ECHA
EUROPEAN CHEMICALS AGENCY

# Grouping speeds up regulatory action

Integrated Regulatory Strategy
Annual Report

May 2020

**Disclaimer**



**Grouping speeds up regulatory action -**
**Integrated Regulatory Strategy Annual Report 2020**

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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 and toxic for reproduction |
| CoRAP | Community rolling action plan |
| COM | European Commission |
| DEv | Dossier evaluation |
| ECHA | European Chemicals Agency |
| ED | Endocrine disruptor |
| EG | Expert group |
| ESR | Existing Substances Regulation |
| 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(E) | Testing proposal (examination) under dossier evaluation |
| vPvB | Very persistent and very bioaccumulative |

## Executive summary

ECHA's Integrated Regulatory Strategy aims to ensure that REACH and CLP processes are coherently implemented and supports authorities to identify and address substances of concern as quickly as possible. Coherent regulatory processes also contribute to meeting the 2030 goals of the World Summit on Sustainable Development.

Together with Member States and the Commission, ECHA has set up approaches to identify substances of concern and to address them without undue delay. An interim goal for the Agency is 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 similar conclusions to be drawn on lower tonnage substances, with a view to having full clarity on all registered substances by 2027.

The implementation of the strategy builds on progress made over the past decade, during which authorities have increasingly focused on the substances of highest concern.

Consequently, as documented in the SVHC Roadmap to 2020 report published in 2018, authorities have addressed all currently known substances with carcinogenic, mutagenic and reprotoxic (CMR), persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvBs) and endocrine disrupting properties of relevance for regulatory action, and progressed them under the appropriate regulatory risk management instruments.

The focus of the strategy is now to identify new substances of concern, and where needed, to generate further information and move relevant ones to regulatory risk management.

The first report on the implementation of the strategy, published last year, set the baseline for following progress on achieving the policy goals, in particular, through the mapping of all registered substances, the so-called "chemical universe".

In December 2019, ECHA published an update of the chemical universe on its website based on the most recent mapping (data from August 2019), together with a list of over 21 000 REACH registered substances allocated in the different pools. The list of substances gives companies and other stakeholders more transparency on the work of authorities and the progress made in regulating chemicals.

The mapping of the universe of registered substances indicated the following (as of August 2019):

- **Around 390 substances have regulatory risk management ongoing.** For these substances there is no need for further immediate regulatory action. In 2019, eight more substances have been identified as substances of very high concern (SVHCs) and included on the Candidate List, and seven restriction proposals have been submitted.
- **Around 330 substances have regulatory risk management under consideration.** These substances have been identified or are currently being considered for regulatory risk management (for example, all substances under regulatory management option analysis (RMOA) or for which there is an intention or ongoing proposal for identification as an SVHC).

- **Around 1 550 substances are under data generation.** These substances require additional information or assessment before authorities can decide whether or not further regulatory risk management is needed. It is expected that for most of these substances there will be no need for further regulatory risk management at EU level. However, where registered uses indicate high potential for exposure to humans or the environment, further hazard information is necessary to confirm this assumption. 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 700 substances currently have no further actions proposed after review by authorities.** Authorities have focused on identifying substances of concern, which need further regulatory risk management. However, in carrying out these activities, they have reviewed many other substances for which they have identified no current need for further regulatory action based on available data on hazard and uses. If new information becomes available on hazardous properties or uses, these substances may be subject to further regulatory actions.

In 2019, ECHA and Member States reviewed around 220 substances registered above 100 tonnes and allocated them to the relevant chemical universe pools. As such, the “not yet assigned” area of the chemical universe above 100 tonnes was reduced to around 2 400 by the end of 2019.

ECHA has moved from a substance-by-substance approach to addressing groups of structurally similar substances. Most of the screening of groups is currently done by ECHA to focus the resources of Member States on follow-up regulatory risk management actions. While concentrating on substances above 100 tonnes per year, the grouping enabled us to also scrutinise around 230 substances registered below 100 tonnes and 78 substances registered only as intermediates. This grouping ensures that all available information is used more effectively and enhances the coherence and consistency of authorities’ work when progressing with similar substances. This, in turn, supports informed substitution.

Most of the substances screened and registered (excluding substances only registered as intermediates) have been allocated to the pool of substances for which more data needs to be generated (56 % of the substance screened) or to the pool of substances for which currently no further action is proposed after review by authorities (20 % of the substances screened). This confirms last year’s assumption that a significant number of the substances in the “not yet assigned” pool will require further data generation through compliance checks or substance evaluation in the coming years. Non-compliant registrations are hampering progress and, to that end, ECHA has adopted an evaluation joint action plan with the Commission to ensure that the registrations are compliant and contain the necessary information to establish safe use. This has resulted in a significant increase (50 %) of the number of substances checked for compliance.

ECHA has progressed in clearing the chemical universe and moving substances from the “not yet assigned” area to the other pools of substances. While further hazard information is needed for many of these substances, the work with groups of substances has also identified cases where Member States can start working on harmonised classification and labelling or restriction. Furthermore, the work on groups has also enabled authorities to identify recurring issues (for instance, sensitisers in consumer mixtures and the formation of nitrosamines) where further work by authorities will support substances to be regulated across several groups in an efficient and coherent manner.

Overall, the Integrated Regulatory Strategy has started to deliver and most substances brought to regulatory risk management processes result from the work done under screening, RMOA, compliance check and substance evaluation.

To shorten the time between identifying 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 a need to initiate harmonisation of classification or actions under other legislation more swiftly. Where there are valid reasons for not moving forward with regulatory action, authorities should document these conclusions transparently to achieve full clarity on all higher tonnage substances in the chemical universe. A working group of Member States and ECHA has been set up to facilitate the follow up of agreed regulatory risk management actions including a review of past conclusions.

## MAIN RECOMMENDATIONS

- Screening groups of substances, data generation and assessment should be further optimised to ensure 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 are taken.
- The priority and appropriateness of previously identified, but still pending, follow-up actions should be reviewed and those substances which need further regulatory risk management should be progressed without delay.
- The compliance of registration information needs to be improved, in particular, for substances with a high potential for exposure and currently lacking appropriate hazard data.
- Compliance of dossiers, their systematic review and updates of registrations based on new information, remains industry's responsibility. ECHA welcomes the initiative of industry associations to develop review programmes to help registrants review chemical safety data.
- Further enhance cooperation and coordination between authorities.

# 1. Introduction

Since 2015, ECHA's Integrated Regulatory Strategy has brought together all REACH and CLP processes and provided support to authorities to address substances of concern as quickly as possible.

The 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.

Implementing the strategy will also contribute to the goals of the World Summit on Sustainable Development[1] and to the United Nations' 2030 Agenda for Sustainable Development[2].

**Objectives and timelines**

To have concluded which substances:

(i) are of high priority for regulatory risk management;
(ii) need more data for a judgement to be made; or
(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.

The further integration of the REACH and CLP processes was initiated through the implementation of the SVHC Roadmap to 2020, which set up a system that enabled new substances of concern to be identified. In that context, authorities have addressed the substances with confirmed hazards and which are of relevance for regulatory action, by moving them under appropriate regulatory risk management instruments. In other words, the objectives of the SVHC Roadmap have been achieved[3].

In December 2018, ECHA published its strategic plan for 2019-2023. The first strategic priority is to identify and manage the risks of substances of concern, with the objective to:

(i) accelerate data generation and intensify identification of substances of concern; and

(ii) accelerate regulatory action on substances of concern.

ECHA's strategic plan was updated in 2019[4]. To support this work, ECHA mapped the universe of registered substances ("the chemical universe") for the first time in May 2018.

Identifying and managing the risks of substances of concern is carried out together with Member States. Industry sectors and companies can proactively contribute to this work by keeping their registration dossiers up-to-date and by providing better use and exposure information.

[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
[4] https://echa.europa.eu/documents/10162/13609/programming_document_2020-2023_en.pdf

Ensuring dossier compliance and data quality is one of the main responsibilities of ECHA. To speed this up, an action plan with 15 actions was agreed and published together with the European Commission[5] in 2019. As one of the actions, the minimum target of dossiers checked for compliance was raised to 20 % in each tonnage band aiming to reduce information gaps. This will result in approximately 30 % of all registered substances being checked by 2027[6].

This is the second annual report of the Integrated Regulatory Strategy and presents the state of play and achievements in implementing the strategy (see Figure 1).

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 the activities being carried out by authorities; and
- provides an overview of the substances in the "not yet assigned" area, the actions ongoing to address these substances and the progress made since last year.

The ultimate aim is to have every substance either:

- processed under further regulatory action; or
- concluded as currently not needing further regulatory action because:
    - regulatory risk management is already ongoing; or
    - the substance is of low concern.

Overviews of the pre-regulatory steps (screening of groups by ECHA or Member States, expert group assessment and regulatory management option analysis), the evaluation processes and the regulatory risk management activities under REACH and CLP are provided in annexes 1, 2 and 3, respectively.

[5] https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

[6] COMMISSION REGULATION (EU) 2020/507 of 7 April 2020 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards the percentage of registration dossiers to be selected for compliance checking available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0507&from=EN.

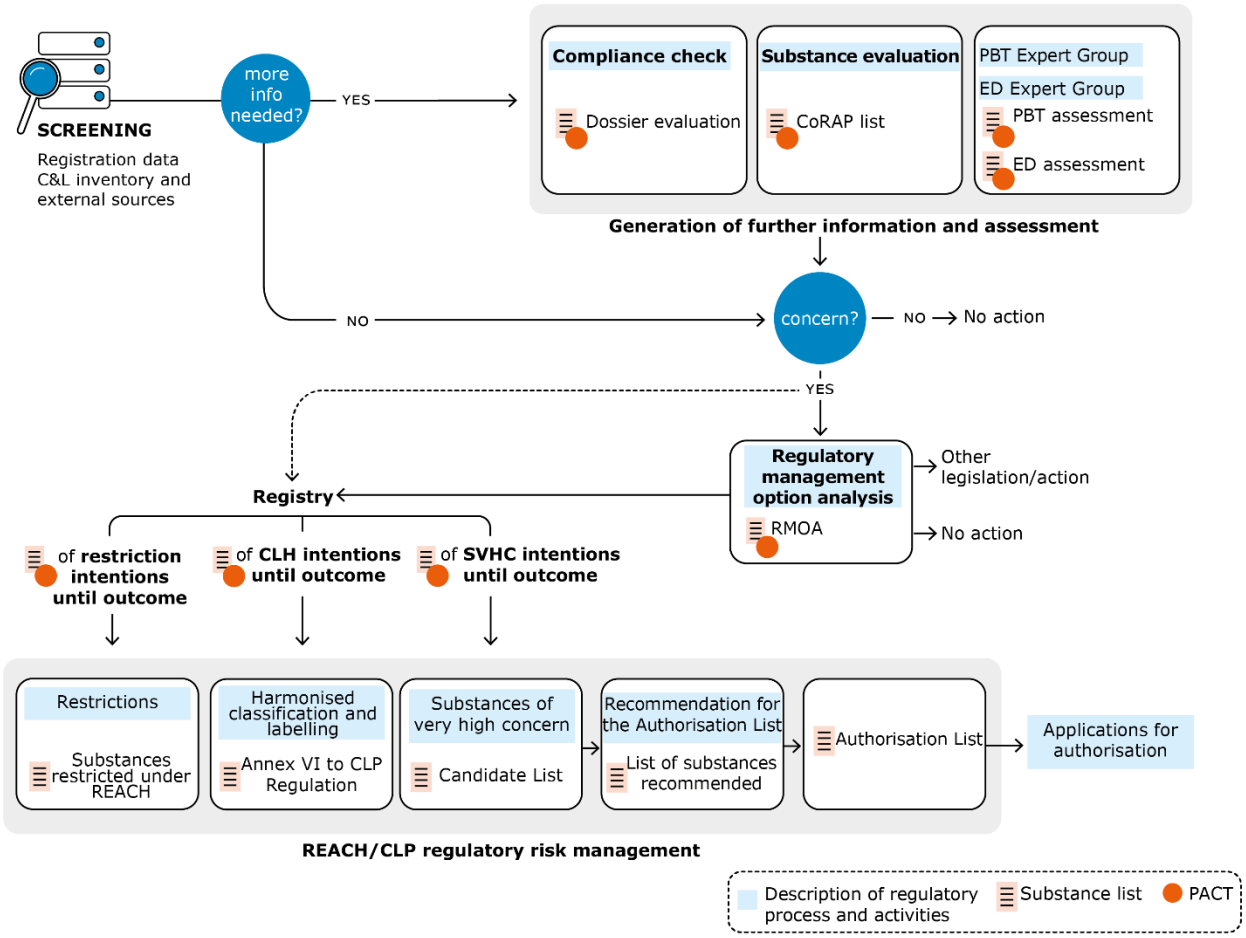



**Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy and the SVHC Roadmap[7]**

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

# 2. The universe of registered substances

## A tool to support authorities to plan and monitor progress

The chemical universe currently comprises over 21 000 registered substances[8]. Based on available knowledge, each of these substances have been allocated into one of the following pools:

- regulatory risk management under consideration;
- data generation;
- currently no further regulatory actions proposed.

Substances that have not yet been looked at are currently placed in the "not yet assigned" area.

### The chemical universe in numbers

The second mapping of registered substances was carried out on a snapshot of the REACH registered substances database from August 2019. The database is constantly changing – new substances are registered, changes in uses are indicated, new hazard information is provided and regulatory actions are concluded.

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. ECHA is also investigating whether a real-time version can be created. However, if possible, this would not be available before 2021.

In December 2019, the list of substances belonging to each pool was published on ECHA's website.

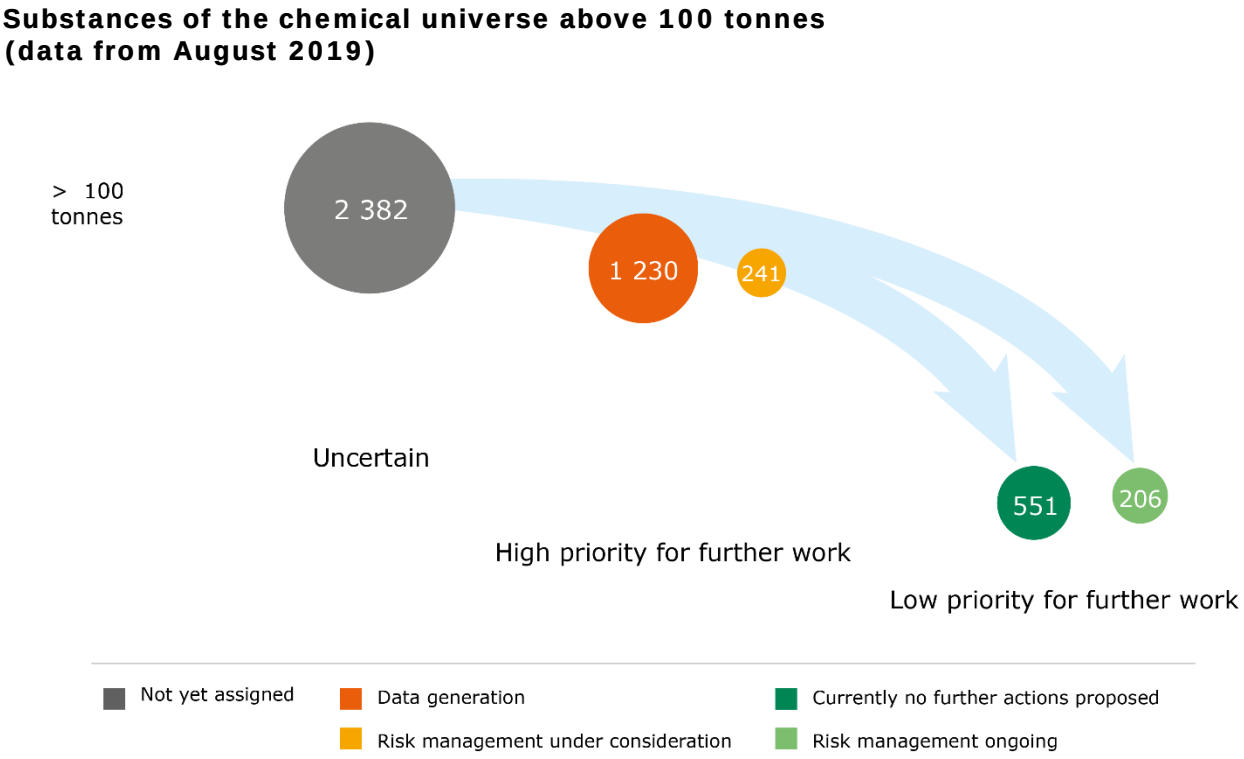
The chemical universe is available at https://echa.europa.eu/universe-of-registered-substances.

