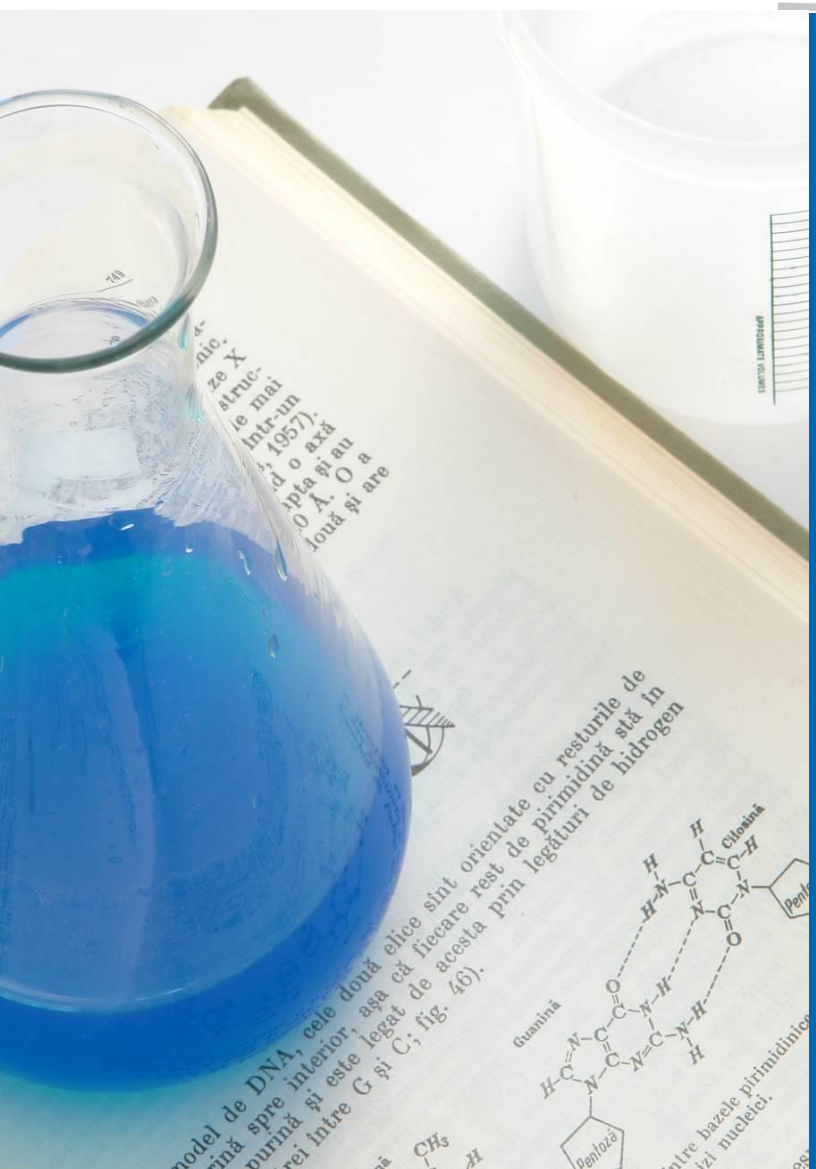

European Commission

Outlook from authorities' point of view: Way forward

Lessons learnt on
Applications for Authorisation

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What do we want to achieve with REACH authorisation?

Article 55 REACH:

1) Proper control of risks from use of SVHCs
2) Progressive replacement of SVHCs by by suitable alternatives where technically and economically viable

Ultimately:
SUBSTITUTION

What do we not want to achieve with REACH authorisation?

- Only companies with deep pockets applying
- Small players being kicked out of the market
- Substitute EU production by imported finished goods
- Burdensome and costly bureaucratic procedure
- Postpone substitution longer than necessary
- Discourage substitution / discourage business producing / using safer alternatives
- Substitute with potential SVHCs
- Discourage innovation

So, where is the problem?

Applying for authorisation is costly and burdensome: Why?

- Broad scope (no volume threshold, all uses, wide range of operators covered)
- New, relatively broad and demanding information obligations (CSR, AoA, SEA):
  - Some elements not regulated in detail (AoA, SEA)
  - External expertise may be needed (for some operators)
  - Supply chain coordination is a must
- Applicant not necessarily a M/I of chemicals → not necessarily acquainted with REACH
- Not much experience / reference cases

… and what are we doing to solve it?

REACH legislator could not anticipate all elements needed for the implementation of the authorisation requirement:

- Legal interpretation and guidance
- Streamlining and simplification of authorisation application procedure in specific cases
- General streamlining of authorisation applications (all cases, more fit-for-purpose)?

1) Legal interpretation and guidance

- Legal interpretation and guidance on REACH provisions has been provided by COM and ECHA along the way:

  (e.g. scope of authorisation and exemptions from it, applications submitted by ORs, indication of criteria for setting and counting of review periods)

- Further clarification still needed on other elements:
  - Description of the applied-for use
  - Reference to RMM related to worker exposure: interface with OSH legislation
  - AoA: suitability and availability of alternatives for the applicant and for the DUs

2) Streamlining and simplification of authorisation procedure: specific cases

Experience so far has shown specific cases where authorisation requirement might impose disproportionate administrative burden on operators (reference to REFIT Communication of June 2014)

- Uses in low volumes
- Uses in legacy spare parts
- Uses in products subject to type-approval
- Uses as biologically essential elements

ECHA-COM TASK FORCE ON AFA SIMPLIFICATION

2.1) Low volume uses:

- **Rationale for simplification**: disproportionality between cost of a full-scale application and potential benefits for human health/environment
- **Public consultation** launched on 5/02/2015 (http://ec.europa.eu/yourvoice/consultations/index_en.htm):
  - *Scope of "low volume" cases*:
    - volume limit per substance and per legal entity/year
    - limited to applications for own uses
    - exclusion of cases with potential consumer exposure in substance lifecyle
  - *Simplified information requirements* (within framework of Article 62 REACH): draft CSR, AoA and SEA templates developed by Task Force

2.2) Uses in legacy spare parts:

- **"Legacy spare parts":** spare parts intended for articles produced and placed on the market before the sunset date
- **Public consultation** launched on 5/02/2015:
  - On definition and scope (e.g. also mixtures for repair of articles?)
  - On which Annex XIV substances / volumes are concerned in practice
  - On one-time extension of LAD/SD
- **Two-step approach**: one-time extension of LAD/SD and in parallel development of a simplified AfA

2.3) Other specific cases:

- **Uses in products subject to type-approval /certification procedure:**
  - Type-approval / certification requirement is a clear element to be considered in SEA and in calculation of review period (if suitable alternatives are identified)
  - Need (and scope) of simplified procedure still under discussion (CARACAL March 2015)
- **Uses as biological essential elements:**
  - Not yet of concern for existing Annex XIV substances
  - To be addressed in the future

3) General AfA streamlining?

- **CSR**: should it be limited to the elements needed for risk assessment? (e.g. remove sections related to hazard assessment if applicants use the DNEL or dose-response curve recommended by the RAC for the substance)
- **AoA**: is the Guidance sufficient / fit-for-purpose?
- **SEA**: is the Guidance sufficient / fit-for-purpose?

Next steps

- **Low volume uses: Implementing act** concerning streamlining and simplification of application procedure + reduction of fees
- **Legacy spare parts uses**: One-time extension of transitional arrangements for Annex XIV substances concerned and future simplification of application procedure
- **Other specific cases and general simplification**: discussion planned in CARACAL 17

Thank you

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