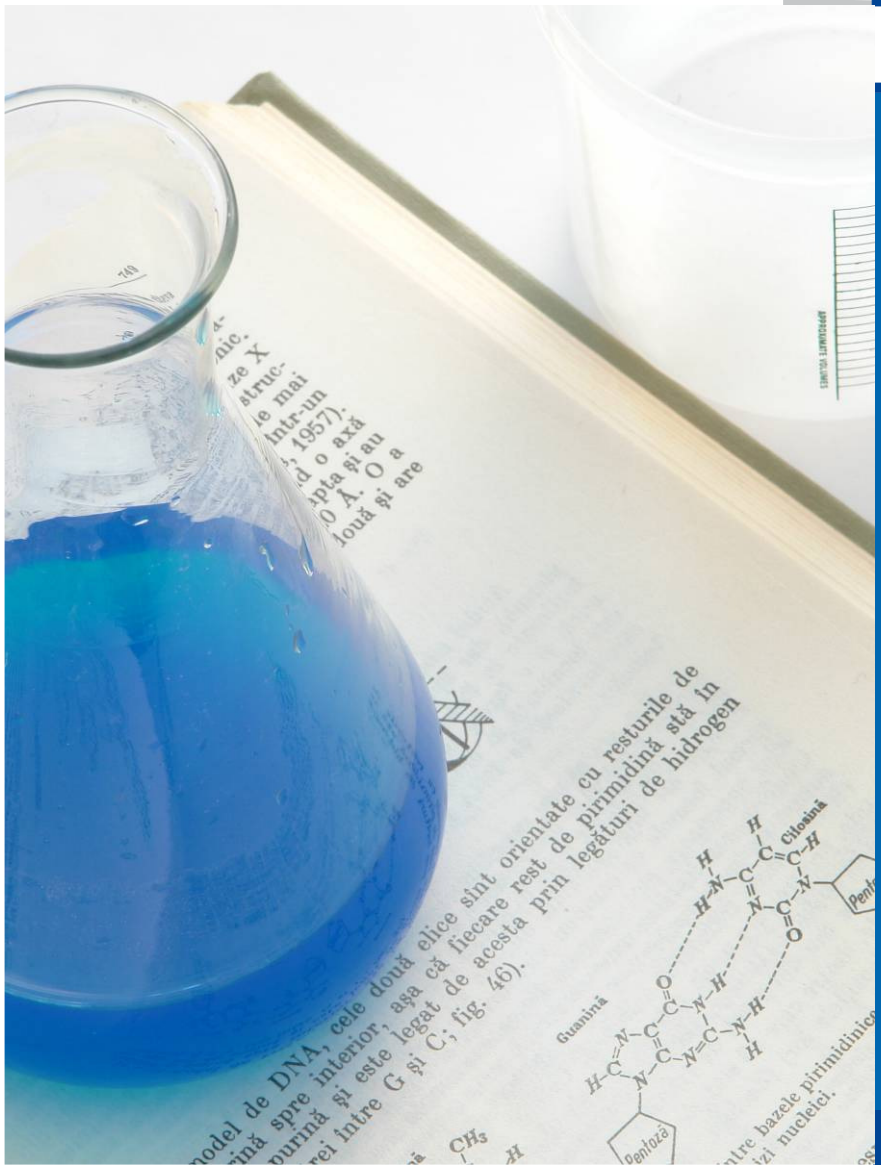

European Commission

REACH Authorisation: a new Risk Management tool

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Where is "substitution" in REACH?

- Literally, in Authorisation (Title VII and related recitals)

Art. 55: "Aim of autorisation and considerations for substitution"

- More generally, REACH provides substitution <u>pressure</u> through registration and effective implementation of evaluation, through

  (1) Favouring less hazardous substances
  (2) Favouring more informed substances

Substitution in REACH

(1) Favouring less hazardous substances

REACH establishes a level playing field with transparency.

Substances with less hazard for the same use will require less risk management and hence be less costly to use.

Substitution in REACH

(2) Favouring more informed substances

REACH CSR (Annex I and Guidance) results in more or less tailored risk management if based on less information (less knowledge on the details of the hazard and exposure)

Substances with more information for the same use will have (less or) more tailored risk management and hence be less costly to use.

REACH Authorisation: why? (1/2)

- A focus on a specific sub-group of substances: Substances of Very High Concern (SVHC)
  - some not specifically regulated yet: PBT, vPvBs, and other substances of "equivalent level of concern"
  - others already regulated, e.g. via workers legislation, but for which a complementary risk management tool was deemed necessary (CMRs)

REACH Authorisation: why? (2/2)

- Goal (protection perspective):
  - ultimately: substitution
  - ensuring proper control of the risks, in the meantime
- Fits with the "reversal of the burden of proof" principle

Restrictions: what has changed?

- Improved process
- Involvement of ECHA, both with scientific committees and coordination by the Secretariat
- Public consultations
- Registration dossiers (and evaluation) as a basis
- The burden of proof (also) on Industry/market operators

Restrictions *vs.* Autorisation (1/2)

- Wider scope for Restrictions:
  - non-SVHC substances
  - manufacturing, presence in articles
  - less general exemptions

- Recital 73: substitution principle also underlying restrictions

- Restrictions, Authorisation and others (incl. outside REACH) are complementary

  Question: how to find and organise the synergies?

Restrictions *vs.* Authorisation (2/2)

- For SVHCs, how these tools should work together is discussed in the implementation of "*2020 Roadmap for SVHCs*"
  - main routes for typical cases
  - sequencing
  - communication

Applying for authorisation, or replacing? (1/2)

- The actual alternatives are:
  - applying for authorisation and engaging in the substitution process,
  - or substituting now.

- A "business" choice:
  - The first question is not *how* to apply for an authorisation; it is *what will happen to my business if the Annex XIV substance can no longer be used in the EU?* (ECHA, Seminar on AfA, Feb. 2013)
  - and, should and can I substitute already now?

Applying for authorisation, or replacing? (2/2)

- In answering these questions, not only direct economical aspects:
  - Can't I take this opportunity to move away for an SVHC, earlier than others?
  - Can't I invest in alternatives, rather than in developing and submitting an application?

- A substance might be critical to your business, but is it also critical for your suppliers, customers, competitors? → You need to look wider than your immediate (commercial, technical, environmental) context (ECHA, Seminar on AfA, Feb. 2013)

Thank you for your attention!