

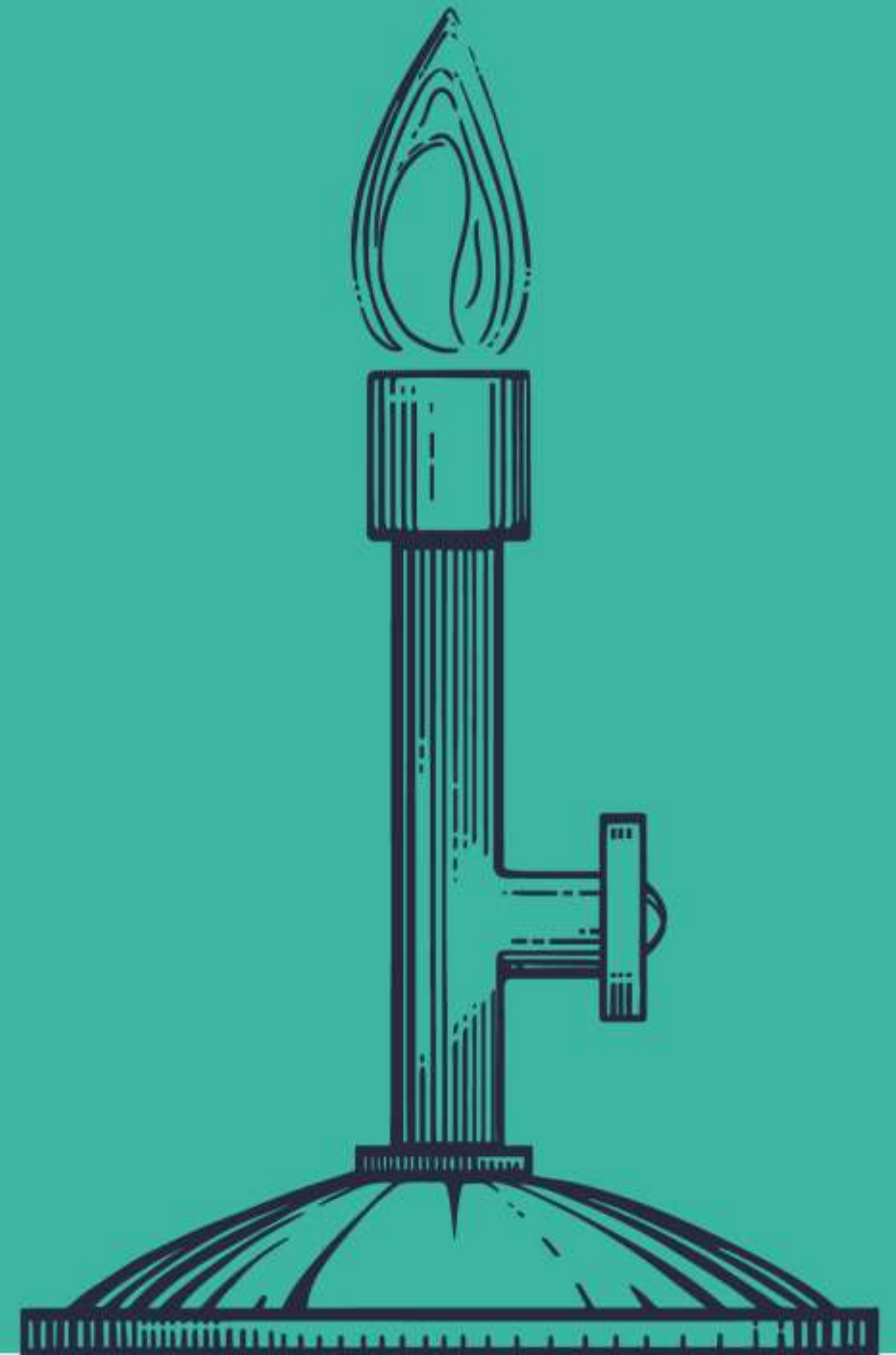
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PFAS Restriction under EU REACH

Environmental Law Institute

PFAS: What's Next? A Global Perspective.

