National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

Swedish Chemicals Agency

Norwegian Environment Agency

Ministry of Environment of Denmark
Environmental Protection Agency

Webinar: Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH

Questions and answers – Answers by the five national authorities to questions on the content of the proposed restriction

ECHA organised a webinar on 5 April 2023 on the proposed restriction of per- and polyfluoroalkyl substances (PFAS) under REACH. This document replies to questions raised during the webinar about the content of the proposed restriction. The replies have been drafted by experts from the five national authorities responsible for preparing the restriction proposal.

A separate document focuses on questions about the consultation, opinion making by ECHA's scientific committees and the REACH restriction process. These replies have been drafted by ECHA's experts. You can find that document here:
https://echa.europa.eu/documents/10162/21388210/230405_upfas_webinar_qa_en.pdf/7a22138a-7250-85a8-cf57-2817ec91f5ff

Editorial changes have been made to the questions to improve clarity and similar questions have been combined.

This document does not address generic restriction issues, or other aspects of REACH.

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Contents

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1. Scope

Question	#	Answer
Are substances that can be degraded by the environment (e.g. FK-5-1-12) exempted from the proposed scope?	1.1	According to the proposal, the indicated substance, dodecafluoro-2-methylpentan-3-one (FK-5-1-12), is in scope. The restriction dossier explains in section B.4.1.3.2 that the mentioned substance degrades to form trifluoroacetic acid (TFA) in the environment.
Trifluoroalkyl trimethoxysilanes hydrolyse quickly in contact with humidity forming (n+1,n+1,n+1-trifluoralkyl)silane-1,1,1-triol **The alkyl group may be: methyl-, ethyl-, propyl-, butyl-** **Does (n+1,n+1,n+1-trifluoralkyl)silane-1,1,1-triol also fall under proposal for a restriction of PFAS?**	1.2	The substances described contain at least one fully fluorinated methyl (CF3-) carbon atom (without any H/Cl/Br/I attached to it). They would therefore fall within the scope of the restriction proposal.
Would the proposed ban cover refrigerants like R-125 or R-142b?	1.3	According to the proposed substance scope, the refrigerant R-125 (pentafluoroethane, EC 206-557-8) is a PFAS and would hence be in scope of the restriction proposal. R-142b (1-Chloro-1,1-difluoroethane, EC 200-891-8) does not fulfil the proposed PFAS definition and, hence, would not be in scope of the restriction proposal.
Trifluoroacetic acid (TFA) is widely used in peptide synthesis, it has a different toxicological profile from other PFAS and can also be present naturally in the atmosphere. Will it also be restricted like other PFAS? Or will it have an exemption?	1.4	According to the definition of PFAS proposed by the Dossier Submitter, TFA is in scope of the proposed restriction. Regarding its presence in nature, see the relevant section in Annex B.1.3.1 of the Annex XV restriction report.
Is there any relation between the PFAS substances found in the proposal and that found in EPA Master List?	1.5	The EPA PFAS Master List is based on the US EPA PFAS definition, not the OECD (2021) PFAS definition. This list can only be used as a starting point to identify potential PFAS. Note that substances in scope are defined by the chemical definition provided in the Annex XV restriction report and there is no exhaustive list of numerical identifiers available.

Question	#	Answer
Have you considered using a similar categorization for PFAS as US EPA working definition? This working definition identifies chemicals with at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated.	1.6	The current scope definition is linked to the OECD (2021) PFAS definition and is considered the most appropriate scope for the universal PFAS restriction proposal.
Are allyl compounds such as 1,1-Difluoroethylene (CAS 75-38-7) or Chlorotrifluoroethylene (CAS 79-38-9) in scope of the proposed restriction?	1.7	According to the proposed substance scope, these two substances are not in scope, since a perfluorinated olefinic carbon atom (=CF2) or an aromatic ring bound directly to an F-atom (–CF=) do not fulfil the proposed PFAS definition alone (text from OECD, 2021). Consequently, olefins and aromatic substances would need additional fluoroalkyl elements to be regarded as PFAS (see section 1.1.1 of the Annex XV restriction report).
The scope of the proposed restriction excludes specific degradable substances. What criteria have been used to determine the substances in question are degradable (e.g. degradation speed)?	1.8	Relevant degradation data such as degradation pathways, kinetics or produced metabolites in relevant environmental conditions have been used. These can also be submitted in the consultation to further strengthen the scope or show that a further specific exclusion might be needed. ECHA's scientific committees can take this information into consideration. For reference, see Annex B.4.1.4 of the Annex XV restriction report.
How will you make sure that industry does not design other versions of PFAS in the future that are not in scope of the proposed restriction?	1.9	The Dossier Submitter assumes that there are limited options for industry to design other versions of PFAS because this restriction proposal is based on a scope definition (not a fixed list of PFAS), covering also future PFAS and, thus, avoiding regrettable substitution.
Who could help if I am not sure if a molecule is a PFAS according to your definition or not?	1.10	The Dossier Submitter recommends using chemical experts in solving these issues. A (chemical) consultant could also advise on these matters.

2. Proposed restriction text / Essential use

Question	#	Answer
Regarding the proposed derogation in paragraph 5s, do you have a more precise definition of "harsh conditions" perhaps in the form of a range of temperature or pressure	2.1	As mentioned in the explanatory note on page 11 of the Annex XV restriction report, the proposed derogation in paragraph 5s relates to the use of lubricants in industrial or professional settings for operations and equipment that require performance under harsh conditions (very high or low temperatures, very high or low pressure,

Question	#	Answer
where the use of PFAS as lubricant could be allowed?		chemical resistance, resistance to radiation, etc). During the development of the proposal, stakeholders have in multiple cases argued that lubricants containing PFAS used under harsh conditions cannot be replaced. A range of pressure, temperature and more is not defined at the moment, but could be considered later on in the process (e.g. by the committees or the European Commission).
Would EU companies be allowed to buy or import fluoropolymers?	2.2	According to the proposal, importing fluoropolymers would be allowed if the intended use of the imported fluoropolymer is proposed to be derogated. Import of fluoropolymers for placing on the market and use in non-derogated uses would not be allowed.
According to the proposal, all products in the retail chain must meet the PFAS restriction after the relevant transition period. Would this also apply to products that were on the market before the PFAS restriction entered into force? **According to the proposal, could mixtures and articles containing PFAS substances be used even after entry into force and the relevant transitional periods?**	2.3	Substances and products placed on the market before entry into force and that are in use (and are not being placed on the market again) can be used after the restriction enters into force. For example, operational equipment containing parts with PFAS do not have to be discarded. However, if products are being placed on the market again (e.g. second-hand articles), or when it comes to spare parts or refilling of systems for which the products are being supplied after entry into force, those have to meet the proposed restriction requirements.
Could you provide us with some additional information on how to interpret paragraph 5a? **Would imported fluoropolymers also have to comply with the ban of PFAS polymerisation aids as set out in paragraph 5a?**	2.4	As REACH is only applicable in the EU/EEA, enforcement activities cannot take place outside the EU/EEA. Therefore, paragraph 5a in the proposed restriction text is only applicable to the production of fluoropolymers in the EU. However, it needs to be noted that, according to the proposal, PFAS-based polymerisation aids cannot be present in imported fluoropolymers in concentrations exceeding 25 ppb for the individual substances after the transition periods mentioned in paragraph 5a. This limit may make it hard for non-EU manufacturers to produce fluoropolymers for the EU market using PFAS-based polymerisation aids.
If there are multiple proposed derogations that would be applicable for certain applications (e.g. processing aids/petroleum mining), what would be the prevalent/limiting derogation?	2.5	It is possible that a certain application is covered by multiple proposed derogations. In that case all derogations are currently proposed to apply in parallel. There is currently no prevalence proposed.

