Procedure in SEAC and involvement of relevant stakeholders

FPP4EU Collaboration Platform Workshop

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Overview

REACH restriction process

Opinion-making in SEAC

Input of stakeholders

REACH restriction

→ Protects our health and the environment from chemical risks
- Addresses a risk that is not adequately controlled
- Where action is required at EU wide level
- Safety net for other REACH and EU processes

→ Usually limits or bans manufacture, placing on the market or use of a substance (also in a mixture/article)

→ Can set out specific conditions such as technical measures or labelling requirements

→ Dossier Submitter can be Member State(s) or ECHA

Restriction proposal

→ Restriction report (Annex XV report) includes:
- Information on hazards, exposures and risk
- Justification for action at EU wide level
- Available information on alternatives

→ Report has to show that a restriction is the most appropriate measure to address identified risk

→ Restriction report may also include socio-economic analysis
- Net benefits (human health, environment)
- Net costs (industry, consumers, social and wider implications)
- Usually included

→ Inform decision maker for final decision (with opinions)

After submission

Expected for 'universal' PFAS: 13 January 2023

- → Restriction report publicly available after submission (pre-publication, not for consultation) Early February 2023
- → Opinion-making process (typically 14 months)
  - Conformity check: RAC and SEAC March 2023 meetings
  - **Six-month consultation** on restriction report 22 March 2023
  - Evaluations of RAC and SEAC documented as 'opinions'
  - **60-day consultation** on SEAC draft opinion
  - Comments submitted in consultation (and responses) published with updated proposal (Background Document)
- → After adoption, opinions published and sent to Commission
- → Scrutiny by EU Council and European Parliament

Restriction process

I Phase

Preparation and submission of a restriction proposal

- Starting the restriction process
- Notification of intention to submit a restriction proposal
- Registry of Intentions
- Preparing the restriction dossier
- Submission and conformity check

II-A Phase

Consultations

- Consultation on the restriction report
- Consultation on SEAC's draft opinion

II-B Phase

Opinion development

- Advice from the Forum
- RAC's opinion
- SEAC's opinion

III Phase

Decision and follow-up

- Commission decision on restriction
- Complying with restriction
- Enforcing the restriction

echa.europa.eu/restriction-process

ECHA
EUROPEAN CHEMICALS AGENCY

Objectives of opinion-making

→ Client is the decision maker (Commission and Member States)

→ Based on the proposal and RAC/SEAC opinions they need to:

- Decide that there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances
- Decide that the risk needs to be addressed on a EU wide basis
- Take into account the socio-economic impacts of the proposal, including the availability of alternatives

→ RAC/SEAC evaluation focuses on 'justification for a restriction'

- Assessment by the Dossier Submitter in restriction report
- Comments by interested parties in the consultations

Objectives of opinion-making – SEAC

→ Formulate an opinion on the proposed restriction and the related socio-economic impacts, taking into account consultation comments

→ What are the impacts of the proposed restriction?

- Costs
- Benefits
- Uncertainties

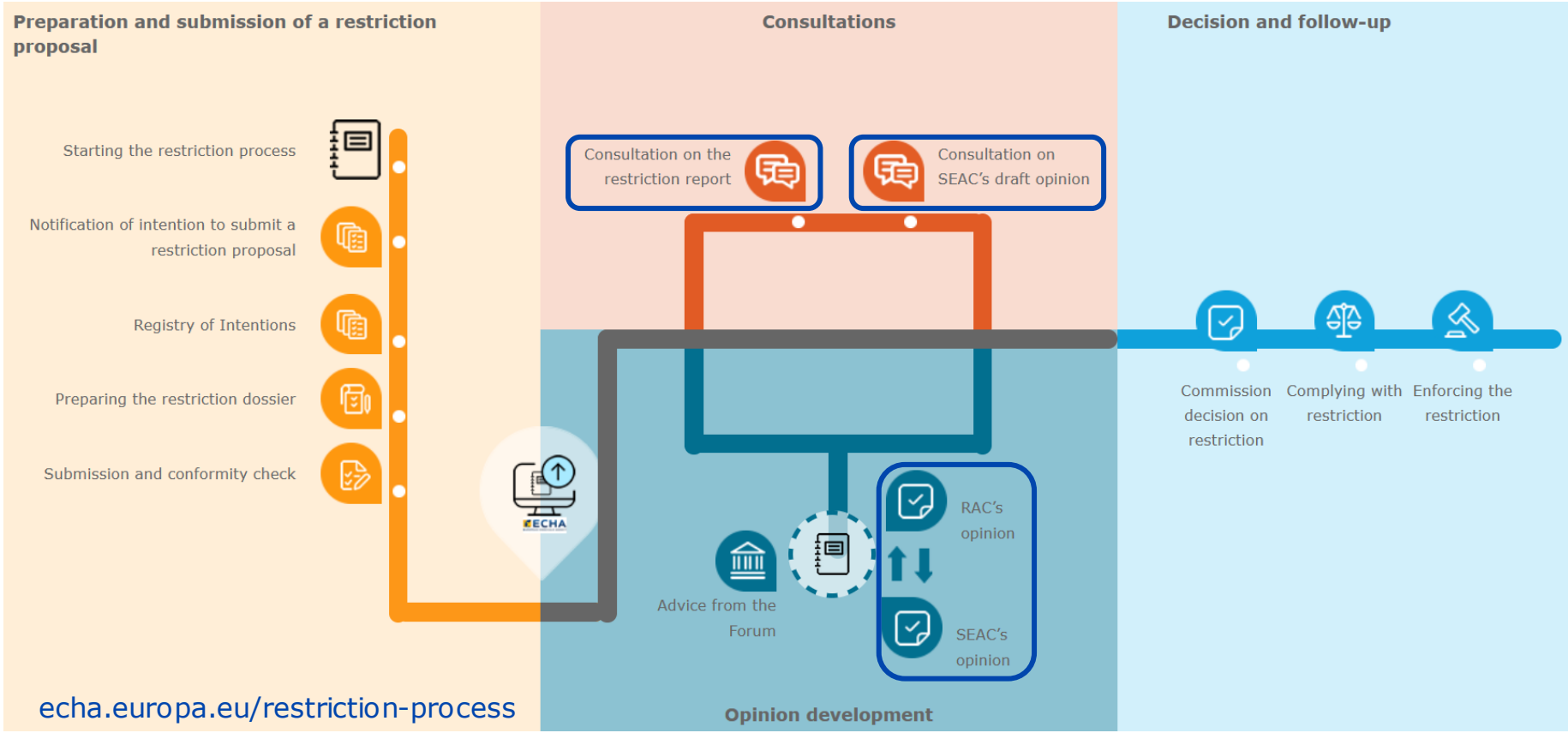
Reliability, representativeness and appropriateness of data/assumptions/methodology; impact of uncertainties on conclusions; can be qualitative or quantitative

