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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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List of abbreviations

Abbreviation	Description
ACT	Activities Coordination Tool
Art.	Article
CCH	Compliance check under dossier evaluation
CLH	Harmonised classification and labelling
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic, toxic for reproduction
CG	Coordination group
CoRAP	Community rolling action plan
COM	Commission
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
ELoC	Equivalent level of concern
IMAP	Inventory Multi-tiered Assessment and Prioritisation (IMAP) run by the National Industrial Chemicals notification and Assessment Scheme (NICNAS) of the Australian government.
ISSTOX Chemical Toxicity Database	The ISSTOX databases are curated by the Istituto Superiore di Sanità, and contain experimental results relative to various types of chemical toxicity.
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
RIME	Risk Management Expert Meeting of Member States Competent Authorities
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
ToxCast assay	US EPA's ToxCast Program seeks to use high-throughput, *in-vitro* biological assays to characterize potential health hazards of chemicals for use in chemical prioritization for more in-depth study. The US EPA's ToxCast Program provides data for 1861 chemicals and 342 assays.
vPvB	Very persistent and very bioaccumulative

Foreword

This is the second 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 in 2015 and the progress made since the adoption of the roadmap in February 2013 until the end of 2015.

The roadmap is now well into its third year of implementation. All the different activities contributing to it (screening, data generation and assessment, risk management option analysis (RMOA)) are in place to support the identification of substances of concern that require EU-wide regulatory risk management measures. Compared to when we published the first annual report in March 2015, the impact of the work under the SVHC Roadmap starts to be more visible. For instance there is an increase in the number of RMOAs concluding on the need to identify the substance as an SVHC as well as in an increase in RMOAs and SVHC identification proposals covering other properties than CMR such as substances with ED or PBT properties.

In 2015, the work under the SVHC Roadmap focused on better integrating compliance check in screening and ensuring that the compliance checks contribute to identifying substances of relevance for further regulatory action. Hence, this fits well with ECHA's integrated regulatory strategy on "safer chemicals – focusing on what matter most", which we also developed in 2015.

Transparency and predictability of the authorities' work is further increased by providing information on the common screening on ECHA's website and by informing all registrants individually when their substances will be manually screened by authorities. These improvements should allow stakeholders and the general public to better predict which substances may be addressed by formal risk management routes in the future.

Next year we will be halfway to implementing 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". Therefore, 2016 will be a good time to start reflecting on the achievements reached so far and discuss potential improvements. The work to review the SVHC Roadmap implementation has already started and will be further reflected in the annual report to be published in 2017.

The foundation of the SVHC Roadmap is there and all the blocks are in place. Nevertheless, there is still work ahead of us to ensure that the system is optimised in a way that the 2020 goals are achieved. The key to success is that all actors give a follow up to the actions identified in the RMOAs and use the the most efficient combination and order of actions to avoid undue delay in addressing substances known to be of high concern.

My sincere thanks go to all staff involved in the Member States for their work in identifying and addressing substances of concern. I am pleased to observe that more Member States have joined the work and that the cooperation in addressing substances that matter is intensified. 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' (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. Implementing the roadmap 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.

This document reports on the main achievements and progress of the activities covered under the SVHC Roadmap in 2015 as well as activities planned for 2016. In addition, an update of regulatory risk management activities under REACH is provided.

Part 1 provides a summary of the activities on screening, data generation and assessment, risk management option analysis (RMOA) and related progress monitoring indicators. Activities and main developments undertaken are reported per substance groups covered by the SVHC Roadmap 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;
- 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.

In the second round of **screening**, 180 substances have been screened by Member States. Around three-quarters of the screened substances were found to require follow-up regulatory actions. For most of these substances it was concluded that further information needs to be generated either through substance evaluation or compliance check (CCH). In 2015, the screening focused in particular on identifying potential substances for harmonised classification and labelling, and substances with endocrine-disrupting (ED) properties. Furthermore, work on supplementary activities (as defined in the SVHC Roadmap implementation plan) proceeded by screening for substances which are structurally similar to the Candidate List substances. These supplementary activities aim to support substitution by indicating early which substances are likely not to be good alternatives from the hazard perspective.

In 2015, the integration of compliance check to the common screening has started. Substances concluded during the manual screening by Member States as requiring compliance check have been checked by ECHA against the priorities identified under the ECHA regulatory strategy on "safer chemicals – focusing on what matter most", i.e. high tonnage registration dossiers with important data gaps and with a high potential for worker, consumer or environmental exposure.

Under **generation of data and assessment**, the work undertaken by the PBT and ED expert groups and the work carried out under substance evaluation is reported. In addition, the results of the compliance check of substances of concern are briefly reflected.

The number of substances under scrutiny for their potential ED properties has increased compared to last year. So far, 55 substances are under assessment for their ED properties and 150 for their PBT properties.

Like for substances with potential PBT properties, most ED substances are first discussed in the ED expert group before being further processed under the decision-making processes (e.g. substance evaluation, SVHC identification). The expert groups support and streamline the assessment of substances with PBT and ED properties.

So far, only few substances are concluded as being PBT, ED, CMR or sensitiser. However, it should be kept in mind that substances concluded, for instance as not being PBT or ED under the expert groups, will not be processed further due to these properties and therefore help to ensure that decision-making processes can focus on the right substances. In addition, the substances concluded under substance evaluation so far are those where generation of information was not needed. We can expect that in the future for more substances their PBT, ED, CMR and/or sensitiser properties will be confirmed.

In summary, 266[1] substances have been or are under generation of data through substance evalution and assessment among which 59 have been concluded and 196 are still ongoing. In addition, 107 compliance checks addressing substances that matter most have been concluded in 2015, over 80 % of which resulted in a draft decision requesting further information.

Risk management option analysis (**RMOA**) is to help authorities decide whether further regulatory risk management activities are required for a substances and to identify the most appropriate instrument to address the concern.

In 2015, 25 RMOAs have been concluded and 44 new RMOAs have been initiated and are ongoing. This brings the number of RMOAs since the start of the SVHC Roadmap in February 2013 to 50 RMOAs concluded and 89 ongoing. Half of the RMOAs concluded so far propose as a follow up to identify the substance as being an SVHC, which is a clear increase compared to last year. The other half identifies either the need for other REACH/CLP regulatory risk management (e.g. restriction), the need for other regulatory risk management such as the use of other regulations than REACH or no action. This demonstrates that the SVHC Roadmap not only supports the identification of substances to be included in the Candidate List but also the identification of the need for restrictions and regulatory action outside of REACH/CLP processes.

Even though many RMOAs cover CMR properties, there is a clear increase of other properties (e.g. ED) compared to previous years. More and more substances with PBT and ED properties are being identified as SVHCs indicating that effects of the SVHC Roadmap implementation start to be more visible.

The Public Activities Coordination Tool (PACT) which is available on ECHA's website has been enhanced and now not only provides y a list of substances which are under risk management option analysis (RMOA) but also substances for which there is an informal assessment of their PBT/vPvB or ED properties.

PACT has significantly increased the **transparency** on which substances are being scrutinised by authorities for potential further regulatory action. **Predictability** has been further enhanced by clarifying links between activities and lists of substances available on ECHA's website allowing a better understanding of what would be the typical journey for a substance through the different steps of the SVHC Roadmap and further regulatory processes.

Transparency and predictability of screening has also been increased through the publication of information on the screening process and scenarios on ECHA's website as well as by sending

[1] This number includes all substances under either one of the expert groups or under substance evaluation but excludes substances under compliance check.

letters to all registrants of substances included on the list of substances to be manually screened by Member States to inform them early in the process that their substances are under scrutiny. It also gives registrants the opportunity to update their registration dossier at a very early stage, when feasible, allowing both authorities and industry to focus resources on those substances that matter most.

In conclusion, many activities have been carried out which will support stakeholders and the general public to better predict which substances may be addressed by formal risk management routes in the future.

The roadmap implementation is a **joint activity of the Member States, the Commission and ECHA**. Expert and coordination groups have continued to support the activities identified under the roadmap. The work on petroleum and coal stream substances has started and a working group with representatives of Member States, the Commission and stakeholders have been set up and is developing an approach to assess those substances as required by the roadmap.

Around two thirds of the Member States are actively involved in the different activities linked to the SVHC Roadmap. The number of Member States developing RMOAs has clearly increased compared to last year.

Part 2 of the report gives an outline of the SVHC Roadmap implementation activities planned for 2016. The further development will focus on:

- Further increasing transparency and predictability of activities falling under the SVHC Roadmap by improving ECHA's website under substances of potential concern by having all substances of potential concern in one place: substances under substance evaluation (CoRAP), substances under RMOAs, substances under informal PBT or ED hazard assessment and substances under compliance check in the context of the CCH strategy to identify the substances that matter most.
- Develop the assessment approach for petroleum/coal stream substances with Member States, the Commission, industry and NGOs and start the assessment of selected substances when relevant.
- Further enhanced the screening by further integrating compliance check, development of the structural similarity and grouping of substances and by further investigating alternative ways of screening and identifying substances that matter most.

The work to review if some elements of the implementation of the SVHC Roadmap need to be adapted has already started and will be further discussed among ECHA, Member States and the Commission to be further reflected in the annual report to be published in 2017.

Part 3 provides an update 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 and CLP processes until the end of 2015.

In summary, the different blocks of the SVHC Roadmap (i.e. screening, generation and assessment, RMOA) are now well in place and support the identification of substances that matter most. The impact of the implementation of the roadmap on the type of substances addressed in the RMOA phase and also in regulatory processes starts to be more visible. It is important to keep in mind that all steps require time. Therefore, to achieve the 2020 goals the most efficient combination and order of actions should be used to avoid undue delay in taking relevant action.

Introduction

The 'Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020'[2] (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.

The first annual report of the SVHC Roadmap was published on 23 March 2015[3] and describes the main achievements and progress in common screening, risk management option analysis (RMOA) and hazard assessment of persistent, bioaccumulative and toxic and endocrine disrupting properties (PBT/ED) since the adoption of the roadmap in February 2013 until the end of 2014. It explains the background and main approaches taken to implement the roadmap but also gives an overview on regulatory risk management activities under the REACH and CLP regulations since the start of their implementation.

This document reports the main achievements and progress of the activities covered under the SVHC Roadmap in 2015. The way in which Member State competent authorities (MSCAs) and ECHA implement the roadmap has not changed.

Therefore, the focus of the annual report for 2015 activities is on reporting the main new developments over the year, updates on numbers and activities planned for 2016. In addition, an update of regulatory risk management activities under REACH compared to the previous report is also provided.

A more comprehensive report on the SVHC Roadmap activities is expected in 2017.

Part 1 provides a summary of 2015 SVHC Roadmap-related activities and more particularly on screening, assessment, RMOA and related progress monitoring indicators. Activities and main developments undertaken are reported per substance groups covered by the SVHC Roadmap 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[4];
- 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 the SVHC Roadmap implementation activities planned for 2016.

Part 3 provides an update of related regulatory risk management activities. An overview of substances under SVHC identification, recommendations for and inclusion of substances in Annex XIV, and applications for authorisation are provided since the start of those different REACH processes until the end of 2015.

[2] Available at http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT
[3] Available at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation
[4] Substances with human health-related hazard properties other than sensitisation can also be considered, if they may 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 as an own substance group).

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.