Question	#	Answer
How can we understand the scope of the different applications that are mentioned in the report (especially from derogation point of view)? There are currently no definitions provided on the application, therefore it is not always clear for which application a certain derogation is proposed to apply or not.	2.6	The explanatory notes (on pages 8 to 12 of the Annex XV restriction report) provide some additional information on the scope of specific derogations. The respective sections in Annex E might also help you to understand the applications for which information has already been available and taken into account when determining derogations. If you still consider the scope of certain derogations unclear after consulting the explanatory notes and Annex E, kindly highlight this in the consultation so that relevant amendments can be considered. Please provide as much detail as possible regarding the concerned application.
Paragraph 8iii foresees that manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers that make use of derogations provide details on the conditions of use and safe disposal. What is this exactly?	2.7	The proposed paragraph 8iii refers to conditions of use which in turn refers to how the substance or mixture is handled and the risk management measures in place to avoid emissions. Information on safe disposal refers to the waste stage. It is proposed that manufacturers, importers and downstream users should demonstrate that mixtures or articles containing fluoropolymers or perfluoropolyethers are appropriately disposed of.
Would the concentration limits for constituents, mixtures and articles in paragraphs 2i, 2ii and 2iii in the proposed restriction need to be met at the same time?	2.8	According to the proposal, all three concentration limits will need to be met for all relevant products, unless derogated. Hence, if a mixture or product exceeds one of the concentration limits, the mixture/product is in breach with the regulation, as currently proposed.
What is the status of on-site isolated intermediates under the proposed restriction?	2.9	On-site isolated intermediates are generally exempted from REACH restrictions according to Article 68(1) of the REACH Regulation.
Are portable fire extinguishers also covered by the restriction proposal?	2.10	Portable fire extinguishers do not fall under the scope of this restriction according to paragraph 9 of the proposed restriction entry. A separate restriction proposal on PFAS in firefighting foams was submitted by ECHA in 2022. See also question 4.5 in the webinar Q&A document containing responses from ECHA.
The restriction proposal includes a derogation for "calibration of measurement instruments and as analytical reference materials" in paragraph 5t. Is this an additional remark to the generic exemption for R&D of Article 67 of REACH Regulation (including QC uses), or the general R&D exemption will not apply?	2.11	Paragraph 5t is proposed to be complementary to the generic exemption for scientific research and development set out in Article 67(1) of the REACH Regulation, which continues to apply. Derogation 5t focuses on the use of PFAS for analytical testing required to enable effective enforcement of the proposed restriction. Some additional information on this derogation is provided as part of the explanatory notes on page11 of the Annex XV restriction report.

Question	#	Answer
With regard to the 18-month period after entry into force, would this mean all PFAS-containing materials have to be substituted by non-PFAS materials after 18 months? For instance, in production equipment. Or will it be sufficient to change these PFAS containing parts when the reach end of life?	2.12	As stated in paragraph 2, the proposed restriction applies to the placing on the market in another substances (as a constituent), a mixture or in an article, while paragraph 1 prohibits the manufacture, use and placing on the market as a substance on its own. As such, articles in use by consumers, professional or industrial users, including articles in production equipment, remain unaffected by the proposed restriction and can continued to be used until the end of their service life. However, the placing on the market of spare parts containing PFAS (and consequently its use) is not allowed based on the current proposal. Similarly, offering existing production equipment on the second-hand market is prohibited as it constitutes, by definition, a form of placing on the market (which is in Article 3(12) of the REACH Regulation defined as the action of "supplying or making available, whether in return for payment or free of charge, to a third party").
Would products that contain PFAS substances (e.g. residual raw materials, by-products, impurities) be subject to the proposed PFAS restriction (e.g. especially as regards the threshold values)?	2.13	Yes, the concentration limits in paragraph 2 of the proposed restriction entry text would apply also to PFAS present in other (non-PFAS) substances, mixtures or articles even if it is not intended (e.g. residues).
Please explain how the reporting is planned. Would the information be reported to ECHA or to Member States? Is a Substance Data-Sheet communication planned? How to avoid double reporting?	2.14	The Dossier Submitter's proposal currently foresees that the information is reported to ECHA. To prevent double reporting and high administrative burden, the obligation should not apply to downstream users but to manufacturers, distributors and formulators. See page 12 of the Annex XV restriction report.
As far as I understood, the limit of PFAS content also refers to recycled products. Considering the recycling of food packaging (PFAS-PPA containing), does this mean that the recycling of materials produced before the proposed ban enters into force and the placing on the market of post-consumer recycled products will be limited and restricted?	2.15	Yes, the concentration limits stated in paragraph 2 of the proposed restriction apply to articles regardless of whether they are made from virgin or recycled materials. During the call for evidence and second stakeholder consultation, no specific information from stakeholders was obtained that supported a derogation. As such, the placing on the market of post-consumer recycled products would be restricted based on the current proposal if the stated concentration limits cannot be met. There is, however, strong awareness about a potential for widespread implications of the proposed restriction on the recycling industry. To increase the evidence base on this aspect, *specific information request 4* of the consultation specifically asks for information on the impacts on recycling industry, e.g. the impacts that the concentration limits would have on the technical and economic feasibility of

Question	#	Answer
		recycling processes. Any information will be carefully scrutinised with a view of determining whether adaptions should be made to the proposed restriction.
Under REACH, substances < 1 tonne per year do not require registration. Would PFAS substances used in < 1 tonne/year quantities be exempted from the proposed restriction?	2.16	No, the mentioned tonnage bands are linked to registration not to restriction. In other words, the proposed restriction would apply regardless of the tonnage annually placed on the market.
The Dossier Submitter has marked some of the proposed derogations for reconsideration. Is it foreseen that the length of these derogations is reduced or increased?	2.17	According to the proposal, the potential derogations marked for reconsideration can be adjusted either by reducing or increasing the proposed duration of the derogation periods. All derogations – proposed and potential for reconsideration – and their derogation periods are under scientific scrutiny by both the Dossier Submitter and ECHA's scientific committees (RAC and SEAC). Derogations and transition times may be changed based on incoming information during the consultation. Additionally, the proposed derogation may also be removed or rephrased depending on the input from the consultation. The committees will also form an opinion on the proposed length of derogations including by taking into account information submitted.
Why has the essential use concept not been taken into account in the universal PFAS restriction proposal?	2.18	Essential use is not a concept within REACH or other EU legislation. As currently no criteria about essential use exist, the Dossier Submitter decided to not use the essential use concept when drafting the restriction proposal.

3. Derogations

Question	#	Answer
Why are uses, e.g. industrial uses of solvents or catalysts, without environmental emissions restricted? Why are these uses not exempted with additional requirements like reporting and demonstrating containment equivalent to strictly controlled conditions?	3.1	The main criteria for the Dossier Submitter to propose a time-limited derogation relate to alternatives, e.g. if technically and economically feasible alternatives are not available at all or they are not available in sufficient quantities. For details on the criteria, see section 2.3.1 of the Annex XV restriction report. The trade-offs associated with derogations, i.e. reduced costs in exchange for continued emissions are described in Table 13. If you consider that restricting the use of PFAS for specific applications is disproportionate, i.e. costs are too high in comparison to avoided emissions, submit relevant, ideally quantitative, information in the consultation. This information should include data on emissions and costs associated with relevant uses to enable ECHA's scientific committees to assess whether the current proposal

Question	#	Answer
		is proportionate or whether additional derogations should be added. *Specific information request 6* in the consultation provides a good indication of the information to consider.
Will there be any exemptions for spare parts for long lasting products (repaired as produced)?	3.2	Spare parts placed on the market 18 months after the restriction enters into force are proposed to fall under the restriction and are not proposed to have a derogation, unless specifically mentioned. The same goes for products that are made from recovered or recycled materials (from waste). These fall under the restriction as well. If an additional derogation is deemed necessary, submit relevant information in the consultation. *Specific information request 6* in the consultation provides a good overview of the information that is of relevance.
If my use is not subject to a specific derogation, would I have to comply with the restriction immediately upon entry into force?	3.3	The Dossier Submitter proposes a general transition period of 18 months after entry into force which is normal for restrictions. The consultation that started on 22 March 2023 offers the possibility to also comment on the different transition periods that are proposed in the Annex XV restriction report. However, any claim for a longer transition period needs to be supported and justified with additional evidence that can be used on an EU scale.
Why does it seem that polytetrafluoroethylene (PTFE) will be banned in 2025 for cookware and not for industrial bakeware? What is the difference between the applications?	3.4	Industrial bakeware includes a broad category of equipment such as ovens, stoves etc. For such equipment operating conditions are likely to be more demanding (e.g. continued use throughout the day). It will be (economically) harder to replace industrial bakeware than consumers cookware, such as pots and pans.
Will it be possible to apply for authorisation for some specific uses?	3.5	No, there is no possibility to apply for authorisation. This is the REACH restrictions process. In this process, however, there is the possibility to submit a request for derogation. Please see also question 2.9 in the webinar Q&A document containing responses from ECHA on this topic for further information regarding the type of information you should submit to underpin this type of request.
For uses of PFAS not assessed in the Annex XV restriction report, is it preferable to make derogation requests for as narrow a scope as possible?	3.6	It is the intention of the Dossier Submitter to propose derogations as specific as possible but sufficiently generic to cover as many similar applications as possible. Please see question 2.9 in the webinar Q&A document containing responses from ECHA on this topic for further information regarding the type of information you should submit to underpin this type of request.

