ECHA webinars

EUROPEAN CHEMICALS AGENCY

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

Questions and answers – Answers by ECHA to questions on the consultation, opinion making and the restriction process

ECHA organised a webinar on 5 April 2023 on the proposed restriction of per- and polyfluoroalkyl substances (PFAS) under REACH. This document replies to questions raised during the webinar about the consultation, opinion making by ECHA's scientific committees and the REACH restriction process. The replies have been drafted by ECHA's experts. A separate document focuses on questions about the content of the proposed restriction and replies come from the five national authorities who have prepared the proposal. You can find that document here: https://echa.europa.eu/documents/10162/2156610/230405_upfas_webinar_qa_ds_en.pdf/3f47fdcc-17c5-4b37-b758-720bb7e462f3?t=1687893645025

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

This document does not address generic restriction issues, or other aspects of REACH, which are addressed on our website.

If you need further clarification or if a specific question that you asked has not been answered, contact us. For the most up-to-date advice on restrictions, refer to our support material.

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Contents

1. Practicalities of the consultation

Question	#	Answer
Where can I find the restriction proposal and the comments submitted to the consultation? Is publishing the comments once a month a legal requirement for ECHA?	1.1	All documents relevant to the consultation, including the Annex XV restriction report (= restriction proposal) and the comments submitted to the consultation, can be found on ECHA's website. All non-confidential comments will be published on ECHA's website monthly during the consultation period. Publishing the comments on a monthly basis is not a legal requirement. In addition, the Dossier Submitter, and ECHA's committees – the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) – will respond to the issues raised in the consultations. These responses will be published on ECHA's website later, after RAC has adopted its opinion. The committees may also reflect on topics raised during the consultation in their opinions. The Dossier Submitter may do the same in the accompanying Background Document.
How can I contact ECHA to ask clarifications about the consultation and whether my substance and use could fall in the scope of the proposed restriction?	1.2	You can send us questions through our contact form: https://echa.europa.eu/contact Please, do not submit questions for clarification through the consultation or by email.
Where can I find more information about the consultation and how to take part?	1.3	You can access all relevant information regarding the restriction proposal on ECHA's website. Click "*Give Comments*" and you will be redirected to the consultation webform, where you will find instructions on how to provide comments. You can also watch the recording of the webinar and check the presentations for a step-by-step guide on how to submit your comment.
Would it be possible to translate the documents related to the proposed restriction into other EU languages?	1.4	ECHA does not plan to provide translations of the Annex XV restriction report.
Why is there no early deadline for comments in this restriction proposal consultation? Are all comments equally important regardless of when they are sent?	1.5	In this case, there is no early deadline for comments. Consultations on submitted Annex XV restriction reports usually contain both a final and an early deadline for submitting comments. The early deadline is meant to encourage stakeholders to provide information early on in the opinion-making process, so that ECHA's committees can take it into account when they discuss their first draft opinions. For this restriction proposal, the end of the consultation and the discussion of the first draft opinions in the committees are expected to coincide, hence there is no

