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Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures

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Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures

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Foreword from the Executive Director

This is the first report on the progress of implementing "the Roadmap for SVHC identification and REACH Risk Management measures from now to 2020". It describes the main achievements and progress since the adoption of the Roadmap in February until the end of 2014.

The Roadmap and its implementation plan give direction and set out common priorities for the authorities' work on substances of concern. They provide the basis to jointly identify which substances matter most for the protection of human health and the environment. They also define the most efficient and proportionate way to address these substances and foster innovation by stimulating the substitution of the most hazardous substances with safer alternatives. The extensive cooperation between Member State competent authorities, the Commission and ECHA in implementing the Roadmap helps to avoid overlapping work and gaps in priority areas and by that contributes to a more streamlined and coherent management of substances of concern.

ECHA's website contains a wealth of information on which substances of potential concern are on the authorities' radar and the type of regulatory risk management that authorities consider the most appropriate for each identified substance. Not only has this increased the transparency of the work that precedes the regulatory processes, it has also increased the predictability of the authorities' work. This will in turn support proactive industry to define their business strategies towards substances of potential concern and may be subjected to regulatory action in the future. At the same time, this supports all stakeholders in getting prepared, in particular to provide their contributions during the public consultations when any of the regulatory processes are initiated.

Since the entry into operation of the REACH and CLP regulations, ECHA and its regulatory partners undertook a lot of work to assess and address substances with a harmonised classification due to their carcinogenic, mutagenic and reprotoxic properties. The regulatory attention is now more and more focused on newly identified potential substances of concern. Often this requires generating further data and assessing the hazard information in detail. These are time and resource consuming processes but are essential for ensuring the generation of new health and environmental benefits by addressing the right substances of concern.

I welcome the good start in implementing the SVHC Roadmap. The foundation created now is essential as we have a lot of work ahead of us to achieve the policy goal set out in the Roadmap: "to have all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020".

My sincere thanks go to all staff involved in the Member States for their work in identifying and addressing substances of concern. I invite more Member States to join this collective effort for a better future.

Geert Dancet
Executive Director
European Chemicals Agency

Executive summary

The 'Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020' [1] (called the SVHC Roadmap) provides an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020.

During 2013, together with the Member State competent authorities and the Commission, ECHA developed a plan on how to implement the SVHC Roadmap until 2020 [2].

This document reports on the main achievements and progress of the SVHC Roadmap to 2020 since its adoption in February 2013 until the end of 2014. It is the first report of its kind on the SVHC Roadmap and ECHA plans to provide one each year.

Regulatory risk management activities took place before the Roadmap was implemented. Therefore, the information reported in this first report reflects what has been achieved since the adoption of the Roadmap but also the risk management activities resulting from the implementation of the REACH and CLP regulations in the previous years.

Part 1 provides a summary of the activities carried out from February 2013 until the end of 2014 regarding the implementation of the SVHC Roadmap and more particularly on screening, assessment, risk management option analysis (RMOA) and related progress monitoring indicators. The main focus is to report activities undertaken for each of the SVHC Roadmap substance groups:

- Carcinogenic, mutagenic or toxic for reproduction substances of categories 1A or 1B (CMRs),
- Sensitisers and substances with other human health related hazard profiles which may give rise to equivalent levels of concern [3],
- Persistent, bioaccumulative and toxic substances (PBTs) and very persistent, very bioaccumulative substances (vPvBs),
- Endocrine disruptors (EDs), and
- Petroleum/coal stream substances with CMR or PBT properties.

The work involved in implementing the Roadmap should provide a strong basis to identify the substances which matter most and to timely and effectively address them under the REACH and CLP regulations where appropriate. According to the Roadmap, this should be and has been achieved by:

[1] Available at http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT
[2] Accessible at: http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf
[3] Substances with human health related hazard properties other than sensitisation can be considered, if they qualify as SVHCs because they appear to give rise to equivalent levels of concern in accordance with REACH Article 57(f) (endocrine disruptors are, however, dealt with as their own substance group).

- Having a **clear plan and defined priorities for screening and risk management option analysis** of the different substance groups.

  The SVHC Roadmap implementation plan gives an overview of the screening and RMO activities including the scope, planning and priorities.

- Ensuring a **rolling exercise that takes into consideration new information** (for example, newly classified CMRs) but also the **efficient use of information** deriving from other REACH processes (registration, dossier and substance evaluation) for **identifying needs for regulatory risk management**.

  ECHA has set up and implemented a common **screening approach** to support different REACH and CLP processes: further information generated under substance evaluation and potential further regulatory risk management measures (harmonised classification and labelling, authorisation, restriction).

  This screening will be done on a yearly basis and will ensure that new information is processed. The first screening round last year resulted in 350 substances being listed for further work. This work is done by ECHA with the support of both the CMR and sensitiser coordination groups and the PBT and ED expert groups.

  The integration of REACH and CLP processes will be further enhanced by the incorporation of compliance check to the common screening, in line with the new ECHA strategy on "safer chemicals – focusing on what matters most" [4].

  Under **assessment**, the work undertaken by the PBT and ED expert groups and the work carried out under substance evaluation, which is one of the main tools for generating further information, is reported.

  The PBT and ED expert groups[5] support the informal assessment of the PBT and ED properties of substances. 129 substances have been discussed under the PBT expert group since 2012. The ED expert group started its work in 2014 and it has discussed 14 substances so far. Endocrine disruptors are identified according to the WHO (2002) definition[6]. Experience shows that for many of the potential PBT and ED substances, further information generated under substance evaluation is needed to conclude whether they have these properties. Therefore, it will take substantial time before these substances move to the RMOA step.

  The final conclusion and confirmation on the PBT and ED properties can only be achieved through the

[4] Available at http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf
[5] More information on the groups is accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan
[6] http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/ :
"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

SVHC identification process. So far, five endocrine disrupting substances have been included in the Candidate List. 20 PBT/vPvBs have been included in the Candidate List, out of which two are in the Authorisation List.

The purpose of a risk management option analysis (**RMOA**) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern. RMOA is an important step, agreed in the SVHC Roadmap, but it is voluntary as it is not part of the processes defined in the legislation. The RMOA has nevertheless become a standard approach to enhancing common understanding between authorities on the need for and type of further regulatory action.

During 2013 and 2014, 24 RMOAs have been concluded and the RMOA work is ongoing for 74 substances. By this, the interim target set out by the Commission to have 80 substances subject to an RMOA by the end of 2014 has been met. As the practical implementation work has started to progress substances through the screening and assessment steps, it is expected that a growing number of new RMOAs will be seen in the coming years.

Much work has focused on already known CMRs with a harmonised classification in Annex VI to CLP. All registered CMRs have been screened and work to identify structurally similar substances is ongoing. The vast majority of the registered known CMRs has been scrutinised or are undergoing an RMOA to conclude on the need for further action. This work, which started already before the Roadmap implementation, has resulted in the inclusion of 145 CMRs in the Candidate List, out of which 29 are currently included in the Authorisation List.

This means that the efforts of ECHA and the Member States can be directed to identifying new CMRs. This will be done either by proposing new harmonised classification and labelling (based on available data) or, where further information is needed, through substance evaluation or compliance check.

- **Increased transparency and predictability towards stakeholders and the general public**

  Generic information on the Roadmap and its implementation plan is now available on ECHA's website[7]. Since September 2014, the first part of the Public Activities Coordination Tool (PACT)[8] has also been available. It provides a list of substances which are under RMO assessment as well as the conclusions when the RMOAs have been finalised.

  It is important to note that RMOAs or RMOA conclusions published on the PACT only reflect the views of the author authority. It does not preclude other Member States or the European Commission from considering or initiating regulatory risk management measures if they would deem this appropriate.

[7] Accessible at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
[8] Accessible at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact

The publication of information on substances undergoing RMOA through the PACT has significantly increased the transparency of the authorities' work. Stakeholders and the general public can now better predict which substances are likely to be addressed by formal risk management routes in the future.

- **Defined list of responsibilities, involvement and cooperation of all relevant actors in implementing the Roadmap**

  The roadmap implementation is a joint activity of the Member States, the Commission and ECHA.

  Expert and coordination groups gather input to the screening from the Member States and Commission and by that enhance a common view among authorities on which substances matter most. These groups also help to make sure that the identified substances are duly processed further. Furthermore, they support a number of other developments, such as discussion on additional properties potentially leading to equivalent levels of concern or training of less active Member States.

  Around two thirds of the Member States are actively involved in the different activities linked to the SVHC Roadmap.

Part 2 of the report gives an outline of the SVHC Roadmap implementation activities planned for 2015. The further development of the implementation will focus on:

- Improving the common screening approach further;
- Increasing the transparency and predictability of activities with the foreseen update of PACT to include information on substances under assessment in the expert groups;
- Developing an approach to address the petroleum/coal stream substances under the SVHC Roadmap implementation;
- Continuing to build capacity within Member States to increase their involvement in the screening and RMOAs.

Part 3 provides an overview of related regulatory risk management activities. An overview of the progress made on harmonised classification, different steps of the authorisation and restrictions is provided since the start of those different REACH processes until the end of 2014.

In summary, a good start has been made with the implementation of the SVHC roadmap. The work carried out in 2013 and 2014 has laid a foundation for efficient and effective screening of the registration information allowing candidate substances to be identified for further manual screening and potential regulatory intervention.

Introduction

The 'Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020' [9] (called the SVHC Roadmap) gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020.

During 2013, ECHA developed a plan on how to implement the SVHC Roadmap until 2020 [10], together with Member State competent authorities and the Commission. This plan sets out how to identify substances which have SVHC properties and to determine whether they are relevant according to the criteria set out in the SVHC Roadmap and therefore should be included in the Candidate List. The Roadmap implementation work also supports carrying out other regulatory risk management processes defined in the REACH and CLP regulations.

The SVHC Roadmap implementation plan (RIP) focuses on how the following work can be organised, coordinated and carried out:

- Screening to identify new substances of concern, and
- Analysing the risk management options (RMOs) appropriate to the particular substance of concern.

The implementation plan also provides an outline of how progress monitoring and communication towards stakeholders and the general public is envisaged.

Figure 1 gives an overview of all activities under the SVHC Roadmap as well as the direct links to closely related activities such as compliance check and substance evaluation. Timelines of the different steps are indicated in order to provide a general understanding of the time typically needed to go through these different steps.

This document reports the main achievements and progress of the SVHC Roadmap to 2020 since the adoption of the Roadmap in February 2013 until the end of 2014. It is the first report of the SVHC Roadmap and such a report will be provided each year.

Regulatory risk management activities took place before the Roadmap was implemented. Therefore, the information reported in this first report reflects not only what has been achieved since the adoption of the Roadmap but also activities that took place before.

Part 1 provides a summary of the activities carried out from February 2013 until the end of 2014 regarding the implementation of the SVHC Roadmap and more particularly on screening, assessment, Risk Management Option Analysis (RMOA) and related progress monitoring indicators. The main focus is to report activities undertaken for each of the SVHC Roadmap substance groups i.e.:

- Carcinogenic, mutagenic or toxic for reproduction substances (CMRs) (cat 1A/1B),
- Sensitisers and substances with other human health related hazard profiles which may give rise to equivalent levels of concern[11],

[9] Available at http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT
[10] Accessible at: http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf
[11] Substances with human health related hazard properties other than sensitisation can be considered, if they qualify as SVHCs because they appear to give rise to equivalent levels of concern in accordance with REACH Article 57(f) (endocrine disruptors are, however, dealt with as their own substance group).

- Persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB) substances,
- Endocrine disruptors (EDs), and
- petroleum/coal stream substances which have CMR or PBT properties.

Part 2 of the report gives an outline of SVHC Roadmap implementation activities planned for 2015.

Part 3 provides an overview of related regulatory risk management activities. An overview of substances under SVHC identification, recommendation for and inclusion of substances in Annex XIV, applications for authorisation are provided since the start of those different REACH processes until the end of 2014. The report focuses on SVHC Roadmap substance groups.

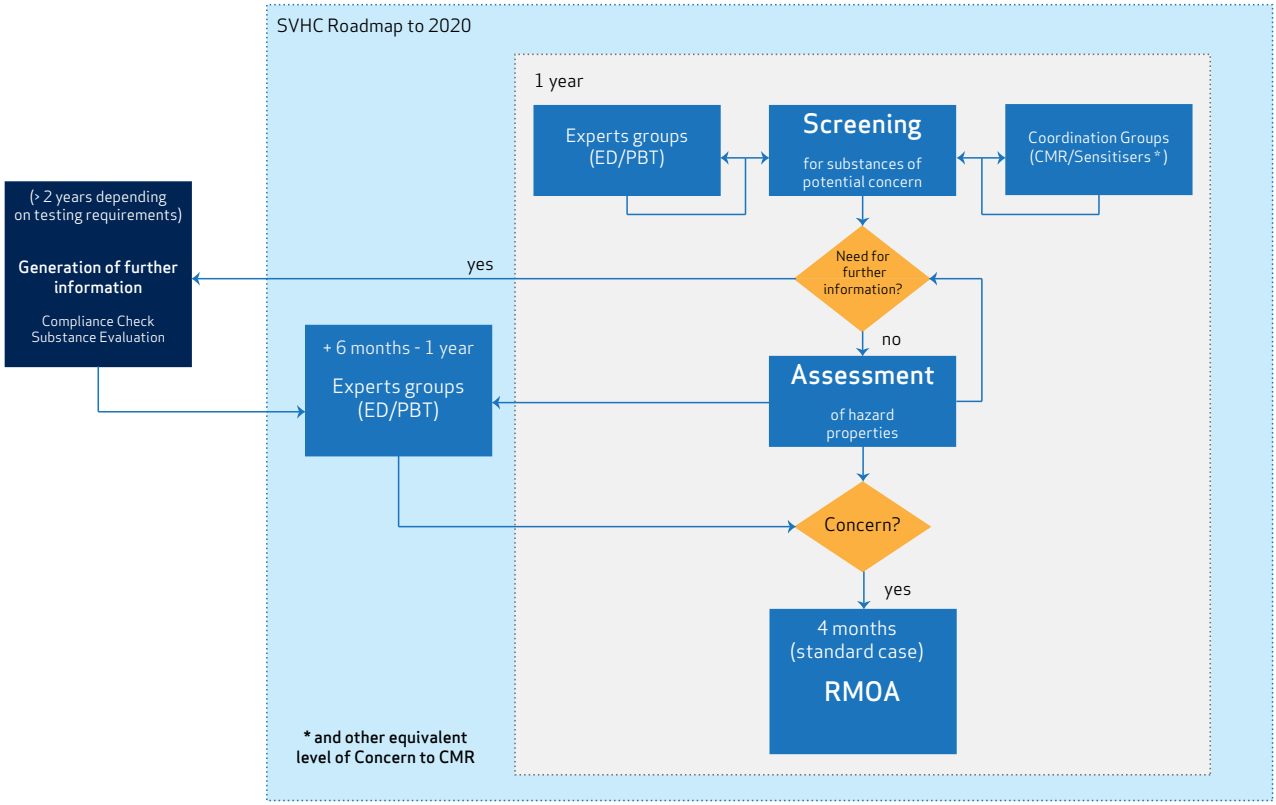


Figure 1: Overview of activities under the Roadmap with indicative timelines and links to closely related activities (compliance check, substance evaluation).

