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Roadmap on Substances of Very High Concern

Introduction

In 2010, Vice-President Tajani and Commissioner Potočnik committed to have **136 Substances of Very High Concern** (SVHCs) on **REACH candidate list** by **end of 2012**. The list is the first step in selecting substances to be subject to authorisation.

Thanks to the joint efforts of Member States, Commission and ECHA, this commitment was met in December 2012 and 138 SVHCs are now included in the candidate list.

Considering the long term, Vice President Tajani and Commissioner Potočnik have agreed to **have all currently known SVHCs included in the candidate list by 2020.** This second commitment means that by 2020, we will need to analyse the information on a large number of substances, not only to determine the relevance of SVHCs that are known today, but also to identify new potential SVHCs that will come out of REACH registration and evaluation.

The roadmap on Substances of Very High Concern for 2020

To achieve this objective, the Commission, with the collaboration of ECHA, drafted a Roadmap, which was discussed with Member States Competent Authorities for REACH. All competent authorities recognised the need for a Roadmap. Comments from competent authorities were taken into account in the version attached.

With the Roadmap, the Commission intends to define a process to identify and assess the following categories of potential SVHCs:

- CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction),
- PBTs (substances that are Persistent, Bioaccumulative or Toxic for the Environment),
- vPvBs (substances that are very Persistent and very Bioaccumulative),
- substances of equivalent concern (such as endocrine disruptors or sensitisers).

The Roadmap describes how to examine the substances that may belong to one of the above categories, by giving priority to those that have been registered and are not used only as chemical intermediate. Potential SVHCs excluded by this selection could still be considered after 2020. The Roadmap aims to improve planning, predictability, communication and to define responsibilities and deliverables.

The Roadmap is based on the Risk Management Options (RMO) approach. Consistent with the principles of better regulation, the RMO identifies the best regulatory option to manage the risk, either in REACH (authorisation, restriction or substance evaluation) or outside of REACH (with another legislation).

Next steps

The Commission considers that the 2020 objective can only be met if all actors involved co-operate to ensure an appropriate sharing of the workload. The Commission therefore invites Member States to work together with the Commission and ECHA on SVHC identification. ECHA and the Commission will continue to contribute by providing assistance, coordination and sharing experiences with the Member States.

Annex: Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020



EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL

Water, Marine Environment & Chemicals

Chemicals, Biocides and Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Resources Based, Manufacturing and Consumer Goods Industries

REACH

Chemicals Industry

Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020

Objective

In 2010, Vice-President Tajani and Commissioner Potočnik committed to "**have all relevant currently known Substances of Very High Concern (SVHCs) included in the candidate list by 2020**". In a letter sent to Member States in August 2012, the two Commissioners restated this commitment and underlined their will to continue working with Member States to develop a roadmap by the **end of 2012**. Additionally, they stated that the roadmap "should build on the RMO[1] framework, setting out clear milestones, deliverables and division of work between the Commission, Member States and the European Chemicals Agency".

[1] Risk Management Option.

In defining the Roadmap, it is fundamental to remind that the aim of the authorisation process, as stated in Article 55 of REACH, is "to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable".

In a preliminary discussion, a number of Member States Competent Authorities for REACH expressed support for the idea of developing the Roadmap together with the Commission and ECHA. Furthermore, they expressed the ambition to have a broader scope for this Roadmap.

The starting point remains the Commissioners' commitment to identify and include in the candidate list all SVHCs, relevant for the European Union, by the end of 2020. By doing so, as explained in this document, Member States, ECHA and the Commission will also be able to ensure progresses in other areas of REACH (for example, restrictions). Moreover, they will efficiently use information deriving from other REACH processes (registration, dossier and substance evaluation) for identifying needs for regulatory risk management, assessing the most appropriate action to address concerns and initiating regulatory risk management processes.

Introduction

Achieving the objectives of the Roadmap would need the collaboration of Commission, ECHA and all Member States. **The involvement of all the actors in drawing up the Roadmap would therefore be crucial for its successful implementation.**

The Commission considers that **no numerical goal** should be identified in the Roadmap **for the number of substances that will be included in the candidate list**, as it cannot be pre-judged how many or which substances will be identified as relevant SVHCs. Rather, the Roadmap should focus on presenting a credible process to ensure the 2020 objective: defining a process or methodology, with clear deliverables, on how to assess the different groups of potential SVHCs (CMRs,[2] PBTs,[3] vPvBs,[4] endocrine disruptors, respiratory and dermal sensitisers, etc.) from now to 2020. The Roadmap could include an estimation of the number of substances we are aiming at assessing by 2020, to facilitate the calculation of the resources needed to achieve the goal.