Question	#	Answer
		need for an early deadline. While we encourage stakeholders to submit information as early as they can to facilitate the work of the committees, all information submitted by the end of the consultation is taken into account, regardless of when it is submitted.
Can stakeholders based in non-EU countries take part in the consultation?	1.6	Yes, stakeholders based in non-EU countries may submit relevant information. Make sure that you include a justification for why the information you have is relevant to the proposed restriction.
Do the textboxes in the consultation webform have a character limit?	1.7	The consultation webform has no character limit. Each field can technically store up to 64 000 characters. In addition, you can submit information by attaching files.
Can I submit information in other languages than English?	1.8	Comments can be submitted in any of the official EU languages. However, we encourage you to submit information in English, as this is the working language of ECHA's committees.
As the restriction proposal is very broad, is it possible to extend the consultation period? Are ECHA's committees able to consider information that is only available after the consultation has ended, for example if a study is finalised at a later stage?	1.9	The consultation is held in accordance with REACH Article 69(6) which defines a duration of six months for the consultation. The consultation on the restriction proposal (Annex XV restriction report) submitted by the five national authorities runs until 25 September 2023. If you wish ECHA's committees to consider your information in the opinion making, please submit by the deadline. For more information on how the committees intend to treat information received during the opinion making, see the RAC and SEAC framework for developing opinions on restriction proposals.
Can I make more than one submission to the consultation (e.g. separate by use)? When submitting in parts, should I refer to earlier submission numbers? Is it possible to update my own submission later during the consultation period?	1.10	You can make as many submissions to the consultation as you like. We advise you to clearly indicate in any follow-up submissions (either in the '*General comments'* box or, if relevant, in your attachments to the consultation) that these are complementing earlier submissions. You can identify your earlier submissions by referring to the date of these submissions. It is not possible to edit your submission later. However, you can make another submission and provide additional information in this way. Indicate clearly, which other submissions your new submission refers to. Do not submit the same information more than once.
I have confidential information that I think is relevant. How can I submit it? Do I need to disclose the name of my organisation/institution? What is the difference between submitting non-confidential and confidential information?	1.11	You have the option to submit confidential information. Such information must be submitted in *Section V* of the webform as a confidential attachment. You need to provide a valid reason for keeping information confidential. In *Section II* you can also choose to keep the name of your organisation or institution confidential. Do not include any confidential information (including the name of your organisation if you

Question	#	Answer
		don't want to disclose it) in the textboxes of the webform. You can find more information in the webform itself. Confidential information will only be used by ECHA and its committees, the Member State competent authorities and the European Commission. Confidential information will not be published on ECHA's website. In their opinions, ECHA's committees can only refer directly to non-confidential information. We, therefore, strongly suggest you only claim confidentiality where this is strictly necessary. If there is an access to documents request, ECHA is only able to keep information confidential for reasons indicated in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 regarding public access to documents. It is therefore important that you provide valid reasoning for why the information you submit is confidential (a reason could be, for example, that the protection of your commercial interests, including intellectual property, would be undermined).
Can I send consultation comments only as attachments or do I need to write something in the textboxes?	1.12	Comments can be only submitted as attachments. However, we encourage you to provide in the relevant textboxes short summaries or indications of the type of information contained in the attachments. This helps to process the comments for ECHA's committees.
Will ECHA's committees or the Dossier Submitter contact those taking part in the consultation if there are questions? Our organisation would like to meet with ECHA or the Dossier Submitter to discuss information we would like to provide. Is that possible?	1.13	Please provide any information you wish ECHA's committees to consider during their evaluation through the consultation webform before the consultation ends. If the committees need clarifications about your submission, ECHA may contact you and request additional information where necessary. For more information on how the committees intend to treat information received during the opinion making, see the RAC and SEAC framework for developing opinions on restriction proposals.
Can I submit password-protected files through the consultation?	1.14	The consultation webform allows you to submit confidential information, so we ask you not to submit password-protected files. When submitting confidential information, it is important that you provide a reason in accordance with Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 regarding public access to documents. A reason could be, for example, the need to protect your commercial interests, such as intellectual property.
Do I need to answer to all consultation questions to have a valid submission of comments?	1.15	No, you do not. All information you submit is admissible, regardless of whether you provide general information, information regarding only one, some or all specific information requests.
Can I submit videos to the consultation?	1.16	Videos (and other media) can be submitted to the consultation either as links or attachments. If they contain confidential information, they should be submitted as

Question	#	Answer
		attachments in *Section V* of the webform. Note that the maximum file size for attachments is 20MB. If videos (and other media) are included in your submission, it is important to explain why these are important.
I have relevant information. Can I send it to ECHA by email?	1.17	Please submit any information you wish ECHA's committees to consider during their evaluation through the consultation webform before the consultation ends. We ask you not to send any information or questions by email.

