

PFAS: Forever Chemicals – The Story in the EU

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Herbert Estreicher, J.D., Ph.D.



Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.



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Ales Bartl



Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products and product and food safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues. Ales also advises on product recalls and withdrawals.

Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).



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I. Context: Chemicals Strategy for Sustainability

Chemicals Strategy for Sustainability



Chemicals Strategy for Sustainability (CSS) announced in October 2020:

<https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

- ◆ See our REACH 30/30 presentation on CSS of August 12, 2020
- ◆ PFAS restriction: first battle-field for ‘essential uses’ and ‘grouping’ concepts

Current Status of CSS



- ◆ CARACAL meeting of 3–4 March 2021:
 - ◆ Roadplan for REACH revision
 - ◆ Roadplan for CLP revision

Roadplan for REACH Revision

- ◆ Revisions as announced in the October 2020 communication but much more!
- ◆ Example: extend the use of the generic approach to risk management (Article 68(2) REACH restrictions, packaging restrictions etc.) to:
 - ◆ ED, PBT/vPvB
 - ◆ Immunotoxicants, neurotoxicants, respiratory sensitizers, STOTs (later)
 - ◆ Extend to professional uses
 - ◆ Exempt essential uses

Timing of REACH Revision

- ◆ Impact assessment roadmap for 4 weeks stakeholder consultation: March – April 2021
- ◆ Supporting actions and studies (Q1 2021 to Q1 2022)
- ◆ Impact assessment: Autumn 2021 – Early Autumn 2022
- ◆ Draft proposal for revision of REACH – 2022
- ◆ Commission adoption of proposal – end 2022

Roadplan for CLP Revision

- ◆ Proposed revisions include changes in:
 - ◆ HCL
 - ◆ New hazard classes (ED, PMT, new hazard classes for PBT)
 - ◆ New criteria for immunotoxicity and neurotoxicity
 - ◆ Other (clarifications [e.g., on bridging principles], labeling exemptions etc.)
- ◆ Indicative timing: draft CLP amendment September 2021; adoption end 2021

PFAS One of the Priorities of the CSS

- ◆ The following action with respect to PFAS:
 - ◇ REACH restriction of all PFAS as a group in fire-fighting foams as well as in other uses, allowing their use only where they are essential for society
 - ◇ Address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste
 - ◇ Address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries
 - ◇ Provide financial support under research and innovation programs

II. REACH restriction of PFAS under preparation

EU REACH Restrictions

- ◆ EU Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals ('REACH')
- ◆ Substances subject to restriction: Annex XVII REACH
- ◆ Updated list: <https://echa.europa.eu/nl/substances-restricted-under-reach>

Status of PFAS Restriction Proposal, Timing



- ◆ Driving MS: Germany, The Netherlands, Denmark, Sweden, and Norway
- ◆ Not yet officially announced in ECHA Registry of Intentions
- ◆ Expected timing:
 - ◇ Announcement of restriction intention to ECHA: during the first half 2021
 - ◇ Publication of actual proposal expected first half 2022
 - ◇ The final restriction should be adopted by the European Commission in 2025
- ◆ Check: <https://echa.europa.eu/registry-of-restriction-intentions>

Scope

- ◆ PFAS on their own, in mixtures and in articles above a specific threshold (example of PFOA-related substances: ≤ 1 mg/kg)
- ◆ PFAS to be banned for all 'non-essential societal uses'
 - ◇ The concept of 'non-essential uses' is currently being debated at the EU level; the criteria should be developed mid-2021

Developments on ‘Essential Uses’ Concept

- ◆ **March CARACAL document: ‘Summary of and response to comments to CA/61/2020’** provides more insight:
 - ◆ Concept goes beyond REACH
 - ◆ Concept of essentiality in the Montreal Protocol as a starting point to initiate discussions
 - ◆ MP takes into account four elements: criticality, alternatives, use (minimise emission), and availability (not relevant to REACH)
 - ◆ Client Earth: The Montreal Protocol, the work of Cousins et al. and many EU regulations offer indications of the sectors that are non-essential: luxury, convenience, leisure, cosmetics, toys, or decorative products

Proposed Client Earth's Criteria:



- ◆ Is the use relevant for safety or health?
- ◆ Are material, energy, performance efficiency affected?
- ◆ Is the product without the substance accessible for the general public or for innovation?
- ◆ Whether or not the use significantly extends the lifetime of a product, improves durability, less consumption of raw materials, less consumption of energy
- ◆ Whether the use creates hazardous waste after a short lifetime
- ◆ Inspiration can come from the EU taxonomy regulation and the criteria for sustainable activities established therein

PFAS Covered by REACH Restriction

- ◆ ECHA presentation of October 29, 2020 entitled ‘Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH’:

https://echa.europa.eu/documents/10162/31366392/pfas_webinar_slides_en.pdf/361234ba-5b0c-d5d0-df0d-4145c3e08c73

- ◆ Substances that contain at least one aliphatic -CF₂- or -CF₃ element
- ◆ Includes precursors that can be transformed/ degraded to PFAS
- ◆ This covers many substances of various structures:
 - ◆ PFAAs, PFSAAs, PFAEs
 - ◆ Side-chain and backbone fluorinated polymers
 - ◆ Hydrofluorocarbons
 - ◆ Side-chain fluorinated aromatics etc. ...

Public Consultations

1st public consultation:

- ◆ After publication of the proposal (i.e., expected first half 2022)
- ◆ Input will be used for the preparation of draft ECHA Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis (SEAC) opinions
- ◆ Duration: six months public consultation: open to everybody

2nd public consultation:

- ◆ After draft SEAC opinion
- ◆ Focused on economic aspects and on derogations
- ◆ Duration two months

Potential for advocacy with the European Commission at the final stage (example of Fluorocouncil and C9-C14 PFCAs)

Public Consultations: Why to Participate



- ◆ Request longer sell-off period, permanent derogation (essential use), spare parts derogation
- ◆ Derogation from the scope (some PFAS off the scope: sufficient data available that there is no risk)
- ◆ Request later date of applicability (default 12-24 months, may be up to 36 months or more if justified)
- ◆ Request higher permitted concentration limits

Arguments:

- ◆ Socio-economic analysis (e.g., low emissions/volumes vs. impact on consumers and economy (high costs of substitution not an argument))
- ◆ Alternatives not available (yet) - R&D efforts should be demonstrated
- ◆ Confidentiality of comments granted if requested (but data available to ECHA)
- ◆ If submitted via a law firm/consultant, company name confidential also towards ECHA

Final Thoughts

- ◆ Not an easy task for EU authorities
- ◆ Questionable from the legal principles perspective (proportionality, subsidiarity, legal certainty, abuse of power, freedom to conduct business etc.)
- ◆ Long process: there will be numerous opportunities to participate in public consultations/ad hoc advocacy activities
- ◆ Let your voice be heard



Please join us at 1:00 PM Eastern U.S.
Wednesday, March 24, 2020
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, April 7, 2021
www.khlaw.com/TSCA3030

Thank You

Any Questions?

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