FPE Response to the Proposal for a General PFAS Restriction

Flexible Packaging Europe (FPE) is the industry association representing the interests of more than 85 small, medium-sized and multinational manufacturers of flexible packaging. They operate with a workforce of 57,000+ people at more than 350 sites across Europe. The member companies account for almost 90% of European sales of flexible packaging made of various materials, mainly plastics, aluminium, and paper.
Flexible packaging is intrinsically linked to household staples, and for good reason: it provides adequate protection against contamination and product spoilage, and keeps food nutritious, fresh, and savoury for the required shelf life. Products can be safely and properly delivered to consumers without losing their properties, which has the advantage of making them affordable and easily accessible, while reducing the risk of food waste.
We manufacture packaging for an extremely wide variety of products, all of which have specific requirements. Baby food, for example, needs special protection to ensure the product is nutritious and safe for children to eat. Coffee, whether bean, ground or instant, can easily lose flavour and aroma if not packaged properly. Flexible packaging offers the right protection here, in addition to the appropriate format. The same applies to perishable foods such as fresh cheese, meat or salad/vegetables/fruit.
50% of all food sold in the European retail market is packaged in flexible packaging, yet it only accounts for 17% of the packaging waste generated – that's resource efficiency and waste prevention in action!

In principle, FPE is in favour of phasing out PFAS, focusing primarily on those PFAS that have been shown to pose a risk to human health, the food chain or organisms in the environment. For PFAS for which risks are unknown and for which there are not yet viable alternatives, we are convinced that there are ways to manage this transition without disproportionately disrupting our industry, our customers and society as a whole.

I. Hazard and Risk

Section 1.1.4 of the Annex XV Restriction Report on PFAS states that "all PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal. Further supporting concerns vary among these PFASs. These properties include bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects (sections 1.1.4.3-9) and concerns related to a combination of properties (section 1.1.4.10)."

We would like to comment on this as follows:

1. Persistence by itself is obviously an important property in the context of this Restriction proposal but does not mean that all PFAS are considered PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative), PMT (persistent, mobile, toxic) or vPvM (very persistent, very mobile) under Regulation (EC) No 1907/2006 or Regulation (EC) No 1272/2008. In particular, we would like to note that fluoropolymers do not meet the criteria for listing as SVHC or for classification as hazardous under the CLP Regulation.

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2. According to the fluoropolymer industry, fluoropolymers meet the OECD criteria for polymers of low concern, are non-toxic, are not bio-available, non-water soluble and non-mobile in the environment.
3. Section 1.1.4.2 of the Annex XV Report confirms that molecules containing only perfluorinated carbons do not degrade, such is the case with PTFE and other fluoropolymers. The part on polymeric PFAS in section 1.1.4.9, which deals with effects on human health, has not identified any health risks associated with the fluoropolymers used in our industry.
4. Section 2.4.2 of the Annex XV Report addresses the human health effects of exposure to PFAS. The text does not appear to consider the case of fluoropolymers which are not water soluble, not mobile in the environment and not toxic. They are expected to result in minimal human exposure and have no known human health effects. Remediation of the release of fluoropolymers into the environment appears to be much more feasible than for other types of PFAS, as the fluoropolymers tend to remain where they were released.
5. Section 2.4.3 of the Annex XV Report deals with the environmental impact assessment. Table 11 confirms that environmental emissions of PFAS used in food contact materials account for only 3% of the amount used. Without further clarification of this data, it appears that short-chain PFAS used in paper and board packaging have been lumped together with polymeric PFAS used in plastic packaging – based on their physical properties alone, it can be assumed that polymeric PFAS cause proportionately less emissions.
6. In our understanding of REACH, the Restriction process requires that there must be an unacceptable risk to human health or the environment, arising from the manufacture, placing on the market or use of substances. The risk assessment should consider hazards, exposure, and the risks associated with these hazards in specific exposure cases. We question whether such risks related to fluoropolymers have been properly identified in the Annex XV Restriction Report or its annexes and appendices.
7. Section 2.4.4 of the Annex XV Report states that for the Restriction to be effective, it should not affect users or actors in the supply chain who are not associated with the identified risk. It also states that the efforts that the actors need to make to implement the restriction options should be proportionate to the adverse effects that are being avoided. The Annex XV Report therefore indicates that the proposed restriction on fluoropolymers would not be effective or proportionate.
8. For the reasons outlined above, we suggest that a general time derogation for fluoropolymers (without exemptions) of EiF + 6.5 years, or longer for uses subject to specific derogations, would be the reasonable approach for this Restriction proposal.

II. Availability of Alternatives

The Annex XV Restriction Report on PFAS states that the derogations and their duration are mainly based on the availability and applicability of alternatives to PFAS. The proposed Restriction includes derogation 6a for fluoropolymers and perfluoropolyethers for use in food contact materials for the purpose of industrial and professional food and feed production (until 6.5 years after EiF). The explanatory notes give some examples of uses covered by the derogation, e.g. seals, O-rings, rollers, tanks, lubricants etc. On the other hand, food and feed packaging is excluded from this potential derogation 6a for reasons that are not explained.

We would like to comment on this as follows:

A. The use of PFAS in food and feed packaging materials.

1. The industrial production and distribution of food and feed requires the use of food packaging for most of these products in order to support the productivity of the food industry, prevent food spoilage and minimise the huge environmental impact of food waste.
2. Fluoropolymers are used in some food packaging materials, either as processing aids (copolymers of vinylidene fluoride, tetrafluoroethylene and/or hexafluoropropylene) in the thin film extrusion of polyethylene and polypropylene films, or as PTFE waxes to modify the surface friction properties of inks and coatings applied to food contact materials.
3. Section 1.3.2.3 of the Annex XV report describes the use of PFAS as processing aids, but has not identified the use of PTFE waxes which do have a function in the final product (nor does it describe the use of PFAS in production equipment to manufacture the packaging material – see section B of this chapter).
4. For reasons of assured continuity of supply of packaging materials to the food and feed industry it is important not to restrict the PFAS uses identified above until such time as viable alternative technologies are available at scale and have proven themselves in the supply chain and in the use of these packaging materials.
5. Table 8 in section 2.4.1 of the Annex XV report states that there is sufficiently strong evidence that alternatives exist to replace polymeric PFAS used as processing aids in the production of plastic film, and that there is a high substitution potential at EiF. According to the information available to us, these statements are not based on facts, as explained below.
6. The alternatives for fluoropolymer processing aids mentioned in Table 8 are boron nitride and polyethylene waxes.

    6.1. Our member companies are using and testing processing aids in PE film extrusion, typically when using LLDPE resins. The two important parameters being monitored as a function of the extruder speed expressed in rpm (rounds per minute), are melt fracture and melt pressure. Melt fracture is a visual inspection of the appearance of the extruded polymer, especially the so-called “sharkskin”, a surface roughness leaving the film wrinkled, less glossy and less transparent, so that it is no longer accepted on the market. The melt pressure is a measurement of the shear rate of the polymer melt in the extruder, which is crucial for process stability.

    6.2. A boron nitride based masterbatch has been tested as processing aid in film extrusion, compared to the conventional fluoropolymer processing aid.

    Looking first at the melt fracture, it was found that from the base speed of 25 rpm, the fluoropolymer processing aid allowed the extruder speed to be increased to 100 rpm before melt fracture appeared. With the alternative boron nitride processing aid, the experimental finding was that melt fracture appeared already at the base speed of 25 rpm, in other words it was completely ineffective.

    When the melt pressure was measured, it was experimentally found that the melt pressure of the polymer to which the boron nitride processing aid was added was identical to that of the polymer to which no processing aid was added at all at the base extruder speed of 25 rpm, again proving that the boron nitride processing aid is completely ineffective. In comparison, the fluoropolymer processing aid results in a 22% reduction in melt pressure at the base speed

and, more importantly, allows the extruder speed to be increased to a point where the melt pressure is twice as high, still without causing melt fracture.

Besides not functioning as an extrusion processing aid, there is an issue with boron nitride being abrasive to the extrusion equipment. This would lead to increased maintenance costs and also to some degree of contamination with metals in the products.

Moreover, as boron nitride is a white insoluble powder it is not possible to produce transparent films with it.

6.3. Also, PE waxes have been tested in similar experiments. In these particular experiments the extruder base speed was 20 rpm, and with the conventional fluoropolymer processing aid it was possible to increase the extruder speed to 90 rpm before melt fracture appeared. With the two alternative processing aids based on PE waxes, the limit was at 25 rpm, so basically ineffective.

With regard to the melt pressure, the experimental finding was that at the base extruder speed, the melt pressure of the polymer to with a processing aid based on PE waxes was added, was identical to that of the same polymer without any processing aid added. In comparison, the use of the conventional fluoropolymer-based processing aid resulted in a melt pressure at base speed that was 8% lower in this experiment. With the fluoropolymer processing aid the extruder speed could be increased to the point where the melt pressure was twice as high before melt fracture appeared.

6.4. DoverClear, a commercial PFAS-free processing aid currently offered on the market from Dover Chemicals, has been tested. The chemistry of this processing aid is understood to be a secondary polymeric polyphosphate. The results of corresponding experiments show that this processing aid releases fumes and a terrible odour during extrusion and has only a very limited influence on the elimination of melt fractures.

7. A functional processing aid for the extrusion of flexible films, in particular of LLDPE resins, is so important because it enables the production of thinner packaging materials with optimal technical performance and good productivity on the packaging lines used in the food industry. Less efficient and thicker films would cause major productivity losses in the food industry and would probably require the replacement of a large number of packaging lines. Additionally, thicker films and increased waste in film production and on food packaging lines are no preferred options given our sustainability targets.

8. Alternatives for PTFE waxes used in food and feed packaging materials have not been identified in the Annex XV report.

9. Finding suitable alternatives is a technical challenge, but an additional hurdle is the need for food contact authorisation under Regulation (EU) No 10/2011. This is very time-consuming as typically it could take 1-2 years to collect the require data, 2 years for the EFSA safety assessment, and an additional year for the amendment of the Regulation, making for a total of 4-5 years in the most favourable scenario. This does not include the time needed for technical investigations for identification of suitable substances prior to the decision to pursue food contact authorisation.

10. For the reasons listed above we request a time derogation of at least EiF + 6.5 years for the use of PFAS in food and feed packaging materials.

B. The use of PFAS in manufacturing equipment for packaging materials for food and feed, pharmaceutical products, medical devices, and other healthcare items as well as in

manufacturing equipment and vessels/tanks of the supplying industry (chemical industry).

11. Fluoropolymers and perfluoropolyethers are used in industrial equipment for the production of packaging materials, notably as seals, O-rings, rollers, tanks, lubricants, and in many other applications. This production equipment, such as film extrusion lines, coating machines, and printing presses, can represent an investment of up to some tens of millions of euros for each individual flexible packaging production site. In addition, there is various auxiliary equipment for quality control, testing labs, maintenance, slitting, packaging, etc. The availability of spare parts, consumables and other supplies needed to operate our production plants over the many years of their service life is a huge concern.
12. These are important uses of PFAS that have not been identified in Table 2 of section 1.3 of the Annex XV report.
13. For reasons of assured continuity of supply of packaging materials it is important not to restrict the PFAS uses in packaging production equipment until such time as viable alternative technologies are available at scale and have proven themselves in the production environment of these packaging materials.
14. The existence of a derogation of 6.5 years after EiF for PFAS used in industrial and professional food and feed production is a clear recognition that for this use, alternatives are not currently available. The production of food and feed packaging, as well as packaging for pharmaceutical products, medical devices, and other healthcare items, uses many pieces of equipment and materials that are identical to those used in food and feed production, and for which no alternatives are currently available either.
15. Section 2.4.3.3, paragraph (b)(i), of the Annex XV Report and Table 13 of section 2.4.4.1 confirm that the derogated use of PFAS in industrial and professional food and feed production leads to only small additional emissions. As the packaging production industry is a lot smaller than the food and feed production industry, similar uses of PFAS in production of packaging would result in even smaller additional PFAS emissions.
16. As there are currently significant gaps in identifying uses of PFAS in industrial production of packaging materials, and there is not even the beginning of an understanding on the availability of alternatives for these uses, we request a time derogation of at least EiF + 6.5 years. In our opinion, given the long service life of the equipment concerned, the huge investments to replace all affected equipment, and the potential for significant disruption of important supply chains, it would be more appropriate to give a time-unlimited exemption.
17. It is of particular importance to protect materials and production equipment used to manufacture packaging for food, pharmaceutical products, medical devices, and other healthcare items, as these applications require very long qualification periods for changes to the packaging. It would make sense to allow derogations for PFAS in the manufacturing process of packaging materials and in the resulting packaging materials for at least the same time period as is allowed for the pharmaceutical products, medical devices and other healthcare items which are being packed. A potential ban on fluoropolymers in the production equipment would severely affect the packaging manufacturers' operations. It has to be ensured that obtaining maintenance and repair parts for existing equipment, such as PFAS-embedded gaskets or seals, will be further possible and that supply chains will not be interrupted for theses uses. Otherwise, this would lead to last-time buys and eventually affect the ability to keep existing equipment (and manufacturing lines) running. Given the long service

life of the equipment concerned, the huge investments required to replace all affected equipment, and the potential for significant disruption of key supply chains, it would be more appropriate to grant a time-unlimited exemption.

18. The packaging converting industry as well as the supplying chemical industry use machinery and other devices like laboratory equipment, vessels and tanks containing fluoropolymers. These applications have to resist high temperatures and aggressive chemicals. To our knowledge, alternatives are currently not known for these applications. The use of fluoropolymers contributes to the safety and durability of industrial machinery and devices as well as of tanks and vessels. Any alternatives with less resistance to chemicals and temperature would lead to higher wear and tear of machine parts/vessels, which might have a higher environmental impact compared to the use of long-lasting fluoropolymers in this area because they have to be replaced and disposed more often. Furthermore, industrial machinery and tanks/vessels are usually properly disassembled and disposed and are not subject to littering.

C. The use of PFAS chemicals in R&D or quality control laboratories

19. Reagents are required in R&D and for analytical purposes in quality control laboratories, e.g. CAS No 25561-30-2 N, O-bis(trimethylsilyl)trifluoroacetamide, which is used as a reagent in gas chromatography, or CAS No 422-64-0 pentafluoropropionic acid, which is needed for buffer solutions.

20. Broad PFAS restrictions may have an impact on the substance availability. Therefore, we ask to clarify in the legal text that the manufacture/supply chains for these uses must not be interrupted.

III. Derogation Support for the Packaging of Terminally Sterilised Medical Devices

The Annex XV Restriction Report on PFAS includes under point 6. (n) a potential derogation for packaging of terminally sterilised medical devices until 13.5 years after EIF. This potential derogation is marked for reconsideration according to the Annex XV Report consultation.

We would like to comment on this as follows:

1. Our member companies produce packaging materials for medical devices that are terminally sterilised via methods such as ethylene oxide gas, irradiation, steam, or dry heat sterilisation. The integrity of this packaging is critical to ensure the sterility of the packed medical devices. The choice of the sterilisation method and of the packaging material depends on the type of medical device, its need for mechanical protection, the aseptic presentation of the medical device during use, the intended use and expiration date, the type of packaging equipment in use at the customer, and the requirements imposed by transport and storage conditions.
   Packaging for terminally sterilised medical devices is subject to the requirements of ISO 11607:2019 parts 1 and 2.
2. The types of terminally sterilised medical devices packed in our products include the following non-exhaustive list of examples:
   - wound care bandages, dressings, medical tapes and adhesives, gauzes
   - hypodermic needles and syringes
   - orthopaedic implants, plates, screws, nails, pins, and wires

- medical fluid bags for electrolyte imbalance treatment, blood transfusions, and oral or enteral patient nutrition
- catheters, guidewires, and stents used in coronary interventions
- diagnostics medical devices testing for pregnancy, blood glucose, clinical laboratory diagnostics, HIV tests, COVID-19 tests
- medical disposable drapes, gloves, and protective wear
- procedural and in-hospital kit such as surgical sutures
- medical tubing and fluid collection systems

3. The types of packaging materials used for these medical devices include flexible plastic films and plastic laminates as well as combinations of plastic films with paper and/or aluminium foil and other barrier layers. Our products are then used to make flowpacks, 4-side seal packs, bags, and pouches, lidding against thermoformed plastics or sealing film against medical porous web (paper or non-woven).
   The PFAS used in these products are fluoropolymers that are used for two purposes:
   - as processing aids in plastic film extrusion to optimise the processability of the plastic resins and the quality and performance of the finished film;
   - as a wax added to inks and coatings to improve their scratch resistance, gloss, surface friction, and water repellence.

4. Table 2 of the Annex XV Report aggregates the PFAS use in medical device packaging together with the PFAS use in the medical devices themselves, so it is not possible to derive packaging-specific information on the annual tonnage from Table 3 of the Report (however, it is clear that the combined tonnage is not that high compared to several other use categories). For the same reason, the information in Table 4 on the contribution to emissions is not packaging-specific.
   The same comment applies to Table 11 in section 2.4.3.2 and Table 12 in section 2.33, dealing with the baseline environmental impacts and the environmental impacts of the restriction options.
   According to information from the suppliers, fluoropolymers are non-toxic, non-water soluble, non-mobile in the environment, non-bioaccumulative and resistant to degradation. They are also not migrating out of the polymer films in which they have been incorporated, so emissions to the environment at the end of life of the medical device packaging, if any, remain localised to the point of emission and do not lead to widespread environmental contamination.

5. Table 8 of section 2.4.1.1 in the Annex XV Report states that there is some evidence that technically and economically feasible alternatives to PFAS used in terminally sterilised medical device packaging is not generally available.

   We can confirm this as follows:

   5.1. For the fluoropolymers used as processing aids in extrusion of plastic films, we currently don't have any alternative in place. The issue is to identify alternative components that are equivalent in performance while also ensuring zero risk to the sterility and functionality of the medical devices.

   The Annex XV Report identifies boron nitride and PE waxes as alternatives for the fluoropolymer processing aid. Both recommended solutions have been tested in film extrusion processes at our member companies' plants and it was found that they are ineffective – compared to not using a processing aid at all, these two materials do not give any improvement in melt fracture and melt pressure.

   Without a processing aid that matches the performance and properties of the fluoropolymer, the current film properties and productivity of the process cannot be achieved. It is possible that films and finished packaging material could be reformu-

lated, but such reformulation is not trivial to implement in the market of sterilised medical devices – more on this in points 6 and 7 of this document.

5.2. For the fluoropolymer waxes used to improve the properties of coatings, inks and varnishes, the Annex XV Report does not suggest any available alternatives. We are not aware of solutions that can be easily implemented without extensive testing. A particular challenge when using fluoropolymers is that the required performance characteristics only manifest themselves in the customer's packaging operation and are therefore to some extent outside the quality control and testing capabilities of the packaging material manufacturer. This causes delays in finding the best solution.

6. Table 8 in section 2.4.1.1 of the Annex XV Report furthermore recognises that high socio-economic costs would likely result from a ban on PFAS in applications where packaging is vital for functionality and safety, and where no available alternatives exist that meet the technical requirements.

   Our view is that the extensive array of tests needed on the packaging of terminally sterilised medical devices, the time needed for such reformulation projects, and the impact of such testing on the production processes of both the packaging manufacturer and the medical device manufacturer lead to higher-than-average costs. The additional need for validation, risk assessment, post market surveillance, and involvement of a notified body for regulatory clearance should be considered. There are so many uncertainties in these multiple procedures that the total cost cannot be estimated.

7. Table 9 of section 2.4.1.1 of the Annex XV Report states that there is some evidence that identification, development, and certification of alternatives would take more than five years to complete.

   We can provide the following details on this:

   It is expected that PFAS-free alternatives to the fluoropolymers currently used in our products will not be equally effective in all the applications for which they are needed. It is highly likely that certain product formulations will need to be changed or new packaging formats proposed.

   A particular complication in the market of packaging for terminally sterilised medical devices and similar sensitive applications is that changes to the packaging material need to be made in cooperation with the customer (the medical device manufacturer). This is a market that is very cautious about accepting any changes, for concern of risks to the medical device and ultimately the patient depending on it. There is a history of seemingly minor changes to the product resulting in high-profile and very expensive court cases against the medical device manufacturer. Consequently, the testing procedures involved with any change to the product, or its packaging can be very extensive and time-consuming.

   In addition to the extensive testing of the product and its packaging, the medical device manufacturer may need to re-apply for certification under the Medical Device Regulation, depending on interactions between the packaging and the medical device or changes to the medical device needed because of a different packaging format being selected. In the situation that the current packaging material is going to become banned from a certain date, this procedure needs to be carefully managed so as to ensure the continued availability of the medical device on the market – risks to the proper functioning of healthcare systems are not acceptable.

   Given the current lack of available alternatives to the PFAS used in packaging for terminally sterilised medical devices, and experience with previous packaging reformulation projects, we estimate that if technically suitable alternatives exist, introducing them at the

level of the packaging manufacturer may take three years, followed by a similar amount of time for testing in combination with the medical device and its use in the field. Regulatory clearances would take extra time. If technically suitable alternatives are not found for a particular application, then developing a new packaging concept and/or adaptations to the medical devices would take more time. The long shelf life of most medical devices is a factor in this.

8. Point (h)(xiii) in section 2.4.3.3 of the Annex XV Report on the environmental impact of the Restriction options states that there is no evidence available about the precise amount of additional emissions from the proposed derogation. It is assumed that additional emissions will be a small fraction of emissions under the reference scenario.
9. For the reasons outlined above, our position is that when an unlimited exemption is not possible for these critical applications, then a derogation of 13.5 years after EiF is appropriate.

IV. Derogation Request for the Packaging of Non-sterilised Medical Devices

The Annex XV Restriction Report on PFAS includes under point 6.(n) a potential derogation for packaging of terminally sterilised medical devices until 13.5 years after EIF, but not for non-sterilised medical devices.

We would like to comment on this as follows:

1. The Annex XV Report appears to be unaware that also non-sterilised medical devices are placed on the market in the same types of packaging, and that these have similar requirements to sterilised medical devices. The companies bringing these non-sterilised medical devices to market are largely the same as those for the sterilised devices. Internal qualification procedures at the various stages of the supply chain are very similar and time-consuming.
2. Our member companies produce packaging materials for various non-sterilised medical devices, including the following non-exhaustive list of examples:
   - wound care bandages, dressings, medical tapes, gauzes, closure strips
   - braces and supports for the knee, ankle, wrist, and other joints; orthopaedic inserts for foot and ankle conditions, orthopaedic tapes and bandages for joint support and compression
   - diagnostic devices such as self-tests for pregnancy, thermometers, test kits for clinical laboratories
   - medical disposable drapes, gloves, and protective wear
   - procedural and in-hospital kit with items used for medical treatments
   - medical tubing and collection systems for fluids, tubing for gases
3. The types of packaging materials used for these medical devices include flexible plastic films and plastic laminates as well as combinations of plastic films with paper and/or aluminium foil and other barrier layers. Our products are then used to make flow-packs, 4-side seal packs, bags, and pouches, lidding against thermoformed plastics.
   The PFAS used in these products are fluoropolymers that are used for two purposes:
   - as processing aids in plastic film extrusion to optimise the processability of the plastic resins and the quality and performance of the finished film;
   - as a wax added to inks and coatings to improve their scratch resistance, gloss, surface friction, and water repellence.
4. As the Annex XV report doesn't mention the use of PFAS in packaging for non-sterilised medical devices, it has no data on the volume of PFAS used in this application or the

quantity of emissions expected at the end-of-life of the PFAS-containing packaging. We also don't have concrete numbers on this, but we estimate the market for flexible packaging used for non-sterilised medical devices to be somewhat smaller than that for the sterilised medical devices, and therefore the PFAS use and emissions at end-of-life to be proportionally lower.

PFAS emissions during the use are not expected as the fluoropolymers are not migrating out of our products. They are also not water-soluble and not mobile in the environment, don't degrade and don't bioaccumulate, so even if not collected at end-of-life they wouldn't lead to widespread contamination of ecosystems.

5. The polymeric PFAS used in packaging for non-sterilised medical devices have a unique set of properties that make them hard to replace with non-PFAS alternatives. We are currently not aware of functionally equivalent non-PFAS alternatives being available at scale in the supply chain:

   5.1. For the fluoropolymers used as processing aids in extrusion of plastic films, we currently don't have any alternative in place. The issue is to identify alternative components that are equivalent in performance during extrusion and available at scale in the supply chain, while also keeping all the functionalities of the packaging material for the medical devices intact.

   The Annex XV Report identifies boron nitride and PE waxes as alternatives for the fluoropolymer processing aid. Both recommended solutions have been tested in film extrusion processes at our member companies' plants and it was found that they are ineffective – compared to not using a processing aid at all, these two materials do not give any improvement in melt fracture and melt pressure.

   Without a processing aid that matches the performance and properties of the fluoropolymer we cannot achieve the current film properties and the productivity of the process. It is possible that films and finished packaging material could be reformulated, but such reformulation is not trivial to implement in the market of medical devices – more on this in points 6 and 7 of this document.

   5.2. For the fluoropolymer waxes used to improve the properties of coatings, inks and varnishes, the Annex XV Report does not suggest any available alternatives. We are not aware of solutions that can be easily implemented without extensive testing. A particular challenge when using fluoropolymers is that the required performance characteristics only manifest themselves in the customer's packaging operation and are therefore to some extent outside the quality control and testing capabilities of the packaging material manufacturer. This causes delays in finding the best solution.

6. The range of testing needed on the packaging of non-sterilised medical devices, the time needed for such reformulation projects, and the impact of such testing on the production processes of both the packaging manufacturer and the medical device manufacturer leads to significant costs. The additional need for validation, risk assessment, post market surveillance, and in some cases involvement of a notified body for regulatory clearance, should be considered. There are so many uncertainties in these multiple procedures that the total cost cannot be estimated.

7. Identification, development, and certification of alternatives would take more than five years to complete. It is expected that PFAS-free alternatives to the fluoropolymers currently used in our products may not be equally effective in all the applications for which they are needed. It is highly likely that certain product formulations will need to be changed or new packaging formats proposed.

A particular complication in the market of packaging for non-sterilised medical devices and similar sensitive applications is that changes to the packaging material need to be made in cooperation with the customer (the medical device manufacturer). This is a market that is very cautious about accepting any changes, for concern of risks to the medical device and ultimately the patient depending on it. Consequently, the testing procedures involved with any change to the product, or its packaging can be very extensive and time-consuming.

Given the current lack of available alternatives to the PFAS used in packaging for non-sterilised medical devices, and experience with previous packaging reformulation projects, we estimate that if technically suitable alternatives exist, introducing them at the level of the packaging manufacturer may take three years, followed by a similar amount of time for testing in combination with the medical device and its use in the field. Regulatory clearances would take extra time. If technically suitable alternatives are not found for a particular application, then developing a new packaging concept and/or adaptations to the medical devices would take more time. The long shelf life of most medical devices is a factor in this.

8. For the reasons outlined above, our position is that when an unlimited exemption is not possible for these critical applications, then a derogation of 13.5 years after EiF should be granted.

V. Derogation Request for the Packaging of Pharmaceutical Products

The Restriction proposal contains an exemption for PFAS that are active substances in human and veterinary medicinal products and proposes derogations for PFAS used in certain critical packaging applications such as for terminally sterilised medical devices but does not address the equally critical packaging of human and veterinary medicinal products (other than PCTFE-based packaging).

We would like to comment on this as follows:

1. Pharmaceutical products must undergo rigorous testing and regulatory approval before they can be marketed and sold to the public.
2. Our member companies produce packaging materials for various pharmaceutical products, including the following non-exhaustive list of examples:
   - oral solid dose medication such as tablets or capsules containing pain relievers, antibiotics, vitamins, and supplements
   - oral powder or liquid medications containing pain relievers, antibiotics, antihistamines, and cough and cold medicines
   - dermal products such as creams, lotions, gels, foams, sprays, and ointments for treatment of skin disorders, or patches and gels that deliver medication directly into the bloodstream bypassing the digestive system
   - pulmonary medications such as bronchodilators, corticosteroids, anticholinergics, antibiotics, and mucolytics delivered via inhalers or nebulizers or delivered directly into the lungs through a mask or other specialised equipment
3. The types of packaging materials used for these medical devices include flexible plastic films and plastic laminates as well as combinations of plastic films with paper and/or aluminium foil and other barrier layers. Our products are then used to make flowpacks, 4-side seal sachets, stickpacks, pouches, coldform foils, lidding against thermoformed plastics.

4-side seals sachets, stickpacks, and pouches are mainly used for oral powder or liquid medicinal products. Sachets are also used for dermal applications. Flowpacks are mainly used as secondary packaging, e.g., to pack an inhalation device (pulmonary products). Liddings are used in combination with coldform base webs or thermoformable foils mainly used to pack oral solid dose medication.

In some cases, the pharmaceutical packaging referred to here is not the direct packaging of the active preparation, but instead an outer packaging used to contain items such as inhalers, pipettes, dermal patches, or a secondary packaging used to contain bulk quantities of certain medications such as powders, tablets, and capsules.

The PFAS used in these packaging materials are fluoropolymers that are used for the following purposes:

- as processing aids in plastic film extrusion to optimise the processability of the plastic resins and the quality and performance of the finished film;
- as a wax added to inks and coatings to improve their scratch resistance, gloss, surface friction, and water repellence.

4. The pharmaceutical packaging referred to in this document, be it the direct packaging for the active preparation, or an outer packaging or secondary packaging, plays an important role in the marketing of medicinal products. Some of the key considerations that pharmaceutical companies take into account when selecting packaging for the active preparation relate to product stability (protection from moisture, oxygen, light), interactions between the product and its packaging (potentially affecting the efficacy of the product or the health and safety of the consumer), regulatory clearances, ease of use for the user and consumer, and in some cases requirements related to child-resistant packaging, tamper-evident seals, and other safety features.

5. We don’t have quantitative data available on the size of the pharmaceutical packaging market, but we would estimate the volume to be somewhat bigger than that of packaging of medical devices.

6. The polymeric PFAS used in packaging for non-sterilised medical devices have a unique set of properties that make them hard to replace with non-PFAS alternatives. We are currently not aware of functionally equivalent non-PFAS alternatives being available at scale in the supply chain:

   6.1. For the fluoropolymers used as processing aid in extrusion of plastic films, we currently don’t have any alternative in place. The issue is to identify alternative components that are equivalent in performance during extrusion and available at scale in the supply chain, while also keeping all the functionalities of the packaging material for pharmaceutical products intact.

   The Annex XV Report identifies boron nitride and PE waxes as alternatives for the fluoropolymer processing aid. Both recommended solutions have been tested in film extrusion processes at our member companies’ plants and it was found that they are ineffective – compared to not using a processing aid at all, these two materials do not give any improvement in melt fracture and melt pressure.

   Without a processing aid that matches the performance and properties of the fluoropolymer we cannot achieve the current film properties and the productivity of the process. It is possible that films and finished packaging material could be reformulated, but such reformulation is not trivial to implement in the market of pharmaceutical packaging – more on this in point 7 of this document.

   6.2. For the fluoropolymer waxes used to improve the properties of coatings, inks and varnishes, the Annex XV Report does not suggest any available alternatives. We are not aware of solutions that can be easily implemented without extensive testing.

A particular challenge when using fluoropolymers is that the required performance characteristics only manifest themselves in the customer's packaging operation and are therefore to some extent outside the quality control and testing capabilities of the packaging material manufacturer. This causes delays in finding the best solution.

7. Table 9 in section 2.4.1.1 of the Annex XV Report states that there is some evidence that identification, development, and certification of alternatives to PCTFE-based pharmaceutical packaging would take more than five years to complete. The same is true for other types of pharmaceutical packaging:

   7.1. The development of a pharmaceutical product, more specifically the forms in which it can be brought to market, goes hand in hand with considerations about the appropriate packaging material to ensure the quality of the product during its shelf life and the instructions for use for the consumer. On average, it can take 10 to 15 years for a pharmaceutical product to reach the market.

   7.2. As part of that development process, information on the packaging – pack format, packaging specification and composition, packaging process, product conditioning inside the packaging – is part of the filing that needs to be made to regulatory authorities in each jurisdiction (in the EU it is the European Medicines Agency) for their regulatory review prior to a decision on a permission to bring the packed pharmaceutical product to market. For certain applications also compliance with the European Pharmacopoeia needs to be ensured.

   7.3. From previous pharmaceutical packaging reformulation projects, we would estimate that replacing the PFAS-containing packaging material with an alternative PFAS-free packaging could take three years for the packaging manufacturer for initial development and testing and another five years for the pharmaceutical company to validate and risk-assess the replacement material, conduct stability testing of the packed pharmaceutical product and resubmit regulatory submissions.

   7.4. It is not certain that such reformulation projects would be successful in every case. The replacement material would need to have good technical performance in the complete packaging structure (e.g. adhesion, mechanical strength, thermoformability, optical clarity), needs to allow sufficient product shelf life with assured stability of the product, should preferably run on the existing packaging production lines and the pharmaceutical packaging lines, should not reveal surprises during risk assessment (e.g. on extractable and leachable substances from the packaging), needs to pass the regulatory review, etc.

8. In our view, high costs clearly follow from the elaborate procedures for bringing packed pharmaceutical products to market as explained under point 7. In addition, changing the packaging may require reformulations to the pharmaceutical product or may require investments in the packaging production equipment or the pharmaceutical packaging equipment.

   We would assume that, given sufficient time for the transition, all conceivable testing will be carried out before the new packaging material is put on the market so that the health and safety of consumers is not jeopardised in any way. On the other hand, in cases where a PFAS-free packaging material cannot be introduced in time, the impact on consumers would be to find an alternative treatment.

9. PFAS emissions during use are not expected as the fluoropolymers are not migrating from our products. They are also not water-soluble and are not mobile in the environment, do not degrade and do not bio-accumulate, so even if they are not collected at the end of life, they would not lead to widespread contamination of ecosystems.

10. For the reasons outlined above, our position is that when an unlimited exemption is not possible for these critical applications, then a derogation of 13.5 years after EiF should be granted.

VI. Derogation Request for Recycled Materials

The flexible packaging industry aims for increasing the recyclability of the packaging materials that are put on the EU market to fulfil the targets that are set out in the draft Packaging and Packaging Waste Regulation (PPWR). Thus, an increase in mono PE / mono PP films and mono paper packaging is to be expected, which will enter the respective recycling streams after disposal. Also, the recycled content in packaging has to be increased according to the targets of the PPWR.

Today, mainly fluoropolymer-containing processing aids are used for the production of thin, flexible PE and PP films. These films may be printed and/or coated with PTFE-containing inks and lacquers. Even if alternatives for those processing aids and additives would be available at EiF for plastic film packaging (with or without derogation), those PFAS-containing plastics will enter the recycling stream and the fluoropolymers will not be removed in the cleaning step of the plastic recycling processes.

The PFAS content in recycled materials will only decrease when PFAS are no longer used in the virgin materials for a sufficiently long period of time so that the recycling loops for PFAS-containing materials are closed**.** As long as PFAS-containing materials continue to be recycled, it cannot be ensured that the resulting recyclate is PFAS-free.

A particular problem is that recycled materials are made from collected waste from many sources and having many different untraceable compositions, so that the precise formulation of the recycled material cannot be known in detail. It is not feasible and not economically viable to produce recycled material and only then find out if the recycled plastic meets the proposed 50 ppm limit for PFAS from fluoropolymers, or the recycled paper and board will meet the applicable even lower limit for short-chain PFAS, with probably a rather high probability that it exceeds the limit.

The only solution is to have a PFAS limit on recycled materials that applies only when the collected input waste is certain to be sufficiently PFAS-free so that the recycled material is quasi automatically below the applicable limit.

Therefore, an exemption or at least a sufficient long derogation is needed for a PFAS restriction on recycled materials. This is important for creating a viable market for recycled packaging materials so that we can achieve the EU targets as laid down in the draft PPWR of increasing the recycling rates and the recycled content in plastic and paper packaging.

The exemption for recycled plastics and paper including packaging made from recycled plastics and paper may be re-evaluated after a certain period after the final phase out of the derogations potentially granted for paper and plastic packaging materials.

As FPE, we and our experts are available at any time to answer any questions you may have and to engage in further discussions.

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