

This document contains SEAC's evaluation of sector-/use-specific aspects. It should be read in conjunction with the Committee's evaluation of the general elements of the proposed restriction, which is documented in the *SEAC Opinion*.

Committee for Socio-economic Analysis (SEAC)

[Draft] Evaluation of sector-/use-specific aspects of the opinion
on an Annex XV dossier proposing restrictions on
Per- and polyfluoroalkyl substances (PFAS)

Textiles, upholstery, leather, apparel and carpets (TULAC)

Date: 10 March 2026

SEAC
COMMITTEE FOR
SOCIO-ECONOMIC ANALYSIS

SEAC EVALUATION OF SECTOR-/USE-SPECIFIC ASPECTS OF THE
OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

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S-0 Overview of the sector

For the purposes of the assessment the Dossier Submitter disaggregates the textiles, upholstery, leather, apparel and carpets (TULAC) sector into the following uses and sub-uses:

- Home textiles: includes carpets and rugs, curtains and blinds, and textile-based coverings (e.g. table cloths, bedding)
- Consumer apparel: includes outdoor wear, indoor wear, sportswear, footwear, and accessories
- Professional apparel and PPE: includes professional apparel (including professional sports-/footwear and uniforms) and personal protective equipment (PPE) for industrial and professional use
- Leather
- Home fabric treatment (sprays)

It is important to note that the following uses can also be linked to textiles, but the Dossier Submitter chose to assess them elsewhere in the Background Document:

- Packaging: assessed under "Food contact materials and packaging".
- Optical fibre weaving solutions for lighting applications in health, costumes, automotive, safety, environment, communication, architecture and industrial applications: assessed under "Electronics and semiconductors".
- Latex printing inks: assessed under "Printing applications".
- Processing equipment in the textile industry, e.g. parts of dyeing machines, conveyor belts: assessed under "Sealing applications" and "Machinery applications".
- Technical textiles: assessed under "Technical textiles" to better account for the overlap that exists between this application and other sectors (such as "Construction products" and "Transport").
- Second-hand market and recycling: "Second-hand articles" and "Impact on recycling and circular economy" are assessed as overarching issues.

S-1 Justification that action is required on a Union-wide basis

See SEAC Opinion.

S-2 Regulatory risk management options other than restriction

Relevant sections of the Background Document:

Annex E, section E.2.2.

SEAC conclusion(s):

SEAC agrees with the Dossier Submitter's conclusion that a REACH restriction remains the

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most appropriate EU-wide measure. While the measures the Dossier Submitter mentions in the Background Document (IED BAT conclusions, mandatory separate textile waste collection, instructions on appropriate disposal) can and have contributed to a reduction in risk related to the use of PFAS, they cannot fully and adequately address the risks identified by the Dossier Submitter, as confirmed by RAC.

Key elements underpinning the SEAC conclusion(s):

As the Dossier Submitter indicates in the Background Document, several respondents to the consultation on the Annex XV report consider that the requirements of the Industrial Emissions Directive (IED) (2010/75/EU) are already appropriate to manage the risks of PFAS and that the proposed restriction is not required (e.g. #6395, #9403, #9478). These stakeholders consider that releases of PFAS from TULAC production processes are controlled via the use of specific operational conditions and risk management measures as specified in the IED Best Available Techniques (BAT) conclusions (EC, 2022a) and BREF (Best Available Techniques Reference Document) for the textiles industry (EC et al., 2023). It is even indicated that applying BAT can reduce emissions from production to close to zero (comment #9403).

The Dossier Submitter notes that the requirements and techniques that are described as BAT for the textile industry have not been demonstrated to be appropriate or effective to remove PFAS and that, as such, it has not been demonstrated that implementing BAT would ensure that releases of PFAS from TULAC production processes would be minimised. The Dossier Submitter also notes that it is unlikely that all relevant facilities in the EU/EEA would be subject to the requirements of the IED as there is a minimum size threshold for inclusion (i.e. "treatment capacity" that exceeds 10 tonnes per day). Additionally, the Dossier Submitter indicates that BAT for water, oil and soil repellence of textiles clearly state that the substitution of PFAS is the best way to address the risks, which is in line with the proposed restriction.

Other stakeholders indicate that the mandatory separate collection of textile waste as proposed under the revision of the Waste Framework Directive (2008/98/EC) would address risks associated with end-of-life. The Dossier Submitter however considers that mandatory separate collection does not ensure that PFAS-containing textiles will be subject to re-use, recycling or end-of-life treatment that will minimise releases of PFAS to the environment. The Dossier Submitter notes that RAC has previously concluded that releases of PFHxA and related substances from TULAC during article service life and end-of-life disposal were not adequately controlled, justifying the need for a restriction of PFHxA and related substances. RAC has confirmed that this conclusion also holds true for the other PFAS covered by the proposed restriction.

During the consultation on the Annex XV report, it was also indicated that life cycle related risks could be addressed by providing instructions on appropriate disposal to end users (e.g. #8272). The Dossier Submitter notes that emissions could still occur during the article service life (e.g. cleaning or washing) and that the most appropriate means of disposal (e.g. incineration at extremely high temperatures) are not available to all actors.

SEAC therefore agrees with the Dossier Submitter's conclusion that a REACH restriction remains the most appropriate EU-wide measure. While the above-mentioned measures can and have contributed to a reduction in risk related to the use of PFAS, they cannot fully and adequately address the risks identified by the Dossier Submitter, as confirmed by RAC.

S-3 Availability and technical and economic feasibility of alternatives

Relevant sections of the Background Document:

Main report, section 2.4.1; Annex A, section A.3.3; Annex E, section E.2.2.

SEAC conclusion(s):

SEAC agrees with the Dossier Submitter's conclusion that there is sufficiently strong evidence for high substitution potential in the following cases:

- Home textiles
- Consumer apparel
- Professional apparel
- Leather
- Home fabric treatments (sprays)

SEAC notes that there is significant overlap between alternatives for some of the above-mentioned uses. *Home textiles*, *consumer apparel* and *professional apparel* can therefore not be seen as completely separate from each other.

SEAC disagrees with the assessment performed by the Dossier Submitter for the following use:

- Personal protective equipment (PPE): The Dossier Submitter concludes for PPE overall that there is sufficiently strong evidence for low substitution potential. SEAC finds that, based on its assessment of alternatives utilising the risk categorisation defined in the EU PPE Regulation¹, there is only sufficiently strong evidence for low substitution potential for risk categories III(a), III(c), as well as PPE used in military, firefighting and other emergency response activities in general. It is however unclear from the available information if alternatives will become available in the near future for PPE used in military, firefighting and other emergency response activities. With respect to the other risk categories: either there was sufficiently strong evidence for high substitution potential, there was no indication that PFAS are used or needed to reach the required level of performance to ensure the safety of the users, there was weak evidence, or no evidence at all to conclude on substitution potential.

SEAC notes RAC's conclusion that, based on the available information, alternatives that are likely of lower concern than PFAS have been identified for several applications of PFAS in the TULAC sector.

Key elements underpinning the SEAC conclusion(s):

The analysis of alternatives in Annex E of the Background Document is supported by numerous references to scientific literature, patents or patent applications, assessments by governmental bodies and other data sources. As such, SEAC finds the assessment of the use of PFAS in the TULAC sector to be robust.

¹ Regulation (EU) 2016/425

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PFAS are used in the TULAC sector primarily to impart one or more of the following properties to a product: water/oil repellence, stain resistance and soil protection.

SEAC notes the broad use of a wide variety of PFAS substances. The Dossier Submitter was in fact able to identify and discern between the use of the following PFAS groups in this sector: non-polymeric C2-C3, non-polymeric C4, non-polymeric C5, non-polymeric C6, non-polymeric C9-C14, other non-polymeric species ($\geq$ C14, aromatic compounds and salts), fluoropolymers and side-chain fluorinated polymers.

Based on the evidence collected by the Dossier Submitter the following potential alternative substance groups have been identified: hydrocarbons (e.g. paraffin- and melamine-based), polydimethylsiloxanes (often referred to as “silicones” by stakeholders), polyurethane resins, dendrimers, nanomaterials. Additionally, the Dossier Submitter has identified alternative technologies (spinning and weaving techniques). The biggest challenge according to stakeholders when it comes to technical feasibility of alternatives is stated to be the replication of all the functionalities that PFAS provide. Especially when more than just water repellence is required, alternatives perform less well.

A more detailed assessment per use (and sub-use) by SEAC of the information in the Background Document and provided during the Annex XV report consultation, can be found further below. Table 1 provides an overview of relevant information from the Background Document as well as SEAC’s view on the assessment performed by the Dossier Submitter.

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Table 1: Dossier Submitter's (DS) overview of the use of PFAS in TULAC and SEAC's view

Uses	Sub-uses	PFAS function	Tonnage [1]	Alternatives (technical and economic feasibility) (EiF)	Alternatives (availability) (EiF)	Substitution potential (EiF)	Derogation proposed by the DS (derogation period)	SEAC's view on the analysis of alternatives* [2]
Home textiles	Carpets and rugs		PFAAs and PFAA precursors Midpoint: 3 036 t/y Range: 1 310-4 762 t/y	Yes	Yes	High	No	SEAC agrees with the DS assessment
	Curtains and blinds		Polymeric PFAS Midpoint: 13 763 t/y Range: 4 920-22 606 t/y					
	Textile-based covering		Total PFAS Midpoint: 16 799 t/y Range: 6 230-27 368 t/y					
Consumer apparel	Outdoor wear	Water repellence, oil repellence, stain resistance, soil protection	PFAAs and PFAA precursors Midpoint: 8 169 t/y Range: 2 099-14 238 t/y	Yes	Yes	High	No	SEAC agrees with the DS assessment
	Indoor wear		Polymeric PFAS Midpoint: 19 486 t/y Range: 6 062-32 910 t/y					
	Sportswear		Total PFAS Midpoint: 27 655 t/y Range: 8 161-47 148 t/y					
	Footwear							
	Accessories							
Professional apparel and PPE	Professional apparel (including professional sports-/footwear and uniforms)		PFAAs and PFAA precursors Midpoint: 601 t/y Range: 101-1 101 t/y	Yes	Yes	High	No	SEAC agrees with the DS assessment

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	PPE (all applications, including re-impregnation agents)		Polymeric PFAS Midpoint: 894 t/y Range: 664-1 123 t/y Total PFAS Midpoint: 1 495 t/y Range: 765-2 224 t/y	No	No	Low	Yes (12 years)	SEAC disagrees with the DS assessment
Leather	E.g. indoor and outdoor wear, footwear, professional sportswear and footwear, and seat coverings		Unknown	Yes	Yes	High	No	SEAC agrees with the DS assessment
Home fabric treatments (sprays)			PFAAs and PFAA precursors Midpoint: 6 106 t/y Range: 3 489-8 723 t/y Polymeric PFAS Midpoint: 11 663 t/y Range: 11 553-11 773 t/y Total PFAS Midpoint: 17 769 t/y Range: 15 041-20 496 t/y	Yes	Yes	High	No	SEAC agrees with the DS assessment

Explanation of colour coding

DS assessment colour coding	Sufficiently strong evidence	Weak evidence	Inconclusive evidence	No evidence
*SEAC opinion colour coding	Confident	Uncertainties (negligible)	Uncertainties (significant)	

[1] Collated from Annex A of the Background Document. 2020 figures.