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 up until the end of 2019, whereas the numbers for the universe of registered substances are based on a snapshot from August 2019. Therefore, there may be discrepancies between the numbers in the different explanatory sections and those provided on the chemical universe.

Figures 2 and 3 provide an overview of the chemical universe.

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

[8] This number includes substances registered as intermediates under Articles 17 and 18.




*> 100 tonnes: Substances for which there is at least one registration under Article 10 of REACH registering at a tonnage above 100 tonnes per year.*

**Figure 2: Substances of the chemical universe registered above 100 tonnes in their pools (update from August 2019)**

The different pools of substances are:

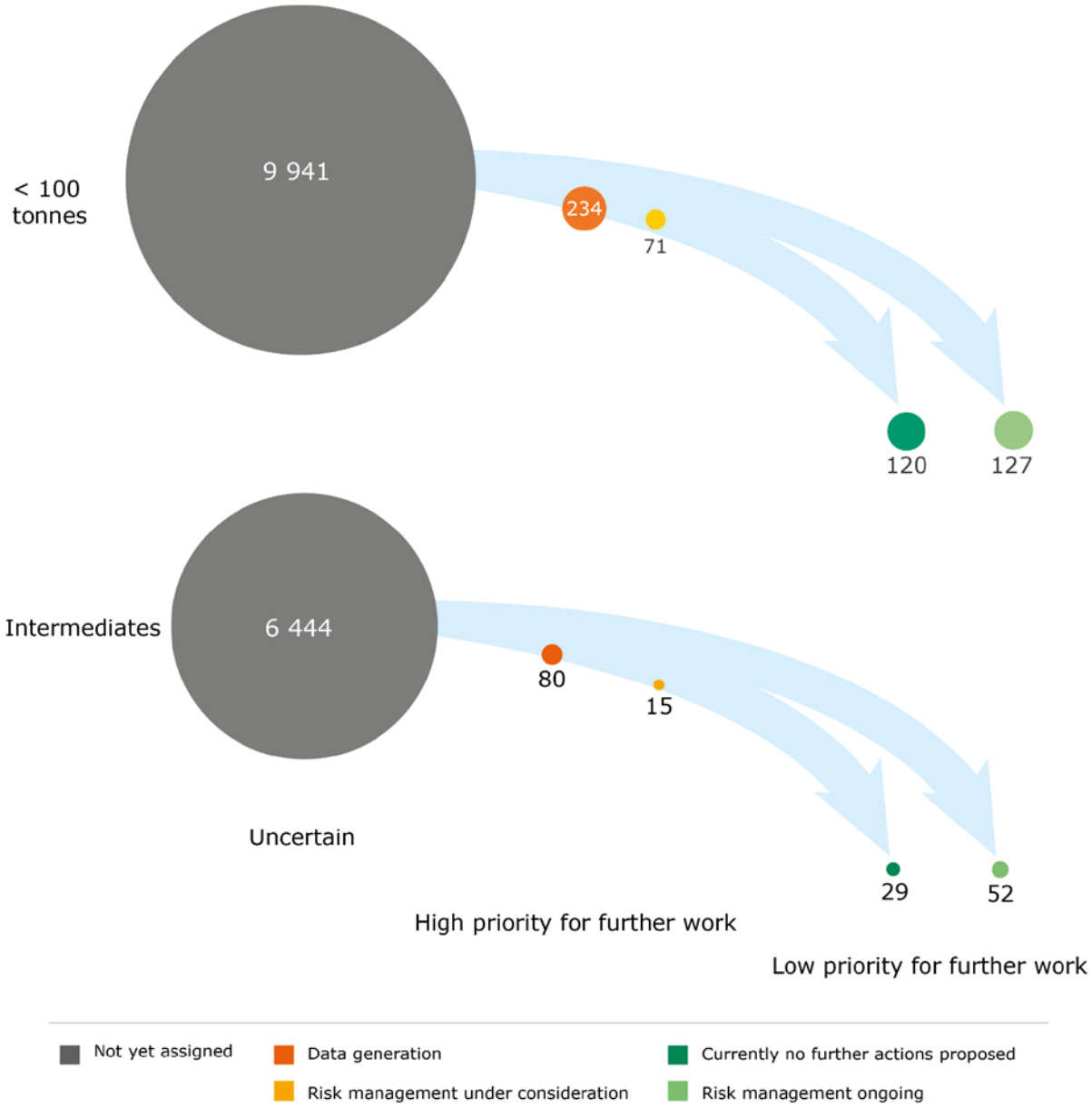
- **Not yet assigned:** Any substance that is currently registered under REACH and has not yet been assigned to any of the other pools.
- **Data generation:** Any substance that requires additional information or assessment before it is possible to identify whether further regulatory action should be proposed. This pool includes, for example, all substances currently under dossier or substance evaluation, substances being assessed by the PBT and ED Expert Groups, and groups of substances under specific investigations (such as petroleum and coal stream substances).
- **Regulatory risk management under consideration:** Any substance that has been identified or is currently being considered for regulatory risk management. This pool includes all substances under regulatory management option analysis (RMOA) or for which there is an intention or ongoing proposal for identification as a substance of very high concern (SVHC). It also includes substances where authorities have identified that further regulatory risk management might be needed, but where this action has not yet started. These pending cases may come from substance or dossier evaluation, RMOA, PBT/ED assessment, or preliminary assessment by ECHA and the Member States.
- **Regulatory risk management ongoing:** For the substances in this pool, a relevant regulatory approach has been identified for the substances and will be followed. Additional assessments or measures are usually not foreseen and therefore, for the

purposes of the chemical universe mapping, they are considered as low priority for *additional* EU-level regulatory action. However, for some substances in this pool, there may still be significant work required, for example, prioritisation on the Authorisation List or restriction proposals for certain PBT/ED substances. This pool includes, for example, substances on the Candidate List, certain substances restricted under Annex XVII to REACH, active substances in biocides and pesticides, and persistent organic pollutants (POPs).

- **Currently no further actions proposed:** Authorities review many substances during the course of regulatory work (for example, screening of groups of substances, dossier or substance evaluation, or RMOA) and may not identify a need for further regulatory action at that moment. This could be due to low hazard, low potential for exposure, or because sufficient risk management measures are already in place. Substances addressed under the Existing Substances Regulation (ESR), which have not been mapped to other pools, are also included here. If the situation changes and, for example, if companies report new uses or new data on the substance's hazardous properties, or if regulatory priorities change, these substances may be subject to further regulatory actions.

By 2027, the aim is to have all substances registered above one tonne allocated to these pools. Even though the focus has so far been on those substances registered above 100 tonnes per year, authorities have already addressed substances registered at lower tonnages (see Figure 3). In addition, around 6 600 substances are solely registered for use as intermediates under strictly controlled conditions to minimise exposure to workers and the environment (Articles 17 or 18 of REACH).

**Substances of the chemical universe below 100 tonnes and registered only as intermediates (data from August 2019)**




*< 100 tonnes: Substances for which there is at least one registration under Article 10 of REACH registering at a tonnage between 1 and 100 tonnes per year, and for which there are no registrations at a tonnage above 100 tonnes per year under Article 10 of REACH. All substances previously notified as NONS (around 3 000 substances), and for which there are no registrations under Article 10 of REACH are also included.*
*Intermediates: Substances which are solely registered for intermediate use under Articles 17 or 18 of REACH.*

**Figure 3: Substances of the chemical universe registered below 100 tonnes and only registered as intermediates under Article 17 or 18 of REACH in their pools (update from August 2019).**

**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 radar of authorities 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 consultations that run during formal decision-making processes.

PACT covers:

- substances under regulatory management option analysis (RMOA);
- substances under informal hazard assessment for persistent, bioaccumulative and toxic (PBT),very persistent and very bioaccumulative (vPvB) 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 towards addressing **groups of structurally similar substances** rather than single substances. Since 2017, groups of substances of potential concern have been the main starting point for authorities' work.

The work on groups of substances:

- Enhances the regulatory coherence of authorities' work and consistency in addressing similar 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 for which information on hazard and exposure is lacking, for example, because they are currently registered at a lower tonnage band or not registered at all. Grouping should also reduce the need to generate hazard data where it is not necessary and could slow down the confirmation of the hazard (through harmonised classification and labelling or placement on the Candidate List) or the initiation of further regulatory risk management (restriction, authorisation, or measures under other legislation).

- Supports better informed substitution by industry, as grouping ensures that substances currently not registered or registered only for intermediate uses, but which could be potential substitutes for known substances of concern, are considered.

The methods used to group substances based on structural similarity are 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 from external sources.

Structurally similar substances are identified within the universe of registered substances around pre-selected substances 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.

Note that these methods are different from grouping as defined in Section 1.5 of Annex XI to REACH and therefore do not constitute validated read-across and category information. Nevertheless, they provide a useful starting point for grouping substances that may eventually be subject to further work towards regulatory action by authorities.

ECHA is now grouping substances in the "not yet assigned" 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 substances belonging to the groups can start and will result in substances being allocated to appropriate pools and later to different REACH and CLP processes. Note that not all substances in one group are necessarily allocated to the same pool after assessment.

Figure 4 shows the current map of the chemical universe and how grouping supports the clarification of the "not yet assigned" 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.

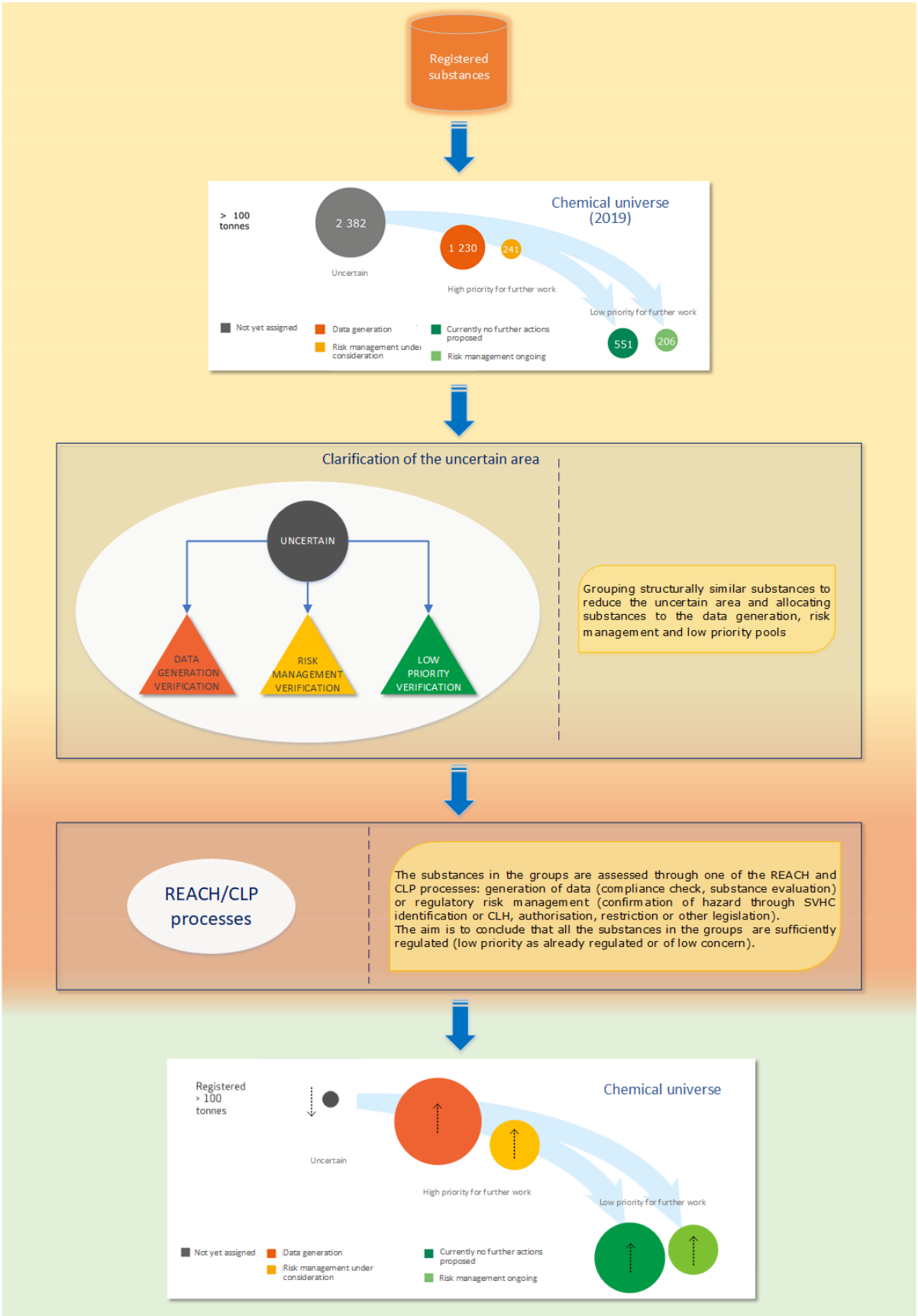



**Figure 4: Clarification of the uncertain area through grouping and further processing of substances by authorities**

## 3. Substances under data generation

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


Substances under data generation and assessment are substances that:

- are being evaluated under compliance check or substance evaluation for further data generation;
- are being assessed, for example, 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, for example, screening has concluded that there is a need for compliance check or substance evaluation, or 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

The data collected in REACH registration dossiers is the backbone upon which successful EU chemicals management can be built. The data allows us to:

- see the properties and uses of chemicals;
- decide which ones are safe and which are hazardous;
- make information visible for citizens and industry; and
- Find effective routes for phasing the most harmful substances out of the market.

By the end of 2019, around 880 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 being requested or generated by 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 (2012-2019)**

| Number of substances with an ongoing assessment in the PBT and ED Expert Groups, substance evaluation and compliance check (2012-2019) | | |
|---|---|---|
| | Ongoing assessment | Postponed assessment[9] |
| PBT Expert Group | 84 | 17 |
| ED Expert Group | 76 | 3 |
| Substance evaluation | 178 | - |
| Compliance check (full compliance checks) | 684 | - |

Some substances in Table 1 are counted more than once. For example, Member States use the expert groups to support their work under substance evaluation and around 70 % of the substances with potential PBT and ED properties listed in the Community rolling action plan (CoRAP) between 2012 and 2019 were discussed in the PBT and ED Expert Groups. In addition, a compliance check is usually carried out on substances listed in the CoRAP for substance evaluation, meaning that these substances are also counted more than once.

In 2019, ECHA, together with the European Commission, put up a joint evaluation action plan[5] to speed up dossier compliance and data generation, as appropriate. The minimum required number of compliance checks was increased from 5 % to 20 % of registration dossiers in each tonnage band. A series of improvements was initiated, which allowed ECHA to increase the number of substances checked for compliance by 50 % in 2019.

ECHA carried out 301 full compliance checks covering 274 unique substances throughout 2019, whereas in 2018, 196 full checks covering 182 substances were done. Including targeted compliance checks, ECHA carried out a total of 390 checks on 3 750 dossiers covering 338 unique substances last year.

Overall, since 2009, ECHA has performed more than 2 400 compliance checks (both full and targeted) corresponding to more than 11 000 registration dossiers. So far, across all tonnage bands, more than 1 000 substances underwent a full check for compliance.

By the end of 2019, ECHA had checked more than 20 % of substances above the 1 000 tonnage band for compliance. More information on progress in evaluation and data generation from 2009 until the end of 2019 is available in Annex 2 as well as on ECHA's website[10].

In addition, to further accelerate data generation, ECHA launched projects in 2019 covering several groups of substances to understand whether compliance checks and substance evaluations could be done in parallel. The progress showed that such an approach is valuable: it speeds up data collection, allowing quicker decisions on the most appropriate ways to manage chemical risks. The combined approach will continue in 2020. For the first group of five antimony-containing substances, ECHA issued nine draft decisions (five under compliance check and four under substance evaluation) in 2019[11].

