ECHA
EUROPEAN CHEMICALS AGENCY

Faster action on groups of harmful chemicals

Integrated Regulatory Strategy
Annual Report

June 2022

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Faster action on groups of harmful chemicals -
Integrated Regulatory Strategy Annual Report 2022

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

Foreword

Welcome to our fourth annual report under our Integrated Regulatory Strategy. We're excited to update you on how much progress we made in 2021 to identify substances of concern and prioritise them for regulatory action. Our aim is to carry out this prioritisation for all registered substances by 2027.

Several years ago, we shifted our focus to working with groups rather than individual substances in an effort to accelerate regulatory risk management for substances of concern. With this approach now maturing, we have seen a significant increase in substances being assessed in 2021 – 30 % more than the previous year.

We have identified several groups which need risk management, which were included in the European Commission's Restrictions Roadmap supporting the Chemical Strategy for Sustainability.

At the end of 2021, we published the first assessments of regulatory needs for groups of substances. 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.

We also consolidated our collaboration with the European Food Safety Authority (EFSA) to identify substances with potential plasticiser uses in different food contact materials. This shows the potential that grouping has for improving coherency and consistency of actions across different pieces of legislation and paves the way towards a 'one substance, one assessment' approach.

We continue to optimise and adapt our work to make it more effective in meeting such ambitious goals. But this will need concerted effort from all those involved, including Member States – the benefits of doing so are obvious.

It is clear to me that this is how we need to be working in the future: grouping improves our understanding on how the chemicals landscape will look in the EU in 2027 and beyond, and what challenges the future versions of REACH and CLP will need to solve.

I invite you to dive further into this report and see the progress we have made. Enjoy!

Ofelia Bercaru

Director of Prioritisation and Integration

Executive summary

ECHA's Integrated Regulatory Strategy (IRS) is accelerating data generation, identification of groups of substances of concern, and progressing regulatory risk management (RRM) action by ensuring that different regulatory processes are coherently, effectively and efficiently used. The good collaboration between ECHA, Member States and the European Commission is a vital part of the strategy and has allowed us to deliver.

ECHA's grouping approach can help authorities to use all available data to cover a bigger share of registered substances, including those where hazard and exposure information is lacking. It also helps to improve regulatory consistency and increases the predictability of authority actions when similar substances are addressed together.

During 2021, we finalised the assessment of regulatory needs of more than 1 900 substances, mostly grouped based on their structural similarity. Out of these, around 1 650 are registered under REACH, and nearly 700 above 100 tonnes per year.

To conclude on the regulatory needs for groups of substances, reducing information gaps is essential. At the end of 2021, the group assessment work identified around 440 substances for which data generation is needed. Where feasible, we used data available on structurally similar substances to propose coherent regulatory risk management actions. It is important for industry to proactively update their registrations with any new information, as the registration information is the basis for the assessment of regulatory needs.

In addition, we have identified around 650 substances that potentially require further risk management measures (for around 300 of these, risk management actions could be initiated immediately), and around 800 substances that currently do not require further action. For the remaining substances, further assessment will be possible once additional information is available (either on the substance itself or for a related substance).

In 2021, ECHA finalised the assessments of regulatory needs for specific groups that merited additional focus, such as phthalates and bisphenols.

To increase transparency on the regulatory actions being pursued and the progress made on groups of substances, ECHA published the first assessments of regulatory needs for 19 groups covering more than 450 substances at the end of 2021. These included groups of phthalates and phthalate-like substances that were assessed due to their potential reprotoxic, endocrine disrupting, or persistent, bioaccumulative and toxic (PBT) properties. A potential restriction has been proposed for some to limit potential releases from articles. Some ortho-phthalates require harmonised classification and labelling, identification as substances of very high concern (SVHCs) or both. For other substances in these groups, there is currently not enough information to confirm a potential hazard, and a few do not require any new regulatory actions for now. All the assessments will be gradually published on ECHA's website in the public activities coordination tool (PACT).

The regulatory needs of close to 1 300 substances registered above 100 tonnes per year still need to be assessed. ECHA will continue optimising the IRS process based on lessons learned during the strategy's implementation to clarify which registered substances are a high priority for regulatory risk management or data generation, and which are currently a low priority for further regulatory action.

Based on group assessments carried out during 2019-2021, three quarters of substances that have been assessed do not need currently further regulatory risk management and can be deprioritised as they seem to have low hazard, low exposure potential or there are already

sufficient risk management in place. EU regulatory risk management actions are expected for the remaining 25 % of assessed substances. However, most of these substances require further data generation and confirmation of their hazards (through harmonised classification or SVHC identification) before the need for planned further regulatory risk management actions can be confirmed or initiated.

We have made considerable progress in addressing substances in groups and showing the added value of this way of working. ECHA's assessments of regulatory needs are becoming the main source of candidates for EU regulatory risk management action:

- Several assessed groups, where the most appropriate risk management instrument is identified as restriction, have been included in the Commission's Restrictions Roadmap. This Chemical Strategy for Sustainability (CSS) output prioritises groups of substances for restrictions under REACH, ensuring transparent and timely commitments by authorities.
- Three times the number of candidates for harmonised classification were identified as a follow-up action to dossier evaluations in 2021 compared to 2020, for example, a group of 29 resin and rosin acid derivatives that was recommended for harmonised classification.

However, to ensure progress, regulatory actions need to be initiated without delay, and Member States need to allocate sufficient resources. For this to happen, adequate resources are required. Unfortunately, authorities have, in general, yet to start preparing proposals for harmonised classification and labelling for many identified substances. This accumulation of candidates for harmonised classification is a bottleneck for the efficient implementation of the Integrated Regulatory Strategy, as harmonised classification is often a prerequisite for moving ahead with other regulatory measures under REACH, such as authorisation, or under other EU legislation. This is also a potential issue with the groups of substances included in the Restrictions Roadmap.

The regulation revisions accompanying the CSS aim to address this bottleneck with several actions, including implementation of the Generic Approach to Risk Management. However, this may take considerable time so, in the meantime, there is a need for Member States to dedicate more resources to preparing dossiers and committee work, as well as continued attention to good collaboration across Members States and with ECHA.

Progress in implementing the Integrated Regulatory Strategy can be followed through the chemical universe web page[1] and the outcomes of the group assessments of substances that are regularly published[2].

[1] https://echa.europa.eu/universe-of-registered-substances
[2] https://echa.europa.eu/-/first-assessments-of-regulatory-needs-for-groups-of-chemicals-published

MAIN RECOMMENDATIONS

- Optimise the Integrated Regulatory Strategy based on lessons learned during its implementation with the aim of ensuring it meets the target of assessing all remaining substances not yet addressed by the end of 2027.
- The work on substances needing further regulatory action, particularly classification and labelling, should progress without delay. Member States must, therefore, ensure adequate resources to initiate regulatory risk management, where necessary.
- Intensify collaboration between Member States and ECHA so they can discuss and agree on prioritisation. Use the Commission's Restrictions Roadmap to identify candidates for restriction.
- Continue publishing the assessments of regulatory needs as this gives stakeholders transparent information on potential regulatory action.
- Industry needs to be proactive in updating their registrations, as the information they provide is the basis for the assessment of regulatory needs.

1. Introduction

1.1 Addressing substances of concern efficiently

This is ECHA's fourth annual report in its Integrated Regulatory Strategy and presents the achievements and state of play of its implementation in 2021.

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 data generation, the identification of groups of substances of concern, and regulatory action on them.

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

Regulatory risk management (RRM) in this context means: harmonised classification and labelling (CLH)[3], authorisation, restrictions or EU-wide actions under other legislation.

The work carried out under the Integrated Regulatory Strategy contributes to chemicals management in the EU. Other regions can use or adapt the 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)[4], 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.

1.2 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 helps authorities to decide the most appropriate way to address an identified concern including whether further data or assessment is needed and whether further regulatory risk management activities are necessary. The assessment of regulatory needs is an iterative, informal process, linking the regulatory processes under REACH and CLP.

Data generation clarifies whether or not a substance has hazardous properties. The main tools for generating missing hazard information are compliance checks, testing proposals and substance evaluation. Additionally, the work carried out by the ED and PBT expert groups

[3] Harmonised classification and labelling (CLH) is an important regulatory risk management measure. It helps companies achieve appropriate risk management throughout the EU through communication of hazards. Classification results in an exposure and risk assessment requirement in the chemical safety assessment (CSA) (which includes exposure scenario development and associated operating conditions and regulatory risk management) and leads to duties under occupational safety and health (OSH). In addition, CLH is also the basis for many other legislative provisions on the risk management of chemicals, including generic restrictions (e.g. under Article 68(2) as well as restrictions in legislation for toys). CLH is expected to play an even bigger role in the future of chemicals risk management in the EU, with the anticipated extended generic risk management approach currently discussed under the CSS.

[4] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

supports the identification of persistent, bioaccumulative and toxic or endocrine-disrupting substances.

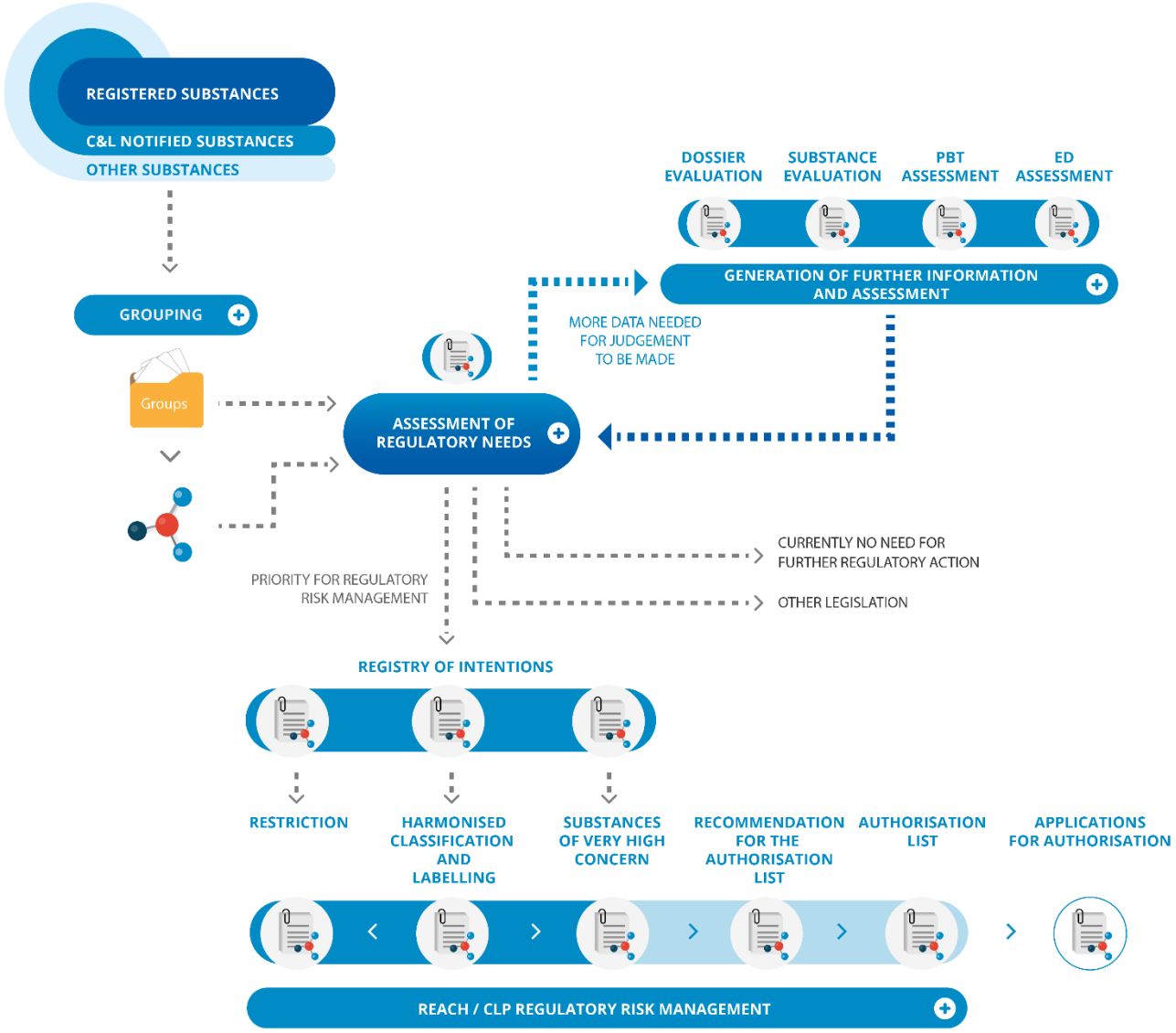
The **regulatory risk management measures** to confirm hazards under REACH and CLP are harmonised classification (CLH) and identification as a substance of very high concern (SVHC). A substance is normally subject to harmonised classification and labelling if it meets the criteria for carcinogenicity,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

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

Stakeholders are informed about a substance entering regulatory risk management in the registry of intentions until outcome and the public activities coordination tool (PACT)[5].

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

Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy[6]



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

2. The universe of registered substances

2.1 Enhanced transparency on addressing substances of concern

The **chemical universe**[7] 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 Commission monitor the progress made in identifying substances of (potential) concern and appropriate regulatory actions. It also makes the actions of authorities more transparent for industry and other stakeholders through the PACT, including publication of the assessments of regulatory needs (ARNs).

In the chemical universe, each registered substance is allocated to one[8] 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 evaluation 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) or under the ECHA-Cefic collaboration on dossier compliance. This pool also includes those substances where authorities have identified the need for further data generation or assessment, but where the action has not yet started. These pending cases may come from substance or dossier evaluation, PBT/ED assessment, or RMOA or group assessment by authorities.

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 formal regulatory processes. In earlier IRS reports, these substances were mapped to the pool 'risk management under consideration'. However, to better reflect the informal character of the assessments of regulatory needs (including RMOA), we have introduced this new pool. An additional benefit of this separation is that the 'risk management under consideration' pool is not inflated by the high-throughput process of ECHA's group assessments, and therefore more correctly represents the number of substances for which a need for risk management action is indeed identified. Finally, most substances will only remain in this pool for a short period of time and will then move to the 'data generation' pool or the 'currently no need for further action' pool once the assessment is finalised. Only if a direct need for regulatory risk management is identified will these substances be mapped to the 'risk management under consideration' pool.

