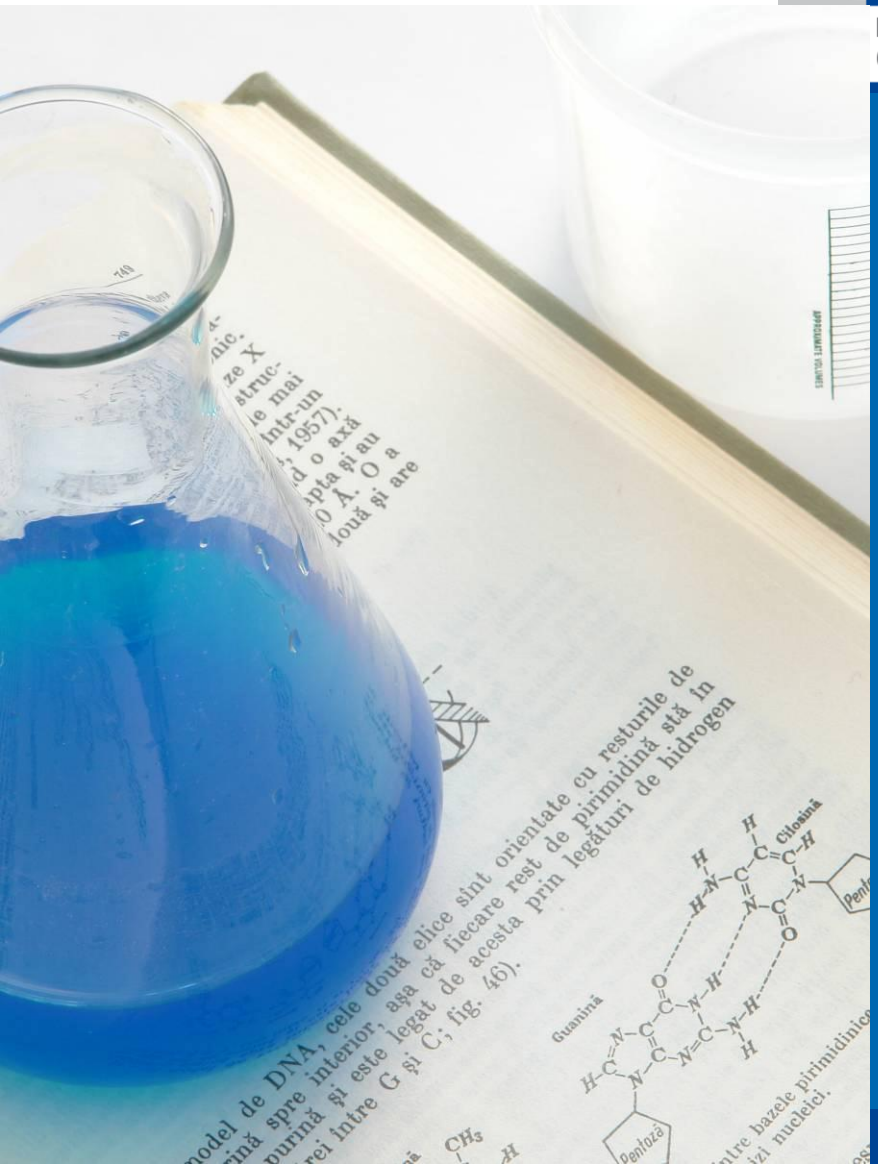

European Commission

The SVHC Roadmap

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REACH Information and Experience Exchange Forum (RIEF I)

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 "**
    - Currently :138 (10 more substances in the pipeline for June '13)
  - "**have all relevant currently known SVHCs included in the candidate list by 2020"**
    - August 2012: in a letter to Ministers, the two Commissioners restated this commitment and underlined the will to continue working with Competent Authorities to develop a roadmap by the **end of 2012**
    - In the same letter, they stated that the roadmap "should build on the RMO framework, setting out clear milestones, deliverables and division of work between the Commission, Member States and the European Chemicals Agency"

The SVHC Roadmap

- Roadmap document - The Commission and MS worked together (2nd half of 2012)
  - CARACAL, Workshops, informal discussions
- Roadmap implementation: engagement and collaboration of all actors needed
  - Council (Competitiveness 18-19 Feb 2013; Environment 21 March 2013)
  - ECHA (authorities) Workshop (17-18 April 2013)
  - CARACAL

Roadmap's outlook

- Collaboration of all actors needed to make the implementation a success.
- **No numerical goal** has been 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.
- The Roadmap focuses on presenting a credible process to ensure the 2020 objective: defining a process or methodology, with clear deliverables, planning and share of responsibilities.

What has been done until now

- Key points:
  - CMR screening almost completed
  - PBT working group has been established and more PBTs and vPvBs are going to be identified as SVHCs
  - First SVHC identifications according to art. 57(f)(respiratory sensitisers, STOT and endocrine disruptors (an ED working group will be established in 2014))
  - RMO process is well established and has the support by all MSs, Commission and ECHA
  - Discussion on a proper communication and possibilities of involving stakeholders started

We are starting to move from CMRs to less known and less regulated SVHCs

What is not a "relevant" SVHC by 2020?