Question	#	Answer
Could you explicitly give us the reference in the proposal to the five time-unlimited derogations?	3.7	The five time-unlimited derogations proposed by the Dossier Submitter can be found in paragraphs 4, 5j and 5t of the proposed restriction text.
Information that was provided on alternatives has been summarised in Annex E to the report. For some uses there is evidence that alternatives are not available. Why is no derogation proposed?	3.8	In this case, information was not sufficient for the Dossier Submitter to develop a proposed derogation. Further relevant information should be provided in the consultation to enable the Dossier Submitter and the committees to assess, if a derogation should be proposed.
Under the PFAS in firefighting foams process, the proposed transition period is different depending on the type of industry. No such distinction is made under the current universal PFAS restriction proposal. Will a similar approach be introduced as for PFAS in firefighting foams, to allow certain industries enough time for transition? **Also, some uses are proposed to be derogated for 5 and others for 12 years. How was the length determined?**	3.9	The approach taken by the Dossier Submitter is based on the use of default derogation periods of 5 and 12 years (in addition to the general transition period of 18 months) based on a clear set of criteria set out in section 2.3.1 of the Annex XV restriction report. As stated in section 2.3.1, the Dossier Submitter considers these time periods normally sufficient for industry to take benefit from technical progress and to carry out R&D activities to find and deploy technically and economically feasible alternatives. Challenges with respect to completing substitution in the available timeframe are also taken into account in this context. A 5-year derogation is proposed for uses where the Dossier Submitter found that: (i) alternatives to PFAS do not exist on the market at the assumed date of entry into force but where possible alternatives have already been identified despite needing further development; (ii) known alternatives are not available in sufficient quantities when the proposed restriction enters into force; or (iii) known alternatives cannot be implemented before the transition period ends. A 12-year derogation is proposed if the Dossier Submitter found that: (i) there is sufficiently strong evidence showing that no alternatives have been identified so far or (ii) there is sufficiently strong evidence that certification of PFAS-free alternatives cannot be achieved within a five-year transition period.

Question	#	Answer
		Stakeholders are encouraged to comment on the proposed derogation periods and are advised to submit well-substantiated evidence in the consultation if they consider the proposed timeframe to be too short for their sector to complete the substitution process (see, for example, *specific information request 6f* in the consultation). Note that this information should be representative for affected companies in the relevant industry sector, i.e. information that some companies will struggle to complete substitution in the given timeframe is not sufficient for the Dossier Submitter to propose a change to the derogation if the majority of affected companies deems it feasible to complete substitution in the given timeframe. The proposed transition period and derogations will be scrutinised by ECHA's committees who may suggest further changes based on their evaluation of the restriction proposal and information submitted in the consultation.
In our field (organic electronics), only small quantities of PFAS are processed and the devices we manufacture are encapsulated and usually recycled at the end of life. Is recyclability an argument in favour of derogation?	3.10	Impacts of the proposed restriction on recycling industry and feasibility of recycling were considered by the Dossier Submitter to ensure that the proposed restriction would be proportionate and would not lead to negative impacts to society that would be disproportionate in comparison to the benefits, approximated through the volume of avoided emissions of PFAS. Specific information on this aspect is requested in *specific information request 4* of the consultation. Depending on the information provided on the impacts on the recycling industry, derogations for recycled products might be proposed by the Dossier Submitter or ECHA's committees.
What information is needed to prove that alternatives are not available for a sector, use or application? Why is "No alternatives available" not sufficient?	3.11	Where information is assessed by the Dossier Submitter to be inconclusive, conflicting evidence could not be explained and reconciled. For example, information from some stakeholders during the drafting of the proposal might have suggested that alternatives exists while others suggested that they do not. This might be due to a difference in stakeholders' knowledge – some can be more advanced in R&D than others – or a result of different functionality requirements in the application, or even referring to different applications. Where information was assessed to be inconclusive, there was not enough information for the Dossier Submitter to understand what the reasons for these differing conclusions were. To allow a meaningful evaluation of the situation and for the Dossier Submitter and the committees to judge whether your conclusion that alternatives do not exist are representative for the entire sector, you are encouraged to be specific when describing the application and, for example, explain why alternatives used for other applications in your sector are not feasible. Joint submissions at sector level by

Question	#	Answer
		industry associations are also encouraged. Submissions at company-level are less useful as it is difficult for the Dossier Submitter and the committees to judge how representative the information is for other companies. In short, consult the Information Note for the consultation describing the information requirements, identify where the main gaps for your sector are and collaborate with your sector associations to coordinate your efforts and submit relevant information on the applications for which you deem substitution is difficult at sector level.

4. Overlap with existing/other restrictions/regulations

Question	#	Answer
The F-gas regulation also aims at reducing the use of certain PFAS. Why is there no derogation for F-gases?	4.1	It is the Dossier Submitter's understanding that the F-gas regulation has a different objective than the REACH Regulation. According to the Dossier Submitter's assessment, it aims at reducing global warming, not at ensuring the safe use of chemicals. Therefore, the Dossier Submitter assumes that it cannot serve as a basis for a derogation from the proposed restriction. Note that the F-gas Regulation would apply in addition to the universal PFAS restriction proposal. Thus, both regulations would need to be adhered to.
How have sector-specific regulations, e.g. the Regulation on Food Contact Materials been taken into account?	4.2	Sector-specific regulations have been considered by the Dossier Submitter during the preparation of the restriction proposal and when determining whether or not to propose derogations based on the criteria described in section 2.3.1 of the Annex XV restriction report. In most cases the Dossier Submitter did not see the possibility to propose derogations based on the existence of sector-specific regulations as these do not specifically address the concerns associated with PFAS. An exception is the proposed derogation for active substances in biocidal, plant protection and medicinal products (see paragraph 4 of the proposed restriction text). For these, the Dossier Submitter considers that the concerns related to PFAS can be better addressed in the relevant sector-specific regulations. To support this, the Dossier Submitter suggests combining the proposed derogation with a reporting requirement.
Has the Dossier Submitter looked at whether other countries or regions are currently also	4.3	There are PFAS bans in several US states. Also, in other countries like China, Thailand, Australia, New Zealand and Canada, (specific) PFAS are regulated more

Question	#	Answer
considering PFAS bans?		and more. See also the Annex XV restriction report page 66-67.

5. Persistence

Question	#	Answer
Why are fluoropolymers - even those with US Food and Drug Administration or similar approval - included in the proposal?	5.1	This is an EU-wide restriction proposal, not an approval system. The Dossier Submitter considers the risk arising from fluoropolymers based on scientific evidence enough to include these in this restriction proposal.
What is the specific reason why the proposal is so wide and includes everything that falls under the PFAS definition, even fluoropolymers that are considered polymers of low concern?	5.2	The proposed substance scope is broad to avoid regrettable substitution. Moreover, fluoropolymers in the EU are not considered polymers of low concern (PLC) but cause concern predominantly, but not exclusively, in the manufacture and the end-of-life stage.
Which temperature is considered sufficient to ensure complete destruction of PFAS during incineration?	5.3	The studies available to the Dossier Submitter during the development of the proposal are not conclusive on this yet. It also should be noted that laboratory scale experiments may have optimal conditions whereas operational conditions of waste incineration plants may not always have these conditions.
Polytetrafluoroethylene (PTFE) materials are widely used in e.g. the food and pharma industries in e.g. gaskets, valves and coatings. It is non-toxic, highly chemical resistant and not likely to migrate into the products or outside environment. Is there any scientific justification for including PTFE in the restriction?	5.4	According to the substance scope proposed by the Dossier Submitter, PTFE is in scope of the proposed restriction. As indicated in the Annex XV restriction report, the concern is mostly – but not solely – at the manufacturing and end of life stage.
Does the proposal mean to restrict substances purely on the grounds of the persistency, regardless of whether they are toxic or not?	5.5	The substances which are proposed to be restricted share the concern of being very persistent. Since the group of substances is large and diverse, many other supporting concerns are taken into account as well.
Does the restriction apply to the "substance" or also to "polymers" (polymers are generally considered stable)?	5.6	Polymers are also substances and are in scope of the restriction proposal.

6. Fluoropolymers

Question	#	Answer
The proposed derogation for polymerisation aids in the production of polymeric PFAS does not take into account the qualification time of downstream uses. How will this be considered?	6.1	In this case, evidence should be submitted in the consultation on the time needed for qualification and why fluoropolymers are at all needed in the specific applications. This information can then be taken into consideration by the Dossier Submitter and ECHA's committees.
If monomeric PFAS are not used, can polytetrafluoroethylene (PTFE) or other polymeric PFAS be manufactured and marketed in the EU?	6.2	PTFE is a PFAS and is covered by the restriction proposal and can only be manufactured, placed on the market and used for the proposed derogated applications. The same applies for other polymeric PFAS.
All polyvinylidene fluoride (PVDF) polymers appear to be in scope. Is this correct?	6.3	Yes, PVDF polymers are in the substance scope.

