

Restriction procedure, ECHA

Updated: February 2023

This document aims at presenting a brief introduction to the PFAS restriction process and a detailed account on the current stage (March, 2023) of consultation at ECHA. It describes the steps followed at ECHA – clarifying stakeholders’ participation and involvement. It also highlights how ECHA’s committees conduct their respective assessments. The outlined process is expected to help better understand the ongoing process of the EU PFAS restriction proposal and to inform on how to make contributions. Below the PFAS restriction timeline:

THE EU PFAS RESTRICTION PROPOSAL



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The PFAS restriction proposal at a glance:

On 7 February 2023, a proposal for a European- level restriction process on PFAS was published by ECHA. The proposal was submitted by the Netherlands, Denmark, Germany, Norway and Sweden.

The ultimate aim of the restriction proposal is a ban on the use of these substances to limit the risks to people and the environment. The proposal focuses on the entire group of PFAS substances (in accordance with the definition of PFAS handed by OECD) in order to avoid one PFAS being replaced by another.

Three stages can be identified in the process. The first (completed) stage was to prepare and submit a restriction proposal. As a second stage there is a public consultation.

Who can submit feedback to public consultation? This instance is open to anyone having interest and making a submissions supported by evidence. **ECHA provided in 2020 a document serving as [Guidance](#):** "companies, organisations representing industry or civil society, as well as authorities. Stakeholders from both the EU and outside the EU are invited to submit comments". Information is processed, and the ECHA Scientific Committees (RAC and SEAC) then prepare their opinions.

In the final stage, the European Commission drafts a proposal.

Restriction process under ECHA: Public consultation stage

Start of Public consultation for PFAS restriction proposal: 22 March, 2023.

Duration: 6 months

When a restriction proposal reaches ECHA, an adequacy assessment takes place, after which the proposal is finally published. At this point, ECHA starts a public consultation process, in which stakeholders, including industry, NGOs, and the public, are invited to provide input. This information is used to inform the risk assessment and the recommendation on the most appropriate measures to restrict the use of the chemical.

Stakeholders can provide [comments and additional information on the restriction within six months](#) of its publication on the ECHA website. Noteworthy, commercially confidential information can be excluded from the parts of the dossier made available for public consultation.

It is worth mentioning that more than one submission can be made. Below an excerpt of the [ECHA guidance](#), dated 2020, which touches upon the **timeliness of submissions**; the earlier it is made, the more *influential* the comments may be.

"If the information shared within the consultation on the Annex XV restriction report is to have a significant impact in the Committees discussions, it should be submitted early in the process (see the plenary plan in the specific information note for the restriction and the consultation page on ECHA's website for each restriction proposal). In any case, the information should be sent as early as possible in the process and it should cover all the elements of the restriction proposal and not only on the risk covered in the Annex XV restriction report.

*While all information submitted within six months of the start of the consultation will be considered by RAC and SEAC, **information received within five months of the start of the consultation will be able to be included in discussions in the 2nd RAC and SEAC plenary discussions**; these are the key plenaries to shape the opinions of the Committees”.*

Notes from other restriction processes point to the possibility **to submit more than one consultation response during the six month period¹** and that in **early comments respondents may outline when they plan to submit subsequent comments and on which topics. This information can assist the Rapporteurs of the committees to plan their evaluation²**.

As was recently shared in an exclusive webinar on the EU PFAS restriction process³: When submitting information during consultations, it is important to keep in mind that derogations are considered based on the availability of alternatives, and not on the essentiality or the socio-economic impact⁴. [...] The approach taken by authorities is not to assess different types of uses but the impact of the release of PFAS in the environment.

Another relevant point not to be overlooked (and likewise highlighted in the webinar), is that even if unlimited derogations are granted, equivalent requirements will be developed under future revisions of sectoral legislation. Thus, it was stressed that substitution plans should be given priority.

Risk assessment – Committee’s opinions

ECHA conducts a risk assessment to determine the potential risks posed by the chemical and to identify the most appropriate measures to restrict its use. This risk assessment is based on the best available scientific evidence and considers the entire life cycle of the chemical, from production to disposal.

The assessment is made by the two ECHA committees: Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC).

RAC

Within nine months of the proposal publication date, RAC will give its opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment – on the basis of information provided in the dossier and during the consultation. RAC’s opinion is not open for comments.

SEAC

Simultaneously, SEAC drafts an opinion about the socio-economic impacts of the suggested restrictions. For this assessment, it takes into account the comments and socio-economic analyses submitted by stakeholders.