2. Submitting information to the consultation

Question	#	Answer
How and in what order will the committees evaluate the comments? Should stakeholders give priority to submitting certain type of information first?	2.1	There is no specific order in which ECHA's committees evaluate the comments received. While we generally encourage stakeholders to submit information as early as they can to facilitate the work of the committees, all information submitted by the end of the consultation is taken into account, regardless of when it is submitted.
How can I provide replies to specific information requests when my sector and use is not listed in the restriction proposal?	2.2	Information about sectors and uses not specifically listed in the restriction proposal is valuable and we encourage you to submit this information through the consultation. The *specific information request 6* is relevant when it comes to sectors and uses not covered in detail or not yet identified in the proposal. Remember to provide underlying justifications there. Also, indicate the sector or use the information relates to in *specific information request 1*.
If I want to give comments on a certain PFAS, do I need to have the CAS/EC number?	2.3	When you submit information relating to a specific substance, it is important that you clearly identify the substance. The easiest way to do so is to provide an EC or CAS number. If you do not have an identifier, you can also provide a chemical formula.
Is it better to submit jointly, e.g. as an association on behalf of a sector, or individually? Should the manufacturer and user submit together? Can different units in the same organisation each submit their own information?	2.4	Joint submissions are strongly encouraged. When submitting information together, for example through an association on behalf of a sector, you can more easily justify how your contribution applies to the entire sector or use. This makes it easier for ECHA's committees to take your information into account. Similarly, while it is possible for the different units in the same organisation to make individual submissions, we encourage you to submit together wherever possible. This is to ensure that ECHA's committees receive information that is representative for the whole sector or use. Joint submissions also ease the processing and analysis of your submission.

Question	#	Answer
What is the preferred format for submissions: are attachments analysed in the same way as form text? When it comes to attachments, would it be useful for you to have separate documents for different uses?	2.5	All information submitted will be analysed by ECHA's committees, regardless of the format. Keep in mind that confidential information must be submitted in *Section V* of the webform as a confidential attachment. If you submit information as attachments, we encourage you to provide in the relevant textboxes short summaries or indications of the type of information contained in the attachments. This helps to process the comments for ECHA's committees. It is important that you structure your submission in a clear way (e.g. provide a summary section, use bullet points for key topics, prioritise topics, avoid jargon), provide supporting evidence to justify the information and, if documents are attached, indicate why these are important. More information can be found in the Consultation Guidance. You ultimately decide how to structure your submission. The usefulness of separating your submission into use-specific documents depends on your circumstances. Make sure that the information you submit is representative of the relevant use or sector and clearly indicate which use or sector it relates to.
What is the difference of consultation questions 2 and 3, both are about emissions in the end-of-life phase?	2.6	*Specific information request 2* is meant for information regarding emissions during the end-of-life phase more generally, while *specific information request 3* focuses on the effectiveness of PFAS waste incineration (and the resulting PFAS emissions) more specifically.
Could you provide more details and an example of what information would be useful under specific information requests 6 relating to "missing uses"? What is the difference between "missing uses" and "other identified uses" referred to in consultation questions 6 and 8?	2.7	"Missing uses" in *specific information request 6* refers to uses not identified in the Annex XV restriction report. Through this request, ECHA calls for additional information, in particular on the alternatives and socio-economic impacts, to enable ECHA's committees to form an opinion on the proposed restriction in relation to such uses. "Other identified uses" in *specific information request 8* refers to uses and sub-uses, which have already been identified in the Annex XV restriction report. Through this request, ECHA calls for further information on alternatives and socio-economic impacts to help the committees to form an opinion. The Information Note and the Consultation Guidance contain more information on the type of information to be provided. Note that use of PFAS in firefighting foams is not included in this restriction proposal, but is covered by a separate restriction proposal on PFAS in firefighting foams.
Should we submit additional information regarding the use of PFAS in firefighting foams?	2.8	This universal restriction proposal does not cover the use of PFAS in firefighting foams, for which there is a separate restriction proposal. The two proposals are

