ThermoFisher SCIENTIFIC
The world leader in serving science

Input to the public consultation regarding the broad restriction of PFAS under Title VIII of REACH

Re: Specific uses not considered within the proposal

Summary

- The EU Proposal for a broad restriction of PFAS (including polymers) will have a devastating impact on the availability and quality of products used today in life sciences applications, laboratory and environment monitoring, forensics, food/feed manufacturing, bioproduction, drug manufacture, and diagnostic and medical devices.
- Laboratories across the EU rely on chemicals, equipment and apparatuses which uniquely depend on the functional properties of chemical resistance and ultra-low leachability afforded by certain PFAS polymers (e.g., FEP, PFTE, PVDF and ETFE) to ensure safety and reliability.
- PFAS can be found, by way of illustrative example[1], in specialty packaging (closures and containers) used to contain and maintain purity of laboratory and environmental samples, semi-rigid tubing used in bioproduction and other critical laboratory instrument applications, and specialty laboratory apparatuses across healthcare, life sciences laboratories, and bioprocessing applications where stringent standards for purity are paramount.
- We urge ECHA and the EU Commission to consider:
  - A non-time bound derogation for industrial and professional use laboratory equipment/packaging; and/or
  - Providing a regulatory mechanism within the proposal or under the forthcoming REACH revision to allow for an adaptation of the restriction to account for any lack of scientific or technical progress.

About Thermo Fisher Scientific

Thermo Fisher Scientific (Thermo Fisher), the world leader in serving science, is dedicated to helping its customers in their life science research, analytical monitoring, diagnostics, and life-changing therapies. In addition to our contract clinical research and pharmaceutical manufacturing services, our product portfolio ranges include chemicals and reagents, laboratory apparatus and plasticware, and complex analytical equipment used in clinical, industrial, and academic laboratories around the world to support environmental/process monitoring.

The portion of Thermo Fisher's portfolio which contains polymeric PFAS[2] are high-mix/low-volume consistent with industrial and professional use. Our market includes industrial installations,

[1] We will provide description for 3 uses, but other similar applications are certain to exist.
[2] Using the OECD definition currently adopted in the current REACH proposal.

academic institutions, hospitals and clinics, as well as many small and medium enterprises (SMEs) operating smaller specialist laboratories across Europe.

Views on the PFAS restriction proposal:

Thermo Fisher supports the intent of the EU Green Deal and the Chemical Strategy for Sustainability. We recognize the concerns relating to some PFAS during their manufacture and at end-of-life and seek partnership with the EU in devising proportional regulations. We also encourage governmental investments in developing novel (less hazardous) chemistries and practical waste management technologies to avoid prohibiting the use within certain essential articles for which there is no alternative.

Thermo Fisher is concerned that the proposal to broadly restrict PFAS will significantly undermine the European Life Sciences sector, cripple Bioproduction, and severely limit access to key laboratory apparatuses and individually packaged chemicals and reagents which are essential to a broad spectrum of professional and industrial applications. **We are also concerned, without first considering the yet to be clarified 'essential uses' proposed under the ongoing REACH Revision, the broad restriction proposal will create a disproportionate barrier to the Life Science markets that will compromise innovation and competitiveness across the European Life Sciences sector including Bioproduction, Medical Technology and Applied Sciences.**

The Life Science manufacturing sector uniquely supports critical industries such as healthcare, pharmaceutical and medical device manufacturing; clinical testing and diagnosis; veterinary medicine; agricultural production and food supply; genomics; environmental testing; forensic science and toxicology; bio-waste management and bioproduction. REACH provides for use exemptions for substances in medicinal, cosmetic and food/feed products due to consideration of controls afforded under their sectorial legislation. However, the Life Sciences products are key tools in the development and manufacture of such products are subjected to additional burdensome restrictions and requirements. In the case of medical technologies, the device product may be of the same composition and construction as a professional use product. In this context, we call upon ECHA and the Commission to provide flexibility within the EU REACH Regulation to the manufacture and downstream use of substances and mixtures in the Life Sciences sector.

Below we provide examples of PFAS uses not already recognized within the proposed PFAS restriction which will have adverse impact on the overall security of scientific innovation and discovery within the EU. We also suggest ways the proposed Restriction could be adjusted to avoid negative, unintended consequences for R&D, biopharmaceutical production and to the ability to access the very analytical equipment and consumables used in the detection and characterization of PFAS today.

