SUSTAINABLE PFAS ACTION NETWORK

September 22, 2023

SPAN's Response to
ECHA's Annex XV Restriction Report Consultation,
restriction on the manufacture,
placing on the market and use of PFAS

Introduction:
The Sustainable PFAS Action Network (SPAN) is submitting these comments in response to the Annex XV proposal received by ECHA that proposes restrictions on per- and polyfluoroalkyl substances pursuant to REACH.[1]

Section 1: Personal information
These comments are being submitted by
Kevin Fay, Executive Director
Sustainable PFAS Action Network (SPAN)

Section 2: Organizational information
SPAN is a coalition of per- and polyfluoroalkyl substances (PFAS) users and producers committed to sustainable, risk-based PFAS management. Our members[2] advocate for responsible policies that provide assurance of environmental protection while recognizing the important contribution that certain PFAS have made in the form of societal benefits, economic growth and competitiveness in global markets.

Section 3: Non-confidential comments
PFAS are integral to a vast number of sectors in the US economy as well as the European Community, and major markets around the globe. Renewable energy, automotive manufacturing, business equipment, defense and security applications, semiconductor production, medical devices and pharmaceuticals are just some of the industries that would be adversely impacted by unnecessarily broad and immediate restrictions on certain critical uses of PFAS and PFAS-containing products. SPAN was formed to encourage responsible, risk-based PFAS regulations that are implemented in an orderly manner which protect the environment and human health while creating opportunities to maintain certain critical and essential uses until technically feasible alternatives for such uses and products can be identified and operationalized. For these reasons, SPAN is concerned about the scope and inevitable impacts of the proposed REACH Restrictions on PFAS.

[1] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b.
[2] SPAN's current membership consists of the US offices of Arkema, Daikin, Honeywell, Intel, Applied Materials, the Semiconductor Industry Association, the Air Conditioning, Heating & Refrigeration Institute, and the Aerospace Industries Association.

SPAN's concerns with the proposed PFAS restrictions, include:

1. The breadth of the structural definition used to identify PFAS affected by the restrictions;
2. The general presumption of "risk" (without product or use-specific evidence);
3. The presumption that derogations should be time-limited;
4. The absence of permanent derogations for certain critical uses;
5. The absence of a process for renewing time-limited derogations where necessary;
6. The lack of a process for manufacturers and users of PFAS and PFAS-containing products to seek and obtain additional derogations on a going-forward basis;
7. The inclusion of manufactured articles within the scope of the proposed restrictions; and
8. The inevitable negative effect the restrictions will have on global supply chains.

SPAN encourages an alternative approach that would:

1. Reflect an effort to identify and prioritize PFAS and PFAS-containing products for restrictions based on risks (taking into consideration hazard and exposure);
2. Encourage international cooperation and coordination on risk reduction approaches;
3. Provide for targeted PFAS research and collaborative efforts to develop alternatives, PFAS capture and treatment technologies and analytical methods; and
4. Ensure technical assistance is available for governments and local agencies in disadvantaged communities.

SPAN's Core Principles. Our comments are informed by a set of core principles that SPAN has developed to guide our participation in US and international policy processes. These principles include advocating for:

- Aggressive identification and remediation of PFAS-contaminated sites.
- A coordinated, orderly policy approach to avoid a disjointed response.
- Narrowing the definition of PFAS in regulatory contexts to focus on substances most likely to exhibit characteristics affecting risk (toxicity, persistence, bioaccumulation).
- Concentrating efforts on commercially active PFAS and PFAS-containing products with known hazards and those being emitted in the greatest volume.
- Science- and risk-based categorization efforts to select PFAS of greatest concern for prioritizing potential regulatory controls.
- An efficient and constructive authorization process to bring to market new PFAS alternatives (perhaps modeled on the US/Clean Air Act SNAP program for implementing the Montreal Protocol).
- Establishing processes for seeking essential-use exemptions with established criteria when broad prohibitions are being considered or imposed.
- Encouraging long-term goals and benchmarks to achieve PFAS emission reductions.
- Ensuring sufficient funding and resources exist for PFAS-program oversight and implementation.

