains ≥ 0.1 % w/w decamethylcyclopentasiloxane (D5) (EC 208-764-9) or ≥ 0.1% w/w octamethylcyclotetrasiloxane (D4) (EC 209-136-7).

All substances included in the Candidate List are considered as sufficiently regulated because they are all regularly assessed for their priority for inclusion in the Authorisation List. The types of substances which have been recommended since 2015 are described below, demonstrating that the applied approach is working as foreseen and prioritises substances with PBT/vPvB properties and with widespread uses.

Prioritisation of substances from the Candidate List for inclusion in Annex XIV – an overview

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, and those of highest priority are recommended for inclusion first. All substances not recommended at one time as well as newly added substances are considered in future rounds (for more information on Annex XIV recommendation, see Annex 3).

In 2014, ECHA and Member States updated the approach for prioritising Candidate List substances for inclusion in the Authorisation List. The approach was applied in developing the 6th , 7th and 8th recommendations (31 substances in total).

ECHA analysed these recommendations to get further insight on the types of substances which were prioritised for inclusion in the Authorisation list. The analysis focused on the 19 substances that had registered uses. The other 12 substances were not registered – the reason for recommending them was based on the grouping approach, which aims to avoid regrettable substitution, an aspect which ECHA will continue to give importance to in the future.

The analysis shows that:

- all PBT/vPvB substances in the Candidate List with registered uses in the scope of authorisation have been recommended; and
- reprotoxic substances have been recommended either because of the relatively high tonnage in wide dispersive uses in the EU or because they can be used as substitutes for substances already recommended for inclusion in Annex XIV.

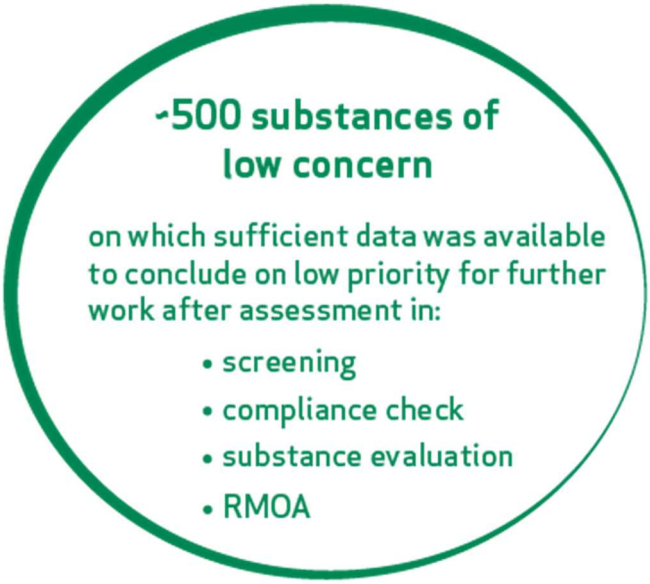
From a use perspective, the analysis highlights that:

- all recommended substances were indicated as having widespread uses (i.e. are used by professional workers, by consumers or in articles);
- the following uses (defined in broad terms) are frequently reported in the registration dossiers:
    - coatings (including paints) (12 out of 19 substances);
    - adhesive/sealants (7 out of 19 substances);
    - cleaning products (7 out of 19 substances);
    - plastics/polymers (7 out of 19 substances).

In summary, the currently applied prioritisation approach is working as foreseen and prioritises substances with PBT/vPvB properties and with widespread uses.

Description of the updated prioritisation approach: https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8.

6. Substances of low priority for further regulatory risk management after assessment



(De)prioritisation to support authorities in focusing on substances that matter

Substances are concluded to be of low priority for further regulatory risk management and placed into this pool after an assessment is made under one of the following processes: screening, compliance check, substance evaluation, or RMOA.

Currently around 500 substances are included in this pool. Substances are considered of low priority for further action based on several factors. Resources are needed to progress substances to regulatory risk management, and (de)prioritisation has supported authorities in focusing their resources on the substances that matter, thereby optimising the system.

(De)prioritisation

Prioritisation factors are applied in screening, compliance check, substance evaluation and RMOA. The priority for action of a substance is not fixed and may evolve if new information on hazards or uses becomes available. Therefore, the decision to consider a substance as being of low priority for further regulatory work need to be regularly reassessed.

Substances are considered of low priority for action mainly based on:

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

In addition, authorities consider the added value of any new risk management measure. For instance a substance can be considered as low priority for further work when the regulation in place already covers sufficiently the hazards under scrutiny. In such case, generating further information on these hazards already sufficiently regulated would not lead to more or improved risk management measures.

Table 5 provides an overview of the origin of the substances considered as low priority for further regulatory risk management.

Table 5: Low priority substances for further regulatory risk management action by source

Source	Percentage
Screening (concluded with no action by Member States during manual screening or by ECHA before initiating a compliance check)	52 %
Compliance check* (concluded with no action or no follow-up action after generation of data)	27 %
Substance evaluation (concluded with no follow-up action)	8 %
PBT/ED Expert Group assessment (concluded as substance not fulfilling the PBT/ED property criteria)	7 %
RMOA (concluded as no need for further regulatory risk management at this point in time)	6 %

*The numbers cover only those high priority compliance checks started in 2015 following the start of the implementation of the Integrated Regulatory Strategy.

Currently the majority of substances in this pool stem from screening activities. Screening supports authorities in focusing on those substances for which further regulatory risk management action may be needed. It was not possible to clarify for this report how many of the substances were concluded to be of low priority due to low hazard, low potential for exposure or low added value for regulatory risk management. The aim is to have this information available next year once the recording capacity in ECHA allows it.

For priority compliance check, the substances are concluded as being of low priority in most cases after new information has been generated.

There are 48 cases that come from substance evaluation. The majority, 39 cases, were concluded to be of low priority due to a low hazard following the generation of hazard information. In 9 cases, low exposure was concluded. The PBT and ED Expert Groups conclude their assessments as low hazard (41 cases, see also Annex 1). The share of low hazard cases compared to low exposure or low added value for regulatory risk management cases may be very different for RMOA, for example, as in most cases the hazard is already confirmed at the level of RMOA development.

An example of a low priority substance under compliance check

ECHA assessed the registration dossier of ethanethiol (in the more than 1000 tonnes per year tonnage band) under compliance check.

The registrant self-classified the substance as Aquatic Acute 1, Aquatic Chronic 1 for environment and as Acute Tox. 4 (oral and inhalation) and Skin Sens. 1B for human health. The dossier had data gaps for higher tier studies. Information on similar mercaptan substances has been used to support the evaluation, and therefore there was adequate information to assess the hazard properties of the substance including reproductive toxicity. Based on all available information ECHA concluded that the substance does not have CMR properties. The environmental properties of the substance have also been assessed, and it was concluded that the substance does not have PBT or vPvB properties.

ECHA concluded that the substance is of low priority for further action and no further hazard information was requested. It would be highly unlikely that generation of further information would change the outcome of the hazard assessment. In addition, it would trigger unnecessary animal testing.

Assessing the substances with low hazard and concluding on their low priority is not the main focus of authorities' work. However, by identifying and setting aside groups of low hazard substances, authorities can focus their resources on substances that matter. Clarity on which substances are considered of low priority at the moment enables a systematic review of this conclusion when new information on hazards or uses become available. We expect that a bigger part of the uncertain area can be clarified at an even faster pace by identifying groups of substances around these low hazard substances.

As mentioned above, the priority of a substance may change. This is particularly true for substances concluded to be of low priority based on low exposure. A good example is a substance with CMR properties currently used only as intermediate. While such a substance would normally be concluded to be of low priority, it could be moved to the pool of substances of high priority for risk management together with structurally similar substances to give a clear signal that it is likely not to be a suitable substitute.

7. Substances in the uncertain area

Efficient grouping to ensure the uncertain area is clarified by 2020

Substances in the uncertain area are the substances not yet looked at by authorities and therefore not belonging to any of the other pools.

10 years of systematic screening has focused on substances of high concern

Currently around 2 700 substances registered at above 100 tonnes per year are in the uncertain area.

Since 2014, ECHA has systematically screened the REACH and CLP substance database to identify potential substances for further regulatory work. External databases have been used to complement the picture. Based on this exercise, around 1 400 substances have been proposed to the Member States for further manual screening, and over the last five years, more than 950 of these have been scrutinised. These substances were substances with an already confirmed hazard, substances structurally similar to substances with a confirmed hazard, or substances for which an indication of potential hazard was seen in the registration dossier (Annex 1).

Before 201, authorities concentrated on single substances with already confirmed hazards, such as substances with harmonised classification as a CMR or assessments carried outunder previous regulations confirming PBT/vPvB or ED properties. As concluded in the SVHC Roadmap annual report[3] published in 2018, all currently known CMRs, PBT/vPvBs and EDs have been either:

(i) included in the Candidate List or identified for other regulatory risk management measures (e.g. restriction); or
(ii) considered as not requiring further regulatory risk management action at present.

Around 70 % of the 950 substances screened required follow-up action, in most cases the generation of new data.

What remains in the uncertain area is what is left after several years of systematic scrutiny. It is expected that these substances are either (i) substances on which there is not enough information in the registration dossiers and other data sources to form a view on their potential hazardous properties or to prioritise them based on uses, or (ii) substances of low priority for further work due to low hazard.

Grouping to prioritise and best address substances in the uncertain area

ECHA intends to further screen the around 2 700 substances by 2020, aiming to clarify the need for regulatory risk management or for generation of further hazard information.

To enable this, substances in the uncertain area will be grouped where possible with substances belonging to the three main pools. The remaining substances in the uncertain area will be grouped together to make full use of all available information. This grouping aims to speed up allocation of substances from the uncertain area to any of the three pools. It is expected that the substances in the uncertain area will be mainly allocated to the data generation pool or to the low priority pool. Compliance checks will likely be needed for substances other than those which can already be concluded to be of low hazard based on the available information.