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

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

2021), this pool also contains substances where authorities are preparing or have submitted a proposal for harmonised classification and labelling under CLP.

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

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

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

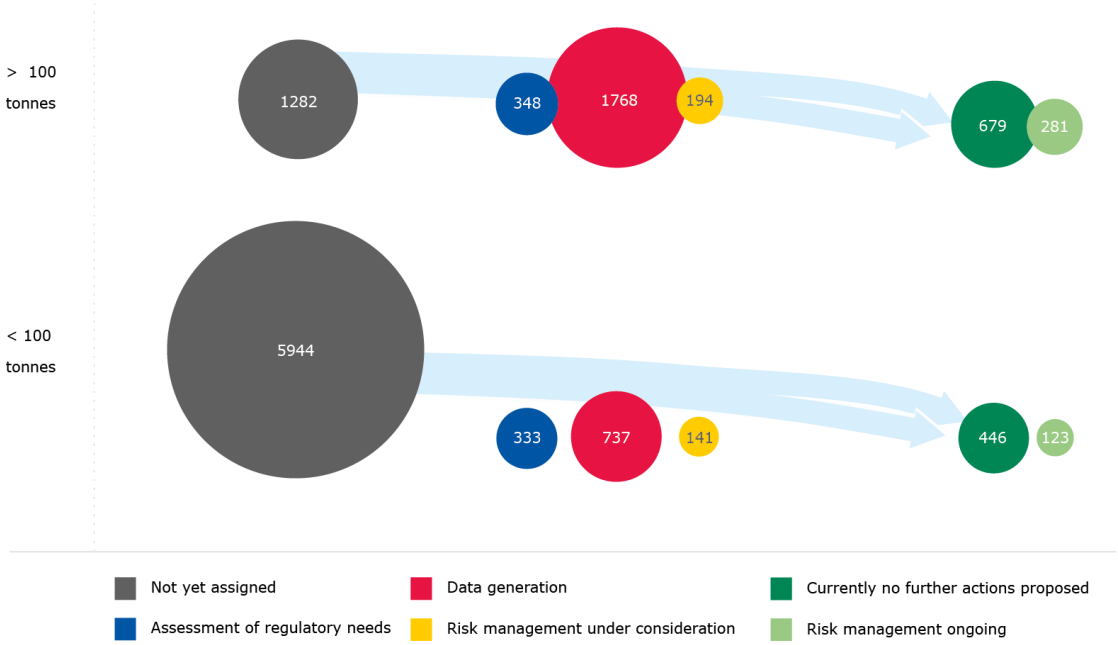
This pool also includes substances that have a harmonised classification on Annex VI to CLP as carcinogenic, mutagenic or toxic for reproduction in categories 1A or 1B, or as respiratory sensitisers in any category. These classifications are severe and trigger several downstream consequences and, therefore,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

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

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

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

Figure 2: REACH chemical universe at the end of 2021: substances with active registrations above 1 tonne per year



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

Table 1: REACH chemical universe at the end of 2021: 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	1 282	348	1 768	194	281	679
1-100 tonnes per year	5 944	333	737	141	123	446
Intermediate	6 172	201	192	39	69	230
NONS - claimed active	977	28	14	4	14	24
Unclaimed NONS	1 633	33	29	13	40	30
Ceased manufacture - REACH	627	20	110	14	49	48
Ceased manufacture - claimed NONS	491	9	4	2	19	5
Total	17 126	972	2 854	407	595	1 462

> 100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage above 100 tonnes per year.
1-100 tonnes: Substances for which there is at least one active registration under Article 10 of REACH registering at a tonnage between 1 and 100 tonnes per year (and which are not covered by the above).

Intermediates: Substances for which there is at last one active registration for intermediate use under Articles 17 or 18 of REACH (and which are not covered by the above).
NONS – claimed active: Former NONS substances for which a registration number has been claimed by a previous notifier, and for which no update has been received under REACH (and which are not covered by the above).
Unclaimed NONS: Former NONS substances for which the registration number has not been claimed (and which are not covered by the above).

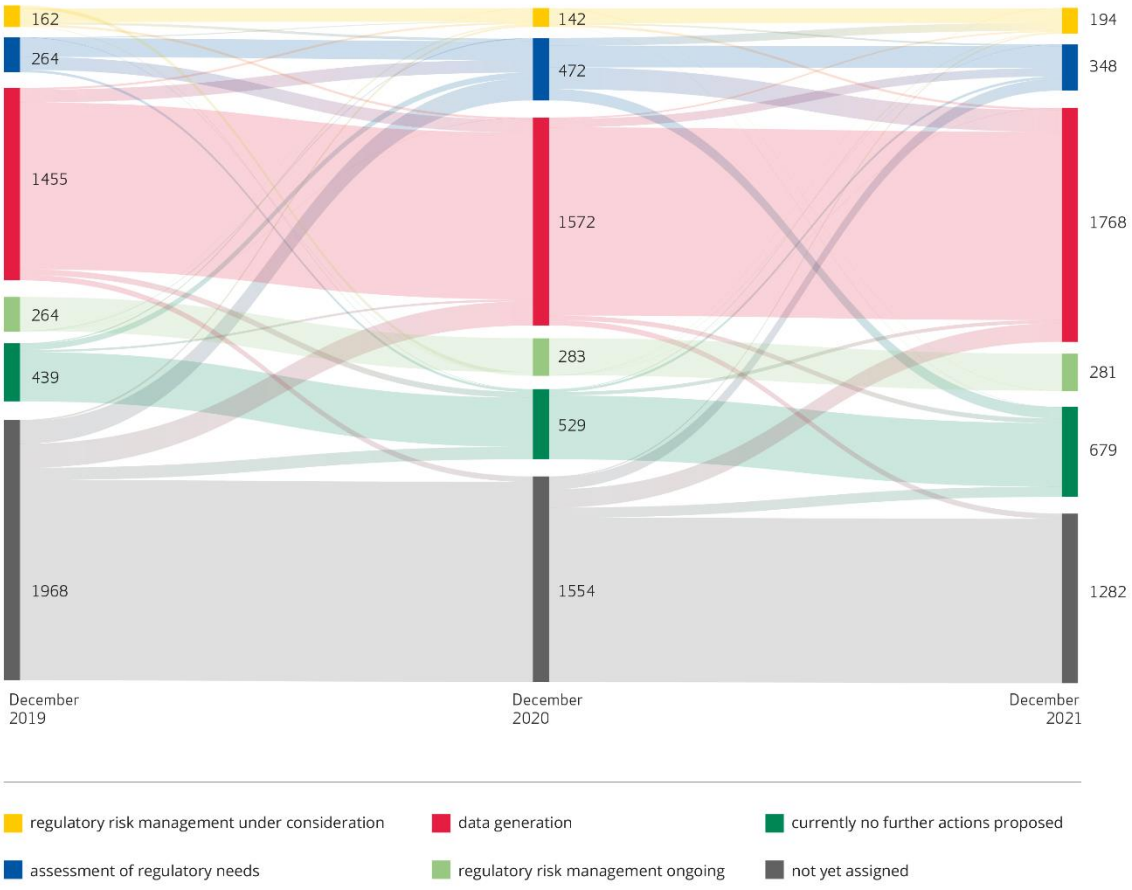
2.2 Progress in allocating substances

The most recent chemical universe mapping presents a snapshot of the allocation of REACH registered substances to the different regulatory pools in December 2021 (see Table 1 and Figure 2).

Figure 3 shows the dynamic nature of the mapping as substances move from one pool to another as regulatory processes continue. When comparing the allocation of substances registered above 100 tonnes per year between December 2019 and December 2021, the most visible development is the substantial progress made in clearing the 'not yet assigned' pool. From this pool, nearly 700 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 2019 to December 2021

Flow of substances registered > 100 tonnes per year



The substances have most commonly 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 group assessment work is visible. Similar trends can be seen for lower tonnage substances in the chemical universe.

For the first time, in 2021 we have cleared more low-tonnage substances (registered at 1-100 tonnes per year) from the 'not yet assigned' pool than high-tonnage substances (registered above 100 tonnes per year).

The regulatory needs of close to 1 300 substances registered above 100 tonnes per year still need to be assessed, as these have not yet been assigned to any regulatory pool in the chemical universe.

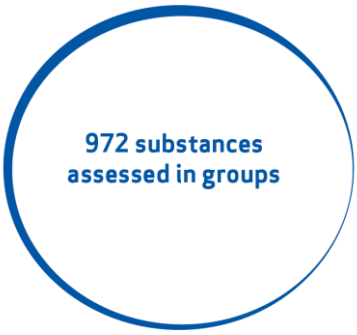
Although there are very few instances, we can also see that some substances have moved back to the 'not yet assigned' pool. This is usually because of improved mapping or data quality issues that have been corrected. It can as well relate to finalised compliance checks where the assessed endpoints did not allow an overall conclusion on relevant hazards[9] to be drawn.

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

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

[9] 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.

3. Assessment of regulatory needs



3.1 Assessment of groups of substances continues with high output

ECHA and Member States have continued working on groups of structurally similar substances to speed up identification of substances that need regulatory action.

Since 2019, ECHA has significantly increased efforts to assess the regulatory needs of groups of structurally similar substances. Overall, the assessment has matured and remains at a high-level pace. In 2021, assessment was finalised for more than 1 900 substances which is 30 % more than in 2020.

Of the assessed substances, around 36 % had been registered above 100 tonnes per year and around 250 were from the 'not yet assigned' pool.

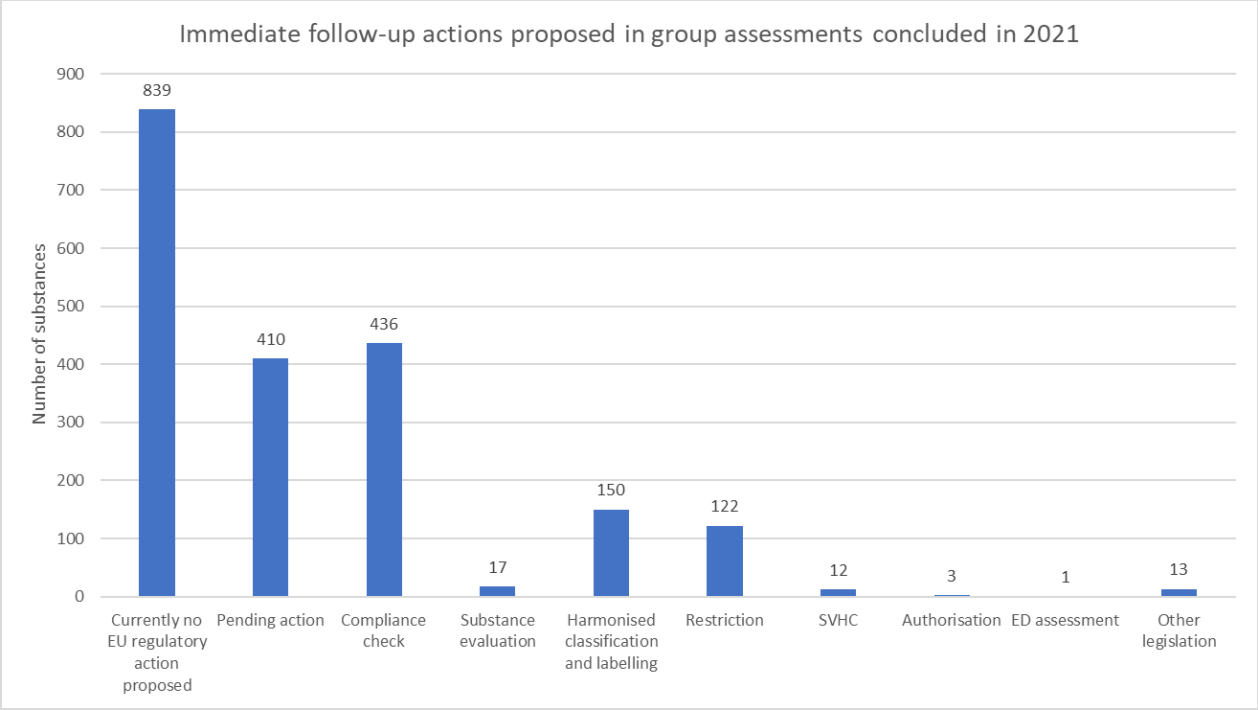
ECHA's assessment of regulatory needs is an iterative assessment that can be done based on any level of information (starting from screening to more in-depth assessment). Immediate follow-up actions are identified based on available information on hazards and uses. In addition, for all substances the foreseen last regulatory action to address the identified concern is suggested in case the potential identified hazards would be confirmed. The assessment will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available. It can be revisited by the same or another authority[10].

ECHA assessed more groups generated around substances of known hazard than in 2020 resulting in an increased number of substances for which regulatory risk management is suggested as an immediate next step.

From all 1 900 substances assessed in 2021, we have identified around 300 that require further regulatory measures (e.g. CLH). For around 800 substances there is currently no need for further regulatory risk management action and for the remaining 800 substances, data needs to be generated before a firm conclusion on the need for further regulatory risk management can be made. For some substances, generation of data (in most cases compliance check) has been suggested whereas for others, the data generation is already ongoing on the substance itself or for a related substance (see Figure 4).

