PerkinElmer, US LLC
710 Bridgeport Ave
Shelton, CT 06484 USA

Phone [redacted]
www.perkinelmer.com

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Subject: Comments for Annex XV restriction report

Background

The proposed phasing-out of per / polyfluoroalkyl substances (PFASs) will have a significant impact on manufacturers of many types of analytical instrumentation, due to the current widespread use of these materials in many critical instrument sub-systems. This report examines the present usage of PFAS materials in PerkinElmer analytical instruments, with particular emphasis on our mass spectrometry products. Options for the use of non-PFAS-containing substitute materials are evaluated, and the overall impact of potential restrictions on the use of PFASs on our instruments and their end users is assessed.

PFAS-Containing Instrument Components and Materials – Overview

The most significant PFAS – containing components used in our instruments are:

- O-ring seals (fluorocarbon elastomers, or elastomers coated / encapsulated with fluoropolymers)
- Components machined from solid fluoropolymer (sheets, rods, blocks etc.)
- Components molded from fluoropolymer resins
- Fluorocarbon-based oil and grease for vacuum systems
- Permanent fluorocarbon coatings for solid materials
- Gas, liquid and vacuum tubing
- Liquid and gas fittings and sealing materials
- Electrical wires and cables
- Precision components for ion optics
- Electronic components and connectors
- Electromechanical components
- Sample handling equipment and containers
- Filtration and gas processing media and devices

Examples of some of the PFAS materials commonly found in, or in association with, PerkinElmer (mass spectrometer) instruments are listed below. Many materials have more than one "trade name".

- FKM - vinylidene fluoride based Fluoroelastomers e.g. trade name "Viton"
- FFKM - Perfluorinated Elastomers e.g. trade name "Kalrez"
- FEPM - Tetrafluoroethylene-Propylene based fluoroelastomers e.g. trade name "AFLAS"
- PTFE - polytetrafluoroethylene e.g. trade name "Teflon"
- PVDF- polyvinylidene fluoride e.g. trade name "Kynar"
- PVF - polyvinylfluoride e.g. trade name "Tedlar"
- PFA - perfluoroalkoxy polymer e.g. trade name "Teflon PFA"
- FEP - fluorinated ethylene-propylene e.g. trade name "Teflon FEP"
- ETFE (polyethylenetetrafluoroethylene) e.g. trade name "Tefzel"
- PFPE - Perfluoropolyether e.g. trade name "Fomblin"
- PCTFE – polychlorotrifluoroethylene e.g. trade name "Kel-F"
- PFSA - Perfluorosulfonic acid e.g. trade name "Nafion"

PFAS-Containing Components and Materials – Details

For each component / material category we will examine:

- Description
- Where, how, and why used in our instruments
- Mitigation of environmental contamination potential
- Potential for the use of non-PFAS alternatives
- Projected impact of PFAS usage restrictions

1. **O-ring Seals and Gaskets**
    a. Description: these are compressible “rubber-like” seals or gaskets; they may either be composed of solid fluorocarbon elastomer (e.g., “Viton” rubber) or they may be an unspecified elastomeric material (for example, Buna-N rubber) which is overcoated or encapsulated with a PFAS material (usually PTFE “Teflon”)
    b. Where, why and how used: o-ring seals are used in many locations throughout mass spectrometer sample inlet and vacuum systems; maintaining a reliable high vacuum seal is a critical requirement for mass spectrometer operation. Viton o-rings are used due to their superior resistance to chemical and thermal degradation, oxidation, and low outgassing rate.
    c. Mitigation of Environmental Contamination: with these solid components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However, when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling. In many cases, these components last the entire service life of the instrument and may be separated for recycling when the instrument is de-commissioned.
    d. Potential Use of non-PFAS Alternatives: elastomers formulated from silicone rubber are an effective substitute in many, but not all, applications. Silicone has a higher coefficient of friction than Viton and is unsuitable for certain mechanical applications involving frequent movement.
    e. Projected impact of PFAS Limitations: In most cases the main impact will be the moderately higher cost of effective substitute components. In some critical applications involving mechanical movement and/or high temperature, no appropriate substitute material is presently available, therefore requiring a significant re-engineering effort. In some applications, outgassing from substitute o-ring materials has been shown to cause serious instrument performance degradation, due to high chemical background, and long-term loss of instrument detection capability due to contamination.