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

Question	#	Answer
Table 8 of the Annex XV restriction report introduces a category called "Technical textiles" including outdoor technical and medical textiles, as well as high-performance membranes. Is this the category into which glass cloth coated with polytetrafluoroethylene (PTFE) is expected to fall (used in wear parts not as an architectural membrane)?	7.1	PTFE-coated glass cloth is woven fabric, that belongs to TULAC and the sub-sector "Technical textiles". They are used in specific reinforcing, electrical and thermal applications. Some examples are releasing tape on heat sealing bars and wires, heat curtains, release fabric for hot plate welding, chute and hopper linings, baking tray lining and sewn sleeves.
Are derogations for personal protective equipment (PPE) like climbing ropes planned?	7.2	Time-limited derogations of 13.5 years after entry into force are proposed for textiles used in PPE, which are intended to protect users against risks as specified in Regulation (EU) 2016/425 (PPE), Annex I, Risk Category III (a) and (c) and textiles used in PPE in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m). Climbing rope access equipment is included in Risk Category III (g) "fall from a height", so it must be CE marked for compliance with Regulation (EU) 2016/425.

Question	#	Answer
		The time-limited derogation of 13.5 years is intended to cover only professional firefighting activities for Risk Category III (g) "fall from a height".
In the published annexes of the Annex XV restriction report, there are acknowledgements of the need for a derogation for military uniforms. However, I cannot see this acknowledgement reflected in the actual restriction proposal since military uniforms are not included in the Regulation (EU) 2016/425. Please clarify.	7.3	REACH includes a provision for a defence exemption under Article 2(3): "Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence."

8. Food contact materials and packaging

Question	#	Answer
Could you explain why car wrapping foil is listed under food contact materials in Annex A.3.4?	8.1	The use sector is defined as food contact materials and packaging. Car wrapping foil is considered a generic packaging material and is therefore covered in Annex A.3.4.
Why are food contact materials exempted in contrast to, for example, regulation in California?	8.2	The Dossier Submitter does not propose a derogation for food contact materials as a whole. The only proposed derogation is for fluoropolymers used in food contact materials for the purpose of industrial and professional food and feed production (as mentioned in paragraph 6a of the proposed restriction text and the accompanying explanatory note).
Is it correct that there is no derogation proposed for consumer cookware and the full ban is proposed to take effect after the transition period of 18 months?	8.3	Yes, this is correct.

9. Fluorinated gases

Question	#	Answer
Given that global warming is the greatest environmental challenge we face, how does it	9.1	The F-gas Regulation does not address the environmental concern that persistent degradation products are formed when PFAS-based fluorinated gases are used,

Question	#	Answer
make sense to include HFC-1234ze in the restriction proposal given it is expected to be the preferred alternative metered dose inhaler (MDI) propellant for the implementation of the F-gas regulation objectives in the long term?		while the PFAS restriction proposal takes this into account. When non-PFAS alternatives to the gas mentioned in the question are available, both global warming and persistent degradation products can be addressed.
Are refrigerants such as tetrafluoropropene (R-1234yf) considered directly as PFAS or just the decomposition products such as trifluoroactetic acid? In case just TFA is affected would this lead to a ban of tetrafluoropropene even though a circular use with small percentage of leakage is possible?	9.2	According to the proposed substance scope, both R-1234yf (2,3,3,3-Tetrafluoropropene, EC 468-710-7) and TFA (trifluoroacetic acid, EC 200-929-3) are PFAS. R-1234yf is covered by the proposal and its use is proposed to be restricted, meaning that it can only be used for the proposed derogated applications.
If the ban does come into effect, what alternative refrigerants are being proposed for the future (hydrocarbons like methane, CO_2, propane, ammonia or hydrocarbon blends or some other refrigerants)?	9.3	The Dossier Submitter's assessment showed that CO_2, hydrocarbons, and ammonia, also called natural refrigerants, are available for many of the applications as alternatives. In addition, other not-in-kind alternatives are available for some uses. The Dossier Submitter's assessment of this can be found in Annex E.2.8.2 of the Annex XV restriction report.
We produce foams with hydrofluorocarbons (HFCs) with global warming potential (GWP) > 150. We benefit from an exemption under the F-gas Regulation (Annex III, point 16, national safety). How could such an exemption be taken into account in this restriction proposal? Can it be included in the list of proposed derogations?	9.4	There is no proposed derogation for foams under national safety considerations. However, a potential derogation for foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after entry into force (see paragraph 5w of the proposed restriction text) has been marked for reconsideration after the consultation as the information currently available to the Dossier Submitter is not sufficiently strong. Please submit additional information about this application in the consultation.
F-gases seem to make up more than 50% of the emissions of PFAS. Could you please explain the sources of the emissions of PFAS and how they were calculated?	9.5	Emissions of PFAS from the different applications, including the various uses of fluorinated gases, are described and estimated in Annex B of the Annex XV restriction report. Emissions of F-gases are reported to the UN Framework Convention on Climate Change and this data is the basis for the assessments in the restriction proposal.
Have you considered that if refrigerants are banned in Europe, many companies will move to non-EU countries?	9.6	The Dossier Submitter has considered the available information also in this perspective. However, if you are of the opinion that this information has not been taken sufficiently into account, you are welcome to submit relevant information in

Question	#	Answer
		the consultation.
Is there a derogation for refrigerant R32 for heat pump installation maintenance?	9.7	R32 is not covered by the proposed scope definition and would, therefore, not be affected by the restriction proposal.
Refrigeration machines, regardless of whether fluorinated gases are used or not, require PFAS-containing sealants, gaskets and fluids to operate. There are no PFAS-free alternatives for sealants, gaskets and fluids. How has this been considered in the restriction proposal?	9.8	Relevant and substantiated information about the use of PFAS-based sealants, gaskets, etc in relevant equipment should be submitted in the consultation so the Dossier Submitter and ECHA's committees can evaluate whether a derogation would be justified.
Will heat pumps be affected by the proposed restriction?	9.9	Yes, according to the restriction proposal, the use of fluorinated gases covered by the PFAS scope definition will in general not be allowed in heat pumps. However, derogations have been proposed for maintenance and refilling of existing HVACR equipment put on the market before [18 months after entry into force] and for which no drop-in alternative exist until 13.5 years after entry into force (see paragraph 5i of the proposed restriction text) and refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives (see paragraph 5j of the proposed restriction text).
How about refrigerants in heat pumps in district heating and cooling? After entry into force, do we have to shut down the heat pumps with PFAS refrigerants?	9.10	District heating and cooling is covered by the restriction proposal and the use of PFAS refrigerants should be phased out. There is no derogation proposed for this use, as alternatives are considered to be generally available. If this does not apply to certain specific applications, information needs to be submitted in the consultation. The proposed derogation for maintenance and refilling of existing HVACR equipment put on the market before [18 months after entry into force] and for which no drop-in alternative exist until 13.5 years after entry into force (see paragraph 5i of the proposed restriction text) applies.
Is the following blend R404A (consisting of R-125/R143a/R134a) considered "b. a mixture" according to paragraph 2 (column 2)? Or is the blend R404A considered "substances on their own" according to paragraph 1 (column 2)?	9.11	R404A is a mixture of R-125 (pentafluoroethane, EC 206-557-8), R-134a (1,1,1,2-Tetrafluoroethane: Norflurane, EC 212-377-0) and R-143a (1,1,1-trifluoroethane, EC 206-996-5). However, regardless of being considered as a blend or not, all three substances fulfil the proposed substance scope definition and would be in the scope of the proposed restriction. Consequently, R404A is also in scope.
F-gases are included because trifluoroacetic acid (TFA) is a breakdown product. TFA is	9.12	The reasoning for including F-gases in the scope of the proposed restriction are described in Annex B.1.3.1. The Dossier Submitter assessed that TFA in fresh water

Question	#	Answer
naturally abundant in the oceans (100s of millions of tonnes) and persistent but toxicologically harmless. The revised EU F-gas Regulation strengthens the control of emissions of F-gases. What are the environmental gains that this restriction on F-gases will bring?		is not naturally abundant, but solely found there because of the manufacture of PFAS.