Product types not currently benefiting from proposed derogations and their uses:

Semi-Rigid/Flexible Tubing

This tubing is used in demanding technical applications such as chromatography, trace metal analysis, pollution sampling, highly reactive catalyst procedures, metallurgical corrosion testing, pharmaceutical manufacturing, dissolutions and hot acid etchings where chemical compatibility and concerns over leaching is an essential property. Used in single-use applications or installed in fluid processing equipment this tubing is entirely comprised of a co-polymer of tetrafluoroethylene and hexafluoropropylene. While some alternatives such as polypropylene and silicone exist for some fluid handling applications where chemical compatibility is not an overarching concern (e.g., Bioproduction[3]), for other uses there is no universal 'drop-in' alternative known.

Industrial and professional users rely on this tubing in analytical equipment and specialist fluid handling applications where hazardous and reactive chemical compatibility is essential and low/no leachability is imperative. While the tubing is highly resilient and can be reliably reused with proper cleaning, certain end applications do require unused tubing (e.g., purification of Active Pharmaceutical Ingredients (API) or preparation of analytical standards for environmental monitoring, drug testing, or diagnostic applications). **Without a derogation for professional and industrial uses for semi-rigid/flexible tubing, access to equipment reliant on fluid handling of aggressive chemicals and pharmaceutical manufacturing will be severely compromised.**

Within the timeframe allotted under the current consultation, as a public company, Thermo Fisher is unable to provide a representational cross-industry estimate of annual production or import quantities of semi-rigid/flexible used across the Life Science industry. Additional time and investments would be necessary to solicit input from competing industries within a structured trade association to provide more relevant information on quantities and waste practices for this use.

Unless contaminated with hazardous materials, the tubing is typically managed as solid waste without consideration of the hazards of the PFAS in the article. This has been consistent with the prior regulatory status of FEP**. It is foreseeable with adequate communications relating to a manufacturers/importers Article 33 obligations and product marking,**

[3] In the case of Bioproduction, silicone is a common alternative for non-aggressive chemicals. However, the D4/D5/D6 cyclosiloxanes present a regrettable substitution challenge.

diversion for adequate treatment is possible from the Life Science sector – as are other hazards managed within a professional and industrial setting. The derogation provided for industrial use of Microplastics establishes precedence in this example.

Specialty Packaging and Containers

To ensure safety, chemicals such as volatile solvents and corrosive substances must rely on specialist packaging to prevent spills during transport and storage. Furthermore, for those chemicals reliant on high purity in their end applications, the packaging must have very low leachability which would otherwise make the product unusable.

These chemicals are supplied for use in academic and industrial laboratories in glass bottles (10ml – 4L) fitted with a PFAS lined closure. The average PFAS content (depending on the size and specific liner design) is less than 1g/closure. While PFTE is the preferred material, a regrettable alternative of ethylene tetrafluoroethylene (ETFE) has been identified to decrease diffusion into the cap material for highly aggressive substances. A few cases, especially highly sensitive analytical work (e.g., calibration solutions for ICP and Mass Spectrometry) rely on both a container and closure made entirely from PFTE. While non PFAS alternatives have been evaluated, nothing has been commercially found that is universally equivalent to PFTE or ETFE.

PFTE and EFTE convey both the physical properties to conform and create a good closure onto the bottle, but also are sterilizable, heat resistant, and compatible with a wide range of chemicals to prevent destruction of or leaching from the closure. Apart from common R&D applications, these chemical products are relied upon in the manufacture of API and calibration standards, in environmental monitoring laboratories, and in small/medium laboratories across the EU wherever analytical science is required. Without polymeric PFAS in the closures, containers would not be able to meet their Dangerous Goods packaging requirements for transport making the chemical products unattainable.

Examples of these closures are illustrated below – as assembled and with the PFTE liner removed:

Within the timeframe allotted under the current consultation, as a public company, Thermo Fisher has been unable to provide a representational cross-industry estimate of annual production or import quantities of PTFE or ETFE used in these applications. However, we estimate our EU quantity of PFAS used in these applications at less than 1 T/year. **Without a derogation for professional and industrial uses, the availability of wide range of commonly used chemicals will be severely compromised across the EU.**

At end of life, these containers with their closures, are either cleaned prior to disposal as non-hazardous solid waste, or are diverted into hazardous waste streams for eventual treatment. **It is foreseeable with adequate communications relating to a manufacturers/importers Article 33 obligations and product marking, diversion for adequate treatment is possible.**

Laboratory Apparatuses

Many chemical applications require laboratory apparatus whose material of construction is compatible with the contained chemistry while providing structural strength in the final application. Where glass is not compatible or able to reliably withstand certain conditions of use, polymeric PFAS (particularly FEP and ETFE) has proven to be a reliable substitute with no universal alternatives. These polymeric PFAS are compatible with most chemicals and provide structural strength and stability for laboratory scale applications. Furthermore, as is critical in many pharmaceutical processes, FEP may be sterilized by common chemical and thermal methods (excluding gamma irradiation) thereby supporting reusability. In processes such as centrifugation where the fragility of glass poses a safety and process hazard, FEP tubes and bottles can withstand the centrifugal forces and can provide a vital enabling capability in common laboratory uses. **Without a derogation for professional and industrial uses, basic laboratory applications will become severely disrupted leading to more incidents of industrial accidents and stymied innovation.**

