SVHC Roadmap to 2020

Linking registrants and authorities work

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Chrystèle Tissier
Risk Management Identification
European Chemicals Agency

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Background

- EU policy commitment
  - **To have all relevant currently known SVHCs included in the Candidate List by 2020**

➢ The Commission, in consultation with the Member States and ECHA, finalised **the SVHC Roadmap** in March 2013

  ➢ Actions needed to achieve this policy goal

  Http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT

➢ ECHA in co-operation with the Commission and Member States draw up the **Roadmap Implementation Plan** in November 2013

  ➢ How to carry out the required actions

  http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan

Relevant substances (1/2)

Substances addressed: Substances of very high concern (SVHC)

- **CMR**: carcinogenic, mutagenic or toxic for reproduction
  - Category 1A or 1B in accordance with the CLP Regulation (EC) 1272/2008
- **PBT, vPvB**: (very) persistent, (very) bioaccumulative and toxic for the environment (PBT or vPvB)
  - According to REACH (Annex XIII)
- **Equivalent level of concern**: identified on a case-by-case basis, cause an equivalent level of concern as with CMR or PBT/vPvB substances
  - e.g. endocrine disruptors, sensitisers

[Article 57 REACH]

Relevant substances (2/2)

What makes an SVHC 'relevant'?

- The substance is registered, i.e. used in the EU
- 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)

Roadmap principles and objectives (1/2)

- Build a common understanding between EU authorities of the main principles how to proceed with SVHCs
  - **Screening** of substances to identify potential SVHCs
  - Assessment of the need for regulatory risk management and **the most appropriate risk management option (RMOA)**

- Work preceding regulatory steps defined in the REACH and CLP Regulations
  - No legal obligation on
    - Authorities (Member States, the Commission or ECHA)
    - Industry

Roadmap principles and objectives (2/2)

- Sets priorities for the authorities' work
  - In which order we process (groups of) relevant substances?
- Ensures transparency for stakeholders by communicating authorities intentions
- Increases predictability for industry for business strategy planning and resources management

Screening: to identify substances of concern (1/3)

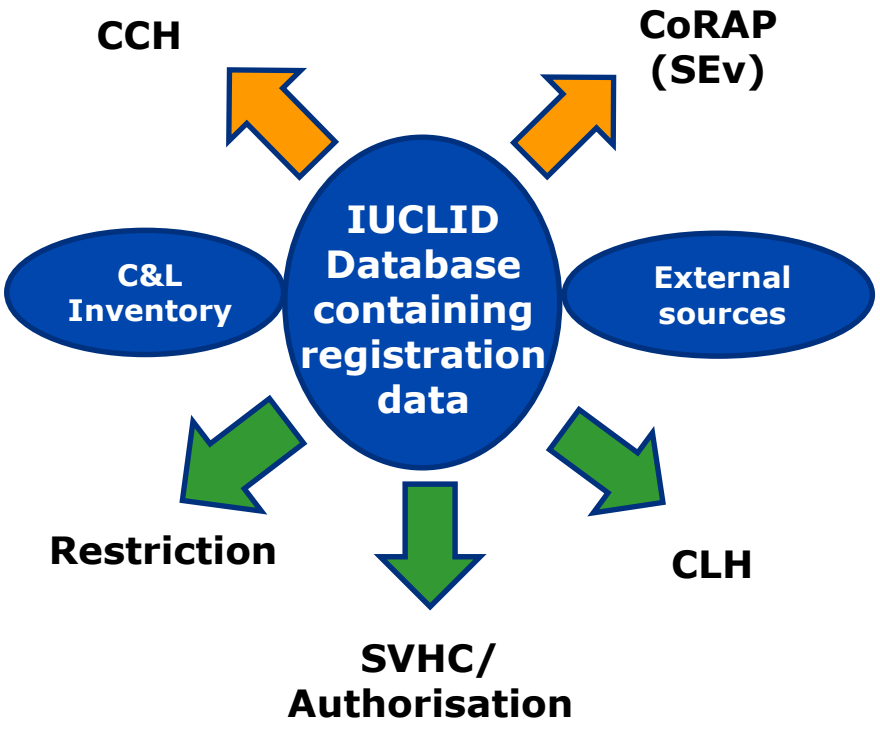
- Use of all available data
- Allocate identified substances to the appropriate process:

