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Progress with implementing the SVHC Roadmap

46th Meeting of the Management Board 21-22 June 2017

Key messages

The Management Board is invited to take note of the state of play of the Roadmap for SVHC identification and the implementation of risk management measures under the REACH.

The work on substances with confirmed SVHC properties has been completed. Those substances which are not included in the Candidate List or heavily restricted although they have harmonised classification as CMRs, are regularly scrutinised.

The screening and prioritisation for further data generation works well where the registration dossiers for the substances are of sufficient quality. However, for registered substances, not picked so far by the common screening, the lack of sufficient quality use information and of long-term effects is a major concern. Moving to work with groups of substances is one of the means to overcome this.

The outcome of a review of the Roadmap will be documented in the next annual report and serve as a basis for a discussion on future actions.

Background

In 2013 the Member States, the European Commission and ECHA agreed on the objective to have all relevant currently known substances of very high concern identified and included on the Candidate list by 2020. "The Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020" was endorsed at the Competitiveness Council (February 2013) and the Environmental Council (March 2013) meetings.

Rationale

ECHA's SVHC Roadmap implementation activities have evolved and now support the main elements of ECHA's integrated regulatory strategy. The implementation of the SVHC Roadmap will provide a strong basis for the work beyond 2020 to identify the substances which matter most and to timely and adequately address them with regulatory measures.

Attachment:

- Annex: Roadmap for SVHC identification and implementation of REACH risk management– State of Play

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Annex: Roadmap for SVHC identification and implementation of REACH risk management measures – State of Play

In 2013 the Member States, the European Commission and ECHA agreed on the objective to have all relevant currently known substances of very high concern identified and included on the Candidate list by 2020. "The Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020" was endorsed at the Competitiveness Council (February 2013) and the Environmental Council (March 2013) meetings[1]. The plan how to implement the roadmap[2] aims also to provide a strong basis for the work beyond 2020 to identify the substances which matter most and to timely and adequately address them under REACH and CLP.

1. SVHC Roadmap and ECHA's integrated regulatory strategy

The SVHC Roadmap implementation activities have evolved and now support the main elements of ECHA's integrated regulatory strategy[3]:

- Integrated selection and prioritisation of substances that matter for further regulatory work
- The mapping of the chemical universe, including drawing conclusions when substances are of low(er) priority for further work
- The effective use of compliance check and substance evaluation to fill in data gaps on substances that matter
- Increase dossier quality, e.g. by
    - letter campaigns to inform registrants already in the screening phase that their substance is under authorities' scrutiny
    - working with sectors (e.g. PetCo)
- Effective use of REACH and CLP regulatory risk management instruments to address the identified concerns
- Increased transparency by early information on the authorities work

One central new element introduced due to the SVHC Roadmap implementation is the common screening, which was developed and is used by ECHA in collaboration with the Member States and the Commission. The common screening ensures yearly screening of all REACH/CLP data, complemented with external data sources, and aims at identifying substances that matter most and for which further data generation via evaluation processes and/or for further regulatory risk management under REACH and CLP should be initiated. As the screening provides a common starting point for Member States' and ECHA's work and for all REACH/CLP processes it has greatly enhanced the further integration of REACH/CLP implementation. In particular, this has resulted in authorities to consider already when a potential concern on a substance is identified whether and what regulatory action is needed would the concern be confirmed. This has helped to focus the evaluation work (both compliance checks and substance evaluation) on substances that

[1] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT
[2] SVHC Roadmap and SVHC Roadmap implementation plan available at: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation
[3] https://echa.europa.eu/documents/10162/1564405/mb_59_2015_update_cch_en.pdf/713315f8-7cbd-4782-a0aa-53621615b965

matter most for the protection of health and the environment. The better integration of the REACH/CLP processes from early on enhances regulatory consistency and predictability and improves collaboration between Member States.

The implementation work is now moving to addressing more and more groups of substances. This is to ensure that data generated can be used to cover as much of the chemical universe as possible and by that speed up the overall work on substances. This will also support a more holistic approach towards structurally similar substances and substances with similar function and hence support sustainable substitution.

The annual reports of the SVHC Roadmap published every year include the different elements mentioned above and as such support the reporting on the progress with ECHA's integrated Regulatory strategy.