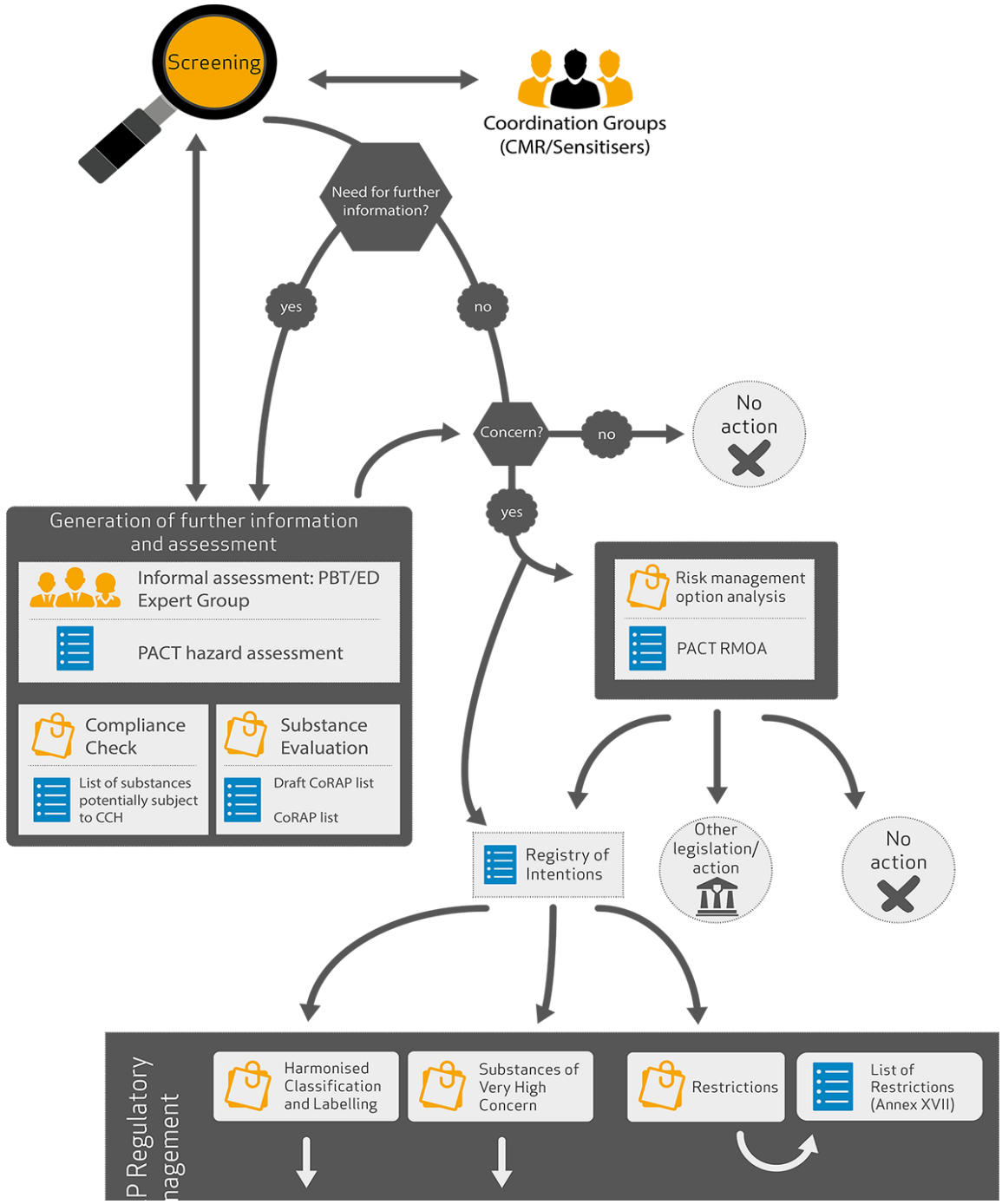

Figure 1: Overview of activities and groups under the Roadmap, links to closely related activities (compliance check, substance evaluation) and follow up regulatory risk management processes[5].

[5] Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Part 1 – Activities carried out in 2015

1. Introduction

Generic information on the roadmap and the roadmap implementation plan (RIP) is available on ECHA's website[6]. Besides identifying and including all relevant, currently-known SVHCs in the Candidate List by the end of 2020, the SVHC 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**
- **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, the ECHA common screening developed to support REACH and CLP processes – as further detailed in the first annual report – is in place. 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 done on a yearly basis and will ensure the processing of new sources of information. The focus in 2015 was on screening for potential harmonised classification and labelling proposals, substances with endocrine disrupting (ED) properties as well as further integration of compliance check.

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

Since September 2014, the Public Activities Coordination Tool (PACT)[7] is available and provides a list of substances which are under risk management option analysis (RMOA) and/or for which there is an informal assessment of their PBT/vPvB or ED properties and at which stage of assessment the substances are (i.e. under development, concluded). PACT allows stakeholders to be informed early enough in the process on individual substances addressed by authorities.

Since March 2015, more detailed information on the common screening is available on ECHA's website, in particular, the definition documents describing screening priorities[8]. In addition, letters have been sent to all registrants of substances included on the list of substances to be manually screened by Member States to inform them early in the process that their substances are under scrutiny.

The website has also been enhanced with a clarification of the links between the different processes covered by the SVHC Roadmap. This enables a better understanding the links between the different processes before REACH and CLP regulatory processes such as screening, RMOA but also between REACH and CLP processes. Member States initiatives at

[6] Available at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation
[7] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact
[8] Accessible at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

national level have also ensured an increased predictability and transparency of the processes (e.g initiative in the Netherlands to better support registrants in finding out their obligations[9]).

- **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 the Member States, the Commission (COM) and ECHA. Coordination groups set up in 2013 have continued supporting activities related to CMR and sensitising substances and more particularly screening and discussions on additional properties potentially leading to an equivalent level of concern to CMR (for example, specific target organ toxicity – repeated exposure (STOT RE)).

From the experience gained working with the groups, it was agreed at the end of 2015 that the two groups would be merged into one single group named the SVHC Human Health Coordination group as most of the activities were already jointly performed.

Both PBT and ED expert groups continued to provide support to the SVHC Roadmap implementation mainly at the level of screening and assessment of substances with PBT/vPvB or ED properties.

For petroleum and coal stream substances, the roadmap foresaw the need to develop an approach to assess that group of substances first. To this end, ECHA has set up a working group with representatives of the Member States, the Commission and stakeholders and the work done so far is further outlined in section 2.3.

More experienced Member States have also continued to organise training on RMOAs and manual screening for less active Member States, which should also ensure that more Member States are supporting the implementation of the roadmap in the long-term.

2. Screening

Screening to find potential substances of (very high) concern is an important element of the SVHC Roadmap to 2020 implementation plan. Main developments and screening results obtained in 2015 are introduced below together with the work done on developing an approach for petroleum and coal stream substances under the PETCO working group.

2.1. Screening main developments in 2015

The common screening approach is now well into its third year with the second round of shortlisted substances screened in 2015. This second round focused on more integration of all processes, with timelines aligned and templates streamlined.

For the first time, the following substances were shortlisted:

- potential candidates for harmonised classification and labelling (CLH), with a focus on substances with potential carcinogenic, mutagenic or reproductive toxicity properties as well as respiratory sensitisers;
- substances being potential endocrine disruptors; and
- substances falling under the supplementary activities defined in the SVHC Roadmap implementation plan. These substances are those which are not registered under Article 10 of REACH (i.e. registration coveres only intermediate uses (art 17/18) or are not registered) but have a harmonised classification as CMR category 1A or 1B and/or

[9] Available at: http://infographic.reachhelpdesk.nl/

sensitisation and are structurally similar to substances on the Candidate List or in the pool of SVHC intentions[10].

Compliance check-specific scenarios are not yet developed in the common screening; however, substances from the 2014 and 2015 rounds of screening for which the outcome of manual screening was compliance check (CCH) were verified by ECHA against the priorities identified under the CCH strategy[11]. When the prioritisation criteria were fulfilled, a compliance check was opened on the related dossiers. Low priority substances not fulfilling the prioritisation criteria are parked for later.

The substances on the 2015 shortlist for manual screening were also the targets of a letter campaign. All registrants of the shortlisted substances were alerted to the fact that their substances might be under scrutiny by Member States and invited to review their dossiers with regard to identified potential hazards and their use and tonnage information. They were also encouraged to review and update their substance identity information and any read-across they might have applied, if needed.

The aim of such a campaign was to increase the transparency and predictability of the screening process by letting registrants know that their substances were shortlisted. The aim was also to trigger updates of dossiers so that both authorities and registrants focus on the right substances if, for instance, some information on uses in the registration dossiers would not be up-to-date anymore. This first letter campaign resulted in some dossiers being updated – even though it was started relatively late in the manual screening process – and allowed ECHA to better define the next letter campaign to make it more effective for authorities and registrants. The campaign was repeated in February 2016.

To better support the identification of substances that matter, ECHA started to investigate other ways of screening to complement the current common screening approach. One area of development is to identify applications where exposure to workers or releases to the environment can be expected and then to start looking at potential substances of concern, including substances with data gaps in relevant endpoints, within those applications.

In general, ECHA, the Member States and the Commission have strengthened their cooperation in developing and improving the common screening approach through a workshop organised by ECHA in the autumn but also by increased communication and exchange with the coordination, experts groups, Member States' exposure network and risk management expert group (RiME).

[10] Registry of intentions available at http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions
[11] Available at: http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf and http://echa.europa.eu/documents/10162/21961120/mb_59_2015_update_cch_en.pdf

2.2. Screening results

In the second round of screening, 254 substances were added to the shortlist as a result of IT-screening and a further 14 substances were added by Member States as a result of their own prioritisation.

Of the 268 substances, 180 were picked for manual screening with the indicative process as CoRAP (117), CLH (40), SVHC (20) or supplementary SVHC (15). In some cases, substances were shortlisted for more than one indicative process. About three-quarters of the screened substances were found to require follow-up regulatory action as reported in Figure 2. Some substances were found to require two parallel regulatory actions so the number of outcomes is actually higher than the number of screened substances.

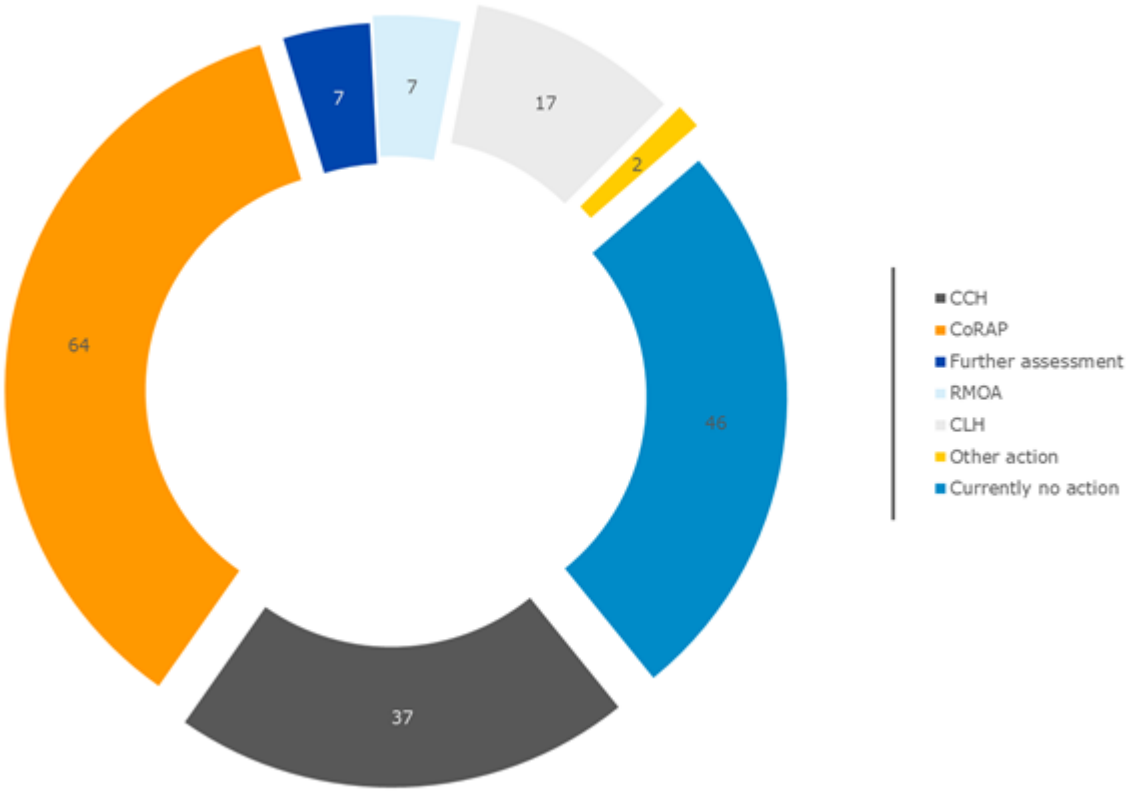

Figure 2: Manual screening outcome[12]

Figure 3 presents the outcome of the screening per trigger for concern and likewise here there can be more than one trigger for concern for some substances.