Question	#	Answer
		complementary. That said, do not submit any information relating to the use of PFAS in firefighting foams to the consultation on the universal PFAS proposal. However, you have until 15 May 2023 to send your comments on the draft opinion of SEAC on restricting PFAS in firefighting foams. Make sure that you submit information relevant to firefighting foams only through this consultation.
Is it possible to add new exemptions or derogations or to extend the transition periods? What needs to be provided to support that? How do we know if an exemption or derogation or a request for a longer transition period is accepted? Who decides on new exemptions or derogations?	2.9	The proposed restriction contains a number of derogations, most of them time limited. In addition to the assessment provided by the Dossier Submitter, ECHA's committees will consider the information submitted through the consultation and give their opinions whether derogations are justified or not. If you consider that a derogation or a longer transition period for your use is justified, then you must submit relevant information and supporting evidence in the consultation. Requests for derogations and longer transition periods must be justified by risk or socio-economic arguments. Your submission should also include a sound justification for why the information is representative of the entire use or sector. More information can be found in the Information Note and the Consultation Guidance. The latter includes information on the implications of incomplete, unsubstantiated or no information submitted in the consultation. The European Commission, together with the EU Member States, will decide on a potential restriction based on the proposal and the committees' opinions.
The dossier has evaluated exemptions based on the evidence that no alternatives are available in time. No cost/benefit calculations have been performed. Is it sufficient also for industry to focus on the evidence of alternatives and can we leave out cost/benefit calculations in our contributions?	2.10	Article 69(6)(b) of the REACH Regulation states that socio-economic analyses are expected from interested parties during the consultation. These analyses should examine the advantages and drawbacks of the proposed restriction and cover the elements described in Annex XVI to REACH. Information on the costs and benefits of the proposed restriction are also relevant when evaluating whether and for how long derogations would be justified. If you have relevant information, for example on costs and emissions, we recommend submitting it in the consultation. Try to be as specific as possible by providing contextual information and calculations behind any estimates. Furthermore, it would be important for the committees to receive information that is representative for the entire associated sector or use. More information can be found in the Information Note and the Consultation Guidance.
What kind of data and arguments are most useful for the committees during the evaluation of the proposed restriction? How do	2.11	We encourage you to submit any information you think is relevant for the opinion making of ECHA's committees. The specific information requests of the consultation

Question	#	Answer
you define 'relevant' and 'substantiated' information?		already point to issues, where the committees would appreciate additional information during the opinion making. 'Relevant' means that the information should relate to the scope of the restriction proposal and either to the risk or the socio-economic impact assessments. It is important to be clear why the submitted information is relevant in the context of the proposed restriction. Where applicable, justify why the information is relevant for the entire sector or use. 'Substantiated' means that you need to provide supporting evidence that justifies the information and arguments you are putting forward. If you, for example, provide information on costs or emissions for your sector, make sure to present them in a way that the committees can assess the conclusions properly (e.g. assumptions taken, calculations made). More information can be found in the Information Note and the Consultation Guidance.
Will ECHA also seek evidence supporting the full ban with no derogations (restriction option 1)?	2.12	ECHA's committees will evaluate both restriction options when forming their opinion and stakeholders are encouraged to submit information relating to either or both of them.
We have identified figures in the restriction proposal, which are not correct according to our evidence. What is the best way to flag this during the consultation?	2.13	The best way to flag this is by submitting the information you have through the consultation. Make sure that you justify the relevance of your comments for the entire sector or use, where applicable, and provide robust supporting evidence where needed. In your submission, you can refer to the figure or other information in the Annex XV restriction report that you believe to be incorrect.
The list of alternatives gives a list of generic substances but does not take into account the change in technologies and technical improvements needed. Inferior properties of PFAS-free alternatives are also not considered. Will such information be taken into account by the committees in their opinions?	2.14	Changes in technologies and improvements needed to substitute PFAS with alternatives, as well as inferior properties of alternatives, are relevant when the committees evaluate the restriction proposal. If you have relevant and substantiated information about these issues, submit it in the consultation.
Is it possible that information submitted in the consultation is being ignored because it contains too many details or studies?	2.15	No, all information submitted in the consultation is considered during opinion making.

