ECHA
EUROPEAN CHEMICALS AGENCY

Speeding up the identification of chemicals of concern

Integrated Regulatory Strategy
Annual Report

July 2023

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Speeding up the identification of chemicals of concern - Integrated Regulatory Strategy Annual Report 2023

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LIST OF ABBREVIATIONS

Abbreviation	Description
ARN	Assessment of regulatory needs
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
DEv	Dossier evaluation
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
MSCA	Member State competent authority
OEL	Occupational exposure limit
PACT	Public activities coordination tool
PBT	Persistent, bioaccumulative and toxic
PetCo	Petroleum and coal stream substances
POP	Persistent organic pollutant
QSAR	Quantitative structure-activity relationship
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals
RMOA	Regulatory management option analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very bioaccumulative

1. Foreword

Welcome to our fifth annual report on our Integrated Regulatory Strategy (IRS) We are excited to update you on the progress made in 2022 to identify substances of concern and prioritise them for regulatory action. Our integrated approach aims at a coherent, efficient and effective use of the different regulatory processes on chemicals at EU level.

We have more than 12 000 substances manufactured or imported in the EU above 1 tonne per year, this is what we call the "chemical universe". The size of the task made us shift our focus several years ago to working with groups rather than individual substances to accelerate identification, prioritisation and risk management of substances of concern. This is one of ECHA's strategic priorities as set out in our Multi-Annual Strategic Plan of 2019-23. We have so far assessed around 5 000 substances and identified over 1 400 substances for which further information or eventually regulatory risk management action may eventually be needed. The other substances do not currently require regulatory risk management follow-up, which is also an important outcome. In addition, we also see progress with regulatory actions for groups rather than on single substances, which not only increases the effectiveness of these actions but it also prevents regrettable substitution.

Transparency is one of ECHA's core values; it is fundamental that stakeholders can follow the latest status of their substances of interest; the rationale behind the latest status is explained in the assessments of regulatory needs (ARNs) published on our website. This transparency allows companies to anticipate potential regulatory actions earlier in the process and make strategic choices in their chemicals' portfolio.

ECHA puts chemicals in groups mainly based on chemical similarity to ascertain which are the relevant concerns for the group and which can be the appropriate next steps to clarify such concerns or eventually take regulatory action. The groups evolve over time as additional information becomes available; other refinements occur in the context of the regulatory processes under the REACH and CLP regulations. In the context of these processes there are well-defined possibilities for stakeholders to provide input.

I also want to mention that this work needs concerted efforts from authorities involved and we are working closely with the Member States and the European Commission. We are gathering experience from these processes assessing whether the regulatory processes and resulting actions are increasingly impactful. As in previous years, we continue to optimise and adapt our work to make it more effective in meeting the goals.

During 2023, we will initiate the review our integrated regulatory strategy to take stock of the achievements and progress to-date and to align with the future ECHA's priorities and strategic focus; the new policy goals under the Chemical strategy, such as "one substance, one assessment" or the new tasks to be re-attributed

to ECHA are new elements to be considered in this review. We aim to consult our stakeholders as we progress this review.

Meantime I invite you to dive further into this report and check the progress we have made.

Ofelia Bercaru

Director of Prioritisation and Integration

2. Executive summary

ECHA's Integrated Regulatory Strategy (IRS) continues to accelerate the identification and prioritisation of groups of substances of concern, the generation of data where necessary, and progressing risk management actions aiming that different regulatory processes under REACH and CLP are coherently, effectively, and efficiently used. The good collaboration between ECHA, Member States and the European Commission is a vital part of the delivery of the IRS.

The process to group chemicals and assess the corresponding need for regulatory action is iterative. It enhances authorities' consistency and coherence in their regulatory actions as they target similar substances at once. It also enables using all available data to cover a bigger share of registered substances, including those for which hazard and exposure information is not available, thereby avoiding unnecessary animal testing.

The grouping is mainly based on structural similarity, associations made by the registrants between substances through read-across and category approaches and category associations from external sources (e.g. OECD categories). These methods are different from grouping as defined in information requirements for registered substances in Section 1.5 of Annex XI to REACH regulation, because the scope is different: our aim with the groups is to be able to efficiently and effectively scrutinise the thousands of chemicals in our database, supporting a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The initial assessment is largely based on the information available in the REACH registrations. Very often, further data generation through dossier evaluation is suggested first, to confirm a suspected hazard. In addition, the possible ultimate regulatory risk management action is suggested if the potential identified hazards would be confirmed after further data generation. Regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group.

The assessment of regulatory needs reports are published in the public activities coordination tool (PACT) on ECHA's website. This brings transparency to the authorities' considerations and makes it easier for companies to predict the actions regulators are planning and, where relevant, helps them make strategic decisions on their chemical's portfolios. In 2021, we initiated publication of reports on the assessment of regulatory needs for the groups and substances and will continue disseminating such reports once finalised internally.

During 2022, we initiated assessments for around 2 000 substances in 61 groups. Of these, around 500 are registered under REACH above 100 tonnes per year.

Reducing information gaps is essential to conclude on the regulatory needs for groups of substances. By the end of 2022, we selected almost 300 substances for compliance check. For most of these there is a suspicion that they may have hazardous properties, but the available data is not sufficient to conclude and more information needs therefore to be generated.

During 2022, we have identified nearly 500 substances where the initial screening identified the potential need for risk management. For nearly 200 of these, risk management actions, mainly harmonised classification and labelling, could eventually be already considered, based on the available information. For the remaining 300, further data generation is needed to confirm the suspected hazard before eventually considering risk management. Over 750 substances assessed in 2022 do not require further risk management action. However, for around 150 of these, further data is still needed to confirm this – either on the substance itself or for a related substance.

During 2019-2022, we assessed around 5 000 substances in groups. Based on group assessments, around 60 % of substances do not need further regulatory risk management as they seem to have low hazard, low exposure potential or there are already sufficient risk management measures in place. Further EU regulatory risk management actions may ultimately be necessary for nearly 30 % of the substances assessed, however, the vast majority would require first confirmation of the suspected hazards through data generation. For the remaining 10 % of the substances, further data generation would be needed before making any assumptions on their any potential hazards; however, for some of these further information cannot be requested within the REACH processes (e.g., due to low tonnage of those substances).

Restrictions under REACH have already focused on groups of substances and progress has been made for several groups listed in the Restriction Roadmap. Among others, ECHA submitted a restriction proposal for EU-wide restriction on the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams, due to their persistence and potential to cause environmental contamination in soil and drinking water. More and more Member States are now also concentrating their efforts into proposing groups of substances to harmonised classification and labelling. Member States and ECHA agreed to work closely together and continue discussions to build further experience in developing group proposals for harmonised classification. These activities will continue in 2023 and it is expected that intentions for some of the groups will be announced in the course of 2023.

During 2023 we will further analyse the best way to approach any remaining (groups of) substances, including substances where the current approach may not lead to an efficient use of EU resources or simply not be effective in confirming their potential hazards.

3. Introduction

3.1 Addressing substances of concern efficiently

This is ECHA's fifth annual report in its Integrated Regulatory Strategy and presents the achievements and state of play of its implementation in 2022.

The strategy provides a coherent basis for close collaboration between ECHA, Member States, and the European Commission to address substances of concern with appropriate and timely interventions. It aims to accelerate the identification of groups of substances of concern, data generation, and regulatory action on them.

The work carried out under the Integrated Regulatory Strategy contributes to chemicals management in the EU. Other regions can use or adapt the published results for their own purposes. This will, in turn, contribute to reaching the United Nations' 2030 Sustainable Development Goals concerning chemicals. The strategy also brings added value to the Commission's Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS)[1], as the sound management of chemicals depends on the ability of the EU and its Member States to make their decisions based on robust, relevant and up-to-date knowledge.

3.2 Integrated processes to achieve the goal

Under the Integrated Regulatory Strategy, several regulatory processes are used by authorities to efficiently identify and address substances of concern (see Figure 1).

Assessing groups of chemically-related substances and their regulatory needs is an iterative, informal process, linking the regulatory processes under REACH and CLP. It helps authorities to decide the most appropriate way to address an identified concern including further data generation when needed and decide whether further regulatory risk management activities are necessary.

Data generation clarifies whether a substance has hazardous properties. The main tools for generating missing hazard information are compliance checks, testing proposals and substance evaluation.

The **regulatory risk management measures** to confirm hazards under REACH and CLP are harmonised classification (CLH) and identification as a substance of very high concern (SVHC). A substance is normally proposed for harmonised classification and labelling if it meets the criteria for carcinogenicity, mutagenicity and toxic for reproduction (CMR) or respiratory sensitisation. Whereas a substance can be identified as an SVHC and placed on the Candidate List if it meets the criteria for a CMR substance, a PBT/vPvB substance, or a substance that gives rise to an equivalent level of concern as such substances, for example, endocrine disruptors.

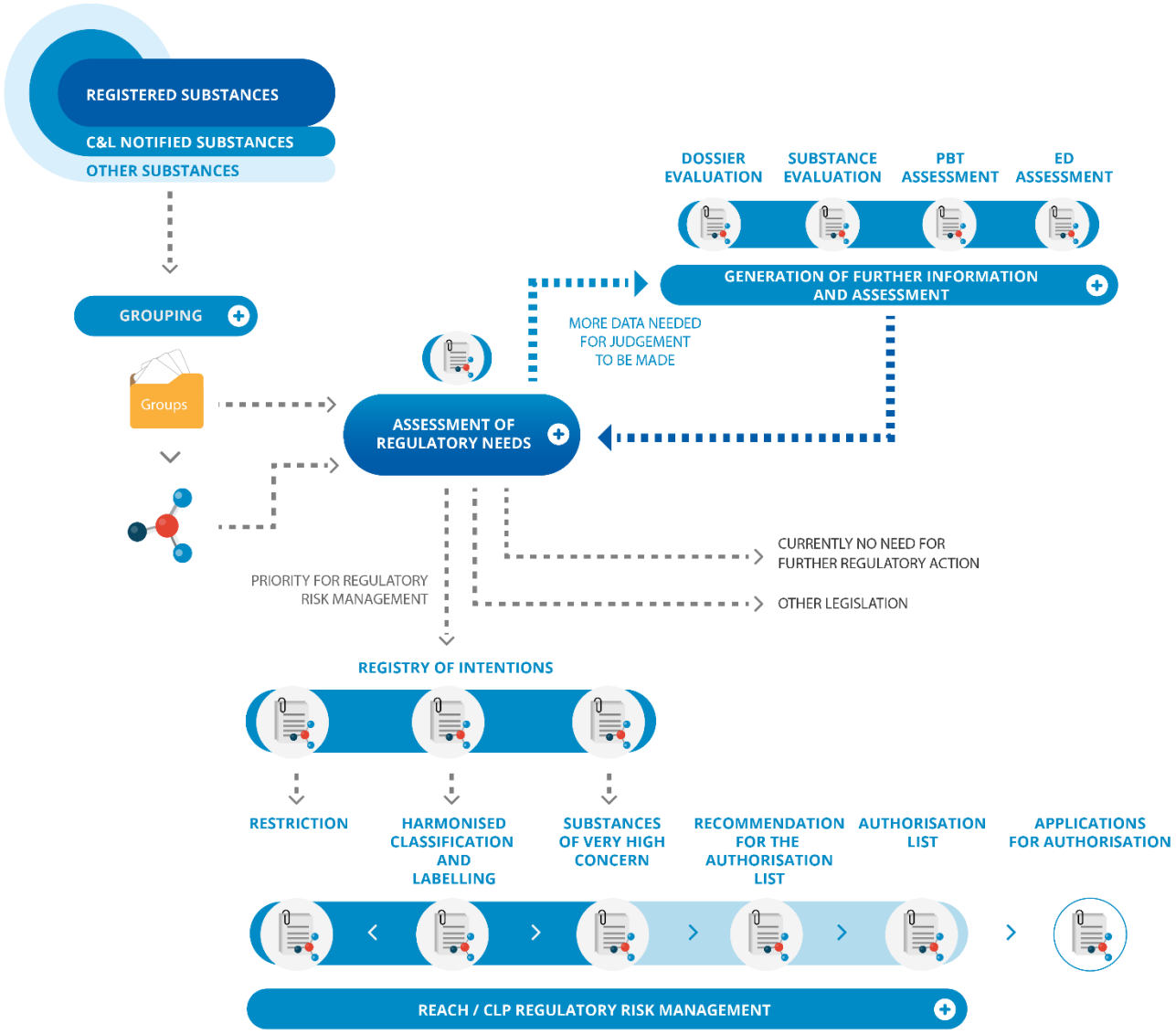
Harmonised classification and inclusion in the Candidate List have important consequences for company-level risk management and they trigger or enable authorities to take further regulatory risk management. Under REACH, authorisation and restrictions are the two main further **regulatory risk management tools**.

[1] Chemicals strategy (europa.eu)

Stakeholders are informed about a substance entering regulatory risk management in the registries of intentions'[2][3][4] and the public activities coordination tool (PACT)[5]. More recently, several groups of substances identified through the IRS have been included in the restrictions roadmap that was adopted and published by the European Commission[6].

[2] Registry of CLH intentions until outcome - ECHA (europa.eu)
[3] Registry of SVHC intentions until outcome - ECHA (europa.eu)
[4] Registry of restriction intentions until outcome - ECHA (europa.eu)
[5] PACT - Public Activities Coordination Tool - ECHA (europa.eu)
[6] DocsRoom - European Commission (europa.eu)

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



[7] Interactive version available at: Addressing substances of concern - ECHA (europa.eu)

4. The universe of registered substances

4.1 Enhanced transparency on addressing substances of concern

The **chemical universe**[8] assigns all substances registered under REACH to a pool that indicates the regulatory actions already initiated or being considered for that substance (see Figure 2 and Table 1). It helps national authorities, ECHA and the European Commission monitor the progress made in identifying substances of (potential) concern and the appropriate regulatory actions

In the chemical universe, each registered substance is allocated to one[9] of the following regulatory pools:

Data generation: This pool contains substances that require additional information or assessment before it is possible to identify whether further regulatory action should be proposed. These include, for example, substances currently under compliance check or testing proposal examination or under substance evaluation, substances being assessed by the PBT and ED expert groups, and substances addressed by the Petroleum and Coal stream working group (PetCo). This pool also includes those substances where authorities have identified the need for further data generation or assessment, but where the action has not yet started. These pending cases may come from substance or dossier evaluation, PBT/ED assessment, or Regulatory management option analysis (RMOA) or assessments of regulatory needs by authorities.

Assessment of regulatory needs: Substances included in this pool are those with ongoing assessments of regulatory needs of (groups of) substances by ECHA or Member States, in preparation for possible formal regulatory processes. These are informal assessments with a high throughput, especially for ECHA's assessments. Most substances will only remain in this pool for a relatively short time and will then move for example to the 'data generation' pool or the 'currently no need for further action' pool. If a need for regulatory risk management is identified, these substances will be mapped to the 'risk management under consideration' pool. However, in case the assessment of regulatory needs cannot be finalised due to ongoing work (e.g., data generation for a related substance), some substances may remain in this pool for a longer period.