[9] The assessment has been postponed for some substances where it was considered that the substance was not a priority for the time being (for example, in the case of a substance with only intermediate uses).
[10] https://echa.europa.eu/progress-in-dossier-evaluation
[11] Adopted decisions were sent to registrants in March 2020. Once publicly available, the decisions are available at: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

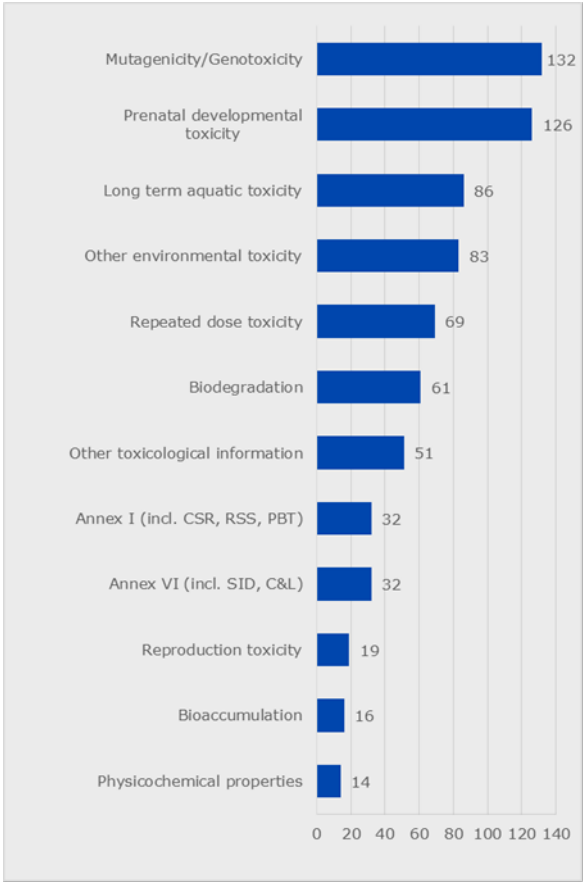
The pool of substances under data generation contains, in addition to those covered in Table 1, substances which have been identified as requiring further data generation, but for which the data generation processes have not yet been initiated. By the end of August 2019, the number of substances additionally identified by Member States or ECHA during their screening process as candidates for compliance check or for inclusion in the CoRAP, was around 200.

The last group of substances included in this pool are the petroleum and coal stream (PetCo) substances. Around 470 PetCo substances are included in this pool for which no other activities have yet been initiated. Around 120 PetCo substances are under testing proposal examination following the work done in the context of the PetCo Working Group[12].

## Every year, a large amount of hazard data is generated and authorities should ensure they follow up

Figure 5 shows the information requested in 2019 under both compliance check and substance evaluation. 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.

**Information requested under compliance check and substance evaluation in 2019**




| Suspected concern | Information requested to clarify the concern | requests* |
|---|---|---|
| Carcinogenicity | Carcinogenicity study | 1 |
| Mutagenicity | *In vivo* mammalian comet assay | 2 |
| Reproductive toxicity | Extended one generation reproductive toxicity study | 1 |
| Endocrine disruption | Fish sexual development test | 6 |
| | Amphibian metamorphosis assay | 2 |
| PBT/vPvB** | Simulation biodegradation test | 4 |
| | Physico-chemical test | 4 |
| | Fish early-life stage (FELS) toxicity test | 2 |
| | *Daphnia magna* reproduction test | 2 |
| | Bioaccumulation in fish: aqueous and dietary exposure | 2 |
| Other hazard-based concern | *In vitro* study for serious eye damage | 4 |
| | Algae, growth inhibition test | 1 |
| | Daphnia magna reproduction test | 1 |
| | Dispersion stability of nanomaterials in simulated environmental media | 1 |
| | Combined sub-chronic 90d toxicity study and reproduction/developmental toxicity screening test | 1 |
| | Combined sub-chronic 90d toxicity study and comet assay | 1 |
| | *In vitro* study for skin irritation | 1 |
| | Human biomonitoring study | 1 |
| | Screening test (24h) on transformation/dissolution of metals and metal compounds in aqueous media | 1 |
| | Determination of presence and size distribution of fibres | 1 |
| | Dustiness test using a rotating drum | 1 |
| | Further information on exposure and/or risk assessment | 8 |
| | **Total** | **48** |

* A decision may contain more than one request.

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

**Figure 5: Information requested under compliance check (left) and substance evaluation (right) in 2019**

[12] https://echa.europa.eu/petco-working-group

Another source for generating hazard information comes from testing proposals made by registrants in their dossiers. An overview of the information requested by ECHA in 2019 under examination of these testing proposals is available on ECHA's website[13]. For mutagenicity and reproductive toxicity properties, testing proposals follow a similar pattern as observed for compliance check requests. However, this is not true for other properties. For instance, registrants have not submitted many requests to clarify the PBT properties of their substances.

In 2019, hazard data was generated for more than 150 substances in response to compliance check, substance evaluation and testing proposal decisions. The 'top five' endpoints for which further information was submitted to ECHA under dossier evaluation (CCH and TPE) were pre-natal developmental toxicity and sub-chronic toxicity (90-day) studies, followed by studies on *in vitro* genotoxicity, toxicity to reproduction and long-term toxicity to fish.

Decisions may contain requests for several studies to be provided. For the most complex ones, companies may have up to 42 months or more to provide them. Then the compliance of the requested information will need to be checked according to ECHA's follow-up process. However, the information submitted by registrants further to an evaluation decision is generally in line with the request and therefore, higher levels of compliance are expected to be seen in the next years.

**An example of a follow up from data generation: new repeated dose toxicity study leads registrant to self-classify Bis(2,4-dichlorobenzoyl)peroxide as Category 1B reproductive toxicant.**

Following a testing proposal, accepted by ECHA, the registrant submitted results obtained in a repeated dose 90-day oral toxicity study in the rat according to OECD Test Guideline 408 and Good Laboratory Practice. The oral study was conducted with the registered substance and included additional investigations on reproductive parameters. The treatment caused effects in male reproductive parameters: it reduced testes, epididymides and cauda epididymis weight, caused tubular atrophy with an accompanying aspermia in the epididymis and thymic atrophy. These changes were considered to represent an adverse effect of treatment. The new study results were taken into account in the update of the chemical safety report of the registrant.

Due to the effects on male sex organs, the registrant self-classified the substance as a Category 1B reproductive toxicant. Following this self-classification, the registrant also updated the uses of the substance: some uses are no longer supported and advised against, such as widespread uses of the substance by professional workers in vulcanisation or polymerisation processes. The substance is nowadays only used in industrial settings.

The evaluation action plan calls for industry to review their registrations and update them when necessary, including by generating new information.

Although dossier compliance is the responsibility of each individual registrant, the obligation to share data and register jointly for the same substance and the efficiency brought by addressing groups of similar substances, lend support to the idea of reviewing and updating registration dossiers in a more structured and systematic manner.

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

Companies with large portfolios and business associations have launched programmes that capture many substances in order to update the registration information appropriately, introduce new knowledge and propose optimised testing strategies, where necessary.

These voluntary industry programmes should, in the future, bring necessary dossier improvements and additional information before ECHA issues compliance check decisions.

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

By the end of 2019, **substance evaluation** was concluded for 117 substances.

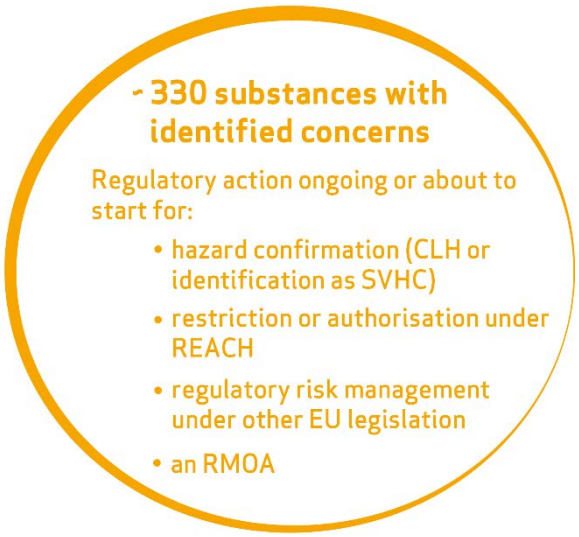
For 57 substances, the Member State considered that further regulatory action was needed:

- **27 substances have been followed up**: Regulatory risk management (harmonised classification (CLH), identification as a substance of very high concern (SVHC), or restriction) was initiated, is ongoing or was concluded for 16 substances. For two substances, an RMOA concluded no need for further regulatory action. For 11 substances, an intention for RMOA or harmonised classification was submitted or an RMOA was proposed to initiate further regulatory risk management.
- **23 substances are yet to be followed up**: Harmonised classification and labelling has been identified as the necessary regulatory risk management measure. For five substances, the proposal would relate to CMR properties. One potential restriction has also been identified in 2019. For 14 substances, substance evaluation was concluded in 2018 or 2019 and, therefore, there may have not been enough time to initiate the CLH proposal or the restriction.
- For four substances, the identified regulatory risk management measure was outside the scope of REACH and CLP, with proposals including for instance occupational exposure limits (OELs). ECHA has no information on whether these cases have been followed up.
- For three substances, substance evaluation concluded that further regulatory risk management may be needed. However, identification of the appropriate measure is pending other actions (for example, the outcome of the substance evaluation of a constituent of the substance, results of a monitoring programme etc.).

So far, 113 substances from compliance check or testing proposal examination have been identified as needing follow-up regulatory risk management action. For 111 substances, harmonised classification was proposed; for one, further need to clarify endocrine disrupting properties was identified and for one, further PBT assessment was proposed.

# 4. Substances under consideration for regulatory risk management

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




Substances under consideration for further regulatory risk management are those:

- in the process of being regulated (for example, where there is an intention for restriction or 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 (for instance, where a substance evaluation has concluded on the need for harmonised classification and labelling or a regulatory management option analysis (RMOA) has concluded on the need for restriction); or
- for which an 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.

An RMOA is a voluntary step performed by authorities that has become common practice. 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. This has been highlighted in discussions with Member States and the Commission during the REACH Review[14].

At the end of 2019, an RMOA had been concluded or was under development for 259 substances (individually or as part of a group). Conclusions are available on 182 substances. Further details on the type of conclusions drawn are presented in Table 2. The results confirm the trend already observed in previous years, that most RMOAs concluding on a need for follow-up regulatory actions under REACH and CLP, are being followed up. For most substances for which the follow-up regulatory action has not yet been initiated, the RMOA was concluded in 2019.

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

**Table 2: Cumulative number of substances for which an RMOA has been concluded per proposed follow-up regulatory action (February 2013-December 2019), together with the progress monitoring indicator (RMOA2) per year.**

| Cumulative number of substances for which an RMOA has been concluded per proposed follow-up regulatory action (February 2013-December 2019), 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 | By the end of 2019 | Follow-up regulatory action initiated under REACH / CLP |
|---|---|---|---|---|---|---|---|
| SVHC identification (authorisation) | 5 | 19 | 27 | 44 | 58 | 70 | 63 |
| REACH restriction | 11 | 15 | 17 | 28 | 37 | 41 | 37 |
| CLH | 1 | 3 | 6 | 7 | 12 | 13 | 6 |
| Other EU-wide regulatory action | 2 | 5 | 8 | 9 | 9 | 11 | - |
| Other (e.g. non EU-wide and/or non-regulatory actions) | 1 | 4 | 5 | 7 | 11 | 12 | - |
| No follow-up action | 5 | 8 | 16 | 23 | 28 | 47 | - |
| **RMOA2 indicator:** Extent to which RMOA concluded with action resulted in regulatory follow-up | 17 % | 68 % | 85 % | 94 % | 88% | 83% | N/A |

Altogether, 15 Member States have been developing RMOAs since 2013, when the work on the implementation of the SVHC Roadmap started (see Annex 1). Through the SVHC Roadmap, which was further strengthened by the Integrated Regulatory Strategy, authorities have a strong foundation on which to work together to assess and identify SVHCs beyond 2020, as well as ensure progress in other areas of REACH (such as restriction) and in other legislation (for example, 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 each year in ECHA's Annual Report[15].

The impact of the Integrated Regulatory Strategy is visible through, for instance, the harmonised classification and labelling (CLH) dossiers between 2015 and 2019. These came mainly from

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

screening, substance evaluation, and, in particular, dossier evaluation. Figure 6 shows that since 2016, at least more than 60 % of substances for which a CLH dossier has been submitted, had previous activities (screening, substance or dossier evaluation, or RMOA).

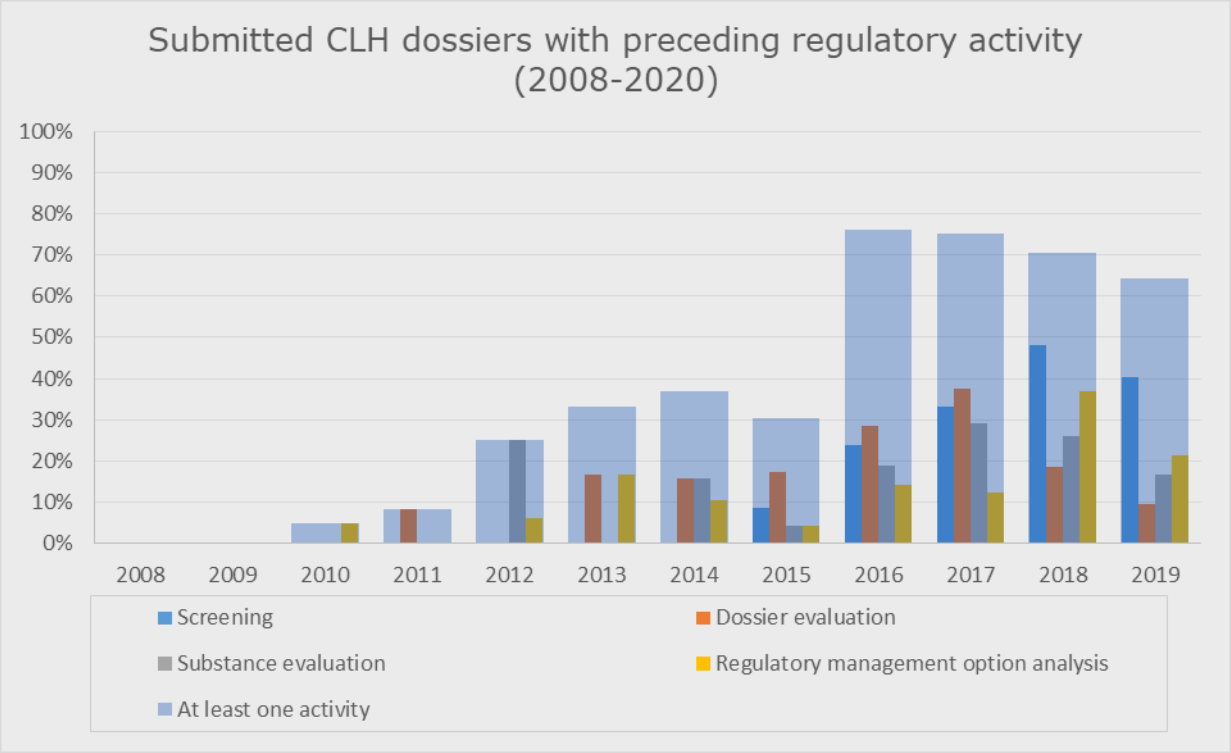



**Figure 6: Sources of harmonised classification and labelling dossiers (2008-2019)**

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

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) 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, as a result of these processes, we have not yet been able to identify candidates for restriction. Nevertheless, ECHA has identified potential restriction needs through its work with groups of substances. An example of such a group assessment is the one carried out for ethylene glycol ethers.

**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 other substances that may need to be regulated in the same way.

In addition, the majority of the substances have irritant or corrosive 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 consideration should be given to expanding the restriction under entry 55 to any linear glycol ether not already covered by a restriction (for example, substances with reprotoxic properties under entry 54) that has irritant or corrosive properties. Given the uncertainty 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 or cleaners.

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

In the chemical universe, around 330 substances are under consideration 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 work and priorities.

**Table 3: Substances of high priority for further regulatory risk management (at the end of 2019)**

| Substances of high priority for further regulatory risk management (at the end of 2019) | | | |
|---|---|---|---|
| | Ongoing or in the process of being regulated | Identified but action pending | Total |
| **RMOA** | 25 % | 16 % | 41 % |
| **CLH** | 12 % | 36 % | 48 % |
| **SVHC** | 4 % | 3 % | 7 % |
| **Restriction** | 2 % | 2 % | 4 % |

Around half of the substances of high priority for further regulatory risk management are substances with a potential need for harmonised classification. For only 12 % of these there is already an intention from authorities to prepare a CLH proposal; for the other substances, actions

need to be initiated by the 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.

The other half are either waiting for a Member State to start an RMOA or have an RMOA ongoing. Currently, 25 % of substances (as single substances or as part of a group) have an RMOA ongoing, while 16 % have been identified through screening and are waiting for a Member State to initiate the work.

As can be seen from Table 3 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 2020 for all those substances.

The number of RMOAs being concluded is less than last year with 21 substances being concluded compared to 28 concluded in 2018. This number has been fluctuating over the years. However, the number of substances for which an intention to prepare an RMOA has been made has increased from 13 in 2018, to 22 in 2019.

