



10 years of Risk Management

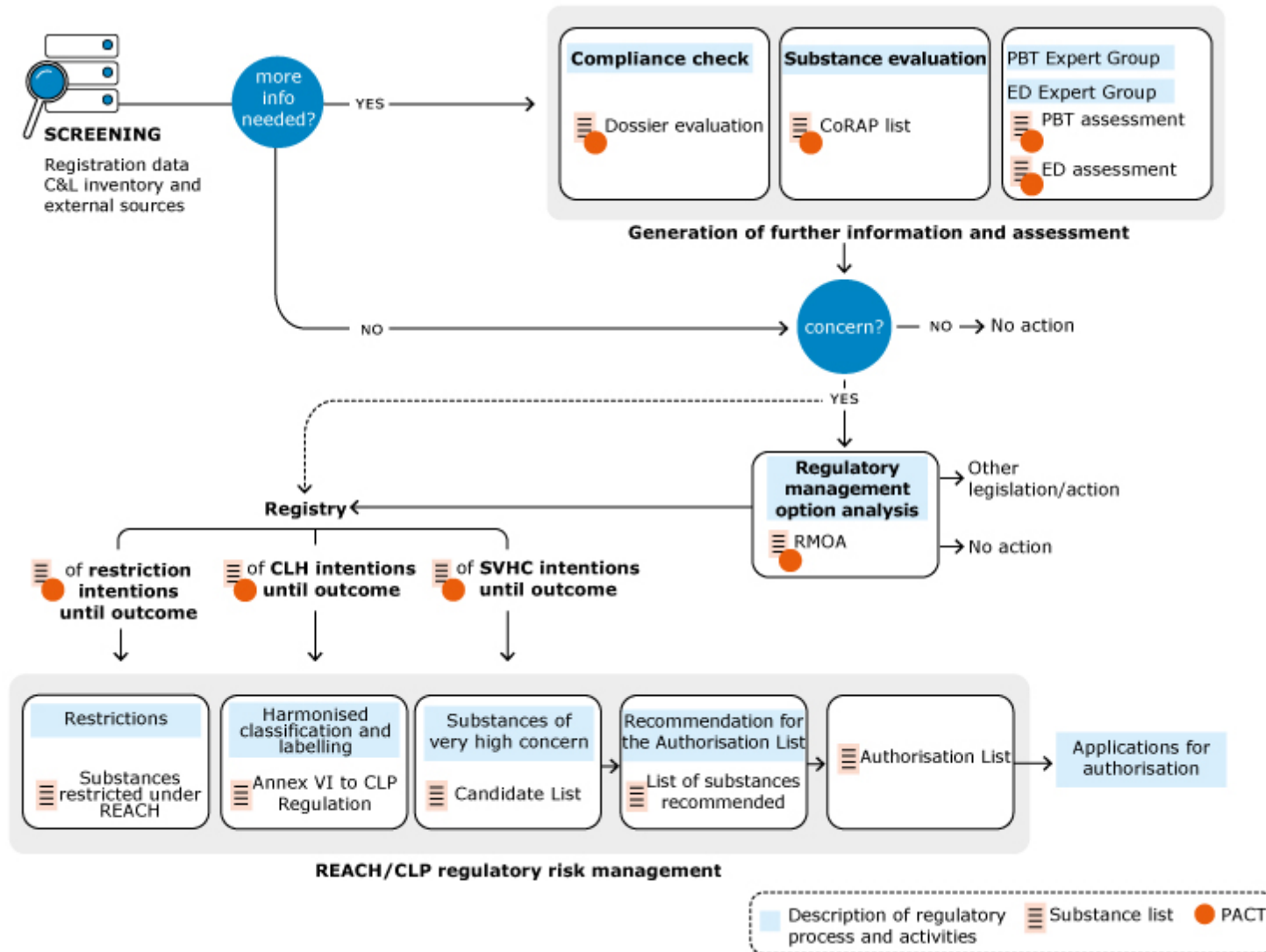
Safer Chemicals – ECHA Conference

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Risk management system



Statistics

Harmonised classification

624 classification proposals

348 opinions

Restrictions

32 conforming submissions

25 opinions

20 decisions

Authorisation

197 substances to Candidate List
- of which 39 PBTs and 14 EDs

74 recommended to Annex XIV
43 included in Annex XIV

27 substances applied for
232 uses applied for
205 opinions per use
133 decisions per use