[2] SEAC does not conclude on the derogations in this section. Please refer to section S-7.

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A. Home textiles

The category home textiles includes carpets, rugs, curtains, blinds and textile-based coverings (e.g. table cloths, bedding, seat coverings). This includes uses in vehicles (e.g. carpets and seat covers) and public settings (e.g. hospital settings and public transport).

The Dossier Submitter indicates that based on a literature study, stakeholder interviews and the call for evidence during the development of the Annex XV report, the following alternatives can be considered technically feasible for use in home textiles (i.e. general practical use has been reported):

- Dendrimer
- Hybrid silicone/hydrocarbons
- Hydrocarbons
- Polyurethane
- Silicones (general use is reported for carpets and rugs only)

Additionally, Glüge et al. (2022) provides several clear and practical examples of companies producing carpets without PFAS. As for home textiles more broadly, a 2020 study commissioned by the European Commission (Wood, 2020) indicates that *"significant developments have been made over the last 10 years to produce a new generation of formulations that do not use any fluorine-based chemistry. [They] are used in a number of countries [...] in an array of products such as consumer applications and carpets."* This report also identified a total of 125 alternatives belonging to the (non-)chemical groups mentioned above and another 47 where no specific substance information was available. Based on its analysis of alternatives, the report also concludes that alternatives are technically feasible for consumer applications which includes home textiles. This conclusion is further strengthened by voluntary sector commitments (e.g. #9481), other restrictions and consumer pressure having already led to a significant decrease and in a lot of cases full elimination of PFAS in home textiles. This is echoed in comment #4024 in the consultation on the Annex XV report, which includes a study on household textiles in Belgium but provides broader observations on the phasing-out of PFAS within the EU textiles sector.

SEAC notes that during the consultation on the Annex XV report the majority of comments related to textiles concern the use of PFAS in uses that require high performance (e.g. technical textiles, PPE). PFAS use in home textiles, when mentioned², is stated to be broadly substitutable. While some stakeholders maintain that alternatives cannot replace PFAS in home textiles, there is overwhelming evidence to the contrary. SEAC also concludes that, based on the discussion in the Background Document and as apparent from the vast majority of stakeholder comments, the high-end functional properties of PFAS are not necessary to reach the required level of performance for home textile products in order for them to function properly.

Based on there being different lines of evidence and them being in alignment with each other as demonstrated in the assessment above, SEAC agrees with the assessment carried out by the Dossier Submitter and consequently also the conclusion that there is sufficiently strong evidence for high substitution potential at entry into force (EiF) for this use.

² E.g. #4017, #4024, #6150, #6206, #7362, #8818, #8863, #9161, #9343, #9481.

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B. Consumer apparel

The category consumer apparel includes outdoor wear, indoor wear, sportswear, footwear and accessories. Example products are (down) jackets, coats, ski wear, hats and shoes. Considering that the sought-after functional properties for these products are broadly similar to home textiles, the discussion below is similar as well.

The Dossier Submitter indicates that based on a literature study, stakeholder interviews and the call for evidence during the development of the Annex XV report, the following alternatives can be considered technically feasible for use in consumer apparel (i.e. general practical use has been reported):

- Dendrimer
- Hybrid silicone/hydrocarbons
- Hydrocarbons
- Polyurethane
- Silicones
- Alternative technologies (general practical use is reported for in outdoor wear, sportswear and footwear only)

For consumer apparel, a 2020 study commissioned by the Commission (Wood, 2020) indicates that *“significant developments have been made over the last 10 years to produce a new generation of formulations that do not use any fluorine-based chemistry. [They] are used in a number of countries [...] in an array of products such as consumer applications and carpets.”* This report also identified a total of 125 alternatives belonging to the (non-)chemical groups mentioned above and another 47 where no specific substance information was available. Based on its analysis of alternatives, the report also concludes that alternatives are technically feasible for consumer applications which includes consumer apparel. This conclusion is further strengthened by voluntary sector commitments, other restrictions and consumer pressure having already led to a significant decrease and in a lot of cases full elimination of PFAS in consumer apparel. This is echoed in comment #4024 in the consultation on the Annex XV report, which includes a study on household textiles in Belgium but provides broader observations on the phasing-out of PFAS within the EU textiles sector that SEAC considers relevant for consumer apparel.

SEAC notes that during the consultation on the Annex XV report the majority of comments related to textiles concern the use of PFAS in uses that require high performance (e.g. technical textiles, PPE). PFAS use in consumer apparel, when mentioned³, is stated to be broadly substitutable. While some stakeholders maintain that alternatives cannot replace PFAS in consumer apparel, there is overwhelming evidence to the contrary. SEAC also concludes that, based on the discussion in the Background Document and as apparent from the vast majority of stakeholder comments, the high-end functional properties of PFAS are not necessary to reach the required level of performance for consumer apparel in order for them to function properly.

Based on there being different lines of evidence and them being in alignment with each other, as demonstrated in the assessment above, SEAC agrees with the assessment carried out by

³ E.g. #4121, #4181, #6150, #6357, #8521, #8818, #8863, #9083, #9161, #9343, #9481.

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the Dossier Submitter and consequently also the conclusion that there is sufficiently strong evidence for high substitution potential at entry into force for this use.

C. Professional apparel and PPE

Professional apparel

The category professional apparel includes professional sports-/footwear and uniforms. However, and as will be apparent from the discussion below, there is significant overlap between the (potential) alternatives for professional apparel and home textiles/consumer apparel. SEAC therefore considers that the higher performance requirements demanded from professional apparel (compared to consumer apparel) are less related to the water and oil repellence imparted by PFAS, but rather to other properties of this type of professional apparel.

The Dossier Submitter indicates that based on a literature study, stakeholder interviews and the call for evidence during the development of the Annex XV report, the following alternatives can be considered technically feasible for use in professional sports-/footwear and uniforms (i.e. general practical use has been reported):

- Dendrimer
- Hydrocarbons
- Polyurethane
- Silicones
- Alternative technologies

SEAC notes that during the consultation on the Annex XV report the vast majority of comments related to professional apparel concern the use of PFAS in PPE. PFAS use in professional apparel, when mentioned⁴, is stated to be substitutable in a lot of cases. As indicated earlier, SEAC considers the high-end functional properties of PFAS not to be an absolute necessity to reach the required level of performance for professional apparel in order for them to function properly (i.e. there is no performance loss).

Based on there being different lines of evidence and them being in alignment with each other, as demonstrated in the assessment above, SEAC overall agrees with the assessment carried out by the Dossier Submitter and consequently also the conclusion that there is sufficiently strong evidence for high substitution potential at entry into force for this use. SEAC notes that some uncertainty is associated with this conclusion due to the more generic discussion in the Background Document on this sub-use, but this does not significantly impact the robustness of SEAC's assessment.

PPE

Personal protective equipment (PPE) can include items such as safety helmets, gloves, eye protection, hazmat suits, high-visibility clothing, safety footwear, safety harnesses, ear plugs, ear defenders and respiratory protective equipment.

⁴ E.g. #6350, #6357.

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The Background Document states that PPE requires a CE marking indicating conformity of the PPE with the applicable requirements set out in the EU PPE Regulation. This means that a set of European (EN) standards must be met for PPE placed on the EEA market.

Annex I of the EU PPE Regulation distinguishes between three types of PPE:

- Category I (a) – (e): protection against minimal risks
- Category II: risks other than those listed in categories I and III
- Category III (a) – (m): risks that may cause very serious consequences such as death or irreversible damage to health

Based on publicly available resources and stakeholder information⁵, the Dossier Submitter tried to examine whether PFAS would or would not be required in order for the PPE to adequately protect against a certain type of risk. SEAC notes that the Dossier Submitter did not use the EU PPE Regulation's categorisation as a basis for its examination of which PPE applications might still require the use of PFAS. In fact, the examination in the Background Document only covers a small portion of the EU PPE Regulation's risk categories. Considering that the derogation proposed by the Dossier Submitter refers to the categorisation from the EU PPE Regulation and proposes to exempt all PPE applications, SEAC finds the approach to the analysis of alternatives insufficiently detailed.

Using the risk categorisation set out in the EU PPE Regulation, SEAC has analysed whether it is likely or not that PFAS are required and/or technically and economically feasible alternatives might be available. Where relevant, information from the Background Document and provided by stakeholders has been taken into account.

A summary of this analysis is provided in Table 2 below.

Table 2: Analysis of alternatives per risk category as defined in the EU PPE Regulation

Risk category	PFAS required?	Alternatives available according to Dossier Submitter?	SEAC's view
Cat. I(a): superficial mechanical injury	No information available to SEAC indicating that PFAS are required to protect against this risk.	Not discussed explicitly.	SEAC could not find information indicating that the use of PFAS is even relevant to provide protection against this type of minimal risk.
Cat. I(b): contact with cleaning materials of weak action or prolonged contact with water	No information available to SEAC indicating that PFAS are required to protect against this risk.	Not discussed explicitly.	For risk category I(e) where higher performance seems to be necessary than for this risk category, the Dossier Submitter states that PFAS will not necessarily be required to fulfil EN 343:2019 ⁶ and that PFAS-free

⁵ Received during dossier development and the consultation on the Annex XV report.

⁶ This European Standard specifies requirements and test methods applicable to ready-made garments, materials and seams of protective clothing against the influence of precipitation (e.g. rain, snowflakes), fog and ground humidity.

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			durable water repellent (DWR)⁷ provide good protection if only water repellence is required. Alternatives assessed under home textiles, consumer apparel, professional apparel and leather might also be relevant for most cases falling under this PPE risk category. More frequent treatment of PPE to re-establish protection might be necessary. SEAC finds that there is some uncertainty on whether the loss of performance associated with alternatives would cause non-compliance with EN 343:2019. There are however no strong indications that PFAS are required to provide sufficient protection against this type of minimal risk. As such, SEAC finds there to be weak evidence for high substitution potential for PFAS used in PPE protecting against this type of minimal risk.
Cat. I(c): contact with hot surfaces not exceeding 50 °C	No information available to SEAC indicating that PFAS are required to protect against this risk. The Dossier Submitter indicates that for risk category III(e) (i.e. higher risk and higher performance necessary) PFAS are not required.	Alternatives discussed under risk category III(e): Protection against heat and flame is or can be brought about with flame inherent fibres (e.g. aramid fibres). These fibres are stated to provide better long-term protection⁸ than flame-treated fabrics.	SEAC agrees with the Dossier Submitter that for this risk category PFAS do not seem to be required. Furthermore, there are no indications that PFAS are used to provide protection against this type of minimal risk.
Cat. I(d): damage to the eyes due to exposure to sunlight (other than during observation of the sun)	No information available to SEAC indicating that PFAS are required to protect against this risk.	Not discussed explicitly.	SEAC could not find information indicating that the use of PFAS is even relevant to provide protection against this type of minimal risk.

⁷ An example of PFAS-based durable water repellent is ePTFE-membranes (e.g. Gore-Tex).