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

Figure 4 Immediate follow-up actions proposed in group assessments concluded in 2021

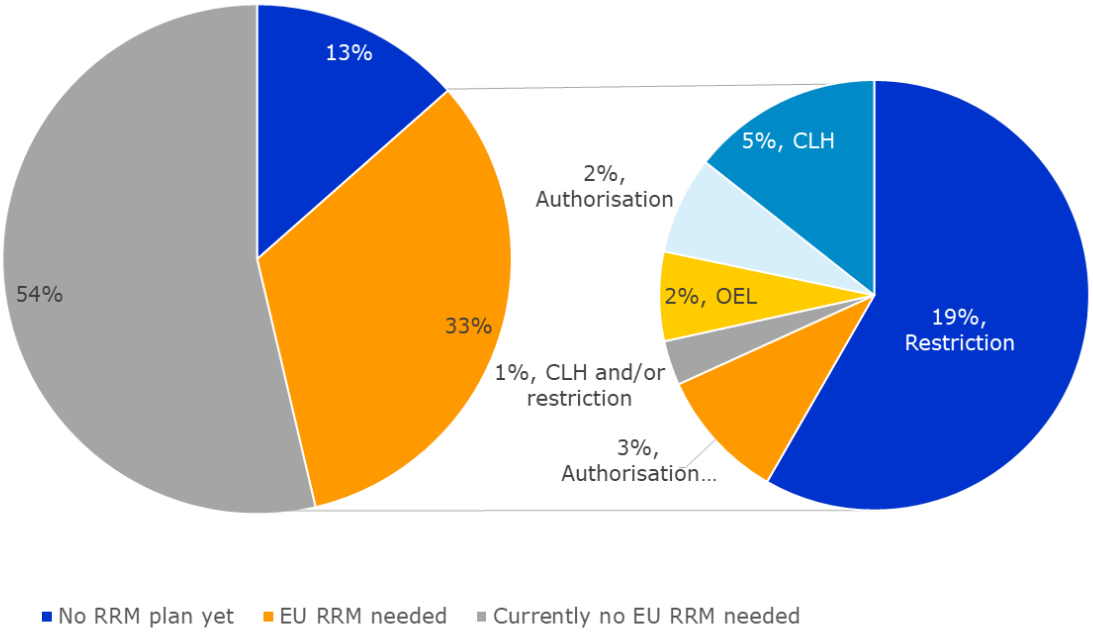


ECHA suggested regulatory risk management actions at EU level as the last foreseen action for 33 % of substances assessed in 2021 (see Figure 5). For 2020, it was only for 20% of the substances assessed. Most of these substances first require data generation and confirmation of hazard (e.g. CLH) before they can progress to further regulatory risk management actions (e.g. authorisation, restriction). These include many likely or potential CMRs, and a few potential EDs, PBTs, and respiratory sensitisers.

Among the substances for which the last foreseen action is that there is currently no need for further EU regulatory risk management, data generation is needed for a third of the substances assessed to confirm the low hazard.

In 2021, the assessments of regulatory needs identified around 400 substances as candidates for compliance check and ARNs are the main source of substances planned for compliance check.

Figure 5: Last foreseen EU regulatory risk management action planned for substances based on group assessments carried out in 2021



Member States have initiated RMOAs on 14 new substances in 2021 and concluded on 22 substances or groups of substances. The focus of the work in Member States has also moved to address groups of substances rather than single substances (e.g. acrylamides, borate minerals, borates in consumer products).

3.2 Publication of assessment reports increases transparency and predictability of authorities work

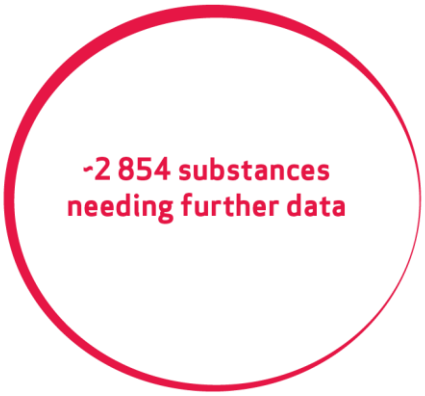
In December 2021, ECHA published its first assessments of regulatory needs for groups of chemicals. Assessments of regulatory needs for 19 groups of substances covering around 450 substances have been published. All assessments done by ECHA will be gradually published on ECHA's website in the public activities coordination tool (PACT)[11]. Registrants and other interested parties can now check if their substances of interest have been assessed.

Publication of group assessments makes it easier for companies to predict what actions regulators are planning and, where relevant, helps them prepare strategies to replace harmful chemicals with safer alternatives. Registrants of those substances for which new risk management is expected are encouraged to start preparing by updating their registration dossiers, verifying the use information, and anticipating the impact of the proposed measures.

[11] PACT available at: https://echa.europa.eu/pact

4. Substances under data generation

4.1 Robust and relevant information on chemicals is needed



At the end of 2021, ECHA had identified around 2 500 substances of potential concern needing further data generation (around 800 of them identified in 2021). This includes substances for which data generation is ongoing and those for which it needs to be started. It also includes substances where action is ongoing on another (structurally) related substance which is expected, based on grouping and screening work, to be relevant for the further assessment of regulatory needs.

In many cases, the information available in registration dossiers does not fulfil the formal information requirements for the key endpoints and is, therefore, not adequate to identify the risks related to a substance. However, it should be emphasised that this may not represent the general quality of submitted dossiers. During the grouping and screening process, ECHA identifies (potentially) non-compliant dossiers and launches compliance checks on them. This results in a high overall percentage rate of non-compliance.

According to ECHA's analysis conducted in 2020[12], registrants are using existing information and alternatives to avoid unnecessary animal testing. Experimental studies carried out according to relevant test guidelines were available for around 27 % of cases. Overall, registrants have used at least one adaptation to avoid animal testing for around 70 % of substances registered in ECHA's database. However, the adaptations are not necessarily appropriate. Therefore, new requests for information need to be issued for cases where further data generation is identified as the first step in the ARN report.

As outlined in ECHA's Programming Document 2022-2025[13], ECHA's evaluation processes primarily ensure the availability of hazard data on chemicals, which increases knowledge on these chemicals and, more broadly, the chemical groups they belong to. It also leads to improved risk management by industry and the authorities.

Firstly, companies are required to use the newly generated information, for example, to improve their risk management measures, to decide on substitution of hazardous chemicals, or to market the substance as a substitute for a more hazardous alternative. Secondly, ECHA uses the newly generated information in the context of ECHA's Integrated Regulatory Strategy, to identify regulatory actions that may be needed to better protect human health and environment. Thirdly, Member States are also expected to use this knowledge, for example, to propose harmonised classification and labelling. The improved hazard knowledge increases the level of protection within the European Single Market.

[12] ec405150-fc64-a218-dc0e-6696f4aadb9f (europa.eu)
[13] ECHA Programming Document(s) 2022-2025 (europa.eu)

4.1.1 Progress in data generation in 2021

Data generation under REACH plays an important role as it contributes to building up, as further outlined in the Commission's Chemicals Strategy[14], 'a comprehensive information base on all substances placed on the market and on their overall environmental footprint, including their impact on climate, [the lack thereof so far] hinders the proper management of chemicals and products and does not allow for a full sustainability assessment'.

Compliance checks, testing proposals and substance evaluation are the main tools used to generate missing data.

In 2021, ECHA carried out 300 full compliance checks covering 288 unique substances[15]. The full checks focused on addressing relevant higher-tier hazard endpoints for substances in the context of substance groups of potential concern mainly in higher tonnage bands. In addition, ECHA conducted 71 targeted compliance checks, which in total resulted in 371 checks. Overall, the checks covered over 2 100 registration dossiers and addressing 341 unique substances.

Under substance evaluation, ECHA and Member States adopted 10 decisions requesting further data generation in 2021. Requests for information issued by ECHA under compliance check and substance evaluation in 2021 are outlined in Figure 6 and Table 2, respectively. An overview of the cumulative outcomes of all concluded compliance checks and substance evaluations (including those leading towards risk management measures) by the end of 2021 is presented in Annex 2.

As their contributions to the decision-making process and further testing requests, during 2021, the PBT and ED expert groups gave scientific advice[16] on 33 cases concerning PBT properties and 15 cases concerning ED properties of substances[17].

Companies that are aware of missing information in their registration dossiers, must submit a testing proposal if they intend to perform a new test listed in Annexes IX and X to REACH. Therefore, in contrast to compliance check and substance evaluation, the proposals to test substances come from industry and are not initiated by ECHA. Nevertheless[18], ECHA examines all submitted testing proposals and ensures that each testing proposal addresses the actual information needed and avoids unnecessary testing, particularly when testing involves the use of vertebrate animals. Registrants are required to assess the availability of alternative methods to fulfil the data gaps before submitting a testing proposal as the last resort.

In 2021, ECHA performed 227 examinations on tests proposed by registrants, and issued 187 draft decisions covering 201 substances. An overview of testing proposal examinations by the end of 2021 is presented in Annex 2.

For the second time, ECHA has published a list of the substances evaluated in 2021. This list includes full details on the information requests that have been issued to companies as part of

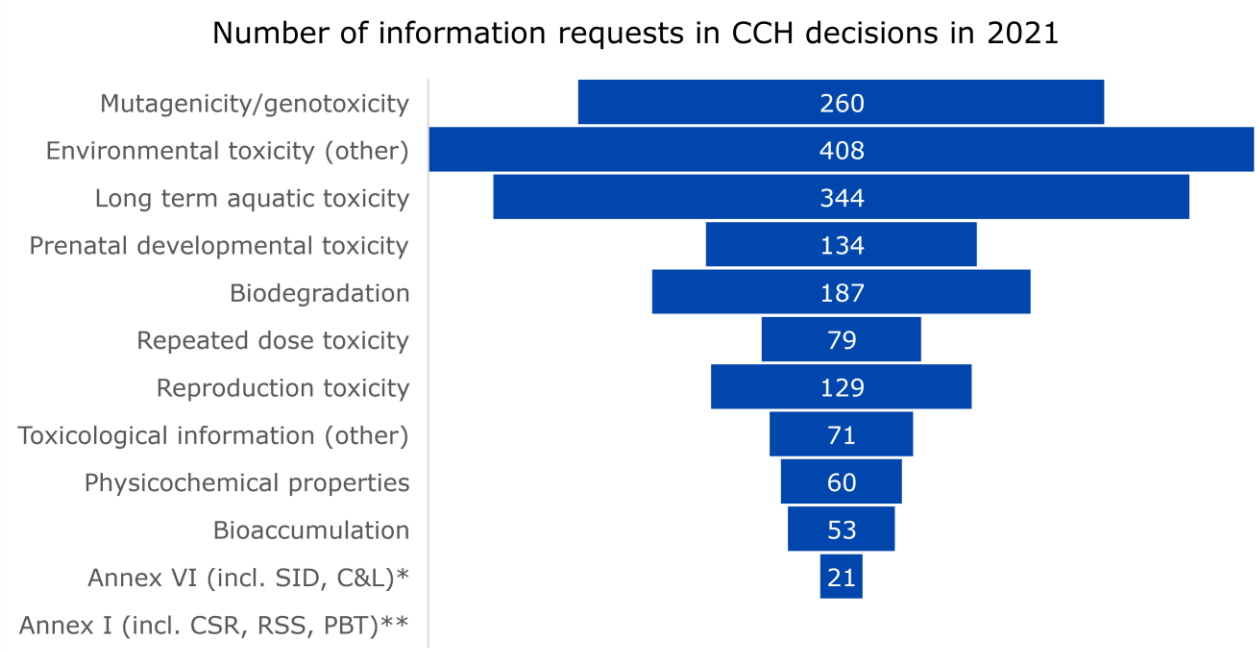
[14] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
[15] In a full compliance check, ECHA performs a systematic evaluation of all information requirements in the registration dossier, including the corresponding elements and conclusions provided in the chemical safety report. In a targeted compliance check, ECHA evaluates only a specific part of the registration dossier based on specified concerns.
[16] Expert group opinions are informal advice given to Member States that are assessing substances and generally consist of advice on ED/PBT properties, testing strategies or information needs.
[17] These numbers also include some substances discussed in the context of the Biocidal Products Regulation and the Persistent Organic Pollutants Regulation.
[18] According to Article 40 of the REACH Regulation.

ECHA's decisions[19], adopted under dossier evaluation processes. More comprehensive information on ECHA's progress on evaluation is available on ECHA's website[20].

According to the amended REACH Regulation[21], the Agency shall select for compliance check, until 31 December 2023, a percentage of those dossiers no lower than 20 % of the total received by the Agency for registrations in tonnage bands of 100 tonnes or more per year. The Agency shall, until 31 December 2027, also select for compliance check a percentage no lower than 20 % of the total dossiers received by the Agency for registrations in tonnage bands of less than 100 tonnes per year. ECHA plans to achieve this by ensuring that all registered substances that have not yet been assessed go through a grouping and assessment of regulatory needs process. Based on the current rate of identification of non-compliant dossiers during assessment, about 30 % of them will be checked for compliance.

Between 2009 and 2021, ECHA performed a full compliance check for 25 % 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). 8 % of the substances registered at 10-100 tonnes per year have also been checked.

Figure 6: Number of information requests in adopted compliance check decisions in 2021



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

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

[19] https://echa.europa.eu/documents/10162/17221/dev_substances_matrix_2021_en.xlsx/bbd3b51a-261a-a033-ee39-d446b8a1d8a6?t=1644401749758
[20] https://echa.europa.eu/overall-progress-in-evaluation
[21] EUR-Lex - 32020R0507 - EN - EUR-Lex (europa.eu)

Table 2: Number of information requests[22] in adopted substance evaluation decisions in 2021

INFORMATION REQUESTED UNDER SUBSTANCE EVALUATION IN 2021		
Suspected concern	**Information requested to clarify concern**	**Number of requests**
PBT/vPvB*	Simulation biodegradation test	7
	Ready biodegradation test	1
	Bioaccumulation test in aquatic species	3
Endocrine disruption	Fish sexual development test	1
	Larval amphibian growth and development assay	1
Other hazard-based concerns	Intra-tracheal instillation study combined with comet assay	1
	Total	**14**

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

4.1.2 Follow-up to evaluation decisions: data generated in 2021

In 2021, hazard data was received for more than 200 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 sub-chronic toxicity (90-day) studies, followed by studies on *in vitro* genotoxicity, toxicity to reproduction and long-term toxicity to fish. For the 363 follow-up evaluations performed in 2021, around 40 % of dossiers remained incompliant and these will require enforcement actions by Member States.

The benefits of substance evaluation are acknowledged. Substance evaluation is the current flexible tool for data generation, going beyond standard information requirements, ahead of expected or possible future regulatory actions, and it is an essential tool for evaluating Member State competent authorities before deciding on regulatory risk management.

In 2021, the substance evaluation of silicon dioxide (nanomaterial) was completed: following an appeal, the Board of Appeal confirmed that the concern was demonstrated and data were generated on four pyrogenic forms. Substance evaluation has contributed to the new REACH requirements applicable to nano-forms, leading to more (physicochemical) characterisation to assess the potential risks and to enable grouping and read-across. In its conclusion, the evaluating Member State reassured that the newly generated data confirmed the concerns and they will use it to submit a CLH proposal.

[22] A decision may contain more than one request.