Other initiatives are also used to clarify the uncertain area. These include work with industry sectors to clarify the potential of exposure of big groups of substances with similar uses or functions, or to improve the quality of registration dossiers. Examples of such cooperation are the Metals and Inorganics Sectoral Approach (MISA) and the plastic additives initiative (PLASI).

The next annual report will cover how substances and groups of substances have progressed from the uncertain area to regulatory risk management, hazard data generation or being found to be of low priority for further work. The aim is to have all substances in the uncertain area allocated to one of the three main pools of substances by the end of 2020.

Working together with industry sectors: PLASI and MISA

The **plastic additives initiative (PLASI)** is a project that set out to clarify the uncertain area from a use and exposure perspective. In late 2016, ECHA and 21 industry sector organisations started a joint initiative to confirm which substances are used as plastic additives and to characterise the uses and the corresponding potential for release from articles.

The initiative produced:

- an overview of over 400 substances confirmed by industry to be used as additives in plastic, including information on their properties, functions and typical concentrations, as well as on the polymers and article types in which they are usually used;
- a method for comparing the release potential of additives from plastic matrices, developed using expert input received from industry, academia and authorities; and
- an indicator value for relative release potential for substances which have not been under regulatory scrutiny.

The relative ranking of the release potential has been used to prioritise substances from the uncertain region and to form groups of structurally similar substances.

For more information, see: https://echa.europa.eu/plastic-additives-initiative.

The **Metals and Inorganics Sectorial Approach (MISA)** is a voluntary programme set up by ECHA and Eurometaux to address technical and scientific issues that the metals and inorganics sectors are facing and to update and improve the registration dossiers in these sectors. In 2018, 18 consortia covering over 300 metals, metal and inorganic compounds signed a framework cooperation agreement.

The agreement includes a rolling action plan for 2018-2020, focused on two equally important parallel tracks:

- A gradual and planned improvement of the compliance, quality and understanding of the metals/inorganics registration dossiers.
- Resolving outstanding technical and methodological issues to allow the improvement of the relevance of hazard information, risk assessment and risk management of metals and inorganics.

For more information, see: https://echa.europa.eu/misa and https://www.reach-metals.eu/metals-and-inorganics-sectoral-approach-misa.

MAIN RECOMMENDATIONS

- Further cooperation and coordination between authorities.
- Further optimisation of data generation and assessment to ensure that substances are progressed to regulatory risk management without delay.
- Harmonised classification and labelling should become a priority, as it has a direct impact on company-level risk management and is often the step before restriction, authorisation, or other measures under other pieces of legislation.
- The priority and appropriateness of previously identified but still pending follow-up actions should be reviewed, and those for substances of high priority should be progressed to regulatory risk management
- The quality of registration information needs to be improved, in particular for substances with a high potential for exposure and currently lacking hazard data.

Annex 1. Update on pre-regulatory steps: screening, PBT and ED Expert Groups, regulatory management option analysis (2008-2018).

1 Screening

Screening to find potential substances of (very high) concern is an integral part of ECHA's Integrated Regulatory Strategy to focus on the substances that matter most.

Figure 1 shows the outcomes of all screening rounds from 2014 to 2018. Around 70 % of the 966 substances scrutinised required follow-up action. For almost half of the substances screened (44 %), the outcome was that further information needed to be generated to confirm the hazard properties and, therefore, for the substance to go either through substance evaluation or compliance check.

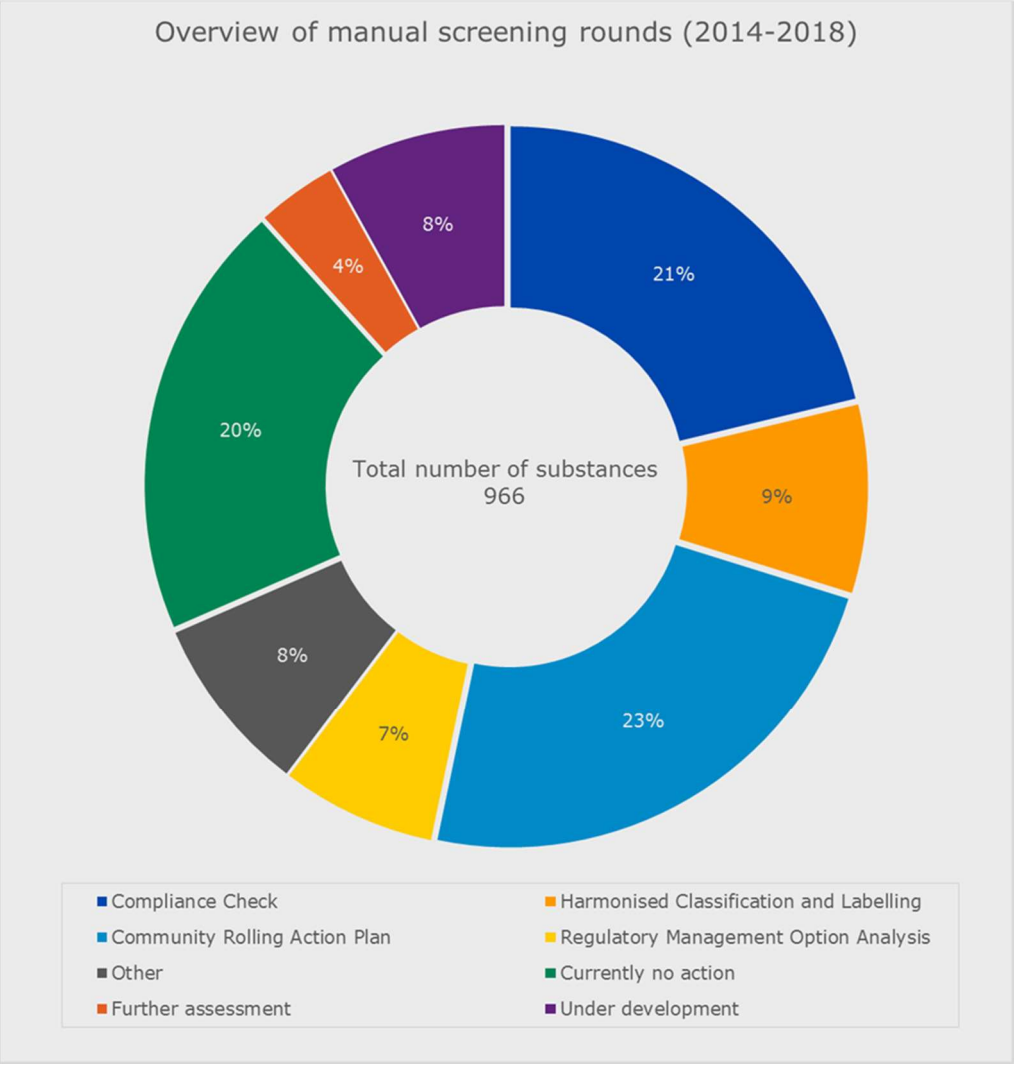


Figure 1: Overview of manual screening outcomes (2014-2018)[11]

[11] Further assessment originally referred to further assessment of PBT and ED properties and consultation of the relevant expert groups. However, it has been recently used to further investigate equivalent level of concern cases, for instance.

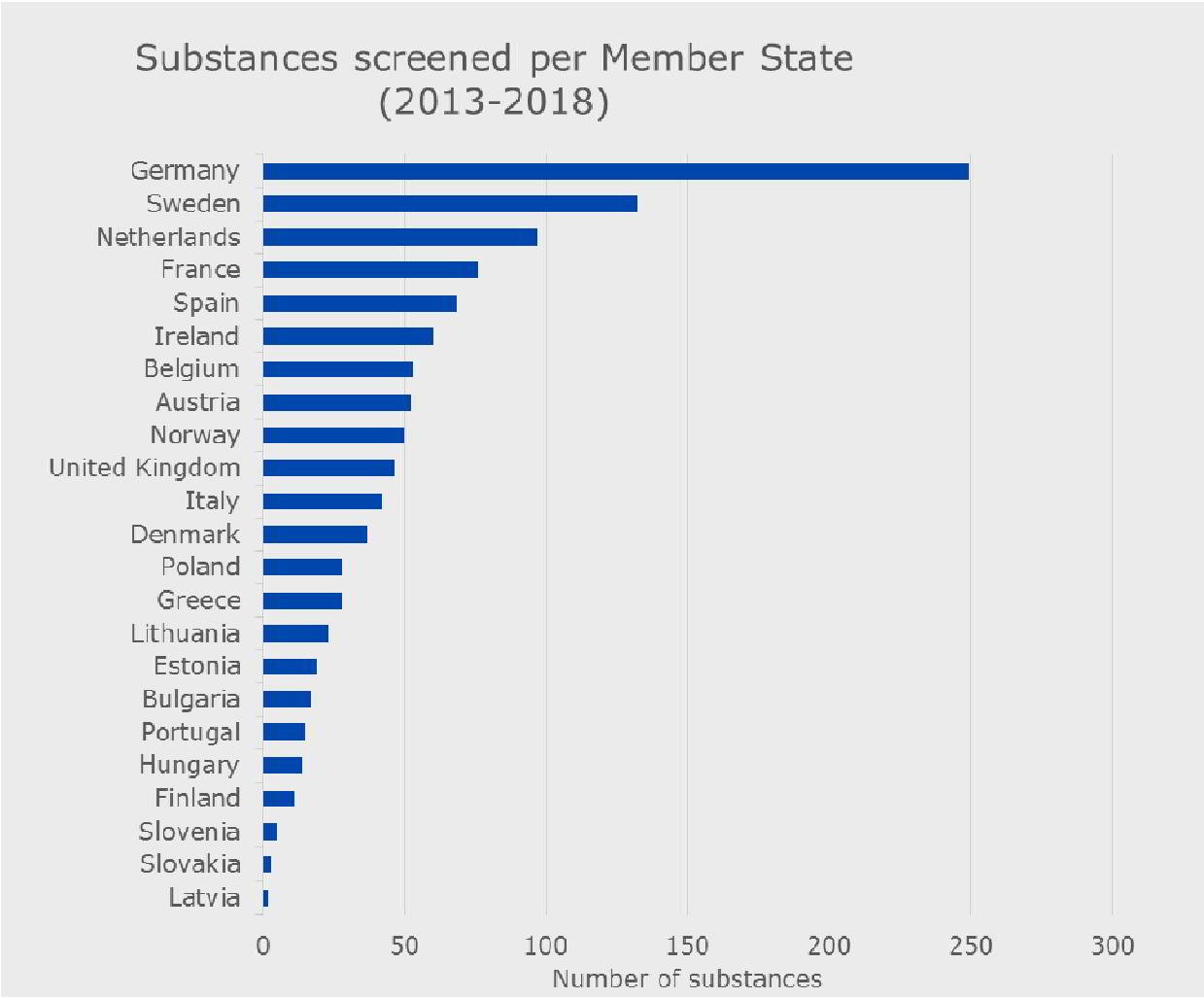


Figure 2: Number of substances screened by Member States and by ECHA (2013-2018)

2 PBT and ED Expert Groups

The PBT and ED Expert Groups were created to support Member States in assessing substances with persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB) or endocrine-disrupting properties. Their main goal is to ensure that the process goes smoothly later on for both substance evaluation and SVHC identification.