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2 Carcinogen, Mutagen, Reprotoxic.
3 Persistent, Bioaccumulative, Toxic.
4 Very Persistent, Very Bioaccumulative.

The Commission hereby defines a roadmap which:

- has a **clear planning** (what are the priorities for screening and RMO assessment of the different groups of potential SVHCs from now to 2020);
- is **predictable** as much as possible (e.g., by making publicly available the substances that will be RMO assessed; by providing the indicative number of substances to be RMO assessed per year);
- is a **rolling exercise** that takes into consideration new information (e.g., newly classified CMR, new and updates of registration dossiers);
- has a well-defined **list of responsibilities** (e.g., by defining (a) group(s) of MSs that volunteer to focus on a specific group/category of SVHCs; by defining the role of ECHA in facilitating the screening and RMO assessment exercises);
- will form a strong basis for further work on SVHC assessment and identification **beyond 2020**.

The Roadmap is without prejudice to the aims or legal provisions of REACH. All Member State competent authorities indicated their willingness to co-operate in creating such Roadmap.

What has been already achieved?

Considerable progress has been made to achieve the Commissioners' commitment of 2010. The main actions are listed below.

- From 2008 to 2012, 138 substances have been included in the Candidate List.
- Member States, the Commission and ECHA agreed in January 2009 to carry out so-called RMO analyses in order to:
    - support the decision-making on which risk management route should be followed and
    - share the conclusions with all parties before submitting Annex XV dossiers.

- From 2010 to 2012, RMOs for around 160 substances have been prepared and shared between MSCAs[5], Commission and ECHA.
- RiME[6] meetings have been set up to discuss technical and scientific issues and to enhance co-operation on screening and RMO assessment.
- Registered CMRs have been screened and results of the different screening exercises combined and shared.
- The screening of potential PBTs and vPvBs and the work on assessing the needs for and generating further information needed for the identification are progressing, thanks to the establishment by Member States and ECHA of a technical working group (PBT Working Group).
- Work has started for the identification of SVHCs falling under Article 57(f) of REACH ("substances of equivalent concern" to CMRs and PBTs), focusing on sensitisers and endocrine disruptors. This work will lead, in the future, to the identification of less known and less regulated SVHCs.

How to approach the 2020 goal? Screening and RMO assessment

With reference to the objectives outlined above, it is important to agree on the meaning of the word "**relevant**".

The Commission believes that, for an efficient use of resources, there is a need to define criteria for selecting the substances that are relevant to for identification as SVHC from the pool of SVHCs.

5 Member State competent Authorities.
6 Risk Management Expert.

The criteria to define if a SVHC is relevant are based on the screening of the registration dossiers as a first step and on the RMO assessment as a second step. Potential SVHCs excluded by the application of these criteria could still be considered after 2020 on a case-by-case basis.

In the Commission's view, a relevant SVHC is a substance that fulfils Article 57(a) to (f) and meets the following criteria:

Screening step: criteria that can be applied using the information from ECHA registration database and other available and relevant data.

1. Shows some evidence of being produced and/or used in Europe in relevant quantities.

   This criterion will be, in most cases, fulfilled by **already registered substances or substances that will be registered by 2020**.

   There might be however cases in which non registered substances can still be considered relevant for identification. One example might be a substance that is currently not produced or used in Europe, but might be used as an alternative to another relevant SVHC. This exemption is particularly relevant when the most appropriate approach is the category approach (i.e., analogous substances).

2. Has not only been registered for **intermediate uses**.

   There might be however cases in which substances registered only for use as intermediate can still be considered relevant for identification. This might happen when a category approach is proposed (see above).

   An additional case is that of a substance known to have a non-intermediate use (*e.g.,* uses which should have been but were not registered) in the EU or with a use reported in the registration which does not comply with the intermediate definition. In such cases, MS should initiate enforcement actions, including the update of the dossier, allowing considering the substance as relevant.

RMO assessment: the questions that will be reflected in the RMO assessment phase for the SVHCs prioritised from the screening step should cover the following aspects:

3. The available information does not, *prima facie*, demonstrate that there is a **risk** that is not adequately controlled and needs to be addressed at EU level. For those uses that have a demonstrated risk, according to Articles 69(1) and 69(4), a **restriction** process should be started[7].

   Information demonstrating the need to initiate a restriction process should make use, as a minimum, of CSRs submitted in the registration dossier, Risk Assessment Reports and, where available, results of substance evaluations. Other information that could be used if available[8]:

   - clear evidence that, for at least one use, the exposure level is above the PNEC, DNEL, DMEL or OEL (binding or indicative),[9] based for example on enforcement reports from Member States,
   - RAPEX notifications for consumers articles,
   - emission to the environment of PBT/vPvB substances.