4.2 Constant flow of substances to data generation

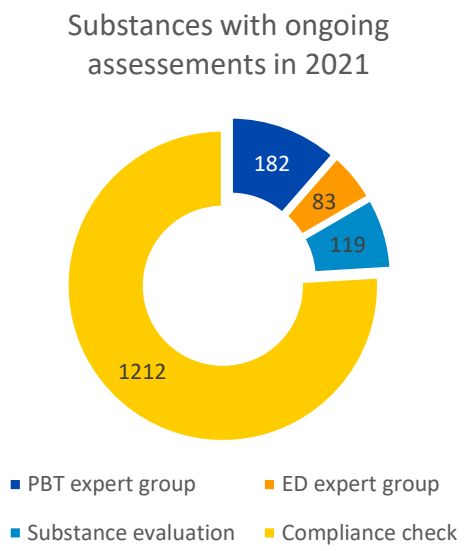


Figure 7: Number of substances with an ongoing assessment in the PBT and ED expert groups, substance evaluation and compliance check at the end of 2021

The number of substances registered above 100 tonnes per year in the 'data generation' pool has slightly increased from the end of 2020 (1 572 substances) until end of 2021 (1 768).

There was a good flow of both new substances being brought to the pool for data to be generated and substances for which data has been generated, moving to the other pools, as was demonstrated earlier in Figure 3. That said, many REACH registered substances of potential concern have an assessment ongoing. By the end of 2021, many substances were in the process of being assessed under compliance check (from the preparatory steps until the follow-up evaluation phase), substance evaluation or in one of the expert groups (Figure 7).

This means that for each of these substances:

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

Some substances in Figure 7 are counted more than once. For example, Member States use the expert groups to support their work under substance evaluation and around 80 % of the substances with potential PBT and ED properties listed in the Community rolling action plan (CoRAP) between 2012 and 2021 were discussed in the PBT and ED expert groups.

In other cases, industry may respond to a compliance check outcome by submitting a testing proposal for other endpoints than those requested. For example, testing proposals for an extended one-generation reproductive toxicity study (EOGRTS) may be submitted based on adverse effects on fertility observed in the sub-chronic 90-day toxicity study, requested at the 100-1 000 tonnage band under compliance check. More information on progress in data generation from 2009 until the end of 2021 is available in Annex 2 as well as on ECHA's website[23].

Newly generated data may play a crucial role on further risk management for individual substances. An example where registrants have changed the self-classification of their substance based on new data is presented in Box 1.

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

Box 1. Newly generated data leading to proposal for stricter classification for a group of substances

1-methylimidazole (EC: 210-484-7), in the substance group "imidazoles"

The substance has been self-classified as toxic for reproduction (developmental toxicity, Cat. 2). The registrant proposed testing for pre-natal developmental toxicity, and ECHA accepted that proposal. The registrant provided the requested study. However, ECHA concluded that in the study performed, the doses were too low and that the study did not follow OECD Test Guideline 414. A new decision pursuant to Article 42(1) was issued asking the registrant to repeat the study using higher doses of the substance. In the new study, conducted using a higher dose, malformations seen in the offspring indicated the need to apply more stringent classification (Cat. 1B) for developmental toxicity.

Similar effects were seen for other substances in that imidazoles group for which some of the members already have a harmonised classification for Repr. 1B (aneurysms and offspring viability) for 1-vinyl (C2), 2-methyl (C1), and 4-methyl (C1) imidazoles as well as non-substituted imidazole. Therefore, CLH for Repr. 1B by applying read-across, should be considered for this substance 1-methyl (C1) imidazole (EC 210-484-7) based on malformations noted in heart (misshapen) and for other non-classified group members such as 2-ethyl (C2) imidazole (EC 214-011-5; 0-10 tonnes per year), and 1-ethyl (C2) imidazole (EC 230-403-9; 0-10 tonnes per year). High priority is proposed for the CLH due to the use of the substance (professional use).

See also – Assessment of regulatory needs report for Imidazoles

In line with actions under the REACH evaluation joint action plan[24], ECHA continued to support industry initiatives that help companies review their chemical safety data and generate new information voluntarily i.e. without formal compliance check processes.

Close cooperation with Cefic continued on how to streamline the collaboration project while still maintaining the best possible support to help companies understand how to improve their registrations. Learnings from the first collaboration groups are expected to be adopted by the companies participating in the project and applied to other groups. Voluntary data generation by the participating companies is currently ongoing for the first groups and ECHA starts to process the related testing proposals in 2022.

In the context of the Petroleum and Coal stream substances (PetCo) working group, ECHA supported Concawe and other consortia in defining a strategy for filling data gaps when assessing the environmental impact of petroleum substances. 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.

Support provided in recent years to the non-ferrous industry through the Metals and Inorganics Sectoral Approach (MISA) also started to deliver. 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.

[24] REACH Evaluation action plan

5. Substances under consideration for regulatory risk management

5.1 Assessment of regulatory needs are the main source of risk management candidates

By the end of 2021, around 400 substances were mapped to this pool which is around 170 more compared to the numbers at the end of 2020.

The majority of substances in this pool – nearly 75 % - are substances for which the need for regulatory risk management has been identified, but that action has not yet started. Processes identifying the need for such risk management actions are mainly ECHA's group assessments of regulatory needs, but also e.g. follow up from compliance check, substance evaluation conclusions or RMOA[25].

Figure 4 in Section 3 gives an overview of the immediate regulatory risk management actions suggested in the assessment of regulatory needs performed by ECHA in 2021. The most common regulatory risk management actions planned are harmonised classification (7 % of all substances assessed) and restriction (6 % of all substances assessed) and SVHC identification (1 % of all substances assessed) and combinations of different actions.

For most of the substances, data generation and confirmation of hazard are needed before further regulatory risk management can be considered in more detail and, where needed, initiated under the relevant process. However, for some groups, regulatory risk management actions can already be initiated (e.g. ortho-phthalates, bisphenols).

In 2021, ECHA finalised assessments of regulatory needs for specific groups that merited additional focus, such as phthalates and bisphenols (see Box 2 below).

[25] Note that substances for which an RMOA or group assessment of regulatory needs is ongoing are now mapped to the "assessment of regulatory needs" pool and therefore – as opposed to earlier version of the chemical universe and the IRS report – these are not anymore included in this pool.

Box 2: Restriction needs identified by authorities on several phthalates and bisphenols

ECHA and Member States have assessed the regulatory needs for two well-known groups of substances, phthalates and bisphenols, and identified the need to restrict many of its members. Subsequently, ortho-phthalates and bisphenols have been included in the Rolling List of the Restrictions Roadmap as planned restrictions that are not yet on the Registry of Intentions (RoI) for restriction.

ECHA assessed the regulatory needs of four groups of phthalates and phthalate-like substances covering 134 substances due to their potential reprotoxic, endocrine disrupting, or persistent, bioaccumulative and toxic (PBT) properties. The groups include a group of *ortho*-phthalates, which have already been under regulatory scrutiny, e.g. several *ortho*-phthalates have been identified as substances of very high concern (SVHCs) and have been included in the Authorisation List. Some are restricted for use in certain articles. However, many structurally similar substances of the group are not yet regulated. The same applies to substances potentially containing such hazardous *ortho*-phthalates as constituents in significant concentrations.

The regulatory needs of 148 bisphenols have also been assessed. Many bisphenols are known endocrine disrupters both for human health and the environment. They also have reprotoxic properties. Three bisphenols (bisphenol A, bisphenol B and 2,2-bis(4'-hydroxyphenyl)-4-methylpentane) have already been identified as SVHCs, however, not all structurally related bisphenols have been under scrutiny. A group restriction has been identified as the best way to manage the risks of 34 bisphenols. This number may change as more information is generated for these and other bisphenols that were lacking data.

ECHA together with Member States are preparing to address these two groups of structurally related substances. On *ortho*-phthalates and as the first step towards restriction, preparatory activities are on-going to develop a CLH proposal. German authorities are also already preparing a proposal to restrict the use of bisphenol A and other bisphenols with endocrine-disrupting properties for the environment. Once it is clearer which bisphenols the German proposal will cover, ECHA and the European Commission will consider any further needs for regulatory action on bisphenols.

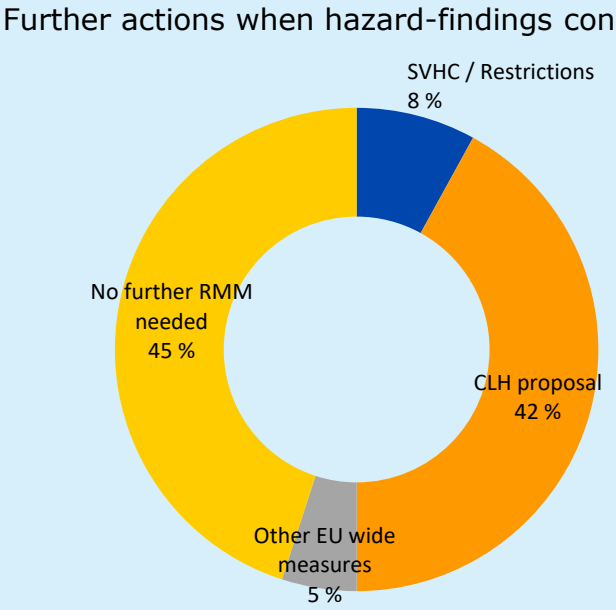
See also: Assessment of regulatory needs list - ECHA (europa.eu)

Under evaluation, ECHA also concluded follow-up assessments for 210 substances that were subject to either compliance checks or testing proposal examinations. From these substances, 44 were proposed for CLH (almost three times more than in 2020), and one was proposed for further assessment of persistent, bioaccumulative and toxic properties. The increase in identification of new CLH candidates is because the group of 29 resin and rosin acid derivatives was recommended for CLH due to reproduction toxicity. An overview of the cumulative outcomes of all concluded substance evaluations (including those leading towards risk management measures) by the end of 2021 is presented in Box 3.

Box 3: Substances from substance evaluation are progressed to regulatory risk management

By the end of 2021, substance evaluation had been concluded for 173 substances, comprising assessment of 808 hazard findings.

When the Member States confirmed the hazards (38 % of all hazards evaluated), they concluded for 55 % of the substances, that there is a need for further EU regulatory risk management. Most of the proposed follow-up actions are that Member States intend to submit a CLH proposal. (Note: a substance can have more than one proposed action).



50 substances were concluded as not hazardous or not demonstrating a potential for exposure, and 9 substances did not require further regulatory action at EU level due to actions by registrants to ensure safety (e.g. changes to supported uses, applied risk management measures, reduction of the aggregated tonnage, cease of manufacture).

5.2 Investments required to progress with substances needing regulatory action

For several years now, the number of (groups of) substances that are candidates for regulatory risk management at EU level, and in particular harmonised classification and labelling, has been growing. However, authorities are processing only a small number of them each year. ECHA's assessment of regulatory needs is now the main source of candidates for EU regulatory risk management action and the number of substances with a need for authorities to initiate action has increased at an even higher pace than before. Those candidates for which restriction has been identified as the most appropriate risk management tool have been included in the Restrictions Roadmap, which aims to prioritise these substances for (group) restrictions under REACH, ensuring transparent and timely commitments by authorities.

ECHA, Member States and Commission are also discussing how to ensure that harmonised classification and labelling progresses further.

Box 4: Restrictions Roadmap box

The Chemical Strategy for Sustainability towards a Toxic Free Environment (CSS) was published in 2020 by the European Commission. The CSS introduces several actions for a toxic-free environment and to protect people and the environment from hazardous chemicals.

One of those actions is to restrict the use of certain substances in mixtures and articles for certain users, while allowing limited exemptions under conditions clearly defined in law. Such a proposal will require some discussion and time before being introduced and implemented in REACH. Therefore, in the meantime, the Commission has prepared a roadmap to prioritise substances with specific hazards for (group) restrictions under REACH.

Substances with the following hazards are a priority:

- Carcinogenic, mutagenic, reprotoxic (CMRs);
- Endocrine disruptors;
- (very) Persistent, (very) bioaccumulation and toxic substances (PBT/vPvB);
- Immunotoxicants ;
- Neurotoxicants;
- Substances toxic to specific organs; and
- Respiratory sensitisers.

The Restrictions Roadmap sets out a rolling list in which restrictions are planned, prepared and progressed. The roadmap aims to ensure transparent and timely commitments by authorities and allow companies to anticipate (potential) upcoming restrictions.

The roadmap will be subject to regular review, which may lead to changes in the anticipated regulatory risk management action. Therefore, substances covered by the Restrictions Roadmap may come off the list while other substances may be added.

See also: Restrictions Roadmap at the European Commission website

An overview of RRM activities under REACH and CLP since 2008 is available in Annex 3. Additional information on regulatory activities is provided each year in ECHA's Annual Report[26].

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

6. Substances with regulatory risk management ongoing

6.1 More substances of concern identified and regulated every year

By the end of 2021, severe regulatory risk management measures were put in place for nearly 600 registered substances (50 % if 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 a restriction proposal for certain PBT/ED substances).

The regulatory actions include:

- Harmonised classification on Annex VI to CLP as carcinogenic, mutagenic or reprotoxic substances (CMRs) in categories 1A or 1B, or as respiratory sensitisers: 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.

The size of this pool has been largely stable since 2019. Some substances have been added to this pool, but that has been offset by other substances leaving this pool temporarily. This concerns substances with an existing harmonised classification as CMR 1A or 1B or as respiratory sensitiser, which are drawn from this pool when another process (e.g. a group assessment, data generation, but also restriction development or SVHC identification) starts. Once these processes conclude, the substances are expected to return to this pool.

In 2021, the Candidate List was updated with 10 new entries[27] (Table 3).

