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

Public consultation

Request for Derogation: Professional Apparel

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 additional applications of **professional apparel**, which are not covered by the derogations in the Restriction Proposal, is needed and justified. Further, we would like to explain why a transitional period of 13.5 years is required.

The conclusions from our statement are summarized as follows:

- Several uses which are for utmost importance to the society and whose protection cannot be sufficiently ensured without the use of PFAS are not covered by the proposed derogations for professional apparel yet.
- Even though it is recognised in the Restriction Proposal that repellence of liquids with low surface tension cannot be done without PFAS, the following end-uses which all require oil-repellence (i.e. repellence of substance with low surface tension) are not covered by the proposed derogations: armed forces, maintenance of law and order, and other emergency response workers (e.g., ambulance, technical rescue, mountain rescue and sea rescue), volunteer fire fighters, professional workers, including public services that are exposed to weather on a regular basis over extended periods of time, as well as workers needing electric arc, immersion protection, or high-visibility garments.
- Besides direct function of oil-repellence (beading off of oil and other chemicals/contamination), oil-repellence is crucial to ensure durable water-repellence and breathability. To date there are no alternatives to PFAS known that provide the level of oil-repellence needed for professional users.
- In addition to not meeting performance requirements, restriction of PFAS before developing alternative materials would lead to less durable products and a significantly higher carbon footprint due to increased resource depletion, consumption, and waste.

I. Derogation Request

Considering the arguments and evidence presented below, Gore respectfully requests the following:

To extend/modify the scope of Column 2, Paragraph 5 b. and c. as follows, to cover personal protective equipment for other workers than firefighters needing protection against heat, flame, and electric arcs as well as for voluntary firefighters:

1. *textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a), ~~and~~ (c), (e) and (h), until 13.5 years after EiF;*

2. *textiles used in personal protective equipment (PPE) in ~~professional~~ firefighting activities intended to protect users against risks as specified in Regulation EU) 2016/425, Annex I, Risk Category III (a) – (m) until 13.5 years after EiF;*

To include the following derogations in Column 2, paragraph 5 of the proposed restriction to cover protective equipment for armed forces and law enforcement personnel and other emergency response workers (e.g., ambulance, technical rescue, mountain rescue and sea rescue) as well as for workers needing immersion protection or high-visibility garments and professional workers performing services while being exposed to weather on a regular basis over extended periods of time:

3. *Protective equipment specifically designed for armed forces or for the maintenance of law and order or other emergency response workers until 13.5 years after EiF. Other emergency response workers are, for example, ambulance, technical rescue, mountain rescue and sea rescue.*
4. *Immersion Protection Garments certified under EN ISO 15027, European Technical Standard Order (ETSO) or International Convention for the Safety of Life at Sea (SOLAS) until 13.5 years after EiF.*
5. *High visibility clothing fulfilling the requirements of EN ISO 20471 Class 1, 2 and 3 until 13.5 years after EiF.*
6. *Weather protection garments for professional workers including public services until 13.5 years after EiF.*

II. Product Examples

In addition to the products covered by Column 2, Paragraph 5 b. and c. of the Restriction Proposal, there are several other products in the TULAC sub-use professional apparel that rely on PFAS. An overview of such products is provided below. The product examples are all based on Gore's laminates, as details of comparable products manufactured on the basis of laminates of other companies are not publicly available. We believe that these products are representative of products manufactured and placed on the EU market on basis of laminates of other companies.

Based on the initial Restriction Proposal the majority of professional apparel applications would not be covered by the derogations proposed for in Paragraph 5 b. and c. To illustrate this, the products covered are highlighted with green background and the products which are not covered with red background:

Table 1. Professional Apparel Products

User	Function	Application
Military/Armed Forces (including army, navy, air force and special forces)	Heat and flame protection	Military operation and training including improvised explosive devices or flash fire during refuelling of military vehicles

	Weather protection (rain, wind, cold)	Military operation and training incl. bivy sleep systems for military use.
	Immersion protection	Military operation and training
	Immersion protection, protection against heat and flame	Military operation and training
	Chemical/biological protection	Military operation and training
Maintenance of law and order/police	Chemical protection, heat and flame protection, weather protection	Operations of the riot police
	Protection against blood and other body fluids, weather protection	Operations of general and special police for normal use and unexpected situations*
	Weather protection	Operations of general and special police for normal use or unexpected situations including extended use*
	Immersion protection	Operations with risk of immersion to water (sea, river, lake etc.)
	Chemical/biologic protection	Specific police operations where protection against chemical and biological agents is needed
Emergency response workers (e.g., technical rescue, ambulance, mountain rescue and sea rescue and other emergency medical services)	Protection against blood and other body fluids, weather protection	Emergency medical services and rescue operations
	Weather protection	Emergency medical services and rescue operations
	Heat and flame protection, weather protection	Traffic accidents and other technical rescue operations
	Immersion protection	Water rescue operations
	Chemical/biologic protection	Specific technical rescue where protection against chemical and biological agents is needed
Professional workers including public services	Chemical/biologic protection	Working environments where protection against chemical and biological agents is needed
	Weather protection	Professional work wear, such as

		garments for railroad workers, garbage collectors, road construction workers, workers at airports, post and parcel deliverers, garbage collectors, professional craftsmen, workers of utility companies and for comparable services.
	Electric arc, heat, and flame protection	Working in high voltage areas (railway workers, industrial workers)
	High-visibility garments	Workwear for end uses / working environments where visibility is crucial for safety purposes, e.g., where workers might be overseen by co-workers, equipment operators, or vehicles. This includes industrial workers, workers at airports, road and railway workers, garbage collectors, workers of utility companies, and comparable workers.
	Immersion protection	Working environments with risk of immersion to water (e.g., off-shore, oil platforms, harbour, aviation)
Professional Fire Fighters	Heat and flame protection, protection against blood and other body fluids, chemical protection, and weather protection	Firefighting, Technical Rescue operations and Fire Fighting Training
Volunteer Fire Fighters**	Heat and flame protection, Protection against blood and other body fluids, chemicals protection and weather protection	Firefighting, Technical Rescue operations and Fire Fighting Training

* The requested level of protection depends on country and police department. Some specify weather protection and other specify additional protection against body fluids.

