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

- Possible preventive impacts annually between 2.7 and 11 statistical cancer cases
- Depends on the exposure levels of platers using Cr(VI)

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

Bisphenol A in thermal paper


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.

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

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.*

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

*Source: Horizon 2020*

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
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