Regulatory risk management under consideration: This pool includes substances that are currently being considered for regulatory risk management. For the majority of substances in this pool, authorities have identified that further regulatory risk management might potentially be needed, but this action has not yet been initiated. Cases may be identified following assessment of regulatory needs, substance or dossier evaluation, PBT/ED assessment or Regulatory management option analysis (RMOA) carried out by authorities.

In addition, this pool includes for example, substances listed in the Registry of intentions for substances of very high concern (SVHC), restrictions under REACH or harmonised classification and labelling under CLP.

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[8] Universe of registered substances - ECHA (europa.eu)

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

Regulatory risk management ongoing: This pool contains substances where severe regulatory risk management measures are already in place. For most of these substances, additional EU level regulatory actions are in general not justified. However, for some substances in this pool, there may still be significant work required at EU level (for example, prioritisation on the Authorisation List or a restriction for use in articles according to Article 69(2) of REACH).

This pool includes, for example, substances on the Candidate List, most substances restricted under REACH (excluding, for example, CMR substances restricted in consumer products), active substances in biocides and pesticides, and substances identified as persistent organic pollutants (POPs).

This pool also includes substances that have a harmonised classification on Annex VI to CLP as CMR in categories 1A or 1B, or as respiratory sensitisers in any category. These classifications are severe and trigger several downstream consequences and, therefore, regulatory risk management can be considered ongoing. However, if there are any additional risk management measures under consideration or further data generation ongoing, the classified substances are mapped in the other pools to highlight this.

Currently no further actions proposed: Authorities review many substances under different processes (e.g. substance or dossier evaluation, PBT/ED expert group assessment, and RMOA or assessment of regulatory needs by authorities) and may identify that currently there is no need for further regulatory action. This is due to low hazard or low potential for exposure, considering that in general company-level risk management measures are sufficient.

This pool also includes substances where ECHA has received a proposal for harmonised classification and labelling under CLP, and the Committee for Risk Assessment (RAC) has concluded on a harmonised classification for categories other than CMR in categories 1A or 1B, or as respiratory sensitisers in any category.

Substances addressed under the Existing Substances Regulation, which have not been mapped to other pools, are also included here as they were reviewed by authorities.

Not-yet-assigned: This pool includes substances registered under REACH that remain to be screened and assessed before they can be assigned to other pools.

Figure 2: REACH chemical universe at the end of 2022: substances with active registrations above 1 tonne per year

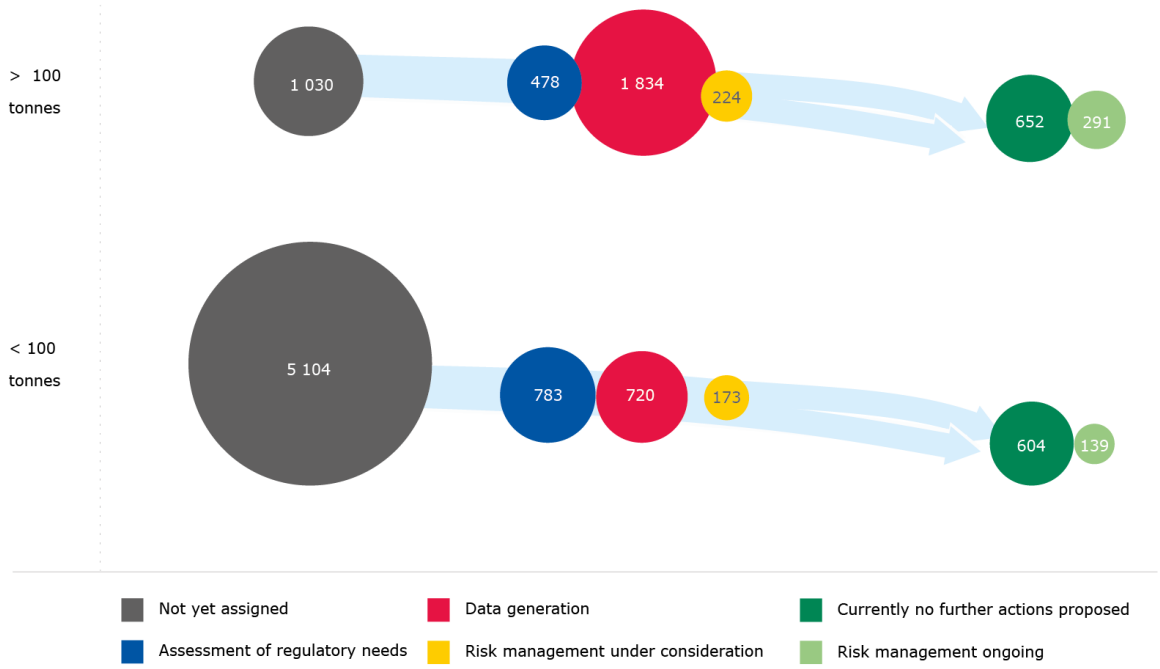


Table 1: REACH chemical universe by the end of 2022: all substances

REACH CHEMICAL UNIVERSE. ALL SUBSTANCES						
Registration status and tonnage	**Not-yet-assigned**	**Assessment of regulatory needs**	**Data generation**	**Regulatory risk management under consideration**	**Regulatory risk management ongoing**	**Currently no further actions proposed**
>100 tonnes per year	1030	478	1834	224	291	652
1-100 tonnes per year	5104	783	720	173	139	604
Intermediate	6053	386	82	78	67	434
Not disseminated	2586	236	122	36	90	169
Total	14773	1883	2758	511	587	1859

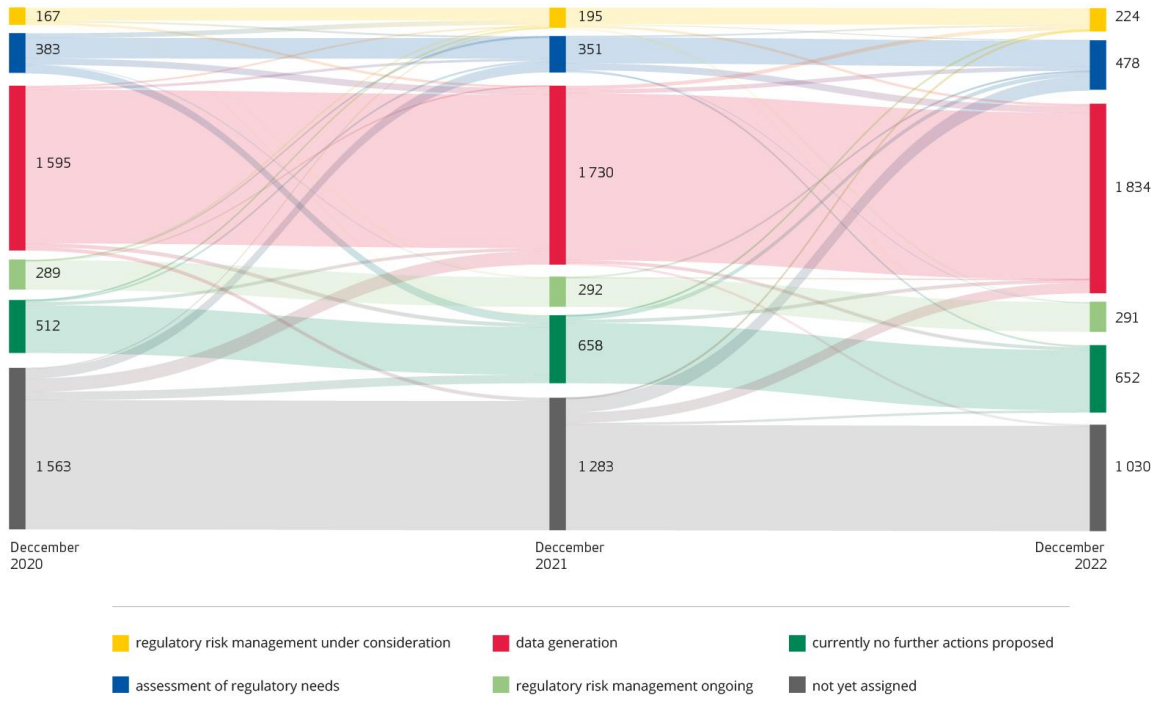
> 100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage above 100 tonnes per year.
1-100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage between 1 and 100 tonnes per year (and which are not covered by the above).
Intermediates: Substances for which there is at last one active registration for intermediate use under Articles 17 or 18 of REACH (and which are not covered by the above).
Not disseminated: Substances registered under REACH for which the tonnage band is not publicly available.

4.2 Progress in allocating substances

The most recent chemical universe mapping presents a snapshot of the allocation of REACH registered substances to the different regulatory pools as of December 2022 (see Table 1 and Figure 2 above).

Figure 3 shows the dynamic nature of the mapping, as substances move from one pool to another with the regulatory processes being initiated. When comparing the allocation of substances registered above 100 tonnes per year between December 2020 and December 2022, the most visible development is the substantial progress made in clearing the 'not-yet-assigned' pool. From this pool, nearly 600 substances were moved to other pools, largely due to ECHA's assessments of regulatory needs of groups of substances.

Figure 3: Flow of substances registered above 100 tonnes per year from December 2020 to December 2022



Substances have mostly moved to the 'data generation' and 'assessment of regulatory needs' pools, where, in particular for the latter, the high turnover and high number of substances addressed by ECHA's assessment of regulatory needs work is visible. Similar trends can be seen for lower tonnage substances in the chemical universe.

The regulatory needs of 1 030 substances registered above 100 tonnes per year still need to be assessed, as they have not yet been assigned to any regulatory pool in the chemical universe.

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

that have been corrected. It can as well relate to finalised compliance checks where the assessed endpoints did not allow an overall conclusion on relevant hazards[10] to be drawn.

[10] For example, physicochemical endpoints assessed in a compliance check are not considered in the chemical universe mapping, based on the assumption that (non)compliance for these endpoints alone does not provide sufficient grounds to conclude on a substance's (potential) hazards on human health and environment.

5. Assessment of regulatory needs

5.1 Assessment of groups of substances continues with high output

ECHA and Member States have continued assessing groups of structurally similar substances. Most assessments are carried out by ECHA.

Through grouping and assessment of regulatory needs, ECHA aims to systematically screen all substances in the database and identify where there is a need for regulatory action as well as where no further action is needed.

The aim of assessing substances in groups is to:

- ensure consistency and coherence in the regulatory actions proposed for similar substances,
- ensure that the risk management actions are taken timely and whenever possible at group level, avoiding thereby regrettable substitution,
- avoid unnecessary animal testing and use all data available and follow a precautionary approach to conclude, whenever possible, on the need for regulatory action at group level.

The assessment of regulatory needs is in essence a screening exercise with high throughput. In this context, ECHA grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories).[11] These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals.

The outcome of these assessments are proposals for immediate (the first action) and subsequent follow-up regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential identified hazards are confirmed. These actions are identified based on available information on hazards and use. Very often, further data generation through compliance check is suggested as a first action, to confirm the identified hazard concern.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout

[11] Working with Groups - ECHA (europa.eu)

the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs itself does not represent a regulatory action but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances. It is an iterative process which does not aim to have the same level of precision as the subsequent regulatory processes where groups, concerns and regulatory decisions are clarified via well-established processes and where input from all stakeholders is foreseen.

Overall, the progress with these assessments remains at a high pace. In 2022, the assessment was initiated for 61 groups, comprising a total of around 2 000 substances. Of these, nearly 500 had been registered above 100 tonnes per year. Since the beginning of this work in 2019, ECHA has assessed around 5 000 substances via its work on groups.

ECHA publishes the assessment of regulatory needs reports in the public activities coordination tool (PACT)[12] on ECHA website. In 2022 we published reports for 63 groups assessed by ECHA, covering around 1 600 substances. These included a group of 148 bisphenols, of which more than 30 are potential candidates for restriction because of endocrine disruptive (ED) or reprotoxic effects, and 52 hydroxycarbyl siloxanes, for which restriction may be considered due to persistent and bioaccumulative properties. However, for many substances in these groups, hazards need to be confirmed before risk management can be initiated.

Publication of assessment of regulatory needs reports brings transparency to the authorities' considerations and makes it easier for companies to predict the actions regulators are planning and, where relevant, helps them make strategic decisions on their chemical's portfolios as well as enabling companies responsible care and company level risk management.

Further information on the assessment of regulatory needs and ECHA grouping of substances can be found on the ECHA Questions and Answers webpage[13].

5.2 Assessment of groups facilitates identification of potential substances of concern

ECHA suggested potential regulatory risk management actions at EU level for 36% of substances assessed in 2022. Figure 4 shows the distribution of the potential last foreseen regulatory risk management actions in cases where hazards for these substances are/will be confirmed. Most of these substances first require data generation and confirmation of hazard (e.g. through harmonised classification and labelling or SVHC identification) and only if the hazard will be confirmed, they can progress to further regulatory risk management actions, e.g. authorisation, restriction (see examples in Box 1 and 2 in Section 4). These include many potential CMRs (mostly potential reproductive toxic substances), and a few potential PBTs and EDs. For the majority, restriction is foreseen as the potential last regulatory risk management action.

[12] PACT available at: PACT - Public Activities Coordination Tool - ECHA (europa.eu)
[13] Questions and Answers webpage (please choose "Assessment of regulatory needs" as Scope and under it you can find for example Chapter 2: Grouping. Also a recorded ECHA webinar on "Assessing groups of chemicals: what you need to know" is available).

From all substances assessed in 2022, we have identified nearly 500 substances that potentially require further regulatory risk management (harmonised classification and labelling, restriction, SVHC identification). For nearly 200 out of these, the data appears to be already sufficient to proceeded with these actions while for nearly 300, data needs to be generated before a firm conclusion on the need for further regulatory risk management can be made. For around 750 substances there is currently no need for further regulatory risk management action because it is considered that they are of low hazard, low exposure or because sufficient risk management is already in place. For some of these substances, generation of data (in most cases compliance check) has been suggested as the immediate follow-up action (next regulatory action) to confirm low hazard, whereas for others, data generation is already ongoing on the substance itself or for a related substance. Figure 5 shows the distribution of the proposed immediate follow-up (regulatory) actions (the next foreseen regulatory action) for substances assessed in 2022 (see Figure 5).