** Firefighting coverage on an honorary basis is quite common in several EU member states including Germany. Volunteer fire fighters need and use the same garments as professional fire fighters.

Besides garments, protective equipment comprises footwear, gloves, hoods, and for military use also bivy bags.

We would like to note that Gore does not manufacture final products but provides laminates to our licensed customers that manufacture the finished products and sell them to various

end-users/buying organisations. Gore Fabrics laminates can have between two and four layers. Figure 1 below shows a typical 3-layer laminate which is composed of an inner lining, membrane [redacted], and outer fabric which also has a treatment. As can be seen in the diagram, the face, membrane, and backer are laminated together to produce the 'final' laminate/fabric.

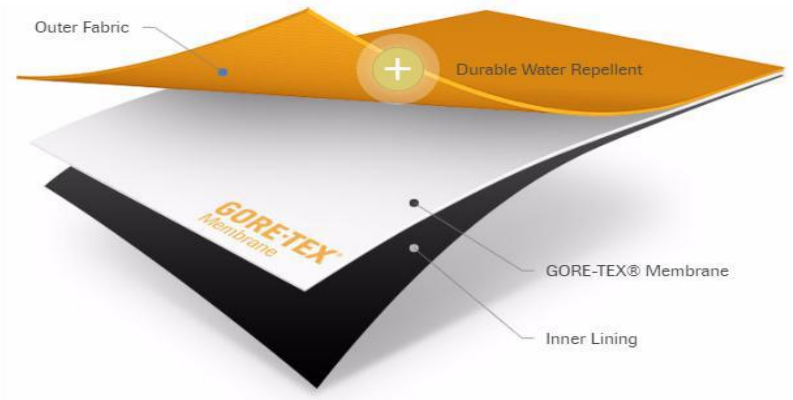

Figure 1. Diagram of the three components of Gore 3-layer membrane

Currently, Gore uses two different types of PFAS for all of the above-stated products: Polytetrafluoroethylene (PTFE) as a membrane and short-chain side chain fluorinated polymers for the treatments.

In the majority of footwear products, only PTFE is used. However, Gore only produces the insert of the shoe/boot, and the manufacturer of the finished footwear article typically applies an external treatment to provide the required functional performance of oil repellency.

PTFE represents the majority [redacted] of PFAS used in the manufacturing process for products covered by this derogation request. PTFE meets the criteria for Polymers of Low Concern (PLCs) based on the definition provided by the OECD Expert Group on Polymers. Gore believes that more than 95% of similar technical performance products on the EU market contain PFAS and that the majority of PFAS used in those products is PTFE.

III. References and Gaps in Restriction Proposal

Gore welcomes the derogations for PPE in paragraphs 5 b. and c. of the Restriction Proposal. These derogations cover PPE for workers handling substances and mixtures which are hazardous to health or harmful biological agents and PPE for professional firefighting activities. In particular, the Dossier Submitters concluded that *"repellence of liquids with low surface tenson cannot be done with non-PFASs"* (Annex E page 28) and that *"none of the PFAS-free finishing agents currently available on the market meet the same levels of performance with respect to repellence against blood, solvents, fuels and liquid chemicals as those containing PFAS"* (Annex E page 20).

Despite the acknowledgment, several end-uses requiring oil-repellence (i.e., repellence of substance with low surface tension) are not covered by the derogations suggested in the Restriction Proposal. For a full list of missing end-uses see Table 1 above. As will be

demonstrated in Section IV below, all products mentioned in Table 1 require – besides other performance requirements – oil-repellence.

We also welcome the recognition that PFAS are *"likely to be required"* in equipment for armed forces and for the maintenance of law and order (see Annex E page 26). However, despite this recognition, protective equipment for armed forces and for the maintenance of law and order is not covered by Paragraph 5.b. of the Restriction Proposal. Paragraph 5.b. refers to Risk Category III (a) and (c) of Annex I of Regulation (EU) 2016/425 (hereinafter 'PPE Regulation'). According to Article 2 para. 2 (a) of the PPE Regulation and as also pointed out by the Dossier Submitters, the Regulation does not apply to equipment designed for armed forces or in the maintenance of law and order/police. In addition, the risks referred to in the Restriction Proposal only cover a very small part of the protective equipment used by armed forces and maintenance of law and order/police (see Table 1 above). Furthermore, the risk categories referred to in the PPE Regulation do not reflect the requirements of military and law enforcement applications, since risks are often unknown, random, and prolonged, creating multi-threat scenarios, and are cumulative. In contrast to industrial workers or laboratory staff, for whom PPE is typically intended, the allocation of certain risks is not applicable here. Military and law enforcement outerwear clothing is not specifically designed to protect against a specific risk as provided for in the Regulation, but rather a whole range of risks and include protection to enhance survivability and mental and physical stamina. The risks here stem in particular from the fact that armed forces personnel are exposed to weather conditions for long periods of time and there is often no possibility for clothing to be replaced while in the field. **Therefore, we believe that the reference to the risks in the PPE Regulation is not appropriate for protective equipment for armed forces and for the maintenance of law and order.** Since the military does not refer to their personal clothing and equipment provided for training and operational use as "personal protective equipment" we would suggest not using this term but the term personal equipment instead. Similar to PPE, this term, also refers to items that are expected to give the users as much protection as reasonably possible, while allowing them to carry out all tasks efficiently and effectively.

