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

Questions and answers

ECHA organised a webinar on 29 October 2020 on Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH. It explained the REACH restriction process and the status of ongoing work by the Netherlands, Germany, Denmark, Sweden and Norway on a potential restriction to limit the risks to the environment and human health from the manufacture and use of per- and polyfluoroalkyl substances (PFAS).

This document compiles the questions and answers from the webinar. Editorial changes have been made to improve clarity, correct spelling mistakes etc. Similar questions have been combined. The document will not be updated.

For the most up-to-date advice on PFAS, contact us or refer to our support material.

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Question	Answer
General process	
What is the timeline for the publication of the conclusions of your assessment and the details of any restriction proposal (Annex XV report)? When will the restriction be implemented and when would industry need to comply.	We expect to notify the proposal in ECHA's registry of intention (RoI) in the first half of 2021 and to submit the completed assessment and proposal to ECHA for opinion making in the first half of 2022. The opinion making phase takes 12 to 15 months. After which, the proposal and the opinions of RAC and SEAC are forwarded to the Commission for decision making by the Commission with the Member States (the entry into force of a restriction is anticipated to take place in 2025). Restrictions can contain transitional periods for compliance. The scope and duration of transitional periods are determined on a case by case basis, and may apply to specific uses. For example, where alternatives for a particular use are available the implementation of the restriction can be immediate whilst for other uses the implementation may be delayed to allow sufficient time for substitution within supply chains. For further details of the process, please refer to the ECHA website: https://echa.europa.eu/regulations/reach/restriction In addition, please see Dr. Lokaj's webinar presentation.
Why you said entry into RoI 1st half of 2021? 14 October entered into RoI with status- Intention and submitter- ECHA	We intend to notify our intention for a broad restriction concerning PFAS into the RoI in the first half 2021. The recent (14 October) entry of the intention into RoI is from ECHA and is concerning the preparation of a restriction proposal for PFAS in fire-fighting foams.
Will processing the call for evidence information be split by member state and how (e.g. will further assessment be split by specific applications / uses?)	Yes, the REACH competent authorities of the five countries divided the tasks, see the presentation of Dr. Lokaj for the details.
When will stakeholder follow-up start and in which format? We understand that consultants will be used to assess 20 applications specifically in the context of derogations, can you tell	Currently we are conducting studies on the use, emissions and alternatives of PFAS in different

us more about these and what to expect for next steps for seeing data from stakeholders?	applications. The follow-up of the information received during the call for evidence (CfE) will be used in these studies and if needed respondents will be contacted for follow-up questions. The REACH competent authorities of the five countries divided the task according to the use area of PFAS (see presentation of Dr. Lokaj). Some countries will be supported in their assessment by consultants which will perform and/or contribute to these studies. These studies will be used by the REACH competent authorities of the five countries to prepare the restriction proposal. As explained during the presentations, the starting scope of the restriction work is a ban for all uses. These above mentioned studies for use areas of PFAS as well as information and data provided on uses, hazards, alternatives etc. by stakeholders supporting their requests for exemptions/derogations from that proposed general ban will be further considered by the REACH competent authorities of the five countries during the preparation of the Annex XV dossier.
Given the large number of Call for Evidence responses, what is the expected RMOA publication date?	We expect the RMOA to be published in the first half of 2021.
How can RMOA be at the same time as the restriction proposal text? There is no valid comparison possible before knowing the exact text and scope.	This was addressed in the presentation by Dr. Lokaj. The current preparatory RMOA work is in advance of an entry into the registry of restriction intentions and the actual work on an Annex XV restriction dossier. This preparatory work will be reported in an RMOA conclusion document, including how the initial scope of the PFAS restriction notified to the RoI was developed. We expect the RMOA conclusions document to be published in the first half of 2021.
Why did the CfE not include some heavy industry sectors, for example, automotive, aerospace and other means of transport? What is the intention of the REACH authorities in doing so? For example, If you do not intend to regulate in these sectors, can you please explain the rationale behind this?	The call for evidence was open to all industry sectors, NGOs and other stakeholders. Public awareness was raised via the websites of ECHA and the national authorities. In addition, all registrants and C&L notifiers of PFAS within the suggested scope were notified that the call for evidence was underway via REACH-IT. In addition, newsletter and national networks were used to

	spread the news and encourage contributions into the CfE. Besides this, "Transportation (automotive, aviation etc.)" was specifically mentioned as a use area in the online questionnaire under Question 7. As explained in the presentation by Dr. Lokaj, in the follow-up a specific sub-work package will consider and assess the use of PFAS in the transport sector.
How will the authorities discuss and engage with industry?	The authorities have already engaged with industry and stakeholders via the CfE which was launched on 11 May and ended on 31 July and this Webinar. There will be follow-up if needed and necessary in the process.
How will the different competent authorities split up the work on the dossier (e.g. will the individual CAs focus on certain applications)?	Yes. We have divided the work between us with different competent authorities taking the lead for different work packages (e.g. monitoring, uses, hazard, risk). In addition, the REACH competent authorities of the five countries divided the tasks to assess specific applications/uses of PFAS. Please refer to the presentation of Dr. Lokaj for details.
How will the restriction proposal be structured - will sectors be distinguished e.g. the healthcare sector? How can users of PFAS identify the whole group of 4 700 substances with some of them without even a CAS Number?	The restriction proposal will be structured using the format for an Annex XV restriction dossier. There are numerous examples of generic group entries for REACH restrictions, as well as other REACH processes. However, it is clear that this needs careful consideration during the development of the proposal. Specifically, Annex XVII of REACH currently includes restriction entry no. 68 on the manufacture, use and placing on the market of PFOA, its salts and related substances. The scope of this entry is determined by the potential for a substance to degrade into PFOA (defined on the basis that a substance includes a specific molecular structural element rather than by a list of specific substances/CAS numbers). For further information please refer to ECHA Q&As 1815 and 1816.
How will the RMOA maintain consistency with past derogations received for PFAS molecules or uses for which no non-fluorinated alternatives exist? Will additional data be required in	As mentioned in the presentation by Dr. Lokaj we are aware of previous derogations for groups of PFAS

those cases?	substances. In our view, it is important to consider all PFAS in one proposal to ensure a coherent approach and avoid regrettable substitution. The availability of alternatives is part of the ongoing studies and will be taken into account in developing the restriction proposal.
Ab welchem Zeitpunkt in der Fertigung treten die eventuellen Forderungen in Kraft (bei der Anlieferung des Rohmaterials oder bei der Auslieferung des Fertigproduktes)?	A proposal for the entry into force date (or dates) for the restriction is part of the work we are currently undertaking.
Is a PFAS manufactured and processed in the EU treated differently than a PFAS imported to the EU after it was integrated to equipment, machines or consumer articles? How can the EU avoid to just transfer PFAS manufacturing and processing to less regulated markets? Is moving production or action into non-regulated markets a sustainable solutions for issues like this?	A REACH Restriction can address PFAS manufactured and used in the EU as well as when placed on the EU market after import. Besides substances and mixtures a REACH restriction can apply to substances in articles, including imported articles. A REACH restriction can have a positive impact outside the EU. For one thing the restriction can cover imported articles which means that those producing articles intended for the EU-market must shift to an alternative.
American, Asian markets are bigger than EU market. EU companies lose competiveness, they strongly depend on these markets. China / India host the most growing and biggest PTFE manufacturers. I cannot imagine that they will follow the EU approach in particular for fluorinated polymers.	An EU restriction can have a positive impact outside the EU. For one thing the restriction can cover imported articles, which means that those producing articles intended for the EU-market would need to comply with the conditions of the restriction. In addition, PFAS are of growing international concern. Amendments of international regulations such as e.g. the Stockholm Convention that recently included PFOA, its salts and related substances and for which PFHxS, its salts and related substances are being discussed, already restrict uses and placing on the market of some members of the PFAS group. In addition, identification of further PFAS as POPs cannot be excluded.
As we were unable to submit this information during the consultation phase under the call for evidence we would like to know if it is still possible to provide input on this use to be considered in the decision making process?	Yes, all information and data is appreciated. Please contact ChemG@baua.bund.de.

