Authorities to focus on substances of potential concern

Roadmap for SVHC identification and implementation of REACH risk management measures - Annual Report

April 2018

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List of abbreviations

Abbreviation	Description
ACT	Activities Coordination Tool
Art.	Article
CCH	Compliance check under dossier evaluation
CLH	Harmonised classification and labelling
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic, toxic for reproduction
CG	Coordination group
CoRAP	Community rolling action plan
COM	Commission
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
ELoC	Equivalent level of concern
MS	Member State
PBT	Persistent, bioaccumulative and toxic
(Q)SAR	(Quantitative) structure-activity relationship
PACT	Public Activities Coordination Tool
PetCo	Petroleum and coal streams
POP	Persistent organic pollutant
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIME	Risk Management Expert Meeting of Member State competent authorities
RIP	Roadmap implementation plan
RMOA	Regulatory management option assessment
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 this fourth and also last report on progress made in implementing the SVHC Roadmap. This report describes what has been achieved since 2013 and how we have progressed in addressing all relevant currently known substances of very high concern (SVHCs). It includes also the outcome of the SVHC Roadmap implementation review initiated by ECHA together with Member States and the Commission in 2016.

We have already moved to implementing ECHA's Integrated Regulatory Strategy. The SVHC Roadmap has set its main foundation and is now part of it. The objective now for all of us is to ensure that we contribute to achieving the World Summit on Sustainable Development (WSSD) 2020 goals by having sufficient understanding of the substances registered above 100 tonnes by 2020.

One important achievement is that we have now moved to working with groups of substances, which will help us to identify more substances of concern and to support informed substitution. We need to continue and further strengthen this work, which implies also more cooperation between authorities and industry.

The SVHC Roadmap review takes good steps towards better supporting the implementation of the Integrated Regulatory Strategy, by further integrating the REACH and CLP work. We now need to optimise the system in place to achieve our objectives.

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

Bjorn Hansen
ECHA Executive Director

Executive summary

The implementation of the SVHC Roadmap has since 2013 provided a common goal and framework for the Member States, Commission and ECHA and helped to streamline the use of the different REACH and CLP processes. To support the practical work, authorities have set up a system to identify substances of concern and progress them towards further regulatory action.

The common screening is central in identifying substances with potentially high impact on human health and the environment and it has ensured that all relevant currently known substances of very high concern (SVHCs) are identified and addressed. It has been used already for several years to identify new substances of potential concern for which more information needs to be generated before subjecting them to regulatory action. Besides focusing authorities on those substances that matter, common screening has also further optimised the use of different REACH and CLP processes. This has provided the basis for setting up the Integrated Regulatory Strategy.

Each year, ECHA has screened the full REACH/CLP substance database to identify substances for further work. External databases have also been used to complement the picture. Based on this exercise, around 1 200 substances have been proposed to the Member States for further manual screening, and in the last four years, **more than 750 of these have been scrutinised**. Around 73 % of the substances scrutinised required follow-up action, in most cases the generation of new data. The common screening has also brought the key actors together – on average, 22 Member States contributed to the manual screening every year.

757 substances are currently having new data generated or are having data assessed. Around 400 substances are having their dossiers checked for compliance. For most of these substances, we need to clarify whether they have the properties of substances that are persistent, bioaccumulative and toxic (PBT), endocrine disruptors (EDs) and/or carcinogenic, mutagenic or toxic for reproduction (CMR). For substances which were evaluated under the Community rolling action plan (CoRAP) in 2012-2014 and for which further information was requested in ECHA decisions, the first data submissions arrived in 2016-2017. More will come in 2018 and 2019. Information requested under compliance checks as an outcome of the compliance check strategy also started to arrive in 2017. These data will enable us to confirm or refute the concern identified through screening and to initiate regulatory risk management measures where needed.

It must be acknowledged that the generation of higher-tier test data takes time. However, experience shows that when hazard data has become available and is based on a well-defined testing strategy, the final confirmation of the properties through harmonised classification and labelling (CLH) or SVHC identification processes can be done swiftly. Such confirmation in turn obliges industry to implement further company-level risk management measures and enables authorities to initiate further regulatory action, such as restriction under REACH.

In the context of screening, authorities have moved to address **groups of structurally similar substances** rather than single substances. This will ensure that a bigger share of all registered substances are addressed, including substances on which information on hazard and exposure is lacking. In addition, this ensures that substances of low priority for further work but of relevance for substitution (e.g. substances currently not registered, or registered only for intermediate uses) are considered. This will increase consistency of the authorities' work and support better informed substitution by industry.

In 2017, groups of substances were included for manual screening alongside single substances. Around 77 % of the substances in groups required further follow-up actions, whereas the respective percentage for single substances was much lower. This seems to confirm the trend identified in the annual report for 2016, namely that it is more and more difficult to find single substances for further regulatory action, and shows the benefit of moving towards addressing groups. Working with groups of substances should speed up the process, but it requires more cooperation and coordination between ECHA and the Member States at the start.

To speed up the identification of substances of concern, alternative ways of gathering and generating information on substances and groups of substances are being implemented, such as sector approaches (e.g. in the context of the petroleum and coal stream substances (PetCo) working group, plastic additives initiative). This work also allows us to set aside those substances that are currently of low priority for further work and to focus resources on substances that matter.

There is a consensus among authorities that the **risk management option analysis (RMOA)** approach is functioning adequately and fulfils its objectives, i.e. to provide clarity on what the submitting authority wishes to achieve with the proposed action and allow early input from other authorities. The number of RMOAs increased in 2017, with 194 substances now listed in the **public activities coordination tool (PACT)**, which is accessible through ECHA's website. In total, 98 RMOAs have been concluded and published, 31 of which in 2017. Two thirds of these concluded on the need to initiate further regulatory action, with 33 RMOAs concluding that the substance be identified as an SVHC. The concluded RMOAs have all been followed by the submission of an Annex XV dossier. In 2017, 36 new RMOAs have been initiated, included in PACT, or already been concluded.

Early in 2013, the Member States, the European Commission and ECHA agreed to have **all relevant currently known SVHCs on the Candidate List by 2020**. When setting up the SVHC Roadmap, authorities considered that to ensure the efficient use of resources, there was a need to define which substances currently on the EU market should be addressed as a priority. To this end, the roadmap set out criteria for selecting relevant substances for further regulatory action.

In accordance with the roadmap and its implementation plan, authorities have also further elaborated whether and when respiratory and skin sensitisers could be regarded as SVHCs. As a separate work stream, an approach to address petroleum and coal stream substances was developed and its implementation started.

Today, all currently known CMRs, PBT/vPvBs and EDs have been either:

RELEVANT AND CURRENTLY KNOWN

Relevant substances under the SVHC Roadmap are substances registered for uses within the scope of authorisation. This means that priority is given to the substances on the EU market with consumer, professional and non-intermediate industrial uses. In addition, to discourage regrettable substitution, substances that are not registered or are registered as intermediates only, may be prioritised for further action if structurally similar to those regarded as relevant substances.

Currently known substances are substances for which we have clarified the hazard properties and concluded that they are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) or endocrine disruptors (EDs).

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

The analysis annexed to this annual report indicates that out of the 1 700 substances addressed, there are only 13 potential PBT/vPvB substances that stem from the previous new substances regime (NONs) that may require further work.

To continue the work beyond the SVHC Roadmap targets, ECHA has agreed, together with Member States and the Commission, in line with the World Summit for Sustainable Development (WSSD) 2020 goals, to have a sufficient understanding of all remaining substances registered above 100 tonnes by 2020. The aim is to conclude for all these substances whether registrants need to generate more information, authorities need to initiate further regulatory risk management actions, or the substances are currently of low priority for further regulatory work. The decision to consider a substance as being of low priority for further regulatory work will be regularly reassessed, in particular when new information on the substance (e.g. on uses or hazards) becomes available.

MAIN RECOMMENDATIONS

- Strengthened prioritisation and grouping of substances to ensure authorities address all substances that matter.
- Increased quality of registration information and keeping registration dossiers up to date from a use and exposure perspective.
- Further optimisation of data generation and assessment to ensure that substances are progressed towards regulatory risk management measures without delay.
- Further cooperation and coordination between authorities and better integration of their work.

1 Introduction

The Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020 (SVHC Roadmap) gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) identified and included on the Candidate List by 2020. Over the years, the implementation of the roadmap has also supported the further integration of other REACH and CLP processes, with the aim to clarify which other, yet unknown, substances have SVHC properties and to get further regulatory risk management measures in place where needed.

ECHA has developed and coordinated the implementation of the SVHC Roadmap. Progress in implementing the roadmap has been reported every year in the annual report. More information on the SVHC Roadmap and the roadmap implementation plan is available on ECHA's website[1].

In 2016, ECHA, the Member States and the Commission started to review the different elements of the implementation of the SVHC Roadmap. Besides reporting on the progress in addressing all relevant currently known substances, the elements reviewed were: the RMOA approach; transparency and predictability; how to deal with impurities of concern; sensitisers and specific target organ toxicity (STOT) in screening; and cooperation and coordination of authorities' work. All these points have been discussed with the authorities.

The review confirms that the implementation of the SVHC Roadmap provides a strong basis for the work beyond 2020 and has ensured the setting up of a system for identifying new substances of concern and addressing them in a timely and effective manner under the REACH and CLP regulations. This system has provided a basis for and already supports the implementation of ECHA's Integrated Regulatory Strategy[2]. These conclusions are supported by the wider REACH review[3] undertaken by the Commission, which recognised that the work under the SVHC Roadmap is progressing beyond expectations.

This annual report focuses on:

- explaining why we can say that all currently known substances confirmed as CMRs, PBT/vPvBs and EDs have been addressed;
- demonstrating that authorities have set up a system that allows identification of groups of new potential substances of concern through screening, data generation and assessment, and RMOA, so that these substances can be progressed to further regulatory risk management measures; and
- discussing how to further optimise the system in place to ensure that substances with potentially high impact on human health and the environment are identified and addressed.

[1] Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation.
[2] Available at: https://echa.europa.eu/echa-irs.
[3] Commission's communication on the REACH Review available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN.

The SVHC Roadmap – an established system

Since 2013, the implementation of the SVHC Roadmap has already consolidated the following core elements of the roadmap:

- Clear planning and defined priorities for screening and risk management option analysis (RMOA).
- A rolling exercise that takes into consideration new information (e.g. in relation to substances newly classified as carcinogenic, mutagenic or toxic for reproduction (CMR)) and efficiently uses information derived from other REACH processes (e.g. registration, dossier and substance evaluation) to identify needs for regulatory risk management as part of the common screening.
- Increased transparency and predictability towards stakeholders and the general public (e.g. through the use of the Public Activities Coordination Tool (PACT)).
- A defined list of responsibilities based on the involvement and cooperation of all relevant actors (Member States, the Commission and ECHA), reflected in the groups set up in the context of the roadmap's implementation (e.g. the Endocrine Disruptor Expert Group (ED EG), the Petroleum and Coal stream substances working group (PetCo)).

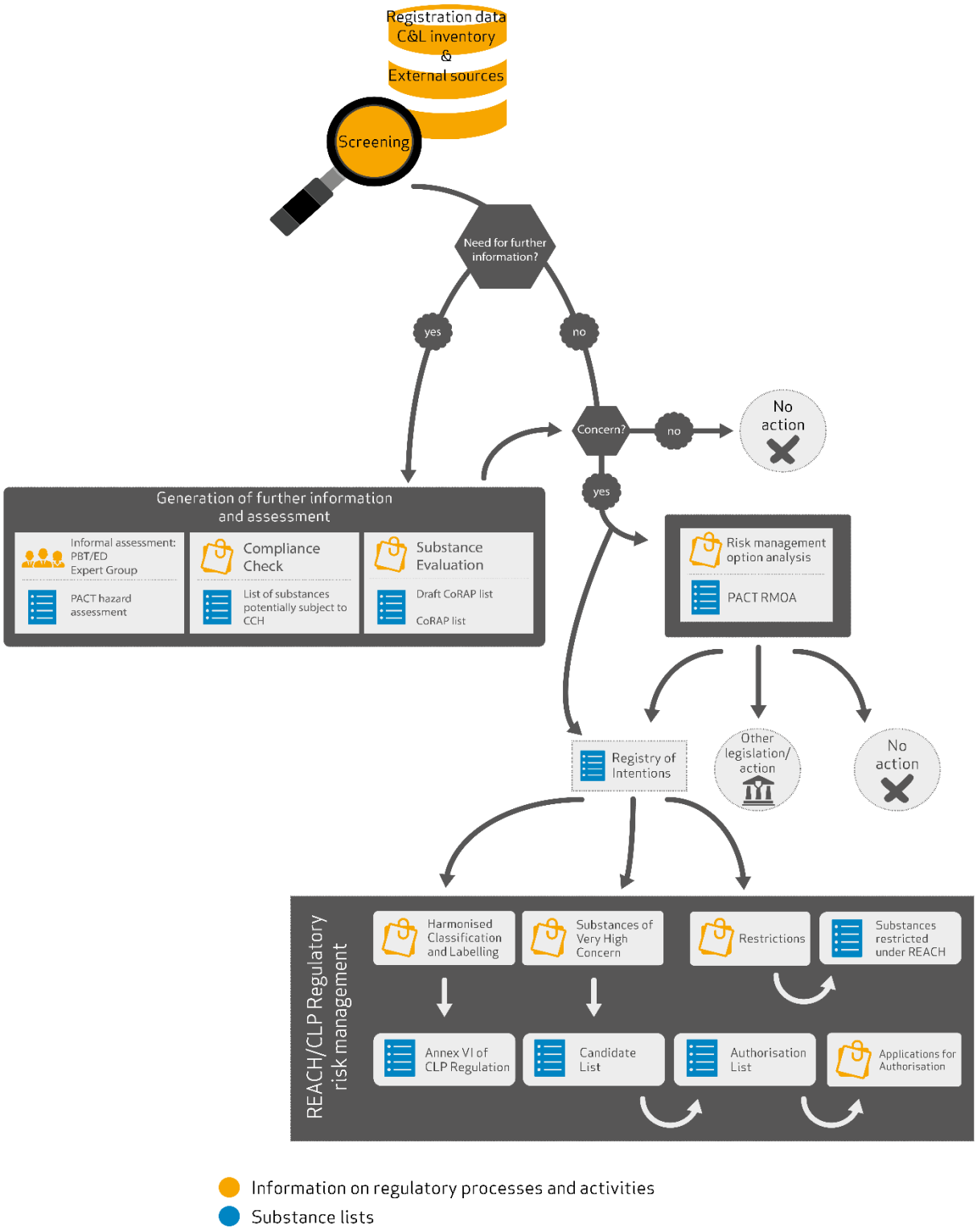


Figure 1: REACH and CLP machinery serving ECHA's Integrated Regulatory Strategy and the SVHC Roadmap[4].

[4] Clickable version available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern.

2 All currently known CMRs, PBT/vPvB and EDs addressed by authorities

When setting up the SVHC Roadmap, authorities considered that for resources to be used efficiently, there was a need to define which substances currently on the EU market should be addressed as a priority. To this end, the roadmap set out the criteria for selecting the substances that are relevant for further regulatory action.

Relevant substances as defined under the SVHC Roadmap are substances that are registered for uses within the scope of authorisation. This means that priority is given to the substances on the EU market with consumer, professional and non-intermediate industrial uses. In addition, the roadmap considered that to support informed substitution, substances that are not registered, or are registered as intermediates only, may be prioritised for further action if structurally similar to those regarded as relevant substances.

Currently known substances are substances for which we have clarified the hazard properties and concluded that they are CMRs, PBTs/vPvBs or EDs.

In accordance with the roadmap and its implementation plan, authorities have also further elaborated on whether and when respiratory and skin sensitisers could be regarded as SVHCs. As a separate work stream, an approach to address petroleum and coal stream substances has been developed and its implementation started.

Today, we can say that all currently known CMRs, PBT/vPvBs and EDs have been either:

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

In addition, several potential PBT/vPvB and EDs are under scrutiny by authorities.

This conclusion is substantiated by the analysis done by ECHA (Appendix 1) and summarised below.

All currently known SVHCs have been addressed

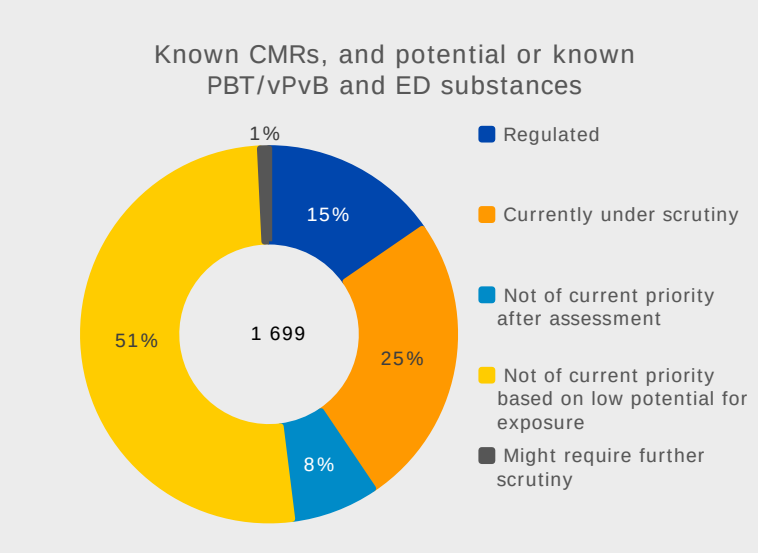
ECHA carried out an analysis of the work done by authorities on substances with CMR, PBT/vPvB and ED properties. The analysis considered all substances known to be CMRs (Annex VI to CLP) and any known or potential ED or PBT/vPvB substances before the SVHC Roadmap implementation, and tracked whether these substances (i) have been scrutinised by authorities and appropriate regulatory action has been taken, (ii) are currently under scrutiny, or (iii) are of low priority for the time being (e.g. not registered, no relevant uses).

Known CMRs: Annex VI to CLP.

Potential and known PBT/vPvBs: Substances which had been assessed by the Technical Committee of New and Existing Chemicals subgroup on identification of PBT and vPvB substances under the previous EU chemicals legislation and Substitute It Now (SIN) list substances.

Potential and known EDs: Potential ED identified by the Commission (categories 1 and 2) and SIN list substances.

A total of 1699 substances have been looked at. Among these, 1146 substances have been identified as possessing CMR properties, 250 are (potential) PBTs/vPvBs, and 377 are (potential) ED substances. Some substances have more than one hazardous property.

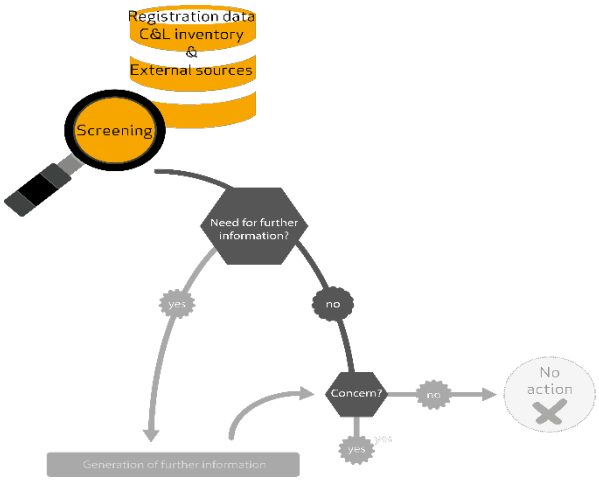


Around half of the substances analysed (870) are not of current priority within the scope of the SVHC Roadmap. 762 of these are not registered substances. Should the status of such low priority substances change, this will be identified in the screening process set up by ECHA together with Member States and Commission, allowing the substances to be considered as potential candidates for regulatory action.