3. Opinion making in the Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) Committees

Question	#	Answer
How can I ensure that the data I submit is evaluated by RAC and SEAC and that I can see the conclusion of their evaluation in their opinions?	3.1	ECHA's committees will assess all information submitted during the consultation. In addition, the Dossier Submitter and the committees will respond to the issues raised in the consultation. These responses will be published on ECHA's website after RAC adopts its opinion. The committees will also reflect on topics raised during the consultation in their opinions, where relevant. The Dossier Submitter's assessment of the comments may also be reflected in the Background Document.
Can well-substantiated comments change the proposal?	3.2	The consultation is about providing ECHA's committees with all available information that helps them form scientifically sound opinions on the proposed restriction. It is, however, possible that the Dossier Submitter adapts the proposal based on information submitted in the consultation. If this happens, it is reflected in the so-called Background Document, which is eventually sent, together with the committee opinions, to the European Commission for decision making. Ultimately, the European Commission, together with the EU Member States, will decide on the potential restriction based on the proposal and the committees' opinions. In other words, information you submit in the consultation can potentially lead to changes in the Background Document, be considered in the committees' opinions and taken into account by the European Commission and EU Member States when they decide on the potential restriction. The Annex XV restriction report, which was submitted in January 2023 and published in February 2023, remains unchanged.
What information would the committees need to evaluate the suitability of alternatives in their opinions?	3.3	Information related to the availability, technical and economic feasibility, hazards and risks of alternatives is valuable. Also, information about the time needed to move to alternatives, including clear steps and timelines, is important. Remember to provide supporting evidence to justify any information submitted in the consultation. If this is not the case, the committees may not be able to assess the information. The Information Note and the Consultation Guidance contain more information on the type of information to be provided.
Does the Enforcement Forum also consider the information submitted in the consultation? How is enforceability of the restriction proposal evaluated?	3.4	The Forum provides advice and support to RAC and SEAC on the enforceability of the restriction proposal based on an examination of the Annex XV restriction report. The Forum does not systematically review the information submitted in the consultation. However, if needed, the RAC and SEAC rapporteurs may ask for the

Question	#	Answer
		Forum's view on specific issues that emerge during opinion making, including from the consultation. Read more about the enforceability of restrictions.
How can the committees evaluate the expected flood of derogation requests coming in through the consultation? Will ECHA's committees divide the workload? How is ECHA ensuring that stakeholders take part in all relevant meetings?	3.5	In both committees, several RAC and SEAC members are helping the rapporteurs during opinion making, including the analysis of consultation comments. Also, additional support from ECHA is in place to analyse the consultation comments. Where needed, *ad-hoc* meetings of RAC and SEAC can be organised in addition to the plenary and RAC restriction working group meetings. This has also been done in previous complex restriction cases, where such meetings have been used to allow the committees to discuss specific topics and relevant and substantiated consultation comments. In case such *ad-hoc* meetings are organised, the participation will follow the same registration procedure as in RAC and SEAC plenaries and RAC restriction working groups.
How will ECHA ensure due process and avoid conflict of interests during the opinion development?	3.6	It is essential that the opinion making is transparent and independent. ECHA has clear procedures that staff and members of the committees need to follow. Everyone working in or for ECHA needs to make a declaration of interests. Anyone with a declared interest will not be involved in the opinion making. More information can be found on ECHA's website.
Who are the appointed rapporteurs in the committees (RAC and SEAC)?	3.7	The names of the rapporteurs become public once the opinions are published.
How is RAC going to assess the different applications from a risk perspective? Should we provide sector-specific information? Will RAC prioritise specific sectors in its evaluation (e.g. based on the essentiality of the application)?	3.8	RAC (and SEAC) will evaluate the restriction proposal in its entirety. Each sector and use for which information is available will be looked at by the committees. We encourage you to submit any information you believe is relevant for the committees' work. Sector- and use-specific information is very relevant and such information has been requested as part of the specific information requests included in the consultation. When submitting information, remember to provide supporting evidence and a justification for why the information is representative to the sector or use.
During the committee plenaries of June 2023, how many stakeholders are able to contribute to the debate? How will the committees ensure that the views of the industry are represented?	3.9	You can contribute to the work of ECHA's committees on this restriction proposal and raise issues of concern through the third-party consultations (on the Annex XV restriction report and on SEAC's draft opinion). All relevant and substantiated information submitted will be assessed and considered in the opinions. Information on how the committees grant access to the regular or occasional stakeholders to observe the discussions can be found in the Approach on the Admission of stakeholder organisations to the work of the ECHA committees. The following extracts from the above document are relevant:

