

The SVHC Roadmap report and perspectives for the future

Chemical Watch event: The future of authorisation

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What this presentation is about

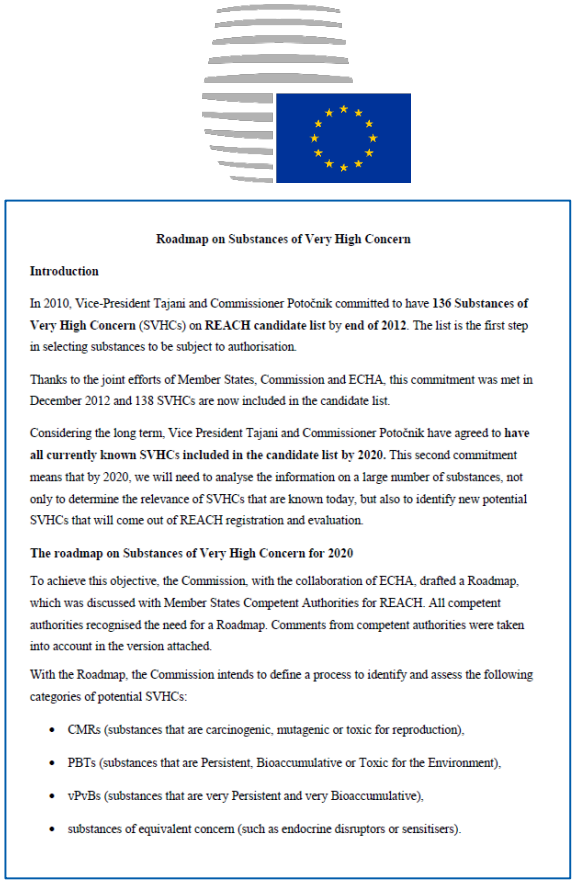
- SVHC Roadmap to 2020: key features
- SVHC Roadmap report
- Trends in regulating the most hazardous substances
- RMOA: suggestions for improvement
- Let’s talk about substitution: perspectives

SVHC Roadmap to 2020

- 2013 publication: "Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020“
- Goal: all relevant, currently known **substances of very high concern** (SVHCs) included in the Candidate List by **2020**
- Starting point: CMRs, PBTs, vPvBs, substances of ELoC (ED, sens.).
- Methodology: process to identify and assess potential SVHCs

  1. Screening to identify new substances of concern, and
  2. Analysing the **risk management options** (RMOs) appropriate to the particular substance of concern

- Reporting: annually, by ECHA



Roadmap on Substances of Very High Concern

Introduction

In 2010, Vice-President Tajani and Commissioner Potočnik committed to have **136 Substances of Very High Concern** (SVHCs) on **REACH candidate list** by **end of 2012**. The list is the first step in selecting substances to be subject to authorisation.

Thanks to the joint efforts of Member States, Commission and ECHA, this commitment was met in December 2012 and 138 SVHCs are now included in the candidate list.

Considering the long term, Vice President Tajani and Commissioner Potočnik have agreed to **have all currently known SVHCs included in the candidate list by 2020.** This second commitment means that by 2020, we will need to analyse the information on a large number of substances, not only to determine the relevance of SVHCs that are known today, but also to identify new potential SVHCs that will come out of REACH registration and evaluation.

The roadmap on Substances of Very High Concern for 2020

To achieve this objective, the Commission, with the collaboration of ECHA, drafted a Roadmap, which was discussed with Member States Competent Authorities for REACH. All competent authorities recognised the need for a Roadmap. Comments from competent authorities were taken into account in the version attached.

With the Roadmap, the Commission intends to define a process to identify and assess the following categories of potential SVHCs:

- CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction),
- PBTs (substances that are Persistent, Bioaccumulative or Toxic for the Environment),
- vPvBs (substances that are very Persistent and very Bioaccumulative),
- substances of equivalent concern (such as endocrine disruptors or sensitisers).

RMO Approach in the SVHC Roadmap 2013: identify best regulatory option to manage the risk (in or outside REACH)

HAZARD: CMR, PBT/vPvB, ELoC

1

SCREENING:

Substance produced or used in relevant quantities (registered)

Not only intermediate

2

RMO ASSESSMENT:

Restriction: uses with demonstrated risk (with some exceptions)