A quarter of all substances analysed are currently under scrutiny and the authorities' priority should be to ensure that these move forward in the process once the concern is clarified.

13 potential PBTs/vPvBs from the previous new substances regime may require further work.

3 Common screening



Integrating REACH and CLP processes into common screening to provide a solid basis for identifying groups of new substances of concern.

Screening to find potential substances of (very high) concern is an important element of the SVHC Roadmap implementation plan as well as an integral part of ECHA's Integrated Regulatory Strategy to focus on the substances that matter most.

Prioritisation to focus resources on substances that matter most

In order to focus the resources of authorities and industry on substances that are most relevant for the protection of human health and the environment, the common screening prioritises substances for which we can expect regulatory risk management measures to be needed.

Low priority substances are defined in the SVHC Roadmap (e.g. intermediate, non-widespread, not registered). Substances that are currently of low priority may become of priority if their use or registration status changes, or if new information on their hazard properties become available. ECHA regularly runs and updates the screening process to ensure that any new information is adequately taken into account for prioritisation. This means that ECHA and Member States will continue to monitor all substances in the REACH/CLP database for any relevant changes.

Prioritisation of substances is a concept that is present in all pre-regulatory steps (manual screening by Member States, screening by ECHA before compliance check, RMOA).

(De)prioritisation

Together with Member States and the Commission, in line with the World Summit on Sustainable Development (WSSD) 2020 goals, ECHA has agreed to have a sufficient understanding of all remaining substances registered above 100 tonnes by 2020. The aim is to conclude for all these substances whether registrants need to generate more information, authorities need to initiate further regulatory risk management actions, or the substances are currently of low priority for further regulatory work.

Priorities for action are distinguished into two types:

- priority for further regulatory risk management; and
- priority for data generation.

Substances are considered of low priority for action based on three main factors:

- low hazard – the substance is likely to be non-hazardous, based on available information;
- low exposure – the substance has low potential for exposure to humans and/or release to the environment, based on current currently available information;
- low added value of risk management measures – the substance is already adequately regulated.

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

How the common screening identifies groups with new substances for further regulatory action

Since 2014, ECHA has screened the full REACH/CLP substance database to identify potential substances for further work. In four years of common screening, Member States have manually screened 767 substances. Few substances (15 %) have been identified for direct regulatory risk management measures (e.g. harmonised classification and labelling (CLH), risk management option analysis (RMOA)). This was the case particularly in the first years of screening, and mainly in relation to substances with a harmonised classification and labelling as CMR categories 1A/1B or PBT/ED properties confirmed under previous legislation. Now the pool of substances with already confirmed hazards has been emptied. It should be noted that already before the SVHC Roadmap, significant efforts had been made to identify and move to potential regulatory actions known CMRs, PBTs and EDs (see also the analysis done by ECHA on the all currently known SVHCs in Appendix 1).

The system in place ensures that all potential substances of concern are addressed and moved forward when relevant. Figure 2 shows the outcomes of all screening rounds from 2014 to 2017. It shows that for most substances screened (51 %), the outcome was the need to generate further information to confirm the hazard properties and therefore for the substance to go either through substance evaluation or compliance check. These substances are new potential substances of concern for which data needs to be generated to confirm the concern.

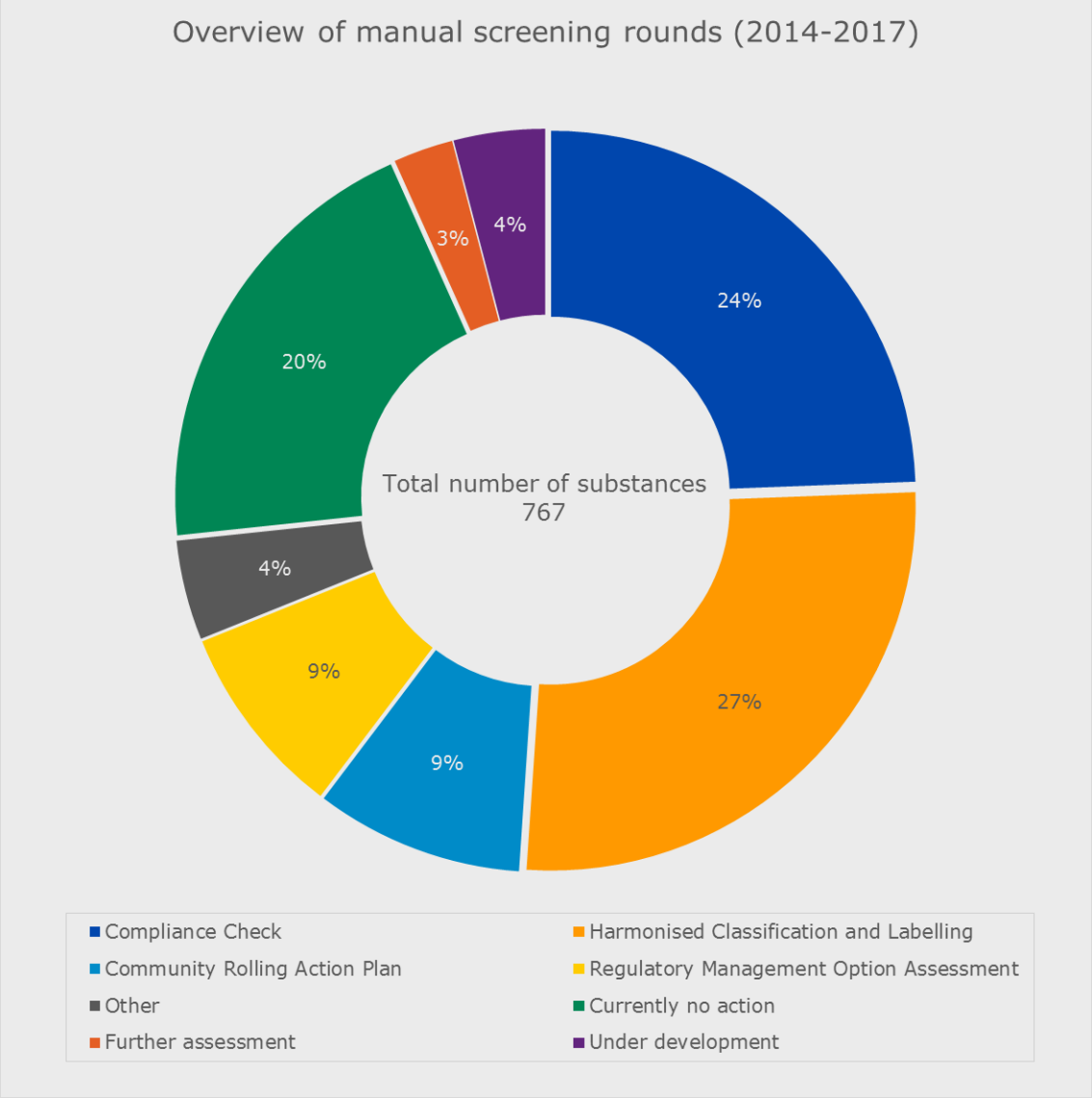


Figure 2: Overview of manual screening outcomes (2014-2017)[5].

The common screening approach also results in conclusions for certain substances stating that they are currently of low priority for further work by authorities, as explained above.

An example of a low priority substance under manual screening

1,3-dichlorobenzene was proposed for manual screening to Member States based on suspicion of PBT/vPvB properties. The manual screening concluded that the substance is not a potential PBT/vPvB substance. In addition, although the substance is registered for uses within the scope of regulatory action under REACH, these uses are unlikely to lead to significant exposure to humans or release to the environment.

Therefore it is concluded that this substance is currently of low priority for action under REACH.

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

The common screening has developed over time to include more scenarios (e.g. bioaccumulation in air-breathing animals) and sources of information (including external sources) on individual substances, while also moving to address groups of structurally similar substances, which will ensure in the long term that all substances of potential concern are addressed and moved when relevant towards further regulatory action. The system is in place and ready to address new challenges such as low tonnage substances.

Over the years, Member States have demonstrated a high interest in this activity and have participated actively (Table 1). For most Member States the common screening is the main source of substances for further work under both REACH and CLP.

Table 1: Number of Member States participating in manual screening (2014-2017).

	2014	2015	2016	2017
Number of MS participating in manual screening	17	21	22	22

Since 2016, the common screening system which was first developed to identify candidates for manual screening by Member States has been enhanced to identify also candidates for compliance check. The screening for compliance check candidates is performed by ECHA and aims at ensuring that substances of potential concern with data gaps are moved swiftly to data generation. More information on screening for compliance check candidates by ECHA and the outcome is available in the progress report on evaluation under REACH[6].

Working with groups of substances – the way forward

Since 2016, together with Member States and the Commission, ECHA has actively identified groups of structurally similar substances as part of the common screening.

Working with groups of substances will ensure consistency and coherence in how related substances are treated, as well as enhanced coherence of the work by authorities throughout the whole process, from screening and further information generation (compliance check, substance evaluation, other means such as direct contact with industry) to regulatory risk management (harmonised classification and labelling, SVHC identification and authorisation, restriction, and possibly also actions under other legislation).

[6] Available at: https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf/24c24728-2543-640c-204e-c61c36401048.

Working with groups of substances to support informed substitution

Under the SVHC Roadmap and ECHA's regulatory strategy, priority is given to substances registered for non-intermediate uses within the scope of regulatory action under REACH/CLP.

However, there may be other cases of priority for action for authorities. One example is a substance that is not registered, i.e. not produced or used in Europe, but which may be an alternative to another relevant SVHC.

The grouping approach ensures that structurally similar substances, including those not registered or registered as intermediates only, are looked at and assessed together by authorities. Without a grouping approach, these substances would not be identified early enough and substances with similar hazards to the ones listed on the Candidate List could erroneously be seen as viable alternatives.

In the fourth round of screening, which took place in 2017, ECHA applied a grouping approach where related substances were grouped together using structural similarity and read-across or category arguments. This means that when a substance of potential concern was identified, ECHA also identified related substances of lower priority, or substances where there was a lack of information on hazard and exposure. Altogether, Member States manually screened 133 substances (16 out of the 22 groups proposed). Three groups will be concluded on in the first half of 2018, following the outcome of the respective collaborative approach (COLLA) pilot projects. COLLA projects differ from regular manual screening in that registrants are actively involved in the clarification of identified concerns as well as in the discussion on potential needs for testing. More information on the COLLA pilot projects is available in the 2017 progress report on Evaluation under REACH[6].

Table 2 provides an overview of the evolution of the indicator used to measure the progress in screening under the Roadmap (progress monitoring indicator). For about 69 % of the substances (individual and part of a group), the manual screening concluded on the need for follow-up action.

Table 2: Evolution of the progress monitoring indicator – substance screening 1.

Indicators	Target	Results (%)				
		2013	2014	2015	2016	2017
Percentage of substances identified for further work to clarify a concern (substance evaluation, compliance check) or propose regulatory risk management measures (RMOA, CLH, other action)	high	-	83.5	75.8	69.6	69.1

Around 77 % of the substances in groups require further follow-up actions, whereas this is the case only for 60 % of the individual substances. For many of the individual substances screened

manually, the outcome has been no action. This seems to confirm the trend identified in the 2016 annual progress report that it is more and more difficult to find single substances for further regulatory action using the screening scenarios that were developed in 2013. Most of the substances identified through screening are nowadays related to other substances with ongoing action, which shows the need to address groups of related substances. Most of the other substances do not have enough information in their registration dossiers to ensure proper prioritisation based on uses or identification of potential hazardous properties. As a consequence, the identification of substances for the fifth round of manual screening that started in 2018 resulted in even fewer individual substances being identified, with only 18 substances being proposed for manual screening to Member States, alongside 40 groups covering 218 substances.

Working with groups of substances will entail more cooperation and sharing of expertise and resources among authorities, particularly with respect to larger groups. Cooperation may need to increase among registrants as well as between authorities and industry. The experience from the COLLA projects, together with the first two rounds of screening that included groups of substances, will help to better understand how to work together among authorities and industry in the context of screening.

Addressing a complex group of substances – the PetCo Working Group

The Petroleum and Coal stream Substances (PetCo) Working Group was set up in 2015 to develop an approach to prioritise and address those substances and also to plan how to implement the approach in practice. The group has progressed on several aspects in 2017:

- The approach was finalised and published on ECHA website.
- There was a general agreement among authorities and industry that the PetCo working group should continue as an exchange platform to ensure that the work on PetCo substances moves forward. It will also ensure that progress is made on improving the registration dossiers and further regulating petroleum and coal stream substances where necessary.
- The PetCo inventory is available and currently contains around 650 substances. The different groups include: petroleum substances (supported by Concawe), coal stream substances, hydrocarbon solvents, lower olefins and aromatics (LOAs), higher olefins and polyalphaolefins (HOPAs) (with all these groups supported by a consortium), as well as several so-called orphan substances.

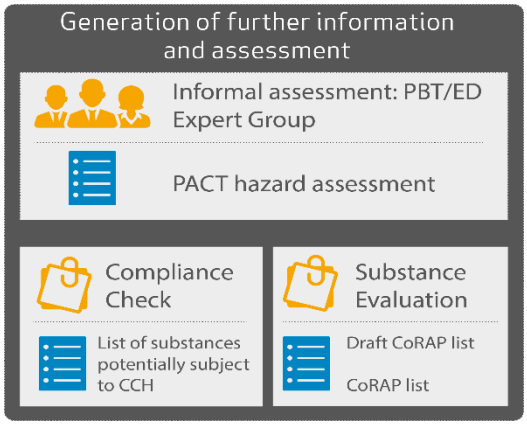
Work is progressing on the different PetCo substance groups with the aim of a better understanding of both uses and hazards.

In addition, the work carried out so far confirms that this is a typical group of substances which needs to be looked at in a holistic manner due to the substances' similarity of structure and hazard, so as to avoid duplication of work, testing and avoid regrettable substitution.

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

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

4 Data generation and assessment



Data generation and assessment focuses on the new substances of concern for potential further regulatory risk management.

Common screening identifies new substances of potential concern for data generation and assessment

For most of the substances under scrutiny to confirm SVHC properties, the first need is to generate information, undergo further assessment and/or propose harmonised classification and labelling. Compliance check and substance evaluation are the main tools for generating missing hazard information. Figure 3 shows the type of information requested in the context of both compliance check and substance evaluation. The data requested is focused on information needed to clarify the endpoints of priority in the context of the SVHC Roadmap, e.g. simulation testing to clarify the persistency of a potential PBT/vPvB substance, or reproductive toxicity and genotoxicity and mutagenicity data for clarifying CMR properties.

Most of these substances have been identified through the common screening. A few additional substances have been brought forward by Member States each year under substance evaluation and have been included in this common pool based on the Member State's own national priorities.

The common screening supports the identification of substances where data needs to be generated, and for most of these substances the information to be generated is of relevance to the SVHC Roadmap. The system focuses resources of both ECHA and Member States to these substances, which are relevant either as potential PBTs/vPvBs, CMRs or EDs.

Information requested in the 139 adopted ECHA compliance check decisions in 2017. Altogether, the decisions contained 679 standard information requests.

Suspected Concern	Types of information requested to clarify the concern	Total requests†
PBT/vPvB	Simulation biodegradation test	16
	Daphnia magna reproduction test	6
	Physico-chemical tests	5
	Aqueous exposure bioaccumulation fish test	5
	Ready biodegradability test	4
	Fish, early-life stage (FELS) toxicity test	3
	Sediment-water *Chironomid* toxicity test	2
	Toxicity of sediment-associated contaminants with freshwater invertebrates	1
	Aquatic toxicity test with bivalves	1
	Freshwater algae and cyanobacteria, growth inhibition test	1
	Sediment-water *Lumbriculus* toxicity test	1
Reproductive toxicity	Extended one-generation reproductive toxicity study	3
	Combined repeated dose toxicity study with reproduction/developmental toxicity screening test	1
Mutagenicity	*In vivo* mammalian alkaline comet assay	3
	Combined mammalian erythrocyte micronucleus test and mammalian alkaline comet assay	3
	Transgenic rodent somatic and germ cell gene mutation assay	3
	In vitro mammalian cell micronucleus test	2
Endocrine disruption	Fish sexual development test	3
	Larval amphibian growth and development assay	1
	H295R steroidogenesis assay	1
Sensitisation	Skin sensitisation local lymph node assay	2
Other hazard-based concerns	Information on composition	7
	Sediment-water *Lumbriculus* toxicity test	1
	Daphnia magna reproduction test	1
	Sediment-water *Chironomid* toxicity test	1
	Sub-chronic 90-day toxicity study	1
	Total	79

Information requests to clarify hazard-based concerns within decisions taken during 2017 under substance evaluation.

Figure 3: Information requested under compliance check and substance evaluation in 2017 (source: *Evaluation under REACH: Progress Report 2017*[6]).

Few substances are directly identified from the common screening for further assessment by the PBT and ED Expert Groups. Substances discussed in these expert groups are mainly substances under substance evaluation by Member States or for which a dossier for SVHC identification is under development. Around 70 % of the substances with potential ED and PBT properties listed on the CoRAP (2012-2017) were discussed in the ED and PBT Expert Groups. All substances proposed by Member States for inclusion in the Candidate List due to their PBT and/or ED properties have been first discussed in these expert groups.

How does the work of the PBT/vPvB and ED Expert Groups support the identification of substances of concern?

Assessing PBT/vPvB or ED properties of substances is usually very complex. Discussion among experts helps in the identification of appropriate testing strategies which after data generation would enable concluding on the properties of the substance.

The expert groups support Member States in (i) defining the testing strategy for clarifying the PBT/vPvB or ED properties and (ii) assessing the information and concluding on the properties.

Under REACH, most substances discussed in the PBT and ED Expert Groups are substances that have been included in the Community rolling action plan (CoRAP) for substance evaluation by Member States and further generation of data. In most cases, before a substance enters the formal substance evaluation decision-making process, Member States consult the expert groups to define the best testing strategy and data to be requested in a substance evaluation decision. This happens during the 12-month period given to Member States to evaluate the substance, and therefore does not affect the duration of the overall process.

Once the data has been generated, the information is assessed by the Member States to conclude on the properties. At this important stage, the Member States request support from expert groups. Furthermore, the expert groups regularly provide support on SVHC identification before a substance enters the formal regulatory process. Many substances are brought to the expert groups before being moved to SVHC identification, which has resulted in improved dossier quality and less need for discussion at Committee level. Once the properties of a substance are confirmed, identification as an SVHC can be very quick.

Most new potential substances of concern need further generation of data and/or assessment

Currently there are 757 substances under generation of data or assessment either in compliance check, substance evaluation, or one of the expert groups. 412 of these substances have been evaluated by ECHA as high priority substances under compliance check. These also include substances listed on the CoRAP for which a compliance check is done before the substance evaluation by Member States starts.

An overview of all substances under assessment (under one of the expert groups or under substance evaluation) from 2012, which corresponds to the set-up of the PBT Expert Group and the first cases under substance evaluation, until the end of 2017 is provided in Table 3 below. Some substances are counted more than once as they are, for instance, under substance evaluation but also looked at by the PBT and ED Expert Groups before entering the formal process. More information on the outcome of these activities per property is available in Tables 4 and 5.

Table 3: Overview of the number of substances under PBT and ED Expert Group assessment and substance evaluation (2012-2017).