For some substances the need for further action (RMOA, harmonised classification and labelling) has already been known 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 the need for regulatory action and the appropriateness of the previously identified action is revisited. Where there are valid reasons for not moving forward with regulatory action, authorities should document these conclusions in a transparent manner to achieve full clarity on all higher tonnage substances in the chemical universe. This was already highlighted in last year's report and resulted in the setting up of a working group of Member States and ECHA to facilitate the follow up of agreed regulatory risk management actions including a review of past decisions.

## 5. Substances with regulatory risk management ongoing

**New substances of concern are identified and regulated every year**


Substances in this pool are those with ongoing regulatory risk management measures that do not need additional regulatory action at the EU level, including:

- substances included on the Candidate List of substances of very high concern (SVHC);
- substances under the POPs Regulation;
- substances covered by certain restrictions; and
- approved pesticide and biocidal active substances.

Currently, 390 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 restriction proposals adopted or going through the restriction process from 2009 until December 2019, is available in Annex 3. Approved biocide and pesticide active substances have been added, as these substances have been undergone a thorough assessment and an exhaustive set of hazard information is already available.

Substances addressed under the Existing Substances Regulation (ESR) have been removed from this pool as time has passed and some may need to be reviewed.

In 2019, eight more substances were identified and included in the Candidate List (see Table 4). In addition, intentions for the following seven restrictions[16] were submitted for:

- Restriction on leave-on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1% shall not be placed on the market. In addition, wash off and rinse off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market.
- Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses
- Restriction of the use of intentionally added microplastic particles to consumer or professional use products of any kind.
- Textiles, leather, hide and fur articles containing skin sensitising substances.

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

- PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof.
- Undecafluorohexanoic acid (PFHxA), its salts and related substances must not be manufactured, or placed on the market as substances on their own from [date] and must not, from [date], be used in the production of, or placed on the market in (a) another substance, as a constituent; (b) a mixture; (c) an article, in concentrations equal to or above x % w/w.
- The use of calcium cyanamide as a fertiliser as it poses an unacceptable risk to the environment.

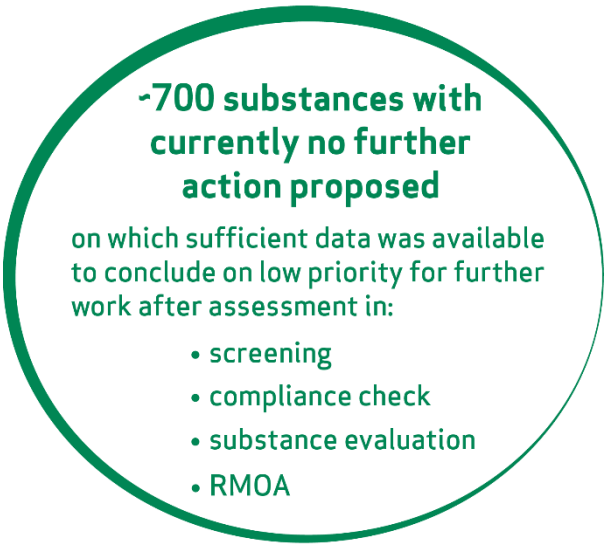
**Table 4: SVHC proposals discussed in 2019 and their reasons for inclusion.**

| SVHC proposals discussed in 2019 and their reasons for inclusion | |
|---|---|
| **Substances** | **Properties** |
| Diisohexyl phthalate | Toxic for reproduction |
| 2-benzyl-2-dimethylamino-4'morpholinobutyrophenon | Toxic for reproduction |
| 2-methyl-1-(4methylthiophenyl)-2morpholinopropan-1-one | Toxic for reproduction |
| Perfluorobutane sulfonic acid (PFBS) and its salts | Equivalent level of concern having probable serious effects to human health and environment |
| 2-methoxyethyl acetate | Toxic for reproduction |
| Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4nonylphenol, branched and linear (4-NP) | Endocrine disrupting properties – environment |
| 2,3,3,3-tetrafluoro-2(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) | Equivalent level of concern having probable serious effects to human health and environment |
| 4-tert-butylphenol | Endocrine disrupting properties – environment |

All substances included in the Candidate List are mapped to the “regulatory risk management ongoing” pool because they are all regularly assessed for their priority for inclusion in the Authorisation List unless a restriction has been initiated.

Most of the new substances brought to regulatory risk management have resulted from the work done on groups of substances. Some of those substances are also clearly the result of joint work by ECHA, the Member States and the Commission (for example, the work done on per- and polyfluorinated alkyl substances (PFASs) discussed under the PFAS task force).

## 6. Substances with no further action currently proposed after review




### Focusing the work on substances that matter

Substances are placed into this pool after a review by authorities under screening, compliance check, substance evaluation or RMOA.

Currently, around 700 substances are included in this pool and they are therefore currently considered to not need further regulatory action at the EU level based on several factors. Resources are needed to progress substances to regulatory risk management, and (de)prioritisation supports authorities in using their resources wisely and optimising the system to focus on the substances that matter.

#### Focusing authorities on substances that matter

Identifying that there is a need for action on a substance is not a fixed process and may evolve if new information on hazards or uses becomes available or when the regulatory interest or political priorities change. Therefore, the decision to consider a substance as currently not needing further regulatory work at the EU level needs to be regularly reassessed.

Substances with no further action currently proposed after review are mainly those with:

- 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 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 to not currently need further regulatory risk management when the regulation in place already sufficiently covers the hazards under scrutiny. In such cases, generating further information on hazards that are 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: Substances with no further regulatory action currently proposed after review in different activities (e.g. screening, compliance check).**

| Substances with no further regulatory action currently proposed after review in different activities (e.g. screening, compliance check). | |
|---|---|
| **Source** | **Percentage** |
| Screening (with no action currently proposed by Member States or ECHA during screening) | 55 % |
| Compliance check (concluded with no action or no follow-up action after generation of data) | 24 % |
| Substance evaluation (concluded with no follow-up action) | 8 % |
| PBT/ED Expert Group assessment (concluded as substances not fulfilling the PBT/ED property criteria) | 6.5 % |
| RMOA (concluded as no need for further regulatory risk management at this point in time) | 6.5 % |

Currently, the majority of substances in this pool stem from past screening activities and more recent work with groups of substances by both Member States and ECHA.

ECHA selects substances for compliance if it cannot be concluded that the substance needs further regulatory risk management or that there is no need for action at the moment.

**An example of a compliance check: conclusion - no need for further generation of data for a category of monomers and polymers of glycerol**

ECHA assessed a category that included several substances composed of monomers and polymers of glycerol. The category approach was considered as acceptable, despite several deficiencies in the data provided for the higher tier endpoints.

ECHA noted that the registrants mainly used old studies, and some of them were not GLP compliant and no guidelines were followed. However, no hazard or indication of toxicity could be identified.

In addition, one of the substances was also subject to an assessment by the European Food Safety Authority (EFSA) as a food additive where EFSA concluded on the absence of adverse effects after repeated oral administration.

Taking all the facts together, ECHA considered that it would be highly unlikely that generation of further information would change the outcome of the hazard assessment or lead to improved risk management measures.

There are 60 cases that come from substance evaluation. The majority (50 cases) were concluded with no need for further regulatory risk management due to a low hazard following the generation of hazard information. In 10 cases, low exposure was concluded.

The PBT and ED Expert Groups concluded that 47 substances are of low hazard (see 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 stage of RMOA development.

Assessing the substances with low hazard is not the main focus of authorities' work. However, by identifying and setting aside groups of lower hazard substances, authorities can focus their

resources on the substances that matter. Clarity on which substances are not currently considered to require further regulatory risk management makes it easier to systematically review this conclusion when new information on hazards or uses become available.

The work with groups of substances supports the clarification of the “not yet assigned” area at an even faster pace by identifying groups of substances around these low hazard substances.

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

**An example of a group for which no further action has been proposed after review: aliphatic fatty acids non-branched (C5-C24)**

ECHA has assessed a group of 32 mono-constituent, multi-constituent or UVCB substances that belong to the aliphatic (carbon chain length) fatty acids, non-branched and cover carbon chain lengths from C5 to C24 with no additional functional groups in their structure. These are used in various applications and included in numerous consumer products, such as in lubricants, construction materials, air care products, household products and biocides. They are expected to be of low toxicity by their nature (similar to high purity fatty acids of natural origin which do not need to be registered as included in Annex V to REACH). Due to the high potential for exposure to workers, the general population and the environment, ECHA considered it important to look at all substances in the group to confirm their low toxicity potential.

The hazardous properties of these substances have been assessed based on experimental data available in registration dossiers and previous assessments (under the Biocidal Products Regulation, harmonised classification and labelling, EFSA opinions and OECD assessments).

Based on available information, ECHA concluded that the substances in the aliphatic fatty acids non-branched (C5-C24) group do not need further data generation to clarify their hazard.

From a human health perspective, substances in this group are considered to have a low systemic toxicity profile with no specific target organ toxicity or CMR properties. Some have irritant and/or corrosive properties that are reflected in the classification and labelling. Risk from these properties can be avoided by implementing risk management measures in supply chains based on the correct classification and labelling of products.

From an environment perspective, substances in this group are not considered PBT/vPvB. They degrade rapidly and have a low potential for bioaccumulation. The ecotoxicological properties of the group members are adequately covered by information in the registration dossiers.

Therefore, there is no need for further action on the substances belonging to the group of aliphatic fatty acids non-branched (C5-C24) based on currently available information.

# 7. Substances in the “not yet assigned” area


### Efficient grouping as the main tool to support clearing of the “not yet assigned” area

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

## Grouping to prioritise and best address substances in the “not yet assigned” area

After more than 10 years of systematic scrutiny by authorities, what remains in the “not yet assigned” area are expected to be substances:

(i) for which there is not enough information in the registration dossiers and other data sources to form a view on their potential hazardous properties or uses;
(ii) with lower hazards; and
(iii) that are complex for which additional elements need to be considered before deciding on further action (such as slags and residues).

In 2018, around 2 700 substances were mapped to the “not yet assigned” area. For those substances, the aim is to have clarity on the need for regulatory risk management or the need for generation of further hazard information by 2020.

To enable this, all substances in the “not yet assigned” area were grouped in line with the methods described in Section 2. The majority of the resulting groups are so-called standard groups of substances that will be further scrutinised by authorities. Should a conclusion on the hazard not be possible due to a lack of data, these substances might need a compliance check.

However, ECHA has also identified (groups of) substances that are difficult to address in a standard way because they require further work before further action can be decided. Examples of such group of substances are product residues (for example, ashes and slags). For other types of substances, cooperation with industry sectors has been initiated. The Metals and Inorganics Sectoral Approach (MISA)[17] is one example of such cooperation.

## Standard groups of substances are assessed and further regulatory actions identified

In 2019, ECHA started to systematically screen groups of substances. This resulted in the screening of 707 substances belonging to 36 groups of substances. Member States have continued to support the screening of groups with 213 substances selected. So far, the screening

[17] More information available at: https://echa.europa.eu/misa

has been completed for 178 substances belonging to 28 groups. For the remaining 35 substances, screening is still ongoing.

Until 2019, most screening was done by Member States with an average capacity of 200 substances per year, while ECHA was supporting the identification of substances to be screened by developing IT tools, data mining capacity and screening approaches.

As most substances required further hazard information to be generated first, it was increasingly difficult to identify substances of concern that could go directly to regulatory risk management. Therefore, ECHA has allocated more resources to screening to speed up actions and, in particular, compliance checks. As a consequence, most screening is nowadays performed by ECHA with Member States focusing on ensuring follow up with regulatory risk management action (such as harmonised classification and labelling and SVHC identification).

The number of substances screened by authorities clearly increased in 2019, with more than 900 substances being scrutinised as shown in Figure 7. This increase is particularly as a result of the increase in resources allocated by ECHA to screening groups of substances.

The work initiated in 2019 by ECHA has paved the way for 2020, where the aim is to further increase the pace of screening in order to achieve the 2020 goals.

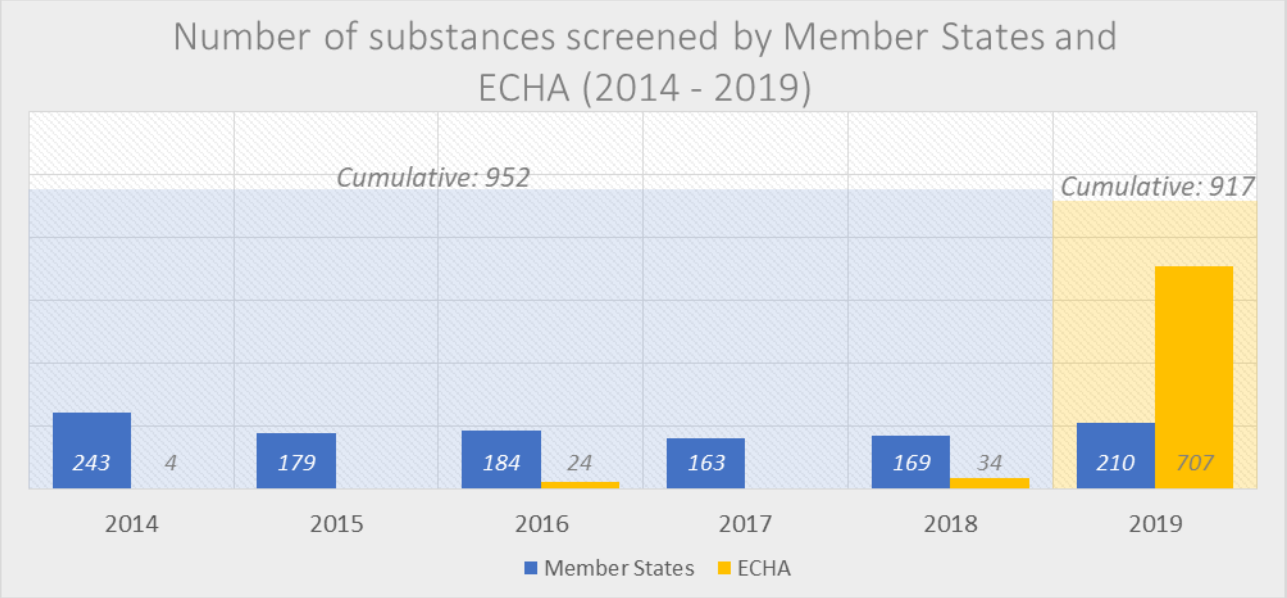



**Figure 7: Overview of substances screened by Member States and ECHA (2014-2019)**

For each group of substances, authorities consider whether or not there is a need to initiate further regulatory risk management activities on the group, at the level of individual substances or for a subgroup of substances. Assessing and identifying potential further regulatory risk management needs early on, as well as the steps required once the hazard is clarified, aims to speed up the actions (such as harmonised classification and labelling).

In 2019, out of 917 substances screened, 529 were from the “not yet assigned” area and were allocated for screening (97 by Member States and 432 by ECHA), among which 219 registered above 100 tonnes per year, 232 registered below 100 tonnes per year and 78 registered as intermediates.

The outcome of the screening is not yet ready for all those substances due to, for instance, cases initiated towards the end of 2019 and for which the outcome will be recorded in 2020. Table 6 provides an overview of the outcome of those substances for which the screening has been completed so far.

**Table 6: Overview of the outcome of screening in 2019 of substances from the "not yet assigned" area**

| Number of substances screened in 2019 from the "not yet assigned" area and outcome | | | |
|---|---|---|---|
| **Outcome** | **Registered above 100 t/y** | **Registered below 100 t/y** | **Intermediates** |
| **Need for CCH** | 106 | 98 | 0 |
| **Need for CLH** | 14 | 10 | 4 |
| **Currently no need for action** | 49 | 26 | 24 |
| **Pending the outcome of other substances** | 32 | 27 | 25 |

In 2019, ECHA progressed in clearing the chemical universe and moving substances from the "not yet assigned" area to the other pools of substances. Many substances have been moved to the data generation pool, however the work with groups of substances has also identified substances with a need for harmonised classification and labelling, as well as potential restriction needs (see the information on glycol ethers in Section 4).

Furthermore, work on groups has also allowed authorities to identify recurring issues of relevance to several groups of substances and for which further work is needed (examples of such issues are reported in the information box on skin sensitisers and nitrosamines later in this section). Those issues will support authorities in identifying risk management needs which will potentially help regulating several substances across groups.

Overall, the Integrated Regulatory Strategy has started to deliver, and most substances brought to regulatory risk management processes result from the work done under screening, RMOA, compliance check and substance evaluation as highlighted in the previous sections of the report.