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

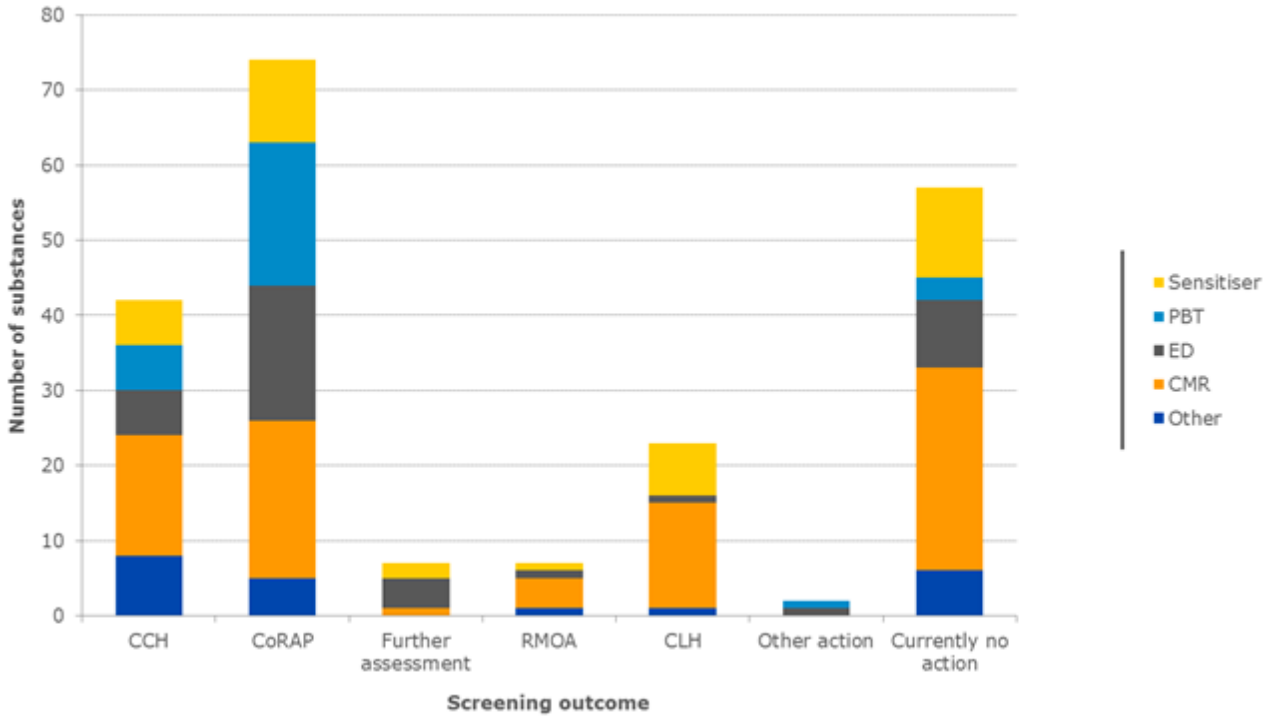

Figure 3: Manual screening outcome per properties[13].

21 Member States participated in the second round of manual screening, representing an increase of three Member States from the first round. The number of substances screened per Member State (and ECHA) is reported in Figure 4. Some Member States have collaborated on the manual screening, sharing expertise and resources.

[13] 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) but other HH and ENV related properties. 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.

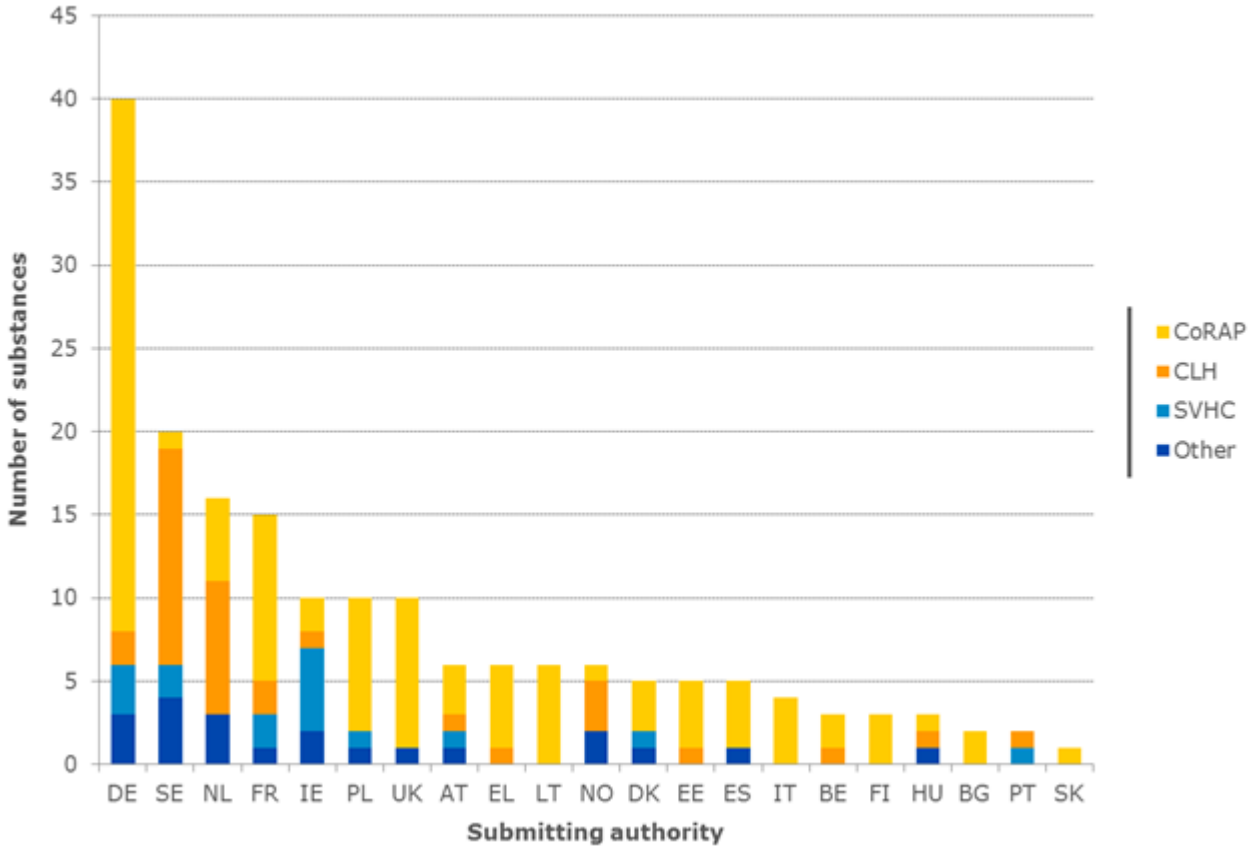

Figure 4: number of substances screened per (group of) Member States and indicative processes in 2015[14].

2.3. Petroleum and coal stream substances

Petroleum and coal stream substances are substances of very complex and variable/partly undefined composition (UVCBs). Those substances are clearly of potential concern for human and environmental health due to their potential CMR and/or PBT properties, their high volume and the indication from the registration data that these substances are not just used as intermediates or in fuels but also in other uses of relevance for regulatory risk management. However, for this group of substances, the roadmap notes that there is first a need to develop an approach on how to assess these.

The aim of the PETCO working group is to develop an approach to identify and address PETCO substances and plan the practical implementation of the approach. In 2015, two meetings of the PETCO Working group were held. The first one with only Member States and the Commission, and the second one with interested accredited stakeholders in addition. These first meetings resulted in a plan on how to approach those substances building on the experience gained from the work done together with Concawe on petroleum stream substances.

Based on the results of a survey done by Concawe to clarify the uses of their substances and tonnages falling under those uses, ECHA prioritised substances for further work. Those with uses by consumers and at professional settings were prioritised to focus first on the substances

[14] Other refers to those substances proposed to be added by Member States on the short list of substances to be manually screened and for which there was no indication on the foreseen outcome.

which matter most for the follow up regulatory processes. This resulted in 64 substances out of 207 being of high(est) priority for further work for which the working group agreed on further actions to better understand their hazards. Substances used only as fuels and/or intermediates are considered as low(est) priority.

Based on this experience, it was also agreed that a similar approach will be applied to other petroleum and coal stream substances not covered by the Concawe survey.

The outcome of the work done so far by the PETCO working group is a work plan, including a list of actions, on how to approach those substances and how to focus on the substances that matter the most. The agreed approach will also describe why the substances that will not be further addressed now are of low(er) concern.

3. Data generation and assessment

3.1. Main developments

For most of the substances, including those with potential CMR properties, to be able to assess the SVHC properties further and confirm them, there is a need to generate further information, go for further assessment and/or propose harmonised classification and labelling. The SVHC Roadmap implementation is supported by the ECHA regulatory strategy on "safer chemicals-focusing on what matters most" which focuses on those substances with one or more suspected data gaps in the higher tier human health or environment endpoints[15] and high potential for exposure of humans or the environment and hence relevance for safe use.

Even though substance evaluation and compliance check are not covered in the SVHC Roadmap as such, they are the main tools for generating missing information (see

Figure 1).

As already highlighted in the first report, most of the CMRs with harmonised classification have been considered already for further regulatory risk management. The new screening scenarios identifying potential CMRs should also increase the number of CLH proposals in the future.

So far, the substance-specific discussions under PBT and ED expert groups[16] have supported the assessments and made them fit for regulatory purpose. Most of the substances under CoRAP[17] with potential PBT properties were also discussed in the PBT Expert Group. A clear increase of the use of the ED Expert Group to discuss potential ED CoRAP substances has also been observed in 2015. All substances for which an Annex XV dossier to propose the substances to be identified as an SVHC due to their PBT and/or ED properties are first discussed in the PBT and ED expert groups respectively.

Besides the assessment of PBT and ED properties, the two expert groups discuss how to improve methodological aspects of the assessment. For instance, a document summarising the different approaches for assessing the PBT properties of UVCB substances was developed. This will be further developed this year and included in an update of the PBT guidance together with other topics being set as high priorities by the group to improve the PBT assessment (e.g. role of enhanced ready biodegradability test in persistence assessment).

[15] The endpoints of priority are genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.
[16] PBT and ED expert groups can discuss, in addition to CoRAP substances, other substances including substances not in the scope of REACH (for example, biocides and veterinary medicine)
[17] Available at http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Based on a set of WHO/IPCS templates, a framework has been proposed to the group on how to document the substance's mode of action and adverse outcome pathway assessment to improve documentation and support discussion in the ED Expert Group. This framework has been generally very well-received and is already applied in most cases brought to the expert group.

3.2. Overview of substances under generation of data and 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 2015 is provided in Figure 5 below.

Information on each of the substance groups defined under the SVHC Roadmap is reported. The number of substances under assessment is further split into substances for which an assessment is ongoing, postponed[18] 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". For the time being, information related to compliance check has not been integrated with the others and is reported separately but further integration of data will be done in the future reports.

The first CoRAP substances were evaluated in 2012 and more experience is gained every year. The scope of substance evaluation clearly covers more properties 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 are not reported in Table 1 and Figure 5 below.

So far, there have been a total of 150 substances with potential PBT/vPvB properties under PBT assessment, that are either listed under substance evaluation or for which an informal assessment was carried out ("non CoRAP" substances). The "non CoRAP" substances mainly originate from a screening shortlist generated before the SVHC Roadmap to 2020 and the common screening.

Since its establishment in February 2014, the ED expert group has discussed 33 substances. There is a total of 55 substances with potential ED properties under assessment that are either listed under substance evaluation or for which an informal assessment was carried out.

The second round of screening (2015) did not result in identifying new potential PBT substances for further assessment but four substances with ED properties were identified for further assessment and should come to the ED Expert Group in 2016.

The number of substances with potential ED properties in the CoRAP for which the ED Expert Group has been consulted has increased. From the substances with ED indicated as a potential initial concern listed in the CoRAP in 2015, 9 out of 10 substances were discussed in the expert group.

106 CMRs and 45 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

[18] 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 of low(er) priority at present (for example, only uses as intermediates).

CMR). Therefore, the total number of substances under each concern is not equal to the total number of substances under evaluation. This is true for both Table 1 and Figure 5 below.