Further information generations

- Substance evaluation (SEv)
- Compliance check (CCH)

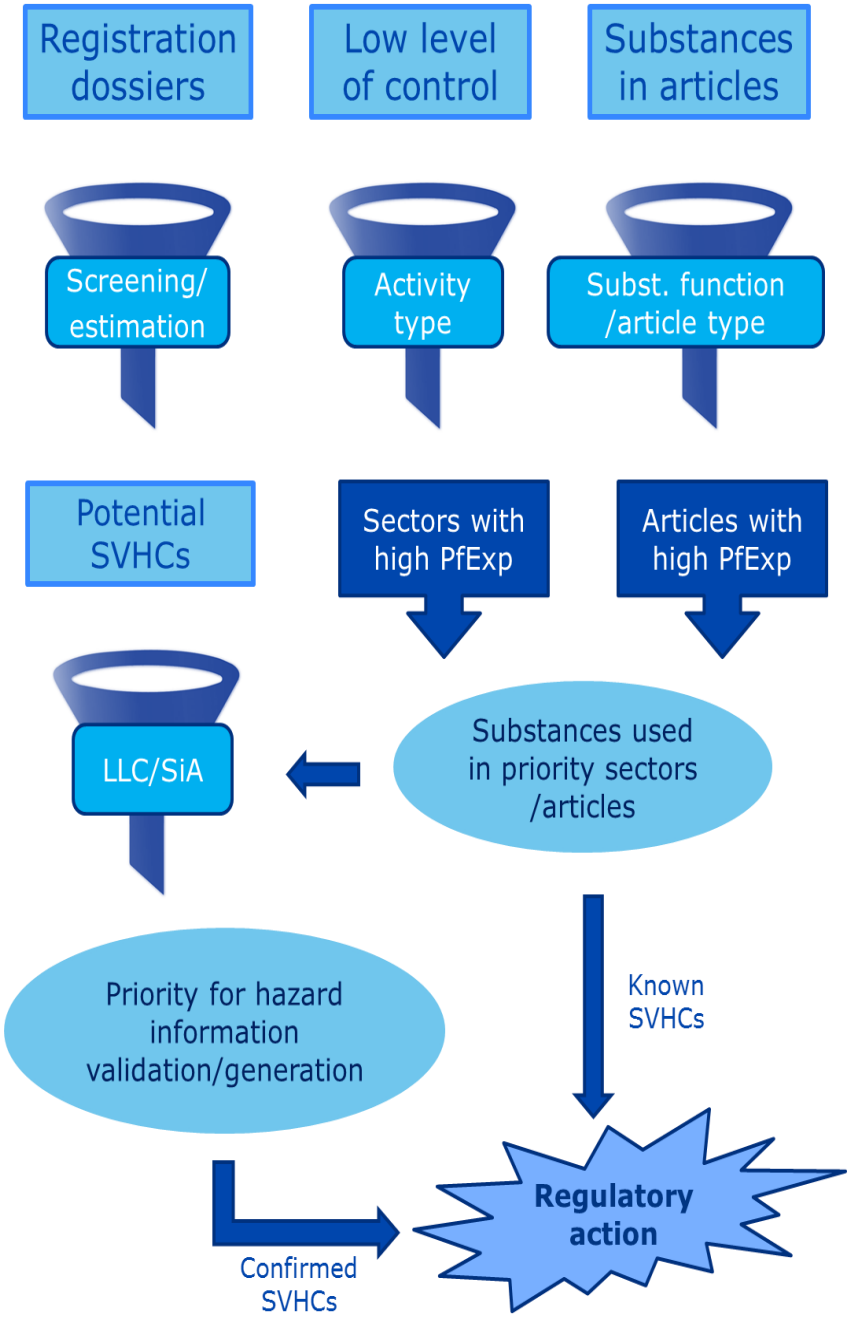
Regulatory risk management

- Harmonised classification and labelling (CLH)
- Identification of SVHCs (possibly leading to Authorisation)
- Restriction