Table 1 gives an overview of the number of substances ongoing and concluded on under the PBT and ED Expert Groups.

Many substances are under assessment and at first glance it may seem that very few receive confirmation of their hazardous properties after assessment. However, at this level it is important to not miss potential substances of concern. As such, the criteria used to select potential PBT and ED substances are stringent, which results in the selection of many borderline cases that after further scrutiny or data generation are confirmed as not fulfilling the property criteria.

Table 1: Number of substances concluded on under the PBT and ED Expert Groups and conclusions (2012-2018)

Property	Number of substances ongoing and postponed	Total number of substances concluded on	Number of substances concluded on	
			Considered not to fulfil the hazard properties	Considered to fulfil the hazard properties
PBT Expert Group	115	52	37	15
ED Expert Group	55	12	4	8

Since 2012, 20 Member States have been active in substance evaluation, 19 in the PBT Expert Group and 10 in the ED Expert Group (Figure 3).

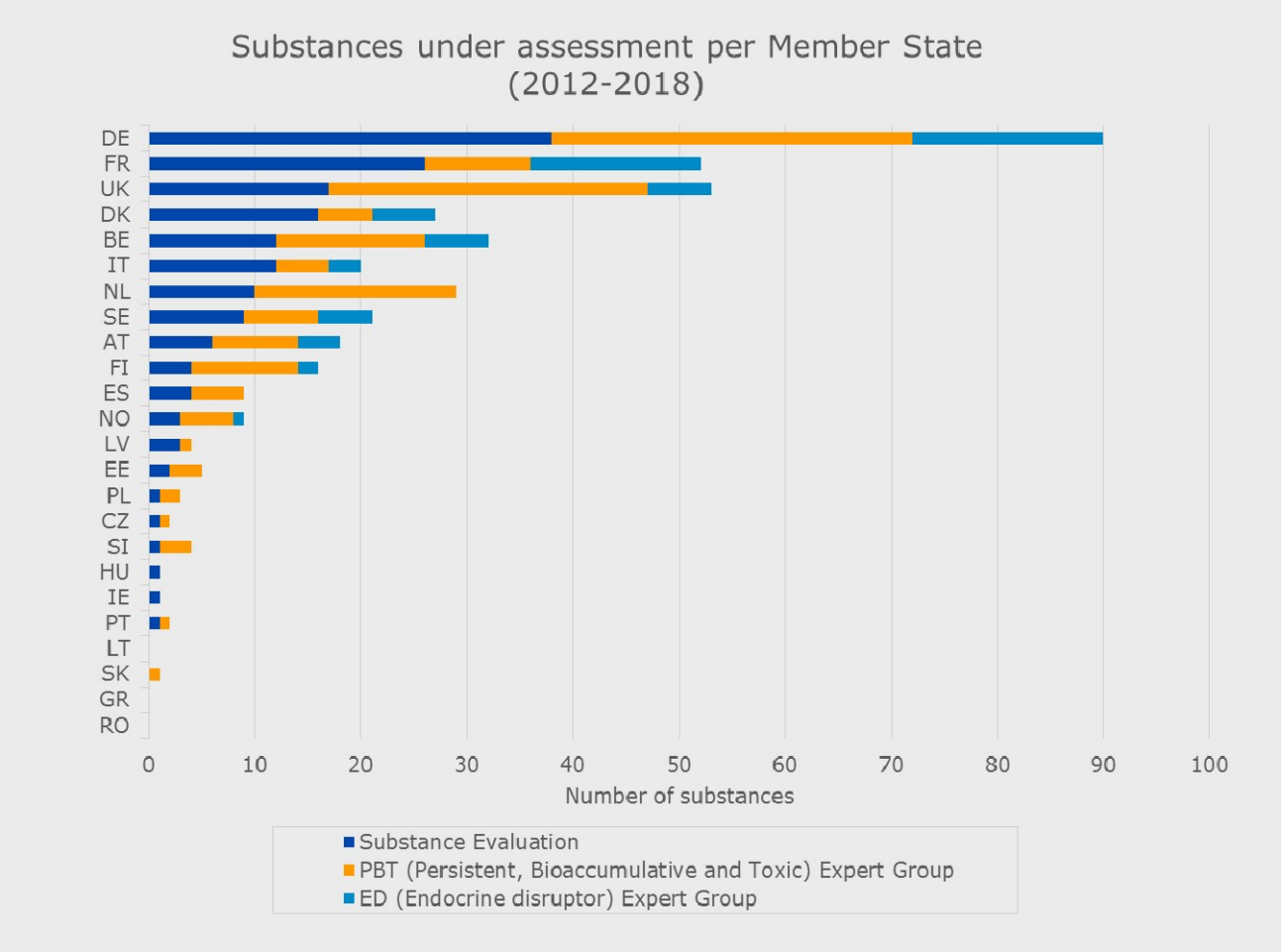


Figure 3: Number of substances under assessment in the ED Expert Group, the PBT Expert Group and substance evaluation, per Member State

3 Regulatory management option analysis

The purpose of a regulatory management option analysis (RMOA), a voluntary approach developed in 2009, is to help 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.

Sharing the RMOA early with other authorities allows them to give early input on the information available and express concerns or views on the benefits and drawbacks related to the use of different risk management instruments. This in turn provides a better basis for deciding on whether and how to proceed with further regulatory risk management as well as input to drafting the regulatory risk management dossier. The RMOA process also allows early consideration and preparation by other authorities for the regulatory processes, which can speed up the formal opinion forming and decision making.

Furthermore, an RMOA should increase transparency and predictability of authorities' work and thereby help stakeholders prepare for the regulatory processes, in particular for public consultations.

Currently, an RMOA has been concluded or is under development for 248 substances.

Figure 4 gives the number of RMOAs concluded or under development from the implementation of the SVHC Roadmap in 2013 to the end of 2018, subdivided according to hazardous property.

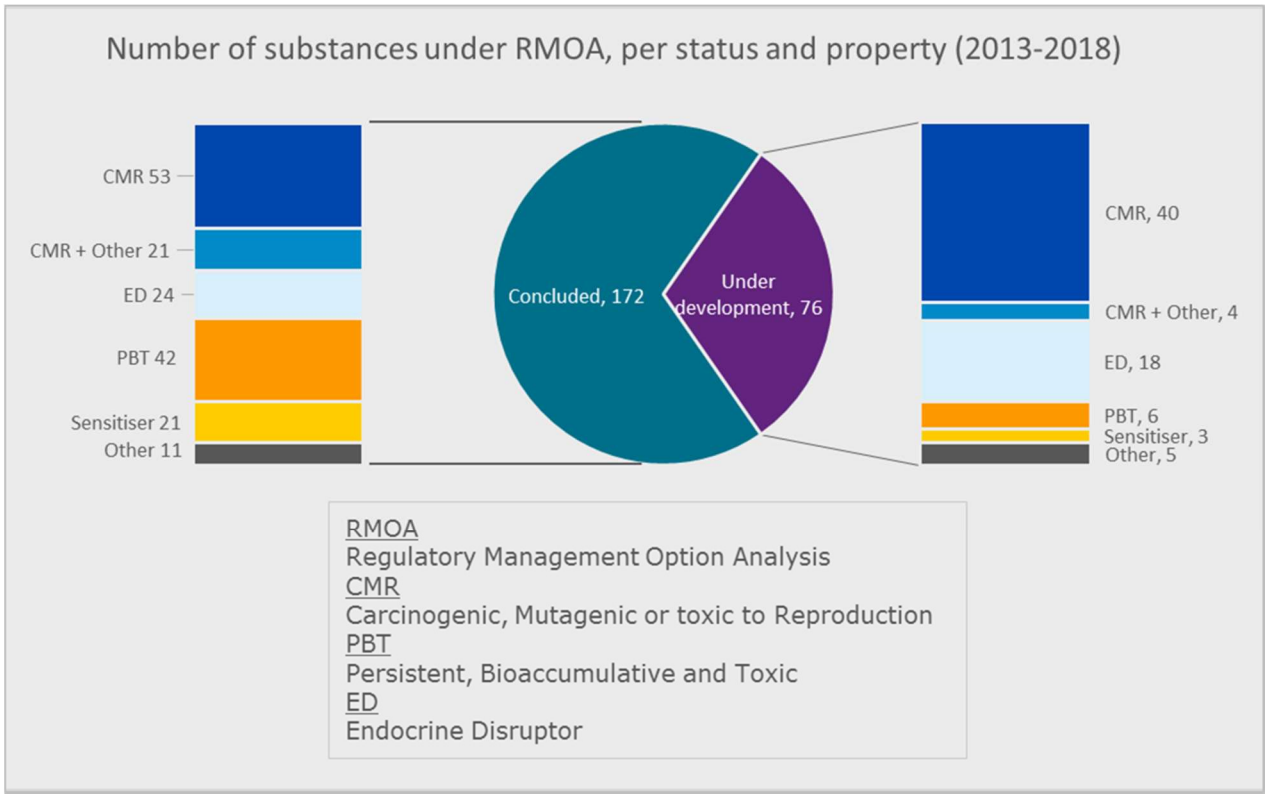


Figure 4: Number of RMOAs concluded and under development per hazardous property (February 2013 - December 2018)

15 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 5).