Question	#	Answer
		• The number of observers representing mainly industry and trade and the number of observers representing other interests [civil society] is kept at a similar level to ensure a balanced representation of different interests. • To ensure a balanced selection, organisations representing similar interests can be approached as one group and asked to make a proposal for observer representation of the whole group. Rules on rotation shall be agreed upon. For the RAC-65 and SEAC-59 plenaries in June 2023, the participation of occasional stakeholder observers and their experts for the relevant agenda item will be decided by the Chair along the above lines once all registrations to the meetings have been received (deadline is 5 May 2023). Late registrations will not be considered. At the start of the RAC-65/SEAC-59 discussions, the Chairs will allow stakeholders to make brief statements either jointly or on their own. These statements will be published as an annex to the minutes of the meetings. The ECHA Secretariat will contact the registered participants to collect expressions of interest to make such statements after the 5 May registration deadline. Given the expected high level of stakeholder interest, only very brief and focused interventions on scientific aspects will be accepted during the plenaries and working group discussions.
Since PFAS are used in almost every sector and it is difficult to quantify the number of applications, how does SEAC extrapolate from the provided data to other applications which might become essential in the future?	3.10	For the uses identified in the Annex XV restriction report, the Dossier Submitter has made assumptions regarding how the market will develop in the future. If you have more information about how the market may change in the future (either for the identified uses or new uses), you should submit this information in the consultation. It is necessary to provide supporting evidence to justify the information.
What are the roles of the two scientific committees? Who are the members and observers?	3.11	The role of RAC and SEAC is to provide an opinion on the proposed restriction. The two opinions of the committees contribute to the decision of the European Commission. RAC gives its opinion on whether the proposed restriction is appropriate in reducing the risks to the environment and to people's health, whereas SEAC gives its opinion on the socioeconomic impacts, i.e. benefits and costs to society, associated with the proposal. The members of the two scientific committees are nominated by Member States and appointed by ECHA's Management Board in their personal capacity. The members are not allowed to be given instructions by their nominating or employing Member State and must also declare any conflicts of interest on the proposal. On the other hand, Member States are obliged to support the work of their nominees.