### Working with groups of substances supports authorities to identify issues of relevance for more substances – example of skin sensitisers and formation of nitrosamines

In the context of the work on groups of substances, ECHA identified recurring issues of relevance to several groups of substances. For instance, we have encountered several cases of substances:

- having a harmonised classification as **skin sensitisers** (either on their own or due to the presence of an impurity with a harmonised classification as a sensitiser); and
- ending up in consumer mixtures (such as cleaning products).

The main concern with those substances is that they may be present in consumer mixtures at concentrations above the regulatory threshold for classification but without correct labelling. This may happen even if registrants have stated in their registration dossiers that such substances should not be included in consumer mixtures above the concentration limits.

There is no certainty that downstream users comply with the information they receive from their suppliers or label their products correctly if they still use the substances above the concentration limit. Therefore, consumers are unlikely to be sufficiently aware and protected when using such mixtures. Registrants could advise against such uses or national enforcement authorities could enforce the labelling requirement. ECHA has suggested that the Member States either take sufficient enforcement actions or consider regulatory action (such as restriction).

Another example is the identification of the potential hazard (cancer) from the creation of **nitrosamines** by a number of substances under specific conditions. These substances share a common functional group (amine), and in the presence of nitrosating agents, the potential for carcinogenic nitrosamines to be formed cannot be excluded. Formation of nitrosamines can occur due to combined exposure to a substance with an amine functional group and a nitrosating agent during the use (industrial, professional or consumer) of the amine substance.

Further work by national authorities is needed to investigate the potential for nitrosamine formation, such as identification of exposure situations or scenarios where such formation of nitrosamines can be expected, and to identify regulatory measures to address this concern.

## MAIN RECOMMENDATIONS

- Screening groups of substances, data generation and assessment should be further optimised to ensure 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 are taken.
- The priority and appropriateness of previously identified, but still pending, follow-up actions should be reviewed and those substances which need further regulatory risk management should be progressed without delay.
- The compliance of registration information needs to be improved, in particular, for substances with a high potential for exposure and currently lacking appropriate hazard data.
- Compliance of dossiers, their systematic review and updates of registrations based on new information, remains industry's responsibility. ECHA welcomes the initiative of industry associations to develop review programmes to help registrants review chemical safety data.
- Further enhance cooperation and coordination between authorities.

# Annex 1. Update on pre-regulatory steps: screening, PBT and ED Expert Groups, regulatory management option analysis (2008-2019).

## 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 manual screening rounds from 2014 to 2019. Around 70 % of the 1 179 substances scrutinised by Member States required follow-up action. For almost half of the substances screened (42 %), 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. The screening work done on groups of substances by ECHA in 2019 is not included in this graph.

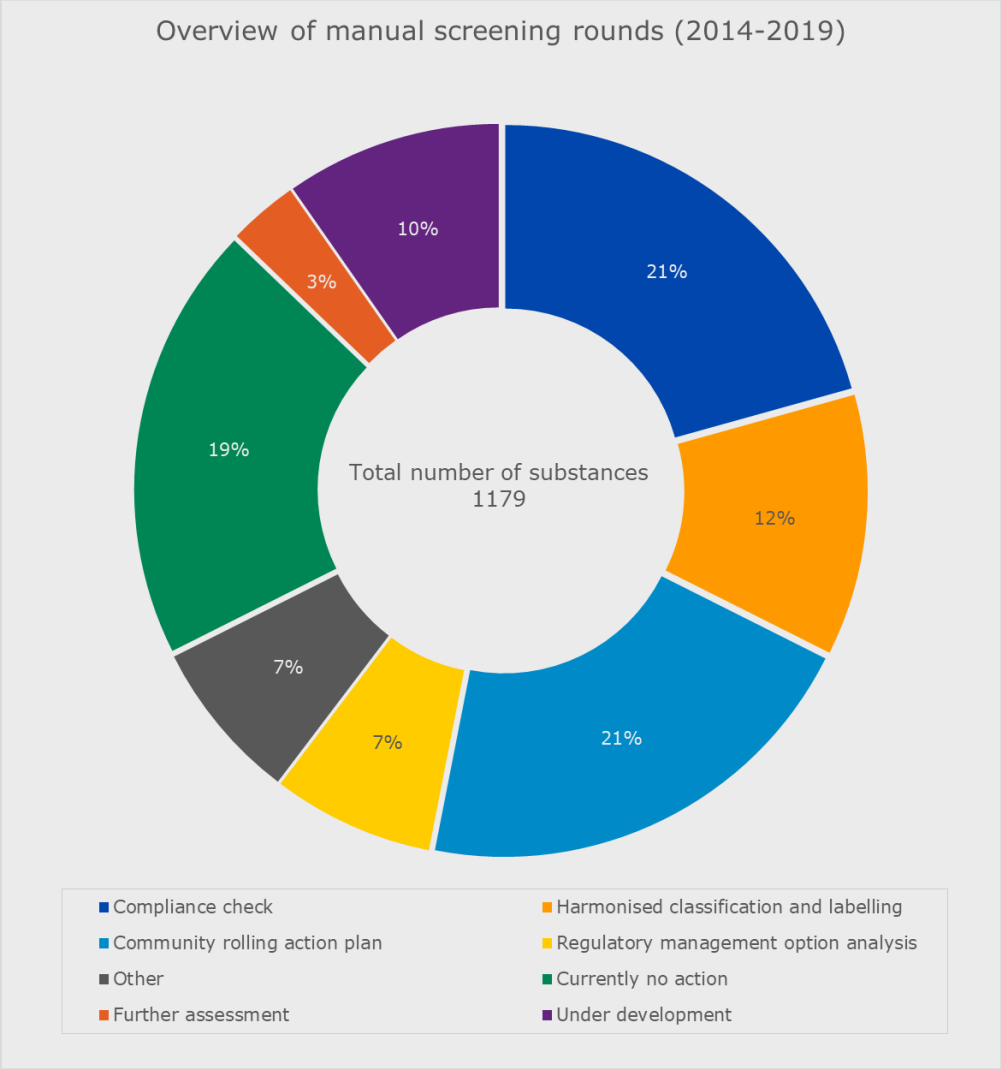



**Figure 1: Overview of manual screening outcomes (2014-2019)**[18]

[18] 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.

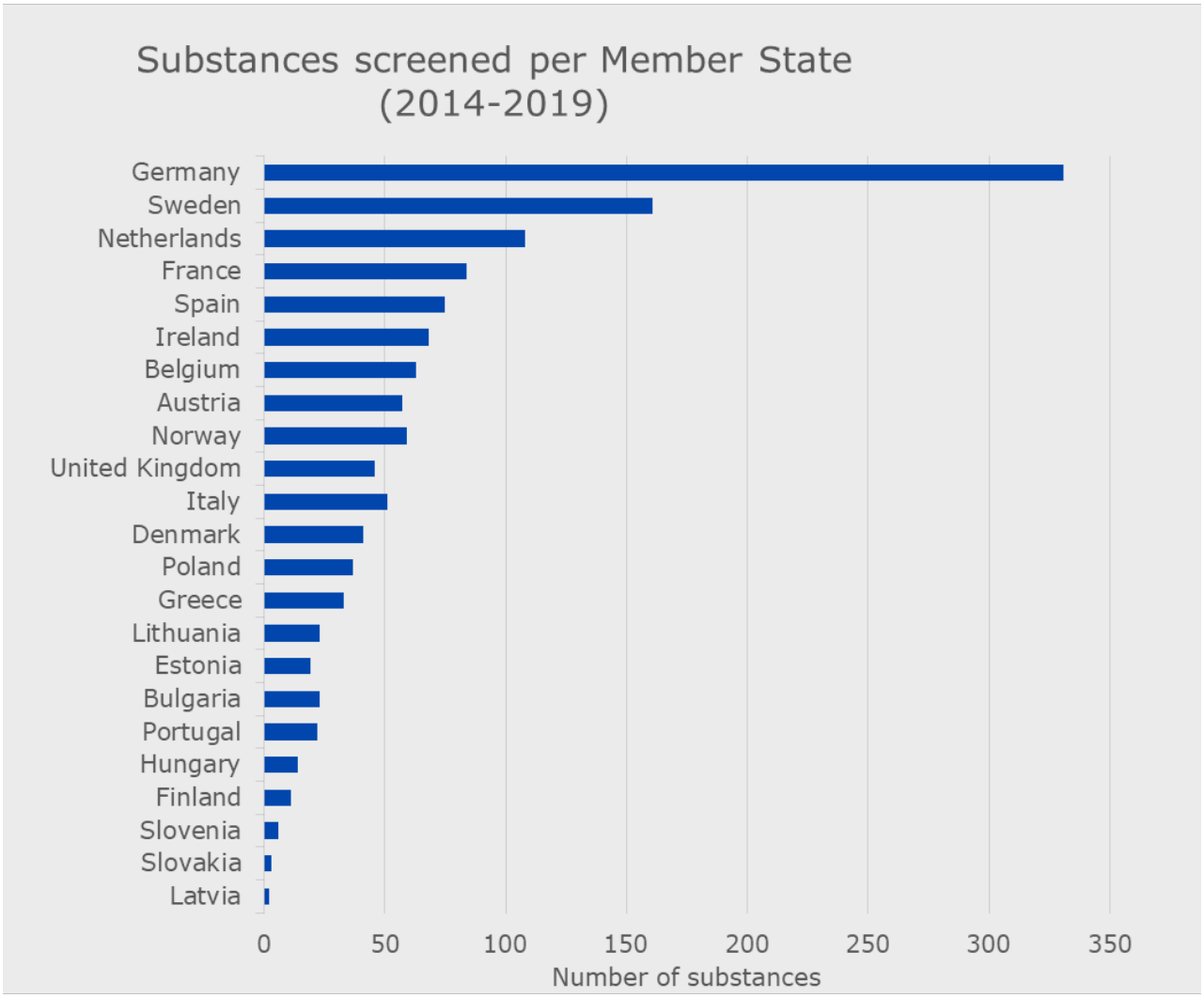



**Figure 2: Number of substances screened by Member States (2014-2019)**

## 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 identification of substances of very high concern (SVHC).

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 (2012-2019)**

| Number of substances concluded on under the PBT and ED Expert Groups and conclusions (2012-2019) | | | | |
|---|---|---|---|---|
| | | | Number of substances concluded on | |
| Property | Number of substances ongoing and postponed | Total number of substances concluded on | Considered not to fulfil the hazard properties | Considered to fulfil the hazard properties |
| PBT Expert Group | 101 | 73 | 43 | 30 |
| ED Expert Group | 77 | 14 | 4 | 11 |

Since 2012, 19 Member States have been active in the PBT Expert Group and 13 in the ED Expert Group (Figure 3).

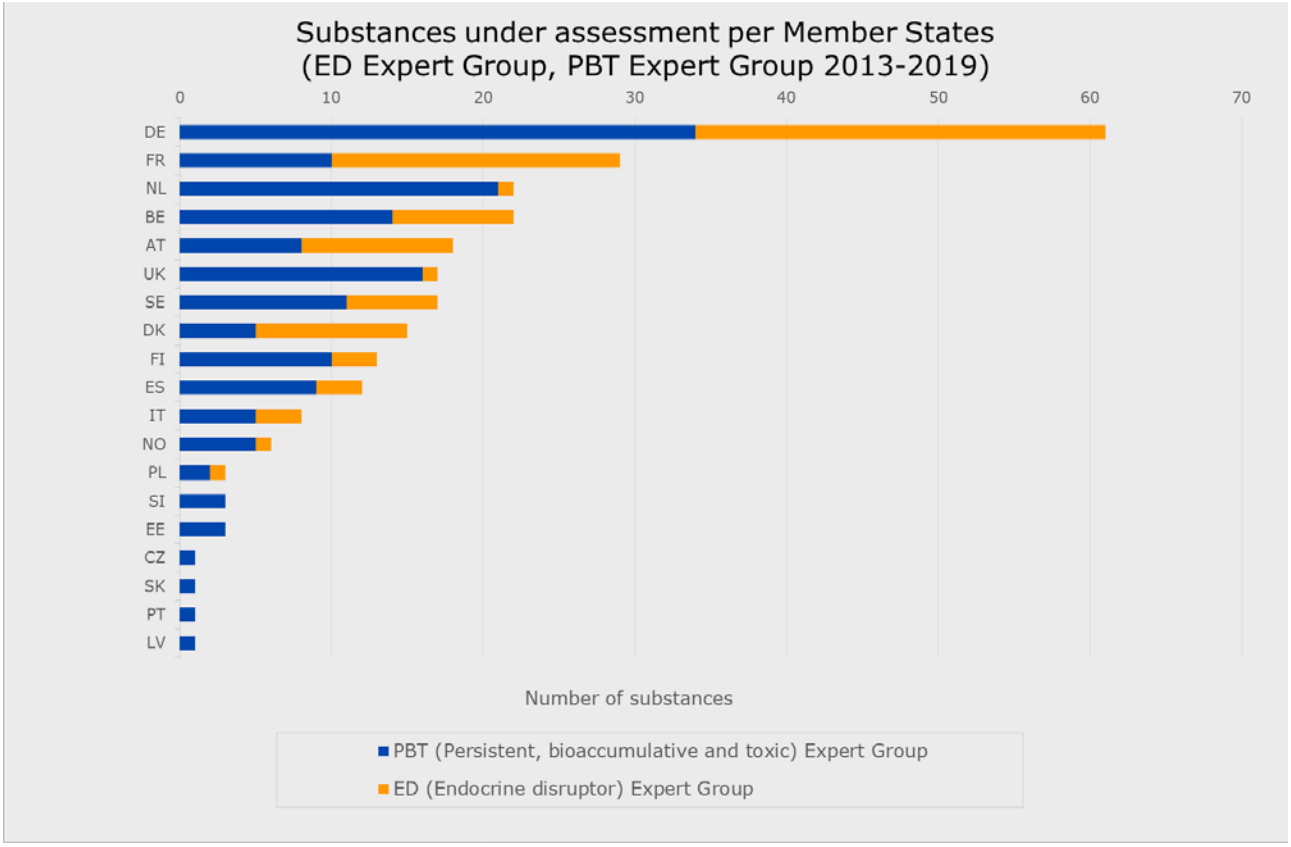



**Figure 3: Number of substances under assessment in the ED Expert Group, the PBT Expert Group per Member State**

# 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 consultations.

Currently, an RMOA has been concluded or is under development for 280 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 hazard property.

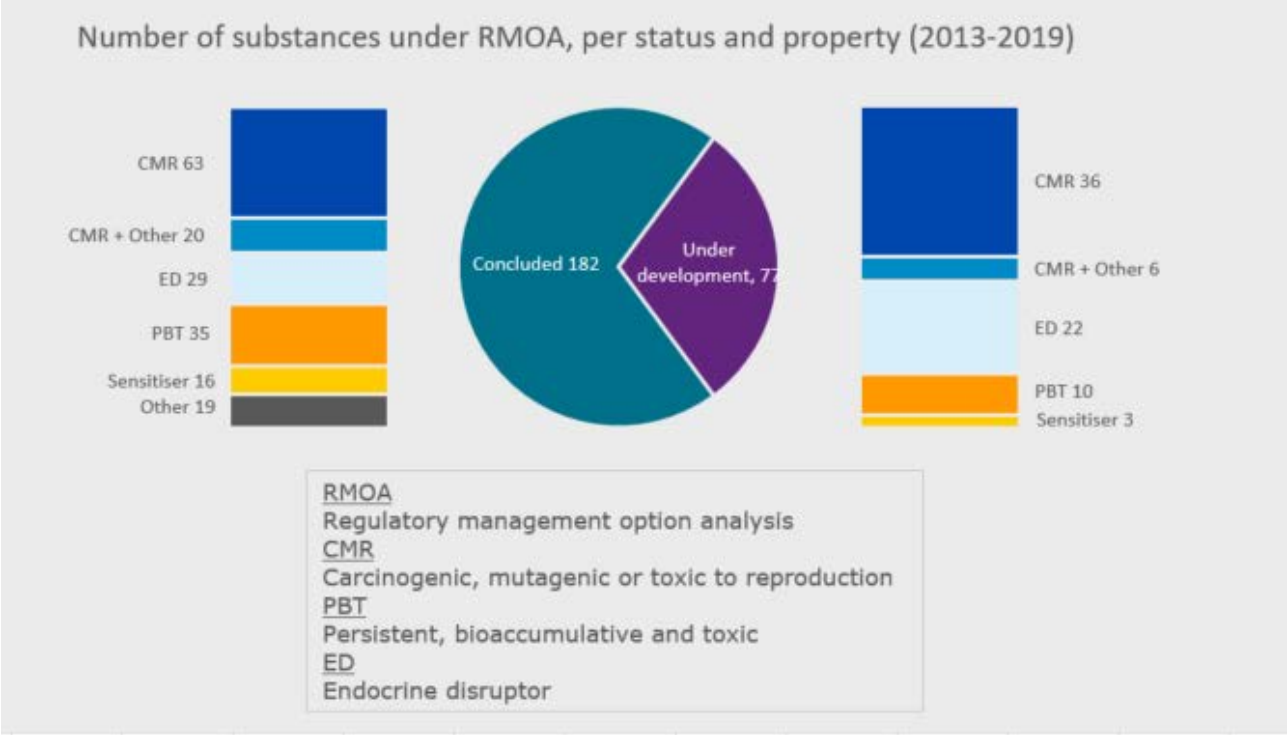



**Figure 4: Number of RMOAs concluded and under development per hazard property (February 2013 - December 2019)**

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).