Figure 4: Last foreseen regulatory risk management action proposed for substances based on assessments of regulatory needs carried out in 2022

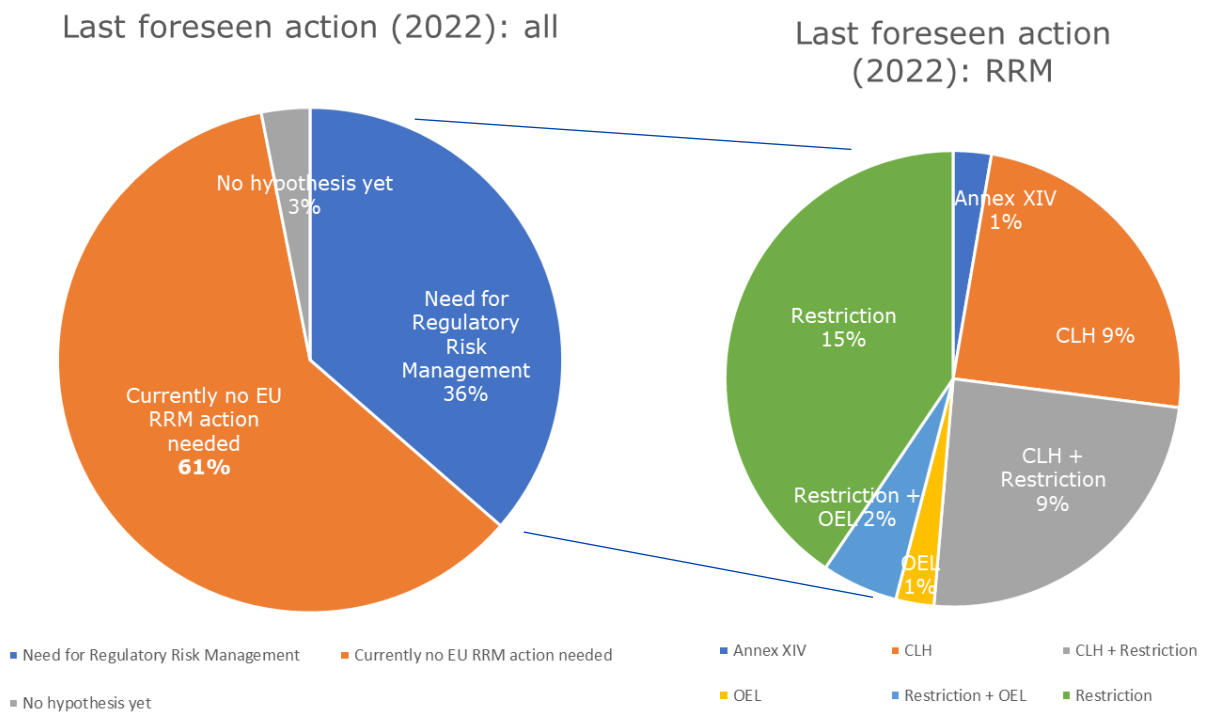
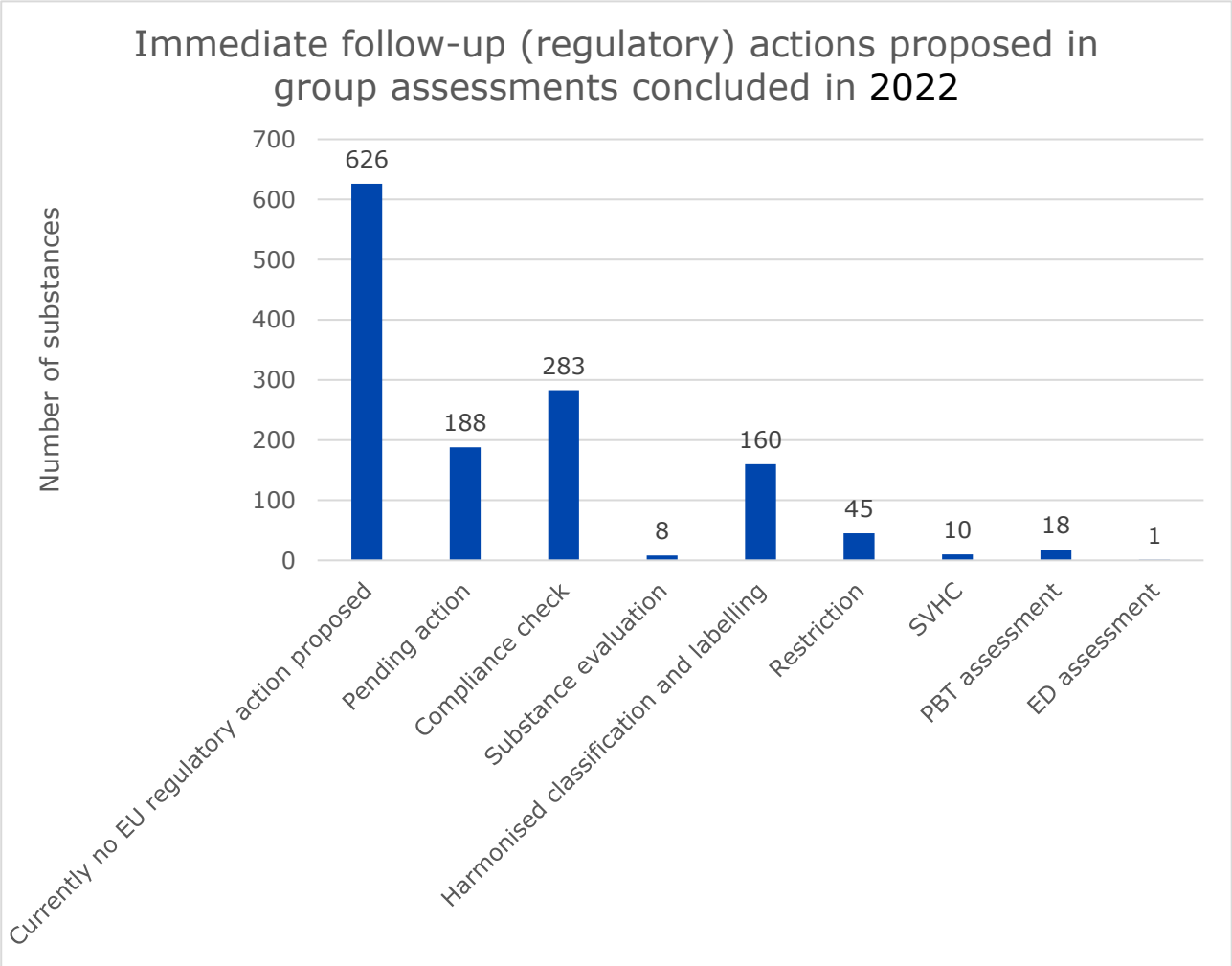


Figure 5: Immediate follow-up (regulatory) actions proposed in assessments of regulatory needs concluded in 2022



Besides the assessments of regulatory needs done by ECHA to identify substances of potential concern, Member States initiated an analysis of the most appropriate risk management measures (RMOA=risk management option analysis) for seven substances in 2022.[14]. They also concluded RMOAs on 13 substances and one group of five substances. SVHC identification was proposed as the next regulatory action for 11 substances, harmonised classification and labelling for 5 and restriction for 1 substance. For one substance it was concluded that there is currently no need for further action.

[14] Assessment of regulatory needs list - ECHA (europa.eu)

5.3 Gaining experience in assessing groups of complex UVCB substances[15]

In 2022 ECHA started also assessing groups containing mainly complex UVCB substances.[16] Due to their complex and variable composition, the assessment of such groups is in general more demanding compared to groups of mainly well-defined substances. The uncertainty related to the potential hazard and appropriate regulatory risk management measures is in general higher, mainly due to:

- variability and insufficient granularity of information on composition, which hampers adequate hazard assessment (e.g., of PBT properties), assessment of substance similarity and read-across,
- low data density within the groups and extensive use of read-across by registrants (in many cases not adequately justified),
- lack of information on testing material for the available studies.

Adequate information on composition is crucial for hazard assessment and to decide on the most appropriate (regulatory) risk management actions. To identify the constituents of concern and define an appropriate testing strategy or evaluate whether a testing strategy proposed by registrants is appropriate, sufficient data on the composition is needed, often beyond what is normally required for assessing substance identity.

ECHA's and Member States' experience from evaluation processes shows that the information on composition provided and considered by the registrants in their assessments is often not sufficient for an appropriate hazard assessment, in particular for the PBT assessment and read-across justifications. This was confirmed also in the context of the above-mentioned assessments of regulatory needs. Such deficiencies lead to incompliance of information requirements, delays in data generation to clarify the hazards and in taking appropriate (regulatory) risk management actions, where necessary. For UVCBs, targeting regulatory risk management action to constituent(s) of concern is often the preferred approach. Since the same constituent can be present in many substances, we need to address them holistically for the regulatory action(s) to be effective.

Over the years, ECHA has collected learnings from addressing UVCB substances. In some cases, it appears to be difficult to conclude on the need for regulatory risk management for such substances as the current regulatory framework may not provide sufficient tools. These learnings have been communicated to the European Commission and Member States for consideration under the ongoing review of the chemicals legislation.

[15] UVCB substances: substances of Unknown or Variable composition, Complex reaction products or Biological materials.
[16] Amphoacetate and amphopropionate derivatives of N-hydroxyethylimidazolines

6. Substances under data generation

6.1 Robust and relevant information on chemicals is needed

As outlined in ECHA's Programming Document 2022-2025[17], evaluation processes under REACH are key building blocks of the integrated regulatory strategy. They primarily ensure the availability of hazard data on substances, which increases knowledge on these substances and, more broadly, the chemical groups they may belong to. This in turns leads to improved risk management by industry and the authorities, as well as contributing to the chemicals' assessment as outlined in the European Commission's Chemicals Strategy for Sustainability[18].

Until the end of 2022, ECHA had identified that around 1800 substances registered above 100 tonnes/year, need further data generation. Around 400 of them were identified in 2022. This includes substances for which data generation is ongoing and those for which it needs to be initiated.

In 2022 ECHA selected 294 substances, representing 46 groups, for compliance check. For almost 70 % of them there is suspicion that they may have hazardous properties, but the available data is not sufficient to conclude, or the data does not allow making any hypothesis on the potential hazard. For the remaining substances, it is considered, based on the available data, that hazard is unlikely, however further data is still needed to confirm the low hazard for the substance itself and/or for the (sub-) group to which this substance belongs.

[17] ECHA Programming Document(s) 2022-2025 (europa.eu)
[18] Chemicals strategy (europa.eu)

6.2 Constant flow of substances to data generation

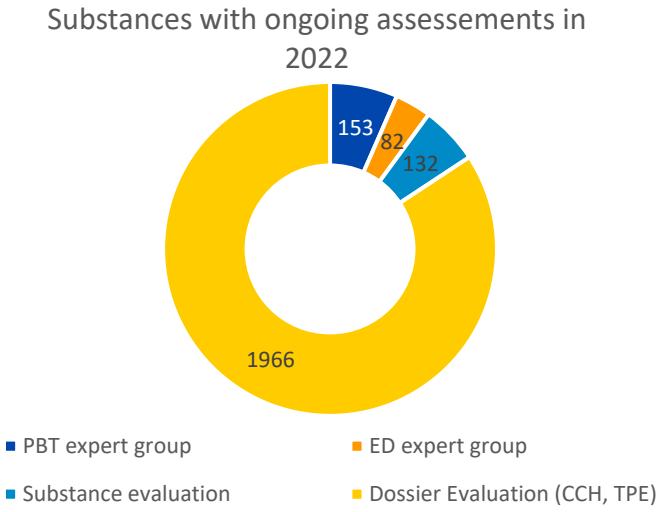


Figure 6: Number of substances with an ongoing assessment in dossier, substance evaluation or the PBT and ED expert groups at the end of 2022

By the end of 2022, more than 2300 substances were at different stages under dossier evaluation (from the preparatory steps until the follow-up evaluation phase), substance evaluation or in one of the expert groups (Figure 6).

This means that for each of these substances:

- an assessment is under way; or
- missing information is being requested or generated by registrants; or
- authorities are assessing the information submitted by registrants.

Some substances in Figure 6 are counted more than once, if more than one data generation or PBT or ED assessment process is on-going at the same time.

6.3 Progress in data generation in 2022

Compliance checks, examination of testing proposals and substance evaluation are the regulatory processes under REACH where ECHA can request generation of missing data.[19]

In 2022, ECHA adopted 252 compliance check decisions addressing 1 612 information requirements for which data gaps were identified. In addition, the Agency adopted 169 testing proposal decisions addressing 347 information requirements for which testing was originally proposed.

The list of substances evaluated under dossier evaluation in 2022 was published on ECHA website. This list includes full details on the information requests that have been issued to companies as part of ECHA's decisions[20], adopted under dossier evaluation processes.

Substance evaluation allows generation of data beyond standard information requirements when a potential risk posed by a substance needs to be clarified. Under substance evaluation, ECHA in collaboration with Member States adopted 9 decisions requesting further data in 2022.

[19] Evaluation process - ECHA (europa.eu)
[20] List of substances evaluated and requests issued in 2022

As their contributions to the decision-making process and further testing requests, during 2022, the PBT and ED expert groups gave scientific advice[21] on 17 cases concerning PBT properties and 17 cases concerning ED properties of substances[22].

6.4 Newly generated data contributes to identification of substances with severe hazardous properties

In 2022, hazard data was received for more than 240 substances in response to compliance check and testing proposal decisions sent in previous years. The 'top five' endpoints for which further information was submitted to ECHA under dossier evaluation were pre-natal developmental toxicity and toxicity to reproduction followed by sub-chronic toxicity (90-day) studies, studies on in vitro genotoxicity, and toxicity to aquatic algae and cyanobacteria.

Dossier evaluation is essential to ensure that data is available to enable hazard assessment, identification of hazardous substances and proper risk management. For around 20 % of dossier evaluation cases completed between 2020-2022, the results of the data generated suggest the need for potential risk management actions, for example the need for harmonised classification and labelling, particularly due to reproductive concerns.

Examples where newly generated data under dossier and substance evaluation led to identification of severe hazardous properties are presented in Boxes 1 - 2 below.

Information of the overall progress of compliance checks, testing proposal examinations and substance evaluations between 2009 - 2022 is presented in Annex 2 as well as on ECHA's website.[23]

[21] Expert group opinions are informal advice given to Member States that are assessing substances and generally consist of advice on ED/PBT properties, testing strategies or information needs.
[22] These numbers also include some substances discussed in the context of the Biocidal Products Regulation and the Persistent Organic Pollutants Regulation.
[23] Progress in evaluation - ECHA (europa.eu)

Box 1. Newly generated data leading to a proposal for stricter classification for reproductive toxicity

Substance : 2-ethyl-2-(hydroxymethyl)propane-1,3-diol (EC: 201-074-9)

This substance is widely used by consumers and professional workers for example in adhesives, sealants, paints, coatings, where high potential for exposure can be expected.

ECHA carried out a compliance check and requested an extended one-generation reproductive toxicity study (EOGRTS) which was missing from the dossier with unjustified reasons. The provided study showed effects which further support a stricter classification for developmental toxicity.