⁸ <https://www.dupont.com/knowledge/flame-resistant-technology.html> [Accessed 30/08/2024]

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Cat. I(e): atmospheric conditions that are not of an extreme nature	The Dossier Submitter states that PFAS will not necessarily be required to fulfil EN 343:2019 ⁶ and that PFAS-free durable water repellent (DWR) ⁷ provide good protection if only water repellence is required.	Technically and economically feasible alternatives are available to provide sufficient protection against water. Highest level of protection (level 4) might not be fulfilled in certain cases with alternatives known to the Dossier Submitter. While the Background Document indicates that ePTFE membranes may be used together with a non-PFAS water repellent treatment, SEAC notes that stakeholders taking part in the consultations during development of the restriction dossier have indicated that polyurethane- and polyester-based membranes are proven alternatives to PTFE membranes.	Alternatives assessed under home textiles, consumer apparel, professional apparel and leather might also be relevant for most cases falling under this PPE risk category. More frequent treatment of PPE to re-establish protection might be necessary. SEAC finds that there is some uncertainty on whether the loss of performance associated with alternatives would cause non-compliance with EN 343:2019. There are however no strong indications that PFAS are required to provide sufficient protection against this type of minimal risk. As such, SEAC finds there to be weak evidence for high substitution potential for PFAS used in PPE protecting against this type of minimal risk.
Cat. II	The Dossier Submitter mentions two specific risks associated with this category: - Electrostatics: PFAS not required, antistatic fibres provide protection. - Visibility: PFAS are not required to achieve high visibility. This was echoed by a stakeholder in the Annex XV report consultation (#6350).	Not relevant.	Due to the broadness of potential risks covered here (risks not falling under Cat. I and III), SEAC cannot assess whether PFAS are required to protect against all applications covered by this type of risk based on the information in the Background Document. Comments provided in the consultation on the Annex XV report referencing Cat. II risks do not provide substantiated information either (#9403). SEAC does however agree with the Dossier Submitter's assessment of the two risks they discussed (i.e. that PFAS are not required).

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Cat. III(a): substances and mixtures which are hazardous to health	The Dossier Submitter states that PFAS are required to repel liquids with low surface tension. SEAC notes that PFAS also have high chemical resistance which is most likely also required to protect against this risk (besides water and oil repellence).	Indications that there are no alternatives.	SEAC finds that there is sufficiently strong evidence for low substitution potential for PFAS used in PPE protecting against this type of risk. The consultation on the Annex XV report strengthens this conclusion.
Cat. III(b): atmospheres with oxygen deficiency	No information available to SEAC indicating that PFAS are required to protect against this risk.	Not relevant.	SEAC finds that there are no indications that PFAS are required to provide protection against this type of risk.
Cat. III(c): harmful biological agents	The Dossier Submitter states that filters protecting against this risk need to have sufficient efficiency in collecting viruses and microorganisms (HEPA efficiency level). PTFE porous membrane filters are stated to achieve this level of efficiency (Annex XV report consultation: #8040, #8139). While the peer-reviewed article from Karim et al. (2020) only refers to reusable surgical gowns, it does indicate that medical textiles using materials other than PTFE have poor resistance to liquid and/or microbial penetration.	Indications that PFAS currently provide the highest possible protection.	SEAC agrees that there is sufficiently strong evidence for low substitution potential for PFAS used in PPE protecting against this type of risk.
Cat. III(d): ionising radiation	The Dossier Submitter indicates that metal-polymer composites or	No indications that PFAS are used or required to protect	Neither the Dossier Submitter nor stakeholders provide any indication that PFAS (fluoropolymers specifically) are

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	metal foams incorporating high Z metal compounds (e.g. bismuth, tungsten, tantalum, antimony) provide excellent protection against this type of risk, are lightweight, flexible, non-toxic, non-corrosive, and have good mechanical properties.	against this type of risk.	required or even used in PPE that protect against this type of risk. SEAC did not find any indications that high Z metal-polymer or metal foam composites require the use of PFAS. In fact, the information that is available to SEAC mentions the following polymer materials: polymethyl methacrylate (PMMA) ⁹ , polyimide (PI) ¹⁰ , acrylonitrile-butadiene-styrene (ABS) ¹¹ . SEAC does however note that even though there are no indications that PFAS are required, the uncertainty associated with this conclusion is not insignificant.
Cat. III(e): high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C	The Dossier Submitter indicates that PFAS are not required since protection against this type of risk is reached by using flame-inherent fibres. Information provided by stakeholders indicates that PFAS can provide additional protection. It is stated that this is due to their oil repellent qualities and oil and dirt being risk factors when it comes to flammability.	Protection against heat and flame is or can be brought about with flame inherent fibres (e.g. aramid fibres). These fibres are stated to provide better long-term protection than flame-treated fabrics. Heat reflective fabrics can be used to protect against heat radiation. These do not seem to use PFAS.	Based on the available information SEAC agrees with the Dossier Submitter that PFAS are not a prerequisite for use in PPE protecting against this type of risk. While stakeholders indicate that PFAS can provide additional indirect protection against this risk, SEAC notes that stakeholders do not indicate whether this is necessary to comply with the standards associated with this risk category. The Background Document is unclear on how this risk category specifically relates to firefighting activities ¹² .
Cat. III(f): low-temperature environments the effects of which are comparable to those of an air temperature	The Dossier Submitter indicates that PFAS are not required and that several non-PFAS semi-permeable materials with satisfactory cold protection are	PFAS not required to protect against this type of risk.	SEAC finds that there are no indications that PFAS are required to provide protection against this type of risk.

⁹ <https://www.mdpi.com/2073-4360/15/9/2142> [Accessed 13/08/2024]

¹⁰ <https://www.sciencedirect.com/science/article/pii/S2214914723000557> [Accessed 13/08/2024]

¹¹ <https://4spepublications.onlinelibrary.wiley.com/doi/10.1002/pc.27906?af=R> [Accessed 13/08/2024]

¹² The Background Document links firefighting activities to risk category III(a)-(m). Some sub-categories do not seem to be relevant to firefighting activities according to SEAC (e.g. Cat III(f)) or there are indications that PFAS are not used to protect against certain risks (e.g. Cat III(g)).

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of -50 °C or less	available on the market.		
Cat. III(g): falling from a height	The Dossier Submitter indicates that alternative materials to PTFE are available (e.g. polyester, polypropylene). The Dossier Submitter however also indicates that PTFE is sometimes used in rope to protect the rope against substances that would weaken it (fatty substances, organic solvents).	PFAS not necessarily required to protect against this type of risk.	SEAC finds the justification for the necessity to use PTFE in some cases to not be backed by technical information and comparisons to other materials (e.g. polyamide, polyester, polypropylene, para-aramid). It is also not clear if its use is in fact required to comply with the standards associated with this risk. As such, SEAC finds that there are no indications that PFAS are required to provide protection against this type of risk.
Cat. III(h): electric shock and live working	The Dossier Submitter mentions PTFE/aluminium-based energetic material and that no alternatives are known.	PFAS required to protect against this risk.	Based on information available to SEAC, PTFE/aluminium-based energetic material is an energetic composite widely applied in explosives, pyrotechnics, and propellants due to its ultra-high energy density and intense exothermic reaction. The Dossier Submitter does not elaborate on any potential use of this material in PPE. SEAC therefore fails to see the relevance of the Dossier Submitter's statements in the Background Document. As no other information was provided in the Background Document and in the consultation on the Annex XV report, SEAC is unable to assess whether PFAS are required to protect against this type of risk.
Cat. III(i): drowning	The Dossier Submitter indicates that PFAS are not required to protect against this risk since other insulating materials can fulfil the requirements associated with this risk category.	PFAS not required to protect against this risk.	SEAC agrees with the Dossier Submitter that for this risk category PFAS do not seem to be required.
Cat. III(j): cuts by hand-held chainsaws	Based on stakeholder input from the consultation on the Annex XV report (#9403) the cut-	PFAS required to protect against this risk.	SEAC notes that based on the information provided by the Dossier Submitter, the use of PFAS can provide additional benefits for PPE protecting against this type of risk. In fact, non-PFAS

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	resistant fabric should be treated with PFAS for its oil repellent qualities. This is stated to be necessary to ensure that the protective properties of the fabric are not affected by the lubricating oil used on chainsaws.		materials are stated by the Dossier Submitter to be regularly used to protect against this risk according to EN ISO 11393. SEAC therefore finds the stakeholder's statements claiming that the use of PFAS for their oil repellent qualities is necessary to ensure the mechanical strength of the cut-resistant fabric to be contradictory. SEAC notes that these statements are not backed by robust technical information to resolve this contradiction. SEAC therefore disagrees with the Dossier Submitter that for this risk category PFAS are required.
Cat. III(k): high-pressure jets	The Dossier Submitter indicates that non-PFAS fabrics are available and used for protection against jets up to 400 bar, but that PFAS fabrics might be required to withstand jets up to 1 000 bar.	PFAS required for jets in the range of 400-1 000 bar.	SEAC notes the lack of information on PFAS used to protect against this type of risk and can as such not properly assess whether PFAS are actually required for high-pressure jets in the range of 400-1 000 bar. Based on the limited information in the Background Document, SEAC does, however, find that there are no indications that PFAS are required for high-pressure jets up to 400 bar.
Cat. III(l): bullet wounds or knife stabs	The Dossier Submitter indicates that aramid materials (e.g. Kevlar) are commonly used to protect against this type of risk. The Dossier Submitter does indicate that aramid garments lose their protective properties when they get wet. This was confirmed in the consultation on the Annex XV report (#4274, #9220, #9478). A confidential comment (known to SEAC) on the other hand indicates that water-soaked ballistic fabric	PFAS are required in order to make sure that the protective properties of aramid garments are retained.	SEAC notes that based on the information provided by the Dossier Submitter, the use of PFAS can provide additional benefits for PPE protecting against this type of risk. While SEAC agrees that water resistance/repellence seems to be important in maintaining the integrity of the aramid garment, it is unclear if water resistance/repellence cannot be provided by alternatives or possibly through other means (encasing aramid materials in other waterproof textiles). As such, SEAC concludes that there is weak evidence for low substitution potential for PPE protecting against this type of risk if/when PFAS are used to provide water resistance/repellence.

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	could however withstand bullet impact. It is not clear however if aramid fabric was used here.		
Cat. III(m): harmful noise	The Dossier Submitter indicates that depending on the specific application and technical requirements, a range of different materials are used to meet the standard requirements set according to the EU PPE Regulation. Beyond this, no further information was provided.	PFAS not necessarily required, but dependent on the specific application requirement for noise control.	SEAC notes the lack of information on PFAS used to protect against this type of risk and can as such not properly assess whether PFAS are actually required to protect against this type of risk.

SEAC notes that where PFAS are required to protect against certain types of risk, the use of impregnation agents should also be taken into consideration when proposing derogations. During the consultation on the Annex XV report a comment by a European industry association (#8934) pointed out that this would indeed need to be taken into account. The same stakeholder also notes that re-impregnation products are mostly used for PPE in risk category III and that alternatives cannot provide the required restoration of protection.