	Ongoing assessment	Concluded assessments	Postponed assessment[7]	Total
PBT Expert Group	117	41	13	171
ED Expert Group	36	11	3	50
Substance evaluation	168	74	-	242

Behind the numbers – How many substances are being assessed and having data generated on them?

757 substances are under generation of data or assessment, either in substance evaluation (CoRAP), compliance check or one of the expert groups, or under more than one activity (e.g. both in the CoRAP and under assessment in the PBT/ED Expert Groups). This number includes both ongoing assessments and concluded ones.

Of the 757 substances, **644** are still being processed, found at different levels of generation of data and assessment under substance evaluation or compliance check. **113** substances have already been concluded on, 6 of them without clarifying the hazardous properties (e.g. because of cease of manufacture). These 6 substances would be considered again, for instance, in the case of a new registration coming in.

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

The total number of substances under data generation and assessment has increased steadily over the years. Data generation, in particular carrying out the higher-tier (eco)toxicological studies, takes time.

Figure 4 below provides an overview of the number of substances for which the information requested, under either substance evaluation or compliance check, is expected by year. This includes requests that may not in the end be generated as they are conditional to the outcome of another request. As highlighted already in the annual report for 2016, the information requested in the early days of substance evaluation only started to arrive in 2016, with more coming in 2017. Some of these substances have been concluded on in 2017, whereas others may still be under follow-up evaluation by the Member States. In some cases, new information may be requested as a result of the follow-up evaluation.

The information requested through compliance check of high priority substances also started to arrive in 2017 and has been evaluated or is in the process of being evaluated. However, most of this data will only arrive in 2018 and 2019.

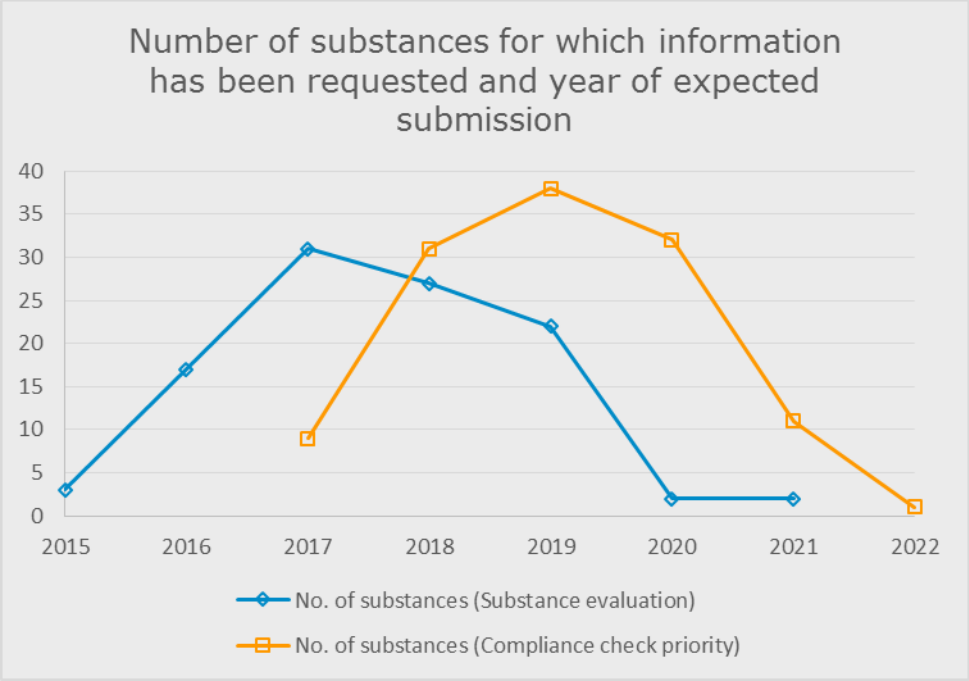


Figure 4: Overview of the number of substances for which information requested under either substance evaluation or compliance check is expected, by year.

Once generated, the new information has to be provided by registrants through an update of their registration dossiers.

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

Substances concluded on in the context of substance evaluation, compliance check and/or informal hazard assessment under PBT and ED Expert Groups are moved to regulatory risk management. Tables 4 and 5 below report on the number of substances under assessment and concluded on per property, in the context of substance evaluation (Table 4) and of the PBT/ED

Expert Groups (Table 5). They also provide the number of substances with confirmed hazards that have been moved to regulatory risk management.

As mentioned previously, many substances are under assessment and at first glance it may seem that after assessment very few receive confirmation of their hazardous properties. However, it should be kept in mind that what is important at this level is not to miss potential substances of concern. Consequently, the criteria used to identify candidates for both substance evaluation and further assessment by the expert groups are stringent and will therefore pick up many borderline cases that are later on (after further scrutiny or data generation) confirmed as not fulfilling the properties.

Substances for which properties have been clarified are moved to regulatory risk management (Tables 4 and 5). All substances discussed in the PBT and ED Expert Groups with confirmed PBT/vPvB and/or ED properties have already been moved to further regulatory risk management (Table 5). From this it is clear that once the properties have been confirmed, the Member States normally follow this with regulatory action.

Table 4: Number of substances under substance evaluation and concluded on per property and conclusion where relevant (2012-2017).

Property	Number of substances per property ongoing	Total number of substances per property concluded on	Number of substances per property concluded on		
			Considered not to fulfil the hazard properties[8]	Considered to fulfil the hazard properties	Moved to regulatory risk management
PBT	78	21	21	0	-
ED	50	16	11	5	1 SVHC, 3 RMOA
CMR	92	45	22	23[9]	3 CLH
Sensitiser	34	21	6	15	4 CLH, 1 RMOA

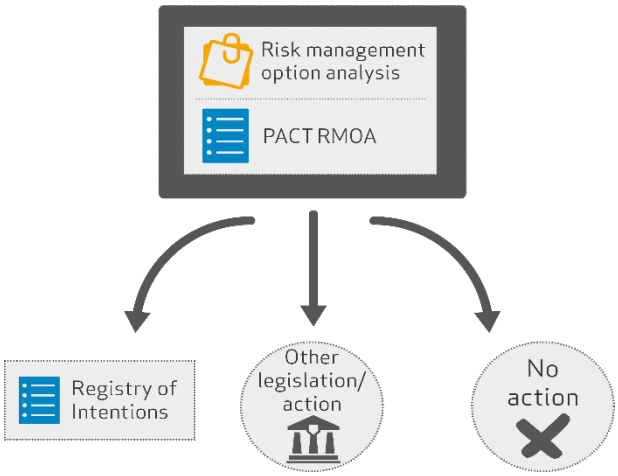
[8] Note that a few substances have been concluded on with no clarification of the hazard properties, due to cease of manufacture, for instance. These substances have been included under the heading “considered not to fulfil the hazard properties”.

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

Table 5: Number of substances concluded on under the PBT and ED Expert Groups and conclusions where relevant (2012-2017).

Property	Number of substances ongoing and postponed	Total number of substances concluded on	Number of substances concluded on		
			Considered not to fulfil the hazard properties	Considered to fulfil the hazard properties	Moved to regulatory risk management
PBT Expert Group	130	41	33	8	3 SVHC, 3 RMOA, 2 restrictions
ED Expert Group	39	11	4	7	4 SVHC, 3 RMOA

5 Regulatory management option assessment (RMOA)



A flexible approach serving its purpose.

The purpose of a regulatory management option assessment (RMOA), a voluntary approach developed in 2009, is to help authorities decide whether further regulatory risk management activities are required for a substance and if so, to identify the most appropriate (combination of) instruments to address a concern.

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

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

An approach supported by authorities which functions and fulfils its objectives

Today, there is consensus among authorities that the RMOA approach serves its purpose as a preparatory step on the journey towards potential regulatory risk management for (groups of) substances. This has been highlighted in discussions with Member States and the European Commission during the SVHC Roadmap review as well as in the wider REACH review[3]. Although it is a voluntary step it has become common practice; for all substances moved to regulatory risk management by authorities, a RMOA has been developed.

Currently a RMOA has been concluded or is under development for 194 (groups of) substances. 15 Member States have been developing RMOAs since 2013, when the work on the implementation of the SVHC Roadmap started (see also Appendix 3). In some cases, RMOAs have been developed in cooperation between Member States.

Figure 5 gives the number of RMOAs concluded or under development from the implementation of the SVHC Roadmap in 2013 to the end of 2017, subdivided by hazardous property.

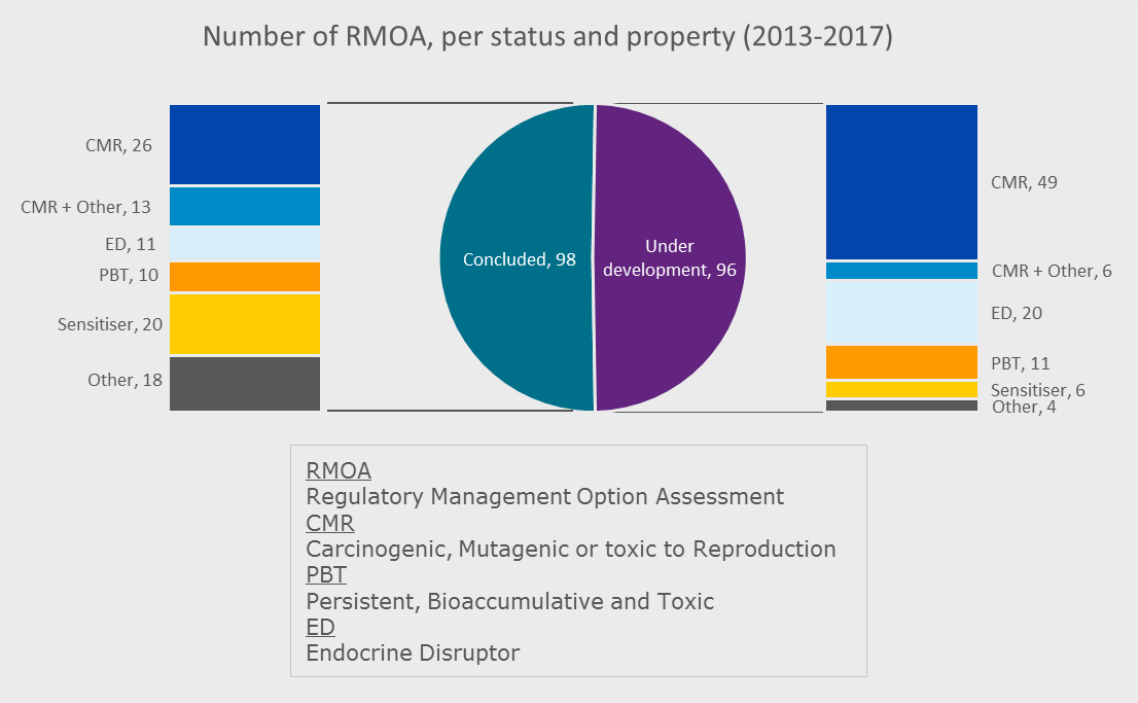


Figure 5: Number of RMOAs concluded and under development per hazardous property (February 2013 - December 2017[10]).

For 98 RMOAs, a conclusion is available and for the remaining 96, the RMOA work is still under development. In 2017, 31 RMOAs were concluded and intentions for 36 new RMOAs were indicated, which is an increase of almost 50 % compared to 2016. This increase results from a concerted effort by some authorities to conclude several long-standing RMOAs and from the fact that the preceding processes are starting to feed substances to the RMOA process. Almost half of the new substances brought to RMOA (17 substances) come either from screening, substance evaluation and PBT/ED assessment or follow a new harmonised classification and labelling for CMR 1A/1B. Other intentions are, for instance, for polycyclic aromatic hydrocarbons (PAHs) as a follow-up of the work of the PetCo Working Group, perfluorinated substances identified as part of the joint activities of ECHA, Member States and Commission on the group on per- and polyfluoroalkyl substances (PFASs) or substances from Member State national priorities.

While the majority of RMOAs relate to CMR substances with a harmonised classification, the number of RMOAs for substances with ED and PBT properties is increasing steadily. RMOAs are now normally carried out in parallel to generation of data or as soon as data is generated.

The SVHC Roadmap included an estimation that RMOAs would be available for 440 substances by 2020. However, RMOAs are also developed for groups of substances, which means that in reality the number of substances covered by the current RMOAs is greater than 194. In addition, it is relevant to note that some substances have been considered as being of low priority for further regulatory action at the level of screening and therefore no RMOA has been initiated for these substances even though there may be a recognised hazard. Such early de-prioritisation of substances with a known hazard was not anticipated at the time of the setting up of the SVHC Roadmap. Nevertheless, de-prioritising substances at this early stage is efficient and ensures

[10] The data reported in the table are until the latest update of PACT in 2016 (15 December 2017).

that the different actors involved in the process will not spend resources on preparing and discussing an RMOA on substances where clear benefits are not foreseen.

Overall, to properly assess the work done by authorities on potential substances of concern it is more appropriate to take a wider view of all pre-regulatory activities than just the number of RMOAs initiated.

SVHC Roadmap implementation also supports other regulatory risk management work

The RMOA thinking is nowadays embedded in the whole process, from screening through data generation processes and assessment. The initial RMOA is not carved in stone; on the contrary, it evolves as the substance moves from one step to the next and more information becomes available for comprehensive assessment and informed decision making.

Furthermore, it is relevant to note that the scope of SVHC Roadmap implementation is wider than only identifying substances for the Candidate List. This is clearly highlighted by the follow-up actions identified. Table 6 provides the number of RMOAs concluded per proposed follow-up regulatory action at the end of each year since the start of the SVHC Roadmap implementation.

The SVHC Roadmap progress monitoring indicator on RMOA is also included in Table 6 below.

Table 6: Cumulative number of RMOAs concluded per proposed follow-up regulatory action (February 2013 - December 2017) and progress monitoring indicator RMOA2.

	By the end of 2014	By the end of 2015	By the end of 2016	By the end of 2017	Follow-up regulatory action initiated under REACH / CLP
SVHC identification (authorisation)	5	16	24	33	33
REACH restriction	1[11]	5	6	9	9
CLH	1	2	4	7	4
Other EU-wide regulatory action	2	3	5	8	-
Other (e.g. non-EU-wide and/or non-regulatory actions)	1	2	3	4	-
No follow-up action	5	11	15	26	-
RMOA2: Extent to which RMOA conclusions resulted in regulatory follow-up (%)	17 %	68 %	84.8 %	94 %	Not relevant

For more than half of the substances for which follow-up regulatory actions were proposed (33), the proposed follow-up was identification as an SVHC. This is similar to what was already

[11] One RMOA covering 11 substances, which is why in this instance it is indicated as a single entry, even though there are 11 entries in PACT.

observed in 2016 and confirms that the impact of the SVHC Roadmap starts to be visible particularly in identifying SVHCs.

Conclusions on the need for SVHC identification or restriction were all followed up with actual proposals. Four (out of seven) conclusions on the need to develop CLH proposals have also been followed up, which is a positive increase compared to 2016.

The number of RMOAs concluding on the need for other EU legislation and/or other measures has also increased, which confirms that the RMOA approach can in practice serve legislation other than regulatory risk management under REACH and CLP.

The extent to which the RMOA conclusions received follow-up has again increased (to 94 %). The trend confirms that most RMOA conclusions now receive follow-up and that it simply takes time for Member States to turn their conclusions into actual proposals for regulatory risk management.

A third of the RMOAs concluded that the substances are currently of low priority for further regulatory action. Like under screening, authorities will ensure that these RMOAs are updated should new information on either the uses or the hazards of these substances become available.

An example of a low priority substance under RMOA – quinoline

Quinoline has a harmonised classification as Carcinogen 1B (Annex VI to the CLP Regulation). Quinoline fulfils Article 57 criteria with uses that fall within the scope of authorisation. However, it is unlikely to meet the current priority criteria for inclusion in Annex XIV for authorisation. It is used in industrial processes only, at a limited number of sites, and at a low to medium tonnage. In addition, as it is unlikely to be present in articles, neither Article 7 nor Article 33 would be invoked.

Registration and downstream user obligations under REACH apply. Furthermore, national enforcement of existing worker protection legislation, in particular Directive 2004/37/EC, and industrial emissions legislation, should continue to contribute to controlling the relevant exposures/emissions.

This means that it has been concluded that there is no need to initiate further regulatory risk management action at this time.

More information available at: https://echa.europa.eu/pact.

PACT increases transparency and predictability of authorities' work

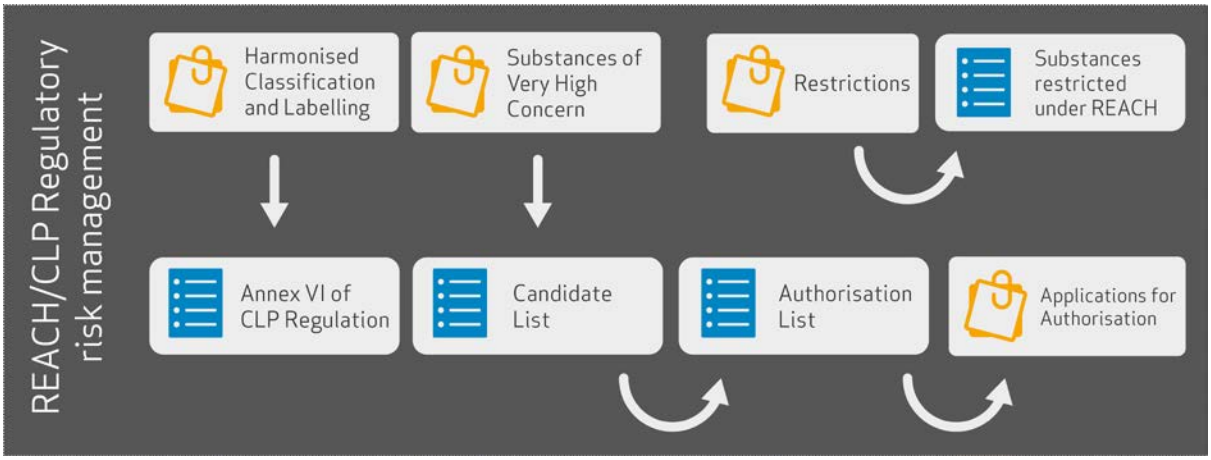
Stakeholders can follow the substances undergoing RMOA in the Public Activities Coordination Tool (PACT). This provides increased transparency and greater predictability. Early awareness gives more time for interested parties to prepare to contribute to the public consultations, which are run during the formal risk management processes and registrants have also the chance to make sure that their registration data is up to date.

Another consequence of publication in PACT is that Member State competent authorities are consulting with industry representatives, stakeholders and national institutions and government departments. The benefits of working together with industry during the RMOA stage have been highlighted by both authorities and industry. Although this can prolong the time it takes to develop the RMOA, this additional time is generally felt to be time well spent.

Concerns were raised regarding the predictability of PACT and the need to improve it. Predictability could be improved by ensuring that there is enough time for industry to provide input to the RMOA. Some RMOAs had been concluded in the past and made publicly available in PACT relatively late or even after the regulatory risk management was initiated. Predictability would be enhanced by giving authorities a clear deadline for finalising the RMOA and a more consistent way of documenting and approaching RMOA. However, it can be argued that the simple fact that industry is made aware of the ongoing RMOA supports predictability, as industry can follow more closely the Registry of Intentions and prepare for upcoming public consultations.

PACT will be further developed in 2018 to include more processes and to provide a better overview of all ongoing activities on a substance. This will help industry to better understand what happened to a substance and also how to best prepare for the follow-up regulatory steps when relevant.