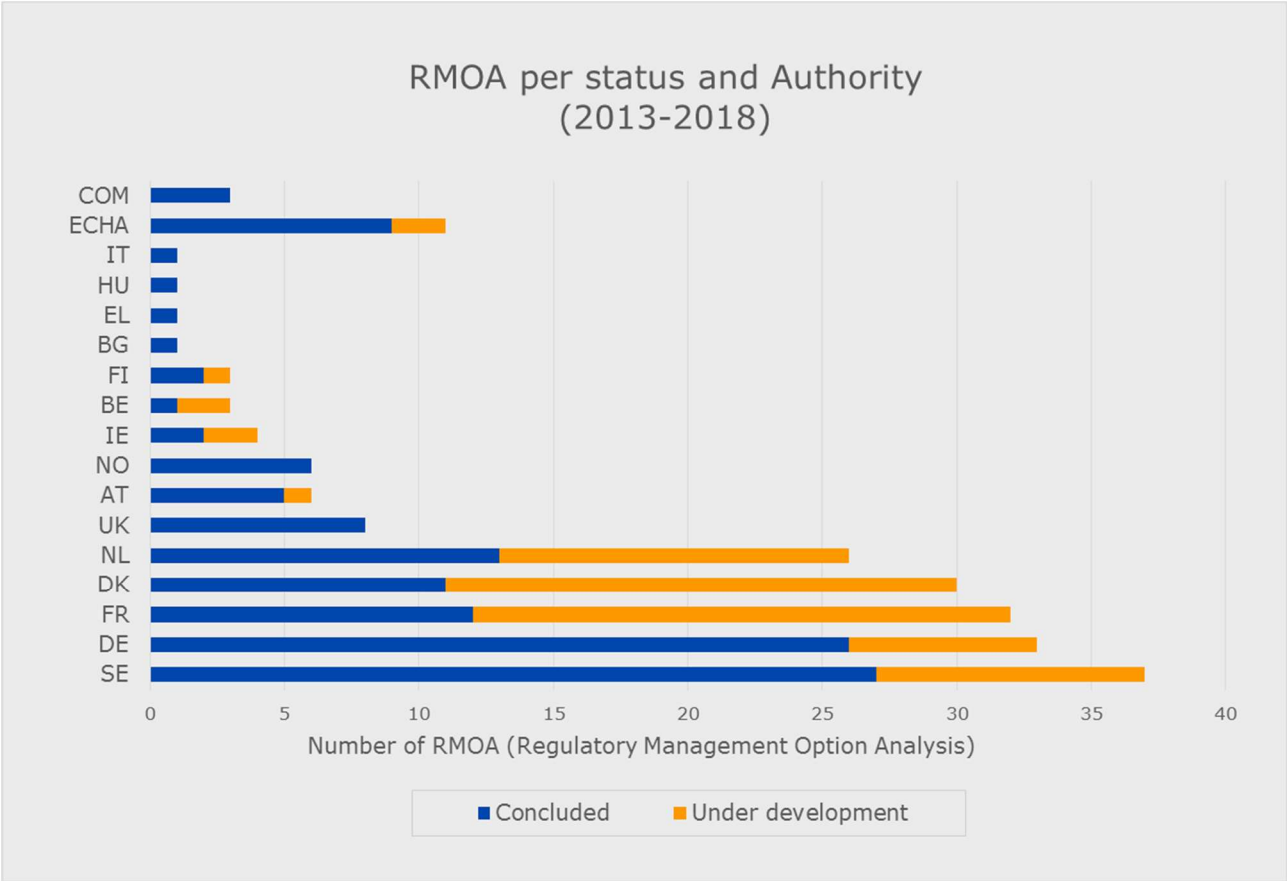


Figure 5: Number of RMOAs concluded or under development per authority (2013-2018)

Annex 2. Update on evaluation activities (2009-2018)

Dossier and substance evaluation have been established as key processes for generating further information on substances. ECHA's web page on progress in evaluation[12] shows more detailed statistics. ECHA also gathered recommendations to registrants[13] resulting from evaluation work.

