SPECTARIS

Impact of the PFAS Restriction on SPECTARIS Members

Technical Impact Report

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Note on report approval

The persons identified above have signed off each stage of this report in accordance with RINA's BMS/QA procedure.

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Issue and Revision Record

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0	Issue 1	Emily Tyrwhitt Jones	Maitheya Riva	Dr Chris Robertson	3 August 2023

EXECUTIVE SUMMARY

RINA Tech UK Limited (RINA) was requested by SPECTARIS to gather information from members to support the stakeholder engagement currently being undertaken for Per- and Polyfluoroalkyl substances (PFAS) under the REACH restriction proposal. Based on this information, this report provides an assimilation of the technical requirements which apply to SPECTARIS members' products regarding uses of PFAS.

SPECTARIS is the German industry association for the high-technology medium-sized business sector and representative body in the areas of medical technology, consumer optics, analytical, bio and laboratory technology, as well as photonics. Owing to the wide range of desirable physical and chemical properties PFAS offer, SPECTARIS members use and need them for a wide variety of products, components as well as the manufacturing processes outlined in this report.

Although many SPECTARIS members are aware of PFAS substances used in their products, not all substances are able to be identified in all products, components, and manufacturing processes. It is necessary to understand that companies (downstream users) collaborate with (upstream) suppliers, in a complex supply chain with many tiers to identify PFAS uses. With the unprecedented large scope of the proposed restriction, the current disclosure requirements via safety data sheets and substances of very high concern (SVHC) declarations are insufficient to build the basis for identification and evaluation of all relevant PFAS uses.

Where SPECTARIS members have reason to believe PFAS perform critical uses for their products, information has been provided in this report wherever possible. Where potential alternatives are considered, the evaluation must be on a case-by-case basis considering technical, regulatory, as well as economic aspects. By its nature, the invention of an alternative has no clearly defined timeline, and, for some applications, there may be no known alternative. When an alternative is not viable, the process of implementing PFAS-free alternatives can take even longer as research and development steps may need to be repeated to find a different chemistry or technology that does not have the same issues. Many SPECTARIS member products have to meet stringent qualification requirements with qualification of alternatives being a highly complex, multi-step, multi-year challenge.

SPECTARIS members rely on fourteen proposed derogations and support the need for a further five potential derogations outlined in the Annex XV report. A number of these derogations need to be adapted to cover additional uses or for a longer timeframe as summarised in Table 0-1. SPECTARIS members also suggest a number of additional derogations, as either the use provides critical functionality not previously covered, or it clarifies the needs for derogations in certain end uses.

SPECTARIS members rely on the derogations for the manufacturing of their products and in their supply chain. It is therefore essential that the derogation needs to be viewed holistically to ensure all justifiable SPECTARIS member's uses of PFAS are permitted. These are summarised in the following table.

Table 0-1 Summary table of derogations upon which SPECTARIS members rely.

#	Derogation	Additional uses	Additional time
Proposed derogations			
5a	Polymerisation aids not excluding the production of PTFE, PVDF and FKM (16+ years required)	X	X
5b	Textiles used in personal protective equipment		

#	Derogation	Additional uses	Additional time
5e	Textiles and membrane filter products used in high performance air and/or liquid applications in industrial and laboratory or professional settings	X	
5f	Refrigerants in low temperature refrigeration		
5g	Refrigerants in stationary refrigeration equipment for industrial use and laboratory test and measurement equipment	X	
5h	Refrigerants in centrifuges and incubators with the maintenance of such items permitted for an unlimited timeframe	X	X
5i	Maintenance and refilling of existing HVACR and refrigeration equipment	X	
5k	Industrial precision cleaning fluids		
5n	Diagnostic laboratory testing		
5s	Lubricants where the use takes place under harsh conditions…		
5t	Calibration and reference materials of measurement instruments and as an analytic reference material (20+ years needed for reference materials)	X	X
5cc	Membranes used for venting of medical devices		
6b	Implantable medical devices		
6c	Tubes, catheters and sterile connectors in medical devices, biopharmaceutical, and pharmaceutical production equipment	X	
Potential derogations			
5v	Hard chrome plating		X
5ee	Semiconductor manufacturing process, related equipment and supporting processes (20+ years needed)	X	X
6j	Coating applications for medical devices (18 years needed)		X
6k	Rigid gas permeable contact lenses, ophthalmic lenses, and other lenses	X	
6n	Packaging of terminally sterilised medical devices (at least 16 years needed)		X
Additional derogations			
-	Fluoropolymers and fluoroelastomers (at least 13.5 years)	NEW	
-	Analytical and laboratory equipment (at least 13.5 years)	NEW	
-	Medical devices, their accessories, and medical tools including equipment used for veterinary applications (time unlimited)	NEW	
-	Plants for the production and transport of ultrapure water used for cleaning precision optics (at least 13.5 years)	NEW	
-	PFAS coated optical multicomponent glass fibres (at least 17 years)	NEW	
-	Fluoropolymers in UV lasers and equipment requiring UV and/or IR resistance (at least 13.5 years)	NEW	
-	Solution for mould release (at least 13.5 years)	NEW	
-	Batteries and battery manufacture (at least 13.5 years)	NEW	

In addition to the above derogations, SPECTARIS members would like to highlight the necessity for the continued use of PFAS in spare parts and repairs of products already placed on the market. SPECTARIS members not only manufacture new products but also service and maintain existing products, machines, and devices. Without the general consideration to permit the use of PFAS in these applications, this will cause the premature end-of-life and scrappage of products which otherwise could be serviced and maintained in service with PFAS-containing parts. It is therefore vital that the restriction

does not impact products already placed on the market. It must be ensured that these products can continuously be made available on the market. With the current definition of “placing on the market” under REACH this would not be possible as any supply or making available to a third party, and hence any resale or lease, for example, is considered “placing on the market” under REACH.

Finally, a formal process for requesting new derogations as well as permitting existing derogations to be extended beyond the originally agreed time period should be established. This is important where PFAS-free alternatives are still either in the early stages of their development, or do not exist as yet and as such the estimations of the minimum steps and time to be considered to qualify alternatives has a significant degree of uncertainty.

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ABBREVIATIONS AND ACRONYMS

AAS	Atomic absorption spectroscopy
BBr_3	Boron tribromide
CAS	Chemical abstract number
DMSO	Dimethyl sulfoxide
ECTFE	Ethylene chlorotrifluoroethylene
ETFE	Poly(ethene-co-tetrafluoroethene)
EU	European Union
FEP	Fluorinated ethylene propylene
FFKM	Perfluoroelastomers
FKM	A family of fluorocarbon-based fluoroelastomer materials defined by ASTM International standard D1418, and ISO standard 1629
HCl	Hydrochloric acid
HPLC	High performance liquid chromatography
ICP(-OES)	Inductively Coupled Plasma Spectroscopy (-for optical emission spectroscopy)
ICP-MS	Inductively coupled plasma mass spectrometry
IOL	Intraocular lenses
IR	Infra-red
IVD	In vitro diagnostic
NA	Numerical aperture
PA	Polyamide
PCR	Polymerase chain reaction
PEEK	Polyether ether ketone
PFA	Perfluoroalkoxy polymer
PFAS	Per- and polyfluoroalkyl substances
PFPE	Perfluoropolyether
ppb	Parts per billion
PTFE	Polytetrafluoroethylene
$POCl_3$	Phosphoryl chloride
PVDF	Polyvinylidene fluoride
RGP	Rigid gas permeable
RINA	RINA Tech UK Limited
RoHS	Restriction of Hazardous Substances
SEM	Scanning electron microscopes
SVHC	Substance of very high concern
$SOCl_2$	Thionyl chloride
TFA	Trifluoroacetic acid
UV	Ultraviolet

1 INTRODUCTION

RINA Tech UK Limited (RINA) has been requested by SPECTARIS to gather information from SPECTARIS members to support the stakeholder engagement which is currently being undertaken for per- and polyfluoroalkyl substances (PFAS) under the REACH restriction proposal.[1] Owing to the wide range of desirable physical and chemical properties PFAS substances offer, they are used in a wide variety of products, components and their manufacturing processes produced by SPECTARIS members. These uses are outlined in this report.

Although many SPECTARIS members are aware of PFAS substances used in their products, not all substances can be identified in all products, components, and manufacturing processes. It is necessary to understand that companies (downstream users) collaborate with (upstream) suppliers, in a complex supply chain with many tiers to identify PFAS uses. The primary disclosure mechanisms mandated by legislation whereby information on hazardous substances can be communicated in supply chains is via safety data sheets and SVHC declarations. However, in most cases PFAS are not classified as hazardous; therefore, in general, evidence of PFAS use would not be declarable via this route. Couple this with the unprecedented large scope of the proposed restriction, these current disclosure requirements are therefore entirely insufficient as a means for identification and evaluation of all relevant PFAS uses. Where the presence of PFAS is in articles they are, in general, not required to be declared to a manufacturer. This is especially challenging when seeking alternatives across the global market, as it can be difficult to ensure that the alternatives being researched are not themselves PFAS. It will take time to work through supply chains to discover precisely what substance is being used in many cases, and further time to establish what could be used as alternatives. Many respondents cannot quantify how long this will take.

When considering if alternatives exist, it is essential that potential alternatives are researched and tested to determine whether they can be used in a functionally equivalent manner. Alternatives must be assessed within the context of already existing regulations (e.g. fire protection, efficiency requirements, safety standards) in order to avoid conflicting regulation. The level of technological maturity and availability of alternatives must also be considered, and as such it is only when all of these factors have been assessed as suitable, that an alternative can be deemed viable. It is also important to note that even if in some cases other substances can be used or alternative processes applied, this does not mean that such an alternative is suitable for the entire range of similar applications. In some cases, it may ultimately be found that a non-PFAS alternative is not capable of providing the required technical function.

In broad terms, SPECTARIS members rely on and support the need for a number of currently proposed derogations and potential derogations. It is also important that a number of additional derogations are also included. The additional derogations suggested by SPECTARIS highlight critical PFAS uses not covered by the currently proposed derogations. Moreover, the need for certain derogations in end uses such as medical and laboratory equipment requires clarification.

1.1 Profile of the SPECTARIS membership

SPECTARIS is the German industry association for the high-technology medium-sized business sector and representative body in the areas of optics, photonics, analytical, bio, laboratory, and medical technology. Innovation and growth characterise the different industry sectors and their 330,000 strong workforce in Germany alone. Technologies developed here are used in almost all branches of industry,

[1] Annex XV reporting format 040615 (europa.eu)

universities, and research institutes making them an essential contributor to the European Union (EU) economy.

In Germany alone, 2700 companies with a workforce of 341,000 achieved a combined turnover of 84.1 billion euros in 2022. These figures refer to companies with 20 employees and more. In addition, one also has to take into account the many small and micro enterprises in these sectors that add to these figures. Figures for the relevant industry sectors are outlined in Figure 1-1.

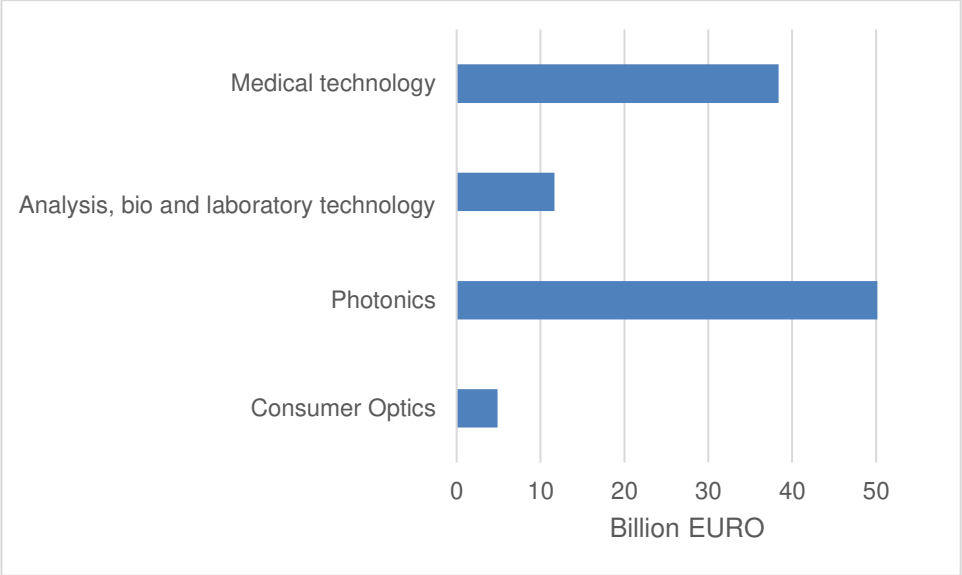

Figure 1-1 SPECTARIS member turnover by sector.[2]

The types of products, components and their manufacturing processes potentially impacted by restrictions are wide ranging, with Table 1-1 providing examples which would be impacted were the restriction to be implemented.

Table 1-1 Examples of the SPECTARIS products, components, and their manufacturing processes utilising PFAS.

Product type	Examples of end use equipment (non-exhaustive list)
Surgical / Medical equipment/devices	Dialysis equipment, incubators, endoscopes, surgical scissors, electrodes, sutures, and sterilisation equipment and related accessories.
Laboratory equipment	Pipettes, burettes, stirrers, sensors, vacuum pumps, liquid handling instruments, dose metering, centrifuges, electrodes, and laboratory consumables.
Analytical (laboratory) equipment	Element analysis; thermal analysis; medical scanner, chromatography, autosamplers, titration and pH measurement, ion chromatography and other ion analysis equipment and electrochemical analysis techniques (including accessories for such equipment to run the analysis).

[2] Source German Federal Statistical Office, SPECTARIS.

Product type	Examples of end use equipment (non-exhaustive list)
Electrical and Electronic Equipment / Connectivity	Fibre optic cables including electrical insulation for aggressive chemical/sterile/heat resistant/ low temperature environments.
Photonic / Optical equipment	X-ray, positioning photographic consumables (e.g. X-ray plates) including lenses for industrial/medical uses and microscopes.
Temperature management	Vaccine refrigerators, cooled centrifuges, and constant temperature equipment (cooling thermostats, circulation and process thermostats, circulation chillers and sample storage).
Vision equipment	Contact lenses, ophthalmic lenses, and lasers for eye surgery.
Specialist systems / equipment	High precision equipment; micropumps; ultraviolet (UV) and infra-red (IR) lamps; high purity coating systems in medical and pharmaceutical equipment.
Microelectronics	Semiconductor manufacturing machines; silicon wafer and associated fibreoptics.
Lasers	Laser equipment for industrial and medical uses.
Industrial, medical and specialty gases	Gas cylinders, cryogenic storage tanks; road tankers and air separation units.

In addition, RINA is aware that many types of electrical and electronic components that are used in many types of SPECTARIS members' products, components and manufacturing processes are either made using PFAS or contain PFAS. For further details on the types of products supplied by SPECTARIS members, please see their website at https://www.spectaris.de .

1.2 Methodology

A questionnaire was devised and circulated to the SPECTARIS membership. The responses from the questionnaire were collated and analysed for common themes in order to give a representation of the whole membership. RINA reviewed all of the responses and categorised them to enable the results to be summarised.

The information shared by SPECTARIS members in this report provides a snapshot at the point of the information being gathered. It is understood that many SPECTARIS members are still collecting data, and as such have not been able to answer all of the questions asked at this time. As mentioned above, it is extremely challenging to collect data in a complex supply chain.

All minimum steps and time to be considered in the report are provided to give an estimated timeline only. Each affected product, component or manufacturing process potentially has a different specific time to be considered to implement PFAS-free alternatives. As such, all minimum steps and time to be considered should be understood to be examples only.

The minimum steps and time to be considered are also built on the assumption that it is possible to identify the parameter(s) in question the first time that tests are completed. If the test is not successful, resulting in tests having to be repeated or if a potential alternative can no longer be considered part way through its development, the timelines will be longer than outlined within this report. Owing to the impacts being unpredictable in nature, the overall impact of this type of outcome cannot be quantified. Therefore, the minimum steps and time to be considered for derogations should assume and take into account that some potential alternatives will turn out to be unsuitable or even not available at all.

2 PROPOSED DEROGATIONS RELIED UPON BY SPECTARIS MEMBERS

SPECTARIS members rely on fourteen proposed derogations outlined in the Annex XV report, however a number of the derogations need to cover additional uses or for a longer timeframe which is outlined in the following sections.

SPECTARIS members rely on the derogations for the manufacturing of their products and in their supply chain. It is therefore essential that the derogations be viewed holistically to ensure all uses of PFAS are permitted.

SPECTARIS members are not in a position to offer additional technical details on derogation '5b-Textiles used in personal protective equipment' as the information is held by their supply chain, but SPECTARIS support the need for such a derogation.

2.1 5a- Polymerisation aids not excluding the production of PTFE, PVDF and FKM

SPECTARIS members rely on this derogation due to their use of polymeric PFAS in their applications. However, the proposed derogation validity period is required to be more than 16 years due to the end uses in which the polymeric PFAS are used in.

It is also important that the derogation includes the production of PTFE, PVDF and FKM in its scope. The change in polymerisation aids in these materials has the potential to change the properties of these materials, and as such component using these would require requalification.

SPECTARIS members are technical users of polymer materials, rather than experts in material development, and, as such, rely upon the effort undertaken by the polymer industry. Sufficient time will need to be permitted to allow SPECTARIS members to test, re-design and go through highly complex, demanding and time consuming regulatory approvals necessary in order to be able to place products on the market.

Polymers provide critical functionality to SPECTARIS members' products, components, and manufacturing processes with Figure 2-1 showing that 48% of unique PFAS uses highlighted by SPECTARIS members[3] relate to polymers.

[3] According to data gathering undertaken by RINA on behalf of SPECTARIS in November 2021 for the initial stakeholder engagement relating to PFAS. For full details refer to the RINA report 2021-0594 'Analysis of PFAS use and potential impacts of PFAS restriction on SPECTARIS Members'.

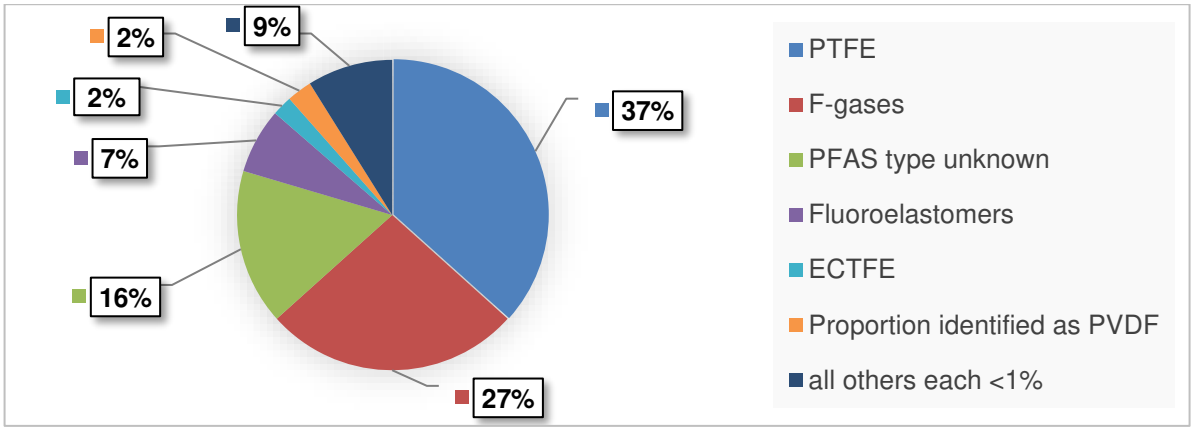

Figure 2-1 Proportion of uses for PFAS substances highlighted by SPECTARIS Members.