2. **Components Machined from Solid Fluoropolymers**
    a. Description: these are typically “hardware” components of instruments that are designed for operation in severe environments; the most common fluoropolymer used for these applications is PTFE “Teflon”.
    b. Where, why, and how used: examples of typical usage include: liquid drain fittings for ion sources; mounts and isolators for high voltage electrical components; and internal components of solenoid valves. The ability of PTFE to simultaneously withstand high voltage, high temperature, and highly reactive chemicals, makes it particularly suitable for use in electrospray and ICP ion sources. The low-friction characteristic of PTFE is of great value in certain mechanical applications.
    c. Mitigation of Environmental Contamination: with these solid components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling. In many cases, these components last the entire service life of the instrument and may be separated for recycling when the instrument is de-commissioned.
    d. Potential Use of non-PFAS Alternatives: similar non-fluorinated polymers such as polypropylene are acceptable for use in some applications but cannot be used where high temperature operation is

required. High temperature conditions require alternatives such as PEEK or ceramics, which have very different mechanical properties than PTFE.

e. Projected impact of PFAS Limitations: In most cases the main impact will be the moderately higher cost of effective substitute components. In some critical applications involving mechanical movement and/or high temperature, no appropriate substitute material is presently available, therefore requiring a significant re-engineering effort. This also applies to components which we purchase from vendors, such as solenoid valves.

3. **Components molded from fluoropolymer resins:**
    a. Description: these include many types of liquid-handling fittings, liquid and gas connectors (e.g. compression fittings, push-connect fittings, coolant fittings), liquid sprayers (nebulizers), and spray chambers (as used in ICP-MS and ICP-OES instruments)
    b. Where, why and how used: these components are primarily used, in conjunction with tubing, for transfer and introduction of reagents (liquid or gas phase) and samples to instruments. The most common polymers used are PTFE and PFA. Fluoropolymers are used because of their excellent chemical resistance (e.g. to strong acids and bases), low absorption and release of contaminants, and ability to withstand high temperatures (above 200 degrees C)
    c. Mitigation of Environmental Contamination: as with other solid components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling.
    d. Potential Use of non-PFAS Alternatives: non-fluorinated alkyl polymers such as polypropylene or polyethylene are acceptable for use in some applications, but (due to their low melting points) cannot be used where high temperature operation is required. Many of these molded components are NOT currently available in non-fluorinated polymer form.
    e. Projected impact of PFAS Limitations: without exception, PerkinElmer purchases all molded components from external vendors. It will require considerable time (years) and financial investment for our vendors to develop and market acceptable substitutes for their existing products, particularly for applications involving high temperature operation. In some cases, and applications, substitutes with equivalent performance may never be practical.

4. **Fluorocarbon-based oil and grease**:
    a. Description: these materials are either composed almost exclusively of PFAS substances (as is the case with PFPE oil) , or in some cases they consist of hydrocarbon formulations with PFAS additives.
    b. Where, why and how used: in analytical instruments these materials have two main areas of application: (1) vacuum systems, and (2) mechanical-motion systems. For vacuum systems, these substances offer a unique combination of excellent lubrication and very high resistance to thermal and chemical degradation. The most common use in vacuum systems is for roughing pump oil. For mechanical motion systems, the same properties enable low-friction movement of precision parts for long periods of time under difficult environmental conditions.
    c. Mitigation of Environmental Contamination: Fluorocarbon-based grease is of minimal environmental concern since it is highly insoluble in water, has a very low vapor pressure (does not evaporate), and is generally used in very small (milligram) quantities in analytical instruments. Fluorocarbon based oil (usually PFPE) is of greater environmental concern due to the potential for contamination of soil and ground water, however it is also easily collected and returned for recycling. Techniques are available for effective recycling and re-use of PFPE oil. Some roughing pump designs use removable oil cartridges which minimize the risk of spillage and enable simplified recycling procedures.
    d. Potential Use of non-PFAS Alternatives: Fluorocarbon-based greases may be substituted by hydrocarbon-based greases in many applications, although instrument performance may be degraded, and significantly more frequent and costly routine maintenance is to be expected. In some cases, redesign of instrument mechanical components will be required to deal with less-capable substitute materials. Fluorocarbon pump oils are NOT readily substituted with hydrocarbon oils, and in almost all