1 Compliance check (2009–2018)

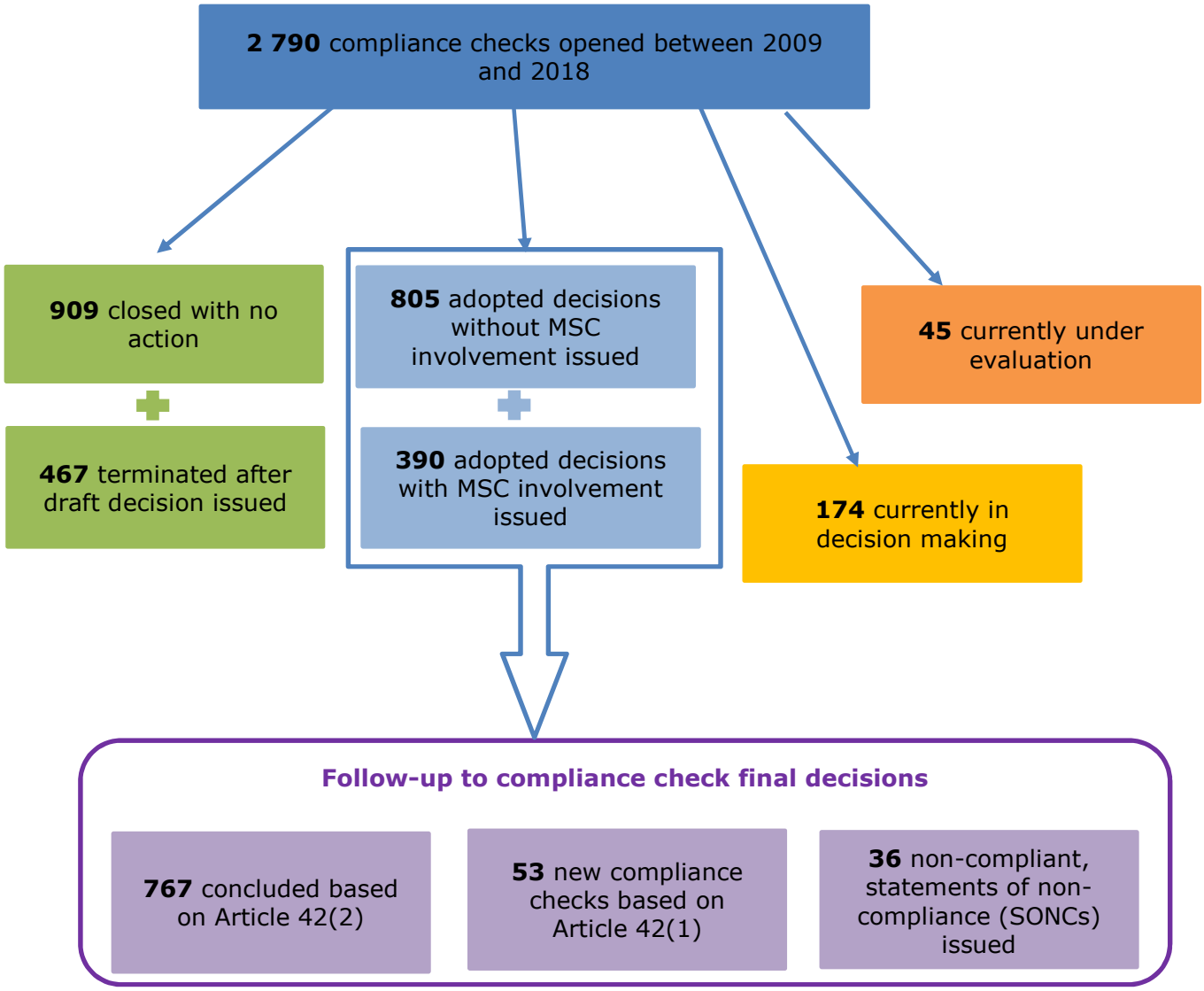


Figure 1: Number of compliance checks between 2009 and 2018

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

2 Testing proposal examination (2009–2018)

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

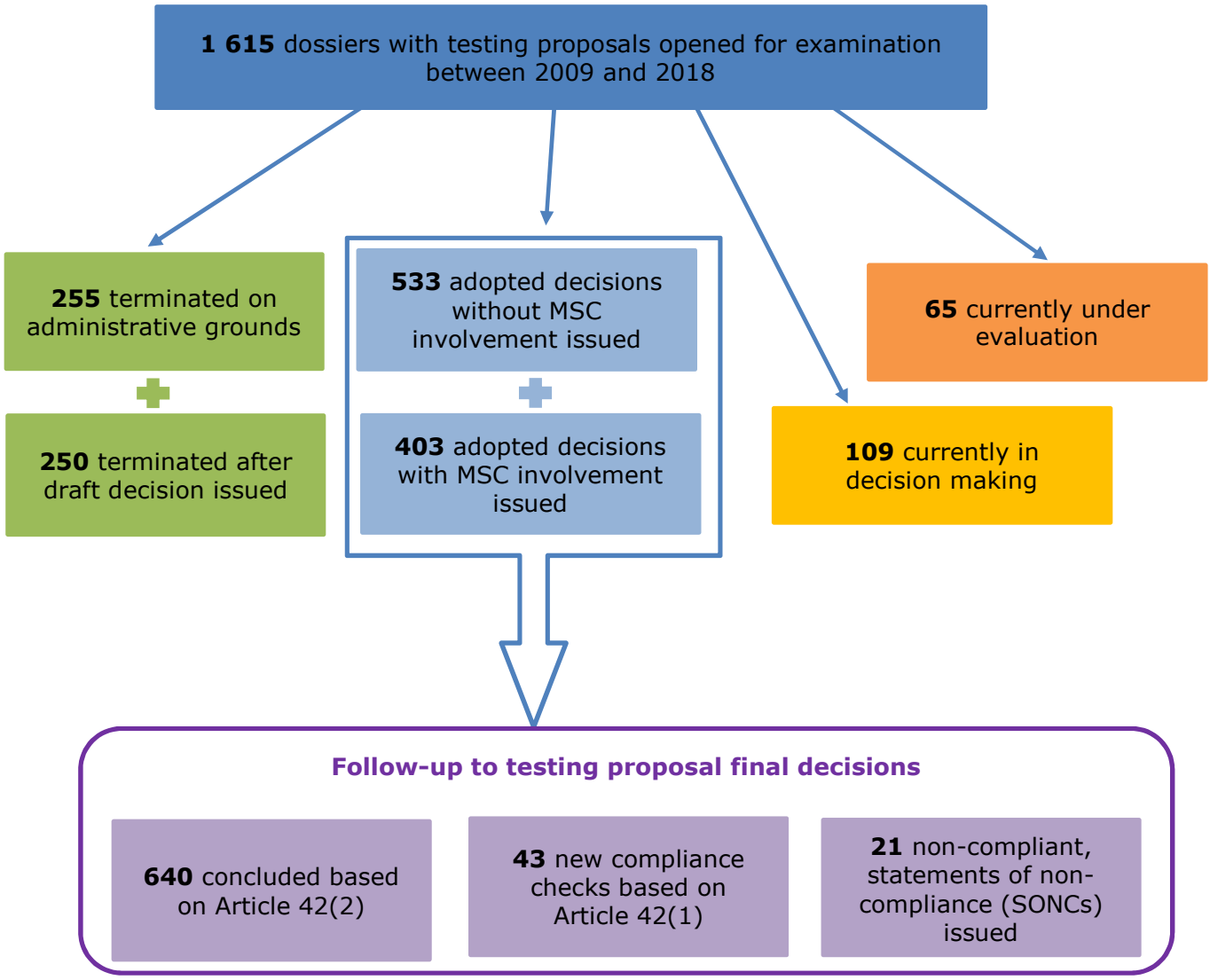
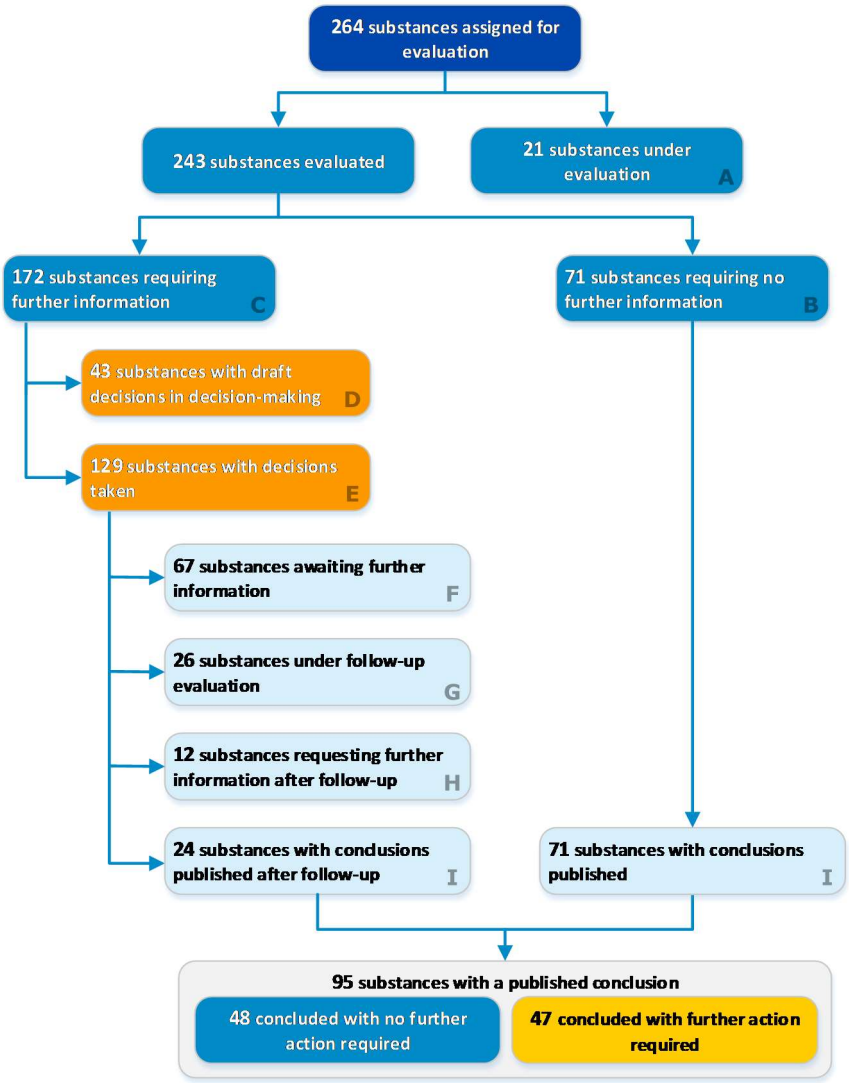


Figure 2: Number of testing proposal examinations between 2009 and 2018

3 Substance evaluation (2012–2018)

3.1 Status of all substance evaluations at the end of 2018



[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 (DD) requesting further information is deemed necessary.
[D] Stages of DD processing: 41 substances currently in decision-making stage. 2 substances currently suspended pending the outcome of an ongoing compliance check.
[E] ECHA evaluation decision taken.
[F] Registrants to submit requested information within timelines specified in decision. For 6 substances, decisions are appealed before the Board of Appeal of ECHA.
[G] Evaluating MSCA is examining all new information in updated registration. For 4 substances, draft conclusion documents are being prepared.
[H] DD requesting further information deemed necessary after follow-up assessment: 9 substances have DD's in decision-making, and 3 substances are awaiting further information according to the timelines specified in the decisions taken.
[I] Conclusion documents published on ECHA's web pages.

Figure 3: Status of all substance evaluations at the end of 2018

3.2 Properties of the substances under substance evaluation (2012-2018)

Table 1 reports the number of substances for which an assessment is ongoing or concluded per property, in the context of substance evaluation.

Table 1: Number of substances under substance evaluation and concluded on per property and conclusion where relevant (2012-2018)

Property	Number of substances ongoing (per property)	Total number of substances concluded on (per property)	From the substances concluded on:	
			Considered not to fulfil the hazard properties[14]	Considered to fulfil the hazard properties
PBT	77	29	27	2
ED	54	19	14	5
CMR	93	57	28	29[15]
Sensitiser	30	29	6	23

[14] Note that a few substances have been concluded on with no clarification of the hazard properties, due to cease of manufacture, for instance. These substances have been included under the heading "considered not to fulfil the hazard properties".

[15] 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 eight CMRs that have either been newly classified or had their classification as CMR upgraded.

Annex 3. Update on regulatory risk management activities (2008-2018)

1 Harmonised classification and labelling

Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity or respiratory sensitisation in any category should normally be subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal products (BPs) or plant protection products (PPPs) 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[16].

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2018, 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 BPs and PPPs and other substances, mainly those subject to REACH registration.

As can be seen, the majority of substances subject to CLH are active substances in BPs and PPPs. The number of REACH substances for which a classification for new[17] and existing CMRs[18] was adopted is also reported.

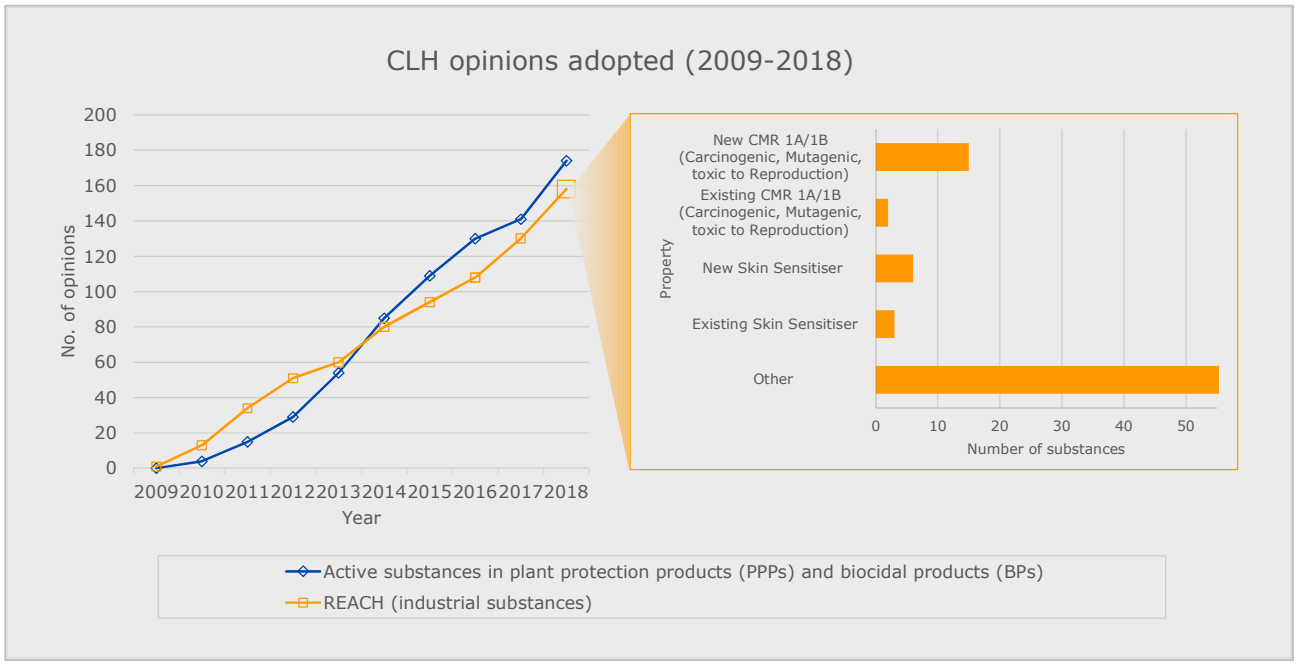


Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2018 and a breakdown of REACH substances for which a CMR 1A or 1A and/or sensitiser proposal was included

[16] For more information on harmonised classification and labelling see: https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

[17] A new CMR is a substance that was not classified as a CMR before.