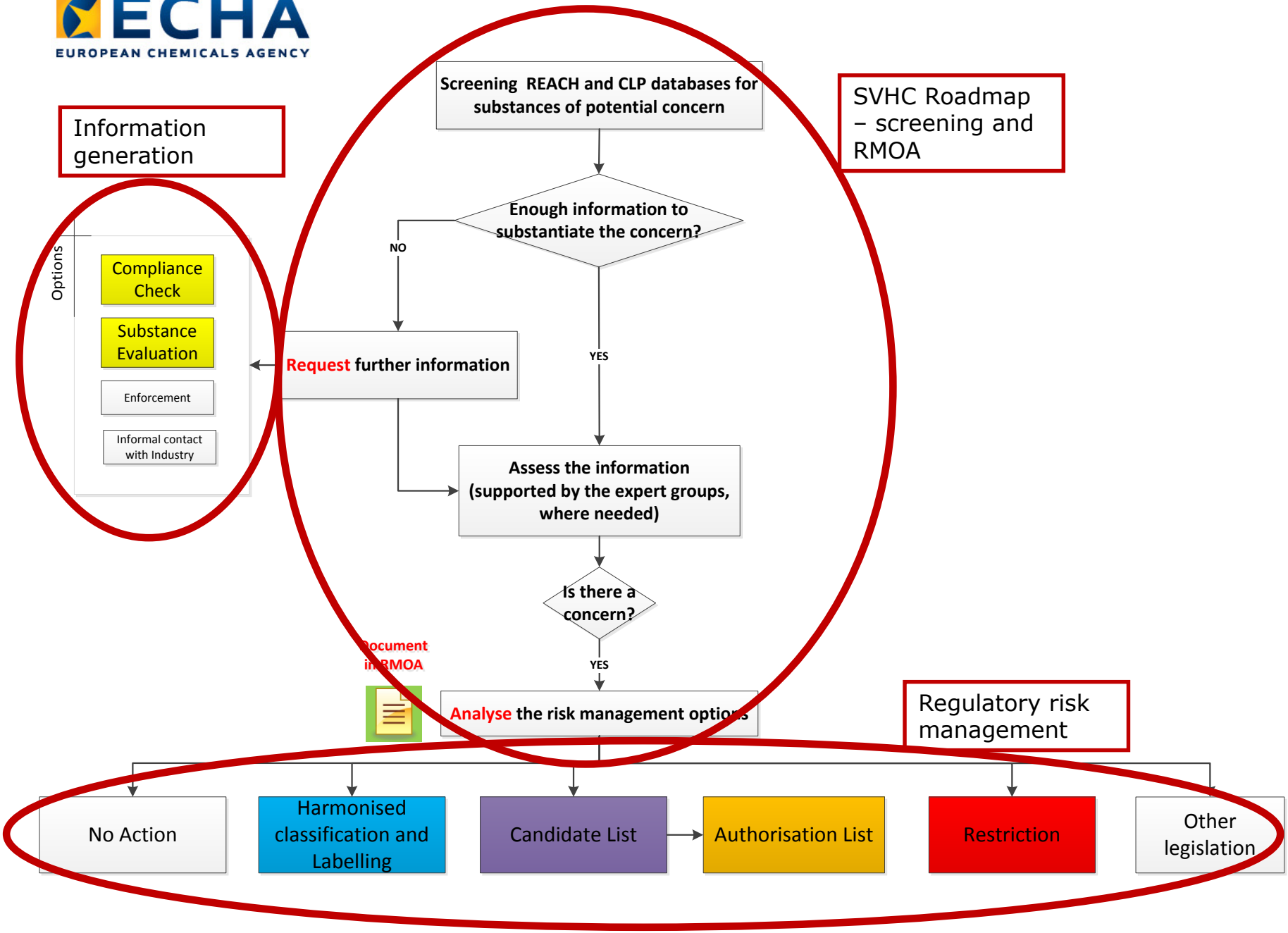
Screening: to identify substances of concern (2/2)