The following are a small sample of indicative uses for which SPECTARIS members need the derogation:

- Medical devices, such as but not limited to, implants ranging from guidewires and catheters, endoscopic devices, electrodes, as well as operating aids, adapters, templates, valve seals, cables, tubes, and scissors.
- Optical fibres for illumination (flexible and rigid optical endoscopes, exoscopes, flexible and rigid video endoscopes) and laser transmission.
- Laboratory equipment such as pipettes, cylinders, and caps and analytical laboratory equipment ranging from stirrer and titration devices to complex chromatographic and spectrographic instruments and process analysers.
- Membrane filters and filter products for air filtration and venting applications in pharmaceutical and biopharma industry.
- Non-sticking surface properties for fluid management for medical, laboratory, pharmaceutical and biopharma application.
- Various pumps and insulators.

The technical functions that the polymeric PFAS provide is specific to the end use application, but include:

- Biocompatibility according to standards such as ISO 10993.
- Electrical insulation to standards such as IEC 60601.
- Sliding properties such as <5N tensile force in atraumatic applications.
- Suitable wear resistance to withstand hundreds of thousands of loading cycles in pipette applications.
- Ability to withstand harsh environments including from cleaning chemicals which can range from a pH of 2 to 14 in hospital environments.
- Ability to be sterilised under conditions such as 134°C for 10 minutes, while still maintaining the necessary physical properties.

- Chemical resistance against aggressive organic solvents, precipitating and abrasive substances in combination with dimensional stability and mechanical flexibility.
- Hydrophobic properties for air filtration and membrane applications.
- Suitable optical properties in certain settings.
- No leaching or adsorption effects for trace analysis.

As outlined in Table 2-1, it should be noted that it takes a minimum of 16 years to test, re-design, test for reliability and in-situ performance, and go through necessary regulatory approvals. This process can only be initiated once a potential alternative to polymeric PFAS is identified. There is a great degree of uncertainty with the minimum time to be considered, as currently there is no known PFAS-free alternative which provides the necessary technical requirements. It is critical that each product change is evaluated due to the differing technical requirements of each component.

In addition, new cleaning processes during production could be required due to the use of different polymerisation aids, therefore extending the time to be considered to develop a viable alternative even further.

Table 2-1 Medical device estimated minimum steps and time to be considered once suitable PFAS-free polymerisation aids have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative of materials / components	2+ years
Reliability testing	3-5 years
Redesign of product for alternative solution	2 years
Testing of in-situ performance	2 years
Product specific requirements (e.g. technical documentation, clinical trials, conformity assessment procedures involving designated notified bodies as independent third party)	2-5 years
Global approvals	5 years
Total time to develop	**16-21+ years**

It is also important that the derogation include the production of PTFE, PVDF and FKM in its scope as any change in polymerisation aids has the potential to change the properties of PTFE, PFVD and FKM. The specific technical characteristics of these materials are the very reason why they are selected for use in SPECTARIS member products. Therefore, any change in the use of PFAS-free polymerisation aids could result in their lack of suitability. In addition, due to the strict legislative requirements that many SPECTARIS member products must meet, the change in materials would trigger the need for recertification.

2.2 5e- Textiles and membrane filter products used in high performance air and/or liquid applications in industrial and laboratory or professional settings

Due to many air filtration applications relying on membrane filter products, SPECTARIS requests that the derogation permits the use of PFAS in 'textiles and membrane filter products used in high performance air and/or liquid applications in industrial and laboratory or professional settings.'

SPECTARIS members use porous membranes in their products and manufacturing processes. Porous membranes are formed by phase transition processes and consist of a continuous polymer layer/sheet with pores in it. Considering textiles, these are usually thought of as woven materials based on fibres; porous membranes cannot be thought of as being included in the definition of textiles.

It is also important that such filters are permitted for the use of separation of liquids or gases, rather than just the combination of both applications, as a number of applications filter only pure liquids or gases. For example, polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) are used in air filtration and/or liquid filtration due to the following technical properties:

- Water and oil-repellence.
- Chemical inertness.
- pH stability.
- Solvent compatibility.
- Irradiation stability and steaming stability (autoclaving and sterilisation).
- Low extractable and leachable content.
- Nearly constant physical material properties in a broad temperature range.

There are no commercial alternatives known to SPECTARIS members. The potential minimum steps and time to be considered needed for the implementation of PFAS-free air and/or liquid applications outlined in Table 2-2 hinges on the fact that first a suitable alternative must be identified. Without the derogation, applications such as the separation and testing of air pollutants would no longer be possible.

Table 2-2 Minimum steps and time to be considered to implement PFAS-free air and/or liquid filtration products once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative materials	2-3 years
Testing of in-situ performance	2-3 years
Industrial process development at significant cost	3-5 years
Qualification of the product at each customer site, with customer specific validation programmes	2-4 years
Total time to develop	**5-10 years** with some steps undertaken concurrently

Professional setting

It is SPECTARIS members' understanding that the term 'professional settings' would include a wide variety of settings which could be characterised as activities relating to a person's means of livelihood or adult education. Therefore, specific settings such as laboratories, pharmaceutical and biopharmaceutical applications would be incorporated in this definition.

2.3 5f- Refrigerants in low temperature refrigeration

SPECTARIS members support the need for a derogation for low temperature refrigeration, with such devices used in a variety of their products.

SPECTARIS members use refrigerants such as R-23 and R-508B which operate from -100 to 220ºC, and other refrigerants which operate below -50ºC, in sample and product cooling, and thermostatically controlled equipment.[4] Such refrigerants are used to achieve long-term durability of samples, and to prolong the shelf-life of materials. Due to their flammability and toxicity potential, alternatives in other applications are not a drop-in replacement for low temperature refrigeration equipment, as these need to meet specific performance and safety requirements.

It is also worth highlighting that when PFAS are used in such devices they are only used in closed systems which are hermetically sealed and regularly inspected for integrity according to legal requirements.[5]

2.4 5g- Refrigerants in stationary refrigeration equipment for industrial use and laboratory test and measurement equipment

Due to the same technical requirement for refrigerants in industrial applications, SPECTARIS requests that the derogation permits the use of PFAS in 'Refrigerants in stationary refrigeration equipment for industrial use and laboratory test and measurement equipment'.

SPECTARIS members use refrigerants such as R-134a, R-449A, R-452A, R-410A, R-407F, R-23 and R-508B in laboratory test and measurement equipment. The same refrigerants are also used in an industrial setting for stationary refrigeration equipment that require precise temperature control (with a precision of ±0.005K in applications such as cooling thermostats) over large temperature ranges, with indicative ranges outlined in Table 2-3.

Table 2-3 Indicative operating temperature of PFAS containing refrigerants in SPECTARIS membership products.

Refrigerant	Indicative operating temperature (ºC)
R-134a	-30 to +200
R-449A, R-452A, R-407F	-60 to +220
R-23, R-508B	-100 to +220
Various PFAS containing refrigerants for cooling in mechanical and plant engineering	-150 to +550

As with the refrigerants outlined in Section 2.3, there are concerns with many potential alternatives related to their flammability and toxicity.

[4] Including 1st and 2nd stages of cascades in cooling thermostats, circulation and process thermostats and two-stage thermostats.

[5] https://climate.ec.europa.eu/eu-action/fluorinated-greenhouse-gases/eu-legislation-control-f-gases_en

The refrigeration equipment is used in industrial sectors such as the following, with example images of the equipment outlined in Figure 2-2:

- Production of biological agents where precise temperature control is critical, starting from the research phase to the optimisation of parameters and upscaling of growth cultures.
- Production and storage of chemical and biological agents.
- Research and development labs for the preparation of test specimens and quality assurance.
- Battery test systems in automotive engineering where batteries and other components are tested for range and temperature stability in climate-controlled chambers.
- Cooling at hydrogen filling stations and electrolysers.
- Semiconductor industry for process cooling and component testing.
- Aerospace industry for material testing and temperature simulation.
- Mechanical and system engineering in laser cutting machines and precision machine tools.

Figure 2-2 Refrigeration equipment in industrial equipment.

Refrigeration equipment is also used in the medical sector for temperature control tasks in heart surgery with hypothermia devices used in operating rooms to stabilise the patient's temperature during surgery, as shown in Figure 2-3.

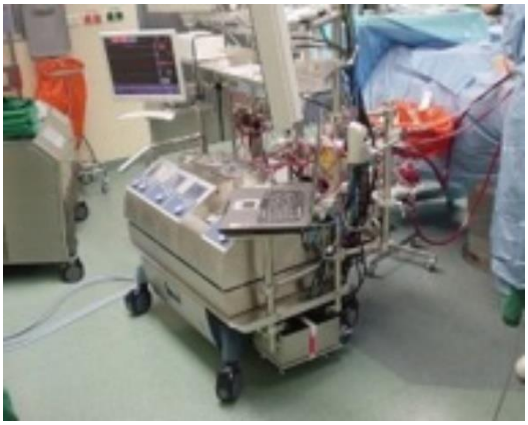

Figure 2-3 Refrigeration equipment in surgery.

F-gases are still of unique functionality not able to be matched by PFAS-free alternatives, mostly due to the flammability concerns. However, even the non-flammable alternative, carbon dioxide, has the limitation that it can only operate down to temperatures of -45°C, but no lower. There is also the consideration that compared to fluorinated gases, carbon dioxide systems have a much higher energy consumption and require special design due to high operating and standstill pressures of up to 90 bar.

As with all other refrigerant uses, the refrigerants in these applications are used within closed systems which are hermetically sealed and regularly inspected for integrity according to legal requirements.

2.5 5h- Refrigerants in centrifuges and incubators

Due to the need for refrigeration in incubators SPECTARIS requests that the derogation permits the use of PFAS in 'refrigerants in refrigerated centrifuges and incubators.' Due to the technical challenges faced by higher performance centrifuges, as yet no technical alternative has been able to be identified and a longer derogation validity period for these products may be required. In addition to this, due to the continued need for maintenance, it is requested that the derogation timeframe for maintenance is unlimited.

Centrifuges

SPECTARIS members use refrigerants such as R-134a and R-452a in the refrigerant circuit of cooled centrifuges, with an example product provided in Figure 2-4. Centrifuges can be broadly divided into the following categories due to the differing technical challenges each category of product faces:

1. Centrifuges with up to 0.1 kW of refrigeration performance, the use of non-PFAS refrigerants are potentially possible if suitable time is permitted to develop and qualify such solutions to the necessary safety requirements.
2. Larger centrifuges with >1kW continuous power of refrigeration performance are unable to use flammable refrigerants due to the safety concerns related to their use. The flammability of potential alternatives is especially important in centrifuges due to the high kinetic energy involved and the implications of gas ignition. The use of carbon dioxide may be possible but is likely to introduce limitations in performance and result in significantly increased energy consumption.
3. Higher performance centrifuges which operate at temperatures –20 °C or lower while having a continuous power consumption of > 1 kW have no potential technical alternative currently identified.

Centrifuges outlined under points 1 and 2 above will require at least 10 years to evaluate and qualify a PFAS-free solution. However, high performance centrifuges currently have no technically viable alternative and as such an estimation of the time to qualify an alternative solution cannot be quantified.

As with all other refrigerant uses, the refrigerants in these applications are used within closed systems which are hermetically sealed and regularly inspected for integrity according to legal requirements.

It is important to note that any potential PFAS-free solution would only be suitable for the use in equipment specifically designed for such refrigerants. As such this would not eliminate the need for maintenance on products already supplied. The average centrifuge's product lifetime is about 7 years, however some have a lifetime of more than 20 years which require maintenance over the whole product life. The refrigerant is only replenished if there has been a leak, however if regular maintenance was no longer possible it could result in the early withdrawal of products as they could no longer be supported. Centrifuges are used in a variety of end uses which range from micro centrifuges (with an estimated product weight of 28 kg) to floor standing centrifuges for blood bags (with an estimated product weight of 355 kg). As such, if a derogation would not permit the continued maintenance of such equipment there would be additional waste generated and the equipment could no longer be used, potentially resulting in shortages of the equipment.

Figure 2-4 Example centrifuge.

Incubators

The refrigerant R513a is also used in refrigerated incubators (both medical and general laboratory equipment) manufactured by SPECTARIS members. As with the refrigerants outlined in Section 2.3, for many potential alternatives there are concerns with the flammability and toxicity of many of the alternatives. A fundamental development in potential alternatives needs to occur for which at least 10 years are required due to the challenges associated with this.

The average lifecycle of incubators is 7 years, but some are on the market for more than 10 years. So, as with the concern raised with the centrifuges, the restriction has the potential to limit the maintenance of equipment and could result in the early disposal of equipment. An incubator weighs between 103 to 175 kg, with 200g of refrigerant per unit. If a derogation would not permit the continued maintenance of such equipment there would be additional waste generated and the equipment could no longer be used, potentially resulting in shortages of the equipment.

2.6 5i- Maintenance and refilling of existing HVACR and refrigeration equipment

Due to the continued need for maintenance and refilling of existing refrigeration equipment SPECTARIS requests that the derogation permits the use of PFAS in existing refrigeration equipment. Therefore, SPECTARIS suggest amending the derogation to 'maintenance and refilling of existing HVACR and refrigeration equipment …'.

SPECTARIS members wish to highlight the similar requirement for maintenance and refilling of existing refrigeration equipment[6], for which there is no drop-in alternative. As with HVACR, refrigeration systems require maintenance including the refilling the refrigerant if there are leaks. Without the derogation, the whole system would require replacement. It is also worth noting that existing equipment cannot be refilled with potential PFAS-free alternatives due to design and other constraints.

SPECTARIS members use refrigerants such as HFC125, HFC134a, HFO1234yf, HFO1234ze(E) and HCFO1233zd(E) in refrigeration equipment as additives to improve the thermodynamic characteristics and thus the energy efficiency. SPECTARIS members are dependent on the timely development of suitable drop-in solutions by the chemical industry. To date, drop-in solutions, even for the latest generation of industrial chillers, are not yet available.

It is also important to note that SPECTARIS members are reliant on sophisticated HVAC equipment for the production infrastructure of their equipment to create highly temperature-controlled areas. HVAC equipment is essential for the manufacture of medical equipment and photonics, with the full description of end sectors SPECTARIS members support outlined in Section 1.1.

2.7 5k- Industrial precision cleaning fluids

SPECTARIS members support the need for a derogation for industrial precision cleaning fluids as they are critically used within their products. For many SPECTARIS members due to the technical requirement to use PFAS-containing lubricants, only PFAS containing cleaning fluids can offer the necessary cleaning ability required.

SPECTARIS members use industrial PFAS cleaning fluids such as methyl nonafluorobutyl ether (CAS 163702-07-6) for the cleaning of metal parts which are contaminated by PFAS-containing lubricants. The cleaned metal parts are reused, which supports the principles of a circular economy and would otherwise have to be scrapped. Due to the need for chemical similarity between solvent and lubricant which has to be removed by the solvent, the only commercially available solvents are PFAS-containing. Many SPECTARIS members already employ methods to reduce the use of PFAS industrial cleaning fluids to the minimum amount through the use of an aqueous pre-cleaning step with suitable detergents which remove rough contamination such as particles.

Other solvents, such as alcohols, ketones, and esters (such as acetone or ethyl acetate), low molecular hydrocarbons (such as pentane, hexane, heptane) have been tested by SPECTARIS members as possible alternatives but due to their lower solvent power these leave residues of lubricant. It is also important that any potential alternative meets national safety standards such as the German Bundesimmissionsschutzverordnung[7] (BImSchV), which places strict control measures related to the

[6] It should be noted that such refrigeration equipment does not operate below -40°C and as such is not affected by the derogation 5f.

[7] 2. BImSchV - unofficial table of contents (gesetze-im-internet.de)

emissions of solvent vapours. Meeting general workplace and fire safety requirements may introduce additional considerations if the potential alternative is flammable.

The minimum steps and time to be considered to implement PFAS-free industrial cleaning fluids is very much dependant on the timeline that PFAS-containing lubricants could be phased out. Only once suitable alternatives for PFAS-containing lubricants and in correlation to that PFAS-free industrial cleaning fluids have been identified, can substitution be implemented by SPECTARIS members. The minimum steps and time to be considered for implementation is indicated in Table 2-4.

Table 2-4 Minimum steps and time to be considered to implement PFAS-free industrial cleaning fluids.

Qualification Stage	Estimated time to be considered
Testing of alternative of materials / components	3 - 5 years
Reliability testing	2+ years
Global approvals	1 - 3 years
Implementation of new product equipment	2 - 4 years
Total time to develop	**8 - 14 + years**

It is important to note that any potential emissions of the cleaning fluid are abated in the cleaning device itself with PFAS-containing solvent back fluxed in a closed system. The PFAS containing solvent is generally condensed in two deep cooling zones, which aims to prevent the breakthrough of solvent vapours and losses by solvent evaporation to the greatest extent possible.

2.8 5n-Diagnostic laboratory testing

SPECTARIS members support the need for a derogation in diagnostic laboratory equipment which is understood to relate only to the testing of biological or medical samples. However, due to the similarity in technical requirement and essential uses analytical and laboratory equipment also provide, it is important that a derogation also permits these uses, with information outlined in Section 4.2.

The term diagnostic laboratory equipment is understood to relate to the testing of biological or medical samples and includes in vitro diagnostic (IVD) medical devices, of which SPECTARIS members produce a variety of essential pieces of equipment. One such piece of equipment is high performance liquid chromatography (HPLC) which is used for applications such as drug/nutrition analysis such as the diagnosis of vitamin D deficiencies of children, Polymerase Chain Reaction (PCR) Test-Routine for applications such as COVID-19 detection, research in immunology, haematology and oncology, and next-generation sequencing, preparation for DNA analysis to name a few applications. Equipment such as this is essential to the medical sector and the overall healthcare of EU citizens. It should be noted that SPECTARIS members also produce equipment for general laboratory uses, which is outlined in Section 4.1.

SPECTARIS members use PTFE, perfluoroalkoxy polymer (PFA), e-PTFE, poly(ethene-co-tetrafluoroethene (ETFE), ethylene chlorotrifluoroethylene (ECTFE), fluorinated ethylene propylene

(FEP), FKM[8], perfluoroelastomers (FFKM), PVDF, perfluoropolyether (PFPE) and Fluorolink® (CAS 162492-15-1) in diagnostic laboratory testing equipment.

PFAS are used in a variety of components and equipment, including the following: ring gaskets, sandwich seals, cable bushings, bearing seals, material distribution blocks, valve plates, valve bodies, display foils, stirrers, porous filtration frits, immersion tubes, various vacuum pumps (including diaphragm, screw, and rotary vane), vacuum equipment including controllers, gauges, and networks, tubing, fittings, valves, stirring fish (magnetic stirrer), filters and cable insulation. Furthermore it is also used in metal parts with non-stick coatings, for applications such as liquid handling using tips to reduce friction. In addition to the use in articles, PFAS is also used in lubricants/greases, adhesives, and analytical aids such as immersion oil (outlined below).

PFAS provide essential technical performance, with the exact combination of factors depending on the end use application of the product:

- Chemically inert against harsh chemicals used within hospitals for cleaning and reprocessing, due to its extremely low surface energy.
- UV resistant used within some reprocessing activities.
- Thermally stable, therefore may be hot steam sterilised and operate at temperatures of up to 200°C which are experienced in vacuum pumps.
- Water and oil-repellence.
- Low extractable and leachable content.
- Long-term reliability which is important for some applications which are used continuously (up to 24/7).

Each use is tested and validated for its specific application.

Use outside of a professional setting

It is worth noting that although the vast majority of the laboratory equipment is used within a professional setting, there are also instances where associated equipment is used within a domestic setting. An example of this is the use of in vitro diagnostic kits which are used at home to test for attributes such as COVID-19. The testing kits involved in such testing need to meet the same rigorous technical requirements as those used within a professional setting, which is why they also rely upon PFAS. They are also subject to stringent sectorial legislation such as the in-vitro diagnostic regulation (IVDR) and thus must comply with safety and performance requirements as well as undergo extensive conformity assessment procedures before they may be placed on the market.