10. Medical devices

Question	#	Answer
Does the ban apply to metered dose inhalers (MDIs)? MDIs treat serious respiratory illnesses. The medical propellants used in MDIs underwent extensive safety testing and are approved by health regulators globally. What is the basis for banning these essential propellants so quickly? How will shortages be avoided? Industry is developing propellants with low global warming potential for MDIs. This requires long development and approval timelines. If R-1234ze is banned, these efforts will be jeopardized and we will be left with only one alternative with risk of supply security.	10.1	The proposed restriction applies to propellants in MDIs. HFC-1234ze ((1E)-1,3,3,3-tetrafluoroprop-1-ene, EC 471-480-0) is in scope of the proposed restriction, as are the currently used propellants HFC-134a (1,1,1,2-Tetrafluoroethane: Norflurane, EC 212-377-0) and HFC-227ea (1,1,1,2,3,3,3-Heptafluoropropane, EC 207-079-2). The justifications for including these substances are the same as for all substances covered by the proposal (see section 1.1.2 of the Annex XV restriction report). For propellants in MDIs, HFC-152a has been identified as a "drop-in substitute" that is not in scope. Uncertainties regarding costs and implementation period for the transition to HFC-152a (1,1-Difluoroethane, EC 200-866-1) are highlighted in Annex E.2.9. Any substantiated information that can reduce these uncertainties (or other relevant aspects, such as security of supply considerations) would be appreciated in the consultation. If relevant information provided in the consultation demonstrates that an extended transition period (or other adjustment to the proposed restriction) is warranted, then the Dossier Submitter will consider such an adjustment.
Paragraph 6b of the proposed restriction text proposes a derogation for implantable medical devices (not including meshes, wound treatment products, tubes and catheters). What is meant by the term meshes? All surgical meshes (e.g. hernia, prolapse, incontinence) or only the hernia meshes mentioned under paragraph 6h?	10.2	The term "meshes" in paragraph 6b refers to all implantable meshes. The stakeholder consultations conducted before submitting the restriction proposal provided little or no information on surgical meshes (other than hernia meshes). A derogation for these surgical meshes can be only considered if relevant and substantiated information justified by risk or socio-economic arguments is provided in the consultation. For further details on the type of information required, please refer to the Information Note (particularly *specific information request 6*) and the Consultation Guidance.

Question	#	Answer
Does the proposed restriction apply to articles covered by the Medical Devices Regulation (2017/745/EU)? Some PFAS applications in medical devices (such as medical guidewires, applications in dentistry and eye surgery, and emerging applications in preclinical stage) are not mentioned in the Annex XV restriction report. Are these uses covered by the proposed restriction?	10.3	Medical devices are covered by the proposed restriction. For some applications of PFAS in medical devices time-limited derogations are either proposed or marked for reconsideration (see paragraphs 5 and 6 of the proposed restriction text). Derogations for other applications of PFAS in medical devices can be considered by the Dossier Submitter if relevant and substantiated information justified by risk or socio-economic arguments is provided in the consultation. For further details on the type of information required, please refer to the Information Note (particularly *specific information request 6*) and the Consultation Guidance.
The medical device sector comprises 33 000 small and medium-sized enterprises with little or no experience of restrictions. Also, presumably umbrella groups don't have time to compile socio-economic data for each of the hundreds/thousands of unique device types containing PFAS. How will device users get the derogations they need?	10.4	If you consider that a derogation is justified, then you must submit relevant information and supporting evidence in the consultation. It is important for the Dossier Submitter to receive information that is representative for the whole sector or use and, as such, joint submissions of relevant and substantiated information during the consultation, for example through the relevant sector associations, are strongly encouraged.
Time-limited derogations are being proposed to promote development of alternatives, including for most medical devices. Is it not more likely to lead to a permanent drop in performance, particularly as fluorinated chemicals are unique, and the safety and wellbeing of users will suffer?	10.5	For medical device applications where the Dossier Submitter has concluded that the evidence provided during stakeholder consultations is sufficiently strong that technically and economically feasible alternatives are not generally available, derogations have been proposed (see Annex E.2.9.2). Derogations for other applications of PFAS in medical devices can be considered by the Dossier Submitter only if relevant and substantiated information concerning them is provided in the consultation. For further details on the type of information required, please refer to the Information Note (particularly *specific information request 6*) and the Consultation Guidance.
The use of PFAS in medical devices and environmental releases seem by far overestimated due to the fact that F-gases are considered medical devices. The Annex XV restriction report describes on page 59 that the presented examples are not medical devices. Consequently, shouldn't these quantities be	10.6	F-gases are used in medical devices. One example is as propellants in metered dose inhalers (MDIs). The reference to page 59 of the Annex XV restriction report seems to be a misunderstanding. On page 59, estimated growth rates for PFAS in some medical uses are mentioned. In the text it is noted that these specific uses (anaesthetics, contrast media, pharmaceuticals) are not medical devices by definition, but the reported growth rate estimates are still used as proxies for growth rates for use of PFAS in medical devices, for lack of better data. Tonnage

Question	#	Answer
removed from that use?		estimates for medical devices (in Annex A.3.10) and emission data (Annex B.9.10) do not include anaesthetics, contrast media or pharmaceuticals. If other relevant market growth rate estimates for PFAS applications in medical devices are available, these should be submitted during the consultation.
What about pharmaceutical packaging (for example packaging for tablets) as well as packaging for inhalers, operation plates, injections and so on? These products are in the Annex XV restriction report not covered within the section on medical devices. So, we can assume that these applications would be banned 18 months after entry into force?	10.7	Some applications of PFAS in packaging of pharmaceuticals and medical devices are marked in the proposal as potential derogations for reconsideration. See paragraphs 6l-n of the proposed restriction text. For these applications further information is required for derogations to be considered by the Dossier Submitter. See Information Note (particularly *specific information request 7*) and the Consultation Guidance for more details. For other applications in medical packaging, no derogations are proposed, and a ban is proposed to apply 18 months after entry into force. Derogations for these applications can be considered by the Dossier Submitter if relevant and substantiated information concerning them is provided in the consultation. For further details on the type of information required, please refer to the Information Note (particularly *specific information request 6*) and the Consultation Guidance.

11. Transport

Question	#	Answer
Related to proposed potential derogation in paragraph 6o of the proposed restriction text, please clarify what is included in transport. Are applications such as e.g. railway, tractors, aircraft (planes), aerospace (space shuttles) proposed to be potentially derogated as well? How is "use" defined in relation to the above potential derogation? Can a plane with fluoropolymer O-rings land in the EU – is that considered a use?	11.1	Transport covers any kind of transport vehicle. The transportation sector encompasses the following sub-sectors: automotive, maritime, aviation, and railway. See also Annex A.3.11.1 of the Annex XV restriction report. This also includes military transport. The term "use" is defined in REACH Article 3(24). It means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. So, the Dossier Submitter does not consider landing a plane with parts made of fluoropolymers a use of PFAS. However, the use of fluoropolymer articles in the production of the plane in the EU would be covered by the proposed restriction.
Are PFAS materials used in the manufacturing of vehicles, such as torch tips, covered under	11.2	If the torch tips are incorporated in the vehicle and necessary for its proper functioning, materials used for manufacturing torch tips is intended to be covered by

Question	#	Answer
the proposed potential derogation in paragraph 6o of the proposed restriction text? Are sealings, tires and general rubber goods covered?		the proposed potential derogation. If the torch tips are used in equipment that is used to produce articles that will be incorporated in vehicles, they are, however, not intended to fall under the proposed potential derogation. Yes, sealings, tires and general rubber goods are intended to be covered under the proposed potential derogation listed in paragraph 6o.
Would the use of fluoropolymers be prohibited in the automotive industry, if the restriction proposal were to be implemented?	11.3	Yes, unless it affects the proper functioning related to the safety of transport vehicles and the safety of operators, passengers or goods (see paragraph 6o in the proposed restriction text). Note, however, that this derogation is currently only proposed as potential derogation for further consideration, i.e. more information is needed for the Dossier Submitter to actually be able to propose this derogation. If you have relevant and substantiated information, kindly send it in the consultation.
Can you explain the term "proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods"?	11.4	In the broadest sense this term covers the regular conveyance of passengers, goods, animals etc as well as the transport vehicle itself without malfunctions, unusual incidents or even accidents. The intention is to cover applications of PFAS that are needed for a transportation vehicle to provide its function (i.e. move passengers or goods from one place to another) and to cover applications that are needed for the safety of transported passengers or goods. This includes, for example, all parts of the propulsion-, steering- or brake-system (needed to move a vehicle from one place to another) but also airbags, anti-lock braking system (ABS), distance sensors, life rafts, etc (needed for the safety of transported goods or passengers).

12. Electronics and semiconductors

Question	#	Answer
In Table 2 of the restriction report, there is a category for electronics and semiconductors, but in paragraph 5ee of the proposed restriction text only the term "semiconductor" is used. There are no explanatory notes for paragraph 5ee. Does paragraph 5ee only apply to semiconductors or also other electronics?	12.1	The proposed potential derogation 5ee is intended to only apply to semiconductors, not other electronics.