cases, modifications to mechanical systems will be required. These modifications would in most cases involve addition of chemical vapor filtration traps (to protect the hydrocarbon oil from aggressive chemical vapors) combined with much more frequent replacement of pump oil. Both of these approaches add significant cost, as well as negative environmental impact (i.e. frequent disposal and/or recycling of additional materials, such as chemical trap media and oil). Roughing pumps may also be replaced with non-oil-sealed ("dry") pumps, however in the majority of cases this results in much (3x to 10x) higher initial and recurring costs (e.g. most dry pumps require foreline traps, and need to be returned to their manufacturer for routine maintenance) and negative environmental impact.

e. Projected impact of PFAS Limitations: as noted above, instruments can be re-designed to eliminate the need for these oils and grease, however both costs and maintenance requirements will be dramatically increased to the end user in most cases. Presumably these higher costs would then be reflected in higher costs for chemical analysis procedures, and related end products and services.

5. Permanent Fluorocarbon coatings for solid materials

a. Description: these are thin, permanent PFAS coatings used to enhance the surface properties of solid (usually metal) components. The most common application is a coating of Teflon resin to provide a low friction and chemically inert surface.

b. Where, why, and how used: this approach may be used as a design alternative to either fluorocarbon seals or solid parts, typically where a sliding pressure or vacuum seal is required, and the use of grease is not practical (due to temperature or chemical compatibility concerns). Examples include sliding vacuum "gate" valves used in some mass spectrometer instruments.

c. Mitigation of Environmental Contamination: as with solid PFAS components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling. In many cases, these components last the entire service life of the instrument and may be separated for recycling when the instrument is de-commissioned.

d. Potential Use of non-PFAS Alternatives: in this particular application, there are currently no equally effective substitute coatings.

e. Projected impact of PFAS Limitations: In most cases, re-engineering will be required to produce an equally effective mechanical system with comparable thermal and chemical tolerance. Cost and lifetime of the system will both be negatively impacted.

6. Fluorocarbon-based flexible tubing for gas and liquid transfer:

a. Description: hollow, flexible tubing designed to work with the molded fittings discussed in section (3) above. The most common fluoropolymers used for tubing are PTFE and PFA.

b. Where, why and how used: fluoropolymer tubing is primarily used in analytical instrumentation due to its low reactivity and high compatibility with a wide range of high purity liquid and gaseous reagents. Instrument designers count on fluorocarbon tubing to transfer reagents and samples to and between instruments and sub-systems without adding, removing, or retaining chemicals. The high-temperature compatibility of these materials means that tubing can be heated to minimize adsorption and carry-over of the liquids and gases being transported. In addition, the mechanical flexibility of these tubings enables greatly simplified design, assembly, and repair of instruments.

c. Mitigation of Environmental Contamination: as with other solid components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling.

d. Potential Use of non-PFAS Alternatives: non-fluorinated alkyl polymers such as polypropylene or polyethylene have good chemical inertness properties, and are acceptable for use in some applications, but due to their low melting points they cannot be used where high temperature operation is required. For other applications, stainless steel (or other metal) tubing is an acceptable substitute, however its lack of flexibility makes it unsuitable for certain applications (such as autosamplers). Glass, quartz, PEEK, silicone, or fused silica tubing may be an acceptable substitute in some specific applications.

e. Projected impact of PFAS Limitations: without exception, PerkinElmer purchases all PFAS-based tubing from external vendors. It will require considerable time (years) and financial investment for our vendors to attempt to develop and market acceptable substitutes for their existing products. Prior to the wide availability of PFAS-based tubing, the most commonly used material was stainless steel or related alloys. Reversion to this material for construction and interconnection of instruments is feasible in some, but not all cases, and it is a certainty that such reversion will lead to both higher instrument manufacturing costs and, in many cases, reduced instrument performance due to chemical background and reactivity concerns inherent in metal tubing.