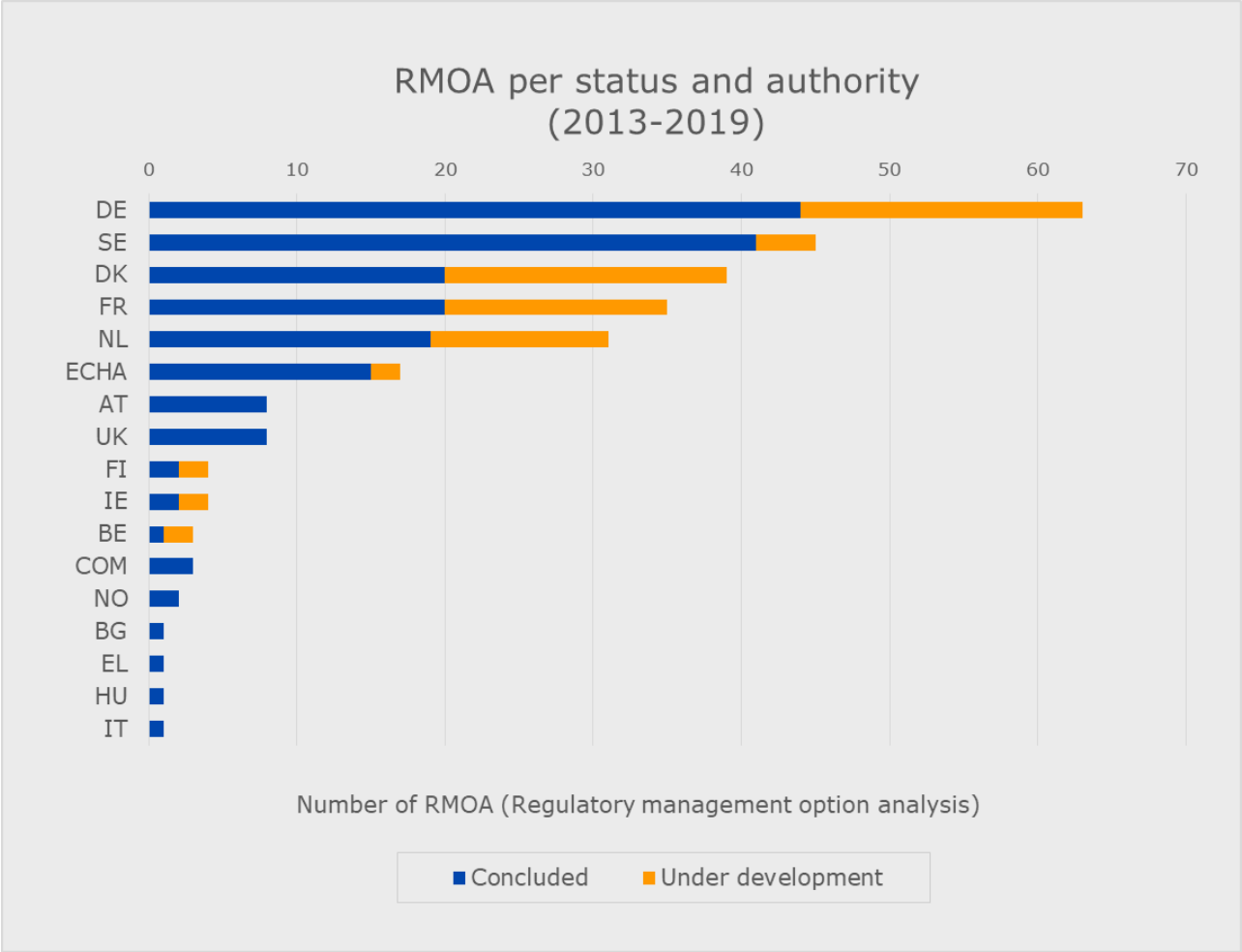



**Figure 5: Number of RMOAs concluded or under development per authority (2013-2019)**

# Annex 2. Update on evaluation activities (2009-2019)

Dossier and substance evaluation have been established as key processes for generating further information on substances. ECHA's web page on progress in evaluation[19] shows more detailed statistics. ECHA also gathered recommendations to registrants[20] resulting from evaluation work.

## 1 Compliance check (2009–2019)

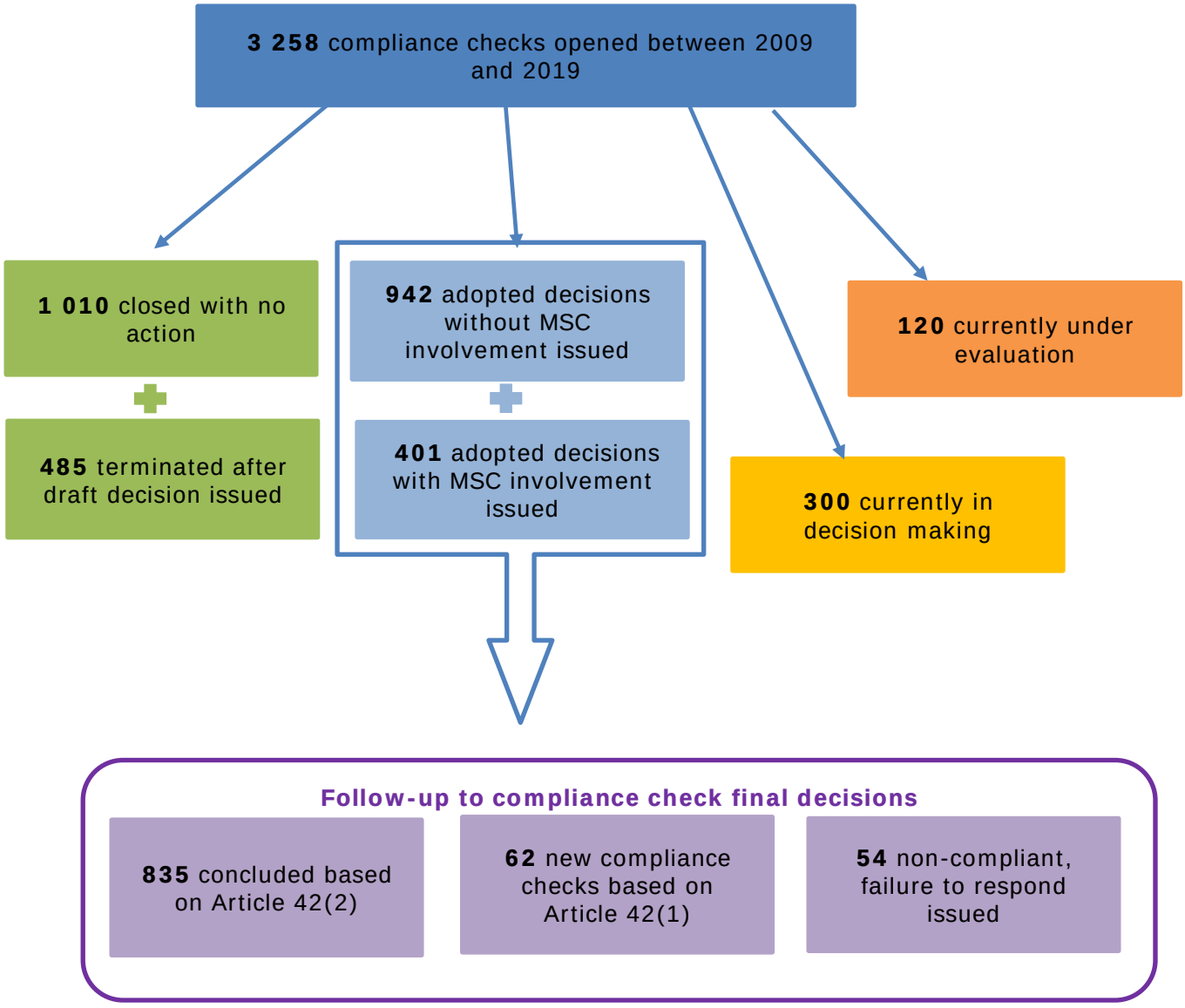



**Figure 1: Number of compliance checks between 2009 and 2019**

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

## 2 Testing proposal examination (2009–2019)

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.

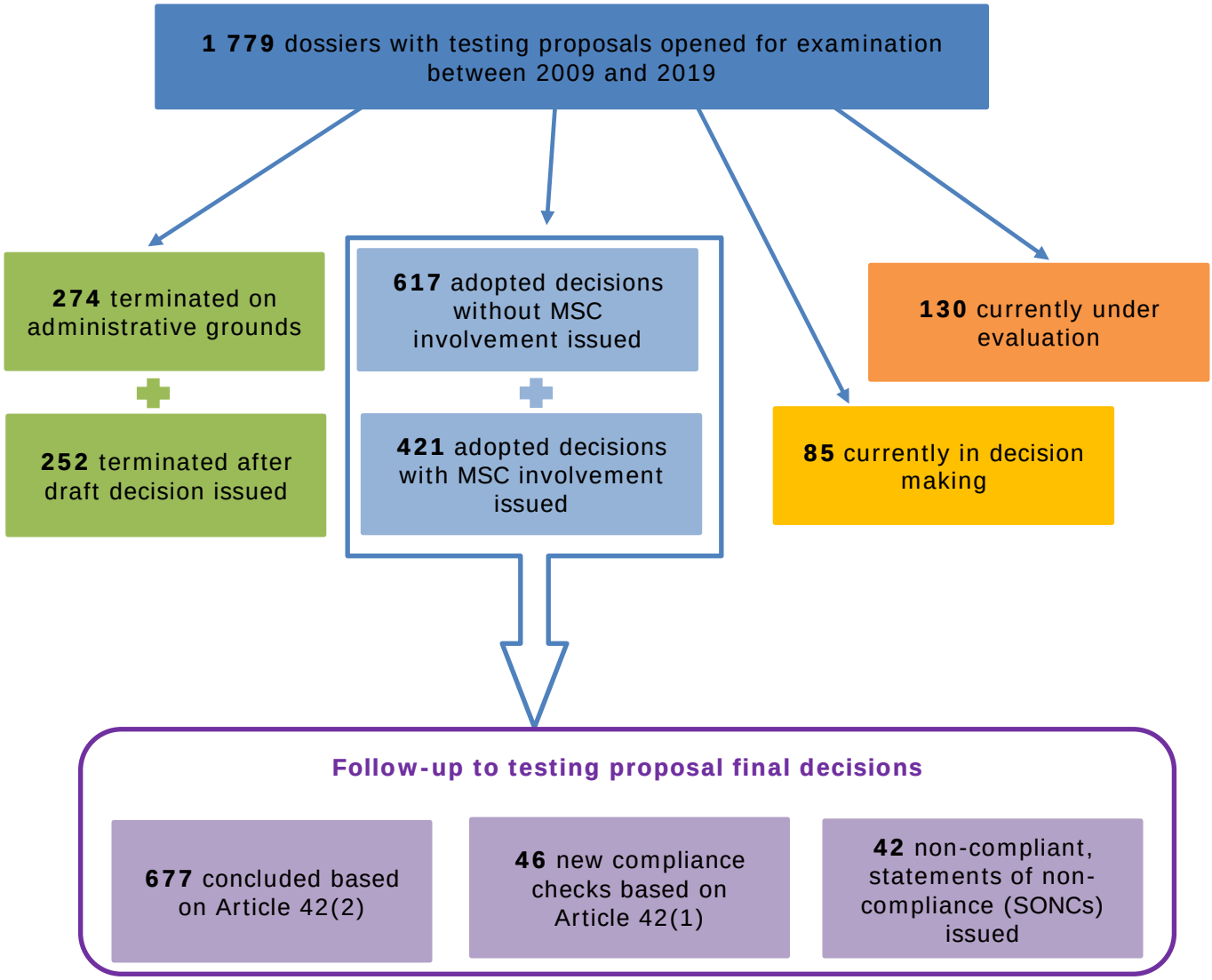
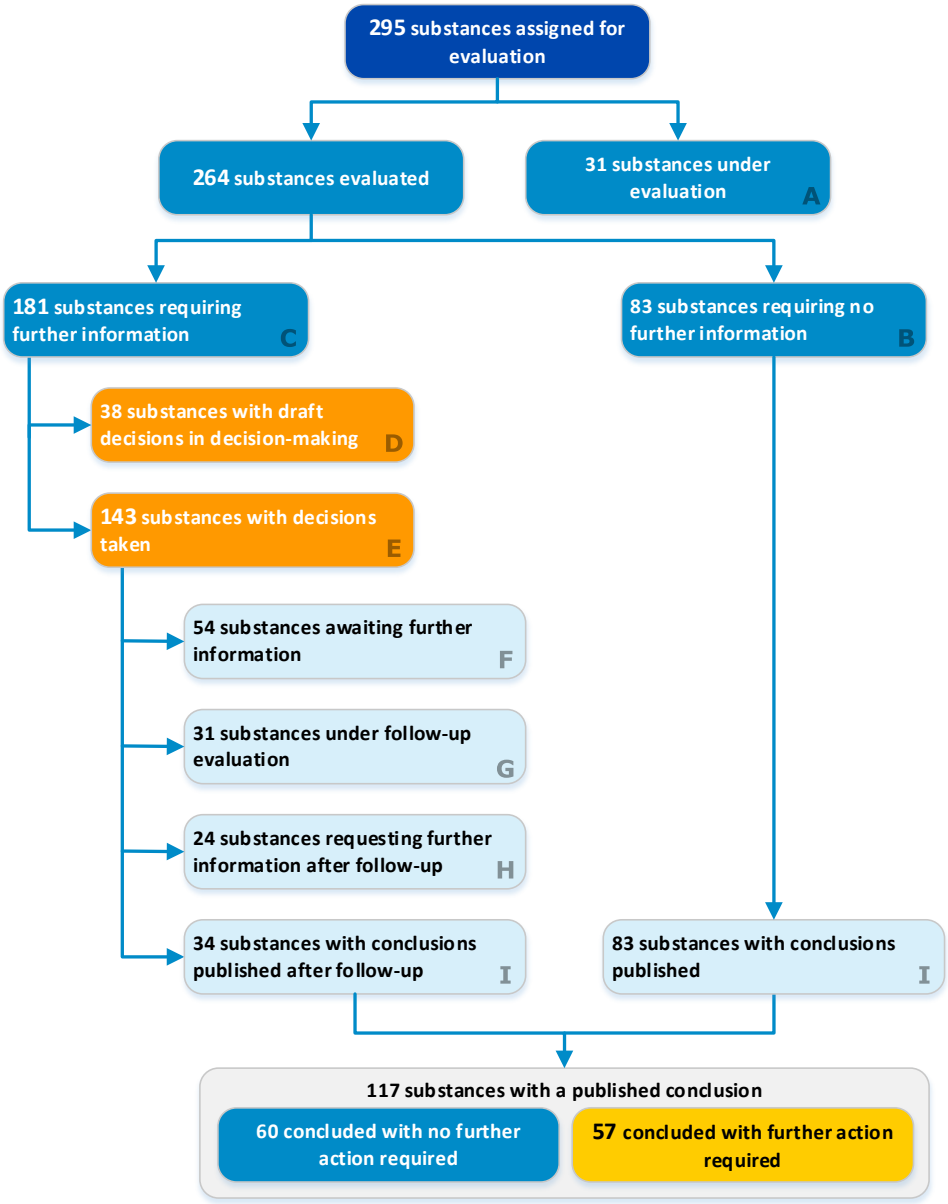



**Figure 2: Number of testing proposal examinations between 2009 and 2019**

# 3 Substance evaluation (2012–2019)

## 3.1 Status of all substance evaluations at the end of 2019




[A] Substance under evaluation by Member State competent authority (MSCA).
[B] Evaluating MSCA can conclude on suspected risk based on available information.
[C] Draft decision requesting further information is deemed necessary.
[D] Stages of draft decision processing: 35 substances currently in decision-making stage. Three 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 two substances, decisions are appealed before the Board of Appeal of ECHA.
[G] Evaluating MSCA is examining all new information in updated registration. For six substances, draft conclusion documents are being prepared.
[H] Draft decision requesting further information deemed necessary after follow-up assessment: 17 substances have draft decisions in decision-making, and seven 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 2019**

## 3.2 Properties of the substances under substance evaluation (2012-2019)

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 (2012-2019)**

| Number of substances under substance evaluation and concluded on per property and conclusion where relevant (2012-2019) | | | | |
|---|---|---|---|---|
| | | | From the substances concluded on: | |
| Property | Number of substances ongoing (per property) | Total number of substances concluded on (per property) | Considered not to fulfil the hazard properties[21] | Considered to fulfil the hazard properties |
| PBT | 90 | 35 | 33 | 2 |
| ED | 59 | 24 | 18 | 6 |
| CMR | 93 | 72 | 38 | 34[22] |
| Sensitiser | 27 | 35 | 7 | 28 |

[21] Note that a few substances have been concluded on with no clarification of the hazard properties, due to low potential for exposure, for instance. These substances have been included under the heading “considered not to fulfil the hazard properties”.