Immersion oils

Immersion oils are used in microscopy to enhance the resolution of the features observed during a microscopic investigation as it increases the numerical aperture (NA). The microscopic resolution is proportional to 1/NA, therefore the higher the NA value, the higher the resolution and the smaller the features in objects to be investigated by microscopy which can be visualised. The NA of the immersion oil needs to match that of water to be able to observe biological structures, such as cells filled with water. The closer the NA of the immersion oil to water, the smaller the image distortions as the differences

[8] A family of fluorocarbon-based fluoroelastomer materials defined by ASTM International standard D1418, and ISO standard 1629.

between the refractive indexes are minimised. PFAS-containing immersion oils have a refractive index close to that of water which are reliant on the intrinsic properties of the C-F bond (the highly electronegative fluorine atom draws the electron density towards the fluorine atom). Again, due to the intrinsic properties of the C-F bond, the electrons are not easily polarisable by light which causes the refractive index to be very low. Due to the intrinsic properties of PFAS playing such a crucial role, it is unknown if a PFAS-free alternative could be implemented that could deliver the same technical performance.

The amount of immersion oils produced and used annually is estimated to be 50 kg. All PFAS-containing immersion oils are disposed of as hazardous waste and sent to incineration plants capable of destroying PFAS.

2.9 5s- Lubricants

SPECTARIS members support the need for a derogation for lubricants where the use is undertaken in harsh conditions, or the uses are needed for the safe functioning and safety of the equipment. Many SPECTARIS members rely on the critical functionality such lubricants provide to their products, components, and processes.

SPECTARIS members use lubricants in a number of applications where the use takes place either under harsh conditions, or the use is needed for safe functioning and safety of equipment. Indicative examples include:

- UV Laser systems in end applications such as semiconductor inspection, optical lithography, and Raman spectroscopy where low outgassing and/or UV resistance are required.
- Scanning electron microscopes where low outgassing (due to impact on image quality and ability to use in vacuum), high radiation / UV stability, chemical inertness (preventing early corrosion of lubricated metal parts) and excellent tribological properties over a long period of time are required.
- Microscopes in sliding and rolling bearings of rotational and translational guide units which require good lubricating properties over a wide temperature range and low hydroscopic water absorption.
- Analytical equipment such as gas reaction chamber in gas chromatography, ICP (Inductively Coupled Plasma) Spectroscopy and all mass spectrometry methods which require low outgassing due to their operation under vacuum conditions.
- Optometric devices where low outgassing, chemical inertness, negligible stick-slip behaviour low creep behaviour, very low coefficients of friction (<< 0.1) guarantees the necessary technical function over long lifetimes.
- Endoscopes due to their chemical inertness to cleaning chemicals and UV resistance while maintaining biocompatibility.
- Lithographic optics which operate in ultraclean environments that need to have low outgassing and UV resistance.
- Turbo Molecular pumps or screw pumps which create a vacuum environment down to levels from 5×10^{-3} mbar to 10^{-10} mbar due to their low outgassing requirements and high operational temperatures.

The types of PFAS containing lubricants include PTFE greases and sprays, and lubricants with PFAS thickeners such as PFPE or PTFE.

An alternative based on silicone lubricants and silicone oils is not viable due to the ability for volatile silicon-containing compound to be deposited on an optical surfaces and their behaviour under UV light. The UV light polymerises the silicon from the lubricant, forming a SiO_2-like film on the optical surfaces. Even in extremely small amounts (at concentrations in the gas phase below the detection limits of the best analytical equipment), this forms layers of several tens of nanometres or more in a short time resulting in the inoperability of the equipment. This phenomenon has been outlined in multiple studies, including in the following domains: space science[9], laser fusion[10], photomasks for lithography[11] and lithography scanner optics.[12] It should also be considered that silicone alternatives can contain D4-, D5-, and D6-ring siloxanes which are classified as substances of very high concern (SVHC) under the REACH Regulation due to their classification as persistent, bio accumulative and toxic-substances. A change from PFAS-based lubricants to silicone is therefore not viable.

As such, there are no alternatives to PFAS-containing oils and lubricants available which show the same low outgassing behaviour and the same stability against chemical decomposition and UV light as the PFAS-containing oils and lubricants do. In addition, in many of the applications, PFAS-free lubricants and oils have a shorter lifetime and thus would require shorter maintenance intervals and/or require more comprehensive maintenance activities, or higher wear and scrap rates of the affected parts.

2.10 5t- Calibration and reference material of measurement instruments

Due to the continued need for analytical reference materials in applications such as spectrometers, SPECTARIS requests that the derogation permits the use of PFAS in the 'calibration and reference materials of measurement instruments and as an analytic reference material.' For reference materials it is expected that at least 20 years would be needed to implement a PFAS-free alternative, from the moment where a potential alternative has been identified.

SPECTARIS members use PTFE in white light colour standards for spectroscopic products and measurements in reflection as a reference material and so-called integrating spheres. Under the current wording the derogation would not cover this use as reference materials are currently limited to analytical reference standards only. Spectroscopic products support end sectors such as agriculture and food production, recycling plastics and paper products, healthcare and pharmaceutical industries in drug development and clinical research, environmental monitoring (water and air quality and soil analysis) among many other applications.

PTFE standards are used as they provide the highly specific combination of technical attributes:

- Homogeneous and reproducible optical behaviour necessary for an optical standard.

[9] Boeder, Paul & Visentine, James & Shaw, Christopher & Carniglia, Chuck & Alred, John & Soares, Carlos. (2004). Effect of a silicone contaminant film on the transmittance properties of AR-coated fused silica. Proceedings of SPIE - The International Society for Optical Engineering. 10.1117/12.560859. Mossman, D. L., Bostic, H. D., & Carlos, J. R. (1987, January). Contamination induced degradation of optical solar reflectors in geosynchronous orbit. In Optical Systems Contamination: Effects, Measurement, Control (Vol. 777, pp. 12-19). SPIE. Luey, K. T., Olson, K. R., & Coleman, D. J. (2018). Optical system contamination: formation of films and droplets. Journal of Astronomical Telescopes, Instruments, and Systems, 4(3), 036001-036001.

[10] Mangote, B. & Tovena-Pecault, I. & Néauport, J. (2012). Study of the LIDT degradation of optical components by intentional organic contamination. Proceedings of SPIE - The International Society for Optical Engineering. 8530. 25-. 10.1117/12.968573.

[11] Grenon, Brian. "Impact of micro-contamination on advanced lithography."

[12] Meute, J., Rich, G. K., Hien, S., Dean, K. R., Gondran, C., Cashmore, J. S., ... & Dewa, P. G. (2002, July). Contamination and degradation of 157-nm stepper optical components: field experience at International SEMATECH. In Optical Microlithography XV (Vol. 4691, pp. 724-733). SPIE.

- Reflectivity > 99 % at 350 to 1500 nm and > 95 % at 1500 to 2500nm.
- Usable spectral range, meaning that there are no absorption bands in the operating range: 250 to 2500nm.
- Uniform bidirectional reflectance distribution that functions over almost all angles.
- Nearly perfect Lambertian diffuse reflective material.
- Operating and storage temperature range: -50 to 250°C.
- Operating and storage humidity range: 5 to 95%.
- Suitable for vacuum applications.
- UV-resistant.
- Non-polar, insulator.
- Water repellent.
- Chemically inert.
- Able to be cleaned without affecting the technical performance.
- No PTFE is released during the measurement by such spectroscopic calibration measurements.

No other material is known to possess all of these required technical characteristics, and there is uncertainty that such an alternative exists. Table 2-5 outlines the minimum steps and time to be considered for such a standard to be developed, however this must first be preceded by the identification of a suitable alternative which as yet has not been found.

Table 2-5 Minimum steps and time to be considered to implement PTFE-free white light colour standards for spectroscopic products and measurements once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Fundamental material development to identify material with all essential technical characteristics	Unknown (>10 years)
Testing of alternative of materials / components	5+ years
Reliability testing (including outgassing test in vacuum)	5+ years
Redesign of product for alternative solution	5+ years
Testing of in-situ performance	5+ years
Total time to develop	**20+ years** once an alternative has been identified

2.11 5cc- Membranes used for venting of medical devices

SPECTARIS members support the need for a derogation for membranes used in medical devices for venting purposes. At least 13.5 years expected to be needed, if not longer, as a potential alternative has not yet been identified.

SPECTARIS members use PFAS such as PTFE, PVDF and FKM in membranes for the venting of medical devices. The types of medical devices including flexible endoscopes, rigid bottles for gravity infusion (particle filter) for ophthalmic surgery and particle filtering and water stop in ophthalmic devices. PFAS are used due to the hydrophobicity of filter membrane while keeping demanding technical performance such as the following:

- Suitable Air Flow.
- Water repellent.
- Water Break Through.

A potential alternative solution has as yet not been identified and the full validity period of the 13.5 years proposed, if not a longer time period, will be required.

2.12 6b- Implantable medical devices

SPECTARIS members support the need for a derogation for implantable medical devices due to the unique combination of technical characteristics PFAS currently provide and the criticality of such devices for society.

SPECTARIS members produce a number of implantable medical devices, such as stents and heart valves just to name a few. A further example are permanent implantable intraocular lenses (IOL) which rely upon PVDF for the specialised properties needed. PVDF is used due to its high flexibility, inertness to chemicals and ethylene oxide, temperature resistance (> 120°C), special haptics and compatibility with surgical cauterisation. These unique properties enhance the stability of the IOL in the eye, thus allowing the implantation of intraocular lenses even in patients with a weak or defective capsular bag of the eye. This special patient group cannot be treated with other types of intraocular lens and would otherwise suffer from loss of vision.

IOL with PVDF-based haptic properties are especially suitable in cases where the capsular bag ruptures (scleral fixation). This procedure allows implantation of a lens when unforeseen issues occur during surgery and a proper lens position is not possible due to the absence of capsular bag support. For this technique, the three-piece lens is implanted, and the haptics externalised on the conjunctival surface. The haptics are then heated up using low-temperature cautery to create flanges or round stoppers at the distal end, which prevent the haptics from retracting into the posterior chamber.

PFAS-free material, such as silicon-based material or polypropylene are unsuitable due to the following disadvantages:

- PFAS-free material lacks mechanical stability in small cross-sections. This means that it is not capable of fixating the IOL within the capsular bag, nor is it capable of fixating the IOL in cases where capsular bag support in the eye of the patient is missing.
- PFAS-free material has reduced mechanical flexibility. As this impacts the injection behaviour of the material it is not suited for microincision surgery.
- PFAS-free material is unable to prevent cell growth on intraocular lenses which leads to adverse effects like post-capsular opacification.
- PFAS-free material chemically alters over time. Therefore, it cannot remain in the eye of a patient for an extended period of time leading to unwanted side effects.
- PFAS-free material is much less flexible and therefore not sufficiently adaptable to the natural movement of the eye.
- PFAS-free material lacks the chemical or thermal stability needed to withstand the mandatory sterilisation process using ethylene oxide.

Only if all the above technical concerns can be overcome, the minimum steps and time to be considered to develop a PFAS-free alternative in implantable intraocular lenses is estimated in Table 2-6.

Table 2-6 Minimum steps and time to be considered to implement PFAS-free implantable intraocular lenses once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative of materials / components	1-3 years
Reliability testing	2 years
Redesign of product for alternative solution	2-3 years
Testing of in-situ performance	2-3 years
Product specific requirements (e.g. clinical trials or notified body approval)	2-5 years*
Total time to develop	**9– 16 years**

* Utilising PFAS-free alternatives requires re-design and testing. Should a wave of products and components need testing at the same time, this estimate could be significantly longer.

Additional implants such as scleral buckles, used for treatment of retinal detachment, and the palpebral strip, used for ptosis treatment requiring brow suspension, contains ePTFE due to its biocompatibility, durability, colonizability[13], stability over time and stretchability.[14] Alternative implant materials such as silicone, do not offer the feature of colonizability, therefore limiting the treatment options of surgeons and negatively impacting patients and causing a morbidity increase. To date no alternative material can replace ePTFE.

2.13 6c- Tubes, catheters and sterile connectors in medical devices, biopharmaceutical, and pharmaceutical production equipment

SPECTARIS support the need for a derogation to permit the use of PFAS in the 'tubes, catheters and sterile connectors in medical devices, biopharmaceutical and pharmaceutical production equipment'. However, SPECTARIS would like to raise the concern over the limitation of the derogation to only the listed product types. This style of derogation will lead to essential cases of PFAS being missed which is why a derogation for medical devices (as outlined in Section 4.3) or polymers (as outlined in Section 4.1) are proposed.

A clarification of the scope of 'tube' in the derogation would be welcomed as this should not be limited to tubes which carry liquid and gases, as the same technical requirements also apply to a broader range of uses.

Medical Devices

The following are a small sample of indicative uses that SPECTARIS members need to rely upon PFAS in tubes, catheters, and sterile connectors in medical devices:

- Medical devices ranging from guidewires and catheters, electrodes, endoscopic devices, and stents. For example, endoscope uses include (but are not limited to) upper gastrointestinal endoscopes, colonoscopes, bronchoscopes, sigmoidoscopes, laryngoscopes, pharyngoscopes,

[13] The ability of the blood vessels to use the PFAS-based structure for creating a functional revascularization of the tissue.

[14] J.-M. Ruban, C. Burillon, E. Tabone, M. Mallem, C. Donne & D. Milea (1996) A new material in ptosis surgery with brow suspension: Wide porous expanded polytetrafluoroethylene: Analysis of our first 75 cases, Orbit, 15:2, 67-76, DOI: 10.3109/01676839609150070.

duodenoscopes, nasopharyngoscopes, and rhinoscopes. Figure 2-5 outlines some of the treatment tools and PFAS uses within devices of this type.

- Covering of medical devices such as forceps, dissectors, and scissors.
- Electrosurgical instruments utilising heat shrink tubing, to allow precise cuts and tissue coagulation in one step, such as those used in brain surgery. These devices accounts for 80%[15] of all cutting and coagulation surgeries performed at this time.
- Fluid management for medical devices, including various pumps, valves, and insulators.

The types of PFAS include[16]:

- ECTFE,
- FKM,
- PTFE,
- PFA,
- FEP,
- PVDF,
- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and 1,1,2,2-tetrafluoroethene (CAS 25190-89-0),
- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene (CAS 9011-17-0),
- Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene (CAS 56357-87-0),
- Ethene,1,1,2,2-tetrafluoro-, homopolymer (CAS 9002-84-0),
- Propane,1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-, polymer with 1,1,2,2-tetrafluoroethene (CAS 26655-00-5),
- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1,2,2-tetrafluoroethene (CAS 25067-11-2), and
- Ethene, 1,1-difluoro-, homopolymer (CAS 24937-79-9).

[15] As estimated by a SPECTARIS member.

[16] In addition to this the polymeric precursors are also required which is outlined in Section 2.1.

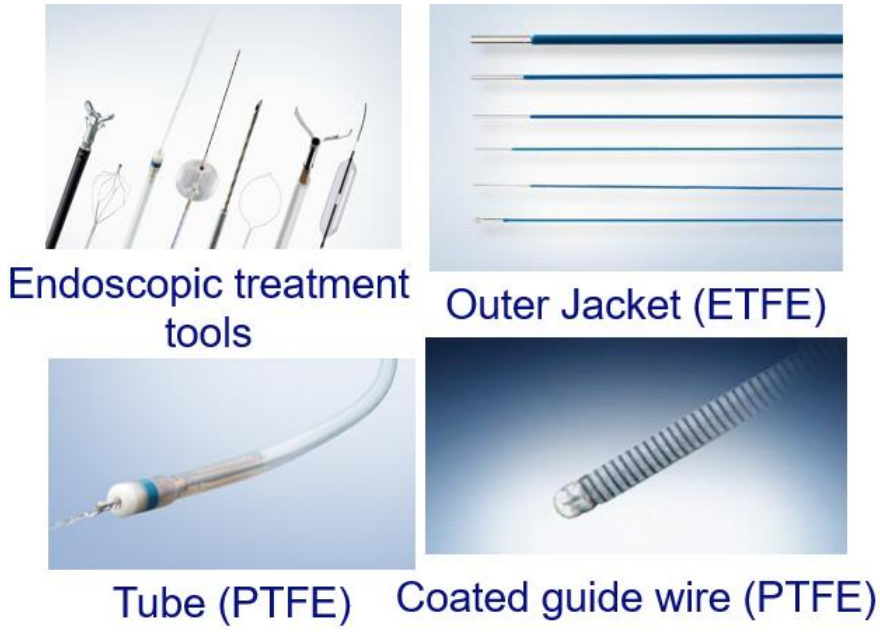

Figure 2-5 Example endoscopic treatment tools and PFAS uses.

The technical function that the PFAS provide is specific to the end use application, but include:

- Biocompatibility to standards such as ISO 10993.
- Electrical insulation to standards such as IEC 60601 with minimal wall thicknesses.
- Water and oil repellence.*
- Very low extractable and leachable content.*
- Near constant physical material properties (flexibility and stability) over broad temperature range (-60^{o}C in applications which require freezing and 150^{0}C for sterilisation).*
- Sliding properties such as <5N tensile force in atraumatic applications.
- Ability to withstand harsh environments including from cleaning chemicals which can range from a pH of 2 to 14 in hospital environments, or argon fluoride gas in medical laser applications.
- Ability to be sterilised under conditions such as 134^{o}C for 10 minutes, autoclave or irradiation for multiple cycles, while still maintaining the necessary physical properties.*
- Long term reliability with some medical lasers having a lifetime of up to 8 years.
- Gas tight mechanical fittings for some applications such as medical lasers, with pressures of up to 10mbar in some devices.

SPECTARIS members have interpreted the derogation term of “tube” to apply to a hollow cylinder, rather than limited to tubes which transport liquids and gases only. It is important that all types of tube are included in the scope of the derogation as they have the same technical requirements (as detailed below), and they also contribute to the limitation of more invasive procedures and/or procedures that are more painful to patients. A clarification on the scope of the derogation would be welcomed to ensure this is consistently understood. Heat shrink tubing as described here also requires a derogation.

Heat shrink tubing and the sheathing of medical devices, must have technical characteristics such as the following:

- Suitable durability to allow a minimum of 100 reprocessing cycles for reusable instruments, with some device requiring 600 cycles.
- Chemical resistance: against alkali cleaners and other medical/clinical disinfection agents for a minimum of 100 reprocessing cycles for reusable instruments.
- Shrinking rate: 2:1 - 4:1.
- Dielectric constant: ~2.
- Dielectric strength: 50 - 80 kV/mm.
- Biocompatibility: according to ISO 10993.
- Temperature resistance: ~134°C for steam sterilisation.
- Small dimensions to allow minimal invasive surgery.

This allows the tube to fit tightly on the cables, which prevents mechanical damage to the instrument (which could cause electrical shock to the patient) with minimal wall thicknesses.

Alternative general tubes are commercially available, but they need to be validated to ensure that they offer all of the technical requirements outlined above. As such the minimum steps and time to be considered as outlined in Table 2-1, equating to minimum of 16 years of qualification are required, with potentially more time required as their use needs to be trialled by the users of the equipment.

Biopharmaceutical and pharmaceutical production equipment

Tubes and sterile connectors and disconnectors are needed in biopharmaceutical and pharmaceutical industry for production and filling of drugs in specialist production equipment. The technical performance of such equipment in this industry sector has many of the same technical requirements as medical devices, with the properties marked with a * in the list outlined on the previous page. The qualification requirements for any material changes need to undergo the same rigour as the medical industry outlined above, with additional qualification requirements often required by the end customer.

3 POTENTIAL DEROGATIONS RELIED UPON BY SPECTARIS MEMBERS

SPECTARIS members rely upon a number of potential derogations currently identified in the Annex XV report which are outlined in the following sections of this report.