In total, 266 substances are under generation of data or assessment either in substance evaluation (CoRAP) or one of the expert groups or under more than one activity (e.g. both in the CoRAP and under assessment in the PBT/ED expert groups). This number includes both ongoing assessments and concluded ones. Among those 266 substances, 196 are ongoing whereas 59 have already been concluded (Figure 5).

In addition, with the implementation of the CCH strategy, substances of potential concern are also clearly addressed under compliance check. In 2015, 107 of the compliance checks concluded by ECHA addressed high priority substances (i.e. high tonnage registration dossiers with important data gaps and with a high potential for worker, consumer or environmental exposure). Out of the 107 priority compliance checks concluded, the evaluation outcome was a draft decision in 82 % of the cases and no action in the remaining 18 %. The most common suspected concerns were as follows:

- 82% suspected of reproduction toxicity and/or mutagenicity concerns (CMRs)
- 63% suspected of bioaccumulation, persistence and environmental toxicity concerns (PBT)
- 45% suspected of other human health related concerns
- 9% suspected of endocrine disruption or sensitisation concerns

It is worth noting that a substance may have more than one of the above-mentioned concerns. More information is available in the annual evaluation report[19]. Some substances under compliance check are also under substance evaluation or informal assessment in one of the expert group for another property.

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

Table 1: Overview of the number of substances under "generation of data or assessment" for each concern (2012 - 2015)

		PBT	ED	CMR	Sensitisers
Expert groups – non CoRAP substances	ongoing[20]	42	6	-	-
	postponed	10	1	1	-
	concluded	24	1	-	-
Expert groups – CoRAP substances	ongoing	62[21]	24[22]	-	-
	concluded[23]	5 (+3)	1	-	-
CORAP substances but not discussed in the expert groups	Ongoing	1	19	-	-
	Concluded	3	2 (+1)	-	-
Total CoRAP substances under evaluation	Ongoing	59	40	87	34
	Concluded	8(+3)	3(+1)	17(+2)	11(+1)
Total number of substances under either generation of data or assessment		150	55	106	46

[20] The status (ongoing/postponed/concluded) is the status valid under the expert groups. Postponed means that the assessment has been postponed as the substance was for example only registered as intermediate.
[21] Note that four of these substances are not listed in the CoRAP due to potential PBT properties.
[22] Note that one of these substances is not listed in the CoRAP due to potential ED properties.
[23] The number indicated in brackets refer to conclusion documents under preparation.

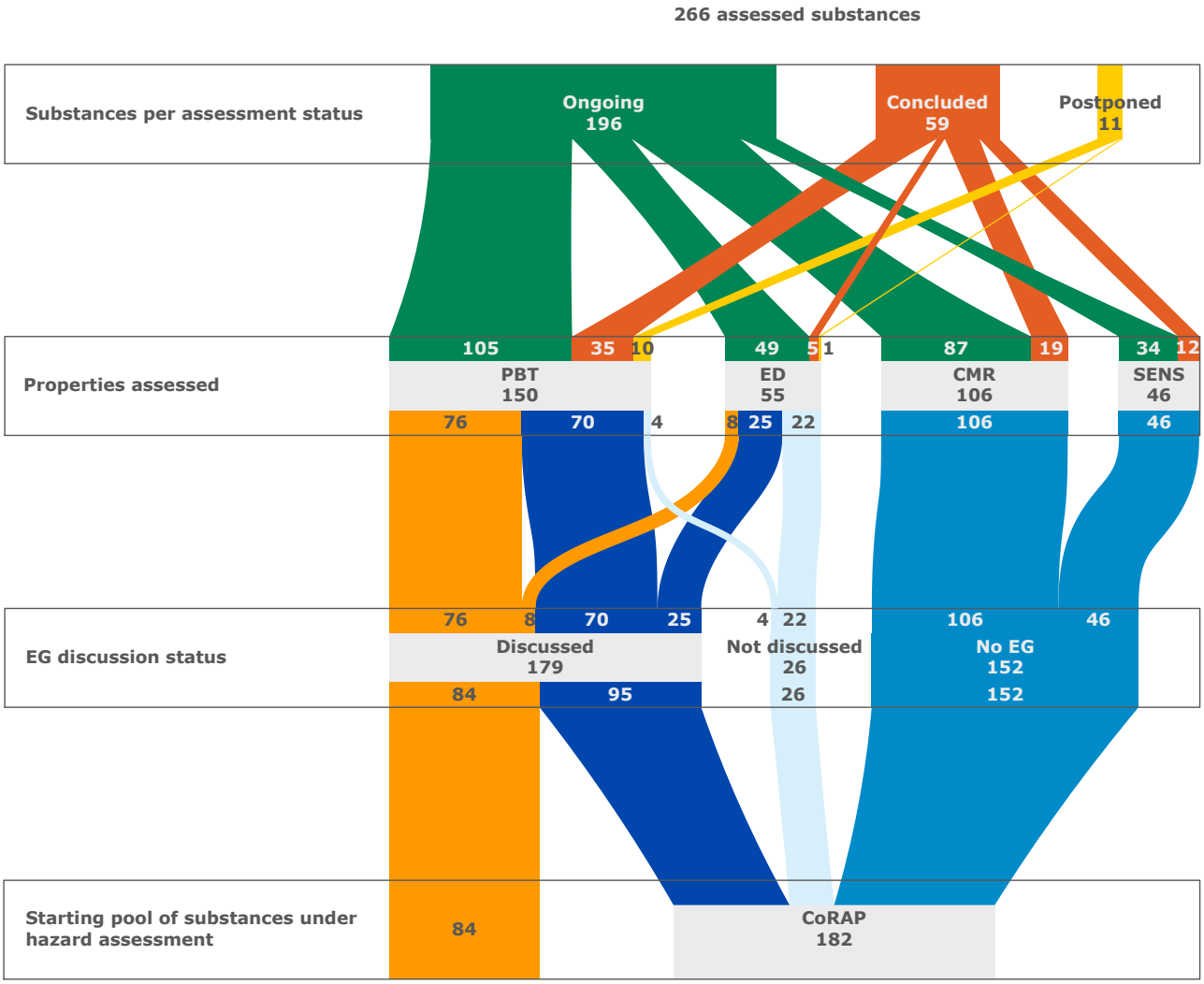

Figure 5: Substances and properties under "assessment" (2012-2015)[24]

Figure 6 gives an overview of substances under "generation of data and assessment" per Member State and specifies those that are under substance evaluation and those brought either to the PBT or ED expert groups.

[24] EG status: Status under the expert groups where the substance could have been discussed or not. Note that for CMR and sensitiser there is no expert group (No EG).

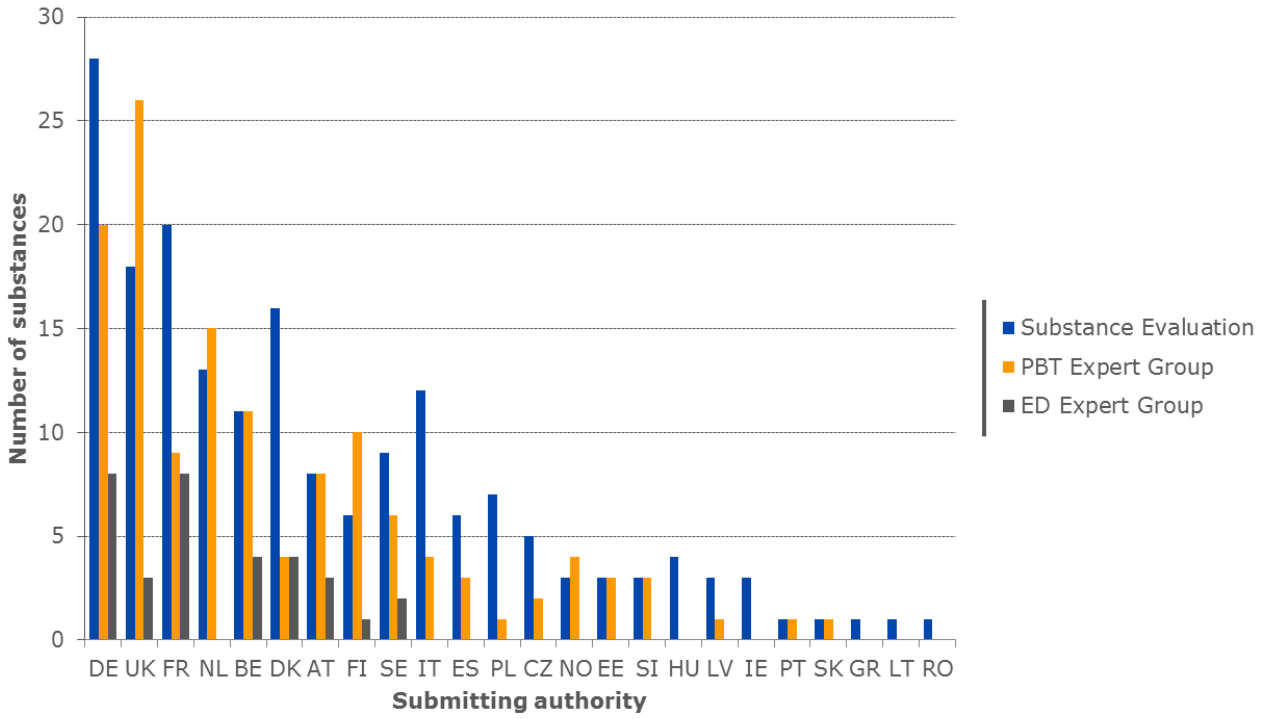

Figure 6: Number of substances under assessment per Member State in the ED Expert Group, PBT Expert Group and substance evaluation.

3.3. Overview of conclusions

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

So far, the assessment of 35 substances (out of the 150 substances) with potential PBT/vPvB properties have been concluded and 1 substance is considered to be fulfilling the PBT or vPvB properties. For ED, 5 substances out of 55 substances with potential ED properties have been concluded and 1 of them is considered to fulfil the ED properties (in accordance with the WHO/IPCS (2002) definition)) as reflected in Table 2 below. As said before, for most of the substances further information need to be generated and it takes time before the results are available and assessed.

So far, 106 substances are under evaluation for their CMR properties and 17 (and two under preparation) have already been concluded. 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 (but for example, exposure). Therefore the number considered to fulfil the hazard properties for CMR and sensitisers in Table 2 refers to substances where classification as CMR/sensitiser has either been confirmed or newly identified.

Regarding sensitisers, 34 substances are ongoing and 11 have already been concluded of which 7 are skin sensitisers and 4 are respiratory sensitisers as reported 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 to 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 - 2015)

Property	Total number of substances concluded[25]	Number of substances concluded	
		Considered to fulfil the hazard properties	Considered not to fulfil the hazard properties
PBT EG (CoRAP and non CoRAP)	32	1	31
PBT – substance evaluation	8	0	8
ED EG (CoRAP and non CoRAP)	2	1	1
ED – substance evaluation	3	0	3
CMR – substance evaluation	17	3 CMR cat 1[26] 5 CMR cat 2[27]	9
Sensitiser – substance evaluation	11	7 skin sensitiser 4 respiratory sensitiser	4

4. Risk management option analysis (RMOA)

4.1. Overview of substances in the RMOA stage

Figure 7 provides the number of RMOAs concluded or under development from the implementation of the SVHC Roadmap in 2013 to the end of 2015. For 50 RMOAs, a conclusion is available and for the remaining 89, the RMOA work is ongoing. In 2015 25 RMOAs were concluded and there has been 44 new RMOA intentions.

[25] For substances under substance evaluation only those conclusions that are already available and documented on ECHA's website are reported but not the conclusions under preparation.
[26] **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).
[27] **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).