Question	#	Answer
How would this restriction be applied to complex articles like vehicles or electronics (such as smartphones) that use PFAS-containing semiconductors? Would it apply to each disassembled article/part?	12.2	A complex article like a phone or a vehicle consists of numerous individual articles. The limit values in the restriction proposal are intended to apply to the individual articles.
Why are some uses listed and included with a derogation, while others are not, e.g. polymer electrolyte membrane (PEM) fuel cells vs PEM electrolyser? The functionality is very similar, but only one is proposed to be derogated.	12.3	Derogations are considered justified by the Dossier Submitter if evidence on the non-availability of alternatives is conclusive. For PEM fuel cells, evidence has been provided indicating that no transition to alternatives can be achieved within 18 months, but alternatives are available making it possible within a longer time period. Similar evidence has not been provided for PEM electrolysers. So, even though a similar technology is used, the Dossier Submitter considers that insufficient evidence of alternatives and transition time have been submitted. Stakeholders using this technology have to assess the availability of alternatives as well as time for industry to adopt the new alternatives. It is not sufficient to indicate that no alternatives are available or that it will not be possible within 10 years. The data should demonstrate that potential alternatives are currently not able to provide the required functionalities (properties) and it needs to be sufficiently clear what would be the consequences of using inferior alternatives. Additionally, a substitution plan or detailed outlook on intended R&D efforts would be helpful. Such information must be submitted in the consultation.
Some alternatives have been listed while others are not, e.g. for front sheets of solar panels. Why is this the case?	12.4	In general, the Dossier Submitter has considered information on alternatives that was available at the time of putting together the restriction dossier (e.g. from relevant literature and information provided during calls for evidence). In general, only limited information on the (non-)availability of alternatives has been submitted and part of that information was inconclusive. To include additional information, stakeholders are asked to provide information on the use and function of potential alternatives, including the setting in which this use occurs, in the consultation.
There are use cases, where PFAS are required by law to handle dangerous substances. An example is the handling of NF3 (a gas used in semiconductor manufacturing) which requires the use of polytetrafluoroethylene (PTFE) or	12.5	The current proposal includes a time-unlimited derogation for use of refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives (see paragraph 5j of the proposed restriction text). Similar considerations may apply for other uses of PFAS. Therefore, please submit

Question	#	Answer
polychlorotrifluoroethylene (PCTFE) as sealing material for pressure receptacles. How are such situation considered in the restriction proposal?		relevant documentation in the consultation, to ensure that it can be considered by Dossier Submitter and the scientific committees.
How is semiconductor manufacturing defined in relevant the proposed potential derogation? Does this also cover manufacturing equipment?	12.6	The proposed potential derogation for the semiconductor manufacturing process is intended to cover PFAS used in the production of a semiconductor but not PFAS in the equipment used to produce semiconductors.
Table 8 of the restriction report mentions a high substitution potential for fluoroelastomers for chip manufacturing, but a detailed explanation on alternatives seems to be missing. Where can I find further information on alternatives?	12.7	Polyether ether ketone (PEEK) is currently suggested as an alternative in chip manufacturing. The current evidence, however, is considered weak by the Dossier Submitter. Therefore, please submit additional information for clarification under what circumstances PEEK is considered a feasible alternative and under which circumstances not. Robust data is required, including detailed information on expected impacts in case PEEK is used. Further information on alternatives can be found in Annex E and Appendix E.2.

13. Lubricants

Question	#	Answer
Can you please define lubricants and what it includes (e.g. bearing materials)?	13.1	The Annex XV restriction report does not include a specific definition encompassing all lubricants. Lubricants can be found as solid, semi-solid and liquid forms and their primary function is to reduce friction between surfaces. Annex A.3.15.1 covers the different types of lubricants included in the Annex XV restriction report and these are defined in this section. Some lubricants are used under harsh conditions and others are meant for consumer products. Lubricants cover a large span, where some uses include addition of micro-powder polytetrafluoroethylene (PTFE) as thickeners in mineral oil or synthetic oil. Lubricants also cover dry film, where a polymeric PFAS layer remains on the surface of the area of lubrication when the water-based solution evaporates. For bearing material to work properly, usually a base oil can be used or, in high temperatures, dry film may be used. The bearing itself is not considered a lubricant.
Polymeric PFAS are used as a lubricating layer on tools for extrusion processes with very high	13.2	A derogation has been proposed by the Dossier Submitter if there is sufficiently strong evidence that no alternatives exist. For the specific use mentioned the

Question	#	Answer
pressure (more than 1 000 bar) and alternatives are not available. Can the specific use be derogated?		Dossier Submitter considers that there are indications that alternatives exist/are being developed. Currently, a derogation is proposed for lubricants used under harsh conditions (see paragraph 5s of the proposed restriction text). An explanation of such conditions is included in the explanatory notes of the Annex XV restriction report. Please consider whether your application could be covered under this derogation. If not, you can submit a well-substantiated proposal how this proposed derogation could be widened to cover your use. Please note that any derogation requests have to be fully justified by risk or socio-economic arguments.

14. Petroleum and mining

Question	#	Answer
Are applications in petroleum and mining of fluoropolymer ingredients > 500 ppm covered under a derogation?	14.1	A specific time-limited derogation has been proposed for the use of fluoropolymers in petroleum and mining. This applies for any concentration of the fluoropolymers for 13.5 years after entry into force of the proposed restriction.
Fluoropolymers are used in thousands of tonnes per year, e.g. as additive in offshore drilling. Will a less restrictive legislation on fluoropolymers have considered high contents of impurities, as well as degradation if applied under conditions with high friction, heat and/or other chemicals?	14.2	The application described in the question has so far not been considered in the restriction proposal. Relevant information with supporting evidence should be submitted in the consultation. Uses of fluoropolymers within petroleum and mining are proposed to be derogated for 13.5 years after entry into force.
A derogation is planned for use of fluoropolymers in the petroleum and mining industry. Does this mean that any component in mining equipment made of e.g. fluorine kautschuk material (FKM) or polytetrafluoroethylene (PTFE) may continue to be used? For example, an FKM O-ring used in the hydraulic pump of a shovel excavator.	14.3	Yes, according to paragraph 6f of the proposed restriction entry the use of FKM and PTFE in mining is derogated for 13.5 years.
What is the definition or explanation of "petroleum and mining" in the framework of the	14.4	Uses and sub-uses within petroleum and mining industries are described in Annex A.3.16 and this assessment may be used for clarification of the derogation.

Question	#	Answer
restriction proposal?		

15. Active substances

Question	#	Answer
The Annex XV restriction report proposes a derogation for active substances in plant protection and biocidal products and in human and veterinary medicinal products. Would this derogation also cover the preceding steps in the synthesis of an active substance?	15.1	Yes, any proposed derogation is intended to also cover all preceding steps that are necessary to produce the product.
Does the proposed time-unlimited derogation for medicinal products also include biopharmaceuticals?	15.2	The proposed time-unlimited derogation for medicinal products is intended to apply to active pharmaceutical ingredients (APIs), not to medicinal products overall, which means that the excipients (co-formulants) would not be derogated. If you have relevant and substantiated information on biopharmaceuticals, please submit this in the consultation.
The biopharmaceutical sector is highly regulated and changes require approval by health authorities, which take a significant time and will result in an increased burden on authorities. Has this been considered? A 12-year derogation period is proposed for medical devices, can this be applied to the biopharmaceutical industry?	15.3	The biopharmaceutical sector is like any other regulated pharmaceutical industry, where all changes in medicines require an approval by the European Medicines Agency (EMA)/national health authorities. Relevant information regarding biopharmaceuticals, including approval conditions and times, can be submitted in the consultation.

Question	#	Answer
PFAS are widely used in single-use systems (SUS), process aids and process equipment and analytics in the manufacture of biopharmaceutical products including filters, films, tubing, fittings, pump components (diaphragm, seals & gaskets), product primary packaging such as vial and syringe stoppers, perfluoroalkoxy alkanes (PFA) bottles, trifluoroacetic acid (TFA; used in analytics and processes), drug substance (DS) storage containers, personal protective equipment (PPE), autoclave bags etc. Can an unlimited derogation be applied to the above components as direct replacement is not possible due to specific characteristics of these materials?	15.4	The Dossier Submitter's conclusion on whether a time-limited derogation is proposed is mainly based on criteria relating to alternatives, e.g. if technically and economically feasible alternatives are not available at all or they are not available in sufficient quantities. Given potential differences in the functionality requirements for different types of products, conclusions on the technical feasibility of alternatives might also differ. It is important to clearly describe the functionality requirements for specific types of products and provide the information requested in *specific information requests 6, 7 and 8* of the consultation at product type level, to allow for an assessment of whether a derogation is warranted for the mentioned components. Take note of the general advice provided in the Information Note and the Consultation Guidance when preparing your submission. Also note that some of the components mentioned in the question are already covered in the Annex XV restriction report and derogations are proposed as considered relevant by the Dossier Submitter. Filters and PPE are, for example, covered under technical textiles and professional apparel covered in Annex E.2.2. Table 8 and Table 9 in the Annex XV restriction report are a useful starting point for getting an overview of all assessed applications and associated derogations.
Does the proposed derogation in paragraph 4c of the proposed restriction text also cover medicinal products that contain PFAS including if PFAS are contained as impurities.	15.5	The derogation applies to active pharmaceutical ingredients (APIs) only, not to medicinal products. Hence, the derogation is also not applicable to impurities that might be present (as co-formulants) in medicinal products.