3.1 5v-Hard chrome plating

SPECTARIS member products and components use hard chrome plating in equipment such as medical devices and laboratory equipment. Due to the demanding technical requirements of these products alternatives are not possible. The derogation is therefore required beyond the currently proposed 6.5 years. Due to the number of components utilising hard chrome plating and end use applications, significant development time is required.

SPECTARIS members rely upon hard chrome plating for example in the following applications:

- **Medical devices:** as functional plating for patient protection against carcinogenic, mutagenic, or toxic for reproduction substances, resistance against cleaning, disinfection, and sterilisation agents and to allow the smooth and atraumatic use of medical devices.
- **Laboratory equipment:** as a functional plating for the protection of components which are subjected to abrasive degradation due to their function. This includes:
  - Guide components in moving module assemblies which are subject to abrasive degradation,
  - Components exposed to alternating loads (including mechanical, thermal, vibration, and combinations of these factors), and
  - Components with adhesive stress due to high surface pressure and without lubrication (e.g. in vacuum applications).

Hard chrome plating is only possible through the use of PFAS in its production, with SPECTARIS members expecting the plating industry to provide detailed technical information on its uses. As such, without PFAS hard chrome plating would not be able to be used. Alternative surface hardening processes can only be used in combination with materials that are suitable for this purpose but often they have different technical parameters including corrosion resistance, residual magnetism and suitability for vacuum application which mean they are not suitable for certain applications.

One such example is the scanning electron microscope (SEM) where any residual magnetism would disturb the electrons which are generated in the microscope to scan the sample (as well as the backscattered and the secondary electrons produced in the scan, and which are recorded to allow the elemental analysis of the sample). Moreover, as SEMs operate under vacuum, the heat dissipation is significantly reduced as no convection is possible. This results in significantly higher temperature loads for the components when compared to their operation under atmospheric conditions. SEMs operate at the sub-micrometre range, which requires short displacements to be travelled at extreme frequency, resulting in a high wear load for many components. In the vast majority of instances this wear cannot be mitigated through the use of lubricants due to the operation of the equipment under vacuum. For all of these factors, hard chrome plating is essential to the operation of such equipment.

A further consideration is that any material change needs to undergo lengthy re-qualification testing, which for medical devices is especially time consuming. One SPECTARIS member has estimated that the redesign effort for hard chrome plating would affect an estimated 3,500 different products, including

an estimated 50,000 individual parts and therefore would take a considerable time beyond the currently propose 6.5 years to fully complete.

3.2 5ee-Semiconductor manufacturing process, related equipment and supporting processes

SPECTARIS members rely upon semiconductors in their equipment and produce equipment that supports the manufacture of semiconductors. The semiconductor industry shares technical requirements across the entirety of its equipment and processes, including the manufacturing equipment for semiconductors. As such SPECTARIS requests that the derogation permits the use of PFAS in the 'semiconductor manufacturing process, related equipment and supporting processes.' It is expected that 20 years or more would be required to qualify PFAS-free materials due to the highly complex technical requirements that they will have to meet.

SPECTARIS members produce equipment which supports the semiconductor industry:

Optics for semiconductor patterning must achieve precision in the sub-nanometre range. This requires the use of high power deep UV lasers (248 nm, 193 nm) or extreme UV light (13.5 nm). In addition, there is the need for extreme cleanliness for particles (down to 30nm size) and molecular contamination (down to parts-per-trillion concentration). PFAS-containing fluoropolymers must be used in this environment for sealing, vibration damping, and electrical isolation.

Highly specialised optical measurement devices used at multiple points during the semiconductor manufacturing process. PFAS are contained e.g. within pump oils, tubing, and fittings to protect optics against damage. Furthermore, they are found in vessels and pump housings, ultra-high vacuum gaskets, cables, vibration dampening elements, hydrophobic coatings, and photoresist. PFAS are also used in the production of such equipment to etch glass.

Measurement equipment such as x-ray microscopes and scanning electron microscopes which use high vacuum and high voltages in its devices. The semiconductor industry relies on these devices for research and development, as well as process and quality control. PFAS are contained within components such as O-rings, sealings, slide ring seals, cable sheathing, electrical connectors, heat shrink tubing and material for high voltage insulation.

Mask repair systems must deliver very reactive gases to an electron beam to remove or add patterns on a photomask at a nanometre scale. Fluoropolymers are used for delivering these gases while maintaining ultra-high cleanliness.

Vacuum technology for the production of solar cells. Solar cell wafers are doped in a low pressure diffusion furnace with phosphoryl chloride ($POCl_3$) or boron tribromide (BBr_3). Diaphragm pumps, gauges and controllers are exposed and need to be inert against the highly aggressive chemicals. Doping of semiconductors is an important step in the fabrication of semiconductor devices.

Vacuum technology for drying process, such as after etching processes, and backing pumps used in high vacuum pumping stations in physical vapor deposition. The vacuum technology for these are exposed and need to be inert against the highly aggressive chemicals.

PFAS are used as they provide the following combination of technical functions, with the exact technical requirements depending on the end application:

- High temperature (up to 200°C in the production of solar cells) and radiation/UV stability[17] without embrittlement or outgassing. The materials must not produce any particle emissions, which would otherwise disturb the function of the equipment.
- High chemical resistance against aggressive chemicals (such as HF,O_3, H_2SO_4, $POCl_3$, and BBr_3), as well as against reactive radicals such as O*, OH*, OOH* H* and H-Plasma.
- Very low outgassing into vacuum and into ultrapure inert gases, and low water absorption.
- Isolation properties and dielectric strength at high electrical voltages.
- Good sliding properties which is important for the feedthrough of components that operate under vacuum.
- Hydrophobic properties which are kept in the presence of strong oxidisers.

It is the intrinsic properties of the C-F bond in PFAS which impart many of the unique properties which trigger the use of the substances in a number of ways described in the following paragraphs. For example, fluorinated gases and fluids have unique technical performance which allows the directional etching of silicon oxide in certain semiconductor manufacturing processes. Potential alternatives would have high global warming potential and low destruction/removal efficiencies.

Potential alternative materials also cause issues in terms of outgassing and contamination. Hydrocarbon elastomers, even if marketed for vacuum use, outgas by a factor of 1000 more than FKM. There have been outgassing studies like these summarised in the Outgassing Database of Spacecraft Materials from NASA[18] that show how fluorinated materials have the lowest outgassing values, followed by silicon and then hydrocarbon-based elastomers. Outgassing is a critical property for optics as outgassing produces substances which will be deposited on optics. This leads to films that absorb light or have a different refractive index which impact the function of the equipment.

In addition, potential alternatives also degrade under oxygen radical and/or UV exposure. This is due to energy of a photon used in high end lithography (248 nm, 193 nm, or 13.5 nm) that is far above the binding energy of C-C (3.98 eV corresponding to about 312 nm) or C-H bond (4.28 eV corresponding to about 290 nm). Fission of the C-C bond leads to a degradation of the polymer, causing embrittlement, particle shedding and subsequently failure of the function.

The presence of oxygen enhances the UV degradation of hydrocarbon polymers. The initial radicals formed by the UV light can undergo further reactions with the oxygen. As such, specialist testing is required that goes beyond the normal 'UV resistance' testing as the oxygen radicals and UV radiation degrade polymers readily, as outlined by the review by Reddy.[19] Due to higher rates of degradation, the materials will need to be exchanged significantly more frequently, leading to considerably more waste and higher energy consumption. e.g. due to increased transport requirements.

[17] Including wavelengths which are far shorter than UV experienced at ground level.

[18] National Aeronautics and Space Administration (NASA) Outgassing Database of Spacecraft Materials https://outgassing.nasa.gov/

[19] Reddy, M. R. (1995). Effect of low earth orbit atomic oxygen on spacecraft materials. Journal of Materials Science, 30, 281-307.

Most perfluorinated substances also have the benefit of a low intrinsic UV absorption as evidenced by multiple studies[20] and as such do not require UV absorber additives which can outgas or form particles such as TiO_2 which would impede the optics.

Potential silicon-based alternatives would cause issues if volatile silicon compounds were deposited on an optical surface when irradiated with UV light. The UV light polymerizes the silicon from the lubricant, forming a SiO_2 like film on the optical surfaces. Even in extremely small amounts (at concentrations in the gas phase below the detection limits of the best analytical equipment), this forms layers of several tens of nanometres or more in a short time resulting in the inoperability of the equipment. This phenomenon has been outlined in multiple studies, including in the following domains: space science,[21] laser fusion,[22] photomasks for lithography,[23] and lithography scanner optics.[24]

Many applications in the semiconductor industry, including supporting equipment for the semiconductor industry, require fundamental development to identify a potential alternative that could be taken forward for the first stage of testing. Only once a suitable alternative has been identified, can further steps, that require further time, follow. This is outlined in Table 3-1 below.

Table 3-1 Minimum steps and time to be considered to implement PFAS-free alternatives in the semiconductor industry once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative of materials / components	10+ years
Reliability testing	5+ years
Redesign of product for alternative solution	5+ years
Testing of in-situ performance including testing and validation by users of the equipment	5+ years
Total time to develop	**Minimum of 20 years**

[20] Rothschild, M., Bloomstein, T. M., Fedynyshyn, T. H., Liberman, V., Mowers, W., Sinta, R., & Orvek, K. (2003). Fluorine—an enabler in advanced photolithography. Journal of fluorine chemistry, 122(1), 3-10. Cybulski, Walter & Peterjohn, William. (1999). Effects of ambient UV-B Radiation on the above-ground biomass of seven temperate-zone plant species. Plant Ecology. 145. 175-181. 10.1023/A:1009820320031. Showing spectra comparing PTFE and Mylar®. Dever, Joyce & Pietromica, Anthony & Stueber, Thomas & Sechkar, Edward & Messer, Russell. (2002). Simulated Space Vacuum Ultraviolet (VUV) Exposure Testing for Polymer Films. 39th Aerospace Sciences Meeting and Exhibit. 10.2514/6.2001-1054. Showing FEP is transparent well below 200 nm.

[21] Boeder, Paul & Visentine, James & Shaw, Christopher & Carniglia, Chuck & Alred, John & Soares, Carlos. (2004). Effect of a silicone contaminant film on the transmittance properties of AR-coated fused silica. Proceedings of SPIE - The International Society for Optical Engineering. 10.1117/12.560859. Mossman, D. L., Bostic, H. D., & Carlos, J. R. (1987, January). Contamination induced degradation of optical solar reflectors in geosynchronous orbit. In Optical Systems Contamination: Effects, Measurement, Control (Vol. 777, pp. 12-19). SPIE. Luey, K. T., Olson, K. R., & Coleman, D. J. (2018). Optical system contamination: formation of films and droplets. Journal of Astronomical Telescopes, Instruments, and Systems, 4(3), 036001-036001.

[22] Mangote, B. & Tovena-Pecault, I. & Néauport, J. (2012). Study of the LIDT degradation of optical components by intentional organic contamination. Proceedings of SPIE - The International Society for Optical Engineering. 8530. 25-10.1117/12.968573.

[23] Grenon, Brian. "Impact of micro-contamination on advanced lithography".

[24] Meute, J., Rich, G. K., Hien, S., Dean, K. R., Gondran, C., Cashmore, J. S., & Dewa, P. G. (2002, July). Contamination and degradation of 157-nm stepper optical components: field experience at International SEMATECH. In Optical Microlithography XV (Vol. 4691, pp. 724-733). SPIE.

We assume that the semiconductor industry will submit further detailed information on technical requirements that need to be met. These are equally applicable to the supporting equipment that SPECTARIS members manufacture and supply to the semiconductor industry.

Semiconductors are also relied upon by SPECTARIS members in their equipment. For example, semiconductors are used in medical electrical devices to ensure the products function, as well as safety. This is illustrated by semiconductor use in optical diagnostic equipment with the semiconductors controlling the high frequency surgical equipment and insufflators which pump carbon dioxide into a patient to create sufficient space in the abdominal cavity for the surgeons to work. If the semiconductor fails, there is an extremely high risk of patient injury or death. Another issue with electrical medical devices is that strict sectorial legislation such as the EU Medical Devices Regulation does not permit any redesigned product to be placed on the EU market prior to reliability and safety testing followed by an extensive conformity assessment procedure involving certification by a Notified Body. Different components and circuit design would, however, be required should a PFAS restriction result in critical semiconductor components becoming obsolete. It is important to understand that stringent sectorial requirements will add another 5 – 10 years before any re-designed medical device can be marketed in the EU and timescales can be even longer with very complex products or if new software is required.

One risk is that semiconductor manufacturers will discontinue some of their products made in the EU due to the proposed PFAS restriction. It is highly unlikely that change to existing production processes can or would be made. SPECTARIS members who use semiconductor components would have to redesign their products due to differences in function, software, and features of different semiconductors. This can take many years in addition to the timescales described elsewhere in this report.

3.3 6j- Coating applications for medical devices

There is a constant search for alternatives, but SPECTARIS members have not been able to identify non-PFAS alternatives that fulfil the functionalities legally required. Therefore, it is essential to extend the derogation timeline considerably to at least 16 years to take into account mandatory qualification requirements from stringent sectorial legislation.

The following are a small sample of use cases where SPECTARIS members rely upon PFAS in coating applications in medical devices:

- Minimal invasive surgery equipment including surgical electrodes and endoscopic devices.
- Guidewires and catheters.
- Implants, such as stents.
- Operating aids (for example, forceps, scissors, dilators, retractors, punches, probes, brushes, hooks, knot holders, cannulas, knives, chisels, rasps, etc.), adapters, templates, valve seals, cables, and tubes.
- Trocars, other tubular shaft instruments and obturators.
- Camera heads.

The types of PFAS include:

- ECTFE,
- FKM,
- PTFE,
- PFA,

- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and 1,1,2,2-tetrafluoroethene,
- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene,
- Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene,
- Ethene,1,1,2,2-tetrafluoro-, homopolymer,
- Propane,1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-, polymer with 1,1,2,2-tetrafluoroethene,
- 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1,2,2-tetrafluoroethene, and
- Ethene, 1,1-difluoro-, homopolymer.

The technical function that the polymeric PFAS provide is specific to the end use application, but include:

- Biocompatibility according to standards such as ISO 10993.
- Electrical insulation to standards such as ISO 60601 or ISO 61010.
- Sliding properties such as < 5N tensile force in atraumatic applications.
- Ability to withstand harsh environments including from cleaning chemicals which can range from a pH of 2 to 14 in hospital environments or argon fluoride gas in medical lasers.
- Long term reliability with some products and their components lasting up to 8 years.
- Gas tight mechanical fittings and sealing at 10mbar in medical laser applications.
- Resistance to UV- and IR- light in medical laser applications.
- Ability to be sterilised under conditions such as 134°C for 10 minutes, while still maintaining the necessary physical properties.

Resectoscopes, used in urology for the removal of superficial tumours in the urinary bladder or for benign enlargement of the prostate in men, are an example use case. The resection loop is partially coated in PFTE for electrical insulation up to 800V[25], whilst also being biocompatible, low friction, does not adhere to dirt or tissue and is able to be reprocessed at high temperatures. Ceramics have high electrical dielectric strength but are unsuitable due to pressure load during operation and the size requirements that limit the thickness of the coating for minimally invasive instruments. Thin ceramic sleeves would break sharply in the body, injure the urethra and/or the urinary bladder and would for patient safety reasons are not permitted. Ceramic coatings thus cannot be considered as alternatives.

One equipment manufacturer has tested polyether ether ketone (PEEK) as a potential alternative. However, during in vitro experiments electrical breakdown was repeatedly observed after only a few seconds of operation. Therefore, PEEK cannot be considered as an alternative either. There is a constant search for alternatives but a viable alternative with the needed performance has not been identified.

[25] In other equipment this can be as high as 4000V or 20 kV/mm.

It is therefore necessary, to considerably extend the derogation period for this use in order to ensure the continued supply of these devices. Only once an alternative has been identified the minimum steps and time to be considered as outlined in Table 2-1 (at least 16 years) would be able to be undertaken.

3.4 6k- Rigid gas permeable contact lenses, ophthalmic lenses, and other lenses

SPECTARIS requests that the derogation is scoped to include all forms of PFAS for 'Rigid gas permeable contact lenses, ophthalmic lenses and other lenses.' Due to the use of non-polymeric forms of PFAS in the manufacturing process, it is recommended that the derogation is moved under section 5, rather than section 6 of the restriction.

It should be noted that the assessment presented in Annex E based on the previous SPECTARIS (RINA, 2021) report submitted, is incorrect. Nowhere does SPECTARIS (RINA 2021) state that '*the assessment of alternatives indicates that both technical and chemical alternatives are widely available*' for rigid gas permeable contact lenses. On the contrary, RGP contact lenses provide unique and non-substitutable functionality that relies upon the functionality of PFAS. A number of medical conditions preclude the use of other lens types. As yet no technical alternative is available.

Rigid Gas Permeable Contact Lenses

2,2,3,3-Tetrafluoropropyl methacrylate (CAS 45102-52-1) and hexafluoro isopropyl methacrylate (CAS 3063-94-3) are used worldwide, as liquid monomers at concentrations between ~10% and up to 60% by weight, for rigid gas permeable (RGP) contact lens polymer production.

Fluorine containing monomers are used to impart the following combination of technical characteristics, which to date no non-fluorine containing monomer has been able to achieve:

- Low adherence of proteins and lipids to impart antibacterial material properties such that the lens products are as hygienic as possible and thus clinically safer.
- High levels of the oxygen permeability.
- Reduction of the amount of tear film deposits, thus better biocompatibility of the medical products, less disturbances, irritations, and incompatibilities.
- Enhanced products lifetime via easier lens cleaning by the patient.
- Robust mechanical properties to ensure lens shape stability and mechanical handling resilience.

RGP are used for:

- Optical correction (spherical, astigmatism and presbyopia),
- Ectatic corneal diseases, which is the progressive thinning and subsequent bulging of the corneal structure,
- Irregular astigmatism such as in cases with scars from corneal injuries,
- After refractive surgery,
- Orthokeratology, which reshapes the cornea to improve vision, and
- Aphakia where there is no lens in the eye.

Higher material density with fluorine content has in some cases had advantages in the seating behaviour of the lenses. It is important to note that although spectacles offer many users benefits in correcting vision, spectacles are not effective solutions in these instances as they do not act on the eye directly.

RGP are also used when softer contact lenses with water content (hydrogels) are unsuitable due to considerations such as dry eyes, fluctuations in visual acuity, deposits, and contact lens-induced infections. Due to these factors, RGP lenses can be chosen by users or prescribed by medical practitioners when hydrogels are not suitable.

As mentioned above, up to now no non-PFAS based alternative has been found. It should be noted that the conclusions presented on page 335 of Annex E, which states '*rigid gas permeable (RGP) contact lenses, the assessment of alternatives indicates that both technical and chemical alternatives are widely available'* is incorrect as evidenced by the previous SPECTARIS report and information provided in this report. Only once a PFAS-free alternative has been found that provides for all the above functionalities needed for RGP lenses could a substitution process begin. This process is outlined in Table 3-2.

Table 3-2 Minimum steps and time to be considered to implement PFAS-free RGP lenses once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternatives of materials / components	Unknown (>10 years)
Reliability testing	2-3 years
Redesign of product for alternative solution	1 years
Testing of in-situ performance	2 years
Product specific requirements: biocompatibility testing and evaluation including toxicological assessment; clinical trials and notified body approval	3-5 years[26] (Test length has to reflect lenses wearing time of 12-18 months)
Global approvals	2-3+ years
Total time to develop	**10-14+ years** only after a viable alternative material has been identified

SPECTARIS members, when using the monomers in production and material processing, use air analysers to demonstrate that there are no releases of PFAS. Due to the medical nature of the products, the lenses are tested, including extraction testing, to standards such as ISO 18369-4[27] and ISO 10993-18[28]. PFAS extracts are not found at all under physiological conditions, and trace amounts, in the low µg range, can only be determined by destructive extraction with non-polar vehicles. The waste from manufacturing and material production is collected in its entirety and incinerated as hazardous waste so does not end up in the environment in an uncontrolled way.

