

September 25, 2023

ECHA
Telakkakatu 6
00150 Helsinki, Finland

Re: PFAS rulemaking

Dear ECHA staff members,

The International Safety Equipment Association (ISEA) is pleased to submit this comment to the ECHA rulemaking. ISEA is the association for companies that design, test, manufacture and supply a wide range of personal protective equipment (PPE), including protective equipment, respiratory protective devices, hard hats and more.

Not all PPE includes PFAS. ISEA would like to comment that where personal protective equipment includes some level of PFAS, it may not be known by the manufacturer. This is because trade secrets may prevent some in the up-stream supply chain may prevent one component supplier from disclosing such information to others. Because of this, ISEA asks for a time unlimited derogation on all personal protective equipment. There is a strong socio-economic benefit to this derogation. We discuss more below.

ISEA believes unlimited derogation is required for firefighting turn-out gear (firefighting coat-and-pants ensemble). Currently, ECHA calls for a 12-year derogation. Turn-out gear includes a specialized internal fabric that serves as a moisture barrier.

In addition, ISEA believes an unlimited derogation for PTFE, used as a moisture barrier in gas detection equipment is needed.

Gas Detection Equipment and PTFE

ISEA believes gas detection equipment ought to have a time-unlimited derogation because of the importance of health, safety and functioning of society these products offer. Gas detection equipment can be portable or fixed. Gas detection equipment is critical for life safety for fire fighters, public utility workers (especially those who work in sewers or other tunnels) and workers in the oil and gas industry. A vast number of workers depend on gas detection equipment to stay safe when atmospheres could have low oxygen levels or have other amounts of dangerous chemicals.

PTFE is used in gas detection equipment to prevent moisture from entering the detector's housing where the critical sensors are located.

ISEA agrees with the British Fluid Power Association (BFPA) in its comments submitted on 2023/08/18:

The broad group of Per- and PolyFluoroalkyl Substances (PFAS) includes sealing materials such as PTFE and FKM along with other fluoroplastics and fluoroelastomers that are used as versatile barrier and sealing materials BFPA. ... These PFAS materials are used because they are not

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harmful to human health, they are unreactive to most chemicals, have excellent mechanical strength over a wide temperature range combined with, in the case of PTFE and similar materials, a low coefficient of friction. These attributes benefit the industry by preventing the leakage into” the housing of gas detectors.

As stated by Aleksandrov, et. al, “no evidence was found that PFAS substances are released into the air during the incineration process of PTFE (Aleksandrov et al.; Chemosphere, vol. 226, July 2019, pages 898-906¹).”

ISEA further agrees with the BPFA in its comment that:

PTFE is classified as PFAS based on its molecular structure, however its toxicological and ecotoxicological characteristics are fundamentally different from PFOA, PFOS, C9-C14 PFCAs-like PFAS. First, PTFE is considered as low concern polymers by OECD, which is non-toxic, non-bioavailable and water-insoluble. And it is considered to have no significant impact on the environment and humans;

Moreover, there is a wealth of data showing that fluoropolymers such as PTFE do not degrade in the environment or release substances of toxicological or ecotoxicological concern (Hintzer & Schwertfeger; <https://doi.org/10.1002/9781118850220.ch21>).

ECHA’s own assessment sends mixed signals. Appendix E², Section E.2.11 addresses electronic equipment and semiconductors. Gas detection equipment is electronic equipment. The sensors enclosed in the gas detection equipment must be protected from moisture and other ambient gases, which can poison the sensors. PTFE is used widely to make certain gas detectors will work as intended across a wide range of use environments.

E.2.11.3. Environmental impacts Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.11.3., assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options: • RO1, adopting a ban of all PFAS used in the electronics and semiconductor industry; • RO2, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two scenarios are distinguished, i.e. a 5-year derogation (RO2a) and a 12-year derogation (RO2b). (Annex XV; Annex E, [page 397](#);)

And yet in the same section on electronics, ECHA says... “Based on the available limited evidence, **no use-specific derogations are proposed for the electronics sector**. Several alternatives are available in general, but limited information suggests that users must identify and choose suitable alternatives for a large variety of very different applications. The Dossier Submitters note that the applicability of alternatives often depends on specific use conditions. Sometimes it is not clear whether no alternatives are available at all, or whether users argue that for their specific use and the surrounding conditions no alternative is available. Additionally,