Part 1 – Activities carried out from February 2013 until the end of 2014

1. Introduction

The SVHC Roadmap to 2020 aims to identify and include all relevant currently known SVHCs in the Candidate List by the end of 2020. The Roadmap implementation work should also provide a strong basis for the work beyond 2020 to identify the substances which matter most and to timely and effectively address them under the REACH and CLP regulations. According to the Roadmap, this should be achieved by:

- **Having a clear planning and defined priorities for screening and RMO of the different substance groups**

The SVHC Roadmap implementation plan gives an overview of the screening and RMO activities including the scope, planning and priorities. In addition for screening, a yearly cycle of activities have been defined as further detailed in section 2 (Figure 3).

- **Ensuring a rolling exercise that takes into consideration new information (for example, newly classified CMRs) but also the efficient use of information deriving from other REACH processes (registration, dossier and substance evaluation) for identifying needs for regulatory risk management**

Since February 2013, one of the main achievements is the setting up and implementation of the ECHA common screening developed to support REACH and CLP processes as further detailed in section 2. This common screening approach has been developed to identify substances which may be potential SVHCs and to identify which follow up action is the most appropriate for those.

The screening is based on the use of registration information but also other additional sources (for example, C&L Inventory, downstream user reports, and external sources). In practice, there is often a need to generate further data to conclude on the hazard properties. Depending on the case, such further data can be requested from the registrants under compliance check (CCH) or substance evaluation (SEv).

The screening will be done on a yearly basis and will ensure the processing of new sources of information.

- **Increased transparency and predictability towards stakeholders and the general public**

Generic information on the Roadmap and the Roadmap implementation plan (RIP) is available on ECHA's website[12]. Since September 2014, the first part of the Public Activities Coordination Tool (PACT)[13] has also been made available. It provides a list of substances which are under Risk Management Option Analysis (RMOA) and at which stage of assessment (i.e. ongoing, concluded) the substances are. For substances that are already concluded, a summary of the conclusion is available. The PACT will allow stakeholders to be informed early enough in the process on individual substances addressed by authorities. The PACT is the outcome of a commitment between ECHA, Member States and the Commission to make the work on substances more transparent and predictable to the outside world.

[12] Accessible at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
[13] Accessible at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact

- **Defined list of responsibilities and involvement and cooperation of all relevant actors in the implementation of the Roadmap**

The Roadmap implementation is a joint activity of Member States, the Commission (COM) and ECHA. Coordination groups supporting activities related to CMR and sensitising substances were set up at the beginning of October 2013. So far these coordination groups have been particularly supporting screening and the general improvement of the Roadmap processes. They have also supported preliminary discussions on additional properties potentially leading to an equivalent level of concern to CMR (for example, specific target organ toxicity – repeated exposure (STOT RE)).

An Endocrine disruptor expert group has also been set up in early 2014 and the existing PBT expert group has aligned its activities to support the SVHC Roadmap implementation. The PBT and ED expert groups support the assessment of PBT/vPvB and ED properties of substances.

For petroleum and coal stream substances, the Roadmap foresaw the need first to develop an approach to assess that group of substances. To this end, ECHA has worked together with industry to better understand the challenges linked to these substances.

To enhance the participation of Member States in implementing the SVHC Roadmap, ECHA organised a workshop at the beginning of 2014 to find ways to better support Member States that are not yet active. Active Member States also participated in the workshop and this resulted in some Member States that were not yet active collaborating with more experienced ones at the level of screening and later on RMOAs. More experienced Member States have also taken the initiative to organise training on RMOAs for less active Member States which should also in the long-term ensure that more Member States are supporting the implementation of the Roadmap.

2. Screening

2.1. COMMON SCREENING APPROACH

Screening activities to find potential substances of (very high) concern is an important element of the SVHC Roadmap to 2020 implementation plan[2]. A common screening approach[14] is governed and initiated by ECHA with a view to serve the REACH and CLP processes (see also Figure 2):

- Community rolling action plan (CoRAP) under substance evaluation (SEv);
- Potential further regulatory risk management measures under the REACH and CLP regulations i.e.:
  - Harmonised classification and labelling
  - Authorisation
  - Restriction

Although the common approach has indirectly identified cases for compliance check (CCH), it has not been an explicit part of the approach. Identifying cases for CCH will be included in future rounds of screening. This is to ensure an integrated prioritisation and selection mechanism for improving dossier quality and for selection of substances for CoRAP and regulatory risk management measures.

[14] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

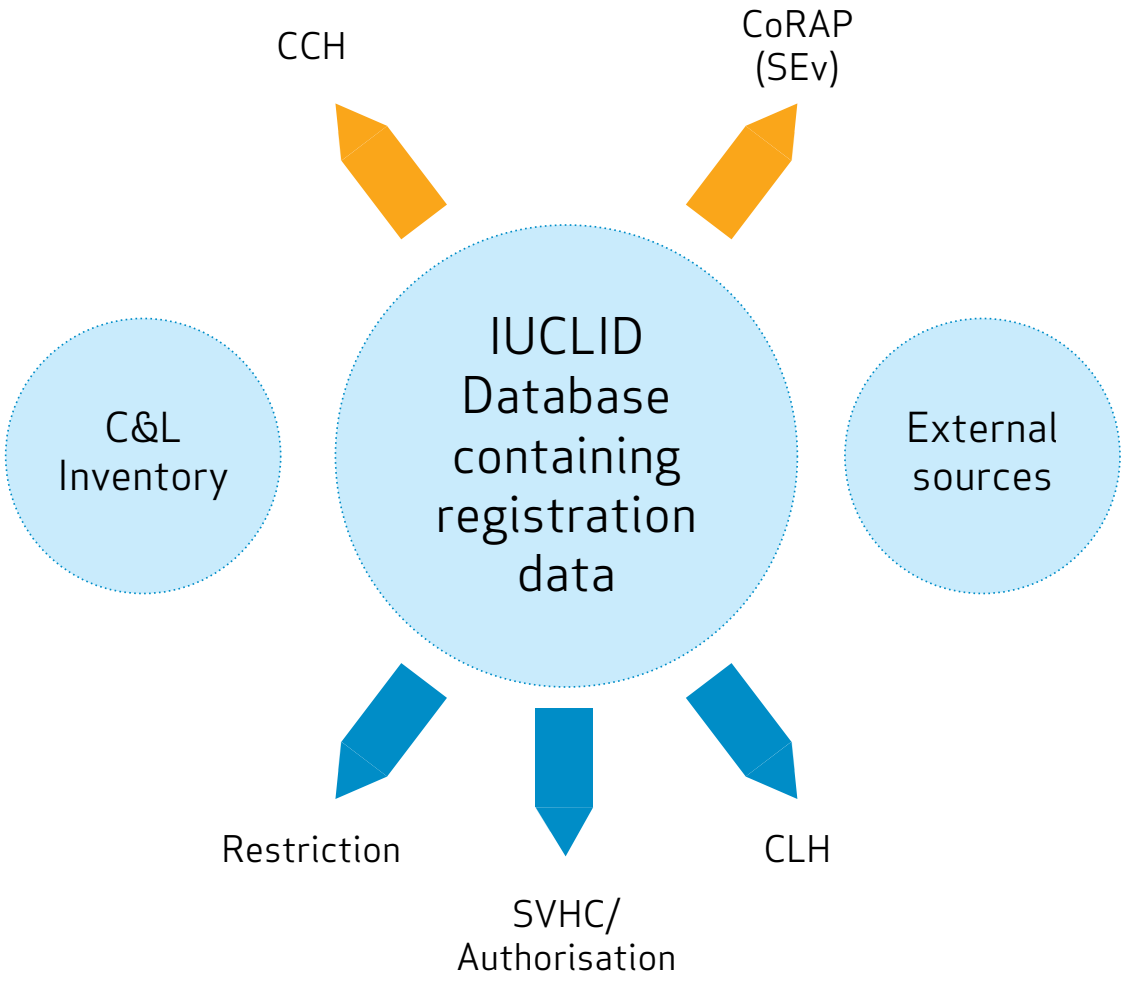


Figure 2: Common screening approach

The ultimate goal of the common approach is to have substances with certain hazard(s) (human health, environment), exposure and ultimately risk profiles, i.e. substances which matter the most, identified and processed through the most appropriate REACH or CLP process. This common approach is intended to ensure the swift progress of the screening activities, avoid duplicating work and minimise the risk of having the same substance being identified as a suitable candidate for different processes unless there are valid reasons for that and the parallel processing is done in coordinated manner.

There are several steps involved in the screening round, separated into two different phases: 1) IT mass screening phase, and 2) manual screening phase.

During the IT mass screening phase, ECHA develops screening scenarios (in consultation with coordination and experts groups (CGs and EGs)), documents them in definition documents, implements and applies algorithms to all registered and notified substances in order to generate lists of potential candidates to be further manually screened by authorities (ECHA, Member States).

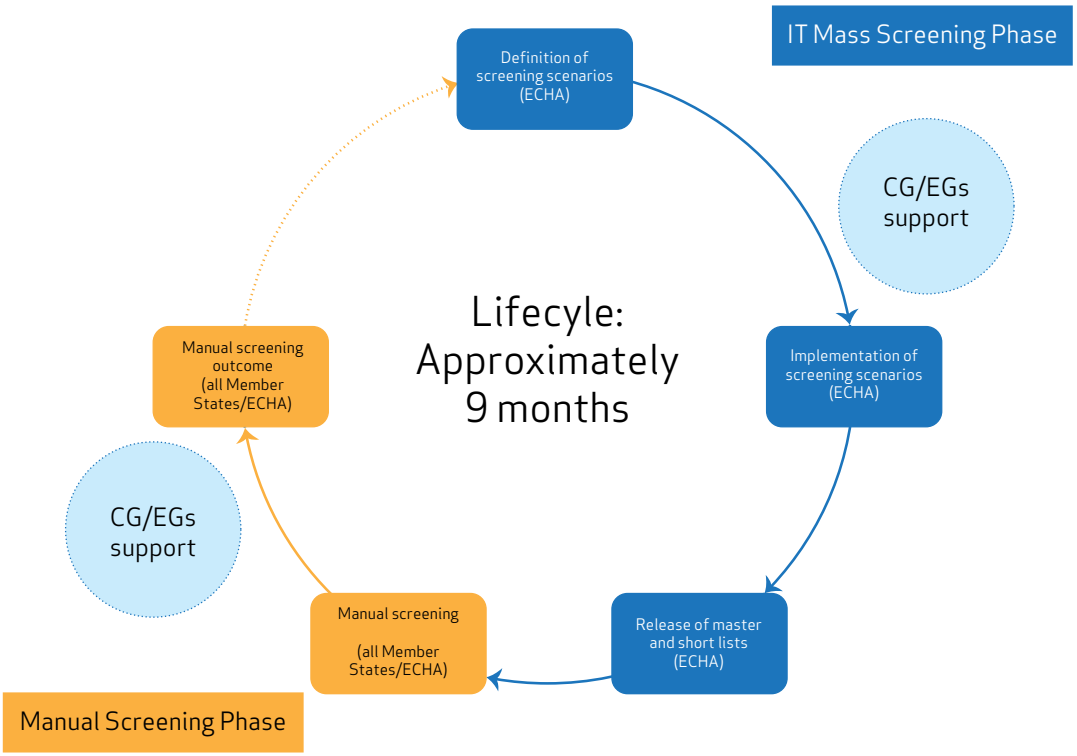


Figure 3: yearly round of screening

Manual screening is defined as a targeted, substance specific assessment of the information provided in the registration dossiers in relation to the search criteria applied. This manual screening is intended to scrutinise the outcome of the automated IT mass screening and to verify and better define the identified SVHC/CLH hazard profile or the risk based concerns of relevance for substance evaluation and/or compliance check. It is not a full assessment of the information available on the substance but aims to ascertain whether these substances should be progressed further down a REACH and/or CLP process.

The manual screening could, for instance, result in:

- a need for further information due to data gaps that are a standard requirement, and therefore the missing information should be requested through compliance check;
- developing a justification document for listing the substance on the CoRAP;
- identifying that there is a need for further assessment by one of the expert groups (PBT/ED) before considering the substance for further regulatory action;
- an apparent need for further regulatory risk management and an RMOA needs to be developed;
- there is a need for harmonised classification and labelling at EU level;
- the substance does not need to be taken further at this point in time;
- other action (for example, enforcement at national level).

Over the course of 2013/2014, substantial effort has been spent by ECHA and the CGs and EGs to define and

further develop the mass screening scenarios. In addition to integrating all REACH and CLP processes into a common screening approach, particular efforts have been made by ECHA to implement the supplementary activities of the SVHC Roadmap, especially screening algorithms for finding substances that are structurally similar to known SVHCs.

2.2. SCREENING RESULTS

For manual screening of both CoRAP and SVHCs, 351 substances have been included in short lists for manual screening and 247 have been manually screened by Member States. Most of the substances on the list for manual screening have been proposed by ECHA as a result of the application of the common screening approach. Additionally in the context of CoRAP, some Member States have also proposed their own candidate substances.