Malformations had already been observed in available prenatal developmental toxicity studies (mainly skull and brain malformations together with increase in post-implantation loss). Based on that, the registrants self-classified the substance as Repr. Cat 2 for reproductive toxicity.

The results of the requested EOGRTS also showed clear and consistent effects on development (reduced post-implantation survival, decreased pup weights and viability, macroscopic findings in the brain/skull and/or eye reported in the cohorts 1A, 1B and F2), strengthening the evidence for severe reproductive toxicity properties. It has been therefore concluded that the classification in Category 1B for development would be justified.

Consequently, in agreement with ECHA's conclusion, Finland submitted in May 2022 an intention to prepare a dossier for harmonised classification and labelling, proposing a classification as Repr. 1B, H360D.

If harmonised classification as Repr. 1B will be confirmed through the CLH process, it will have direct effect on certain uses of this substance. For example, this will require company level risk management measures (RMM) for workers to be in place and restrict the presence of the substances in consumer mixtures under REACH legislation.

Box 2. Newly generated data confirmed substances as very persistent and very bioaccumulative

Substance: 4,4'-methylene bis(dibutyldithiocarbamate) (EC 233-593-1)

The substance has widespread uses by consumers and professional workers, including e.g. in lubricants, greases, hydraulic fluids, with high potential for exposure to the environment. The substance was originally included by the German Member State Competent Authority (evaluating MSCA) in the Community Action Plan (CoRAP) for Substance Evaluation (SEV) to clarify concerns related to its potential PBT/vPvB properties. Since the CoRAP inclusion, generation of information related to i.a. the degradation and bioaccumulation properties of the substance has been required by ECHA under compliance check.

ECHA opened a concern-driven compliance check (suspected PBT/vPvB) and requested simulation studies, data on bioaccumulation and long-term toxicity to fish. Based on newly generated data, ECHA concluded the substance may be a vPvB (the T remaining inconclusive at this stage). This conclusion has been supported by the PBT EG and the evaluating MSCA without the need to further initiate a substance evaluation process. Therefore, it was proposed to confirm the vPvB properties via SVHC identification as next regulatory action.

Link to Summary Report of the PBT Expert Group Meeting: 466ce7a9-c507-d085-f218-9c7f6b31abbf (europa.eu)

Substance: Octamethyltrisiloxane (L3) (EC 203-497-4)

The substance has high potential for exposure to the environment, professional workers and consumers from widespread uses, e.g. in cosmetics, personal care products, washing and cleaning, polymers and articles. The substance was included in CoRAP to clarify concerns related to its potential PBT/vPvB properties. Following evaluation of the available information, a simulation study and further information on the exposure assessment were requested by ECHA under substance evaluation to clarify the concern.

Based on the newly generated data, the evaluating MSCA (Norway) concluded the substance as having vPvB properties and proposed SVHC identification to confirm the vPvB properties and subsequent restriction as follow-up regulatory risk management actions.

This substance is part of the group Hydrocarbyl siloxanes assessed by ECHA, for which a group approach to confirm PBT/vPvB properties, is proposed (see Box 4).

See also: substance evaluation conclusion document:
https://echa.europa.eu/documents/10162/8419cc85-de6a-66e2-94a4-fd99e27e3d2c

See also: Assessment of regulatory needs list - ECHA (europa.eu)

6.5 Continued support for industry initiatives

In line with actions under the REACH evaluation joint action plan24, ECHA continued to support industry initiatives that help companies review their chemical safety data and generate new hazard information[25] voluntarily i.e., without formal compliance check processes.

Under the Cefic-ECHA initiative, ECHA continued the support by giving feedback on groups proposed for voluntary data generation. In general, companies have followed commitments to generate supporting data and submit strategies on groups of substances to ECHA. In some cases, there have been significant delays in data generation particularly due to impacts of covid on test house capacities. Due to such delays, ECHA now expects formal examination of the four initial projects (started 2020) to begin in 2023. In 2021, five more collaboration projects were added and one in 2022. ECHA and CEFIC are encouraging that companies apply the lessons learnt from the collaboration projects to improve their own group-based strategies. There have also been developments which impact their strategies. For example, the changes to the REACH Regulation concerning the need of compositional information to support read across for UVCBs. ECHA expects to be examining the collaboration projects further as they mature in the coming few years. ECHA will keep under review what other support for the collaboration with CEFIC is necessary.

In the context of the Petroleum and Coal stream substances (PetCo) working group, ECHA supported consortia in defining a strategy for generating missing hazard data of petroleum substances. The aim is to ensure that the data generated is fit for purpose (e.g., for filling data gaps and at the same time limiting the use of animal testing) and enables identification of future regulatory risk management needs. More data is needed to describe the chemical composition in detail and to justify the use of current available hazard data between related petroleum substances. ECHA is reviewing with industry the need for submission of testing proposals for all categories, and the associated timelines.

As it will take time to generate hazard data, in parallel petroleum substances have been included in the Restriction roadmap[26] (pool 2) with the view to further investigate the potential risks of petroleum substances used in consumer and/or professional mixtures.

Support provided in recent years to the non-ferrous industry through the Metals and Inorganics Sectoral Approach (MISA) has now been completed. An analysis of dossier updates for metals indicates that around 60 % of substances under MISA have received updates for human health and environmental endpoints – twice the rate of updates for metals not covered under the approach[27]. Overall, a good participation from industry consortia/associations and practical outcomes of the technical and scientific work led to a positive impact on dossier updates. However, some important metal and inorganic substances were missing from the programme and filling some specific data gaps remains an issue as data availability is still low.

[24] REACH Evaluation action plan
[25] Hazard information not subject to testing proposal according to Article 40 of REACH
[26] DocsRoom - European Commission (europa.eu)
[27] MISA Final Report

7. Substances under consideration for regulatory risk management

7.1 Assessments of regulatory needs are the main source of regulatory risk management candidates

By the end of 2022, around 500 substances were mapped to this pool. For the vast majority (nearly 400 substances) the proposed risk management action, in most cases harmonised classification and labelling, has not yet been initiated. For the remaining around 110 substances, at least an intention has been submitted, either for harmonised classification (around 80 substances) or SVHC identification/restriction (around 30 substances). The pool is fed by activities conducted by ECHA or Members States.

In 2022, the assessments of regulatory needs identified nearly 200 substances for possible immediate regulatory action (including some hydrocarbyl siloxanes, (see Box 3 below)). For most of these substances the identified potential action is harmonised classification and labelling.

Evaluation processes also contributed to identification of candidates for regulatory risk management. The assessment of submitted data for 249 substances that were subject to either compliance checks or testing proposal examinations led to the conclusion that for 37 substances harmonised classification and labelling may be appropriate.

Substance evaluation was completed for 31 substances during 2022 and, conclusion documents from the evaluating Member States were published on ECHA website. Of these 31 concluded cases, the authorities recommended further regulatory risk management measures for 18 substances.

7.2 Restrictions more and more focusing on groups of substances

The European Commission published in April 2022 a Restrictions Roadmap[28] covering ongoing and future work on restrictions under REACH. In 2022, ECHA and Member States have played an active role in contributing to the implementation of the roadmap by submitting 5 restriction proposals[29] for groups of substances identified in the Restriction Roadmap (pool 0).

ECHA submitted, on request by the European Commission an EU-wide restriction on the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams due to their persistence and potential to cause environmental contamination, both in soil and drinking water. If adopted, this restriction could reduce emissions of PFASs into the environment by more than 13 000 tonnes over 30 years.

[28] Available here: DocsRoom - European Commission (europa.eu)

[29] Six restriction proposals were submitted in 2022: five addressing group of substances discussed in this section (PFASs in firefighting foams; MCCPs and other substances containing chloroalkanes (C14 to C17); Creosote and Creosote related substances; Bisphenols with endocrine disrupting properties for the environment and their salts; and N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP)), and one addressing an individual substance (Terphenyl, hydrogenated).

In addition, ECHA submitted, on request by the European Commission a restriction proposal on medium-chain chlorinated paraffins (MCCPs) and other substances containing chloroalkanes (C14 to C17). The scope of the restriction, which will cover any substance containing C14-C17 chloroalkane constituents with PBT/vPvB properties, is a concrete example of a grouping-based approach to risk management that aims at ensuring risk reduction by preventing regrettable substitution. The scope of the restriction proposal covers 69 different substances.

In 2022, Member States also contributed to the implementation of the Restriction Roadmap by submitting four restriction proposals. Three out of the four restriction proposals submitted by Member States are on group of substances which have either similar uses or are chemically similar: (i) on Creosote and Creosote related substances, (ii) on Bisphenols with endocrine disrupting properties for the environment and their salts, and on (iii) N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP).

The Risk Assessment Committee (RAC) adopted opinions on restriction proposal for 2,4-dinitrotoluene and 3 restriction proposals identified in pool 0 of the Restrictions Roadmap[30] as groups of substances: (i) substances containing polycyclic aromatic hydrocarbons (PAHs) used in clay pigeons, (ii) lead and its compounds in ammunition for outdoor shooting and in fishing tackle, and (iii) Dechlorane Plus and its syn- and anti-isomers.

[30] Available here: DocsRoom - European Commission (europa.eu)

Box 3: Restriction needs identified by authorities for several hydrocarbyl siloxanes

The assessment of regulatory needs report for the hydrocarbyl siloxanes has been published in November 2022. There are 52 substances in this group, all of which are considered as potential PBT/vPvBs.

The substances have wide dispersive uses, including uses in cosmetics and personal care products, in washing and cleaning products, coatings and paints, leading to a high potential for release to the environment.

The substances are at different regulatory stages, and some are already identified as SVHC for PBT/vPvB properties, having some uses restricted. The placing on the market of D4 and D5 in wash-off cosmetic products (above 0.1 %) is already restricted (entry 70 of Annex XVII to REACH). The European Commission is in the decision-making process for the restriction for use of D4, D5 and D6 in consumer and professional products.

Some substances in the group contain constituents with confirmed PBT/vPvB properties, whereas for some data generation is needed to confirm their PBT/vPvB properties. For some others read-across could be applied to identify them as SVHCs due to their PBT/vPvB properties. The assessment of regulatory needs suggests to first consult the PBT Expert group on the possibility to apply such read-across approaches to identify some further substances as vPvB/PBT.

As the ultimate regulatory risk management action, the assessment of regulatory needs proposes a restriction of all siloxanes for which PBT/vPvB properties are/will be confirmed. The restriction may cover the substances as such, as a constituent in other substance, in mixtures, as unreacted monomers in polymers and in articles used by consumers, professional workers and industrial workers.

See also: Assessment of regulatory needs list - ECHA (europa.eu)

7.3 Preparatory work on-going to progress with groups of substances needing harmonised classification and labelling

As in previous years, the number of (groups of) substances that could potentially proceed to regulatory risk management at EU level continued to grow, in particular for harmonised classification and labelling. ECHA's assessment of regulatory needs was the main source of such candidates. Whenever feasible and appropriate, actions should be considered at (sub)group level and not per (single) substance.

As shown above, restriction already focuses on groups of substances and progress has been made for several groups listed in the Restriction Roadmap. For harmonised classification and labelling, more and more Member States are now also concentrating their efforts into proposing groups of substances. As already stated above, the need to substantiate a group approach for harmonised classification may be different than under restriction. Smaller groups and consolidated information on read-across are often needed to successfully proceed with harmonised classification for a group of substances.

There are currently no examples of groups of substances proposed for harmonised classification as a follow up of the initial screening done by ECHA underassessment of regulatory needs. This is because, in general, Member States would need to consolidate the outcome of the assessment of regulatory needs work to prepare a CLH dossier which can stand the RAC scrutiny. In October 2022, Member States, ECHA, and the European Commission initiated discussions in the context of RiME+[31], on how to best progress groups under harmonised classification and labelling. Member States and ECHA agreed to work closely together and continue discussions to build further experience in:

- developing dossiers for harmonised classification and labelling for groups of substances,
- deciding on the most efficient way forward, i.e. in which cases to proceed with a group proposal and in which cases with single substance or subgroup proposals,

These activities will continue in 2023 and it is expected that intentions for some of these groups may arrive in the course of 2023.

[31] RiME+ (Risk Management and Evaluation) platform - ECHA (europa.eu)

8. Substances with regulatory risk management ongoing

8.1 More substances of concern identified every year

By the end of 2022, regulatory risk management measures are in place for nearly 600 registered substances (50 % of which were registered above 100 tonnes per year). Use of these substances is already subject to ongoing risk management obligations.

Hazards and risks related to the use of these substances have been assessed, and additional EU level regulatory actions are usually not expected. However, for some substances in this pool, there may still be significant work required (for example, prioritisation on the Authorisation List or restriction for use in articles according to Article 69(2) of REACH).

The regulatory actions include:

- Harmonised classification on Annex VI to CLP as CMRs in categories 1A or 1B, or as respiratory sensitisers: these are severe and trigger several downstream consequences. Therefore, regulatory risk management can be considered ongoing. However, if there are any additional risk management measures under consideration or further data generation ongoing, the substances are mapped in the other pools to highlight this;
- Inclusion on the Candidate List of substances of very high concern (SVHCs);
- Substances covered by certain restrictions under REACH;
- Regulated through the POPs Regulation; and
- Approval as pesticidal or biocidal active substances.

More information on substances on the Candidate List, the Authorisation List, or restriction proposals adopted, going through the restriction process, or that were subject to Article 69(2) screening from 2009 until December 2022, is available in Annex 3.

In 2022, the Candidate List was updated with 5 new entries.[32]

ECHA's Committee for Risk Assessment (RAC) adopted opinions proposing harmonised classification for 29 substances registered under REACH, for 17 of those proposing classification for CMR properties.

The size of this pool has been largely stable since 2019.

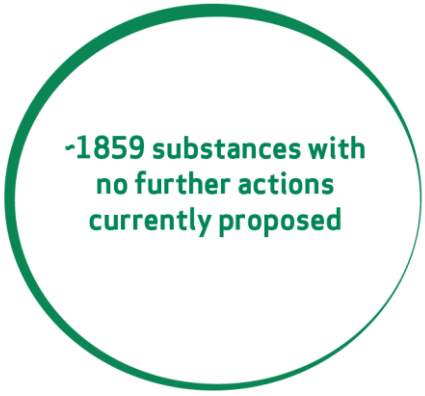
Although a substantial increase in substances in this pool may be expected due to faster identification of potential risk management candidates, through the assessment of regulatory needs work, there are several reasons for this not yet to be the case, including:

[32] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

- For most of the (groups of) substances for which potential need for regulatory risk management was identified, the hazard potentially leading to the regulatory risk management action needs first to be confirmed by generating further data. In most cases it takes several years to generate the relevant data.
- Where the data is sufficient to confirm the hazard, the assessment of regulatory needs itself does not automatically trigger regulatory risk management action. These are expected to be initiated by authorities according to the established procedures.
- Before initiating any such process, the authority may need to carry out preparatory work, including further analysis/assessment to confirm or further define the scope of the regulatory action, preparation of dossiers, etc. This preparatory work is in general more demanding and time consuming when the action is intended for a group of substances.
- Regulatory risk management processes follow well-established procedures and (legal) timelines and may take several years to complete; only when the process is concluded can (groups of) substances move to the "Regulatory risk management ongoing" pool.
- For some substances/groups there may be several subsequent regulatory risk management actions needed (e.g. harmonised classification and subsequent restriction), therefore they may stay in the 'regulatory risk management under consideration' pool until all these processes are concluded.
- The limited capacity in the Member States and also in ECHA Committees which issue opinions.