Will there be other opportunities for industry to comment or provide further input to impact the final outcome?	If you like to provide specific information and data related to PFAS please send this to ChemG@baua.bund.de. In addition, as shown in presentation by Dr. Lokaj during the REACH restriction process there will be the formal possibilities to comment and provide further data and information concerning the restriction proposal, i.e. six month consultation of Annex XV restriction dossier and two month consultation on the SEAC draft opinion.
What can researcher do to support the proposal for restriction?	There are several aspects that need further investigation, as compiled by the OECD. We would appreciate to receive information about substance ID and the tonnages (amount) of use in different products to be able to estimate human and environmental exposure and emission into the environment. On the other hand information on the physico-chemical properties of the PFAS used and data on toxicity, mobility and bioaccumulation etc. are appreciated and necessary for the assessment.
PFAS restriction vs. other restrictions	
Several PFAS are already subject to restrictions or on their way to being restricted. This is for instance the case for PFHxA, its salts and related substances. How will already restricted PFAS be handled under the future restriction on all PFAS?	As mentioned in the presentation by Dr. Lokaj we are aware of the different on-going discussions for groups of PFAS substances. In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution.
Are the ECHA and the 5 MS are also considering the feedback to the PFHxA consultation (socio-economic impact, a lack of alternatives, restriction is proposed only due to persistence and a sufficient grace period is required to prepare for the restriction) for PFAS, too?	As mentioned in the presentation by Dr. Lokaj we are aware of the different on-going discussion for groups of PFAS substance including the ones for PFHxA. In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution. However, we are not looking into the specific comments provided in the public consultation for PFHxA as this is a different process.
Could you tell us how this restriction will be arranged with the two others PFHxA and pfoa?	As mentioned in the presentation by Dr. Lokaj we are aware of the different on-going discussions for groups

	of PFAS substances. In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution.
Can you please explain what is the relation between the different PFAS (PFOS and PFOA) listed as POP in the Stockholm Convention and the REACH restriction process?	As mentioned in the presentation by Dr. Lokaj we are aware of the different on-going discussion for groups of PFAS substances including the POP in the Stockholm Convention. In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution and also to align regulations. The current work has a considerably broader scope than just PFOS and PFOA with the potential that the manufacture, placing on the market and use of many other PFAS are restricted in the EU.
F-gases are already regulated under the F-gas regulation and should not fall under the PFAS group of chemicals. How will you avoid double regulation?	The PFAS restriction will have a borderline with the F-gas regulations, and a part of the assessment that is now ongoing is a mapping exercise that will identify which F-gases are regulated under the different regulations. The resulting overview will be used in the further development of the restriction proposal. However, it should be appreciated that REACH restriction can be considered as a safety net and further action under REACH can be appropriate if risks are not sufficiently addressed by other EU legislation.
Will the PFAS restriction proposal apply to F-gases beyond those already covered under the revision of the EU's F-gas regulation?	This is an important question that will be considered during the development of the proposal. The PFAS restriction will have a borderline with the F-gas regulations, and a part of the assessment that is now ongoing is a mapping exercise that will identify which F-gases are regulated under the different regulations. The resulting overview will be used in the further development of the restriction proposal. However, it should be appreciated that REACH restriction can be considered as a safety net and further action under REACH can be appropriate if risks are not sufficiently addressed by other EU legislation.
F-gases (HFC/HFO, HCFC/HCFO) and refrigerants were included in the scope of the Call for Evidence. Has a decision been taken on whether they will be included in the scope of the	F-gases will be considered during the development of the proposal. However, it should be appreciated that

REACH restriction? Do you intend to restrict HFCs/HFOs which do not behave as other PFAS and are already regulated under the F-gases II Regulation?	REACH restriction can be considered as a safety net and further action under REACH can be appropriate if risks are not sufficiently addressed by other EU legislation.
Are the Member States and ECHA aware that all of the fluorochemicals used in fire-fighting foam would be covered by the proposed PFHxA REACH restriction?	In addition to PFHxA-related substances, other non-regulated PFAS are also used in fire-fighting foams, or could be substitutes for PFHxA-related substances in the future. On this basis it is appropriate to explore if a REACH restriction on PFAS in fire-fighting foams is necessary.
Why were fire-fighting foams included in the call for evidence on PFAS and why has ECHA started a separate REACH restriction for PFAS in foam?	In addition to PFHxA-related substances, other non-regulated PFAS are also used in fire-fighting foams, or could be substitutes for PFHxA-related substances in the future. On this basis it is appropriate to explore if a REACH restriction on PFAS in fire-fighting foams is necessary. The Commission has recently requested ECHA to develop an Annex XV dossier in accordance with Article 69(1) of REACH for a potential restriction of PFAS in fire-fighting foams. A registry of restriction intentions for this work was notified 1 October 2020."
How do you (the five REACH authorities) intend to regulate substances when emissions are already controlled during the whole life-cycle? Would you regulate in a uniform manner, or consider case-by-case actions?	In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution. Emissions of PFAS during production, use and waste stage i.e. the whole life-cycle will be carefully considered in the restriction proposal. Information on emissions from specific processes or uses is highly appreciated.
According to proposed restriction of PFHxA, its salts and related substances (part of PFAS), we concluded the usage of fluorinated fire-fighting foams by professional firefighters (state, municipal) would be limited to 5 years after entry into force. Would you confirm our assumption?	The proposed restriction on PFHxA, its salts and related substances is not part of the current proposal. Please refer to the ECHA website for further details of this proposal and the status of the opinion-making process. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d
Are you considering a similar approach to derogations as currently discussed in the microplastic restriction? i.e. derogations for industrial uses where the substances are	We will consider different restriction options when preparing the dossier.

contained.	
If there would be a restriction for PFAS in fire-fighting foam, when could it at it's earliest be active and would there be a hard deadline or would a transition period be used?	ECHA is currently preparing a separate restriction proposal for PFAS in fire-fighting foams. Please refer to the ECHA website here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6
In terms of Transition from AFFF fire-fighting foams to fluorine free foams: How would be defined/measured/controlled an acceptable residual level of PFAS in the rinse waters after emptying and cleaning foam tanks and equipment?	ECHA is currently preparing a separate restriction proposal for PFAS in fire-fighting foams. Please refer to the ECHA website here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6 This issue will be considered by ECHA as part of this restriction proposal.
The shelf life of fluorinated fire-fighting foam concentrates is above 10 years. The substitution to fluorine free fire-fighting foams in shorter period causes economic loss due to disposal cost of currently held stockpiles. Is the ECHA considering to propose the longer transition period?	Fire-fighting foams are not within the scope of the investigation in the broad PFAS restriction work. However, the disposal costs for fire-fighting foams have been considered as part of previous restriction proposals on specific PFAS (i.e. PFOA, PFHxS, PFHxA). ECHA will continue to consider these costs as a part of its new work on PFAS on fire-fighting foams. Please see details on the ECHA website here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6
If you were to receive data demonstrating that a group or particular PFAS molecule has no environmental and/or exposure concerns, will you exempt that group or particular PFAS molecule from the restriction proposal? By what date would you need to receive such data?	In our view, it is important to consider all PFAS in one proposal to assure a coherent approach and avoid regrettable substitution. There are several aspects that need further investigations, as compiled by the OECD. We appreciate to receive information about substance identity and the tonnages (amount) of use in different products to be able to estimate human and environmental exposure and emission into the environment. On the other hand information on the physico-chemical properties of the PFAS used and data on toxicity, mobility and bioaccumulation etc. are

	appreciated and necessary for the assessment. If you like to provide specific information and data related to PFAS please send this to ChemG@baua.bund.de.
Thank you for your answer to the question about possible overlaps with other restrictions of PFAS, either already adopted or under consideration. But it is not clear if you intend to merge all these restrictions in one?	Depending on the outcome of the various restriction proposals it could, indeed, be appropriate for these to be rationalised together in the future. However, no decision on this has been made.
PFAS Restriction vs. innovation	
The EU Green Deal relies on access to substances with high performance such as PFAS. For instance, C6 fluorotelomer chemistry lies at the heart of components for green transportation (electric- and hydrogen-powered vehicles), solar power optimisation, lubrication for offshore wind generation, and carbon capture and storage. How can you ensure that PFAS will be allowed for Green Deal objectives?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Determining an appropriate scope is part of the work we are currently undertaking.
What is your (the 5 REACH authorities) response to the notion that innovative technologies may be hindered by a REACH restriction on chemicals indispensable to their manufacture or use, e.g. in the battery sector, and other sectors that are a priority under the European Green Deal?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Determining an appropriate scope is part of the work we are currently undertaking.
The EU is highly reliant on imported chemicals. The EU Industrial Strategy requires the EU to build up industrial production for strategic value chains –e.g. industrial internet of things, low-CO2 emission industry–, which depend on access to these materials. How can these strategic value chains be secured if entire groups of chemicals such as PFAS are being banned?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Determining an appropriate scope is part of the work we are currently undertaking.
The Sustainable products initiative is requesting an evaluation of the environmental footprint of the product along its life-cycle at the design phase. In many cases PFAS contribute to a higher environmental performance such as ensuring longer lasting products. How can you ensure that PFAS can be used when it can be demonstrated that its benefits exceed its environmental impact?	A socio-economic analysis (also accounting potential benefits of the use of PFAS) will be part of the Annex XV report supporting the proposed restriction.
A number of substances designated as PFAS in your CfE are used as feedstocks or intermediates or could, in the future be the basis of innovative technologies. Restrictions	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS

would prevent research and development (for example, in the battery sector) as companies would not invest given potential hurdles of having to gain "essential uses". How do you plan to let innovation flourish under your proposed restrictions?	may have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Determining an appropriate scope is part of the work we are currently undertaking.
Restrictions would prevent research and development (for example, in the battery sector) as companies would not invest given potential hurdles of having to gain "essential uses". How do you plan to let innovation flourish under your proposed restrictions?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS may have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Determining an appropriate scope is part of the work we are currently undertaking.
The Sustainable products initiative is requesting an evaluation of the environmental footprint of the product along its life-cycle. How can you ensure that PFAS can be used when it can be demonstrated that its benefits exceed its environmental impact?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. In the proposal we will assess, in an overall evaluation, the advantages as well as the impacts on human health and the environment according to the usual socio-economic assessment procedure, and taking into account the 'essential use' concept as appropriate.
Scope definition	
Have you found sufficient evidence to date to exclude certain substances and/or end uses from the original scope? Which ones?	We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined during the process. Therefore, the scope is not finalised yet.
Will the proposal for restriction address 4 700 PFAS as one group or will it distinguish between different groups of PFAS based on, e.g., different uses, chemical characteristics, or industries, and thus associated risks?	A group-based restriction under REACH is in line with the ECHA strategy on group-based risk management. In the meantime, we will address suitable scenarios to prevent regrettable substitution. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined during the process. Therefore, the scope is not finalised yet.
What data will the RMOA accept to demonstrate there is no unacceptable risk of a group or particular PFAS molecule, e.g., what environmental and exposure data would you wish to receive in order to fill any data gaps in relation to a group of or particular PFAS molecule?	We appreciate to receive information about substance identity and the tonnages (amount) of use in different products to be able to estimate human and environmental exposure and emission into environment.

	On the other hand information on the physico-chemical properties of the PFAS used and data on toxicity, mobility and bioaccumulation are necessary for the assessment.
Is Persistence alone sufficient for restriction and is that the unacceptable risk used to justify restriction for PFAS? If yes, what is the legal foundation for persistence alone to justify restriction in REACH? If not persistence alone, what is the concern beyond persistence that you believe presents an unacceptable risk?	A key concern for the PFAS group is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.
The CfE suggests that the assessment will be considering solely "persistency" on its own. Under REACH the minimum requirement is that a substance is classified as vPvB or PBT or "of equivalent concern". What arguments do you have to justify that PFAS as a group is of equivalent concern? We would like to know what is the legal foundation for using "persistency" alone?	A REACH restriction does not require prior classification as PBT, vPvB or equivalent concern; these are the criteria for inclusion on the candidate list for authorisation, which is a different REACH process. A REACH restriction can address any unacceptable risk. A key concern for the group of PFAS is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.
Under REACH, a Risk Assessment is required, and restrictions can only be considered if there is an unacceptable risk. How do you intend to conduct a risk assessment for a large group of substances with very diverse applications?	A key concern for the group of PFAS is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.
PFAS are a group of 4 700 substances with completely different physico-chemical	A class-based restriction under REACH is used in line

characteristics and thus completely different toxicological and ecotoxicological properties. How do you plan to assess restriction of the PFAS family e.g. risk based approach PBT substances first?	with the ECHA strategy on group-based risk management. In the meantime, we will address suitable scenarios to prevent regrettable substitution. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined during the process. Therefore, the scope is not finalised yet.
What is the concern beyond persistency that you believe is an unacceptable risk?	A key concern for the PFAS group is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.
Are you for example considering to separate legislation for sub groups, such as fluoropolymers?	Our work is focusing on a restriction under REACH (Annex XVII). We are carefully looking at the scope of the restriction. In the call for evidence we used a broad scope as starting point. Fluoropolymers are included in the broad scope as starting point.
Based on the evidence provided by stakeholders, are you considering to adapt your definition of "PFAS" or at least further subdivide based on physico-chemical properties? Are you subsequently, considering to change the scope of the restriction?	Yes, evidence and information from stakeholders is very important and appreciated. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined in the course of the process. Therefore, the scope is not finalised yet.
How realistic is phasing out of PFAS really? Do you observe resistance from industry pointing to the widespread applications? And: Are there equally good alternatives? Thanks	We are carefully looking into this. Based on the evidence provided by stakeholders, we will consider the need for possible exemptions and derogations.
The main concern expressed with the PFAS substances as seen in the Call for Evidence has been the presence of PFAS substances in the environment and their potential for accumulation with time. Would you consider excluding from the restriction scope those PFAS substances or uses that do not contribute to adding up in the environment, or that do not end up in the environment themselves? And if not, why? (a) For example, would you agree to exclude from the restriction scope those PFAS substances, mixtures and articles	We are carefully looking to the scope of the restriction. In the call for evidence we used a broad scope as starting point and it can be further developed during the process on the basis of further information, especially based on the evidence provided by stakeholders. The need for possible exemptions and derogations will be

containing PFAS contained by technical means to prevent releases to the environment during production, use or end-of-life phase? (as seen in the case of the currently developed REACH restriction on microplastics)	assessed as well in the process.
If the OECD has an existing list of 4 700 PFAS substances already, wouldn't it be more efficient to focus on these 4 700 substances for restrictions instead of resurveying the industry for additional substances?	We are familiar with the OECD list and we are using it extensively. However, we need to consult with industry to get more information on their manufacture and use of the substances.
Will the revised definition of PFASs that is currently being developed within the OECD PFAS Terminology Project taken into account?	We will do our own evaluation of the scope of our proposal, but the OECD PFAS Terminology Project will be taken into account.
Why did you deviate from the generally accepted list of substances that are in the OECD catalogue of PFAS?	A single, globally harmonised PFAS classification has not (yet) been defined, resulting in lack of recognition of important distinctions between PFASs. The OECD list of PFASs is a useful starting point. Given the serious worldwide concerns regarding health and environment, a broad PFAS group restriction proposal is foreseen in line with the ECHA strategy on group-based risk management to prevent regrettable substitution. Therefore, this OECD list of PFAS would need e.g. to be complemented with PFAS registered for manufacture and import in the EU and an assessment of the hazard properties of the different PFASs.
I don't believe you answered the question and further divergence causes problems further into the future. Is the OECD catalogue of PFAS being taken as a starting point?	A single, globally harmonised system for PFAS classification has not (yet) been defined, resulting in lack of recognition of important distinctions between PFASs. The OECD list of PFASs is a useful starting point. Given the serious worldwide concerns regarding health and environment, a broad PFAS group restriction proposal is foreseen in line with the ECHA strategy on group-based risk management to prevent regrettable substitution. Therefore, this OECD list of PFAS would need e.g. to be complemented with PFAS registered for manufacture and import in the EU and an assessment of the hazard properties of the different PFASs. We will do our own evaluation of the scope of our proposal, but the OECD PFAS Terminology Project will be taken into account.