In all, 247 substances were manually screened in the screening round of 2013-2014. 195 of these substances were provisionally identified as CoRAP candidates and the remaining 52 substances were provisionally identified as SVHC candidates. The lower number of SVHC candidates reflects the fact that a lot of work has been done since 2008 in identifying SVHCs. For instance, most of the already harmonised CMRs 1A/1B and known PBT/vPvB and EDs have already been considered by Member States and, where relevant, regulatory processes have been initiated. The main consequence is that it can be expected that for most of the potential new SVHC substances there will first be the need to generate further information and/or harmonise the classification.

The results from the screening are reported in Figures 4 and 5 below. No specific scenario was developed for identifying good candidates for CCH and CLH in the screening round of 2013-2014. However, some candidates were identified during the manual screening as Member States proposed both compliance check and CLH as the most appropriate next step. The figures report combined results from both the CoRAP and SVHC lists.

The results of the common screening approach are encouraging, as for the majority of the substances selected for manual screening there will be a follow-up evaluation or risk management process. There are also a high number of substances for which compliance check have been proposed and for most of them ECHA considered that they were of high priority for compliance check. This indicates that the screening also supports the selection of relevant candidate substances for compliance check.

For several substances, more than one property was found to be of concern and for many substances more than one outcome was also found to be appropriate as shown in Figures 4 and 5.

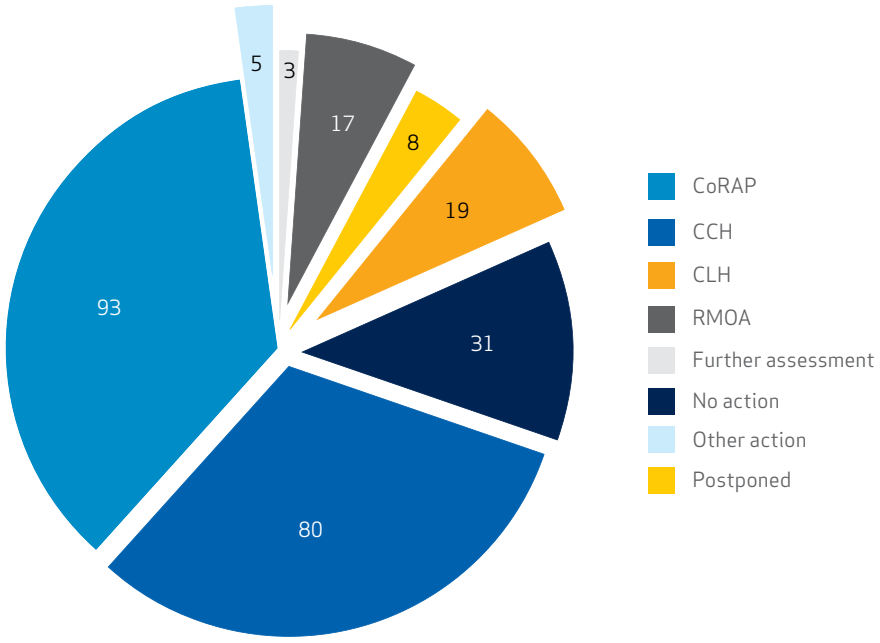


Figure 4: Manual screening outcome (combining results from SVHC and CoRAP lists).

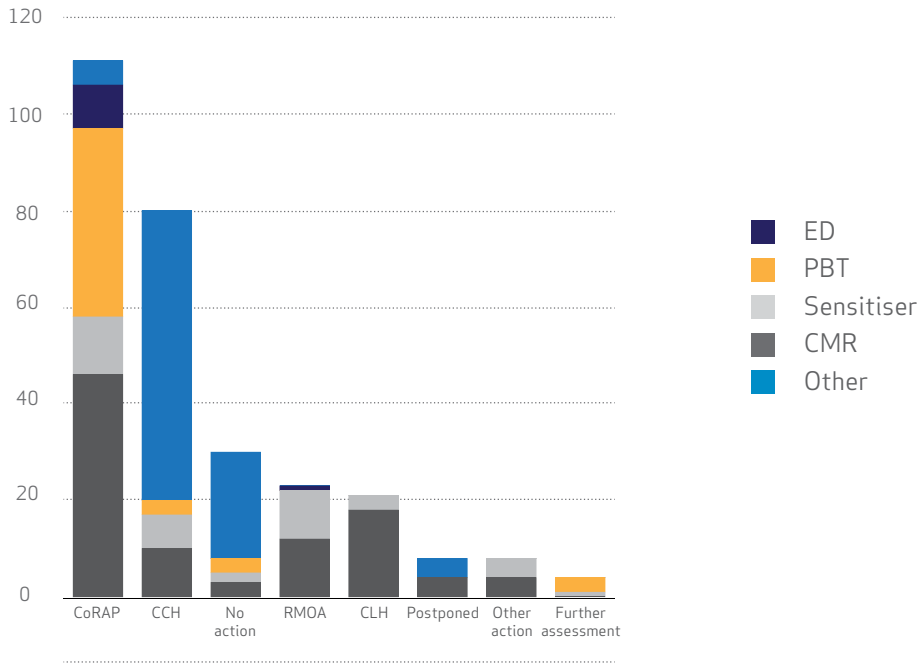


Figure 5: Manual screening outcome per properties (combining results from the CoRAP and SVHC lists)[15].

[15] As mentioned already, there was no specific screening scenario to identify substances for compliance check. This explains why the majority of the substances for which the main outcome is compliance check (CCH) do not necessarily concern one of the hazardous properties identified in the SVHC Roadmap (CMR, PBT, sensitiser or ED). Therefore, those have been indicated as "other" which explains the high number of "other" for CCH. The same applies to the manual screening outcomes "No action" and "postponed". This will be improved in the next round of screening.

The number of substances screened per Member State (and ECHA) is reported in Figure 6.

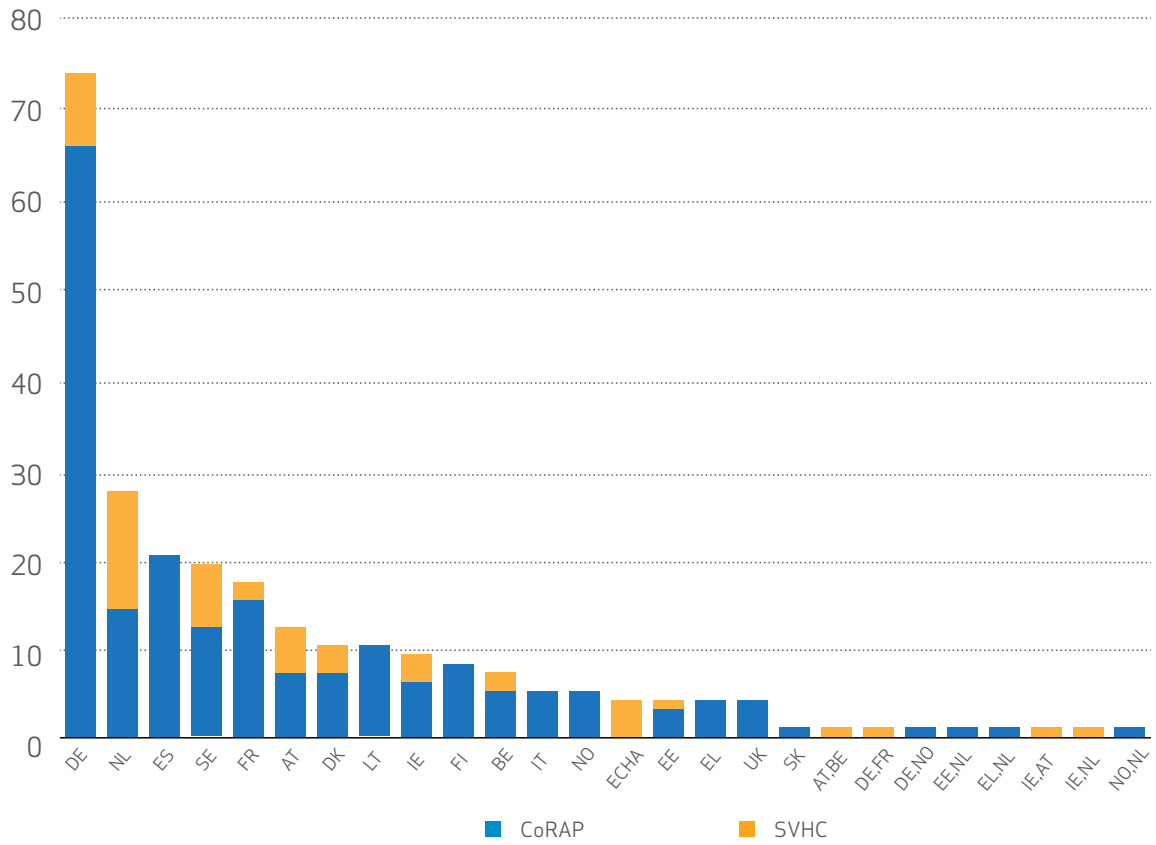


Figure 6: number of substances screened per (group of) Member States and by ECHA.

3. Assessment

3.1. INTRODUCTION

Figure 1 gives a summary of the different steps foreseen under the SVHC Roadmap. In many cases, the generation of further data (for example, through compliance check or substance evaluation) is needed before being able to assess the SVHC properties of a substance further and this applies to all SVHC properties[16] (PBT, vPvB, ED, CMR, sensitisers and potential other equivalent level of concern (ELoC) properties).

Substance evaluation aims to verify whether a substance constitutes a risk to human health or the environment from an EU-wide perspective. The substances prioritised for such evaluation are listed in the Community rolling action plan (CoRAP). Member States are responsible for evaluating the substances and upon completion of their evaluation, may propose to request further information from registrants if

[16] With the exception of already harmonised CMRs 1A/1B.

the available information does not fully address the potential risks. More information on the substance evaluation process, from updating the CoRAP to decision-making, is available on ECHA's website[17]. The Progress Evaluation Report provides an overview of the progress achieved under substance evaluation[18] each year.

Member States have 12 months from the date of the CoRAP publication to evaluate substances and request further information. The evaluation addresses at least the concerns originally identified in the justification documents for CoRAP listing, but this does not limit the scope of the Member States' evaluation. The Member States may also identify additional concerns during their evaluation, and propose to request further information to clarify any potential risk of the substance.

If there is enough information then data are assessed and it can be concluded whether or not the substance is of concern. In most cases, there is a need for further assessment of existing information for concluding on the SVHC properties of a substance. How this is done in practice depends on the property and on the case.

So far, the need for further generation of data was mainly on PBT and ED properties. However, as most of the known harmonised CMRs (1A/1B) have been identified and considered for further regulatory risk management already, in the near future we can expect that data will also need to be generated for new CMRs. For some substances (for example, those with a need to generate further information or a need for further assessment) more time will be needed than for already known SVHCs (for example, already harmonised CMR) before a conclusion can be reached. However in the long-term, more SVHCs that are less known and less regulated are expected to be identified.

PBT and ED expert groups[19] support the assessment of PBT/vPvB and ED properties of substances and can be consulted if there are further assessment needs. Both groups provide informal, non-binding scientific advice on questions related to the identification of PBT/vPvB and endocrine disrupting properties of chemicals respectively. This advice does not anticipate or interfere with decision-making under the REACH Regulation, which exclusively remains the responsibility of the competent bodies designated in the REACH Regulation. The groups can discuss assessments carried out for REACH but also for substances falling under the Biocidal Products Regulation or in support of other regulatory purposes. Many of the substances under substance evaluation are also discussed by the experts groups in order to get advice from Member States before deciding on the way forward under substance evaluation for PBT and ED properties.

For CMRs and sensitisers (and other ELoC), no specific expert group to support the hazard assessment (similar to the PBT and ED expert groups) exist. The role of the CMR and sensitiser (and other ELoC) coordination groups is to provide support at the level of manual screening on deciding the best way forward for a substance (for example, ELoC, clarification of classification status under CLP). Discussions on CMR and sensitising properties take place when dossiers for harmonised classification and labelling are prepared and submitted by Member States and discussed by the Risk Assessment Committee (RAC). This is further developed under Part 3 of this report "Report on regulatory risk management activities".

To conclude, what is reported under assessment is on one hand the work undertaken by the PBT and ED expert groups and on the other hand the work carried out under substance evaluation. As explained previously, substance evaluation is not as such in the SVHC Roadmap but is one of the main tools for generating missing information (see also Figure 1).

[17] Accessible at: http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
[18] http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports
[19] More information on the groups is accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan

3.2. OVERVIEW OF SUBSTANCES UNDER ASSESSMENT

An overview of all substances under assessment from 2012, which corresponds to the set-up of the PBT expert group and the first cases under substance evaluation, until the end of 2014 is provided in Figure 7 below. Information on each of the substance groups defined under the SVHC Roadmap is reported. For petroleum/coal stream substances no information has been reported so far as for this group of substances there is a need first to develop an approach on how to carry out the assessment. The number of substances under assessment is further split in substances for which an assessment is ongoing, postponed[20] and concluded. As many substances that are under substance evaluation are also discussed in the PBT and ED expert groups, the substances evaluated by the expert groups have been distinguished between "CoRAP" and "non-CoRAP".

The first CoRAP substances were evaluated in 2012 and experience is gained every year. The scope of substance evaluation clearly covers more than the substance groups indicated in the SVHC Roadmap (CMR, PBT/vPvB, ED, sensitisers and other ELoC). However, as this represents only a few substances, the other concerns[21] are not reported in Table 1 and Figure 7 below[22].

In addition to CoRAP substances, the expert groups can discuss other substances including substances not in the scope of REACH (for example, biocides and veterinary medicine). So far, the substance specific discussions were felt to be very useful by all participants in improving the assessments and make them fit for regulatory purpose. In the future, it is expected that the vast majority of substances under substance evaluation with PBT and/or ED concern would be discussed first in the PBT and ED experts groups.

So far, there have been a total of 133 substances with potential PBT/vPvB properties under PBT assessment, that are either listed under substance evaluation or for which a preliminary or advanced assessment was carried out ("non CoRAP" substances; status currently ongoing, postponed or concluded). The "non CoRAP" substances mainly originate from a screening shortlist generated before the SVHC Roadmap to 2020 and the common screening. Approximately half of the current substances under substance evaluation with suspected PBT/vPvB properties originate from that list and were added to the CoRAP as a result of preliminary assessment and discussions in the PBT expert group.

Among the "non CoRAP" substances, it can be expected that approximately half of them will need generation of further data and hence need to undergo substance evaluation in the future. The other half can be concluded without further information generation.

