EUROPEAN COMMISSION

Directorate-General for Environment
Circular Economy and Green Growth
Sustainable Chemicals

Directorate-General for Internal Market, Industry, Entrepreneurship and SME's
Chemicals and Consumer Industries
REACH
Chemicals and Plastic Industries

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37th Meeting of Competent Authorities for REACH and CLP (CARACAL)

Open session

17-18 November 2020

Concerns: **SVHC Roadmap Closure**

Agenda point: Information Point 4

Session: REACH

Action requested: Member State Competent authorities and observers are invited to take note of enclosed document

Written comments to this document should be sent to *rime@echa.europa.eu* by *07.01.2021*.

SVHC Roadmap 2020 – achievements beyond expectations

This document finalises the implementation of the SVHC Roadmap 2020. The main achievements, including that the aim to have all known SVHCs included in the Candidate List has been achieved, have been reported already in previous annual reports. Therefore, this can be seen as a closure of the roadmap implementation work and will be published as an "in-brief", i.e. a four pager where only the most important key messages and results are included with supporting images and graphs aimed at stakeholders and the public alike. This document contains the text that has been drafted for the report. Once the document is finalised, it will be placed in an in-design format. The final in-brief is planned to be published in Jan 2021. ***All numerical outputs will be included in January 2021****.*

Background

From the commitment of having 136 Substances of Very High Concern (SVHCs) on the Candidate List for Authorisation by the end of 2012, Member States, the Commission and ECHA moved to a more ambitious goal of having **all relevant currently known SVHCs identified and included on the Candidate List by 2020 and to put in place a process to identify any new potential SVHCs**. The Roadmap for SVHC identification and implementation of REACH risk management measures to 2020 (SVHC Roadmap, February 2013) was established in order to ensure that this goal could be reached. Its aim was to support authorities to deal with a large number of substances efficiently by improving planning, predictability, communication and by defining clear responsibilities and deliverables. No numerical goal was set, rather the Roadmap was expected to deliver a credible process and methodology to ensure that the objectives were met.

The **regulatory management option analysis (RMOA)** has been central in the implementation of the SVHC Roadmap. RMOA helps authorities clarify whether regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern either under REACH, CLP or other EU legislation, thereby extending the Roadmap to considering other options beside inclusion in the Candidate List.

Relevant substances under the SVHC Roadmap were substances registered for uses within the scope of authorisation. This meant that priority was given to the substances on the EU market with consumer, professional and non-intermediate industrial uses. In addition, to discourage regrettable substitution, substances that were not registered or were registered as intermediates only, could be prioritised for further action if structurally similar to those regarded as relevant substances. **Currently known** substances were defined as substances for which hazard properties had been clarified and concluded as carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) or endocrine disruptors (EDs).

Achieving the objectives of the Roadmap was based on collaboration and sharing of work between Member States, the Commission, and ECHA. ECHA coordinated the

implementation of the Roadmap. Progress in implementing the roadmap has been reported every year in the annual report.

Core achievements[1]

1. **All currently known CMRs, PBT/vPvBs and endocrine disruptors** were included in the Candidate List or identified for other regulatory risk management measures (e.g. restriction); or considered as not requiring further regulatory risk management action at present. To date, xx substances have been included in the Candidate List (Fig 1). However, many of the screened substances lacked the necessary hazard information to conclude on their SVHC properties. Hence, more SVHCs are expected to be identified from the substances that are currently undergoing substance evaluation or dossier evaluation.
2. A robust and coherent **process for identifying new substances of concern through screening** and addressing them in a timely and effective manner with the most appropriate regulatory measures was established. In order to focus the resources of authorities and industry on substances that are most relevant for the protection of human health and the environment, a screening approach was developed. Since 2014, the full REACH/CLP substance database was screened to prioritise substances for which we can expect regulatory risk management measures to be needed. As an outcome of establishing such a process, most substances brought to regulatory risk management processes nowadays result from the work done under screening, RMOA, compliance check and substance evaluation. The RMOA approach has promoted early discussion and sharing of information among authorities and stakeholders and helped create a common understanding of the appropriate regulatory action to be taken. By the end of 2020, authorities had screened over xx substances (Figure 2) and carried out xx RMOAs for xx substances (Figure 3).
3. In order to speed up the identification of chemicals that need regulatory action, **authorities moved to addressing groups of structurally related substances rather than single substances**. The approach brings consistency and improves the coherence of regulatory opinions and decisions, ensures that substances that need regulatory action are identified more quickly (also those for which information on hazard and exposure is lacking), and makes the early identification of substances that do not require further action possible. Substances registered for intermediate uses only, or those not currently registered but which could be potential substitutes for known substances of concern, are also identified early on. The grouping approach supports the further integration of all REACH and CLP processes and the link with other legislation, helping to identify new SVHCs and allowing authorities to focus their resources and attention on substances that matter.
4. **Transparency and predictability** of authorities' assessments and activities under REACH and CLP was increased by making this information available to stakeholders and the general public on ECHA's website through the Public