Why is persistency also showing ED property for the PFAS?	Persistence cannot show ED properties. Persistence and ED are different and not related properties of a substance. ED is a toxic effect. Both properties should be assessed independently.
Do you plan to include a list of CAS numbers for substances that will be subject to the PFAS restriction?	In the restriction proposal the scope will be clearly described. A non-exhaustive list of CAS numbers could be helpful for both companies and enforcement. However, regrettable substitution by new PFAS (with new CAS numbers) should be avoided. There are numerous examples of generic group entries for REACH restrictions, as well as other REACH processes. Specifically, Annex XVII of REACH currently includes restriction entry no. 68 on the manufacture, use and placing on the market of PFOA, its salts and related substances. The scope of this entry is determined by the potential for a substance to degrade into PFOA (defined on the basis that a substance includes a specific molecular structural element rather than by a list of specific substances/CAS numbers). For further information please refer to ECHA Q&As 1815 and 1816.
We are "users" of formulations which "potentially" contain PFAS substances. We only check on CAS#. Groupings do us no good. Our "capture net" consists of CAS# to determine if the substance is present. The only way we know if it is present is if it is stated in a Safety Data Sheet (SDS).	In case of this group restriction, it should be clear to all users which substances are covered. There are numerous examples of generic group entries for REACH restrictions, as well as other REACH processes. Specifically, Annex XVII of REACH currently includes restriction entry no. 68 on the manufacture, use and placing on the market of PFOA, its salts and related substances. The scope of this entry is determined by the potential for a substance to degrade into PFOA (defined on the basis that a substance includes a specific molecular structural element rather than by a list of specific substances/CAS numbers). For further information please refer to ECHA Q&As 1815 and 1816.
Even though you say PFAS substances can survive for a long time, since not all are mobile they are easily collected and have been shown to be fully destroyed in industrial waste incinerators. Shouldn't the development of proper incineration conditions and requirements	We will use a life-cycle approach in the evaluation, rather than focusing narrowly on the use phase. One argument is that a continuous release of fluorinated

regarding waste water facilities, combined with emissions testing satisfy environmental concerns?	substances into the environment is not acceptable. Their extreme persistence and the emissions linked to their production, use, and large uncertainties regarding their safe end-of-life treatment cannot be ignored.
Do you differ in the restriction process on uses of PFAS? For example due to their risk for exposure to humans. I see a difference in PFAS used in food contact material that is widely used daily and contact to others uses for a restricted group of exposed people.	Exposure assessment is a part of the preparation of restriction dossiers, so yes. The final regulation will be based on an overall evaluation of the different assessments.
Does the PFAS need a special carbon chain length like C9-C14 that these are get the REACH registration? Or as in the PFOA topic is special process for the manufacturing necessary?	The focus of the work is a REACH restriction of all PFAS and not a REACH registration. Given the serious worldwide concerns regarding health and environment, a broad PFAS group restriction proposal is foreseen in line with the ECHA strategy on group-based risk management to prevent regrettable substitution.
PFAS cover a huge range of substances. Which substances or substance classes are in focus for restriction or ban (PFOAs, PFCs, HFCs, …)?	As explained in the presentations, the starting scope of the call for evidence was that all substances containing at least one aliphatic CF2- or CF3-unit were considered to belong to the PFAS group and therefore in focus of a restriction or a ban. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined during the process. Therefore, the scope is not finalised yet.
PFAS definition in this restriction proposal include a huge range of substances, from molecules with one CF2 group till polymers composed of CF2 monomers. These substances have different eco-toxicological properties. Will be several levels of restriction for the substances depending on their hazards?	The common concern for all PFAS is their persistence i.e. that either the substance itself is persistent or the substance is a precursor of a fluorinated persistent substance that will be formed upon its degradation. We will consider different restriction options (including possible derogations) when preparing the dossier.
PFAS is a big unregulated group, some don't even have a CAS. How can/will ECHA ensure they show up properly on SDSs and/or consumer labelling?	In addition to a ban on use of manufacturing, a REACH restriction can ensure that products are appropriately labelled. According to Article 32 of REACH, suppliers who do not need to supply a safety data sheet (SDS) still need to provide relevant information about the substance to enable appropriate risk management measures to be applied.

Thank you for your answer. I guess according the existing regulations ("POP potential") they should, but I don't see then on SDS or consumers labels on what I assume PFAS containing products. "PFOS-free" is the only label on can expect, but if it's been replaced by C6 or no-PFAS stays unknown.	This could indeed be a benefit of a labelling requirement in the PFAS restriction. The current proposal on microplastics includes a requirement to include relevant information on product labels or SDS.
So far only CF2 and CF3 moieties are part of the regulation. That means CF1 such as fluorinated aromatics are not part of the regulation so far. (such as perfluorobenzoic acid used in pharma). What is the rationale of excluding them? Are they not persistent?	The main concern for the group of PFAS is their persistence in combination with supporting concerns. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS. Therefore, the scope is not finalised yet.
Will C1 and C2 fluorochemicals be covered by the restrictions of the PFAS?	They may be. They were included in the scope of the call for evidence that was conducted this summer. However, the chemical scope, including chain length cut-off of the restriction proposal has not yet been finally concluded.
ECETOC recently presented a very interesting study on "Conceptual framework for improving P assessments" using additional assessment factors when assessing the chemical persistence, such as environment conditions. Are you aware of this work, and would you consider including such additional factors/considerations when deciding on different risk management options?	Yes, we are aware of this recent work at ECETOC, Concawe and Cefic-LRI and when appropriate we will consider it.
A small quantity of short-chain (C6) fluorinated, high molecular weight polymer (0.1% on weight of fiber) extends the useful life of spot-cleanable fabrics. What weight will ECHA give to the negative environmental impacts of shortening product life by removing stain protection?	A socio-economic assessment (also accounting potential benefits of the use of PFAS) will be part of the restriction proposal.
How does the ECHA process reflect the different stages and exposures during PFAS life-cycle? Manufacture (PFAS)->Supply->Processing(intermediate)->Product(part)->System(i.e.vehicle)->Disposal (end-of-life)? At manufacture PFAS may be hazardous, at the level of exposure (i.e. vehicle) it may be safe.	Annex I of REACH, and associated ECHA Guidance, set out the various life-cycle stages that should be considered in a REACH risk assessment. Different conclusions are possible at different life-cycle stages.
Why are C1-C4 fluorinated covered by the PFAS definition in the Restriction proposal. They are validated substitutes for Greenhouse Gases: as they are typically gaseous, they break down within days in the atmosphere; also, they are neither persistent, nor bioaccumulative, nor toxic.	C1-C4 fluorinated substances are a very diverse group of substances that fall within our PFAS definition and are either persistent themselves or will degrade to persistent substances. Some are persistent and/or gaseous, some are not. Some are bioaccumulative and/or toxic, some are not. We will assess these together with the other PFASs in an overall life-cycle assessment and present our findings in the restriction

	proposal.
Why are Fluoropolymers included in the restriction proposal, even though they are regarded as "polymers of low concern" according to the OECD standard?	We will assess fluoropolymers in a life-cycle perspective including substances used during production and substances produced at end-of-life such as incineration. In general, we will consider whether derogations for selected uses are warranted.
Thank you very much for your response. Two follow-up questions: 1. Will the life-cycle assessment be global or just concerning Europe? 2. Will life-cycle assessment be re-done periodically? Or how are technological advances in production and disposal of fluoropolymers being taken into account?	For a restriction under REACH a justification for an EU-wide measure has to be given. Therefore, assessment of the EU-wide concern and PFAS used and imported to the EU market are in focus. However, global data can be used (and was also used in previous restriction proposals concerning PFAS) to support the concern and also life-cycle assessment.
Why are you focusing on persistence alone in the absence of any other shared characteristics at all? Not all substances that contain -CF2 - or -CF3 groups are soluble in water or fat. What comes after a PFAS ban? A ceramics ban? A glass ban? Durability is desirable in construction materials.	A key concern for the group of PFAS is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during their life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable.
Apparently, PTFE and similar substances for food contact use can be produced through different routes using e.g. short chain of long chain fluorinated polymers. Will it then be the PTFE and similar substances that will be restricted, or the substances used in the different routes or both?	The final scope of the restriction proposal has not yet been decided. However, it is not unlikely that both the product and the substances used in its preparation are covered as long as they are within the chemical scope.
Even though you say PFAS substances can survive for a long time, shouldn't the development of proper incineration conditions and requirements regarding waste water facilities, combined with emissions testing satisfy environmental concerns?	We will use a life-cycle approach in the evaluation, rather than focusing narrowly on the use phase. One argument is that a continuous release of fluorinated substances into the environment is not acceptable. Their extreme persistence and the emissions linked to their production, use, and large uncertainties regarding their safe end-of-life treatment cannot be ignored.
Have been told the substance Methyl Perfluorobutyl Ether is considered a PFAS, will that be covered by this restriction? When used in Cosmetics?	The CfE defined PFAS as substances containing at least an aliphatic -CF2- or CF3- unit, which will be considered during the development of the proposal. This means,

