SPECTARIS

Impact of the PFAS Restriction on SPECTARIS Members

Socioeconomic 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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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 socio-economic impacts for 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. SPECTARIS companies contribute significantly to the EU, with members with 20 or more employees having a combined turnover of €84.1 billion in 2022. In addition to these figures, small and micro sized companies also contribute to the EU economy.

It is important to note that given the proposed PFAS restriction has an unprecedented large scope and for many PFAS there is no regulatory requirement to declare to manufacturers that the substances are present, SPECTARIS members and their supply chain are still gathering information on all of the PFAS uses. As such, the report is based on the information known to date and the timeline to gather information on all uses cannot be estimated. It is therefore essential that the derogation timeframes requested are granted and if other PFAS uses are identified later on in the process there is facility to request other derogations if technically necessary.

The importance of PFAS for SPECTARIS members cannot be overstated, as PFAS provide a unique set of essential properties critical to meeting existing safety standards and requirements. No alternatives exist which offer the necessary technical performance. Over half of responding SPECTARIS members state that 80-100% of their products, components, and manufacturing processes rely directly upon the functionality that PFAS provides. The 'Impact of the PFAS Restriction on SPECTARIS Members-Technical Impact Report', Report number 2023-0343 outlines the proposed and potential derogations providing essential uses to SPECTARIS members, as well as the additional derogations which are essential to SPECTARIS members. Without the derogations 72% of the responding membership state that the loss of revenue would be so significant that it is unlikely that the businesses will be able to operate. This has the potential to result in a loss of turnover in the EU of €60.6 billion per annum based on the assumption that these businesses were no longer able to operate.

A differentiated approach to the restriction is essential, with derogations permitting the suitable time for the qualification of potential alternatives. Without such derogations the following impacts should be expected:

- Medical technology The health of EU citizens would be endangered, as the majority of medical devices will no longer be able to be marketed in the EU, as PFAS-free components do not offer the necessary technical and safety performance. For example:
  - Life-saving surgeries spanning well-established and state-of-the-art surgical procedures could no longer be performed as ventilators and anaesthesia devices would no longer be available.
  - The diagnosis and/or therapy in many medical fields could not be carried out due to the reliance on PFAS in analytical techniques.
  - 10 million endoscopic or minimally invasive procedures per year undertaken only in Germany, would be affected and no longer be able to be undertaken.
  - Rigid gas permeable (RGP) contact lenses provide unique and non-substitutable functionality capability for certain conditions and currently do not have a suitable PFAS-free alternative identified.

  - Ophthalmic and other lenses if forced to use PFAS-free alternatives would have a lifetime of one third of a PFAS-lens, creating an additional 3335 tonnes of waste per annum. In addition, PFAS-free lenses will have lower technical performance, with haze at an estimated 50% higher level which leads to significantly reduced vision and therefore safety concerns.

- Analytical, bio and laboratory technology plays a critical role in many critical end sectors such as materials testing, pharmaceutics, food testing, environmental standards for air and water, energy supply, petroleum industry and research and education. Its equipment is necessary for the control and enforcement of legal regulations. If there were no derogations, the testing to support these standards would no longer be able to be carried out. In many cases PFAS-free materials will not satisfy safety standards and as such the products could not be released to the market.
- Consumer optics and photonics supports many critical applications, such as optical fibre sensors for safety and security in innovative aerospace and submarine applications and landslide early warning all of which would not be possible without PFAS.

  Many of SPECTARIS member products utilise semiconductors in their equipment, which also rely upon PFAS. Without these the equipment would not be able to function, and the absence of semiconductors is contrary to the EU's goals under the Chips Act.

For a substitution to be successful, it must meet all of the following criteria: the necessary functionality and performance is preserved, and the potential substitute must meet regulatory requirements. The use of the potential substitute substance must therefore be tested and permitted on the basis of legal and normative requirements. In addition to this the potential substitute must provide a benefit for the environment and health. It must not present higher risks than the substance to be replaced otherwise it may be considered a regrettable substitution. There are some potential alternatives, which would introduce other health hazards, and as such may be a regrettable substitution. Others, such as using alternatives to F-gases may not be permitted by law for some equipment due to the implications on safety.

The forced substitution of PFAS-free products, components, and production processes, for most parts would directly impact the products ability to perform its intended function and result in premature obsolescence, challenging the EU's position on circular economy. For a limited number of applications, the use of potential alternatives will have a significant impact on a product's lifetime, with products which previously lasted up to 10 years lasting less than a day and effectively becoming single use devices.

Potential alternatives for many applications need considerable investment in development, qualification, and validation, including legislative requirements for highly regulated products. It should be noted that even once an alternative may be developed there will be continued financial impacts on SPECTARIS members. For example, 90% of SPECTARIS members expect to have to raise their product prices due to the need for extensive testing and redesign of their equipment. For institutions having limited budgets, the benefits from new technology would be delayed due to redesigning existing portfolios, which will have a detrimental impact on advancements in healthcare and research. For some applications, this will result in a competitive disadvantage for EU companies, as commercially they would not be able to raise prices, and thus loose business within the EU – potentially even entirely. This may also cause companies to move manufacturing outside of the EU.

SPECTARIS members have tried to estimate the costs of substitution, based on the assumption that technical alternatives are available for their applications, however they are highly challenging to estimate. From the estimations able to be made, the higher the complexity of the device and the more numerous the PFAS used within a system the higher the indicative costs. The overall financial impact to a business depends on the types of devices which they manufacture, as well as the number of devices affected by the PFAS restriction. However, the majority of SPECTARIS members expect this to be highly

impactful. For one SPECTARIS member, the combined costs of substitution for their portfolio of medical devices exceeds €1billion based on the assumption that PFAS-free potential alternatives can offer the necessary technical performance. However, for this SPECTARIS member this amount exceeds their annual revenue by a factor of 10, which indicates the severity of the impact to their business.

Beyond the costs associated with identifying PFAS-free potential alternatives, due to the reporting requirements embedded in the restriction proposal, there will be additional costs for SPECTARIS members. SPECTARIS members estimate indicative costs of reporting, under part 7 of the restriction to cost on average €490k per company per annum, with significant costs associated with the creation of suitable systems within companies. Reporting under part 8 of the restriction, was estimated to indicatively cost €66k per company, and the annual update less than half of this.

If PFAS were to be restricted with no derogations, the vast majority of SPECTARIS members would no longer be able to market their products and components. But even if an alternative were available, it takes many, many years before a new product can reach the market due to strict regulatory requirements. Considering that for many applications there is no viable alternative it is estimated that 237 600 jobs may potentially be lost in the EU, with additional jobs lost from SPECTARIS members supply chain and contractors.

In order for potential alternatives to be qualified each of the SPECTARIS members would need to hire on average over 10 additional highly specialised staff. It needs to be considered that in many of the sectors, there is a significant skills shortage and finding appropriately experienced and qualified staff is challenging. It is therefore arguable that the pace of innovation in products will continue to slow as more resources are diverted from innovation to removal of restricted substances from new and existing products, with either no innovative product or technological benefit.

It is therefore essential that the derogations as outlined in the Technical Report are granted due to the unique properties PFAS currently bring to SPECTARIS member components, products, and manufacturing processes. Without this the broad societal goals such as the EU Green Deal or European Chips Act cannot be achieved.

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ABBREVIATIONS AND ACRONYMS

CAS	Chemical abstract number
CE	Conformité Européene
CLP	Classification, Labelling and Packaging Regulation
EU	European Union
FKM	Fluoro rubber
FTE	Full-time equivalents
HVACR	Heating, ventilation, air conditioning, and refrigeration
IOL	Intraocular lenses
IR	Infra-red
IVDR	In Vitro Diagnostic Regulation

MDR	Medical Device Regulation
PBT	Persistent bioaccumulative and toxic substances
PCR	Polymerase chain reaction
PFAS	Per- and polyfluoroalkyl substances
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene fluoride
R&D	Research and development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RINA	RINA Tech UK Limited
RGP	Rigid gas permeable
RoHS	Restriction of Hazardous Substances
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SME	Smaller and medium sized enterprises
SVHC	Substance of very high concern
Technical Report	Impact of the PFAS Restriction on SPECTARIS Members-Technical Impact Report, Report number 2023-0343
UV	Ultra-Violet
vPvB	Substances that are very Persistent and very Bio-accumulative

1 AIMS OF THE SOCIO-ECONOMIC ANALYSIS

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] SPECTARIS member products are characterised by the highly technical and demanding applications they operate in, and as such they have to meet stringent regulatory requirements with qualification of potential alternatives being a highly complex, multi-step, multi-year challenge.

This report is intended to provide information about the likely socio-economic impacts of a restriction on SPECTARIS members products, components, and processes. Specifically, the report comments on the risk management option proposed within the Annex XV report to provide evidence that SPECTARIS members rely on fourteen proposed derogations, support the need for five potential derogations and request that a number of the derogations need to cover additional uses or a longer timeframe as outlined in Table 1-1. This report supports the previous Technical Report[2] which outlines the impact of the PFAS Restriction on SPECTARIS Members.

Table 1-1 Summary table of SPECTARIS members relying upon derogations, with changes highlighting proposed amendments.

#	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		
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		

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

[2] 'Impact of the PFAS Restriction on SPECTARIS Members-Technical Impact Report', Report number 2023-0343.

#	Derogation	Additional uses	Additional time
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 and a formal process for requesting new derogations as well as permitting existing derogations to be extended beyond the originally agreed time period.

2 SCOPE OF THE SOCIO-ECONOMIC ANALYSIS

Without the derogations listed above SPECTARIS members will no longer be able to produce their products and components. As explained in SPECTARIS technical submission, no alternatives have been identified that are able to offer the necessary **combination of technical characteristics** PFAS currently provide.

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 examining use cases, their supply chains and the impact of a potential ban and as such have not been able to answer all of the questions asked at this time. In particular, smaller and medium sized enterprises (SME) that have less resources and insufficient trained staff with specialised chemical background gave feedback to SPECTARIS that they are overwhelmed and cannot answer many questions regarding PFAS uses. Although SPECTARIS started very early in the process about informing its members and contributing to previous consultations, SPECTARIS roughly estimates that approximately only 10-20% of its member companies will respond to the consultation. It is thus to be expected, that there will be a lack of sufficient information at the end of the consultation process.

2.1 SPECTARIS Membership Importance to Society

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. Innovation and growth characterize the different industry sectors and their 341,000 strong workforce. Technologies developed here are used in almost all branches of industry, making them an essential contributor to the EU economy. Additional details on the SPECTARIS members can be found on the website at https://www.spectaris.de/

The medical technology sector includes products, services or solutions used to save and improve people's lives and include:

- Medical devices.
- In vitro diagnostics (reagents, equipment and consumables) which are non-invasive tests used on biological samples to determine the status of a person's health.
- Digital health which are the tools and services for improvement, prevention, diagnosis, treatment, monitoring, and management of a person's health.

The world market for the medical sector is outlined based on data from 2019, in Figure 2-1.