[1] All numerical outputs to be included in Jan 2021

Activities Coordination Tool (PACT). By publishing the RMOAs, an early stage of authorities' assessment work, that had previously not been visible, was made publicly available.

5. A **coherent approach on how to prioritise and address petroleum and coal stream substances** under the SVHC Roadmap was developed by a dedicated working group with members from Member State competent authorities, the European Commission, ECHA and industry stakeholders. These substances had previously been postponed from consideration for potential further regulatory action due to the complexity in defining and assessing them (e.g. difficulties in concluding on the SVHC properties of these substances and their constituents). The implementation of the PetCo approach continues. Based on the experience gained, authorities are elaborating which regulatory actions can be used effectively and efficiently to manage substances containing constituents of concern.
6. An **expert group on endocrine disruptors** was established with the support of the competent authorities for REACH, CLP and biocides to provide consistent scientific advice related to the screening of potential endocrine disruptors and to the testing and assessment of endocrine-disrupting properties. **EU-wide criteria for defining endocrine disruptors** under the biocides and pesticides regulations and the related guidance have been taken into consideration in the assessment of substances under REACH. So far xx substances have been screened for ED properties and xx have been confirmed as being endocrine disruptors. Also, the **work of the PBT Expert Group has continued** throughout this period providing scientific advice on the identification of persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) properties of chemicals.
7. The Roadmap also provided an important EU contribution to the United Nation's 2030 Sustainable Development goals of reducing the negative impacts of hazardous chemicals and ensuring an environmentally sustainable management and safe use of chemicals.

Key background material

SVHC Roadmap to 2020
Authorities to focus on substances of potential concern (April 2018)
The approach on how to address PetCo substances
Integrated Regulatory Strategy Annual Report 2019

Graphs (placeholders, to be developed further)

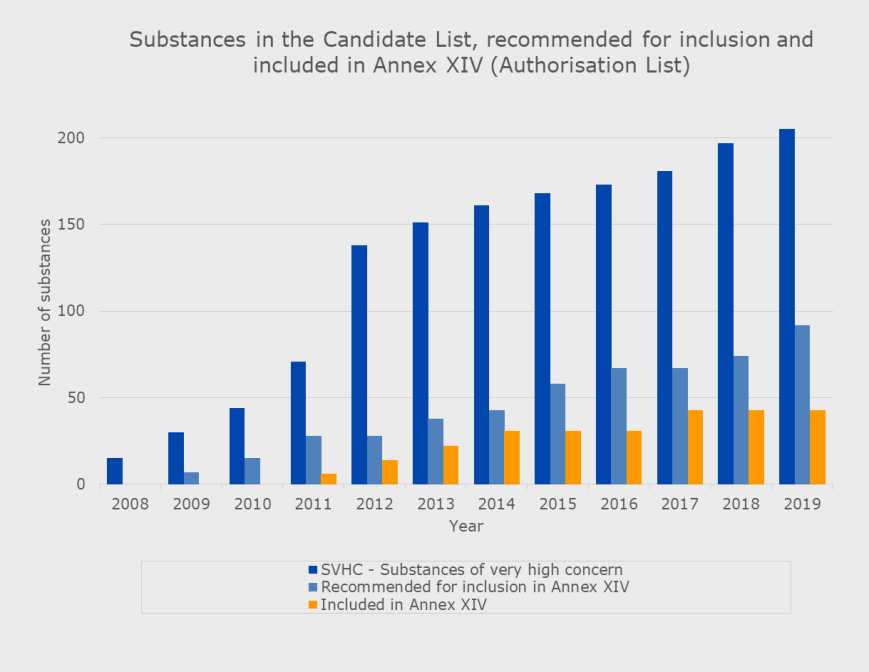

Figure 1. A figure to be developed to show the progress made in identifying SVHCs. ***To be updated with 2020 data.***