	that the substance in question is currently in scope. In addition, cosmetics is one of many uses included in the scope. Substances used in cosmetics are not excluded from a restriction under REACH when there is an environmental concern. We are at the stage of collecting data and information and the exact scope of the restriction proposal for PFAS will be determined during the process. Therefore, the scope is not finalised yet.
Is PTFE also in scope of the proposals for restriction? PTFE is listed on the OECD list, but it is used in a broad range of products, without any adequate replacement.	Yes, PTFE is in scope of the current PFAS restriction work. The CfE defined PFAS as substances containing at least an aliphatic -CF2- or CF3- unit, which will be considered during the development of the proposal. Whether or not these uses are essential will need to be evaluated. We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produces at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic.
Your criteria for the proposal is persistence. So you are taking the position that fluoropolymers, which are persistent, but not toxic, are equal to PFAs which are highly toxic. Why not consider different levels of control and restriction based on additional criteria beyond just persistence.	We will consider the different PFAS substances and polymers in a life-cycle approach, including what will happen with them at end-of-life. A key concern is persistence, while mobility, bioaccumulation and toxicity are other concerns.
Bisphenole AF is used for curing FPM materials. There are no residual monomers available for environment in finished FPM, FKM-materials (products). Why is there need of restriction?	A different perspective is that the whole life-cycle should be considered e.g. production and waste disposal/incineration. Please be aware that Bisphenole AF would also be in scope of the DE CA restriction intention with regard to BPA and related substances https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea.
Is there a list with all the 4 700 PFASs?	Yes, you can download an Excel-file of the OECD-list at their website: http://www.oecd.org/chemicalsafety/portal-

	perfluorinated-chemicals/ Here is the direct link to the Excel file http://www.oecd.org/chemicalsafety/risk-management/global-database-of-per-and-polyfluoroalkyl-substances.xlsx
Most of the PFAS are persistent but not all of them are: Will non persistent PFAS are also restricted? e.g. CF3OH?	Most PFAS are extremely persistent, either themselves or they degrade to other extremely persistent PFAS. PFAS precursors break down to stable arrowhead substances, such as different PFCA.
CF3OH is one of the few PFAS which is non persistent it degrade in at room temperature in the present of humidity to HF and CO2 so again my question will non persistent fluorinated compounds be excludes from Regulation ?	We are carefully looking at the scope of the restriction, keeping in mind the potential to degrade of the various subclasses. In the call for evidence, we used a broad scope as starting point. CF3OH is included in the broad scope as starting point.
Most of the properties shown as cause for concern are shared by salts - i.e. cooking salt. With information of real harmful effects lacking - as was presented - how do the originators plan to differentiate between PM substances which need a restriction and PM substances which do not?	There is a big difference between persistent organic substances and inorganic salts. We will do an assessment of PFASs and of their properties, including persistence, mobility, bioaccumulation and toxicity, and the assessment will be part of our justification in the final restriction proposal.
No mobility means no exposure facilitation: are you going to derogate from banning on the basis of no mobility?	We will consider the different properties of the PFASs, including mobility, in a life-cycle approach. Based on our findings we will develop our proposal and regulatory scope.
Not all PFAS have health hazards (e.g. some fluoropolymers are considered polymers of low concern) and some PFAS have proven to be not persistent. How will you take this into account in the restriction? How to make sure that PFAS that are not of concern are not restricted.	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produced at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic. We will assess available literature on human health and environmental hazards (including persistency).
Previous definitions of PFAS have suggested a definition of C(n)F(2n+1) (Buck et al. 2011). However, the definition [used for the call for evidence] is any chemical containing a CF2 or CF3 group. What is the justification for this and is this the definition that will be used in the	We will do an independent evaluation of the chemical scope of our proposal. We are familiar with the Buck et al. definition. The justification for our selected scope will

restriction?	be included in the restriction proposal when submitted.
PTFE materials are critical for many applications and will not pose the same risks as other PFAS. However, some of the substances used to make PTFE may be of more concern. How will this consideration be incorporated by ECHA?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produced at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic. In general, it will be considered whether derogations for selected uses are warranted.
Some of the chemicals that you are considering, such as many fluoropolymers, are polymers of low concern according to OECD criteria. How does this influence your assessment of whether or not to include them in the scope of the restriction?	We will do an assessment of the fluoropolymers in a life-cycle approach and the evaluation will be presented in the restriction proposal document. Potential proposals for regulatory measures will be based on this assessment.
The current definition of PFAS under this process is very broad. Has or will this definition be revised?	The scope will be considered during the development of the restriction proposal. However, we see a concern for a broad range of PFASs and the scope will be set accordingly.
There is often little info about presence and toxicity of PFAS in supply chain. Should this not be better addressed before restrictions are coming?	We believe there is enough information for us to act. The main concern for the group of PFAS is their persistence in combination with supporting concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable.
Under REACH, a Risk Assessment is required, and restrictions can only be considered if there is an unacceptable risk. How do you intend to conduct a risk assessment for a large group of substances with very diverse applications?	A key concern for the group of PFAS is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.

What about differentiation between use of chemicals and the unintended transfer into products by recycled material?	At this moment, we cannot answer this. We are aware that for example in paper recycling this can be a topic. In the past in several restrictions, a concentration limit was used to address unintentional use.
What is the rationale putting same restrictions to highly mobile and bioaccumulative and non-mobile such as polymeric PFAS?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produces at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic.
Will non-stick food contact coatings and non-stick coated food contact articles (e.g. bakeware, baking papers) be directly involved, and if YES to what degree?	We are carefully looking at the scope of the restriction. In the call for evidence we used a broad scope as starting point. Non-stick FCMs (consisting of PTFE) are included in the broad scope as starting point.
Will PFAS still be cheap and available for fundamental research at universities?	REACH restrictions shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development (Article 67(1)).
Will there be any PFAS substances banned or only restricted?	We are carefully looking to the scope of the restriction. In the call for evidence we used a broad scope as starting point. And it can be further developed during the process on the basis of further information, especially based on the evidence provided by stakeholders. The need for possible exemptions and derogations will be assessed as well in the process.
Will this not force users to select poorer materials for critical uses causing even bigger problems	We are aware of the unique and useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS.
Will you differentiate between water soluble PFAS and non-water-soluble PFAS?	We will do an assessment of PFASs and of their properties, including persistence, mobility, bioaccumulation and toxicity, in a life-cycle perspective. The assessment will be part of our justification in the final proposal. There may of course be different concerns associated with water-soluble vs. non-water-soluble substances, but at the moment we are not

	grouping based on this difference.
Would you also consider nanoparticles within the restriction?	Our restriction proposal will not consider particle size, only chemical composition. Hence, all materials fulfilling the final description will be included.
Fluoropolymers	
Are PTFE and PFA (Perfluoroalkoxy alkane) both included in the list of PFAS that are being considered for banning?	We are carefully looking at the scope of the restriction. In the call for evidence we used a broad scope as starting point. PTFE and PFA are included in the broad scope as starting point.
What evidence of harm to people and the environment is there for PTFE and PFA (Perfluoroalkoxy alkane)?	Most PFASs are considered to be extremely persistent in the environment or to degrade to such persistent substances during their life-cycle. Fluoropolymers may for example degrade to harmful PFASs during incineration.
If the concern is leachables from fluoropolymers, shouldn't this be handled by scientific studies on leachables, followed by proper regulation on residuals if landfilled?	As indicated our concern is broader than leaching from fluoropolymers. A key concern is the extreme persistence of the chemicals (also the ones used during production and emitted during the waste stage).
Regarding the concern about mobility, fluoropolymers are solids and not mobile at all in the environment. Doesn't this greatly (significantly?) reduce the risks you are suggesting (i.e. persistence and mobility)?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Substances used during production and substances produced at end-of-life such as incineration could be persistent, bioaccumulative, mobile or toxic. We will present our evaluation of these issues in the restriction proposal. In general, we will consider whether derogations for selected uses are warranted.
Some of the chemicals that you are considering, such as many fluoropolymers, are polymers of low concern according to OECD criteria. How does this influence your assessment of whether or not to include them in the scope of the restriction?	We will assess fluoropolymers in a life-cycle perspective including substances used during production and substances produced at end-of-life such as incineration. In general, we will consider whether derogations for selected uses are warranted.
Are Fluoropolymers considered as "Polymers of Low Concern"? According to the OECD Polymers of Low Concern (PLC) are those deemed to have insignificant environmental and	A different perspective on the fluoropolymers is that they may degrade to harmful PFASs during incineration,

