

REACH Restriction process

EPEE APPLIA Regulating
refrigerants: a sustainable route
towards Green Deal objectives

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REACH restriction

- Restriction is a tool for protecting our health and the environment from the risks posed by chemicals
 - Address a risk that is not adequately controlled
 - Where action is required at Union level
 - Safety net for other REACH and EU processes
 - Restrictions usually limit or ban manufacture, placing on the market or use of a substance (also in a mixture/article)
 - A restriction can also set out specific conditions such as technical measures or labelling requirements
- Dossier **submitter** can be a Member State or ECHA
 - **Evaluated** by ECHA's committees for risk and socio-economic analysis
 - **Decision making** by COM with Member States
 - **Scrutiny** by Council of the EU 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 () Public consultations

- Public consultation on the restriction report
- Public 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



Starting the process

- If Member States, Commission or ECHA have a concern that a substance poses a risk to our health or the environment, preparatory work starts to investigate the problem through risk management option analysis (RMOA)
- If they conclude that a restriction is the best way forward a notification is made
 - **Registry of intentions**
 - 12 months prior to submission
- Enables interested parties (citizens, organisations, companies and authorities) to plan for how they will contribute the restriction process

echa.europa.eu/registry-of-restriction-intentions



Restriction proposal

Annex XV report

- Annex XV report should contain:
 - Information on hazards, exposures and risk
 - Justification for action at EU-wide level
 - Available information on alternatives
- Proposal has to show that a restriction is the **most appropriate risk management measure** to address identified risk
- Multiple restriction options can be assessed
- Proposal would typically also include socio-economic impact analysis



Evaluation (~12 months)

After submission by ECHA

- Risk Assessment Committee (RAC)
 - Socio-Economic Analysis Committee (SEAC)
 - Effectiveness, practicality and monitorability of the proposed restriction(s)
 - An appropriate restriction must be:
 - Targeted to effects or exposures resulting in the risk
 - Capable of reducing these risks within a reasonable time period proportionate to the risk
 - Socio-economic analysis
 - Net benefits to society (human health and environment)
 - Net costs to society (manufacturers, importers, consumers)
- } opinions

Consultations and stakeholder input

- Proposed restrictions subject to a 6 month consultation
- Draft SEAC opinion consultation for 60 days



RAC-related information

- Annex XV will use best available information
 - Could be 'default' values or reasonable assumptions
- Stakeholders could have information to refine the risk assessment e.g.
 - Effectiveness of risk management measures
 - Closed systems and minimisation
 - Exposure/releases throughout the life cycle
 - Manufacture
 - Service life
 - End of life
- Claims **must** be substantiated with argumentation or data
- ECHA guidance
- Always best to provide information early

SEAC-related information

- Availability and performance of alternatives
- Impacts of the proposed restriction
 - Costs and benefits for affected actors
 - Other impacts (e.g. climate impacts)
 - Analysis demonstrating that the conditions of the proposed restriction would be disproportionate
 - AKA **derogation requests**
- Relevant elements of impact assessment detailed in Annex XVI of REACH
- ECHA guidance
- **Always best to provide information early**

Summary

- Restriction is a flexible risk management tool to address risks for chemicals
- A dossier contains
 - a risk assessment
 - Justification that the proposed restriction is effective, practical and monitorable
 - Impact assessment for restriction opinion(s)
- 6 month consultation
 - Information on risk assessment
 - Impacts of the proposal (positive and negative)
- Decision making takes into account RAC/SEAC opinions

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