Resulting from the first screening round under the SVHC Roadmap to 2020, the first two substances under the SVHC Roadmap to 2020 screened as suspected PBT/vPvB were discussed in the PBT expert group in autumn 2014.

The ED expert group is relatively recent and has therefore not yet gone through many substances whereas the PBT expert group is already well established. 14 substances have been discussed by the ED expert group, 12 of which were discussed in the third meeting in November 2014. Under substance evaluation, 26

[20] Postponed means that it is the assessor's opinion that further information would be needed to confirm the hazard properties but follow-up work is not relevant at present (for example, only uses as intermediates)
[21] Only for eight substances under substance evaluation is the concern different from PBT, ED, CMR and sensitiser (for example, other hazard or exposure concerns).
[22] The CoRAP is available at: http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan

substances are currently under evaluation for clarification of ED properties and none of them have been concluded.

70 CMRs and 27 sensitisers are (or have been) under assessment in the context of substance evaluation. Under substance evaluation, in most cases more than one property can be of concern for a single substance (for example, one substance can be both a potential PBT and a potential CMR). Therefore, the total number of substances under each concern is not equal to the total of substances under evaluation. This is true for both Table 1 and Figure 7 below.

In total, 213 substances are under assessment either in one of the expert groups, under substance evaluation (CoRAP) or in both.

Table 1: Overview of the number of substances under "assessment" for each concern (2012 - 2014)[23].

		PBT	ED	CMR	SENSITISERS
Expert groups	Non CoRAP substances ongoing	46 (+4[24])	4	NR	NR[25]
	Non CoRAP substances postponed	11	0	NR	NR
	Non CoRAP substances concluded	24	0	NR	NR
	CoRAP ongoing	47	10	NR	NR
	CoRAP concluded	1	0	NR	NR
CORAP substances assessed but not discussed in the expert groups	Under evaluation	1	16	61	21
	Concluded	3	0	9	6
Total CoRAP substances under evaluation	Under evaluation	48[26]	26	61	21
	Concluded	4	0	9	6
Total number of substances under "assessment"		133(+4)[27]	29	70	27

[23] For eight substances under substance evaluation, the concern is different from PBT, ED, CMR and sensitiser (for example, other hazard or exposure concerns). These substances have not been reported in the Table 1. One substance can cover several concerns and therefore the total number of substances in Table 1 is not equal to the number of substances under evaluation.
[24] 50 Non-CoRAP substances are ongoing in the PBT expert group among which four are non-REACH substances (three biocides, one veterinary medicine)
[25] NR: Not Relevant
[26] In CoRAP, one substance appears twice with different identifiers. This substance has been counted only once in the context of this reporting.
[27] 137 substances among which four are not REACH substances (three biocides and one veterinary medicine)

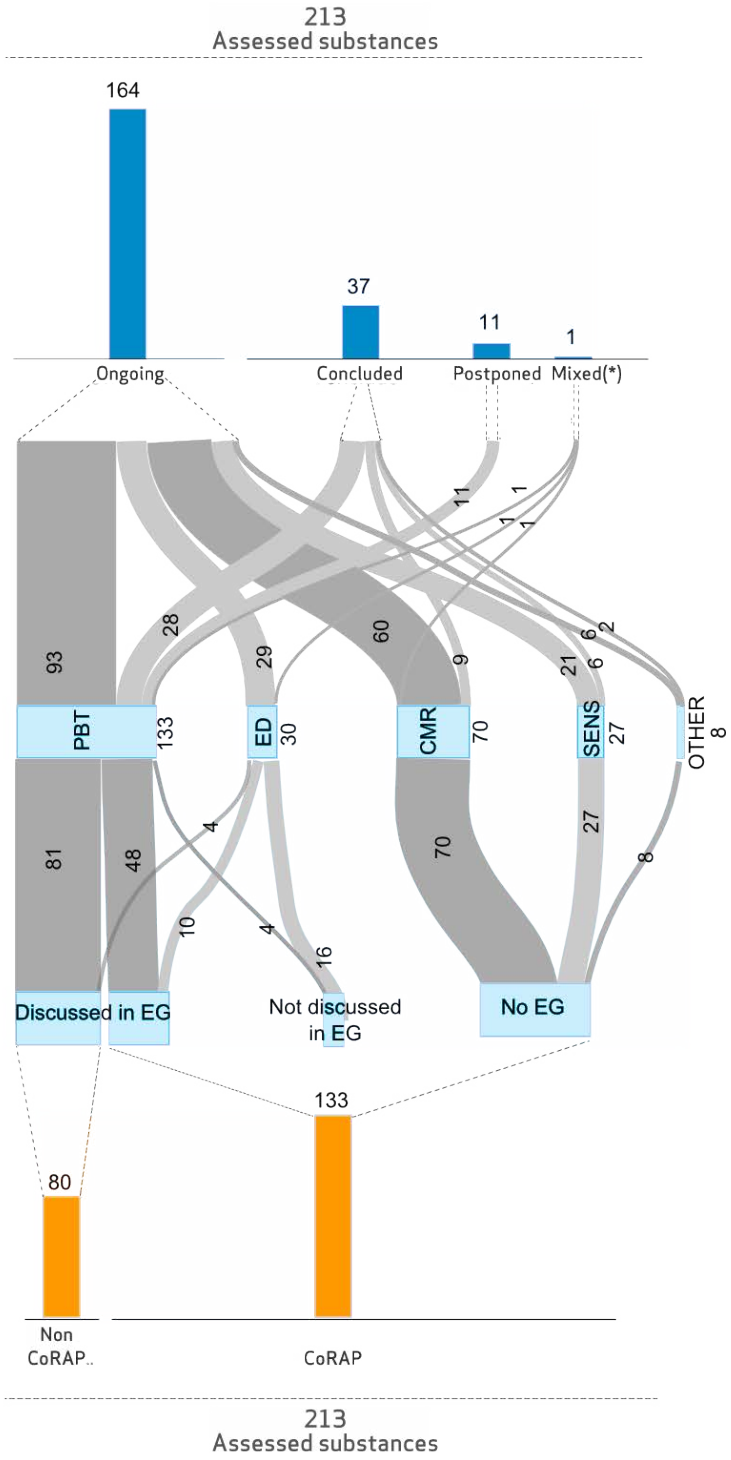


Figure 7: Substances and properties under "assessment" (2012-2014) [28]

[28] Mixed status refers to one substance postponed in the PBT expert group but ongoing in the context of the CoRAP for a different property.

Figure 8 gives an overview of substances under "assessment" per Member State and specifies those that are under substance evaluation and those brought either to the PBT or ED expert groups.

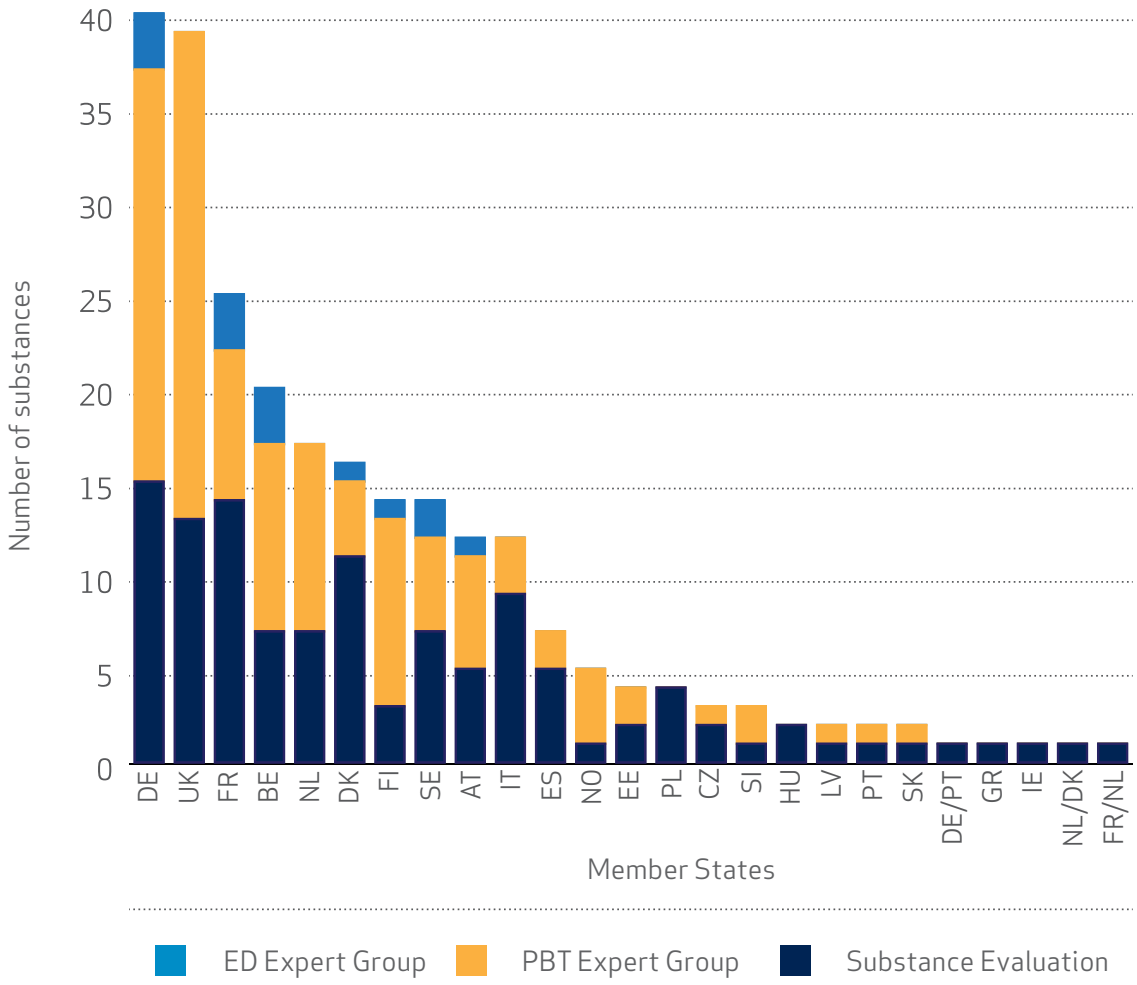


Figure 8: Number of substances under assessment per Member State in ED expert group, PBT expert group and substance evaluation.

3.3. OVERVIEW OF ASSESSMENT CONCLUSIONS

Table 2 reports on the number of substances for which there is a conclusion on the hazard properties under assessment.

So far, 24 substances out of the 134 substances with potential PBT/vPvB properties under PBT assessment have been concluded. Five are considered to be fulfilling the PBT or vPvB properties.

For ED, all of the substances discussed to date are under ongoing assessment and none of them have been concluded as reflected in Table 2 below.

So far, 61 substances are under evaluation for their CMR properties and nine have already been concluded among which two as CMR category 1. It should be highlighted that the number of substances under evaluation includes substances that are (potential) CMRs but for which the main concern under substance evaluation was not to clarify the CMR properties (for example, exposure). For reporting reasons, those substances are also counted in Table 2 even though the interest is mainly on those substances listed on the

CoRAP for clarifying the CMR properties in order to make it clear how many new CMRs are expected to come out from the substance evaluation process.

Regarding sensitisers, 21 substances are under evaluation and six have already been concluded of which two are skin sensitisers and two are respiratory sensitisers as reported in Table 2.

So far, conclusions for 13 substances under substance evaluation have been received. As mentioned before, some substances cover more than one property and are therefore counted twice or more in Table 2.

It should be noted that the final conclusion and confirmation on the properties can only be achieved for PBT and ED properties through the SVHC identification process and inclusion in the Candidate List and for CMR and respiratory sensitisers through the harmonised classification and labelling process and inclusion in Annex VI of the CLP Regulation. For further information, please see part 3 sections 4.2 and 2 respectively.

Table 2: Number of substances concluded and conclusions where relevant (2012 - 2014)

PROPERTY	TOTAL NUMBER OF SUBSTANCES CONCLUDED	NUMBER OF SUBSTANCES CONCLUDED	
		CONSIDERED TO FULFIL THE HAZARD PROPERTIES	CONSIDERED NOT TO FULFIL THE HAZARD PROPERTIES
PBT (CoRAP and non CoRAP)	24	5	19
PBT – substance evaluation	4	0	4
ED (CoRAP and non CoRAP)	0	NR	NR
CMR – substance evaluation	9	2 CMR cat 1[29] 5 CMR cat 2[30]	2
Sensitiser – substance evaluation	6	2 skin sensitiser 2 Respiratory sensitiser	2

[29] **CMR cat 1:** generic term for known carcinogenic category 1 and/or mutagenic category 1 and/or reprotoxic properties category 1 (according to CLP harmonised or registrant self-classification or CLP Inventory). The number indicated in the table covers those substances where the classification as category 1 has been confirmed or those substances newly identified as CMR category 1.
[30] **CMR cat 2:** generic term for known carcinogenic category 2 and/or mutagenic category 2 and/or reprotoxic properties category 2 (according to CLP harmonised or registrant self-classification or CLP Inventory). The number indicated in the table covers those substances where the classification as category 2 has been confirmed or those substances newly identified as CMR category 2.

4. Risk Management Option Analysis (RMOA)

4.1. INTRODUCTION

The purpose of a Risk Management Option Analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is an important step, agreed in the SVHC Roadmap, but it is voluntary and is not part of the processes as defined in the legislation. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a relevant substance of very high concern (SVHC) in the sense of the SVHC Roadmap[31]. For authorities, documenting the RMOA allows the sharing of information and promotes early discussion, in particular on the "relevancy" of the substance towards SVHC identification, which helps lead to a common understanding of the action pursued.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (for example, harmonised classification and labelling, Candidate List inclusion, Annex XIV inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State competent authorities and the European Commission as defined in REACH and CLP.

The substances for which an RMOA is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013 are now included in the Public Activities Coordination Tool (PACT) on ECHA's website[32].

By communicating information on substances undergoing RMOA through the PACT, stakeholders and the general public can better predict what substances may be addressed by formal risk management routes in the future. This communication gives registrants the opportunity to ensure that their registration data is up-to-date, to consider the best business strategy to address substances of potential concern, and to get prepared for public consultation during any subsequent regulatory processes. The PACT also provides the contact details of the national authority performing an RMOA, which gives the possibility for stakeholders to feed the RMOA development process with their contributions and comments; it should however be reminded that it is the decision of the national authority how to take into account any input from stakeholders.

