SARTORIUS

ECHA Consultation Contribution to PFAS Restriction Proposal
Submitted, 05.09.2023

Analysis of alternatives and socio-economic analysis
Follow-up to contribution 4075, part 7 (submitted 10.05.2023)

Sartorius would like to present first results of an ongoing SEA analysis as a follow-up to contribution 4075 (part 7, submitted 10.05.2023).
Sartorius is a leading international technology provider and partner for the biopharma, pharmaceutical, laboratory and life science industry.
The Sartorius product portfolio comprises equipment and technology for Pharma and Biopharma production, cell culture media & technology, fluid handling & management, process filtration, medical devices as well as Lab systems & Services with focus on Life Science Industry. Our products and technology solutions are essential for our customers to develop and produce drugs and vaccines safely, timely and economically (see consultation contribution 4075).

Sartorius acknowledges the concerns raised regarding potential adverse effects of PFAS on human health and the environment and is committed to support efforts to minimize and mitigate the use of these and to actively work on identifying alternatives where possible.

The analysis of the business impact in case of a PFAS restriction will not be finished before the end of the consultation period in September. Identifying the usage of PFAS in all process steps of our manufacturing as well as in the supply chain is challenging and not necessarily obvious for our supplier base and their suppliers. Especially, the identification of the PFAS usage in raw materials, processing of materials and plastic parts/components will require additional time & detailing. According to the OECD, PFAS polymers are classified to be non-hazardous substances and are therefore usually not specified by the suppliers in detail.

"Missing uses" in PFAS restriction proposal (Question 6)

1. **We have identified that our target markets, the Pharma, Biopharma and Life Science Industry are a "missing use" in the current restriction proposal.**
   These industries are not listed in Table A.1 of Annex A and Table 8 and 9 of the PFAS restriction proposal, which summarize PFAS applications. Hence, PFAS use for this industry and the impact of PFAS restriction on our products and our target industry, requirements and regulations valid for this industry are not considered in the restriction proposal.
   Our target industry has described the situation under the proposed conditions of PFAS restriction itself, e.g., see consultation contributions: EFPIA (C4455), BioPhorum (C4313), BAH e.V. (C5578).
   The Pharma and Biopharma industry has a very high responsibility for human health – producing lifesaving medication - and the effectiveness of drugs and therefore, is highly regulated and has very high quality and validation requirements for process control as well as for the purity and function of materials & components. PFAS polymers are commonly used - especially in the complete Biopharma manufacturing processes and for final sterilization of Injectables for the Pharma & Biopharma industry. Suitable material alternatives must be developed, qualified, commercially available and finally approved for use in the Pharma and Biopharma industry. Even if material alternatives were available, any change (material and process) in biopharma and pharma production processes is connected with a high risk for the final drug product and the quality & regulatory status of

the production process and the product. Any material or process change is only possible after comprehensive resource- and cost consuming validation activities for both, the product manufacturer and the product user, which can take easily more than 20 years depending on the workload of the impacted regulatory bodies e. g. EMA, FDA, which need to approve such changes before implementation.

Pharma and Biopharma industry depend on our equipment and manufacturing technology to produce drugs and vaccines. PFAS-polymer based materials, parts and components are an essential part of the production technology and of our products (see consultation contribution 4075). The material selection is the result of long-term development and experience gathered from the application. Materials have proven themselves in practice and are approved for application. Substitution, if at all possible, will be a time- and cost-consuming activity and depending on approval by regulatory institutions.
Unlimited exemptions for the use of PFAS polymers in Pharma, Biopharma and Life Science Industry and the complete supply chain are required to assure access to medicines in Europe produced in Europe.
As the recent pandemic has shown, an interruption of the international supply chain results in shortage of important & live saving drugs. Therefore, the European Commission has initiated a "structured dialogue on the security of medicines supply" from 17th of October 2022 (DG Health & Food safety) to strengthen the resilience of pharmaceutical supply chains and ensure the security of supply of medicines, without compromising the affordability of medicines.