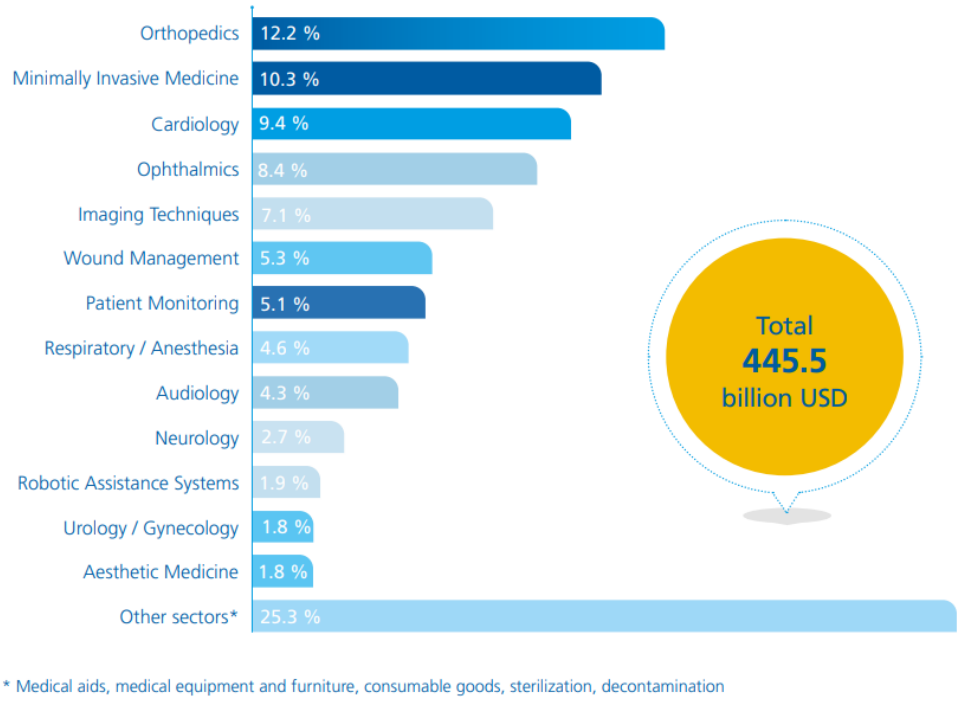

Figure 2-1 World market for medical technology by sector.[3]

The medical technology sector employs 0.3% of the total employment in Europe directly equating to more than 800,000 people, with the highest number in Germany.[4] The German medical technology

[3] Spotlight_Medical_Technology_2020.pdf (spectaris.de)

[4] the-european-medical-technology-industry-in-figures-2022.pdf (medtecheurope.org)

industry is strongly dominated (93% with fewer than 250 employees) by medium sized shaped medical technology companies, which experience specific challenges in managing the size of the PFAS change as discussed in this report. In addition Medical and In-vitro devices are regulated by product specific legislation of 2017/745/EU and 2017/746/EU respectively which require specific regulatory controls which add to the qualification of PFAS-free alternatives for this sector.

Diagnostic laboratories are one type of laboratory in the healthcare field, which detects different diseases and this allowing clinicians to adapt, begin, and stop treatment, which would be hindered in the absence of medical laboratory facilities. Diagnostic laboratories services include drug discovery and development, bioanalytical and toxicologic testing and clinical trial-related services.

Analytical laboratories offer services that classify, assay and/or analyse chemical, material, biological, geological, and environmental samples. Analytical testing covers a much broader range of testing not limited to biological samples and includes for example the analysis of food and drinking water. Europe's analytical laboratory services market is expected to reach the value of over €132 billion by 2030, with bioanalytical testing segment accounting for the largest proportion of the market.

Besides analytical and diagnostic laboratories, laboratories serve a wide range of academic and industrial areas, such as basic research, small scale production for example of chemicals, vaccines, and medicines, and up to large scale production of solar cells. The EU market for analysis, bio and laboratory technology sector is valued at €74 billion in 2022, with an annual EU growth rate of 11%.[5]

Europe's photonics industry holds 2nd place global ranking for growth, with 16% of the global market share. By 2019 the industry had grown to €103 billion with a 7% annual growth rate.[6] Germany is the leading photonics nation with >40 % of European photonics production taking place in Germany. France and Great Britain are also key players, with 15% of production occurring in each jurisdiction. Due to complex value chains and increasing specialisation, all countries with photonics expertise are important trading partners for the EU photonics industry.

Photonic technologies enable energy-efficient, resource-saving, and clean applications in key social sectors such as healthcare, transport, and communications through their problem-solving capabilities. The importance of photonics can be seen through the recent awards of the Nobel Prize, for example in 2015 for the high-resolution fluorescence spectroscopy. Semiconductor lithography represents a pinnacle of innovation in photonics. The world's leading semiconductor manufacturing technology and equipment rely on the most advanced optical systems invented and manufactured by SPECTARIS members. Lithography optics enable the continued progress of digitalization. Almost all sectors and industries rely upon semiconductors to enable and enhance the design, manufacturing, and distribution as well as the functionality and usability of its products. Digital technology is also a key enabler to realise the objectives of the EU Green Deal and the European digital transition. Some example products enabled with this technology are shown in Figure 2-2.

[5] Trendreport_Analysen_Bio_und_Labortechnik_2022.pdf (spectaris.de)

[6] Europe's photonics industry holds 2nd place global ranking (europa.eu)

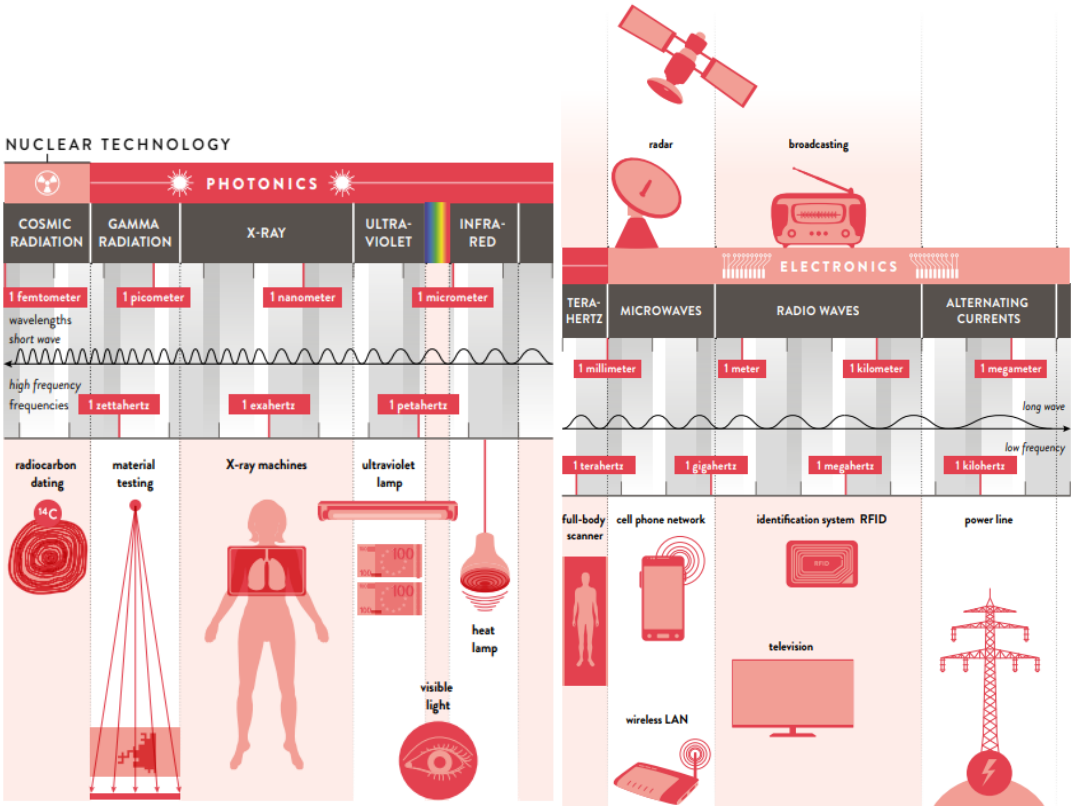

Figure 2-2 Examples of photonics enabled products.

PFAS in SPECTARIS member products

SPECTARIS members significantly rely upon PFAS within their product ranges, with over half of members who responded stating that 80-100% of their products, components, and manufacturing processes rely directly upon the functionality that PFAS provides, as outlined in Figure 3-4. The impact is even greater when associated equipment used as a part of a wider system is also considered. In a single SPECTARIS member company, PFAS can be contained within 3,500+ products directly, with all other products and components offered by the same company indirectly affected. Therefore the scale of technical challenges cannot be overstated in its impacts to SPECTARIS member companies.

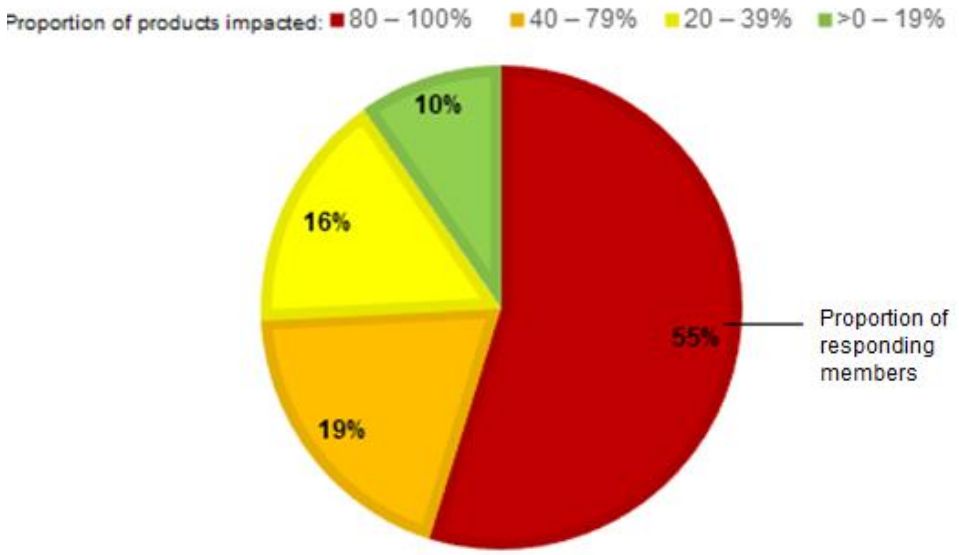

Figure 2-3 Proportion of products, components, and manufacturing processes affected by the PFAS restriction known to date.[7]

It is important to note that the identification of PFAS within SPECTARIS member products, components and processes is still under development in many companies, with the challenges in gathering this information outlined in the previous technical report. As such, many companies are unable to fully estimate the impacts of the restriction and this will only become apparent in the coming months. Therefore, it is likely that the impacts outlined in this report are even more significant.

3 IMPACT IDENTIFICATION AND ASSESSMENT

SPECTARIS members utilise a number of proposed derogations outlined in the Annex XV report which are outlined in detail in the Technical Report[2]. SPECTARIS members support a number of different sectors including medical technology, consumer optics, analytical, bio and laboratory technology as well as photonics. Where information is known to relate to a specific proposed derogation this has been highlighted in the report.

The importance of PFAS for many SPECTARIS members cannot be overstated and, in many applications, PFAS are used in light of many other already existing regulations (e.g., fire protection, efficiency requirements, safety standards). PFAS provide a unique set of properties, without which SPECTARIS member products, components, and manufacturing processes will no longer function, as all currently known potential alternatives are unable to offer the necessary technical function and performance as well as meet the existing regulatory requirements and at the same time bring a benefit to avoid regrettable substitution. A differentiated approach to the restriction is essential, with derogations permitting the suitable timescale needed for the identification, testing and qualification of potential alternatives. SPECTARIS member products, components, and manufacturing processes are essential in achieving broad societal goals such as the EU Green Deal, as well as the goals outlined in the European Chips Act. Without PFAS these goals cannot be achieved.

[7] Based on 36 responding SPECTARIS members.

3.1 Human Health and Environmental Impacts

The intrinsic properties of PFAS impart high resistance to demanding operational requirements, which as yet alternatives are not able to offer. PFAS-free alternatives will either result in SPECTARIS member products not having the same technical function (so may no longer be suitable for the intended use), or experience very significantly faster degradation, causing faster replacement of parts and therefore a significant increase in waste. It is essential that the restriction permits the continued provision of spare parts. Otherwise it could lead to the situation where previously a spare part could ensure the continued use of a piece of equipment, but without this provision the equipment would have to be scrapped with considerable waste implications and contrary to the principles of a circular economy.

SPECTARIS member products contribute to environmental sustainability in a number of ways including indirect climate protection potential of photonics. The potential environmental impact for the majority of SPECTARIS member products and components is likely to be at the end-of-life of the equipment where recycling is usually carried out only by licensed EU recyclers which are regulated by the Industrial Emissions Directive, during such processes all PFAS should be completely destroyed.