It is important to note that RMOAs or RMOA Conclusions published on the PACT only reflect the views of the author authority, it does not preclude other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate. In addition, RMOAs and their conclusions are compiled on the basis of available information and may change in the light of new information or further assessment.

4.2. OVERVIEW OF SUBSTANCES IN THE RMOA STAGE

Figure 9 provides the number of RMOAs concluded or ongoing over 2013 and 2014. For 24, an RMOA

[31] For more information on the RMO analysis under the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan
[32] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact

conclusion is available and for the remaining 74, the RMOA work is ongoing. By this, the interim target set out by the Commission to have 80 substances subject to an RMOA by the end of 2014 has been met.

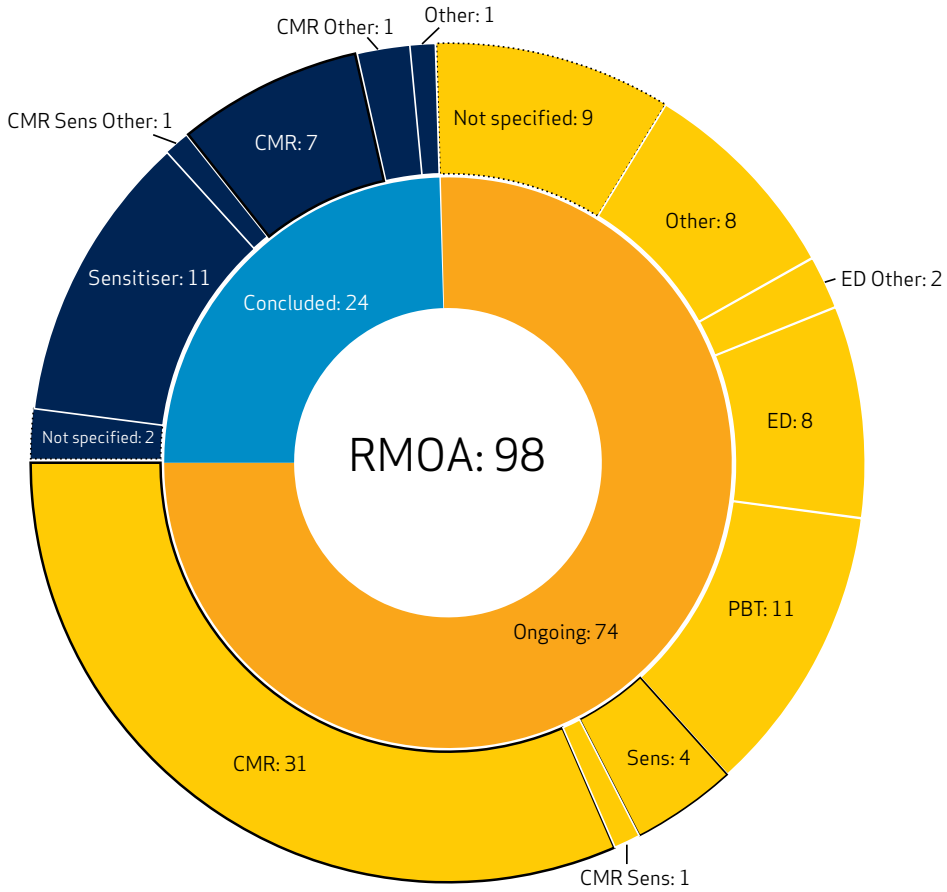


Figure 9: Number of RMOAs and intentions per property (February 2013 – December 2014 [33])

[33] The data reported in the table are until the latest update of PACT in 2014 (5 December 2014).
RMOAs appearing as "on hold" in PACT are counted here under "number of RMOAs ongoing".
Some RMOAs cover more than one substance, and potentially a lot of substances, because they have in common a chemical element which is the origin of the concern (for example, "lead and lead compounds") or all lead to same degradation products of concern (note that two entries in PACT are for "groups of substances"); for those, only one entry has been created in the PACT, and one RMOA has been counted in the present statistics. On the contrary, when two very separate substances have been RMOA-assessed within the same RMOA, for example, due to similarities in properties and/or uses, but do not have in common a chemical element which is the source of the concern and can easily be distinguished and identified, two entries have been created in the PACT, and two RMOAs have been counted for these statistics.
Substances or group of substances which have been RMO-assessed more than once (for example, due to different concern addressed), have here been counted only once. This is the case for seven substances which have been assessed twice, by two different Member States.
"Other" means other scope than PBT, ED, CMR or sensitiser (for example, substances which give rise to an equivalent level of concern due to their specific target organ toxicity (STOT) or substances which are not PBTs (or vPvBs) but show similar properties).
"Not specified" means that no specific scope of the RMOA is available in terms of properties.

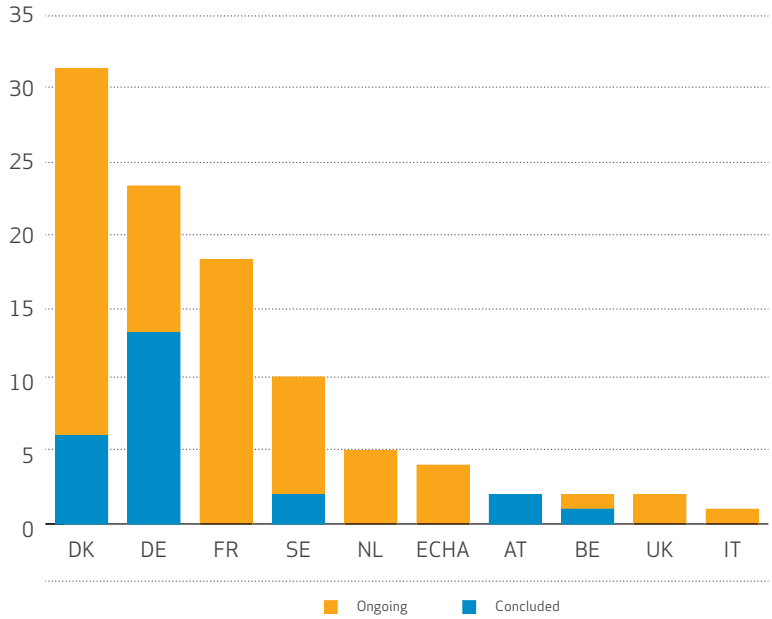


Figure 10 : number of RMOAs per Member State and by ECHA.

4.3. OVERVIEW OF RMOA CONCLUSIONS

Table 3 provides the number of RMOAs concluded per proposed follow up regulatory action during 2013 and 2014. The share of RMOAs for which a conclusion is available is still relatively small. For almost half of the substances (11) for which there is a conclusion the proposed follow-up was restriction whereas for five of them the conclusion was SVHC identification. It should be emphasised that these RMOAs and their conclusions do not necessarily reflect yet the SVHC Roadmap implementation as many of these RMOAs started before 2013.

Table 3: Number of RMOAs concluded per proposed follow up regulatory action (February 2013 - December 2014) [34]

REGULATORY FOLLOW UP	NUMBERS
SVHC identification	5 (4: "SVHC" / 1: "SVHC" + "Other")
Restriction	11
CLH	1
Other EU legislation	1
Other (e.g. non EU-wide measures)	2 (1: "Other" / 1: "SVHC" + "Other")
No follow up action	5

[34] Some RMOAs may include multiple follow-up regulatory actions. In these cases, the RMOA is counted more than once, because it is added to the relevant rows.

5. Progress monitoring indicators

5.1. INTRODUCTION

To monitor the progress in implementing the SVHC Roadmap to 2020, i.e. "to have relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020" progress monitoring indicators have been defined.

Indicators will be measured from the start of the SVHC Roadmap implementation (February 2013) and reported every year in this report.

Indicators reflect **screening,** assessment and RMOA activities (see description of indicators in Annex 2). In the context of screening, appropriate information from internal databases (registration database, C&L Inventory) are used by ECHA and Member States to identify which substances are best candidates for further investigation and for potential further regulatory risk management measures. As explained before, generating further information where needed to clarify the concern is an integral part of the SVHC Roadmap implementation. Therefore, the indicators proposed for screening also include the screening for identification of CoRAP substances. The indicator related to substance evaluation (called "Substance screening 2") mainly reflects the screening and less the following process for the inclusion of the substance in CoRAP and the evaluation process as such.

The proposed indicators measure whether the screening is performed in a way that most (i.e. a high rate) of "all relevant substances" have been identified. Relevant substances are:

- Substances for which there is a need later on for regulatory risk management under REACH or CLP.
- Substances for which there is a need to obtain further information before concluding on the risks and on the potential need for (regulatory) risk management.

Assessment may be one necessary step before concluding on the SVHC property of a substance. This step is usually resource intensive for both Member States and ECHA, therefore, an indicator for assessment is also included. This assessment indicator is specifically targeted towards the experts groups and reflects the effectiveness of the manual screening but also the efficient use of the expert groups.

Two indicators monitor the progress of the SVHC Roadmap implementation for **RMOAs:**

1) the number of RMOAs produced each year with the target number referred to in the SVHC Roadmap to 2020 as a basis,
2) the number of RMOAs produced under the SVHC Roadmap that are in practice followed by proposals for RRM.

This should reflect how effective the system is and how efficient it is to identify all relevant SVHCs. None of the indicators should be looked at in isolation but as one element of the overall yearly report of the SVHC Roadmap.

Indicators are reported on a yearly basis however as explained above for some of them effects will be seen only in the long term.

5.2. PROGRESS MONITORING INDICATORS: TARGET AND RESULTS.

The results of the measurements of the progress monitoring indicators are available in Table 4. The interpretation of the results has to be done carefully considering all parameters.

The indicators reflect the progress of the implementation of the SVHC Roadmap from February 2013 (when the Roadmap was adopted) until the end of 2014. Regulatory risk management activities, screening, substance evaluation and RMOA have also taken place before the adoption of the SVHC Roadmap. Therefore, during the first years of reporting, the indicators will not only reflect the progress of the implementation of the Roadmap but also what has been done previously (for example, many RMOAs have been done before the start of the SVHC Roadmap implementation).

Regarding **Screening** indicators, one should take into account that screening scenarios and criteria to identify potential substances of concern will be improved and further developed over the years. Therefore, it cannot be assumed that most of the substances will be identified in the first years of screening. Several criteria may change over the years making it difficult to compare measurements from one year to the next without having a good understanding of what is behind the values. Such changes could be:

- Use of different cut-offs in the screening scenarios to extend the search for finding more potential relevant substances for the Roadmap.
- Update of registration dossiers, new dossiers that may come in and therefore be added to the IT mass screening pool. This can happen at any time but it is clear that the pool of substances screened will be impacted by the 2018 registration deadline.
- Use of other information sources in addition to the registration database (such as data mining of the C&L Inventory, use of other existing non REACH/CLP databases, use of QSAR estimates etc.)

Therefore, the changes in the number of substances identified by the screening over the years will partially reflect the work done in the previous years but also which new or updated algorithm is used.

For **assessment**, in theory it can be expected that with increasing experience in both the experts groups and substance evaluation the efficiency of the process should increase.

For **RMOA** indicators, as most of the work on known CMRs cat 1A/1B has been carried out already before the adoption of the SVHC Roadmap it may be that for this group of substances, for which registration dossiers were expected already in 2010, the peak of activities related to RMOA has happened whereas we are still at the stage of gathering information for other hazard properties such as PBT and ED. This could explain why, so far, the number of RMOA of PBT/ED substances is rather low and why in the coming years we may have a very low number of RMOAs for CMRs. It will take time before new CMRs are identified as SVHCs as these substances first need to go through the classification and labelling harmonisation process.

Indicators are reported on a yearly basis, however, as explained above for some of them effects will be seen only in the long-term.

For Substance Screening 1, only substances identified during the IT mass screening and subsequently manually screened are included. Those substances identified by Member States are not included in the analysis. The indicator Substance Screening 2 cannot be calculated at this stage but is included for completeness. For RMOA1 and RMOA2, the reported figures cover the substances listed in PACT in its latest update for 2014, dated 5 December 2014.

RMOA2 reflects the number of substances for which an RMOA was completed after February 2013 which was followed-up by the submission of a proposal for a regulatory follow-up under the REACH or CLP regulations by 31 December 2014 (i.e. an Annex XV proposal for identification of SVHC or for restriction under REACH, or an Annex VI proposal for harmonised classification and labelling under CLP). So far, only 17% of the RMOAs concluded, resulted in a regulatory follow-up action. It should be noted that these are only dossiers to identify a substances as an SVHC. In Table 3, around half of the RMOAs concluded indicate restriction as a follow up regulatory action, which may take more time than to prepare a dossier for SVHC identification and can explain why RMOA2 is so low, so far.

Current intentions for, or past submissions of a proposal for a regulatory follow-up under the REACH or CLP regulations for substances which are not listed in PACT in its latest update for 2014, or for which PACT indicates that the RMOA is still "under development", are not counted.

Table 3: Progress monitoring indicators target and results [35]

Indicators	Target	Result
Substance Screening 1: Percentage of substances identified for further work to clarify a concern (substance evaluation, CCH[36]) or propose RRM (RMOA, CLH, other action)	- [37]	83.5%
Substance Screening 2: Percentage of substances for which the outcome of manual screening has been substance evaluation and which ends up later in a RMOA.	high	NA[38]
Assessment 1: Percentage of substances for further assessment (PBT/ED) or with need for advice which ends up in a RMOA/substance evaluation..	high	NA[36]
RMOA1: Number of (groups of) substances subject to an RMOA	80[39]	91[40]
RMOA2: Extent to which (percentage of) RMOA conclusions resulted in regulatory follow-up	high	17%

[35] All progress monitoring indicators for the SVHC Roadmap are calculated starting with the implementation of the Roadmap in 2013.
[36] In this document, CCH is intended as the follow up necessary to clarify a risk where it requires the request of standard information requirements only. It is not proposed for the time being to measure the percentage of substances flagged for CCH after the manual screening that would lead to further regulatory action or substance evaluation.
[37] The target is to have substance screening one indicator high and at least equal to the baseline which is set as 2014.
[38] Not available as it is too early in the process to calculate this indicator
[39] According to the SVHC Roadmap, "around 80 substances, in addition to the substances already assessed and/or listed today in the Candidate List, will be subject to an RMO by the end of 2014".
[40] Two entries in PACT are for "groups of substances"

Part 2 – Outline of activities planned for 2015

1. Introduction

Activities in 2015 will mainly focus on the following items which are further developed in the specific sections below:

- Further development and improvement of the common screening approach.
- Increase of transparency and predictability of activities with the foreseen update of PACT with
- information on substances under assessment in one of the expert groups (PBT/ED).
- Definition of the scope of the work foreseen for petroleum/coal stream substances with Member States, the Commission, industry and NGOs and how to organise the cooperation and coordination. Continue to build capacity within Member States to improve and increase the involvement in the screening and RMOA.