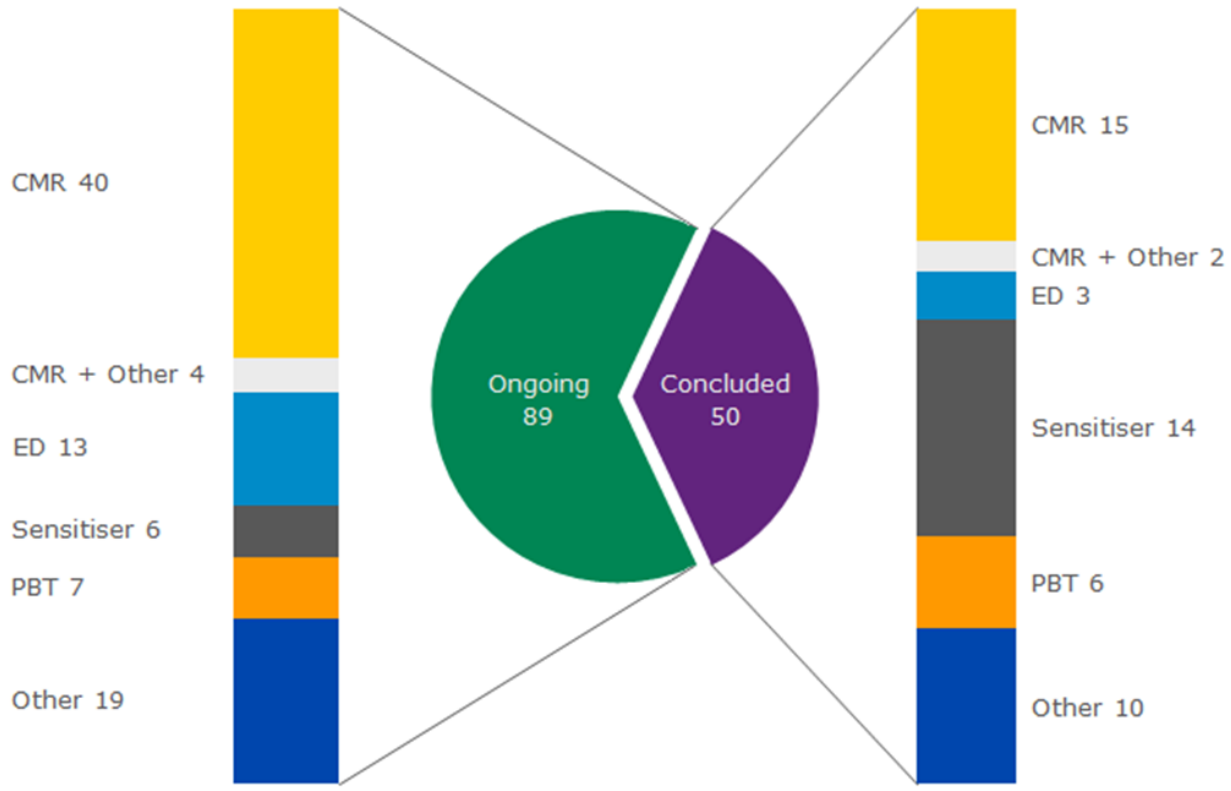

Figure 7: Number of RMOAs concluded and ongoing per property (February 2013 – December 2015[28])

The majority of RMOAs – both ongoing and concluded – are still for CMR substances. However, the number of RMOAs investigating substances with ED properties has clearly increased compared to last year. On the contrary, only few RMOAs analysing substances with sensitisers properties are ongoing.

As more and more substances are under generation of information and assessment for both PBT and ED properties under either substance evaluation, compliance check or in one of the expert groups, it can be expected that the number of RMOAs covering substances with those properties would increase. However, it should be kept in mind that, as the generation and assessment of information takes often substantial time, it will also take more time before the RMOAs can be concluded.

[28] The data reported in the table are until the latest update of PACT in 2015 (11 December 2015).
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 a chemical element in common which is the origin of the concern (for example, "lead and lead compounds") or all lead to same degradation products 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 a chemical element in common 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.
Under CMR, PBT, ED and sensitiser, also RMOAs which cover in addition to these properties also other properties, are reported.
Under CMR + other, RMOAs are reported covering CMR properties but also one other property listed under the SVHC Roadmap i.e. CMR+PBT and CMR+ED properties.
Under "other", RMOAs reported with another scope than PBT, ED, CMR or sensitiser or for which no indication of scope are available in PACT.

Figure 8 provides the number of RMOAs concluded or ongoing per Member State or ECHA (at the request of the Commission) since 2013.

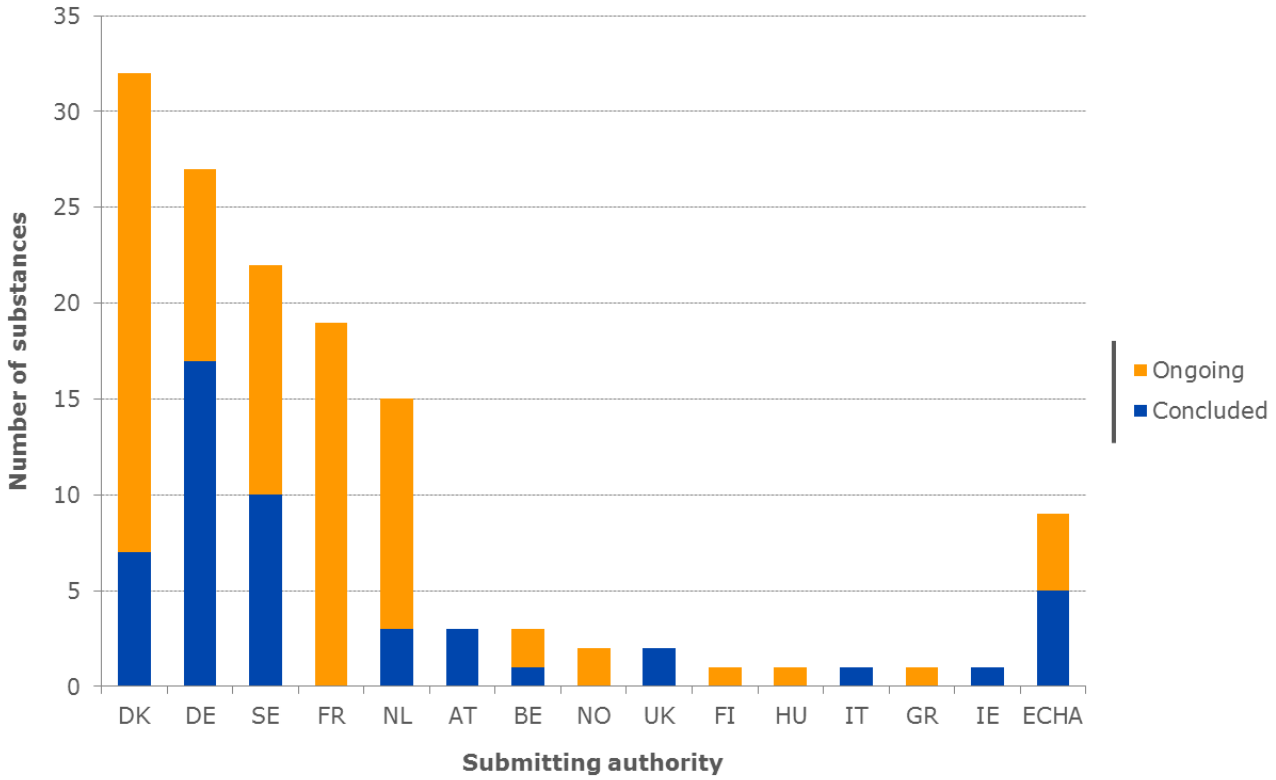

Figure 8: number of RMOAs per Member State and by ECHA.

14 Member States have submitted RMOAs since the start of the SVHC Roadmap, which represents an increase of four Member States compared to the first annual report. This clearly shows the willingness of Member States to be active and invest resources in these activities, and for new Member States to develop their expertise in the field of risk management.

4.2. Overview of RMOA conclusions

Table 3 provides the number of RMOAs concluded per proposed follow-up regulatory action by the end of 2014 and the end of 2015. There is clearly an increase in the share of RMOAs for which a conclusion is available compared to last year.

For half of the substances (15) for which there is a conclusion, the proposed follow-up was the identification of the substance as an SVHC, which is again a clear increase compared to last year where the number of RMOAs concluding SVHC identification as a follow-up was relatively low (5).

This seems to indicate that the impact of the SVHC Roadmap implementation starts to be visible particularly in identifying substances as being substances of very high concern. The number of RMOAs concluding on the need for other EU legislation and/or other measures has also increased which confims that the RMOA tool is open and can in practice serve other legislation than regulatory risk management under REACH and CLP.

Table 3: Cumulative number of RMOAs concluded per proposed follow up regulatory action (February 2013 - December 2015)		
	By end of 2014	By end of 2015
SVHC identification (authorisation)	5	15
REACH restriction	1[29]	5
CLH	1	2
Other EU-wide regulatory action	2	3
Other (e.g. non EU-wide and/or non regulatory actions)	1	5[30]
No follow-up action	5	8

5. Progress monitoring indicators

Progress monitoring indicators reflect screening, assessment and RMOA activities[31] and are measured and reported every year from the start of the SVHC Roadmap implementation.

As already highlighted in the first annual report, the activities and regulatory processes monitored in the context of the SVHC Roadmap have taken place before the adoption of the SVHC Roadmap. Therefore, during the first years of reporting, the indicators may also reflect past activities. Indicators are reported on a yearly basis; however, for some of them, effects will be seen only in the long-term and for others it will not be possible to calculate them before some time as it is still too early in the process. This is, for instance, the case for Substance Screening 2 and Assessment 1.

Substance Screening 2, Assessment 1 and RMOA2 are cumulative indicators. Even though RMOA1 is foreseen to be reported on a yearly basis also the cumulative number over several years of implementation of the roadmap will be reported in the text.

[29] One RMOA covering 11 substances which is the reason why it is indicated as one only, even though there are 11 entries in PACT.
[30] For one substance included here, there is a need for follow-up regulatory action at international level and/or under other EU legislation than REACH
[31] Description of the progress monitoring indicators is available at the end of the first annual report of the SVHC Roadmap at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation.

Table 4: Progress monitoring indicators target and results[32]		
Indicators	**Target**	**Result**
Substance Screening 1: Percentage of substances identified for further work to clarify a concern (substance evaluation, CCH or proposed RRM (RMOA, CLH, other action)	- [33]	75.8%
Substance Screening 2: Percentage of substances for which the outcome of manual screening has been substance evaluation and which ends up later in an RMOA.	high	-
Assessment 1: Percentage of substances for further assessment (PBT/ED) or with need for advice which ends up in an RMOA/substance evaluation.	high	-
RMOA1: Number of (groups of) substances subject to an RMOA	55	42
RMOA2: Extent to which (percentage of) RMOA conclusions resulted in regulatory follow-up	high	65%

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. Nearly 76 % of substances that were picked up by the IT based mass screening were found to require further follow up actions. This number is slightly lower than last year. This is probably linked to the fact that the same database is being searched for some years now with very similar scenarios (e.g. for CMR substances) and very few updates of dossiers received leading to less good candidates for manual screening.

Further improvements of the screening and identification of substances of potential concern are under development and should be reflected in the years to come. For instance, ECHA together with the Member States has started to investigate how to identify substances where exposure to workers or releases to the environment can be expected (see also the further developments foreseen in section 2).

For RMOA1 and RMOA2, the reported figures cover the substances listed in PACT in its latest update for 2015 (11 December 2014).

RMOA1 provides the number of (groups) of substances subject to an RMOA as published in PACT. It is the only indicator reporting on the number of substances. All other RMOA indicators and figures in that report provide the number of RMOAs. 42 new (groups of) substances have been subject to an RMOA in 2015 which brings the number of substances subject to RMOA to 130.

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 2015 (i.e. an Annex XV proposal for

[32] All progress monitoring indicators for the SVHC Roadmap are calculated starting with the implementation of the roadmap in 2013.
[33] The target is to have substance screening one indicator high and at least equal to the baseline which is set as 2014.

identification of SVHCs or for restriction under REACH, or an Annex VI proposal for harmonised classification and labelling under CLP).

16 Member States submitted proposals for regulatory risk management measures under REACH or CLP which is a clear increase compared to last year. The extent to which the conclusions from the risk management option analysis (RMOA) received further follow-up clearly increased (65 %, compared to 17 % in 2014).

This increase is partly due to the time needed to prepare the regulatory proposal after the RMOA conclusion has been confirmed. However, it also indicates high commitment to follow up the work done under the SVHC Roadmap. In particular, the identified need to initiate SVHC identification or restriction processes were followed up well (in 80 % of cases). By the end of 2015, CLH dossiers had not been submitted for the two substances for which CLH was concluded as the best RMO.