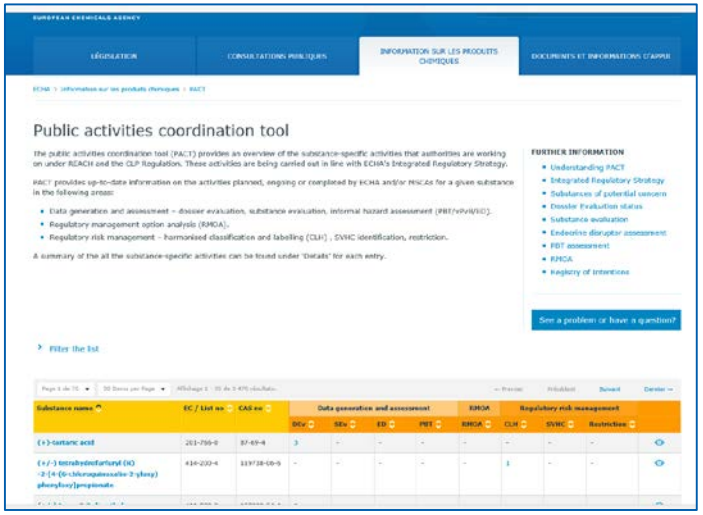
SVHC / Authorisation

Substance evaluation (insufficient data), etc.

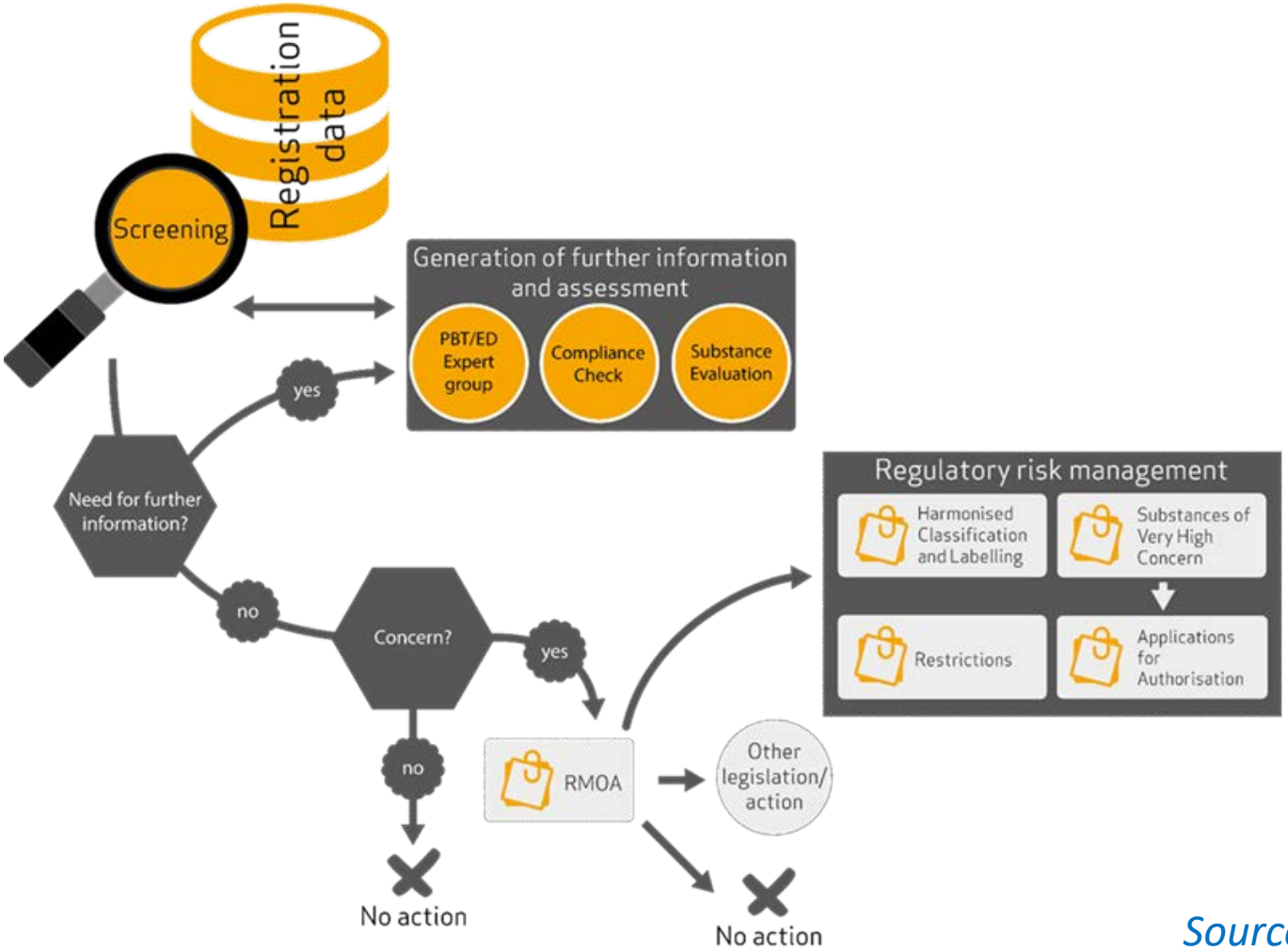
Aims of authorisation (Art 55): "*to ensure the good functioning of the internal market while assuring that the risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies* […]"