In regard to PPE used for **military activities**, the Background Document indicates that the use of PFAS is required to protect against the types of risks they are exposed to, i.e. water and oil repellence enabling protection against fire and chemical, biological, radiological and nuclear agents. Based on the description in the Background Document, these types of activities can be linked to at least risk categories III(a), III(c-e), III(j) and III(l). SEAC notes that several stakeholders have indicated in the Annex XV report consultation that PFAS are required for use in military applications and alternatives cannot provide sufficient levels of performance in this instance (e.g. #4419, #6350, #6395, #6398, #6454, #7655, #8038, #8156, #8521, #8934, #9220, #9343, #9403, #9539). Furthermore, the standards and requirements associated with military applications mentioned in the Background Document seem to go beyond the corresponding standards and requirements associated with the above-mentioned type III risk categories when considering use cases overall. As such, SEAC finds it plausible that the substitution potential is low at entry into force for PFAS in PPE used in military activities¹³. It is unclear from the available information if alternatives will become available in the near future.

¹³ SEAC notes that when PPE (any risk category) are used for military activities the conclusion for PPE in military activities overrides the conclusions in Table 2. The substitution potential for the same PPE can therefore be different depending on its use. For example, the substitution potential for PPE covered by category I(b) in non-military activities is high, but in military activities the substitution potential is low.

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In regard to PPE used for **firefighting and emergency response activities**, the Background Document indicates that the use of PFAS is required to protect against the types of risks they are exposed to. This was also echoed in the consultation on the Annex XV report (e.g. #6350, #6395, #6398, #6454, #7655, #7868, #8521, #8934, #9059, #9220, #9343, #9403). The main argument for this is that firefighters, and other first responders, do not know in advance which high-risk situations they will be confronted with and that as such the PPE they employ need to cover all relevant category III risks and provide the best possible protection. SEAC notes that certain stakeholders indicate that the protection requirements could be reduced and that the risks associated with the use of PFAS should also be taken into account (#9547) or that there is an overuse of PPE with the highest level of protection (#6350). Overall, SEAC finds it plausible that the substitution potential is low at entry into force for PFAS in PPE used in firefighting and emergency response activities¹⁴. It is unclear from the available information if alternatives will become available in the near future.

Based on the above assessment, which considers different lines of evidence, SEAC disagrees with the Dossier Submitter that for PPE as a whole there is sufficiently strong evidence for low substitution potential. SEAC finds that in regard to the proposed restriction and using the “strength of evidence” approach proposed by the Dossier Submitter and agreed upon by SEAC, PPE can be divided into the following groups:

- PPE covered by risk categories III(a), III(c) as well as PPE used in military, firefighting and emergency response activities in general. SEAC concludes that there is sufficiently strong evidence for low substitution potential at entry into force for PFAS used in PPE protecting against these types of risk or in these types of activities.
- PPE covered by risk categories I, II, III(b) as well as III(d-m). These types of PPE are grouped here for different reasons. Either there was sufficiently strong evidence for high substitution potential, there was no indication that PFAS are used/required, there was weak evidence, or no evidence at all to conclude on substitution potential.

D. Leather

The category leather includes indoor and outdoor wear, footwear, (professional) sportswear and footwear, and seat coverings. Example products are leather bags, wallets, belts, gloves, saddles.

Based on the analysis performed by the Dossier Submitter and considering the sought-after functional properties for these products, SEAC also notes significant overlap with the discussion on home textiles and consumer apparel.

The Dossier Submitter indicates that based on a literature study, stakeholder interviews and the call for evidence during the development of the Annex XV report, the following alternatives can be considered technically feasible for use in leather (i.e. general practical use has been reported):

¹⁴ SEAC notes that when PPE (any risk category) are used for firefighting and emergency response activities the conclusion for PPE in firefighting and emergency response activities overrides the conclusions in Table 2. The substitution potential for the same PPE can therefore be different depending on its use. For example, the substitution potential for PPE covered by category I(b) but not used in firefighting and emergency response activities is high, but when used in firefighting and emergency response activities the substitution potential is low.

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- Hybrid silicone/hydrocarbons
- Hydrocarbons
- Polyurethane
- Silicones

In line with the discussion on home textiles and consumer apparel, SEAC concludes that technically and economically feasible alternatives exist, especially for leather applications where only water repellence is required. There are also clear indications that when oil repellence and soil protection are expressly wanted, alternatives provide sufficient performance though not at the same level as PFAS. The Committee does however agree with the Dossier Submitter that the evidence is somewhat weaker for leather products.

SEAC notes that during the consultation on the Annex XV report the majority of comments related to textiles concern the use of PFAS in uses that require high performance (e.g. technical textiles, PPE). PFAS use in leather, when mentioned¹⁵, is stated to be broadly substitutable even though some disadvantages regarding oil and stain repellence are noted. This loss of performance was however considered acceptable by stakeholders. SEAC concludes that, based on the discussion in the Background Document and as apparent from the vast majority of stakeholder comments, the high-end functional properties of PFAS are not a crucial or even necessary technical requirement for leather in order for it to function properly.

Based on there being different lines of evidence and them being in alignment with each other, as demonstrated in the assessment above, SEAC agrees with the assessment carried out by the Dossier Submitter and consequently also the conclusion that there is sufficiently strong evidence for high substitution potential at entry into force for this use.

E. Home fabric treatment (sprays)

The Dossier Submitter notes that alternatives for home textiles might also be valid here. SEAC could easily verify this by looking at the product offering of online retailers and brick-and-mortar stores which reveals that PFAS-free home fabric treatment sprays are indeed readily available. This was also confirmed by multiple stakeholders during the consultation on the Annex XV report (e.g. #4024, #4121, #6150, #8521). Some stakeholders note that the alternatives do have some loss of performance (reduced heavy rain resistance or dynamic water repellence and lack of oil and stain repellence). Based on all the available information and the conclusions reached for home textiles the Dossier Submitter however concludes that the high-end functional properties of PFAS are not necessary to reach the required level of performance (i.e. the loss of performance associated with alternatives is acceptable according to industry stakeholders).

SEAC therefore agrees with the assessment carried out by the Dossier Submitter and consequently also the conclusion that there is sufficiently strong evidence for high substitution potential at entry into force for this use.

¹⁵ E.g. #6150, #8521, #8881, #9366.

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Comments provided in the consultation on the Annex XV report

SEAC notes that during the consultation on the Annex XV report the majority of comments related to textiles concern the use of PFAS in uses that require high performance, i.e. technical textiles and PPE.

The use of PFAS in technical textiles is not assessed by the Dossier Submitter under TULAC but under a separate sector assessment (see “Technical textiles” in the Background Document).

In regard to PPE, the consultation did not provide enough granular information to allow an in-depth discussion on each and every specific risk category. SEAC did however take on board any relevant and substantiated comment (see discussion above). The consultation did however indicate that alternatives provide insufficient functionality to replace the use of PFAS in PPE used for military, firefighting and emergency response purposes (see discussion above).

For the other sub-uses the vast majority of comments indicate clearly that the use of PFAS is not necessary to reach the required level of performance in order for products to function properly.

S-4 Socio-economic analysis

S-4.1 Costs

Relevant sections of the Background Document:

Main report, section 2.4.1; Annex A, section A.3.3; Annex E, section E.2.2.

SEAC conclusion(s):

SEAC notes that the Dossier Submitter has provided a detailed and well-structured discussion on costs, which considers numerous factors that affect the economic impacts due to a restriction. SEAC acknowledges that collecting quantitative data (e.g. the number of companies affected by a ban, information on sales losses resulting from business closure, etc.) and performing a full quantitative cost assessment is difficult for such a broad sector, covering several uses and sub-uses for which the situation differs. The Dossier Submitter made reasonable assumptions and accompanied parts of the (sub-)uses affected with quantitative cost data based on the information available (e.g. from EURATEX (2022)) or based on feedback provided by stakeholders during the consultations performed by the Dossier Submitter and the Annex XV report consultation. SEAC notes that these data do support the otherwise qualitative cost assessment.

The Dossier Submitter discusses the following cost components on a use and, where relevant, sub-use basis:

- **Costs to directly affected companies: producer surplus losses** due to business closure or substitution
- **Costs to customers: consumer surplus losses** due to price changes as a result of substitution
- **Costs in the supply chain:** producer surplus losses due to business closure
- **Social costs** due to **unemployment**

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- **Welfare losses** due to **loss of functionality** or changes in the **characteristics** (e.g. quality, lifetime) of products, the **unavailability of products**, or **additional costs** (e.g. increased energy costs when using the good)

A summary of the conclusions on costs for the TULAC sector is provided in Table 3 below. Details with regard to (sub-)uses covered are provided in the key elements section below.

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Table 3: Summary of the cost assessment for the TULAC sector and SEAC conclusions

Sector	Derogation proposed by the DS (derogation period)	Costs	
		Information from the Background Document	SEAC's conclusion
TULAC Sector overall (covering the sub-uses listed in the key elements section below)	Yes (12 years) for: - PPE intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I. - PPE specifically designed for armed forces, the maintenance of law and order and other emergency response workers. - Impregnation agents for re-impregnation of articles referred to above.	WITHOUT DEROGATION (RO1): <u>VERY HIGH costs</u> - A significant number of companies being affected given the size of the sector (between 4 700 and 24 800 companies). - Overall high producer surplus losses as well as high consumer surplus losses related to business closures and substitution (magnitude depending on the sub-use affected). - Given that technically and economically feasible alternatives are not available for the sub-use covering PPE. High welfare losses and/or additional costs as a result of lower functionality of products, specifically critical for PPE sub-uses. Considerable employment losses to be expected (figures reported range from 26 700 to 32 500 lost jobs, based on the sub-uses considered¹⁶), mainly in relation to the sub-use of professional apparel and PPE (95%). - Quantitative information provided by stakeholders in the Annex XV report consultation (comment #6454) indicate costs associated with RO1 in relation to PPE of ~ €4.017 billion per year (loss of profits and employment impacts).	WITHOUT DEROGATION (RO1): SEAC agrees with the Dossier Submitter's conclusion that costs are expected to be very high¹⁷ for RO1 , i.e. a full ban, due to the following reasons: - The large size of the sector. - The fact that feasible alternatives are not available for all (sub-)uses covered. - A significant number of companies operating in the TULAC sector indicating that substitution costs won't be low. - Expected substantial social costs due to health or safety implications in relation to PPE uses.
		WITH DEROGATION (RO2): <u>MODERATE costs</u> A significant number of companies being affected given the size	WITH DEROGATION (RO2): SEAC agrees with the Dossier Submitter's conclusion that costs are expected to be moderate¹⁷ for RO2 , i.e. a ban with use-specific derogations for PPE, due the following reasons:

¹⁶ SEAC notes that specifically the higher number of lost jobs, as reported in Annex XV report consultation comment #9403, also includes technical textiles, which is, however, assessed by the Dossier Submitter in another section of the Background Document.

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		of the sector. Costs for home textiles, consumer apparel, professional apparel, leather and home fabric treatment (sprays) unchanged compared to RO1. Mitigation of costs related to the derogations proposed for PPE: • Minor producer surplus losses due to business closures and substitution. • Minor consumer surplus losses resulting from price changes associated with substitution. • Minor welfare losses and/or additional costs as a result of lower functionality of products. • Minor employment losses.	• The large size of the sector. • A significant number of companies operating in the TULAC sector indicating that substitution costs won't be low. • The fact that the proposed derogation accounts for the non-availability of feasible alternatives for PPE (sub-)uses and mitigates costs related to these (sub-)uses. • Avoided and/or mitigated social costs due to health or safety implications in relation to PPE (sub-)uses.
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Key elements underpinning the SEAC conclusion(s):

Table 4 below summarises the Dossier Submitter's assessment in regard to the (sub-)uses covered by the TULAC sector. The qualifiers used by the Dossier Submitter for categorizing certain cost components into "minor", "medium" and "major" costs are to be understood in comparison with other uses within the TULAC sector¹⁷.