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 2015, or for which PACT indicates that the RMOA is still "under development", are not counted.

Part 2 – Outline of activities planned for 2016

1. Introduction

Beside the activities further described below, ECHA will mainly focus on:

- Further increasing transparency and predictability of activities falling under the SVHC Roadmap by improving ECHA's website by having all substances of potential concern in one place. To this end the PACT will be expanded to cover in addition to substances under RMOAs and under informal PBT or ED hazard assessment also substances under substance evaluation (CoRAP) and under compliance check in the context of the CCH strategy to identify the substances that matter most.
- Develop the assessment approach for petroleum/coal stream substances with Member States, the Commission and industry and start the assessment of selected substances when relevant.
- Continue to build capacity within Member States to improve and increase the involvement in the screening and RMOA.

The work to review if some elements of the implementation of the SVHC Roadmap need to be adapted has already started and will be further discussed among ECHA, Member States and the Commission to be further reflected in the annual report to be published in 2017.

2. Screening

Activities in 2016 will mainly focus on further developing and improving the common screening approach mainly by integrating compliance check and implementing the changes related to the update of IUCLID.

More specifically this means that new substances will be proposed to be manually screened in 2016 by Member States based on the scenarios developed in the definition documents for the ongoing round of screening (third round of common screening). The scenarios proposed as well as an indication of the timelines are available on ECHA's website[8]. Examples of such scenarios are:

- Terrestrial toxicity scenarios to further support the bioaccumulation potential for terrestrial organisms reflected in the log K_{OA};
- SVHC supplementary activities for identifying potential PBT and ED substances based on structural similarity;
- Scenarios for human health that incorporate external lists and assessments made by several other bodies and regulatory authorities have been added. These include, for instance, the IMAP assessments made by the Australian Government Department of Health and the ISSTOX Chemical Toxicity Database;
- Scenarios that integrate the toxicity prediction tool (e.g. the Derek Nexus toxicity prediction tool);
- Additional scenarios to identify substances having potential endocrine disruptors properties (e.g. ToxCast assay results that are relevant for endocrine disruption, Danish QSAR database, use of keyword search in IUCLID free fields and chemical safety reports);
- Additional scenarios for the detection of substances likely to cause mutagenicity.

The newly developed scenarios will be implemented in the common screening only in 2017 for practical reasons.

Due to the upgrade of IUCLID to IUCLID 6.1, there will not be new scenarios implemented in 2016 (fourth round of common screening). The work will focus on developing scenarios for 2018 manual screening round (fifth round of common screening).

ECHA together with Member States will continue to further investigate different ways of screening such as identifying applications where high potential for exposure to human health and/or release to the environment is expected or how to better identify substances of concern used in articles.

ECHA has started to considerably enhance the structural similarity approach to identify similarities among substances and together with Member States will investigate how to develop further the screening of groups of substances.

ECHA together with the coordination and expert groups will also further reflect on how to identify substances under the supplementary activities of the SVHC Roadmap and further clarify how to deal with skin sensitisers.

3. Generation of data and assessment

Based on the outcome of the manual screening performed in 2015 by Member States, some substances will be further assessed by the ED Expert Groups (no substances have been identified for further assessment due to PBT properties). In addition, several substances have been proposed for inclusion on the CoRAP[17] which was published in March 2016.

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 but also on the capacity and commitment of Member States.

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 progress 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 9).

This section aims to report on regulatory risk management activities. Activities are reported since the entry into operation of REACH in 2008. It should be noted that the impact of the SVHC Roadmap implementation on regulatory risk management activities in the early stages if implementation is to be interpreted with caution as part of the regulatory actions outlined below may still result from screening/RMOA activities before the SVHC Roadmap was implemented. There will be in most cases 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). Additional information on regulatory activities is available on a yearly basis in ECHA's General Report[34].

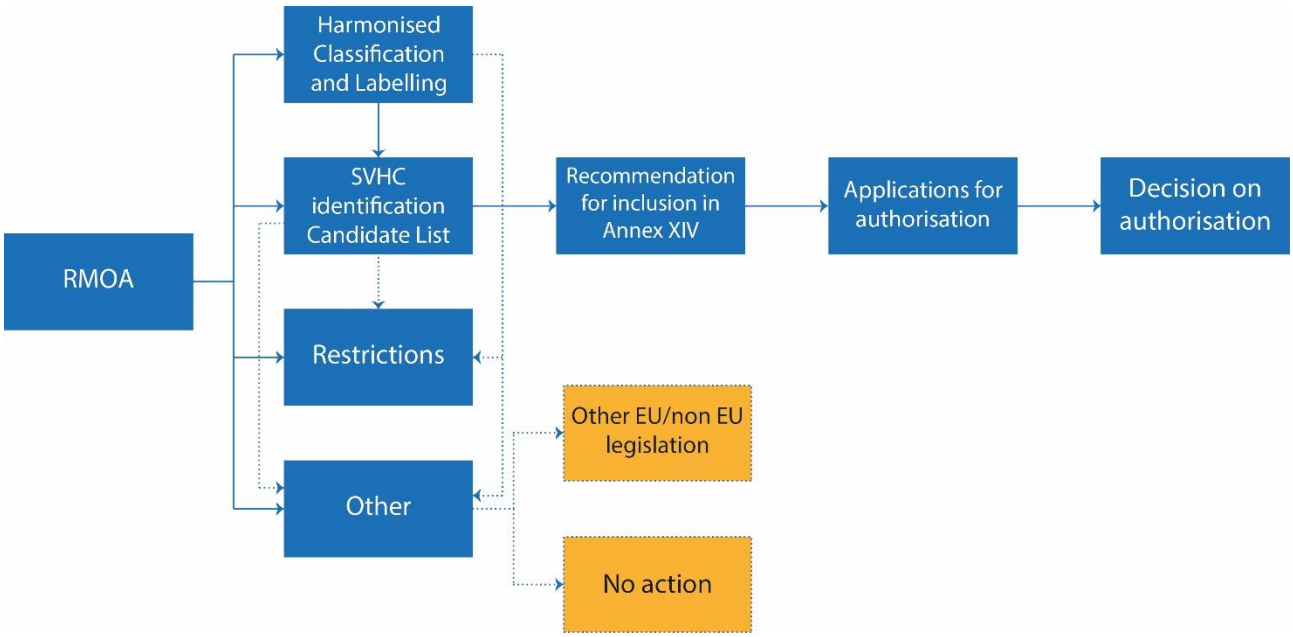

Figure 9: Overview of potential (regulatory) risk management after RMOA

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

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.

Figure 10 below reports numbers of proposals adopted by the Risk Assessment Committee (RAC) from 2009 until December 2015 and Figure 11 shows the number of proposals received[35] 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 REACH substances for which a classification for new[36] and existing CMRs[37] was adopted is also reported.

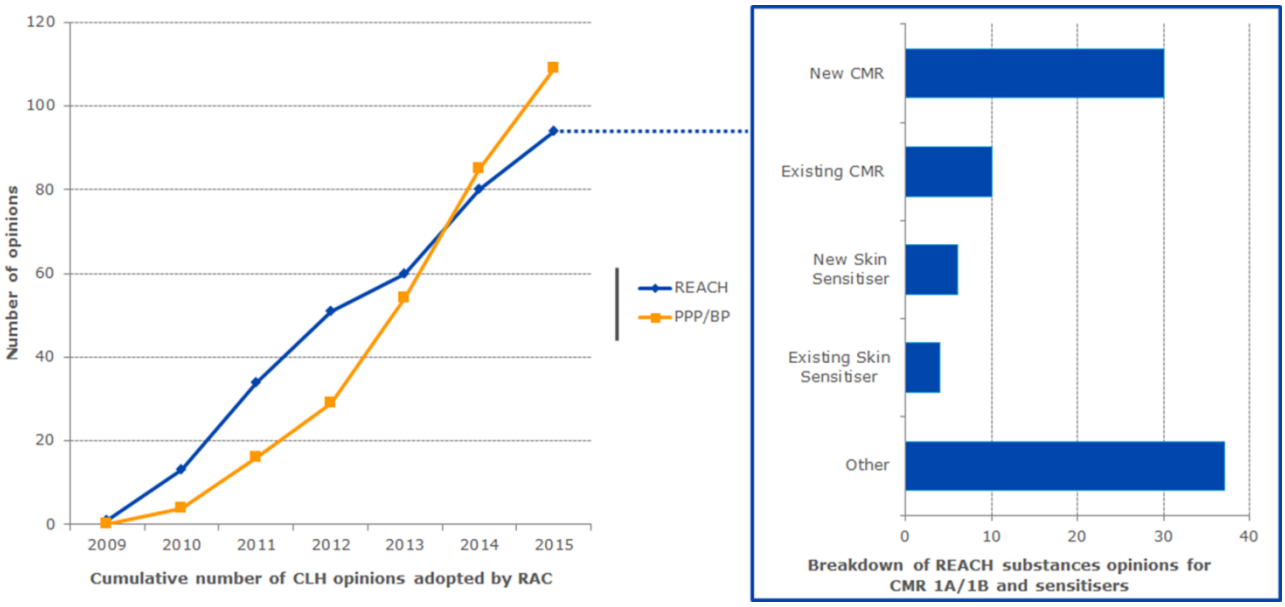

Figure 10: Numbers of CLH opinions adopted by RAC from 2009 – December 2015 and a breakdown of REACH substances for which a CMR 1a or 1b and/or sensitiser proposals was included.

Figure 11 gives an overview of Annex VI CLH dossiers submitted by each country.

[35] Proposals received mean that the dossiers were successfully submitted and ready for public consultation
[36] New CMR means the substances were not classified as CMR before.
[37] Existing CMR means the substances were already classified as CMR and the proposal was to amend something else than the CMR classification.

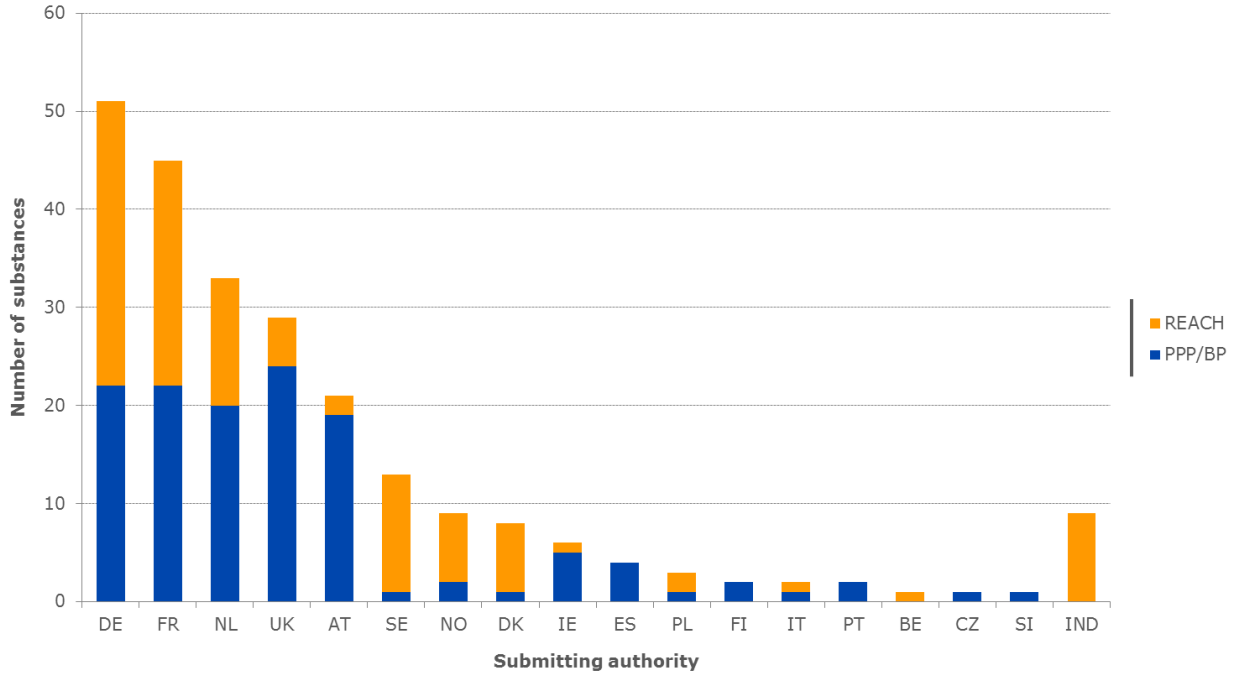

Figure 11: Number of CLH dossiers submitted per Member State that were found to be in accordance (2008 – December 2015)

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.