SVHC Roadmap: key implementation features progressively developed

- Relies on « adequate resources from ECHA and Member States »
- ECHA coordination and report to CARACAL
- RiME (Risk Management Experts) → RiME+ (Risk Management and Evaluation) platform
- PACT: Public Activities Coordination Tool, for more transparency
- Prioritisation for Annex XIV / scoring

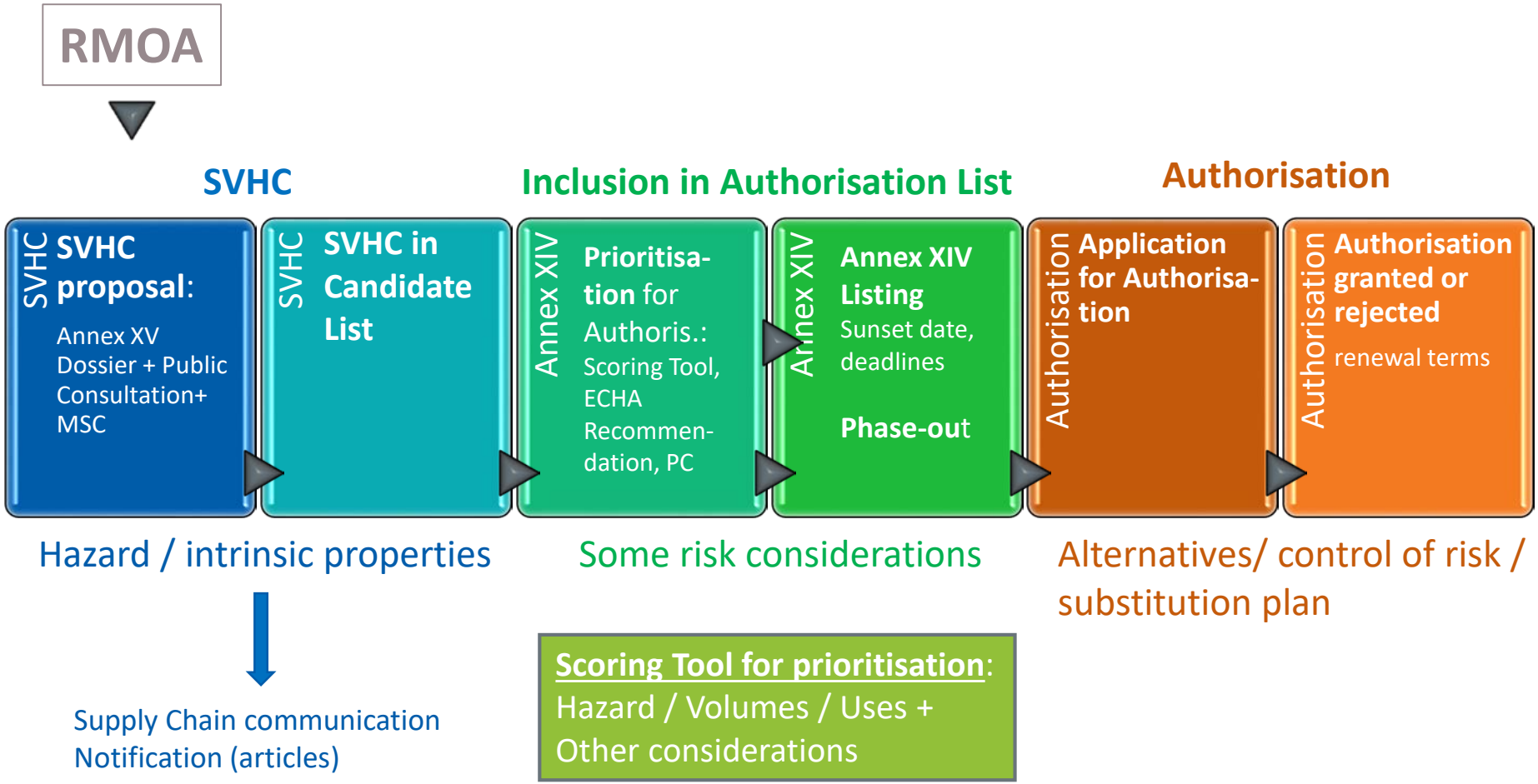


RMOA: the broader picture in 2018



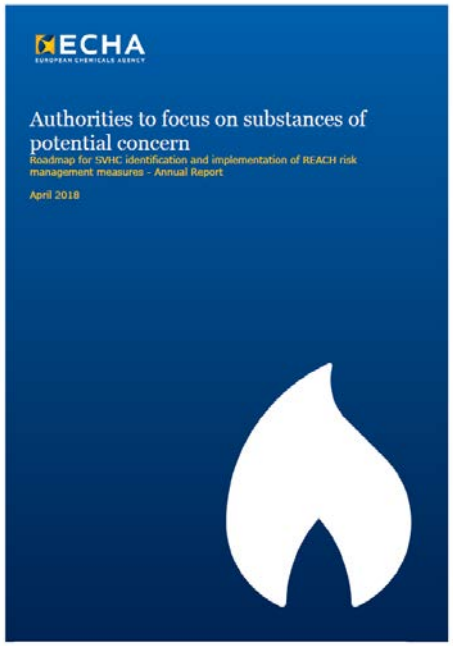
Source: ECHA website

From SVHC to Authorisation



SVHC Roadmap implementation status

- **April 2018: 4th progress report**
  - **RMOA approach is functioning**
  - From *ca.* 440 substances (original worst case assessment) to 1700 substances now addressed: « All currently known SVHCs (CMRs, PBT/vPvBs and EDs) have been addressed »
  - > 750 registered substances scrutinised -> 73% follow-up action: generation of higher-tier data
  - From individual substances to **groups of structurally similar substances**
  - From SVHC Roadmap to ECHA's Integrated Regulatory Strategy / **UN WSSD 2020 goals**: **beyond the SVHC Roadmap targets,** all substances > 100 T/yr



The positives from our perspective

- SVHC Roadmap goals achieved (and beyond)
- PACT is helpful : improves predictability and transparency
- RMOA is useful (improvements desired)
- Prioritisation for Annex XIV inclusion is transparent

Trends in regulating the most hazardous substances under REACH

- Restriction **or** Authorisation
  - → Restriction **and** Authorisation ?
- Substances of **Very High** Concern
  - → Substances of Concern
- Restrict **specific** substances in specific uses
  - → Restrict **categories** (endpoints, uses), work by derogation
- SVHC as "candidate" for authorisation
  - → **SVHC-alone** as RMM / black-listing substitution basis
- Improve supply chain **communication** on hazardous substances and uses

Suggestions for enhancements: RMOA

SVHC Roadmap: "*RMO assessment is a voluntary but critical step in the definition of the relevance of a SVHC*"

⇨ Enhance RMOA:

- **One substance – one RMOA – one RMM (at a time)**
- **Adapt RMM / RMOA to the use**: for process chemicals, intermediates and monomers, does SVHC/authorisation bring added value ? OSH for workplace?