Question	#	Answer
		In addition, it is the role of the chairs of the committees to ensure that the evaluation is independent and consistent with other opinions made by the committees. ECHA provides support to the committee members appointed as rapporteurs. Regular and occasional stakeholders observe the meetings of RAC and SEAC to ensure the transparency of opinion making. More information can be found here: RAC | SEAC
Is there an opportunity to provide comments to the combined ECHA opinion?	3.12	No, it is only possible to provide comments on SEAC's draft opinion during the 60-day consultation, which is organised once SEAC has agreed on its draft opinion.
Will the risk and socio-economic analysis weigh equally in the combined ECHA committees' opinion?	3.13	The two committees focus on different aspects when developing their opinions on the restriction proposal. RAC gives its opinion on whether the proposed restriction is appropriate in reducing the risks to the environment and to people's health, whereas SEAC gives its opinion on the socio-economic impacts, i.e. benefits and costs to society, associated with the proposal. As such, the two opinions are complementary to each other. Both opinions of ECHA's committees contribute to the decision of the European Commission and help the Commission to take a balanced view of the identified risks and of the benefits and costs of the proposed restriction.
Will the committees contact other EU institutions with responsibilities in certain sectors (e.g. the European Medicines Agency) to understand the potential impacts of the restriction?	3.14	There is always the possibility to exchange information with other EU institutions on restriction proposals when it is relevant for their activities. According to Article 110 of the REACH Regulation, ECHA cooperates with other EU bodies to ensure mutual support in their respective tasks, in particular to avoid duplication of work. More information on how we work with other EU institutions can be found on ECHA's website. ECHA has signed agreements with several of EU agencies to strengthen this cooperation, including exchanging information and scientific data, running joint projects and coordinating processes.
Can the committees or the Commission decide on derogations beyond 12 years and have there been cases in the past where derogations for longer than 12 years have been granted?	3.15	There have been restrictions proposed under REACH that included derogations without a time limit, which have been supported by ECHA's committees and reflected in the European Commission's decisions. A few derogations without a time limit have also been included in this restriction proposal (e.g. for PFAS used as active substances in plant protection products, biocidal products, and human and veterinary medicinal products). It is important to note that ECHA's committees will evaluate all derogations proposed by the Dossier Submitter and derogation requests submitted in the consultation. It is crucial to provide supporting evidence to justify any derogation requests as without adequate evidence, the requests cannot be evaluated by the committees. It is also possible that the committees consider derogations proposed

Question	#	Answer
		by the Dossier Submitter or requested in the consultation as not justified. More information on derogations can be found in the Consultation Guidance. Ultimately, the final decision on whether to grant a derogation or not is taken by the European Commission.

4. Other aspects related to the restriction process

Question	#	Answer
Where can I find a list of PFAS (CAS and/or EC numbers) subject to the restriction proposal?	4.1	The restriction proposal does not contain a list of PFAS because the substances in scope are defined by their chemical structure rather than by their numerical identifiers. Therefore, we recommend that you refer to the definition provided in the Annex XV restriction report.
Does ECHA plan to create lists of products and processes where PFAS are used?	4.2	Information about the uses of PFAS is available in the Annex XV restriction report (e.g. Annex A). ECHA does not intend to create a list of products and processes where PFAS are used.
What are the timelines for ECHA's opinion making and for decision making in the European Commission? When could the restriction enter into force?	4.3	As with all restriction proposals, ECHA aims to deliver the opinions to the European Commission in the shortest possible timeframe while ensuring proper scrutiny by the scientific committees. Once the opinions are sent to the Commission, it has three months to provide a draft amendment to the list of restrictions in Annex XVII to REACH. The final decision is taken in a comitology procedure with scrutiny involving the Member States, the European Parliament and the Council of the EU.
According to the legal text of REACH, a risk has to be demonstrated to restrict uses of substances. Is it possible to restrict substances solely based on persistence when no harm has clearly been demonstrated?	4.4	According to the REACH Regulation, a restriction can be proposed by a Member State if it considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed on a Union-wide basis. In the proposed restriction, grouping of PFAS is based on structural similarity that triggers similar hazards and risks among the substances covered, primarily related to persistence. However, the risk assessment included in the proposed restriction does not only rely on persistence. The assessment explains that persistence of PFAS in combination with other concerns, such as bioaccumulation, mobility or toxicity, leads to risks that are not adequately controlled. The grouping of PFAS and the risk assessment included in the restriction proposal will be evaluated by RAC, taking into account also any relevant and substantiated information submitted in the consultation.

