Executive Summary

The European Chemicals Agency (ECHA) is currently discussing the restriction of per- and polyfluoroalkyl (PFAS) substances. 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. Due to the breadth of the proposed restriction (affecting over 10,000 substances and polymers) and the scale of the scoping challenge, Cytiva is calling on ECHA to take further time to analyze the risks and meaningfully consider the most proportionate approach by which to address them for the life sciences, bioprocessing and biopharmaceutical sectors so as to minimize unintended socio-economic costs to society. Specifically, Cytiva has identified 5 niche industrial uses of specific Polymers of Low Concern (PLCs) in critical equipment used in the manufacturing supply chain for pharmaceutical and biopharmaceutical products that may require further time-derogations.

Cytiva is a supplier of hardware, specialized chemicals, consumables, and medical device products. Our products are used in applications ranging from fundamental biological research to making lifesaving vaccines, biologic drugs, and novel cell and gene therapies. We have 16,000 associates across 41 countries worldwide, including manufacturing sites in Sweden, Denmark, Germany, Belgium, the Netherlands, and Austria. As a company our mission is to advance and accelerate therapeutics.

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, can also 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.

As it currently stands, the proposed restriction on per- and polyfluoroalkyl substances (PFAS) did not specifically consider the life sciences and biopharmaceutical industry sectors and product groups where PFAS are used. We are concerned that passage of the current proposal risks having significant unintended effects on the bioprocessing industry in the EEA with industry groups such as EFPIA and BPSA estimating that 94-100% of biopharmaceutical manufacturing campaigns in the EU will be impacted. Further, although used in small volumes, certain specific PFAS uses contribute to critical operational characteristics and performance functions: a proportional approach must therefore be taken to protect the development of new therapeutic medicinal therapies, drug availability, and ultimately the patients we serve.

As the life sciences and biopharmaceutical sectors are not significant PFAS users or emitters, our industry received insufficient consideration of costs and impacts and further analysis is required to identify the most effective approach to phasing out PFAS across our supply chains with the least socio-economic impact. **At the very minimum, we believe additional time derogations are required for the 5 missing uses detailed below.**

Cytiva's consultation response[1]:

- endorses related ECHA sector responses: as a member of the bioprocessing industry committed to sustainable solutions, we also support related industry group sector responses, including those from the American Society of Mechanical Engineers: Bioprocessing Equipment (ASME-BPE)[2], Bioprocess Systems Alliance (BPSA)[3], BioPhorum[4], European Sealing Association (ESA)[5], European Federation of Pharmaceutical Industries and Associations (EFPIA)[6], and MedTech Europe[7];
- seeks to outline the specific industry uses, impacts, benefits, and costs that must be proportionally considered; and
- addresses specific information requests for 5 key missing uses that merit careful consideration, largely associated with biopharmaceutical equipment manufacturing and the medical/biopharmaceutical supply chain:
    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.

[1] This consultation response does not in any way consider or object to the separate EU restriction of PFAS in firefighting foams.
[2] American Society of Mechanical Engineers: Bioprocessing Equipment. ECHA consultation response #6298.
[3] Bioprocess Systems Alliance. ECHA consultation response #pending publication.
[4] BioPhorum. ECHA consultation response #4313.
[5] European Sealing Association. ESA position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry.
[6] European Federation of Pharmaceutical Industries and Associations. ECHA consultation response #4455.
[7] MedTech Europe. ECHA consultation response #6208.