20 February 2024



Regulatory status

- ▶ Substances and groups of substances belonging to the wider category of PFASs are already regulated on a global level by the Stockholm Convention and corresponding provisions of Regulation (EU) 2019/1021 (POP Regulation). This holds true e.g. for PFOS, PFOA, PFHxS or C9-14 PFCAs.
 - ▷ Further ban of PFAS already addressed in the European Green Deal and the Chemicals Strategy for Sustainability (“forever chemicals”)
 - ▷ Procedure to ban the use of all PFAS as a group in firefighting foams at its final stages (consultation on draft SEAC opinion closed on 15 May 2023)
- ▶ The Netherlands, Germany, Norway, Denmark and Sweden submitted a restriction proposal to cover a wide range of PFAS uses in January 2023.
 - ▷ **universal PFAS restriction** („uPFAS“ restriction)

Legal basis

- The adoption of new restrictions and the amendment of existing restrictions in Annex XVII find their legal basis in Art. 68 REACH.
- Restrictions can be imposed if the use or placing on the market of a substance on its own, in a mixture or in an article poses an unacceptable risk to human health and the environment that needs to be addressed at EU level.
 - ▷ Risks to humans and the environment cannot be adequately controlled
 - ▷ Decision has to take into account socio-economic impacts
 - ▷ Decision has to take into account availability of alternatives

Potential restriction of PFAS

- Restriction Proposal on PFAS is based on Article 68(1) REACH
- Manufacture, use and placing on the market of PFAS as such shall be prohibited
- Placing on the market of PFAS as constituent of another substance, in a mixture or in an article shall be prohibited if certain threshold limits are exceeded
- Variety of exemptions and derogations proposed and under further review; requests for additional exemptions and derogations submitted in public consultation
- In general, restriction shall apply 18 months after entry into force; derogations will be granted for additional 5 or 12 years

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>Per- and polyfluoroalkyl substances (PFASs) defined as:</p> <p>Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it).</p> <p>A substance that only contains the following structural elements is excluded from the scope of the restriction:</p> <p>CF₃-X or X-CF₂-X',</p> <p>where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R'''';</p> <p>and where R/R'/R''/R'''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).</p>	<ol style="list-style-type: none"> 1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: <ol style="list-style-type: none"> a. another substance, as a constituent; b. a mixture, c. an article <p>in a concentration of or above:</p> <ol style="list-style-type: none"> i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) iii. 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. By way of derogation, paragraphs 1 and 2 shall not apply to <ol style="list-style-type: none"> a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. active substances in human and veterinary

Status of restriction process

RESTRICTIONS PHASES

Restricting the manufacture, placing on the market or use of substances involves the following phases:



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

2021

2022

2023



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

approx. 2024/2025



III Phase

Decision and follow-up

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

approx. 2025 et seqq.

Legal Concerns (1)

- ▶ Failure to meet precautionary principle due to lack of scientific evidence
 - ▷ Grouping approach on basis of „persistence“ and *inter alia availability* of PFAS in drinking water sources, i.e. groundwater and surface water
 - ▷ Group-based approach to avoid potential risks from even still unknown PFASs.
 - ▷ Ban on all PFAS despite lack of scientific data
 - ▷ Estimates of a worst-case scenario for the effects of combined PFASs due to the lack of data are considered sufficient
 - ▷ Sufficient evidence for exposure only possible for known PFAS (PFOS, PFOA, PFHxS and PFNA), but not for non-regulated PFAS

Legal Concerns (2)

- Violation of the principle of proportionality
 - ▷ No possibility of extension of the 5- or 12-year exemptions provided if the presumed availability of a possible alternative for PFAS does not materialize.
 - ▷ Application of authorisation principles within proceeding on restriction but without procedural rights for industry
- Contradictory justification
 - ▷ Admission that sufficient predictive tools are not available, while proposal outlines predictions for concentration of PFASs in the environment.
 - ▷ On the one hand, all PFAS (as defined in the proposal) are considered hazardous, on the other hand, hazard/risk assessment available only for certain substances
 - ▷ Numerous conclusions in knowledge of lack of scientific evidence and existing uncertainties

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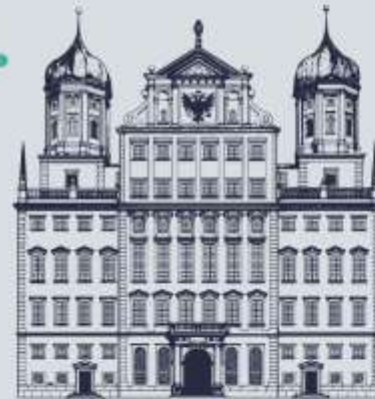


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