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PFAS regulatory compliance approach, December 2025

Dear Valued Customer,

This letter seeks to provide you with an update on the applicability of the European Chemicals Agency (ECHA)'s draft restriction of per- and polyfluoroalkyl (PFAS) substances to our products and the support available to you for global PFAS reporting.

Global Restrictions
We fully support efforts to minimize and mitigate the presence of substances that pose a threat to human health and the environment. We can confirm that products supplied to our customers do not contain the C8 (and higher) short chain PFAS chemicals, perfluorooctanoic 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.

Proposed ECHA Restriction of PFAS in the European Economic Area
As originally proposed, the draft ECHA PFAS restriction would 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, Cytiva has called on ECHA to exclude fluoropolymers in certain industrial uses for the following imperative reasons: (i) given that many fluoropolymers are fluorosurfactant-free, thereby posing minimal environmental risk from resin manufacture through end-of-life, (ii) other bioprocessing fluoropolymers can be well-managed through resin creation and lifecycle, 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 insufficient scientific evidence from which to draw conclusions on the risks posed by fluoropolymers in industrial use using good manufacturing practices, nor is there sufficient analysis of the availability of technically and economically feasible alternatives to justify conclusions as to the socio-economic costs.

Cytiva works alongside customers to provide the right products, technologies, expertise, and services at every phase, from pre-clinical pipeline research all the way through to commercial-scale manufacturing. Our product portfolio serves academia, research, and biopharma companies of every size. 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. We view sustainability as a fundamental part of how we conduct responsible business across every aspect of our organization.

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.

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Applicability of ECHA proposal

Following several updates to the restriction process in August, it is Cytiva's current understanding that ECHA will not include the following sectors in their socioeconomic and risk assessments: printing applications, sealing applications, machinery applications, other medical applications, military applications, explosives, technical textiles, broader industrial uses. As use-restrictions that have not been properly assessed would be contrary to past practice, we expect ECHA will therefore leave these sectors out of the upcoming restriction proposal. It is expected that separate measures will be taken for these applications in the future. However, the European Commission retains the power to apply the restriction or "horizontal measures" (e.g. PFAS management plans, environmental emission limits, mandatory reporting systems). Cytiva will continue to engage with the authorities to ensure that uses for Life Sciences and research are given their proper consideration, both in terms of the complexity to replace these materials, and the low risk fluoropolymers in these specific risk-controlled applications pose to human health and the environment.

A number of uses also have derogations in the updated background document restriction proposal. As such, it is currently unclear if ECHA intends to remove these derogations when exempting sectors such as sealing applications. These derogations are for 13,5 years. Cytiva currently estimates that this will result in a restriction deadline around mid-2041 at the earliest.

Note that this understanding under the PFAS restriction scope is continuing to evolve and is subject to change as ECHA continues to clarify its intent for the PFAS restriction.

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.

Overview of key Cytiva technologies with respect to ECHA PFAS proposal and applicable derogations and sectors

Product type	In scope	Not in scope	Applicable derogation in restriction draft	Sector expected to be excluded from final restriction
Virus Filtration	Ultipor VF DV50, Ultipor VF DV20, Pegasus SV4 filters have PVDF membrane	Pegasus Prime filters have PES membrane		Technical textile and/or other medical applications
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.		Technical textile and/or other medical applications
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	-	5mm (HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases)	Technical textile and/or other medical applications
Aseptic Connectors	Kleenpak™ sterile connectors (KPCHT) and Kleenpak™ Presto sterile connectors (peel strip component)	--	6p (sealing applications in industrial uses)	Sealing applications, other medical applications and broader industrial uses
Process Filters	-	HDC® II filters, Profile® II filters		Technical textile and/or other medical applications

Tangential Flow Filtration (TFF)	-	Centrasette and Centramate filters used either PES or regenerated cellulose membranes.		Technical textile and/or other medical applications
Single-use fittings, connectors, clamps, mixer components, hardware, O-rings etc	Materials with PVDF, PTFE, FKM (e.g., Viton™) considered in scope	-	6p (sealing applications in industrial uses)	Sealing applications, other medical applications and broader industrial uses
Hardware systems (electrical, O-rings,	AKTA, BiaCore, AxiChrom, XDR, Xuri, Sepax		6h (wire and cables), 6l (insulation material of electrical components), 6j (anti-drip agents in plastics of electronic components) , 6p (sealing applications in industrial uses), 6q (machinery applications in industrial uses)	Sealing applications, machinery applications, other medical applications, broader industrial uses.
Hydrophobic filter membranes in medical devices	Versapor RC Emflon PTFE Supor RKC Hydrophobic Glass Fiber Media (XB070D, XE1008, XE1340, and XT028F types)	Versapor WO/WA, Versapor W/WA, Versapor TN W/WA, Supor, Melt-blown polypropylene media, Nylon membranes, Asymmetric Polyethersulfone (PES) membranes	6d. invasive medical devices	Technical textiles, other medical applications
Medical OEM Vent Devices	13 mm, 25 mm, 37 mm, and 50 mm Air and Gas Filters, Hydrostripe Supor Filters	Medical OEM Acrylic syringe filters for liquid filtration applications	6d. invasive medical devices	Technical textiles, other medical applications
Medical OEM IV Filter Devices	IV-3, IV-5, IV-6, Micro IV, Mid-Volume (AEF)	Gardian 100 High Pressure Filters	5mm. HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009)	Technical textiles, other medical applications
Breathing Filters	Ultipor 50	Ultipor 25, Ultipor 100 BB50T	5mm. HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009)	Technical textiles, other medical applications
Medical IV Filter Devices	ELD family, NEO family, NLF family, AEF family, and TNA family	-	6d. invasive medical devices	Technical textiles, other medical applications
Healthcare Syringe Filters	PharmAssure 25 mm Hydrophobic Vent Filter	PharmAssure syringe filter with Supor membrane, Syringe filters with Ultipor	6d. invasive medical devices	Technical textiles, other medical applications
Acrocap Filters	Acrocap with Versapor RC filter	-		Technical textiles, other medical applications
Medical Gas Filters	Acro 37, Intervene, Laparoshield Laparoscopic Smoke Filter, PTFE Gas Filter	-	5mm. HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009)	Technical textiles, other medical applications

It is Cytiva's 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.

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 found. 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 aims 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.

Global Reporting Obligations

We welcome measures that help us understand, monitor, assess, and address risks to human health and the environment and we welcome the EU's intent to gain a better understanding and oversight of PFAS uses and emissions. Cytiva works continuously to meet reporting requirements such as SCIP, FIFRA, and PFAS reporting in countries and states, and we also provide transparent documentation on our website on topics such as SVHCs and microplastics in our products to help our customers meet their regulatory obligations in a simplified manner.

For the reporting requirements on PFAS in products such as those set out by the US (federal as well as states such as Minnesota), Canada EPA, and the Australian Department of Health, Disability and Ageing, please note that it is the manufacturer or importer of record's 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 conducts ongoing regulatory intelligence to identify any relevant reporting requirements and 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

For the EEA, although the scope and specifics of horizontal and reporting measures remains to be determined, Cytiva can assist you with your scoping exercises by providing data on which products provided by Cytiva containing PFAS on request.

Signature: DocuSigned by: David Jansson E8EB4855DC2D4AA... Date signed:

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