3.1.1 Reduced Lifetime of Products and Components

Due to the fundamental characteristics of the strength of the C-F bond, PFAS have high resistance against aggressive chemicals, heat and radiation for prolonged periods of time, and therefore have low maintenance requirements. As yet no PFAS-free potential alternative is able to offer the same technical performance. Materials that do not show the same technical performance will reduce the overall technical performance of SPECTARIS member products and components. As such SPECTARIS member products and components will experience faster degradation of the components which will require replacement and thus causing more waste.

The following are examples of SPECTARIS member products estimated reduction in lifetimes when potential PFAS-free alternatives were assessed. It is important to note that for the vast majority of products, components and production processes, PFAS-free alternatives also adversely impact the function, safety, and performance of SPECTARIS members' products. Additionally, there is real possibility that PFAS-free alternatives would impact the service life of these products challenging the EU ambition to a circular economy. The following examples illustrate this issue:

- Long lasting microwave digestion vessels which would usually last at least 5 years using PFAS components, would have to be treated as consumables to be replaced every couple of weeks or months due the lower chemical resistance of alternatives. This frequency of replacement should therefore be thought of as being not a viable alternative, especially when a device of this type is usually ~€30k.
- Metal seals may be a potential alternative to PFAS containing O-rings and gaskets in a limited number of applications, however they would be a single use item as the seal would need to be deformed to be removed. Compared to seals which would usually last the lifetime of the product and would require a high level of service and/or maintenance of the equipment to support the use of such seals.
- Friction parts with PFAS-free alternatives would have to be replaced after approximately every 2 to 3 years (or less), rather than the lifetime of the product which is at least 8 years. In addition to this it would result in lower precision sliding guides with a potential impact on the function of the device.
- Certain analytical and laboratory equipment would only last half a day with PFAS-free alternatives, whereas previously it had an expected lifetime of 5-10 years. Affected products would effectively become a disposable part, with a substantial increase in waste associated with this change.

As mentioned above, the decrease in component or material lifetime will mean for many products that they can no longer serve their intended function, and as such cannot be marketed. One such example of this is PFAS containing lubricants used in the high vacuum area of a scanning electron microscope, where less stable lubricants can lead to contamination of customer samples being analysed and thus can falsify or nullify research results. Such impacts are not limited to the specific examples cited, but across a wide variety of SPECTARIS member products, including medical devices which are discussed in more detail in Section 3.1.4.4.

Associated with the impact of reduced lifetime, it is also expected that there may be higher unpredicted service intervals and system downtime for SPECTARIS customers. Considering that many SPECTARIS member products and services provide critical, or lifesaving features the absence of such equipment can have significant consequences.

3.1.2 End-of-life, and Waste Considerations

SPECTARIS member products contribute to environmental sustainability in the following ways:

- Photonics solutions are used in the following applications, with the indirect climate protection potential of photonics outlined in Figure 3-1[8]:
  - Energy generation using photovoltaics.
  - Energy efficient lighting, displays and energy saving in optical communication technology in data centres and 5G mobile networks.
  - Optical early detection of forest fires and wildfires.
  - Efficient turbo engines for aircraft technology using laser-based processes.
  - Laser processes for high-performance batteries in car manufacture.
  - Laser spectroscopy for emissions measurement technology.
  - Optical sorting of recycling as shown in Figure 3-2.

[8] Study_GreenPhotonics_2020_final.pdf (photonics21.org)

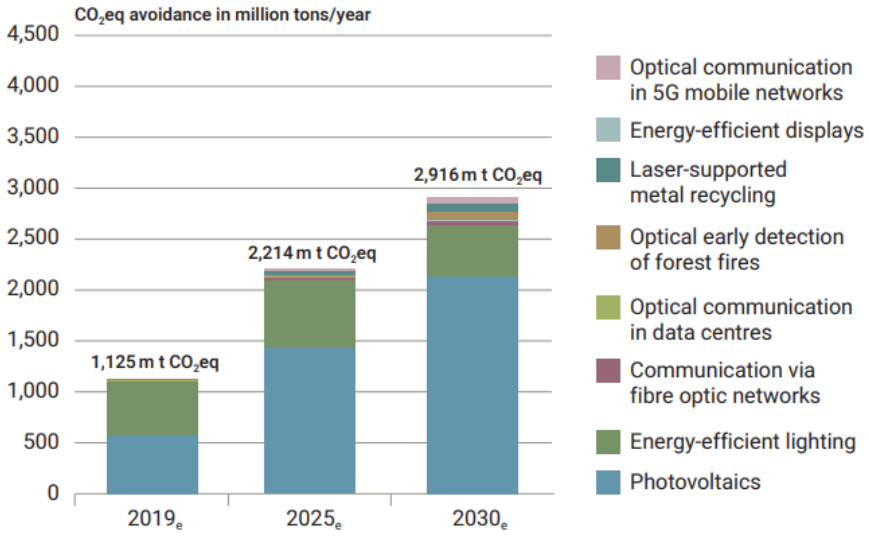

Figure 3-1 Indirect climate protection potential of photonics, based on selected examples.

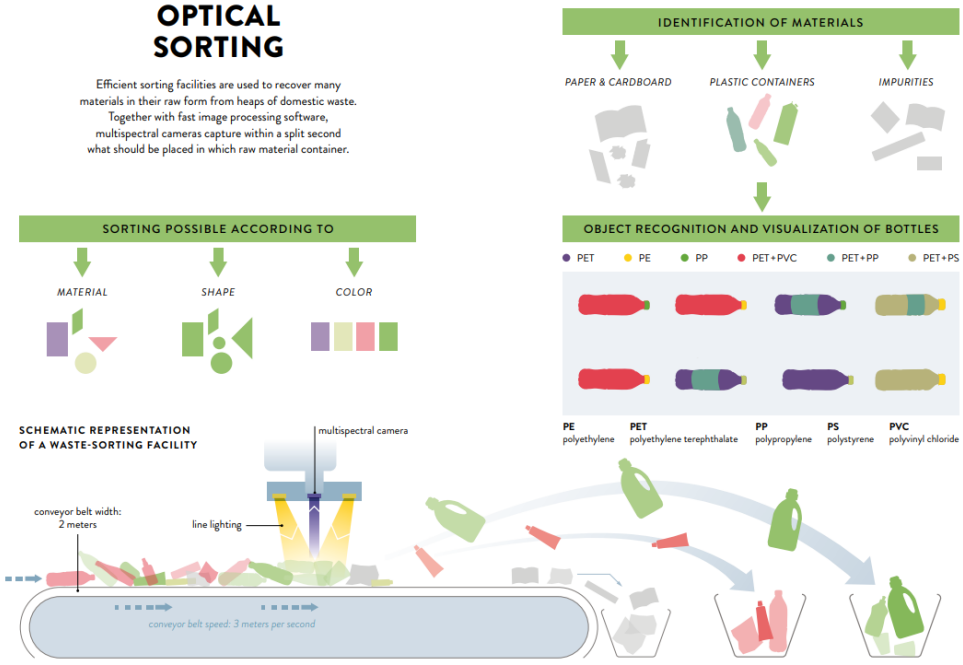

Figure 3-2 Optical sorting of recycling.

SPECTARIS members generally do not synthesise PFAS but use them in their products or production processes, with the majority of PFAS used by members relating to the polymeric forms of PFAS. Most PFAS emissions are understood by SPECTARIS to occur during the manufacture of PFAS substances and their use to make polymers and other chemicals. The potential environmental impact for the majority of SPECTARIS member products and components is likely to be at the end-of-life of the equipment.

Recycling is usually carried out only by licensed EU recyclers which are regulated by the Industrial Emissions Directive (2010/75/EU). At the high process temperatures used for metal recovery or the

treatment of medical waste, all PFAS should be completely destroyed so there would be negligible emissions at end of life[9]. Recent studies have been published that show that no harmful PFAS emissions occur with well-run incinerators.[10] A similar study identified that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment.[11]

There are certain applications where SPECTARIS members utilise PFAS as a monomeric substance, e.g. the use of refrigerants, lubricants, and processing aids, each of which is outlined in the following paragraphs.

SPECTARIS member equipment utilising refrigerants design the equipment such that the refrigeration fluid is contained within closed (sealed) systems with no intended release to the environment. The only times the refrigerant could potentially be released is during system failure. Prior to any maintenance activities, the refrigerant in the equipment is drained into collection containers for direct use or reclaim. If any of the refrigerant fluid is required to be managed as waste, the fluid is typically managed for destruction by incineration or thermal destruction by certified waste management facilities. It is important to understand that these fluorinated gases as well as maintenance processes are strictly regulated in the EU by Regulation (EU) No 517/2014.

Some lubricants require replenishment during the lifetime of the product but do not need to be replenished as often as other lubricants as they are designed to be long-lasting. As such the potential exposure for most lubricants are limited to product damage, or at end-of-life. Lubricants are commonly sent for incineration in specialised waste incineration facilities which utilise incineration temperatures and exhaust gas washers/scrubbers to prevent releases of hazardous substances into the atmosphere.

3.1.3 Spare Parts

Spare parts are essential for repair of devices already placed on the market and spare parts need to be readily available to ensure that the equipment can quickly be repaired, and the function returned to the equipment. If the restriction as proposed is adopted, 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. As such, those replacement parts that contain PFAS could not be supplied.

It is likely that in many applications there will not be a drop-in replacement for PFAS on a 1:1 basis due to different properties. Systems already placed on the market will therefore need to be redesigned to permit the use of PFAS-free spare parts. For one SPECTARIS member manufacturing medical devices they estimate that this could cost their business €35-50M, with the assumption that PFAS-free alternatives are technically suitable for all applications. It is therefore clear that 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-

[9] Two seconds at 1000°C should be enough to destroy PFAS, according to https://www.epa.gov/sites/default/files/2019-09/documents/technical_brief_pfas_incineration_ioaa_approved_final_july_2019.pdf. Most steel and non-ferrous smelters operate at much higher temperature.

[10] Aleksando, K., Gehrmann, H-J., Hauser, M., Matzing, H., Pigeon, D., Stapf, D., Wexler, M. (2019). Waste Incineration of Polytetrafluoroethylene (PTFE) to Evaluate Potential Formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in Flue Gas and Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, A. Krasimir et.al. Chemosphere 226 (2019) 898 – 906.

[11] Dr. Gehrmann, Hans-Joachim; Dr. Habil. Bologa, Andrei; Dr. Aleksandrov (2023) Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions

containing parts. For products such as microscopes a service life of over 25 years is not uncommon, so it is therefore important that at least this length of time is permitted after product or application specific derogations expire. If no spare parts can be supplied, where SPECTARIS member products support healthcare, EU hospital patients' health could be harmed when equipment that is needed cannot be repaired.

Unless such a consideration is incorporated, it could lead to the situation where previously a spare part could ensure the continued use of a piece of equipment, the equipment would be scrapped, and a completely new complete piece of equipment is procured. This option is of course only viable when a PFAS-free alternative has been implemented, and for situations where this is not the case, the function of the equipment would no longer be available.

3.1.4 Product Specific Impacts

The following are examples of product specific impacts, where if the restriction were to be enforced as currently proposed, this will introduce significant new human health and/or the environment considerations.

3.1.4.1 Analytical and Laboratory Equipment

Analytical and laboratory equipment plays a critical role in many critical end sectors such as materials testing, pharmaceutics, food testing, environmental monitoring for air and water. Its equipment is necessary for the control and enforcement of legal regulations such as the REACH, Restriction of Hazardous Substances (RoHS) in electrical equipment, drinking water guidelines, the safety of toys, and various environmental laws, to name a few. If there were no derogations, test houses would not be able to buy new equipment or repair malfunctioning products so that the testing to demonstrate compliance with these laws would no longer be able to be carried out. This would include the testing for PFAS e.g. in water. This is due to the consideration that, as yet, no PFAS-free potential alternative has been qualified in analytical and laboratory equipment, and in many applications as yet a potential alternative with suitable characteristics has not been identified.

Due to the difference in technical performance, the precision and accuracy of analytical and laboratory equipment would be affected if PFAS-free components were to be used. PFAS-free materials can leach into samples as they are less chemically resistant than PFAS. Due to the possibility of this contamination, multiple samples would need to be tested to reach the same result (testing with replicates) increasing the amount of waste associated with such testing. In addition to this, the sensitivity of the testing may decrease due to unavoidable contamination, which may lead to environmental contamination as restricted substance managed by such legislation may enter the environment.