- Main source: registration information
- Screening based on
  - SVHC properties
    - E.g. PBT (substance, substance containing PBT constituent), CMR (substance, substance containing CMR impurity)
  - Uses and tonnage information
    - Are uses in the scope of authorisation?
    - Is most of the tonnage falling in uses in the scope of authorisation?
    - Potential for exposure


Registration dossiers
Low level of control
Substances in articles
Screening/ estimation
Activity type
Subst. function /article type
Potential SVHCs
Sectors with high PfExp
Articles with high PfExp
LLC/SiA
Substances used in priority sectors /articles
Priority for hazard information validation/generation
Known SVHCs
Confirmed SVHCs
Regulatory action

Risk Management Option Analysis (RMOA)

- The RMOA aims to:
  - Clarify whether further regulatory risk management (RRM) is required for a substance and
  - Identify the most appropriate RRM instrument to address a concern
    - REACH: authorisation, restriction, CLH
    - Outside REACH: with another EU legislation
- RMOA is a voluntary action, not required by REACH
- Case-by-case analysis by authorities
- Conclusions publicly available


ECHA
EUROPEAN CHEMICALS AGENCY
Information generation
SVHC Roadmap – screening and RMOA
Screening REACH and CLP databases for substances of potential concern
Enough information to substantiate the concern?
NO
YES
Options
Compliance Check
Substance Evaluation
Enforcement
Informal contact with Industry
Request further information
Assess the information (supported by the expert groups, where needed)
Is there a concern?
YES
Document in RMOA
Analyse the risk management options
Regulatory risk management
No Action
Harmonised classification and Labelling
Candidate List
Authorisation List
Restriction
Other legislation

Communication towards stakeholders and the public

Screening: improve transparency and predictability

- Transparency on screening to be increased in the future
  - Documentation already provided to stakeholders of both PBT and ED EG in the current screening round
  - Publication of the general description and supporting documentation of the screening on ECHA website in 2015 (first quarter)
- Should increase predictability on
  - which substances are considered of concern at the level of screening based on hazard properties
    - No substance specific information!
  - which substances have the highest priority

