Questions on the PFAS REACH Restriction proposal
The same basis is used for the microplastic restriction (persistency, presence long term, risk for future generations, but no harm clearly demonstrated (yet). If legally a risk has to be demonstrated as per the current REACH, how do you think this could affect the PFAS restriction in terms of standing?
Will there be exemptions for applications of fluoropolymers for the production of laboratory articles? This application is not listed in the proposal.
Is it correct that if the proposal remains unchanged the production and use of PVDF, PTFE, ETFE, FKM etc. could be banned in Europe for the categories without derogation?
There is a time-unlimited derogation for medicinal products. Would this include biopharmaceuticals?
What is happening in regards with R&D for alternatives to PFAS for specific applications, any major actor making grants or investment funds available?
Does the restriction of FKM include FEPM and FFKM?
Will PTFE waxes in printing inks also be banned or will there be an exception with an extended transition period?
The definition of the various classes of derogations are in some cases very detailed and in others very broad, and, vague. Is there a way to get clarification on the ECHA intent for each category of derogation?
Do you believe public consultation timeline may be extended given the number of sectors impacted and the need for industry to gather data and information?
Could you please inform what the concentration limits practically mean? Does it mean that PFAS can be added below the proposed limits?
In case we are placing on the market a product containing PFAS that will be still allowed as part of a derogation but we rely on a supplier providing us with a PFAS-containing precursor - will this still be allowed even if there is no dedicated derogation for the precursor?
Why does it seem that PTFE will be banned in 2025 for cookware and not for industrial

bakeware? Which is the difference between the applications?
I did not see any guidance for PTFE membranes used for gas or liquid filtration in life science applications (Pharma/BioPharma)? Which category as presented do these falls into?
The Restriction dossier has evaluated exemptions based on the evidence that no alternatives are available in time. No cost/benefit calculations have been performed. What does that mean for industry in the public consultation? Is it sufficient for industry to focus on the evidence of alternatives and can we leave out cost/benefit calculations in our contributions?
Will the ECHA committees or the dossier submitters contact the contributors to the public consultation in case of questions? If a contribution is too specific, too generic or leaves some questions we are willing to provide more information. Will we be contacted?
In general it is said that a lot of evidence regarding the availability of alternatives is inconclusive. What information is required in order to consider it conclusive? What level of detail? Are research reports of research projects of individual companies needed? We have identified over 60 uses of PFAS in electronics. Do we have to submit a report on alternatives for each of those 60 uses?
Information that has been provided on the availability of alternatives has been summarized in Annex E to the report. For electronics there is a lot of information that says that alternatives are either not available or can only be used in less-demanding applications. From all contributions it is very clear that electronics industry cannot do without PFAS. Why an exemption is not being proposed?
Will the PFAS REACH Restriction ban the use of PFAS as feedstock? There is no specific mention on the proposal.
The definition of transport is not clear. Is aerospace included in the transportation sector?
The definition of "Lubricant" is not clear. There are many applications where Vespel acts as a friction lowering component; is that a Lubricant?
Are applications in Petroleum and mining of fluoropolymer ingredients > 500ppm covered under derogation?
With the 15 major use sectors, the Dossier Submitters believe to have covered rather exhaustively the PFAS uses. It is recognized though that it is impossible to be complete, given

the large number of PFASs and the broad range of processes and products they are useful for. The dossier submitters admit that not all uses have been assessed. By definition these 'niche applications'/'applications of little relevance in the EU' will therefore be banned by default, 18 months after EiF. But how do the Dossier Submitters explain and justify this ban if applications have not been assessed?
How can we know which are the alternatives for each application?
There is a lack of applications assessment and on alternatives eg for uses such as Chemical Industry. Sub uses are also missing, like other hydrogen applications (water electrolysis, energy/H2 storage, other types of membranes around fuel cells). How these points will be clarified?
For pharmaceuticals, even though there is derogation for packing nothing around the production of pharmaceutical is mentioned. Will PFAS which are used for the production of pharmaceuticals be derogated?
In some cases the development of alternatives is still at research stage in the university. How did the dossier submitters evaluate the viability of alternatives? What are the criteria?
How can we access the information on the availability of alternatives? Will the dossier submitters provide the information?
If a material is durable it will be very probable persistent as well. How are the alternatives assessed in terms of risk for human health and the environment?
There are gaps in the proposal as the risk to the environment in the manufacturing step and how to mitigate and the risk at EOL and how to mitigate. Can MS provide answers to these gaps?
Some PFAS are already regulated under other REACH restrictions, or EU POP, or F-gas regulation. What is your view on how to combine them with the future PFAS restriction to ensure consistency between regulations?
Could you provide us with some additional information on how to interpret paragraph 5 a? *By way of derogation, paragraphs 1 and 2 shall not apply to:* *a. polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM.*