[27] Published in January and July 2021

Table 3: SVHC proposals discussed in 2021 and their reasons for inclusion

SUBSTANCES ADDED TO THE CANDIDATE LIST IN 2020 AND THEIR REASONS FOR INCLUSION	
1,4-dioxane	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health); Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment)
2,2-bis(bromomethyl)propane-1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)	Carcinogenic (Article 57a)
2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers	Toxic for reproduction (Article 57c)
4,4'-(1-methylpropylidene)bisphenol; bisphenol B	Endocrine disrupting properties (Article 57(f) - environment); Endocrine disrupting properties (Article 57(f) - human health)
Bis(2-(2-methoxyethoxy)ethyl) ether	Toxic for reproduction (Article 57c)
Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	Toxic for reproduction (Article 57c)
Glutaral	Respiratory sensitising properties (Article 57(f) - human health)
Medium-chain chlorinated paraffins (MCCP)	PBT (Article 57d); vPvB (Article 57e)
Orthoboric acid, sodium salt (group)	Toxic for reproduction (Article 57c)
Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	Toxic for reproduction (Article 57c); Endocrine disrupting properties (Article 57(f) - human health); Endocrine disrupting properties (Article 57(f) - environment)

Altogether, one restriction proposal was adopted in 2021 on a group of per- and polyfluoroalkyl substances (PFASs) based around perfluorohexanoic acid (PFHxA), the opinion development for a group of substances in single-use baby diapers was concluded, and four other restrictions were going through the restriction process[28].

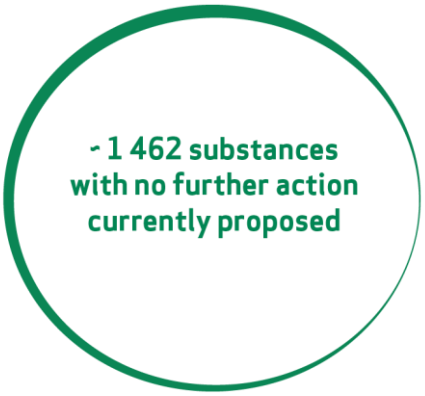
With regard to the restriction proposal on substances in single-use baby diapers, ECHA's Committee for Risk Assessment (RAC) concluded that the proposal had not demonstrated an EU-wide risk and the Committee for Socio-Economic Analysis (SEAC) concluded that the proposal was not demonstrated to be proportionate. The combined opinion of RAC and SEAC was sent to the European Commission for decision making. The European Commission can still take action based on the precautionary principle.

Furthermore, ECHA continued the screening of uses in articles for substances included on the Authorisation List for which the sunset date has passed. If the use of these substance in articles presents risks to human health or to the environment that are not adequately controlled, then ECHA is required to prepare a restriction proposal. Several screening investigations were ongoing in 2021, and one was concluded with no need to prepare a restriction proposal for the moment (for arsenic acid).

More information on substances on the Candidate List, on the Authorisation List, or restriction proposals adopted, going through the restriction process, or going through the Article 69(2) screening from 2009 until December 2021, is available in Annex 3.

[28] Dechlorane plus, 2,4 Dinitrotoluene (Article 69(2) restriction), Polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting (Article 69(2) restriction extended to 68(1) to avoid regrettable substitution) and lead in outdoor shooting and fishing.

7. Substances with no further EU RRM action currently proposed



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

By the end of 2021, around 1 460 registered substances were concluded not to currently need further EU regulatory risk management action based on assessments carried out during compliance check, substance evaluation, RMOA, or group assessments, with ECHA's assessments of regulatory needs being the main driver (Table 4). Nearly 50 % of these substances were registered at a volume of at least 100 tonnes per year.

This figure increased by over 50 % compared to December 2020 (around 920 substances), which itself is an increase of over 50 % since December 2019 (nearly 600 substances).

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**
Assessment of regulatory needs	76 %
Compliance check	20 %
Substance evaluation	1.4 %
CLH	1.4 %
ESR	1.2 %

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

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

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

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

As depicted in Figure 3, substances can be reallocated from the 'no need for further EU RRM' pool back to other pools, for example, based on new information that indicates a need to initiate further regulatory risk management. This is particularly true for substances where no need for action has been decided based on low exposure. A good example is a substance with CMR properties currently used only as an intermediate. While such a substance would normally be concluded to not need immediate regulatory risk management, it could be moved to the pool of substances for risk management together with structurally similar substances to give a clear signal that it is likely not a suitable substitute.

DIHYDROPURINEDIONE DERIVATIVES: GROUP ASSESSMENT, LEADING TO THE CONCLUSION OF CURRENTLY NO NEED FOR FURTHER EU REGULATORY RISK MANAGEMENT

Box 5: Dihydropurinedione derivatives

Dihydropurinedione derivatives (15 substances as group members) have the presence of the xanthine moiety in common. Xanthine derivatives are found in common food products and beverages such as cocoa, tea, coffee and as active ingredients in pharmaceuticals and cosmetics.

Based on information reported in the REACH registration dossiers, only caffeine has widespread uses including uses in cosmetics that would result in potential for exposure. The substances in the group are also used in pharmaceutical applications in human and veterinary medicine (i.e. theophylline and aminophylline for the treatment of asthma and breathing difficulties).

The available information indicates that the substances in the group present no or an unlikely hazard for the environment. However, the substances have the potential for reproductive toxicity. This is based on findings in experimental animal studies with caffeine, theobromine and theophylline and is extrapolated based on structural similarity to all the substances in the group.

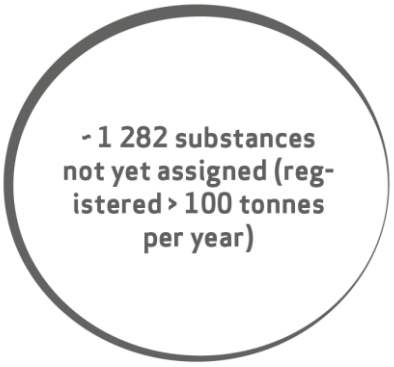
ECHA concluded in their assessment of regulatory needs that there is **currently no need for EU regulatory risk management** action on all the substances in the group for the following reasons:

- A proposal for harmonised classification and labelling (CLH) for theophylline is ongoing for reproductive toxicity (development). This should lead to the recommendation by registrants of sufficient risk management measures at company level according to workplace legislation as the substance is only used as an intermediate. The harmonised classification will also support regulatory action under the Cosmetic Products Regulation (EC) No 1223/2009 as CMR category 1 substances are restricted.
- For caffeine and theobromine, the reproductive effects are seen at very high exposure levels that do not occur in real life exposure situations. In addition, theobromine is only registered for intermediate uses and the registrations do not report uses of caffeine and theobromine in cosmetic products.
- For the remaining registered substances, the exposure potential is assumed to be low.

See assessment of regulatory needs

8. Substances in the 'not yet assigned' area

8.1 Progress in mapping and grouping the not yet assigned pool



The pool of substances that had not yet been assigned to any other chemical universe pool continued to shrink during 2021.

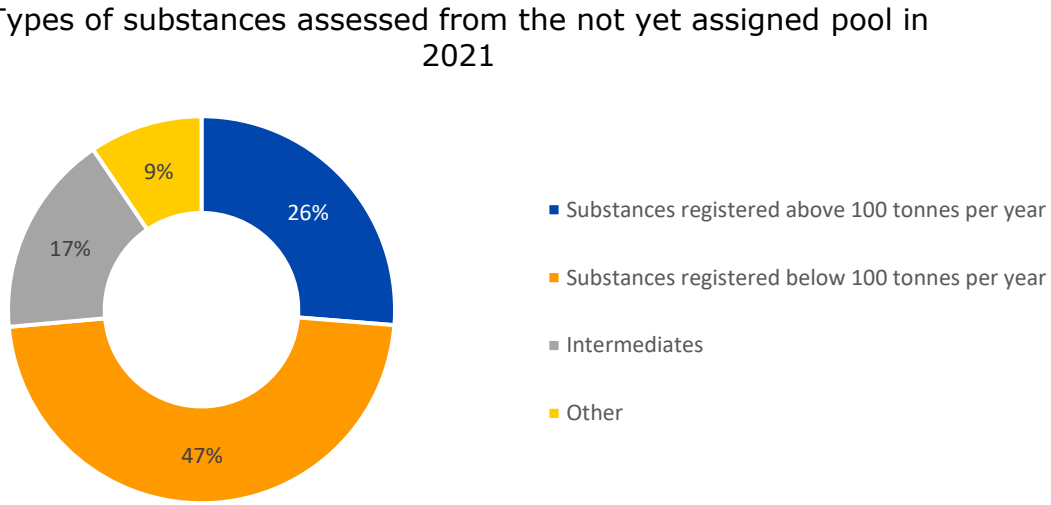
We could assign over 250 substances registered above 100 tonnes per year to another pool as well as more than 500 substances registered between 1-100 tonnes.

As such, at the end of 2021 there were around 1 280 substances registered above 100 tonnes per year left that had not yet been assigned to any other pool, and approximately 5 940 substances registered between 1-100 tonnes.

Of the around 750 substances registered above 1 tonne per year, which were removed from the not yet assigned pool during 2021, the vast majority is due to ECHA's group assessments of regulatory needs.

It is worth noting that we reached a tipping point in 2021. For the first time, more substances registered below 100 tonnes per year have been cleared from the not yet assigned area, than those registered above 100 tonnes. This trend is expected to continue towards 2027.

Figure 8: Overview of the types of substances assessed from the not yet assigned pool in 2021



Of the group assessments of regulatory needs concluded in 2021, over 50 % of substances registered above 100 tonnes per year were proposed for further data generation under compliance check, followed by 40 % of substances being concluded as currently not needing further EU regulatory action (Table 5). These are slightly higher rates compared to those proposed in 2020.

As in 2020, for substances registered at 1-100 tonnes per year, 'currently no action proposed' was the most common outcome of ECHA's group assessments of regulatory needs (41 %), whereas compliance check was the second most frequent common outcome (37 %).

Need for data generation under substance evaluation was identified for six substances. This means that tailored data beyond standard information requirements may be generated. In 2021, no substances were proposed for ED or PBT assessment or for inclusion in the Candidate List or Authorisation List.

For a subset of substances (about twice as high as in 2020), in its group assessments of regulatory needs ECHA proposed further regulatory risk management based on the available data: altogether 58 substances for harmonised classification, 12 substances for preparation of a restriction proposal, and three substances to be considered under other than REACH or CLP regulation.

Table 5. Number of substances from the not yet assigned pool for which a group assessment was concluded in 2021 and the concluded proposal

NUMBER OF SUBSTANCES FROM THE NOT YET ASSIGNED POOL FOR WHICH A GROUP ASSESSMENT WAS CONCLUDED IN 2021 AND THE PROPOSAL				
Group assessment proposal	**Registered above 100 t/y**	**Registered below 100 t/y**	**Intermediates**	**Total**
Need for CCH	92	127	4	227
Need for Substance Evaluation	2	3	1	6
Need for CLH	4	32	10	58
Restriction	5	6	0	12
Other legislation	0	0	2	3
Currently no need for action	77	142	90	344
Pending the outcome of other substances	14	36	16	82

By the end of 2021, around 25 % of substances contained in this pool had been assigned to groups to be assessed. Of the grouped substances, around 54 % are substances registered above 100 tonnes per year.

A major share of the remaining 1 280 substances registered above 100 tonnes per year in the 'not yet assigned pool' are expected to be substances that have less severe hazards but also chemicals for which group assessments could not yet start due to many ongoing clarifications on substance identity or data generation, or that are complex, such as slags and residues, and for which additional elements need to be considered before deciding on further action.

On the other hand, for many of the remaining 5 940 substances registered between 1-100 tonnes, there is not 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.

9. Conclusions

The work carried out in 2021 shows that authorities have successfully used the group approach to accelerate the identification of new substances of potential concern. As a result of the group assessments concluded in 2021, 650 substances were identified as potentially warranting further EU regulatory risk management, out of which nearly 300 substances could be immediate candidates for action.

The group assessment approach has matured due to the strong investments of resources by ECHA ensuring a high pace of the work, tenfold compared to the screening carried out between 2014-2018.

In 2021, assessment was finalised for more than 1 900 substances, 30 % more than in 2020. In the coming years, ECHA can use the lessons learned while implementing the Integrated Regulatory Strategy's to further optimise the group approach and ensure it meets the target of assessing all remaining substances not yet addressed by the end of 2027. To meet this goal, collaboration with Member States needs to improve so that actions are initiated, where relevant, especially for harmonised classification and labelling.

Based on group assessments carried out during 2019 to 2021, EU regulatory risk management actions are expected for 25 % of assessed substances, while there is currently no need for EU regulatory action for about 75% of the substances assessed. However, further data generation is often required before the need for planned actions can be confirmed or actions are initiated. Therefore, impactful compliance checks remain a priority for ECHA in the coming years.

For the assessment of regulatory needs, it has proven important for ECHA to use all available information when assessing structurally similar substances and propose substances for data generation only when hazards remain unclear. Where possible, if we can already conclude no need for regulatory action or data already sufficient for regulatory action in an otherwise coherent group of substances, these may be of low priority for compliance checks. This will avoid the need for new data to be generated for substances where data on similar substances are available and will contribute to reduce further testing on vertebrate animals compared to the situation where each substance is assessed separately.

Close cooperation with Cefic continued and discussions were held on how to streamline their project while still maintaining the best possible support to help companies understand how to improve their registrations.

The group assessment work has shown that after compliance checks, substances can often proceed directly to regulatory risk management.

We have introduced a new 'assessment of regulatory needs' pool to the chemical universe. This better reflects the informal character of these assessments as the 'regulatory risk management under consideration' pool is no longer inflated with this high-throughput process.

Substantial numbers of substances have been identified as needing regulatory risk management but have not yet been picked up by authorities. The majority of these require harmonised classification and labelling (CLH). The accumulation of pending CLH candidates is a bottleneck in efficiently implementing the strategy, as CLH is often the prerequisite for moving ahead with regulatory measures under REACH, such as authorisation, or under other EU legislation.

As we can see from the group assessments concluded in 2021, the number of CLH candidates is expected to rise even further. Increasing the throughput of CLH proposals is important for the future, considering the generic risk assessment approach that significantly increases their impact.

To shorten the time between identifying a concern and regulatory action being taken, Member States need to ensure that such substances are progressed without delay so that regulatory risk management can be initiated, where necessary.

Member States are encouraged to ensure sufficient resources for regulatory risk management and intensify collaboration with each other, and with ECHA, to maximise the outcome of their work. The regulation revisions accompanying the Commission's Chemicals Strategy for Sustainability (CSS) aim to address this bottleneck through a number of actions. In addition to more resources for Member States in dossier preparation, there is also the need for more resources in committee work to ensure good collaboration across Member States and with ECHA.