In some applications, such as pipette tips, a significantly higher mechanical force would need to be used to dispense the liquid, which introduces additional safety hazards. The PFAS polymers provide a non-wettable surface to ensure the accuracy of measurement, so this, too, would be impacted.

Another such example is the potential switch to glass as the only potential viable substitute for some applications rather than polymer laboratory equipment. However, this too, introduces additional safety considerations as the injury from broken glass is possible, and as a consequence is conceivable that workplace injuries will increase. Also, occupational health and safety laws that protect workers would have to thoroughly be assessed to ensure that potential PFAS-free solutions are actually legally permitted. Any conflicting requirements such as an obligation to use PFAS-free alternatives on the one hand where, on the other, these are legally not permitted would have severe legal implications such as lawsuits and claims for damages.

Prior to the launch of a product to market, the product is safety-tested according to all relevant norms and standards, it is conceivable due to the introduction of risks associated with PFAS-free components, many products like centrifuges would not fulfil safety standards. As such the product would not be released to the market.

3.1.4.2 Refrigerants

Many technical and scientific applications that are essential for the wellbeing of people and society depend on bio-analytics and laboratory refrigeration equipment.

Fluorinated refrigerants are used in various bio-analytics and laboratory refrigeration equipment such as refrigeration systems, refrigerated centrifuges, process chillers, cryogenic freezers, constant temperature equipment, and customer specific cooling systems used for highly precise temperature control. Bioanalytics and laboratory refrigeration equipment is highly specialised and essential in many applications, of which a few are outlined below:

- Preserving biological samples - including vaccine, blood, plasma, and tissue storage as well as bone allograft.
- Separating whole blood for the purpose of transfusion.
- Sample preparation for clinical diagnostics.
- Pharmaceuticals, maintaining quality control in the pharmaceutical and food industry.
- Production and storage of chemical and biological agents.
- Safeguarding valuable research materials.
- E-mobility battery testing.
- Hydrogen fuelling.
- Manufacturing of semiconductors.
- Critical computer chips.

The highly specialised equipment is at imminent risk of being banned from the European market if no appropriate derogations are granted. The consequences for society and the internal market would be enormous – for some people life threatening: blood components for transfusion would no longer be produced, and vaccines, blood, plasma, and tissue no longer safely stored; there would be a dramatic loss in manufacturing capabilities of semiconductors, critical computer chips and pharmaceuticals.

Potential non-PFAS alternatives, such as propane and ethane are more volatile and in case of employee exposure poses a higher safety risk due to their flammability. As such they require increased fire protection and are not a like-for-like replacement for PFAS refrigerants. Refrigerated centrifuges, for example, are used to separate substances by rotation. The separation of substances causes extreme rotational energy which, in the event of a crash, can lead to an explosion of the refrigerant. Therefore, alternative natural refrigerants cannot be used without compromising safety. At the same time, high rotation generates extreme heat that needs to be cooled adequately to preserve a constant temperature control. Current applicable harmonized specific safety standards such as EN 61010-2-011, neither allow for alternatives such as R744 (CO_2) in high-pressure refrigeration systems nor permit the use of flammable refrigerants above 150g. To the best of SPECTARIS members knowledge there is no adequate harmonized and international accepted alternatives exist at this point that could be used

instead. It cannot be foreseen, whether an alternative high-performance refrigerant will be possible at all, since the possibilities are limited by the nature of thermodynamic systems.

In addition to this, the potential alternative of carbon dioxide at high-pressure has the risk of suffocation at high concentrations and a risk of injury if any of the substance escaped or any of the components failed. Therefore, these natural refrigerants are only potentially viable for a very limited number of very specific – and particularly only for new products. They cannot be incorporated into current products.

Equipment utilising such potential alternatives would require considerable design changes, including additional qualification requirements for flammable and high-pressure refrigerants. In order to avoid shortages of devices and the risk of a health crisis -it is essential that sufficient qualification time is permitted as outlined in the Technical Report[2] as well as a thorough assessment of the legal requirements for the use of PFAS-free alternatives is undertaken.

For some bio-analytics and laboratory refrigeration equipment, additional strict sector specific regulatory requirements such as the Medical Device Regulation (MDR (EU) 2017/745) and In-vitro Diagnostics Regulation (IVDR (EU) 2017/746) have to be fulfilled, which serve to protect patients and users. Long transition periods are absolutely essential. Not including time needed for aspects such as fundamental design changes and testing to ensure performance and safety requirements, will result in products not be able to be placed on the market. The mandatory certification process alone under these regulations may take up to 2 years and hinges on the availability third party conformity assessment bodies which have known capacity issues.

3.1.4.3 Lubricants

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.

Silicone oils may be considered by some as potential technical alternatives to PFAS-based lubricants in some applications which do not require low volatility or outgassing. However, silicone oil fumes are reported as irritating for the respiratory system and eyes and is toxic to aquatic life with long lasting effect (Aquatic Chronic 2, H411). There is also the possibility that silicone oils contain D4-, D5- and D6-ring siloxanes, which have been classified as substances of very high concern (SVHC) under the REACH Regulation and included in the Candidate List for Authorisation in June 2018 due to their Persistent, Bioaccumulative and Toxic (PBT) and/or very Persistent, very Bioaccumulative (vPvB) properties. Recently, the European Union has proposed to list D4, D5 and D6 in Annex B to the Stockholm Convention on Persistent Organic Pollutants.[12] As such, it can be considered that in the limited applications where SPECTARIS members may be able to utilise silicone as an alternative, this will either be classified as a regrettable substitution or not legally permitted.

In general, the quantity of lubricants in all SPECTARIS member systems is low. A lack of lubricants in the systems would trigger the need for much more frequent maintenance, the occurrence of unplanned downtime due to component failures and increased chemical usage of cleaning fluids and resultant waste. For example, an optometric device weighing over 30kg uses a PTFE-based lubricant in the sub-gram level without the need for any cleaning fluid. However, the system would require an entire redesign to permit the use of PFAS-free lubricants to encapsulate the optics to exclude lubricant contamination, which would require frequent maintenance and cleaning with specialist fluids. This also has the result of making the overall system bulkier and more complex due to the need to exclude the lubricants from

[12] Proposal to list D4 D5 and D6 in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants (europa.eu)

some parts of the device, which is therefore more likely to increase the production cost for such equipment.

In applications where low volatility and/or low outgassing are required there are currently no viable PFAS-free alternatives. Devices such as these include analytical and laboratory equipment which is used to undertake critical research and development, diagnostic testing, and environmental monitoring which, if they use less stable lubricants, can lead to contamination of the samples to be analysed and thus can thereby falsify or nullify research results.

3.1.4.4 Health Care

The absence of a derogation for medical equipment will affect products and components manufactured by SPECTARIS members in the following ways:

- A limited number of devices, such as specific diagnostic devices, the use of PFAS-free components will result in the significant drop in the durability of the devices such that the components become 'single-use', with some examples outlined in Section 3.1.1.
- The majority of medical devices will no longer be able to be marketed in the EU, as PFAS-free components do not offer the necessary technical and safety performance. With examples, discussed in the following sections.

Most medical devices cannot work without essential parts made of fluoropolymer materials. Usually, a combination of the unique properties of these materials is required and no other materials can fulfil these requirements.

For low friction parts like sealings and bushings, PFAS-free parts significantly reduce the lifetime/durability of parts and potentially result in the impaired functionality of the device. If no suitable alternatives can be found and qualified, many medical devices would have to be withdrawn from the market with a detrimental effect on patients and their well-being.

Considering the widespread and diverse use of PFAS in medical devices and their accessories it can be expected that without derogations many products and components would no longer be available on the EU market. As a consequence, many well-established, state-of-the-art surgical procedures could no longer be used and many diagnosis and/or therapy in many medical fields could not be carried out which will cause harm to EU patients.

SPECTARIS members have learnt from the impact of the relatively recent change from the Medical Device Directive transformation into the Medical Device Regulation (MDR) that companies when faced with large scale changes such as this, have to make difficult decisions on which products to prioritise and qualify. The decision is made usually based on an investment basis and as such products for special procedures, for example in children[13] or rare diseases, are the ones that often do not justify the additional effort from a financial perspective and are removed from the market. If a complete PFAS ban is placed on medical equipment, then companies will again face this decision, and this could result in essential products no longer being marketed in the EU. SPECTARIS members estimate that the impact of a complete PFAS ban will be 3 to 4 times that of the impact from MDR due to the widespread uses of PFAS and the concern over the availability of suitably qualified persons as outlined in Section 3.3.1. Of note: the Commission had put forward in January 2023 a proposal to amend the MDR that was approved by the European Parliament and Council in an expedited procedure in order to avoid shortages of

[13] Products specific to children can require multiple sizes to cover specific age/size ranges. As such, compared to the sales of adult equipment the number of products sold can be significantly lower.

devices and the risk of a health crisis.[14] The consequences of a PFAS ban without an appropriate derogation for medical devices would be manifold and counteract all efforts made to provide for the continued supply of safe medical devices and functioning of healthcare services.

3.1.4.4.1 Intensive Care Devices

Intensive care equipment such as ventilators, anaesthesia devices and neonatal incubators contain fluoropolymers parts such as tubes, hoses, washers, sealings and membranes. No other material provides sufficient long-term stability in contact with high concentrations of oxygen or anaesthetic gases and resistance against disinfectants, heat, and pressure. Gas sensors used in this kind of equipment contain PTFE membranes in concentrated acid electrolyte that must be extremely resistant and microporous at the same time. Fluoropolymer coatings of electrodes and particles in the electrolyte are necessary to control wettability and electric insulation in this harsh environment.

Figure 3-3 Example Intensive Care Device.

Without fluoropolymers, intensive care ventilators, anaesthesia devices and neonatal incubators would no longer be available. Equipment already in use at the hospitals would no longer work after a short period due to the absence of spare parts or consumables. In a pandemic event like COVID-19, thousands of patients would most likely die without ventilators. Live-saving surgeries would not be possible anymore without anaesthesia machines. Premature born babies would not survive due to the lack of neonatal incubators.

3.1.4.4.2 Endoscopic Instruments

Medical devices utilise PFAS in part due to its electrical resistance. Other materials would either result in parts failing the insulation tests or necessitate a massive increase in volume / geometry of the device. Endoscopic instruments would need approximately twice the diameter if PFAS could not be used. This means that some procedures could either no longer be performed at all or, as a minimum, lead to longer recovery time of the patients and/or higher incidence of wound infections. This would counteract the advantages of minimally invasive surgeries. For other devices such as electrical devices used in surgery this will not fulfil safety standards such as IEC 60601-2-2 for the application which would preclude its ability to be marketed as it would introduce a significant risk for both the patient and the surgeon. More

[14] See regulation (EU) 2023/607, Recital 5: "*In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. … The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements*."

than 10 million endoscopic or minimally invasive procedures per year, looking at German figures only, would be affected and no longer be able to be undertaken.

3.1.4.4.3 Implantable Medical Devices

PFAS-based haptics are currently the only technical viable solution for scleral fixation without suturing or gluing techniques. Haptics rely upon the material construction which contains PFAS to allow for cauterisation and the formation of the desired shape. Techniques relying upon suturing or gluing may lead to side effects for a portion of patients due to the complexity of the procedure, eventually leading to post operative complications.[15] The use of sutures is also associated with a high occurrence of suture breakage and degradation related complications.

PVDF-based material in the 3-piece intraocular lens (IOL) have additional benefits, because the PVDF-haptics present high flexibility, inertness to chemicals and ethylene oxide, temperature resistance (> 120°C) and biocompatibility. These unique properties enhance the stability of the IOL in the eye which allows the implantation of intraocular lenses even in patients with a weak or defective capsular bag of the eye. Accordingly, if PFAS-containing haptics are banned, this particular patient group cannot be adequately treated.