Would imported fluoropolymers also have to comply with the ban of PFAS polymerisation aids as set out in paragraph 5a? Imported PTFE, FKM, PVDF would no longer be allowed to be produced with PFAS polymerisation aids in 1.5 y after EiF, and in 6.5y after EiF for the other fluoropolymers? Or is paragraph 5a only applicable to fluoropolymers manufactured *within* the EU**?**

Question regarding concentration limits/PFAS measurement:

On Page 170 of the Annex XV Restriction Report, the there is a section named "Concentration Limits." Therein, there is a statement about "*25 ppb for any PFAS*" followed up by "*concentrations measured by targeted PFAS analysis, which currently covers above 40 different PFASs (limited by the availability of reference standards).*"

- Does the 25 ppb limit only apply to the "40 different PFAS" – if so, what are they?
- What qualifies as a "reference standard"? How is that defined? What if no "reference standard" exists?
- If there are other PFAS present that are not part of the "40 different PFAS," the 50 ppm limit then applies, correct?
- Is this list expected to expand?

> The limit value **1) 25 ppb for any PFAS** (except polymeric PFASs) shall be compared with PFAS concentrations measured by targeted PFAS analysis, which currently covers about 40 different PFASs (limited by the availability of reference standards).

What is intended by testing provisions of paragraph 2 "i" and "ii"? Is it intended that all types of substances, mixtures and articles be tested before being placed on the market? If so, implementation time will have to be greatly extended, as the number of labs providing this testing capability is limited, and testing methodologies for most substances, mixtures and articles will have to be developed.

In the testing provision of paragraph 2 "i" and "ii" it says "fluoropolymers are excluded from quantification". Does that mean fluoropolymers do not have to be tested for other PFAS or that fluoropolymers need not be considered when as a "targeted PFAS" under any circumstance? In either case, what is the definition of fluoropolymer in these paragraphs?

Paragraph 5ee: There is a lack of clarity in the proposed restriction, paragraph 5ee, regarding semiconductor manufacturing.
Does this cover fluorinated gases, fluorinated liquids, and fluoropolymers used in the manufacture of semiconductors? Furthermore, what is the definition of semiconductor manufacturing? What is the distinction between semiconductor manufacturing and "normal"

electronic equipment manufacturing? In table 2 (page 54), there is a category for electronics and semiconductor, but in paragraph 5ee (page 7) only the term "semiconductor" is used. There are no explanatory notes for paragraph 5ee. Also, what about semiconductor products that may fall under scope?

Derogation 6a: food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;

Further explanation on derogation 6a – page 30:
For food contact materials used in the industrial production of food and feed, a time-limited derogation is proposed. The following applications are inter alia covered by this derogation:
-Piping and tubing for drinking water applications;
-Filters to capture contaminants from, for example, steam filtration in food processing;
-Seals, O-rings, gaskets, tubing and pipes, expansion joints;
-valves and fitments, conveyor belting, chutes, guiding rails, rollers, funnels and sliding plates, tanks, funnels, rollers, linings, blades of knives and scissors, springs, filter membranes and sensor covers, lubricants;

What does "inter alia" mean? Are filtration membranes used for water and waste water treatment derogated as well?

Derogation 6o: [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF].

What is included in transport? Are applications such as e.g. rail, tractors, aircraft (planes), aerospace (space shuttles) derogated as well?
How is "use" defined in relation to the above derogation? For instance, can a plane with fluoropolymer o-rings land in EU - is that considered a use? What about maintenance?

In transportation, the focus is on proper functioning related to the safety of vehicles. Does PFAS materials used in the manufacturing of vehicles such as torch tips get covered under this derogation? Also, what about semiconductor uses in the transportation industry?

Derogation 5s: lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF;

What constitutes harsh conditions?
Definition of lubricant is not clear. Could an article be defined as a lubricant? There are many applications where polymers compounded with fluoropolymers act as a friction lowering components. Would those be considered lubricants?

Is this derogation only applicable to fluoropolymers used in packaging of terminally sterilised medical devices or does it also cover PFAS use in the production of the packaging for terminally sterilised medical devices?