human health impacts? It is the experts' opinion that Fluoropolymers can be considered as Polymer of Low Concern and should be registered as such. Therefore Fluoropolymers and components/products made from Fluoropolymers should be exempt from restrictions, this especially in view of the Safety and Health contributions of Fluoropolymer based products in Transport (Aerospace and Automotive), Chemical and Medical applications.	and many products containing fluoropolymers end their life in waste incineration plants. We will assess fluoropolymers in a life-cycle perspective and also consider whether derogations for selected uses are warranted.
Are Fluoropolymers considered as "Polymers of Low Concern"?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life. Fluoropolymers may degrade to harmful PFASs during incineration, and many products containing fluoropolymers end their life in waste incineration plants.
Multiple peer-reviewed scientific articles are unambiguous in articulating the effectiveness of incineration as an end-of-life mineralization tool for PFAS. Despite the strength of the carbon-fluorine bond, even the most recalcitrant of PFAS are entropically driven to decompose at temperatures above 1200°C, well within the operating window of high temperature commercial waste incinerators. At the same time, thermooxidative processes employed by even municipal incinerators have been shown to completely mineralize side chain fluorotelomer polymers, articles containing them and even PTFE high polymers at temperatures as low as 830 °C for four seconds and 1000 °C for two seconds. References: Tsang, W.; Burgess Jr., D. R.; Babushok, V. "On the Incinerability of Highly Fluorinated Organic Compounds" Combustion Science and Technology (1998) 139(1), 385 – 402. Taylor, P. H.; Yamada, T.; Striebich, R. C.; Graham, J. L.; Giraud, R. J. "Investigation of waste incineration of fluorotelomer-based polymers as a potential source of PFOA in the environment" Chemosphere (2014) 110, 17 – 32. Yamada, T.; Taylor, P. H.; Buck, R. C.; Kaiser, M. A.; Giraud, R. J. "Thermal degradation of fluorotelomer treated articles and related materials" Chemosphere (2005) 61, 974 – 984. ser, M.; Matzing, H.; Pigeon, D; Stapf, D.; Wexler, M. "Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas" Chemosphere (2019) 226, 898 – 906. I would like to warn to take it too lightly as 'Polymers of Low Concern'. As we see now also in the environmental issues regarding plastics, microplastics and nanoplastics. All polymers break down at any point into persistent breakdown products (arrowhead)	Thank you very much for the input.

Fluoropolymers are designed to provide durability for plenty of products, in line with the Green Deal and the New Circular Economy Action Plan objectives. Do you foresee any action on fluoropolymers?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Substances used during production and substances produces at end-of-life such as incineration could be persistent, bioaccumulative, mobile or toxic. In general, we will consider whether derogations for selected uses are warranted.
Polymers are not mobile, insoluble and non-transformable to other substance or degrading to bio-available PFAS. Why are macro-molecular PFAS considered in the same group as molecular PFAS?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produced at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic. In general, we will consider whether derogations for selected uses are warranted.
How can you be confident that you are at all able to assess thousands of fluoropolymers in a life-cycle perspective, and within half a year, without a thorough look at life-cycle information (which is unlikely to be fully available to you)?	The restriction dossier is planned to be submitted to ECHA in the first half of 2022. Any further information assisting the assessment of the life-cycle of fluoropolymers is welcome in the process.
Fluoropolymers are exceptionally stable which is one of their benefits. Will the life-cycle analysis compare their use against potential replacement materials? Comparing the impact of POP degradation products with CO2 emissions of alternatives that would need replacing more frequently, for example?	We will do an assessment of the fluoropolymers in a life-cycle approach and the evaluation will be presented in the restriction proposal document. Potential proposals for regulatory measures will be based on this assessment.
I'm not clear on the scope of your life-cycle analysis. Will it look at the life-cycle of the PFAS on its own? Or will the life-cycle analysis compare the environmental impact with the next best alternatives?	Life-cycle addresses the production of PFAS, use of PFAS and end of life of PFAS, including emissions to be expected from that life-cycle. Alternatives are to be assessed in line with the usual procedure for restriction proposals.
Fluoropolymers are regarded as Polymer of low concern. Will they be excluded from the restriction because they do not have the same property as other PFASs	A different perspective on the fluoropolymers is that they may degrade to harmful PFASs during incineration, and many products containing fluoropolymers end their life in waste incineration plants. We will assess fluoropolymers in a life-cycle perspective and also consider whether derogations for selected uses are

	warranted.
Fluoropolymers should be exempted. Although they are persistent, they are non-toxic and non-bioaccumulative.	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. In general, we will consider whether derogations for selected uses are warranted.
PTFE polymers are widely used to protect coating and ink films from damage during applications, processing and ultimate use of the finished item. Which sector will include these applications? Food contact materials? Transportation? Construction?	PTFE polymers and other fluoropolymers are widely used. We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Different uses of e.g. PTFE polymers will be assessed under the different studies that we are currently conducting for different applications including FCM, transportation and construction products.
Fluoropolymers that meet the OECD polymer of low concern, for example, PTFE, are non-toxic, bio-compatible, non-soluble, and immobile molecules. Any prohibitions or restrictions without exemptions or derogations will be a concern to the industry?	Most PFASs are considered to be extremely persistent in the environment or to degrade to such persistent substances during their life-cycle. Fluoropolymers may for example degrade to harmful PFASs during incineration.
"May degrade to harmful" is different than will degrade to harmful though. Several million molecules may degrade to harmful by-products that impact people or the environment, but how can one demonstrate viable risk to enable restriction in this context?	A key concern for the group of PFAS is their persistence in combination with other concerns such as bioaccumulation, mobility and toxicity and concomitant consequences of their use from direct and indirect sources during its life-cycle, e.g. potential contamination of ground, soil, and drinking water and being not retrievable. The risk assessment approaches to be used under REACH are set out in Annex I of the REACH Regulation.
How do you plan to address fluoropolymers containing non-polymeric PFAS as impurities?	We are carefully looking at the scope of the restriction. Both polymeric and non-polymeric PFAS are included in the broad scope as starting point. We have not yet discussed limit values which may be relevant when it comes to impurities.
How is (per)fluoro-rubber categorized? Cross-linked rubber is neither a polymer nor a molecule, unless you would consider the whole rubber part as one molecule.	Thanks for your question. Under REACH, rubber is typically considered as a polymer. If it would be considered as a substance then it would be subject to registration requirements.

How would be your approach towards PFAS restriction in fluoropolymers production, use in mixtures and articles?	We are carefully looking at the scope of the restriction. The production and use of fluoropolymers are included in the broad scope as starting point.
If persistence is the main common concern for high MW Fluoropolymers this would then also apply for instance to sand, coal, iron or quartz?	Persistent organic substances are very different from the inorganic materials mentioned. We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production and substances produced at end-of-life such as during incineration could be e.g. persistent, mobile, bioaccumulative and/or toxic.
In their talks the speakers referred to short and long chain PFAS. This refers traditionally to chain length C1-C14. Do you have any health and/or environmental studies available on longer chains e.g. fluoropolymers or PFPE that justify a restriction of these molecules?	Fluoropolymers, PFPE etc. will be evaluated in a life-cycle approach, including what will happen to them at their end of life. In the final restriction proposal, we will include a justification with references to scientific information.
Is polyvinylidene difluoride (PVDF) considered as a PFAS substance?	As it contains aliphatic CF2 moieties PVDF fulfils the broad definition of scope that was used in our call for evidence. The scope of the restriction proposal will be developed during the preparation of the proposal. It has not been finally decided.
Essential use	
General note: In their Chemicals Strategy <https://ec.europa.eu/environment/strategy/chemicals-strategy_en> , the Commission outlines their approach to essential uses in order to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. The five countries will take this into account during the development of the restriction proposal.	
Who can decide what is essential or not for the society?	As explained in the introduction of the webinar, we will not get into the question how essential use will be defined during this webinar.
According to the Chemicals Strategy for Sustainability, the Commission will "Define criteria for essential uses, taking into account ... the Montreal Protocol". This is expected by 2021-	We are following the general processes on the development of the concept of essential use closely, and we will align our process with the general development.