The need for protective material for emergency response workers such as ambulance, technical rescue, mountain rescue, and sea rescue are not considered in the Restriction Proposal. Despite the recognition that there is no non-fluorinated finishing agents currently available on the market meeting the same levels of performance with respect to repellence against blood, a derogation is not proposed. In particular, Paragraph 5.b. of the Restriction Proposal does not cover emergency response workers like ambulance, technical rescue, mountain rescue, and sea rescue. Bodily fluids such as blood are not considered as harmful biological agents within the meaning of the Annex I, Category III (c) PPE Regulation. As can be seen from the guiding document,[1] harmful biological agents are, for example, micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity, or multi-resistant bacteria. The mere fact that body fluids such as blood might be dangerous is not

[1] PPE Regulation Guidelines - Guide to application of Regulation EU 2016/425 on personal protective equipment, p. 86 (available at https://ec.europa.eu/docsroom/documents/54277).

sufficient to qualify it a harmful biologic agent. All the aforementioned professional groups come into contact with blood on a regular basis.

The need for PFAS in high-visibility garments is mentioned in the Restriction Proposal but rejected based on the argument that garments can be regularly washed to avoid the high visibility material from getting permanently dirty.

Professional apparel needed to protect against electric arc are not mentioned in the Restriction Proposal. The need to use PFAS is rejected with regard to heat and flame protection other than for fire fighters. The Dossier Submitters state that use of PFAS is related to oil- and dirt-repellence as risk factors regarding flammability and that the required protection against flammability can be reached by using inherent fibers which provide the needed protection (see Annex E page 30).

Immersion protection apparels are not mentioned at all. Although several alternative materials are mentioned in the TULAC Section of Appendix E.2., no material is identified as an alternative to PFAS for professional apparel. Rather, it is stated that no specific substances were found for PPE for industrial applications e.g., for chemical workers, fire-fighters, oil and gas workers, law enforcement, and military forces.

IV. Need and Justification for Derogation Request

The suggested derogations for professional apparel are needed and justified. **Without the derogations the safety risks of affected end-users are expected to significantly increase.** We propose that the derogations are justified based on the following points:

- The **performance requirements** for professional apparel
- The **lack of current alternatives** that would provide a sufficient level of performance
- The **time required** to develop, test, and commercialize new products, once a feasible material option is identified
- The **large socio-economic cost** of restricting the applications.

1. Performance Requirements

We believe that the Dossier Submitters concluded that PFAS are not necessary in most of the considered PPE due to missing information on water- and oil-repellence, and in particular the indirect function of oil-repellence in protective equipment. Therefore, we would like to further explain the importance of oil-repellency for the specific performance requirements relevant for professional apparel as well as the performance requirements in general.

There are five main performance requirements for professional apparel. The first four requirements are relevant for all applications and the last only for applications requiring protection against heat, flame, and/or electric arc.

a) Waterproofness

Waterproofness means that water (rain and snow) cannot pass through a material. The challenge for apparel is to prevent water from the outside from passing through

while ensuring that water vapour/sweat can get from the inside to the outside. Therefore, a water vapour permeable material (membrane) is required.

Waterproofness of state-of-the-art laminates is ensured by the membrane based on expanded PTFE. Each square inch of membrane has several billion pores. Each of these tiny holes is 20,000 times smaller than a water droplet. Therefore, rain and snow simply cannot get through.

b) Durable Water-Repellence

Water-repellence means that the water beads up on a surface and is able to roll off rather than soak into the textile layer.

Water-repellence of state-of-the-art laminates is ensured by treatments of the outer layer of laminate (textile) with short-chain side chain fluorinated polymers. These polymers have properties that are distinct from hydrocarbon structures due to the chemical nature of fluoroalkyl groups, which can produce polymers with very low surface tension. This means that water and other liquids cannot soak into the textile. Instead, they remain on the surface and bead off. Durable Water-Repellence (DWR) treatment is achieved by coating the fabric with an aqueous dispersion formulation including a short-chain side chain fluorinated polymer which is bonded to the textile surface by curing the fabric at elevated temperatures.

Water-repellence is a very important element to keep the user warm in cold conditions. Even though the user will not get wet in case of failure of DWR due to waterproofness of the membrane, the user will feel wet and get cold quickly due to water pick up of the outer textile layer. Since the thermal conductivity of water is 23 times higher than air, water soaking into the outer layer of a garment leads to rapid cool down of the user (so-called Cold Bridge Impact) and increased risk of hypothermia. In extreme conditions of cold injuries, this can become life threatening.[2] In addition, the wet pick up alters the garment's form/fit/drape and reduces the air layers within the garment and its insulation effectiveness. This also leads to a more rapid cooling as well as a higher weight of the garment.

While the standard clothing to protect against rain (EN 343) does not require oil-repellence to be met, EN 343 sets very basic requirements, including very low requirements with regard to breathability and durability of waterproof performance. Basic EN343 garments typically target more cost-sensitive markets and are less durable with a shorter product life, i.e., need to be replaced more frequently.

Oil repellence is needed to archive a durable water-repellence. Water-repellence will be impaired if the textile material gets contaminated by oil or chemicals since such contamination will degrade the DWR performance significantly, allowing water to enter/fill the outer textile layer, becoming "wet-out". Figures 2 and 3 demonstrate a properly functioning DWR and a contaminated/degraded DWR with water soaked into the textile.

[2] For further information on related risks see Section 2a) below.