SPAN encourages international cooperation on PFAS use and emissions reductions. SPAN emphasizes its support for an international approach to sustainable management of PFAS. We encourage efforts to harmonize approaches to PFAS manufacturing and use limitations; a disjointed approach will otherwise adversely impact critical and essential PFAS and PFAS-containing products

made available through international supply chains. We believe that international coordination is critical to sustainable PFAS management so as not to create a patchwork of ineffective regulations around the world that would impede global economic progress, and threaten the continued strengthening and development of international supply chains.

SPAN encourages a more limited scope of PFAS covered and a more targeted definition. The REACH proposal defines the scope of PFAS included as "[a]ny substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)".[3] Degradation products of these substances also are included within scope. SPAN appreciates that the proposal has identified and excluded a few fully degradable PFAS subgroups because they not considered highly persistent. However, SPAN advocates for the exclusion of fluoropolymers and gases from the final scope. Fluoropolymers characteristically present less risk of biological uptake and bioaccumulation. Fluorinated gases are critical to the gradual phase down of global warming chemicals under the Kigali Amendment, and are better regulated under the EU's F-gases regulation. SPAN favors narrowing the definition of PFAS when used in restriction measures to focus on substances most likely to exhibit characteristics affecting risk during current uses in the EU.

An overly broad definition of PFAS can include as many as 14,000 chemical formulations, while there is likely to be less than 1,000 commercially active PFAS compounds in world markets. In light of this, SPAN recommends that "per- and polyfluoroalkyl substances" be defined as "a group of synthetic perfluoroalkyl and polyfluoroalkyl substances, and their known degradation products, that contain two sequential fully fluorinated carbon atoms, excluding polymers, gases, and volatile liquids, but including side chain fluorinated polymers."

Because SPAN is aware of concerns raised in other contexts about the scope of this proposed definition, SPAN wants to state that our proposed definition includes within its scope:

(i) fluorosurfactants
(ii) PFOA, PFOS and their salts and precursors; and
(iii) PFNA, PFHxS, PFBS, and HFPO-DA and their associated salts

SPAN is concerned about the absence of risk determinations and consideration of conditions of PFAS use. The Restriction Proposal makes clear (if accepted without changes) that effectively all uses of all PFAS within scope will be unlawful after the conclusion of certain time-limited derogation periods. Where no derogation is provided, the PFAS and its uses will become unlawful after a brief transition period of 18 months. As proposed, the Restrictions could effectively ban nearly all PFAS and PFAS uses on the basis of what is fundamentally a persistency concern; without a science-based demonstration that each substance within scope present an unacceptable risk. By failing to identify an "unacceptable risk to human health or the environment" that can only be addressed on a "Community wide basis" through the proposed restrictions, the Proposed Restrictions do not satisfy the criteria for a restriction under Article 68.1 of REACH.

[3] SPAN observes that the PFAS definition is not being applied in the Proposed Restrictions in accordance with the OECD's guidance which ich states that it is not meant to be a *regulatory* definition. https://www.foodpackagingforum.org/food-packaging-health/per-and-polyfluoroalkyl-substances-pfass.

SPAN recommends including derogations based on essential use determinations, and a process for seeking such derogations going forward. The Proposal assumes chemical substitutes for PFAS either already exist or will become available before the conclusion of the derogation period provided. For many derogations however, ECHA has indicated a basic skepticism and advised that not all proposed derogations will be retained in final form if not supported with technical evidence. Thus, for many derogations, if substantial technical evidence is not provided (e.g., to demonstrate the lack of alternatives), then prohibitions affecting those PFAS and their uses will be finalized with no derogation retained. SPAN members produce a substantial number of products which provide immense societal benefits and for which alternatives that are technically feasible do not exist. SPAN member's customers depend on their products produced in processes which rely on PFAS in certain manufacturing processes and/or in vital components. Such products have uses in critical equipment and other processes, including in major medical devices, energy saving building materials, components delivering clean energy technologies, and in aerospace and defense technologies critical to transportation, climate preservation efforts, and national security and intelligence applications. Following review of the information submitted during the consultation, SPAN encourages the Commission consider implementing a more flexible approach, including by providing accommodations through enhanced and more long-lasting derogations in the final version of the restrictions and by narrowing the scope of PFAS restricted. SPAN recommends the Commission establish a going-forward procedure with defined criteria pursuant to which manufacturers and product users can request and provide the necessary substantiation for essential use determinations and receive appropriate derogations for such substances and products.