Most new substances progressing to regulatory risk management have resulted from the work on groups of substances, demonstrating that the impacts of the group approach are starting to be visible.

This is demonstrated through a number of substances assessed through the grouping approach that have been included in the Restriction Roadmap, including *ortho*-phthalates, bisphenols, skin sensitisers and flame retardants. The impact of group work on the number of substances for which regulatory risk management is ongoing is expected to increase further in the coming years as information needed to conclude on their hazards becomes available through data generation.

Annex 1. Overview of pre-regulatory steps (2008-2021)

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 2012-2021. In 2021, the PBT and ED expert groups advised on 33 PBT cases[1] and 15 ED cases[2].

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

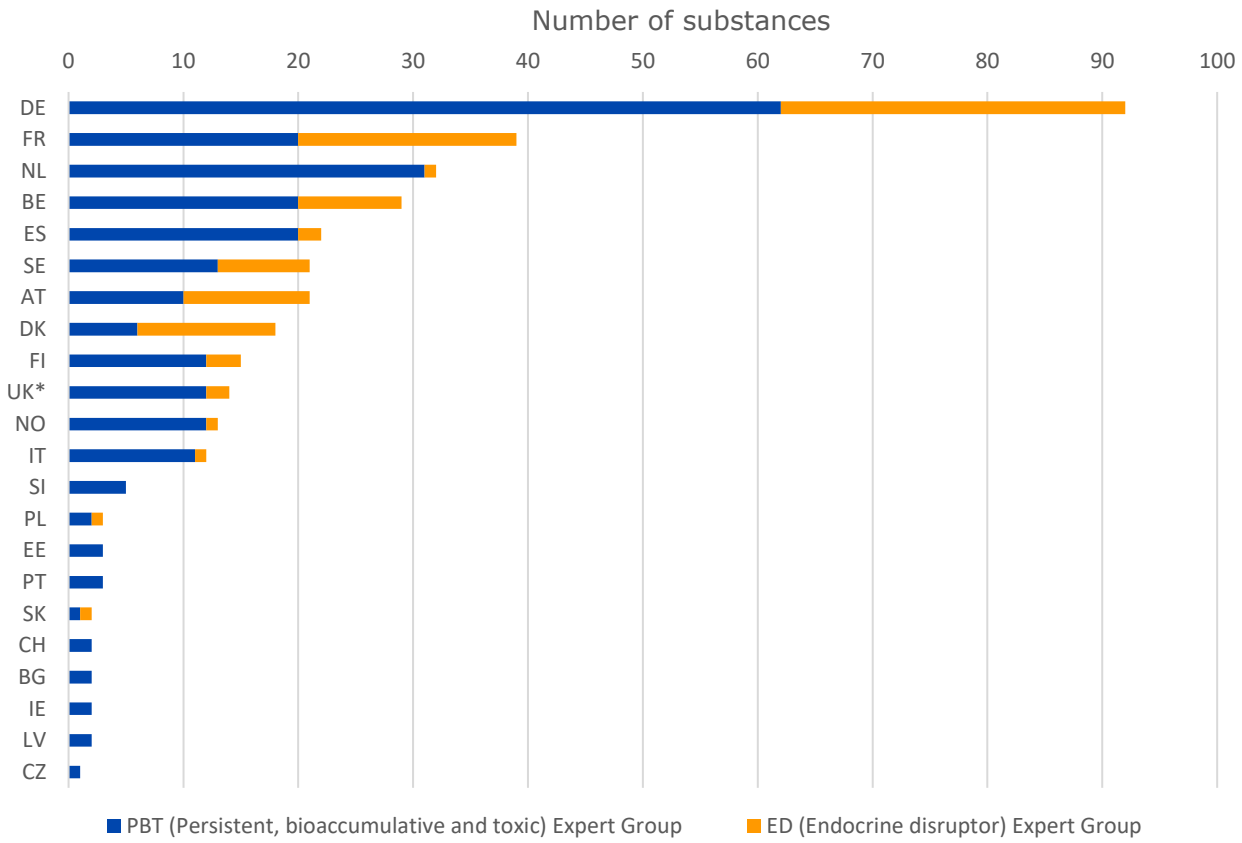
Table 1: Number and outcome of substances considered by the PBT and ED expert groups (2012-2021)

OVERVIEW OF SUBSTANCES CONSIDERED BY THE PBT AND ED EXPERT GROUPS				
Property	**Substances concluded on**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties**	**Substances ongoing or postponed**
PBT	105	26	68	166
ED	19	14	1	78

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

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

Figure 1: Number of substances under assessment in the ED Expert Group, the PBT Expert Group per Member State 2013-2021



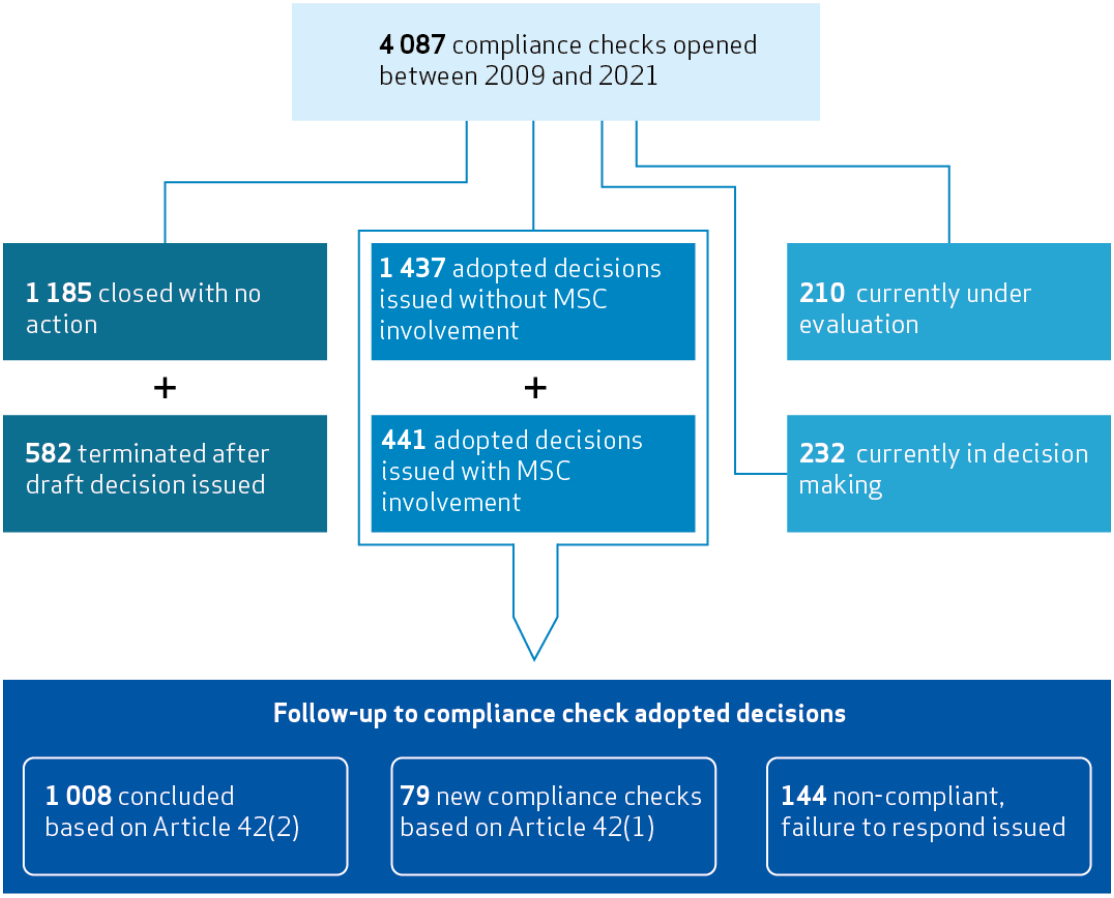
*Member State until 31 January 2020

Annex 2. Overview of evaluation activities (2009-2021)

Compliance check 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 carried out between 2009 and 2021 and their outcome[1], and Figure 2 shows the status of substance evaluations at the end of 2021. Table 1 gives an overview of the properties of substances evaluated between 2012 and 2021. For more detailed statistics on the progress in evaluation[2] and recommendations to registrants[3] resulting from evaluation work, consult ECHA's website.

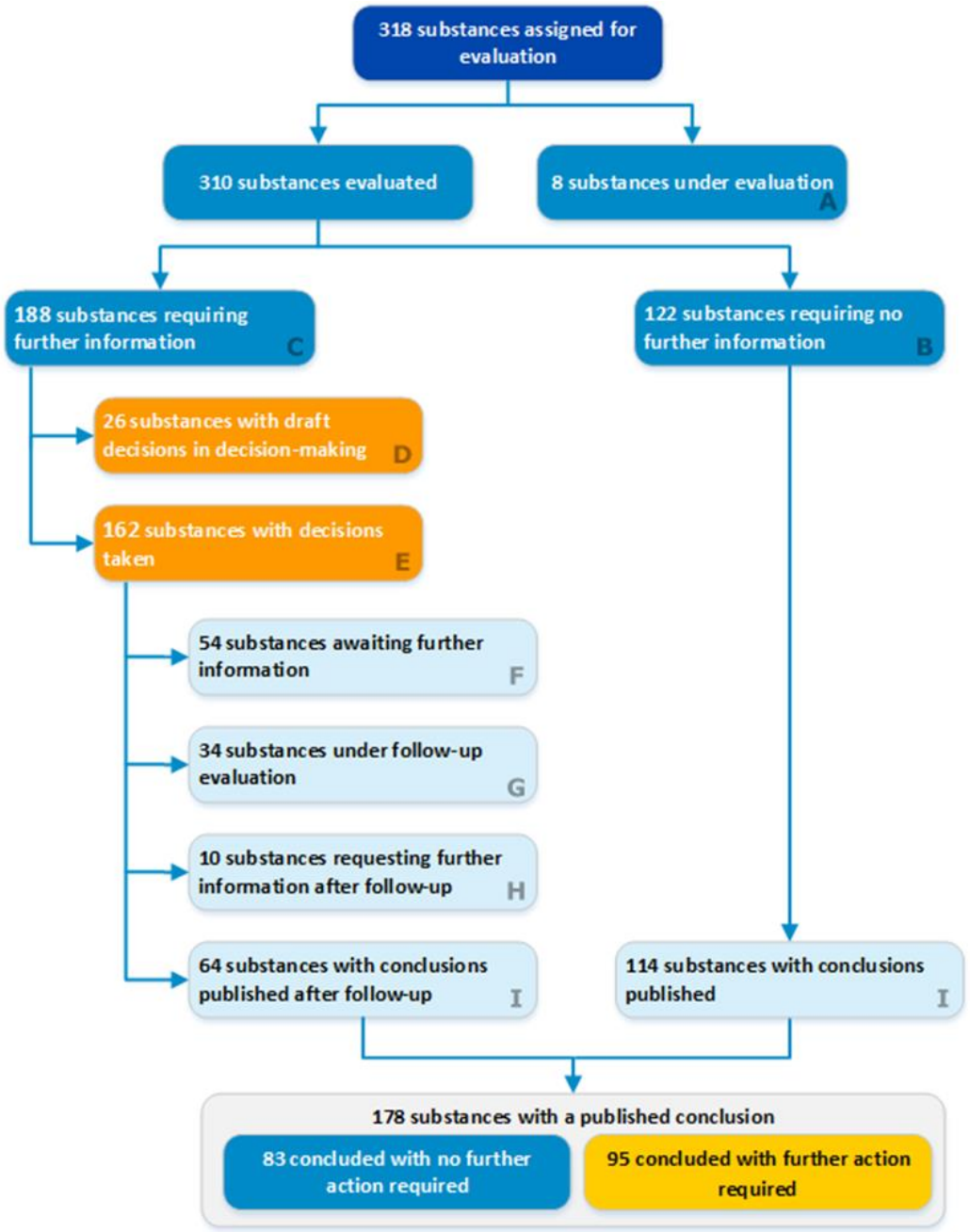
Figure 1: Number of compliance checks between 2009 and 2021



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

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

Figure 2: Status of all substance evaluations at the end of 2021



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

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

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

[D] Stages of draft decision processing: 16 substances currently in decision-making stage. 10 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, 185 SEv decisions adopted.

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

[G] Evaluating MSCA is examining all new information in updated registration. For 13 substances, draft conclusion documents are being prepared.

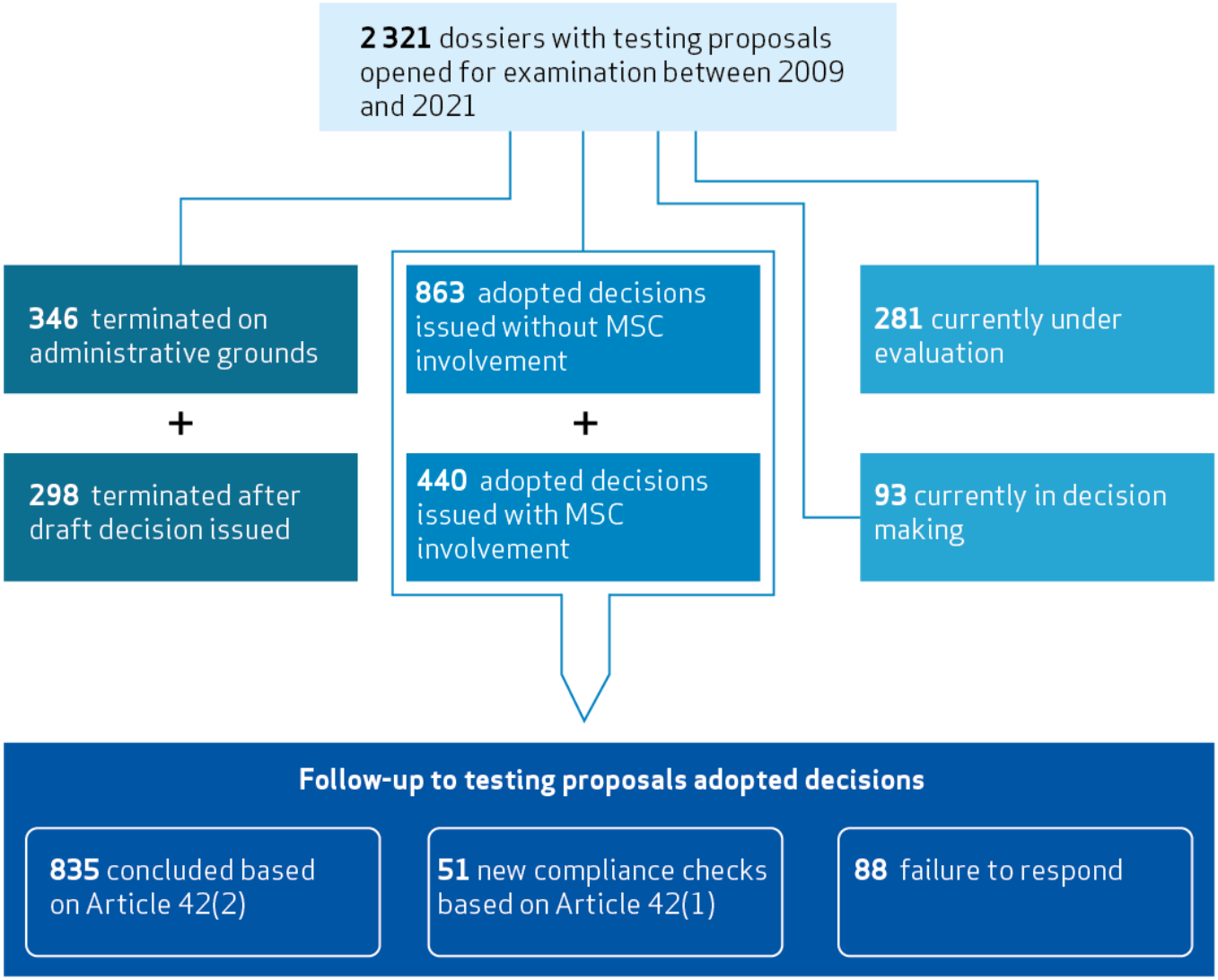
[H] Draft decision requesting further information deemed necessary after follow-up assessment.