¹⁷ According to the Dossier Submitter's impact assessment approach (see SEAC Opinion for further information) costs are classified as "low – very low – moderate – high – very high". For TULAC, this classification is applied on a sector-basis in order to make this sector comparable to other sectors and to allow for an overall cost assessment for the proposed restriction.

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Table 4: Summary of the cost assessment for the sub-uses covered by the TULAC sector and SEAC's view

Uses	Sub-uses	Derogation proposed by the DS (derogation period)	Costs	
			Information from the Background Document ¹⁸	SEAC's view on the cost assessment
Home textiles	Carpets and rugs	No	No. of companies affected: 1 110-5 760 Most likely reaction of companies affected: Mix of substitution and business closure. Offsetting potential¹⁹: high • Minor producer surplus losses related to business closures (directly affected companies). • Medium producer surplus losses related to substitution (directly affected companies). • Medium consumer surplus losses related to substitution. • Minor producer surplus losses in the supply chain.	Based on the information available to SEAC, the Committee agrees with the Dossier Submitter on the following aspects for all (sub-)uses covered by TULAC: • Non-use scenarios established. • Cost components identified. • Assumptions taken for assessing costs. • Conclusions drawn for (sub-)uses covered. SEAC acknowledges the quantitative cost figures provided by stakeholders in the Annex XV report consultation and notes that it clearly supports the Dossier Submitter's assessment and conclusions.
	Curtains and blinds Textile-based covering			
Consumer apparel	Outdoor wear	No	No. of companies affected: 3 270-16 910 (including also companies producing professional apparel) Most likely reaction of companies affected: Mix of substitution and business closure. Offsetting potential¹⁹: high • Medium producer surplus losses related to business closure (directly affected companies). • Major producer surplus losses related to substitution (directly affected companies).	
	Indoor wear Sportswear Footwear Accessories			

¹⁸ SEAC notes that the extent of costs (major/minor) of cost components assessed is to be understood in comparison to other TULAC (sub-)uses. Furthermore, the key factors being relevant for the conclusion are provided by the Dossier Submitter in Annex E of the Background Document, Table E.40 (Conclusions on total economic impacts on directly affected companies resulting from a full ban of PFAS).

¹⁹ For the offsetting potential, the Dossier Submitter discussed the extent to which producer surplus losses resulting from business closures of affected companies are offset by gains in producer surplus of EU companies that already provide alternative-based products.

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			• Major consumer surplus losses related to substitution. • Minor producer surplus losses in the supply chain.	
Professional apparel and PPE	Professional apparel (including professional sports-/footwear and uniforms)	No	No. of companies affected: 160-830 (PPE only) Offsetting potential¹⁹: low WITHOUT DEROGATION (RO1): Most likely reaction of companies affected: Mix of substitution and business closure with a tendency towards business closure (especially in relation to PPE).	
	PPE (all applications, including re-impregnation agents)	Yes (12 years) ²⁰	• Medium producer surplus losses related to business closure (directly affected companies). • Minor producer surplus losses related to substitution (directly affected companies). • Minor consumer surplus losses related to substitution. • Major producer surplus losses in the supply chain. • High welfare losses due to performance loss (quality, lifetime) and absence of some affected products (certain types of PPE) and additional costs to downstream users (early replacement, cleaning costs). • Employment losses related to business closure (25 702 workers being affected according to information provided in the Annex XV report consultation (comment #9403). • Yearly turnover loss of €1.08 billion (comment #9403). • €4.017 billion per year (loss of profits and employment impacts, Annex XV report consultation comment #6454). -----	

²⁰ Derogations for (i) Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I; ii) Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers; iii) Impregnation agents for re-impregnation of articles referred to above.

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			WITH DEROGATION (R02): Most likely reaction of companies affected: Substitution, assuming that alternatives will be identified for PPE. • Minor producer surplus losses related to business closure. • Minor producer surplus losses related to substitution (due to companies being expected to pass on costs to customers to a large extent). • Minor consumer surplus losses related to substitution. • Mitigation of the other cost components mentioned above, such as welfare losses, additional costs and employment losses, mainly for the PPE sub-uses due to the suggested derogation.	
Leather	E.g. indoor and outdoor wear, footwear, professional sportswear and footwear, and seat coverings	No	No. of companies affected: 190-1 290 Most likely reaction of companies affected: Mainly substitution. Offsetting potential¹⁹: low • Minor producer surplus losses related to business closure (directly affected companies). • Minor producer surplus losses related to substitution (directly affected companies). • Minor consumer surplus losses related to substitution. • Minor producer surplus losses in the supply chain.	
Home fabric treatment (sprays)		No	No. of companies affected: unknown Most likely reaction of companies affected: Mainly substitution. Offsetting potential¹⁹: unknown • Minor producer surplus losses related to business closure (directly affected companies). • Unknown producer surplus losses related to substitution (due to the lack of information on the number of companies directly affected). • Unknown consumer surplus losses related to substitution.	

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			• Minor producer surplus losses in the supply chain.	
Relevant for all sub-uses mentioned above			• Welfare losses related to lower functionality (quality, lifetime) of products and additional costs related to e.g. <i>increased cleaning cost, reimpregnation of products, and other aspects.</i> • Employment losses related to business closures.	SEAC notes that for welfare losses and additional costs (except for PPE uses, for which a derogation is proposed), the Dossier Submitter provides information with respect to which key cost factors (e.g. shortage of products, changes in lifetime of products, etc.) may induce any such costs without providing specific qualifiers (minor/major) for these cost types on a sub-use basis. SEAC notes the Dossier Submitter's conclusions for these cost types for the TULAC sector overall, as pointed out in Table 3 above. SEAC finds the Dossier Submitter's assessment of and the justifications for drawing conclusions clear.

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The above conclusions drawn by SEAC are based on the following key elements, for which a detailed discussion is provided by the Dossier Submitter in the Background Document:

- Structuring of the assessment and (sub-)uses/products covered: SEAC agrees with structuring the cost assessment based on the products and/or (sub-)uses affected. The Dossier Submitter also considered information provided by stakeholders in the consultation on the Annex XV report (e.g. comments #4024, #4115, #6350, #6829, #8521, #8881, #9366, #9403, and others) in order to assess the costs of RO1 and RO2. SEAC notes that several (sub-)uses identified relate to applications within other sectors covered by the restriction proposal and that these are discussed within the relevant sector-specific sections of the Background Document. In order to avoid any potential overlaps in the assessment, the Dossier Submitter provided detailed information on the aforementioned aspects (i.e. which (sub-)uses are covered by which sectors of the Background Document) in the TULAC introductory section E.2.2 of Annex E of the Background Document (see also section S-0 above).

With the investigation work done by the Dossier Submitter during the development of the Annex XV restriction proposal and the information provided by stakeholders in the Annex XV report consultation, SEAC is confident that the (sub-)uses identified for the TULAC sector provide a robust overview of products affected by the proposed restriction. SEAC, however, emphasises that the scope of the restriction proposal at hand is extremely broad and it cannot be ruled out that there are applications which haven't been addressed explicitly by the Dossier Submitter and, consequently, by SEAC.

- Qualitative approach: The Dossier Submitter's assessment includes a clear discussion regarding why a full quantitative cost assessment could not be performed; the reason being mainly the lack of robust quantitative data on several aspects necessary for quantification. In SEAC's view, including at least a partial quantitative assessment (e.g. providing possible cost ranges for some of the cost components discussed) would have supported SEAC's evaluation and conclusion on costs and proportionality. SEAC however admits the difficulties encountered for such a quantitative cost assessment and agrees that sufficient (mainly qualitative) information is available in order to discuss the costs for the TULAC sector on a qualitative basis.

For the qualitative assessment performed by the Dossier Submitter, SEAC notes that the approach taken is extensive and well substantiated. The Dossier Submitter clearly explains which information and assumptions the conclusions are based on, and the assumptions taken are presented in sufficient detail and are based on sound socio-economic theory. As an example, the assumptions on the most likely reaction of companies due to a restriction are based on direct feedback from companies provided during the Dossier Submitter's call for evidence or, where not available, on responses provided by companies regarding whether the listed non-PFAS alternatives are technically and/or economically feasible or whether companies are actively working on finding alternatives. This approach enables assumptions about how specific sub-sectors are likely to react (i.e. substitution or business closure). These assumptions, in turn, allow for a qualitative assessment of the related costs, e.g. minor or major producer surplus losses due to business closure or substitution, minor or major consumer surplus losses due to loss of functionality of products and any potential welfare losses, (un)employment effects, or other costs related to a restriction. The

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Dossier Submitter then concludes on costs according to the proposed qualitative categorisation scheme for the TULAC sector overall.

SEAC agrees with this approach, as it is well-explained and sufficient reasoning was provided in cases where different approaches compared to previously established cost estimations²¹ have been applied. Whilst SEAC notes that cost assessments for large sectors, such as TULAC, are inherently subject to uncertainties, the Committee is confident that these uncertainties are not of an extent that would prevent SEAC from concluding on costs for TULAC.

- Factors considered for cost assessment: the Dossier Submitter explains well the factors affecting the economic impacts for the TULAC sector due to a restriction, e.g. the number of companies affected in each sub-sector, the most likely reaction of those companies (e.g. substitution, business closure), the costs related to that reaction, as well as the ability of companies to pass on higher costs to their customers. Furthermore, the Dossier Submitter considers factors such as the profit margin of branches, the price elasticity of demand, the extent of competition, the market share of affected companies, the degree of specialisation and other factors for the (sub-)use specific cost discussion. SEAC notes that the approach taken is well thought through and that relevant factors affecting the costs due to a restriction have been considered. Furthermore, the Dossier Submitter overall explains well the reasons for concluding either one way or the other, e.g. which factors influence the Dossier Submitter's conclusion. As an example, for identifying the most likely reaction of affected companies due to a restriction (substitution or closure of business), the considerations include the technical feasibility of alternatives, the economic impacts on company level, the time required for completing substitution and implementing the product on the market, the time needed for potential certification of products, and others. SEAC agrees that relevant factors have been considered for the qualitative cost assessment. The complete discussion provided by the Dossier Submitter can be found in Annex E of the Background Document, section E.2.2.4.
- Cost components considered: the following cost components have been discussed by the Dossier Submitter for the (sub-)uses covered by TULAC: i) **producer surplus losses for directly affected companies** (due to business closure or substitution), ii) **consumer surplus losses** (due to price changes associated with substitution), iii) **producer surplus losses in the supply chain** (due to business closure), iv) **welfare losses and/or additional costs** (e.g. due to changes in characteristics of products and any related impacts) and v) **employment losses** (due to business closure). The Dossier Submitter further explains which aspects have been considered when assessing these:
 - Business closure: e.g. typical annual sales volumes of companies; profit margins in the sector;
 - Substitution: e.g. costs associated with research and development; one-off costs for new equipment (capital costs); changes in operating costs (e.g. higher

²¹ This is, for example, relevant for assumptions on the price elasticity of demand within the discussion on the expected extent to which companies can pass on costs to customers. In a report by Wood (2020), different conclusions were drawn compared to the conclusions drawn by the Dossier Submitter within the Background Document for the proposed PFAS restriction.