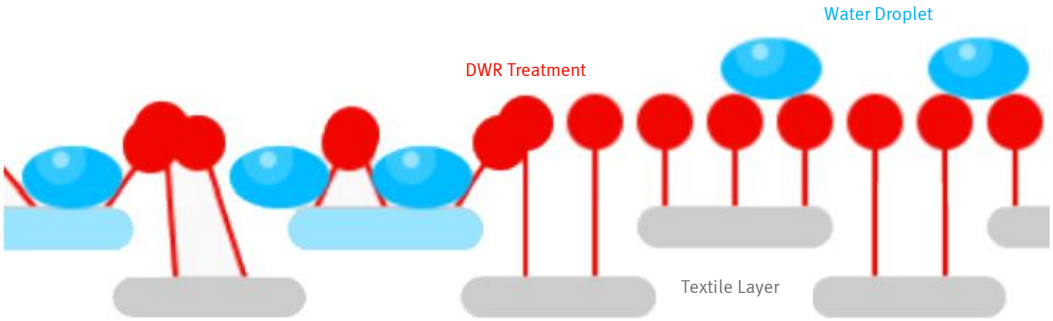

Figure 2. Contaminated/degraded (left) and functioning (right) DWR (schematic illustration)

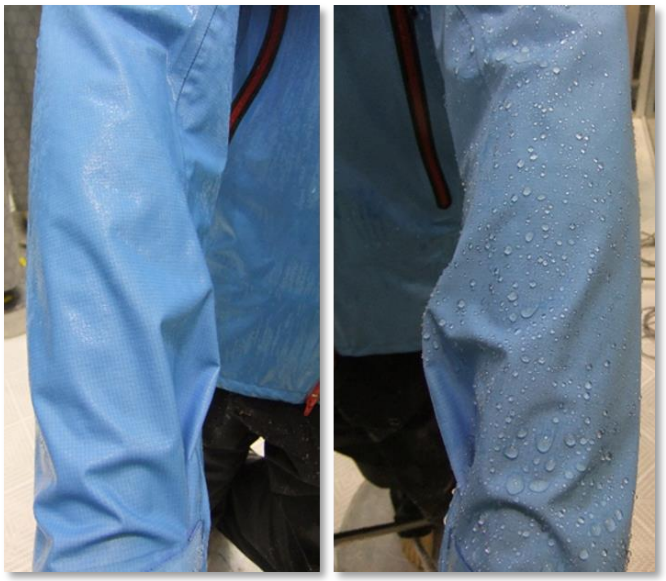

Figure 3. Non-functioning and functioning DWR (picture)

Such contamination cannot be avoided even with garments that are *merely* exposed to normal environmental conditions/weather, as even contamination with creams or body oil is enough to impair the function of non-fluorinated water-repellent treatment and to allow water to soak into the textile. In addition, for most of the end-users listed in Table 1, contact with chemicals or oil/fuel is a typical job-related risk. It is inherent to services provided by railroad workers, garbage collectors, road construction workers, and emergency response workers who may come into contact with oil or other chemicals in the event of car accidents, floodings, water rescue, industrial accidents, or chemical incidents.

Contamination by oil or chemicals is a common DWR failure mode. To maintain water-repellence function for a sufficient period of time, the surface tension needs to be lower than what is needed to repel water to ensure that contaminants like oils and chemicals also bead off the surface.

c) Breathability

Breathability means the ability of a water vapor molecule (i.e., sweat) to be transported from the inside to the outside of the garment.

Breathability of state-of-the-art laminates is ensured by the membrane based on expanded PTFE. Each of the billions of pores is 700 times bigger than a water vapor molecule and therefore allows water vapor to exit the laminate. Breathability is imperative to prevent heat stress of the user. Heat stress has severe consequences for users and their performance.[3]

Breathability will be impaired if the membrane gets contaminated by oils (e.g., body oils) since such contamination will allow liquids to enter the expanded PTFE structure, inhibiting breathability. [redacted]

d) Oil-repellence

Oil-repellence means that oil and other chemicals/contamination bead up on a surface, can roll off, and do not soak into the textile. The liquid can only remain a bead if the surface energy of the contacted material is sufficiently lower than the surface tension of the liquid; otherwise, the molecules would interact. While expanded PTFE has a surface energy of 19 dynes/cm which is sufficient to repeal water with a surface tension of 72 dynes/cm, PTFE is not oil-repellent since the surface tension of typical oils begin to approach the surface energy of PTFE.

As already stated above, oil-repellence is ensured by a treatment with short-chain side chain fluorinated polymers with very low surface tension of ~16 dyne/cm. This is sufficiently lower than the surface tension of typical oils to provide durable oil-repellence.

Oil-repellence has two different functions: As already explained above, it ensures the durability of the water-repellence function as well as breathability. In addition, it ensures roll off of various chemicals, blood, and other body fluids and protects users from contact with such substances, as well as preventing the garment from getting dirty. These functions are needed in many of the applications, such as:

- Roll off of oils and fuels to maintain heat and flame protection for military, fire fighters, riot police, and certain industrial workers. Textiles become more flammable if oil and fuels penetrate into the textile.
- Roll off of blood and other body fluids needed for emergency response workers.

[3] See Section 2b) below.

- Protection against dirt to maintain reflective and color properties of high-visibility clothing and immersion protection garments.

e) High-temperature resistance

High-temperature resistance is needed for heat and flame as well as electric arc protection. Some high temperature resistant textiles form a stable char when in contact with heat and flames at around 220°C. This layer needs a heat resistant layer to hold it in place and maintain protection for the wearer. Due to its high temperature resistance, PTFE neither melts nor breaks open. This function in heat and flame protection products has not been considered by the Dossier Submitters.