Table 5 gives the number of restriction proposals adopted or going through the restrictions process from 2009 until December 2015.

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	1	5	2[38]	0
Restriction process ongoing	1	0	0	0	1
Sent to Commission, but not yet in Annex XVII	2	0	4	0	1
Total (only the ones with substance scope in RoI)	**3**	**1**	**9**	**2**	**2**

[38] 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".

Figure 12 gives an overview of Annex XV restriction dossiers submitted per country.

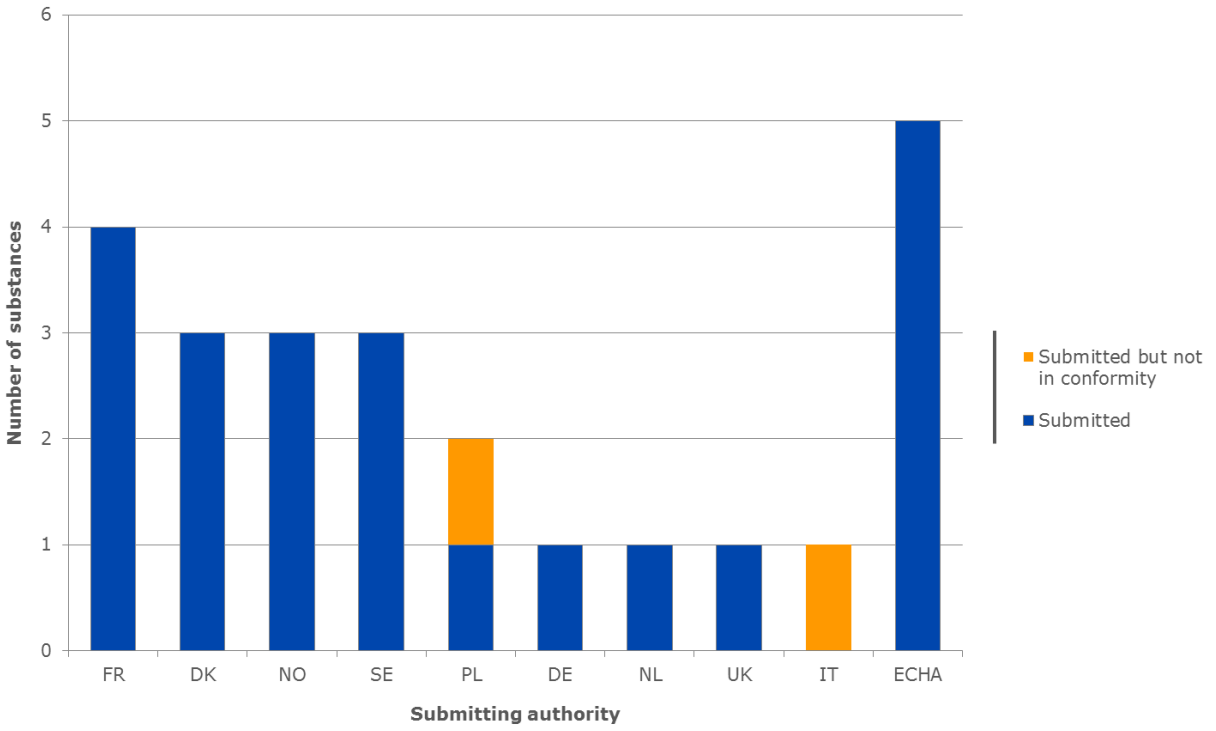

Figure 12: Number of restriction dossiers submitted per Member State and by ECHA (2009 – December 2015)

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 process[39].

Figure 13 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 2015. These numbers are further explained below in their respective sections.

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

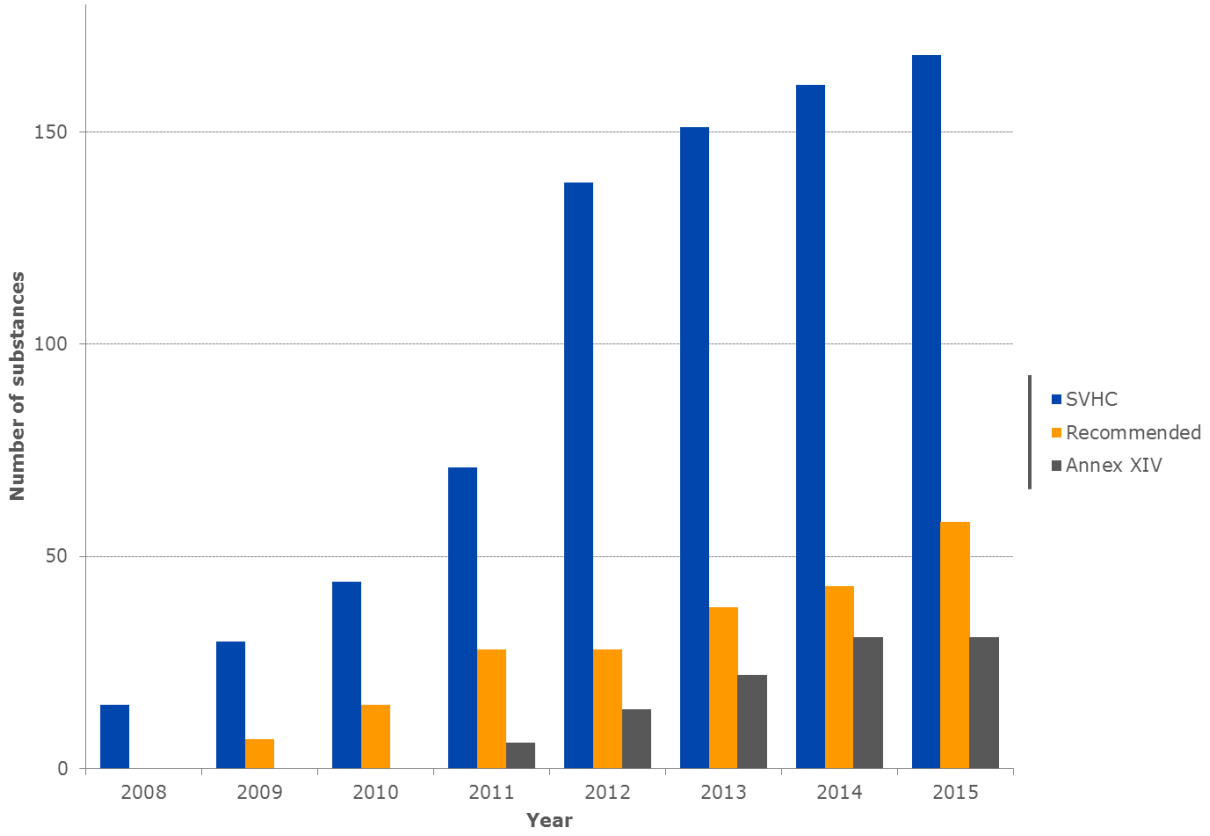

Figure 13: General overview of the number of substances on the Candidate List, recommended for inclusion in Annex XIV (Authorisation List) and included in Annex XIV.

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) (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.

Since 2008, a total of 168 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 14. Some substances cover more than one hazardous property as illustrated below.

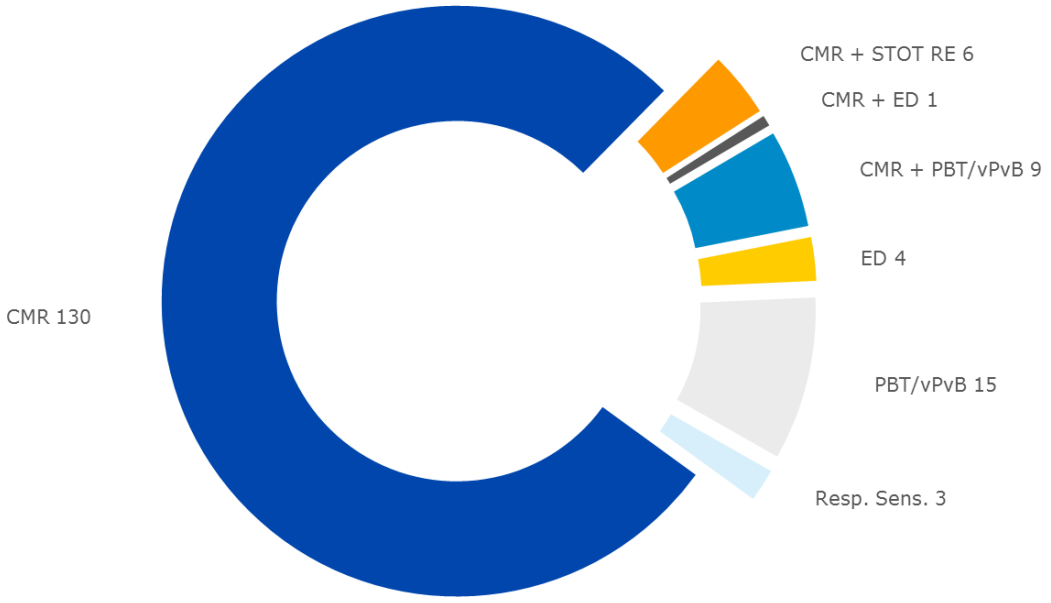

Figure 14: Substances on the Candidate List and overview of their hazardous properties

Figure 15 gives an overview of Annex XV SVHC dossiers submitted per Member State.

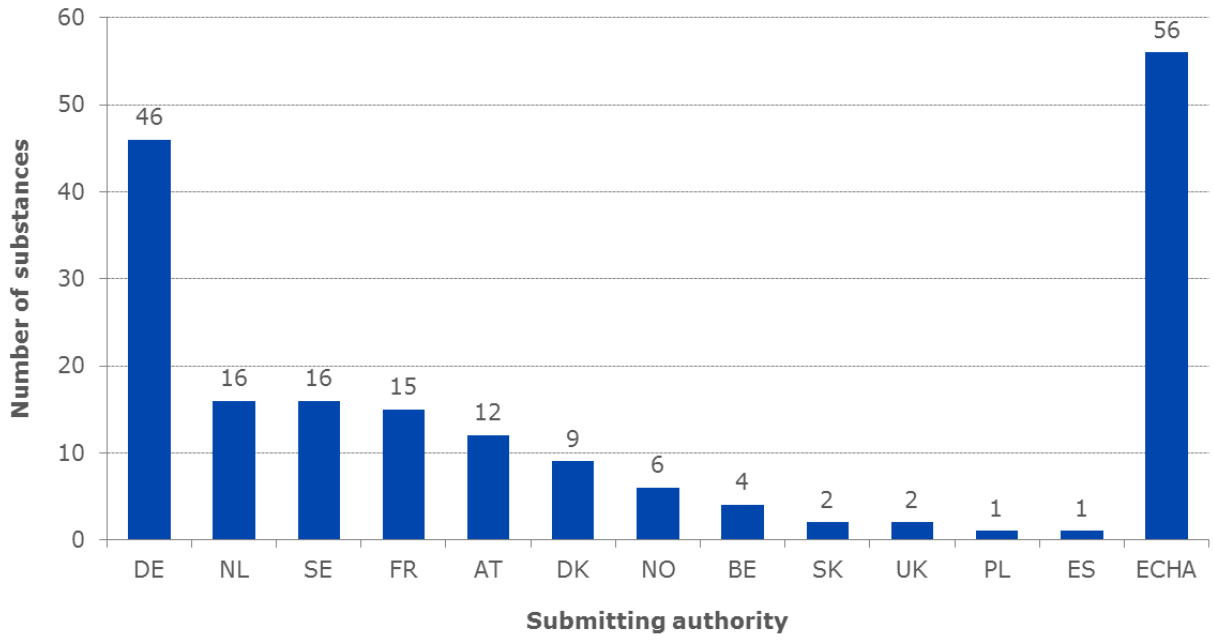

Figure 15: Number of Annex XV SVHC dossiers submitted per Member State and by ECHA.

