Cytiva
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PFAS regulatory compliance approach

Dear Valued Customer,

The European Chemicals Agency (ECHA) is currently discussing the restriction of per- and polyfluoroalkyl (PFAS) substances in the European Economic Area. We fully support efforts to minimize and mitigate the presence of substances which pose a threat to human health and the environment and we welcome the EU's plans to gain a better understanding and oversight of PFAS uses and emissions.

We can confirm that products supplied to our customers do not contain the C8 (and higher) short chain PFAS chemicals, perfluorooctonic acid (PFOA) or perfluorooctane sulfonic acid (PFOS), their salts, and related compounds, at levels exceeding current regulatory limits in Europe, United States, and many Asian countries.

However, the proposed PFAS restriction would also have a large impact on the use of fluoropolymers which are often used in components for their chemical and wear resistance and well as their ability to repel oil and water. As a member of the bioprocessing industry committed to sustainable solutions, Cytiva has both responded to ECHA's public consultation and endorsed industry group sector responses, including those from the American Society of Mechanical Engineers: Bioprocessing Equipment (ASME-BPE), Bioprocess Systems Alliance (BPSA), BioPhorum, European Sealing Association (ESA), European Federation of Pharmaceutical Industries and Associations (EFPIA), and MedTech Europe. In line with industry, it is Cytiva's position that that fluoropolymers in certain industrial uses, should be excluded from the scope of the restriction for the following imperative reasons: (i) given that they are Polymers of Low Concern (PLC) as per the OECD criteria; (ii) that the disposal of waste in life sciences and biopharma manufacturing environments is well controlled and regulated; and (iii) that the proposal would have unintended consequences on the global manufacturing of life science and biopharmaceutical products. We believe that there is currently not a sufficient scientific evidence base to conclude on the risks posed by fluoropolymers in industrial use using good manufacturing practices, nor a sufficient comprehensive analysis of the availability of technically and economically feasible alternatives to justify the socio-economic costs.

We welcome measures that help us understand, monitor, assess and address risks to human health and the environment. We supply the tools and services that help our customers do their work better, faster and safer. Some of our products, such as filters and membranes which contain fluoropolymers, can support a range of applications in industries outside of biological research and manufacturing; these same types of membranes are also used in the manufacturing of semiconductors and in other cutting-edge manufacturing industries. We are finding ways to support our customers while respecting resource constraints and the effects of our industry on climate change and plastics waste. As we advance the development of therapies of the future, we are custodians for future generations and our 'Designing in Sustainability' strategy is business critical for us.
Given that products for research and development use (including quality control) are exempt from restriction under REACH, it is our assessment that the following product groups would be impacted by ECHA's proposed restriction, as currently drafted.

For a list of materials impacted by the proposed restriction and PFAS free alternatives offered by Cytiva, see the table below. For more details on our PFAS free alternatives, see please reach out to a Cytiva sales representative.

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Product type	In scope	Not in scope
Virus Filtration	Ultipor VF DV50, Ultipor VF DV20, Pegasus SV4 filters have PVDF membrane	Pegasus Prime filters have PES membrane
Sterilizing grade liquid filtration	Fluorodyne II Filters have PVDF membrane (part numbers include DFL,DJL,DBL,EDF,EDT)	Supor™ filters (EKV,ECV,EAV,EBV, Prime) use PES membranes. Ultipor N66, Posidyne filters use nylon.
Gas Filtration	Emflon II filters employ PVDF membrane (part numbers include V002) Emflon PFR filters employ PTFE membrane Versapor® R and Versapor RC membrane products Supor® RC membrane product	-
Aseptic Connectors	Kleenpak™ sterile connectors (KPCHT) and Kleenpak™ Presto sterile connectors (peel strip component)	--
Process Filters	-	HDC® II filters, Profile® II filters
Tangential Flow Filtration (TFF)	-	Centrasette and Centramate filters used either PES or regenerated cellulose membranes.
Single-use fittings, connectors, clamps, mixer components, hardware, O-rings etc	Materials with PVDF, PTFE, FKM (e.g., Viton™) considered in scope	-

It is Cytivas position that (<C16) PFAS pose a much larger threat to the environment and human health compared to fluoropolymers. In addition not all fluoropolymers are manufactured in ways that require (<C16) chemicals or processing aids, for instance PVDF manufacturers have taken steps to pre-emptively phase out these substances, further reducing any potential risk to the environment and human health. Because of these facts we consider it disproportionate to restrict (<C16) PFAS and fluoropolymers as if they are equally hazardous.

Cytiva has called on ECHA to take further time to analyze the risks and meaningfully consider the most proportionate approach by which to address PFAS for the life sciences, bioprocessing and biopharmaceutical sectors so as to minimize unintended socio-economic costs to society. Specifically, Cytiva has identified the 5 following missing industrial uses, 4 of which (points 2-5) are specific Polymers of Low Concern (PLCs) impacting us and our customers and have submitted evidence to ECHA to support consideration of appropriate time-derogations :

- 1. Hydrophobic and/or oleophobic filtration membranes in pharmaceutical processing;
- 2. Fluoropolymer-based bioprocessing materials (e.g. membranes, gaskets, seals, fittings, etc.) in which no PFAS (<C16) chemicals or processing aids are used to manufacture the polymer;
- 3. Fluoropolymer-based bioprocessing materials (e.g. membranes, gaskets, seals, tubing, O-rings, pumps, connectors) in which PFAS processing aides may be used in the manufacture of the polymer (e.g. PTFE filtration membranes, gaskets, seals, etc.);
- 4. Fluoropolymer used as auxiliaries on sites to manufacture chemicals vital to the bioprocessing industry;
- 5. Membranes used in medical device-related applications, including oleophobic, PTFE, and PVDF.

In line with its position that (<C16) PFAS pose a much greater risk to the environment and human health compared to fluoropolymers, Cytiva is taking steps to remove small molecule PFAS in its products and manufacturing wherever it is found in our products, to learn more about our work to phase out small molecule PFAS please reach out to a customer representative (link below) who can put you in contact with the appropriate experts.

In addition Cytiva aim to identify polymeric PFAS free alternatives for some critical components such as O-rings in our ReadyToProcess columns. Testing and shelf-life studies are planned to start pre-emptively in select cases where redesign and validation timelines would be particularly long.

For the reporting requirements on PFAS in products such as those set out by the US and Canada EPA, please note that it is the manufacturer or importer of records responsibility to report the PFAS placed on the market, in the vast majority of cases that will be Cytiva for any Cytiva products sold in the US. In Canada, Cytiva as the brand owner is responsible for all Cytiva products placed on the Canadian market. Cytiva will ensure that all products in scope of the reporting will be reported to the appropriate authorities.

If you have identified Cytiva products in scope of US reporting requirements where you would be the importer of record and require support to assess the PFAS content in the products, please reach out to our material experts by initiating "Support Cases" via your cytiva.com account or website:

https://www.cytivalifesciences.com/en/us/support/contact-us

Signature: DocuSigned by: David Jansson E8EB4855DC2D4AA...

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