In addition to PTFE, the treatment with short-chain side chain fluorinated polymers is of great importance. As just explained in the oil-repellence section above, the treatment ensures that oils/chemicals which would add extra fuel/energy cannot be absorbed by the textile. The additional energy could break open the membrane and allow heat or flames closer to the body. Without a sufficient oil-repellency treatment, materials absorb oils and chemicals which cause even non-flammable materials to start burning when exposed to flames.

The heat and flame protection of a properly functioning garment is demonstrated in the following video: https://www.youtube.com/watch?v=2oPUpWY1RhI2.

2. Rationale for Specified Performance

In the Restriction Proposal it is questioned whether the performance specifications reflect the actual need, or whether they are based on the performance of PFAS which may exceed what is needed (See page 5 of Annex F).

The highest possible protection should be ensured for the end-users where derogations are requested since the protective products are integral to the end-user's health and safety. While functional impairments in the consumer sector leading to a loss of comfort and a reduced durability are acceptable, reduced performance is unacceptable for industries such as the armed forces, law enforcement, fire fighters, ambulance and other emergency responders, technical rescue, and professional workers performing services while being exposed to weather on a regular basis over extended periods of time. For such uses, the mentioned functionalities are not only a question of comfort but are essential for their protection and health maintenance. By reducing the quality of the end-products, health and safety risks are expected to increase significantly.

Lower performance, in particular with regard to DWR, breathability and oil-repellence comes with significant risks. While the risks associated with exposure to chemicals due to insufficient performance of protective equipment are more obvious, risks for other types of users are also significant.

a) Durable Water-Repellence

As stated above, water-repellence helps keep the user warm. The effects of cold are familiar to anyone who has ever tried to close their bike lock after a ride in winter with insufficient

protection for their hands. Based on scientific research, there are several physiological impacts of cold strain. Cold muscles are weaker and average muscle strength is reduced with increased cold exposure.[4] Likewise, cold fingers lose dexterity and strength at skin temperature below 15°C, causing hands to dramatically lose performance and increase likelihood of accidents in professional workers.[5] Similarly, decrease in mental performance caused by low core body temperature is distinguished as a root cause of serious or even fatal outdoor workplace accidents.[6] It is well reported that the probability of accidents increases with thermal discomfort, and consequently relative accident frequency increases more than 35% with too cold or too warm work place temperatures.[7] Moreover, the higher heat conduction of water compared to air leads to rapid cooling of the body when wet, increasing the risk of hypothermia – which in extreme conditions of cold injuries, can become life threatening.[8]

b) Breathability

If a garment has poor breathability, sweat cannot properly escape, which is critical to cool the body. For professional users such as a fire fighter, poor garment breathability has been shown to rapidly influence user performance, leading to early exhaustion and impaired judgement.[9] Without adequate levels of breathability workers can experience heat stress – a leading cause of fire fighter injury[10] – which occurs after prolonged exposure to extreme heat. Heat stress causes a perceivable and distracting discomfort, with impacts including diminished hearing, cognitive ability, and motor control. Such lapses impede the wearer's ability to make quick, potentially life critical, decisions in an emergency situation. In extreme cases, heat stress can ultimately result in irreversible damage to the central nervous system, kidneys, heart, and possibly death.[11]

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[4] Oksa, J., Rintamaki, H., and Rissanen, S. "Muscle performance and electromyogram activity of the lower leg muscles with different levels of cold exposure." European Journal of Applied Physiology (1997) 75: 484-490.
[5] Kay, H. , "Report on Arctic Trials on Board H.M.S. Vengeance February-March 1949," Royal Naval Personnel Research Committee, Report Number 534. London, Medical Research Council, 1949.
[6] Holmer et al, "Cold Stress: Effects on Performance and Health," in Patty's Toxicology. https://doi.org/10.1002/0471435139.tox097.pub2.
[7] A Study of exposure in cold stores. William DK, Cherenko FA and Hamley EJ (1984).
[8] Schellenberger et al., Journal of Cleaner Production Volume 217, 20 April 2019, Pages 134-143.
[9] This is demonstrated by Mukhopadhyay and Midha (2016), Ho (2011), Roy Choudhury, A. K., Majumdar and Datta, C (2011), Wang, F (2011) as well as other published studies.
[10] Leonidas G. Ioannou, Josh Foster, Nathan B. Morris, Jacob F. Piil, George Havenith, Igor B. Mekjavic, Glen P. Kenny, Lars Nybo & Andreas D. Flouris (2022): Occupational heat strain in outdoor workers: A comprehensive review and meta-analysis, Temperature, DOI: 10.1080/23328940.2022.2030634.
[11] U.S. Naval Flight Surgeon's Manual (1991), available at https://www.operationalmedicine.org/TextbookFiles/FlightSurgeonsManual.pdf; US Center for Disease Control, available at https://www.cdc.gov/niosh/topics/heatstress/heatrelillness.html; USARIEM Technical Report T13-3 (2012), Management of Heat and Cold Stress, Guidance to NATO Medical Personnel; Wang, F., Clothing Evaporative Resistance: Its Measurements and Application in Prediction of Heat Strain, 2011; Parsons, K., Human Heat Stress, 2019; Heat Stress Control and Heat Casualty Management, US Army Technical Bulletin, Medical (2022), available at https://armypubs.army.mil/epubs/DR_pubs/DR_a/ARN35159-TB_MED_507-000-WEB-1.pdf).

c) Oil-repellence

Besides impairment of DWR, breathability, and related risks, the absence of oil-repellence means that the garment will not offer protection against various, low surface-tension chemicals, blood, and other bodily fluids. This poses a health and safety risk to the users, especially for emergency services and military. Without oil repellence, the garments will also likely get dirty quicker during a workers 'normal activity', (e.g., using oils, greases, etc.) which can have significant consequences in terms of visibility and protection against heat, flame, and electric arc. In particular, there is an increased risk of flammability hazards following exposure to flammable liquids (oil, hydraulic fluid). If oil penetrates the textile of the garment, the oil can make the garment more flammable. As demonstrated in Section IV.1e) above, the additional energy added by the flammable liquid might lead to a failure of the garment, i.e., a significantly increased risk of burn injuries or death of the wearer.