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raw material costs due to differences in the unit cost of alternatives or a higher volume of alternatives being required); costs related to re-certification and approval.

SEAC agrees with considering the aforementioned cost components and the main factors considered when assessing these. SEAC also notes that, where possible and available, the Dossier Submitter considers quantitative cost information in the assessment, which was provided by stakeholders during the consultation on the Annex XV report. Even if the quantitative information provided is not representative for the restriction overall – due to factors such as limited sample sizes, company-specific data that cannot be extrapolated to the entire sector, or the inclusion of sub-uses not relevant for TULAC but discussed by the Dossier Submitter in other sections of the Background Document (e.g. technical textiles) – it provides some further insights into possible economic impacts due to a restriction and supports the Dossier Submitter’s assessment and conclusions that costs for the sector due to a full ban are very high.

- Total impact on EU industry: SEAC notes that the total impacts on the EU industry are not only dependent on companies being directly affected by the proposed restriction (PFAS users) and companies within the supply chain, but also on companies providing alternatives/alternative-based products. The Dossier Submitter provides a discussion on the offsetting potential for the different TULAC (sub-)uses (potential for producer surplus gains of EU companies that already provide alternative-based products) based on the criteria laid down in SEAC’s approach to assessing changes in producer surplus (ECHA, 2021e). SEAC agrees with the Dossier Submitter’s conclusion, that negative economic impacts for affected companies due to the proposed restriction will partly be offset by positive economic impacts for companies providing alternatives/alternative-based products. However, due to lack of data, the assessment is linked to uncertainties as, for example, the share of EU competitors out of all competitors providing non-PFAS products is completely unknown. As such, SEAC cannot draw a conclusion on the overall offsetting potential for the TULAC sector. Information on a sub-use basis is provided in Table 4 above.

Comments provided in the consultation on the Annex XV report

SEAC notes that several stakeholders provided (publicly available as well as confidential) information on costs during the Annex XV report consultation, e.g. comments #4024, #4115, #6350, #6829, #7007, #8521, #8881, #9220, #9314, #9366, #9403, and others. SEAC notes that the Dossier Submitter considered the information provided for updating the Background Document. Even though the information provided did not allow for a full quantification of costs for the TULAC sector, SEAC notes that the cost information provided by stakeholders supports the conclusion drawn by the Dossier Submitter, i.e. that costs for the TULAC sector overall can be regarded as very high in case of a full ban.

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S-4.2 Benefits

Relevant sections of the Background Document:

Main report, section 2.4.3; Annex A, section A.3.3; Annex B, section B.9.3; Annex E, section E.2.2.

SEAC conclusion(s):

The benefits of a restriction in the TULAC sector have been estimated quantitatively for both restriction options RO1 (full ban) and RO2 (ban with use-specific derogations) via the expected emission reduction. For the latter, an assessment of (reduced) benefits through additional emissions associated with the proposed 12-year derogation (following the general 18-month transition period) for three specific uses of personal protective equipment (PPE)²² has been provided.

SEAC notes that RAC disagrees with the emission estimates for RO1 and RO2 as quantified by the Dossier Submitter and has provided its own recalculated figures, resulting in overall lower emission estimates for the sector. Nevertheless, SEAC agrees with the Dossier Submitter's conclusion that a full ban of PFAS used in the TULAC sector, i.e. RO1, will contribute to the reduction of PFAS emissions. SEAC notes that the emission reduction potential is reduced under RO2 (compared to RO1). SEAC's conclusion is based on RAC's estimation of the emission reduction potential of RO1 and RO2 over the 30-year assessment period (369 369 t and 363 040 t, respectively). In spite of the effectiveness of RO2 being only slightly lower than that of RO1 (94% and 95%, respectively), RAC's calculations show that a 12-year derogation for the three specific sub-uses of PFAS in PPE results in additional emissions of 5 899 t.

Based on the above considerations, SEAC agrees with the Dossier Submitter's conclusion that a restriction of PFAS will contribute to the reduction of PFAS emissions, leading to a **wide range of associated benefits for the environment and human health, which are qualitatively as well as partly quantitatively described in section 3.4.2.2.3 of the SEAC Opinion**. SEAC notes that their magnitude differs between the two assessed restriction options RO1 and RO2.

A summary of the conclusion on benefits of the proposed restriction for the uses covered by the assessment is provided in Table 5 below.

²² For the wording of the derogations proposed, see Table 5 below.

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Table 5: Summary of benefits assessment of RO1 and RO2 for the TULAC sector

ROs assessed	Derogation proposed by the DS (derogation period)	Benefits		
		Dossier Submitter's conclusion	RAC's conclusion on the emission reduction potential	SEAC's view on the benefit assessment
RO1 (overall)	No	A full ban of PFAS in the TULAC sector will reduce PFAS emissions by 634 277 t (range: 262 152 t to 1 006 402 t) over 30 years, corresponding to 95% of baseline emissions (i.e. a decrease from 664 871 t to 30 594 t).	A full ban of PFAS in the TULAC sector is an effective measure to minimise emissions and exposure of humans and the environment. However, based on the diverging views on the approach to calculate emissions from fluoropolymers and a different set of waste-stage release factors, RAC has recalculated the emission estimates, resulting in an emission reduction of 369 369 t over 30 years, corresponding to 95% of baseline emissions (i.e. a decrease from 387 185 t to 17 816 t).	SEAC concludes on the basis of RAC's recalculated emissions and emission reduction potential that a full ban of PFAS used in the TULAC sector (including all its sub-uses) will contribute to the reduction of PFAS emissions, leading to the associated benefits for the environment and human health.
RO2 (overall)	Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I (12 years) Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers (12 years) Impregnation agents for re-impregnation of articles referred to above (12 years)	A ban of PFAS in the TULAC sector with a 12-year derogation (following the general 18-month transition period) for PPE (proposed derogations specified in column to the left) will reduce PFAS emissions by 627 490 t (range: 261 265 t to 993 715 t) over 30 years, corresponding to 95% of baseline emissions (i.e. a decrease from 664 871 t to 37 381 t). Additional emissions due to the three proposed derogations amount to 6 787 t over 30 years.	RAC's recalculation results in an emission reduction of 363 040 t over 30 years, corresponding to 94% of baseline emissions (i.e. a decrease from 387 185 t to 23 715 t). According to RAC's recalculations, additional emissions due to the three proposed derogations are significant and amount to 5 899 t over 30 years. RAC proposes to require additional risk management measures to ensure PFAS emissions are minimised along all life cycle stages in case derogations are supported by the decision maker.	SEAC agrees with the Dossier Submitter's conclusion that a restriction with the proposed 12-year derogation for three specific uses of PPE will contribute to the reduction of PFAS emissions, leading to the associated benefits for the environment and human health. SEAC notes, however, that the benefits are reduced compared to RO1, considering RAC's conclusion on the additional emissions compared to RO1. However, SEAC points out uncertainties regarding the absolute amount of emissions reduced due to uncertainties regarding the share of emissions attributable to the proposed derogations.

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Key elements underpinning the SEAC conclusion(s):

- Tonnage and emission estimates: In their estimations on the development of the tonnage volumes over the assessment period²³ the Dossier Submitter distinguishes between more than the three PFAS groups otherwise generally used for the assessment throughout the report (PFAAs and PFAA precursors, fluoropolymers, fluorinated gases). A more granular approach was chosen assessing eight different groups of PFAS with increasing chain length on the grounds that each of the assessed groups have distinct properties directly impacting their area of application and the corresponding market development. However, SEAC notes that the restriction of PFHxA and related substances²⁴ was not taken into account by the Dossier Submitter as the restriction had not been adopted at the time of submission of the PFAS restriction proposal at hand. SEAC notes that this could impact the baseline considerably due to the high share of C6 PFAS used in the TULAC sector. The development of the tonnage volume was assessed based on the call for evidence, the Dossier Submitter's second stakeholder consultation and market considerations and was transparently presented for each PFAS group. SEAC notes that consumer and producer awareness, specifically concerning consumer apparel, was taken into account but that possible impacts due to pending future policies and regulations were not considered. Where in-depth information was lacking, the Dossier Submitter applied a 2% default growth rate, however, without providing further justification for the chosen value. SEAC notes the Dossier Submitter's reflection that the lower bound estimate of the use tonnage and accordingly the lower bound emission estimate may be more realistic than the reported midpoint estimates. However, SEAC notes also that RAC confirms that using the midpoint estimates for further considerations on emission estimates is appropriate, since there are also uncertainties which may result in an underestimation of volumes.

Furthermore, SEAC notes that RAC does not agree with the Dossier Submitter's emission estimates based on diverging views on the approach to estimate emissions from fluoropolymers as well as emissions from the waste stage (detailed reasoning provided in the RAC Opinion). Considering these concerns, RAC has recalculated emissions, including for fluoropolymers only the non-polymeric emissions and applying a different set of waste-stage release factors that RAC considered more appropriate than those provided by the Dossier Submitter. SEAC notes that according to RAC's recalculations, baseline emissions of the TULAC sector amount to 387 185 t over 30 years.

Lastly, SEAC notes RAC's assessment that, in addition, fluoropolymers can be emitted in particulate form. The emissions of this particulate fraction were not quantified by RAC. Further details are provided in section 3.4.2.2.3 of the SEAC Opinion.

²³ The assessment period regarded by the Dossier Submitter extends over 30 years from 2025 to 2055. SEAC notes that the development of the tonnage volumes was assessed until 2070 but confirms that only the development until 2055 was taken into account for the environmental impact assessment.

²⁴ Commission Regulation (EU) 2024/2462 of 19 September 2024 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances

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- Emission reduction under RO1 (full ban): The Dossier Submitter expects an emission reduction of 95% of the baseline emissions over a 30-year period due to a full ban of PFAS used in the TULAC sector (including all its sub-uses). The effectiveness of RO1 is therefore assessed as high by the Dossier Submitter. SEAC notes that emissions were recalculated by RAC and with TULAC being one of the sectors with the highest use tonnage and emissions, the emission reduction potential as recalculated by RAC corresponds to approximately 369 369 t of avoided emissions over 30 years. RAC concludes that RO1 is considered as an effective measure to minimise PFAS emissions and exposure of humans and the environment (effectiveness of 95%).
- Emission reduction under RO2 (ban with a 12-year derogation for three specific uses of PPE): The Dossier Submitter proposes a 12-year derogation (following the general 18-month transition period) for the use of PFAS in:
 - Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I
 - Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers
 - Impregnation agents for re-impregnation of articles referred to above

As use specific tonnage and emission data for each of these sub-uses as well as for PPE overall was scarce, the Dossier Submitter approximated additional emissions associated with the proposed derogations through expert information. SEAC acknowledges that the Dossier Submitter systematically assessed the information available to them including information from the consultation on the Annex XV report on precise use data and approximate market share and transparently presented assumptions. Through this, the Dossier Submitter reaches a conclusion on the share of PFAS used in PPE (including re-impregnation) in relation to the whole quantifiable use of “professional apparel and PPE”. SEAC points out that despite their thorough assessment, the Dossier Submitter could only estimate that the three specific uses of PPE proposed to be derogated represent between 30% and 90% of the volumes and emissions of the entire professional apparel and PPE (sub-)sector.