7. Fluorocarbon-polymer tapes and sheets

a. Description: these are PFAS materials in the form of very thin, flexible sheets
b. Where, why, and how used: the most common example of this material format is "Teflon tape", a very thin and flexible form of PTFE. Teflon tape is widely used to provide a flexible and removable high-quality leak-free seal between threaded fittings (liquid, gas, or vacuum).In addition to the ability to withstand high pressure, high vacuum and high temperature conditions, the combination of chemical inertness, immediate usability (i.e. there is no "curing time") and removability (i.e. joined parts may readily be separated if required) leads to the very wide use of Teflon tape in scientific instruments which involve flows of liquids or gases.
c. Mitigation of Environmental Contamination: being solid and highly inert materials, there is no risk of evaporation or dissolution in the environment. Also, the quantities of these materials typically used are negligible compared to the overall mass of the instrument. In any event, discarded material is easily collected for recycling, and is generally left as part of intact larger assemblies (for liquid or gas flow), which makes recycling straight-forward. On a weight basis, the amount of Teflon tape used in an instrument is extremely low (parts per million).
d. Potential Use of non-PFAS Alternatives: setting-type liquid sealants (such as Loctite, RTV silicone, epoxy, UV-curing resins etc.) are some potential substitutes; however, most are considered to be permanent and non-removable, and very few can rival the chemical inertness and high temperature capability of Teflon.
e. Projected impact of PFAS Limitations: liquid and gas / vacuum connecting fittings can be re-designed to use other sealing approaches, however significant cost increases for both instrument manufacturing and maintenance will be associated with this change.

8. Insulation for Electrical wires and cables

a. Description: Teflon and related polymers are very widely used as insulation for electrical wires and cables in analytical equipment.
b. Where, why, and how used: Teflon insulation is valued for its desirable properties of very high insulation strength (per unit thickness) and excellent lifetime, particularly under high temperature conditions. The low-outgassing properties of Teflon make it particularly attractive for use inside high vacuum systems.
c. Mitigation of Environmental Contamination: there is minimal risk of unintentional environmental contamination from Teflon-insulated wire. When instrument wiring is to be replaced, the material is readily returned to the manufacturer for recycling.
d. Potential Use of non-PFAS Alternatives: non-fluorinated polymers such as PVC, nylon and silicone are also widely used for wire and cable insulation, although no single material has the same combination of desirable characteristics as Teflon. Alternative materials in general have higher outgassing rates, which can negatively impact instrument performance (due to background contamination) and lifetime.
e. Projected impact of PFAS Limitations: In most cases an alternative wire insulation may be substituted, although engineering design changes may be required to accommodate these different materials (e.g. increased thickness, or greater spacing from heat sources may be necessary).. If significant design changes are required, instrument cost will be increased.

9. Electronic Components

a. Description: Teflon and similar solid polymers are widely used as insulators in many electronic components and connectors.
b. Where, why, and how used: Teflon has found almost universal application in high-frequency RF connectors, due to its excellent insulating and RF-loss properties, and freedom from limitations of other materials (such as ceramics, which are subject to cracking and contamination). RF connectors with Teflon insulators are also less expensive to produce than connectors using rigid insulators.
c. Mitigation of Environmental Contamination: as with other solid components, there is no risk of air or water contamination. Connectors may be easily returned to the instrument manufacturer when repair or replacement is required.
d. Potential Use of non-PFAS Alternatives: the use of non-Teflon insulators (such as polypropylene, glass, ceramic etc.) is possible for connectors, however in many cases the electrical losses of these alternatives are much greater, particularly in RF applications. In addition, in many cases, components (such as RF connectors) using these alternative insulating materials are simply not available.
e. Projected impact of PFAS Limitations: Substitution of less-efficient RF insulators, if and when available, means that the associated electronic circuits will need to be re-designed for higher output (to compensate for greater losses), and the size, power consumption, and heat generation of these revised circuits and connectors will be negatively impacted. Prior to (future) availability of commercial connectors using non-PFAS insulators, instruments will need to be re-engineered to use alternative RF connection techniques, leading to very significant cost increases in many cases.