[18] 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.

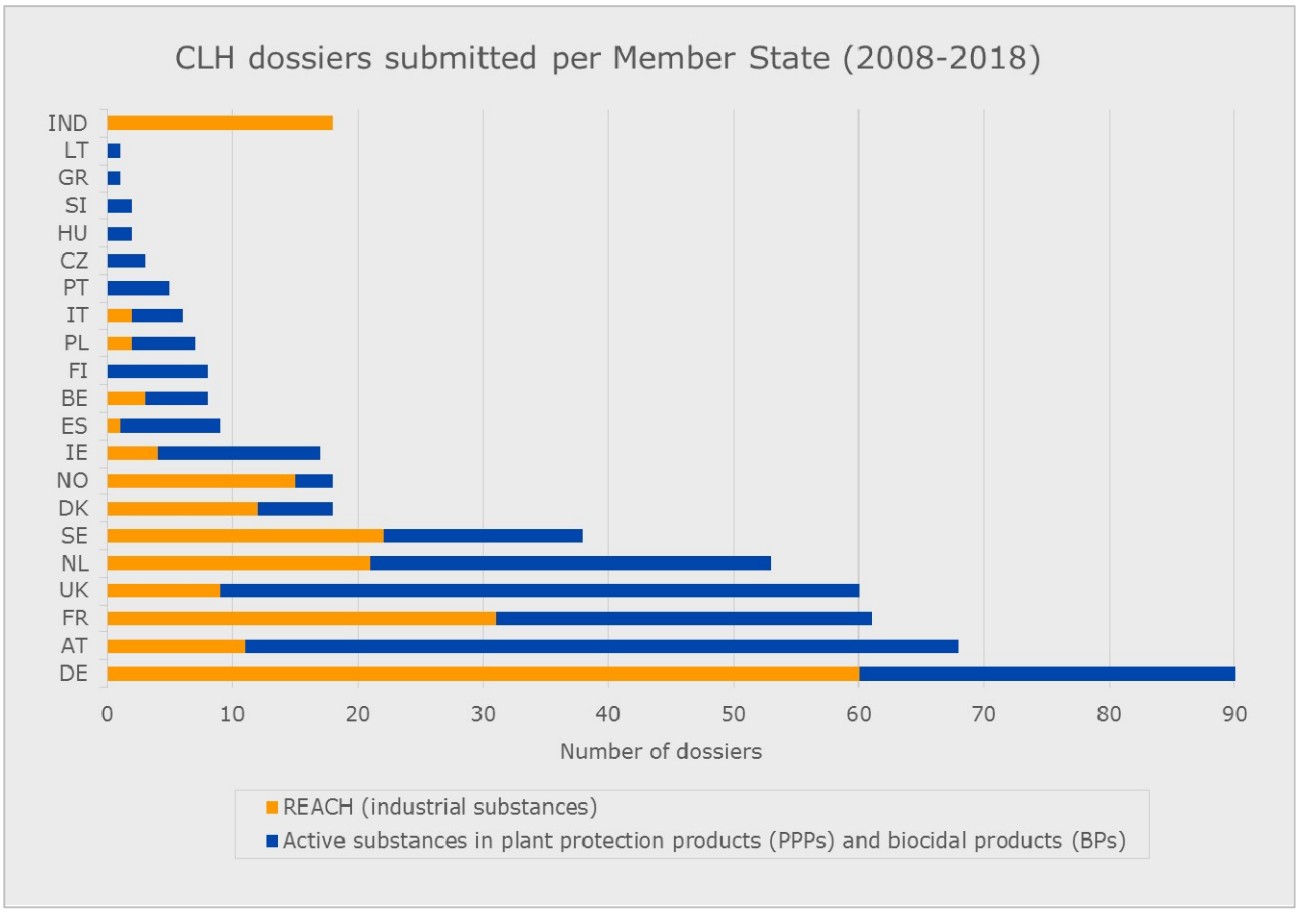


Figure 2: Number of CLH proposals submitted per Member State (2008 – 2018)

2 Authorisation process

2.1 Introduction

In 2008, the first substances of very high concern (SVHCs) under REACH were identified, marking the start of the REACH authorisation process[19].

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 2018. These numbers are further explained below in their respective sections.

[19] For more information on authorisation, see: http://echa.europa.eu/regulations/reach/authorisation.

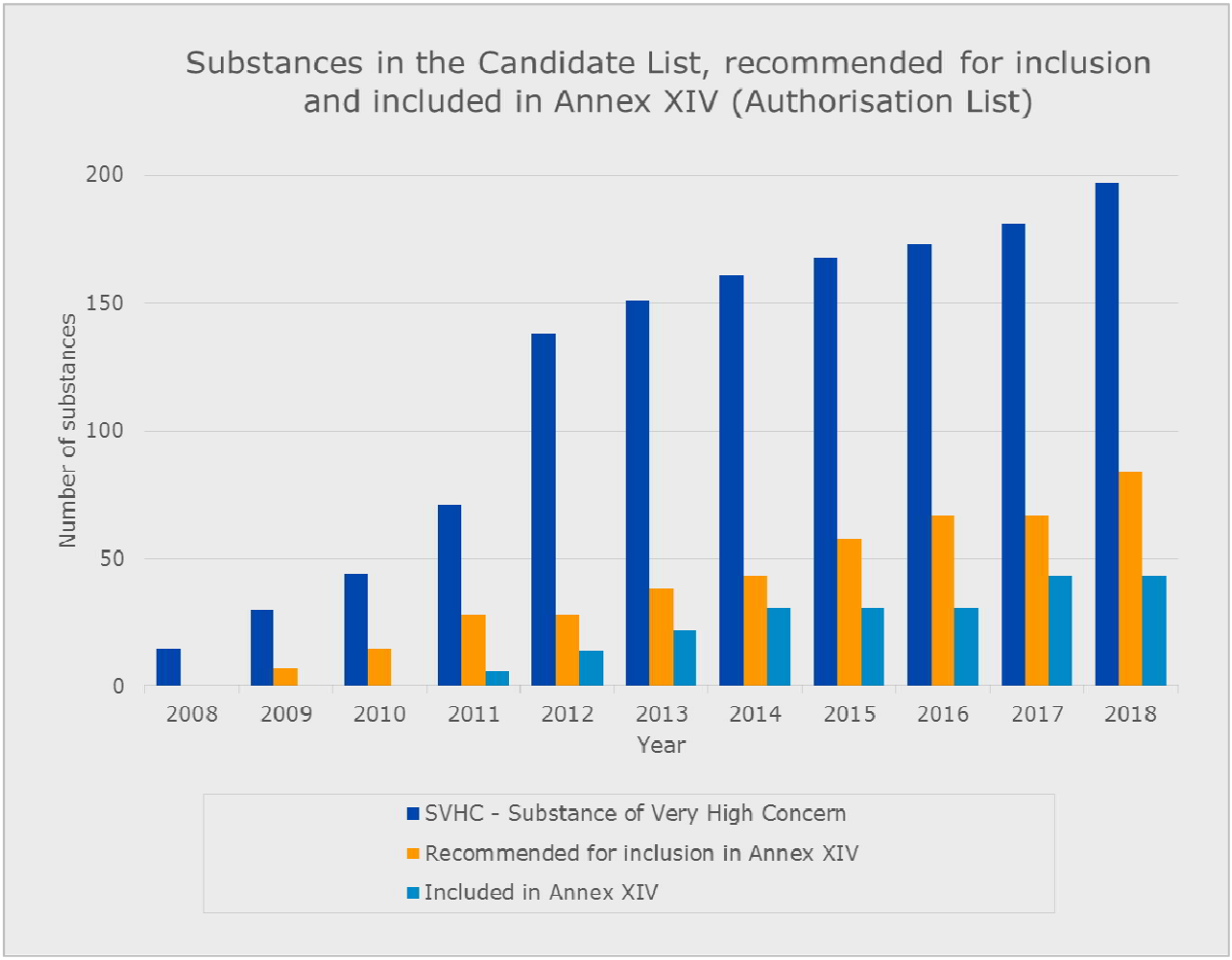


Figure 3: General overview of the number of substances on the Candidate List, recommended for inclusion in Annex XIV (Authorisation List), and included in Annex XIV

2.1.1 SVHC identification

A Member State or ECHA, at the request of the European Commission, can propose a substance to be identified as a substance of very high concern (SVHC).

SVHCs:

- 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 an SVHC, the substance is 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, 197 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 below in Figure 4 and Table 2.