Table 2 below demonstrates which risks would become apparent to the different types of users when there are insufficient levels of waterproofness, water-repellence, breathability, oil-repellency, and high-temperature resistance.

Table 2. Risks to end-users when sufficient level of protection is not ensured

User	Function	Risk
Military/Armed Forces (including army, navy, air force and special forces)	Heat and flame protection	Oils and fuels readily soaking into textiles, significantly increase the risk to users of burn injuries or death.
	Weather protection (rain, wind, cold)	Depending on the weather conditions, insufficient performance either increases the risk of heat stress or hypothermia. For defence, workers can be outside for hours to days in bad weather/sleep outside in a bivy sleep system. Army tours can last 6 months with reduced possibilities to have replacement clothing. Both heat stress or hypothermia may lead to illnesses (colds, etc.) or loss of performance of the wearer. For defence workers, reduced performance can have life-threatening consequences.
	Immersion protection and protection against heat and flame	Immersion protection garments rely on waterproofness and durable water-repellence. If sufficient performance level is not ensured, the risks related to cold-water immersion will significantly increase, such as hypothermia and/or death. In Immersion Protection Garments, the treatment is of particular importance as the garments must stay clean in critical situations, such as water recovery, storms, and explosions to aid search efforts. Cleanliness and thus visibility is directly linked to survival. In addition, the survival risk in emergencies where the user is exposed to fire before water immersion tremendously increases (e.g., helicopter crash, explosion on oil-platform). If fire damages the garment because of oil soaked into the textile, then the suit could leak and not provide the needed protection against cold water.
Maintenance of law and order/police	Chemical protection, heat, and flame protection	Increased risk due to exposure of chemicals and significantly increased burn injury risk. For riot police, this is relevant as exposure to hot steam, attacks with petrol bombs (Molotov cocktails), or exposure to other chemicals is to be expected.

	Protection against blood and other body fluids	Increased risk of infection/illness from exposure to bodily fluids.
	Weather protection	Depending on the weather conditions, insufficient performance either increases the risk of heat stress or hypothermia. Since law enforcement personnel might need to withstand any weather conditions over a longer period of time (potentially >8 hours), DWR and breathability are very important factors. Both heat stress or hypothermia, may lead to illnesses (colds, etc.) or loss of performance of the wearer. The latter can bear serious consequences to both the wearer and their colleagues.
	Immersion protection	Immersion protection garments rely on waterproofness and durable water-repellence. If sufficient performance level is not ensured, the risks related to immersion to cold-water will significantly increase, i.e., hypothermia and/or death. In addition, it is important that the high conspicuity material remains clean in critical situations, such as storms and explosions. Otherwise, law enforcement personal might get lost or not been seen during rescue operation.
Emergency response workers (e.g., technical Rescue, ambulance, mountain rescue and sea rescue and other emergency medical services)	Protection against blood and other body fluids	Significant increase of occupational risk of contracting infectious diseases or other illnesses from exposure to bodily fluids. Since all emergency response workers come into contact with blood on a regular basis, proper repellence function is needed to ensure that body fluids cannot be soaked into the garments.
	Weather protection	Depending on the weather conditions, insufficient performance either increases the risk of heat stress or hypothermia. Since emergency responders often need to work in extreme weather conditions (mountain and sea rescue) or are exposed to the weather for long periods of time (ambulance and in particular technical rescue), durable water-repellence and breathability are very important factors. Both, heat stress or hypothermia, may lead to illnesses (colds, etc.) or loss of performance of the wearer. The latter can bear serious consequences to both the wearer, his colleagues (e.g., accidents) and, in particular, for the person to be rescued.

	Heat and flame	Oils and fuels readily soaking into textiles significantly increase the risk to users of burn injuries or death.
	Immersion protection	Immersion protection garments rely on waterproofness and durable water-repellence. If sufficient performance level is not ensured, the risks related to immersion to cold-water will significantly increase, i.e., hypothermia and/or death. In addition, it is of particular importance that the high conspicuity material remains clean in critical situations, such as storms and explosions. Otherwise, emergency response workers might themselves be difficult to locate during a rescue operation.
Professional workers including public services	Weather protection	Depending on the weather conditions, insufficient performance either increases the risk of heat stress or hypothermia. Since workers are outdoors for extended hours all year and their services in general involve a high level of activity, DWR and breathability are very important factors. Both, heat stress or hypothermia, may lead to illnesses (colds, etc.) or loss of performance of the wearer. In particular, for railway and road construction workers, as well as professional craftsman, the latter leads to an increased risk of accidents.
	Electric arc and heat and flame protection	Oils and fuels readily soaking into textiles significantly increase the risk to users of burn injuries or death.
	High-visibility garments	Insufficient visibility due to contamination of high-visibility garments will increase the risk of accidents with presumably serious or fatal injuries, i.e., road worker gets hit by car.
	Immersion protection	Immersion protection garments rely on waterproofness and durable water-repellence. If sufficient performance level is not ensured, the risks related to cold-water immersion will significantly increase, such as hypothermia and/or death. In Immersion Protection Garments, the treatment is of particular importance to keep the garment clean in critical situations, such as water recovery, storms, and explosions to aid search efforts. Cleanliness and thus visibility are directly linked to survival.

