

Procedure in SEAC and involvement of relevant stakeholders

FPP4EU Collaboration Platform Workshop
12 December 2022


European Chemicals Agency



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

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

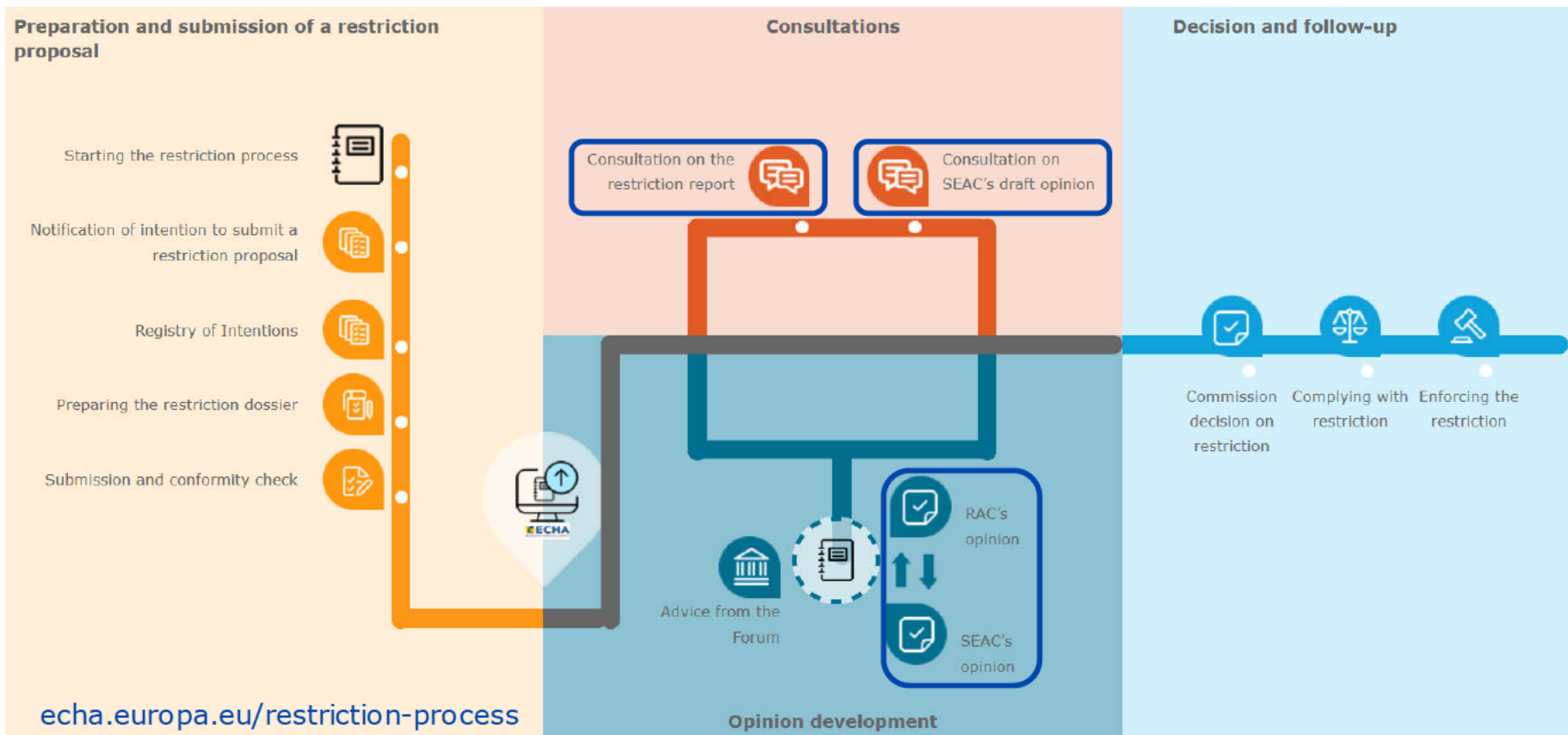
Objectives of opinion-making – SEAC

- 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
- 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

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

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?



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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