[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 (2012-2021)

CONCLUDED AND ONGOING SUBSTANCE EVALUATIONS PER PROPERTY (2012-2021)				
Property	**Substances concluded on**	**Considered to fulfil the hazard properties**	**Considered not to fulfil the hazard properties***	**Substances ongoing**
PBT	78	7	75	103
ED	44	7	38	60
CMR	126	56	119	98
Sensitiser	94	55	49	23

Figure 3: Number of testing proposal examinations between 2009 and 2021



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

Harmonised classification and labelling

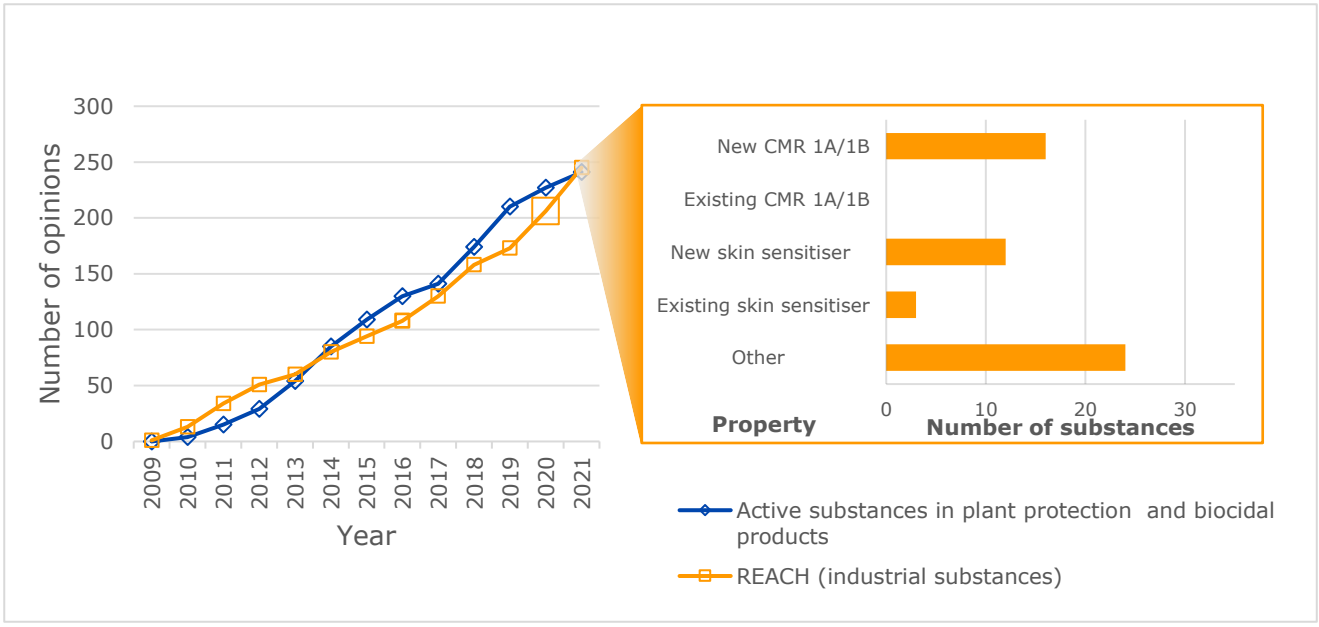
Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity, or respiratory sensitisation in any category, are normally subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal products or plant protection products should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

For all other hazardous substances, CLH can be sought if a justification is provided that shows such an action is required at EU level[4].

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2021, 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[5] and existing CMRs[6] was adopted is also reported.

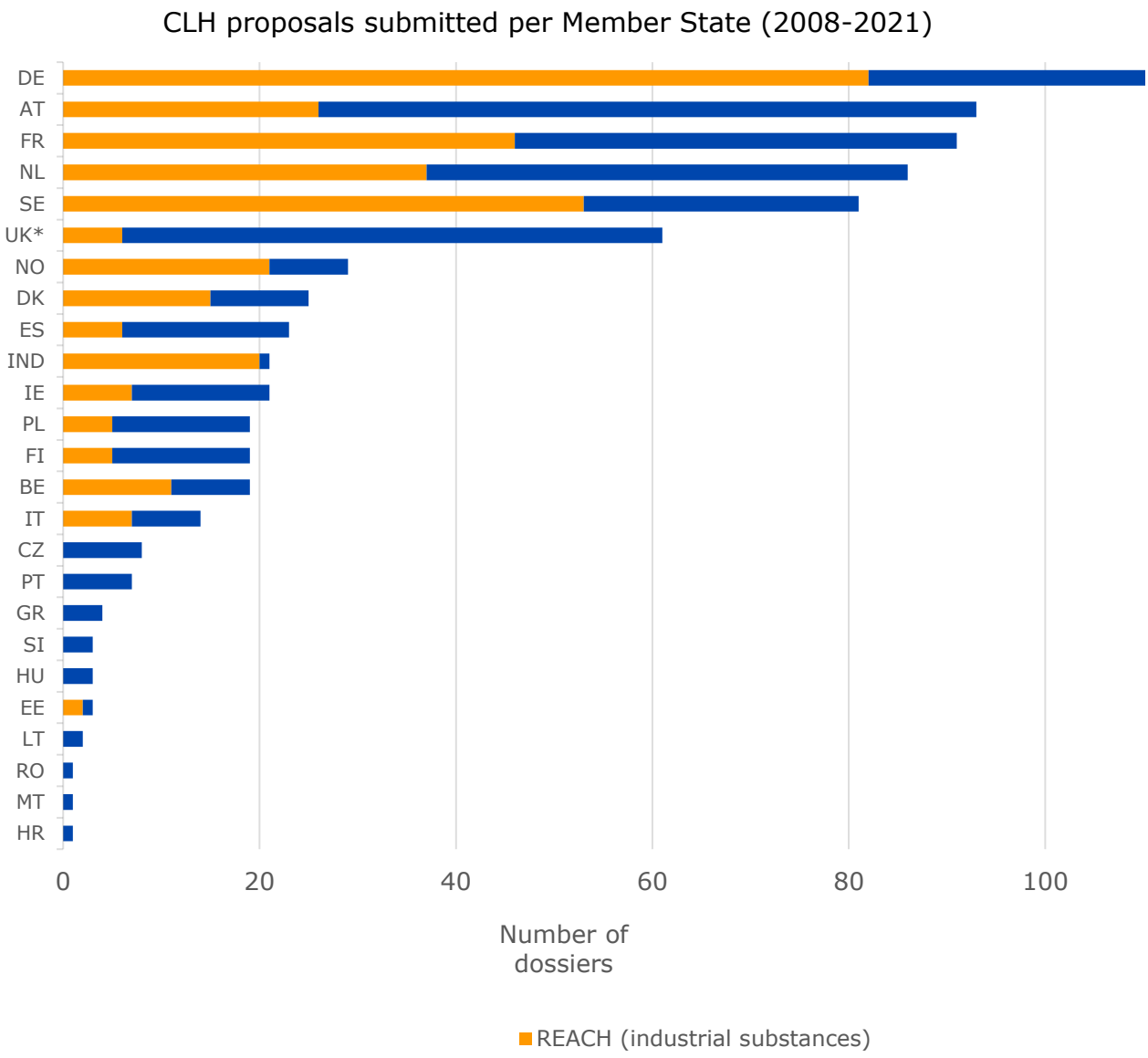
Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2021 and a breakdown of REACH substances for which a CMR 1A/1B or sensitiser proposal was included



[4] https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling
[5] A new CMR is a substance that was not classified as a CMR before.
[6] 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 submitted per Member State (2008–2021)



* Member State until 31 January 2020

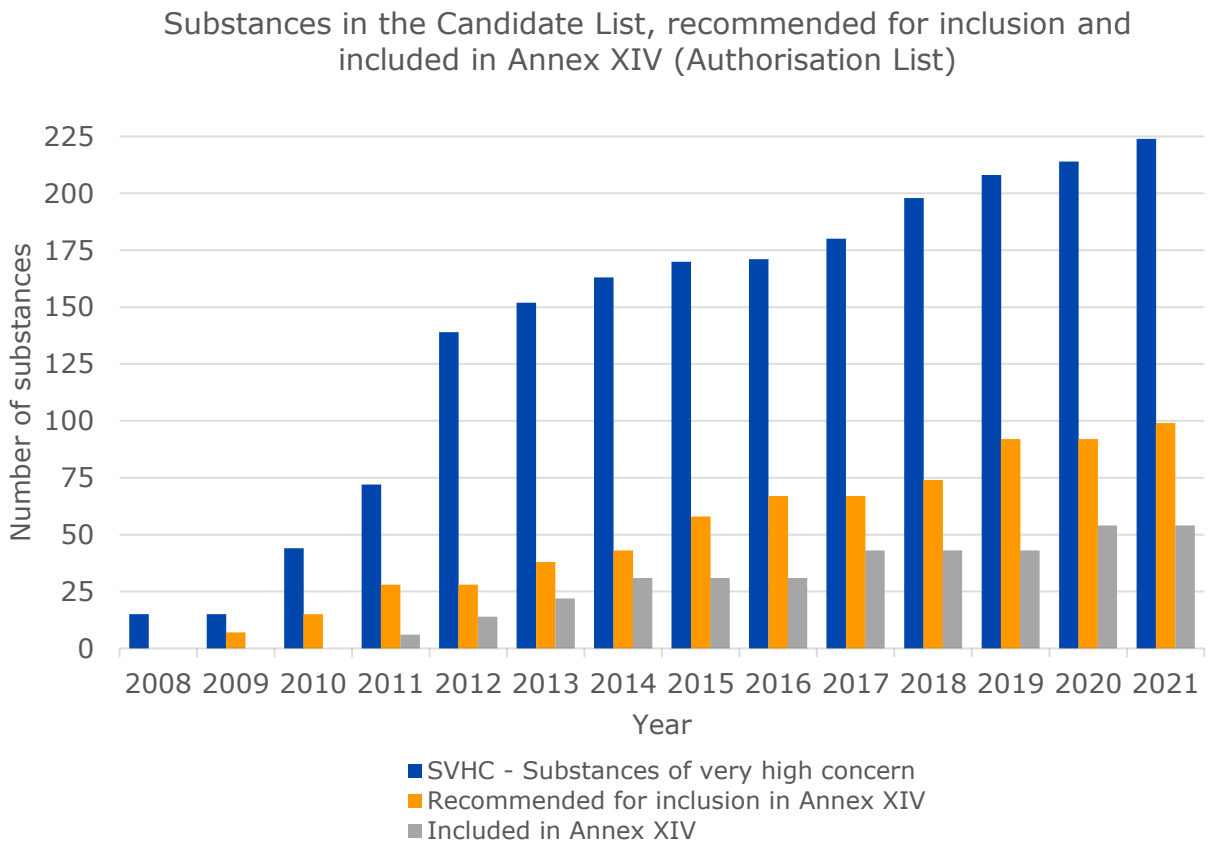
Authorisation

In 2008, the first substances of very high concern (SVHCs) under REACH were identified, marking the start of the REACH authorisation process[7].

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

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 2021. 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:

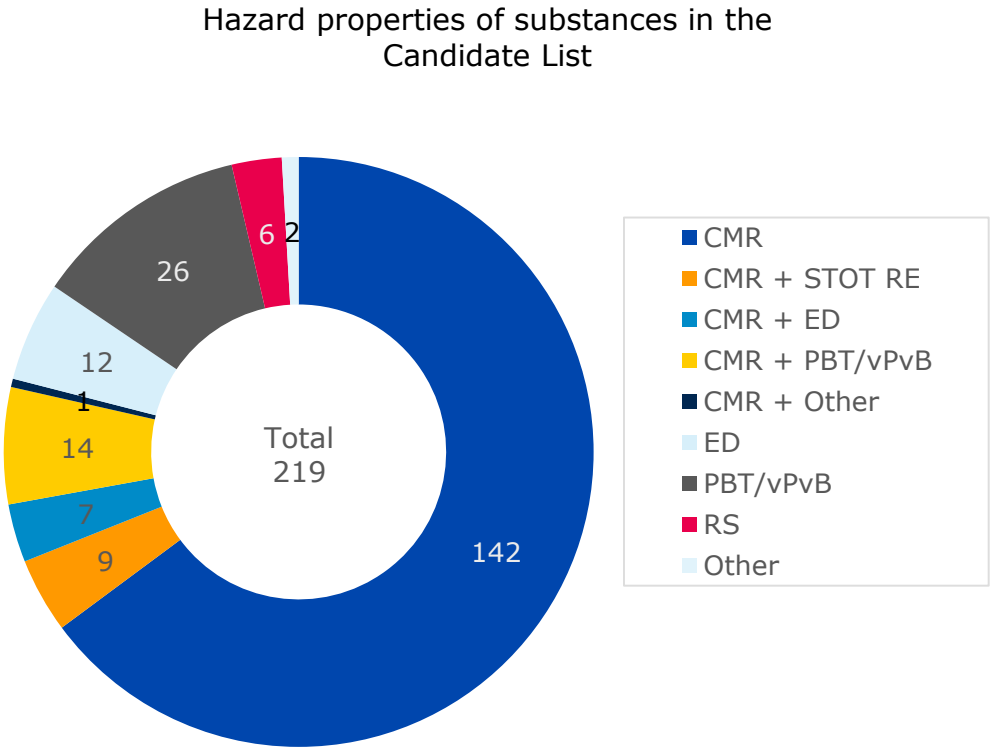
- they meet the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction (CMR) (Category 1A or 1B);
- are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- are identified on a case-by-case basis for which there is scientific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

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

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



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

In 2021, 10 more (groups of) substances were included in the Candidate List.