Question	#	Answer
We know that active ingredients (biocides/plant protection products/pharmaceuticals) are derogated due to the fact that they are regulated under other regulations than REACH. But why do they have time-unlimited derogations when the point of the restriction is emission reduction? Especially plant protection products and biocides, which can have wide dispersive uses?	15.6	The Dossier Submitter recognises that active ingredients in biocides, plant protection products and pharmaceuticals are regulated in the EU with extensive evaluations and approval processes in place. Hence, it is proposed to derogate the use of PFAS as active substances (but not the use of PFAS as co-formulants/excipients) in plant protection, biocidal and medicinal products. Given the risks associated with PFAS in the scope of the restriction proposal, the derogation comes with a recommendation to the European Commission to address these concerns in the respective regulations to reduce the use and emissions of PFAS as much as possible. To support further actions, the proposed derogation includes reporting requirements for placing PFAS-containing active substances on the market, which is applicable to manufacturers and importers of plant protection products, biocides and human and veterinary medicinal products. Under the Plant Protection and Biocidal Products Regulations, there is a re-evaluation and renewal of the approval of active substances every 5 to 15 years. If a substance meets the criteria for substitution, the re-evaluation includes an assessment of possible alternatives.
The Dossier Submitter proposes a derogation for active pharmaceutical ingredients (API), without referring to process equipment to manufacture or to package and deliver the final medicinal product. Is this also included in the derogation? **In addition, market authorisation of a drug product covers the primary packaging. PFAS containing primary packaging appears not to be derogated in the proposal. The EU pharmaceutical sector uses multiple forms of primary packaging; most are necessary to provide medicines to the patient and both frequently contain PFAS.**	15.7	Indeed, the proposed derogation does not cover specific PFAS equipment that is needed to produce the active ingredient/article/product or packaging. A separate derogation would be needed for this. Substantiated information for these cases can be submitted in the consultation.

Question	#	Answer
Unfortunately, only blister packaging has been derogated. Was it an oversight to not derogate other forms e.g. PFAS-lined elastomers used in vials, syringes and cartridges?		
Active pharmaceutical ingredients (APIs) are proposed to be derogated, but development products seeking this approval are not. Is it intended that clinical testing of drug candidates with perfluorinated entities can only happen outside of the EEA? **Product and process orientated research and development derogations are excluded from the proposal. This will result in a barrier for R&D in the EEA. It is common for EU pharmaceutical sites to undertake late-stage testing of PFAS APIs with >1 tonne/year of the API and its isolated PFAS intermediates. Has this been an oversight? It will drive such R&D out of the EEA.**	15.8	According to the current proposal, clinical testing with PFAS-containing drug candidates would be restricted. However, the Dossier Submitter fully sees the advantages of such testing. We encourage you to submit relevant information in the consultation. An additional derogation can be proposed either by the Dossier Submitter or by RAC and SEAC, if it can be sufficiently justified with the information provided.

16. Missing uses / Resubmitting information

Question	#	Answer
What about uses not addressed by the Dossier Submitter (e.g. industrial and chemical industry, sealing applications, pulp & paper, military/defence, laboratory/analytical equipment and laboratory/analytical equipment)? Does the proposed restriction apply to these?	17.1	This proposal targets all uses of PFAS, including uses that are not specifically mentioned. Only uses for which a derogation has been proposed are intended by the Dossier Submitter to be allowed until the time period of the derogation has passed. As PFAS have a very broad application range, not all uses have been addressed in the Annex XV restriction report. If your use is currently not addressed in the Annex XV restriction report, it is recommended to submit relevant and substantiated information on this use, especially by answering *specific information request 6* of the consultation.
There are many polytetrafluoroethylene (PTFE) consumer products other than cookware, like gardening and cutting tools. What is the timeline for restriction of these sectors?	17.2	If a use is not specifically mentioned, it means that it is proposed to be banned 18 months after entry into force.
I did not see any guidance for PTFE membranes used for gas or liquid filtration in life science applications (pharma/biopharma)? Which of the use sectors presented in the Annex XV restriction report do these falls into?	17.3	Life science applications cover applications in health, agriculture, medicine, and the pharmaceutical and food science industries. PTFE membranes used for gas or liquid filtration in life science applications are covered in the Annex XV restriction report under "Technical textiles", which is a sub-sector of textiles, upholstery, leather, apparel and carpets (TULAC).
Has the Dossier Submitter taken into account all information submitted during the call for evidence when drafting the proposal? Should we resubmit this information?	17.4	Information submitted during the call for evidence or during the second stakeholder consultation has been taken into account during the drafting of the proposal. Hence, there is no need to resubmit this information. However, any information that has come in after the end of the second consultation, could, for practical reasons, not be considered. Hence, there might be a need to resubmit. However, before doing so, check whether this information is already covered in the proposal, for example from other information sources. Also, keep in mind that any claims and statements need to be substantiated by scientific evidence. If you think that the information you sent in previously was well-substantiated, but has not been considered, you can resubmit it.

17. Alternatives

Question	#	Answer
Is there a list of alternatives available for each application?	18.1	Investigation of alternatives is the responsibility of industry and the supply chain. This is where the specific knowledge is. However, the Dossier Submitter has compiled an overview of alternatives based on the information that was available at the time of preparing the proposal. This can be found in Appendix E.2 (Excel spreadsheet). Further information on alternatives can also be found in Annex E.
When an application is not derogated in the proposal, will you communicate whether this is because 1) someone flagged the existence of alternatives, or 2) there was insufficient evidence to substantiate the need for the use of the PFAS?	18.2	When assessing the existence of alternatives, the Dossier Submitter distinguishes between cases with sufficiently strong evidence, weak evidence, inconclusive evidence and no evidence. Derogations are only proposed when sufficiently strong evidence points to the lack of alternatives or to problems with implementing alternatives in the available timeframe. When the evidence is weak, proposed derogations are marked for reconsideration (more details on these levels of evidence and associated implications can be found in section 2.4.1.1 of the Annex XV restriction report). Table 8 of the Annex XV restriction report provides a summary of the main conclusions on alternatives, including information on the level of underlying evidence. As such, information allowing stakeholders to understand the reason why a derogation was or was not proposed is available in the Annex XV restriction report. A more detailed overview of the information on alternatives that is available to the Dossier Submitter is provided in Annex E and Appendix E.2.
How was the availability of alternatives assessed for the restriction proposal?	18.3	The assessment of alternatives was based primarily on information from stakeholders, but also on other information that was available and was sufficiently specific and justified. The Dossier Submitter put much emphasis on well-substantiated information from stakeholders that alternatives actually are available for an application whereas unsubstantiated claims from other stakeholders that alternatives are not available in these applications were not acknowledged. Policy objectives are also kept in mind, although assessment of alternatives is primarily a technical exercise.

18. Analytics

Question	#	Answer
Are there currently available validated methods that can quantify PFAS in the suggested limit concentrations? If so, can you provide an overview/list of them? According to our understanding, targeted PFAS analysis currently covers around 40 different PFAS (limited by availability of reference standards). Does the 25 ppb limit in paragraph 2i only apply to the PFAS for which targeted analysis is available? If so, what are they?	19.1	The measurement methods for different PFAS are shown in Appendix E.4. A generally valid list of PFAS for which a targeted analysis is possible does not exist. This is because with a thorough search for relevant reference standards, it is possible to find more than the specified approx. 40 different PFAS. The number of reference standards depends on the type of laboratory or supplier. There are also custom synthesis laboratories that provide reference standards on request. Therefore, it is likely that the number of PFAS that can be analysed via targeted analysis will continue to increase over time. A good starting point for a list of PFAS that can currently be analysed can be found in Appendix 3 of this report. The total number of PFAS that can be analysed with targeted measurements in this report is higher than 40, however, even for several substances it was not possible to find a laboratory that can offer the analysis of specific substances (red 0 in the table). Under the restriction proposal, any available targeted PFAS analysis can be used to demonstrate compliance with the 25 ppb limit in paragraph 2i of the conditions of the restriction.
What qualifies as a "reference standard" for targeted analysis? How is it defined? What if no "reference standard" exists?	19.2	A reference standard is a pure sample of the substance for which the analysis is being carried out. It is needed to make a profile of the substance under the given conditions of the analytical method. This enables a quantification of the substance. Up to now, there is no reference standard for all PFAS covered by the restriction proposal (see question above). If no reference standard is available, there are two alternatives: 1) An analytical method can be chosen in which non-polymeric PFAS contained in the sample are degraded before measurement to known PFAS for which methods exist. In this case, a limit value of 250 ppb applies to the sum of the PFAS (i.e. paragraph 2(ii). 2) As a second possibility, which is also applicable for polymeric PFAS, the total fluorine content can be determined analytically. Here, a limit value of 50 mg F/kg (50 ppm) applies (i.e. paragraph 2(iii). Fluorine concentrations of non-PFAS, e.g. inorganic fluorine, can also be measured with this method. Therefore, supply chain