Professional Fire fighters	Heat and flame protection	Oils and fuels readily soaking into textiles, significantly increase the risk to users of burn injuries or death.
Volunteer Fire fighters	Heat and flame protection	Oils and fuels readily soaking into textiles, significantly increase the risk to users of burn injuries or death.

3. Assessment of Alternatives

In September 2022, we provided a full Socio-Economic Assessment (SEA) prepared by eftec. The SEA has been submitted to all 5 Dossier Submitters. Since this information was provided after the end of the Call for Evidence in September 2021, the SEA is attached as **Annex IV** to this derogation request. The SEA contains a comprehensive assessment of alternatives (see Section 3 (pages 33-56)).

To make the information more easily available and to account for the information provided in the Restriction Proposal, we have summarized the information on alternatives in this section, which also contains updated and supplementary information obtained after the SEA was submitted. The conclusions from the section below are:

- Testing and real-life experience confirm that alternative membrane materials are inferior in terms of the combined properties of breathability and durability compared to PTFE. Gore is confident that new expanded polyethylene (ePE) membrane technology can be improved in the future to meet needs of professional users.
- To date, there are no alternatives to PFAS known that provide the level of oil-repellence needed for professional users.

a) R&D

[redacted]

Due to the significantly higher and more complex performance requirements of professional apparel, the technology developed for the consumer business cannot simply be transferred to all professional applications. Through the R&D work to transition its consumer business, Gore has gained considerable knowledge on alternative materials. In addition, Gore has already spent over [redacted] on testing alternative substances as potential substitutes for the use of PTFE and short-chain side chain fluorinated polymers for its professional (technical oriented) fabrics business.

Gore continues to work intensively to find acceptable alternatives for professional end-users. The focus is on further development of the ePE option that is being introduced to our

consumer markets. There are still many technical hurdles to delivering the complex combination of properties required by the broad community of professional end-users.

b) Alternative Assessment for PTFE Membranes

There are alternatives to PTFE membranes on the European market. Most of them are based on polyurethane, but, so far, they are inferior in terms of the combined properties of breathability and durability in addition to other properties including heat resistance. A ban on PTFE before improving alternative materials would therefore impact the safety of the end-user (see for consequences Section IV.1. above) and drastically reduce the longevity of products creating additional environmental impact through increased resource consumption and waste generation. Alternative membranes, such as polyurethane, invariably result in compromises of one property to deliver another. For example, to achieve a high level of moisture vapour transport, it needs to be made very thin which leads reduced mechanical strength. Thus, the end-products are less durable.

Gore has done extensive work to understand durability in use and why garments fail before the expected end of service life. Based on these failures, Gore has had various alternative technologies tested at the Hohenstein Institute to assess potential failures. The data presented in **Annex I**, confirm that PTFE has higher durability and breathability compared to other known materials.

This has also been confirmed in real life. Some customers who have tried to switch to non-PTFE-based products primarily for cost reasons have experienced the significant disadvantages in terms of breathability and durability and eventually returned to PTFE-based products. Examples of this [redacted]

c) Alternative Assessment for Treatment with Short-chain Side Chain Fluorinated Polymers

As demonstrated above, oil-repellence function is crucial to ensure durable water-repellence and breathability as well as to ensure that chemicals, oils, and other substances cannot contaminate garments. Both are needed to reduce risks for end-users from heat, cold, fire and electric arc, blood, and other body fluids as well as the risks from not being

[redacted]

highly visible. To date there are no alternatives to PFAS known that provide the needed level of oil-repellence.

In addition, non-fluorinated treatments are inferior with regard to water-repellence. We have tested water beading ratings[13] of over 40 different non-fluorinated DWR chemistries that belong to the following chemical classes: polyurethanes, acrylates, silicones, wax dispersions, dendritic materials, and hybrids. Data from these tests showed a wide range of performance, with just a few alternatives providing comparable water repellence to short-chain side chain fluorinated polymers. However, so far the performance is not sufficiently durable, i.e. it loses performance with regard to breathability and water-repellence due to contamination (e.g., by body oils) that cannot be prevented due to missing oil-repellence function.

Figure 4 below shows the latest data (from 2019) of non-fluorinated DWR chemistry samples (red dots) tested for weight gain and Gore Rain Room rating in comparison to short-chain side chain fluorinated polymers. The Gore Rain Room method is a test framework (similar to the CEN EN 14360 Protective clothing against rain - test method for readymade garments), which mimics actual rain reproducing real drop size distribution and impact pressure. It measures water beading rating and water pickup parameters as well as incorporating multiple test modes (e.g., initial, stressed state regeneration, etc.) connected to field trial results and combined with simulated wash cycles. The data showed a wide range of performance. A Gore rain room rating below 3 would mean that water will enter/fill the outer textile layer with water with the consequence that the wearer experiences thermal discomfort. Only a few alternatives (including hydrocarbon-based urethane and hydrocarbon acrylate) were able to reach relatively high level of water repellence (above 3); however, as already mentioned above, these materials lack sufficient durability.

[13] Beading rating determines ability to prevent the outer textile layer from filling with water or “wet out” and is based on modified ISO 4920:2012 rating scale.

[redacted]

4. Timeline

As demonstrated above, we made significant progress with new membrane technology based on ePE and are confident in achieving the required level of performance in the future. Even though an alternative for the treatments has not been identified yet, Gore set the internal goal to transition the entire professional business to non-fluorinated materials as soon as a material with a sufficient level of performance can be identified. Gore will continue to work intensively on the identification/development of alternative materials.