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7 This does not preclude using the authorisation process for the remaining uses when the annex XV dossier is finalised. The final decision on the route to follow (authorisation and/or restriction) for each uses of the substance will be a case by case one, based on the relevance of the different uses of the substance. The RMO assessment will serve the purpose to document the choice.

8 The intention is that the workload should be very limited and should not entail any literature research. To this end the wording needs to be further developed to reflect that applying this criterion must remain simple and easy.

9 Predicted No Effect Level, Derived No Effect Level, Derived Minimal Effect Level, Occupational Exposure Limit.

4. The known uses of the substance:

    - are not **exempted** from the authorisation requirement on the basis of Article 2(5) or Article 56(3), (4) or (5) or Article 60(2),
    - are not **already regulated by specific EU legislation**[10] that provides a pressure for substitution, leading to the conclusion that no further regulatory action is needed under REACH.

An **exception** from **criteria 3 and 4** is foreseen for:

- Substances fulfilling Articles 57(d) or (e) (PBTs and vPvBs),
- Substances fulfilling Article 57(f) for a hazard property without harmonised criteria in Annex I of CLP (for example, endocrine disruptors).

In such cases, the Commission believes that, irrespective of the RMO chosen, an official SVHC identification as such by the Member States Committee (MSC) via an Annex XV dossier could be foreseen. If a restriction is considered necessary, then the SVHC identification through the MSC will avoid the need to discuss the hazard properties in the restriction process. In this case, the substance would therefore be included in the candidate list even if a restriction is foreseen. However, this does not apply if the RMO concluded that there is no need for further regulatory action under REACH.

[10] Examples of legislation that can be considered in the application of this criterium are Directive 2002/95/EC on electrical and electronic equipments (RoHS) and Directive 2000/53/EC on End of Life Vehicles (ELV).

Other reasons might exist to deviate from the criteria 1 to 4. For example, SVHCs extensively present in consumers' articles (including imported ones) could still be considered relevant for the purpose of collecting information according to Articles 7(2) and 33 of REACH.

As a consequence of the process defined above, the RMO assessment is a voluntary but critical step in the definition of the relevance of a SVHC. Its role in the decision on the need and the choice of a Risk Management Measure for a specific substance allows extending the Roadmap to considering other options beside SVHC identification by inclusion in the Candidate List.

The level of detail needed to reach a conclusion in the RMO will depend on the complexity of the case and the available information. In any case, the Authority drafting the RMO will decide on the necessary level of detail. The minimal information should include inter alia:

- what the concern identified for the substance is, including a *prima face* screening evaluation if there are risks which are not adequately controlled
- if and how the substance is already regulated
- what the relevant REACH RMOs are
- what the most suitable RMO is and why
- what the planned time-schedule is.

While evaluating criteria 3 and 4, the conclusion on the need for other RMOs (under REACH or outside REACH) could be reached. Indeed the RMO assessment could conclude that the available data are not sufficient to identify the substance as SVHC or to choose the best RMO. In such cases, dossier or substance evaluation could be foreseen.

Since the RMO assessment serves the purpose of documenting if the criteria above are fulfilled, it shall be, normally, shared with MSCAs and COM/ECHA prior to the submission of an Annex XV SVHC identification dossier. The RMO could be updated after the substance has been included in the candidate list and prior to its inclusion in Annex XIV in the cases where the public consultations provide new information that could potentially lead to a change in the RMO conclusion.

The proposal for a Roadmap to achieve the 2020 target

Resources and workload

The Commission made a preliminary, worst case estimation of **440** substances to be RMO assessed between 2013 and 2020. This would require developing around 55 RMOs per year.

In the years from middle 2009/end 2012, RMOs for around **160** substances have been prepared by ECHA and MS and **138** substances have been included in the Candidate List.

A mid-tem objective is that around 80 substances, in addition to the substances already assessed and/or listed today in the candidate list, will be subject to a RMO by the end of 2014. This number is below the estimation of 55 RMOs/year because the Commission considers that, in 2013, resources will be needed to prepare the implementation of the Roadmap.

Resources are also needed:

i) to ensure that sufficient information is generated on the PBT/vPvB and endocrine disruptor properties to allow comparison to the criteria in Annex XIII and future endocrine disruptor criteria,

ii) to assess whether sensitisers can be regarded as substances of equivalent concern,

iii) to screen the registration data base to conclude whether the criteria for being 'relevant' are met,

iv) to prepare and process the Annex XV SVHC dossiers,

v) to prioritise substances from the Candidate List and recommend their inclusion in Annex XIV.