Question	#	Answer
		information or supplementary analyses in the sample must be provided and can be used to show which part of the measured fluorine content is not PFAS.
Does the following paragraph "ii. 250 ppb for the sum of PFAS measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors" mean that it is optional to do a TOP analysis in combination with targeted PFAS analysis to evaluate if a sample is compliant with the limit value?	19.3	Yes, this is correctly understood.
Are the concentration limits for products made from recovered/recycled materials and substances different from those for products made from pristine materials?	19.4	No, the concentration limits are the same for all products (articles), i.e. substances containing PFAS as a constituent, and PFAS in mixtures and articles. So, recycled materials have to comply with the same rules as virgin materials.
Are the concentration limits also meant to apply to uses for which a derogation is proposed?	19.5	No, the concentration limits are proposed to only apply to products (mixtures, articles and substances with PFAS as constituents) that do not fall under a derogation, or for which the derogation period/transition period has passed. No concentration limits are proposed for PFAS in products that fall under a derogation.
What is the status and plan for analytical methods and concentration limits for PFAS within the restriction proposal?	19.6	The availability of different analytical methods for PFAS has been evaluated in the restriction proposal, and the assessment can be found in section 2.5 of the Annex XV restriction report, in Annex E.4, as well as in Appendix E.4 (including information on performance and detection). Included in this assessment is the description of a sampling and analytical strategy for how you can analyse the different fractions of fluorine/PFAS in a sample: total fluorine, organic/inorganic fluorine, targeted PFAS analysis, and suspect and non-target screening of PFAS etc. Total fluorine methods, like e.g. AOF, are highly relevant and considered. The different methods are currently under development, both within research groups and standardisation bodies. It is not expected that targeted analysis will be available for all individual PFAS anytime soon, but methods like TOP, EOF, AOF etc. will cover PFAS for which a reference standard is not available. In the sections mentioned above, the validation/standardisation of methods is also described. Currently available standard methods are listed in Appendix E.4. In the absence of standard methods, validation of methods can be done in-house at the different laboratories. The Dossier Submitter does not recommend specific laboratories and does not intend to identify

Question	#	Answer
		limit values for food in the restriction proposal for PFAS. There is no list of PFAS that can be measured with targeted PFAS analysis as there is continuous development in the field. No PFAS should be used in products, unless the application in question is derogated, and the authorities may use any relevant targeted measurement of PFAS in enforcement of the potential regulation. It should also be kept in mind that it is not a prerequisite for a restriction proposal that the necessary analytical methods are in place before submitting the proposal.
Will the analytical methods to analyse PFAS be specified?	19.7	There is no one single PFAS method that would apply to every scenario. All available information about analytical methods has been collected and compiled in the dossier. The Dossier Submitter has looked at both research methods and standardised methods and for different matrices. There is currently very fast development of new methods for PFAS, of both the standard type and research type. There are different kinds of methods that are relevant. There are targeted PFAS analyses that rely upon the availability of analytical reference standards that can quantify about 40-50 different specific PFAS (see also question above). And there are the total fluorine methods that are more general and that will detect any kind of organic fluorine in the sample, including polymeric materials. This is described in detail in the Annex XV restriction report, and an overview is in a separate Excel spreadsheet (Appendix E.4).
How can one ensure that the very low threshold limits proposed in the dossier are met?	19.8	First, it should be known throughout the supply chain, which chemicals have been used to manufacture a product (an article). Hence, it should already be known which PFAS are relevant for a certain product. Read more about the currently available analytical methods for PFAS above.
Detection limits "for any PFAS as measured with targeted PFAS analysis" at ppb levels can show peaks for other PFAS at lower levels. This may cause issues in quantification. Could the wording "<25 ppb for targeted PFAS including other related substances with a total not exceeding …" be a solution?	19.9	This is not a good solution. Methods should be able to separate the different analytes to achieve an appropriate performance.
Are there fluoropolymers for which the 50 ppm/50 mg F/kg threshold is not proposed?	19.10	All types of fluoropolymers that are covered by the scope definition (see "proposed restriction" in Annex XV restriction report, page 4) should comply with the 50 ppm (50 mg F/kg) limit value. However, there are some derogations that have been

Question	#	Answer
		proposed for specific applications (rather than for types of fluoropolymers). See Annex E.4.1.4.1 for the relationship between ppm and mg F/kg sample.
How many PFAS are there in total? How are these substances classified into subsets? It is impossible to test all PFAS for all product manufacturers.	19.11	Section 1.1.1 in the Annex XV restriction report describes the identity of the substances, including grouping and the number of PFAS substances.
Which materials or types of articles do you expect will need to be tested to demonstrate compliance thresholds in articles proposed under RO2?	19.12	It is proposed that industry should not use PFAS in their products and processes (unless derogated) and should be certain that PFAS are not present in their products. Regarding enforcement, the proposal foresees that authorities use available methods to test any product to verify compliance with the potential regulation.
How were the proposed concentration limits chosen?	19.13	The selection of proposed concentration limits is discussed in section 2.5.2 of the Annex XV restriction report.
In Appendix E.4, no specific analytical methods are available for "Medical" and "Flame Retardants." Is the understanding correct that appropriate analytical methods for these applications will be provided after the consultation on the proposed restriction?	19.14	The Dossier Submitter has compiled the information about available analytical methods. If additional methods are needed e.g. by industry, they should develop such methods themselves. Please submit any relevant information to the consultation.
Will there be a distinction made between unintentional trace presence of PFAS and intentionally added PFAS regarding the applicability of the proposed thresholds (25 ppb, 250 ppb, 50 ppm F)? Or will the thresholds apply regardless of the source of the PFAS?	19.15	No differentiation is proposed between intended and unintended presence of PFAS. The concentration limits are proposed to apply on a content basis. PFAS impurities are very seldom formed unless PFAS are used intentionally in a process or intentionally added to a product.
Is it true that limits are proposed in gross-weight units? Not in moles, CF2- or F-equivalents?	19.16	The limit values proposed relate to 25 ppb, 250 ppb and 50 ppm weight concentration, irrelevant of the type of PFAS.

Question	#	Answer
For the total F level of 50 ppm, are we looking at the new AOF method DIN 38409 now being considered at ISO (WD 18137)? This would be far more selective as a screening tool for PFAS than just total F?	19.17	It is appreciated if this information (including some more technical details on the method) were submitted in the consultation.
A PFAS solvent is necessary for a laboratory measurement unrelated to restriction enforcement. Attempts to replace PFAS have been unsuccessful. Will the laboratory measurement be banned?	19.18	If this information is justified and submitted in the consultation, ECHA's scientific committees may consider proposing a derogation for this application. However, it is a prerequisite that the same analysis cannot be solved with a different non-PFAS based technique.

19. Supply chain

Question	#	Answer
Can you give some advice to formulators of mixtures on how to ask suppliers of substances/mixtures/articles whether the items supplied by them meet the limits for PFAS according to the proposed restriction?	20.1	The Dossier Submitter suggests involving trade associations to address this supply chain communication issue as the responsibility for this lies in the supply chain.
How will distributors know if products contain PFAS?	20.2	The Dossier Submitter is aware that this is a difficult task as some supply chains are very long and, therefore, it may be hard to gather such information. Nevertheless, the Dossier Submitter advises you to seek out this information as it will be relevant in the context of this restriction proposal. As the Annex XV restriction report covers more than 10 000 substances, it is necessary to ask about information on the chemical structure rather than CAS numbers. For importers and producers within the EU, certain obligations under REACH apply. These obligations vary depending on the tonnages of substances manufactured or imported each year. Therefore, additional information on PFAS will likely be available.
Does the responsibility of ensuring processes are PFAS free lie with the	20.3	This is a joint responsibility and responsibility needs to be taken by all actors in the supply chain. The proposed restriction entails a ban on the manufacture, use or

Question	#	Answer
manufacturer/supplier or end user of the material?		placing on the market of PFAS as substances on their own (as set out in paragraph 1 of the proposed restriction text), unless these are supplied for derogated uses. Also, it encompasses a ban on the placing on the market of PFAS as a constituent in another substance, in a mixture or in an article, if the concentration of PFAS is above the limits set out in paragraph 2 of the proposed restriction text. As such, manufacturers need to take responsibility for ensuring compliance with the proposed restriction by not supplying PFAS for use in non-derogated applications. However, this does not free the downstream users from their responsibility to build knowledge on the content of the restriction and ensure that their actions are compliant. The same applies to every stage of the supply chain. In general, manufacturers and importers of substances, mixtures and articles within the EU will have the main responsibility. When it comes to uses for derogations, end users will have an important responsibility as well.