Prior to adopting its final opinion, the draft opinion of SEAC is open for comments. Comments on the SEAC draft opinion itself should be submitted within 60 days of its publication. SEAC will then adopt its final opinion within 12 months of the start of the first consultation on the restriction proposal.

¹ From note on Creosote: <https://echa.europa.eu/documents/10162/ad017f4e-1ea5-a0c7-7126-7b6563070904>

² From note on PFAS FFF: <https://echa.europa.eu/documents/10162/3d12e975-6a81-b28d-5b6b-1d4a2333f4de>

³ Webinar organised by EPPA and Royal HaskoningDHV on the Restriction of PFASs. February 15, 2023.

⁴ Societal costs of inaction are deemed more important than the cost of a universal ban of PFAS, as the restriction proposal on PFAS reads, and as was said by a Senior Consultant at the Royal Haskoning DHV.

To note, the Forum of enforcement authorities from Member States can provide advice (non-binding) to the committees on the enforceability of the proposed restriction. ECHA provides the Forum with technical, scientific and regulatory intelligence during the process.

Issuance of recommendation by ECHA

Based on the results of the risk assessment, ECHA makes a recommendation to the European Commission on the most appropriate measures to restrict the use of the chemical. The recommendation is based on the results of the risk assessment and the comments received during the public consultation phase.

Decision

The European Commission must then strike a balanced view of the identified risks and of the benefits and costs of the proposed restriction, considering the opinions of RAC and SEAC. The European Commission adopts a restriction decision, which is binding on all Member States. The restriction decision sets out the measures to restrict the use of the chemical.

Within three months of receiving two committees' opinions, the Commission will in principle provide a draft amendment to the list of restrictions in Annex XVII to REACH. The timeline is indicative, as subject to modifications if more drafting time is needed from the Commission. The final decision is taken in a **comitology procedure under qualified majority** with scrutiny involving the Member States and the European Parliament. The REACH committee not only provides information but has competency to vote on the restriction.

The Commission submits the draft amendment to the WTO to guarantee no technical barriers to international trade are created.

Implementation and enforcement

Once the restriction has been adopted, **Member States are responsible for enforcing the restriction**. The industry as a whole has to comply (including manufacturers, importers, distributors, downstream users, and retailers). National helpdesks act as contact point for any query on compliance.

Details on the committee's risk assessment

Risk Assessment Committee (RAC):

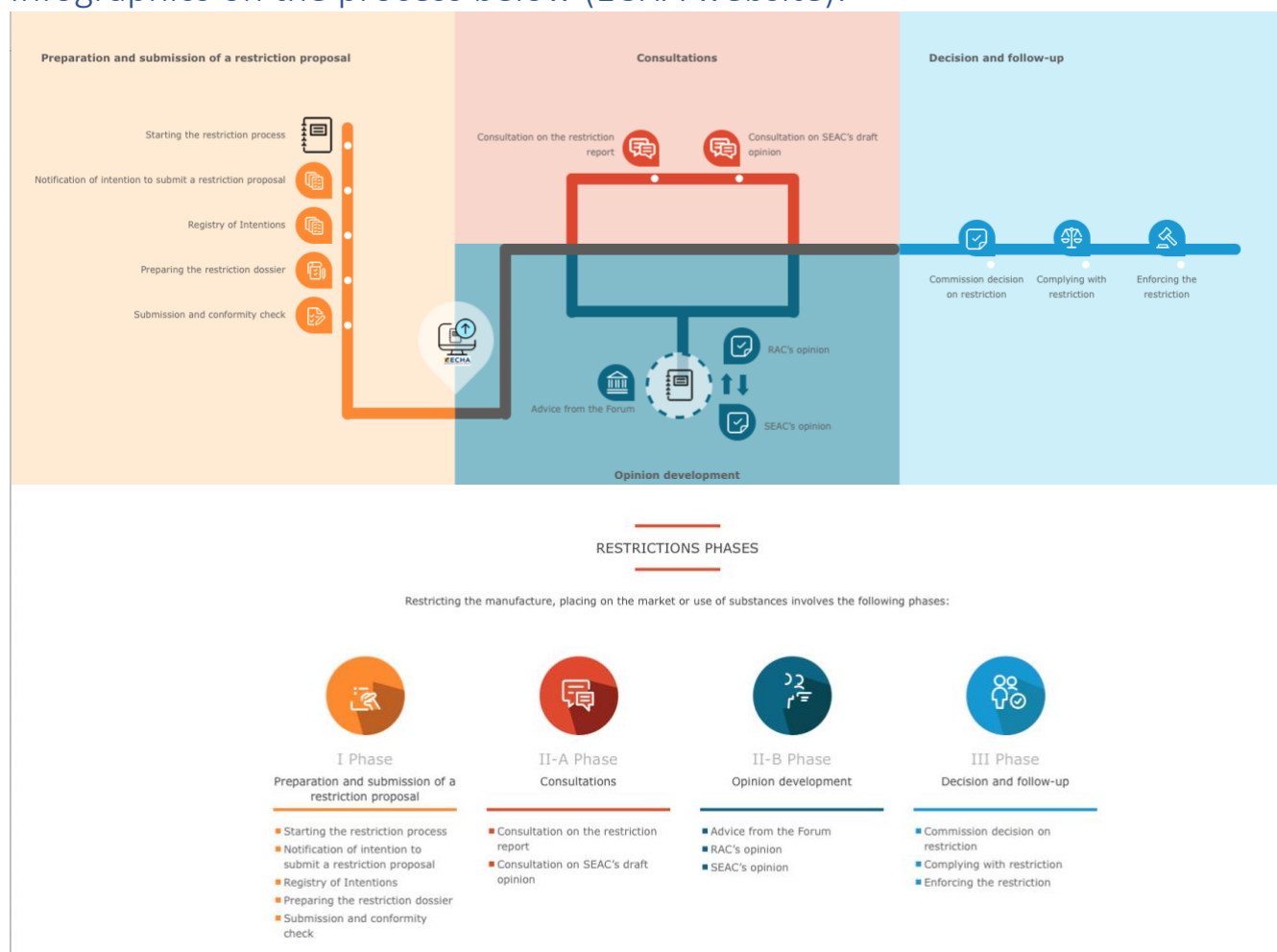
- RAC is responsible for conducting a scientific risk assessment of the proposed restriction of a chemical.
- RAC is made up of independent experts from across Europe who have expertise in toxicology, environmental science, and other relevant fields.
- RAC's review process involves the following steps:
 - Review of the proposal and supporting scientific evidence:
 - RAC reviews the proposal to restrict the use of a chemical and the supporting scientific evidence provided by the proposer.
 - This includes an evaluation of the hazardous properties of the chemical and its potential impacts on human health or the environment.
 - Consideration of comments received during the public consultation process:
 - RAC takes into account the comments received during the public consultation process and considers any additional information provided by stakeholders.