6 Substances are moved to regulatory risk management



Through the establishment of the SVHC Roadmap, the Commission has formed a strong foundation on which authorities can work together on the assessment and identification of SVHCs beyond 2020, but also ensure progress in other areas of REACH (e.g. restriction). Therefore, this annual progress report would not be complete if the regulatory follow-up steps were not reported. An overview of all relevant regulatory risk management activities under REACH and CLP since REACH entered into force in 2008 is available in Appendix 2. Additional information on regulatory activities is available on a yearly basis in ECHA's General Report[12].

The trend confirms that most RMOAs concluding with a need for follow-up regulatory actions under REACH now receive follow-up (Table 4).

The impact of the system in place starts to become more visible through, for instance, the recently submitted harmonised classification and labelling (CLH) dossiers (2015-2017), more and more of which are coming from screening, substance evaluation and in particular dossier evaluation. This can also be seen from the data presented in Figure 6 below.

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

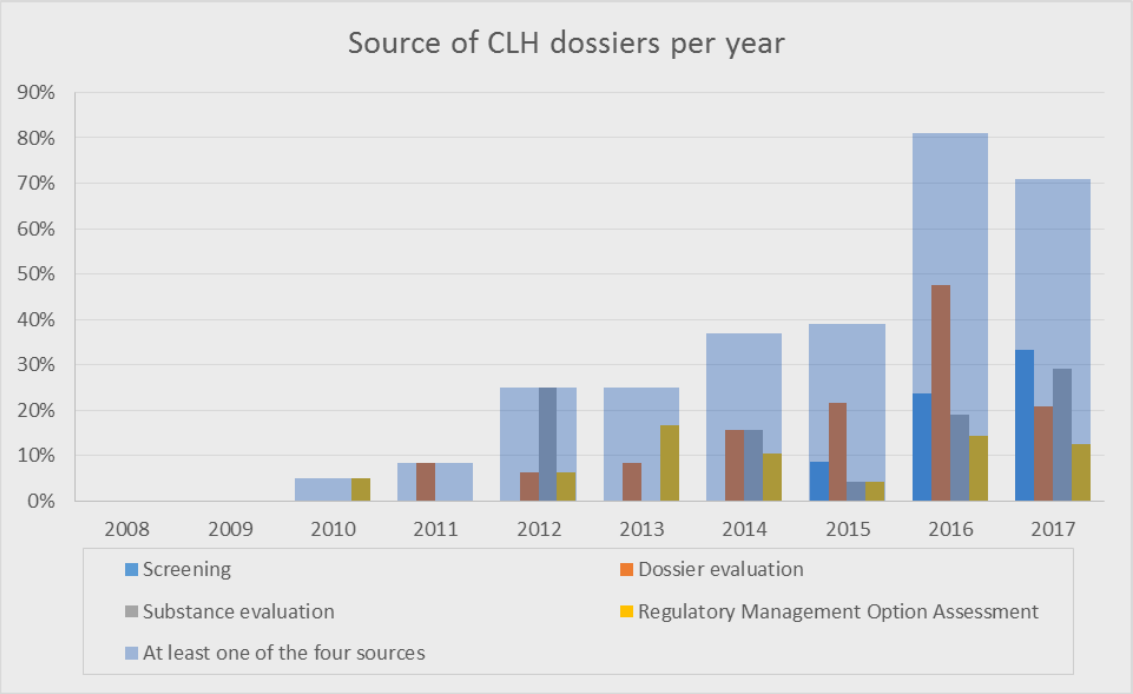


Figure 6: Sources of harmonised classification and labelling (CLH) dossiers (2008-2017).

Recently submitted dossiers (2015-2017) for restriction and SVHC identification all had an RMOA. In general, there are very few SVHC and restriction cases per year, and it is therefore difficult to observe relevant trends based on so few submissions.

Few of the cases brought to either restriction or SVHC identification are actually the result of joint work by ECHA, the Member States and the Commission, and they are mainly pertaining to perfluorinated substances under the PFASs task force. Even though this work is not as such a direct result of the system, it has used the screening tools developed in the context of the common screening and clearly exemplifies the importance of a joint effort by the authorities.

So far, very few restriction cases have been identified through the system. As said earlier, the main outcome of screening has been the need to generate more information and therefore to move the substances either to substance evaluation or compliance check. For both substance evaluation and compliance check, the first step has been to generate information to clarify the substance properties. Without confirmation of the hazardous properties, it is difficult to identify a (potential) risk posed by the substance and move it to restriction. In addition, compliance check looks generally only at single dossiers and as such does not consider all information available on a substance from a use and exposure perspective as a whole. Identification of candidates for restriction will be a priority for authorities in 2018.

Tetrafluoroethylene – from screening to regulatory risk management action

Tetrafluoroethylene (TFE) is used primarily in the synthesis of fluoropolymers, particularly the homopolymer polytetrafluoroethylene (PTFE or Teflon). TFE is manufactured in the EU and imported as a polymer. It is used in the formulation of paints and coatings and in the manufacture of fluoroplastics and fluoro-rubber. It is not reported as having any professional or consumer uses, but has article service life in plastics and rubber. Uses advised against include all professional and consumer use of the substance as an unreacted monomer.

ECHA proposed TFE for manual screening to Member States in 2016. The initial concern was carcinogenicity. The substance is self-classified as a carcinogen Category 1B via inhalation in the joint registration dossier and by approximately 27 % of notifiers to the classification and labelling inventory. There is no harmonised classification for this endpoint in Annex VI to CLP. The outcome of manual screening by Ireland was the need to propose a harmonised classification for carcinogenicity for this substance.

In March 2017, TFE was included in PACT under RMOA development, and in December 2017, Ireland included an intention to develop a proposal for harmonised classification of the substance as Carcinogen 1B. The proposal is expected to be submitted in 2018.

7 How to further optimise the system

Authorities have addressed the substances with known hazards of relevance for regulatory action and moved them under the appropriate actions (see the analysis on all currently known SVHCs in Appendix 1). The REACH and CLP processes have been further integrated through the SVHC Roadmap and this has been recently strengthened through ECHA's Integrated Regulatory Strategy.

From the SVHC Roadmap to an integrated regulatory strategy

The aim of the Integrated Regulatory Strategy is to bring together coherently all the REACH and CLP processes, to achieve the aims of these regulations as well as contribute to the 2020 goals of the World Summit on Sustainable Development (WSSD) that "by 2020 chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment".

The system put in place is able to identify new substances of concern, and where needed generate further information and move the relevant ones under regulatory risk management. However, there are still many challenges ahead. Automated screening can be used to further clarify the relative priority of substances for further work when we get new registration dossiers (e.g. for low-tonnage substances arriving in 2018). However, for the already registered substances, automated screening will only support further identification of substances of potential concern if registrants improve the quality of data in the registration dossiers, unless there are new or better external databases which indicate potential concerns for the registered substances.

Many substances are under generation of data and assessment and there is a need to find ways to optimise and speed up these processes to be able to conclude on suspected hazards and on the need for further regulatory risk management. Authorities have started to work on optimising the system to cope with all these issues as well as new challenges brought by the Integrated Regulatory Strategy. More work is needed on optimising the system even further to ensure that we meet the 2020 goals set out in the WSSD. Proposals on how to optimise the system are further presented below.

Combining the REACH and CLP processes into an integrated regulatory strategy

ECHA's ambition is to have mapped the 'universe of registered substances' above 100 tonnes by 2020 through a number of actions. These actions are intended to reduce the pool of substances of potential concern and to allow for conclusions on as many substances as possible regarding the need for specific action – further data generation or further regualtory risk management – or that a given substance is currently of low priority for further work.

The work is carried out in collaboration with Member States. Industry sectors and companies can proactively contribute by updating their dossiers and by providing better use and exposure information, on their own initiative or at the latest when they are informed of the results of the common screening.

The integrated strategy ultimately aims to:

- efficiently select substances that raise potential concern, generating the necessary information for assessing their safety through a compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable regulatory risk management instrument;
- ensure appropriate and timely intervention from all actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible through the regulatory risk management measures;
- promote confidence among stakeholders and the public that registrants meet REACH information requirements, followed up by improved communication on safe use in the supply chain.

Strengthened prioritisation and grouping of substances to ensure authorities address all substances that matter

The concept of prioritisation of substances is present in all pre-regulatory steps (manual screening by Member States, screening by ECHA before compliance check, RMOA). This (de)prioritisation has supported authorities in focusing their resources on the substances that matter, thereby optimising the system. Working with groups of structurally similar substances has further enhanced the system by ensuring that substances structurally similar to known substances of concern and for which there may not be enough data to identify them as potential substances of concern are considered in the assessment, which turn supports informed substitution.

As highlighted before, working with groups of structurally similar substances has many benefits. However, it also means using more authorities' resources in the early stages of assessment and in particular screening. Furthermore, to get all benefits of addressing groups of substances, also the evaluation and regulatory risk management processes need to be adapted. The work on screening groups of substances was initiated in 2016. We are still in the early days of addressing groups of substances from screening to generation of data and assessment to further regulatory

risk management, and experience still needs to be gained by authorities on how to do this efficiently.

All authorities need to allocate appropriate resources to these early stages of assessment to ensure groups of substances are properly addressed and the substances of relevance moved further to regulatory risk management.

Finding good candidates for further regulatory action and deprioritising those substances of lower concern is a challenge, mainly due to the lack of relevant exposure and use information in registration dossiers. The annual screening letter campaign is one way to gather more information and to enhance awareness of industry on the importance of uses and exposure information. However, it is essential that registrants keep their dossiers up to date to ensure resources of all actors are focused on the substances that matter from the early stages of assessment onwards.

To speed up the identification of substances of concern, as well as of substances of low priority for further work, alternative ways of gathering and generating information on substances and groups of substances are being implemented, such as sector approaches (e.g. in the context of petroleum and coal stream substances, plastic additives). These initiatives are also about grouping of substances, but they do not necessarily take structural similarity as a starting point. For instance, in the case of plastic additives, the main driver has been the function of the substances. Such initiatives led to generation of data particularly on uses and exposure, which allowed authorities to prioritise substances with relevant uses and/or exposure before assessing the hazards further. These initiatives require resources and have for the time being been applied only to a few groups of substances, in cases where the traditional approach would have required even more resources and potentially given very few results (e.g. in the case of petroleum substances). Authorities are continuing to learn how to best use these approaches.

Working with industry sectors to facilitate (de)prioritisation of substances – the plastic additives initiative

The release of hazardous substances from plastic materials is an area of high public interest.

For the first two registration deadlines, several substances with an indication that they are used as additives in plastics were registered in a tonnage band level of 100 tonnes per year or more. For many of these substances, there is lack of knowledge on their release from plastics and uncertainties on the hazards.

As of November 2016, ECHA, manufacturers of plastic additives and compounders and converters of plastics have worked together on a plastic additives initiative.

The aim of the project is to ensure that there is sufficient information, particularly on use and exposure, to prioritise and deprioritise substances used as plastic additives for further regulatory risk management, and to support improved supply chain communication on uses and conditions of safe use.

The work will help industry in improving REACH registration information on the use of plastic additives and the related exposure potential, and authorities in prioritisation and de-prioritisation of registered substances for further information generation and other regulatory measures.

Further optimisation of data generation and assessment to ensure substances are moved to regulatory risk management

As explained in Chapter 3, more than 700 substances are having data generated on them or are being assessed before authorities will be able to clarify the hazard properties and, when relevant, move the substances to further regulatory risk management.

Testing and generation of data for most of these substances will take time. Therefore, it is important to consider whether generating information is always necessary or whether alternative approaches such as grouping and/or one-to-one read-across could also support the hazard assessment of the substance. A systematic consultation of the expert groups may help to get a view on the remaining uncertainty on the hazardous properties of a substance, which can support decision making on whether further information would indeed be needed before processing a substance to regulatory risk management. Potentially, authorities may have to agree to bring cases to the formal regulatory processes where there is less certainty on the regulatory outcome, and also accept to conclude that a substance does not fulfil for the time being the hazardous properties with less certainty. This doesn't mean that we expect a lower level of justification, which may impair and delay the formal process. Rather, we accept that, with the same level of justification, we bring forward cases where we have less certainty that the concern is real.

As far as possible, authorities should also consider parallel processing of the substance under different regulatory processes, to ensure that while data is being generated on one endpoint it is still possible to move the substance to some regulatory risk management actions for other endpoints. This is even more important when dealing with groups of substances, where there should be an optimal sequencing of the work to be done on the different substances belonging to the group at each regulatory step.

At EU and national authority levels, experts involved in different processes should work together more closely to ensure that the information generated in one step is of use in the one that follows. For instance, further integration of REACH and CLP experts would optimise the generation of data under both compliance check and substance evaluation which would be of use for the dossiers that are subsequently submitted for harmonised classification and labelling.

As mentioned in Chapter 4 of this report, much data will be generated in the coming years as a result of the first years of evaluation. Resources should be allocated to the follow-up of those cases to ensure timely initiation of further regulatory risk management. Should a Member State lack resources, it is important from them to inform the other Member States and ECHA and to search either for cooperation or agree that another Member State takes over. It is the responsibility of all authorities to ensure that progress is made on substances of concern and to consider the potential consequences in terms of the human health and environmental impact of not taking action.

In general, it will be important for authorities to speed up the process by reducing time in between steps.

How to speed up screening, testing and assessment of suspected PBT/vPvB substances?

Currently the regulatory work and data generation can take 5-10 years, depending on which kinds of test data need to be generated. As a consequence, it is always necessary to carefully consider if the available data provide a sufficient basis for concluding on the substance properties and the likelihood that further data may change the conclusion.

Where possible, measures should be taken to shorten the period between identification of the PBT/vPvB concern and regulatory risk management implementation. Whereas it is recognised that testing as such cannot be shortened and that it will take time to generate new experimental data, the PBT Expert Group has agreed that there are some options to further optimise the system:

- Consideration of the possibility to request all data relevant to clarify a PBT/vPvB concern in one decision under substance evaluation.
- Re-consideration of the appropriate deadlines for sequential testing strategies.
- Annual tracking of the status of suspected PBT cases.

Further integration and coordination of authorities' work

Cooperation and coordination of activities between authorities was one central element in the SVHC Roadmap implementation plan, particularly when it comes to screening and RMOA activities. This is in order to:

- help optimise the efficiency of the work, avoiding overlaps or duplication of work;
- enhance and combine knowledge, in order to increase the overall effectiveness of the work being carried out;
- increase the common understanding and acceptability of the work on single cases/groups of substances;
- enhance common understanding on new issues.

It was also thought that effective coordination and cooperation would speed up the work by encouraging and enabling more Member State competent authorities to get involved in the implementation of the roadmap.

A more structured approach to cooperation among authorities and coordination of authorities' work was set up. The common screening and RMOA (through regular RiME meetings) was used as a starting point and further developed to integrate all REACH and CLP processes. As part of the SVHC Roadmap review, authorities acknowledged that even more cooperation and coordination than before is needed now that more processes are integrated. Working with groups of substances also means an increased need for cooperation and for support from more experienced Member States and ECHA to less experienced Member States. Member States and ECHA will have to learn from the first years of experience working with groups of substances to optimise the system.

Authorities have agreed on a new structure to support not only the SVHC Roadmap but also more specifically the Integrated Regulatory Strategy, acknowledging the challenges in coordinating a higher number of processes. The collaboration structure is currently being revised accordingly.

MAIN RECOMMENDATIONS

- Strengthened prioritisation and grouping of substances to ensure authorities address all substances that matter.
  - Further support to the work based on grouping of structurally similar substances (e.g. enough resources are allocated and the system is optimised).
  - Better prioritisation of resources and focus on the substances that matter.
  - Enhanced cooperation and coordination of the work under the different processes, in particular when dealing with a group of substances
  - Ensuring good quality of registration dossiers and keeping registration dossiers up to date on uses and exposure.
- Further optimisation of data generation and assessment to ensure that substances are moved to regulatory risk management without delay.
  - Consider carefully whether more data needs to be generated.
  - Consider progressing a substance in several regulatory processes at the same time when relevant.
  - Plan and allocate resources to ensure swift follow-up once data is generated.
- Further cooperation and coordination between authorities and better integration of their work.

Appendix 1. Analysis of all relevant currently known substances of very high concern (SVHCs)

1 Introduction

In early 2013, the Member States, the European Commission and ECHA agreed an objective to have all relevant currently known substances of very high concern (SVHCs) on the Candidate List by 2020. When setting up the SVHC Roadmap[13], authorities considered that for an efficient use of resources, there was a need to define which substances currently on the EU market should be addressed as a priority. To this end, criteria for selecting the substances that are relevant for further regulatory action were set out in the roadmap.

Relevant substances under the SVHC Roadmap have been defined as being substances that are registered for uses within the scope of authorisation. This means that priority is given to the substances on the EU market with consumer, professional and non-intermediate industrial uses.

Currently known substances are substances for which we have clarified the hazard properties and concluded that they are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs), or endocrine disruptors (EDs).

In accordance with the roadmap and its implementation plan, authorities have also further elaborated whether and when respiratory and skin sensitisers could be regarded as SVHCs. As a separate work stream, an approach to address petroleum and coal stream substances has been developed and its implementation started.

By 2020, all currently known CMRs, PBT/vPvBs and EDs should have been either:

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

In addition, the system that we have implemented for identifying substances of potential concern and moving the confirmed ones to regulatory risk management has enabled the identification of new substances of concern which may still be under scrutiny by 2020, as data needs to be generated and assessed first. This system also supports informed substitution. It does this by identifying non-registered substances, or substances registered as intermediated only, that are structurally similar to those regarded as relevant substances.

To get an overview of how far we are in achieving the SVHC Roadmap objective, an analysis of the work done by authorities on substances with (potential) CMR, PBT/vPvB and ED properties has been carried out. The analysis takes into account **all substances known to be CMRs** and **any known or potential EDs or PBT/vPvB substances** from before the implementation of the SVHC Roadmap and tracks whether these substances:

(i) have been scrutinised by authorities and appropriate regulatory action has been taken;

(ii) are currently under scrutiny; or

(iii) are of low priority for the time being (e.g. not registered, no relevant uses).

[13] The SVHC Roadmap and the SVHC Roadmap implementation plan are available at: https://echa.europa.eu/svhc-roadmap-to-2020-implementation.

2 Identification of substances of concern – overview of the work done by authorities

2.1 Work done before the setting up of the common screening

Authorities have been working together since REACH entered into force to identify SVHCs. Already in 2009 an informal expert group involving six Member States worked on identifying potential SVHCs on the basis of substances already identified as CMRs or PBT/vPvBs. The aim of the project was to identify the SVHCs that should be prioritised for inclusion in the Candidate List.

The sources of known CMRs and PBTs at that time were, respectively, Annex I to the Dangerous Substances Directive (67/548/ED) and the results from the Technical Committee of New and Existing Chemicals (TC NES) working group on PBT identification set up to support the implementation of the pre-REACH chemicals legislation[14]. Member States used indicators such as exposure, uses and volume to prioritise these substances. However, this work was carried out at a time when there were no registration dossiers available and consequently the information on uses and volumes was limited. The work resulted in a list of 99 substances, of which several, including many CMRs, were included in the Candidate List in the early years. Substances on this list which were not included before the end of 2012 have been regularly scrutinised as part of the common screening.

We can therefore conclude that the pool of harmonised **CMR and known PBT/vPvB substances** has been extensively and regularly scrutinised by Member States and ECHA.