¹ <https://www.sciencedirect.com/science/article/pii/S0045653519306435>

² <https://echa.europa.eu/documents/10162/57812f19-8c98-ee67-b70f-6e8a51fe77e5>

most stakeholders do not specify impacts from using alternatives with reduced functionality, e.g. likelihood of material failure, costs for early replacement of materials, etc.” ([page 405](#))

ISEA Discussion

In matters of occupational safety and health, PTFE is used to make sure water, moisture and toxic gases do not ruin a gas detector’s internal sensors. Gas detection is used in a wide variety of workplaces to keep workers, the public, and workplaces safe from a range of hazards. The use conditions in which gas detectors are needed widely vary: one day the work tasks could be underground, and on the next day it could be to work in a rail tank car. Finally, users are not generally trained to make informed decisions on “suitable alternatives.”

ISEA Recommendation:

ISEA asks for an unlimited derogation for PTFE when used in gas detection equipment. This is because there is no other high-performing moisture barrier on the market. In addition, the way gas detectors are built, the PTFE would not be exposed to the environment when gas detectors are taken out of service.

PPE and Firefighting PPE

Page 116 of Annex XV notes that “In light of the sufficiently strong evidence pointing to the unavailability of alternatives for Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c)³; and Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m)...”

Also in Table 9, ECHA suggests a ban with a transition period of 18 months and a 12-year derogation. This is because “no potential alternatives are identified as of now, it is likely that they will not become available in the near future.”

As noted below, ISEA asks for a time-unlimited derogation for PPE; especially a time-unlimited derogation for firefighting turn out gear meeting EN469.

ISEA asks for this because, in general, many manufacturers, who rely on other companies for component parts or mixtures, are unlikely to be able to receive PFAS ingredient information from such suppliers because of confidential business information from one or more component suppliers. This process is also likely to be repeated a number of times throughout the supply chain. ISEA notes there are some cases where manufacturers are getting some information about PFAS in their components, and in these cases, PPE manufacturers are seeking to remove PFAS from products.

Second, US and European turn out gear requires moisture barriers. The European protective clothing standard for fire services is EN469:2020. This standard uses ISO 11092:2014 as a moisture barrier test.

³ Category III (a) and (c), respectively are: (a) substances and mixtures which are hazardous to health; and (c) harmful biological agents; <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0425>

Currently, moisture barrier materials that include PFAS are the only means of passing this robust moisture barrier test.

Finally, the moisture barrier in protective clothing for firefighters meeting EN469, is not intended for environment release.

ISEA Recommendation - PPE

ISEA asks for a time unlimited derogation for all PPE in Regulation (EU) 2016/425, Annex I. PPE that protects European workers against risks categorized under this regulation's Annex 1, Category I - III should be covered.

- PPE protective against risks in Risk Category I include gloves; adhesive bandages and more.
- PPE protective against risks in Risk Category II are used every day by millions in the European Union's workforce. This PPE includes items such as hard hats, safety eyewear, high-visibility vests and more.
- PPE protective against risks in Risk Category III, in addition to (a) and (c), include devices that protect against atmospheres with oxygen deficiency; falling from a height; harmful noise; and many others.

Any disruption in providing these safety measures to workers in the EU would have negative socio-economic impacts to both workers, employers and the economy as a whole.

Page 146 of Annex XV notes that PPE, when disposed of will be "below additional emissions under worst-case scenarios⁴." In some cases, manufacturers do not always know if those in their supply chains have added PFAS to their component products or mixtures. While there is an effort, in general, to reduce or eliminate PFAS in PPE, manufacturers should be given time to make this adjustment. A time-unlimited derogation would make certain there are no supply disruptions for workers, who rely on this equipment to keep safe from hazards of their jobs.

ISEA Recommendation – Fire fighting PPE

ECHA must provide a time-unlimited derogation for protective clothing for firefighters meeting EN469. This is because there is no other high-performing moisture barrier on the market that can pass ISO 1102:2020, which is used as a moisture barrier test for these garments. This is an important part of the whole ensemble. A time-unlimited derogation would also make certain there are no supply disruptions for this essential protective gear.

Please contact me at + [REDACTED] or at [REDACTED]@safetyequipment.org if you have any questions on these comments.

Sincerely,

Daniel Glucksman
Senior Director for Policy
International Safety Equipment Association

⁴ <https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>