→ Is the proposed restriction the most appropriate means to address the identified risk (Annex XV criteria)?

- Effectiveness (to address the risk)
- Practicality (including enforceability)
- Monitorability

Proportionality to address the identified risk; can the measure be enforced (not necessarily by analytical means); is risk reduction monitorable over time?

Input of stakeholders – When?



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Input of stakeholders – When?

→ Consultation on the restriction report
- Make use of the early submission deadline if possible
- Multiple submissions can be made

→ RAC and SEAC meetings
- Ensure that relevant stakeholders are registered to follow the discussions
- Further info on committees' procedures:
  echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment
  echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis

→ Consider the indicative evaluation schedule

Indicative evaluation schedule

Committee plenary meeting	Committee for Risk Assessment	Committee for Socio-Economic Analysis
2.5 months after consultation starts	• Verify scope (of risk assessment) • Conclude evaluation of hazard assessment • Initial evaluation of exposure and risk	• Verify scope (of impact assessment) • Conclude that action is required on an EU-wide basis • Conclude on appropriateness of other regulatory RMOs • Initial evaluation of AoA • Initial evaluation of costs and benefits • Initial evaluation of practicality and monitorability
5.5 months after consultation starts	• Conclude evaluation of exposure and risk and that action is required on an EU-wide basis • Initial evaluation that the proposed restriction is the most appropriate EU-wide measure (effectiveness, practicality and monitorability; all assessed restriction options and RMOs to be evaluated)	• Conclude evaluation of AoA • Conclude evaluation of costs and benefits • Initial evaluation of proportionality
8.5 months after consultation starts	• Address comments from the Annex XV report consultation • Conclude evaluation that the proposed restriction is the most appropriate EU-wide measure • Summarise, evaluate and conclude on uncertainties • **Adopt opinion**	• Address comments from the Annex XV report consultation • Conclude evaluation that the proposed restriction is the most appropriate EU-wide measure (costs, benefits, proportionality, practicality and monitorability) • Summarise, evaluate and conclude on uncertainties • **Agree draft opinion**
	• Not relevant	• Conclude on issues raised during SEAC draft opinion consultation • **Adopt opinion**

Input of stakeholders – How?

Consultations

- → Detailed information should be submitted through consultations
- → Use of alternative routes is discouraged – response will be to submit the information through the consultations
- → Non-confidential submissions will be published
- → RAC/SEAC members also have access to confidential submissions
- → All consultation submissions analysed in detail by Rapporteurs – responses to (non-confidential) submissions published

RAC/SEAC meetings

- → Input during meetings should be brief scientific/technical points to aid discussions
- → Keep in mind the remit of each Committee

Input of stakeholders – What?

Information typically relevant for SEAC

→ Alternatives and their performance/suitability

→ Impacts of proposed restriction

→ Uses affected by the proposal missing from the assessment

Make impactful consultation submissions

→ Structure submissions clearly – provide a summary section, use bullet points for key issues, prioritise issues, avoid jargon

→ Answer specific questions that have been asked

→ Provide supporting information and evidence – if documents are attached be clear why these are important

→ Requests for derogations or longer transition periods must demonstrate that the impacts of the proposal would be disproportionate – be realistic

Conclusions

REACH restriction is a flexible tool – it addresses chemical risks that cannot be addressed otherwise

Opinion-making is about facilitating informed decision-making – SEAC's focus is on socio-economic impacts

Stakeholder inputs are important throughout the process – clear submissions to consultations are key

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