Based on the above it is expected that it will take still some years before significant impact of the assessment of regulatory needs work will be reflected in the number of substances in this pool.

9. Substances with no further action currently proposed



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

By the end of 2022, for 1 859 registered substances it has been concluded that currently there is no need for further EU regulatory risk management action. This conclusion is based on assessments carried out during compliance check, substance evaluation, RMOA, or assessments of regulatory needs. The hazards and uses of substances in this pool do not raise concern to justify regulatory actions at EU level. The two main reasons for allocating a substance to this pool are:

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

In addition, this pool contains also hazardous substances which are currently considered sufficiently regulated.

The number of substances in this pool has been steadily increasing, by over 400 during 2022 alone, with ECHA's assessments of regulatory needs being the main driver, accounting for around 75 % of the substances in this pool. 35 % of the substances in this pool were registered at a volume of at least 100 tonnes per year.

Table 4: The source activity where the outcome of currently no need for further EU regulatory risk management was proposed

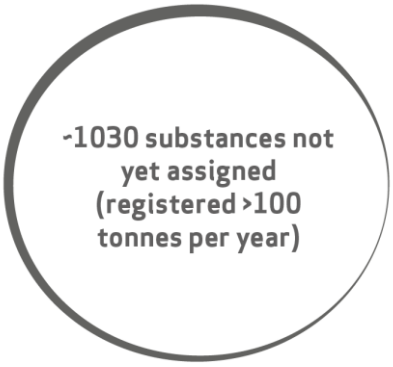
SUBSTANCES WITH NO FURTHER REGULATORY ACTION CURRENTLY PROPOSED AFTER REVIEW IN DIFFERENT ACTIVITIES	
Activity	**Proportion**
RMOA / assessment of regulatory needs	76%
Compliance check	20%
Substance evaluation	1%
PBT/ED expert group assessment	0%
Other	3%

As depicted in Figure 3 in section 2, some substances have also moved from the 'currently no further actions proposed' pool to other pools of the universe. This is usually due to the assessment of regulatory needs work.

Differentiating between substances needing and not needing further EU regulatory risk management is crucial for addressing substances of concern efficiently as it allows authorities to focus their resources on substances that matter. Identification and transparent information on substances of low hazard would potentially help developing safer materials and moving away from the use of hazardous substances.

10. Substances in the 'not-yet-assigned ' area

10.1 Progress in mapping and grouping the not-yet-assigned pool



The pool of substances that still require an initial screening and assessment, the so-called "not-yet- assigned pool" continued to shrink during 2022.

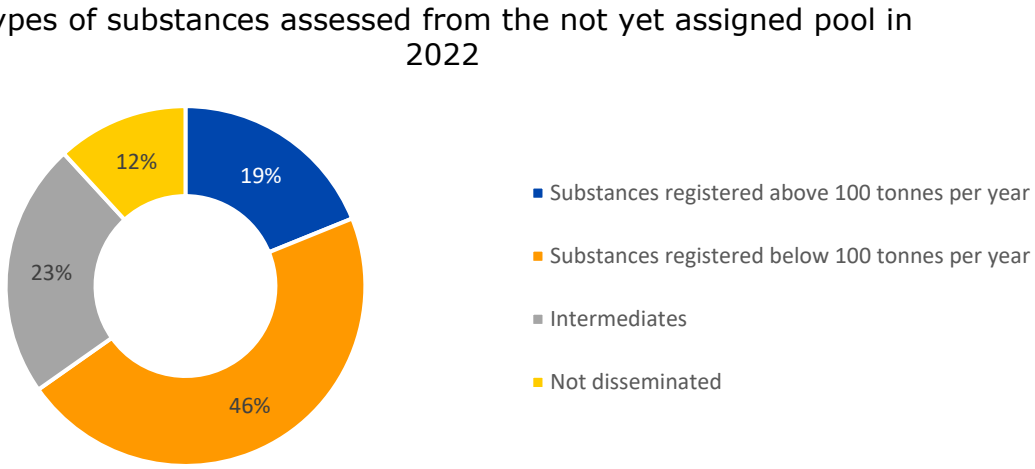
Over 250 substances registered above 100 tonnes per year and more than 600 substances registered between 1-100 tonnes have been moved out from this pool and assigned to the other pools.

As such, at the end of 2022 there were 1 030 substances registered above 100 tonnes per year and 5 104 substances registered between 1-100 tonnes left in the not-yet-assigned pool.

Of the nearly 900 substances registered above 1 tonne per year, which were removed from the not-yet-assigned pool during 2022, the vast majority is due to ECHA's assessments of regulatory needs.

As in 2021, more substances registered below 100 tonnes per year have been cleared from the not-yet-assigned pool than those registered above 100 tonnes. This is not surprising since in the past years, assessments were prioritised for groups composed mostly of high tonnage substances and these have to large extent been completed. While the priority is still on high tonnes substances, the remaining groups to which such substances belong are more diverse in terms of tonnage, containing mainly substances registered below 100 tonnes per year. Consequently, more low tonnes substances from the 'not-yet-assigned pool' are being assessed.

Figure 8: Overview of the types of substances assessed from the not-yet-assigned pool in 2022



A major share of the remaining 1 030 substances registered above 100 tonnes per year in the 'not-yet-assigned pool' are substances expected to have less severe hazards but also complex

chemistries (e.g. complex metal compounds, slags and residues, pigments and other colorants). In addition, some remaining substances registered above 100 tonnes per year are those which are the only high-tonne substance in the ECHA group formed around it. ECHA is accelerating the clearance of substances registered above 100 tonnes per year aiming to clear more than 90% of them by end of 2023.

In 2022, ECHA started with few assessments of regulatory needs addressing only substances registered below 100 tonnes to explore how to optimise the approach to address the remaining substances registered between 1-100 tonnes. In general, only for a minority of these there is enough information in the registration dossiers and other data sources to form a view on their potential hazardous properties or uses. This holds especially true for substances registered below 10 tonnes per year.

11. Conclusions

In 2022 the group assessment work continued with high pace resulting in substantial cleaning of substances from the 'not-yet-assigned area'. It was the main source of new substances identified for potential regulatory risk management action.

Assessments of regulatory needs were initiated for 61 groups comprising in total of around 2000 substances. These included for the first time also groups of complex UVCB substances.

As a result of the assessments of regulatory needs concluded in 2022, 500 substances were identified as potentially warranting further EU regulatory risk management. Nearly 200 of these substances could be immediate candidates for regulatory risk management action. For the remaining ones, further data generation is needed before the need for risk management actions can be confirmed. At the same time 750 substances were concluded not to currently require any action.

The group assessment facilitated prioritisation of substances of potential concern for further data generation. Almost 300 substances were selected for data generation under compliance check, to clarify the hazard. For around 20 % of dossier evaluation cases completed between 2020-2022, the results of the data generated suggest the need for potential risk management actions.

ECHA continued supporting industry initiatives aiming at improvement of the registration dossiers, in the context of Cefic-ECHA initiative and the Petroleum and Coal stream substances (PetCo) working group. The collaboration with the non-ferrous industry through the Metals and Inorganics Sectoral Approach (MISA) lead to a positive impact on dossier updates, although some important metal and inorganic substances were missing from the programme and filling some specific data gaps remains an issue as data availability is still low.

As a result of the group work the number of (groups of) substances identified as needing regulatory risk management has grown further. The majority of these are candidates for harmonised classification and labelling as the next regulatory risk management action. Considerable number of these might subsequently move to restriction. To efficiently manage and effectively regulate these substances, authorities are more and more concentrating their efforts into progressing substances to regulatory risk management as groups, where appropriate. This is shown for restrictions, where progress has been made for several groups listed in the Restriction Roadmap.

Similar trend is observed also in relation to proposals for harmonised classification and labelling, although not yet visible from the official records. This is mainly because the Member States are first carrying out further investigations in preparation of potential intentions. Member States and ECHA agreed to work closely together and continue discussions to build further experience in with the aim of building experience in developing proposals for harmonised classification and labelling for groups of substances, developing best practices to streamline processing of such proposals through the harmonised classification and labelling process and increasing collaboration among Member States and ECHA.

Although there are still some resources constraints in progressing with risk management actions, we see that interest and willingness to work on groups is increasing and we expect to see positive impact on group approach and regulating groups in the future.

Overall, good progress has been made in clearing the 'not-yet-assigned ' area of the chemical universe. There are still 1 030 substances registered above 100 tonnes per year and over 5 000 substances registered between 1-100 tonnes left to be assessed. ECHA aims to clear more than 90 % of the above 100 tonnes substances by the end of 2023 and at the same time exploring

how to optimise the approach to address the remaining substances registered between 1-100 tonnes.

Annex 1. Overview of pre-regulatory steps (2008-2022)

PBT and ED expert groups

The PBT and ED expert groups support Member States in assessing substances with persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB) or endocrine-disrupting properties (EDs).

Their main goal is to ensure that the process goes smoothly for both substance evaluation and identification of substances of very high concern (SVHCs).

Table 1 gives an overview of the number of substances that have been considered by the PBT and ED expert groups during 2012-2022. In 2022, the PBT and ED expert groups advised on 17 PBT cases[33] and 17 ED cases[34].

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

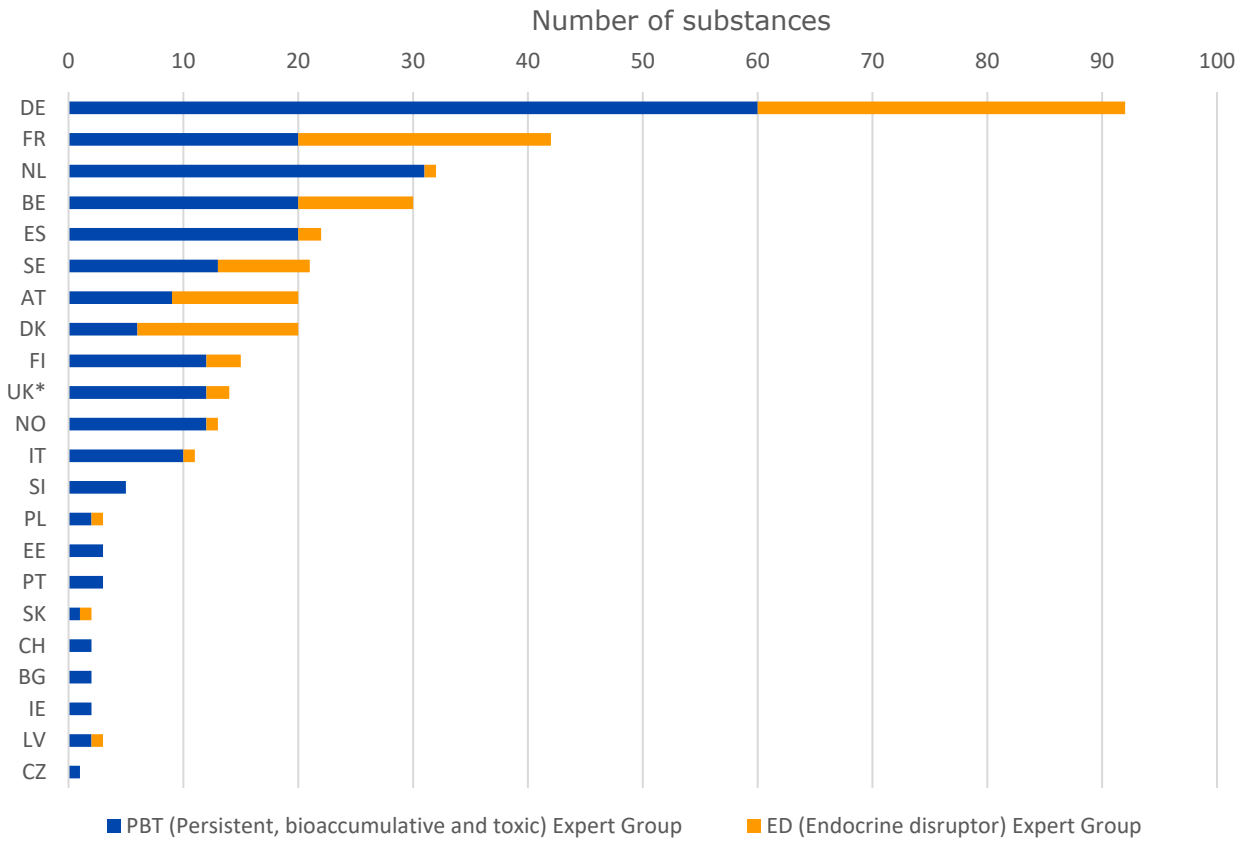
Table 1: Number and outcome of substances under PBT and ED assessment (2012-2022)

OVERVIEW OF SUBSTANCES CONSIDERED BY THE PBT AND ED EXPERT GROUPS							
Property	**Concluded**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties**	**Information insufficient; hazard property inconclusive**	**Ongoing**	**Withdrawn**	**Total**
ED	**24**	**16**	**6**	**2**	**68**	**15**	**107**
PBT/ vPvB	**122**	**34**	**73**	**15**	**136**	**16**	**274**

Since 2012, 21 Member States have been active in the PBT Expert Group and 14 in the ED Expert Group (Figure 1).

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

Figure 1: Number of substances under ED and PBT assessment per Member State 2012-2022



*Member State until 31 January 202

Annex 2. Overview of evaluation activities (2009-2022)

Dossier and substance evaluation

Dossier and substance evaluation are key processes for generating further information on substances. Figure 1 provides an overview of the number of compliance checks and Figure 2 an overview of testing proposal examinations carried out between 2009 and 2022 and their outcome[35]. Figure 3 shows the status of substance evaluations at the end of 2022. Table 1 gives an overview of the properties of substances evaluated between 2012 and 2022. For more detailed statistics on the progress in evaluation[36] and recommendations to registrants[37] resulting from evaluation work, consult ECHA's website.

Overall, between 2009 and 2022, ECHA performed a full compliance check for 27 and 28 % of the substances registered in the two highest tonnage bands (above 1 000 tonnes per year and from 100 to 1 000 tonnes per year, respectively). 11 % of the substances registered at 10-100 tonnes per year have also been checked.