22. How will the 5 Euro countries ensure alignment between the Commission criteria and the PFAS restriction?	The indicated timelines fit the restriction proposal quite well.
The concept of "Essential Use" is not defined in REACH, how can an RMOA include this concept? Do you intend to consider the concept of essential use in the restriction proposal?	As explained in the introduction of the webinar, we will not get into the question how essential use will be defined during this webinar. In their Chemicals Strategy <https://ec.europa.eu/environment/strategy/chemicals-strategy_en> , the Commission outlines their approach to essential uses in order to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. The five countries will take this into account during the development of the restriction proposal.
The term of essential uses has not been touched as a concept under REACH Review and a restriction cannot be based today under the current legislation on essential uses except if REACH Regulation is amended. How the competent authorities are thinking of dealing with this concept?	As correctly noted, we did not discuss the term essential use today. Development of the scope is part of the work we are currently undertaking, including the issue if and how this will fit into the REACH regulation.
How do you define an essential use? Is there a specific set of criteria?	During this webinar, we will not get into the question how essential use will defined. Development of the scope is part of the work we are currently undertaking.
What do you think about defining the "essential uses" according to the Decision IV/25 of the Montreal Protocol?	During this webinar, we will not get into the question how essential use will defined. Development of the scope is part of the work we are currently undertaking. We are aware and will look into the definition of the Montreal Protocol.
What is the view of the REACH authorities on the concept of essential use of chemicals? How and where will this be defined and do you feel it is even legally possible to define what uses are essential and not?	During this webinar, we will not get into the question how essential use will be defined. Development of the scope is part of the work we are currently undertaking.
What is considered a non-essential use (statement that the aim is to restrict ALL PFAS in non-essential uses)	During this webinar, we will not get into the question how essential use will defined. Development of the scope is part of the work we are currently undertaking.
There is an internationally recognised definition of 'essential use' in the Montreal Protocol. Why look for another definition if that one fits?	Development of the scope is part of the work we are currently undertaking, including the issue if and how

	this will fit into the REACH regulation. In general, we expect that this will in part be used to consider whether derogations for selected uses are warranted.
What makes something essential for the functioning of society? Is it only protecting health or are there other critical functions? (Example: What about essential transportation? Would essential transportation include all modes of transport, including mass transit?)	During this webinar, we will not get into the question how essential use will be defined. Development of the scope is part of the work we are currently undertaking.
When defining 'essential uses', will you focus on the essentiality for society of specific applications or on the essentiality of the use PFAS, given the availability of alternatives and the properties they confer to various applications?	During this webinar, we will not get into the question how essential use will defined. Development of the scope is part of the work we are currently undertaking, including the issue if and how this will fit into the REACH regulation.
Does use of PFAS in the synthesis of pharmaceutical ingredients fulfil "essential use" criteria – and therefore exempt from a Restriction?	During this webinar, we will not get into the question how essential use will be defined. Development of the scope is part of the work we are currently undertaking.
For the essential use a Socioeconomic analysis is needed for the non essential ban.	Development of the scope is part of the work we are currently undertaking. The socio-economic implications of the restriction will be assessed as part of the development of the restriction proposal.
What is the view of the REACH authorities on the concept of essential use of chemicals? How and where will this be defined and do you feel it is even legally possible to define what uses are essential and not?	During this webinar, we will not get into the question how essential use will defined. Development of the scope is part of the work we are currently undertaking, including the issue if and how this will fit into the REACH regulation.
Some of the MSs have already established which sectors and professions are considered of systemic relevance/critical to the functioning of society, a definition along the established principle of "systemic relevance" and/or "critical infrastructure" for the functioning of society could give guidance.	Thank you for this information. It would be appreciated/helpful if further detail to references and literature could be provided and sent to restrictiePFAS@rivm.nl in order for these and other aspects to be taken into account in the discussions and development of the scope of the proposal.
Products delivering essential functionality in system relevant and critical infrastructure sectors (e.g. medical, transport, I&CT, energy, chemical) should be considered essential (see 2018/114/EC, 2020/C 102 I/03).	We are doing a literature research. For example also Montreal Protocol is mentioning essential use. It would be appreciated/helpful if further detail to references and literature could be provided and sent to restrictiePFAS@rivm.nl in order for these and other

	aspects to be taken into account in the discussions and development of the scope of the restriction proposal.
PFAS are widely used in a number of different medical devices that are essential for patients and healthcare professionals. How do you plan to assess those if no alternatives are available?	The availability of alternatives is part of the ongoing studies and will be taken into account in developing the restriction proposal.
Shall essentiality be approached in the context of socio-economic impact assessment? Is there something missing today?	During this webinar, we will not get into the question how essential use will be defined. Development of the scope is part of the work we are currently undertaking.
Will a legal definition of "essential use" be needed, considering there are plans to phase out various substances, including PFAS, from all use except "essential use"?	As explained in the introduction of the webinar, we will not get into the question how essential use will be defined during this webinar.
The notion of essential uses seems to be broader that the PFAS restriction in the context of CSS. Are you planning a wider discussion involving a wider group of stakeholders?	We are aware of this broader discussion. It is also clearly mentioned in the EU chemicals policy published by the Commission. We will have close contacts with the Commission.
Derogations and Alternatives	
Are APIs for veterinary products included in the planned PFAS ban/restrictions? Same question for the compounds used to produce/test the veterinary pharmaceuticals.	We are carefully looking to the scope of the restriction. In the call for evidence we used a broad scope as starting point and it can be further developed during the process on the basis of further information, especially based on the evidence provided by stakeholders. The need for possible exemptions and derogations will be assessed as well in the process.
Are the member states aware that any foam derogations whether they are part of a PFHxA or PFAS REACH restriction must be accompanied by a derogation for the production of C6 fluorosurfactants in order to be meaningful?	Derogations for C6 PFAS have been included in previous REACH restrictions (i.e. for PFOA, C9-C14 PFCAs). These would be considered as part of the 'baseline' for the current analysis. However, please note that C6 PFAS are within the scope of the current investigation and a proposed restriction on PFHxA, its salts and related substances proposed by Germany that is currently being considered by RAC and SEAC.

Do you foresee to exempt PFAS chemicals used as either APIs or in the manufacture of medicines from the proposed restriction?	This (and other) aspects will be part of the considerations in preparing the dossier.
Given the large scope of the PFAS RMOA and the large number of different substances, chemistries, and users, will the RMOA consider [not least for proportionality principle considerations] de minimis exemptions per user [e.g., ___ kg per year] to exempt minor users coupled with a register of such minor users and mandatory reporting of the minor use to, e.g., ECHA, to ensure traceability and monitor overall utilization.	We will consider different restriction options (including possible derogations) in preparing the dossier.
Would you consider excluding from the restriction scope also certain critical uses, such as Medical Devices and Personal Protective Equipment, as seen in the cases of the PFOA and the currently developed PFHxA restrictions? The Medical Device Regulation (EU) 2017/745 does already regulate the use of chemical substances.	These (and other) aspects will be part of the considerations in preparing the dossier.
Will there be exemptions/exclusions from PFAS restriction for substances used in veterinary medicines?	We are carefully looking to the scope of the restriction. In the call for evidence we used a broad scope as starting point, and it can be further developed during the process on the basis of further information, especially based on the evidence provided by stakeholders. The need for possible exemptions and derogations will be assessed as well in the process.
How can we be assured that life-saving medicines that rely of fluorinated functional groups are not swept into restrictions either for intermediates in the process or as critical process chemicals.	We are carefully looking to the scope of the restriction. In the call for evidence we used a broad scope as starting point, and it can be further developed during the process on the basis of further information, especially based on the evidence provided by stakeholders. The need for possible exemptions and derogations will be assessed as well in the process.
The Human and Animal Pharmaceutical sectors manufacture a variety of API that contain at least one aliphatic -CF2- or -CF3 group which would make them fall under the current broad scope of the PFAS group. Possible to narrow the scope?	This (and other) aspects will be part of the considerations in preparing the dossier.
What about the use of PFAS as intermediates? Will this use also be restricted?	This (and other) aspects will be part of the considerations in preparing the dossier.
How do ECHA validate the EHS of alternative/claimed to PFASs in a specific application at an early stage when too less information on EHS is available on a potential substituent?	Thanks for your question. The effectiveness of a restriction (how well does it address the identified risk) is considered by ECHA's committee's for risk (RAC) and socio-economic analysis (SEAC). This evaluation would

	be intended to highlight any uncertainties in the Dossier Submitter's assessment as well as any potential for regrettable substitution.
How do you plan to address uses for which there are no available alternatives, and which are essential to the attainment of the Green Deal climate neutrality ambition?	We are aware of the unique and often useful properties of PFAS from a technical point a view. However, PFAS have harmful properties as well. The proposal aims to restrict the non-essential use of PFAS. Development of criteria for essential use is part of the work we are currently undertaking.
Is there a definition of "acceptable effort" to change to an alternative of PFAS? e.g. if an alternative would imply the use of heavy steel packaging instead of an light weight plastic container, which leads to higher emission during production, transport and use, would this be in balance with the target of the PFAS initiative?	The dossier will include a general assessment of the alternatives.
Will possible alternatives be assessed from an overall Life-cycle Analysis point of view, e.g. to avoid regrettable substitution?	The dossier will include a general assessment of the alternatives. It will not include a comparable LCA.
Would you consider including a similar exemption of the PFHxA restriction proposal for critical PFAS uses in defense applications in this upcoming PFAS restriction?	We will consider different restriction options (including possible derogations) in preparing the dossier.
Analytical methods and limit levels	
Are there any on-going studies/planned intentions on implementing sum parameters as AOF and EOF for regulating PFAS?	Concentration limits based on sum parameters is one option that may be considered. Options for analysing PFASs in order to monitor the efficiency of the regulation and for enforcement, including the total organic fluorine methods like AOF and EOF will be assessed as a part of the restriction proposal.
Is a sum parameter for all PFAS not a more recommendable approach in view of the 4700 already existing compounds and the continuing development of new replacements?	It is too early to conclude on this now for this particular process. In general, the choice of limit values will need to match the regulatory level one seeks to reach. This will be assessed and described in the restriction proposal.