Furthermore, SEAC points out that RAC does not agree with the Dossier Submitter’s emission estimates and has conducted its own recalculations. The 363 040 t of avoided emissions over 30 years under RO2 as calculated by RAC show a smaller emission reduction potential than under RO1, but still lead to an effectiveness of 94% of RO2. In spite of the similarly high effectiveness under RO2 compared to RO1 (95% and 94%, respectively), SEAC notes, based on RAC’s recalculations, that the proposed derogations for PFAS used in PPE lead to expected additional emissions of 5 899 t over 30 years (acknowledging the uncertainties associated with this value as pointed out above). Accordingly, RAC notes the significant additional emissions associated with the proposed derogations and proposes to require additional risk management measures to ensure PFAS emissions are minimised along all life cycle stages in case derogations are supported by the decision maker.

Moreover, SEAC points out the information the Dossier Submitter received from three firms in the PPE sector following the Dossier Submitter’s second stakeholder consultation, indicating that 80% of the tonnage used in the PPE sector is associated with PPE protecting against category I or II risks, with only 20% associated with the

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highest risk category III. Uncertainties remain, however, regarding the representativeness of this estimate provided by three firms in the PPE sector as well as the associated emissions.

Overall, SEAC notes that the derogations proposed for the three above-named specific uses of PPE lead to lower benefits for the environment and human health. The benefits forgone by each unit of emission are further elaborated on in section 3.4.2.2.3 of the SEAC Opinion.

S-4.3 Other relevant impacts

Relevant sections of the Background Document:

No other impacts have been assessed by the Dossier Submitter than those discussed in the above sections.

SEAC conclusion(s):

No additional conclusions to those discussed in the above sections.

Key elements underpinning the SEAC conclusion(s):

No additional conclusions to those discussed in the above sections.

S-4.4 Proportionality

Relevant sections of the Background Document:

Main report, section 2.4.4; Annex E, section E.2.2.

SEAC conclusion(s):

For the TULAC sector, the Dossier Submitter has provided a proportionality assessment on a sector basis according to step 6 of the impact assessment approach²⁵ established for this restriction proposal. For this, the aggregated level of costs for all (sub-)uses within the TULAC sector was compared to the effectiveness in terms of emission reduction of the restriction options RO1 (full ban) and RO2 (ban with use-specific derogations for PPE). Based on this comparison, the Dossier Submitter concludes that RO1 is likely not proportionate (costs: very high; effectiveness: high) and RO2 is likely proportionate (costs: moderate; effectiveness: high) from a sector perspective.

Based on the information available, **SEAC agrees with the Dossier Submitter that RO1, i.e. a full ban of PFAS in the TULAC sector, is likely not proportionate.** Instead, SEAC considers **a ban with use-specific derogations**, where costs to society of a restriction outweigh the benefits, as **appropriate to ensure proportionality of a restriction for the sector.**

Under **RO2**, the Dossier Submitter proposes a ban with a 12-year derogation (following the general 18-month transition period) for the use of PFAS in:

- Personal protective equipment (PPE) intended to protect users against risks as

²⁵ The approach and SEAC's view are in detail explained in the SEAC Opinion.

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specified in Regulation (EU) 2016/425, Annex I

- Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers
- Impregnation agents for re-impregnation of articles referred to above

Based on SEAC's evaluation of the available information on alternatives, costs, and benefits, there is evidence supporting specific derogations for the use of PFAS in PPE. However, as pointed out in section S-3 above, SEAC has doubts that a **broad derogation, covering all three risk categories I, II and III** (for PPE intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I), is justified based on the information available on the feasibility and availability of alternatives. Furthermore, for PPE specifically designed for armed forces, the maintenance of law and order and other emergency response workers, SEAC finds there is **insufficient information to justify a 12-year derogation period** based on the criteria used by the Dossier Submitter. SEAC therefore was not able to determine if substitution could be achieved within a shorter timeframe.

However, for the TULAC sector, SEAC **can conclude** the following:

- SEAC notes that there is evidence that a 12-year derogation (following the general 18-month transition period) is justified for **PPE intended to protect users against risk categories III(a) and III(c) as specified in Regulation (EU) 2016/425, Annex I**, in order to ensure **proportionality** of a restriction for the sector. SEAC notes that, due to a lack of sufficiently robust cost and benefits data, the Committee **could not determine** whether a derogation is needed for **other sub-categories covered by risk category III** in order to ensure proportionality of a restriction for the sector. SEAC, however, regards this as likely as costs of a ban related to these other sub-categories (due to potential health and safety issues) could be substantial.
- Furthermore, SEAC notes that there is evidence to support a **time-limited derogation for PPE specifically designed for armed forces, the maintenance of law and order and other emergency response workers** in order to ensure **proportionality** of a restriction for the sector. The **duration** of the derogation could, however, **not be determined** by SEAC due to a lack of data.
- SEAC notes that a time-limited derogation for **impregnation agents for re-impregnation of articles referred to above** is necessary in order to **ensure proportionality** of a restriction for the sector.

For the **other sub-uses** assessed by the Dossier Submitter within TULAC, SEAC concludes that based on the evaluation of the available information on alternatives, costs and benefits, there is evidence that **no derogation is needed in order to ensure proportionality** of a restriction for the sector.

Key elements underpinning the SEAC conclusion(s):

No cost-effectiveness analysis (CEA) was provided by the Dossier Submitter due to a lack of quantitative cost data. SEAC agrees and notes that the quantitative information available to the Committee is not sufficient to perform a CEA. Therefore, the Dossier Submitter assessed proportionality of RO1 and RO2 for the TULAC sector based on step 6 of their proposed impact assessment approach through comparing the level of aggregated costs (very low, low, moderate, high, very high) to the effectiveness of the restriction options (RO1 and RO2) in terms of emission reduction (very low, low, moderate, high, very high) on a sector basis. For

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concluding on the magnitude of costs as well as effectiveness, specific criteria have been introduced. SEAC has concerns with this approach (details on the approach as well as the reasoning for SEAC's concerns are provided in the SEAC Opinion). In order to conclude on proportionality, SEAC therefore notes the following key aspects identified in the analysis of alternatives, the cost and benefits assessment and the consultation on the Annex XV report:

- Analysis of alternatives (for details please consult section S-3): SEAC agrees with the Dossier Submitter's conclusion that there is sufficiently strong evidence for high substitution potential in the following cases: home textiles, consumer apparel, professional apparel, leather and home fabric treatments (sprays).

SEAC disagrees with the assessment performed by the Dossier Submitter for personal protective equipment (PPE). SEAC finds that based on its assessment there is only sufficiently strong evidence for low substitution potential for risk categories III(a), III(c), as well as PPE used in military, firefighting and other emergency response activities in general.

- Costs (for details please consult section S-4.1): SEAC agrees with the Dossier Submitter's conclusion that a full ban of PFAS for (sub-)uses covered by the TULAC sector would lead to very high costs, which is demonstrated by the Dossier Submitter's qualitative cost assessment and supported by (qualitative and quantitative) information received in the Annex XV report consultation. SEAC also agrees that a 12-year derogation for the specified PPE uses is expected to reduce the costs compared to a full ban with an 18-month transition period.
 - Derogation for personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I: Considering the substitution potential, SEAC recommends limiting this derogation to PPE intended to protect users against category III(a) and III(c) risks as specified in Regulation (EU) 2016/425, Annex I, instead of covering also category I, II and the remaining sub-categories of category III. However, SEAC has no information on how this would influence the (mitigation of) costs, due to cost data not being available on such a granular level. SEAC notes the reasoning of the Dossier Submitter that in case of alternatives not functioning sufficiently well and not providing a sufficient level of protection, high costs due to health implications can be expected. However, SEAC notes that high costs related to health and safety issues due to loss of functionality or unavailability of products are mainly linked to risk category III. This is because category I is designed to protect users against minimal risks with products such as garden gloves or kitchen aprons. SEAC doubts that high health costs are to be expected due to PFAS being no longer available for these products. The same might be applicable to risk category II, which is designed to protect users against risks covering products such as oven gloves, swimming aids or safety footwear. SEAC additionally lacks sufficiently granular information on other potential cost impacts such as substance substitution costs, reformulation costs, re-certification costs and others.
 - Derogation for PPE specifically designed for armed forces, the maintenance of law and order and other emergency response workers: SEAC notes that the information available to the Committee does not allow an evaluation of the costs related to derogation periods that differ from the proposed 12 years.

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- Benefits/emission reduction potential (for details please consult section S-4.2): SEAC notes RAC's conclusion that a full ban (RO1) of PFAS in the TULAC sector is an effective measure to minimise emissions and exposure of humans and the environment, consequently leading to benefits associated with the emission reduction of 369 369 t (over the assessment period of 30 years) for the sector. SEAC notes that a 12-year derogation for the three specific sub-uses of PPE as suggested by the Dossier Submitter is expected to reduce the emission reduction potential to 363 040 t (over the assessment period of 30 years) for the sector. Consequently, the benefits of a ban are reduced by additional emissions amounting to 5 899 t compared to RO1 due to the proposed derogations under RO2, resulting in a reduction of the effectiveness from 95% (RO1) to 94% (RO2).

SEAC notes RAC's conclusion that significant additional emissions of PFAS are related to the three derogations proposed by the Dossier Submitter under RO2.

However, SEAC notes that limiting the derogations to specific risk categories or sub-categories, as discussed above, would further reduce the emission potential of the derogations and enlarging the related benefits. This is also supported by information provided by three companies from the PPE sector (in a stakeholder consultation performed by the Dossier Submitter) indicating that only 20% of the tonnage used in the PPE sector is associated with PPE for protection against category III risks. Uncertainties remain, however, due to a lack of concrete emission data for the individual PPE (sub-)categories.

Lastly, SEAC is not able to conclude on the benefits under a potentially shorter derogation period for PPE specifically designed for armed forces, the maintenance of law and order and other emergency response workers, as no such information is available to the Committee.

S-5 Practicality, including enforceability

See SEAC Opinion.

S-6 Monitorability

See SEAC Opinion.

S-7 Sector-/use-specific derogations

SEAC conclusion(s):

The Dossier Submitter proposes a 12-year derogation (following the general 18-months transition period) for the use of PFAS in:

- Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I
- Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers

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- Impregnation agents for re-impregnation of articles referred to above

SEAC agrees that specific derogations for the use of PFAS in PPE are justified to ensure proportionality of a restriction for the sector (see section S-4.4 on proportionality above). SEAC notes, however, that based on the analysis of alternatives as well as socio-economic considerations, the derogations should be more targeted than those proposed by the Dossier Submitter.

Based on the information available, SEAC concludes that a **12-year derogation** (following the general 18-month transition period) is **justified** for the use of PFAS in:

- **Personal protective equipment (PPE)** intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, **risk categories III(a) and III(c)**.

Furthermore, based on socio-economic considerations, SEAC notes that a **time-limited derogation** (following the general 18-month transition period) may **be warranted** for the use of PFAS in:

- **Additional sub-categories within risk category III**, i.e. **III(b) and III(d-m)**. However, SEAC notes that cost information is not available on a sufficiently granular level in order to determine the need for a derogation for any of these sub-categories.