There are derogations for certain applications for 13.5 years. However, the corresponding raw material production/import is not derogated. Will this be considered? Where will these sectors with long derogations get their raw materials?
If there are multiple derogations that are applicable for a certain applications (e.g. processing aids/petroleum mining), what is the prevalent/limiting derogation?
Many PFAS are used in industrial processes where there are currently no alternative, which should be able to meet best available techniques from an emissions perspective, nevertheless it seems that the current derogation proposals don't support EU industrial applications. What is the reason for there not being any industrial process derogations?
Seals, o-rings, gaskets are derogated in food contact applications, but not for other critical safety related applications in chemical and industrial processing. This does not seem to be consistent?
It seems that the derogations have not included many essential applications that are covered by the EU Green Deal (such as renewable energy, clean road transport, public health (EU4Health), electronics) and the transition pathways for chemicals (such as international competitiveness, reduction of dependencies, electrical infrastructure (hydrogen, transport), digital objective). These will probably not be possible in the short term without PFAS. The Annex XV does not seem to take this in consideration, can you explain?
Paragraph 5 of the restriction, Table 2 (page 53) and Annex E are missing major market segments: Industrial, Chemical manufacture, Pulp & Paper, Military/Defense, laboratory/analytical equipment. Heavy industrial applications are not considered. These markets are different from oil refining/energy. Similarly, laboratory/analytical equipment is missing as a separate category. Although this application is listed in Annex A under medical equipment, this is not obvious by reading Annex XV. Can you explain why those are not considered?
Table A.1. in Annex A lists several industries, notably the Chemicals Industry and the Defense industry as not researched in detail and the reasoning described in the text above the table is "For these, however, no detailed assessment was performed, e.g. because they concerned niche applications or because the applications are currently of little relevance in the EU." Since both Chemicals and Defense are critical industries (Chemicals is fairly large and has enormous downstream impact on industries they are producing for), these appear to have been excluded because they have "niche applications"? This is not aligned from a socio-economic point of view? Important industries with critical applications should be excluded from regulations because banning the small amount of PFAS they use would have a disproportionately large societal effect.
Item #7 requires manufacturers and distributors of PFAS-containing articles to submit yearly reports pertaining to which derogation they are using. But in many cases the end use of the

articles is unknown to producers. The argument given on page 12 concerning formulators is still invalid considering these scenarios. How will this be resolved?
The current dossier does not distinguish between consumer use vs. industrial and professional uses. How will this be considered?
Will there be a derogation for existing products deployed in the field? How will spare parts be handled (e.g. for chemical processing, air planes)? **For example, the aerospace industry has very long qualification times (5+ years) on top of long design phases (~10 years) that are regulated by governmental entities. Since aircraft are precision engineered to material specs, PFAS-free options would need to be designed into the next engine build. In addition to the long development times, spart parts need to be available for the life time of those planes.** Similar considerations are valid for the chemical/processing industry.
What about inventory. Will there be a transition period inclusive of materials currently in inventory?
Why are Food Contact Materials not excluded in this dossier when plastics/food contact are specifically covered under EC 1935/2004 & more specifically EU 10/2011? Pharmaceuticals were excluded because they fall under separate regulatory requirements.
Semiconductor Section: Table 8. RO1 - Summary table of alternatives and cost impacts for PFAS manufacture and major PFAS use sectors resulting from a full ban of PFAS: A high substitution potential for fluoroelastomers is mentioned in for chip manufacturing" However, the detailed explanation regarding alternative substances seems to be missing?
On page 83, Table 8 introduces a category called "Technical Textiles" and includes several examples, including outdoor technical textiles and medical textiles, as well as high-performance membranes. Is this the category into which glass-cloth coated with PTFE is expected to fall? (Cloth is used in wear parts, not as an architectural membrane.)
Is there a mistake in paragraph 4 (page 5)? Section ii) is referenced. Should that be section iii ?
The document references FKM, but does not comment on FFKM, specifically FFKM as articles. Should FFKM be grouped with other non-polymeric PFAS?
ECHA exempted Active Pharmaceutical Ingredient (API), but not the process equipment to manufacture or formulate the medicines nor the chemicals and raw materials used to manufacture the API, or to package and deliver the final medicinal product. Is this an oversight?

Could you let us know if ECHA will respond to the information received in submissions during the consultation? Are the Committees obliged to respond? And will that be to each comment from all submissions? How will this be done in practice? Will the stakeholder information and the ECHA responses be made public? At what stage in the process would that happen?