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

[36] Progress in evaluation - ECHA (europa.eu)

[37] Recommendations to registrants - ECHA (europa.eu)

Figure 1: Number of compliance checks between 2009 and 2022

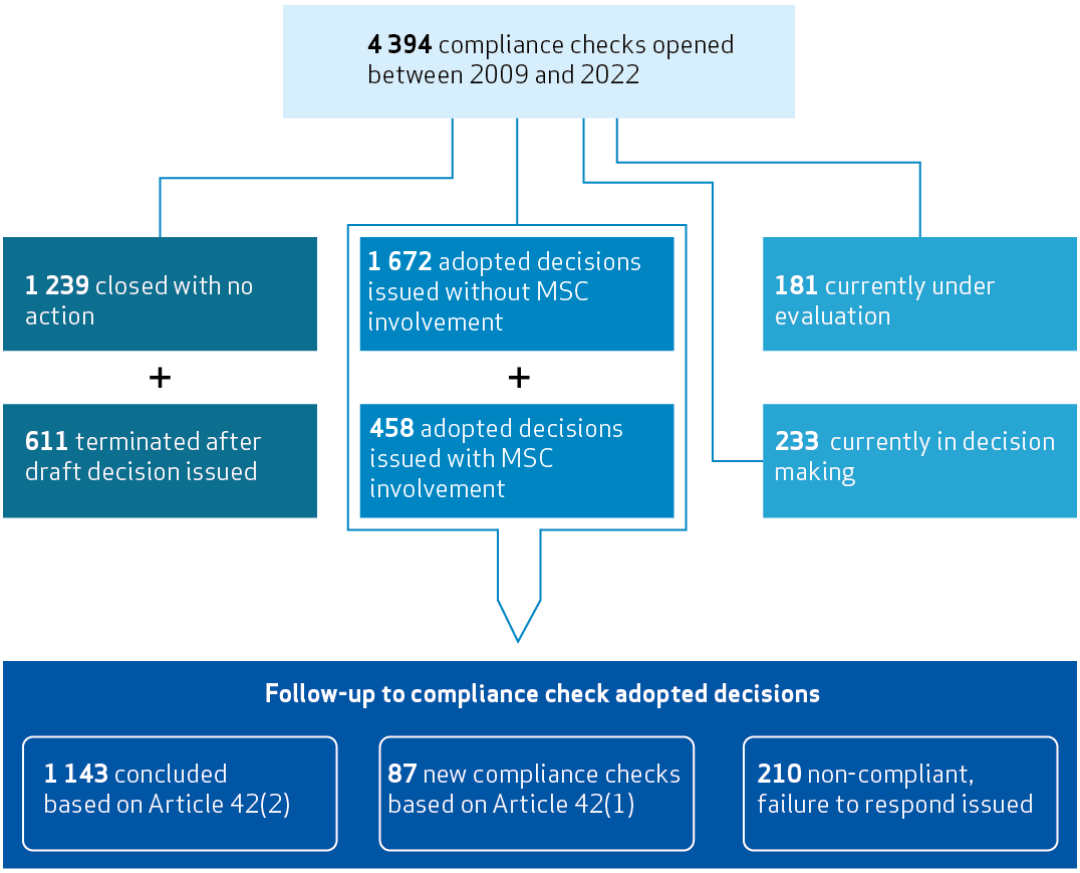


Figure 2: Number of testing proposal examinations between 2009 and 2022

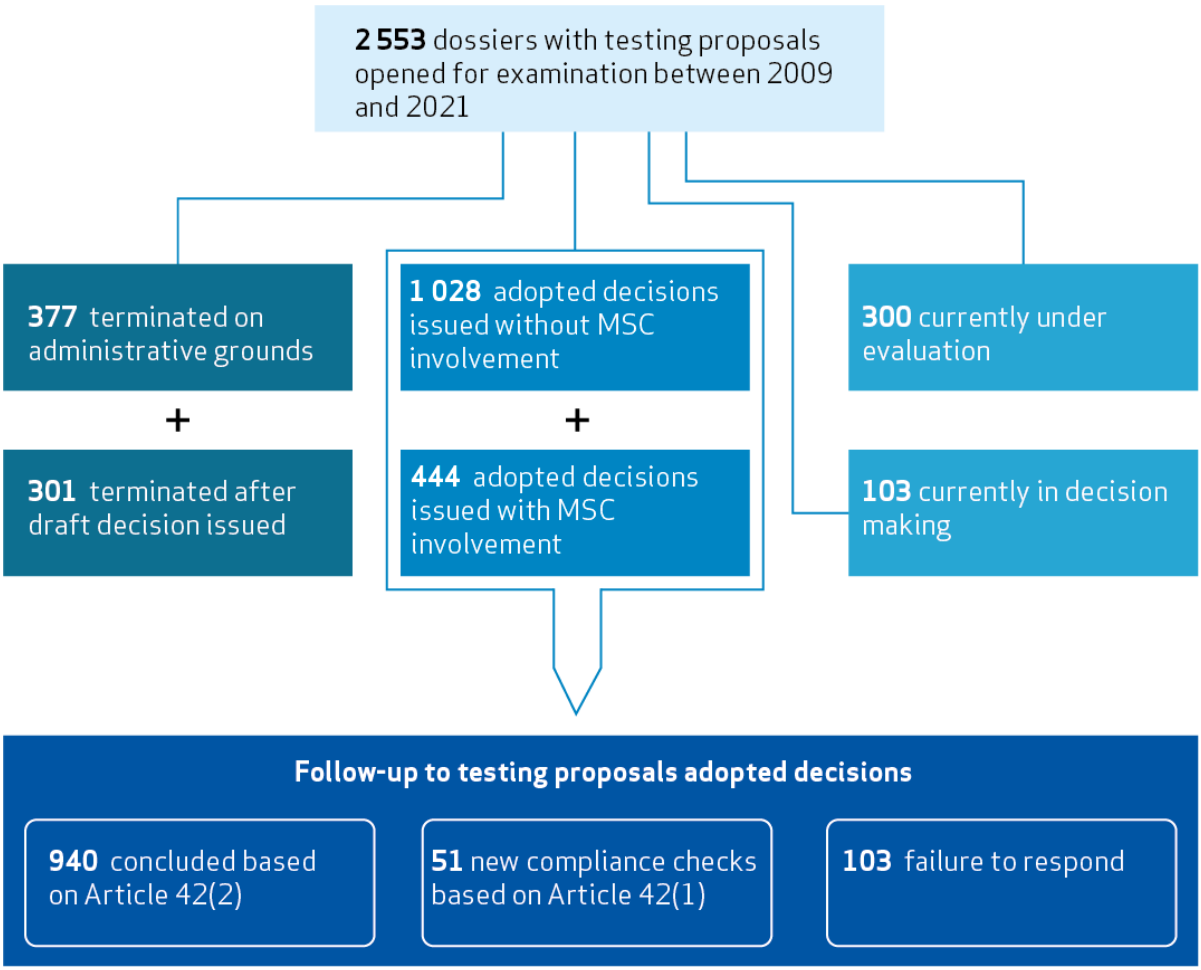
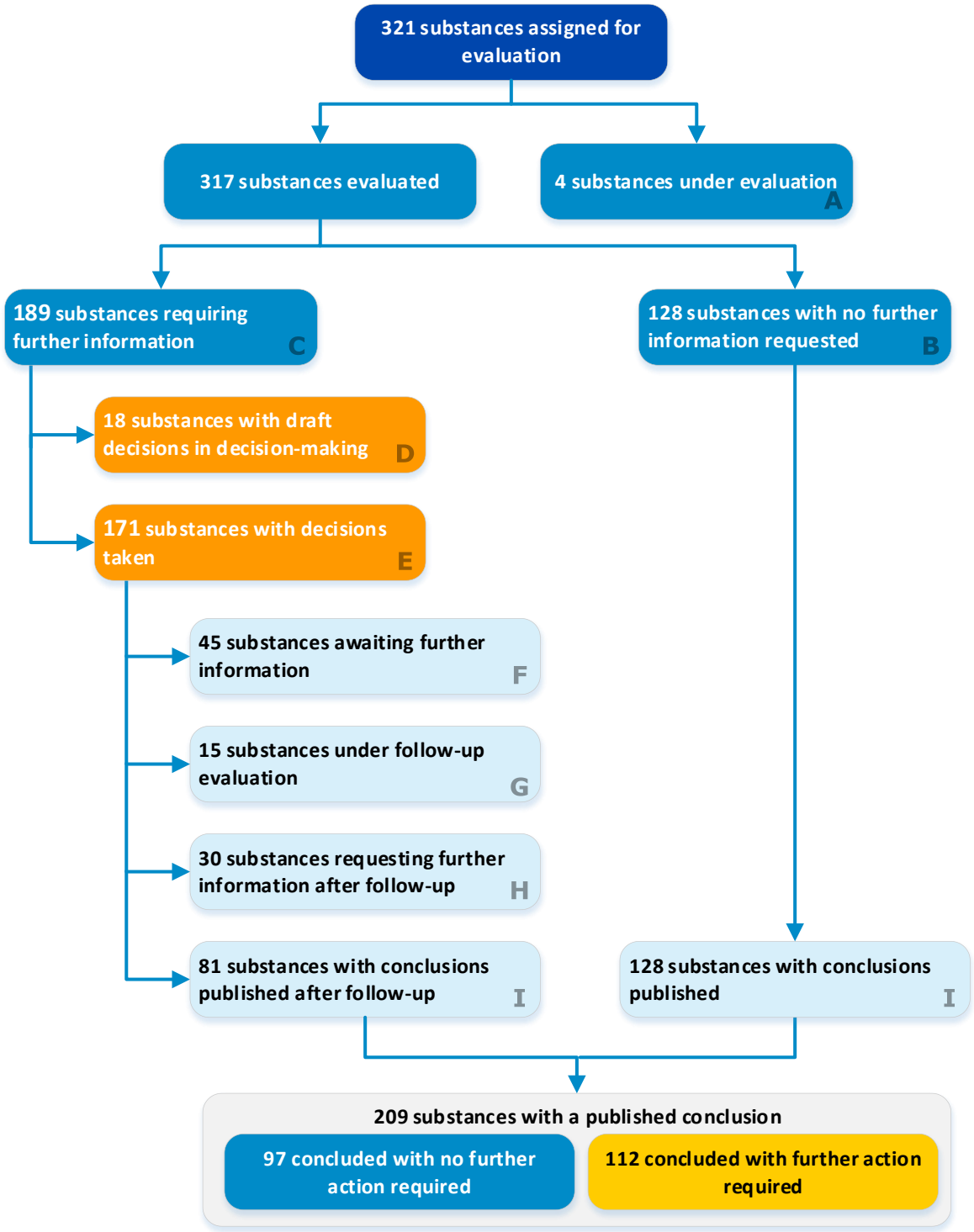


Figure 3: Status of all substance evaluations at the end of 2022



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

[B] For 95 substances, the evaluating MSCA could conclude on the suspected risk based on the available information. For 33 substances, substance evaluation was concluded since further information was either requested via compliance check or could not be requested due to cease of manufacture of all Registrant(s) of the substance.

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

[D] Stages of draft decision processing: 11 substances currently in decision-making stage. Eight substances currently suspended pending the outcome of an ongoing compliance check.

[E] ECHA evaluation decision taken. Note: a substance may have more than one adopted SEv decision (Overall, 194 SEv decisions adopted).

[F] Registrants to submit requested information within timelines specified in decision. For one substance, decision is appealed before the Board of Appeal of ECHA.

[G] Evaluating MSCA is examining all new information in updated registration. For 9 substances, draft conclusion documents are being prepared.

[H] Draft decision requesting further information deemed necessary after follow-up assessment.

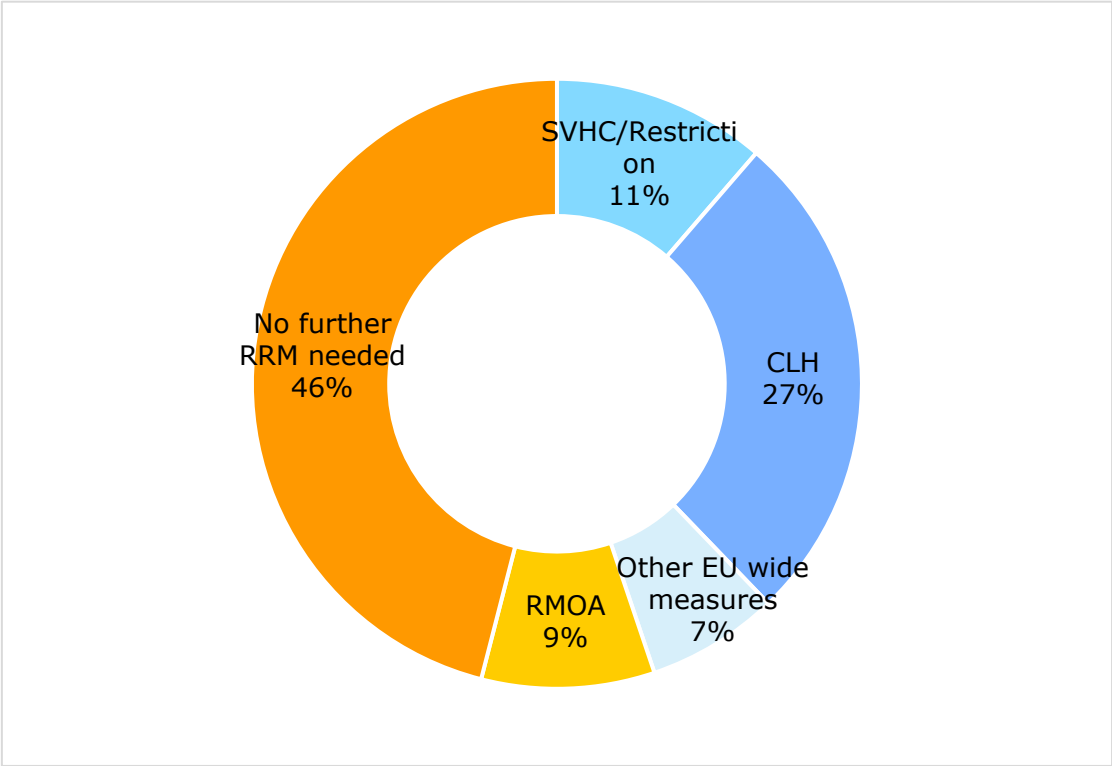
[I] Conclusion documents published on ECHA's web pages.

Table 1: Number of substances for which an assessment under substance evaluation has been concluded or is ongoing per property (2012-2022)

CONCLUDED AND ONGOING SUBSTANCE EVALUATIONS PER PROPERTY (2012-2022)				
Property	**Substances concluded on***	**Considered to fulfil the hazard properties*****	**Considered not to fulfil the hazard properties****	**Substances ongoing**
PBT	85	7	78	99
ED	48	7	41	60
CMR	136	65	71	95
Sensitiser	102	59	43	21

* In some cases, the assessed property was not an identified concern (e.g. an initial concern defined in the CoRAP entry) but was assessed during the course of the substance evaluation process.
** Some substances were concluded with no clarification of the hazard properties (e.g. due to low potential for exposure). These substances were included under the heading "Considered not to fulfil the hazard properties".
*** Substances already with a harmonised classification and labelling are included here even though they were not necessarily included in substance evaluation to clarify this concern.
There are 17 CMRs that have either been newly classified or had their classification as CMR upgraded.