SEAC concludes that a **time-limited derogation** is **justified** for the use of PFAS in:

- **Personal protective equipment (PPE)** specifically designed for **armed forces**, the **maintenance of law and order** and **other emergency response workers**. SEAC does not consider the proposed 12-year derogation period to be fully justified. However, due to insufficient information regarding both the analysis of alternatives as well as the socio-economic analysis, SEAC cannot determine a different (shorter) derogation period.

SEAC concludes that a **time-limited derogation** is also **justified** for the use of PFAS in:

- **Impregnation agents** for re-impregnation of articles referred to above.

Based on SEAC's evaluation of the available information (analysis of alternatives and socio-economic analysis) for the **other sub-uses identified** by the Dossier Submitter, **no further derogations are considered justified** by SEAC.

Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter proposes a 12-year derogation for the following uses of PFAS in PPE:

- Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I: this proposal is based on the Dossier Submitter's conclusion that there is sufficiently strong evidence that no technically and economically feasible alternatives are available at entry into force. SEAC disagrees with this conclusion and finds that a **derogation is justified for risks as specified in Regulation (EU) 2016/425, Annex I, risk categories III(a) and III(c)**. SEAC further finds that a derogation **may be warranted for risks as specified in Regulation (EU) 2016/425, Annex I, risk categories III(b) and III(d-m)**. SEAC's conclusion is based on the following considerations:
 - SEAC only found sufficiently strong evidence for low substitution potential for risk categories III(a) and III(c). For the other risk categories there was either sufficiently strong evidence for high substitution potential, there was no

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indication that PFAS are used or needed to reach the required level of performance to ensure the safety of the users, there was weak evidence, or no evidence at all to conclude on substitution potential.

- The information on socio-economic impacts available to SEAC supports the Committee's conclusion that a 12-year derogation (following the general 18-month transition period) for risk categories III(a) and III(c) is justified. Even though no quantitative cost-benefit assessment was possible, the qualitative cost information available is regarded as sufficient by SEAC to support this conclusion. The cost information available indicates potentially substantial costs related to health and safety issues due to loss of functionality or even absence of products if PFAS are no longer available. Limiting the derogation to specific applications (i.e. to risk categories III(a) and III(c)), where the evidence is sufficiently strong that feasible alternatives are not readily available, ensures limiting also the additional emissions due to a derogation. SEAC notes that no concrete emission data for the individual PPE (sub-)categories is available, though. SEAC notes that a time-limited derogation may also be warranted for additional sub-categories within risk category III, i.e. III(b) and III(d-m). However, the uncertainties for these sub-categories, mainly the lack of sufficiently granular cost information, are of an extent that SEAC cannot determine whether a derogation is needed for other sub-categories covered by risk category III.

For risk categories I and II, SEAC finds it plausible that costs related to a ban are limited, as one of the main cost components considered by the Dossier Submitter, i.e. high welfare losses due to lower functionality of products/absence of products, are likely not relevant for these categories. Additionally, SEAC notes that according to information the Dossier Submitter has received from stakeholders, 80% of the tonnage used in PPE is used for protection against category I and II risks. This supports SEAC's conclusion that a derogation for PPE intended to protect users against risk categories I and II as specified in Regulation (EU) 2016/425, Annex I is not justified.

- Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers: SEAC agrees that a **time-limited derogation is justified** but notes that the proposed 12-year derogation period (following the general 18-month transition period) **is not fully justified**. SEAC's conclusion is based on the following considerations:
 - SEAC agrees with the Dossier Submitter's conclusion that there is sufficiently strong evidence for low substitution potential²⁶. SEAC does however note that the Dossier Submitter has not sufficiently justified the need for a 12-year derogation period since it is unclear from the available information (including the consultation on the Annex XV report) whether alternatives will become available in the near future or not. Additionally, the available information on

²⁶ SEAC notes that this conclusion is only valid when PPE (any risk category) are used for military, firefighting or emergency response activities. The substitution potential for the same PPE can therefore be different depending on its use. For example, the substitution potential for PPE covered by category I(b) but not used in military, firefighting or emergency response activities is high, but in military, firefighting or emergency response activities the substitution potential is low.

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alternatives (including the consultation on the Annex XV report) also does not indicate that when certification or regulatory approval is necessary, this cannot be done in a 5-year derogation period²⁷. Furthermore, there are indications from the consultation on the Annex XV report that protection requirements could be reduced (#9547) or that there is an overuse of PPE with the highest level of protection (#6350).

- SEAC notes that the information available to the Committee on costs and benefits does not allow drawing a conclusion on a different (shorter) derogation period.
- Impregnation agents for re-impregnation of articles referred to above
 - SEAC agrees with the Dossier Submitter that any derogation for PPE should also allow the use of impregnation agents to restore the protective properties of the derogated PPE.

SEAC notes RAC's conclusion that the derogations for PPE, as proposed by the Dossier Submitter under RO2, are associated with significant additional emissions. Based on SEAC's evaluation of the analysis of alternatives, RAC notes however that a full ban (i.e. RO1) could lead to negative effects on the health and safety of workers, including on the protection from chemical risks. RAC therefore supports a derogation for PPE (including their impregnation agents) but considers that it should be targeted as much as possible to the specific categories of PPE discussed by SEAC to avoid risks to workers. SEAC also notes that RAC proposes to require additional risk management measures to ensure PFAS emissions are minimised along all life cycle stages in case derogations are supported by the decision maker. SEAC has no information on costs related to these measures.

SEAC also notes RAC's conclusion regarding the risk of alternatives as summarised in section S-3 above.

Lastly, SEAC notes that for the restriction proposal on PFHxA, its salts and related substances, SEAC also limited a related derogation for PPE to specific products covered by risk category III²⁸. SEAC notes that the assessment of both the technical and economic feasibility of alternatives as well as the socio-economic impacts has advanced since SEAC adopted its opinion on this restriction proposal in 2021. SEAC has therefore taken into account new information included in the Background Document and submitted during the consultation on the Annex XV report. SEAC notes that the conclusion on PPE for the currently proposed restriction is consistent with the conclusion reached in the PFHxA restriction proposal.

²⁷ See SEAC Opinion for more details on the approach used to determine either a 5-year or 12-year derogation period.

²⁸ Details can be found in SEAC's opinion on the restriction proposal for PFHxA, its salts and related substances: [97eb5263-90be-ed5-0dd9-7d8c50865c7e \(europa.eu\)](https://echa.europa.eu/97eb5263-90be-ed5-0dd9-7d8c50865c7e) [Accessed 20/08/2024]

S-8 Summary of uncertainties

Relevant sections of the Background Document:

Main report, section 3; Annex F.

SEAC conclusion(s):

SEAC notes that the uncertainty assessment performed by the Dossier Submitter in section 3 of the main report as well as Annex F is performed on a general basis rather than on sector and/or (sub-)use level. SEAC's view on the approach is provided in the SEAC Opinion.

For the TULAC sector, no specific uncertainty assessment was performed by the Dossier Submitter.

SEAC has identified uncertainties in regard to the analysis of alternatives as well as the socio-economic analysis for several sub-uses covered by the sector at hand. One reason is the lack of data which are necessary to take robust assumptions in order to qualitatively or quantitatively assess the socio-economic impacts of a restriction. Another reason is the lack of more granular data in order to conclude on socio-economic impacts on a sub-use basis, which is a relevant factor in order to evaluate whether or not derogations and their length are justified. Some of the identified uncertainties prevented SEAC from reaching a conclusion in certain instances as pointed out in the respective sections. However, in those instances where SEAC was able to draw a conclusion, the Committee does not regard the uncertainties as so high that the conclusions drawn for alternatives, costs, benefits, and proportionality would change. More details are provided in the key elements section below as well as the topic-specific sections throughout this document.

Key elements underpinning the SEAC conclusion(s):

SEAC notes the following uncertainties for the TULAC sector:

- **Analysis of alternatives:**

- Professional apparel: The discussion in the Background Document is brief which leads to some uncertainties regarding SEAC's evaluation. This did however not impact SEAC's conclusion significantly since there is considerable overlap with the discussion on home textiles and consumer apparel.
- PPE: While the Dossier Submitter provided a discussion on possible risks against which PPE need to protect, a structured assessment of alternatives was not performed on the basis of the risk categories defined in the EU PPE Regulation. While the conclusions for risk category I are not substantially impacted by the uncertainties identified, the discussions for risk categories II and especially III are.

In regard to risk category II, SEAC notes that a broad range of risks can be covered, but the Dossier Submitter only highlights two. SEAC however acknowledges the difficulties in providing a complete assessment for a very broadly defined risk category, but the Committee cannot provide a robust assessment of all applications of PPE intended to protect against risks covered by risk category II and whether PFAS are required or not.

In regard to risk category III, SEAC notes a distinct lack of information for certain sub-categories which significantly hampered the Committee's

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evaluation and could affect the impact on society (i.e. protection against the risks linked to risk category III in case of a full ban) or human health and the environment (i.e. risks related to PFAS emissions in case of a derogation).

- **Costs:** Uncertainties mainly relate to the fact that the Dossier Submitter concludes on costs for TULAC on a sector basis overall, and not on a use basis (e.g. for home textiles, consumer apparel, leather, etc.). Even though the single cost components are discussed on a use basis, the conclusions are drawn on a sector basis overall only. Whilst SEAC agrees that this is a valid way to perform the cost assessment for the TULAC sector, it leads to difficulties when concluding on derogations as the cost data available to SEAC is not of a granularity that would allow evaluating the cost mitigation related to targeted derogations and proportionality, respectively. Detailed information is provided in sections S-4.1 on costs and, specifically, derogations S-7 above.
- **Benefits:** SEAC notes several uncertainties regarding tonnage and emission estimates as pointed out in detail in the RAC sector-specific evaluation. This induces uncertainties with respect to the benefits associated with the emission reduction potential of RO1 and RO2. Furthermore, the emission estimates available to SEAC are not of a granularity that would allow evaluating the reduced emission reduction potential related to more targeted derogations, as discussed throughout this document. Detailed information is provided in sections S-4.2 on benefits and S-7 on derogations above.
- **Proportionality:** SEAC's view on the Dossier Submitter's approach to assess proportionality is provided in the SEAC Opinion. For the TULAC sector, SEAC notes that costs were assessed qualitatively, which generally leads to a certain degree of uncertainty. Further uncertainties regarding the Dossier Submitter's cost and benefits assessment are relevant for the proportionality assessment as well; these are pointed out above and in sections S-4.1 on costs and S-4.2 on benefits. In SEAC's view, these uncertainties have, however, no influence on SEAC's ability to assess and conclude on proportionality for RO1. Instead, for RO2 (ban with use-specific derogations), SEAC notes that there is uncertainty whether a derogation for PPE intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, risk categories III(b), and III(d-m) is needed in order to ensure proportionality for the sector overall. The main reason that prevents SEAC from a concrete conclusion relates to the lack of information on additional emissions associated with these risk categories as well as a lack of sufficiently granular cost information. SEAC, however, emphasizes that costs of a restriction related to these risk categories could be substantial.

S-9 References

Karim, Nazmul, Shaila Afroj, Kate Lloyd, Laura Clarke Oaten, Daria V. Andreeva, Chris Carr, Andrew D. Farmery, Il-Doo Kim, and Kostya S. Novoselov (2020). Sustainable Personal Protective Clothing for Healthcare Applications: A Review, *ACS Nano* (2020), 14, 12313–12340.

Other references are included in the Background Document.