

## Should the pharmaceutical industry be concerned about PFAS?

Elastomeric components used for container closures are typically coated with a film to prevent extractables from the compounds which may leach into the drug product and adversely interact. Furthermore, the coatings are used to improve mechanical behaviors such as prevention of stickiness and to improve friction and gliding ability on movable parts like plunger stoppers for prefilled syringes or cartridges.

These coatings are typically made of ETFE, PTFE, or PCTFE films, and though they are currently not listed under the OECD definition of PFAS<sup>1</sup>, the ongoing work with ECHA Regulation is expected to broaden the definition of PFAS to "substances containing at least one -CF<sub>2</sub> - or -CF<sub>3</sub> group", and hence these coatings will be included and will be impacted by the existing and future legislative changes in both EU and in the USA<sup>3</sup>. In EU, some temporary exemptions to the regulations exist until June 2023, and other exemptions, e.g. for medical devices, exists until June 2025<sup>4</sup>, however the EU commission does not expect a general essential use exemption will be substantiated.

Currently, various branch organizations and companies are arguing for the continued use of -CF<sub>2</sub> and/or -CF<sub>3</sub> groups in drug products, medical devices and in primary packaging either under the term "essential use" and/or with the reasoning that no feasible alternative exist. While the use of -CF<sub>2</sub> or -CF<sub>3</sub> groups in drug products (APIs) are not technically the same or in many cases fall under "essential use"<sup>3</sup>, there are hardly the same arguments for the broad use in primary packaging, where there currently are commercially available feasible alternatives, e.g. based on the use of the virtually chemically inert TPE materials<sup>5</sup> for container closures. Examples are the vial stoppers by Aseptic Technologies, rigid needle shields by Aptar, and plunger stoppers for prefilled syringes by Injecto.

ECHA defines PFAS as "forever chemicals" which are harmful by nature, both in regard to human health but also for the environment<sup>6</sup>.

In short, with the regulation change by ECHA, the majority of the coatings used in parenteral primary packaging are by definition PFAS, and there is substantial existing and ongoing legislative work towards banning PFAS to the widest possible extent in both EU and in USA. Consequently, the legislation and regulation will impact the ETFE, PTFE and PCTFE used as coating in primary packaging, especially on container closure systems for prefilled syringes, cartridges, and vials, and hence the business should potentially seek to reconcile the use of such.

So, whether the pharmaceutical industry should be concerned about the ban of PFAS is a highly relevant question, but moreover the questions should be, what can the pharmaceutical business do to prevent the use and spread of PFAS? Are PFAS coatings in primary packaging really a necessity when there are feasible alternatives? Do we wish to participate in the environmental consequences of using PFAS based coatings?

Most companies are currently putting considerable efforts into corporate environmental awareness, to minimize their carbon footprint and to implement various sustainability programs, so why not also be proactive and turn this potential challenge into a value proposition.

- 1) <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>
- 2) <https://osha.europa.eu/da/legislation/directives/regulation-ec-no-1907-2006-of-the-european-parliament-and-of-the-council>
- 3) [https://www.efpia.eu/media/636866/pfas-position\\_-\\_efpia-and-animalhealththeurope-january-2022.pdf](https://www.efpia.eu/media/636866/pfas-position_-_efpia-and-animalhealththeurope-january-2022.pdf)
- 4) <https://www.foodpackagingforum.org/news/eu-publishes-pfoa-regulation>
- 5) Holden G., Kricheldorf H.R., Quirk R.P., Hanser, Thermoplastic elastomer, 3<sup>rd</sup> edition, Cincinnati, 2004, Plastics engineering, April 2015

6) <https://chemicalsinourlife.echa.europa.eu/da/why-we-care-about-forever-chemicals-and-why-you-should-too>