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ECHA Convenes Online Information Session Regarding the Proposal to Restrict More than 10,000 PFAS under REACH

Article By:

Lynn L. Bergeson

On April 5, 2023, the European Chemicals Agency (ECHA) convened an **online information session** as part of the consultation period regarding the proposal to restrict more than 10,000 per- and polyfluoroalkyl substances (PFAS) under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The speakers during the information session explained how the REACH restriction process works, provided details regarding the restriction proposal, and described how stakeholders and interested parties can participate in the consultation. Stakeholders are strongly encouraged to submit comments, accompanied by supporting evidence, until the **September 25, 2023**, deadline.

Background

On February 7, 2023, ECHA **announced** the availability of a **detailed proposal** to restrict more than 10,000 PFAS under REACH. The national authorities of Denmark, Germany, the Netherlands, Norway, and Sweden (dossier submitters) submitted the proposal after finding risks in the manufacture, placement on the market, and use of PFAS that are not, in their view, adequately controlled and need to be addressed throughout the European Union (EU) and the European Economic Area (EEA). The proposal suggests two restriction options —

a full ban and a ban with use-specific derogations — to address the identified risks. A six-month consultation on the proposal started on March 22, 2023. More information regarding the restriction proposal is available in our February 13, 2023, memorandum.

Summary of REACH Restriction Process

At the outset of the information session, Mercedes Marquez-Camacho, Restriction Process Coordinator at ECHA, presented a summary of the REACH restriction process. The goal of the restriction process is to protect human health and the environment from chemical risks. Restrictions provide a means to address a risk that is not adequately controlled in cases where action is required at the EU level. Restrictions limit or ban manufacture, placing on the market, or use of a substance or group of substances on their own or in mixtures and articles. Restrictions are enacted via amendments of Annex XVII of REACH.

Following the public consultation period, the restriction proposal will be evaluated by the ECHA Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) for the effectiveness of a proposed restriction to address risks and for socio-economic impacts. The opinion issued by the committees will serve as the basis for the European Commission's (EC) decision, made together with the member states and the REACH Committee. The last step in the process will be scrutiny by the European Council and the European Parliament.

Necessity to Regulate PFAS

Wiebke Drost from the German Environment Agency (Umweltbundesamt (UBA)) identified the main concerns surrounding PFAS and the reasons strict regulation at the EU level is believed to be necessary. The high persistence, long-range transport potential, mobility, accumulation in plants, bioaccumulation potential,

(eco)toxicity, and endocrine activity of PFAS make regulation necessary. This combination of properties leads to causes of concern, according to UBA, including:

- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]

Because PFAS are ubiquitous in humans and the environment, a broad group restriction for PFAS with use-specific, time-limited derogations is required, with restriction based on persistence and supporting concerns, on an EU-wide level. According to the dossier submitters, the restriction proposal, if adopted in its current version, would lead to a reduction of four million metric tons of PFAS emission over 30 years.

Details of the Restriction Proposal

Thijs de Kort, Coordinator for Universal PFAS Restriction at the National Institute for Public Health and the Environment in the Netherlands (RIVM) presented a summary of the restriction proposal, highlighting key provisions to achieve its ambitious goal and emphasizing the importance of industry working on switching to PFAS alternatives. It is the broadest restriction proposal under REACH to date, and a full ban as proposed would achieve a PFAS emission reduction of 96 percent in 30 years.

The restriction proposal covers 14 uses and use sectors, and 78 sub-uses, considered in detail (*See* Table 2 of the Proposal). It contains conclusions on alternatives, costs, and environmental emissions based on these uses. Table 8 of the Proposal and Appendix E2 list proposed alternatives submitted with the proposal dossier, according to the information available to the dossier submitters at the time of the submission. Among the uses listed are, for example, textiles, food contact materials, consumer mixtures, cosmetics, medical devices, and lubricants. It is important to note, however, that the proposed ban would apply even if a certain use or use sector is not mentioned among the examples in the document.