Available PFAS analysis methods are for water. Is there any work going on in ECHA to develop PFAS detection method in solids (Fluoropolymers)?	There is a lot of attention on development of analytical methods for PFAS in different matrices ongoing in the academic communities etc. New or advanced methods are developed and published regularly. Information on such methods will be collected and compiled during the preparation of the proposal.
How is the release into the environment defined? If PFAS are bound to an object, which is then controlled recycled is this a release? Do you have any threshold like kg/year/application to be released? If e.g. the PFAS is chemically bound to plastic, which is not release to the environment as the plastic is controlled recycled?	At the moment we are conducting several pre-studies needed for the dossier. Limit values is something we will discuss further during the development of the proposal.
Is ECHA working to develop standardised test methods for determining poly and perfluoro alkyls in various products?	No. The Commission may initiate standardisation work on analytical methods where appropriate. The availability of standard methods is not a prerequisite for a REACH restriction. However, the practicality of proposed restrictions (including enforceability) is part of the dossier submitter's assessment and is also considered by RAC, SEAC and FORUM during the evaluation of proposals after they are submitted.
Is there a harmonized analytical method for testing PFAS in articles?	There is no single harmonized method covering articles in general. However, information on analytical methods for PFAS will be collected and compiled as a part of the restriction proposal.
Is there a limitation on quantity an application is using PFAS? Is there something like a negligible quantity?	Since PFAS may be regarded as PBT-like substances the aim should be to minimise releases as far as possible. We have not yet discussed limit values.
The enforcement of restrictions requires harmonised analytical methods to detect the presence of chemical substances in the products. These analytical methods are missing for PFAS chemistries. How can the upcoming restriction on all PFAS be enforced without analytical methods?	The absence of harmonised analytical methods cannot be an argument for not having the option of introducing regulatory measures for protecting human health or the environment. In any case, the options for analysing PFASs in order to monitor the efficiency of the regulation and for enforcement will be assessed and described in the restriction proposal.

Simple answer: ECHA says its a PFAS, I say it isn't. Where does the proof lie? Do ECHA need to show it is a PFAS or do I as a potential user of a substance need to prove it is not a PFAS?	The restriction proposal will describe clearly which substances are in scope and considered to belong to the PFAS group to be restricted or banned. The concerns, risk, justification and need for EU-wide measures will be described in the dossier. The CfE describes the starting hypothesis that will be revised during the further work depending on the information obtained or to be provided on the substances in scope. Further the scope of the restriction proposal will be discussed by RAC and SEAC and decided upon by the European Commission with the Member States.
What is the stance on sum parameters like AOF (Adsorbable Organically bound Fluorine) or EOF (Extractable Organically bound Fluorine) for the regulation of PFAS in addition to the target-analytic approach today?	The options for analysing PFASs in order to monitor the efficiency of the regulation and for enforcement will be assessed and described in the restriction proposal, including both total organic fluorine methods, like AOF and EOF, and target-analytical approaches. The total organic fluorine methods are of course relevant for a broad restriction, however the selected method must match the specific parts of the regulation it aims to investigate.
Which requirements have to be achieved by a PFAS sum parameter to be considered in the regulation process?	PFAS sum parameters among other non-specific methods allow to estimate the total load of organic fluorine. In many cases the detection level is considerably higher compared to the targeted PFAS analyses. However, the options for analysing PFASs in order to monitor the efficiency of the regulation and for enforcement will be assessed and described in the restriction proposal.
Will methods for analyzing total organic fluor (TOF) be suggested/recommended in relation to the restriction as a way to ensure no intentional use of all PFAS instead of analysing individual PFAS?	TOF is a relevant method when considering a general restriction for PFASs. The method is in general developing fast in R&D groups these days. However, it has not been finally decided exactly how limit values will be proposed and what analytical methods will be suitable.
Wie kann man die Produkte "als i.O" prüfen (sauber) werden?	The restriction proposal may for example include specific limit values for different applications, and manufacturers and importers will have to make sure

	their products are within the regulatory requirements - for example by means of analytical measurements.
Further questions	
The argument that degradation products "may contain or produce" toxic or bioaccumulative substances is illogical as a premise for restriction. That argument expands to millions of molecules, and most importantly, includes no data to substantiate the claim	We will do an assessment specifically of PFASs and of their properties, including persistence, mobility, bioaccumulation and toxicity, in a life-cycle perspective. The assessment will be part of our justification in the final proposal.
Wouldn't it be easier to set up a recycling program with safety measures for products containing PFAS? Many organic chemicals form toxic substances during incineration, e.g. dioxin.	Interesting idea. However, with a widespread use of PFAS in a large number of products, such a recycling program would need to be very comprehensive. Preventing the use of such substances of high concern may be a more efficient approach.
Wouldn't it be easier to set up a recycling program with safety measures for products made of Fluoropolymers if you claim that there is risk at the time of incineration?	We will assess fluoropolymers in a life-cycle perspective including production and end-of-life such as incineration. Non-polymeric PFASs used during production will also be considered.
PFAS thresholds have been introduced in the new Drinking Water Directive. Will the restriction ensure that water resources are not contaminated in the long term? Removal in water works is extremely difficult and expensive.	Many PFASs are persistent and mobile in the aqueous environment, and one of the concerns is the contamination of water. Hence, one aim with the proposal is to avoid such contamination.
PFAS uses are not obviously declared to the public. For example food contact material has no declaration on the package that it contains PFAS. At which point of the process will be decided if further regulations are needed?	Labelling is one of the possible risk management options that are assessed in the RMOA-analysis which is a first step of the process (RMOA = risk management option analysis).
Will the restriction include extended producer responsibility (EPR) to ensure the polluter pays if for example extra treatment becomes necessary for drinking water?	It is outside of the scope of our restriction proposal to consider whether companies should be held responsible for their previous pollution. We refer to the Commission's Chemicals Strategy <https://ec.europa.eu/environment/strategy/chemicals-strategy_en> for ideas on how to address PFAS in the broader picture. However, in general we support the ambition to extend producer responsibilities which could be considered as

	part of a restriction.
How do you plan to assess the thyroid disrupting hormone activities of many PFAS? Looking at in vivo REPs (see Dutch RIVM) and in vitro REPs by PFAS CALUX looks quiet promising to evaluate this complex toxic mixture of 6000 PFAS by such HPTS screening. Why not proposing TEFs/TEQs guided PFAS level.	Persistence is considered a key concern. Eco/toxicity is also a relevant concern. The plan is to assess existing eco/toxicity data and if possible to take mixture effects in to account. For the hazard assessment we will consider all available human health relevant data but pre-dominantly take into account in vivo studies (e.g. repeated dose toxicity and reproductive toxicity studies) and epidemiological studies, while in vitro studies, such as TR CALUX, can serve as important supporting evidence. In-vitro-studies can particularly be helpful to assess and compare the mode of action, e.g. for endocrine disrupting properties, of substances. However, the mechanism on thyroid hormone-related effects (on HH) are not clear for PFAS. During the preparation of the restriction proposal no new data will be generated by the dossier submitter but all available data will be taken into account. Data from high-throughput screening assays would be desirable for as many PFAS as possible but they will not be available for all PFAS within the timeline of preparing the restriction proposal. Therefore, due to the lack of data, the concept of toxic equivalency (factors) cannot be applied but mixture toxicity will be discussed in the restriction proposal.
As a consequence of a restriction for a certain use, manufacturers may no longer produce a certain substance in lower volumes, undermining an essential use. Can you comment on this downside aspect?	This kind of supply chain impacts can be considered as part of the socio-economic analysis.