3.1.4.4.4 Rigid Gas Permeable (RGP) Contact Lenses

RGP lenses rely upon PFAS for their technical function which include up to 12-months wear time and are a separate and distinct product from disposable 1-day contact lenses which this report does not address. RGP contact lenses provide an important societal function, with up to 30% of citizens in European countries wearing contact lenses, of which some as RGP contact lens users.[16] It is estimated by SPECTARIS members that 400,000 EU citizens rely upon the unique functionality of RGP lenses, which without a derogation would no longer be able to provide unique visual correction for these users.

Currently there are no technical alternatives to PFAS in RGP lenses, with any potential alternative likely to be softer and less chemically resistant due to the absence of the strength of the C-F bond. This will have the result in a product with unsuitable technical characteristics such as the reduced durability of lens and faster agglomeration of film deposits like lipids, lipoproteins and bacteria leading to irritation and higher risks for inflammation.

Hydrophobic, softer, and more adhesive polymers are less biocompatible. This may lead to the development of specialised coatings, cleaning regimes, alternative polymers, or other solutions. However, as yet it is not known which or even if, any of these potential alternatives will be able to offer the necessary technical requirements. It is also important to note that if alternative polymers are developed utilising siloxane, that siloxane toxicity increases as their molecular size decreases[17]. In addition to this, cyclic and low molecular weight siloxane monomers[18] are extremely lipophilic and

[15] Complications can include corneal decompensation, intraocular lens tilt and decentration, secondary glaucoma, cystoid macular edema, vitreous hemorrhage, postoperative hypotony and transient corneal affects.

[16] Contact lens wearers in Europe in 2020 | Statista

[17] Mojsiewicz-Pieńkowska Krystyna, et al., Direct Human Contact with Siloxanes (Silicones) – Safety or Risk Part 1. Characteristics of Siloxanes (Silicones), Frontiers in Pharmacology, Volume 7, 2016, DOI 10.3389/fphar.2016.00132.

[18] A molecular weight of less than 500.

essentially dissolve cell membranes and cause cytotoxicity through release of the cell's contents.[19,20] As such a suitable length of time is required to investigate potential alternatives with suitable technical characteristics.

A derogation will allow for the development of suitable processing parameters of the lenses and clinical trials, which alone take 2 years and costs each manufacturer at least €1M (e.g. for orthokeratology lenses). Otherwise, the companies manufacturing such lenses, would expect to lose up to 30% of their sales or even go out of business.

Without a derogation RGP lenses which are the preferred solution in the following instances, would no longer be able to be supported:

- Refractive abnormalities in the paediatric population.[21]
- Non-surgical treatment of keratoconus (thinning and expansion of the cornea).[22]
- Non-surgical treatment to reshape the cornea for vision improvement (Ortho-Keratology).[23]
- Patients with strong corneal astigmatisms as soft lenses cannot be used for fittings, especially those with irregular astigmatisms such as scars and corneal injuries.[24]
- Management of myopia (progressive eye disorder which affects vision, quality of life and increases eye health risks across a person's lifetime).
- Patients after refractive surgery as soft lenses cannot be used.
- Advantages in presbyopia fitting (a refractive error limiting near sight) due to the changed fitting behavior of RGP compared to soft lenses.
- Patients which do not tolerate corneal contact lenses.[25]
- Patients which do not tolerate soft contact lenses due to "Dry Eye Symptoms", due to dry eyes or severe deposition problems.

[19] Daniela Flassbeck, Bettina Pfleiderer, Rainer Grümping, and Alfred V. Hirner, Analytical Chemistry 2001 73 (3), 606-611, DOI: 10.1021/ac000738z.

[20] Tri Manh Tran, Khalid O. Abualnaja, Alexandros G. Asimakopoulos, Adrian Covaci, Bondi Gevao, Boris Johnson-Restrepo, Taha A. Kumosani, Govindan Malarvannan, Tu Binh Minh, Hyo-Bang Moon, Haruhiko Nakata, Ravindra K. Sinha, Kurunthachalam Kannan, A survey of cyclic and linear siloxanes in indoor dust and their implications for human exposures in twelve countries, Environment International, Volume 78, 2015, Pages 39-44.

[21] Shaughnessy, Michael P. MD; Ellis, F. J. MD; Jeffery, Amy R. MD; Szczotka, Loretta OD, MS. Rigid Gas-Permeable Contact Lenses Are a Safe and Effective Means of Treating Refractive Abnormalities in the Pediatric Population. CLAO Journal 27(4):p 195-201, October 2001.

[22] Zhang XH, Li X. Effect of rigid gas permeable contact lens on keratoconus progression: a review. Int J Ophthalmol. 2020 Jul 18;13(7):1124-1131. doi: 10.18240/ijo.2020.07.17. PMID: 32685402; PMCID: PMC7321943.

[23] Mark A. Bullimore, Leah A. Johnson, Overnight orthokeratology, Contact Lens and Anterior Eye, Volume 43, Issue 4, 2020, Pages 322-332.

[24] Kompella, Viswanadh B. M.S.; Aasuri, Murali K. M.D.; Rao, Gullapalli N. M.D.. Management of Pellucid Marginal Corneal Degeneration with Rigid Gas Permeable Contact Lenses. CLAO Journal 28(3):p 140-145, July 2002.

[25] Ye, Ping O.D.; Sun, Amy; Weissman, Barry A. O.D., Ph.D.. Role of Mini-Scleral Gas-Permeable Lenses in the Treatment of Corneal Disorders. Eye & Contact Lens: Science & Clinical Practice 33(2):p 111-113, March 2007. | DOI: 10.1097/01.ICL.0000258593.20221.c6.

3.1.4.4.5 Ophthalmic and other lenses

Due to the technical characteristics of PFAS coatings which combine high water (>105°) and oil (>60°) contact angles among other attributes outlined in the Technical Report[2], there currently is no technical alternative to PFAS coatings for these applications. All PFAS-free alternatives have significantly reduced durability which will reduce the lens lifetimes considerably, due to the need for more frequent cleaning and a high likelihood of scratching the surface. SPECTARIS members estimate that PFAS-free alternative would have a lifetime of one third of a PFAS-lens. The warranty period and average use period of the lenses tends to be between 2-3 years for this lens type. With the exact use period depending on the customer.

Based on information from SPECTARIS members it is estimated that over 266 million lenses are sold in the EU per annum. The lens weight varies between products with specific lenses varying from around 9g to over 45g for heavy lenses, with the average lens weight calculated at 19.5g of which only a very small proportion of the lens is PFAS. As such, with the performance of such lenses decreasing by 66%, an additional 3335[26] tonnes of lenses will become waste per annum. Not considering that lenses are produced from semifinished product with an average weight of 50g.

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, driving during the day against low standing sun, or pedestrian or cyclists in the rain. It may increase the risk of accidents and related injuries that in the worst case may be fatal. For this reason, eye protection standards include a specific requirement for light scattering.

3.2 Economic Impacts

SPECTARIS members significantly contribute to the EU economy, with SPECTARIS companies with 20 or more employees having a combined turnover of €84.1 billion in 2022. Additional revenue is also generated by the numerous small to medium-sized enterprises which also underpin the sectors SPECTARIS members operate in. The turnover by sector is outlined in Figure 3-4.

[26] Number of lenses sold per annum x average weight of lens x decrease in performance of lens.

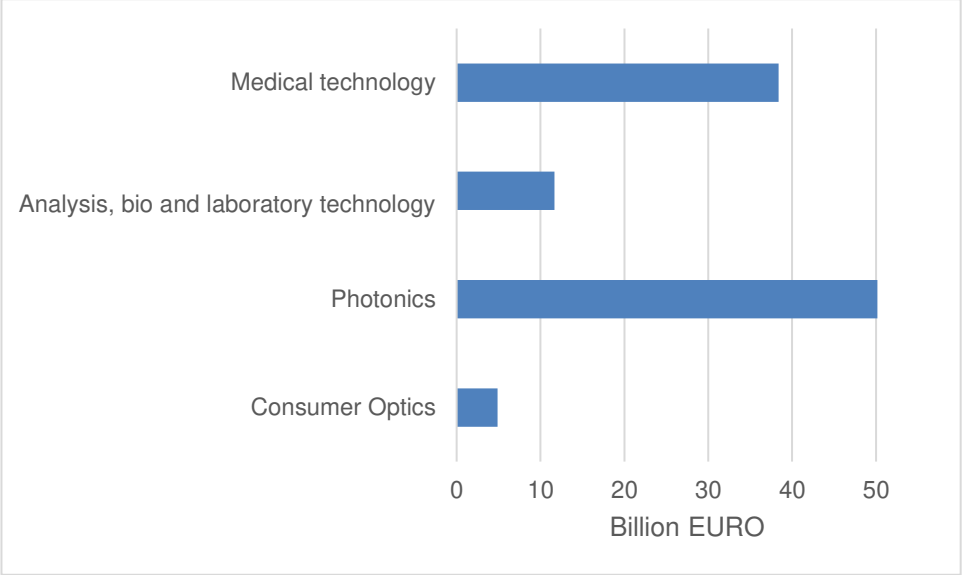

Figure 3-4 SPECTARIS member turnover by sector.[27]

If the relevant derogations are not granted, then over a third of SPECTARIS members surveyed would have an 80 to 100% loss of revenue due to the critical nature of PFAS to their product ranges. An additional 38% of members anticipate a 40 to 70% loss of revenue, as outlined in Figure 3-5. In both of these scenarios, a combined 72% of the membership, the loss of revenue is so significant that it is unlikely that the business will be able to operate and could result in a loss of turnover of €60.6 billion per annum if these businesses were no longer able to operate. This scenario is confirmed by members as potentially realistic: no company stated that there would be no expected losses (other than those members who could not estimate the impact) if no derogations were to be granted. All members stated they would be severely or moderately affected, as outlined in Figure 3-6.

There would also be wider economic impacts, including the far reaching and unpredictable knock-on effects on sectors and industries using SPECTARIS members' products. For example, the consequences of lithography optics that would no longer be able to be undertaken, would very quickly filter through to semiconductor equipment and manufacturing, into all industries whose products and/or processes depend on chips and digital technology. This would lead to significant short and long term production disruptions across industry, on a scale far larger than the COVID-19 related chip shortages and having a significant impact on the European Union's industrial base and competitive position.

[27] Source German Federal Statistical Office, SPECTARIS.

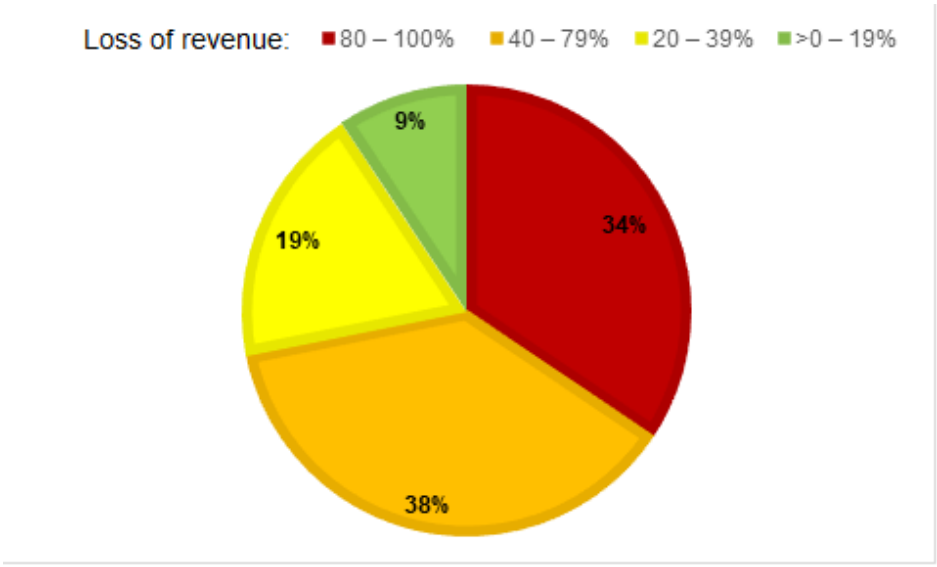

Figure 3-5 Loss of revenue from respondents were no derogations to be granted.