Figure 4: Further actions when hazard-findings confirmed



By the end of 2022, substance evaluation had been concluded for 209 substances.

For 54% of the substances assessed (112 substances), the Member States concluded that there is a need for further EU regulatory risk management. For most of them the next proposed regulatory risk management action is CLH (Note: a substance can have more than one proposed action).

85 substances were concluded as not hazardous or not demonstrating a potential for exposure, and 12 substances did not require further regulatory action at EU level due to actions by registrants to ensure safety (e.g., changes to supported uses, applied risk management measures, reduction of the aggregated tonnage, cease of manufacture).

Annex 3. Overview of regulatory risk management activities (2008-2022)

Harmonised classification and labelling

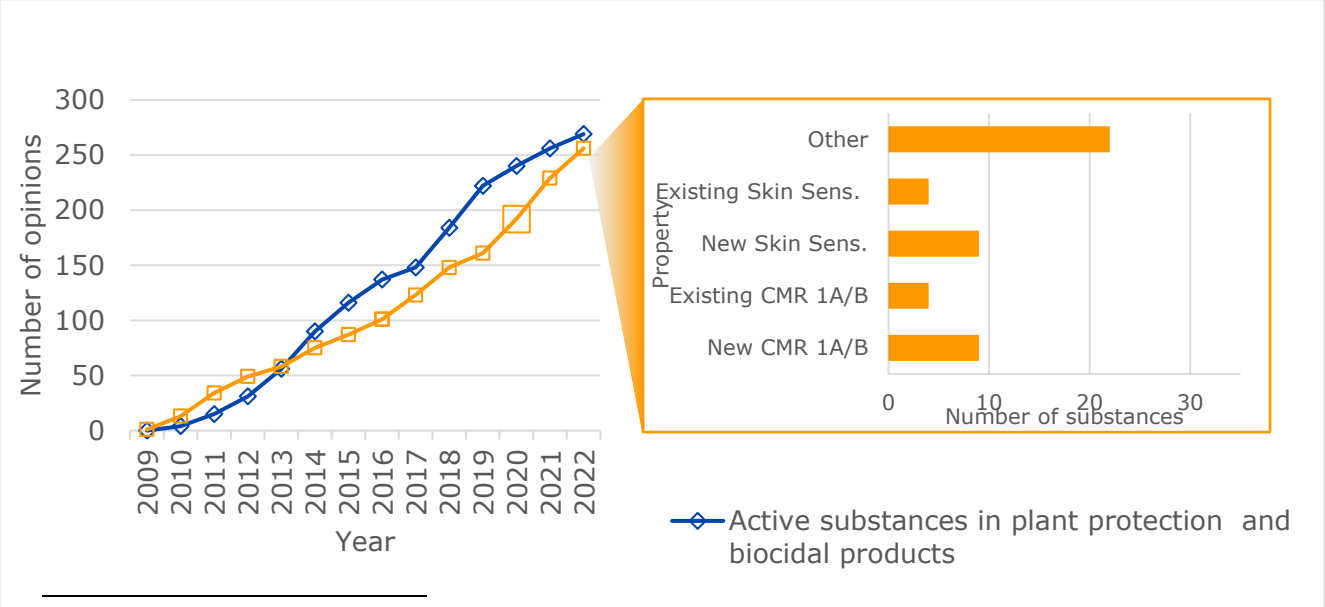
Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity, or respiratory sensitisation in any category, are normally subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal products or plant protection products should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

For all other hazardous substances, CLH can be sought if a justification is provided that shows such an action is required at EU level[38].

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2022, and Figure 2 shows the number of proposals submitted during the same time period. The numbers are further broken down into proposals for active substances in biocidal and plant protection products as well as other substances, mainly those subject to REACH registration.

About half of the substances subject to CLH are active substances in biocidal and plant protection products. The number of REACH substances for which a classification for new[39] and existing CMRs[40] was adopted is also reported.

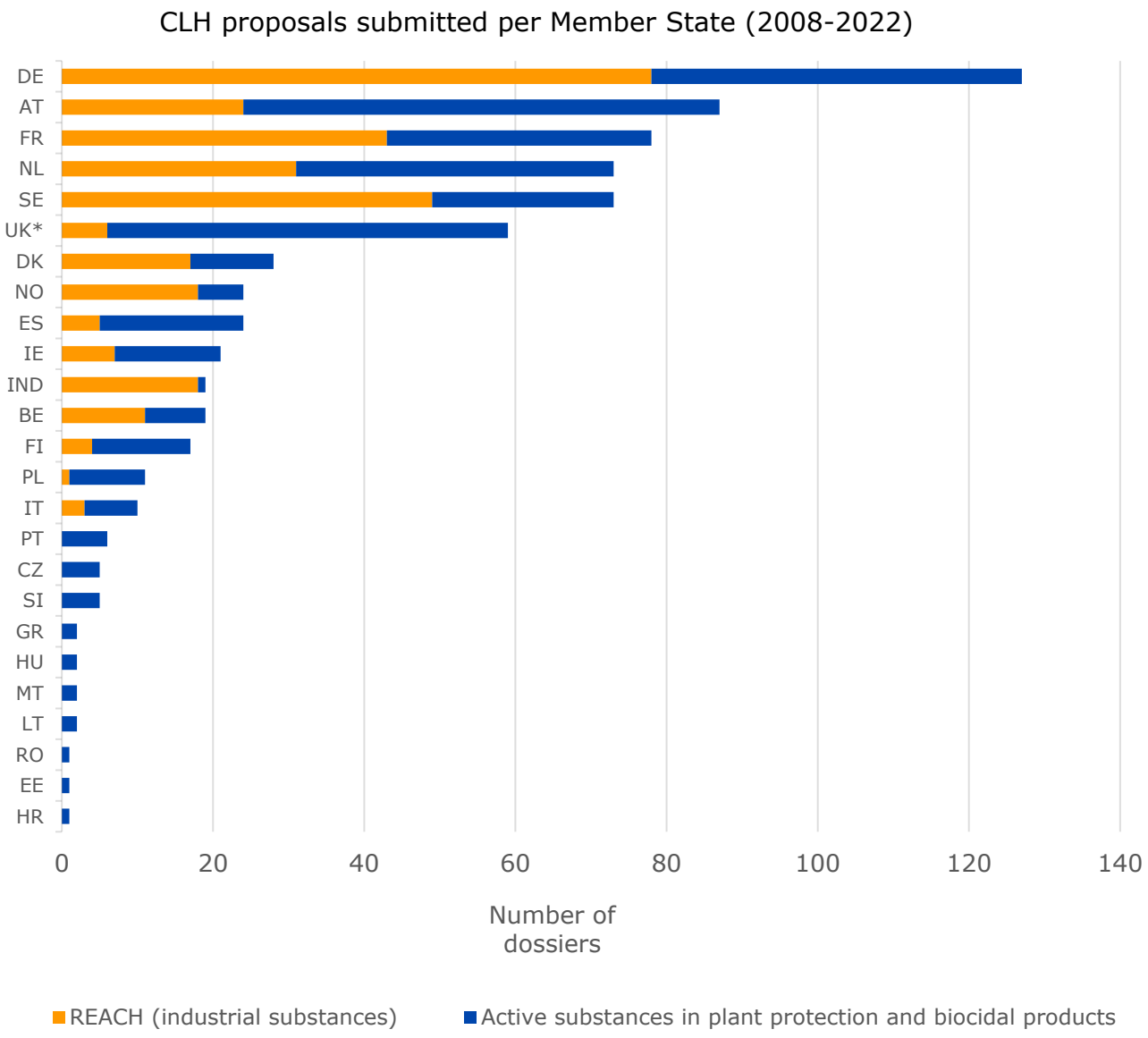
Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2022 and a breakdown of REACH substances for which a CMR 1A/1B or sensitiser proposal was included in 2022.



[38] Harmonised classification and labelling (CLH) - ECHA (europa.eu)
[39] A new CMR is a substance that was not classified as a CMR before.
[40] 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 (and industry).

Figure 2: Number of CLH proposals per Member State (2008–2022)



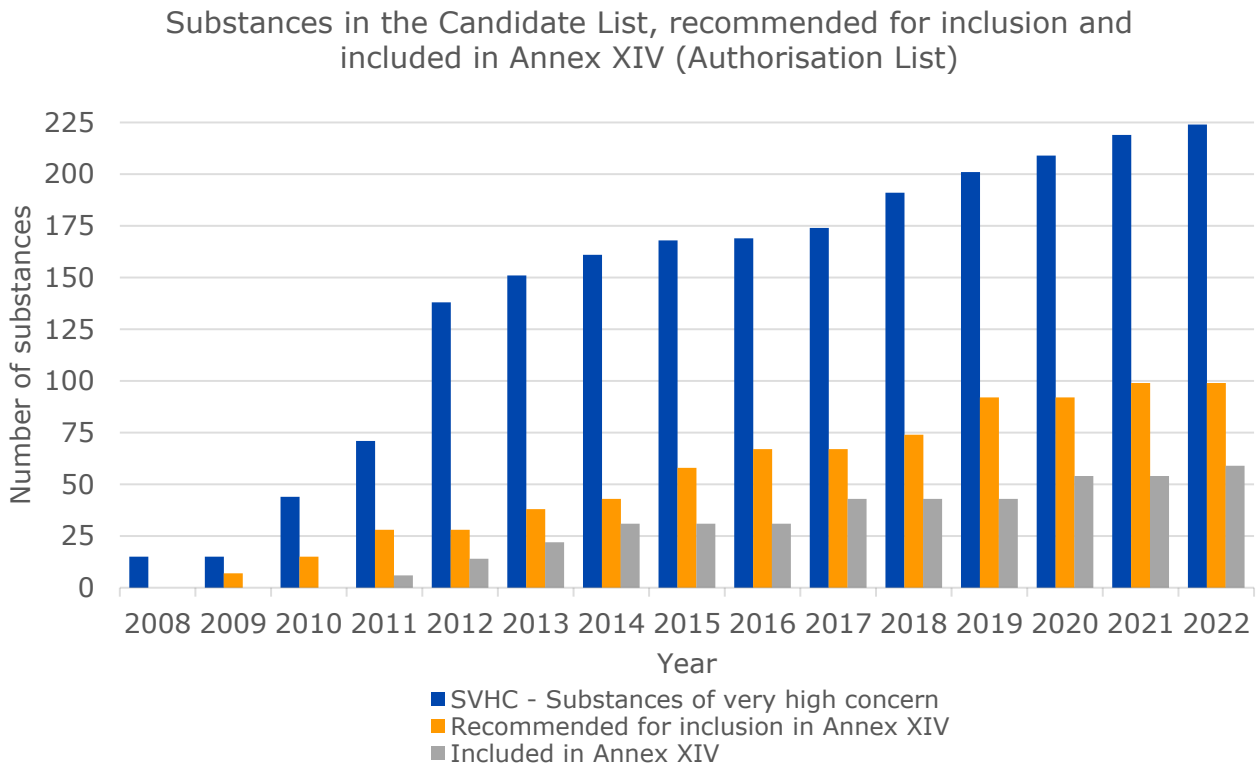
* Member State until 31 January 2020

Authorisation

In 2008, the first substances of very high concern (SVHCs) under REACH were identified, marking the start of the REACH authorisation process[41].

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 2022. These numbers are further explained in their respective sections.

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



SVHC identification

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

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

[41] Authorisation - ECHA (europa.eu)

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

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

Since 2008, 224 substances or groups of substances have been identified as SVHCs and included in the Candidate List. The properties leading to inclusion in the Candidate List are listed in Figure 4. Some substances are identified based on more than one hazardous property, as illustrated in Figure 4 and Table 1.

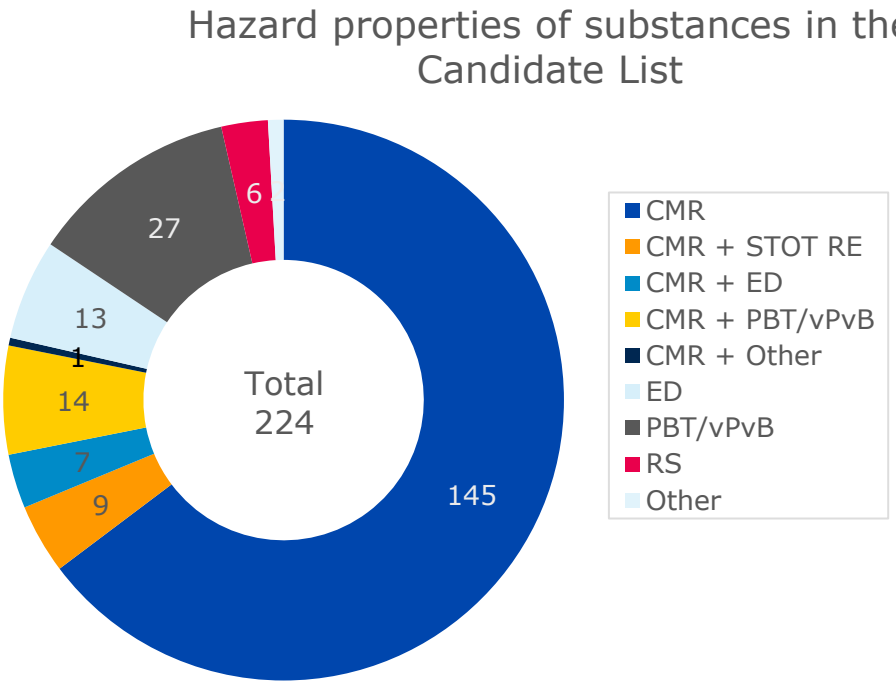
In 2022, 5 more substances were included in the Candidate List.