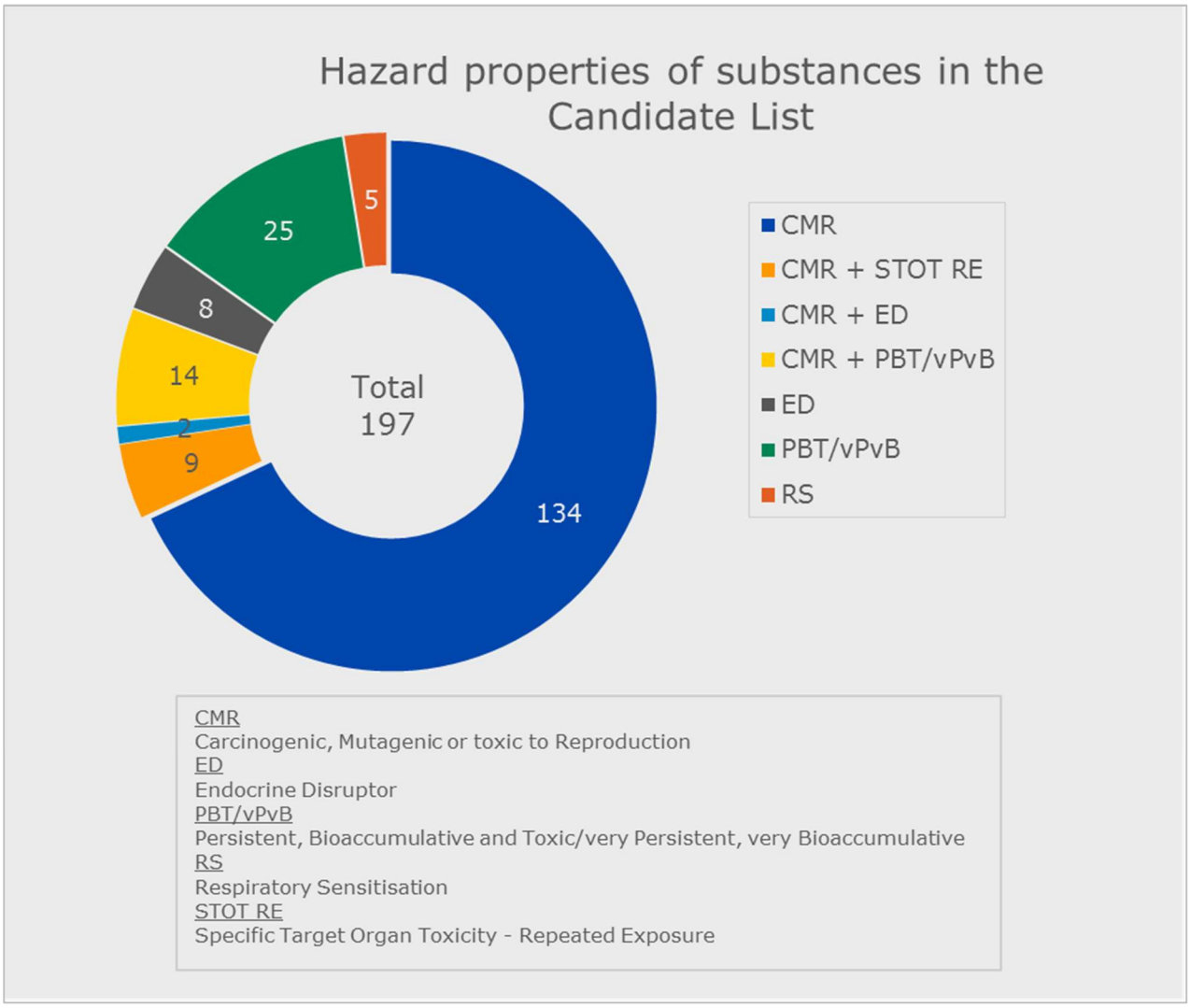


Figure 4: Substances on the Candidate List and overview of their hazardous properties

In 2018, 16 more substances were identified and included in the Candidate List.

Table 1 gives an overview of the number of substances included in the Candidate List per properties since 2008.

Table 1: Overview of number of substances included in the Candidate List by property (2008-2018)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
CMR	10	13	16	26	57	13	8	4	3	5	6	**161**
PBT/ vPvB	5	6	0	0	5	2	2	4	2	4	9	**39**
ED	3	1	0	1	2	1	0	0	3	1	2	**14**
STOT RE	0	0	0	0	0	3	3	0	0	3	0	**9**
Resp. sensitiser	0	0	0	0	3	0	0	0	0	0	2	**5**

Figure 5 gives an overview of Annex XV SVHC dossiers submitted per Member State.

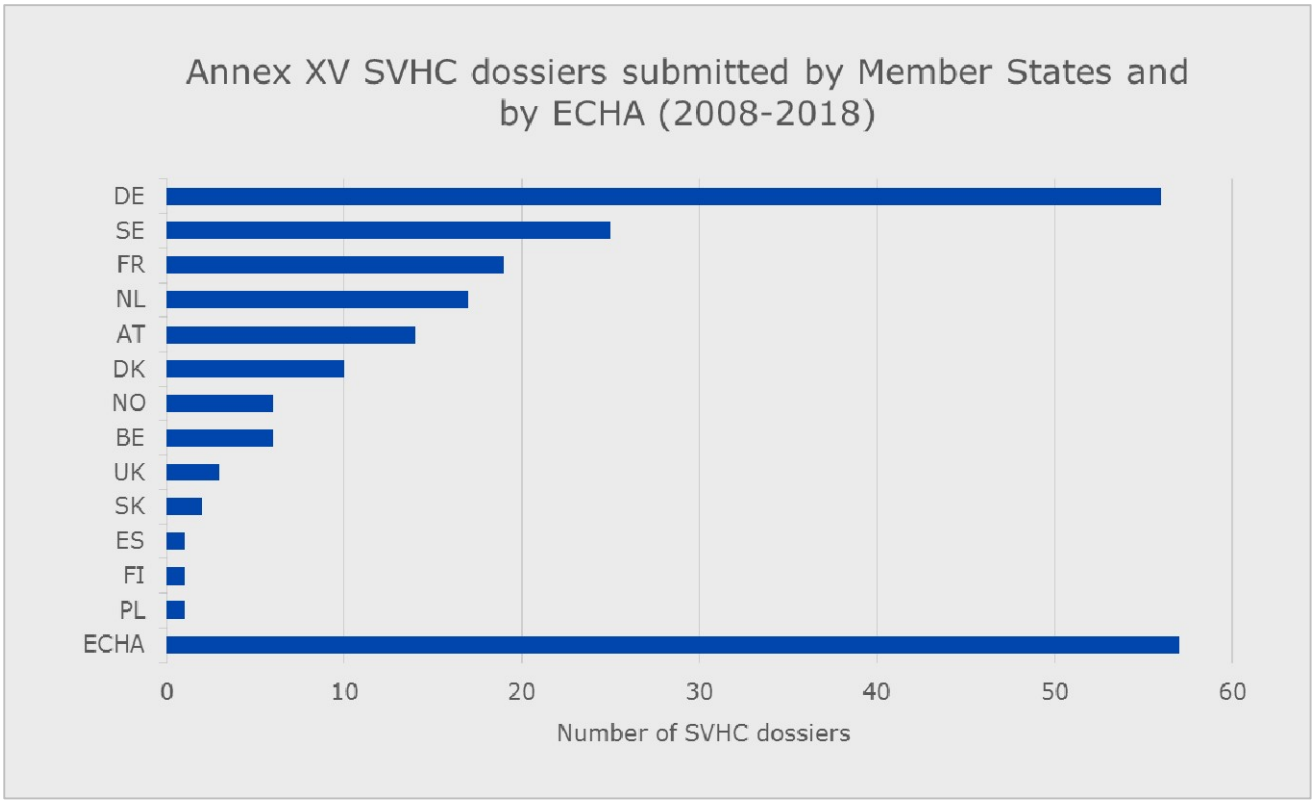


Figure 5: Number of Annex XV SVHC dossiers submitted by Member States and by ECHA (2008-2018)

2.2 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[20]. Prioritisation is carried out based mainly on information in the registration dossiers. However, information from public consultation on the SVHC identification as well as other REACH/CLP information is considered, too.

Figure 6 gives an overview of the substances recommended by ECHA to be included in Annex XIV until the eighth recommendation as well as of the substances included in the Authorisation List (Annex XIV)[21].

The eighth recommendation was sent to the Commission in February 2018[22]. The substances recommended within the seventh and eighth recommendation will be considered by the Commission for the next amendment of Annex XIV (planned for 2019).

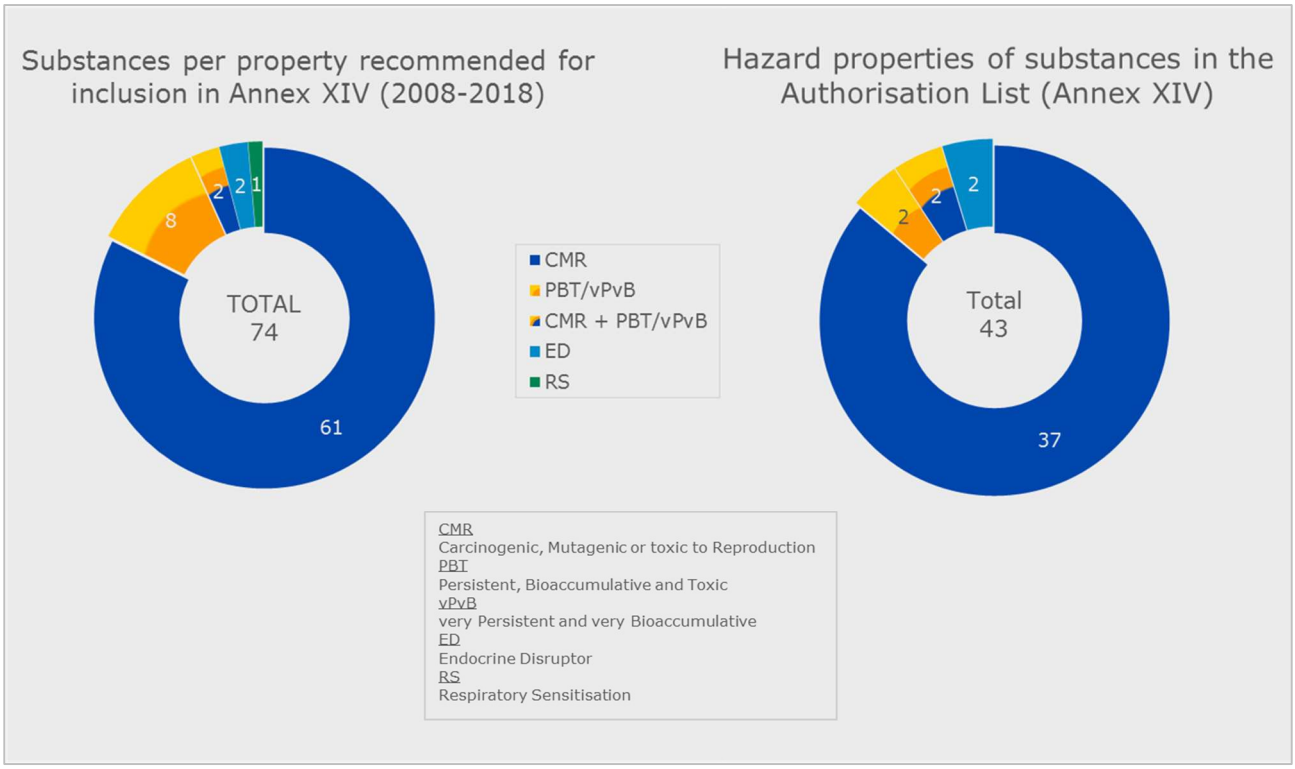


Figure 6: Overview of number and properties of substances recommended for inclusion in

[20] The prioritisation approach is available at: https://echa.europa.eu/regulations/reach/authorisation/recommendation-for-inclusion-in-the-authorisation-list.
[21] Substances included in Annex XIV can be found at: https://echa.europa.eu/authorisation-list.
[22] An overview of substances recommended by ECHA is available at: https://echa.europa.eu/previous-recommendations.