The proponents advocate for an EU-wide ban instead of regulation on a member state level for several reasons. The high persistence of PFAS, the large variety of emission sources, the ubiquitous presence, increasing levels in environmental media, and the cross-border mobility of PFAS make management on a member state level less effective. Creating EU-wide bans and restrictions for PFAS creates a level EU-wide playing field, and it allows for uniform implementation of control measures and enforcement.

The chemical scope of the restriction proposal is defined as “[a]ny substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).” The proposal notes that this definition is aligned with the Organization for Economic Cooperation and Development (OECD) definition of PFAS that was published in 2021, “that has been scrutinized by the international scientific community and is widely accepted.” According to the proposal, this definition encompasses more than 10,000 PFAS, “including a few fully degradable PFAS subgroups.” Because these fully degradable subgroups do not fulfil the underlying concern of high persistence, the dossier submitters excluded them from the scope of their restriction proposal. The dossier submitters opted for a formula-based definition of PFAS instead of providing a list of excluded substances, because a list would create the potential to develop new

PFAS substances that are not listed, to circumvent the regulation.

The proposed restriction would institute a ban on manufacture, use, and placing on the market of PFAS as substances on their own, as constituents in mixtures, and as articles. The ban applies to imports as well, because they fall under the definition of “placing on the market,” according to REACH. The proposed limits for PFAS as constituents, in mixtures, or in articles are ? 25 parts per billion (ppb) for any PFAS, ? 250 ppb for the sum of PFAS measured as the sum of targeted PFAS analysis, and ? 50 parts per million (ppm) for PFAS, respectively. The ban also applies to products made from recovered and recycled materials.

The restriction proposal analyzes the proportionality of a full ban (Restriction Option 1 (RO1)) of all PFAS. The national authorities suggest that RO1 enter into force after a transition period of 18 months. The restriction proposal compares RO1 to Restriction Option 2 (RO2), a ban of all PFAS except, in most cases, time-limited, defined, use-specific derogations of either a duration of five or 12 years after the end of the transition period. This option would provide more time for industry to find or develop alternatives. The duration of the transition period and derogations are summarized below:

Restriction Option	Transition Period before Restriction Option Takes Effect	Duration of Derogation
RO1: Full ban	18 months	Not applicable
RO2: Ban with use-specific derogations	18 months	Five years after transition period ends 12 years after transition period ends Time-unlimited (only for specific uses)

The restriction proposal lists two types of derogations: proposed derogations, for which sufficiently strong evidence exists to warrant a derogation, and potential derogations, for which the proponents did not find sufficient evidence during the drafting of the proposal to warrant a derogation. If a use is not listed as a derogation, then the restrictions

would apply. Both proposed and potential derogations are subject to change between the current version of the proposal and the ultimately adopted regulation. Stakeholder input is particularly important in this regard. Based on well-documented comments submitted during the consultation period, sufficient evidence can be collected to change a potential derogation to an actual derogation. Conversely, a proposed derogation can be taken off the list of derogations if sufficient evidence is provided to demonstrate that a derogation is not warranted. More derogations, not currently listed, can be added during the proposal phase by the committees or the EC, based on information received. Information regarding the derogations can be found throughout the proposal, but specifically in Table 9, as well as in **Annex E**.

The proposal contains mandatory reporting requirements for the majority of derogations. These reporting requirements apply to manufacturers and importers of active substances, or articles, or to the formulators of mixtures. The reporting would relate to information on use (which derogation it refers to) and the identity and quantity of substances placed on the market. Manufacturers, importers, and downstream users of fluoropolymers subject to derogations would have to develop a site-specific management plan to identify the substances and products they are used in, the justifications for the use, the conditions of use, and information about safe disposal.