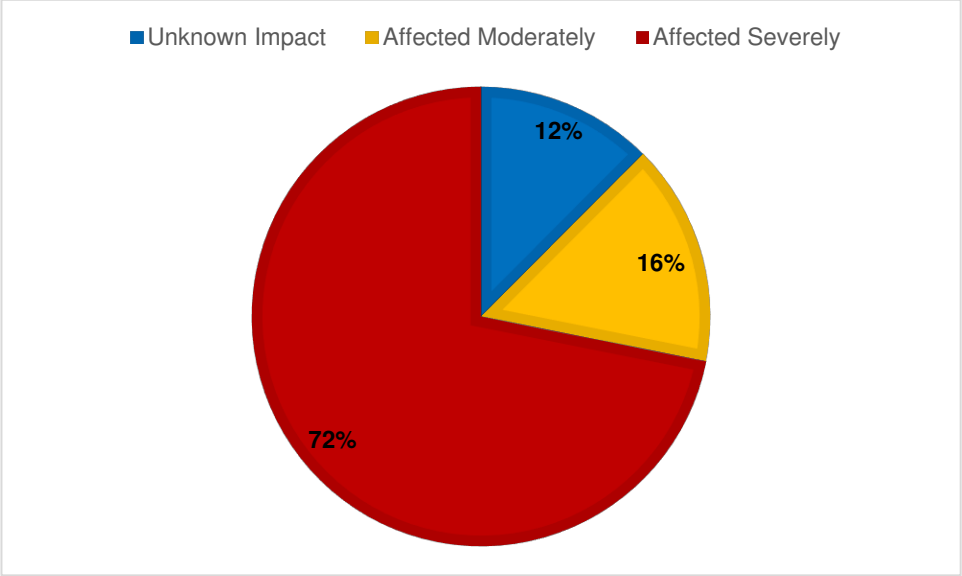

Figure 3-6 Market share impacted were no derogations to be granted.

3.2.1 Product Price Increases

Due to the considerable technical challenges identifying PFAS-free potential alternatives in SPECTARIS member products, components, and manufacturing processes, 90% SPECTARIS members expect to have to raise their product prices based on the critical assumption that a technically suitable alternative would be able to be identified. For most members this is due to the need for extensive redesign of their equipment resulting in significant qualification costs. As well as redesign leading to a more complex system design and/or an expected increase in material and manufacturing costs.

For example, the use of polytetrafluoroethylene (PTFE) in white light colour standards for spectroscopic products and measurements[28] would experience a significant increase in production costs resulting in 5-10% price increase being passed onto customers. This is based on the assumption that a PFAS-free alternative was indeed able to be identified.

For institutions such as research and development organisations and healthcare providers in EU Member States (i.e. hospitals and clinics), operating budgets are rarely increased due to legislative requirements imposed on equipment such as a PFASs restriction. Consequently, if prices were to increase, less new equipment would be able to be purchased and the benefits from new technology would be delayed. This in turn would result in the impact for healthcare products as the less effective treatment of patients leading to reduced quality of life and inferior outcomes. For research institutions this may result in the delay of new discoveries. It is therefore arguable that the pace of innovation in products will continue to slow as more resource is diverted from innovation to removal of PFAS from new and existing products, with no innovative product benefit. EU research institutions may also become less competitive compared with non-EU organisations who would be able to continue to obtain lower-priced equipment containing PFAS.

For laboratory equipment, some SPECTARIS members indicate that the costs associated with manufacturing equipment would increase by a factor of up to 10, with an associated level of impact to product prices. The exact price increase will be determined by the PFAS-free material, which as yet no technical alternatives are available. Complex analytical and laboratory equipment often requires substantial capital investment from purchasing companies, with indicative prices for equipment outlined in Table 3-1, and as such even a relatively small percentage price increase will have a significant impact on the ability for such devices to be purchased.

Table 3-1 Indicative costs of complex analytical and laboratory equipment.

Equipment	Indicative price (k€)	Function of equipment
Laboratory Microwave Systems	30	Sample digestions with highly concentrated acids in closed vessels at temperatures up to 300°C and 100 bar. Solvent sample extractions with organic solvents in closed vessels at temperatures up to 150°C and 20 bar. To allow for subsequent analysis of inorganic or organic.
Laboratory Reactor and pressure vessels	10- 100 depending on volume and configuration	Synthesize new substances or other items such as pharmaceuticals or to test materials at high temperatures and pressures with different reagents. Operation can be up to 300°C at 200 bar and often configured to specific customer requirements.
Ion Chromatography	120 (+installation and training)	Fully automatic determination of anions with sequential suppression and cations. Used for a variety of samples, from trace analysis to wastewater analysis.
Scanning Electron Microscope with additional Focused Ion Beam and associated equipment	1500	Develop new materials, understand, and tailor their physical and chemical properties. Explore applications examples from nanoscience, engineering, and energy materials. Prepare, image, and analyse samples in 2D and 3D on a nanometre scale.

[28] The use of which is supported by the proposed derogation 5t (Calibration and reference material of measurement instruments).

Such significant price increases will have a significant impact on SPECTARIS members ability to operate, with one SPECTARIS member stating without a derogation they would expect the market share they have established over 80 years to be reduced from 60% down to 10%. Competitors who manufacture outside of the EU will be able to continue to serve non-EU markets after a PFAS restriction enters force in the EU, but companies that manufacture in the EU will be prevented from producing PFAS-containing products so cannot sell to non-EU markets.

3.2.2 Cost of Substitution

SPECTARIS members utilise PFAS for their unique technical capability as outlined in the Technical Report[2]. Potential alternatives must be evaluated on a case-by-case basis considering technical, regulatory, as well as economic aspects. For the purposes of the assessment, it has been assumed that the necessary technical performance is able to be offered by the PFAS-free alternative. This is unlikely to be the case for all applications as PFAS substances in many applications do not have a known viable alternative or these are at a very early stage in their development. In some cases, substitution may prove to be impossible so that the only option will be to withdraw the product from sale in the EU.

Although the costs of alternative solutions are outlined in this section it is important to note that there are other factors to consider, such as the indications outlined in Section 3.1.1, that the lifetime of certain products is expected to be reduced.

Due to the highly technically demanding end applications SPECTARIS member products and processes are utilised in, the majority of the qualification requirements are technical in nature. The majority of responding SPECTARIS members state 90% of the cost associated with qualification are technical in nature with the following being an indicative list of qualification steps highlighted by SPECTARIS members:

- Research and development testing.
- Component qualification.
- Equipment Modification/Installation, including operational equipment validation.
- Implementation in serial production.
- CE Marking.
- Product specific requirements such as redesign, recertification cost for Notified Body approval and for some medical devices, also clinical evaluation.

It is very likely that, in particular the first three steps mentioned above will need to be repeated several times. In the experience of SPECTARIS companies, multiple changes and adjustments are required until a functional product based on a viable alternative can actually move to serial production.

The remaining effort, indicatively 10% for most respondents, relate to organisational costs such as training, the update of documentation, marketing, and permit fees.

The following section outlines indicative costs expected, per member company associated with the qualification of PFAS-free potential alternatives. The costs are calculated on a company basis as the cost to qualify the first in an equipment series, which will be the most costly and time consuming part of the development. Similar equipment within the same manufacturer may benefit from previous qualification testing, however, significant costs will still be incurred.

3.2.2.1 Medical Technologies

The qualification of PFAS-free alternatives for medical devices will have a significant impact on the availability of life saving and disease alleviating devices. The devices must meet highly demanding technical and clinical requirements. It is essential that sufficient time is permitted to allow the transition wherever possible to PFAS-free alternatives. Due to the varying technical requirements of medical devices produced by SPECTARIS members, as well as the uncertainty that PFAS-free alternatives are technically suitable in many applications, estimating a cost for substitution is highly challenging. Based on the assumption that PFAS-free alternatives would be viable, SPECTARIS members have provided indicative costs for the substitution of PFAS in a few of the many devices they manufacture, as outlined in Table 3-2. The list only reflects a small number of devices, but it can be seen that the higher the complexity of the device and the more numerous the PFAS used within a system the higher the indicative costs. The overall financial impact to a business depends on the types of devices which they manufacture, as well as the number of devices affected by the PFAS restriction. However, as outlined in Figure 3-5 the majority of SPECTARIS members expect this to be highly impactful.

For one SPECTARIS member, the combined costs of substitution for their portfolio of medical devices exceeds €1 000 million based on the assumption that PFAS-free alternatives can offer the necessary technical and clinical performance. For a SPECTARIS member this exceeds the annual revenue by a factor of 10, which indicates the severity of the impact to their business.

Table 3-2 Indicative costs expected for the substitution of PFAS for the portfolio of medical device example in a single company.

Product /Component/ Process Type	Cost of substitution (€M) per company If alternative is viable
Venting of rigid bottles for gravity infusion (particle filter) for ophthalmic surgery	0.75
Particle filtering and water stop in ophthalmic devices	0.75
Teflon-coated seal in a safety-relevant pressure relief valve in a ventilator	0.75
Lubricant of optometric devices to safely and correctly position optical lenses	1
Scleral implants & bio-material strip	2-3
Palpebral suspension strip	2-3
Grease in a surgical tools	3-4
Retinal Surgery liquids (class IIa medical device)	4-5
Coating applied to handles of bipolar forceps used in brain surgery	5
Intraocular lenses with special haptic	5-7
Bipolar clamps, trays, monopolar electrodes, and bipolar electrodes	10-12
Stranded wire, disk sealing, washers, insulating bush, connectors, headrests for patients	75 – 150
Resectoscopes including RF- electrodes, bipolar surgical RF- Instruments and monopolar and bipolar surgical RF- instruments	100

3.2.2.2 Analytical and Laboratory Equipment

SPECTARIS members are manufacturers of analytical and laboratory equipment which support a wide range of functions as outlined in the Technical Report. It is important to note that this is not limited to the testing of biological or medical samples as outlined in derogation 5n as the equipment is used in applications which are much broader in scope.

A significant proportion of analytical and laboratory equipment utilises PFAS due to its high chemical resistance, and as yet it is not known if an alternative will be able to offer the necessary technical performance. Based on the assumption that an alternative is available, SPECTARIS members expect the redesign of the following components in various uses within a companies portfolio of products, would

have the following indicative costs for each company that requires these applications (**note that some companies will need more than one of these**):

- Hard chrome plating used in systems such as scanning electron microscopes ~€1M.
- Mechanic slide bearings for chemically aggressive environments ~€10-30M.
- Redesign of O-rings, seals and sealing materials in contact with chemically aggressive solutions ~€20-40M.
- Tubing and its connectors ~€50-70M.
- High precision housing parts, vessels, stirrers, measuring cells that are in contact with chemically aggressive solutions ~€50-70M.

Analytical and laboratory equipment also utilises PFAS in vacuum systems due to low outgassing properties, high chemical resistance, combined with its UV/IR resistance which is important for some applications. Based on the assumption that there is a viable alternative, some SPECTARIS members expect that the implementation of PFAS-free alternatives could have an indicative cost of €3-5.4M **per device**. If lubricants are used in such devices the technical qualification costs for this alone can range from €2-5M depending on the end application and presuming there is a viable technical alternative.

Some SPECTARIS members calculated the estimated costs for their portfolio of products to implement PFAS-free alternatives, based on the assumption that if viable alternatives were available. Estimating that for example, the update of 600 types of pumps would cost up to €150M per company, with the cost significantly impacted by a companies' portfolio size and specific testing requirements.

The qualification costs expected for specific laboratory equipment, based on the assumption that there are technically viable alternatives available, is outlined in Table 3-3. As stated with the medical devices, the list only reflects a small number of types of devices, but it can be seen that the higher the complexity of the device and the more numerous the PFAS used within a system the higher the estimated costs. For example, in complex machinery the qualification of PFAS-free cable insulation and their plugs by itself can cost €1.2M. The overall financial impact to a business depends on the types of devices which they manufacture, as well as the number of devices affected by the PFAS restriction.

Table 3-3 Indicative cost expected for the substitution of PFAS in example analytical and laboratory equipment per type of device.

