

SVHC Roadmap to 2020 Status update

Ninth Stakeholders' Day

21 May 2014

Elina Karhu
European Chemicals Agency

The Commissioners' commitments

- 2010: Vice-President Tajani and Commissioner Potočnik publicly committed to:
 - *have a Candidate List of 136 substances of very high concern by the end of 2012*
 - *have all relevant currently known SVHCs included in the Candidate List by 2020*
- August 2012: the two Commissioners restated this commitment to develop a roadmap with Member States by the end of 2012
- The Roadmap focuses on presenting a credible process to ensure the 2020 objective
- The Commission finalised the Roadmap in March 2013:
<http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT>



What makes an *SVHC relevant?*

Relevancy depends on whether:

- The substance is registered
- Uses are within the scope of authorisation
 - (e.g. no priority if only registered as intermediate)
- Risks are already known → start restriction process
- Uses are not already regulated by specific EU legislation that provides a (similar) pressure for substitution (as authorisation)

Substances of very high concern (SVHCs)

- Carcinogenic, mutagenic or toxic to reproduction (category 1A/B under CLP)
- PBT/vPvB (Criteria in Annex XIII)
- Substances of equivalent level of concern to the above, e.g. endocrine disruptors

SVHC Roadmap Implementation Plan

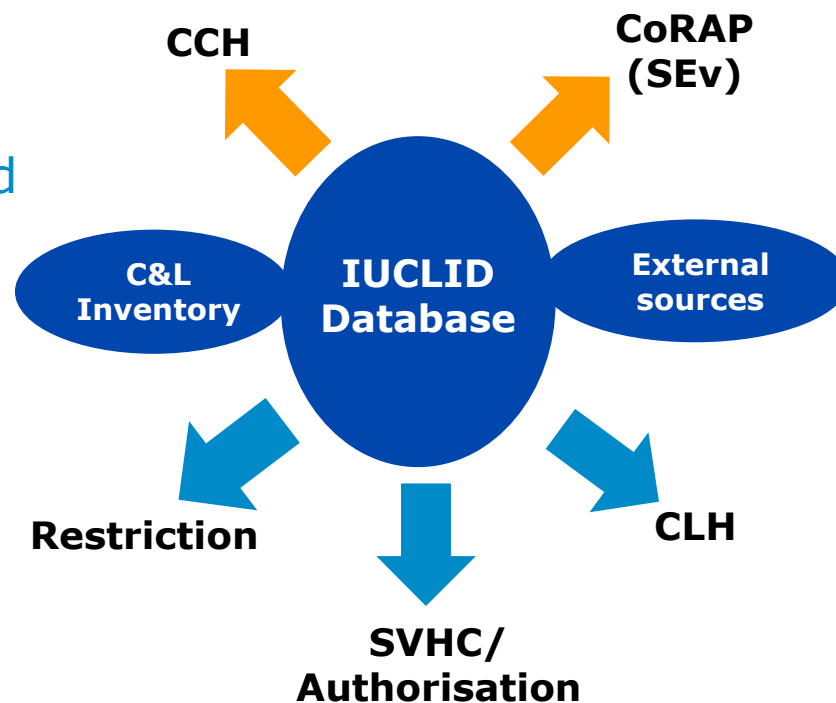


Roadmap Implementation Plan

- Identification of 'Roadmap relevant' SVHCs
 - **Screening** for substances of concern
 - Information generation and assessment (e.g. substance evaluation, PBT EG)
 - Risk Management Option Analysis (**RMOA**)
- Coordination of activities between authorities
- Progress monitoring
- Communication towards stakeholders and the general public
- Focus on:
 - CMRs
 - Sensitisers
 - Endocrine disruptors
 - PBTs/vPvBs
 - Petroleum/coal stream substances

Mass screening to identify substances of concern

- To find potential candidates for ECHA processes:
 - Compliance check
 - Substance evaluation (SEv)
 - Harmonised classification and labelling (CLH)
 - Identification of SVHCs (possibly leading to Authorisation)
 - Restriction



Risk Management Option Analysis (RMOA)

- Purpose: to clarify whether further regulatory risk management (RRM) is needed for a substance and to identify the most appropriate RRM instrument to address a concern
- Given the policy aim of authorisation this, in essence, means that for a registered SVHC the RMOA should document:
 - That the authorisation route is suggested, or
 - that there are specific reasons, which would overrule taking the authorisation route (restriction, other legislation, no action at all)
- Note: The RMOA is not a legally required step in REACH but is a voluntary action

