POSITION

SPECTARIS position on the blanket ban of per- and polyfluoroalkyl substances (PFAS)

PFAS ban must not become a high-tech ban

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SPECTARIS is the German industry association for optics, photonics, analytical and medical technology based in Berlin. The association represents 400 predominantly medium-sized German companies. The consumer optics (ophthalmic optics), photonics, medical technology and analytical, bio and laboratory technology sectors achieved a total turnover of over 84 billion euros in 2022 and employ around 342,000 people.

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1. General / Background

Over the past three years, the REACH authorities of Germany, the Netherlands, Denmark, Sweden and Norway have been investigating the applications, in which per- and polyfluoroalkyl substances (PFAS) are used, and the risks to humans and the environment from their use. According to the latest estimates, the PFAS group comprises more than 10,000 different substances. In January 2023, the five countries submitted a comprehensive proposal for a restriction on the manufacture, placing on the market and use of PFAS to the European Chemicals Agency (ECHA), thus initiating a restriction procedure under REACH. This is not a "regular" EU legislative procedure, which allows political positioning of the Commission, the Council and the Parliament in trilogue negotiations, but "secondary legislation" under the REACH Regulation. The Council and the Parliament are only formally involved at the end of the procedure. Their right of objection is thus very limited.

The aim of the comprehensive restriction is to ban the production and use of all PFASs as far as possible - including the placing on the market of products containing PFAS in the EU. Temporary derogations may be granted for selected products and uses for which no alternatives exist for the time being. For the first time, the authorities plan a broad blanket restriction of an entire group of substances with more than 10,000 different individual substances. Contrary to Article 69 (1) of the REACH Regulation, the broad restriction is thus independent of the proven unacceptable risk of each individual substance to human health or the environment. It is intended to prevent "regrettable substitution" by substances not covered by the restriction - i.e. a substitution that could turn out to be no less dangerous in retrospect. The justification for the blanket substance group ban is based on the main concern that all PFAS are persistent, i.e. they are not degraded in nature. Supporting concerns relate to bioaccumulation, mobility, long range transport potential and toxicological effects of some individual PFAS substances. The present restriction proposal includes a few and very specific derogations, which, however, still have to stand up to detailed examination and approval. In addition, there are general, time unlimited exemptions for the use of PFASs as active substances in plant protection products, biocidal products (e.g. disinfectants) or medicinal products. Of note: medicinal – or: pharmaceutical - products may not be confounded with medical devices and in vitro diagnostic medical devices. Currently there is no general exemption for the use of PFAS in medical devices and in vitro diagnostic medical devices.

2. Evaluation of the German Industry Association SPECTARIS

SPECTARIS supports the goal of the “Chemicals Strategy for Sustainability” that aims to better protect citizens and the environment from harmful chemicals, and boost innovation by promoting the use of safer and more sustainable chemicals. Europe would do well to take the lead on PFASs and innovate to replace them wherever possible. Within the framework of sustainable chemicals regulation, substances that pose unmanageable risks due to their properties and use profile should be restricted or regulated on the basis of scientific assessments, especially in regards to consumer products. However, SPECTARIS strictly rejects the broad regulation of entire substance groups regardless of their proven risk. Such restrictive regulation would cause irreparable damage to Europe, its citizens and its industry, in particular, as there is no such comprehensive restriction of the PFAS substance group outside the EU. The fact that a sub-legislative binding act can cause severe distortions in society and industry must be urgently taken into account by the political decision-makers in the EU and its national member states.

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PFASs have a very wide range of applications. They are found in everyday consumer products such as cosmetics, rain coats and pan coatings. But they also play a major role in industrial processes und uses. High-performance materials containing PFAS are politically doomed for exactly the technical property for which they are needed and predominantly irreplaceable: their durability and resistance even in essential applications, industrial high-tech products and production processes. Thus, large areas of semiconductor production, photonics, analytical, bio- and laboratory technology, ophthalmic optics or medical technology are directly endangered by the broad PFAS ban - not only the products themselves, but also the production processes required for their manufacture. It is incomprehensible why the "essential use" concept demanded by the EU Commission itself was not also applied to such essential areas of application in the PFAS restriction procedure. The Essential Use concept aims to ensure that chemicals are only allowed "when their use is necessary for health, safety or the functioning of society".[1] Medicinal products for humans and animals as well as plant protection products are largely exempted, although these examples, in particular, involve a high level of release to the environment. However, in the case of the industrial, non-exempted application areas, a partitioning of material cycles is often already given or more likely to be achieved.