2. **Production technologies, mechanical and chemical engineering and supply chains are also not considered in the PFAS restriction proposal, which is a further "missing use" aspect.**
Many manufacturing technologies of essential components of our products (drug product contact materials) used by Sartorius depend on fluoropolymers, especially in the fields of membrane production and plastics processing. Production technology/ equipment/ machinery/ technical infrastructure contain PFAS-polymer based components and machine parts, e.g. sealings, gaskets, plastic parts and sliding components for machinery and vessels, tubes & tube connectors and valves, pumps and stirrers. Furthermore, PFAS based lubricants are used and non-sticking surface protection is needed for plastics processing and welding processes (see consultation contribution 4075).
PFAS containing parts and components in our production technology allow efficient production and are relevant for plant safety, protection of workers against hazardous substances and emission control. PFAS containing parts and components are part of certified machinery and production technology, which is approved by authorities. The manufacturing technology is subject to stringent change management requirements. Therefore, a one-to-one material exchange to PFAS-free parts and components is not possible.
As a consequence, even PFAS-free products cannot be produced under the conditions of the proposed PFAS restriction.
Production technology, e. g. for membrane production, cannot be bought as a standardized, ready-to-use plant on the market. It must be engineered according to user requirements considering technology-, safety- and regulatory standards. Usually, different companies are involved in the construction of a production plant and material and component development is the work of many industrial and development partners. **PFAS substitution for machinery and production plants, if technically feasible, is an unsolvable task for a single company.**

Capital expenditures for new production plants are in the double-digit million area and higher. In the last five years, Sartorius has invested hundreds of millions of Euros in new production plants in Europe, which usually have a production time of 30 years and more, which are at risk of remaining operational under the proposed PFAS restriction.
A further important aspect is also the availability of spare parts for maintenance and repair of existing production plants.
The situation of mechanical and plant engineering under the conditions of the proposed PFAS restriction is described in detail by many industry associations, e.g. see consultation contributions of VDMA, https://www.vdma.org/documents/34570/4612817/PFAS_Positionspapier_korr_2023-06-2023.pdf/a2fcdeab-ada7-b16d-b5f5-ae0552b0cdcf?t=1689599857052; Memo (vdma.org) 23.05.2023), BDI (Publikation (bdi.eu); https://bdi.eu/publikation/news/pfas-beschraenkung-bewertung-beschraenkungsvorschlag) and VCI Nord (C4503).

Answers must be provided to our and other industries how to deal with manufacturing technologies and mechanical & plant engineering under the conditions of PFAS restriction.

Conclusions and requirements (Question 7 and 8)

The PFAS Restriction proposal has impact on the following aspects of the Sartorius business:

- **Impact on a considerable part of Sartorius products** representing 20-25% of annual sales (2022 total annual sales revenue: 4,17 Mrd. Euro), especially air filters and venting filters, filters for lab filtration and further products, i.e., consumables and systems for separation, fluid management and cell culture technologies (tubes, sterile connectors and disconnectors, filters) as well as lab products. The analysis is not finished yet (*Status July 2023)* and is limited to PFAS containing products. Further impact due to products produced by PFAS based manufacturing technologies is not considered yet. First estimations point into the direction of minimum 60-70% of annual sales which would be affected by a restriction of PFAS based manufacturing technologies.
- **Impact on raw materials, plastic components and production aids:** PFAS polymers, especially PTFE, PVDF and fluoroelastomers/ FKM are an essential material basis for our products, e.g: foils/films, nonwovens and membranes; PFAS based plastic components, gaskets & sealing materials (Kalrez O'rings), tubes, valves, connectors/ disconnectors (see consultation contribution 4075).
  Only materials and product parts & components, which are approved for application in food and pharma industry can be used.
  First suppliers have announced discontinuation of PFAS based materials, which may result in an interruption of supply chains for these materials.
  Furthermore, delivery disturbances or discontinuations must be considered for PFAS-free materials, which are produced by PFAS based manufacturing technologies.
- **Impact on production processes.** Fluoropolymers and elastomers are used/ are indispensable part of various machine components in production technology, especially for membrane production and plastics processing (see answer to question 6, part 2 and consultation contribution 4075). That means, even PFAS-free products (e.g., membranes) cannot be produced under the proposed conditions of PFAS restriction.

Furthermore, we need to state that:

a) Our products are essential for manufacturing processes of Pharma and Biopharma industry. With our Lab systems & Services we support the biopharma industry in the

early phases of drug development. Having same materials from the early phases of the development eases product transfers and reduces validation efforts.
Drugs and vaccines cannot be developed and produced without our technology solutions and may leave patients without access to lifesaving treatments under the proposed PFAS restrictions.