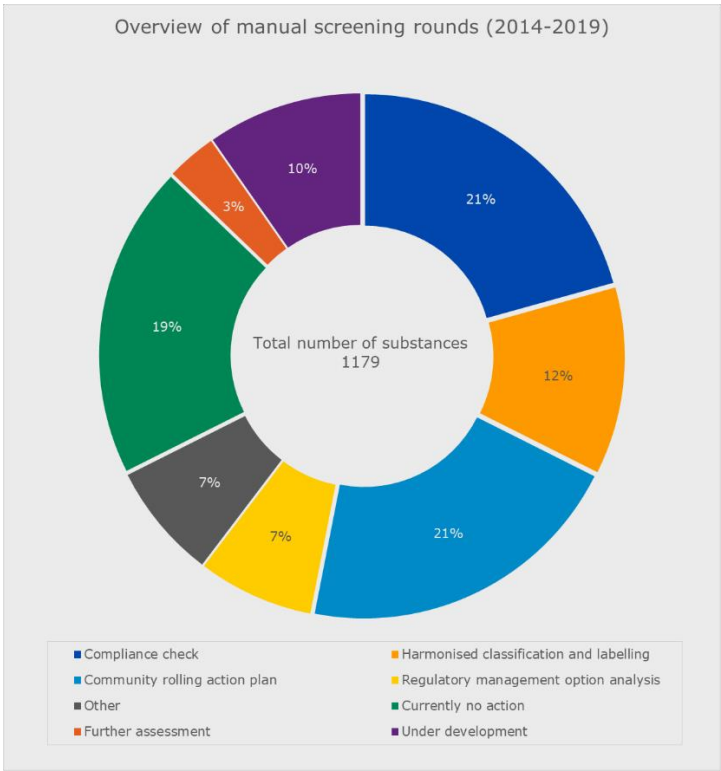

Figure 2. Outcome of screening until 2020. ***To be updated with 2020 data.***

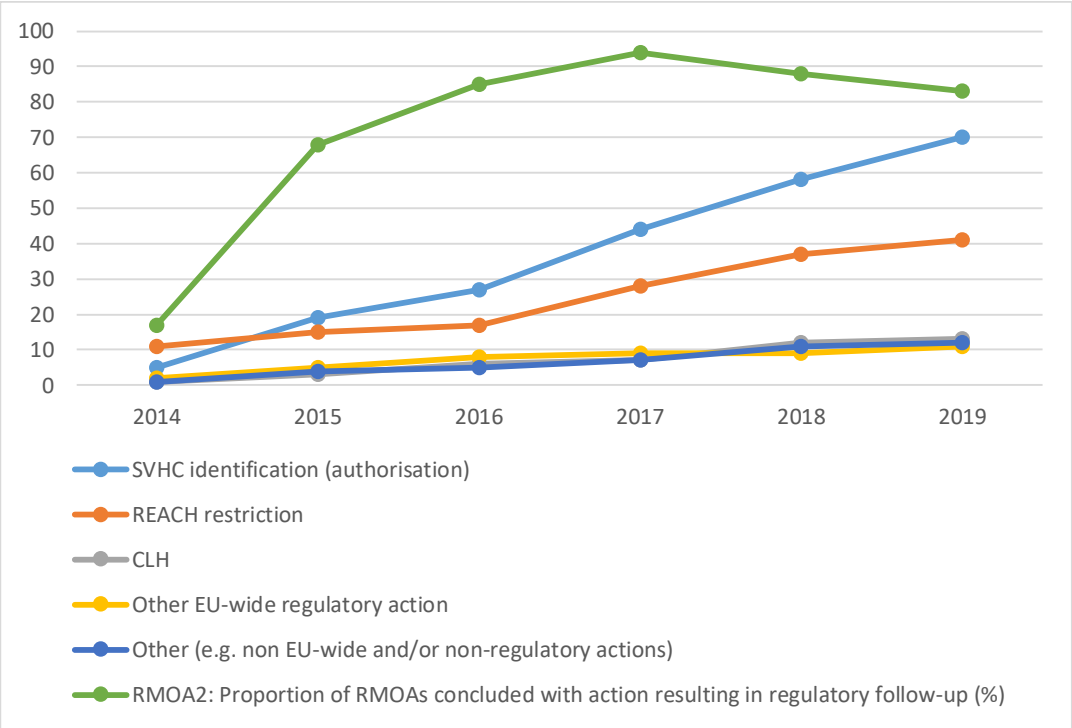

Figure 3. Cumulative number of substances for which an RMOA has been concluded per proposed follow-up regulatory action together with the progress monitoring indicator (RMOA2). To be updated with 2020 data.