2. Screening

New substances will be proposed to be manually screened in 2015 by Member States based on the scenarios developed in the definition documents for the ongoing round of screening. The scenarios proposed as well as an indication of the timelines are available on ECHA's website[6]. Examples of such scenarios are:

- the addition of scenarios to find substances which have a harmonised classification as STOT RE,
- the use of log KoA (octanol – air partition coefficient) for finding substances with bioaccumulating properties (potential PBT/vPvB),
- scenarios to find candidate substances for which a proposal for harmonised classification as CMR 1A/1B could be prepared
- specific ED scenarios to find substances with potential ED properties, and
- scenarios listed under the supplementary activities of the SVHC Roadmap (for example, substances only registered as intermediates but similar to a known SVHC in the RMO pool).

In addition, ECHA will cooperate further with Member States to develop the screening definition documents by adding new screening scenarios for 2016. One of the main aims in 2015 and 2016 will be to better and further integrate the compliance check to the common screening approach, which has so far been an outcome of the manual screening step. For that purpose, at the end of 2014 an additional group of Member States have been created to support screening on use and exposure information. This exposure network will be further developed in 2015 and gives support to exposure and use related screening.

3. Assessment

Based on the outcome of the manual screening performed in 2014 by Member States, some substances will be further assessed by the PBT or ED expert groups. In addition, several substances have been proposed for

inclusion on the CoRAP which will be published in 2015.

PACT has been further developed to include substances under assessment in the PBT and ED expert groups at the beginning of 2015 and will continue to be updated on a monthly basis with information on both RMOAs and hazard assessment.

Information on substances under substance evaluation is available on ECHA's website[17].

4. RMOAs

The number of RMOAs to be undertaken will be largely determined by the outputs from the screening (and assessment) processes as described in Section 2 of Part 1. In the Roadmap, the Commission made a preliminary estimation of a maximum of 440 substances to be RMO assessed between 2013 and 2020. This would mean developing around 55 RMOAs a year.

Based on the intentions received by 31 December 2014 and on the output of the first round of manual screening, ECHAs foresees roughly 50 RMOAs to be started in 2015 and 50 RMOAs to be concluded.

Part 3 – Report on regulatory risk management activities

1. Introduction

The Commission has defined the SVHC Roadmap as being a Roadmap which will form a strong basis for further work on SVHC assessment and identification beyond 2020 but which also should ensure progresses in other areas of REACH (for instance, restriction). Therefore, the picture would not be complete if the regulatory follow up steps were not reported. An RMOA could result in different follow up REACH and CLP regulatory risk management processes such as SVHC identification and inclusion in the Candidate List for eventual inclusion in Annex XIV (Authorisation List), restriction or harmonised classification and labelling proposals (see Figure 11).

This section aims to report on regulatory risk management activities. Activities are reported since the entry in operation of REACH in 2008 for the processes linked to authorisation and from February 2013 until December 2014 for activities initiated under restriction and harmonised classification and labelling. However, it should be noted that the impact of the SVHC Roadmap implementation on regulatory risk management activities in this period has to be interpreted with caution as most of the regulatory actions outlined below result from screening/RMOA activities before the SVHC Roadmap was implemented. In addition, there may be a delay in time between when an RMOA is concluded and the actual initiation of a formal regulatory process. Moreover, the initial conclusions of an RMOA for a given substance or group of substances can be updated with newly available information and/or further considerations by a Member State/ECHA (at the request of the European Commission).

It should also be noted that Member States may carry out an RMOA outside of the SVHC Roadmap implementation context (for example, as a result of a national programme/national priorities).

More information on regulatory activities is available on a yearly basis in ECHA's General Report [41].

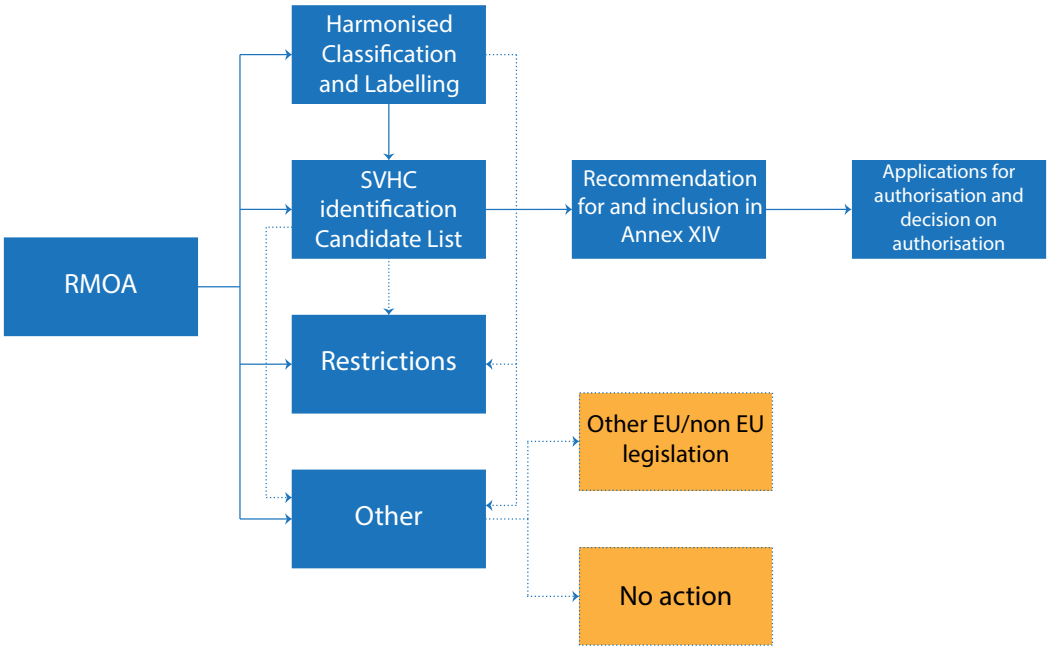


Figure 11: Overview of potential (regulatory) risk management after RMOA

2. 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 or plant protection products (BPs and PPPs) should also normally be harmonised. For all other hazardous substances, a harmonised classification and labelling can be sought, if a justification is provided that demonstrates such an action is required at an EU level.

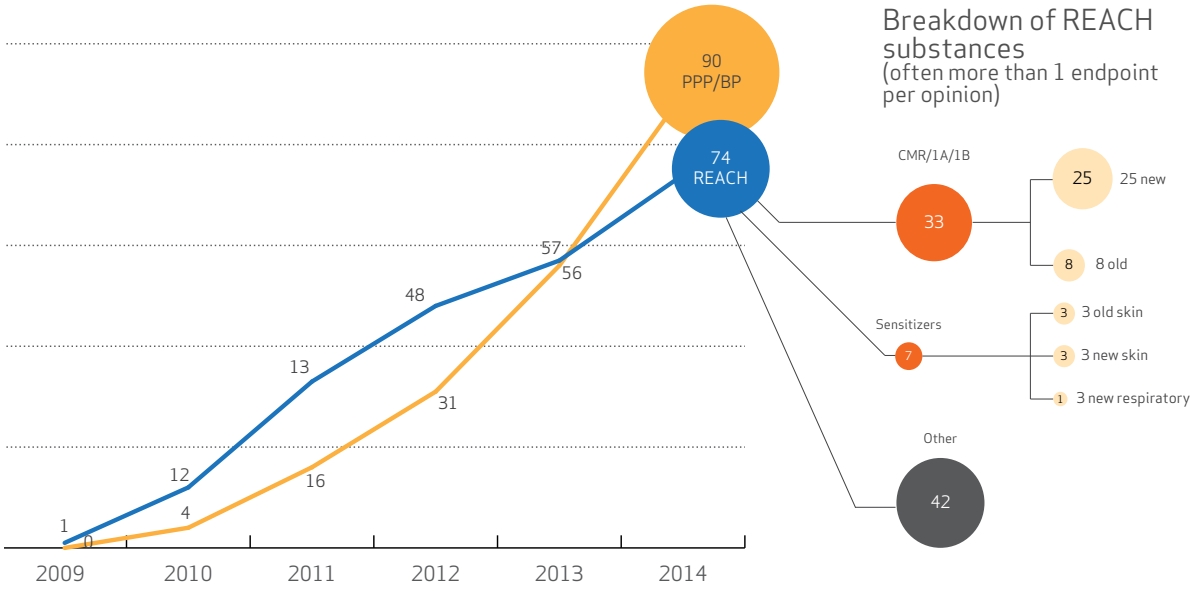
A manufacturer, importer or downstream user of a substance may submit a CLH proposal for that substance, provided it is not already harmonised for that endpoint. For active substances under PPP and BP and all other substances, only Member State competent authorities (Member States) can submit a CLH proposal.

Upon receipt of a CLH proposal which is in accordance with the CLP regulation, ECHA launches a public consultation lasting 45 days. The proposal, along with all the comments received, is then forwarded to the Risk Assessment Committee (RAC), which must adopt an opinion on the proposal within 18 months of submitting the proposal. The opinion is forwarded to the Commission which decides, where appropriate, to include the substance and the classification and labelling on the list of harmonised substances (Annex VI

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

to CLP) by an Adaptation to Technical Progress (ATP). The harmonised classification and labelling must be followed by all manufacturers, importers and downstream users[42].

Figure 12 below reports numbers of proposals received[43] from 2009 until December 2014 and the number of opinions adopted by RAC during the same period. Numbers are further broken down into proposals for active substances in biocidal and plant protection products (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 substances for which a classification for new[44] and old CMRs[45] was adopted is also reported.



PPP/BP: Active substances in plant protection and biocidal products (PPP/BP)
REACH: Other substances than PPP/BP
Other: proposal for other endpoints including proposal for classification as CMR cat.2

Figure 12: Numbers of CLH proposals received from 2009 – December 2014 and proposals for which a CMR and/or sensitiser proposals was included.

[42] For more information on CLH process: http://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling
[43] Proposals received mean that the dossiers were successfully submitted and ready for public consultation
[44] New CMR means the substances were not classified as CMR before
[45] Old CMR means the substances were already classified as CMR and the proposal was to amend something else than the CMR classification.

Figure 13 gives an overview of Annex VI CLH dossiers submitted by each country where other refers to REACH substances for the vast majority.

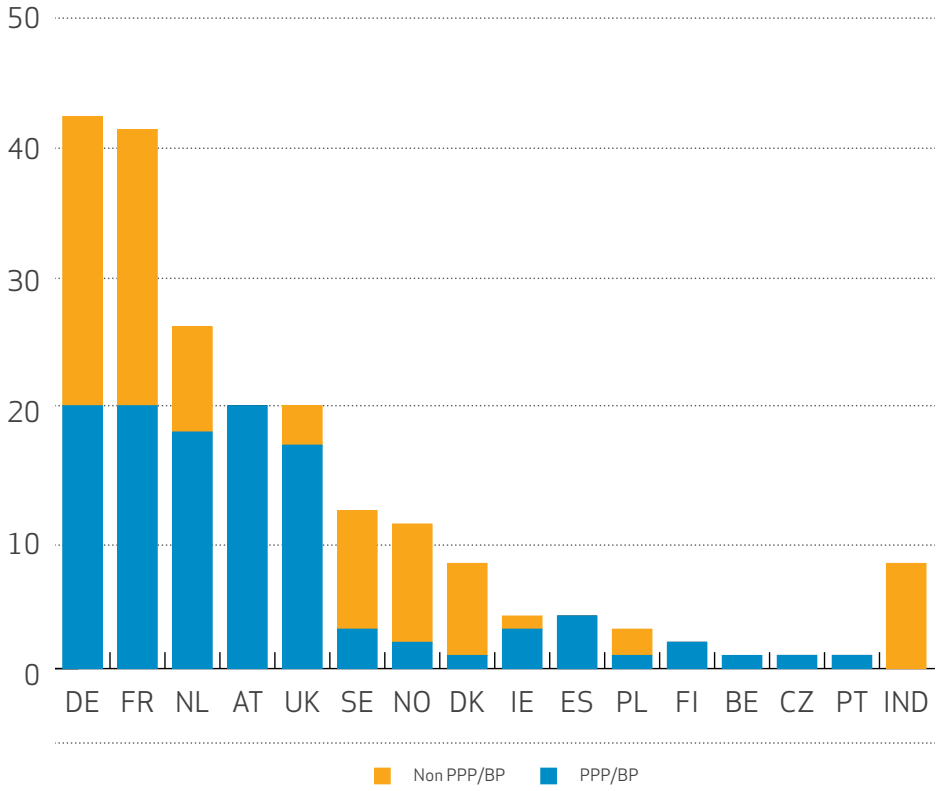


Figure 13: Number of CLH dossiers submitted per Member State (2009 – December 2014)

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 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 they assess there is a risk that is not adequately controlled and there is a need for action at the Union level.

The ECHA Committees (Risk Assessment Committee (RAC) and Committee for Socio-economic Analysis (SEAC)) first check whether the proposal conforms to the requirements of Annex XV (conformity check). If it does, the dossier will be made publicly available for consultation for six months. The Committees will then give their opinions on the proposal; RAC within nine months and SEAC within 12 months of being made publically available. The SEAC draft opinion is then subject to a second public consultation of 60 days.

The two opinions of the ECHA Committees contribute to the decision of the European Commission who decides if they will provide a draft amendment of the list of restrictions in Annex XVII of REACH. The final

decision is taken in a comitology procedure with scrutiny involving the Member States and the European Parliament[46].

Table 5 gives the number of restrictions proposals adopted or going through the restrictions proccess from 2009 until December 2014.