  → integrate in / refine RMOA
- **Stronger coordination by ECHA:** More **harmonisation**, more centralisation, more formalization, more uniformity
- **More use and socio-economic consideration in RMOA e.g.:**
  - RMOA with SEA elements (equivalent to an Impact Assessment for choosing a regulatory instrument)

≠
  - Restriction / Authorisation: 'Full' SEA

Suggestions for enhancements

⇨ **More transparency on RiME**

⇨ **Improve Scoring Tool for prioritisation:** more granularity on uses and exposure

⇨ **Enable Simplified Authorisation**

Let's talk about substitution and… avoiding regrettable substitution

- Substitution is **one of** several RMMs
- **Case-by-case** assessment and decision
- Specific, technical **function in use** and technical performance: prime driver for substance selection
- Alternatives should be **tested to the same extent as the original substance** for health and environment, and risk-assessed
- Based on full **LCA**
- Taking into account technical and economic feasibility
- 'Grouping' to avoid regrettable substitution: yes, but **with care**
  - ✓ similar structure is not enough
  - ✓ same read-across/ grouping justification as for registration

Conclusions

- REACH, due to its novelty, has been and is still learning-by-doing: let's **focus on the fundamentals and make it work** before increasing the ambition level
  - ✓ Extended SDS / exposure assessment
  - ✓ Enforcement
  - ✓ Registration dossiers
  - ✓ Enhanced RMOA and RMM adapted to the use(s)
- **REACH contributes to UN Sustainable Development Goals**. **So do chemicals** (new materials, e.g. purification of water, food protection, energy efficiency, healthcare, etc)
  - ✓ Need to find the right balance
  - ✓ Need to reassure the public
- **Substitution** is one of several options, case-by-case, not a goal in itself and not a measure of sustainability if looked at in isolation

ChemistryCAN !
https://chemistrycan.com/

Designing with energy efficiency in mind ("cool roofs")



Recycling food packaging into school desks





Preserving wild fish stocks



Advanced chemical additives boost the quality of recycled paper