[26] As outlined in Section 2.12 due to the number of products affected by redesign this timeframe could be much longer.

[27] Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials.

[28] Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.

Ophthalmic Lenses and Plano Lenses

Ophthalmic lenses are eyeglasses lenses that provide vision correction and are classified as a medical device.

Plano lenses are lenses which provide no vision correction but include products such as sun protection and safety glasses (optical lenses used in personal protective equipment).

Sophisticated lens coatings utilising PFAS, contribute to vision safety by reducing reflection, protecting against UV radiation and high-energy visible light, and ensuring the long-term durability of the lens by protecting against scratches and soiling. This is achieved through multiple layers of coatings as shown in Figure 3-1.

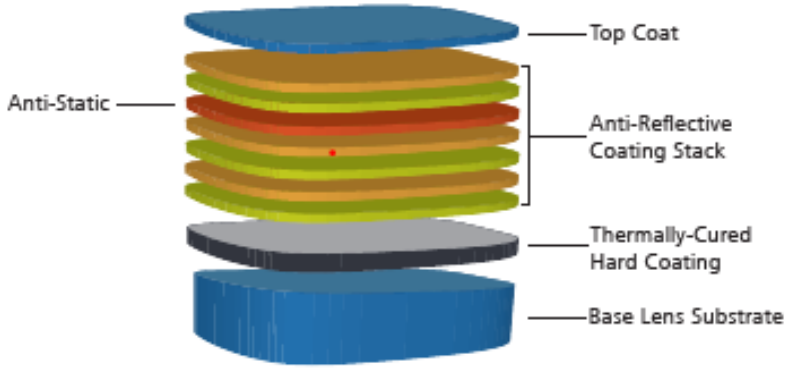

Figure 3-1 Schematic representation of modern lens coating.

Hydrophobic coatings (often also called top coats or anti-smudge coatings):

PFAS are used in the external top coat layer of ophthalmic, plano, and other lenses. The top coat is a hydrophobic and/or oleophobic coating which contributes to vision safety by reducing reflection, protecting against UV radiation and high-energy visible light, and ensures the long-term durability of the lenses by protecting them against scratches and soiling.

The coatings provide the combination of the following properties, with the specific performance depending on the end application:

- High-water contact angle (>105°).
- High oil (hexadecane) contact angle (>60°).
- Cleaning durability: contact angle of water > 90° for >2 years.
- Weathering durability: no significant loss in performance for >2 years.

This allows lenses to always provide clear vision, which is essential for safety (e.g. to avoid glare and reflection-impaired vision during car driving) and to avoid eyestrain.

The top coating reduces sensitivity to dust and dirt contamination on the surface of the eyeglass lens and hence avoids scratches and damage to the lens coating. The top coating enhances clear vision by reducing greasy smudges from skin fat and fingerprints (caused by higher oil contact angle) that create haze at estimated 50% higher level. Haze generates a strong light scattering and under critical light conditions (i.e. light impacting tangential to the lens surface) lenses become opaque. In extreme cases this may significantly disturb/worsen vision in instances such as changing and difficult light conditions, such as driving at night against the headlights of other vehicles. For this reason, **eye protection standards** include a specific requirement for light scattering. Lastly, the top coating also extends the use time of the lenses, which improves their products environmental footprint. It also reduces frequency of cleaning and with that the use of chemical cleaning substances. Durability and optical performance requirements in terms of transmission, absorbance and reflectance limits the number of potential PFAS-free material classes.

The top coating is manufactured via highly effective vacuum deposition, with only several milligrams of PFAS required for up to ~200 lenses, resulting in an extremely thin coating layer polymerised onto the external surface of the lens. Some SPECTARIS members state that certain lens types may possibly contain less than 50 ppm of PFAS in each lens. This, however, cannot be generally stated as this would require harmonized reference standards for total fluorine and targeted PFAS analysis that are currently not available. However, even if the amount of PFAS in some types of finished lenses would be below the limit, PFAS above the limit are still needed in the manufacturing process of such a coating. Therefore, in order to maintain production within the EU, the derogation needs to include the raw materials needed for the manufacturing process.

To date no PFAS-free alternative has been identified for hydrophobic coatings which offers the same necessary technical performance. SPECTARIS members are actively researching alternatives. One SPECTARIS member has already contacted 10 research institutes or qualified suppliers of coatings to try to identify an alternative substance/technology with comparable performance to PFAS, however, to date this has been unsuccessful. A review of published literature on alternative hydrophobic coatings also offers no viable alternatives at this point. Potential alternatives to hydrophobic coatings, such as siloxanes, do not offer the necessary technical performance listed above.

Other lenses

PFAS are also used in the coating of other lens types such as optical lenses in cameras, photography, cinematography, and in sports optics such as in the use of binoculars, spotting, and rifle scopes. PFAS are used for the same reasons as outlined above in ophthalmic and plano lenses.

Hydrophobic coatings (also called anti-fog coating)

PFAS substances including PTFE are used as part of a hydrophobic coating on lenses to maximise the contact angle of water droplets which form due to the natural humidity in the air onto the lens surface. The small droplets without the anti-fog coating form a non-transparent surface across the lens as shown in Figure 3-2, resulting in the product being unable to be used until they are removed. PTFE is crucial in the maximisation of the contact angle formed, and the mechanical removal of the water from the lens via the use of a cloth or wipe can quickly introduce surface defects. Cleaning using this method causes deep scratches in the coating if not protected, causing increased flare, and causing the contrast of the image to reduce. Overall, this has the impact of quickly reducing the performance and lifetime of the product.

Figure 3-2 Example lens with anti-fog coating on right hand side only.

To date no PFAS-free alternative has been identified for hydrophobic coatings which offers the necessary technical performance. Table 3-3 below gives an indication of the time needed for implementation, but can only start once a suitable alternative has been identified.

Table 3-3 Minimum steps and time to be considered to implement PFAS-free lens coating once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Identification of technically viable alternative	Unknown (>10 years)
Testing of alternative of materials	6+ months
Pre-study testing by research institutes and material/technology suppliers to identify suitable characteristics	2+ years
Reliability testing	1+ year
Equipment adaptation (vacuum technology and edging)	1+ year
Redesign of product for alternative solution	6+ months
Testing of in-situ performance	1+ year
Product specific requirements (e.g., documentation for conformity)	3 months
Global approvals	6+ months
Roll-out of alternative solution to the specific factory conditions in each location, potentially changing processing parameters to minimise and standardise remaining rest reflection on the lens and check quality standards. The review of the processes requires specific technical resources and personnel which are finite, so this is unable to be undertaken in parallel. Labelling and packaging adaptations to meet specific market and product requirements.	2+ years
Total time to develop	**>13.5 years** after a viable alternative material has been identified

Considering the highly unknown timeframe for availability of viable PFAS-free alternatives, SPECTARIS request a minimum of 13.5 years for the proposed derogation.

Additional Information

Anti-friction coating: In addition to the above uses of PFAS, PTFE is also used as a seal to form an anti-friction coating in covers or exchangeable devices in thermal sights of hunting and outdoor products, as shown in Figure 3-3. The seals are used to prevent dirt, dust, fibres or hairs from settling quickly into the product, while providing suitable dry lubrication for the cap to be fitted. A greased seal is not possible in products of this type as it would require regular reapplication as the covers are assembled and disassembled by the customer frequently, and the tightness of the fitting needs to be maintained.

Figure 3-3 Hunting and outdoor products with PTFE seals highlighted with red arrows.

As yet there is no potential alternative which offers the necessary technical performance. When a potential alternative is identified it is important that sufficient time is permitted for its testing, as outlined in Table 3-4.

Table 3-4 Minimum steps and time to be considered to implement PFAS-free lens coatings once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative of materials / components	1-3 year
Reliability testing	1+ year
Redesign of product for alternative solution	1-3 year
Total time to develop	**3-7+ years**

PFAS are also used in anti-fog lens wipes and cleaning solutions through the use of surfactants, without which the anti-fog properties could not be achieved based on the current technological developments.

3.5 6n- Packaging of terminally sterilised medical devices

SPECTARIS requests that the derogation timeframe is sufficiently long to allow the necessary changes, which is expected to take over 16 years.

SPECTARIS members also produce packaging of terminally sterilised medical devices. Given each product change must be evaluated it is expected that a minimum of 16 years are required to identify a PFAS-free alternative, with the same minimum steps and time to be considered as outlined in Table 2-1.

4 ADDITIONAL DEROGATIONS REQUIRED FOR SPECTARIS MEMBERS

In addition to the currently outlined potential derogations, there is the technical need for additional derogations to be added to the restriction text. These are outlined in the sections below.

4.1 Fluoropolymers and fluoroelastomers for at least 13.5 years

SPECTARIS requests that an indefinite derogation for fluoropolymers and fluoroelastomers be considered due to both the unique technical properties these offer and the issue in identifying all uses in essential products.

PFAS are needed for many high-tech applications and are indispensable for many important applications. Although SPECTARIS members are making efforts to accurately identify where PFAS substances are used in their products, components and manufacturing processes, there are still many challenges. As such there is likely to be more PFAS identified where there are no alternatives. This is especially challenging for the presence of PFAS in articles, as in general, this is not declared by manufacturers. A list of specific derogations can, therefore, neither cover nor anticipate all critical uses.

PFAS possess a unique set of characteristics that trigger their use in SPECTARIS member products, components and manufacturing processes which include inertness, purity, UV and IR resistance, high temperature stability, resistance to chemicals, low coefficient of friction, optical properties, mechanical properties, biocompatibility, contamination control, electrical properties, processability, minimal outgassing, and long service life (>25 years). The specific combination of properties required depends on the end use application. Many of these properties are intrinsically linked to the strength of the C-F bond within PFAS, and as such there is unlikely to be a like-for-like replacement able to meet all the technical requirements PFAS meet.

PFAS are also required in process equipment and installations which are critical for the manufacture of the machinery used by SPECTARIS members. For example, cleaning devices also require PFAS in components such as seals and gaskets to be able to withstand the chemical conditions or allow ultrasonic cleaning which is the state-of-the art in modern cleaning devices. It is therefore important that sufficient time is permitted such that PFAS-free alternatives can be fully investigated, with alternative solutions undergoing the necessary qualification.

4.1.1 Polymers of Low concern

SPECTARIS supports the goal of the “Chemicals Strategy for Sustainability” that aims to better protect citizens and the environment from harmful chemicals, and boost innovation by promoting the use of safer and more sustainable chemicals. Within the framework of sustainable chemicals regulation, substances that pose unmanageable risks due to their properties and use profile should be restricted or regulated on the basis of scientific assessments, especially in regard to consumer products. It is recognised that the broad restriction of PFAS is to ensure that ‘regrettable substitution’ is not undertaken. However this overlooks the very different intrinsic properties of the over 10,000 substances in the PFAS family. Many of the substances are not classified as hazardous substances according to the Classification, Labelling and Packaging Regulation[29] and they do not display the environmental and toxicological profiles associated with some PFAS which could be considered of concern. Many fluoropolymers relevant to industry, such as PTFE, meet the OECD criteria for "polymers of low

[29] Classification, labelling and packaging of substances and mixtures Regulation.

concern". This means that they are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile.[30]

Unless a differentiated restriction is implemented irreparable damage to Europe, its citizens and its industry will be experienced.

4.2 Analytical and laboratory equipment for at least 13.5 years

SPECTARIS requests that derogation for PFAS in analytical and laboratory equipment, is considered due to the similarity in technical requirements to derogation 5n relating to diagnostic equipment.

A proposed derogation for diagnostic laboratory testing (5n) already exists with details of SPECTARIS members uses outlined in Section 2.8. However, the 5n derogation could be understood to only relate to the testing of biological or medical samples including IVD medical devices, rather than the full scope of laboratory equipment. A substantial part of laboratory equipment, however, deals with analysis of chemical parameters irrespective of its source, as well as processes such as synthesis, work-ups, filtration, evaporation, distillation, purification, fluid aspiration and drying. As such these operations would potentially not be covered by derogation 5n even if the equipment used is mostly identical. Laboratory equipment is indispensable in a number of key industry sectors such as the chemical and pharmaceutical industry, biotechnology, food testing, water and environmental analysis, energy supply, petroleum industry, and research and education.

It is worth noting that although the vast majority of the laboratory equipment is used within the confines of a laboratory setting, there are also instances where associated equipment is used to perform measurements at the production site in situ and ex situ. Examples include the need to take samples of water or soil to measure environmental concerns and the need to measure analytical attributes on industrial sites directly. Additionally, laboratory equipment can be used for various analytical applications in the field. Examples include impurity analysis of environmental water samples. These methods also need to meet the same rigorous technical requirements as those used within a laboratory setting, which is why they also rely upon PFAS.

SPECTARIS members manufacture a wide variety of laboratory equipment which underpins numerous essential sectors, the following is an indicative list of the types of equipment which rely upon PFAS:

- Analysis equipment such as gas and liquid chromatography such as HPLC (including the associated sample introduction equipment) and ion chromatography, spectroscopy such as atomic absorption spectroscopy (AAS) or molecular spectroscopy, mass spectrometry, inductively coupled plasma systems for optical emission spectroscopy (ICP-OES), Inductively coupled plasma mass spectrometry (ICP-MS), elemental analysis, microscopy, titration equipment such as potentiometric and Karl-Fischer titration and pH measurement equipment.
- Cooling devices such as precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, freeze drying equipment, refrigerated centrifuges for sample separation and process chillers for precise temperature control and freeze-drying equipment.

[30] A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers - Korzeniowski - 2023 - Integrated Environmental Assessment and Management - Wiley Online Library

- Specialist laboratory equipment such as laboratory centrifuges, laboratory microwave systems, vacuum drying ovens, laboratory incubators, reactors and pressure vessels, and sub boiling systems.
- Vacuum technology such as chemistry diaphragm pumps, general diaphragm pumps, screw pumps, rotary vane pumps, chemistry hybrid pumps, vacuum controllers, vacuum gauges, vacuum networks, tubing, balls holding the glass resonator in vacuum chambers, fittings and valves used in laboratory equipment.
- Sample preparation equipment and components such as automated sample preparation machinery like liquid handling automation, microwave digestion, dosing systems for liquids, rotary evaporation equipment (including solvent resistance pumps), tip fittings, pipettes and pipette tips, dispensers, containers for storage of solutions for ultra trace analysis, burettes, beakers, volumetric flasks, tubes, and magnetic stirring bars.

Examples of laboratory products utilising PFAS are provided in Figure 4-1.

Figure 4-1 Example analytical and laboratory equipment.

Each of the types of equipment listed above rely upon a combination of PFAS components which include ring gaskets, sealing tape, sandwich seals, cable bushings, bearing seals, material distribution blocks, heat transfer mats between housing and optics, valve plates, valve bodies, display foils, wire insulation, porous filtration frits, ion-exchange membranes, gas-exchange membranes, sensors, and tubing for applications such as immersion, gases, and their connectors. The equipment also relied upon parts with PFA or PTFE corrosion protection coating or lining, or PTFE as a lubricating coating.

Figure 4-2 Example PTFE components in analytical and laboratory equipment.

PTFE embedded into component, such as through a coating, is also used as a dry lubricant/self-lubricant in components such as centrifugation rotors, sliding guides, toothed racks, spindles, leadscrew, plunger balls, yokes, and rotators due to is minimal friction, longevity, and the inability to use greases which could contaminate the liquid samples through drips.

PFAS are also utilised in the refrigerants of cooling devices used in laboratory equipment, with the same rationale for their use and availability of alternatives as outlined in Section 2.4.

4.2.1 Analysis of alternatives

The technical requirements triggering the need for PFAS in many of the devices are similar, with most of the uses requiring high and nearly universal chemical resistance against a broad range of chemicals used in laboratories. This in turn allows the accurate measurement of samples as the inclusion of fluoropolymers does not contaminate samples.

Chemical resistance

Highly aggressive chemicals are often required to be used in analytical and laboratory equipment with the components of such equipment needing to be resistant to the substances to ensure the safety of the users, the equipment, and its proper functioning. One such example is the use of $POCl_3$ or thionyl chloride ($SOCl_2$) which are used for chlorination in applications such as in pharmaceutical research and production, with fluoropolymers being the only polymer known to be able to withstand exposure to such substances.

Chemical resistance is especially important for dispensers of solutions such as solvents, acids, alkalis, or saline solutions which are often harmful to human health and the environment but are necessary to fulfil the assigned task(s). Therefore, only high resistant materials like fluoropolymers can be used in the design and manufacturing of bottle-top dispensers, in order to prevent accidents and ensure maximum protection of the user. Alternative materials with such properties are not available today. The re-design of existing equipment can only be started when these materials are actually available. Only once suitable alternatives have been identified, SPECTARIS members estimate a timeframe as exemplified in Table 4-1.

Table 4-1 Minimum steps and time to be considered to implement PFAS-free materials in high precision analytical instruments once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative of technologies	3-5+ years
Redesign of product for alternative solution	5-7+ years
Introduction to market, engagement with customers, and introduction into DIN, EN, ISO standards	5+ years
Total time to develop	**13-17+ years** once suitable alternative has been identified

Lack of contamination

The identification of the substances contained in the sample and their concentrations is one of the fundamental issues in the examination of samples by chemical analysis in order to draw conclusions about their properties. It is important to identify only the constituents of the samples and not those of the parts of the analytical equipment that come into contact with the sample. Fluoropolymers play a particularly significant role in modern analysis due to their unique combination of properties. The use of other materials would lead to contamination of the samples and thus to incorrect results, or it would not be possible to comply with the required detection limits.

4.2.1.1 Indicative uses in laboratory equipment

PFAS in laboratory equipment are used in a number of different ways, each of them playing crucial part in the overall technical performance of the equipment. For example, PTFE tubing in many applications, and laboratory piston pumps are required to be highly chemical resistant. The tubing must be flexible which prevents the use of alternative materials such as glass or metal. In many applications, components such as these are rarely replaced with a lifetime of over 10 years on average. Were these to be replaced with other polymers, such as polypropylene, it is anticipated that these would have to be replaced every few months thereby creating at least a 10 fold higher disposable volume of polymer waste.

In other applications the tubing must withstand up to 170°C and 5 bar steam pressure, whilst being resistant to any aggressive chemical (which may be present as a result of residues of the autoclaved goods) and be bacterially resistant if it is used in the pharmaceutical industry. As such the only potential PFAS-free alternative would be fixed stainless steel piping. However, this would not be able to be used for all chemicals and thus not a viable alternative. Also, manufacturers of this equipment would have to make significant technology changes with significantly higher material and production costs (due to the need for joints utilising orbital welding or similar techniques). This also has the disadvantage of increasing the space needed inside the devices, which is not available in the current design. Therefore, overall enlargement of the respective device would be an inevitable consequence. Considering that most laboratories have limited space available and, in particular, rely on the standardised size of equipment, such as autoclaves, this would be problematic. Furthermore, if maintenance of the device was required, the use of metallic pipes would lead to higher costs and waste as complete assembly units would need to be changed in the event of the failure of a single component. As such, stainless steel piping may be possible for only the new designs of a limited group of equipment. However, this would not be viable without the re-design of equipment and even then, for the majority of equipment it would not be a viable alternative.

PTFE tubing is also used in the wet parts of liquid nitrogen pump for thermal analysis which operates at -196°C. Due to the extreme cold temperatures, there are only a limited number of potential alternatives that could be considered at such temperatures, which include EEK and polyimide, however these do not have the necessary flexibility required for the tubing. Metals are also not a viable alternative due to their high thermal conductivity, so there is a significant risk of low temperature burns upon unintended contact and frosting due to high thermal conductivity.