Table 5: Numbers of restrictions proposals adopted or going through the restriction process

STEP	PBT	ED	CMR	SENSITISER	OTHER
Restrictions included in Annex XVII	0	0	4	2[47]	0
Restriction process ongoing	2	0	2	0	1
Sent to Commission, but not yet in Annex XVII	0	1	3	0	0
Total (only the ones with substance scope in RoI)	**2**	**1**	**9**	**2**	

Figure 14 gives an overview of Annex XV restriction dossiers submitted per country.

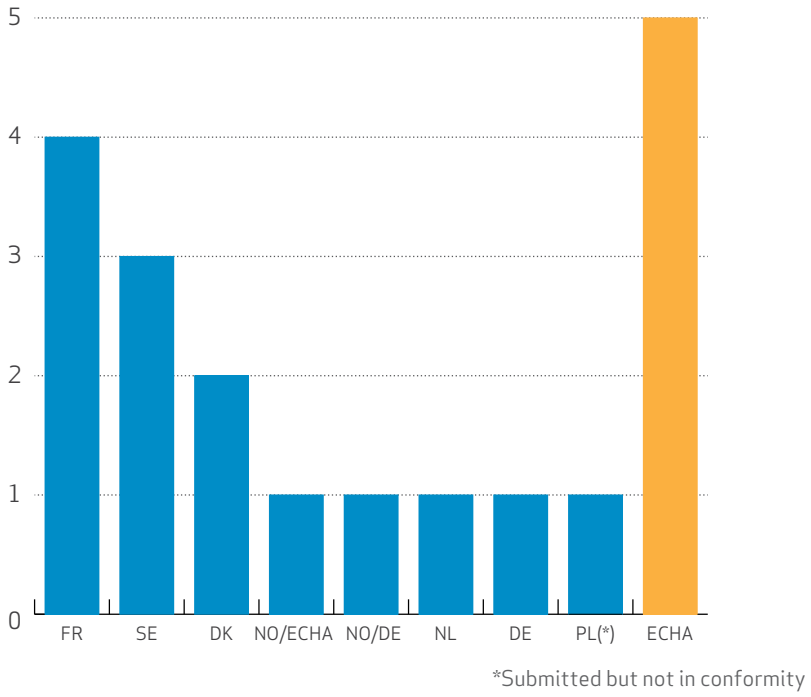


Figure 14: Number of restriction dossiers submitted per Member State and by ECHA (2009 – December 2014)

[46] For more information on restriction see also: http://echa.europa.eu/ regulations/reach/restriction

[47] Note that one of the substances restricted is Chromium VI which is also a CMR substance but is only considered here as a sensitiser as it is the scope of this restriction "Chromium VI in leather articles".

4. Authorisation process

4.1. INTRODUCTION

In 2008, the first substances were identified as substances of very high concern (SVHCs) under REACH marking the start of the REACH authorisation proces[48].

Figure 15 below gives an overview of the number of substances identified as SVHCs, recommended for inclusion in Annex XIV and finally included in Annex XIV from 2008 until the end of 2014. These numbers are further explained below in their respective sections.

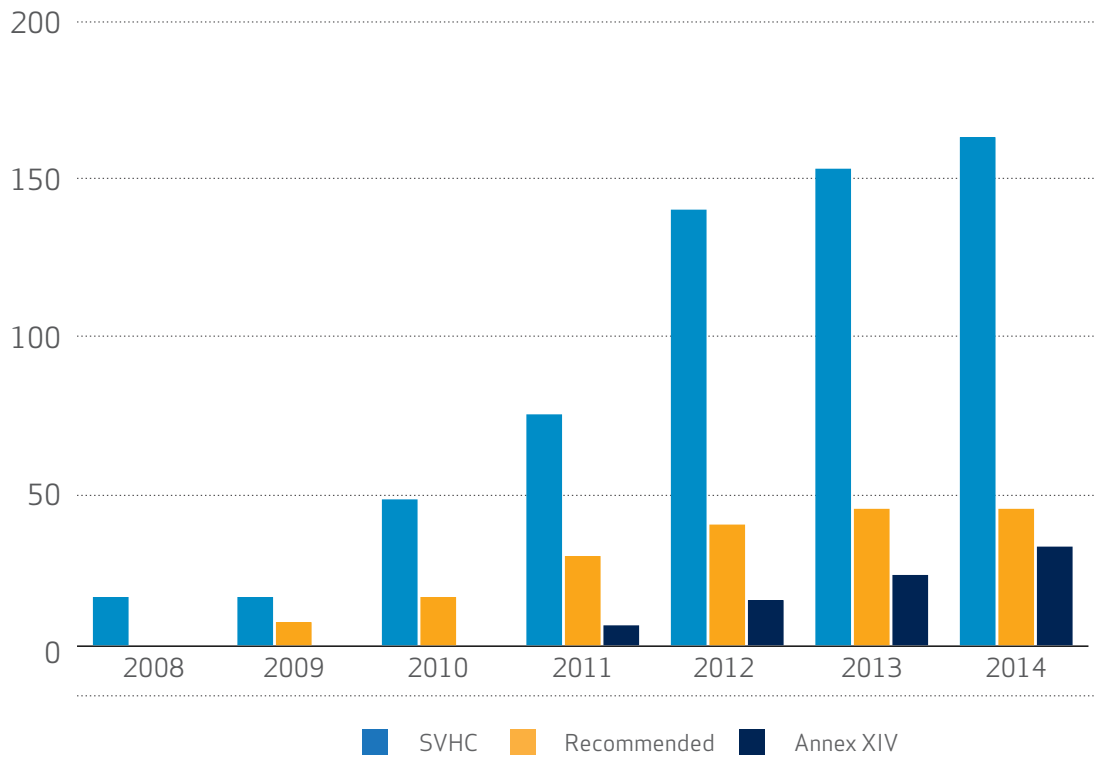


Figure 15: General overview of the number of substances on the Candidate List, recommended for inclusion in Annex XIV (Authorisation List) and included in Annex XIV.

4.2. SVHC IDENTIFICATION

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

- that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR)

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

(category 1A or 1B);
- which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- identified on a case-by-case basis and 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 is the list of candidate substances for eventual inclusion in the Authorisation List (Annex XIV). Furthermore, the 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.

The intention to propose a substance to be identified as an SVHC is made public in the registry of intentions[49] before the proposal is submitted so as to give advanced information to industry and other stakeholders. The proposals will be subject to public consultation. If no comments relevant for the identification are received, the substance is included in the Candidate List. The proposals and the comments will be forwarded to the Member State Committee (MSC) to agree on the identification as an SVHC. If the MSC does not reach a unanimous agreement, the substance will be referred to the European Commission.

Since 2008, a total of 161 substances have been identified as SVHCs and included on the Candidate List. The properties leading to inclusion in the Candidate List are listed in Figure 16. Some substances cover more than one hazardous property as illustrated below.

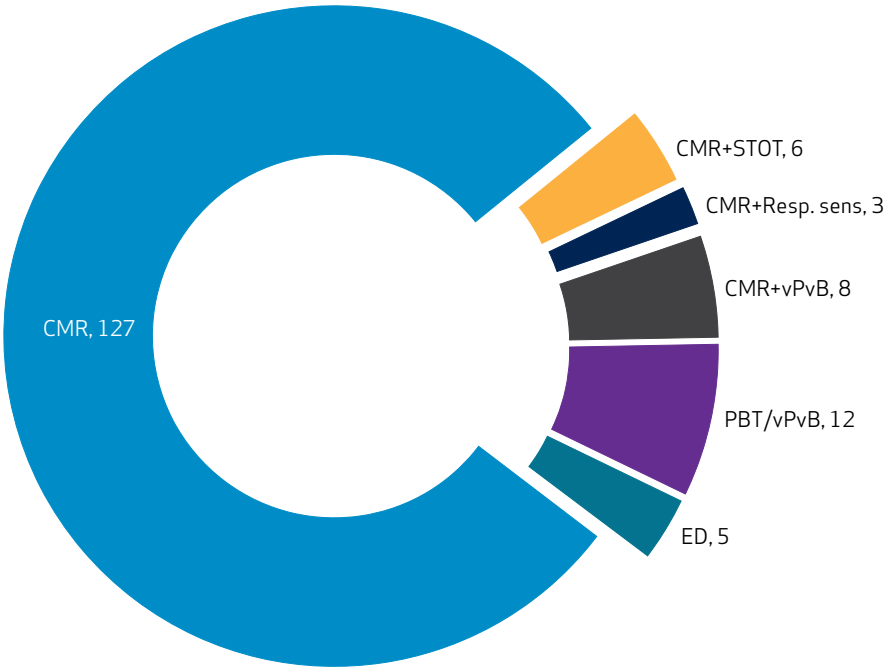


Figure 16: Substances on the Candidate List and overview of their hazardous properties

Figure 17 gives an overview of Annex XV SVHC dossiers submitted per Member State.

[49] http://echa.europa.eu/registry-of-current-svhc-intentions

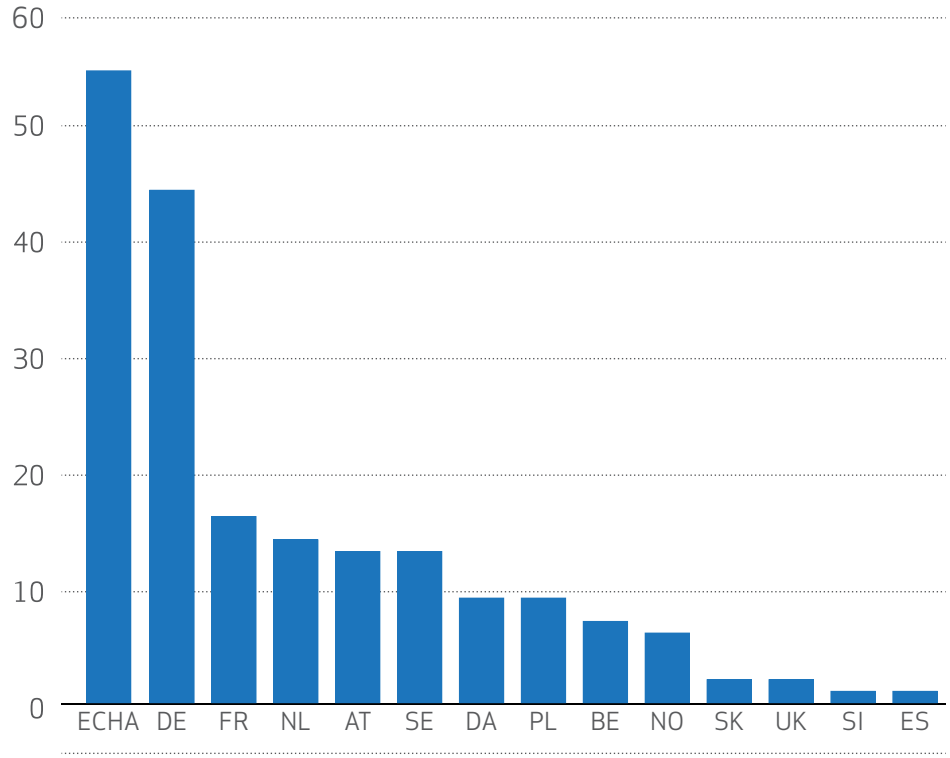


Figure 17: Number of Annex XV SVHC dossiers submitted per Member State and by ECHA.

4.3. RECOMMENDATION FOR AND INCLUSION IN ANNEX XIV

Substances identified as meeting the SVHC criteria are included in the Candidate List for eventual inclusion in the Authorisation List (Annex XIV of the REACH Regulation). ECHA prioritises substances from the Candidate List to determine the order in which the substances should be included in Annex XIV. The substances with the highest priority are recommended first for inclusion. All not recommended substances as well as newly added Candidate List substances are considered in future rounds.

According to Article 58(3), priority shall normally be given to substances with PBT or vPvB properties, or wide dispersive use, or high volumes[50]. The prioritisation is made based mainly on information in the registration dossiers. However, information from public consultation on the SVHC identification and other REACH/CLP information is also considered.

The draft recommendation is subject to a public consultation. The Member State Committee prepares its opinion on the draft recommendation taking into account the received comments. The opinion of the Committee and the comments received during the public consultation will help ECHA finalise its recommendation, which will be submitted to the European Commission, for a decision on the substances to be included in the Authorisation List.

The fifth recommendation[51] was sent to the Commission in February 2014. So far, the Commission has not decided which substances from this recommendation will be included in Annex XIV. The sixth recommendation is under preparation and is foreseen to be sent to the Commission in July 2015.

[50] Prioritisation approach available at: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list
[51] The substances on the fifth recommendation are available at: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

Figure 18 and 19 give an overview of the properties of the substances recommended by ECHA to be included in Annex XIV until the fifth recommendation.