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

Table 1: Number and outcome of substances under PBT and ED assessment (2012-2022)

OVERVIEW OF SUBSTANCES CONSIDERED BY THE PBT AND ED EXPERT GROUPS							
Property	**Concluded**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties**	**Information insufficient; hazard property inconclusive**	**Ongoing**	**Withdrawn**	**Total**
ED	**24**	**16**	**6**	**2**	**68**	**15**	**107**
PBT/ vPvB	**122**	**34**	**73**	**15**	**136**	**16**	**274**

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



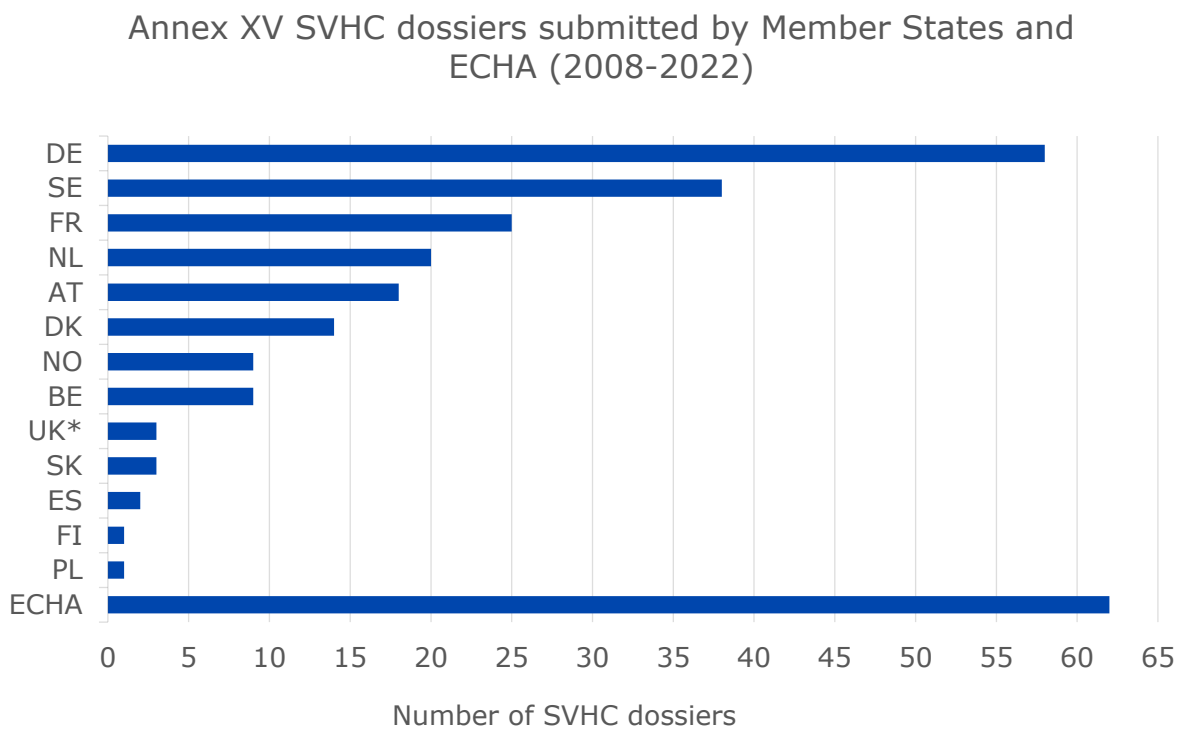
CMR	Carcinogenic, mutagenic or toxic to reproduction
ED	Endocrine disruptor
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent, very bioaccumulative
RS	Respiratory sensitisation
STOT RE	Specific target organ toxicity - repeated exposure
Other	Other environmental and/or human health hazards

Table 1: Overview of the number of substances included in the Candidate List by property (2008-2022)

NUMBER OF SUBSTANCES INCLUDED IN THE CANDIDATE LIST BY PROPERTY (2008-2021)												
Property	**2008 - 2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**Total**
CMR	123	12	8	4	1	2	8	3	4	7	3	175
ED	3	1	1			7	3	2	1	2	1	21
Equivalent level of concern								1	1	1		3
PBT/vPvB	16	2	2	4	1	2	8	4		1	1	41
Respiratory sensitisation	3						2			1		6
STOT RE		3	3				3					9

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

Figure 5: Number of Annex XV SVHC dossiers submitted by Member States and ECHA (2008-2022)



*Member State until 31 January 2021

Recommendation for inclusion and inclusion in the Authorisation List

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

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

Under Article 58(3) of REACH, priority is normally given to substances with PBT or vPvB properties, wide dispersive use, or high volumes[42]. Prioritisation is carried out based mainly on information in the registration dossiers. However, information from consultations 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[43] until the ninth recommendation as well as the substances included in the Authorisation List (Annex XIV)[44] by the end of 2022. Substances recommended within the ninth recommendation have not yet been considered by the European Commission for amending Annex XIV.

[42] Process description for recommendation for inclusion in the Authorisation list
[43] Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)
[44] Substances included in Annex XIV can be found at: Authorisation List - ECHA (europa.eu)

Figure 6: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008-2022)[45]

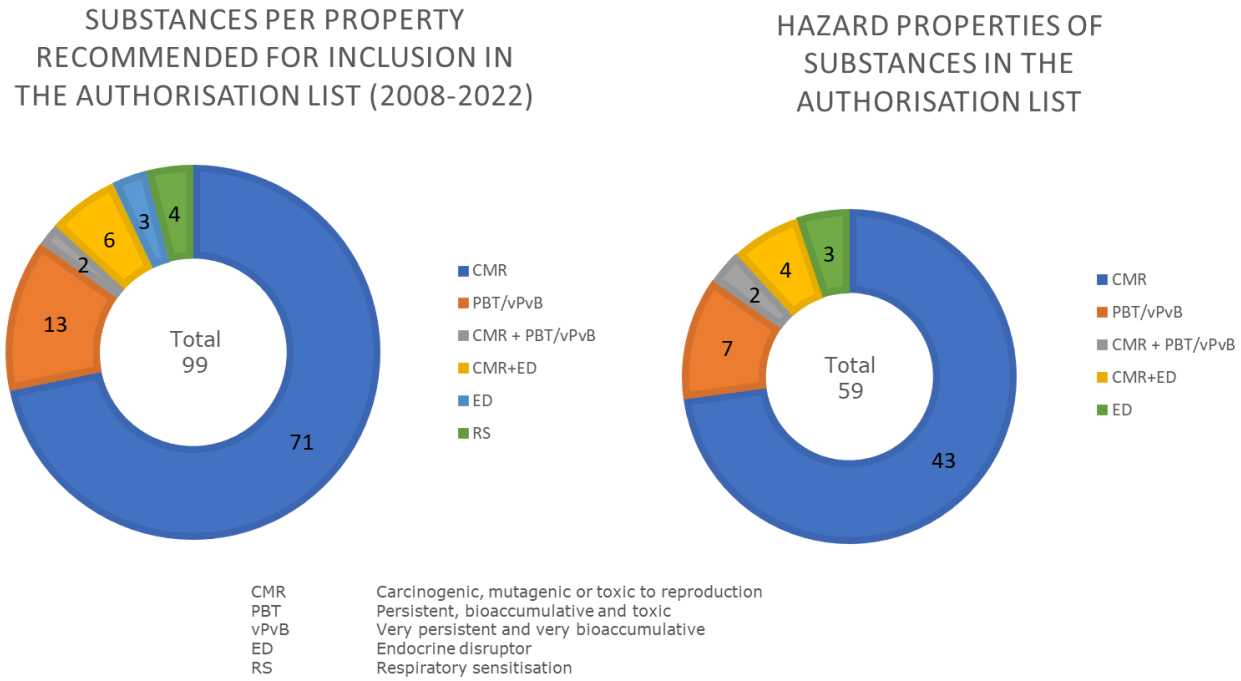


Table 2 gives an overview of the number of substances recommended by ECHA to be included in Annex XIV until the ninth recommendation. It also lists those substances which have been included in the Authorisation List (Annex XIV) and which have not. The European Commission has indicated in the preambles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

[45] 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 therefore is not reported here.

Table 2: Overview of (groups of) substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2022)

OVERVIEW OF SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV AND SUBSTANCES INCLUDED IN ANNEX XIV (2008-2022)							
Date and number of recommended substances			**Amendment of Annex XIV**		**Number of substances included in Annex XIV**	**(Groups of) substances included in Annex XIV**	**(Groups of) substances not included in Annex XIV amendment**
1st	###	7	1st	####	6	Musk xylene, MDA, HBCDD, 3 phthalates+	SCCP*
2nd	17/12/2010	8	2nd	14/02/2012	8	1 phthalate+, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd	20/12/2011	13	3rd	17/04/2013	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) substances
4th	17/01/2013	10	4th	14/08/2014	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th	06/02/2014	5	5th	13/06/2017	1	4-tert-OPnEO	DMF, ADCA, Al-RCF and Zr-RCF
6th	01/07/2015	15	5th	13/06/2017	11	1-bromopropane, 7 phthalates, anthracine oil, CTPHT, 4-NPnEO	4 borate substances
7th	10/11/2016	9	6th	06/02/2020	5	2 borates, 2 phthalates, trixylyl phosphate	4 lead substances
8th	05/02/2018	7	6th	06/02/2020	6	Karanal, UV-328, UV-327,UV-350, UV-320,1 phthalate	NMP
9th**	01/10/2019	18	7th	08/04/2022	5	Tetraethyllead Trityl alcohol RP-HP DOTE/MOTE	EGME, EGEE HHPA, MHHPA Dechlorane Plus 7 lead compounds (PVC) BPA
10th	14/04/2021	7		[n/a]	[n/a]	[n/a]	***
	Total	**99**			**59**		**33**

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

** Dechlorane Plus has been proposed as POP under the Stockholm Convention

*** Substances from tenth recommendation (7) have not yet been considered for amending Annex XIV

+The Annex XIV entries of these four phthalates have been updated with ED properties on 23 November 2021, after the 1st Amendment recommendation (10 July 2019)

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 to grant an authorisation for the uses applied for.

The number of applications for authorisation received between January 2013 and the end of December 2022, as well as the number of Committee for Risk Assessment (RAC) opinions, Committee for Socio-Economic Analysis (SEAC) opinions and Commission decisions are available online and regularly updated[46].

[46] Statistics on received applications for authorisation and review reports - ECHA (europa.eu)

Restrictions

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

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

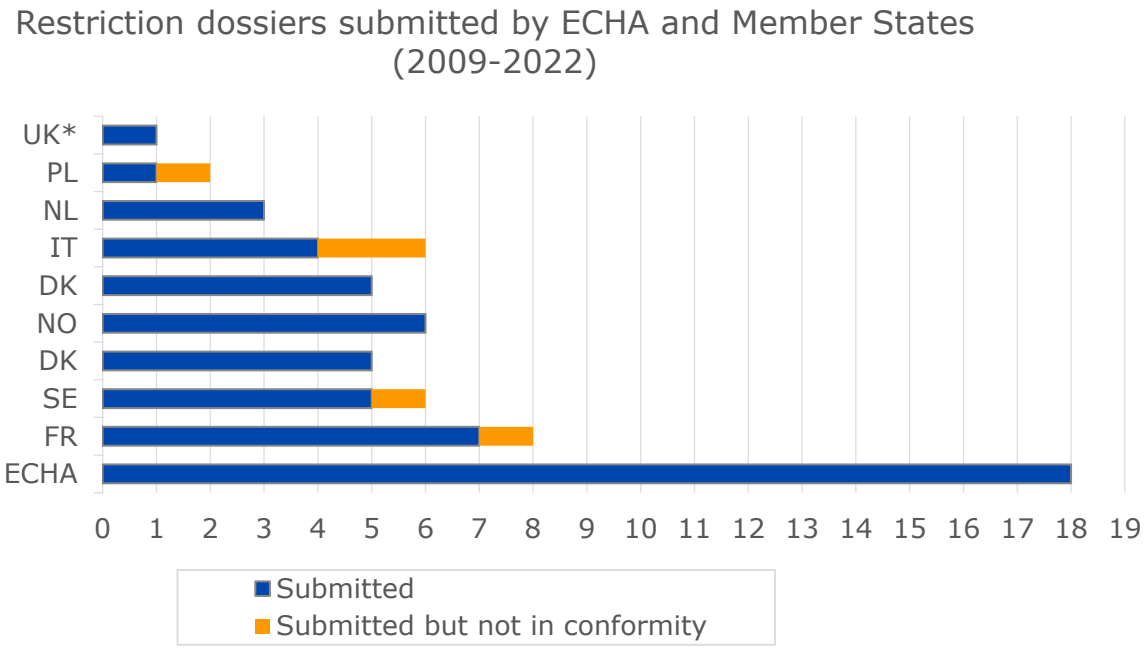
Table 3: Overview of restriction proposals on substances adopted or going through the restriction process from 2009 to December 2022. Some cover groups of substances.

NUMBER OF RESTRICTION PROPOSALS ON (GROUPS OF) SUBSTANCES ADOPTED OR GOING THROUGH THE RESTRICTION PROCESS					
Step in restriction process	PBT	ED	CMR	Sensitiser	Other
Included in Annex XVII	Octamethyl-cyclotetrasiloxane (D4), decamethyl-cyclopentasiloxane (D5), PFOA (and related substances), C9-C14 PFCAs (and related substances), decaBDE	NPE	4 phthalates, NMP, phenyl mercury, lead and its compounds (in jewellery, consumer articles and gunshot used in wetlands), mercury, BPA, chrysotile, DCB, DMF, PAH in rubber granules, Formaldehyde and formaldehyde releasers	Chromium VI*, Diisocyanates (consumer uses, professional and industrial uses)	Ammonium salts, methanol, TDFA, tattoo inks (various hazard properties); PAHs, dioxins, furans,
Process ongoing	Chloroalkanes with carbon chain lengths within the range from C14 to C17, creosote and related substances, Terphenyl, hydrogenated	Bisphenols with endocrine disrupting properties for the environment and their salts, DMAC and NPE			PFAS in firefighting foams
RAC/SEAC opinions adopted but not yet in Annex XVII	D4/D5/D6, PFHxA (and related substances), PFHxS (and related substances), Dechlorane Plus	-	lead in PVC, DNT, lead in outdoor shooting and fishing, 2,4-dinitrotoluene,PAHs in clay targets, soluble cobalt salts**, single-use baby diapers**	Skin sensitisers in textiles	Microplastics calcium cyanamide

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

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

Figure 7: Number of restriction dossiers submitted by ECHA and Member States (2009–2022)



*Member State until 31 January 2021
Note that restriction dossiers co-submitted by several Member States are counted for each of the co-submitters, hence the total number of (co-)submissions is higher than the total number of submitted dossiers.

ECHA is required to investigate whether substances on the Authorisation List, when used in articles, cause uncontrolled risks to the environment or to human health (Article 69(2)). Table 4 provides the number of entries on the Authorisation List screened so far, including the status of the screening.

Table 4: Number of entries on the Authorisation List screened or work ongoing according to Article 69(2) since the first sunset date of 21 August 2014

NUMBER OF SUBSTANCES (ENTRIES) ON THE AUTHORISATION LIST SCREENED OR WORK ONGOING ACCORDING TO ARTICLE 69(2) SINCE THE FIRST SUNSET DATE OF 21 AUGUST 2014				
Status of the screening	Total	No of restrictions proposed	Restriction under preparation	Restriction decided
Screening finalised	24	1	3	4**
Screening ongoing	27	-	-	-
Screening planned to start in 2023	-	-	-	-
Sunset date not passed/screening to start later	5	-	-	-

* 2,4-DNT

** Four phthalates

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