2. Main achievements and state of play

During the first three years of the roadmap implementation ECHA together with Member States have addressed all the substances for which there was sufficient information on the hazard properties (i.e. all registered substances with a harmonised classification as CMR 1A/B and known PBTs). Those substances for which authorities thought there was a need to take regulatory actions are covered by one or more of the relevant regulatory risk management processes – included in the Candidate List and consequently, where relevant, subject to authorisation requirement, being restricted, or undergoing a risk management option analysis. For the remaining substances, the authorities concluded that they do not currently require further regulatory activities.

Since 2013 ECHA has screened every year all registered substances to identify substances for potential further work. From this exercise around 900 substances have been proposed for manual screening to the Member States. More than 600 of them have been scrutinised further. In some cases authorities have concluded that the substance does not need further action while the majority have been moved to either generation of data via compliance check or substance evaluation or directly to further regulatory risk management. More than 500 substances are currently having new data generated or are having their properties assessed[4]. As further explained in the annual reports this data generation and assessment takes considerable time and resources. However, the experience shows that after that conclusions can be drawn and regulatory risk management initiated swiftly.

Since the start of the SVHC roadmap 159 RMOAs have been developed covering single substances or groups of substances. 67 of them have been concluded and around half of those resulted in the conclusion that the SVHC identification should be initiated.

ECHA has also actively looked at the work done by other actors to identify substances of potential concern. An example of this is the SIN list which is regularly screened to see whether the common screening has captured the substances included in that list or if there is a need to scrutinise further (groups of) substances. The outcome of this work demonstrates that the vast majority of the substances under the SIN list have been considered by the authorities and the registered ones are under at least one of our regulatory processes being risk management option

[4] For further details on properties covered, please, see chapter 3 in the SVHC Roadmap report 2016 (https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2017_en.pdf/a8430302-c03c-d55a-b7d1-822451dfc34e) and the Evaluation progress report 2016 (https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8)

analysis, PBT or ED assessment, substance evaluation, harmonised classification and labelling, restriction, candidate list and/or authorisation.

In summary, the work on substances with already confirmed SVHC properties has been completed. Those substances which are not included in the Candidate List or heavily restricted although they have harmonised classification as CMRs, are regularly scrutinised to observe changes in use patterns and, where needed, to initiate further actions. The screening and prioritisation for further data generation works well where the registration dossiers for the substances are of sufficient quality i.e. where (i) the registration dossiers, complemented with other hazard data sources such as QSARs, provide sufficient information to trigger alerts on their potential long-term effects and ii) where the registration data allows sufficient certainty on uses and their exposure potential. However, for the remaining registered substances, not picked so far by the common screening, the lack of sufficient quality use information and of long-term effects is a major concern. Moving to work with groups of substances is one of the means to overcome this.[5]

The SVHC Roadmap implementation work has also lead to increased transparency and predictability by providing early information on the authorities' work (e.g. Public Activities Coordination Tool - PACT) and increased cooperation and coordination in general of authorities' work to better focus resources of authorities on what matters and avoiding duplication of work.

The latest annual report of the SVHC Roadmap implementation, together with the two previous reports, provide a more detailed information on the practical implementation and on the results. The reports cover also the REACH and CLP regulatory actions in order to provide a more holistic view on the state-of play on the implementation of the integrated regulatory strategy[6].

3. SVHC Roadmap review

Last year ECHA together with the Member States and Commission has started a structured review of all the elements of the SVHC Roadmap implementation to get a view on how we have progressed in achieving the goals of the SVHC Roadmap. To support this process ECHA together with volunteering MSCAs and COM carried out a survey among MSCAs (53 responses) followed up by interviews (15). These reviews provide a basis to estimate what can be achieved with the overall resources available and to identify whether there is a need to change the implementation before and/or beyond 2020.

Some elements (e.g. substances with harmonised classification as CMRs, sensitisers, SVHC substances due to impurities) have already been reviewed and discussed at both RIME and CARACAL. The review is still ongoing for the following elements: Cooperation and coordination of authorities' work, RMOA approach (discussed at RIME2/2017), supplementary activities of the SVHC Roadmap (to be discussed at RIME3/2017), transparency and predictability via tools such as PACT, website and annual reports. Further discussion on the outcome of the review is foreseen with Member States and Stakeholders at CARACAL in June and November this year.

The overall review will be documented in the next annual report and serve as a basis for a discussion on future actions in a workshop that is foreseen to take place in 2018.

[5] https://echa.europa.eu/documents/10162/2200151/mb_44_2016_regulatory_strategy_en.pdf/c9d4bb34-25fb-ea0f-2e5a-cab2365869a0

[6] SVHC Roadmap annual reports available at: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation