W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH restriction on PFAS

Public consultation

Request for Derogation: Packaging Vents Used in Transport or Storage of Decomposing Chemicals

August 2023

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFAS) (hereinafter '**Restriction Proposal**').

With this submission, we would like to explain why we believe that a derogation for **packaging**[1] **vents used in transport or storage of decomposing chemicals** is needed and justified. Further, we would like to explain why this derogation should be for unlimited time.

The conclusions from our submission are summarised as follows:

- Packaging vents used in transport or storage of decomposing chemicals, such as strong oxidisers and some disinfectants and agrochemicals are not covered by a derogation of the Restriction Proposal.
- To the best of our knowledge PFAS-based vents are the only option currently on the market that can be used to transport or store decomposing chemicals. Our research presented in this submission, provides evidence that the likelihood of finding alternative material for this application is extremely low.
- Without a sufficient derogation, safe transport and storage of such chemicals will not be possible. This will result in increased likelihood of package failure/leakage creating uncontrolled releases of chemical or potentially shortage of essential products (e.g., agricultural and disinfecting products).

I. Derogation Request

Considering the arguments and evidence presented below, Gore respectfully requests to include the following application-specific derogation in Column 2, paragraph 5 of the proposed restriction:

Packaging vents used in transport or storage of decomposing chemicals[2]

II. Description of the End Use

To clearly define the proposed new derogation, an explanation of end uses, and function of packaging vents is provided below.

Packaging vents equalize pressure that builds up inside a package as a result of chemical or biological decomposition. Altitude and temperature changes are additional factors that will increase pressure build up within packaging[3]. Without the vent, the packaging may bloat and eventually burst, which in the worst case could expose transport operators and the environment to chemicals. Packaging vents are therefore an important safety component of

[1] The Economic Commission for Europe Inland Transport Committee – ADR 2023, defines "Packaging" as the means of one or more receptacles and any other components or materials necessary for the receptacles to perform their containment and other safety functions.

[2] Within this submission, a decomposing chemical is to be understood as a chemical that through a (bio)chemical reaction breaks down into two or more products and one of those products is gas. Another common term for this is "off gassing".

[3] As the altitude is increased the ambient air pressure is reduced and the internal air pressure of the packaging increases causing the package to bloat. Higher temperature increases the rate of decomposition, which results in more gas being released within packaging.

chemical storage and transportation, reducing potential for environmental pollution and human exposure.

There are many chemicals which may decompose and off gas during transport and storage, where packaging vents are needed for safe storage and transport. The most common examples are:

- Dangerous Goods[4]:
    - Hazardous Chemicals categorized as strong oxidisers (e.g., mixtures of Hydrogen Peroxide, Peracetic Acid or Sodium Hypochlorite). The Agreement concerning the International Carriage of Dangerous Goods by Road (further referred as ADR) specifically prescribe venting devices for transport of strong oxidisers[5].
    - Hazardous Chemicals not categorized in a specific ADR class but still having a potential to cause pressure build up[6], due to decomposition in higher temperatures or altitude difference or other reasons.

- Agrochemicals[7]:
    - Pesticides, biopesticides, organic fertilisers and bio-stimulants. Many pesticides may decompose and create overpressure within packaging, and hence require venting. The biological agrochemicals can continue to create gasses while they continue to ferment during storage and shipment because of their organic ingredients and presence of microorganisms.

- Other hazardous chemicals:
    - Decomposing chemicals which are not specifically categorized under the ADR Regulation, because their level of active ingredients fall below the ADR concentration limit thresholds. However, they have similar properties as products listed above, which would lead to packaging failure due to high overpressure.

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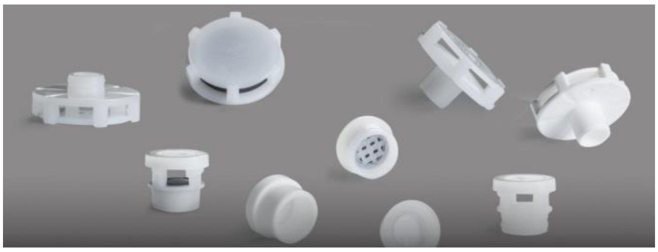
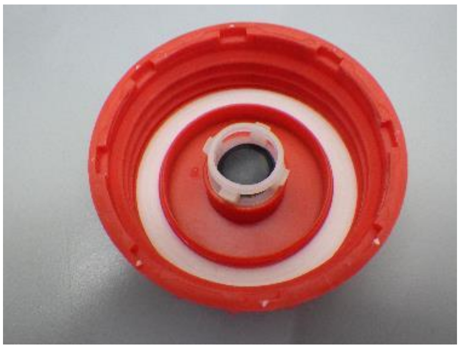
[4] The term 'dangerous goods' refer to those substances and articles that are subject to transport regulations, e.g., ADR (transport by road). ADR provide more information on types and classes of dangerous goods in its Annex A and B

[5] see ADR point 4.1.4.2 p. 167. Also see more details in section 2 of this submission

[6] See ADR Volume II, point 4.1.1.8. p. 55. Also see more details in section 2 of this submission

[7] Agrochemicals fall under a range of EU and national laws. Two key EU laws that govern them include EU Plant Protection Product Regulation No 1107/2009 and EU fertilizing products regulation No 2019/1009

Table 1. Illustration of various packaging vents and their typical position in a closure

Product	Illustration
Packaging Vents	 *Figure 1. Body of the vent, made of plastic (e.g., HDPE)*  *Figure 2. Closure*

It is important to note that the only PFAS-based material in the type of product illustrated above is a membrane that sits inside of a body made of other non-fluorinated plastics (usually HDPE). The body of various shapes and designs (as illustrated in Figure 1) is than plugged into various types of closures (as illustrated in Figure 2).

Gore is a market leader in the packaging vents with an estimated EU market share of 30-35%.[8] We believe that all available packaging vent products on the market, targeting use in transport and storage of decomposing/off gassing chemicals, currently contain PFAS.

Packaging vents are made of polytetrafluoroethylene (PTFE) and perfluoroalkoxy polymer (PFA) with other additional PFAS. Most of the components meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers. The materials used are shown in Table 2 below.

[8] Any discussion of markets, shares, or market sizes or shares in this document is preliminary, based on publicly available information and/or internal estimates, and subject to change. Markets identified are not necessarily only relevant markets (product or geographic) for antitrust purposes, and shares may be incomplete and not reflect all competitive sales or all competitors.

Table 2. Typical PFAS Materials used in Packaging Vents

Gore product	Type of PFAS	CAS number	PLC?
Packaging Vents	PTFE	9002-84-0	Yes
	PFA	26655-00-5	Yes
	[redacted]	[redacted]	[redacted]

III. Reference in Restriction Proposal

Although certain packaging has been researched by the Dossier Submitters (e.g., food contact packaging, advanced semiconductor packaging or packaging for medicinal/medical device products), use of PFAS in packaging of decomposing chemicals have not been discussed.

The Restriction Proposal also includes a derogation for reconsideration for 'PTFE in ophthalmic solutions packaging until 13.5 years after EIF' (Restriction proposal, p. 8, point 6m). Although this application is different from the end uses described in section II of this document, we welcome that the Dossier Submitters justify the potential derogation based on unique properties of PTFE. Namely it mentions that 'It acts as hydrophobic membrane in certain ophthalmic solutions' packaging, allowing the venting of air, while retaining fluid within the container, preventing leakage.' (Annex A, p. 82).

As explained, packaging vents for decomposing chemicals work on a similar principle, but they also utilize other PFAS due to the need (on top of hydrophobicity) for sufficient oleophobicity. It is a key property needed to prevent blockage of the microporous membrane in a packaging vent caused by chemicals with low surface tensions.

The only information on alternatives, referenced by the Dossier Submitters is related to the above-mentioned packaging of ophthalmic solutions. The dossier proposal states that there is *'Weak evidence that technically and economically feasible alternatives are not generally available (...) for PTFE in ophthalmic solutions packaging, and packaging of terminally sterilized medical devices' (Annex E, p. 339).* No specific materials are named as feasible alternatives.

In the sections below, Gore provides information on the lack of alternatives in the end application of packaging vents used for transport or storage of decomposing chemicals. So far, we have not been able to find an alternative and we believe they are unlikely to be developed in the future.

IV. Need and justification for derogation

Without a derogation, transport and storage of certain decomposing chemicals will not be possible due to minimum certification/authorisation requirement not being met. In an unlikely scenario of standards being lowered to accommodate inferior products, it would lead to packaging failure that would endanger health and safety of transport operators, warehouse staff, the general public, as well as the environment.

Some biological agrochemicals (such as organic fertilisers[9], bio-stimulants) and other hazardous chemicals (such as disinfectants), even if not classified as a dangerous goods in line with transport regulations, also require packaging equipped with venting to ensure safe transport and storage.

1. Performance Requirements for Packaging Vents

Packaging vents used for transport and storage of decomposing chemicals have a wide range of unique and technically demanding performance requirements. The primary challenge is providing adequate airflow while ensuring that liquids with low surface tensions (which is common characteristic of chemicals mentioned in Section II) do not penetrate or cross the membrane.

a. Oleophobicity - Barrier to liquids with low surface energy[10]

The material needs to be oleophobic, enabling the membrane to repel a range of fluids with low surface tensions. The ability to repel substances is dependent on surface energy. Surface energy is a typical material property used to characterize oleophobicity. Oleophobicity is tested according to DIN EN ISO 14419:2010-08 and AATCC Test Method 118-2007. The Oilrate tests liquids on a material and results in a score ranging from (1) to (9), where (1) means that chemicals will very easily wet out the membrane clogging the pores and blocking airflow and (9) demonstrates an extremely high performance where the liquid does not penetrate the surface and easily rolls off.

b. Microporous Structure - Good airflow properties

The membranes, which are used in these vents for pressure equalisation, need to be thin and low-mass with mechanical properties and a porous microstructure that enables optimal transmission of gas. After exposure to the liquid, measurable residual airflow should be above 0%.[11] The optimized permeation properties enable the vent structure to rapidly equalize pressure changes that arise from temperature increase/decrease or air pressure differences that may occur during transport or storage.

c. Chemical resistance

The membrane needs resistance to a wide range of chemicals, often oxidizing and/or corrosive, to avoid vent membrane degradation and rupture that could result in leakage of (hazardous) chemicals.

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[9] An organic fertilizer according to Regulation (EU) 2019/1009 is defined as containing organic carbon and nutrients of solely biological origin.

[10] Typical value below which a substance or mixture can be considered as having low surface energy is 45 dynes/cm. It is based on Detergent Regulation FAQ published by EU Commission on Dec 2018 (question 4.6) https://ec.europa.eu/docsroom/documents/33168/attachments/1/translations/en/renditions/native

[11] If the airflow is 0%, it indicates that membrane has been completely blocked and can no longer perform its function to equalize pressure.

2. Standards and Regulatory Compliance

The need for packaging vents for transport and storage of certain kind of packaging is confirmed by standards.

a. *Carriage of Dangerous Goods by Road Law (ADR)*

For some specific classes of dangerous goods, the need for packaging vents is explicitly prescribed[12], such as for:

- UN 1791- Hypochlorite Solutions,
- UN 2014- Hydrogen Peroxide 20-60%,
- UN 2984- Hydrogen Peroxide 8-20%
- UN 3149- Hydrogen Peroxide and Peroxyacetic Acid Mixture with acids, water and not more than 5% peroxyacetic acid)

ADR also explains that 'where pressure may develop in a package by the emission of gas from the contents (as a result of temperature increase or other causes), the packaging or IBC[13] may be fitted with vent (…). The vent shall be so designed that, when the packaging or IBC is in altitude in which it is intended to be carried, leakages of liquid and the penetration of foreign substances are prevented under normal conditions of carriage'.[14] That means that classes of dangerous goods other than those listed above, may also require packaging vents.

Before any packaging can be used to transport dangerous goods, it must be tested and approved by a validated certifying body (such as TUEV or other authorized organisations) according to appropriate test methods defined by ADR.

These test methods are designed to ensure good quality, and hence safety, of transported packaging. We provide tests relevant to this end use below:

- Drop test, point 6.1.5.3 of ADR
- Leak proofness test, point 6.1.5.4 of ADR
- Stacking test, point 6.1.5.6 of ADR
- Chemical compatibility of polyethylene packaging, point 6.1.6 of ADR

The most challenging test for packaging vents is the stacking test. The stacking test simulates a pressure applied on packaging when identical packages are stacked on it in carriage. No sample can leak for the test to pass. For HDPE[15] containers, which are the common choice for the described end uses, the stacking test is performed with standard liquid, such as white spirit. White spirit has a very low surface tension of 24,5 dynes/cm. It therefore easily wets and blocks the vent membrane during the test resulting in leaks unless the membrane is constructed of a very oleophobic material, such as fluoropolymers. To the best of our knowledge only PFAS-based vents can pass this test, and hence, are the only solution

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[12] See ADR point 4.1.4.2 p. 167
[13] Intermediate Bulk Container
[14] ADR Volume II, point 4.1.1.8. p. 55
[15] High density polyethylene

available on the market that can be used for transportation of dangerous goods where a vent is required.

One of our customers also informed us that for certain type of chemicals (which have no assimilation liquid and for which the ADR rule of collective entries[16] does not apply), a real-life warehouse storage test for a period of 6 months in the original packaging with the closure and vent has to be performed. The closure with vent needs to be also oriented sideways for a very short period of time to prove the closure and vent remained intact overtime and photographic evidence need to be sent to the UN certifying authority (namely: BVT, BAM, BVI). If the container and/or closure/vent are not chemically compatible, then leakage is observed. The whole system after the full 6-month storage test with the real chemistry is then drop-tested on-site at the certifying authority's premises, after the empty aged packaging with closures/vent is shipped to certifying authority.

Selection of materials to construct such vents are not prescribed by regulation but are driven by in-field combined experience of packaging and chemical industry, ADR-UN authorized certifying bodies, laboratory experiments (as the one described in Annex I), and the knowledge of materials' intrinsic properties (such as surface energy).

It is also worth noting that passing the stacking test is just a first hurdle for transport of dangerous goods. If in real life conditions, packaging still leaks, the overarching primary principle, to ensure transport safety, would prevail and such packaging cannot be used.

b. EU Plant Protection Products Regulation No 1107/2009[17] and FAO[18] guidelines

Pesticides and bio-pesticides fall under the EU PPP Regulation. It prescribes storage stability tests requirements, namely the CIPAC MT 46.3 accelerated stability test (also recommended by FAO). To pass the test, no significant chemical, physical, or packaging changes should occur. Significant bloating or leak would be classified as a significant change to packaging. These tests are performed at elevated temperatures which favour biological reactions, increasing the likelihood of bloating and leakage. Also, in real life storage and transportation, pesticides/bio-pesticides would be subject to varied and often elevated temperatures.

Biological products are derived from naturally occurring microorganisms, plant extracts, beneficial insects, or other organic matter. High organic matter content and presence of these organisms can result in decomposition and build-up of gases (e.g., CO_2) within containers that store or transport the products.

Stability tests are part of market authorisation process for Plant Protection products, as per EU PPP Regulation.

c. EU Biocidal Product Regulation (EU) 528/2012

Disinfectant products in the EU are regulated under the EU Biocide Product Regulation. Similar to Plant Protection Products, disinfectants need to pass rigorous stability tests (accelerated at elevated temperatures according to CIPAC MT 46.3 and long-term storage stability at ambient temperatures) before they are authorised for market. Long term stability tests are performed in commercial packaging to support product shelf life. One endpoint of these stability tests is

[16] see ADR 4.1.1.21.5
[17] Further referred as EU PPP Regulation
[18] Food and Agriculture Organisation of the United Nations

assessment of stability of packaging. Packaging should not leak or balloon[19]. Without packaging vents, certain types of decomposing disinfectants (e.g., bleach or hydrogen peroxide based) would not pass those tests and would not be allowed for sale.

3. Assessment of Alternatives

To the best of our knowledge, there are currently no alternative non-PFAS venting products on the market that provide a combination of properties necessary for safe transport and storage of decomposing chemicals. In many cases (as in the case of dangerous goods, pesticides and disinfectants) passing mandatory tests (as described above) would not be possible without PFAS-based vents. This would prevent those chemicals from entering the market.

a. *Why Fluoropolymers and other PFAS can uniquely deliver the needed performance*

Today, only PFAS-based vents can meet the required combination of properties. Polytetrafluoroethlene (PTFE) is the primary material used for packaging vents. Additional fluoropolymers and other PFAS listed in Table 2 are used to construct the finished vent and provide an enhanced oleophobic surface on the PTFE membrane so that it more effectively repels the chemicals. Without the enhanced oleophobic surface, the vent could be blocked and ultimately lead to packaging bloating and potentially a leakage of hazardous chemicals.

i. Oleophobicity

Oleophobic treated PTFE has a reduced surface energy and can effectively repel fluids with very low surface tensions.

Many chemicals that generate gases are transported/stored as mixtures with surfactants. For example, the surface tension of household cleaners ranges from 27–32 dynes/cm, and the surface tension of isopropanol is 22 dynes/cm. If these fluids were to penetrate through a vent during transport or storage, they would block the membrane, causing the loss of its functionality, that in turn would lead to packaging bloating and leakage, releasing often hazardous chemicals to the environment.

Expanded PTFE is naturally hydrophobic and has a surface energy of 19 dynes/cm. This allows it to easily repel fluids with low surface tensions. When treated with an additional fluoropolymer (such as PFA), the surface energy can be further decreased, making the membrane durably resistant to very low surface tension liquids that need to be packaged in vented containers.

[19] https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b

Table 3. Surface Energy[20]

Polymer abbr.	Polymer Name	Surface Energy (dynes/cm)	Contact Angles (degrees)
PES	Polyethersulfone	46	90
	Styrene butadiene rubber	48	
PPO	Polyphenylene oxide	47	75
	Nylon 6/6 (polyhexamethylene adipamide)	46	
PC	Polycarbonate	46	75
	Nylon-6 (polycaprolactam)	38	
PET	Polyethylene terephthalate	42	76
PMMA	Polymethylmethacrylate	41	82
SAN	Styrene acrylonitrile	40	74
	Polyimide	40	83
PVC r	Polyvinyl chloride, rigid	39	90
	Polyester	41	70
	Acetal	36	85
ABS	Acrylonitrile butadiene styrene	35	82
PPS	Polyphenylene sulfide	38	87
PVA	Polyvinyl alcohol	37	10
	Polyacrylate (acrylic film)	35	
PVC p	Polyvinyl chloride, plasticized	35	89
PS	Polystyrene	34	72
	Nylon-12	36	
	Surlyn ionomer	33	80
PBT	Polybutylene teraphthalate	32	88
CTFE	Polychlorotrifluoroethylene	31	
PP	Polypropylene	30	88
PU	Polyurethane	38	85
PE	Polyethylene	30	88
PVF	Polyvinyl fluoride	28	
PVDF	Polyvinylidene fluoride	25	80
	Natural rubber	24	
PDMS	Polydimethyl siloxane (silicone elastomer)	23	98
FEP	Fluorinated ethylene propylene	20	98
PTFE	Polytetrafluoroethylene	19	120

ii. Microporous Structure

PTFE is the only known material that has the necessary physical properties such as low surface energy and chemical resistance, and that can also be expanded into a thin, strong microporous membrane to deliver the primary characteristic (good air flow) needed for this end use.

Its microstructure facilitates the air flow, while effectively repelling water and other low surface tension chemicals. The unique combination of properties listed in this section have not been identified in any alternative materials that have been investigated by Gore and other companies to date.

iii. Chemical resistance

Fluoropolymers are used in packaging vents due to their resistance to wide range of chemicals, including oxidizing and/or corrosive chemicals. This is to avoid degradation and rupture of the vent membrane that would result in hazardous chemical leakage.

[20] https://www.tstar.com/blog/bid/33845/surface-energy-of-plastics

In packaging vent applications, it is the combination of microporous structure, chemical resistance, and oleophobicity that drives the selection process for material. We present below a chemical resistance chart to demonstrate the unique performance of PTFE and PFA.

Table 4. Chemical Resistance[21], please note that PTFE is referred to as TFE

	ETFE	FEP/TFE/PFA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, Dilute or Weak	E	E	E	E	E	E	E	G	E	E	G
Acids, **Strong/Concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, Aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, Aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, Aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, Halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, Aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, Strong	E	E	F	F	F	F	F	F	F	G	N

*Not for tubing chemical resistance (except PVC) **Except for oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

EXCELLENT	GOOD	FAIR	NOT RECOMMENDED
30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.	Little or no damage after 30 days of constant exposure to the reagent.	Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.	Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or discoloration, deformation, dissolution or permeation loss.

b. Alternatives tested by Gore

Although no assessment of alternatives for this end use application has been presented by the Dossier Submitters in the Restriction Proposal, Gore would like to present its own research on selected material.

Table 3 above provides comparison of various materials' surface energy, which is a critical performance requirement for this application. It clearly shows that PTFE has the lowest surface energy, which makes it most suitable for this technology. Other non-PFAS materials with low surface energy, such as natural rubber or PDMS are not able to be processed into thin and porous membrane necessary for the functioning of this technology. Therefore, Gore has considered expanded polyethylene (ePE) as a potential alternative to PTFE coated with PFA, because it is a non-PFAS material with the lowest surface energy that can be processed into thin and porous membrane.

Gore has performed a series of tests on packaging vents made with ePE to compare its performance with the current product. The test results presented in Annex I clearly show the deficiency in oleophobic properties for expanded polyethylene, which is of key importance to packaging vent applications. That deficiency ultimately would lead to failure of the vent within

[21] Eason, M., & Vogel, R. (2022, May). Sealing Devices and the need for PFAS. Valve World, 20-22.

the packaging container used to transport decomposing chemicals, whether it is dangerous goods, agrochemicals, or chemicals otherwise considered hazardous.

4. Why time unlimited derogation is required

As explained above and in the Socio-economic Analysis (SEA) in Annex II, so far, no alternative materials or products are available as a potential substitute for our packaging vent products applied in packaging used to transport and storage of decomposing chemicals.

The unique combination of porous microstructure, oleophobic surface, and chemical resistance that provides the combination of properties needed for successful operation in packaging vents was developed and commercialized after more than 50 years of R&D on microporous PTFE materials. Based on our research with other materials such as ePE, Gore perceives the likelihood of replacing PFAS in packaging vents and succeeding commercially as extremely low.

Since an alternative material is not available for packaging vents used for storage and transport of decomposing chemicals, a new material would need to be found or invented. Thus, the development process needs to begin with creating a new material, potentially a fluorine free polymer. The time needed is not known and very difficult to predict.

Examples from the past, show that the time span to develop new materials can vary significantly. For example, the development of acrylic polymer took several decades. The process from the first synthesis of acrylic acid to the introduction of the commercial polymer, was an 85-year journey.[22] While the development of PTFE from the "accidental" discovery to a commercial product took about 10 years, from 1938 to 1948, and then decades more to mature that technology into the materials used today. Development advances over this time have had to occur in polymerization, finishing, lubrication and blending, pelletization, and extrusion to develop forms usable in end products. In absence of such an initial unexpected discovery, we can only speculate that developing a new polymer to be commercially available will take more than 20 years.

As is shown in Table 5, alternatives to PFAS in packaging vents are not expected to be available in the foreseeable future.

Table 5. Estimated Timeline for Substitution

Steps for substitution	What activities does this step entail?	Time required for step
Discovery	Identify and develop suitable alternative materials. Material and process development from lab discovery to prototype scale. This will involve independent development of membrane and treatment	**Unknown** Estimate > 20 years for this use

[22] See https://www.ptonline.com/articles/tracing-the-history-of-polymeric-materials-part-20.

	technologies, as well as confirmation of their compatibility.	
Planning	This involves initiating the substitution project for packaging vents internally.	1 years
Product development	Product Development from Technology Readiness Level 1 to 9, testing in lab, and pilot scale, including modification of polymer to ensure performance needs.	2 years
Qualification and/or Validation	This stage involves testing and validation with customers and/or external testers (e.g., stability accelerated and long term stability tests)	1-2 years
Certification	For dangerous goods, certification by test institutes (such as TüV) to national and international Transport standards. For Plant protection products-potentially market authorisation variations to be submitted	1 year
Production	Set up production, manufacturing capabilities, supply chains.	2 years
Total	All steps	**Unknown** >27 years

5. Additional Information

Specific information requested in the stakeholder consultation is all available in the full SEA which is attached as Annex II to this derogation request. The information provided in the SEA include the following:

- Market and sales (Section 2.3 and 2.5.2);
- Types and volumes of PFAS used (Section 2.4, 2.5.3 and 2.5.5);
- Material flow, including emission volumes Section (2.4.3 and 2.5.3);
- Further information on alternatives (Chapter 3);
- Economic impacts (Section 4.3);
- Impacts on health and the environment (Section 4.4);
- Social and wider economic impact (Section 4.5); and
- Comparison of impacts and proportionality (Chapter 5).

Please note that the SEA covers all products of our venting business. Therefore, it also contains information on other Gore products which fall under different applications/sub-uses.

In the following, we present a high-level summary of parts of the SEA and some additional information relevant to packaging vents. Gore kindly asks the dossier submitters and the committees to also review the SEA in full.

a. Social and Economic Impacts

Not granting a derogation for packaging vent products used in the storage and transport of decomposing chemicals will have large and wide-reaching impacts on the EU. These include significant economic costs throughout the value chain and impacts on employment (lost jobs).

The market of biological pesticides, bio-fertilizers, and bio-stimulants is rapidly growing. The targets of the EU Green Deal are to reduce the use of the most dangerous chemical pesticides by 50% by 2030, and to increase up to 25% the organic farming in the EU.[23] These targets can only be achieved by the development and increased used of bio plant nutrition products. Without appropriate packaging vents, many of those bio-products would not be authorized for the EU market or encounter quality issues in storage and transport, leading to product shortages. Fertilizer shortages can adversely affect agricultural yield, leading to lower food production in the EU.

Following a global mineral fertilizer crisis, on the 9th November 2022, the EU Commission published a number of actions to maintain a sustainable EU fertilizers production and reduce dependencies on non-EU countries. One of the actions envisages substitution of mineral fertilizers by organic fertilizers as well as greater innovation to contribute to increasing yields sustainably, including use of biological alternatives to chemical pesticides. Horizon Europe has also invested 180 million Euro in projects on the optimization of nutrient budgets, alternative fertilizing products and nature-based solutions for nutrient management[24]. This illustrates the importance of a fully functioning EU fertilizer market, which will require safe product transportation and thereby the need for suitable packaging vents.

b. Impacts on Human Health and the Environment

As demonstrated above, there are no viable alternatives for packaging vents needed for safe storage and transport of decomposing chemicals. The loss in product effectiveness and potential product failure from using non-PFAS vents would increase the risk for health and safety of workers and transport operators of exposure to chemically aggressive and hazardous materials.

As explained in previous sections, one type of decomposing chemicals that require packaging equipped with vents are certain types of disinfectants (e.g., bleach, hydrogen peroxide based). Inability to transport these chemistries could lead to product shortages and eventually health concerns (especially in public buildings, such as hospitals, and nursing homes which require a heightened cleanliness level to prevent spread of diseases among vulnerable population).

c. Emissions

It is demonstrated in Section 2.4.3 of the SEA that emissions from product manufacturing, service life, and end of life are negligible. Additional information on responsible manufacturing, processing, and disposal of fluoropolymers and products made from fluoropolymers are provided in our derogation request for fluoropolymers.

In addition, the amount of PFAS materials used for packaging vents is very small. Packaging vents include a porous membrane of PTFE and a PFA fluoropolymer coating on the membrane.

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[23] https://agriculture.ec.europa.eu/farming/organic-farming/organic-action-plan_en
[24] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_6564

The total weight of PFAS materials in one of these vents is approximately 0.6 – 8µg (depending on vent size). Since there are approximately 200 million packaging vents sold in Europe each year, the volume of PFAS materials in this application introduced into Europe is approximately 200kg per year.

Most packaging used for storage and transport of decomposing chemicals are reusable and there are established recycling processes as an end-of-life solution. The packaging is mainly made of HDPE. As a plastic resin, it is reusable, recyclable, and economical to process. While some of the packaging in the consumer market is used just once, packaging of dangerous goods sometimes has a longer lifetime, as it could be either reused or recycled multiple times. There are several collection systems which are focusing on the most economical and ecological way to utilize the raw material. In the recycling process, the packaging will be shredded, followed by an extrusion process where the PFAS and other substances will be filtered out and the new recycled resin have almost the same characteristics as the virgin material. The residue (including PFAS) from the extrusion process will go to incineration or other waste streams.

Annex I – [redacted]

[redacted]

Date: 4/19/2023

Annex II - SEA of restricting the use of PFAS in vents