For a regulation of substances to be sustainable a differentiated approach is required. It must be urgently considered whether a PFAS substance or its use poses an uncontrollable risk to the environment or human health, whether there is any environmental exposure at all, and whether suitable alternatives exist. Alternatives must be researched and tested to determine whether they can be used in a functionally equivalent manner. In addition, they must be assessed and permitted for their use in light of many other, already existing regulations (e.g. fire protection, efficiency requirements, safety standards) in order to prevent conflicting regulation. The examination of alternatives with regard to these mandatory criteria has not been done systematically in the present draft restriction. If no specific risk assessment is carried out, urgently needed chemicals will no longer be available on the market in the future and innovative future technologies cannot be developed. This would have a massive impact on Europe as an economic area and its innovative capacity. Moreover, environmental and climate protection goals of the EU Green Deal as well as the goals outlined in the European Chips Act cannot be achieved.

Ultimately, and with a view to essential technological fields of the future, a blanket PFAS ban would undermine efforts of the EU and Germany towards strategic autonomy.

[1] https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0003.02/DOC_1&format=PDF

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3. Current PFAS proposal would have drastic effects on the products and applications of the SPECTARIS high-tech industries

PFAS are needed for many high-tech applications. Three examples are described in more detail at the end of this positioning paper. PFAS are also indispensable for many existential areas of life. A list of specific derogations can, therefore, neither cover nor anticipate all existential uses. In many cases, products and solutions for existential areas of life are developed and manufactured by the SPECTARIS sectors of photonics, medical technology, ophthalmic optics (as medical products) and analytical, bio and laboratory technology.

The current restriction proposal would also ban essential industrial applications - apart from a few time limited derogations. It lacks information to which extent such applications will no longer be available in the usual required technical quality, will become less safe or will no longer be available at all. Moreover, it does not address the opportunities that these high-performance materials offer for social and technological progress. This prevents a differentiated debate on the pros and cons of such a broad PFAS restriction. On the contrary, a comprehensive ban on PFAS would have the following negative effects on citizens, patients and the European economy:

Discontinuation of numerous products for essential, vital applications due to:

- Lack of broader derogations,
- too short transitional periods for the envisaged derogations, because alternative substances[2] cannot be used at present or in the foreseeable future,
- a non-holistic view of existing supply chains. Any specific derogation becomes obsolete if either required raw material or components may no longer be manufactured and are no longer available[3], or materials or intermediate products needed are not included in the derogation[4],
- migrating manufacturing processes (e.g. semiconductors, vacuum chambers), as PFAS may no longer be used as production or auxiliary materials (e.g. lubricants, seals) and
- reduced competitiveness due to the PFAS supply shortage and thus rising prices.

Furthermore, and in the long term:

- Loss of value creation, jobs and innovativion capacity,
- migration of companies abroad or increase in import quotas from non-EU countries and
- increased dependencies and decimation of own strategic autonomy.

[2] According to the periodic table, fluorine achieves the highest "electronegativity" of all elements with a value of 3.98, which describes its unique position and may explain why there are no obvious substitutes.
[3] The industrial group 3M has already announced that it will cease production of PFAS. If other companies follow suit, the supply chains for numerous products of the SPECTARIS industries will break away.
[4] Exemptions for fluoropolymers are provided, but not for fluorinated polymerisation aids, which are indispensable for the production of certain fluoropolymers.

4. Urgent demands and proposals

Regarding the restriction proposal, SPECTARIS urges that the methodology be fundamentally revised as well as significant changes and additions be made:

A) Methodology

- The PFAS restriction procedure must be based on the regulatory principles of the REACH Regulation, which is designed to assess and regulate substance-specific uncontrollable risks and not a general hazard characteristic or material property such as persistence.[5] In the future, too, it must be possible to use hazardous substances if they are used safely and if they do not pose an uncontrollable risk. Therefore, a comprehensive blanket ban on PFASs as a whole must be abandoned, which in many cases includes PFASs only because of their persistent property.
- In principle, permission for the use of products should go along with the permission of their manufacturing in the EU.