Participating in the Consultation

Throughout the information session, both ECHA and the dossier submitters repeatedly stressed how important stakeholder input is. Comments must be submitted via **ECHA's website**. Any information considered relevant may be submitted or information on the ten specific topics identified by RAC and SEAC or the dossier submitters. Specific topics include sectors and sub-uses, emissions in the end-of-life phase, impacts on the recycling industry, proposed derogations, or missing uses. The most weight and consideration will be given to comments supported by strong documentary evidence, such as technical reports

or references to scientific opinions. Joint submissions, per sector, are encouraged over individual or company submissions. Information submitted may be claimed as confidential. That information will not be published on the ECHA website and will be kept confidential within the committees. Opinions, however, are public documents, and it is difficult to reference confidential information in them. ECHA therefore encourages submitters to provide public information whenever possible.

Information sent after the **September 25, 2023**, closing date of the public consultation period, or via other channels, such as e-mail, will not be considered by RAC and SEAC. More information regarding the submission of comments can be found in the **Consultation Guidance** and the **Information Note** regarding the PFAS restriction proposal. Submitted comments will be published monthly on ECHA's website. Comments will be scrutinized by the proponents of the restriction and by RAC and SEAC. Relevant and substantiated information will be addressed in a background document and/or RAC and SEAC opinion.

Questions and Answers

The information session was concluded with questions and answers regarding the PFAS restriction proposal. A document with all questions and answers is expected to be published on ECHA's website within a month after the information session.

Questions addressed included why the proposal does not distinguish between consumer and industrial applications for PFAS. According to one of the dossier submitters, in some sectors it is difficult to differentiate between consumer and industrial application, and knowledge is limited due to the limited information submitted during the drafting of the proposal. In some cases, such as textiles, the proposal differentiates between consumer and industrial uses in the proposed derogations. For example, derogations are proposed for technical/industrial textiles, such as personal protective equipment

(PPE). Distinctions between the two types of uses were made where possible.

Another question asked whether it is correct that under the current version of the proposal, fluoropolymers would be banned in the EU for all uses unless subject to a derogation. The dossier submitters confirmed that that would be the case if the proposal is enacted in its current form, because fluoropolymers are highly persistent. The entire life cycle must be considered, including production and use, as well as waste. During production, PFAS emissions may occur. Residuals may remain in the product, and PFAS can be released during use. In the waste phase, it is nearly impossible during recycling and incineration to avoid PFAS emissions. The dossier submitters acknowledged that there is a lack of information regarding incineration of PFAS and how much PFAS is emitted. Stakeholders are encouraged to submit more information on this topic.

In response to the question about why the essential use concept was not considered in drafting the restriction proposal, one member of the panel responded that essential use is not a legal concept used under REACH. There were, therefore, no legal criteria for including essential uses into the restriction proposal. Although currently the application of the concept of essential use is under discussion for purposes of REACH, the dossier submitters chose not to include it in the restriction proposal.

Commentary

This much-anticipated information session offered important updates and some welcome clarity regarding the timeline for adoption, the scope, and the applicability of this complex and unprecedented restriction proposal. Initial criticism related to the lack of scientific basis in the proposal for distinguishing among PFAS in a way that reflects the significant variability in environmental and toxicological profiles of PFAS. While it is unlikely that the generic, definition-based approach

will be abandoned in favor of providing a list of banned PFAS, industry, non-governmental organizations, and other interested parties still have ample time to weigh in and submit their supporting evidence for any part of the proposal they would not wish to see enacted. The restriction proposal was drafted based on the information available to the proponents at the time. It is beyond doubt that vast amounts of information exist to support claims regarding certain types of PFAS, whether advocating for the lack of available alternatives, or on the contrary, demonstrating that there are viable alternatives that were not considered when listing a proposed derogation. There will likely be a significant difference between the current version of the proposal and the version that is ultimately adopted and enacted. This consultation period offers all interested parties the opportunity to influence what the provisions of the final versions will look like.

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