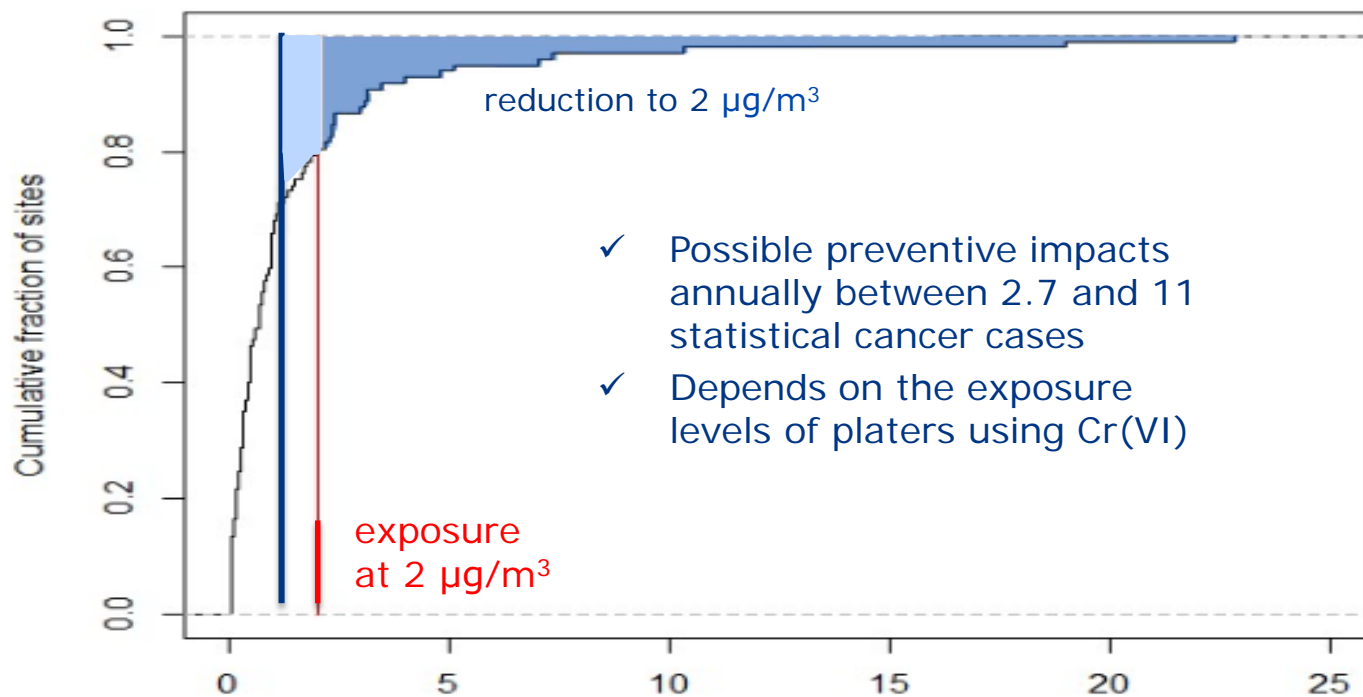
REACH review findings

*“The restriction procedure is generally working, though further improvements in **efficiency** are needed.”*

*“Authorisation is **meeting its objectives** to ensure proper control and foster substitution, where economically and technically feasible alternatives exist.”*

*“The restriction and authorisation processes still need to be implemented more efficiently and with **quicker** decision making.”*

Example: Exposure reduction in Cr(VI) plating



Based on CrVI compounds in plating shops in France 2010-13 (Vincent et al. 2015)

Examples: Restriction



Bisphenol A
in
thermal
paper

Phase-out of Bisphenol A
by 2 Jan 2020.

Substitutes: Bisphenol S, D8, Per-
gafast under substance evaluation
(BE). Other substitutes exist.



Chromium
VI in
leather
articles

In force on 1 May 2015.
Lead to various innovations such
as Sanotan - titanium-based
technology.

Source: ECHA Newsletter 2/2014

Examples: Authorisation



Murano Glass, IT
From arsenic trioxide to cerium oxide and ground granulated blast furnace slag.

Italian government funded research or of safer alternatives leading to substitution.
Arsenic concentrations in Murano air dropped by **98 %** (from 200 ng/m³ in 2014 to 4 ng/m³ in 2016).

Did not apply for authorisation.



European Project
From Cr(VI) to “diamond-like-carbon” coating of cylinders for printing and packaging

Developed prototype system and enabled technology owners to establish joint ventures and licensing deals for market uptake in 2019.

Source: Horizon 2020

<https://cordis.europa.eu/project/rcn/206525/factsheet/en>

Example: Relocation



Use of 1,2-DCE in a pharma application for innovative cancer treatment

Production relocated to the US because of “business uncertainty”. Quantity used under 100 kg per year implying low risk. Value added lost in the EU.

Source: Apeiron

Restriction or authorisation – any preference?

Restriction

- Burden of proof on authorities (resources)
- Level playing field
- Derogations are less clear
- Not only SVHCs
- Any condition
- Known

Authorisation

- Burden of proof on industry
- (Looks) quicker
- Authorisations are transparent
- SVHCs
- New

Combination

- Article 69(2): restriction after authorisation
 - Other combinations?

Increased involvement with stakeholders: Public Activities Coordination Tool (PACT)



Find out what is happening with any substance



Use the user-friendly search



Up-to-date information from ECHA's data

More: echa.europa.eu/substances-of-potential-concern

[Mapping the chemical universe to address substances of concern.](#)
[ECHA. Annual report 2019](#)

Conclusions

- Classification, ED and PBT assessment underpin
- Authorisation: substitution and reduced exposures
 - Diverging views on specific applications
 - Little attention on adding substances to Authorisation List
- Restrictions: reduced risks and promoted substitution
 - Member States and ECHA are using restrictions in more versatile ways
- Increasingly integrated approach in the next 10 years
 - Grouping approach
 - Improved consideration of OELs and measures under other EU legislation
- How (else) to promote substitution?
- Continued input and **dialogue with stakeholders** vital



Thank you!

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REACH Review Actions

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REACH review

Authorisation related actions

5: Promote substitution of SVHCs

- Capacity building, networks, promoting R&D investment

6: Simplify for a more workable authorisation process

- Legacy spares, low volumes, applications for authorisation covering multiple operators, reducing fees for applicants in joint applications

7: Early SEA information for possible regulatory measures

- Consider options to use available socio-economic analysis information at risk management option analysis stage
- Legacy spares



REACH review

Restriction related actions

8: Improve Restriction Procedure

- Public consultations, screening, CMRs in consumer articles

9: Enhance Member State involvement

- Simplify submission dossiers and increase Member State capacities



REACH review Interplay

11: Interplay between authorisation and restriction

- Preparation of a restriction dossier before sunset date (Art 69(2))
- Assess interplay between restriction and authorisation