Communication



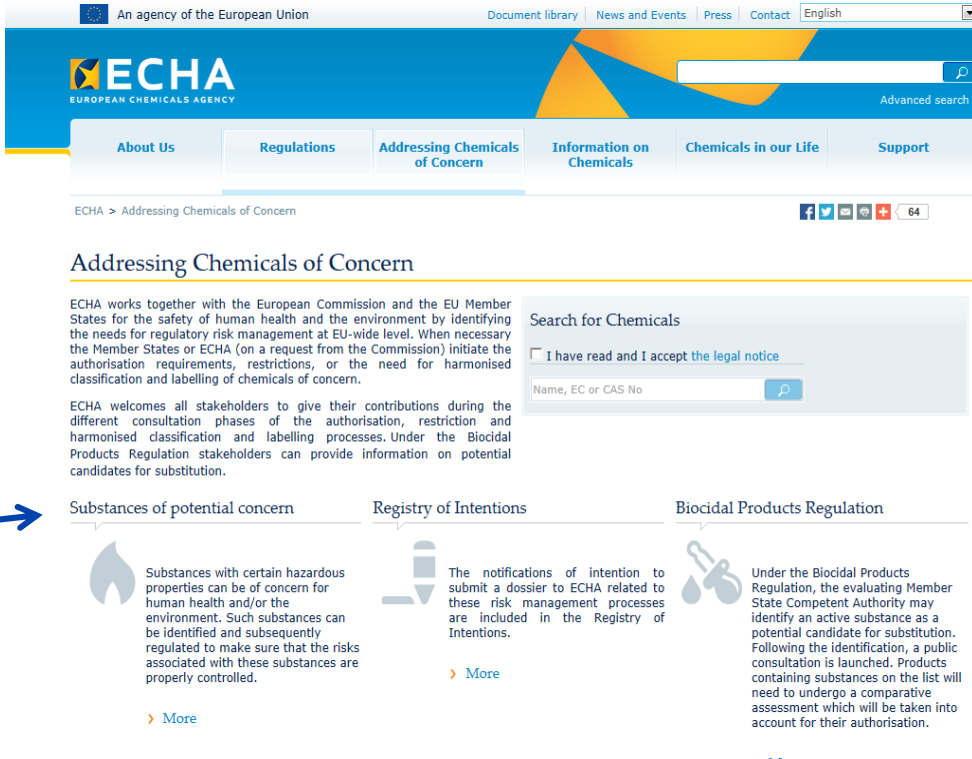
Improve transparency and predictability

- Open and transparent communication of activities under SVHC Roadmap to 2020 will:
 - Help stakeholders and the general public to understand objectives and scope
 - Increase predictability on how substances with certain hazard/fate and use profiles will be dealt with by regulatory authorities
 - Enable long-term planning and support proactive actions by stakeholders

SVHC Roadmap webpages

Substances of potential concern sub-section created under *Addressing chemicals of concern* landing page on ECHA website

Went live in December 2013!

An agency of the European Union | Document library | News and Events | Press | Contact | English

ECHA
EUROPEAN CHEMICALS AGENCY

Advanced search >

About Us | Regulations | **Addressing Chemicals of Concern** | Information on Chemicals | Chemicals in our Life | Support

ECHA > Addressing Chemicals of Concern

Addressing Chemicals of Concern

ECHA works together with the European Commission and the EU Member States for the safety of human health and the environment by identifying the needs for regulatory risk management at EU-wide level. When necessary the Member States or ECHA (on a request from the Commission) initiate the authorisation requirements, restrictions, or the need for harmonised classification and labelling of chemicals of concern.

ECHA welcomes all stakeholders to give their contributions during the different consultation phases of the authorisation, restriction and harmonised classification and labelling processes. Under the Biocidal Products Regulation stakeholders can provide information on potential candidates for substitution.