Furthermore, resources are needed for preparing and processing Annex XV restriction dossiers, where restriction is regarded as a more appropriate approach, and for processing the authorisation applications.

The objectives of the Roadmap could be achieved by a series of actions.

- Ensure adequate resources in ECHA and MSs to work on SVHC identification and RMO assessment.
- Agree on how to share the work among MSs, Commission and ECHA (on the basis of resources and national interest); ECHA could make a regular check on the progress and MSs and ECHA would report on them during RiME meetings;

- Report annually to the meetings of CARACAL[11] and MSCA directors at ECHA;
- Further develop and intensify the work and co-operation for a more efficient use of resources.
    - Use information coming from other REACH processes (registration and evaluation) and limit additional data collection for RMO preparation. Dossier and substance evaluations will likely play an important role in the identification of PBTs, vPvBs and endocrine disruptors.
    - Focus and simplify the RMO assessment. Consolidate and further develop the different tools and templates used for RMO assessment, including lists of questions to be answered. The specific needs of the different groups of substances could be considered.
    - Make full use of the flexibility in the RMO process. This includes, for example, the possibility to update it based on new information and the possibility to change MS/ECHA sponsorship of the particular substance(s) throughout the process, in full respect and information exchange between MS/ECHA/COM.
    - Consider grouping of substances for RMO assessment based on the properties and uses.
    - Develop further screening methods and practices.
    - Increase the duration of RiME meetings to ensure a follow-up of the Roadmap and to discuss more practical aspects (such as RMO templates, screenings, communication).

- Consider the need for establishing an expert group for endocrine disruptors (similarly to what is done for PBTs).

[11] Competent Authorities meeting for REACH and CLP.

Timeline

ECHA will develop a more detailed proposal for the implementation and monitoring of the Roadmap from 2013 to 2020 and how to organise the different steps (data gathering, screening, RMO assessment) for the different groups of SVHCs. Some initial indications for groups of substances that could be covered and possible timelines for carrying out the necessary assessment work are indicated below.

For **CMRs**, the screening of the registration data will be regularly repeated (the intervals to be agreed) and there is a need to develop an approach to assess the petroleum streams (approach 2013-2015, systematic assessment from 2016).

For **sensitisers**, effort will be needed to identify, on a case by case basis, which of the classified ones would fulfil the "equivalent level of concern" criterion. The work could start with the respiratory sensitisers which, according to the current approach, are more likely to fulfil the equivalent level of concern criterion. The assessment of skin sensitisers could follow (2013-2020).

As far as **PBTs and vPvBs** are concerned, all PBT and vPvB substances identified by the PBT expert group should be RMO-assessed. Data from 2013 registration deadline (possibly 2018) should be used to identify potential PBT and vPvB for consideration by the PBT working group. In many cases, we can anticipate the need for additional information, to be generated using dossier or substance evaluation (2013-2017). Assessment for inclusion in Candidate List could start gradually.

A strategy to screen and to prioritise UVCBs/MCSs[12] with PBT properties should be developed by the PBT expert group.

[12] Substances of Unknown and Variable Composition, Complex Reaction Products and Biological Materials/ Multiconstituent Substances.

For **endocrine disruptors**, the EU database (Endocrine Active Substances Information System) should be screened once the criteria are available (starting from 2014 for screening, 2015 for assessment of the fulfilment of the criteria). The need for additional information to be collected via dossier or substance evaluation can be anticipated. It should be considered if an ad-hoc working group needs to be established (as done for PBTs). The RMO assessment would be conducted from 2015 to 2020 on the substances passing the first screening (registered and not only intermediate) and fulfilling the endocrine disruptor criteria.

Until 2020, the registration and the intermediate status for all potential SVHCs excluded with the screening should be checked regularly.

In addition, MSs should continue to develop harmonised C&L dossiers for identifying new CMR and respiratory sensitisers. Newly classified substances should be considered for screening and possibly RMO assessment.

Communication

To document the actions made to achieve the target, the following information could be considered for publication:

- a report on how MS and Commission have selected the relevant SVHCs, including the non-confidential results of the screening for the different groups of substances;

- an annual list of all the substances RMO-assessed. Subject to the agreement on an appropriate communication strategy, the conclusion of the RMO assessment could be made available to the public;

- follow-up actions until and after 2020 (for example, refine the preliminary screening on the basis of new registration information, assess new PBTs, CMRs or EDs).

It will be important to define and target the information to be made available to the public to achieve the objective to have a predictable Roadmap.

In general the RMO is not meant to be made public and no consultation of stakeholders is foreseen. However, the Authority drafting the RMO can consider if the publication and consultation of stakeholders is appropriate.