Tetrafluoroethylene (CAS 31175-20-9) and PTFE are used in ion-exchange membranes and gas-exchange membranes and tubing. The technologies rely upon selective cation or anion exchange in chemically aggressive solutions and the removal of gas through gas permeable membranes respectively. The fluoropolymers are required to have no leaching or adsorption effects for trace analysis, excellent dimensional stability, machinability, long-term stability for uninterrupted use and exchange efficiency. No alternative material is currently known with all of these properties.

Other general laboratory equipment such as PTFE coated magnetic stirrers and pipettes, which are used ubiquitously across laboratories would also be impacted. Such general use equipment is critical to a wide variety of end sectors as without such equipment analytical techniques would not be able to be undertaken.

Certain pipettes, such as those used in fixed tips in liquid handling automation as shown in Figure 4-3, have a PTFE hydrophobic surface coating, and single use pipette tips have a fluoropolymer based superhydrophobic or oleophobic surface coating to. Pipette tips of these types use fluoropolymers to avoid any liquid remaining at the tip's walls when removing the tip from the liquid to avoid volume errors. Fluoropolymers are also used in multiple use pipette tips to provide long term chemical resistance, and for the thorough cleaning required to avoid any cross contamination during the tens of thousands of uses of such multiuse tips.

Figure 4-3 Example of fixed tips in liquid automation.

As discussed in the previous SPECTARIS report on PFAS, tip fittings also use a fluoropolymer containing surface coating to reduce the surface energy and therefore frictional forces on the tip. Considering that these tips can be fitted to multichannel pipettes containing 96 and 384 channels, the loading force required is of critical importance to its functionality.

SPECTARIS members using single use pipette tips have tested potential alternatives to fluoropolymer based superhydrophobic or oleophobic coatings with the necessary technical performance for friction properties, including waxes, chemical vapour deposition and physical vapour deposition coatings. However, regarding multiuse pipette tips, even the most promising alternatives only provided a lifetime of several hundred load cycles compared to hundred thousands of load cycles with fluoropolymer coatings. Without fluoropolymer coatings a pipette with the current state of the art would not be usable, and even on the most cautious of predictions estimated 10-fold higher waste volumes are expected. Regarding single use pipette tips, only fluoropolymers can provide the repellent surface properties to avoid sample loss during dispensing by wetting of the inner surface of the pipette tip. Analysis inaccuracies with possible substitutes would be unacceptable to users.

Fluoropolymer components are also used in high temperature applications, such as O-rings in thermal analysers or the shielded lid on the xenon lamp source chamber which are exposed to temperatures of ~200°C. Due to the high temperature requirements, potential alternatives such as silicone are not viable as these temperatures are above their maximum operating temperature. Often these parts also require chemical resistance for their functionality, cementing the need for fluoropolymers.

In addition to the broad characteristics which are shared irrespective of the end application, there are also end use specific characteristics which are essential, and which are outlined in the following sections.

4.2.1.2 Vacuum Technology

Most processes and equipment in a typical laboratory are based on the use of vacuum technology. For example, the following processes require vacuum: Schlenk-Line (syntheses, work ups, purification), distillation, filtration, evaporation (rotary evaporators), drying ovens and freeze drying. The individual processes are highly dependent on the quality of the vacuum environment. Accordingly, vacuum pumps are of utmost importance for a wide variety of laboratories, as the processes and equipment all have individual vacuum performance requirements.

Common solvents used in rotary evaporators include dimethylformamide, acetic acid, hydrochloric acid (HCl), trifluoroacetic acid (TFA), ethanol, triethylamine, ammonia, ethyl acetate, diethyl ether, tetrahydrofuran, hexane, toluene, dichloromethane, chloroform, acetone, hydrogen peroxide and dimethyl sulfoxide (DMSO). Thus all wetted parts of the equipment (vacuum technology) need to be resistant against these chemicals and are thus made of fluoropolymers. This includes parts as tubing and connection parts, pumping heads, diaphragms, and valves as well as sealings and O-rings. In some instances, PTFE grease is also used in conjunction with O-rings, for example in high vacuum sections of equipment which experience 0.0001 Pa, which otherwise would experience an impact on its analytical capabilities. One such product which utilises a broadly similar process is freeze drying where samples are dried under vacuum without defrosting and used for sensitive samples such as medicines. In order to freeze dry the sample, chemicals such as DMSO, acetonitrile, TFA, acetic acid and HCl are used, and components need to be resistant against these.

The components also need to withstand high temperatures without the loss of their mechanical properties, with internal temperatures in a vacuum pump reaching up to 200°C due to the internal compression. Gas chromatography temperatures may reach up to 300°C and for other applications, similarly high temperatures are required. In addition to these properties, the components need to be

highly reliable as they often are required to sustain continuous operation (up to 24/7) and have low maintenance requirements.

For vacuum technology it is important that the fluoropolymer does not outgas in applications such as lasers, sample and reactant feed, synthesis reaction processes, purification, distillation, reflux, and filtration. Outgassing requirements are specific to the end application as outgassing may hinder the intended process, with applications such as UV laser systems at a wavelength of 266nm requiring a maximum residual contamination of ~0.08 μgm^{-3} of volatile organic compounds. Up to now no suitable substitute for the fluoropolymers used have been identified. It is worth noting that at least 2 years would be required to simply qualify PFAS-free materials in a UV laser systems due to the need for lifetime tests of 10,000 hours over multiple systems. Then, if a material with suitable outgassing requirements cannot be identified, the whole laser system would have to be re-designed in its entirety.

Low outgassing is also important for the lubricants used in such systems which are discussed in a later section.

4.2.1.3 Coated Parts

Coated parts with glass and ceramic coatings and with powder coatings have been assessed by some SPECTARIS members in certain use cases. These substances, however, are unable to provide the universal chemical resistance that fluoropolymers offer. There are also indications that under certain circumstances (e.g. pressure bearing parts) these substances are not a viable solution, due to the potential for chemical attack to weaken parts and introduce operator safety concerns.

4.2.1.4 Microwave Heated Pressure Vessels

SPECTARIS members are producers of microwave heated pressure vessels for acid digestions with concentrated mineral acids such as nitric acid, hydrochloric acid, hydrofluoric acid, sulphuric acid, phosphoric acid up to 300°C and 100 bar. With example products shown in Figure 4-4.

Figure 4-4 Example Specialist Laboratory equipment which use fluoropolymers, with a laboratory microwave system on the left and laboratory reactor and pressure vessels on the right.

The vessels are used for sample preparation in the trace analysis for subsequent analysis of inorganic or organic contaminants by analysis techniques. Examples of the types of testing equipment such as this supports includes the measurement of heavy metals in foodstuffs, waste/surface/drinking water, electrical equipment, pharmaceuticals, and toys. As such, the technique is necessary for the control and

enforcement of (European) law such as Restriction of Hazardous Substances (RoHS), REACH, Drinking Water Guidelines, Environmental Law, Pharmaceutical Law, and Safety of Toys.

The vessels must be absolutely metal-free to avoid contamination of the samples even in the sub-parts per billion (ppb) range, prevent of solvent accumulation to avoid ignition or explosions of flammable solvents and must also be microwave-transparent to allow microwave heating. One SPECTARIS member had started to investigate a non-fluoropolymer based substance utilising a quartz glass vessel. However, it was not compatible with hydrofluoric acid (which is estimated to cover 20-25% of applications) and on top of this still required pressure-resistance sealing caps made of fluoropolymers. Therefore, a completely new technology would have to be developed which does not exist today.

The viability of alternative solutions in many applications is also limited by the maximum temperature of operation, for example silicone-based potential alternatives have an upper operating range of 150°C which is not sufficient. Potential alternatives also often have only limited chemical resistance, rather than the broad stability that fluoropolymers offer.

4.2.1.5 Lubricants

Lubricants are also used to allow smooth installation of mechanical components to avoid any high forces for sensitive and extremely close-fitting structures. For example, Krytox™ a PFAS-based lubricant is used in laser cavities due to its negligible evaporation loss, which plays an important role in vacuum applications. Other PFAS-free alternatives cannot offer such very low outgassing performance, which would lead to contamination of the laser optics. In addition, the higher the degree of outgassing of a potential alternative, the shorter the lifetime of the grease due to its degradation and the increased heat generation and energy consumption. Notwithstanding this, the biggest issue is the potential for generation of particles and contaminants. PTFE based lubricants are also used with vacuum pumps, as mineral oils have a very short service life in systems loaded with plasma and corresponding aggressive chemical samples.

Other systems, such as those utilising pistons or bearing, also rely upon PTFE lubricants due to their exposure to demanding environments for over 10 years of operation in some applications, so long term reliability is key. PTFE in bearing applications provides a viscous, hydrodynamic film that is sufficient to support the load and separate the ball from the raceway, enabling high endurance performance. Lubricants used in high temperature operations also have the added technical requirements of non-flammability, and high stability. PTFE offers not only these but also a unique functionality as it is a self-lubricating solid that slides against itself with very little friction/particle generation.

Lubricants for ball bearings in screw pumps are used to allow the correct mechanical function in temperatures reaching 70°C. As yet there are no known alternatives.

Irrespective of the exact combination of technical characteristics of the lubricant, all uses are characterised by the need to have high reliability due to the nature of the work that laboratory equipment serve. As such an increased level of mechanical failures of moving parts, resulting in an increased need for maintenance and shorter lifetimes of equipment would not be acceptable.

4.2.2 Minimum steps and time to be considered to implement PFAS-free alternatives

As yet there are no alternatives to fluoropolymers in laboratory equipment due to the unique technical parameters they offer. Once a technically viable alternative is identified, SPECTARIS members estimate that at least 14 years will be required, as outlined in Table 4-1. The exact minimum steps and time to be

considered is determined in part by the complexity of the equipment and could take much longer than outlined in Table 4-2.

Table 4-2 Minimum steps and time to be considered to implement PFAS-free laboratory equipment once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative technologies	2-5 years
Reliability testing	3+ years
Redesign of product for alternative solution	2+ years
Acceptance by and introduction into DIN, EN, ISO standards	7+ years
Roll-out	2+ years
Total time to develop	**16-19+ years** Once an alternative has been identified

4.3 Medical devices, their accessories, and tools, including equipment used for veterinary applications for an unlimited time period

SPECTARIS requests that a derogation permitting the use of PFAS in 'medical devices, their accessories, and medical tools, including equipment used for veterinary applications' for an unlimited time is considered due to the essential function these devices perform, strict sectorial requirements (national, EU and international regulations and standards) as well as long timelines needed for a product to reach the market.

SPECTARIS members are manufacturers of medical equipment which rely upon PFAS, the types of devices manufactured are extremely varied. SPECTARIS members estimated that there are more than 500 000 medical devices in Europe alone. The following are indicative examples of such products and components, with images of some of these outlined in Figure 4-5:

- Minimal invasive surgery equipment including surgical electrodes and endoscopic devices.
- Guidewires and catheters.
- Implants, such as stents and vascular implants.
- Ophthalmic devices for eye examinations and medical lasers.
- Retinal liquids.
- Ventilators.
- Anaesthesia machines.
- Incubators
- Patient Monitoring Systems.
- Medical supply systems.

- Hospital Gas Management Systems.
- Medical tools such as operating aid sheaths (e.g., forceps, scissors, dilators, retractors, punches, probes, brushes, hooks, knot holders, cannulas, knives, chisels, rasps, trocars, obturators, etc.),
- Camera heads.
- General components in medical devices uses such as adapters, templates, cannulas, valve seals, cables (including laser cables) and tubes, sealing tape, sliding rings/bushings, bearing bushings, lock housing, spacer sleeves/sleeves, O-rings, luer sealing cap, and others.

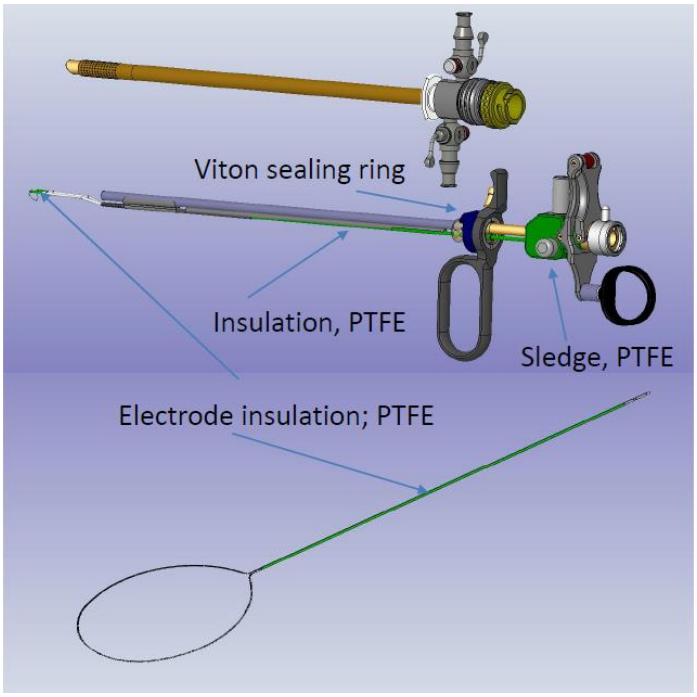

Figure 4-5 Examples of PFAS used in medical equipment.

Accessories

The Medical Device Regulation (MDR) defines accessory as follows: "*accessory" for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)*.'

It is important that the accessories of such products are also covered by the derogation as they often have to meet the same technical requirements as the medical device. An example of an accessory is the high frequency knife which performs medical procedures while confirming lesions with an endoscope. The tip of the needle-shaped knife is equipped with a tip made of insulating material and allows mucosal incision operations with less invasion of deep tissues.

Refractive treatment packs are classified as accessories, which are composed of a lens applied on the cornea, a tube, and a PTFE filter. To perform refractive surgery by cutting and removing the superficial part of the cornea, the laser needs to pass through a neutral mean with no distortion and therefore a vacuum is applied. The vacuum and the laser are generated by the medical device. The application of

the vacuum via air aspiration may cause the eye fluid of the patient to enter the medical device. Every treated patient needs a refractive treatment pack as the lens is in contact with the patient eye and contamination of the device can take place. The PTFE filter of the refractive treatment pack at the end of the tube avoids the contamination of the device and allows its multiple use for many patients along its whole lifetime.

Water Locks as shown in Figure 4-6, are also classified as accessories. Water locks are used when connecting patients to an anaesthesia or gas measurement device, to ensure that there is no cross-contamination. Two PTFE-membranes in combination with two self-sealing filters, separates condensed water and secretions that contain harmful contaminants, such as bacteria and viruses.

Figure 4-6 Water Lock device.

Other accessories also include valves, handpieces, tubes, and cables.

Veterinary products

Since the regulatory framework for medical devices in the MDR does not include medical devices for veterinary use, it is important to note that there are numerous medical devices for veterinary applications, including farm animals (e.g. cattle, poultry), companion animals and endangered wildlife. Minimally invasive systems like that shown in Figure 4-5 for human use, can also be applied (in a modified way) for theloscopy mostly for cattle. This is just one selected example. The arguments displayed for human application of medical devices apply the same for veterinary use.

Medical device PFAS use cases

A wide variety of PFAS are used in these applications as fluoropolymers, fluoroelastomers and greases and lubricants. PFAS are used as they provide unique technical characteristics that alternatives are unable to offer, which include the following: biocompatibility, electric insulation, chemical resistance, which is important for the reprocessing of reusable devices, thermal resistance which is important for both reprocessing and during use in certain applications, low outgassing, and low friction. The exact technical characteristics required are informed by the end use application. The following are more detailed examples of the technical requirements that certain parts of medical devices must operate under, and why PFAS provide unique functionality.

Cables and electrical insulation used for medical devices rely upon PFAS in three key ways; stranded wire insulation, wrapping of wires and cable protection. Most cables consist of several wires which have to be isolated from each other and thus use an insulation layer (stranded wire isolation). Reusable medical devices are reprocessed hundreds of times, in autoclaves which reach temperatures of 135°C, so the insulation layer needs to withstand these temperatures. They also need to have low water vapor permeability of 0.09 at 23°C according to ASTM E-96-53T due to the high humidity during autoclave cycles (often these have high humidity for 18 minutes at 3.04 bar). In addition, they need high insulation

resistance of $1x10^{-18}$ Ohm.cm^{-1} according to DIN53482, non-flammable characteristic (V-0 according to UL-94 safety requirements for medical devices (IEC 60601-1)) and high UV-resistance. There is also the consideration that all of these factors need to be achieved whist maintaining a small diameter due to the size constraints of many devices. PFAS is also used in the wrapping of wires which adds a layer with low frictional resistance between the stranded wires and the cable jacket to increase the flexibility of the wires and allow the wires handling in use. This also results in increased lifetime of the product due to the fact that the single elements of the cable can react better to external types of stress. Lastly, PFAS are used in the cable protection to prevent fungal growth and/or for temperature protection of cables.

Silicone, polyvinyl chloride, and polyurethane are not viable alternatives to FEP and PTFE isolation layer for wires. They do not meet the same flammability requirements and have the potential to become brittle when the plasticizers migrate (most potential substitutes are also less flexible). Silicone also has the concern that it is vapour permeable. Therefore, water can accumulate between the single strands which can lead to corrosion and malfunction of the device, as well as reducing the lifetime of the product. Silicone also has a lower insulation strength compared to the currently used PFAS such as FEP, which would require the insulation wall thickness of each wire to be increased. This would result in lower usability performance of the medical device, as an increased resistance of cable can impact the handling-precision of e.g. ophthalmologic surgical instruments.

PVC and other potential alternatives are not stable at high temperatures and therefore, not suitable for autoclaving.

Electrosurgical instruments, such as those in Figure 4-7, rely upon PTFE in shrinking tubes for insulation which accounts for 80% of all cutting and coagulation surgeries performed at this time. In the instrument on the left, when the two tips connect, current flows, heat develops which can be used for coagulation and cutting (for example in brain surgery) as described in more detail in Section 2.13. The instrument on the right has a PTFE part shown in the magnified image which ensures the isolation of the two powerlines close to the tip. Without isolation, the technology would not be able to be used. In applications such as these, electrical insulation without bulky items is crucial as there is only a tiny space available and minimising the size improves surgical outcomes.

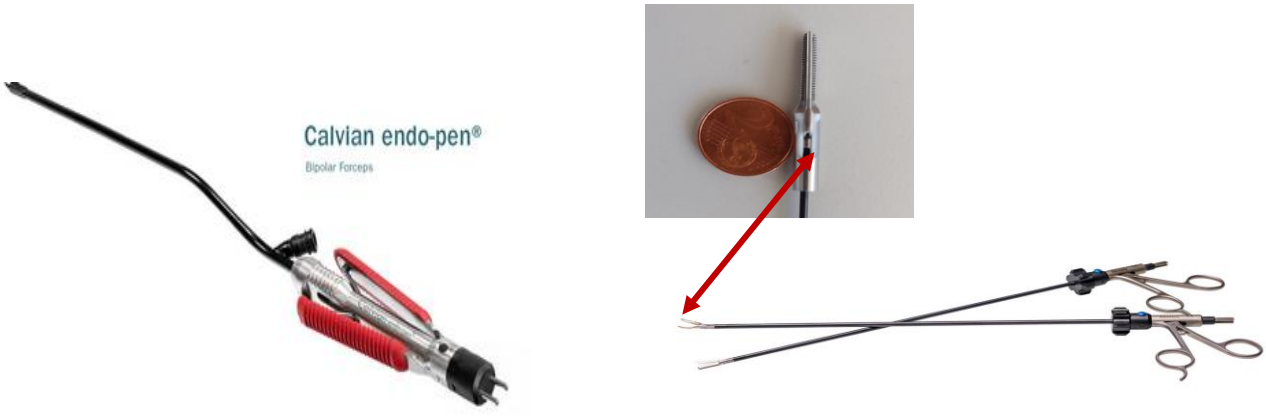

Figure 4-7 Electrosurgical instruments.