Question	#	Answer
How does the proposed restriction relate to other REACH restriction processes that are currently ongoing, such as the proposals on PFHxA or PFAS in firefighting foams? Does information that was submitted in these processes need to be resubmitted to ECHA?	4.5	The assessment performed by the Dossier Submitter only takes into account existing regulations, not pending regulatory processes. RAC and SEAC have adopted their opinions on PFHxA, while opinion making is still ongoing for PFAS in firefighting foams restriction proposal. The European Commission will take a final decision on both cases together with the Member States. There are currently no other pending restriction processes under REACH on PFAS. Information submitted for the PFHxA and PFAS in firefighting foams proposals was taken into account by the Dossier Submitter to the extent possible. However, check the Annex XV report to identify information that you may want to resubmit in case it is not (sufficiently) reflected in the proposal. This will ensure that the information is available to ECHA's committees when evaluating the current proposal. The committees will only assess information submitted as part of the ongoing opinion-making for this proposal and will not access information submitted as part of other processes. Do not resubmit information associated purely with the use of PFAS in firefighting foams. This use is not included in this universal restriction proposal.
Substances used in scientific research and development are exempted from restrictions under REACH. Does that mean that also the production and sale of substances used in scientific research and development are exempted from the restriction?	4.6	REACH defines scientific research and development as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year (Article 3(23) of the REACH Regulation). The provisions for restrictions do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (see Article 67(1) of the REACH Regulation). In simple terms, a substance is exempt from a restriction if its manufacture, use or placing on the market falls within the definition of scientific research and development. For more information, see the Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) and Q&A 1304 on ECHA's website.
Is there a process in place to check that alternatives are available after the transition periods? What if they are not available?	4.7	Transition/derogation periods have been proposed by the Dossier Submitter to allow development of alternatives in specific (sub-)uses where they may not yet be available. ECHA's committees will evaluate the risks and socio-economic implications of the proposed transition/derogation periods taking into account any relevant and substantiated information received during the consultations on the Annex XV restriction report and later on SEAC's draft opinion.

Question	#	Answer
		The European Commission, together with Member States, will decide on specific transition periods based on the proposal and the committees' opinions. It is important that you provide information with supporting evidence on risks and socio-economic implications during the consultations, when requesting different transition periods. According to REACH Article 68 and 69, both the Commission and Member States can review elements of a restriction and propose amendments.
How does the comitology process work in decision making (e.g. Commission's REACH Committee)?	4.8	Information about the comitology procedure can be found on the European Commission's website.
Does the proposed restriction also apply to imported articles?	4.9	Yes. The proposed restriction refers to "placing on the market" which also covers imports into the EU market.
Where do I find the list of restricted substances in the EU/EEA?	4.10	Restrictions on substances, mixtures and/or articles are in Annex XVII to REACH. The list of substances can also be found on ECHA's website.
How does the proposed restriction relate to existing regulations targeting PFAS?	4.11	Specific PFAS are already subject to regulation. PFOS, PFOA and PFHxS are subject to the EU POPs Regulation, which implements the Stockholm Convention. Long-chain PFCAs and TDFA are subject to REACH restrictions in Annex XVII. There are also sector-specific regulations in place that may cover certain PFAS, such as the F-gas Regulation or the Biocidal Products Regulation. According to ECHA's understanding, the proposal is not meant to interfere with any existing regulations and ensures that the strictest EU regulation (including REACH restrictions) applies.
What about regulations targeting PFAS at the Member State level? How would the proposed restriction relate to them?	4.12	The REACH Regulation applies to EU Member States without the need for national implementation. A restriction is, therefore, in force once it has been added into REACH Annex XVII. The proposed restriction would effectively set a minimum standard across the EU with respect to PFAS. However, there may be already stricter requirements in place at national level that your company would have to comply with in that Member State. National authorities can also set stricter requirements in the future.