These devices are strictly sold to professional and industrial users who operate within controlled environments with administrative assurances to prevent the unintended releases of hazardous materials into their waste streams. At end of life, these apparatuses are either cleaned prior to disposal as non-hazardous solid waste or are diverted into hazardous waste streams for eventual treatment. **It is foreseeable with adequate communications relating to a manufacturers/importers Article 33 obligations and product marking, diversion for adequate treatment is possible from the Life Science sector.**

Illustrative examples of these types of laboratory applications are provided below.

Separatory Funnels

Erlenmeyer Flasks

Stopcock assemblies

Centrifuge Tubes

Centrifuge Bottles

Stir Bars

Regarding REACH and the derogations within the PFAS restriction proposal

The overall process to find alternative resins and materials to manufacture these products rely on three principal stages of product development. **When combined, it is foreseen this will require considerably more than 12 years to invent, adapt and implement, and re-qualify alternatives across diverse portfolios**. These phases are envisioned as:

1) **Innovating the C-F bond.** The unique beneficial and hazardous properties afforded by PFAS substances stem back to the carbon-fluorine bond. This bond is one of the strongest bonds to exist and conveys many of the functional properties of PFAS. New chemical solutions must be invented to convey the same properties (without the hazards) then scaled-up to address global needs. There are over 10,000 unique PFAS substances today, it is not known how many iterative developments will be needed in the immediate future (<15 years).
2) **Adaptation into a global supply chain.** Primary manufacturers will need to adapt production processes, tooling and possibly the facilities themselves. Secondary manufacturers (e.g., equipment assemblers) to do the same and internally validate the end-product for intended use.
3) **Re-gain product certifications and customer acceptance.** For most applications in Life Sciences, this includes extensive regulatory engagement across many jurisdictions and downstream user validation.

We ask the Commission to consider a mechanism to afford a review/renewal of the derogations, prior to expiry, to accommodate adaption to scientific and technical progress or to provide a non-time bound derogation for uses within Life Sciences sector.

- Until our knowledge of chemistry and material science has advanced sufficiently to invent chemical alternatives that can be manufactured at a global scale, the hard work of adapting those chemicals into physical product will lag at an unpredictable pace.

- One does not need to look further than the Directive (EU) 2011/65 (RoHS) to see how long it takes to find and implement substances within a finite use (electrical and electronic equipment). It has taken industry 15+ years since Directive 2002/95/EC (aka RoHS I) to find practicable alternatives for the majority of uses, but are still relying upon and renewing >100 unique use exemptions….just within Electrical and Electronic equipment. Based on industry experience with RoHS and the magnitude of the number of unique product applications, product types, manufacturing processes and number of substances that must be identified and replaced within (at most) 13.5 years makes RoHS relatively straightforward.[4]
- Because the finite time-bound derogations afforded under Title VIII of REACH are not adaptable to technical progress, it can be anticipated that many products will need to be withdrawn from manufacture and sale in the EU at the end of the proposed derogations.

There has not been adequate time or available data to conduct an industry-wide use assessment across the Life Sciences sector and their downstream uses for the PFAS used in the product types described herein to justify a specific timeline. This is largely caused by the complexity and depth of our supply chains, lack of regulation applicable to the broad inclusions of polymeric PFAS in the proposal, and the inconsistent regulatory definitions of PFAS leading to a paucity of data to report upon. Furthermore, testing every physical article for all possible PFAS's is not an economic feasibility. The testing is complex, time consuming, and is not adaptable to look for all possible PFAS in a single run. Most companies do not have access to the specialist equipment and personnel and must outsource to only a few certified test labs capable of assessing PFAS at the concentrations dictated in the proposal. As a result, many players in the global supply chain are unable to provide accurate or complete declarations of PFAS according to the EU definition. It is easily anticipated that new (and possibly critically important) uses of PFAS will continue to be discovered after the eventual entry into force.

Universal 'drop-in' alternatives are needed to meet the aggressive timeline of 1.5 – 13.5 years post EiF for PFAS removal from products. One of the reasons that common polymeric PFAS's are used relate to their long track record with a broad range of chemical resistance. Without a 'one-size fits all' solution, each alternative will have to be tested against all possible chemicals and will necessarily delay reintegration into the market.

[4] See also submission to this consultation of the Test & Measurement Coalition anticipating 25 years for a replacement of PFAS in monitoring and control instruments.