B) Recommended changes

- In line with the idea of the "essential use" concept, broader derogations must be created for essential areas of life as well as high-tech and central industrial applications, e.g. for medical devices - not only for pharmaceuticals or plant protection products. Furthermore, the use of PFAS-containing components for industrial plants and facilities as well as intermediate products and auxiliary materials must be comprehensively exempted.
- In addition, due to the sheer quantity of indispensable PFAS for these applications, broader derogations should be defined on the basis of suitable substance groups. An indefinite derogation for fluoropolymers and fluoroelastomers should be considered.
- Special product derogations are useless if raw materials, components or processes needed for the manufacturing of the products are no longer available. All derogations must therefore be considered holistically and include the entire supply chain. This must be clearly and legally enshrined in the legal text of the restriction.
- In order to establish legal certainty, especially for downstream users, the identity of the respective PFAS substances should be clearly and unambiguously identifiable by means of CAS, EINECS and/or EU numbers.
- It is not transparent on which basis and how the evaluation of alternatives is carried out by the authorities. The existence of alternative substances may only be used as justification for a specific ban if these substances are not restricted by other technical regulations for the intended use. These technical regulations have to be systematically investigated by ECHA. The alternatives should be able to replace the PFAS-based solution 1-to-1 in terms of form, suitability and function. This includes, for example, safety-relevant aspects, as well as those related to energy consumption or product and service life.

[5] Article 69 of REACH specifies a substance-based approach, (§69, 2): "The Agency [ECHA] shall assess ... whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled."

- The consultation period for identifying affected PFAS applications as well as the transition periods need to be significantly extended, as the collection of solid data as well as the development of alternatives takes much longer than estimated by ECHA.[6]
- The PFAS restriction proposal must provide for a revision of transition peirods after an overall review of the monitoring data.
- The PFAS restriction proposal must also provide for a quick and straightforward procedure that allows for the timely inclusion of further derogations.
- To be sustainable and economical, time unlimited derogations, or at least significant long transition periods, are needed for the placing on the market of spare parts, wearing parts and used parts.
- Concrete, practicable and EU-wide provisions for enforcement should apply in order to avoid a massive distortion of competition.

5. Three examples from the SPECTARIS industries

The following examples show how a PFAS substance ban affects essential applications and thus massively endangers technological sovereignty and security of supply in the EU. They are representatives of a large number of applications for which exemptions could be sought. Neither today nor after the six-month ECHA consultation period it is certain,

- whether every PFAS use within the supply chains can be identified,
- whether the information submitted to justify a derogation is actually accepted in the absence of transparent evidence criteria,
- whether potential alternatives can be used in a legally secure and technically and qualitatively adequate manner, and
- whether, in the absence of PFAS-based raw materials, intermediates or outward migration of manufacturing, the products will continue to be available despite any derogation.

(1) Example medical technology

Medical technology companies in Europe employed more than 600,000 people in about 66,000 companies (including small businesses) in 2019, with an industry turnover of €107 billion. Medical devices have a very wide range of variation from adhesive plasters to magnetic resonance imaging scanners. An estimated 500,000 different medical devices are used in clinics, doctors' practices and by other healthcare providers such as physiotherapists, opticians and hearing aid acousticians, as well as by patients themselves.

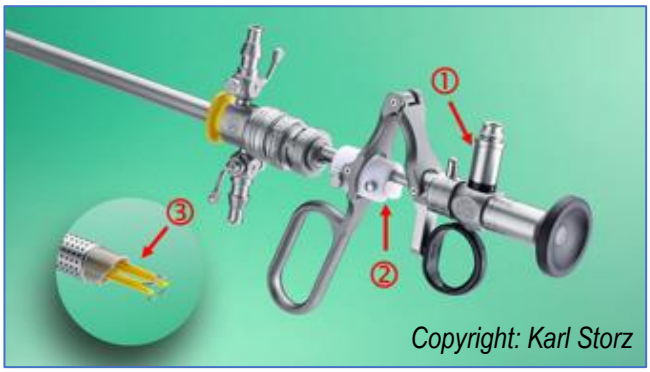
The European Medical Device Regulation (MDR) and the in vitro diagnostic medical devices regulation (IVDR) came into force in 2017. The medical technology sector is among the most strictly regulated industry sectors. Medical devices that come into physical contact with the human body have to prove biocompatibility according to DIN EN ISO 10993. Carcinogenic, mutagenic and reprotoxic substances (CMR) as well as substances with endocrine disrupting properties may only be present in medical devices in very small quantities of up to a maximum of 0.1 % by mass. Only if there are no alternative materials and, in addition, the benefits of the

[6] Under REACH, there is no complete material declaration and not all substances are identified on safety data sheets. Due to complex supply chains, this leads to considerable difficulties in identifying substances used, especially for downstream users.

substances used outweigh the risks for users and patients according to strictly specified criteria, may these substances be used above the specified limit.