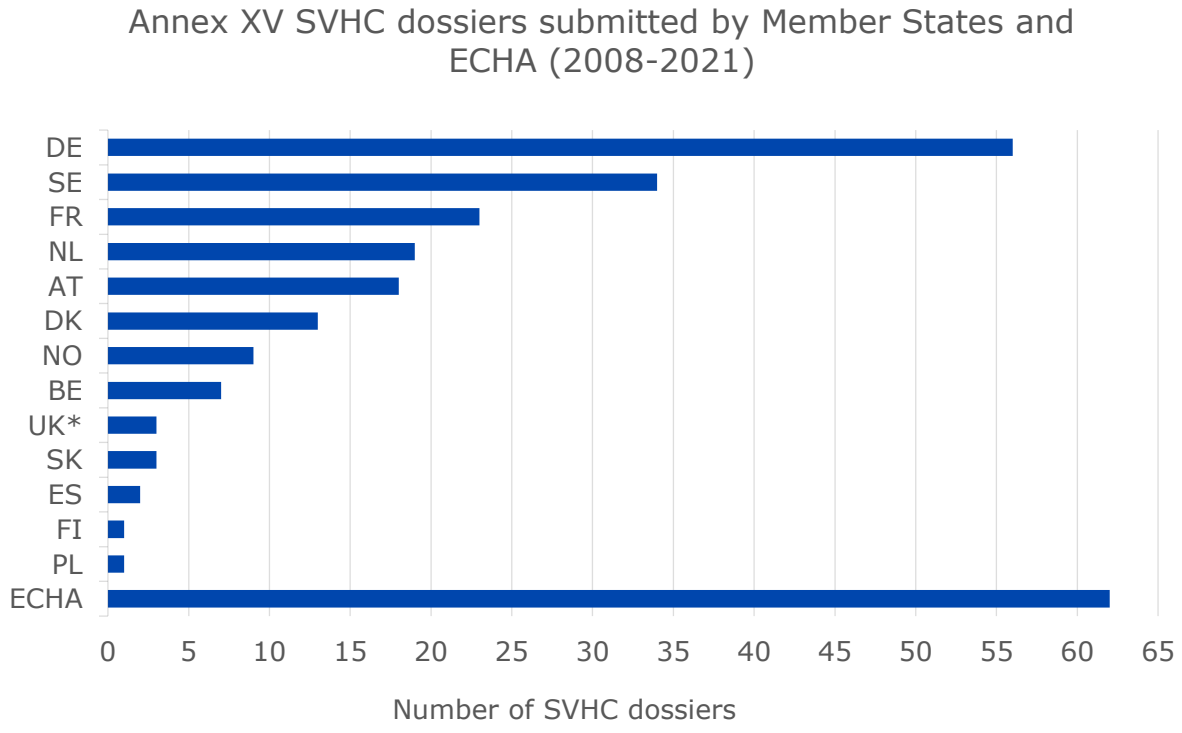
Table 1 gives an overview of the number of substances added to the Candidate List for each property since 2008.

Table 1: Overview of the number of substances included in the Candidate List by property (2008-2021)

NUMBER OF SUBSTANCES INCLUDED IN THE CANDIDATE LIST BY PROPERTY (2008-2021)											
Property	**2008 - 2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
CMR	123	12	8	4	1	2	8	3	4	7	172
ED	3	1	1			7	3	2	1	2	20
Equivalent level of concern								1	1	1	3
PBT/vPvB	16	2	2	4	1	2	8	4		1	40
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 (2008-2021)



*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[8]. 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[9] until the ninth recommendation as well as the substances included in the Authorisation List (Annex XIV)[10] by the end of 2020. Substances recommended within the ninth recommendation have not yet been considered by the Commission for amending Annex XIV.

Figure 6: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008-2020)[11]

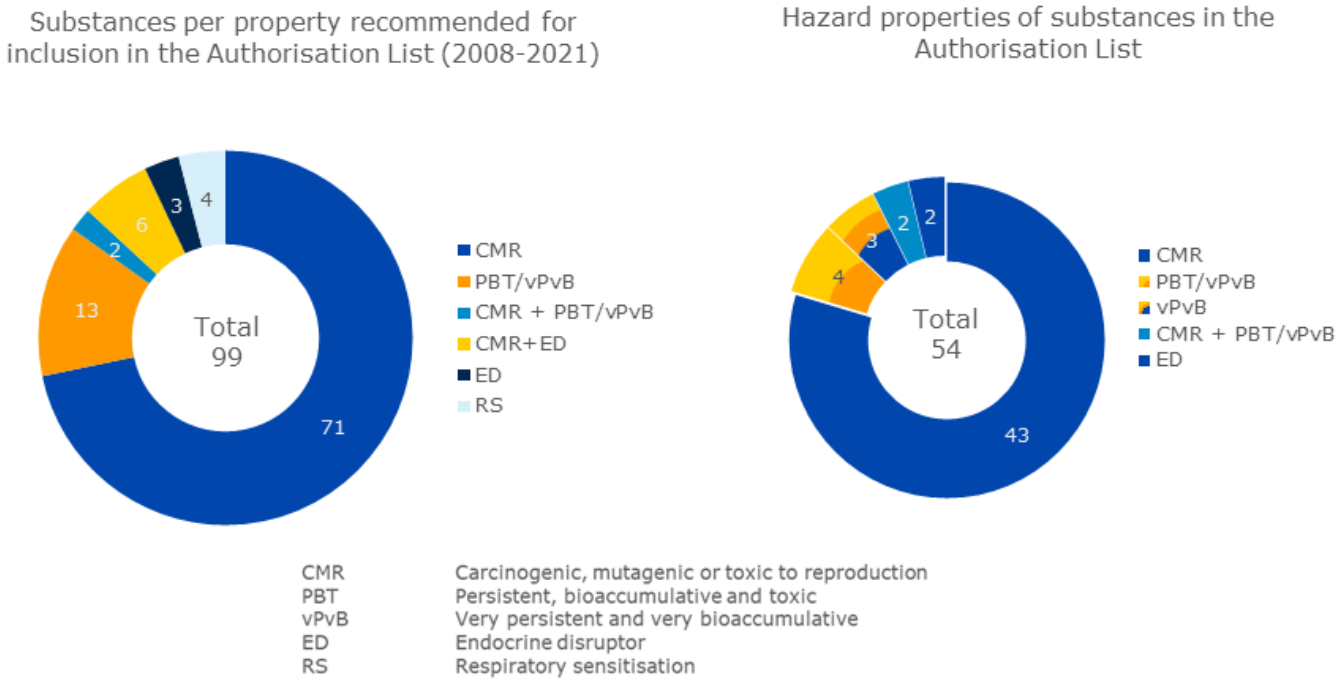


Table 2 gives an overview of the number of substances recommended by ECHA to be included in Annex XIV until the ninth recommendation. It also lists those substances which have been included in the Authorisation List (Annex XIV) and which have not. The Commission has indicated in the preambles of each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

[8] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf
[9] https://echa.europa.eu/previous-recommendations
[10] Substances included in Annex XIV can be found at: https://echa.europa.eu/authorisation-list
[11] Four substances are listed in Annex XIV with CMR properties only, while they also have ED properties. This has not yet been updated in Annex XIV and, as a consequence, is not reported here.

Table 2: Overview of (groups of) substances recommended for inclusion in Annex XIV and substances included in Annex XIV (2008-2021)

OVERVIEW OF SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV AND SUBSTANCES INCLUDED IN ANNEX XIV (2008-2021)							
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	01/06/2009	7	1st	17/02/2011	6	Musk xylene, MDA, HBCDD, 3 phthalates+	SCCP*
2nd	17/12/2010	8	2nd	14/02/2012	8	1 phthalate+, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd	20/12/2011	13	3rd	17/04/2013	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) substances
4th	17/01/2013	10	4th	14/08/2014	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th	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		[n/a]	[n/a]	[n/a]	***
10th	14/04/2021	7		[n/a]	[n/a]	[n/a]	***
	Total	**99**			**54**		**20**

* 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 ninth (18) and tenth (7) recommendation 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 or not to grant an authorisation for the uses applied for.

The number of applications for authorisation received between January 2013 and the end of December 2020, as well as the number of Committee for Risk Assessment (RAC) opinions, Committee for Socio-Economic Analysis (SEAC) opinions and Commission decisions are available online and regularly updated[12].

Restrictions

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

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

Table 4: Overview of restriction proposals on substances adopted or going through the restriction process from 2009 to December 2021. Some cover groups of substances.

NUMBER OF RESTRICTION PROPOSALS ON (GROUPS OF) SUBSTANCES ADOPTED OR GOING THROUGH THE RESTRICTION PROCES					
Step in restriction process	PBT	ED	CMR	Sensitiser	Other
Included in Annex XVII	Octamethyl-cyclotetrasiloxane (D4), decamethyl-cyclopentasiloxane (D5), PFOA (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, lead in shot, DMF, PAH in rubber granules	Chromium VI*, DMFu, diisocyanates	Ammonium salts, methanol, TDFA, tattoo inks (various hazard properties)
Process ongoing	Dechlorane Plus	-	DNT, single-use baby diapers, lead in SHF, lead in ammunition and fishing sinkers, PAHs in clay targets, 2,4-dinitrotoluene	Skin sensitisers in textiles	PAHs, dioxins, furans, PCBs and formaldehyde in singe use baby diapers (various

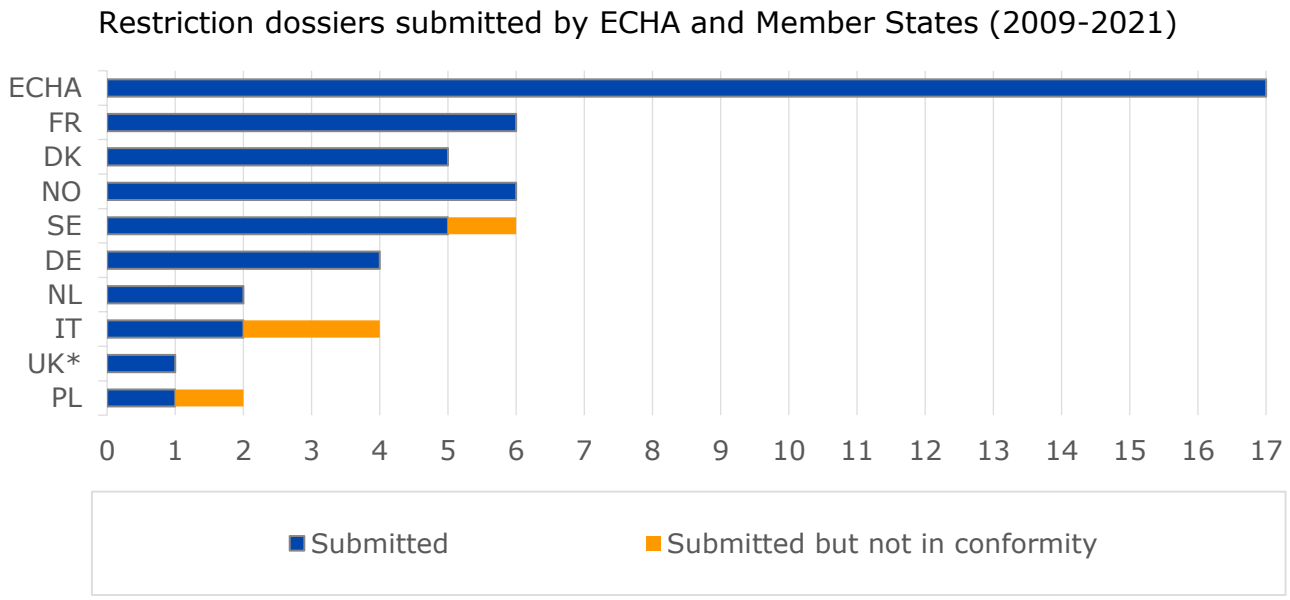
[12] https://echa.europa.eu/received-applications

					hazard properties)
RAC/SEAC opinions adopted but not yet in Annex XVII	C9-C14 (plus supplementary opinion), D4/D5/D6, PFHxA (and related substances), PFHxS (and related substances)	-	Formaldehyde and formaldehyde releasers, soluble cobalt salts, lead in PVC		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 (2009–2021)



*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 risks to the environment or to human health (Article 69(2)). Table 5 provides the number of entries on the Authorisation List screened so far, including the status of the screening.

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

NUMBER OF SUBSTANCES (ENTRIES) ON THE AUTHORISATION LIST SCREENED OR WORK ONGOING ACCORDING TO ARTICLE 69(2) SINCE THE FIRST SUNSET DATE OF 21 AUGUST 2014				
Status of the screening	Total	No of restrictions proposed	Restriction under preparation	Restriction decided
Screening finalised	15	6	6	4*
Screening ongoing	34**	-	-	-
Screening planned to start in 2021	5	-	-	-
Sunset date not passed/screening to start later	-	-	-	-

* Four phthalates

** Screening ongoing for other uses than clay targets for Pitch, coal tar, high temperature (CTPHT). The restriction proposal on the use in clay targets was submitted in 2021.

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