Product /Component/ Process Type	Cost of substitution (€M) per company If alternative is viable
Autoclave	0.2
Immersion oils in microscopy	0.3-0.5
Gas chromatography inlets and seal	1
Centrifuge	1
PCR Cyclers	1
Thermomixers	1
CO_2 Incubators and Lab Shakers	1
Burette	4
Vacuum pump and vacuum equipment	5.4
Dispenser	12
Manual liquid handling	7-15
UV/IR lamps	15
Ion-exchange membranes, Gas-exchange membranes, and tubing	20 - 40

Product /Component/ Process Type	Cost of substitution (€M) per company If alternative is viable
Microscopy used as analytical and laboratory testing equipment, and in the semiconductor industry.	Up to 50
Automated liquid handling systems	Up to 70

It should be noted that all of the above costs are estimates for the redesign of existing equipment. The qualification costs for spare parts for products which rely upon PFAS and already placed on the market are not included and would be in addition to those listed above. Due to the significant amount the testing spare parts would require, it is expected that these costs would also be significant.

Refrigerants in laboratory equipment

For refrigerants in laboratory equipment, such as cooling thermostats, circulation and process thermostats, circulation chillers, based on the assumption that there are viable PFAS-free alternatives, SPECTARIS members estimate that the cost of qualification will be €2.5-5M for each company.

Calibration and reference material of measurement instruments

PTFE is used in industrial spectrometer systems as white light colour standard for spectroscopic products and measurements in reflection as a reference material and so-called integrating sphere. The highly specific combination of technical attributes does not as yet have a technically viable alternative, but when one is identified the indicative costs are considerable and range from ~€5-10M for one company due to the considerable amount of testing which would be required. In addition, equipment modifications are likely required due to the use of a PFAS-free alternative.

3.2.2.3 Rigid Gas Permeable Contact Lenses, ophthalmic lenses, and other lenses

Rigid gas permeable (RGP) contact lenses provide essential capability for certain conditions as outlined in Section 3.1.4.4.4 and currently do not have a suitable PFAS-free alternative identified. When a suitable potential alternative is available, it is expected that the development costs associated will be between €6-8M, with 70% of the costs associated with the clinical testing of the products.

PFAS are used in a number of different ways in ophthalmic and other lenses, which even when a technically viable alternative is identified will take considerable investment, as outlined in Table 3-4.

Table 3-4 Indicative costs expected for the substitution of ophthalmic, and other lenses.

Product /Component/ Process Type	Cost of substitution (€M) If alternative is viable
Accessories for ophthalmic lenses (antifog sprays)	0.5
Wipes for ophthalmic lens	0.5 - 2
Sun protection and safety lenses with no vision correcting requirements (plano lenses)	Up to 5
Easy-to-clean coating on ophthalmic lenses	2-15

3.2.2.4 Other Product Specific Costs

As highlighted in the Technical Report[2] SPECTARIS member products support a number of different end sectors and products.

SPECTARIS members are critical suppliers to the semiconductor manufacturing process and related equipment (derogation 5ee) in which as yet there are no technical alternatives to PFAS which offer the necessary technical requirements. Given the enormous complexity of both the manufacturing processes and the actual equipment for semiconductor manufacturing, respective cost assessments for the development and qualification of PFAS-free potential alternatives for lithography optics and their manufacturing are not yet available. Given that substituting PFAS would entail at least a partial, if not complete redesign of some manufacturing tools, these costs are expected to be very significant. While it is currently not yet possible to give a precise estimate, it is expected by SPECTARIS members that these costs will be several hundred million euros per manufacturing tool.

A number of SPECTARIS members utilise lasers in their equipment in sectors such as medical and aesthetic equipment as well as laboratory equipment, and as such rely upon PFAS coated fibre-optic cables. Fibre optic cable allow dozens of data signals coupled into one single optical fiber and be separated again at the receiver's end. The signals can be very finely distinguished based on their wavelength (spectral colour), polarization, and phase as shown in Figure 3-7. There are a number of technical challenges currently limiting the use of PFAS-free potential alternatives, however if potential alternatives were identified there will be a significant level of testing and development required which SPECTARIS members estimate would cost over €17M per company.

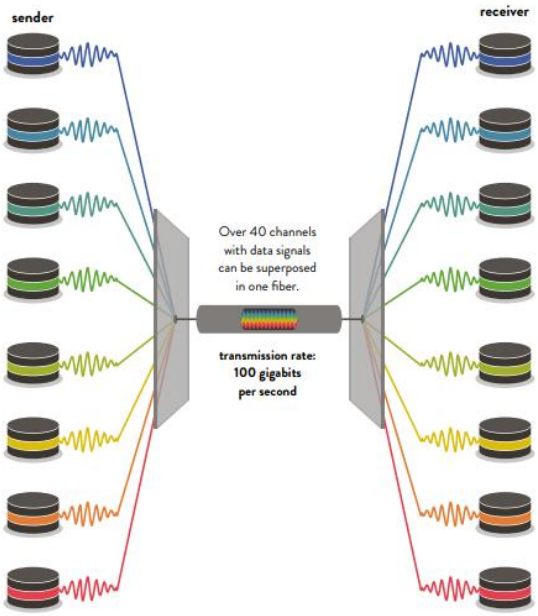

Figure 3-7 Fibre Optic cable allowing undisturbed superposition.

3.2.3 Cost of Reporting

Beyond the costs associated with identifying PFAS-free potential alternatives, due to the reporting requirements embedded in the restriction proposal, there will be additional costs for SPECTARIS members. SPECTARIS members who were able to estimate indicative costs of reporting, indicate that the reporting requirements under part 7 of the restriction to cost on average €490k per company per annum, in part due to the significant amount of testing some companies are anticipating to obtain PFAS information. There are also significant costs associated with the creation of suitable systems within companies, including the software implementation, training, and monitoring and on-going data support for the information gathering.

For the reporting obligations under part 8 of the restriction, requiring site specific management plans for fluoropolymers and perfluoroethers, the initial plan was expected by the majority respondents to be more expensive than the updates of the plan with the site-specific management plan on average costing €66k per annum, and the update less than half of this. The estimations of the costs were broadly correlated to number of sites each SPECTARIS member expected to be required to report on. Details on the estimations provided by SPECTARIS members are outlined in Table 3-5.

Table 3-5 Indicative expected cost of reporting as estimated by SPECTARIS members.[29]

	Indicative expected costs		
	Annual reporting (€k)	Site Plan (€k)	Site plan review (€k)
Average indicative value	491	66	35
Lowest indicative value	0.8	1	0.8
Highest indicative value	4000	300	150

Although these costs have some similarities to the reporting requirements proposed, this does not address the consideration that there will be significant challenges in gathering the necessary information. For example, identity and quantity of the substances placed on the market will only be able to be reported for the substances known. Considering that although significant effort is being expended by SPECTARIS members to identify many PFAS substances, not all substances can yet 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, as outlined further in Section 3.3.2.

For the purposes of the assessment of cost it has been assumed that a similar online tool to SCIP shall be formed to allow for the reporting of these requirements. However, as yet there has been no indication as to how the information is planned to be gathered and as such the indicative costs of reporting outlined above could be much higher.

3.3 Social Impacts

Currently PFAS are key enablers of many SPECTARIS member products, components, and manufacturing processes, and as such without a derogation there will be significant impacts on the employment of SPECTARIS members, its entire value chain, and the ability to undertake new innovations.

3.3.1 Employment Effects

In Germany alone, there are 2 700 companies representing the SPECTARIS sectors. These companies have a combined workforce of 341 000 and 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. Due to the highly technical nature of SPECTARIS member products, a significant number of additional jobs in the EU have been created. For examples, 30 000 additional jobs have been created just in photonics industry between 2015 and 2019 with employment growth at 2.1% per year.[6] Considering that 72% of the responding SPECTARIS membership state they will experience significant revenue loss, 237 600

[29] Based on estimates from reporting for the Substances of Concern In articles as such or in complex objects (Products) (SCIP) established under the Waste Framework Directive, REACH Regulation and the Classification, Labelling and Packaging (CLP) Regulation.

jobs may be potentially lost in the EU. The total number is likely to be significantly higher than this as this does not account for associated jobs in the supply chain or contractors which would increase the number significantly.

If PFAS were to be restricted with no derogations, as stated above the vast majority of SPECTARIS members would no longer be able to market their products and components until they have qualified a potential alternative. The majority of SPECTARIS members would need to hire additional staff to be able to address such a challenging technical requirement, as outlined in Figure 3-8. The average number of additional staff expected by SPECTARIS members is 10.2 full time equivalents (FTE), however this ranges from 1 to 55 FTEs in a single company. These additional employees would need a high degree of training and experience to be able to progress the qualification of PFAS-free alternatives in SPECTARIS member products. These jobs are highly productive, as the value added per employee in the medical device sector is estimated to reach around €184,000 per employee[4], indicating the importance of SPECTARIS members economic and societal impact in Europe, however recruitment of sufficient suitably qualified employees may prove to be extremely difficult and this will delay substitution.

There is already industry recognition that in many of the sectors, such as healthcare and semiconductors, that there is a significant skills shortage and finding appropriately experienced and qualified staff is challenging. This concern is reflected in SPECTARIS member companies with 72% of respondents stating that it is either unlikely or highly unlikely that they would be able to hire the necessary additional staff to be able to adequately resource the qualification of PFAS-free potential alternatives. It is therefore expected that research and development would have to be halted, impacting the innovations of SPECTARIS member products, as outlined in Section 3.3.3.

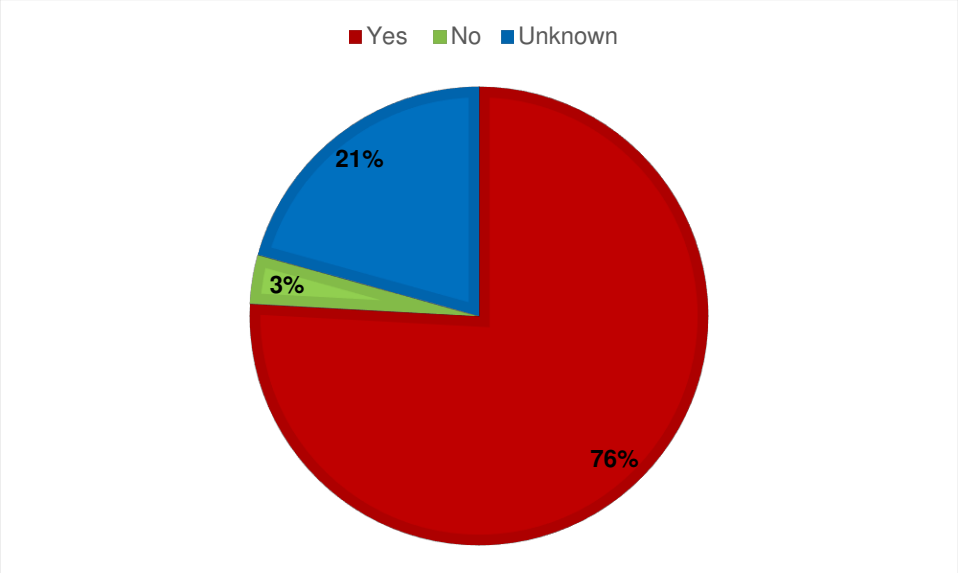

Figure 3-8 Requirement for additional staff to qualify PFAS-free potential alternatives.

