

Online information session on the proposed restriction of PFHxA, its salts and related substances – questions and answers

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Germany prepared a restriction proposal on Perfluorohexanoic acid (PFHxA), its salts and related substances. A 6 month [consultation](#) started on 25 March and it ends 25 September.

According to Germany, PFHxA, its salts and related substances are very versatile and have been used in various sectors such as clothing, polymers and fire extinguishing agents. Their persistent and mobile properties make the control of emissions and exposure difficult, and they may, if the releases are not minimised, cause adverse effects to our health and the environment.

An online information session took place on 23 April 2020 on the proposed restriction, clarifying its scope and explaining how to prepare and submit comments in the consultation.

Participants were asked to send questions about the restriction in advance, which were then compiled in this Q&A document.

This document will not be updated. [Contact us](#) for any further questions.

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1. SEMICONDUCTORS

Extract from the restriction proposal entry:

7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [seven years after the entry into force] to:

(a) photolithography or etch processes in semiconductor industry

1. Does the exemption in point 7 of the restriction proposal cover only process chemicals (i.e. etching agents) or does it also include whole materials/parts in semiconductor manufacturing equipment? For instance, many o-rings, tubes, valves, which are made with fluoroelastomers/resins are used in the equipment. Are there also exempted parts?

The products mentioned above are not exempted. The exemption covers the production process of semiconductors only.

For the products, the limit values of 25 ppb for the sum of PFHxA and its salts and 1000 ppb for the sum of PFHxA-related substances apply.

Additional information from the public consultation will be considered to determine whether a wider derogation is necessary.

2. Does the exemption for semiconductors also cover fluoropolymers?

The exemption covers the production process of semiconductors and fluoropolymers used in this process are covered by the exemption.

For the semiconductor itself, the limit values of 25 ppb for the sum of PFHxA and its salts and 1000 ppb for the sum of PFHxA-related substances apply.

Additional information from the public consultation will be considered to determine whether a wider derogation is necessary.

2. PERSONAL PROTECTIVE EQUIPMENT

Extract from the restriction proposal entry:

9. Paragraphs 1 and 2 shall not apply to any of the following: (b) personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f).

1. Are medical woven textiles included in (a) substances and mixtures which are hazardous to health; or (c) harmful biological agents? Doctors, nurses, and researchers have a risk of being in contact with viruses, blood, body fluids etc.?

The intention of the dossier submitter is to derogate the use of PFHxA, its salts and related substances in textiles when a use significantly reduces severe risks to human health. When lab, doctor or nurse coats reduce the risks from biological agents transmitting, amongst others, blood-borne infections, airborne infection or direct and indirect contact infections, the dossier submitter argues that the use should be derogated.

More concretely:

The above-mentioned laboratory coats or comparable products: if they are worn for protection against (a) substances or mixtures that are hazardous to health or (c) harmful biological agents, they are subject to the PPE Regulation (EU) 2016/425. This is indicated in Annex 1, Risk Category III of the Regulation.

The question of whether the products are assigned to point (a) or (c) is irrelevant, as both are associated with the same conformity assessment procedure. Whether such lab/doctors/nurse coats are to be regarded as PPE, depends primarily on how the manufacturer declares the products.

If only the woven or knitted fabric (bulk goods) is meant, then it is not PPE, as the basic material is not ready for use.

2. If room temperature is 25°C and the substance treated there is 100 or - 50°C, is this situation exempted or should room temperature (environment) itself be at least 100°C/-50°C or less?

Extract from the restriction proposal entry:

- e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C
 - f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less
-

The intention of the dossier submitter is to derogate only uses in high temperature environments. Therefore, if room temperature is 25 °C, the use is not exempted.

The European Commission PPE guidelines¹ may be relevant in this case: "In (e) the risk of exposure to high-temperature environments are related to effects comparable with air

¹ [PPE Regulation Guidelines - Guide to application of Regulation EU 2016/425 on personal protective equipment](#)

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temperature of 100 °C. Scientific literature describes that exposure to an air temperature of more than 100 °C, in combination with other aspects or risks, would result in second degree burn injuries in less than fifteen seconds. This means that the heat flux transmitted to the skin will cause second degree burn within fifteen seconds. This criteria for second degree burn injuries should be regarded as the criteria when deciding if a PPE protecting against heat is Category III PPE or not. This criterion should also be applied where a risk of splashes of hot material and contact with hot surfaces might exist.

The risk related to exposure to low-temperature environments in (f) are related to effects comparable with air temperature of -50 °C, the effects of -50 °C are to be seen in calm air with a wind speed of max. 5 km/h. These conditions can result in frostbite of the exposed surface in less than two minutes. In conditions with higher wind speeds this effect can be reached at less extreme temperatures. Conditions that can result in frostbite of the exposed surface in less than two minutes should be regarded as the criteria when deciding if a PPE protecting against cold is Category III PPE or not."

Thus, what is meant here is not necessarily always the room temperature in which a person is completely immersed (which is certainly the case with protection for firefighters), but the temperature of the three-dimensional space at risk, regardless of the size of the space (room). If it is necessary to stay in such a space with the whole body or even only with parts of the body in temperatures (temperature equivalent) above/below the mentioned limits, then a risk category III exists.