- This information is used to inform the risk assessment and the recommendation on the most appropriate measures to restrict the use of the chemical.
- Development of a draft risk assessment report:
 - RAC prepares a draft risk assessment report, which summarizes the findings of the risk assessment and provides a recommendation on the most appropriate measures to restrict the use of the chemical.
 - The report is based on the best available scientific evidence and considers the entire life cycle of the chemical, from production to disposal.
- Consideration and approval of the draft risk assessment report by the RAC members:
 - RAC members consider the draft risk assessment report and can make changes as necessary.
 - Once the report is finalized, it is approved by the RAC members.

Socio-Economic Analysis Committee (SEAC):

- SEAC is responsible for conducting a socio-economic analysis of the proposed restriction of a chemical.
- SEAC is made up of independent experts from across Europe who have expertise in economics, business, and other relevant fields.
- SEAC review process typically involves the following steps:
 - Review of the proposal and supporting scientific evidence:
 - SEAC reviews the proposal to restrict the use of a chemical and the supporting scientific evidence provided by the proposer.
 - This includes an evaluation of the socio-economic impacts of the proposed restriction on different stakeholders, such as businesses, consumers, and the environment.
 - Consideration of comments received during the public consultation process:
 - SEAC takes into account the comments received during the public consultation process and considers any additional information provided by stakeholders.
 - This information is used to inform the socio-economic analysis and the recommendation on the most appropriate measures to restrict the use of the chemical.
 - Development of a draft socio-economic analysis report:
 - SEAC prepares a draft socio-economic analysis report, which summarizes the findings of the socio-economic analysis and provides a recommendation on the most appropriate measures to restrict the use of the chemical.
 - The report takes into account the economic, social, and environmental impacts of the proposed restriction on different stakeholders.
 - Consideration and approval of the draft socio-economic analysis report by the SEAC members:
 - SEAC members consider the draft socio-economic analysis report and may make changes as necessary.
 - Once the report is finalized, it is approved by the SEAC members.

Infographics on the process below (ECHA website):




Provisions in REACH

[REACH](#) - Title VIII, Chapter 2, Art. 68-73.

Art. 68 – Introducing new and amending current restrictions

Art. 69 – Preparation of a proposal



Art. 70 – Agency opinion: Committee for Risk Assessment
Art. 71 – Agency opinion: Committee for Socio-economic Analysis
Art. 72 – Submission of an opinion to the Commission
Art. 73 – Commission decision