Monopolar and bipolar surgical radio frequency instruments also rely upon a PFAS containing ECTFE coating which (in addition to the above technical requirements) also need to have arc resistance to radio frequency plasma. Devices such as these allow innovative surgeries such as thyroid surgery or tissue ablation in organs such as the ears, nose, or throat.

Benefits of electrosurgery include the ability to make precise cuts and tissue coagulation in one step. Electrosurgical devices are frequently used during surgical operations helping to facilitate surgical procedures and to prevent blood loss. During the development of one SPECTARIS member's product PEEK and ceramic were tried as potential alternatives to PTFE. During electrosurgery sparks are sometimes observed as a common part of the process. Using PEEK causes the sparks to burn and therefore causes a safety issue. Ceramics were also tested, but due to the formation of sparks, an oxide layer formed which was electrically conductive and therefore unable to serve its intended purpose.

Insulating bushes used in ophthalmology, rely upon PTFE tape as a seal. PTFE also provides appropriate sliding properties and meets further technical requirements, such as:

- Hydrophobic and waterproof.
- Minimal stick-slip-effect over lifetime.
- Dry run protection when used in foldable tubes.
- Gas tight, vacuum tight (10 mbar for 24 hours).
- Outstanding UV to IR wavelength range light resistance when used in the lasers associated with the product.
- No degradation of properties over time, with devices having a lifetime of over 8 years.

Polyamide (PA) bushes are being investigated by one SPECTARIS member as a potential alternative, but this has not led to satisfactory results.

PVDF is used as a coating in bipolar forceps, a medical tool used in brain surgery due to the following properties it offers:

- High dielectric strength (950 volts.mil^{-1}) allowing for thin coating, in order to optimise sight lines and accessibility while meeting Means of Protection requirement from IEC 60601-1 of 1500 volts.
- Chemical resistance.
- Non-stick characteristics to minimise unnecessary patient damage and minimise tool cleaning.
- Suitable abrasion and wear resistance.

Potential alternatives such as silicone modified polyester, Nylon™, polyamide or parylene lack suitable abrasion resistance and high enough dielectric strength to allow for a comparably thin coating.

PFAS, including PTFE, Viton™, 1-propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and 1,1,2,2-tetrafluoroethene (CAS 25190-89-0), 1-propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene (CAS 9011-17-0) and ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1-difluoroethene and 1,1,2-trifluoro-2-(trifluoromethoxy)ethene (CAS 56357-87-0), are used in endoscopes in multiple parts and coatings with some uses highlighted in Figure 4-8.

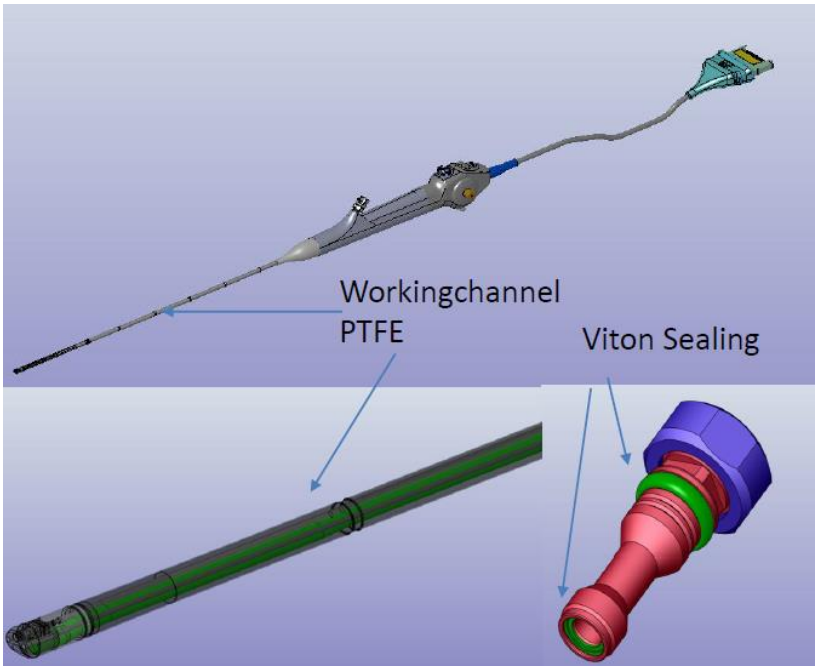

Figure 4-8 Indicative PFAS uses in endoscopes.

PFASs are used as they are able to offer the following properties:

- Excellent biocompatibility, biostability, and a history of patient safety.
- Resistant to chemical, enzyme, and microbiological attacks while eliminating biodegradation issues.
- Low coefficient of friction allows moving parts to slide with ease, generating less heat, and undergoing less wear and tear.
- Low surface energy and hydrophobic nature ensure that it is non-stick, which when combined with its chemical resistance, allows the product to be reused after it has been cleaned and disinfected.

Alternatives such as silicone rubber are not suitable for endoscope application due to their higher coefficient of friction, which impacts the ability to undertake the surgical procedure (especially with difficult anatomical conditions). Potential alternatives such as polyurethane and polyethylene, have comparable mechanical strength to PFAS however, they deteriorate when treated with chemicals or heat sterilised and as such cannot be considered as viable alternatives.

PFTE is used in a number of components such as plates as distance holders, in ophthalmic devices or components such as connectors, O-rings, fans, and in flanges in suction devices due to the low outgassing and the need to operate under vacuum.

Intensive care ventilators, anaesthesia devices, neonatal incubators, patient monitoring systems, medical supply systems and hospital gas management systems (with examples shown in Figure 4-9) contain fluoropolymers such as PTFE, PVDF, PFA, FKM in the following components:

- Hoses, seals, and coatings of gas-carrying parts,
- Electrochemical sensors, and

- Lubricants.

The materials are indispensable mainly due to their resistance to aggressive media, and more specifically:

- Hoses, seals, and other gas-carrying parts in medical devices must be permanently resistant to pure oxygen and anesthetic gases.
- In electrochemical sensors used in medical devices, fluoropolymers are used as membranes in strongly acidic electrolytes (e.g., sulfuric acid) or in the electrodes to control their wetting and prevent dissolution. In lead-free oxygen sensors[31], the materials must also withstand free oxygen radicals that would permeate all other plastics.

Figure 4-9 Example Intensive care ventilators, neonatal incubators, and patient monitoring systems.

PTFE greases are also used in medical equipment, including in applications which operate under vacuum to ensure the tightness of the connection of individual parts while keeping them flexible. While the grease must have suitable lubricant properties (such as minimal stick-slip-effect over lifetime and no corrosive effect with metals), the lubricant must also have a low vapour pressure and have high pressure and temperature (>120°C) resistance. PFAS-based greases are also used in surgical tools which, in addition to the preceding requirements, are also required to be biocompatible, non-toxic, not irritant, and not cytotoxic in case the lubricant comes into contact with the patient. As such, the lubricant needs to be tested to standards such as ISO 10993-5 for cytotoxicity, ISO 10993-10 for skin irritation, and ISO 10993-11 for acute systemic toxicity. Due to the sterilisation process used in the reprocessing activities, the grease also needs to maintain its physiochemical properties (even after exposure to harsh sterilising chemicals such as ethylene oxide) and thermal resistance, to avoid problems caused by the thermally elevated sterilisation process.

[31] Introduced due to the RoHS Directive requirement to avoid lead.

4.3.1 Minimum steps and time to be considered to implement PFAS-free alternatives

Due to the unique technical parameters PFAS offer, as yet no technical alternative has been identified. Only when a viable alternative has been identified, replaced, evaluated, and proven to be suitable, and proven to be no less reliable, accurate or effective and safe can they be used in a medical device, and it can be approved for sale in the EU. It is not possible to estimate how long the invention of a viable alternative would take, and as such due to the critical nature of such products it is essential that a time unlimited derogation is permitted.

Once a viable alternative has been identified, due to the critical nature of medical devices, their accessories, and tools performance, it is essential that sufficient time is permitted to ensure that it offers all of the necessary technical performance and meets safety standards. In order to assess alternatives SPECTARIS members will in general undertake the following stages of qualification:

1. Testing of alternative materials.
2. Production readiness activities.
3. Reliability testing.
4. Redesign of product for alternative solution (if required).
5. Testing of in-situ performance.
6. Product specific requirements: biocompatibility testing and evaluation including toxicological assessment and clinical trials.
7. Production set up (if required).
8. Global approvals.
9. Roll-out.

Each PFAS use needs to be analysed and a specific suitable alternative substance or formulation needs to be identified. Consideration must be given to technical, medical, regulatory, and economic aspects. As such, qualifying alternative materials could require changes in the design of the devices and/ or changes in the manufacturing process to accommodate the properties of alternative materials. Therefore rigorous testing is required to determine if the changes do not have a detrimental impact on the function and performance of the medical device, accessory, or tool. Without taking into account such considerations for testing, the proposed restriction will have a significant and negative impact on the availability of medical devices in the EU.

The use of a different material or substance will generally require a re-design, which takes time. Moreover, any change in material will require re-certification by an EU Notified Body for compliance with MDR. This is essential as without certification of a product, it cannot be placed on the market. For medical devices, the certification process of new devices/components with alternative substances alone can take up to 2 years.

Usually, only one design of medical device is made for the global market and so production lines cannot be changed until approvals have been obtained for all important markets. This is an aspect which should be considered by the European Commission when assessing the business impact of a legislative proposal. A time unlimited derogation is essential for the continued supply to EU hospitals and clinics of these products, so that the sector has the necessary time to develop an alternative for these applications.

The same needs are also applicable for veterinary applications, as the devices are usually designed to the same safety standards.

4.4 Plants for the production and transport of ultrapure water used for cleaning precision optics for at least 13.5 years

SPECTARIS requests that a derogation permitting the use of PFAS in 'Ultrapure water systems' at least 13.5 years is considered as sectors such as the optics industry are only possible due to the use of PFAS.

SPECTARIS members are likely to rely upon PFAS such as PFA in articles such as tanks, tubing, and gaskets in ultrapure water systems. This is based on the knowledge that the equipment manufacturers supporting the semiconductor industry have stated their use of PFA. The semiconductor industry places the tightest requirements on ultrapure water with 0.05ppb for most metals, however other sectors utilising ultrapure water have specifications which outline the conductivity requirements of the water. Given that PFAS are known to be used in semiconductor ultrapure water systems, SPECTARIS members assume that similar PFAS are also used in essential equipment for their industries as well but as yet the ultra-pure water facility makers have not made the same materials declaration.

4.5 PFAS coated optical multicomponent glass fibres for at least 17 years

SPECTARIS requests that a derogation permitting the use of PFAS in 'coated optical multicomponent glass fibres' for at least 17 years is considered. Such fibres are used in a number of SPECTARIS member products, including in medical treatments. Only PFAS provides the necessary combination of properties which includes biocompatibility, chemical resistance, and mechanical properties.

Fibre-optic cables consist of fibres which are plastic-coated and jacketed as shown in Figure 4-10 and Figure 4-11, both of which are provided in different diameter ranges. SPECTARIS members use fibre-optic cables sourced from its supply chain to guide laser energy from a connected laser device by means of total internal reflection to the desired treatment site for medical and aesthetic treatments. The total internal reflection is realised by a different refractive index of the silica core and silica cladding. Fluoropolymers generally have a refractive index of 1.3 - 1.4, which is essential as it is lower than the refractive index of core materials such as silica with a value of ~1.47.

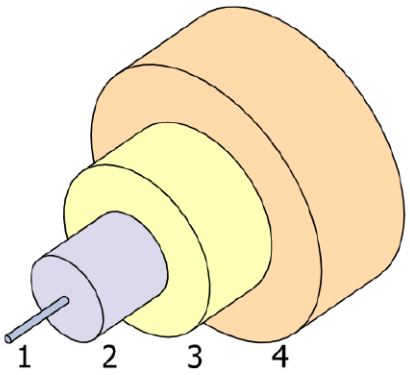

Figure 4-10 Example fibre-optic cable 1-Core, 2-Cladding, 3-Protective coating, and 4-Outer shell & protective tube which contain PFAS.

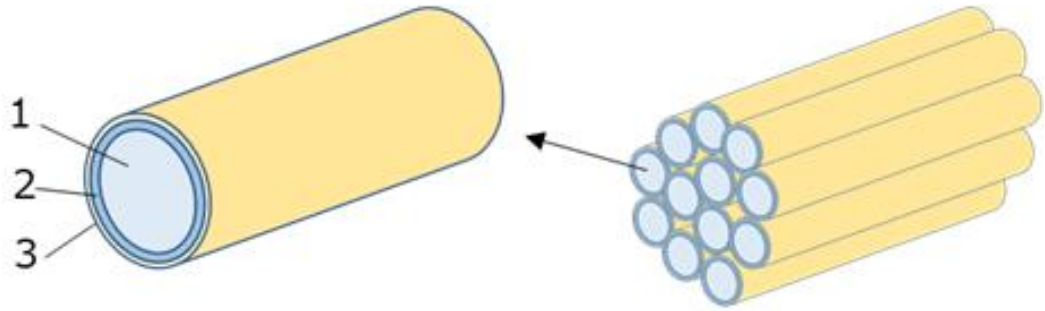

Figure 4-11 Optical fibre in endoscope applications. 1-Core, 2-Cladding and 3-PFAS coating

The fibre-optic cables are used in the following medical sectors to provide medical treatment:

- General surgery.
- Endoscopy.
- Urology.
- Gynaecology.
- Gastroenterology.
- Ears, Nose and Throats.
- Pulmonology.
- Dermatology.
- Aesthetic surgery.
- Vascular surgery.

In addition to the medical applications, the cables are also used in:

- Spectroscopy for astrophysics, such as in the Leibniz Institute for Astrophysics Potsdam and industrial applications such as process monitoring on oil rigs and for measuring the pollutant emissions.
- Aesthetic treatments (partially related to medical treatments) such as: hair removal, tattoo removal and skin discoloration.

The protective coating needs to have the following properties which so far only PFAS containing materials such as Teflon and PFAS containing thermoplastic elastomers can offer:

- Biocompatibility to standards such as ISO 10993.
- Near constant physical material properties over broad temperature range (-60^{o}C in applications which require freezing and 150^{o}C for sterilisation).
- Suitable for ethylene oxide and hydrogen peroxide sterilisation.
- Ability to withstand harsh environments including from cleaning chemicals which can range from a pH of 2 to 14 in hospital environments.
- Elasticity for small bending diameters of the silica fibre.
- Suitable hardness against mechanical forces and tensile forces.
- Sliding properties such as <5N tensile force in atraumatic applications.
- Suitable durability to enable a 2 year lifecycle.
- Electrical dissipative and conductive properties while ensuring the diameter is as thin as possible.

Based on the assumption that the above technical concerns can be overcome, the minimum steps and time to be considered to develop a PFAS-free alternative in the coating of optical silica fibres is outlined in Table 4-3.

Table 4-3 Minimum steps and time to be considered to implement PFAS-free coated optical silica fibres once suitable alternatives have been identified.

Qualification Stage	Estimated time to be considered
Testing of alternative materials / components	5+ years
Reliability testing	2+ years
Redesign of product for alternative solution	5+ years
Product specific requirements such as clinical trials or notified body approval	2+ years
Global approvals	1+ year
Roll-out	2+ years
Total time to develop	**17+ years**

4.6 Fluoropolymers in UV Lasers and equipment requiring UV/IR resistance for at least 13.5 years

Due to the widespread end use applications served by UV lasers and equipment requiring UV and/or IR resistance, SPECTARIS members suggest that a derogation along the lines of the following is included 'fluoropolymers in UV lasers and equipment requiring UV and/or IR resistance' for at least 13.5 years otherwise essential end use applications could be overlooked.

Fluoropolymers are used in specialist equipment, including lasers where UV and/or IR resistance is required. The equipment includes the following which utilise UV radiation:

- Disinfection, including water, surface disinfection used in food packaging (such as to disinfect bottle necks or caps in beverage filling) or other industries for transportation boxes or machinery, air disinfection and odour reduction.
- Curing applications such as those used in 3D printing or electronics.
- Analytical applications (spectrometry).
- Photochemical processes.

Equipment which utilises IR radiation is usually related to curing/hardening such as that undertaken in 3D printing, or heating such as the anti-icing of turbines or similar equipment and curing and heating utilised during electronics manufacturing.

Fluoropolymers are utilised in a number of different components, including PTFE wires, PTF/ FKM / FPM O-rings/seals/gaskets, PTFE insulation material for applications such as high voltage applications and various PFAS used in laser applications, sliding rails, heat shrink and UV sensors. PFAS are utilised as they are the only polymers which are able to offer the combination of UV resistance, high temperature resistance (in some applications up to 300°C), sealing function, electrical insulation, sliding characteristics and in laser applications low outgassing properties while maintaining the required mechanical properties.

For example, FKM O-rings are utilised in a number of laser systems which must have low outgassing. One equipment manufacturer measures[32] the outgassing load (organic compounds) which needs to be less than 6µg/m³ otherwise this would result in an increased degeneration rate of the optical components (induced by interaction of outgassing components and UV light). If the outgassing loads were to increase the product would no longer function as required and as such that would not be viable alternative to FKM at this point.

Due to the combination of unique technical factors fluoropolymers offer, as yet no potential alternative has been identified. When a potential alternative is identified a significant length of time would be required to qualify and potentially redesign systems to utilise such potential alternatives.

4.7 Solution for mould release for at least 13.5 years

SPECTARIS requests that a derogation permitting the use of PFAS in 'mould release' is considered for at least 13.5 years as they are used widely by SPECTARIS members between polymers and their moulds.

SPECTARIS members rely specifically upon mould release agents in the production of diffraction gratings which are essential for spectrometers. PFAS-free alternatives do not offer the necessary technical performance, and alternative manufacturing techniques take 10 times longer and is estimated to cost 100 times more than using the PFAS containing release agent.

PFAS are used as mould release agent between polymers and their moulds, with the most commonly used release agent being PTFE in the formation of polyurethane foam or polycarbonate parts. Although SPECTARIS members are reliant on PFAS in this application, for the vast majority of parts they are reliant on their supply chain for the manufacture of such parts. As a result it is likely that other parts within this report also rely on mould release also.

There is one specific use of methyl nonafluoroisobutyl ether (CAS 163702-08-7) and methyl nonafluorobutyl ether (CAS 163702-07-06) as a mould release agent that SPECTARIS members are able to provide information on. They relate to diffraction grating production processing, with images of different diffraction gratings provided in Figure 4-12. Diffraction gratings are optical elements that disperse light into different wavelengths through micrometre-sized periodic grooves. When light hits a diffraction grating, diffraction occurs and the light is intensified at a specific angle for each wavelength. By this means light of a specific wavelength can be obtained and is essential for spectrometers used for analysis and control in a wide range of fields, including food, pharmaceuticals, environmental monitoring, and textiles. Spectrometers also are key in contributing to the research and innovation in the chemical, physical, pharmaceutical, and biological fields.

[32] Tested as 24g of material at elevated temperature for 24 hours.

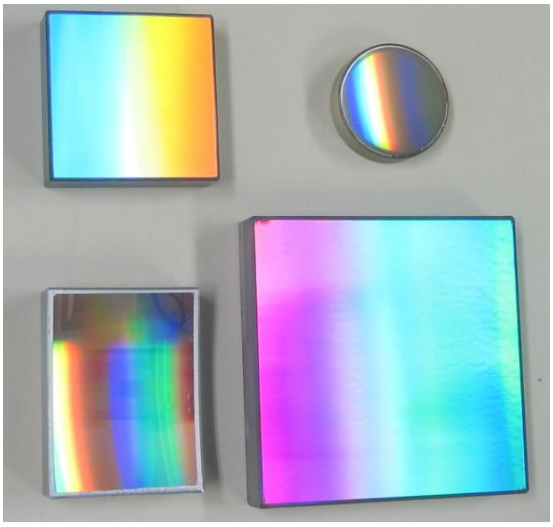

Figure 4-12 Diffraction gratings.

