Executive Summary

Biopharmaceuticals are vital for medicine and have advantages over synthetic drugs, including targeting specific molecules and causing fewer side effects. They are crucial for treating various pathologies such as cancer, and patients rely on their availability. Regulatory action should not undermine their availability in the EU.

PVDF are critical materials for the progress of the European society as they provide multiple benefits in a wide array of very important sectors. In the biopharmaceutical one, PVDF is used, among other applications, in bioprocess filters for separating animal-cells and protein (referred to as microfiltration) and for virus removal (referred to as nanofiltration).

Nanofiltration is an integral part of biopharmaceutical manufacturing, ensuring efficacy and safety. It effectively removes viruses, including those causing blood-borne diseases. Implementing parvovirus-reducing steps improves viral safety.

Microfiltration is an essential step in the manufacturing process to separate proteins of interest such as antibodies or recombinant coagulation factors, from the animal cell in the biopharmaceutical manufacturing. PVDF membranes used in microfiltration are not replaceable as alternatives have a lower transmission of the targeted protein of interest while only PVDF can meet the various performances required for drug product applications.

Nanofiltration, usually the last step before a drug substance becomes a drug product, enhances product safety by removing viruses, including small non-enveloped ones. It effectively removes relevant viruses such as B19, coronavirus, HIV, HCV, and HBV (Hepathitis) or Herpes types. It is a crucial step in ensuring the safety of plasma-derived and recombinant products. Nanofiltration's virus removal mechanism is based on size exclusion.

Bioprocess filters, made with material like PVDF, have excellent properties such as temperature resistance, selective protein permeability, and chemical resistance. They are operated by trained professionals, with no exposure to workers or patients as the PVDF membrane is encapsulated in the filter. No adverse events related to nanofiltration have been recorded, and regulators recognize it as a safe virus removal method.

PVDF, among other fluoropolymers is considered as a polymer of low concern by OECD, does not bioaccumulate in living tissues. The fact that nanofiltration enabled by PVDF is used for many years in a highly regulatory environment is a warrant of its safety for human health. As many essential biopharmaceutical products/drugs would not be able to meet regulatory requirements, the use of PVDF should not be restricted.

After service, used filters need to be incinerated due to their contamination with pathogens at special facilities as hazardous waste at high temperatures (filter is considered as hazardous waste under the Waste Framework Directive. Under these extreme conditions, the C-F bond breaks down, thus completely destroying any PFAS.