Authorities have also actively worked in identifying **potential new CMRs, PBTs/vPvBs** and substances with **potential endocrine-disrupting effects** (EDs) in the context of substance evaluation. Since 2011, candidates for substance evaluation are listed in the Community rolling action plan (CoRAP). Selection criteria for the CoRAP include potential CMRs, PBT/vPvBs, EDs as well as **sensitisers**[15].

In addition, before the setting up of the PBT Expert Group under REACH in 2012, several Member States and ECHA continued the work that started under the PBT working group of the Technical Committee of New and Existing Chemicals. Substances not finalised under the previous regime were followed up and new PBT/vPvB substances were identified. Prioritisation exercises to identify potential PBT/vPvB substances had been done by ECHA under the CoRAP and by the Netherlands, Germany and the United Kingdom. The list put together based on all this work included around 200 substances and was used as a starting point for the current PBT Expert Group under REACH.

Besides the CoRAP screening, since 2012 ECHA has together with Member States screened on a regular basis the potential **ED substances** listed on the Commission list[16] and on the SIN List[17].

[14] Existing chemicals regulation and new chemical regulation (NONs)
[15] Available at: https://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf/67441c3c-75be-4ecd-992e-b90ab2041805.
[16] Available at: http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm
[17] Substitute It Now (SIN) list maintained by ChemSec and aiming at encouraging industry to move away from substances which ChemSec considers as fulfilling the SVHC criteria.

2.2 Common screening since 2013

From 2013 onwards, ECHA and Member States have been running the common screening approach to identify substances of potential concern. Harmonised CMR substances and known/potential ED or PBT substances which have relevant uses within the scope of authorisation as well as substances that are structurally similar to those already identified as SVHCs have been included in this common screening approach. We have even examined substances which contain these substances as constituents or impurities above the concentration limits for classification and PBT/vPvB identification. In addition to the work on the known substances, the common screening approach has also worked on identifying new substances of concern through, for example, reviewing self-classifications and reported data in REACH registrations.

3 Analysis of the different groups of SVHCs within the scope of the SVHC Roadmap

3.1 Introduction

The SVHC Roadmap identified groups of SVHC substances to be addressed by the implementation of the roadmap. These groups were CMRs, PBTs and vPvBs and equivalent level of concern substances such as EDs and sensitisers. In addition, the roadmap identified the need to develop an approach on how to address petroleum and coal stream substances.

A detailed analysis has been done for CMR, PBT/vPvB and ED substances as described below.

Both respiratory and skin sensitisers were addressed under the SVHC Roadmap, as they can potentially be considered of equivalent level of concern to CMRs. An analysis of the work done on sensitisers and the suggested way forward for managing the potential risks posed by them has already been documented and introduced to authorities and stakeholders at CARACAL[18]. More details can be found in Annex 2 to this appendix.

Member States, the Commission and ECHA are working towards addressing the concern posed by skin sensitisers. Two restriction proposals are under way or being considered for skin sensitisers. One aims to restrict the use of skin sensitisers in textiles and the other focuses on skin sensitisers in tattoo inks.

3.2 Analysis of known CMRs and potential and known PBTs/vPvBs and EDs – the starting pool of substances

In the context of the SVHC Roadmap, a **known CMR substance** is a substance that is classified in Annex VI to the CLP Regulation for carcinogenicity, mutagenicity or reproductive toxicity in categories 1A or 1B. Annex VI to CLP contains the legally binding harmonised classification and labelling for over 4 500 substances, which must be followed throughout the EU. There are about 1 100 entries, covering around 1 200 substances, classified as CMRs in categories 1A or 1B in Annex VI to CLP, with about 10 new CMR 1A/1B entries added each year. A handful of these entries are so-called group entries, which cover an open number of substances defined by a certain property (e.g. lead compounds). For clarity, in the analysis reported below we have only included substances identified by EC/CAS numbers on Annex VI to CLP. However, considerable work has been done by ECHA and Member States to identify substances falling under these group entries and many have already been scrutinised. With the inclusion of the tenth adaptation

[18] CARACAL meetings of competent authorities for REACH and CLP.

to technical and scientific progress (ATP) to the CLP Regulation, a total of **1 146** substances have been included in this analysis.

We have considered that **potential and known PBT/vPvB substances** are substances which had been assessed by the Technical Committee of New and Existing Chemicals subgroup on identification of PBT and vPvB substances under the previous EU chemicals legislation. Substances under both the existing and the new chemical regulation (so-called NONs) have been considered in the analysis. In addition, we have included in the analysis substances from the SIN List, which ChemSec considers as fulfilling the criteria for PBTs/vPvBs. In total, **250** substances[19] considered to be potential or known PBT/vPvB substances have been analysed.

Potential and known ED substances are substances that have been identified as potential EDs by the Commission (Categories 1 and 2 only). This Commission list contains 293 substances (with available EC or CAS number). 84 substances identified by ChemSec as potential EDs and included in the SIN list were also added. In total, 377 substances with known or potential ED properties have been analysed.

3.3 Methodology

The lists were analysed with the use of IT tools that retrieve information from ECHA's databases based on the CAS and/or EC numbers provided. Based on the information extracted, substances were assigned to one of five categories, as described in the table below.

[19] 224 substances (126 existing chemicals, 98 new chemicals) going through the TC NES subgroup on PBT identification and 26 substances from the SIN List.

Categories and their descriptions	
Categories	**Description**
1. Substances under regulatory action beyond Annex VI to CLP	A substance was included in this category if it is: - included in Annex XIV to REACH or in the Candidate List, or is formally proposed for SVHC identification; or - included in Annex XVII to REACH (excluding entries 28 to 30, which cover restriction of only consumer uses for substances having a harmonised classification as CMR Cat. 1A/1B), or is formally proposed for restriction; or - listed under the POP Regulation (EC) 850/2004 (Annexes I, III, IV, V) and the Stockholm Convention, UNEP (Annexes A, B, C).
2. Substances currently under scrutiny	A substance was considered under scrutiny if not listed under category 1 and if it is: - currently under RMOA; or - currently under substance evaluation or included in the (draft) CoRAP; or - currently under PBT or ED assessment by the expert groups; or - manually screened, with follow-up actions identified; or - being addressed by the Petroleum and Coal stream Substances (PetCo) Working Group.
3. Substances not considered of current priority after being assessed	A substance was included in this category if it was not listed under categories 1 or 2 and if: - it has been manually screened by ECHA or a Member State and concluded on with no need for further regulatory action at the moment; or - an RMOA or substance evaluation concluded that there is no need for further regulatory action at the moment; or - the PBT or ED Expert Groups concluded, based on currently available data, that the substance is not a PBT/vPvB or ED; or - it was not considered a PBT/vPvB based on the assessment done under previous EU chemical legislations (TC NES).
4. Substances not considered of current priority based on low potential for exposure (not registered, registered only as intermediates, or with industrial uses only)	A substance was included in this category if not listed under categories 1, 2 or 3 and if: - it is not registered under REACH, or is registered only as an intermediate; or - the only uses reported in the registration are industrial uses (no professional, consumer uses or article service life for this substance).
5. Substances that may require further scrutiny	A substance was listed here if it was not included in any of the other groups.

3.4 Results

A full overview of the number of substances in each category for all properties is available in Table 1. A further analysis for each category is provided in the sections below.

3.4.1 Overview of the number of substances under each category having PBT / vPvB, CMRs and / or ED properties

Note that some substances fulfil more than one endpoint and therefore appear in more than one category. As a consequence, the entries in the CMR, PBT and ED columns add up to a number greater than the total number of substances included in the analysis.

Table 1: Overview of the number of substances falling under each category by property.

	Total	CMR	ED	PBT
Number of substances	1699	1146	377	250
1. Regulated substances	262	158	99	46
Annex XIV (included or recommended)	65	52	11	14
Candidate List	154	118	32	36
SVHC dossier submitted/intention	13	6	5	4
Restriction	70	55	21	4
POPs (EC regulation + Stockholm Convention)	63	5	55	12
2. Substances currently under scrutiny	**427**	**352**	**40**	**49**
RMOA under development/on hold	40	20	18	7
RMOA concluded – need for regulatory action	20	14	3	9
Substance evaluation ongoing	40	3	21	20
Substance evaluation concluded – need for further regulatory action	2	2	0	0
PBT EG work ongoing/unspecified/postponed	36	4	10	24
ED EG work ongoing	25	0	18	10
PBT EG concluded substance to be PBT	0	0	0	0
ED EG concluded substance to	1	0	1	0

Table 1: Overview of the number of substances falling under each category by property.				
	Total	**CMR**	**ED**	**PBT**
be ED				
Manually screened (outcome other than no action)	36	11	10	18
PetCo	320	319	0	6
3. Not of current priority after assessment	**127**	**37**	**16**	**80**
Manually screened (outcome – no action)	11	9	2	2
Manually screened (prior to integrated screening)	18	7	5	7
RMOA concluded – no need for further regulatory action	22	21	0	1
PBT EG concluded substance not to be PBT	9	1	2	7
Substance does not fulfil PBT/vBvP criteria under the previous EU chemicals legislation	77	1	3	77
ED EG concluded substance not to be ED	2	0	2	0
Substance evaluation concluded – no need for further regulatory action	6	0	6	0
4. Not of current priority based on low potential for exposure (not registered, registered only as intermediates, or with industrial uses only)	**870**	**599**	**222**	**62**
Not registered (or inactive)	762	541	209	22
Registered as intermediate	33	20	9	6
Registered with industrial uses only (no professional, consumers uses or article service life)	75	38	4	34
5. May require further scrutiny	**13**	**0**	**0**	**13**
Registered with widespread uses	13	0	0	13

3.4.2 Analysis of known CMRs

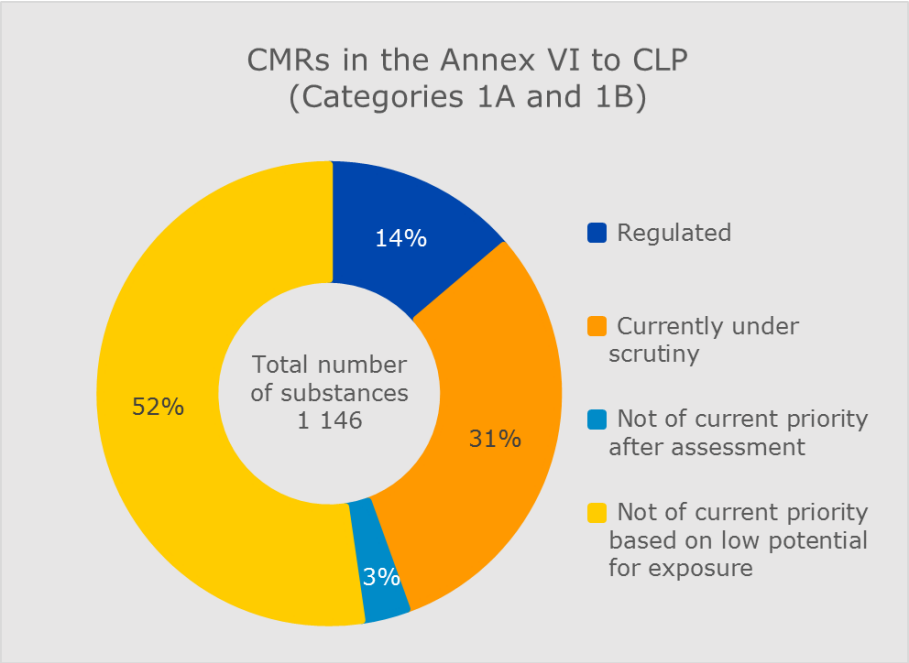


Figure 1: Outcome of the analysis of known CMRs.

Figure 1 shows that over half of the known CMRs in Annex VI to the CLP Regulation are not of current priority. The majority of these substances are actually not registered under REACH.

About one third of the substances (31 %) are currently under scrutiny. Most of those are petroleum and coal stream substances currently being addressed by the PetCo Working Group[20]. There are 330 petroleum and coal stream substances in Annex VI to the CLP Regulation, 275 of which have a conditional classification (notes J, K, L, M, N, P). This means that classification as a CMR applies to those substances only in defined conditions, for example, when a particular constituent is present above a certain concentration.

In this analysis, none of the known CMR substances were found to require further scrutiny. This confirms that all known and relevant CMR substances have been addressed or are currently under scrutiny.

3.4.3 Analysis of potential and known PBTs/vPvBs

Figure 2 shows the outcome of the analysis of potential and known PBTs/vPvBs. It shows that a quarter of the currently known PBT/vPvB substances are not of current priority as they are either not registered or only registered for intermediate uses. This is a much lower fraction than for CMRs and EDs (see Figures 1 and 3).

Another third of the substances has been assessed and concluded on as not being a current priority. Most of these assessments were already concluded by the TC NES working group on PBT identification before REACH came into force. Other substances were concluded not to be PBTs by the PBT Expert Group or in the context of manual screening and RMOA.

[20] More information on the work done under this group is available at: https://echa.europa.eu/petco-working-group.

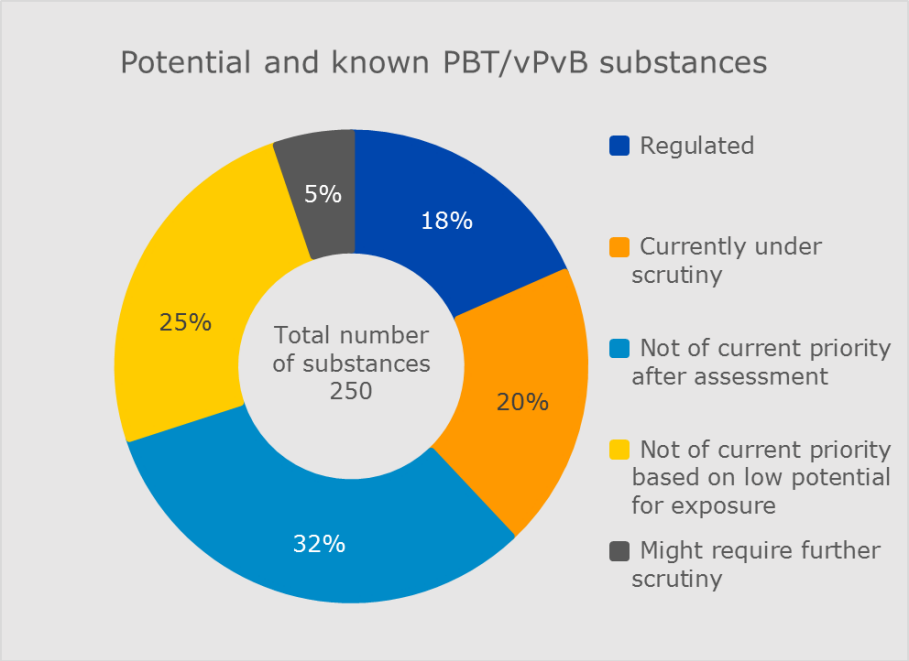


Figure 2: Outcome of the analysis of potential and known PBTs/vPvBs.

There is still a substantial number of substances under scrutiny (20 %). It takes time before a conclusion on their PBT properties can be made as in most cases there is first a need to generate further hazard data.

In this analysis, 13 substances were found that may require further scrutiny (see Annex 2). These are all old NONs which need to be further looked at by authorities in the context of screening. There may be different reasons why these substances have not been picked by the common screening, such as recent updating of the NONs dossiers submitted, or that the screening scenarios did not identify a concern from the information available in the registration dossier. Member States were in charge of these dossiers in the past and have followed them since REACH entered into force. ECHA together with Member States will discuss how to ensure that these substances will be sufficiently addressed.

3.4.4 Analysis of potential and known EDs

Figure 3 provides the outcome of the analysis of potential and known EDs. Almost 60 % of the potential ED substances analysed are not of current priority, with most of them not being registered under REACH. Most of these substances are currently being used only as pesticides and/or biocides (Figure 3).

Most of the substances left in the analysis are already regulated or under scrutiny, and very few have been considered not to be of current priority after assessment.

In this analysis, none of the known ED substances were found to require further scrutiny.

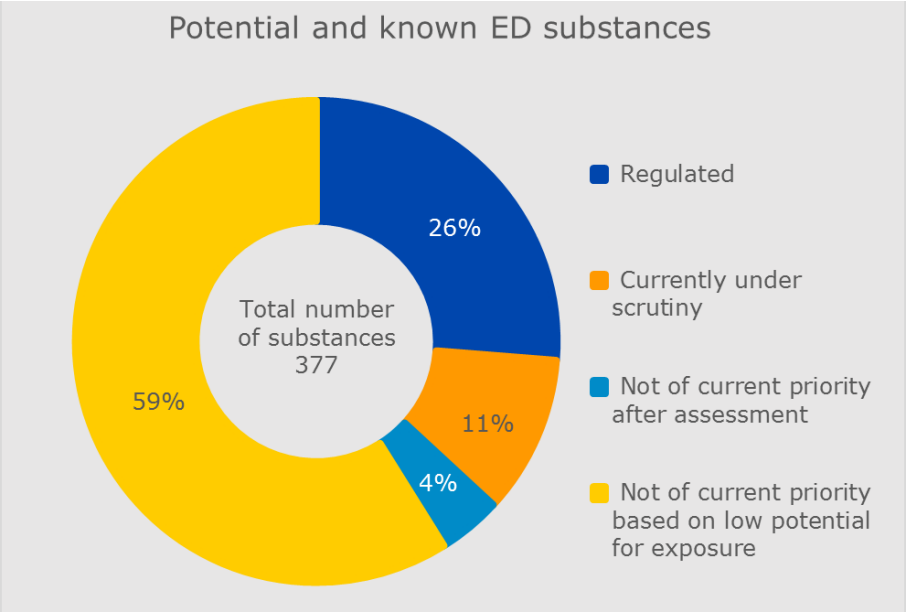


Figure 3: Outcome of the analysis of potential and known EDs.

4 Conclusions

It is clear that the extensive work done by Member States and ECHA both prior to the start of the SVHC Roadmap and in recent years has led to a situation in which virtually all **currently known and relevant** SVHCs have been or are being scrutinised. Among the 1 700 substances, there are only 13 potential PBT/vPvB substances (old NONs) that may require further work to confirm whether or not they are PBTs/vPvBs. ECHA will initiate further discussion with the Member States on what further work is needed to clarify this situation and, where relevant, will initiate regulatory actions.

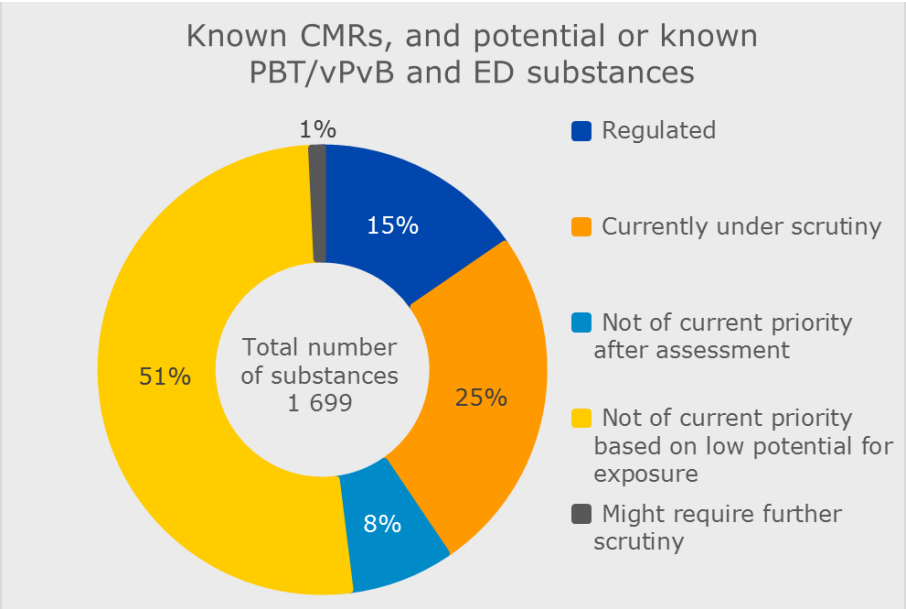


Figure 4: Outcome of the analysis of all substances and their properties.