b) Only suitable and commercially available PFAS-free materials and components, which are qualified, approved and validated for the intended uses in products and production processes can be considered to be technically and economically feasible alternatives in the described industrial context. Those alternatives are rarely available (see consultation contribution 4075). Successful development of materials for Pharma and Biopharma manufacturing equipment and technology requires coordinated efforts of industrial suppliers and users. Development of PFAS-free material alternatives (if at all possible) will be very challenging even within a maximum derogation time of 13,5 years. Furthermore, these additional developments efforts will have a substantial impact on the availability of these resources for new product development. Innovations which may allow to produce drugs and vaccines more economically and faster will be delayed in development and market introduction and limit the introduction process of new life saving drugs for patients. In addition, this will have a negative impact on the competitiveness of the Pharma & Biotech Industry as well as their suppliers, such as Sartorius, located in Europe.
c) Sartorius is not a PFAS producer. We buy and use PFAS polymers and PFAS containing components in our value chain. We not only need derogations for PFAS use to continue our business we also need functioning supply chains and the security of supply for required PFAS materials. Once again, the stability of the PFAS material supply chains is significantly under thread since first suppliers have already announced production discontinuations.
d) We do not expect that PFAS replacement in our raw materials, products and production processes will lead to improvements concerning function and efficiency of products and production processes in the target industry as well as reduction of energy consumption and waste. (see consultation contribution 4075). Vice versa, we expect that the use of PFAS free materials, if available at all, will lead to higher costs and increased waste, since PFAS based products are more durable and need to be replaced with lower frequency, e.g., in air filtration applications. For this reason, we are concerned to lose our competitiveness compared to competitor products produced outside EU under the conditions of PFAS restriction.
e) A positive impact on EU economy and employment by PFAS restriction is unlikely. Disrupted supply chains, supply constraints and higher raw material prices must be expected. Many companies consider transfer of production capacity to areas outside EU.
f) Sartorius is a global industrial player. The unilateral ban of PFAS in the European Union will also lead to further negative business impact and complications as described by international associations, e. g. AmCham EU (C4584); Keidanren (4626)

With the consultation contribution 4075, Sartorius has proposed for derogations or has proposed expansions for derogations, which are listed in the PFAS restriction proposal under point 5 and point 6. Additionally, longer time frames were requested for derogations due to the very comprehensive qualification and validation requirements for our products in the target market (see consultation contribution 4075 with attachment for detailed information).

According to the derogation concept of the current restriction proposal, derogations will be limited in time and a PFAS substitution is needed anyway. Considering the high number of affected products and the comprehensive qualification and validation requirements of our target industry, the proposed derogation time frames are too short taking the overall effort including the required approval by regulatory institutions into account.

Therefore, **even if derogations will be granted, at least the following groups of financial impact must be considered, when the PFAS restriction will be set in force based on the current restriction approach:**

- Loss of business:
  a. PFAS containing products: Approx. 20-25% of annual sales are at risk according to a first analysis. There will be more negative business effects
  b. due to shortage in supply and discontinuations of raw material
  c. if PFAS based production processes and manufacturing equipment and technologies cannot be used for production under the conditions of the proposed PFAS restriction
- Costs for selection and validation of various PFAS-free raw materials, parts and production aids from potential suitable commercial material alternatives, if available
- Costs for development, qualification, validation and marketing of various PFAS-free products
- Costs for development and engineering as well as investment in PFAS free production technologies and production processes

The sum of these costs will be immense. Development costs will be very high and will bind huge parts of our Product Development Resources for years (Total Research and Development Expenditures in 2022: 177,8 million Euros). These resources will not be available for new product development for a long time period and prevent further innovation of bio-pharmaceutical manufacturing technology in Europe.

After careful consideration of our findings, we come to the conclusion that an exemption of PFAS polymers and elastomers for industrial use is needed, which is unlimited in time. This would solve many issues connected with the proposed PFAS restriction not only for our business but also for many other industries.

With the request for unlimited exemption of PFAS polymers from PFAS restriction, we are in alignment with other industrial players and associations and their contributions to the PFAS consultation, e.g. EFPIA (C4455), BioPhorum (C4313), BAH e.V. (C5578), VDMA (https://www.vdma.org/documents/34570/4612817/_PFAS_Positionspapier_korr_2023-06-2023_.pdf/a2fcdeab-ada7-b16d-b5f5-ae0552b0cdcf?t-=1689599857052; Memo (vdma.org) 23.05.2023); VCI Nord (C4503), BDI (Publikation (bdi.eu); https://bdi.eu/publikation/news/pfas-beschraenkung-bewertung-beschraenkungsvorschlag) to name some.

Furthermore, this approach follows the concept applied for Microplastics Restriction which was proposed by ECHA after request of the European Commission. In this case, a derogation was made for use of polymer microplastics at industrial sites, connected with obligations for user instructions and for information of authorities to assure controlled and professional use and use monitoring. Both restriction cases are comparable concerning connected risks. Emissions of polymers can be safely controlled by industry. Waste can be collected and discarded in a controlled and professional way.