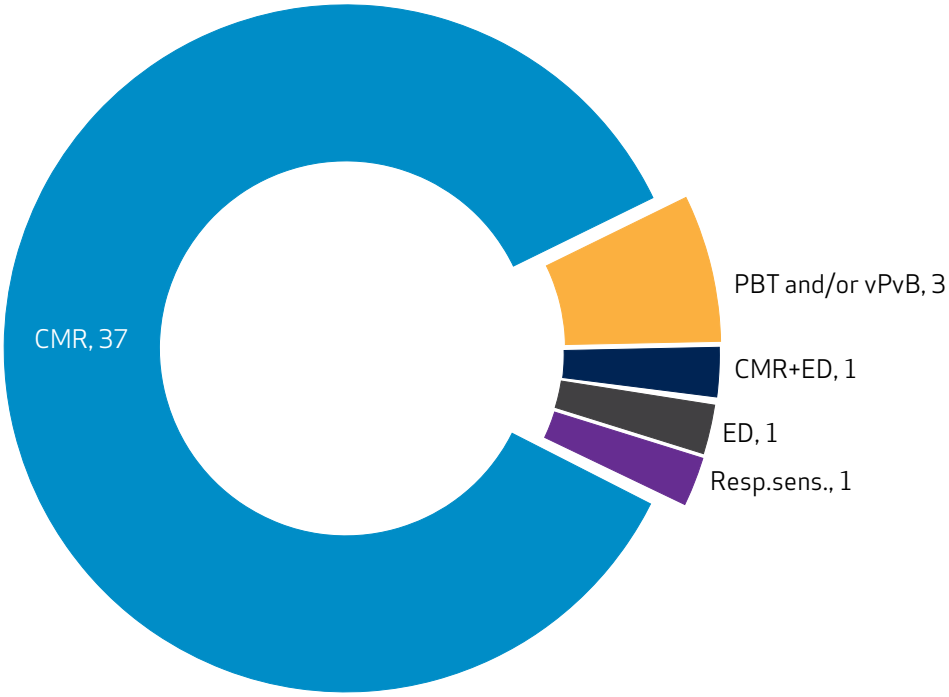


Figure 18: Overview of number and properties of substances recommended for inclusion in Annex XIV (2008 – 2014)

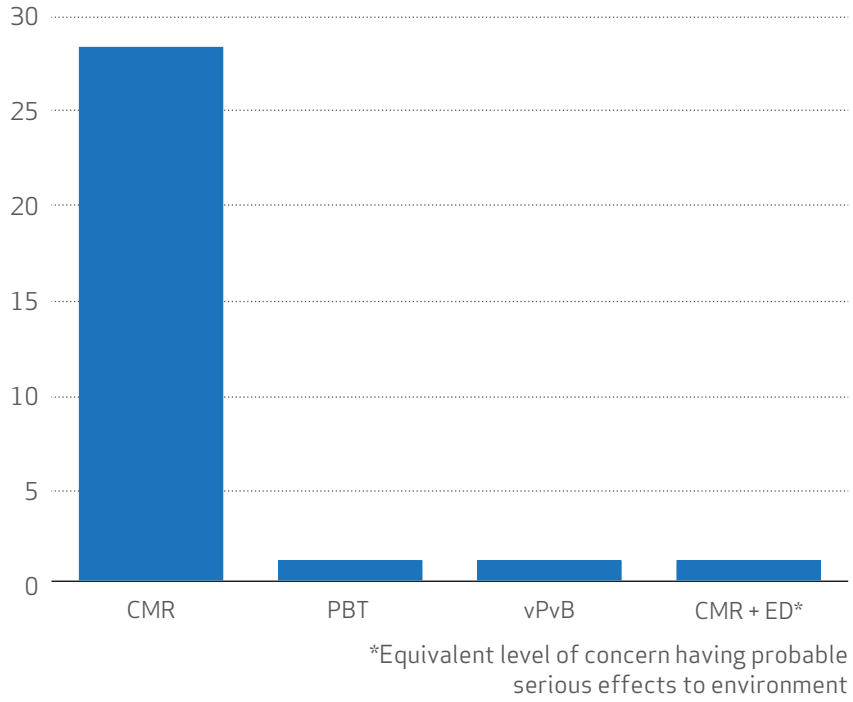


Figure 19: Overview of number and properties of substances included in Annex XIV (Authorisation List)

4.4. APPLICATIONS FOR AUTHORISATION AND DECISIONS ON AUTHORISATION

Once a substance is included in the Authorisation List (Annex XIV), companies shall not place this substance on the market for a use or use it themselves after the sunset date unless an authorisation has been granted for this use. Companies who want to continue the use of the substance after the sunset date need to submit their application(s) for authorisation to ECHA.

Once ECHA has checked that the dossier can be further processed and the applicant has paid the fee, ECHA launches a public consultation on alternatives for the use applied for. The ECHA Committees (Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis (SEAC)) evaluates the applications submitted by companies and the information submitted by third-parties during the public consultation. The Committees will then give their opinions on the application within 10 months of receiving the payment of the fee.

The opinions of the ECHA Committees contribute to the decision-making process of the European Commission who takes a decision on whether or not to grant an authorisation for the uses applied for.

Table 6 gives the numbers of applications for authorisations received from January 2013 – End of December 2014 as well as the number of RAC/SEAC opinions and Commission's decisions.

Table 6: Numbers of applications for authorisations received from January 2013 – December 2014

SUBSTANCE	INTRINSIC PROPERTIES IN ANNEX XIV	RECEIVED APPLICATIONS	APPLICANTS	USES	RAC/SEAC OPINIONS	COMMISSION DECISIONS
DEHP and DBP	CMR	8	10	17	14	2
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	-
Diarsenic trioxide	CMR	4	4	5	5	-
HBCDD	PBT	1	13	2	2	-
Trichloroethylene	CMR	13	15	19	2	-
Total		**27**	**43**	**55**	**35**	**2**

Conclusions

Since February 2013, ECHA has, together with Member States, organised cooperation and coordination, and developed approaches and tools to enable efficient implementation of the SVHC Roadmap. The practical implementation work has started to progress substances through the screening, assessment and RMOA steps in order to conclude whether a certain substance is an SVHC and to decide on the most appropriate set of measures to take under the REACH and CLP regulations (Figure 11). Furthermore, the interim target set out by the Commission in the SVHC Roadmap to have 80 substances subject to an RMOA by the end of 2014 has been met and even exceeded.

One of the main achievements is **the improved integration of the implementation of different REACH and CLP processes** through common screening. ECHA has set up the **common screening approach** which supports the identification of substances both for inclusion in the Candidate List and for further work under other REACH and CLP processes (for example, CLH and substance evaluation). The common screening has already demonstrated that it can identify substances of concern for the different processes and support finding the best combination and order of follow up actions.

This integration of processes will be further enhanced with the incorporation of compliance check to the common screening, in line with the new ECHA strategy on "safer chemicals – focusing on what matters most[52]". One of the main objectives of this strategy is to efficiently select substances that raise potential concern, generating the standard information for assessing safety through compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable regulatory instrument. Using the common screening approach to identify substances for compliance check will lead to improved coordination and a more coherent set of priorities for the different processes.

ECHA has set up new and streamlined the existing coordination and experts groups to support the implementation of the Roadmap. These groups gather input from the Member States and the Commission to the screening and use it to **enhance a common view among authorities on which substances matter most.** These groups also help to ensure that the identified substances are duly processed further. Furthermore, they support a number of other developments, such as training of less active Member States. Several Member States have been very active, in particular in the context of the coordination and experts groups, in supporting the SVHC Roadmap implementation and work. However, it remains ECHA's aim to get more Member States involved in the different screening, assessment and RMOA activities.

Experts groups play an important role in **supporting and streamlining** the **assessment of substances with PBT and ED properties.** Currently, many of the potential PBT and ED substances proposed by Member States to be included in the CoRAP were first discussed in the PBT or ED expert groups. Furthermore, substances listed on the CoRAP are in most cases also discussed in the expert groups to support the Member States in preparing the draft decision. This highlights the important role these groups play in supporting the identification of PBT and ED substances.

The **RMOA** has become a standard approach to enhance a common understanding between authorities on the need for and type of further regulatory action. The publication of information on substances undergoing RMOA through the PACT on ECHA's website has **increased transparency and predictability** of the authorities' work. The stakeholders and the general public can better predict which substances may be addressed by formal risk management routes in the future. This communication gives registrants the opportunity to ensure that their registration dossier is up-to-date, to consider the best business strategy to address substances of

[52] Available at http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

potential concern, and to get prepared for public consultation during any subsequent regulatory processes.

So far, a lot of work has been done and is ongoing at the different steps of the SVHC Roadmap implementation, i.e. screening, assessment and RMOA, and this is reflected in Figure 19 below. Many substances are scrutinised under screening and assessment. This should result in the coming years in a growing number of RMOAs. As shown in this report much work has been allocated in particular on systematic review of already known CMRs, i.e. CMRs which have a harmonised classification in Annex VI to CLP. All registered CMRs have been screened and work to identify structurally similar substances is ongoing.

The vast majority of the **registered known CMRs** have been scrutinised or are undergoing an RMOA to conclude on the need for further action. This work, which started already before the Roadmap implementation, has resulted in the inclusion of 145 CMRs in the Candidate List, out of which 29 are included in the Authorisation List. This means that the efforts of ECHA and the Member States can be directed to identifying new CMRs. This will be done either by proposing new harmonised classification and labelling (based on available data) or, where further information is needed, through initiation of substance evaluation.

Work on potential PBTs is also progressing at cruising speed. However, for many of these substances, further information generation and assessment will be needed to allow concluding whether they are PBTs. Therefore, the number of PBT substances in the assessment phase is high. In particular, where further testing under substance evaluation is needed, it will take substantial time before these substances will move to the RMOA step. So far, 20 PBT/vPvBs have been included in the Candidate List and two in the Authorisation List.

More systematic work under the SVHC Roadmap on EDs has started and is expected to be one of the major activities in the coming years. Four EDs have been included in the Candidate List so far.

In conclusion, a good start has been made with the implementation of the SVHC Roadmap. The work carried out in 2014 has laid a foundation for efficient and effective screening of the registration information allowing for the identification of candidate substances for further manual screening and potential regulatory intervention.

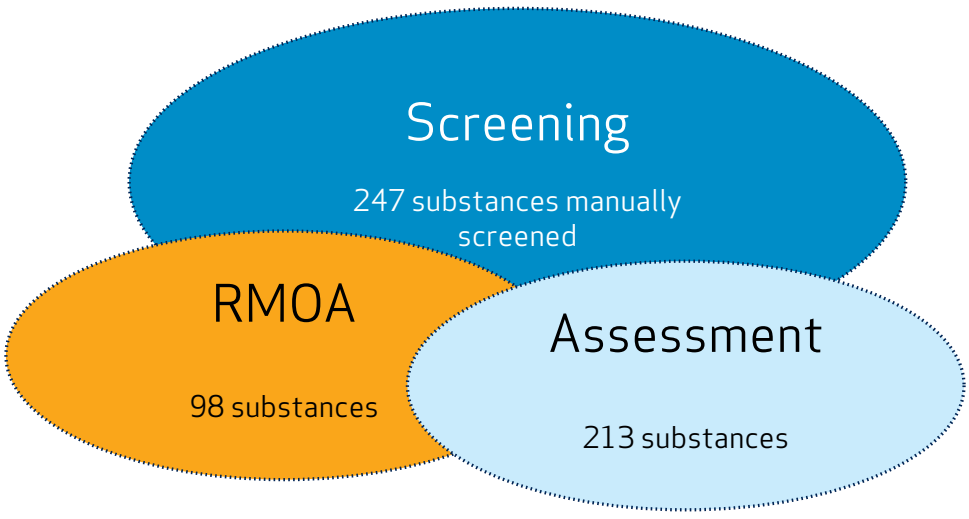


Figure 20: Overview of the number of substances under each of the main step of the SVHC Roadmap.

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	Carcinogen, mutagen, 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	Risk Assessment Committee
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIP	Roadmap implementation plan
RMOA	Risk management option analysis
SEv	Substance evaluation
STOT RE	specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very bioaccumulative

Progress monitoring indicators

Indicators for screening

Measurement name	**Substance screening 1**
Measure	Percentage of substances identified for further work to clarify a concern (SEv, CCH) or propose RRM (RMOA, CLH, other action)
Definition	Percentage of substances included on the short list and resulting from ECHA common screening, selected for manual screening by a Member State and identified as candidates for further work as a result of the manual screening. screening 1 = (number of substances identified as candidates for further work after manual screening)/(number of substances on the short lists) The indicator reflects the effectiveness of the IT mass screening, the short listing and the manual screening to find proper candidates for further work
Data sources	Screening short lists and outcome lists at the end of each year
Availability	Available
Baseline	Percentage of substances identified for further work in 2014
Long-term target	Increase in percentage
Annual target	N/A

Measurement name	**Substance screening 2**
Measure	Percentage of substances for which the outcome of manual screening has been substance evaluation (SEv) and which end up later in a RMOA.
Definition	Percentage of substances for which the manual screening outcome has been SEv (CoRAP listing) and which end up later in a RMOA. Analysis will be done in a batch manner where a group of substances identified in a given year will be analysed at a fixed time-point (for example, three years later). screening 3= (number of substances on CoRAP on year n for which an RMOA is producednumber of substances listed on CoRAP on year n)/ The indicator reflects the effectiveness of the manual screening
Data sources	Screening outcome lists at the end of each year, CoRAP lists, SEv conclusions, ACT (List of RMOs).
Availability	Available
Baseline	Annually defined Community rolling plan; started in 2013
Long-term target	High. Reporting retrospectively; increased percentage of substances ending up with follow up actions.
Annual target	High. Substances evaluated on year n, should be concluded either with a (draft) decision or a conclusion document on year n+1.

Indicator for assessment

Measurement name	Assessment 1
Measure	Percentage of substances for further assessment (PBT/ED) or with need for advice which ends up in an RMOA/SEv.
Definition	Percentage of substances for which the manual screening outcome has been "further assessment (PBT/ED)" or "advice" and which ends up later in an RMOA. Analysis will be done in a batch manner where a group of substances identified in a given year will be analysed at a fixed time-point (for example, three years later). The indicator reflects effectiveness of the manual screening and the appropriate use of resources of the PBT/ED EG.
Data sources	Screening outcome lists at the end of each year, PBT/ED working list, ACT (List of RMOs).
Availability	Available
Baseline	2013
Long-term target	High.
Annual target	High.

Indicators for RMOA

Measurement name	RMOA1
Measure	Number of (groups of) substances subject to an RMOA
Definition	Number of (groups of) substances subject to an RMOA
Data sources	ACT
Availability	Available
Baseline	February 2013 (adoption of the SVHC Roadmap)
Long-term target	Ca. 440
Annual target	Ca. 552

Measurement name	RMOA 2
Measure	Extent to which RMOA conclusions receive follow-up
	Percentage of RMOAs which conclude that RRM is needed that are in practice followed up with proposals for RRM
Data sources	Registry of Intentions, ACT (list of RMOAs)
Availability	Available
Baseline	Feb 2013 (adoption of the SVHC roadmap)
Long-term target	100%
Annual target	High

[45] Some RMOAs cover more than one substance, and potentially a lot of substances, because they have a chemical element in common which is the origin of the concern (for example, "lead and lead compounds") or all lead to same degradation product(s) of concern; for those, only one entry has been created in the PACT, and one RMOA has been counted in the present statistics. On the contrary, when two very separate substances have been RMOA-assessed within the same RMOA, for example, due to similarities in properties and/or uses, but do not have in common a chemical element which is the source of the concern and can easily be distinguished and identified, two entries have been created in the PACT, and two RMOAs have been counted for these statistics.

[46] Figure taken from the SVHC Roadmap

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