[22] 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 11 CMRs that have either been newly classified or had their classification as CMR upgraded.

# Annex 3. Update on regulatory risk management activities (2008-2019)

## 1 Harmonised classification and labelling

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

For all other hazardous substances, a harmonised classification and labelling can be sought, if a justification is provided that shows such an action is required at EU level[23].

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2019, and Figure 2 shows the number of proposals submitted during the same time period. The numbers are further broken down into proposals for active substances in biocidal and plant protection products as well as other substances, mainly those subject to REACH registration.

As can be seen, the majority of substances subject to CLH are active substances in biocidal and plant protection products. The number of REACH substances for which a classification for new[24] and existing CMRs[25] was adopted is also reported.

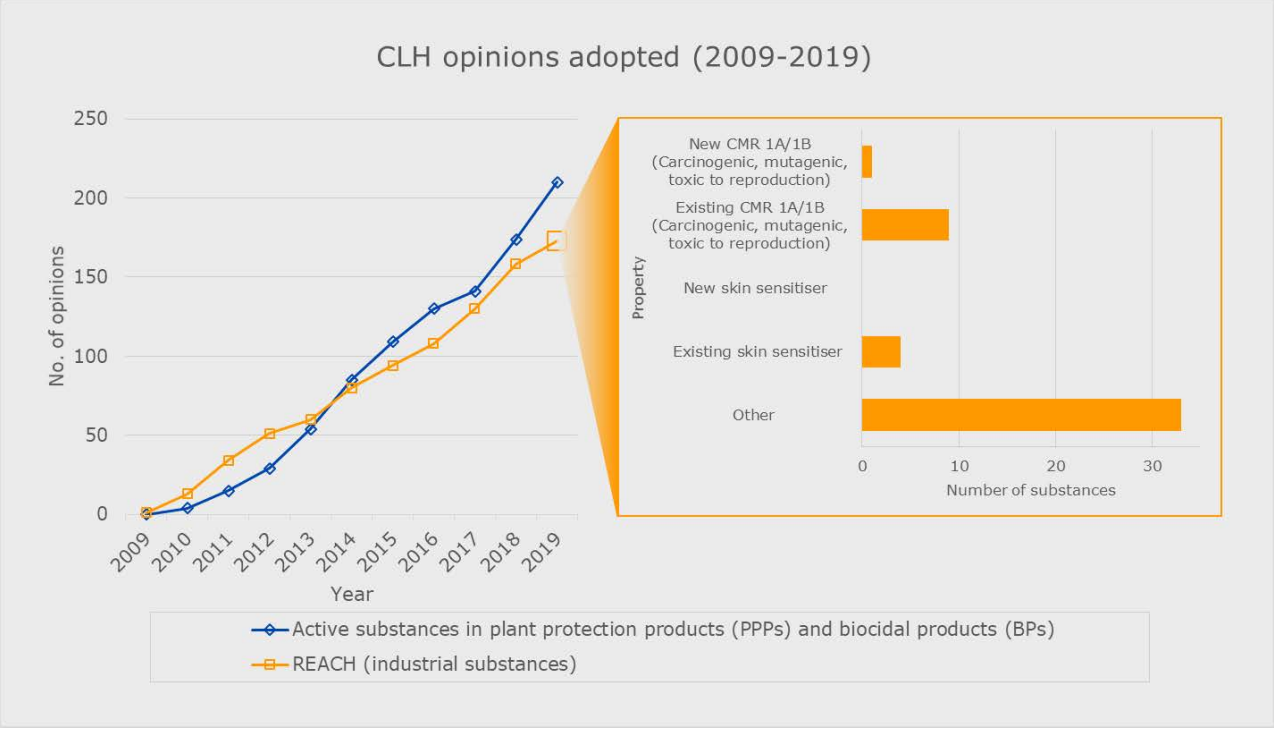



**Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2019 and a breakdown of REACH substances for which a CMR 1A or 1A and/or sensitiser proposal was included**

[23] https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

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

[25] 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.

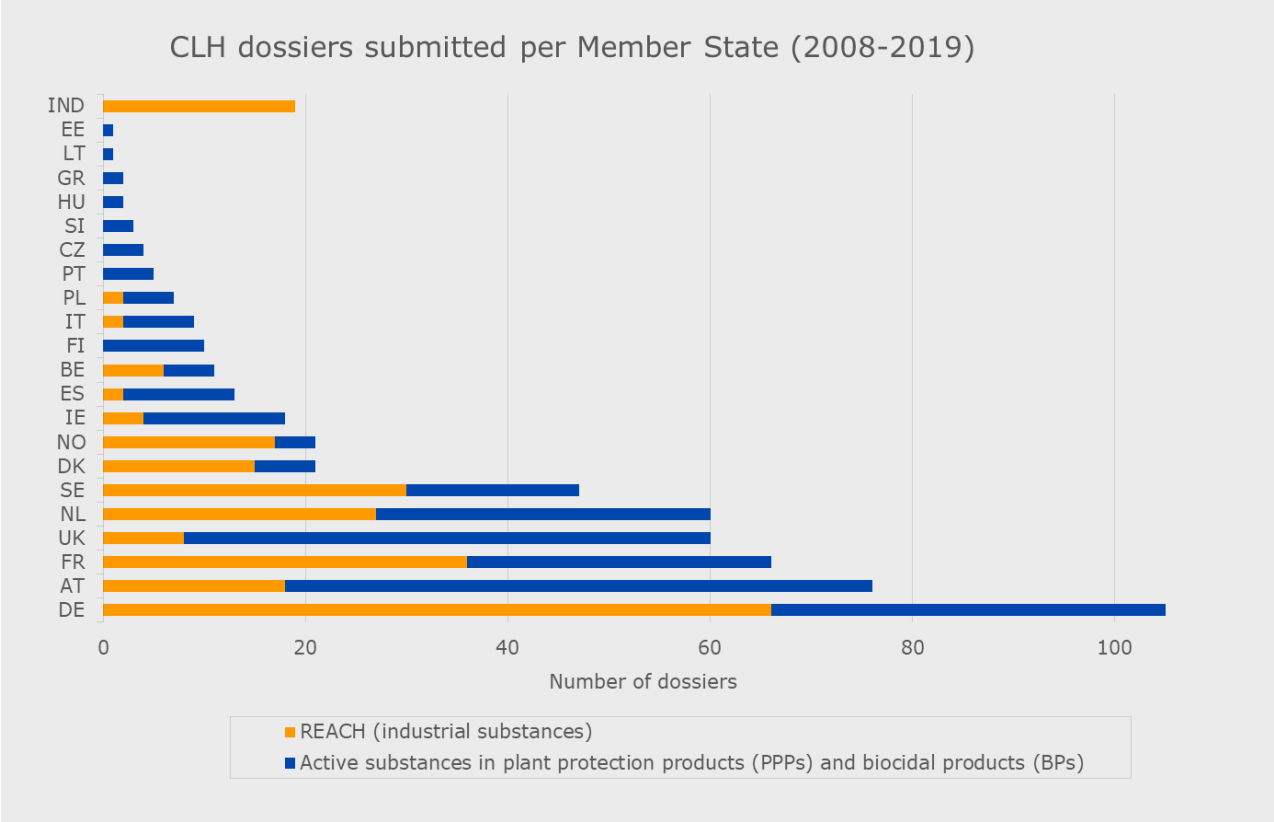



**Figure 2: Number of CLH proposals submitted per Member State (2008–2019)**

# 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[26].

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 2019. These numbers are further explained below in their respective sections.

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

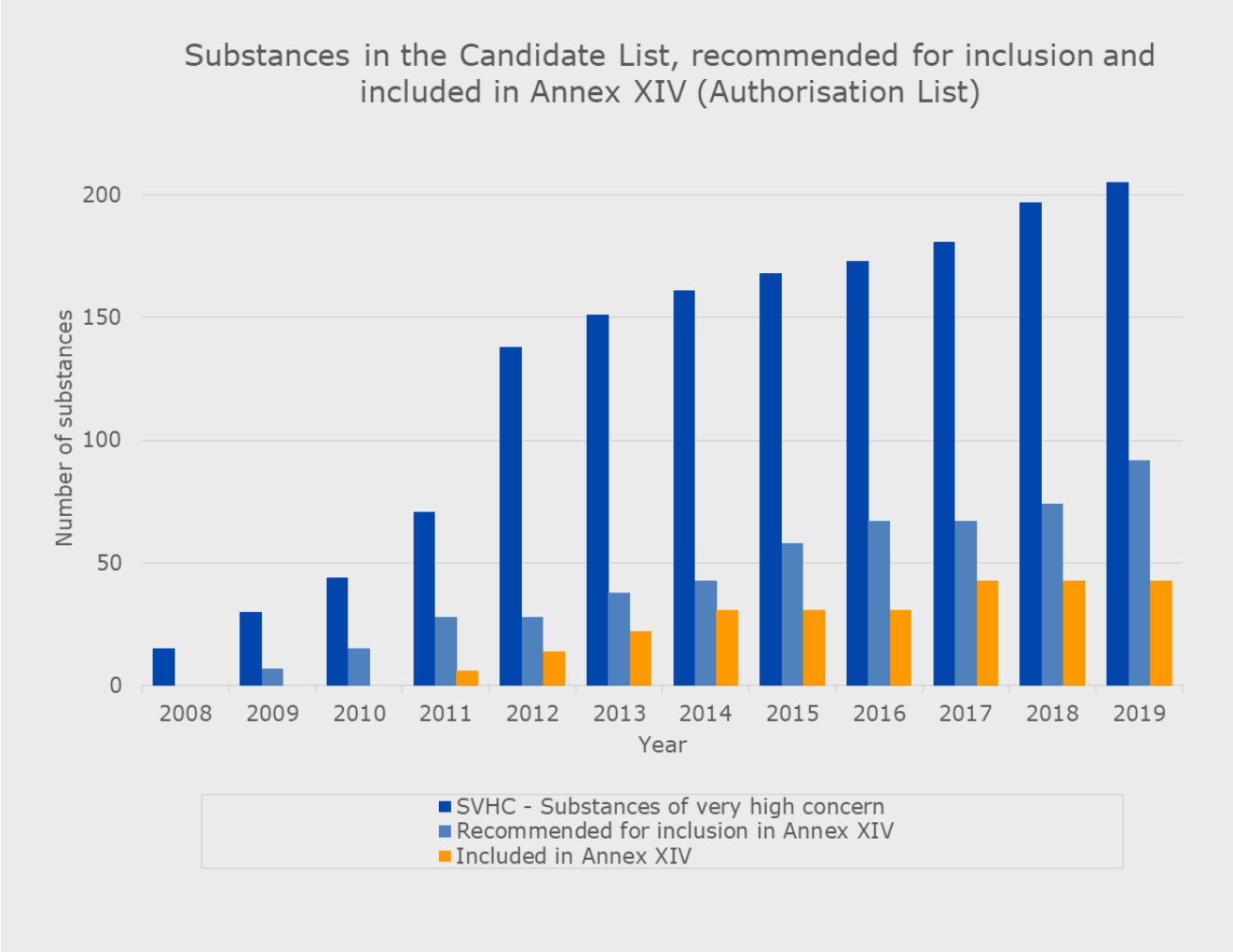



**Figure 3: General overview of the number of substances on the Candidate List, recommended for inclusion in the Authorisation List (Annex XIV), and included in Annex XIV**

### 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) if:

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

If identified as 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, 205 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.

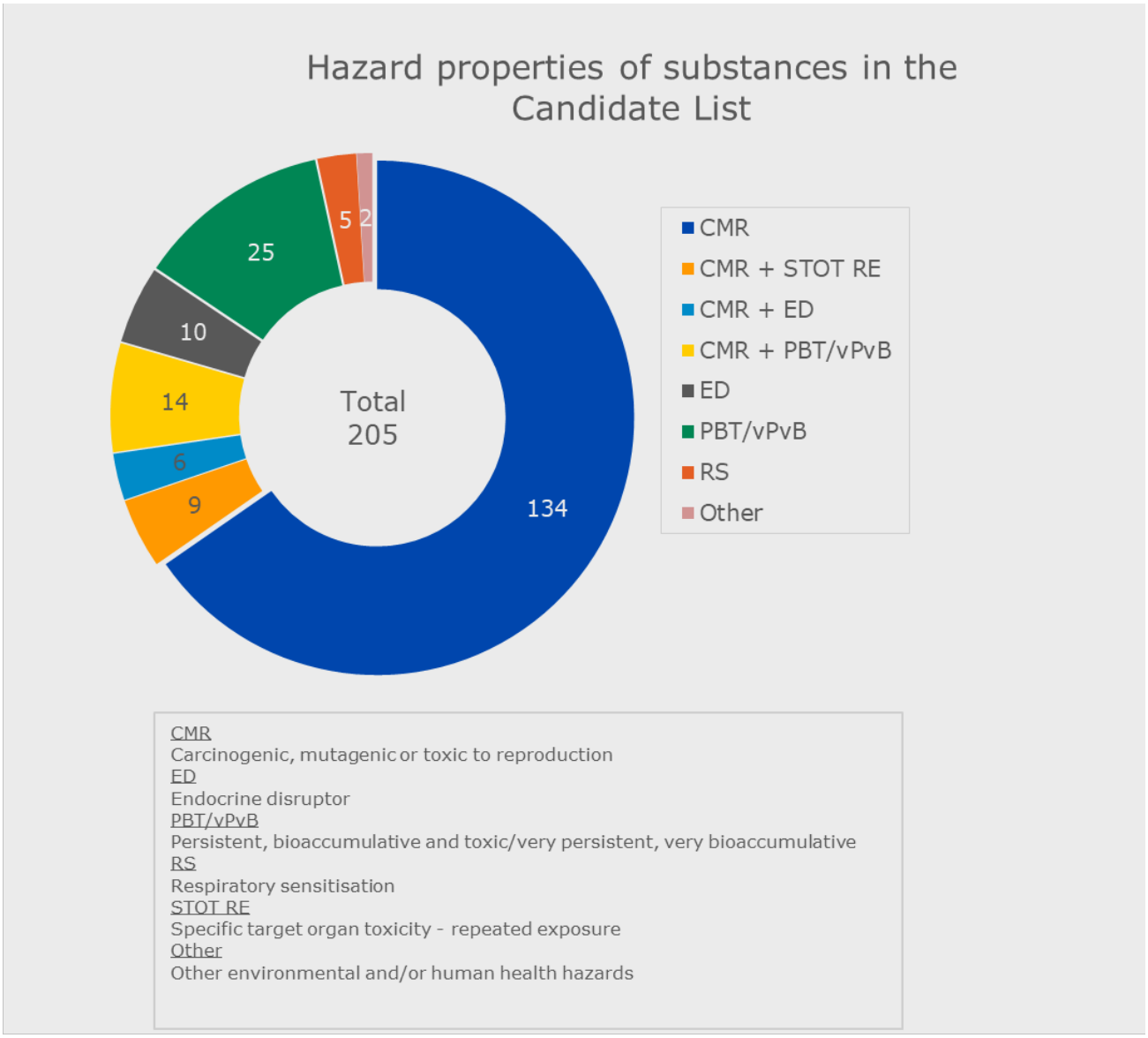



**Figure 4: Substances on the Candidate List and overview of their hazard properties.**

In 2019, eight 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 for each property since 2008.