SPAN recommends that essential use considerations begin with a few basic tenets:

- Some presumptive uses established based on information gathered during the consultation process and the reports and information received during the consultation.
- General criteria should be established for seeking essential use determinations and associated derogations.
    - Essential use derogations should have appropriate time limitations, with the ability to seek extensions.
    - Recipients of essential use derogations should be held to commitments to minimize human exposures to PFAS and environmental releases of PFAS and to annually report the quantities of PFAS produced, used, and distributed pursuant to the essential use derogation received.

Manufactured articles containing PFAS should not be restricted. SPAN recommends that greater focus in the REACH framework be placed on limiting manufacturing methods and disposal practices that unnecessarily intentionally or inadvertently release PFAS, and to mitigating contaminated sites. Such efforts should be at a higher priority over the proposed restrictions on placing in the market and the use of PFAS-containing articles. SPAN supports the proposal's efforts to establish acceptable "de minimis" PFAS content terms[4] when present below certain concentration limits. However, SPAN Members do not

[4] At present, the PFAS levels proposed for products would be at or above 25 ppb for any PFAS (other than polymeric PFAS); 250 ppb for the sum of PFAS (other than polymeric PFAS); or 50 ppm for PFAS (*including* polymeric PFAS included).

think a "one size fits all" approach is suitable for manufactured products which can be as diverse and range from a simple pot or pan with a treated cooking surface to mechanically and technically complex equipment such as MRI and CT scan devices. SPAN favors simple exclusions for certain categories of articles and the establishment of an exclusion process by which product manufacturers and users could seek exemptions for certain products on the basis of a showing it serves an essential use.

Commission policy and regulation should encourage PFAS research and development. SPAN recommends that in addition to prudent and practical restrictions on PFAS, ECHA encourage government and private enterprise collaboration on research and development efforts including on technologies for detecting and mitigating PFAS in the environment and in production processes and emissions streams. SPAN also recommends placing greater emphasis on collaboration intended to improve our understanding of PFAS effects on human health and the environment, and to differentiate between specific PFAS and categories of PFAS on that basis. SPAN also would like ECHA to encourage collaborations in the quest for identifying PFAS substitutes and for PFAS presenting fewer health and environmental concerns which might provide an orderly pathway toward phasing down and eliminating certain PFAS for which the most likely near-term substitutes may still be PFAS. For example, at the May 23, 2023 meeting of the Trade & Technology Council (TTC), the US and the EU agreed to explore "additional ways to collaborate, including how to cooperate on incentives for research on alternatives to the use of per- and polyfluorinated substances (PFAS) in semiconductor manufacturing."

SPAN recommends the Commission encourage public-private partnerships (including international efforts) which could provide access to the best available scientific tools and methods and hasten the aviability of PFAS alternatives. Collaborative efforts scientists in the commercial, public, and academic sectors on an international level will be needed to identify technically feasible PFAS alternatives for substitution in those PFAS uses that currently present the greatest concern for human exposures and environmental releases. To ensure a practical approach is taken, SPAN encourages such efforts to acknowledge that alternatives might need to initially include newly-developed PFAS which possess structural characteristics that make them well-suited as substitutes, but which can be shown to present fewer risks than the existing substances they would replace. ECHA should take measures to ensure that the authorization process under REACH for new chemical substances encourages, rather than impedes, the development and market entry of technically-feasible alternatives, even novel PFAS if they can provide a reduced-risk profile.

Section 4 and 5: non-confidential and confidential attachments – SPAN is providing neither.

Conclusion

SPAN appreciates the opportunity to provide these comments in the Annex XV Restrictions Consultation process. SPAN encourages the Commission to implement substantial changes before making recommendations to adopt PFAS restrictions. Such modifications should include: narrowing the PFAS definition and scope of the restrictions proposed; providing additional derogation based on essential use

determinations while providing an established process for requesting additional essential use derogations going-forward; removing the blanket restriction on PFAS-containing products and articles; placing additional emphasis on reducing and mitigating PFAS emissions and contamination where they already occur; and encouraging public-private-academic collaboration on PFAS research and the identification of technically feasible PFAS alternatives.