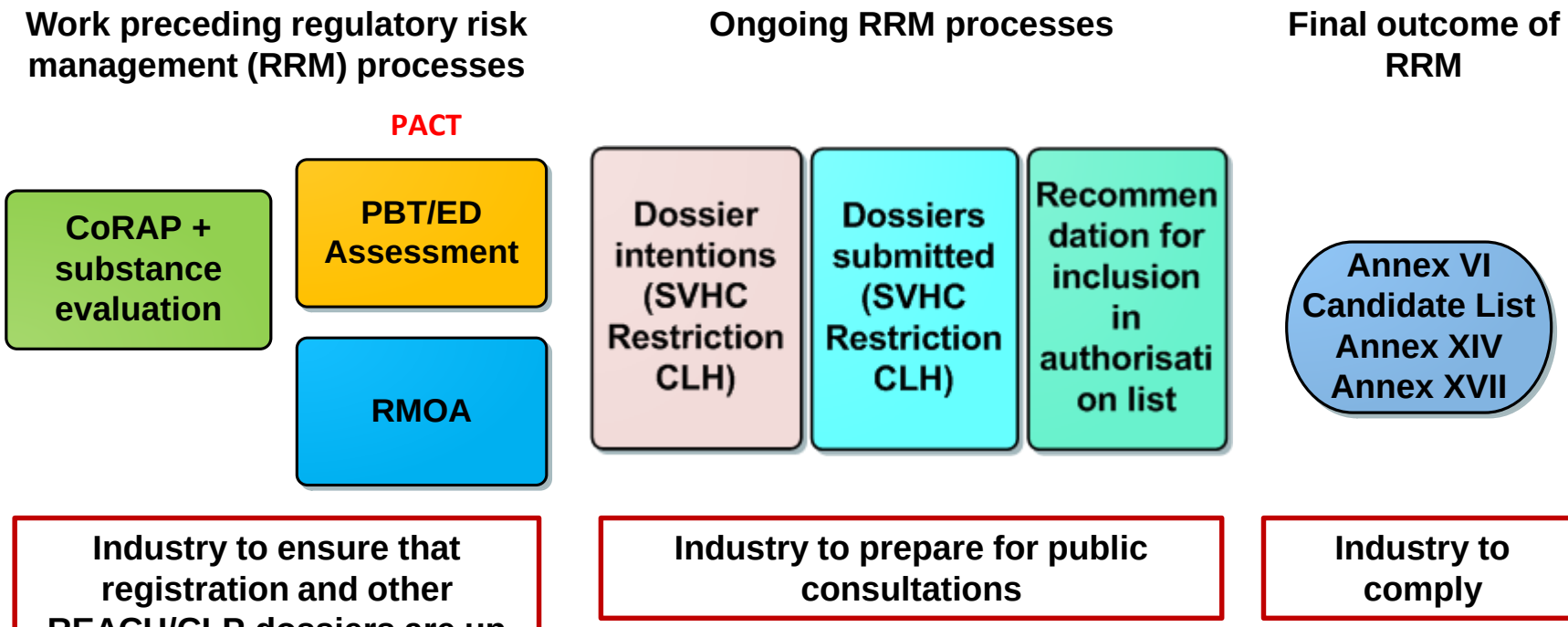
New tool

- NEW communication on **substance specific** activities via **Public Activities Coordination Tool (PACT)**

- Informs on cases where authorities select a substance for:
  - assessment of the hazard properties or
  - analysis of the risk management options

- Inclusion of above substance specific activities in the PACT does not mean confirmed concern or firm regulatory action

