SVHC Roadmap to 2020 Status update

Ninth Stakeholders' Day

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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

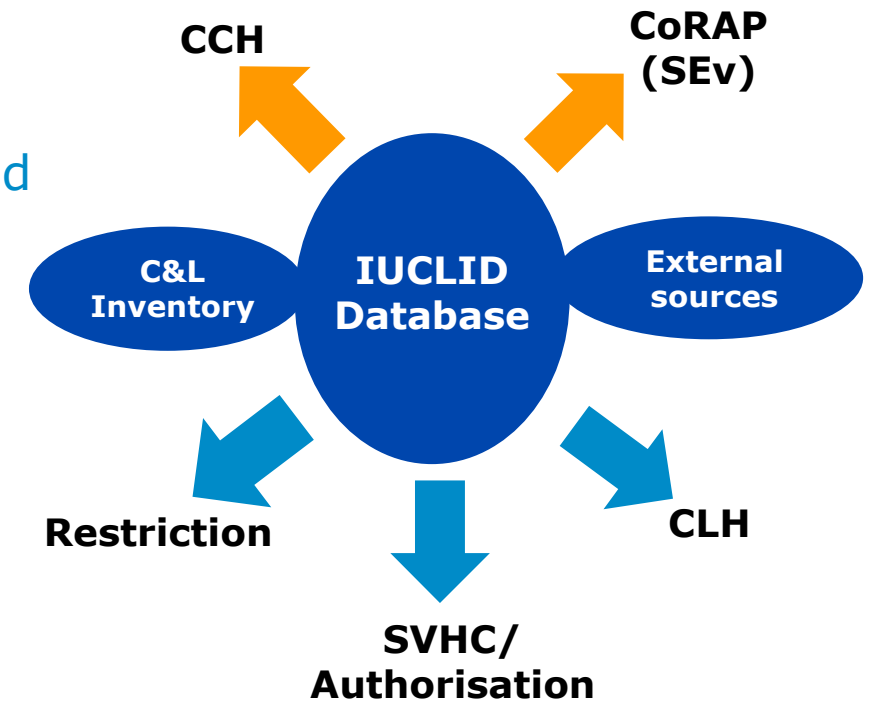
SVHC Roadmap Implementation Plan

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

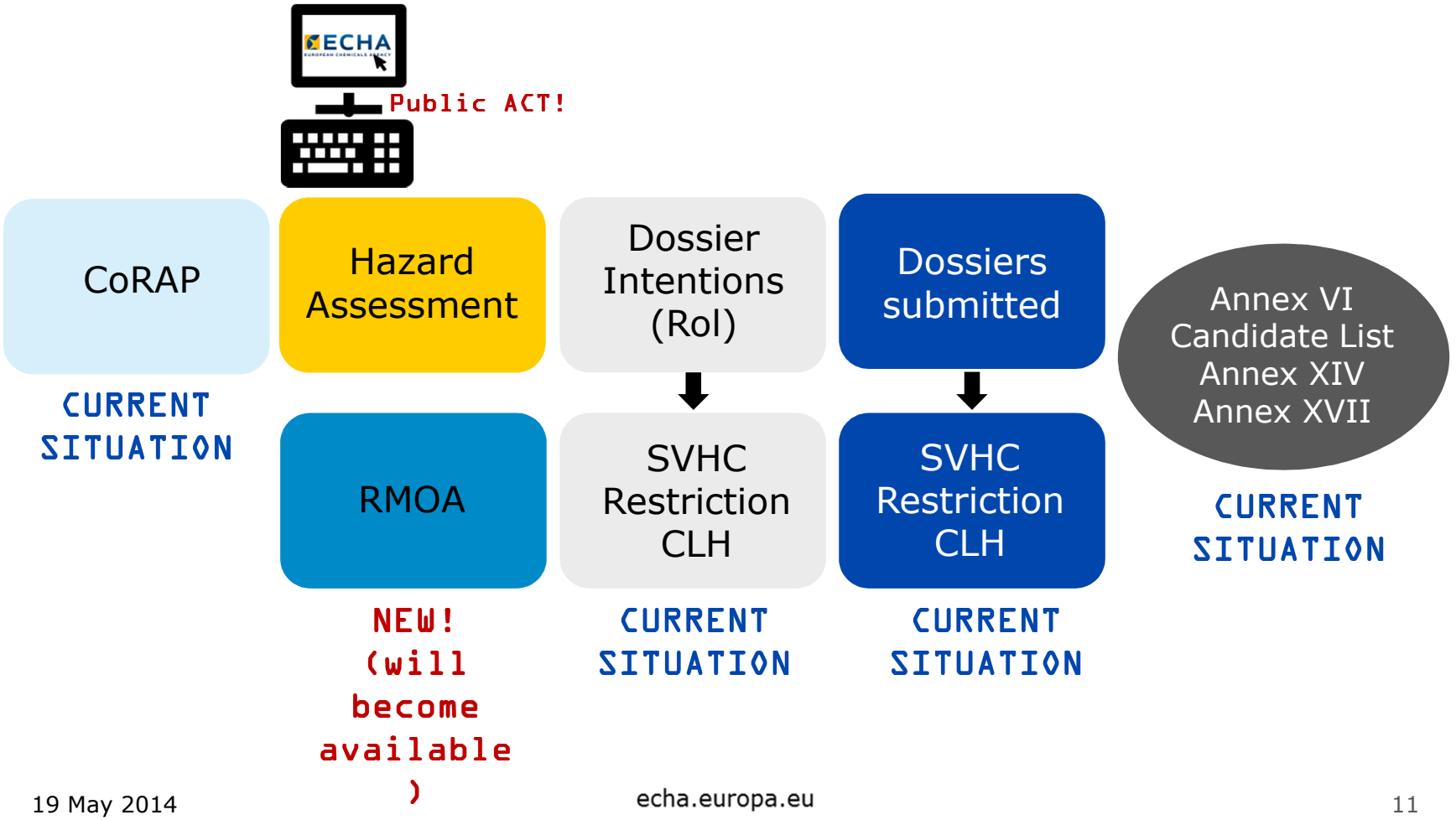
- Open and transparent communication of activities under SVHC Roadmap to 2020 will:
  - Help stakeholders and the general public to understand objectives and scope
  - Increase predictability on how substances with certain hazard/fate and use profiles will be dealt with by regulatory authorities
  -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

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

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