Annex XIV and included in Annex XIV (2008-2018[23])

Table 2 gives an overview of the number of substances recommended by ECHA to be included in Annex XIV until the eighth 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 proposed amendment to Annex XIV the reasons for not taking forward the substances that were recommended by ECHA.

Table 2: Overview of substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2018)

Date of recommendation	Number of substances recommended	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 June 2009)	7	1st (17 Feb 2011)	6	Musk xylene, MDA, HBCDD, 3 phthalates	*[SCCP]*[24]
2nd (17 Dec 2010)	8	2nd (14 Feb 2012)	8	1 phthalate, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd (20 Dec 2011)	13	3rd (17 Apr 2013)	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) compounds
4th (17 Jan 2013)	10	4th (14 Aug 2014)	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th (6 Feb 2014)	5	5th (13 June 2017)	1	4-tert-OPnEO	DMF ADCA Al-RCF and Zr-RCF
6th (1 July 2015)	15		11	1-bromopropane, 7 phthalates, anthracene oil, CTPHT, 4-NPnEO	4 boron substances
7th (10 Nov 2016)	9	[n.a]	[n.a]	[n.a]	*
8th (5 Feb 2018)	7	[n.a]	[n.a]	[n.a]	*
Total	74		43		24

[23] 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.
[24] SCCP was recommended but not included as the substance was included in the POPs Regulation.

* Substances from the seventh and eighth recommendation have not yet been considered for amending Annex XIV.

2.3 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.

Table 3 gives the number of applications for authorisation received between January 2013 and the end of December 2018, as well as the number of Committee for Risk Assessment (RAC)/Committee for Socio-economic Analysis (SEAC) opinions and Commission decisions.

Table 3: Number of applications for authorisation/review reports received from January 2013 to December 2018

Substance	Intrinsic properties in Annex XIV	Received applications	Applicants	Uses	RAC/SEAC opinions per use	Commission decisions per use
DEHP and DBP	CMR	11	13	22	22	10
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	12
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	14	16	20	19	19
Lead chromate	CMR	1	1	1	1	1
Chromium trioxide	CMR	29	67	46	44	17
Sodium dichromate	CMR	20	27	26	26	13
Sodium chromate	CMR	2	4	3	3	1
1,2-dichloroethane (EDC)	CMR	16	18	20	20	11
Chromium trioxide; sodium dichromate; potassium dichromate	CMR	1	6	3	3	3
Potassium dichromate	CMR	4	4	7	7	2
Ammonium	CMR	3	5	4	4	2

Substance	Intrinsic properties in Annex XIV	Received applications	Applicants	Uses	RAC/SEAC opinions per use	Commission decisions per use
dichromate						
Dichromium tris(chromate)	CMR	2	3	3	3	-
Chromium trioxide; dichromium tris(chromate)	CMR	1	2	4	4	4
Strontium chromate	CMR	2	13	3	3	-
Potassium hydroxyoctaoxodizincatedichromate	CMR	1	5	2	2	-
Bis(2-methoxyethyl) ether (diglyme)	CMR	9	9	10	10	4
Arsenic acid	CMR	1	1	1	1	-
Chromic acid	CMR	1	1	1	1	1
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	CMR	1	1	2	2	-
4,4'-methylenebis[2-chloroaniline] (MOCA)	CMR	1	1	1	1	-
Sodium chromate; potassium chromate	CMR	1	1	4	2	-
Pentazinc chromate octahydroxide	CMR	2	3	4	4	-
Total		**129**	**219**	**206**	**201**	**107**

* Two applications covering four uses were withdrawn by the applicants.

3 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 in certain circumstances, can propose restrictions if it assesses that there is a risk that is not adequately controlled and there is a need for action at Union level.

Table 4 gives the number of restriction proposals adopted or going through the restriction process from 2009 until December 2018. Note that some of these restrictions cover groups of substances.

Table 4: Number of restriction proposals on (groups of) substances adopted or going through the restriction process

Step in restriction process	PBT	ED	CMR	Sensitiser	Other
Restrictions included in Annex XVII	3	1	9	2[25]	1
Restriction process ongoing	1	0	2	1	1
Sent to Commission, but not yet in Annex XVII	1	0	2	0	2
Total (only the ones with substance scope in Registry of Intentions)	**5**	**1**	**15**	**3**	**4**

Figure 7 gives an overview of Annex XV restriction dossiers submitted per country.

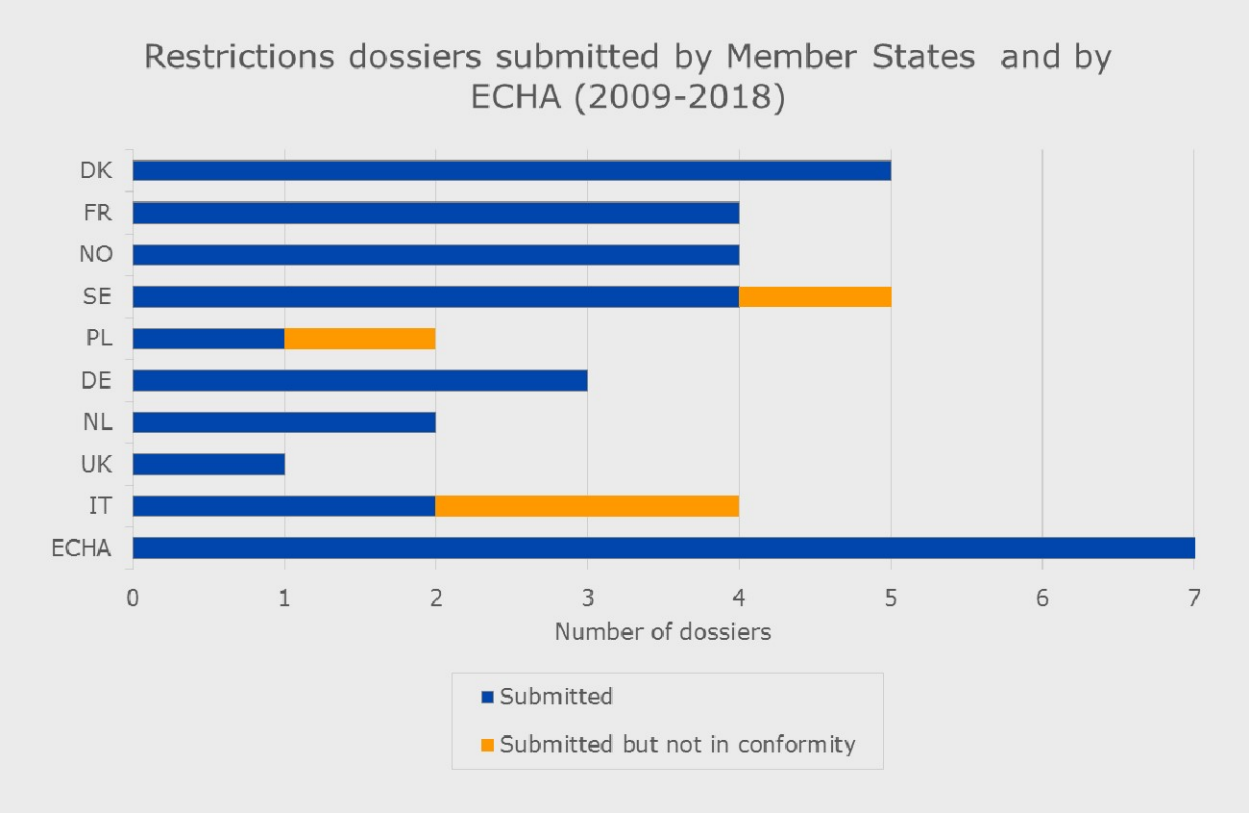


Figure 7: Number of restriction dossiers submitted by Member States and by ECHA (2009 – 2018)

[25] One of the substances restricted is chromium VI, which 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).

Annex 4. Progress monitoring indicators

Note that those progress monitoring indicators were also those used to monitor the progress of the SVHC Roadmap to 2020 implementation.

Table 1: Progress monitoring indicators – target and results

Indicators	Target	Result				
		2013-2014	2015	2016	2017	2018
Substance screening 1: Percentage of substances identified for further work to clarify a concern (substance evaluation, compliance check or proposed regulatory risk management (RMOA, CLH, other action))	- [26]	83.5 %	75.8 %	69.6 %	69.1 %	75.6 %
RMOA1: Number of (groups of) sub-stances subject to an RMOA	55 (or 440 by 2020)	91	42	16	31	13
RMOA2: Extent to which RMOA conclusions resulted in regulatory follow-up	high	17 %	68 %	84.8 %	94 %	88 %

[26] The target is to have the indicator 'substance screening 1' high and at least equal to the baseline (set as 2014).