I have read and I accept the legal notice

Name, EC or CAS No

Search for Chemicals

Substances of potential concern

Registry of Intentions

Biocidal Products Regulation

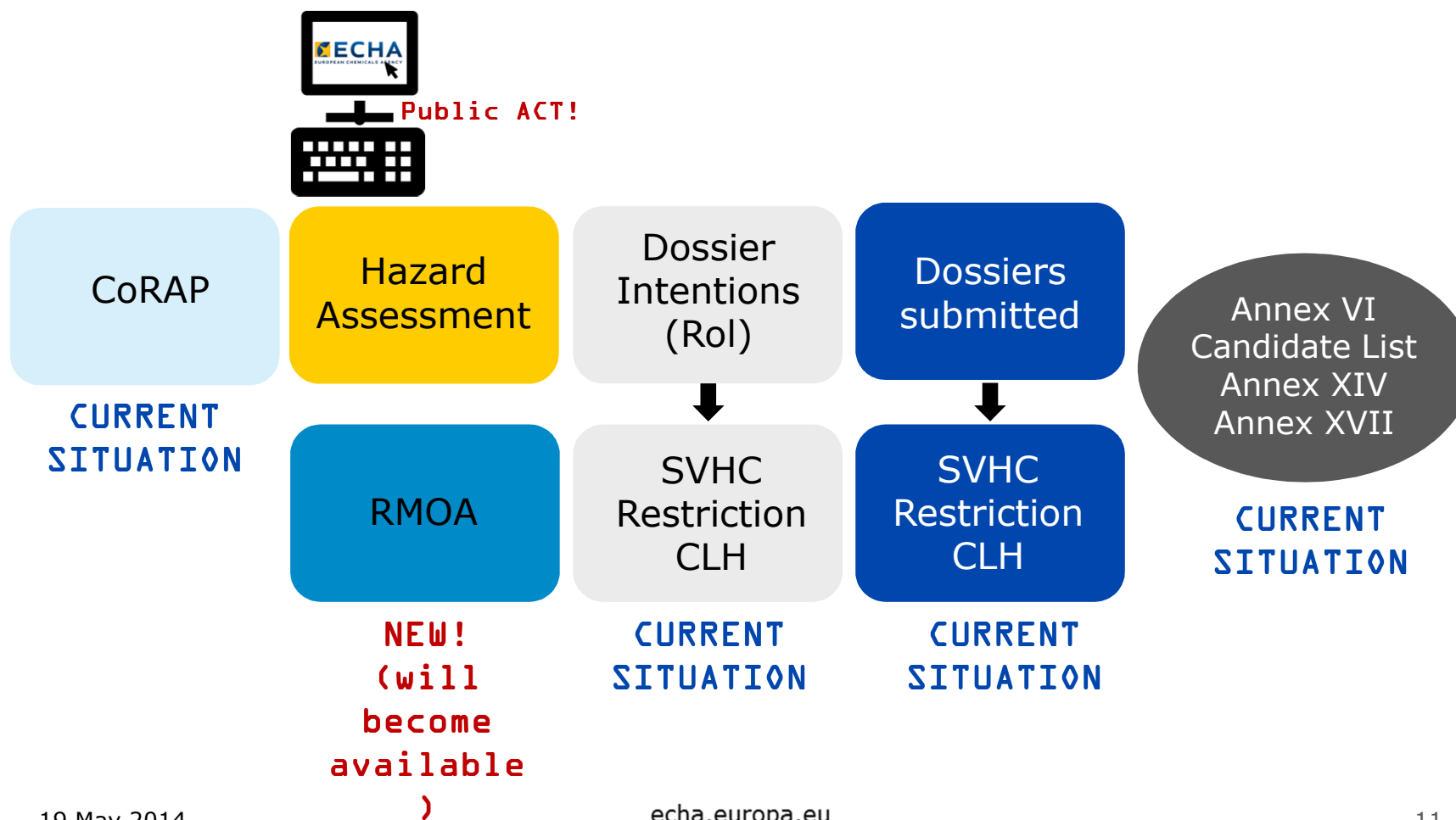
Substances with certain hazardous properties can be of concern for human health and/or the environment. Such substances can be identified and subsequently regulated to make sure that the risks associated with these substances are properly controlled.

The notifications of intention to submit a dossier to ECHA related to these risk management processes are included in the Registry of Intentions.

Under the Biocidal Products Regulation, the evaluating Member State Competent Authority may identify an active substance as a potential candidate for substitution. Following the identification, a public consultation is launched. Products containing substances on the list will need to undergo a comparative assessment which will be taken into account for their authorisation.

> More

Substance specific activities on ECHA website



**How can stakeholders
best prepare?**



Registrants

Make sure registrations are up-to-date:

Uses and exposure parameters

- Clarify uses, use volumes and conditions
- Describe any use as an intermediate with sufficient detail
- Make full use of information from your downstream users

Hazard

- Ensure correct (self)classification (also considering constituents, impurities and additives)
- Draw clear and traceable conclusions on the PBT properties of your substance (including degradation products)
- Include assessment of endocrine disrupting effects

Downstream users

- Make sure that your use is properly covered by registration
 - Communicate your use and use conditions to your supplier
 - If the registrant does not cover your use, make sure that your use is known to authorities by reporting the DU CSR to ECHA
- Make use of all REACH/CLP information to assess the possibilities of transferring to safer alternatives

All stakeholders

- Follow the roadmap section on the ECHA website
- Follow proceedings at open sessions of CARACAL and PBT/ED Expert Groups
- Subscribe to our weekly e-News

<http://echa.europa.eu/subscribe>

Conclusions

- SVHC Roadmap paves the road for an efficient and transparent process for identification of (future) SVHCs and decision-making on the best regulatory action to be taken
- Expected that for most substance groups the main focus will be on the initial steps, i.e. screening and information gathering
- Improved communication should allow stakeholders to follow the intermediate steps and thereby increase long-term predictability of the regulatory risk management processes under REACH

Thank you

elina.karhu@echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
[@EU_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)