10. Electromechanical Components

a. Description: the most common electromechanical components in analytical instrumentation are often electrically-actuated valves (solenoid valves), which are used to switch and regulate the flow of liquid and gaseous reagents within the instrument. Sealing components of these valves are frequently made of Teflon or similar materials.
b. Where, why, and how used: solenoid valves often use Teflon sealing surfaces for the desirable combination of low friction, low outgassing, high temperature capability, and ability to conform to slightly irregular surfaces for optimum sealing and low leak rates. The internal valve seals are normally non-replaceable. The physical quantity of Teflon used within the valve is very small relative to the overall composition.
c. Mitigation of Environmental Contamination: as with other solid components, there is no danger of evaporation, or solubility in water. The only potential environmental risk is posed by solid waste disposal. However, when the need for replacement arises, these components are easily segregated, and may be returned to the manufacturer for safe disposal or recycling. In many cases, these components last the entire service life of the instrument and may be separated for recycling when the instrument is de-commissioned.
d. Potential Use of non-PFAS Alternatives: solenoid valves using PFAS-free seals are available but invariably have compromised performance in one or more critical areas compared to valves with Teflon seals.
e. Projected impact of PFAS Limitations: In some highly critical applications, there is no current viable alternative to solenoid valves with Teflon seals. Substitution of a different valve design would lead to significant reduction in the capability of this type of instrumentation.

11. Sample Handling, Preparation and Storage Equipment

a. Description: this category refers to lab ware and storage containers used to prepare and store samples, prior to analysis with high-performance analytical instrumentation.
b. Where, why, and how used: although traditional lab ware is often made from glass, this material is also a source of significant contamination for certain types of samples and is completely incompatible with others. In particular, preparation and storage of samples for many inorganic analyses (using ICP-MS, ICP-OES, or AA) is generally done (and in many cases MUST be done) using inert plastic lab ware. The types of plastic used for lab ware vary widely, however for many critical analyses Teflon and PFA are the materials of choice. Many types of semi-automated sample handling systems (e.g. autosamplers, auto-dilutors, pipettors) also use components which incorporate PFAS materials. Also, field-collected gas

samples for analysis by GC, GC-MS, and ICP-MS, are typically collected and stored in specialized gas bags made from "Tedlar" (PVF).

c. Mitigation of Environmental Contamination: since these are all solid-phase components, there is no risk of environmental contamination, provided that the components are properly recycled at end-of-use.
d. Potential Use of non-PFAS Alternatives: for many applications (particularly liquid sample storage), materials such as polyethylene and polypropylene are equally effective for even the most critical samples. Of much greater concern are the Teflon-containing pumps and valves used in many types of automatic sample handling equipment, since in many cases there are no suitable PFAS-free components currently available on the market. Field-collected gas samples may be stored in metal cylinders in most cases, or possibly in gas bags made from alternative plastics (Mylar, polyethylene).
e. Projected impact of PFAS Limitations: use of non-PFAS-containing components in sample handling equipment, if and when available, will likely lead to reduced accuracy, increased levels of background contamination, and a need for more frequent calibration and repair of this equipment. Storage of gas samples in non-Tedlar bags will result in significantly higher costs and/or reduced analytical capabilities (e.g. from sample contamination due to outgassing).