Figure 4 shows the outcome of the analysis of all substances and their properties, showing that around half of the substances analysed are not a current priority and are therefore not considered relevant under the SVHC Roadmap. Most of these are substances not registered under REACH. Should the status of these substances change, the common screening set up by ECHA together with Member States and the Commission will identify these and move them under regulatory action.

As further explained in the 2017 progress report on the SVHC Roadmap, the focus of our work is now primarily on ‘new’ substances for which concerns have not yet been clarified and on ensuring that the substances under scrutiny move forward in the regulatory process swiftly.

Annex 1: Analysis of the work done so far in screening and moving substances with sensitising properties to further regulatory action as described in the SVHC Roadmap implementation plan (CARACAL CA/41/2016)

Note that this document is a copy of the CARACAL paper developed in 2016 (without any updates).

1. Background

Sensitisers were addressed under the SVHC Roadmap as they can potentially be considered of equivalent level of concern (ELoC) to CMRs. Both respiratory sensitisers and skin sensitisers are covered by the Roadmap and its implementation plan and have been included under the common screening approach[21] for substances of concern from the start. Currently, almost all substances with a harmonised classification for respiratory sensitisation have been examined, as have a large part of harmonised skin sensitisers. As of now, few skin sensitisers have been subject to further evaluation (such as RMOA) after common screening and no further regulatory risk management has been put in place for skin sensitisers as a result of screening. Some respiratory sensitisers have been found to be of equivalent level of concern to CMRs and placed on the Candidate List while no skin sensitiser has yet been identified as such. However, other regulatory measures, such as restriction, have been proposed or initiated for some skin sensitisers based on work carried out under previous legislation or national activities.

2. Progress made

Overall analysis

Substantial effort has been made in identifying and prioritising sensitisers under common screening for potential regulatory actions. Harmonised sensitisers that have been registered under REACH or notified to the C&L Inventory have been identified, including those falling under group entries on Annex VI to CLP. To date, around 800 skin sensitisers and around 80 respiratory sensitisers have been registered. These registered sensitisers have been further prioritised based on their reported uses and the potential for exposure to humans. Substances where most of the tonnage goes to wide dispersive uses (widespread uses combined with potential for exposure to human (or release to the environment)) have the highest priority. The next priority goes to substances with at least some widespread uses. For the purpose of this paper and in order to give a wider picture of the potential priority of both skin and respiratory sensitisers, all registered substances with widespread uses have been considered in the analysis.

Figures 1 and 2 show the breakdown of the registered skin and respiratory sensitisers respectively, into those with widespread uses and those without widespread uses. They also give the breakdown of the work already carried out on those substances with widespread uses. Please note that the numbers are approximate and based on an IT analysis with limited manual verification. They are not absolutely accurate but give a very good approximation. Please also note that although these substances are sensitisers, the properties for which further regulatory action has been proposed can be different. For instance, several substances with a harmonised classification for skin sensitisation are on the Candidate List, but none of them were identified as SVHCs based on their skin sensitisation properties.

[21] http://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf

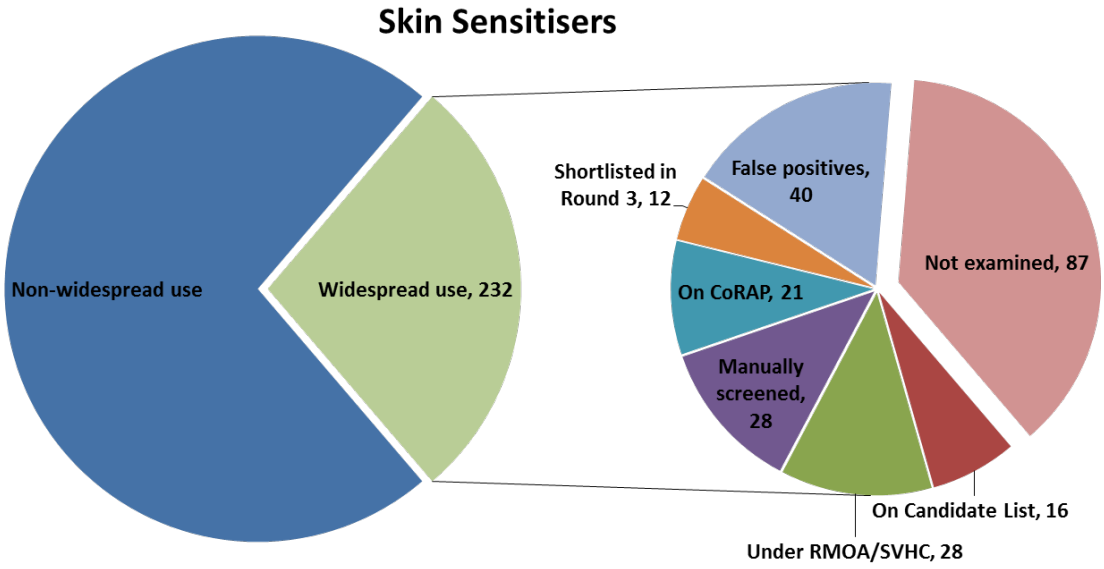


Fig. 1: Registered skin sensitisers and their breakdown into those with widespread uses and those without. Those with widespread uses are then further broken down depending on whether they have been under manual scrutiny. The (hazard-based) false positive rate is an estimate based on a quick manual examination. Although these substances are skin sensitisers, the properties for which further regulatory action has been proposed can be different. False positives are mainly due to poor substance ID in registration dossiers (e.g. wrong IUPAC name). All numbers are approximate and subject to some change.

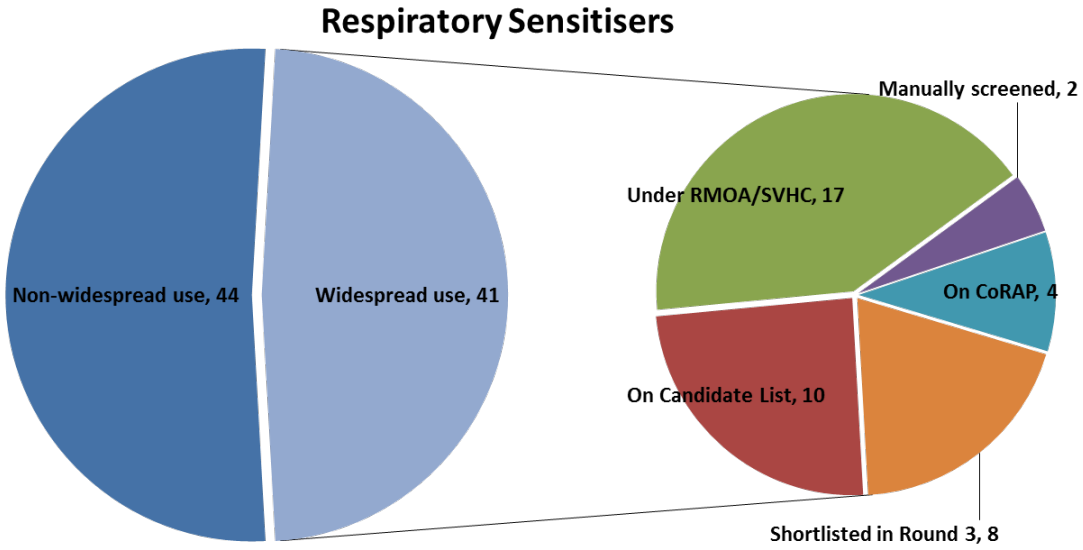


Fig. 2: Registered respiratory sensitisers and their breakdown into those with widespread uses and those without. Those with widespread uses are then further broken down depending on whether they have been under manual scrutiny. Although these substances are respiratory sensitisers, the properties for which further regulatory action has been proposed can be different. All numbers are approximate and subject to some change.

As can be seen from figures 1 and 2, all registered respiratory sensitisers with widespread uses

have been examined or are currently under examination. For skin sensitisers, about a third of substances with widespread uses have not been manually examined.

Manual screening of skin sensitisers

Substances with a harmonised classification for skin sensitisation have been included on the shortlist of substances of potential concern under common screening for the last three rounds (2014-2016). Figure 3 shows the outcome of the manual screening for substances shortlisted solely for skin sensitisation in round 1 and 2 of screening. Manual screening for round 3, where 6 substances were shortlisted for skin sensitisation only, is currently ongoing. As can be seen from Fig. 3, 26 substances out of the 41 shortlisted were selected for manual screening. Of those, only five were proposed for risk management option analysis (RMOA). It should be pointed out that not all of those five were proposed for RMOA for skin sensitisation properties but rather for other properties discovered during manual screening. The five substances are listed in Table 1. None of them have been proposed for SVHC identification based on skin sensitisation. Those substances proposed for other action such as Substance Evaluation or Compliance check were not done so based on their skin sensitisation properties as these substances all have a harmonised classification for skin sensitisation and no further clarification or assessment is required.

As said above, none of the substances shortlisted for skin sensitisation have resulted in a proposal for SVHC identification. However, it should be noted that hexamethylene diacrylate (HDDA), which was proposed for SVHC identification by Sweden based on skin sensitisation, would have been shortlisted in round 2 if action had not already started on the substance. The MSC did not unanimously agree that HDDA was a SVHC and the dossier was forwarded to the Commission.

Please note that the analysis in Fig. 3 includes those substances which were shortlisted for skin sensitisation only and did not have other hazardous properties such as CMRs or PBTs. In total, 52 substances with harmonised classification as skin sensitiser have been shortlisted and 37 were selected for manual screening. For some of these, regulatory risk management measures have been initiated but not based on skin sensitisation concerns.

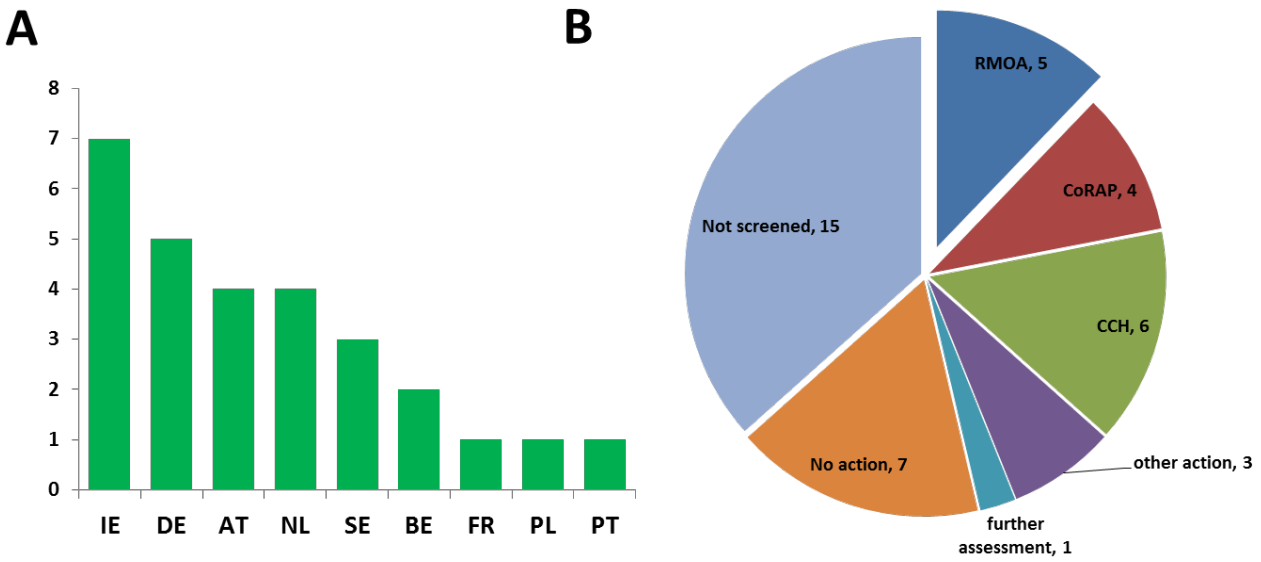


Fig. 3: Outcome of manual screening of substances shortlisted solely for skin sensitisation in rounds 1 and 2 of common screening. Out of 41 substances shortlisted, 36 were selected for manual screening and only

five were proposed for Risk Management Option Analysis. Not all of those five were proposed for RMOA due to skin sensitisation. CoRAP and CCH proposals are based on other properties than skin sensitisation.

Risk Management Option Analysis of sensitisers

To date, around 30 RMOAs have been or are being conducted for substances with sensitisation properties. Some of them cover a group of substances (such as diisocyanates) or a particular sector (such as skin sensitisers in textiles) while others cover only one substance (e.g. HDDA). A review of all these RMOAs and their conclusions is beyond the scope of this paper. Such review could be beneficial to conduct in order to increase common understanding on the most appropriate risk management measures for sensitisers.

Conclusions and next steps

All registered respiratory sensitisers that are relevant from an exposure point of view have been identified and examined. Registered and harmonised skin sensitisers have been extensively scrutinised under the SVHC Roadmap. Very few of the substances proposed for manual screening have been subject to further regulatory action and no skin sensitiser has been identified as an SVHC yet.

From the experience gained so far it is unlikely that the systematic screening of the remaining skin sensitisers would identify further candidates for regulatory action. Therefore, it is proposed that further systematic screening for skin sensitisers by ECHA in the common screening programme is discontinued for the time being. The resources can be reallocated to other tasks. ECHA can provide a list of those skin sensitisers not yet examined, including their registration and use status, to those Member States still wishing to continue the work on them. The systematic screening for skin sensitisers could be repeated after 2018 registration data is available.

It is further proposed that the interested Member States could review the RMOAs already conducted on sensitising substances in order to increase common understanding on how to best regulate those substances. This could also help to re-focus the work on sensitisers.

Screening of respiratory sensitisers will continue to take into account potential changes in registration status or in uses.

Annex 2: Substances for which further scrutiny may be required.

EC Number	Substance name	Registration
250-709-6	Tris(2,4-ditert-butylphenyl)phosphite	10 000-100 000 tonnes per
401-280-0	1-(N,N-bis(2-ethylhexyl)aminomethyl)-1,2,4-triazole	10+ tonnes per year
402-130-7	4,4'-methylen-Bis-(3-Chlor-2,6-Diethylanilin)	100+ tonnes per year
406-200-8	3',5'-dichloro-4'-ethyl-2'-hydroxypalmitanilide	100+ tonnes per year
412-210-3	2-[[2-(acetyloxy)-3-(1,1-dimethylethyl)-5-methylphenyl]methyl]-6-(1,1-dimethylethyl)-4-methylphenol	Confidential
416-250-2	3,6-bis(4-tert-butylphenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione	100+ tonnes per year
418-550-9	Hexadecyl 4-chloro-3-[2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-4,4-dimethyl-3-oxopentamido]benzoate	1+ tonnes per year
420-470-4	A mixture of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide]	Confidential
427-090-8	A mixture of: ethyl (2R,3R)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate; ethyl (2S,3S)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate	10+ tonnes per year
434-210-2	Polyurea grease thickener	Confidential
438-390-3	Alkane 6	1 000 - 10 000 tonnes per year
448-060-0	2-[2-(3-butoxypropyl)-1,1-dioxo-1,2,4-benzothiadiazin-3-yl]-5'-tert-butyl-2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-2'-[(2-ethylhexyl)thio]acetanilide	10-100 tonnes per year
459-290-6	3,4-dichloro-N-(5-chloro-4-{2-[4-[(2-hexyldecyloxy)phenylsulfonyl]butyramido-2-hydroxyphenyl) benzamide	1+ tonnes per year

Appendix 2. Update on regulatory risk management activities (2008-2017)

1 Harmonised classification and labelling

Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity or respiratory sensitisation in any category should normally be subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal products (BPs) or plant protection products (PPPs) should also be harmonised. For all other hazardous substances, a harmonised classification and labelling can be sought, if a justification is provided that shows such an action is required at EU level.

Figure 1 shows the number of proposals adopted by the Committee for Risk Assessment (RAC) between 2009 and December 2017 (December), and Figure 2 shows the number of proposals submitted during the same time period. Numbers are further broken down into proposals for active substances in BPs and PPPs and other substances, mainly those subject to REACH registration. As can be seen, the majority of substances subject to CLH are active substances in PPPs/BPs. The number of REACH substances for which a classification for new[22] and existing CMRs[23] was adopted is also reported.

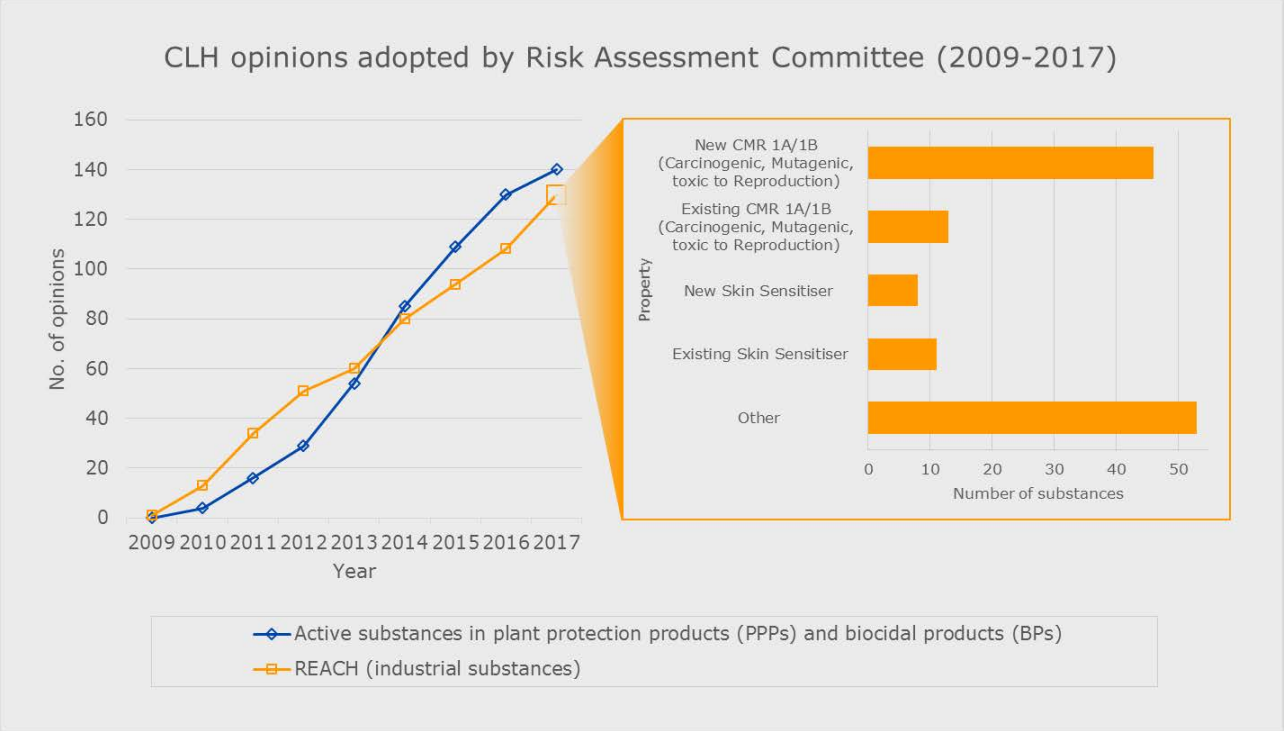


Figure 1: Number of CLH opinions adopted by RAC between 2009 and 2017 and a breakdown of REACH substances for which a CMR 1A or 1A and/or sensitiser proposal was included.