[redacted]

[redacted] In addition, if at any point during the substitution process a step ends with failure (e.g., a potential alternative substance does not pass a specific standard/certification), then the entire process will need to be restarted which can significantly increase the time and resources required. Also, it needs to be considered that the contracts in the area of professional apparel may run from 1 to 10 years. Without a sufficiently long transitional period a restriction would have disrupting effects. **Based on the timeline presented a transition period of 13.5 years is needed to complete the transition.**

[14] Most of the garments covered by the derogation request will be purchased via public tenders. This includes military, police, firefighters, postal service, several emergency response workers, railway workers, road construction workers and garbage collectors.

v. Additional Information in SEA

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

- Market and sales for professional apparel products (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);
- Information on alternatives (Section 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 a slightly broader range of professional apparel products than those for which a derogation is requested for in this submission.

In the following, we present a high-level summary of parts of the SEA. Gore kindly asks the Dossier Submitters and the committees to review the entire document:

1. Social and Economic Impacts

The SEA shows that not granting a derogation for professional apparel products similar to those set out in Table 1 will have large and wide-reaching impacts on the EU. These include significant economic costs throughout the value chain, impacts on employment (lost jobs) as well as adverse impacts on human health and the environment.

The SEA conservatively estimates that the minimum annuity costs, including lost profits and impacts on employment, of restricting the use of PFAS in professional apparels amounts to €4.017 million per year.

2. Impacts on Human Health and the Environment

It is demonstrated in Section 4.4.3 of the SEA, that a restriction of PFAS in professional apparel products would have several adverse effects to human health and the environment. This includes health and safety risks of end-users like defense, maintenance of law and order, other emergency response as well as industrial workers due to lower performing PPE and increases in emissions arising from more frequent replacement of materials. This means more waste and excessive energy use and raw material consumption to replace products.

The durability of the garment (i.e. service life) has the biggest impact on the environmental footprint over its lifetime. Production of less durable products would increase resource depletion, consumption, and waste – as most of the life cycle environmental footprint occurs during the manufacturing and distribution stage (Gore, 2020a). This is confirmed by

Sandin et al (2019)[15] which used a life cycle assessment to understand the total carbon footprint. The paper shows that by doubling the lifetime of a product, the environmental impact of CO_2 is halved.

3. 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, an estimate of worst case emissions based on the "investigation report summaries" published by the DS in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021) is provided (see section 2.5.3). This information has been compiled to create a basis for further consideration within the framework of the SEA. It does not correspond with our knowledge on emissions and in particular our knowledge on emissions from product manufacturing with emission control technologies in place. In our opinion, the emissions from product manufacture provided in the investigation report summaries are significantly overestimated. **But even when applying highly conservative emission factors, the resulting costs of reducing PFAS through restricting professional apparel applications is very high, with a minimum cost of €114,000 to €305,000 per kg PFAS emissions reduced.**

A cost effectiveness estimate does not in itself, indicate whether benefits of a restriction outweigh the costs. For cases where risks and impacts of reducing exposure to a substance are unknown, it is common to compare the cost-effectiveness estimates with some type of benchmark. A study by Oosterhuis et al. published in 2017 found that for PBTs, vPvBs, and substances with similar properties (e.g., lead) emission reduction measures with a cost-effectiveness below €1,100[16] per kg emission reduced were generally not rejected due to costs i.e., the costs were found to be proportionate. Measures with costs above €56,400[17] per kg, on the other hand, were more likely to be rejected, i.e., costs at this level were found to be disproportionate. Cost in between could be either proportionate or disproportionate – a so called 'grey zone' (Oosterhuis et al., 2017). The Oosterhuis benchmarks (BMs) have been used for the assessment of a number of regulations of PBTs and vPvBs, which are substances of very high concern (SVHCs). These BMs are, however, not necessarily applicable to substances of low concern such as PTFE and other PLCs. The reasoning behind this is that the implied willingness to pay (acceptability of costs) would be higher, and the higher the perceived risk of a specific substance. If the Oosterhuis BMs are to be used for substances of low concerns, it is reasonable to make some indicative, quantitative or qualitative, adjustments. For example, if the 'grey zone' for a PBT ranges from €1,100 – €56,400 per kg PBT emission reduced, it is reasonable to assume that upper bound (and likely also the lower bound) would be significantly lower for substances of low concern. This

[15] Mistra future fashion, Environmental assessment of Swedish clothing consumption – six garments, sustainable futures By Gustav Sandin, Sandra Roos, Bjorn Spak, Bahareh Zamani & Greg Peters
[16] €1,000 in original study, uplifted to 2022 prices
[17] €50,000 in original study, uplifted to 2022 prices

means that the cost range identified in the SEA of €114,000 to €305,000 per kg PFAS emissions reduced are several times higher than what would already be determined to be a disproportionate impact.

There are uncertainties associated with all parts of the analysis and a multitude of impacts could not all be quantified and/or monetised. However, due to the consistent conservative approach taken it is believed that the most significant non-quantified impacts are costs of a possible REACH restriction, and would therefore further strengthen the conclusions from the quantitative analysis. **It is therefore concluded that restricting the use of PFAS in professional apparel applications will result in highly disproportionate societal costs for the EU.**

[redacted]

[redacted]

Explanatory Note:

Annex II – Case Study on UK Railway Network Company

- Field test carried out in 1998 with GORE-TEX Garments tested by 300 wearers for 2 years
- Purchased GORE-TEX® garments for 15,000 wearers with no complaints from 1998 – 2012.
- 20% budget cuts across the board in 2012 brought a switch to buying " cheap" garments which met basic norms and basic legal obligations.
- From 2012 onwards mass dissatisfaction from wearers. This lead to additional costs to Network Rail due to multiple replacement garments per person.
- 2015 Network Rail issue a specification which enabled them to procure GORE-TEX(R) Garments again.
- For the following years – No product complaints.
- 2022 Network Rail again award latest tender allowing them to stay with GORE-TEX(R) Garments.

[redacted]