12. Filtration and Gas Processing Media and Devices

a. Description: this refers to manual or automated filtration and separation equipment for liquids or gases.
b. Where, why, and how used: one common but not often considered application, is the use of semi-permeable membranes made from Nafion (PFSA). This material has the ability to selectively separate water vapor from common gases (air, Argon, Nitrogen) with high efficiency, and is therefore used in equipment such as zero air generators and Argon drying devices for ICP-MS.
c. Mitigation of Environmental Contamination: since these are solid-phase components, usually in the form of sealed cartridges, there is no risk of environmental contamination, provided that the components are properly recycled at end-of-use.
d. Potential Use of non-PFAS Alternatives: the properties of Nafion as a water vapor separator are unique; alternatives such as solid-phase traps (e.g. "Drierite") and cryotraps are effective, but require frequent replacement and/or regeneration. Cryotrapping and thermal regeneration of water vapor traps are both energy-intensive processes.
e. Projected impact of PFAS Limitations: removal of Nafion from water-vapor-removal devices will require substitution with older approaches, which in general require larger, more expensive hardware, and have higher energy consumption.

Conclusions: IMPACT of Potential PFAS restrictions on PerkinElmer Analytical Instrument Products

The overall short and mid-term impact of a total removal of PFAS-containing components from our analytical instruments (mass spectrometers in particular) and related peripheral device would be:

- higher manufacturing costs (direct impact of substituting non-PFAS materials)
- increased R&D costs (to redesign instruments; this will be embedded into the cost of new instruments)
  - both of the above will result in significantly higher instrument prices to the end user
- reduced analytical performance, particularly for the highest-performing instruments
- reduced instrument reliability (can be mitigated by more frequent preventive maintenance)
- more frequent and more costly service, repair and preventive maintenance (including parts)
- increased costs due to material recycling requirements (incorporated into a higher cost for instruments, parts, maintenance and service e.g. recycling fees)
- increased complexity of instruments and peripherals
- in some cases, increased energy consumption of instruments (e.g. gas drying apparatus)

All of the above aspects will result in significantly higher costs for instrumental analysis procedures. These increased costs will necessarily be incorporated into the final cost of the associated products and services, ranging from medical / clinical testing, to foods, drinking water, electronic devices, vehicles, environmental testing, and many others.

In the longer term (5 to 10 years or longer) it is possible that alternative non-PFAS materials and approaches will be developed, which may eventually mitigate many of the above issues; or the analytical instrumentation community will simply come to accept lower-performing instruments at higher prices, along with resulting higher costs for all related end-products and procedures.

The Way Forward

The most logical approach would be to remove (from instruments) those PFAS materials which are **not** highly critical to instrument performance (for example: replace Teflon gas delivery tubing with polyethylene or stainless steel) and for which non-PFAS alternatives are available. Then, to exempt (at least on a temporary basis) the most critical components (with no acceptable substitutes, such as RF connectors) from PFAS control regulations. PFAS materials and components used in significant quantities (such as PFPE vacuum pump oils) could be dealt with using more stringent recycling requirements. Perhaps a “content limit” (either by total mass or by mass fractional composition) could be established for PFAS materials in critical analytical instruments.

Additional points of note:

- Analytical instrument manufacturers such as PerkinElmer do not manufacture PFAS materials or components, but rather incorporate existing materials and components into instruments as required and available.

- On a weight basis the total PFAS material content of a typical, current-design analytical instrument system (such as a mass spectrometer) is on the order of 0.2 kg per 200 kg instrument = 0.1% . The total number of new analytical instruments sold in Europe annually is on the order of 10 thousand or less (total of all instrument manufacturers), for a total PFAS usage of roughly 2000 kg (2 metric tons) or less.

- Since these instruments (including ICP-MS, LC-MS and GC-MS categories) are important tools which enable the detection and monitoring of PFASs in the environment, it would be reasonable to grant them a “derogation” (delay in application of restrictions) in order to ensure that instrument availability and performance is not compromised until the necessary re-design and testing of PFAS-free designs can be completed.

Comments authored by,
Bill Fisher, PhD. Principal R&D Scientist
PerkinElmer, Woodbridge, Canada.

Compiled and submitted by,

Richard Covell

Richard K. Covell, Jr.
PerkinElmer US LLC
Global Compliance Engineering Manager
[redacted]
[redacted]@PerkinElmer.com