Endoscopy and minimally invasive surgery are important sub-areas of diagnostic and interventional medicine. There, fluoropolymers from the large PFAS group such as PTFE, PVDF, PFA, ETFE, ECTFE, FEP or fluoroelastomers such as FKM are predominantly used. It was only with these materials that the medical sub-field became as successful as it is today. The situations in which PFASs are used are extremely diverse and include all electronic medical devices. The example of a resectoscope illustrates that also opto-mechanical systems depend heavily on PFAS use. Such a system can be used to remove tissue in the urinary bladder, prostate or uterus in an optically controlled manner.

- The bipolar resectoscope can no longer be used without PFAS: (1) slidable ETFE sheathing of the glass fibres for illumination, to be able to be drawn into the narrow cavity (2) PTFE bulk material for electrical insulation and to minimise friction of the movable slide; due to the fact that adhesive and sliding friction are equally low with PTFE, the adhesive-sliding effect is prevented, which is crucial for fine-motor precision cutting, (3) PTFE sleeves for electrical insulation at 20kV/m breakdown strength. For all external components, the dirt-repellent property, the chemical resistance and generally the temperature resistance up to over 140°C are also relevant.



According to the restriction proposal, such a central medical device and large parts of medical technology are fully affected by the substance ban after an 18-month transition period. An exemplary video shows why substitute materials are unsuitable.[7] The consequence is that such medical devices would be discontinued from the market and patients could no longer be treated with them.

In 2021, according to the Federal Statistical Office[8], there were approximately 60 million operations and treatment measures carried out in German hospitals, not including cases in doctors' practices. It can be roughly assumed that one third to one half of these involve the use of PFAS-relevant products.

Minimally invasive procedures in particular avoid large (abdominal) incisions and have significantly reduced the post-operative length of stay in hospital. A growing proportion of interventions can be performed on an outpatient or day-case basis. This is not possible without PFAS.

[7] https://www.youtube.com/watch?v=ADdZYo4SLBw
[8] https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/Krankenhaeuser/Publikationen/Downloads-Krankenhaeuser/operationen-prozeduren-5231401217014.pdf?__blob=publicationFile ; 15.8 million operations, 14.6 million non-surgical therapeutic measures, 10 million diagnostic measures, 6 million supplementary measures, 13.8 million diagnostic imaging procedures

(2) Example semiconductor manifacturing technology

Computer chips would be hit hard by a PFAS ban. 80% of all computer chips produced worldwide, in particular 100% of the most advanced and powerful chips, are manufactured using ZEISS lithography optics.

Optical photolithography (*hereinafter "lithography"*) is the critical production step in the manufacturing of microchips. It is used to create the nanometre structures that form the transistors in the chip. Lithography optics is therefore one of the key technologies in the field of semiconductor production, in which Germany even has a unique selling point for the latest optical technology worldwide.

This new extreme ultraviolet (EUV) technology was awarded the "Future Prize of the German Federal President" in 2020. It enables the computer applications of the next decade such as autonomous driving, 5G or artificial intelligence. Even with the current standard technology with 193nm or 248nm wavelengths, without which, for example, no modern mobile phone would be possible, Germany has an 80 % market share in lithography systems and is thus far ahead of Japanese competitors. Corresponding optics are manufactured in Oberkochen, Wetzlar and Jena, for example.

The special optics required for the lithography systems weigh up to ten tonnes. They consist of up to 100,000 parts and must be manufactured with a precision that is unique in the world. In addition to this precision, extreme cleanliness is also required; less than a billionth of a gram of contamination in the wrong place destroys the function of the entire system. The combination of UV light, precision and this cleanliness makes it necessary to use materials made of PFAS at various points in the lithography system, for example as sealing material, damping element, insulation and lubricant.

Conventional materials and plastics, e.g. based on pure hydrocarbons or silicones, are much less resistant to UV light and decompose in a short time under the influence of UV radiation. In addition, they outgas chemical substances (contamination) that deposit on the optics and negatively affect the system in its optical function with regard to the required imaging quality in such a way that the system is no longer usable for chip production.

