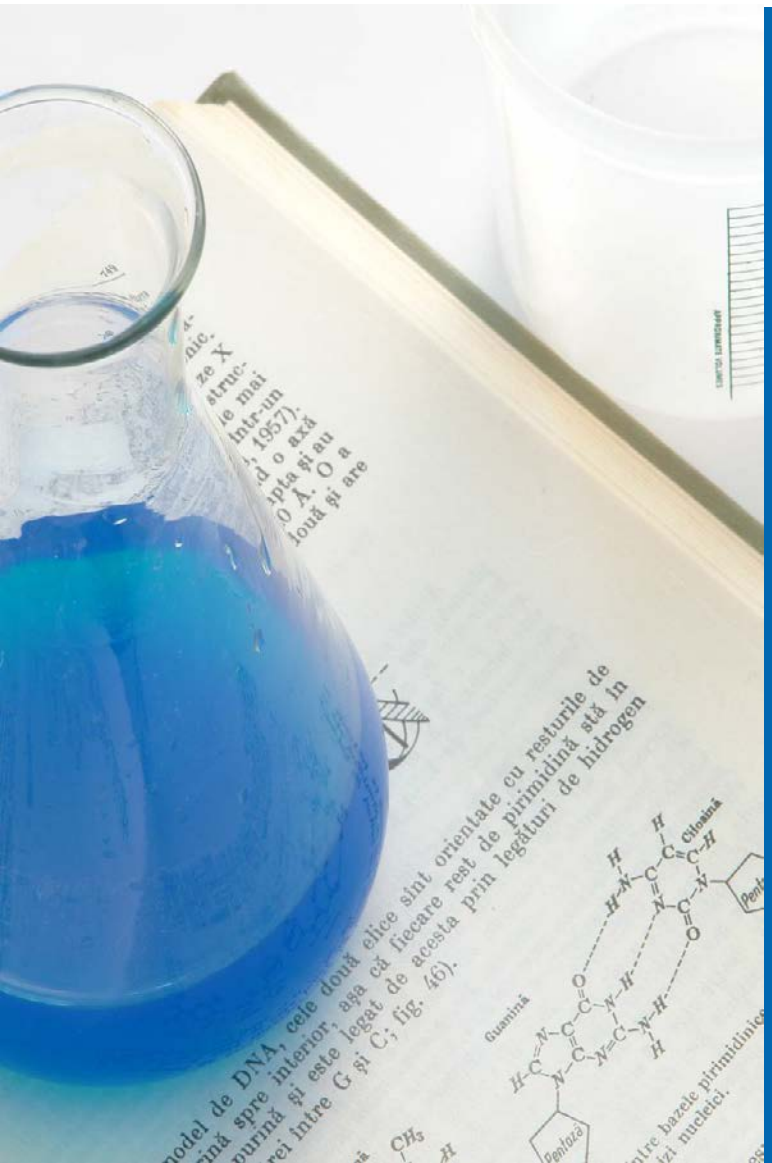

European Commission

The Authorisation Decision-making process

Seminar on Applications for Authorisation

Helsinki, 18-19 April, 2017

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European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
REACH Unit

The role of the Commission

- **Article 60(1) REACH:**
  The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

- **Article 64(8) REACH:**
  The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing authorisation shall be taken in accordance with the procedure referred to in Article 133(3).