PPE is classified in category III:

- if, when using a substance, it is foreseeable that the person using it will expose himself wholly or partially to temperatures or equivalents thereof which are < 50 °C or > 100 °C,
- and there is a risk of irreversible damage if that person is not wearing PPE.

3. AUTOMOTIVE

Extract from the restriction proposal entry:

11. The concentration limit referred to in paragraph 2 shall be 150 ppm for the sum of PFHxA and its salts in fluoroelastomers used in the following usage groups: Automotive and aerospace industry. This derogation shall not apply to articles referred to in paragraph 2(c).

1. The import, manufacture or use of emulsifiers are not clearly mentioned in this exemption. However, it is understood by UBA as it is mentioned on page 26 of the Annex report. Is the import, manufacture or use of emulsifiers included in this exemption?

Emulsifiers are not exempted. The dossier submitter's intention is to enable manufacturers to continue the production of high-performance fluoroelastomers as needed by the automotive and aerospace industries. Additional information from the public consultation will be considered to determine whether a wider derogation is necessary.

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4. MISCELLANEOUS QUESTIONS

1. Does ECHA advise to submit initial information on derogation needs by 13 May, so that it can be considered in the first discussion on the costs of the restriction? Is it correct that derogation requests need to otherwise be submitted by the end of July?

Early submission of comments allows the rapporteurs more time to come back to respondents with follow-up questions and requests for any clarifications that may be needed.

Respondents can submit comments throughout the whole consultation period until 25 September, and all comments will be considered. ECHA encourages respondents to submit their comments as early as possible, so that they can feed into the discussions of the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) in their meetings in September 2020. To have a comment (e.g. a derogation request) considered in these meetings, it would have to be submitted by mid-July.

If comments are submitted closer to the end of the consultation period, they will only be discussed in the following meetings in November/December 2020.

2. Do non-woven medical textiles fall under exemption 9.b?

See previous answer.

The intention of the dossier submitter is to derogate the use of PFHxA, its salts and related substances in textiles when this use significantly reduces severe risks to human health.

When woven textiles reduce the risks from biological agents transmitting amongst others blood-borne infections, airborne infections or direct and indirect contact infections, the use should be derogated.

3. Is it possible that the deadlines for the public consultation will be postponed due to the COVID-19 outbreak?

The COVID-19 outbreak is generally not causing any delays in the process.

If you can provide specific information on significant difficulties caused by the outbreak that are preventing you from sending comments during the consultation, send them to us and they will be taken into consideration.

4. The restriction of PFOA, its salts and PFOA-related substances also affects ski waxes that have been based on C8 fluorocarbons. Manufacturers of ski waxes have now switched to C6 chemistry (example reference). Will the proposed restriction of PFHxA affect those ski waxes in the same way?

The use of so-called C6 chemistry in ski waxes will no longer be possible. Non-fluorinated alternatives are available.

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5. How can ECHA avoid that manufacturers of ski waxes do another regrettable substitution as soon as the decision on the restriction on PFHxA is taken?

We encourage manufacturers of ski waxes to engage with the [call for evidence](#) on the broad PFAS restriction that is currently under preparation. The call contains potentially useful information for the skiing sector regarding the question and answering the call will also help Member States preparing the restriction proposal to identify all use sectors.

6. How can we apply the thresholds (1000 ppb) to polymers?

The thresholds are proposed to be applicable for unbound monomers and other unbound residues.

7. Which polymers are affected? Is a distinction made between Fluoropolymers and Fluorinated polymers?

No distinction is made between fluoropolymers and side-chain fluorinated polymers (SFPs). The thresholds of unbound monomers and other unbound residues are applicable for fluoropolymers and SFPs.

8. Restriction proposal point 11: Derogation for fluoroelastomers: Which polymers or types of polymers are covered by the term “fluoroelastomers”?

Fluoroelastomers cover fluorinated elastomers. IUPAC defines elastomers as polymers that display rubber-like elasticity. These are polymers containing e.g. the monomers vinylidene difluoride (VDF) or hexafluoropropylene (HFP) resulting in FKM, FFKM and FEPM polymers.

9. Restriction proposal point 11: Derogation for fluoroelastomers: Can you explain the sentence “This derogation shall not apply to articles referred to in paragraph 2(c).”?

The derogation covers substances, constituents, and mixtures but not articles. For articles, thresholds are 25 ppb for the sum of PFHxA and its salts and 1000 ppb for the sum of PFHxA-related substances.

10. Certain practical applications in the defence and security industries may be dependent upon the properties of these perfluoroalkylated materials. Can measures be put in place to ensure European manufacturers can continue to manufacture, process, supply and dispose of these materials and items treated with them? For example, by issuing licences to specific end users and other third parties?

The dossier submitter and Committees will consider the need for derogations for particular uses. We encourage you to submit information about this issue through the consultation process. Once restricted under REACH, there is no separate licensing regime for specific uses under other regulatory frameworks.

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**11. Proposed in paragraph 5 (b) on photographic coatings applied to films:
Does this exemption only exempt the coatings, or also the coated films, from
the thresholds set in the restriction proposal?**

The exemption covers both the coatings and the coated films.