A short-term PFAS ban in Europe will mean that lithography systems can no longer be manufactured in Europe. This will have three serious consequences:

- Since ZEISS, together with its international production partners and a strong German value chain, is the only supplier of the future-proof EUV technology, Europe will lose these market leaders. In addition, the advancement of computer chips and applications based on them will come to a standstill in Europe and worldwide. Directly, about 25,000 high-tech jobs are at risk.
- This will further exacerbate the already existing global shortage of computer chips.
- Also, other standard lithography systems can no longer be manufactured in Europe and, as a result of a lack of spare parts, can no longer be operated in the medium term. This will result in a complete migration of chip manufacturing and the necessary production technology from Europe to regions

without a PFAS ban, especially the Far East. The "European Chips Act" will thus become obsolete, although it was intended to regain Europe's sovereignty in chip production. With a PFAS ban, major investments planned by well-known semiconductor manufacturers may also be called into question, as they would not be allowed to purchase the lithography systems needed for high-end chip production in Europe.

Manufacturing process for semiconductors

A large part of semiconductor production is based on silicon, which has already largely migrated to Asia. Currently, Europe is trying with great effort to reduce its dependence on China and is massively promoting the semiconductor industry. The demands on such manufacturing are enormous and beyond human imagination. In addition to lithography, there is a whole series of other production steps in which PFASs are also used. In compound semiconductors which are used to build lasers, LEDs or fast electronics, crystal structures are created by growth in which every atomic layer counts. In other steps, the smallest structures of the semiconductor are etched away by gases containing PFAS. The areas that are not to be etched are protected with PFAS-containing photoresists. The processes take place under ultra-high vacuum in an atmosphere with few residual molecules - comparable to conditions on the moon. In such an environment, neither a seal nor a lubricant may outgas.

If it were at all possible to replace PFAS in the process, one would practically have to start from scratch as hundreds of set screws in the process would have to be changed and adjusted at the same time. This alone would leave Europe without a chance in competition with the rest of the world. Semiconductors are the core for fast 5G / 6G mobile communications, for sensors in autonomous driving, for energy-saving lighting, for defence systems, for digitalisation and many more areas. Unlike hairspray and pizza boxes, the material cycles in the semiconductor industry are closed. Hazardous substances are disposed of professionally.

A blanket PFAS ban would prevent the re-emergence of a European semiconductor industry and promote non-European competition.

(3) Example Chemical analytics

Chemical analytics answers questions about substance identities and substance concentrations. Therefore, it plays a variety of roles in an industrial society. In fact, chemical analytics is irreplaceable for all value chains. Without analytics there are no statements on the composition of substances or products, there is no quality control, no monitoring and no safety control of defective or contaminated products, e.g. in material analytics, quality assurance or damage analysis as an accompanying science for industrial developments and manufacturing. Each and every single industrial product as a whole or in parts, is accompanied by methods of chemical analysis in its development, production and/or distribution. Chemical analytics comprises essentially three technology fields: chromatography, spectroscopy and sensor technology. In addition, there is robotics and sample preparation that is relevant for all fields. These fields of technology have universal significance for a multitude of applications.

The use of fluoropolymers (FKM, FFKM and PTFE) in gas-tight seals for chromatography, especially gas chromatography is essential. Here, sometimes harsh conditions prevail, temperatures of up to 300°C, high pressures or high vacuum. At the same time, chemical resistance and extreme purity are required. Gas chromatography is used to determine volatile or vaporisable compounds. It is often coupled with mass spectrometry, a universal technique for the determination of molecules. This technique must work in high vacuum, often under elevated temperatures, which is also where these seals are used. In addition, there are extreme demands regarding the purity of seals.

Without the availability of sealings containing FKM, FFKM and PTFE, gas chromatography with mass spectrometry (GC-MS) is not conceivable. Substitute materials are currently not known. Without gas chromatography, many food monitoring controls, for example, are technically unavailable. These not only relate to the composition of e.g. flavourings, fats and oils in food, but also to the identification of residues such as pesticides and other contaminants in exactly these foods. In addition, GC-MS is also used in clinical-chemical laboratory diagnostics for, among other things, low-molecular tumour markers or in the analysis of warfare agents or in questions of bioterrorism. Gas chromatography is a very sensitive method for the analysis of substance mixtures and, in combination with a mass spectrometer, is able to detect very small amounts of substances down to the concentration range of picograms/l. This is why GC-MS is used in laboratory diagnostics. Therefore, GC-MS is still considered the reference method in environmental analysis and forensic analysis. Substance group-based PFAS exemptions are urgently needed here.