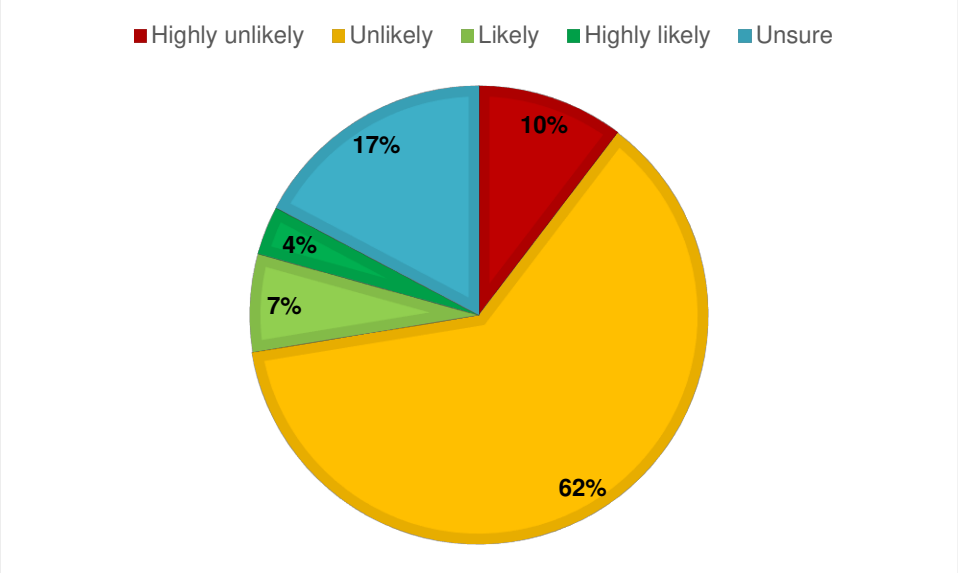

Figure 3-9 Likelihood of finding suitably qualified personnel for PFAS-free qualification.

3.3.2 Supply Chain Effects

The supply chain of SPECTARIS members is highly complex, with a medium sized SPECTARIS member purchasing hundreds of PFAS polymer containing articles from approximately 40 different suppliers. The complexity of the supply chain introduces significant challenges in identifying all PFAS contained within SPECTARIS member products, components and manufacturing processes as such information is only identified as a result of in-depth collaboration which needs to span many levels of the supply chain.

However, due to the unprecedented large scope, the non-hazardous profiles of most of the fluoropolymers, and the low thresholds of the proposed restriction, the current disclosure requirements

via safety data sheets and SVHC declaration are insufficient to build the basis for identification and evaluation of all relevant PFAS uses. Today the presence of PFAS need not, in general, be declared to a manufacturer. This is especially challenging when seeking potential alternatives across the global market, as it can be difficult to ensure that the potential alternatives being researched are not themselves PFAS. It will take significant effort to work through global supply chains to discover precisely what substance is being used in many cases, and further time to establish what could be used as a potential alternative. Many respondents cannot quantify how long this will take. Making this additionally challenging across the global supply chain is lack of consistency in defining PFAS in all jurisdictions and the unique addition of fluoropolymers under the EU definition.

It may be the case that essential PFAS uses will be identified late in the process. Due to these factors, it is essential that a simple formal process for new derogations to be sought after the publication of the restriction is included in the restriction process. It is vital that this be considered as part of the forthcoming REACH revision which will follow, mostly a parallel timeline with this restriction.

In addition, many SPECTARIS members may need to qualify new suppliers. This is particularly common in medical device manufacturers due to the highly regulated nature of the products and can add up to 6 months-3 years of additional time to the qualification timeframes, especially where the products are placed on the global market.

Notwithstanding these challenges there is also the interplaying consideration that many suppliers are making the choice to exit the PFAS market, such as 3M[30], prior to the regulatory obligations. For SPECTARIS members this poses a significant challenge as the qualification timeframes for their products, components and manufacturing processes are lengthy, as outlined in the Technical Report[2]. As such this could cause considerable interruption of the supply of affected products and processes, or the delay of other equipment as resource is diverted to the qualification of potential alternatives on affected items.

3.3.3 Innovation

SPECTARIS members are characterised by their products' innovation, which supports a multitude of critical end sectors, including the following examples:

- Medical technology has the second highest number of patent applications per year[31] and the medical devices sector being one of the most innovative in the EU with companies investing 9% of annual sales volume on new product development.[32]
- Analytical and 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.
- Photonics supports many critical applications, such as optical fibre sensors for safety and security in innovative aerospace and submarine applications allowing structural monitoring of items such as

[30] 3M to Exit PFAS Manufacturing by the End of 2025 - Dec 20, 2022

[31] the-european-medical-technology-industry-in-figures-2022.pdf (medtecheurope.org)

[32] spectaris_the_medtech_industry_flyer_web.pdf

carbon fibre panels and the landing gear in aircraft[33] and landslide early warning.[34] Innovation in the sector is crucial with German companies investing 9% of annual sales volume on new product development.[35]

Investments in research and development (R&D) can have a very long-term horizon with timeframes from 3 to 12 years depending on the product in question. This is in contrast to the fast pace of EU chemical policy as it regularly introduces new requirements which can impact on R&D programmes and increase the risk for long term investment, therefore reducing the capability of companies to develop and bring to the market new medical technologies that offer benefits for patients.

Any restriction entering into force during the R&D phase can force companies to stop the project and it could be expected that the product will be delayed by an additional 3-7+ years to undertake the necessary qualification, clinical investigation, and registrations. The exact timeframe is dependent on the product in question but there is the general trend that the closer to the end of the R&D, the worse this impact is. In a similar way, any restriction entering into force during the sales of a model, can halt the sales as redesigning existing models is usually not an option.

Due to the large scale of the PFAS restriction impact, SPECTARIS members expect that the innovations relating to product development will be delayed or postponed. This is due to the need for very significant investment and skilled workforce dedicated to PFAS substitution which will require the diversion of resources towards activities to replace substances in devices, both in terms of funding and allocation of limited-availability and suitably qualified personnel to work on such devices.

Through the transition from the MDD to MDR which increased the regulatory requirements for medical device manufacturers, the focus of medical device manufacturers has been diverted from new innovative products to managing the regulatory control. As a consequence, as reported by MedTech Europe[36], over 50% of medical device manufacturers are planning portfolio reductions, with a third of companies planning on the discontinuation of products. An even higher level of impact is expected with the PFAS restriction if no derogation is granted due to the widespread and diverse uses of PFAS.

4 SUMMARY OF FINDINGS

SPECTARIS members support a number of different sectors including medical technology, consumer optics, analytical, bio and laboratory technology as well as photonics. These sectors contribute significantly to the EU, with around 2700 companies with 20 or more employees each, and having a combined turnover of €84.1 billion in 2022.

The importance of PFAS for many SPECTARIS members cannot be overstated, with over half of responding members stating that 80-100% of their products, components, and manufacturing processes rely directly upon the functionality that PFAS provides. In many applications, PFAS are used in light of many other already existing regulations (e.g. fire protection, efficiency requirements, safety standards). PFAS provide a unique set of properties, without which SPECTARIS member products, components,

[33] Sensors | Free Full-Text | Innovative Photonic Sensors for Safety and Security, Part II: Aerospace and Submarine Applications (mdpi.com)

[34] Sensors | Free Full-Text | Innovative Photonic Sensors for Safety and Security, Part III: Environment, Agriculture and Soil Monitoring (mdpi.com).

[35] SPECTARIS_Photonik_Talking_Cards_Web.pdf

[36] MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, July 2022, medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf (medtecheurope.org)

and manufacturing processes will no longer function, as all currently known potential alternatives are unable to offer the necessary technical performance. The impact to SPECTARIS members revenue were the requested derogations not to be permitted, would be significant with 72% of the responding membership, stating the loss of revenue is so significant that it is unlikely that the business will be able to operate. This has the potential to result in in a loss of turnover of €60.6 billion per annum based on the assumption that these businesses were no longer able to operate.

A differentiated approach to the restriction is essential, with derogations permitting the suitable time for the qualification of potential alternatives, as outlined in the Technical Report[2].

For a substitution to be successful, it must meet all of the following criteria: the necessary functionality and performance is preserved, and the potential substitute must meet regulatory requirements. The use of the potential substitute substance must therefore be tested and permitted on the basis of legal and normative requirements. In addition to this the potential substitute must provide a benefit for the environment and health. It must not present higher risks than the substance to be replaced otherwise it may be considered a regrettable substitution. There are some potential alternatives, such as silicone based lubricants, that may be able to be used in a limited number of applications. But they would introduce other health hazards, and as such may be a regrettable substitution. Silicone based lubricants may also not be legally permitted soon, as the substances are proposed to be included in the Stockholm Convention. The importance of meeting other regulatory requirements is again highlighted when considering alternatives to F-gases, as alternatives may not be permitted by law for some equipment due to the implications on safety.

The forced substitution of PFAS-free products, components, and production processes will, for most part, directly impact the products ability to perform its intended function. For a limited number of applications, with examples listed in Section 3.1.1, the use of PFAS-free components will have a significant impact on a product's lifetime, with products which previously lasted up to 10 years lasting less than a day. As such, the use of PFAS-free components cannot be considered as alternatives based on environmental considerations.

Based on the assumption that at some point there will be technically viable alternatives available, 90% of SPECTARIS members expect to raise their product prices due to the need for extensive testing and redesign of their equipment. Institutions such as research and development organisations, and healthcare providers have limited budgets and as such the benefits from new technology would be delayed. This in turn would result in the impact for healthcare products with the less effective treatment of patients leading to reduced quality of life and inferior outcomes. For research institutions this may result in the delay of new discoveries. For other SPECTARIS members, due to the nature of some sectors, such price rises will result in a competitive disadvantage that has the potential to cause production to move outside of the EU (as outlined in Section 3.3.1) or the business to no longer continue.

Beyond the costs associated with identifying PFAS-free potential alternatives, due to the reporting requirements embedded in the restriction proposal, there will be additional costs for SPECTARIS members. SPECTARIS members estimate that the reporting requirements under part 7 of the restriction to cost on average €490k per company per annum. For the reporting obligations under part 8 of the restriction (site specific management plans) on average are expected to have an indicative cost of ~€66k, and ~€30k for the annual update. In estimating the values, a number of assumptions had to be made regarding the information submission process, however the major limitation will be the identification of all PFAS in SPECTARIS member products which poses a significant challenge.

SPECTARIS members have tried to estimate the costs of substitution, based on the assumption that technical alternatives are available for their applications in Section 3.2.2. The costs of substitution are highly challenging to estimate due to the varying technical requirements produced by SPECTARIS

members, as well as the uncertainty that PFAS-free alternatives are technically suitable. The estimations only reflect a few of the many devices that SPECTARIS members' manufacture. It can be seen that the higher the complexity of the device and the more numerous the PFAS used within a system the higher the estimated costs. The overall financial impact to a business depends on the types of devices which they manufacture, as well as the number of devices affected by the PFAS restriction. However, as outlined in Figure 3-5 the majority of SPECTARIS members expect this to be highly impactful. For one SPECTARIS member, the combined costs of substitution for their medical devices exceeds €1 billion based on the assumption that PFAS-free potential alternatives can offer the necessary technical performance. For this SPECTARIS member this exceeds the annual revenue by a factor of 10, which indicates the severity of the impact to their business.

If PFAS were to be restricted with no derogations, the vast majority of SPECTARIS members would no longer be able to market their products and components until they have qualified an alternative. In order for potential alternatives to be qualified SPECTARIS members would need to hire additional staff with average number of additional staff expected by SPECTARIS members is 10.2 FTE. These additional employees would need a high degree of training and experience to be able to progress the qualification of PFAS-free potential alternatives in SPECTARIS member products. Considering that in many of the sectors, there is a significant skills shortage and finding appropriately experienced and qualified staff is challenging. It is therefore estimated that the pace of innovation in products will continue to slow as more resource is diverted from innovation to removal of PFAS from products, with either no innovative product benefit or potentially a loss of performance depending on the impact of the substitute substance or technology on the product.

The proposed PFAS restriction has an unprecedented large scope and SPECTARIS members and their supply chain are still gathering information on all of the PFAS uses as PFAS, in particular fluoropolymers of low concern, are not generally required to be declared to manufactures. Although the timeline for the completion of this cannot be estimated, it is essential that sufficient time is permitted and if other PFAS uses are identified later on in the process there is facility to request other derogations if technically necessary.

It is therefore essential that the derogations as outlined in the Technical Report[2] are granted due to the unique properties PFAS currently bring to SPECTARIS member components, products, and manufacturing processes. Without which broad societal goals such as the EU Green Deal or European Chips Act, cannot be achieved.

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