Substance specific activities on ECHA website

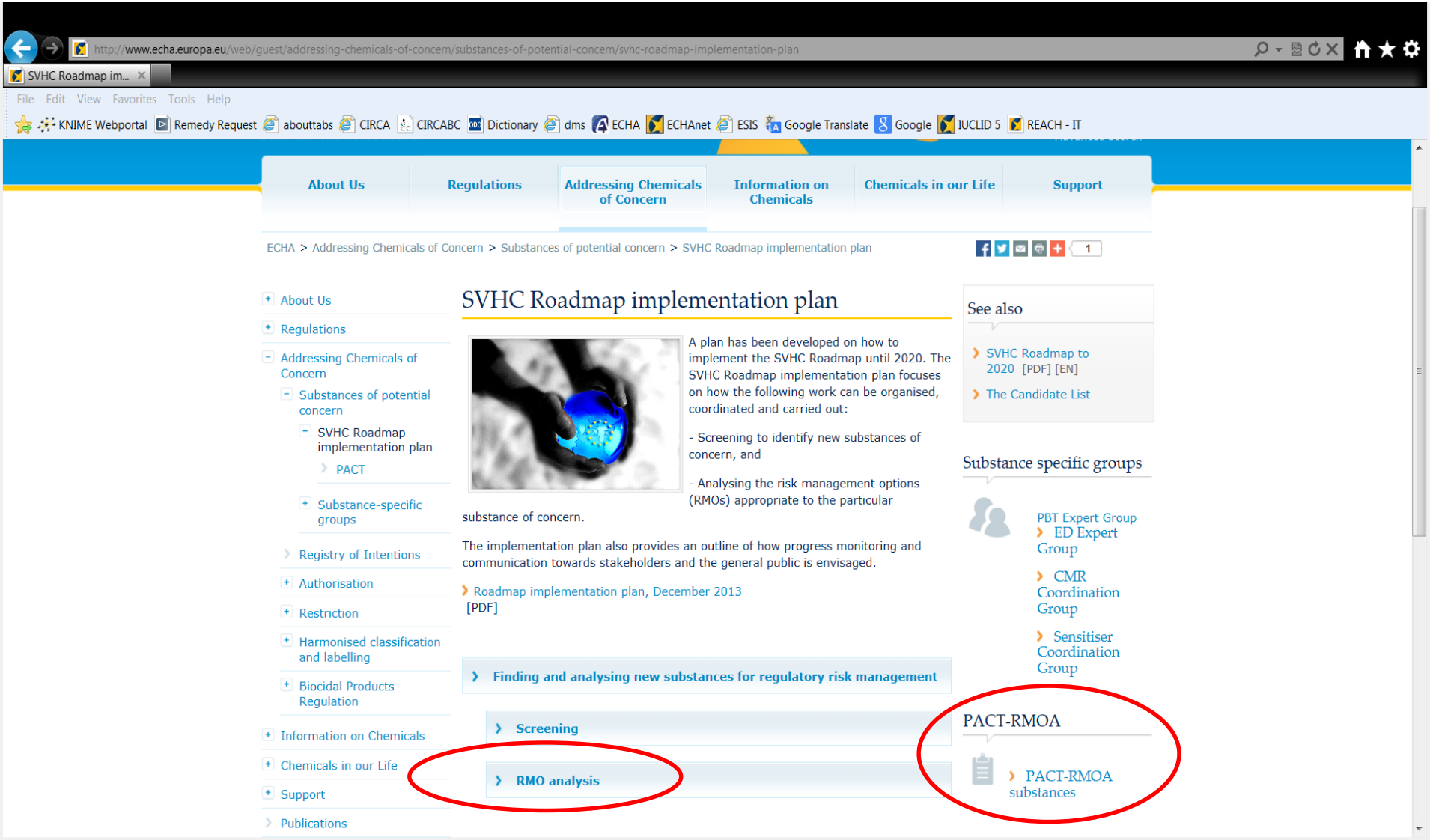


Dossier Quality Important!

Improve transparency and predictability

- Open and transparent communication of activities under SVHC Roadmap to 2020 will:
  - Help stakeholders and general public 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

http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan



How can stakeholders best prepare?

Top tips to prepare (1/3)

Registrants should make sure registrations are up-to-date:

- Clarify uses, including uses as an intermediate, use volumes and conditions
- Make full use of information from downstream users
- Draw clear and traceable conclusions on SVHC properties of your substance (including impurities and degradation products)
- Ensure that you provide sufficient information on the constituents, impurities and additives of your substance and take their properties into account when carrying out classification and assessment of your substance
- Include assessment of endocrine disrupting effects

Top tips to prepare (2/3)

Downstream users (DUs) should make sure that their use is properly covered by a registration

- Communicate your use and use conditions to your supplier
- If registrant does not cover your use, make sure that your use is known to authorities by submitting DU CSR to ECHA
- make use of all information (including REACH/CLP data) to assess the possibilities to transfer to safer alternatives

Top tips to prepare (3/3)

All should:

- Follow the roadmap section on the ECHA website and follow substances being addressed by the authorities
- Chemical search on ECHA website – gives 'hits' for substance specific activities (e.g. SEv, RMOA, Candidate List, Annex XIV)
- Pay attention to the PACT
- If your substance have SVHC properties, consider your business strategy:
  - continue to support the substance: prepare for public consultations and authorisation requirement
  - develop alternatives providing the same function

Conclusions

- SVHC Roadmap paves the road for:
  - An efficient and transparent process for identifying (future) SVHCs ⇒ more systematic work, better communication, increased predictability
- Sufficient and high-quality registration information is essential to avoid unnecessary follow-up from authorities
- Improved communication to increase long-term predictability
- No numerical targets set for the inclusion of substances in the Candidate List or other risk management routes
  - Nevertheless, the expectations are high!

Thank you!

Chrystele.tissier@echa.europa.eu

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