- Indications in the Roadmap:
  - A SVHC that is not registered is not a priority (some exceptions possible in the Roadmap, e.g. category approach)
  - A SVHC that has been registered as intermediate only is not a priority (but enforcement actions *(cf. intermediate)* if appropriate and some exceptions possible in the Roadmap, e.g. category approach)
  - A SVHC that fulfils the conditions of art. 69(1) : if its use(s) pose(s) a risk to human health and environment that is not adequately controlled, a restriction process should be started (second step: SVHC for remaining uses)
  - A SVHC with (all) uses already regulated by specific EU legislation that provides a pressure for substitution or (all) uses exempted from the authorisation (see article 5, 56 or 60)

BUT

What is not a "relevant" SVHC by 2020?

Exception from the two last criteria:

A PBT, vPvB or SVHC fulfilling art. 57(f) for a hazard property without harmonised criteria in Annex I of CLP (*e.g.*, EDs)

In this case, COM believes that an official identification by the Member States Committee via an Annex XV dossier for SVHC identification could be foreseen. If a restriction is considered necessary, this will avoid the need to discuss the hazard properties in the restriction process.

Role of the RMO

- The RMO is a voluntary but critical step in the process of defining the "relevance" of a substance
- It should be built on a screening exercise aimed at identifying substances that, on the basis of the registration dossiers, do not fulfil the first 2 criteria (registered + intermediates) (for example CMR substances used as intermediate only)
- The RMO assessment would be made for the list of substances resulting from such screening
- **The RMO analysis should normally be shared with MSCAs and COM/ECHA prior to the submission of an Annex XV SVHC dossier** (with the possibility to update in case new information is received)

Timeline

- These are initial indications, ECHA is developing a more detailed implementation proposal, including monitoring of the Roadmap from 2013 to 2020:
  - How to organise different steps for different groups of substances.

CMRs:

- Screening almost completed – to be repeated regularly
- Approach to assess petroleum streams needed (2013-2015): start a systematic assessment from 2016

Timeline

Sensitisers:

- Around 1100 sensitisers in CLP (skin + 100 respiratory)
- All sensitisers should be screened to identify those that are registered and have not only intermediate uses
- Not all sensitisers fulfil the equivalent level of concern criterium of art. 57(f) – to identify case-by-case which ones do.
- The current approach considers that the equivalent level of concern is more supported for respiratory sensitisers (ECHA doc) => start with this group
- Skin sensitisers could follow (2013-2020)

Timeline

Endocrine disruptors:

- Criteria for identification of endocrine disruptors to be agreed by the end of 2013
- As from 2014, start with a screening of the EU database (Endocrine Active Substances Information System), registration data and assessment of the fulfilment of the criteria (2015)
- An ED working group to provide advice on SVHC identification of endocrine disruptors (2014)
- RMO-assessment (2015-2020) for those fulfilling the ED criteria and the first Roadmap screening (registered and not only intermediate)
- For some substances there might be the need to generate further information, for example via substance evaluation

Timeline

PBTs and vPvBs:

- All PBT and vPvBs identified by the PBT expert group should be RMO-assessed
- A strategy needed to screen and prioritise UVCBs/MCSs with PBT properties
- Data from 2013 (and possibly from 2018) registration deadline should be used
- For some substances there might be the need to generate further information – dossiers or substance evaluation expected (2013-2017)

Others 57(f): STOT cat. 1 – first cases in the pipeline for SVHC identification

Can we meet the commitment?

- Preliminary "worst-case" estimation between 2013 and 2020: **440 substances need to be RMO-assessed**
- From 2009 to 2012:
  - RMOs for around **160** substances have been prepared by ECHA and MS (around **50/year**),
  - **138** substances have been included in the Candidate List

If we want to RMO-assess 440 substances, we need 55 RMOs/year (80 substances by the end of 2014, 2013 to prepare for the Roadmap implementation).

This is feasible, but we need to put in place some actions

Roadmap implementation

There is a need to:

- ensure adequate resources in ECHA and MSs to work on SVHC identification
- have a clear agreement on how to share the work among MSs, COM and ECHA (on the basis of resources and national interest)
- further develop and intensify work and cooperation
  - RiME, CARACAL

What industry can do?

- Principal source of information for the Roadmap implementation (screening and RMO analysis) : ECHA's database(s)

  => keep your registration dossiers updated

  => submit all information available

- authorities may also be using information coming from other REACH processes (e.g. evaluation, enforcement reports) or other data (e.g., RAPEX, national monitoring information (work place, WFD,…))
- in principle no additional data collection for RMO preparation
- if the authority decides so: consultation with stakeholders

  =>industry invited to collaborate

- once the SVHC identification launched:

  =>industry invited to follow and contribute to the public consultation(s) if and as appropriate

How to communicate on the Roadmap?

- Appropriate communication strategy needed (under discussion)
- Subject to agreement, to document the actions made to achieve the target, the following information could be considered for publication by the end of 2020:

  - A report on how MS and COM have selected the "relevant" SVHCs (including non-confidential screening results for different groups of substances);
  - An annual list of all the substances RMO-assessed (potentially with the conclusion of the RMO analysis);
  - Follow-up actions after 2020 (for example, refine the preliminary screening on the basis of new registration information, assess new PBTs, CMRs or EDs).

Next steps – further outlook

SVHC Roadmap:

- Council – Policy support to the Roadmap Implementation
- ECHA implementation plan under development;
- further work: Regular RiME and CARACAL meetings
- Workshop with stakeholders (autumn 2013)?

Overall REACH Implementation Roadmap:

- Registration, evaluation, restrictions
- Harmonised Classification and labelling

- Timeline: end of 2013?

Thank you