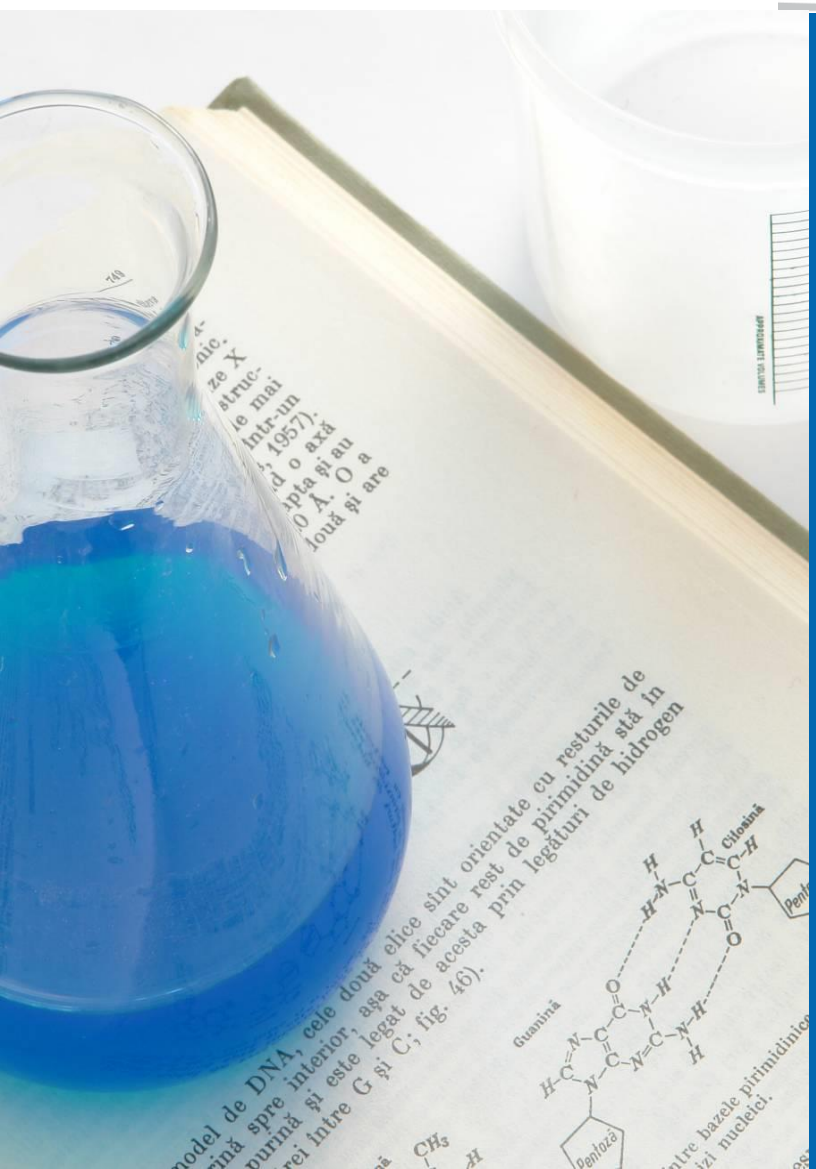

European Commission

The future of REACH authorisation: proposed simplification

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Presentation overview

1) COM reflection on how the authorisation process works

2) Streamlining and simplification initiatives

3) Next steps

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

Challenges of the authorisation requirement for operators

- 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

COM reflection on the authorisation process

- **REFIT Communication – June 2014**

  New measures considered in the medium-term to improve the authorisation process to make it more predictable for business, including:

  - reducing the frequency of Annex XIV amendments;
  - considering more strongly socio-economic impacts when including substances n Annex XIV;
  - **simplifying the authorisation process for some specific low-risk cases.**

- **CARACAL 15 (July 2014)**
  - First ideas for improvement presented to MSCAs
  - Setting up of a **TF for improving the workability of the AfA process**
- **Public consultation on first proposed measures (low volumes and legacy spare parts): Feb-Apr 2015**

Streamlining and simplification initiatives

Two types of initiatives under consideration:

- **Simplification of AfAs in specific cases:**
  - **low volumes**
  - **legacy spare parts**

  } **Public consultation (Feb-Apr 2015)**

    - **uses in products subject to type-approval requirements**
    - **essential biological elements**
    - **process chemicals**
    - **recycled substances)**

- **General streamlining of AfAs**:
  making AfAs fit-for-purpose

Simplification of AfAs in specific cases: low volume uses

- **Rationale**: possible disproportionality between cost of a full-scale application and potential benefits for human health/environment
- **Public consultation** (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

Simplification of AfAs in specific cases: uses in legacy spare parts

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

Other specific cases?

- Cases being considered for simplification but no proposals under consideration yet
- **Uses in products subject to a type-approval / certification procedure:**
  - type-approval / certification requirement is a clear element to be considered in SEA and in the calculation of the review period
  - COM has proposed to consider such cases under general streamlining of AfAs
- **Uses as biological essential elements:**
  - not yet of concern for existing Annex XIV substances but of possible concern in the future

Other specific cases?

- **Uses as process chemicals in quasi-closed systems**
  - Suggested as a possible case at the February 2015 "Lessons learnt" workshop on the basis of low exposure and no consumer exposure
  - COM has proposed to consider such cases under general streamlining of AfAs

- **Uses of recycled substances:**
  - Requested by some industry sectors during CARACAL 17
  - No COM position yet

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 streamlining**:
  MSCAs to comment on COM proposals

Thank you

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