- **Article 61 REACH:**
  Review of authorisation decisions

Content of an Authorisation Decision

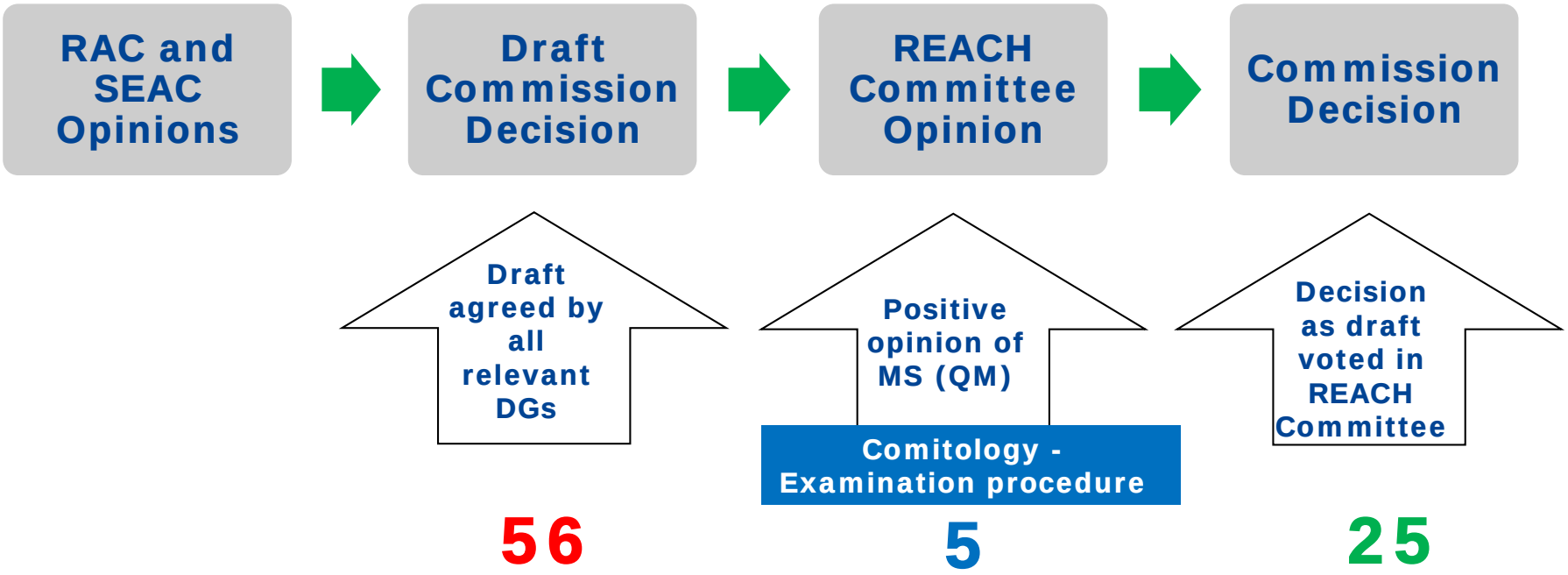
Article 60(9) REACH:

- Legal entity (ies)
- Substance (s) identity
- Use(s) for which authorisation is granted
- Any conditions under which the authorisation is granted
- Time-limited review period
- Any monitoring arrangement

The Decision-making Process

ECHA
EUROPEAN CHEMICALS AGENCY

European Commission



Interface with ECHA

- COM closely follows the opinion-making process in RAC and SEAC (observer in RAC and SEAC meetings and in trialogues)
- ECHA Secretariat observer in REACH Cttee meetings
- Ongoing dialogue with ECHA Secretariat on interpretation questions that may arise during the process (e.g. case of recycled PVC containing DEHP – “end of waste”)

Transparency of decision-making process

- **State of play** on all AfAs on which RAC and SEAC opinions have been received by COM and **adopted Decisions**: https://ec.europa.eu/growth/sectors/chemicals/reach/authorisation_en
- **Draft Decisions** publicly available via Comitology Register: http://ec.europa.eu/transparency/regcomitology/index.cfm?CLX=en
- **Summary of Decisions**: OJEU

Some reflections

- **Use definition**:
  - All processes covered by the use applied for should be referred to in the exposure scenarios
  - Should be specific enough to match with analysis of alternatives -> uses for which there are alternatives should be excluded from the AfA
- **Chemical Safety Report**
  - Quality and representativeness of exposure data for all DUs covered and for all uses applied for
  - Level of risk: DNEL/PNEC for adequate control route, no given risk level for SEA route
- **Analysis of alternatives:**
  - Scope: determined by the function of the SVHC
  - Must be exhaustive: must cover all the uses applied for

Some reflections

- The **Authorisation Decision** does not necessarily follow the RAC and SEAC opinions
- **Scope of authorised use(s)** can be more restricted than the use(s) applied for
- **Conditions** can be imposed to address specific aspects in the practical implementation of the authorisation / review report (e.g. reporting on availability of alternatives, further specifying the uses in the review report)
- **Monitoring arrangements** can be provided – in particular to improve the information on exposure
- **Review periods**: shorter review periods in particular where RAC and SEAC opinions point to significant uncertainties in AfAs

Recent developments

- **Requests for internal review under Article 10 of Regulation 1367/2006 (Aarhus Regulation) of Authorisation Decisions:**
  - Decision authorising uses of DEHP in recycled soft PVC (Decision DEHP-Vinyloop)
  - Decision authorising uses of lead chromate pigments (DCC Maastricht OR)
- **Actions for annulment of Authorisation Decisions:**
  - Decision authorising uses of lead chromate pigments - DCC Maastricht OR (Sweden v. COM)
  - COM Decision replying to request for internal review of authorisation Decision DEHP-Vinyloop (ClientEarth v. COM)

Recent / ongoing initiatives

- **Streamlining AfAs:**
  Practical guide *How to apply for authorisation*
- **Simplifying AfAs in specific cases:**
  - Where risk is expected to be low (low quantities)
  - Where substitution is not feasible (legacy spare parts, repairs)
- **Adapting the fees:**
  - Reducing the fees for simplified AfAs
  - Eliminating the additional fee per each additional applicant in joint AfAs
  - Increasing the fee per each additional use
- **Review periods**:
  - decided on a case-by-case basis (roughly half of the decisions provide 12y, rest vary from 2y – 7y)
  - possibility of review periods longer than 12y: criteria are being developed

Thank you

Disclaimer

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