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[40]. 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 sixth recommendation[41] was sent to the Commission in July 2015. The seventh recommendation is under preparation and is foreseen to be sent to the Commission in 2016.

Figure 16 and 19 give an overview of the properties of the substances recommended by ECHA to be included in Annex XIV until the sixth recommendation.

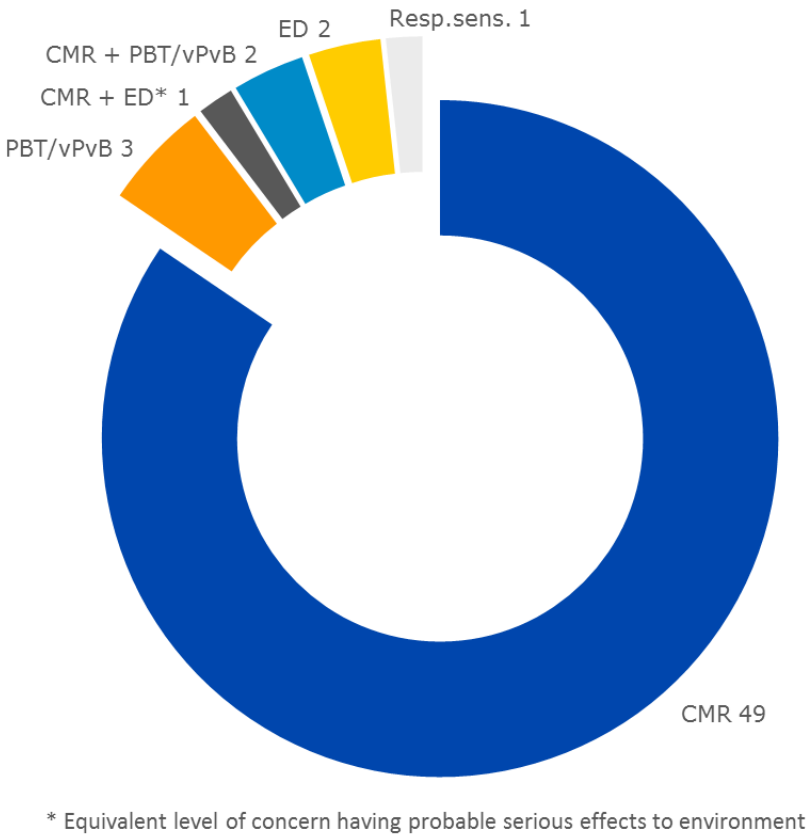

Figure 16: Overview of number and properties of substances recommended for inclusion in Annex XIV (2008 – 2015)

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

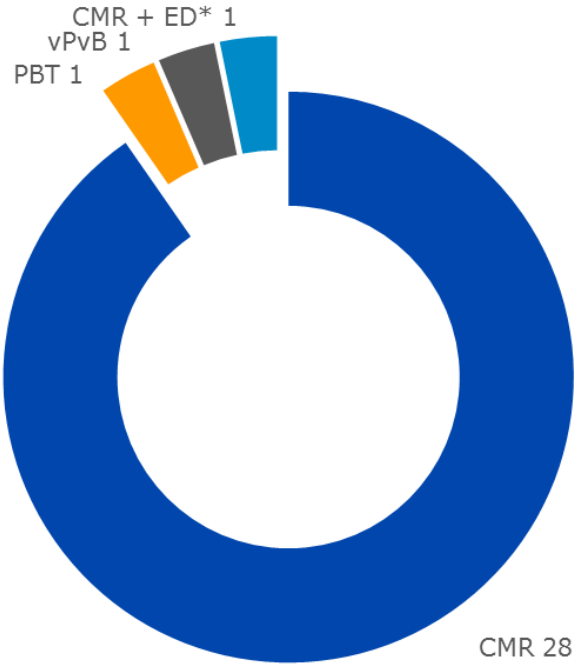

Figure 17: Overview of number and properties of substances included in Annex XIV (Authorisation List)

4.4. Applications for authorisation and decisions on authorisation

Once a substance is included in the Authorisation List (Annex XIV), companies must 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 applications for authorisation to ECHA.

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 2015 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 per use	Commission decisions per use
DEHP and DBP	CMR	8	10	17	17	5
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	-
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	13	15	19	19	2
Lead chromate		1	1	1	1	-
Chromium trioxide		3	15	9	-	-
Sodium dichromate		1	1	1	-	-
Sodium chromate		1	2	1	-	-
1,2-Dichloroethane (EDC)		1	1	1	-	-
Total		**34**	**63**	**68**	**56**	**14**

Conclusions

The different blocks of the SVHC Roadmap (i.e. screening, generation and assessment, RMOA) are now well in place and support the identification of substances that matter most. Focus of the authorities has moved from already harmonised CMRs to identification and further regulatory action on substances with other properties such as PBT and ED. This said, many new potential CMRs are also under scrutiny.

In the first annual report, it was difficult to differentiate activities resulting from the implementation of the SVHC Roadmap compared to activities started before. In this second report, the **impact of the SVHC Roadmap work starts to be more visible**.

RMOAs concluding on the need to identify the substance as an SVHC represent half of the RMOAs concluded and those RMOAs are followed up by the submission of an Annex XV dossier for identification of a substance as an SVHC. Many RMOAs still cover CMR properties; however, there is also a clear increase of other properties (e.g. ED). The fraction of Annex XV dossiers that propose to identify substances as SVHCs on the basis of PBT or ED properties is also increasing.

In 2015, **increased transparency and predictability** has been one of the aims of the work with the update of ECHA's website with the addition of information in PACT on informal hazard assessment but also more information on the screening process and scenarios. Links between activities and lists of substances available on ECHA's website have also been clarified and allows the typical journey for a substance through the different steps of the SVHC Roadmap and further regulatory processes to be understood.

Screening takes place at a very early stage in this journey and therefore the list of substances to be manually screened by authorities is not available on ECHA's website. However, to increase transparency and predictability, ECHA has launched a letter campaign to inform registrants that their substance is under scrutiny. Such initiative has been well received and the feedback received has been used to improve the campaign for substances short-listed in 2016. This campaign gives registrants the opportunity to ensure that their registration is up to date (particularly on uses and exposure information) at a very early stage allowing both authorities and industry to focus resources on those substances that matter most.

Finding good candidates for further regulatory action is a challenge mainly due to the **lack of relevant exposure and uses information** in registration dossiers. The letter campaign is one way to gather more information and to enhance awareness of industry on the importance of uses and exposure information. ECHA together with the Member States will also continue to investigate other ways of screening and identifying substances that matter most, for instance, by enhancing cooperation with industry sectors in identifying applications and materials resulting in high exposure.

REACH and CLP processes have been **further integrated by including the compliance check (CCH)** in the common screening and through the further development of the regulatory strategy on "safer chemicals focusing on what matters most". Substances of potential concern identified by Member States through the common screening and requiring generation of data through compliance check have been addressed by ECHA. In 2015, 107 compliance checks concluded by ECHA addressed those high priority substances and 82 % lead to a draft decision requiring information on higher tier endpoints to clarify, for instance, the potential for toxicity to reproduction, mutagenicity or PBT concern.

The number of substances discussed in the ED expert group has increased compared to the last report and like for the PBT expert group most potential ED substances proposed by Member States to be included in the CoRAP or for which a dossier to identify the substance as being a substance of very high concern (SVHC) are first discussed in the expert groups.

The expert groups clearly support and streamline the assessment of substances with **PBT and ED** properties but also allow clarifying at an early stage those substances that do not contain these hazardous properties in order to focus the attention of decision-making processes to those substances of concern.

RMOA is a standard approach to enhance a common understanding between authorities on the need for and type of further regulatory action.

Half of the RMOAs concluded so far propose as a follow up to identify the substance as an SVHC which is a clear increase compared to last year. The other half identifies either the need for other REACH/CLP regulatory risk management (e.g. restriction) or the need of other regulatory risk management such as the use of other regulation than REACH. This demonstrates that the SVHC Roadmap supports not only the identification of substances to be included in the Candidate List but goes further in identifying also the need for regulatory action outside REACH/CLP processes.

In 2015, the average RMOA target of 55 substances per year has been achieved as 44 new RMOAs intentions (covering 42 (groups of) substances) have been included in PACT and 25 RMOAs have been concluded.

Most of the substances require further information to clarify their potential hazardous properties and are at the stage of generation of data and assessment (Figure 18 below). For potential CMRs, proposals for harmonised classification and labelling (CLH) will also need to be prepared. It is of utmost importance that substances coming from compliance check, substance evaluation, expert groups and CLH are followed up by authorities through RMOA and later on through further regulatory action when relevant.

In conclusion, the implementation of the SVHC Roadmap has been strengthened in 2015 and the impact of the implementation starts to be visible at all steps (screening, data generation and assessment, RMOA). It is and will remain very important to keep in mind that all steps require time. Hence, there is a clear need to optimise the number and order of the steps, to carry out each step in a proportionate and fit for purpose manner but also to reduce time in between processes to avoid undue delay in taking action in order to achieve the 2020 goals.

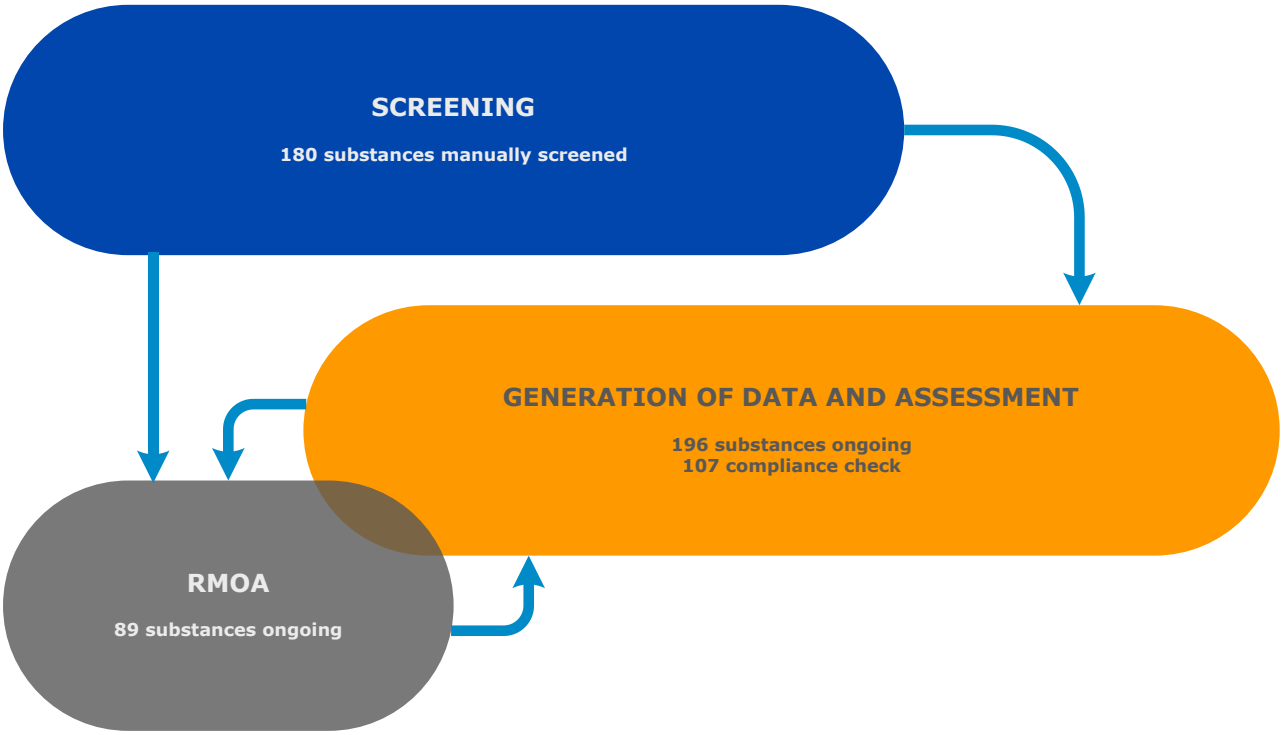

Figure 18: Overview of the number of substances under each of the main steps of the SVHC Roadmap[42].

[42] Please note that there may be overlap between the 196 substances under either SEv or expert groups and those under CCH as CCH may target other endpoints that those under SEv or the expert groups

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