[22] A new CMR is a substance that was not classified as a CMR before.
[23] An existing CMR is a substance that was already classified as CMR and the proposal was to amend something other than the CMR classification.

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

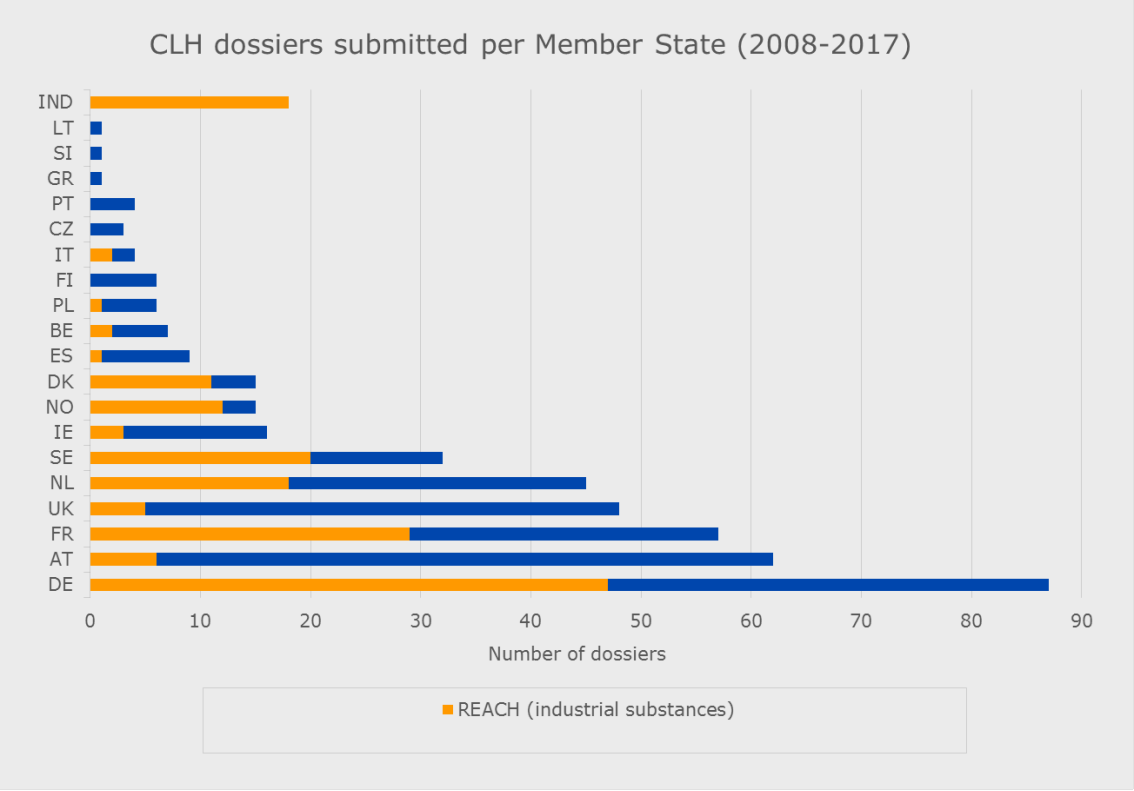


Figure 2: Number of CLH proposals submitted per Member State (2008 – 2017)

2 Authorisation process

2.1 Introduction

In 2008, the first substances of very high concern (SVHCs) under REACH were identified, marking the start of the REACH authorisation process[24].

Figure 3 gives an overview of the number of substances identified as SVHCs, recommended for inclusion in the Authorisation List (Annex XIV) and finally included in the Authorisation List from 2008 until the end of 2017. These numbers are further explained below in their respective sections.

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

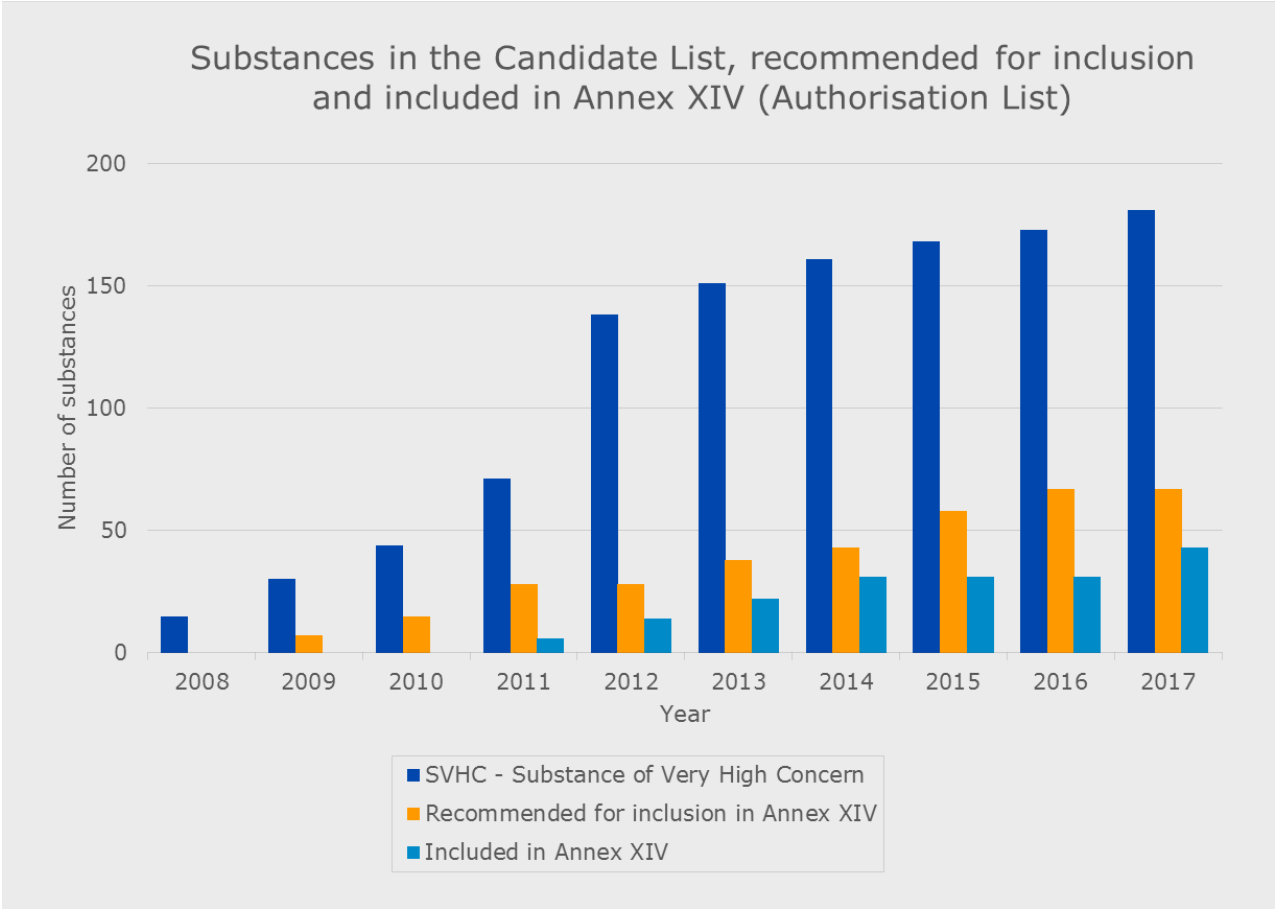


Figure 3: General overview of the number of substances on the Candidate List, recommended for inclusion in Annex XIV (Authorisation List) and included in Annex XIV.

2.1.1 SVHC identification

A Member State or ECHA, at the request of the European Commission, can propose a substance to be identified as an SVHC. SVHCs:

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

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

Since 2008, 181 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 cover more than one hazardous property, as illustrated below.

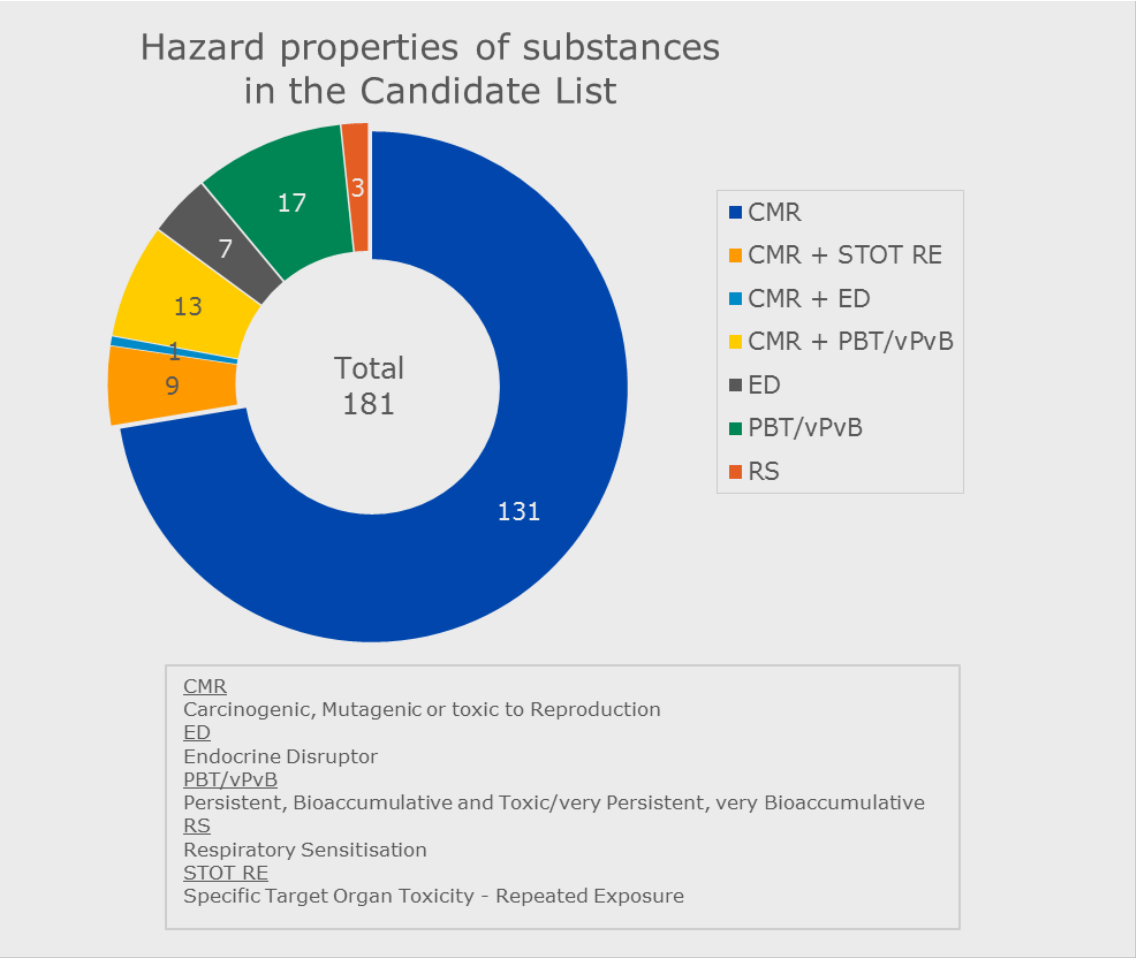


Figure 4: Substances on the Candidate List and overview of their hazardous properties.

In 2017, eight more substances were identified and included in the Candidate List (see Table 1).

Table 1: SVHC proposals discussed in 2017 and their outcome. **Substances added to the Candidate List in 2017**	
4,4'-isopropylidenediphenol (bisphenol A; BPA)[25]	Endocrine-disrupting properties – human health Endocrine-disrupting properties – environment
1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene (Dechlorane Plus™), covering any of its individual anti- and syn-isomers or any combination thereof	vPvB
Benz[a]anthracene Chrysene	Carcinogenic PBT vPvB
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with ≥0.1 % w/w 4-heptylphenol, branched and linear (4-HPbl)	Endocrine-disrupting properties – environment
Cadmium carbonate Cadmium hydroxide Cadmium nitrate	Carcinogenic Mutagenic Specific target organ toxicity – repeated exposure
Perfluorohexane-1-sulphonic acid and its salts PFHxS	vPvB

Among the substances being concluded as fulfilling article 57(f) several cases are due to endocrine disrupting properties, which highlights that such substances can be identified by the Member State Committee and moved forward to further regulatory action.

[25] Note that two SVHC identification dossiers were submitted for bisphenol A in 2017, to identify the endocrine-disrupting properties of the substance towards both the environment and human health.

Table 2 below gives an overview of the number of substances included in the candidate list per properties since 2008.

Table 2: Overview of number of substances included in the Candidate list by property (2008-2017).

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
CMR	10	13	16	26	57	13	8	4	3	5	**155**
PBT/ vPvB	5	6	0	0	5	2	2	4	2	4	**30**
ED	3	1	0	1	2	1	0	0	3	1	**12**
STOT RE	0	0	0	0	0	3	3	0	0	3	**9**
Respiratory sensitiser	0	0	0	0	3	0	0	0	0	0	**3**

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

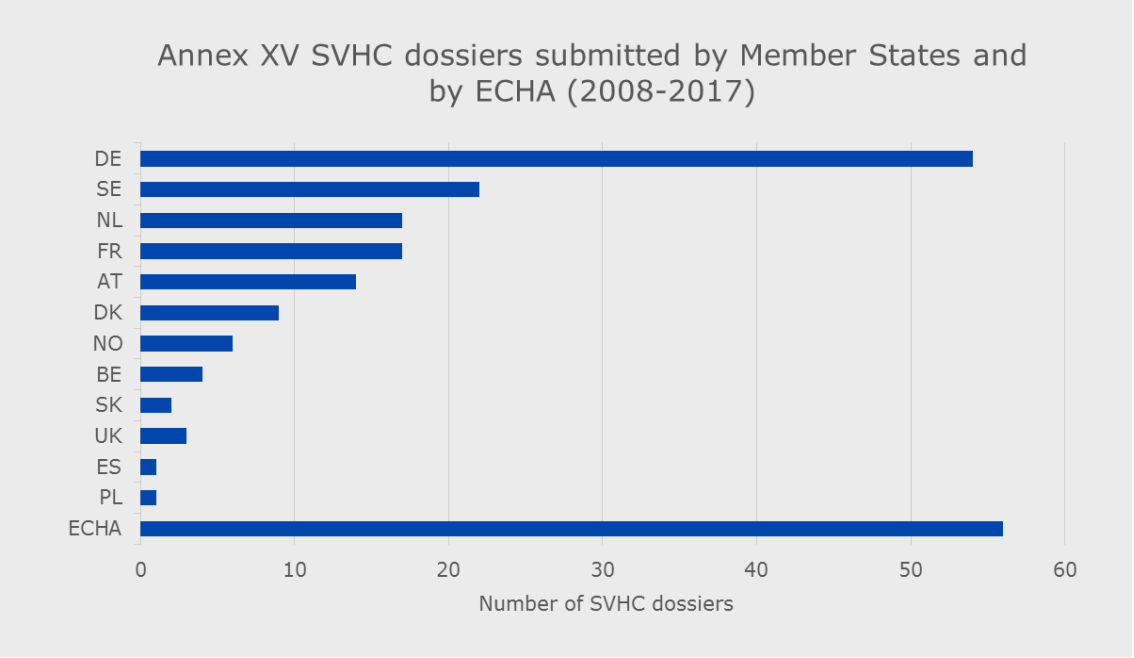


Figure 5: Number of Annex XV SVHC dossiers submitted by Member States and by ECHA (2008-2017).

2.2 Recommendation for inclusion and inclusion in the Authorisation List

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

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

Under Article 58(3), priority is normally given to substances with PBT or vPvB properties, wide dispersive use, or high volumes[26]. Prioritisation is carried out based mainly on information in the registration dossiers. However, information from public consultation on the SVHC identification as well as other REACH/CLP information is considered, too.

The seventh recommendation was sent to the Commission in November 2016. The eighth recommendation was worked on during 2017 and sent to the Commission in February 2018[27].

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

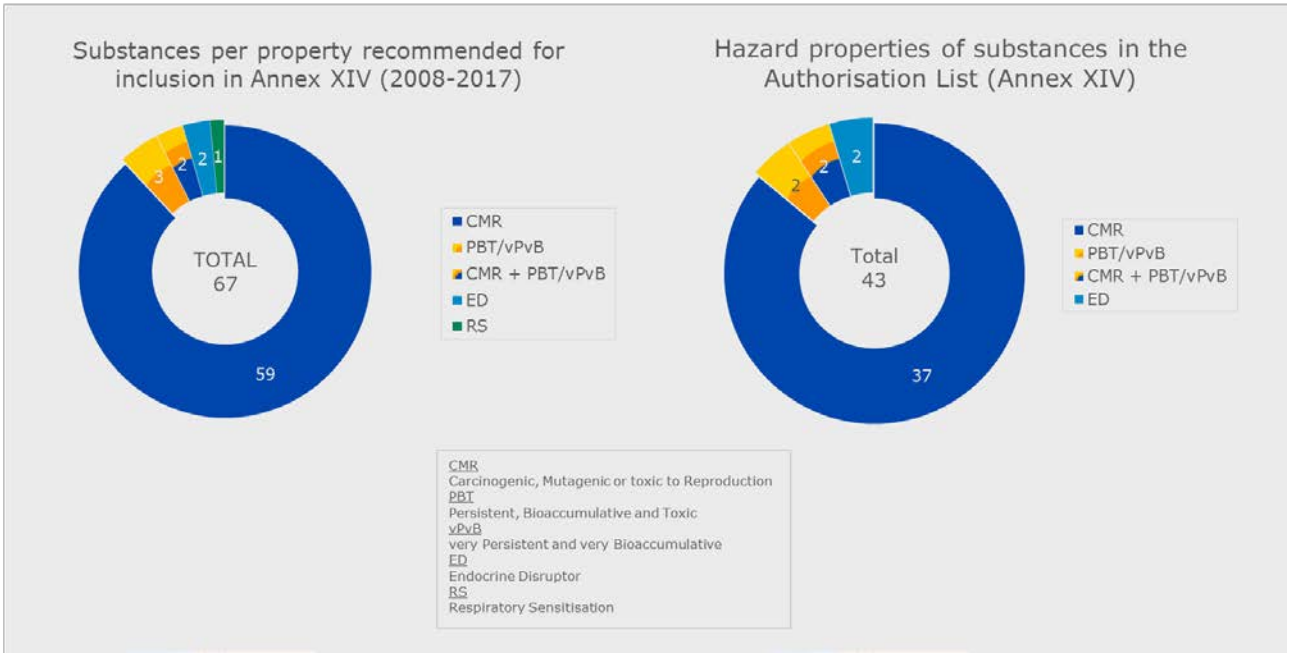


Figure 6: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008-2017[29])

Table 3 gives an overview and names of the substances recommended by ECHA to be included in Annex XIV until the seventh recommendation. It also lists those substances which have been included in the Authorisation List (Annex XIV) and which not. The Commission has indicated in the preambles of each proposed amendment to Annex XIV the reasons for not taking forward the substances that were recommended by ECHA.