The types of materials able to be used as holographic materials are very limited as they require extreme long-term stability to be able to have consistent properties over the necessary use period of the product. Diffraction gratings are manufactured using a master diffraction grating as a mould, and then manufactured by layers of release layer, coating, resin, and replica substrate formed on the master diffraction grating. The process is outlined in Figure 4-13, with the layers bonded, and the replica is parted from the master. Without a release agent on the master, the replica cannot be parted from the master.

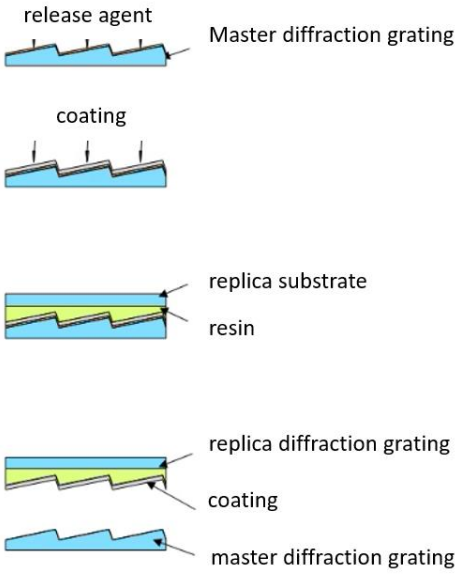

Figure 4-13 Manufacturing Process of diffraction gratings.

A PFAS-based mould release is used due to the following technical characteristics:

- Quick drying time, which is only a few minutes.

- Ability to form thin, uniform films that do not damage the microstructure of the diffraction lattice.
- Stability such that it does not react with or damage the metal when depositing a metal film on the release film.

Silicone-based alternatives have been trialled by some SPECTARIS members. For many types of replicas the release from the master was poor compared to PFAS release agents and the quality requirements of the part were determined to be a failure.

An alternative method for manufacturing diffraction gratings is possible via the use of a holographic exposure method which is PFAS-free. However, the process takes ten times longer and is estimated to cost one hundred times more than using the master diffraction grating technique with no added benefit as the currently utilised technique offers the necessary technical performance.[33]

The use of mould release agents for diffraction gratings is limited and estimated to be 50 kg annually. The mould release agent, when used in production, is disposed under controlled conditions following the local legislation. The estimated residue of the mould released on the master grating is estimated to be <530ppb and significantly less on the replicas as they are subject to liquid cleaning and plasma cleaning.

Once a PFAS-free release agent is identified, testing to ensure that the release is suitable but not damage the coated metal replica would be required. The manufacturing process would also have to be adapted and include the consideration of aspects such as the selection of equipment for mass production, experiments to establish conditions, preparation of production documentation, training at production sites and the communication of production management related information to customers. Due to the lack of a potential alternative for this production method at this time combined with the time required to test a potential alternative once it has been identified, a derogation for 13.5 years is required.

4.8 Battery and battery manufacturers for at least 13.5 years

SPECTARIS requests that a derogation permitting the use of PFAS in 'batteries and battery manufacturers' for at least 13.5 years is considered as many SPECTARIS members rely upon batteries functionality for their products or as an alternative power source as a means of backup. SPECTARIS members are manufacturers of vacuum technology equipment used in production of lithium ion batteries where PFAS provide unique technical functionality.

Many SPECTARIS members are reliant on batteries performing essential requirements in their equipment or as an alternative power source as a means of backup. As such, SPECTARIS supports the continued need for batteries and the associated PFAS used within them, but only has limited technical information on their uses.

Vacuum technology equipment used in production of lithium-ion batteries

SPECTARIS members manufacture vacuum technology equipment which is used in production of lithium-ion batteries during the electrolyte filling processes. The vacuum technology equipment is needed in order to prevent foaming of the electrolyte and ensure the cells are free of air.

Fluoropolymers such as PTFE, ETFE, ECTFE, FKM, FFKM and FEP are used in rigid applications such as piping, tubing, or flanges and in flexible applications such as diaphragm or valves. Fluoropolymers

[33] Costs have been estimated by one SPECTARIS member with more precise detail unable to be shared due to the confidential nature of the assessment.

are used due to their resistance to the highly corrosive chemicals such as $SOCl_2$ which is used in the electrolyte. Fluoropolymers guarantee a long lifetime, low maintenance requirements and high reliability which are needed for the very often required continuous operation (up to 24/7). The polymers are also able to operate at high temperatures experienced in vacuum pumps, which may reach up to 200°C due to the internal compression of gases, while still offering the necessary mechanical properties.

No other material is known to have the same wide range of chemical resistance over long time periods, and less chemically resistance materials will lead to the irreparable failure of the system after extremely short time periods.

5 GENERAL CONSIDERATIONS

Beyond the specific derogations outlined in the above sections, SPECTARIS members would like to highlight the need for the following broad considerations which need to be applied to all derogations.

5.1 Spares and Repairs

It is very important to note that PFAS are not only needed to manufacture new products and components but also for servicing and maintaining existing products and components and existing machines and devices already placed on the market – often for many years or even decades. It is likely that in many applications there will not be a drop-in replacement for the PFAS on a 1:1 basis due to different technical properties. Systems will therefore need to be redesigned to permit the use of PFAS-free alternatives. Without the general consideration to permit the use of PFAS in these applications, this will cause the premature end-of-life and scrappage of products which otherwise could be serviced and maintained in service with PFAS-containing parts.

For many SPECTARIS members' who produce complex systems, their systems can contain thousands of PFAS containing parts which are geometrically distributed over the full system. As such, this would require the complete disassembly of the product and would make the endeavour uneconomic and in some cases will be impossible as removal of some parts may cause irreparable damage. The inability to upgrade such systems not only has severe implications on waste due to its increase (as typically 90% of the parts can be used in such a project), but also has economic implications as companies can have up to 50 of these types of projects a year.

It is therefore vital, that the restriction does not impact products and components already placed on the market. In addition, it must be ensured that these products and component can continuously be made available on the market. With the current definition of "placing on the market" under REACH this would not be possible as any supply or making available to a third party, and hence any resale or lease, for example, is considered "placing on the market" under REACH.

Service, maintenance, and repairs are crucial for the success of the European Green Deal when it comes to better resource efficiency and therefore it is important that this is reflected in all of the derogations.

5.2 Derogation Extension Process and New Derogation Process

As is outlined in the respective sections of this report, PFAS substances in many applications do not have a known viable alternative or are at a very early stage in their development. It is important to keep in mind that although minimum steps and time to be considered have been estimated in this report, they have a significant degree of uncertainty due to the number of steps still left to be undertaken and the possibility of unforeseen challenges yet to be identified.

In addition to this the following assumptions have been used which underpin their estimation:

- A potential substitute with suitable technical characteristic will be identified. For the majority of PFAS uses potential PFAS-free alternatives have not yet been identified and it is not known how long it will take to identify suitable materials or design. In some cases, this may prove to be impossible so that the only option will be to withdraw the product from sale in the EU unless a derogation is granted.
- Necessary resources are available to complete the testing. Considering that the elimination or substitution of a whole class of chemicals, like PFAS, is unprecedented this has the potential to

add a significant amount of time to identify and implement each alternative as SPECTARIS members will be facing the need for the concurrent qualification of many thousands of parts.

It is therefore necessary to include a simple mechanism and formal process for extending derogation timelines beyond the timelines outlined in the dossier.

Although SPECTARIS members and their supply chain are actively engaged in gathering information on the uses of PFAS within their products, components, and manufacturing processes, manufacturers are far from having identified all PFAS uses and substances. In part this is due to the challenges in their identification as many PFAS used in mixtures have not been classified as hazardous per the Globally Harmonised System for classification and labelling. In addition, they have not been listed as SVHC or included on the Candidate List of SVHC for Authorisation. Therefore, many PFAS are not shown on safety data sheets even though the substance is present. Moreover, when PFAS are used as articles or articles in complex objects, suppliers are currently under no regulatory obligation to highlight the presence of PFAS.

Due to these factors, it is essential to understand that there will not be sufficient data available after the end of the consultation period to determine all use cases and necessary derogations. It is estimated that a broad range of applications and uses to be missed which – if then banned from the market – will have a severe impact along the supply chain, and society. It is therefore important to establish a simple mechanism and formal process for adding derogations once the restriction is published.

6 SUMMARY OF FINDINGS

SPECTARIS members rely upon a number of proposed derogations outlined in the Annex XV report which are essential to SPECTARIS members' products, components, and manufacturing processes. SPECTARIS members would also like to highlight the need for a number of new derogations.

SPECTARIS members rely on the derogations for the manufacturing of their products and in their supply chain. It is therefore essential that the derogation needs to be viewed holistically to ensure all uses of PFAS are permitted.

Proposed Derogations

5a- Polymerisation aids: SPECTARIS members will rely upon this derogation due to their use of polymeric PFAS in their applications, however the proposed derogation validity period is required to be more than 16 years due to the end uses the polymeric PFAS are used in. It is also important that the derogation includes the production of PTFE, PVDF and FKM in its scope as the change in polymerisation aids in these material would change its properties and require requalification.

5e- Textiles and membrane filter products: Due to many air filtration applications relying on membrane filter products SPECTARIS proposes that the derogation permits the use of PFAS in 'textiles and membrane filter products used in high performance air and/or liquid applications in industrial and laboratory or professional settings.'

It is SPECTARIS members' understanding that the term 'professional settings' would include a wide variety of settings which could be characterised as activities relating to a person's means of livelihood or adult education. Therefore specific settings such as laboratories, pharmaceutical and biopharmaceutical applications would be incorporated in this definition.

5g- Refrigerants in industrial applications and laboratory test and measurement equipment: Due to the same technical requirement for refrigerants in industrial applications, SPECTARIS proposes that the derogation permits the use of PFAS in 'Refrigerants in stationary refrigeration equipment for industrial use and laboratory test and measurement equipment'.

5h- Refrigerants in centrifuges: Due to the need for refrigeration in incubators SPECTARIS requests that the derogation permits the use of PFAS in 'refrigerants in refrigerated centrifuges and incubators.' Due to the technical challenges faced by higher performance centrifuges, as yet no technical alternative has been able to be identified and a longer derogation validity period for these products may be required. In addition to this, due to the continued need for maintenance, it is requested that the derogation timeframe for maintenance is unlimited.

5i- Maintenance and refilling of existing HVACR equipment: Due to the continued need for maintenance and refilling of existing refrigeration equipment SPECTARIS requests that the derogation permits the use of PFAS in 'maintenance and refilling of existing HVACR and refrigeration equipment …'.

5n-Diagnostic laboratory testing: SPECTARIS members support the need for a derogation in diagnostic laboratory equipment as they are producing a variety of essential pieces of equipment. Due to the limitation of the scope, which is understood to relate only to the testing of biological or medical samples, there is the need for a broader derogation covering either analytical and laboratory equipment due to the similarity in technical requirements, or a general derogation for fluoropolymers is required.

5t- Calibration and reference material of measurement instruments: Due to the continued need for analytical reference materials in applications such as spectrometers SPECTARIS requests that the derogation permits the use of PFAS in the 'calibration and reference materials of measurement

instruments and as an analytic reference material.' As yet no known alternatives exists and SPECTARIS expects that a derogation of at least 20 years from the date an alternative has been identified will be needed for reference materials.

6c- Tubes and catheters in medical devices: SPECTARIS requests that the derogation permits either the use of PFAS in the 'tubes, catheters and sterile connectors in medical devices, biopharmaceutical, and pharmaceutical production equipment. However would like to raise the concern over the limitation of the derogation to only the listed product types. This style of derogation will lead to essential cases of PFAS being missed which is why a derogation for medical devices (as outlined in Section 4.3) or polymers (as outlined in Section 4.1) are proposed.

SPECTARIS have interpreted the term tube to not be limited to tubes which only carry liquid and gases, as the same technical requirements also apply to a broader range of uses. The confirmation of this interpretation would be welcomed to ensure that it is being consistently understood.

SPECTARIS members support the need for derogations 5f- Refrigerants in low temperature refrigeration, 5k- Industrial precision cleaning fluids, 5s- Lubricants, 5cc- Membranes used for venting of medical devices and 6b- Implantable medical devices. For each of these derogations, additional technical details as to how they are used by SPECTARIS members are outlined within their respective sections.

SPECTARIS members also support the need for 5b- Textiles used in personal protective equipment but are not in a position to offer additional technical details on derogation as the information is held by their supply chain.

Potential Derogations

5v-Hard chrome plating is relied upon by SPECTARIS members in medical equipment, laboratory equipment, components exposed to alternating and components with adhesive stress and require sufficient time to qualify alternatives in their products and components. The demanding technical requirements of products such as scanning electron microscopes introduce more limiting factors as to why alternative PFAS-free plating's are not possible. Due to the number of components utilising hard chrome plating and end use applications SPECTARIS members' products operate requiring significant development time, the derogation may be required beyond the currently proposed 6.5 years.

5ee-Semiconductor manufacturing, related equipment and supporting processes: SPECTARIS members produce equipment that supports the semiconductor industry which has the same technical requirements as the semiconductor industry. As such SPECTARIS requests that the derogation permits the use of PFAS in the 'semiconductor manufacturing process and related equipment.' SPECTARIS members also rely upon semiconductors for critical applications in their products. A 20+ year derogation is needed due to the highly complex technical requirements PFAS need to meet.

6j- Coating applications for medical devices: SPECTARIS members produce medical devices which rely on a number of different PFAS for a wide range of products, with technical details provide in Section 3.3. The derogation time period is requested to allow the continued use of PFAS for at least 16 years such that the necessary product testing and approvals are able to be undertaken.

6k- Rigid gas permeable contact lenses, ophthalmic lenses, and other lenses: It should be noted that the assessment presented in Annex E is incorrect. The SPECTARIS (RINA 2021) report concludes that RPG contact lenses provide unique and non-substitutable functionality that relies upon the functionality of PFAS. A number of medical conditions preclude the use of other lens types. As yet no technical alternative is available. Hence, patients in need for specific treatment of their condition would be

deprived of such a possibility without this derogation. As yet, there is no technical alternative to fluoromethacrylates in RPG contact lenses as outlined in Section 3.4.

SPECTARIS also requests that the derogation is scoped to include 'Rigid gas permeable contact lenses, ophthalmic lenses, and other lenses' due to the similar technical need for PFAS in these applications. Due to the use of non-polymeric forms of PFAS it is recommended that the derogation is moved under section 5, rather than section 6 of the restriction.

6n- Packaging of terminally sterilised medical devices: SPECTARIS requests that the derogation timeframe is sufficiently long to allow the necessary changes, which is expected to take over 16 years to identify and qualify a PFAS-free alternative.

Additional Derogations

Due to the additional PFAS identified within SPECTARIS members product ranges and review of the derogations outlined in Annex XV, SPECTARIS would like to request that the following derogations are also included in the restriction.

Fluoropolymers and fluoroelastomers for at least 13.5 years. Fluoropolymers and fluoroelastomers possess a unique set of characteristics that trigger their use in SPECTARIS member products, components and manufacturing processes which relate to the fundamental characteristics of the C-F bond. As such, the viability of alternatives is uncertain. Until alternatives can be fully investigated, with alternative solutions undergoing the necessary qualification, a vast array of products and components will be negatively impacted and especially those within high-tech applications. Given the identification of PFAS is still underway additional time would allow the identification of all essential uses.

Many fluoropolymers relevant to industry, such as PTFE, meet the OECD criteria for "polymers of low concern". This means that they are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile. Unless a differentiated restriction is implemented irreparable damage to Europe, its citizens and its industry will be experienced.

Analytical and laboratory equipment for at least 13.5 years. SPECTARIS members manufacture a wide variety of laboratory equipment which underpins numerous essential sectors, which can test chemical parameters or other aspects. The technical characteristics of such devices are similar to derogation 5n however this only relates to diagnostic laboratory equipment and therefore is not broad enough in scope. It is worthwhile highlighting that although the vast majority of the laboratory equipment is used within the confines of a laboratory setting, there are also instances where associated equipment is used to perform measurements in situ.

Medical devices, their accessories, and tools including equipment used for veterinary applications for an unlimited time. SPECTARIS members are producers of medical equipment which rely upon PFAS, the types of devices manufactured are extremely varied. Medical device accessories and tools also have the same requirements and as such would benefit from being specifically included in the scope of the derogation. Medical devices provide essential functions to ensure the health of EU citizens, and a multitude of PFAS and components are fundamental in the design of such equipment. Due to the rigorous standards such equipment is tested to, the qualification timeframe is considerable and for many applications an alternative to PFAS is not yet known.

The same needs are also applicable for veterinary applications, as the devices are usually designed to the same safety standards.

Plants for the production and transport of ultrapure water used for cleaning precision optics for at least 13.5 years. Ultrapure water system, such as those used within the semiconductor industry as well as sectors such as the optics industry are only possible due to the use of PFAS such as PFA. As such SPECTARIS requests that a derogation is permitted to allow the development and qualification for PFAS-free alternatives.

PFAS coated optical multicomponent glass fibres for at least 17 years. SPECTARIS members use fibre-optic cables sourced from its supply chain in its products, including in medical treatments. Only PFAS provides the necessary combination of properties which includes biocompatibility, chemical resistance, and mechanical properties, and at least 17 years are required to develop a PFAS-free alternative.

Fluoropolymers in UV Lasers and equipment requiring UV/IR resistance for at least 13.5 years. Due to the widespread end use applications served by UV lasers and equipment requiring UV and/or IR resistance SPECTARIS members suggest that a derogation along the lines of the following is included 'fluoropolymers in UV lasers and equipment requiring UV and/or IR resistance' for at least 13.5 years otherwise essential end use applications could be overlooked.

Solution for mould release for at least 13.5 years. Mould release agent is used broadly by SPECTARIS members between polymers and their moulds. SPECTARIS members also rely upon mould release agents in the production of diffraction gratings which are essential for spectrometers. PFAS-free alternatives do not offer the necessary technical performance, and alternative manufacturing techniques take 10 times longer and is estimated to cost 100 times more than using the PFAS containing release agent.

Battery and battery manufacturers for at least 13.5 years. Many SPECTARIS members are reliant on batteries performing essential requirements in their equipment or as an alternative power source as a means of backup. As such, SPECTARIS supports the continued need for batteries and the associated PFAS used within them, but only has limited technical information relating to vacuum technology equipment used in production of lithium ion batteries.

Spares and Repairs. PFAS are not only needed to manufacture new products and components but also for servicing and maintaining existing products and existing machines and devices already placed on the market. Without the agreement that spares and repairs can continue to support such equipment this will cause the premature end-of-life and scrappage of products and not support the success of the European Green Deal when it comes to better resource efficiency. Equipment will be made with PFAS until substitution is possible and as long as this is permitted by derogation. A spare parts derogation will be needed to allow the repair of this equipment made using PFAS for the lifetime of these products, which can be more than 20 years.

Derogation Extension Process and new derogation process. Every effort has been made to accurately estimate the PFAS uses. However, data gathering for PFAS uses is still ongoing. Due to the broad scope of the derogation, the complexity of the supply chain and no reporting obligations for all PFAS in the supply chain, data at the end of the consultation phase will be incomplete and have big gaps. It is therefore necessary to include a simple mechanism and formal process for adding derogations once the restriction is published. Also, additional time to the derogations may be required due to unforeseen challenges. Substitution efforts can be delayed due to many different factors including additional testing or development requirements identified due to the early stage of development process, lack of suitable alternatives and resources. Therefore, it is necessary to include a simple mechanism and formal process for extending derogation timelines beyond the timelines outlined in the dossier, if needed.

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