**Table 1: Overview of number of substances included in the Candidate List by property (2008-2019)**

| Overview of number of substances included in the Candidate list by property (2008-2019). | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CMR | 10 | 13 | 16 | 26 | 57 | 13 | 8 | 4 | 3 | 5 | 6 | 5 | **166** |
| PBT/ vPvB | 5 | 6 | 0 | 0 | 5 | 2 | 2 | 4 | 2 | 4 | 9 | 0 | **39** |
| ED | 3 | 1 | 0 | 1 | 2 | 1 | 0 | 0 | 3 | 1 | 2 | 1 | **15** |
| STOT RE | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 0 | 0 | 3 | 0 | 0 | **9** |
| Resp. sens | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | **5** |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | **2** |

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

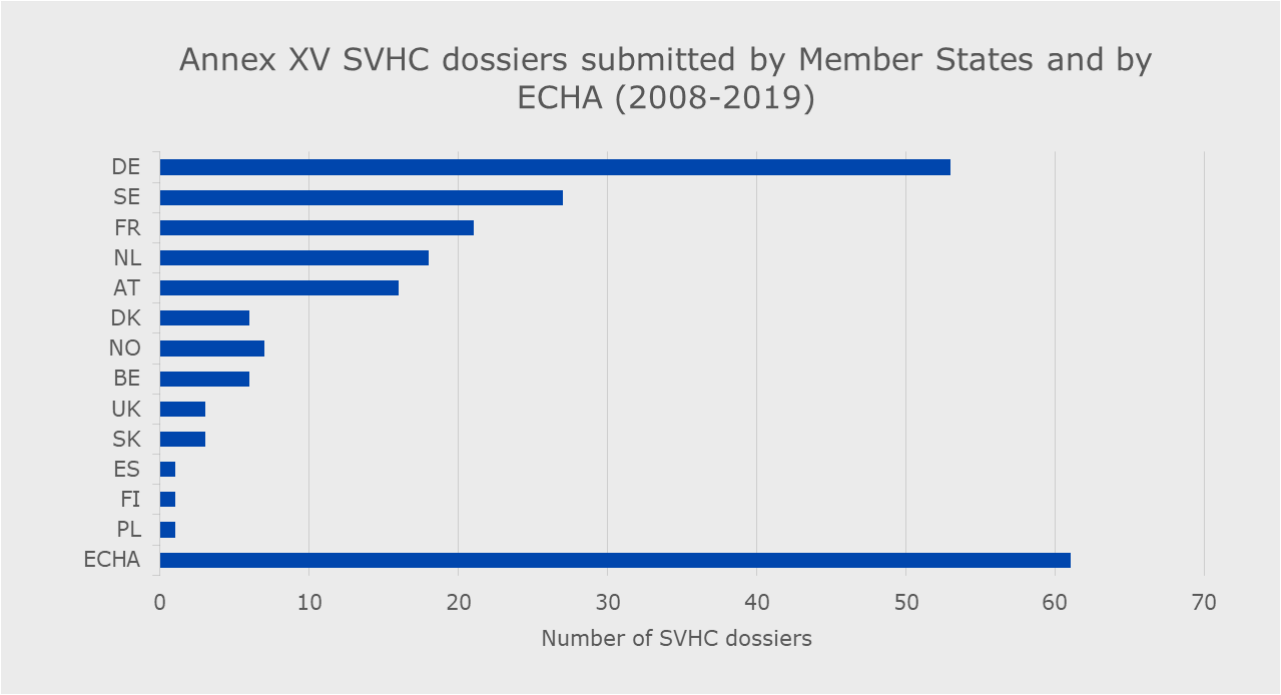



**Figure 5: Number of Annex XV SVHC dossiers submitted by Member States and by ECHA (2008-2019)**

## 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[27]. Prioritisation is carried out based mainly on information in the registration dossiers. However, information from the consultation on the SVHC identification as well as other REACH information is also considered.

Figure 6 gives an overview of the substances recommended by ECHA to be included in Annex XIV until the ninth recommendation as well as of the substances included in the Authorisation List (Annex XIV)[28] by end of 2019.

The ninth recommendation was sent to the Commission in October 2019[29]. Substances recommended within the seventh and eighth recommendation have been considered by the Commission for the next amendment of Annex XIV[30].

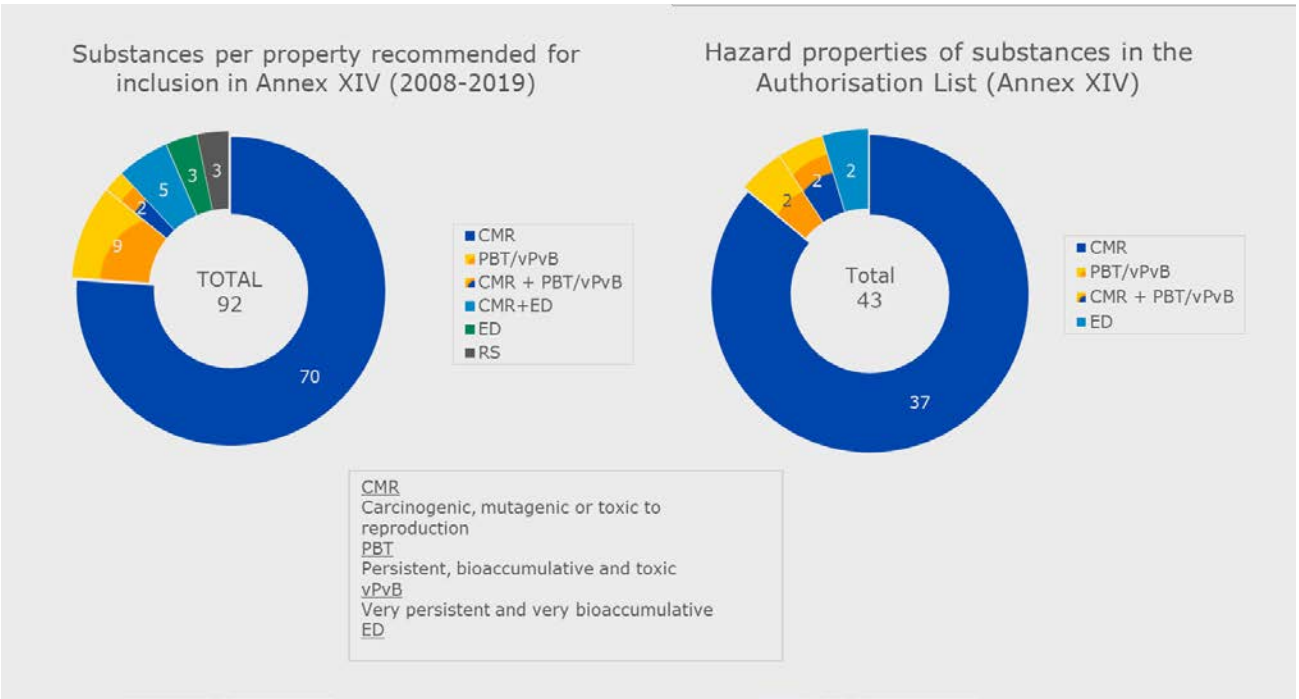



**Figure 6: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008-2019)[31]**

[27] https://www.echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf.
[28] Substances included in Annex XIV can be found at: https://echa.europa.eu/authorisation-list.
[29] An overview of substances recommended by ECHA is available at: https://echa.europa.eu/previous-recommendations.
[30] Note that Annex XIV has been amended and published in February 2020; however, this is not reflected in this report:https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0171.
[31] Four substances are listed in Annex XIV with CMR properties only, while they also have ED properties. This has not yet been updated in Annex XIV and, as a consequence, is not reported here.

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

Entries in the Authorisation List may need to be updated, for example, if a substance already listed in Annex XIV is identified as having additional SVHC properties and the Candidate List has been updated accordingly. This was the case for four phthalates (DEHP, BBP, DBP and DIBP) included in the Authorisation List for their toxic to reproduction properties. Based on their later SVHC identification as endocrine disruptors, ECHA made, for the first time, an amendment recommendation to add the endocrine-disrupting properties to the respective Annex XIV entries of these four phthalates[32].

[32] https://echa.europa.eu/-/endocrine-disrupting-properties-to-be-added-for-four-phthalates-in-the-authorisation-list.

**Table 2: Overview of substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2019)**

| Overview of substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2019) | | | | | |
|---|---|---|---|---|---|
| **Number and 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,<br>MDA,<br>HBCDD,<br>3 phthalates | *[SCCP]*[33] |
| 2nd (17 Dec 2010) | 8 | 2nd (14 Feb 2012) | 8 | 1 phthalate,<br>2 arsenic substances,<br>3 lead chromate substances,<br>TCEP,<br>2,4-DNT | |
| 3rd (20 Dec 2011) | 13 | 3rd (17 Apr 2013) | 8 | Trichloroethylene,<br>7 chromium (VI) substances | 5 Cobalt (II) compounds |
| 4th (17 Jan 2013) | 10 | 4th (14 Aug 2014) | 9 | Polymeric/crude MDA,<br>Diglyme,<br>EDC,<br>MOCA,<br>4 chromium (VI) substances | DMAC |
| 5th (6 Feb 2014) | 5 | 5th (13 June 2017) | 1 | 4-tert-OPnEO | DMF<br>ADCA<br>Al-RCF and Zr-RCF |
| 6th (1 July 2015) | 15 | | 11 | 1-bromopropane,<br>7 phthalates,<br>anthracene oil,<br>CTPHT,<br>4-NPnEO | 4 borate substances |
| 7th (10 Nov 2016) | 9 | [n/a] | [n/a] | [n/a] | * |
| 8th (5 Feb 2018) | 7 | [n/a] | [n/a] | [n/a] | * |
| 9th (1 Oct 2019) | 18 | [n/a] | [n/a] | [n/a] | * |
| Total | 92 (58+34) | | 43 | | 15 |

* Substances from the seventh, eighth and ninth recommendation (in total 34) have not yet been considered for amending Annex XIV.

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

## 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 2019, as well as the number of Committee for Risk Assessment (RAC) opinions, Committee for Socio-economic Analysis (SEAC) opinions and Commission decisions.

This information is regularly updated and published[34].

**Table 3: Number of applications for authorisation / review reports received from January 2013 to December 2019**

| Number of applications for authorisation / review reports received from January 2013 to December 2019 | | | | | | |
|---|---|---|---|---|---|---|
| **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 | 11 |
| 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 | 20 | 19 |
| Lead chromate | CMR | 1 | 1 | 1 | 1 | 1 |
| Chromium trioxide | CMR | 36 | 76 | 56 | 54 | 26 |
| Sodium dichromate | CMR | 21 | 28 | 27 | 26 | 17 |
| Sodium chromate | CMR | 3 | 5 | 4 | 3 | 3 |
| 1,2-dichloroethane (EDC) | CMR | 16 | 18 | 20 | 20 | 20 |
| Chromium trioxide; sodium dichromate; potassium | CMR | 1 | 6 | 3 | 3 | 3 |

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

**Number of applications for authorisation / review reports received from January 2013 to December 2019**

| Substance | Intrinsic properties in Annex XIV | Received applications | Applicants | Uses | RAC / SEAC opinions per use | Commission decisions per use |
|---|---|---|---|---|---|---|
| dichromate | | | | | | |
| Potassium dichromate | CMR | 4 | 4 | 7 | 7 | 3 |
| Ammonium dichromate | CMR | 3 | 5 | 4 | 4 | 4 |
| 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 | 8 |
| Arsenic acid | CMR | 1 | 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 | 2 |
| 4,4'-methylenebis[2-chloroaniline] (MOCA) | CMR | 1 | 1 | 1 | 1 | - |
| Sodium chromate; potassium chromate | CMR | 1 | 1 | 4 | 2 | 2 |
| Pentazinc chromate octahydroxide | CMR | 2 | 3 | 4 | 4 | 2 |
| 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated | ED ENV | 37 | 49 | 56 | 2 | |
| 4-Nonylphenol, | ED ENV | 4 | 4 | 4 | | |

| Number of applications for authorisation / review reports received from January 2013 to December 2019 | | | | | | |
|---|---|---|---|---|---|---|
| **Substance** | **Intrinsic properties in Annex XIV** | **Received applications** | **Applicants** | **Uses** | **RAC / SEAC opinions per use** | **Commission decisions per use** |
| branched and linear, ethoxylated | | | | | | |
| 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated; 4-Nonylphenol, branched and linear, ethoxylated | ED ENV | 4 | 14 | 15 | | |
| Pitch, coal tar, high-temp. | CMR, PBT, vPvB | 4 | 4 | 4 | 1 | |
| Pitch, coal tar, high-temp.; Anthracene oil | CMR, PBT, vPvB | 4 | 4 | 4 | | |
| **Total** | | **191** | **305** | **301** | **215** | **146** |

* 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 2019. 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**

| 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[35] | 2 |
| Restriction process ongoing | 2 | 0 | 2 | 1 | 2 |
| Sent to Commission, but not yet in Annex XVII | 2 | 0 | 5 | 1 | 0 |
| **Total (only the ones with substance scope in Registry of Intentions)** | **7** | **1** | **16** | **4** | **4** |

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

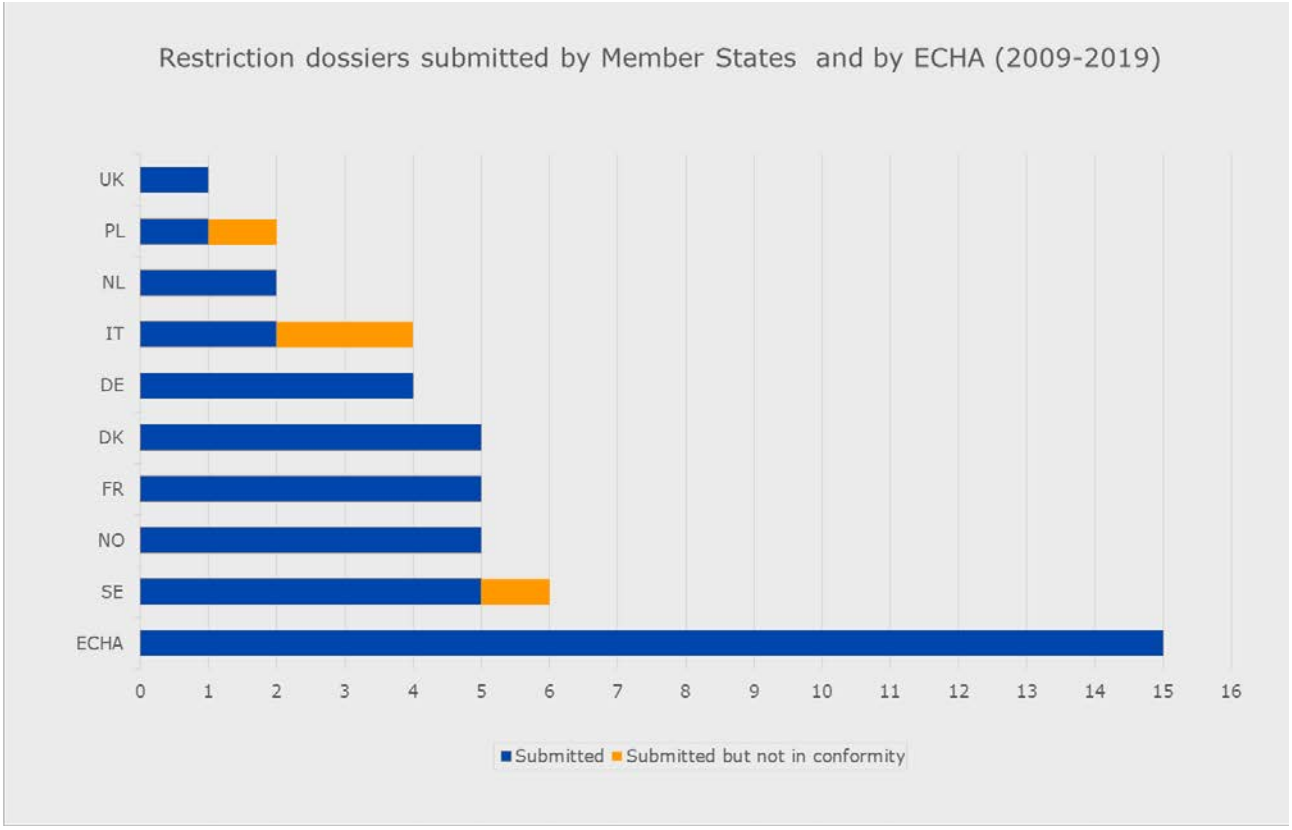



**Figure 7: Number of restriction dossiers submitted by Member States and by ECHA (2009 – 2019.**

[35] One of the substances restricted is chromium VI, which is also a CMR substance but is here only considered as a sensitiser, as this is the scope of the restriction in question (chromium VI in leather articles).

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