[26] The prioritisation approach is available at: https://www.echa.europa.eu/regulations/reach/authorisation/recommendation-for-inclusion-in-the-authorisation-list.
[27] An overview of substances recommended by ECHA is available at: https://echa.europa.eu/previous-recommendations.
[28] Substances included in Annex XIV can be found at: https://www.echa.europa.eu/authorisation-list.
[29] One substance is listed in Annex XIV with CMR properties only, whereas it also has ED properties. This has not yet been updated in Annex XIV and as a consequence is not reported here.

Table 3: Overview of substances recommended for inclusion in Annex XIV and substances included on Annex XIV (2008-2017)

Date of recommendation	Number of substances recommended	Amendment of Annex XIV	Number of substances included in Annex XIV	(Groups of) substances included in Annex XIV	(Groups of) substances not included in Annex XIV amendment
1st (1 June 2009)	7	1st (17 Feb 2011)	6	Musk xylene, MDA, HBCDD, 3 phthalates	*[SCCP]*[1]
2nd (17 Dec 2010)	8	2nd (14 Feb 2012)	8	1 phthalate, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd (20 Dec 2011)	13	3rd (17 Apr 2013)	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) compounds
4th (17 Jan 2013)	10	4th (14 Aug 2014)	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th (6 Feb 2014)	5	5th (13 June 2017)	1	4-tert-OPnEO	DMF ADCA Al-RCF and Zr-RCF
6th (1 July 2015)	15		11	1-bromopropane, 7 phthalates, anthracene oil, CTPHT, 4-NPnEO	4 boron substances
7th (10 Nov 2016)	9	[n.a]	[n.a]	[n.a]	*
Total	67		43		24

* Substances from the seventh recommendation (as well as from the eighth recommendation, which was sent to the Commission in February 2018) have not yet been considered for amending Annex XIV.

[1] SCCP was recommended but not included as the substance was included in the POP Regulation

2.3 Applications for authorisation and decisions on authorisation

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

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

The opinions of ECHA's committees contribute to the decision-making process of the European Commission, which decides on whether to grant an authorisation for the uses applied for.

Table 4 gives the number of applications for authorisation received between January 2013 and the end of December 2017, as well as the number of Committee for Risk Assessment (RAC)/Committee for Socio-economic Analysis (SEAC) opinions and Commission decisions.

Table 4: Number of applications for authorisation/review reports received from January 2013 to December 2017.

Substance	Intrinsic properties in Annex XIV	Received applications	Applicants	Uses	RAC/SEAC opinions per use	Commission decisions per use
DEHP and DBP	CMR	10	12	21	17	10
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	12
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	13	15	19	19	13
Lead chromate	CMR	1	1	1	1	1
Chromium trioxide	CMR	27	63	44	37	6
Sodium dichromate	CMR	19	25	25	24	7
Sodium chromate	CMR	2	4	3	3	1
1,2-dichloroethane (EDC)	CMR	16	18	20	19	5
Chromium trioxide; sodium dichromate; potassium dichromate	CMR	1	6	3	3	-
Potassium	CMR	4	4	7	7	2

Table 4: Number of applications for authorisation / review reports received from January 2013 to December 2017.

Substance	Intrinsic properties in Annex XIV	Received applications	Applicants	Uses	RAC / SEAC opinions per use	Commission decisions per use
dichromate						
Ammonium dichromate	CMR	3	5	4	4	2
Dichromium tris(chromate)	CMR	2	3	3	2	-
Chromium trioxide; dichromium tris(chromate)	CMR	1	2	4	4	4
Strontium chromate	CMR	2	13	3	2	-
Potassium hydroxyoctaoxo dizincatedichromate	CMR	1	5	2	2	-
Bis(2-methoxyethyl) ether (diglyme)	CMR	8	8	9	9	1
Arsenic acid	CMR	1	1	1	1	-
Chromic acid	CMR	1	1	1	1	-
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	CMR	1	1	2	2	-
4,4'-methylenebis[2-chloroaniline] (MOCA)	CMR	1	1	1	1	-
Sodium chromate; potassium chromate	CMR	1	1	4	-	-
Pentazinc chromate octahydroxide	CMR	2	3	4	-	-
Total		**123**	**210**	**200**	**177**	**71**

* One application for two uses was withdrawn by the applicant.

3 Restrictions

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

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

Table 5 gives the number of restriction proposals adopted or going through the restriction process from 2009 until 2017 (December). Note that some of these restrictions cover groups of substances.

Table 5: Number of restriction proposals on (groups of) substances adopted or going through the restriction process.

Step in restriction process	PBT	ED	CMR	Sensitiser	Other
Restrictions included in Annex XVII	3	1	7	2[30]	1
Restriction process ongoing	1	0	3	1	0
Sent to Commission, but not yet in Annex XVII	0	0	2	0	2
Total (only the ones with substance scope in Registry of Intentions)	**4**	**1**	**12**	**3**	**3**

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

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

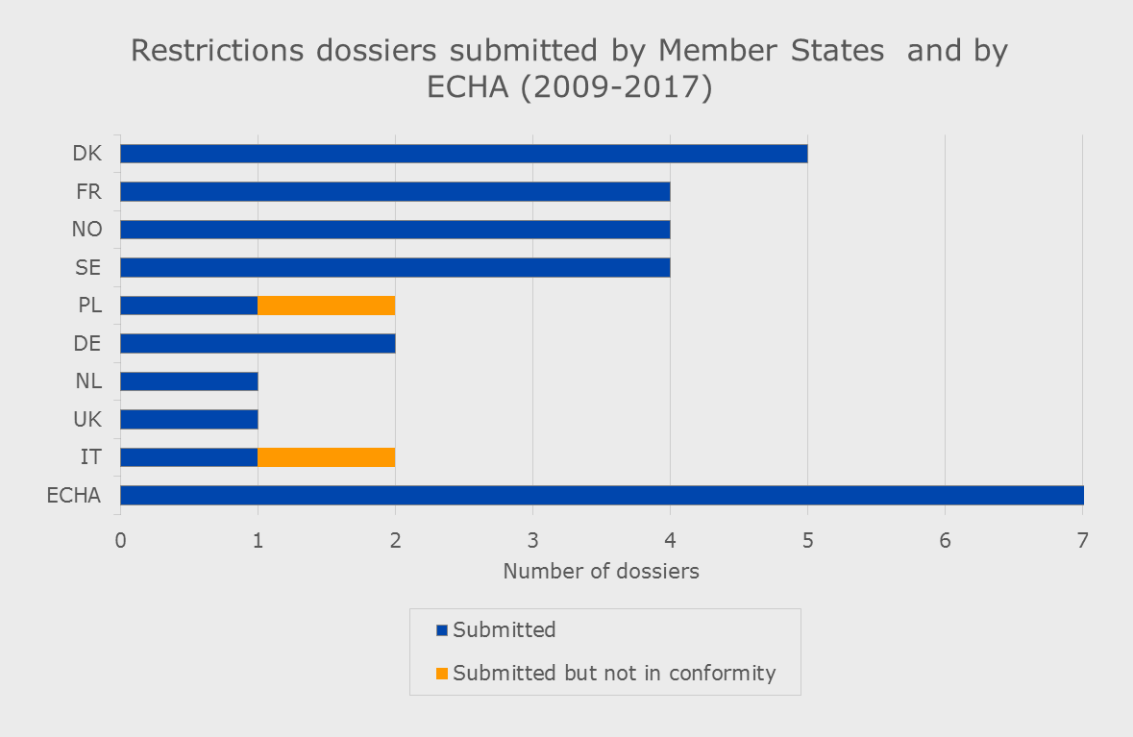


Figure 7: Number of restriction dossiers submitted by Member States and by ECHA (2009 - 2017.

Appendix 3. Overview of Member State activities in screening, RMOA, substance evaluation and the PBT and ED Expert Groups.

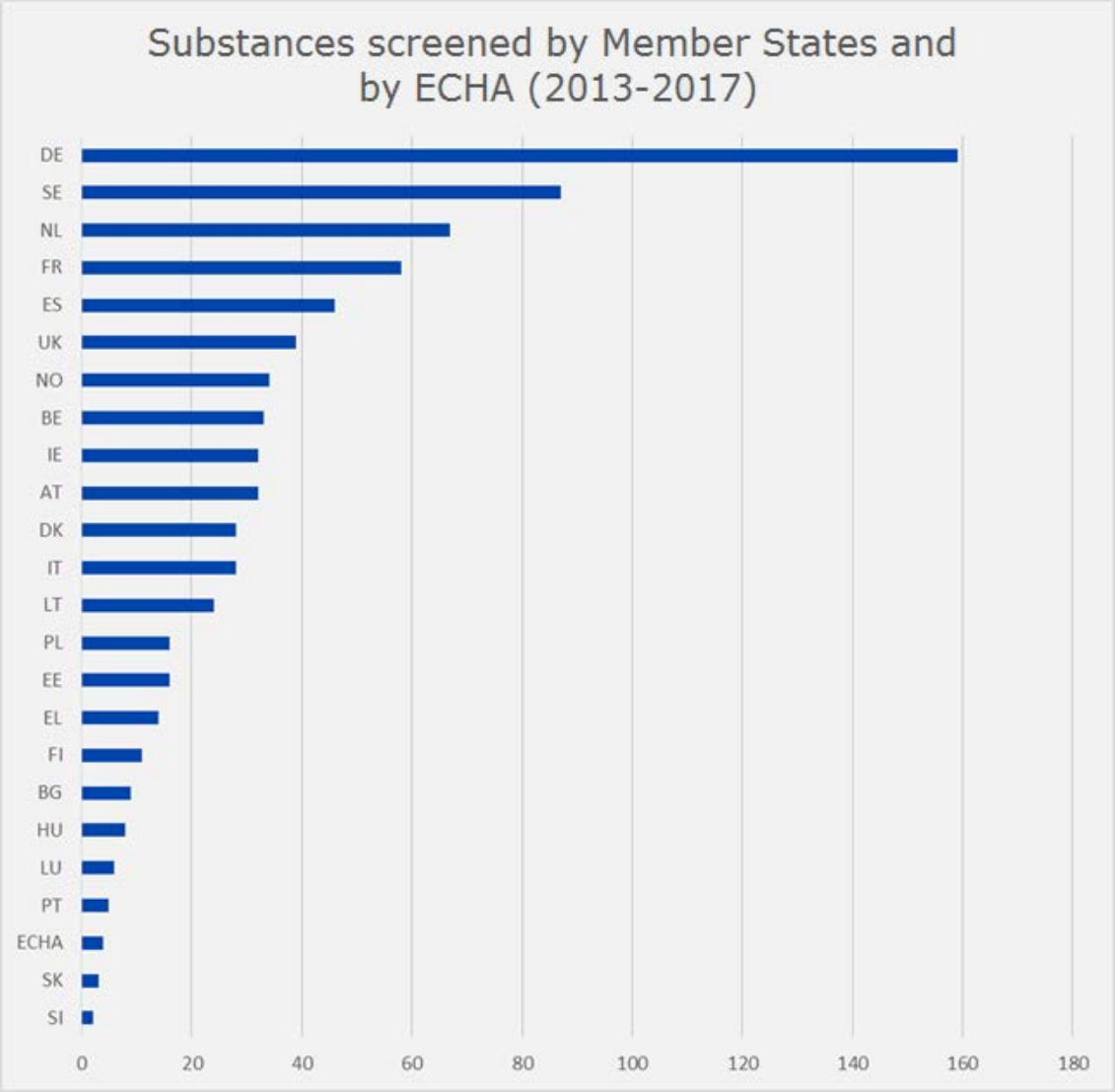


Figure 1: Number of substances screened by Member States and by ECHA (2013-2017).

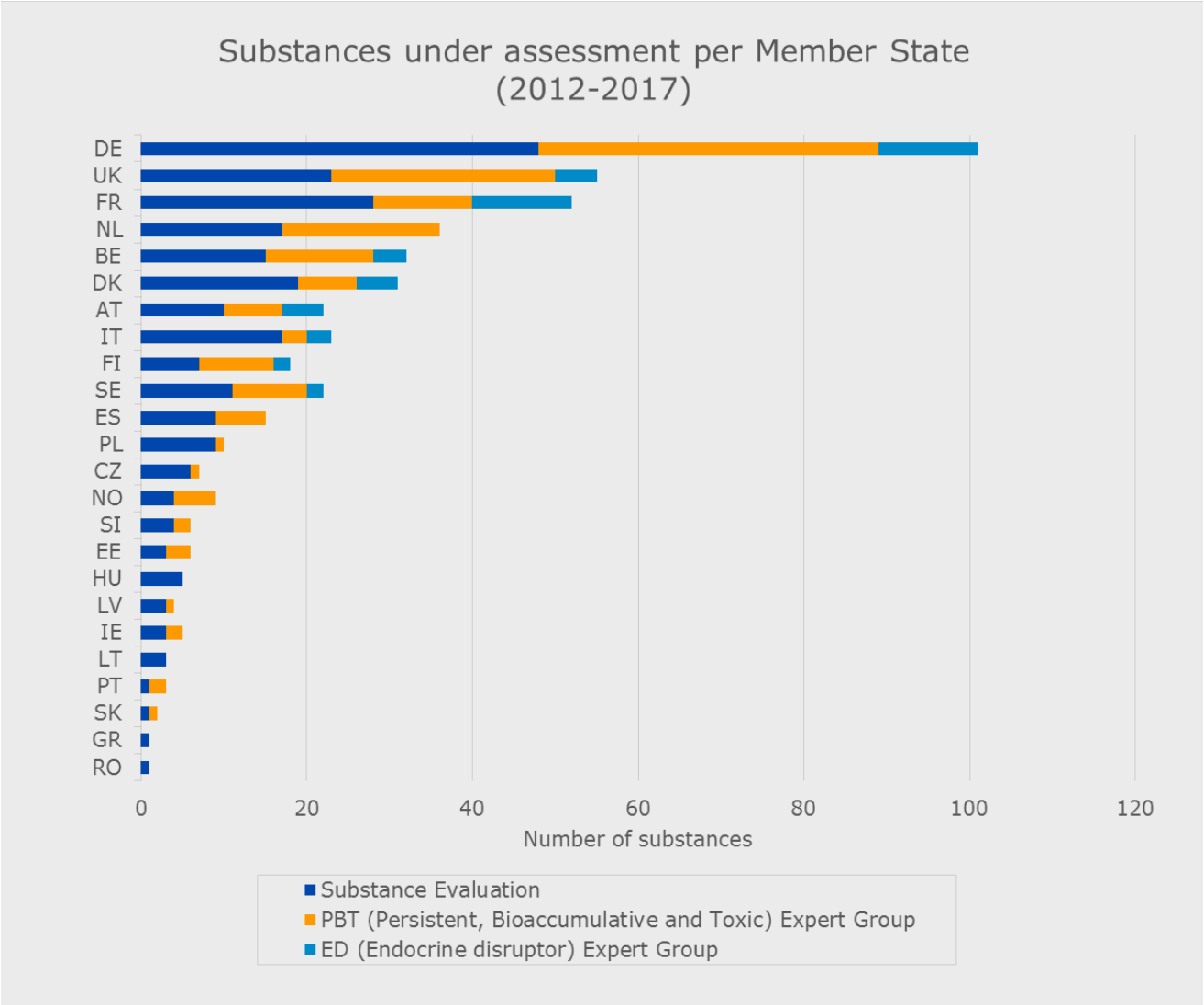


Figure 2: Number of substances under assessment in the ED Expert Group, the PBT Expert Group and substance evaluation, per Member State.

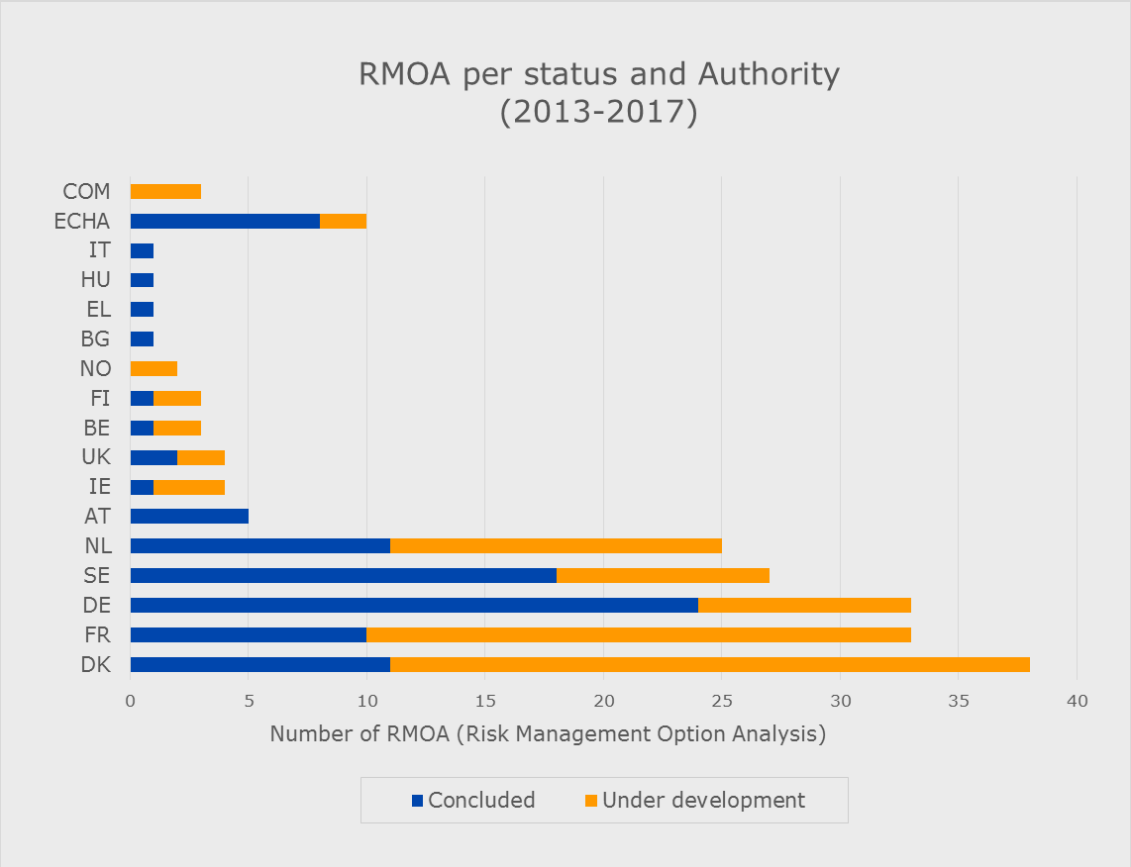


Figure 3: Number of RMOAs concluded or under development per authority (2013-2017).

Appendix 4. Progress monitoring indicators

Progress monitoring indicators – target and results[31]					
Indicators	**Target**	**Result**			
		2013-2014	**2015**	**2016**	**2017**
Substance screening 1: Percentage of substances identified for further work to clarify a concern (substance evaluation, Compliance check or proposed regulatory risk management (RMOA, CLH, other action))	- [32]	83.5 %	75.8 %	69.6 %	69.1 %
RMOA1: Number of (groups of) sub-stances subject to an RMOA	55 (or 440 by 2020)	91	42	16[33]	31[33]
RMOA2: Extent to which (percentage of) RMOA conclusions resulted in regulatory follow-up	high	17 %	68 %	84.8 %	94 %

[31] All progress monitoring indicators for the SVHC Roadmap are calculated starting from the implementation of the roadmap in 2013.
[32] The target is to have the indicator "substance screening 1" high and at least equal to the baseline which is set as 2014.
[33] 16 new intentions, but this covers four groups of substances and therefore more than 16 substances.