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PFHxA: the Commission's proposal

An explainer on law and implementation

Executive summary

In December 2021, the scientific committees of the European Chemicals Agency (ECHA) formulated their opinion on a REACH restriction proposal on an important family of PFAS, PFHxA and related substances.[1] In June 2023, the Commission proposed legal text that would substantially modify and weaken the measures proposed by the Dossier Submitter (DS), the Risk Assessment Committee (RAC) and the Committee for Socio-economic Analysis (SEAC), while disregarding the justifications of RAC and SEAC.

While the Commission has the legal power to diverge from the restriction proposal and opinion, it has the equally legal obligation to explain its reasons in a detailed annex,[2] which has not been published. The recitals of the proposal appear to cherry-pick passages from the opinion, overlook others and interpret the opinion in the weakest possible way.

In this report, we explain the legal background on the topic (section 3), confront the different text sources (Committees' opinion and Commission proposal) (section 4) and make recommendations to improve the effectiveness of the restriction to protect people and the environment:

- *Avoid further delays in the process to restrict PFHxA. Although this process was not what it should be, not restricting the proposed uses certainly is not either.*
- *In the light of the principle of good administration, justify any divergence from the work of the DS, RAC and SEAC.*
- *Ensure the Commission sticks to legal timelines. Ensure the Commission focuses on its legal tasks and prerogatives.*
- *Work towards full implementation of the PFHxA restriction, as proposed by the DS, RAC and SEAC.*

The reader familiar with the topic is invited to start reading from section 2.

I would like to thank Hélène Duguy from Client Earth and my colleagues Ruby Silk, Christine Hermann and Dolores Romano for productive discussions and useful suggestions.

This report has been written with the best intentions for technical, legal and logical stringency. In case you find any errors or mistakes, we would appreciate being informed.

[1] Throughout this report, we use "PFHxA" to refer to the whole family of PFHxA, its salts and related substances, i.e. all those in the proposed substance scope of the restriction. In other words: all substances that have the potential to degrade into PFHxA, the "arrowhead substance". In still other words: all C6 PFAS.

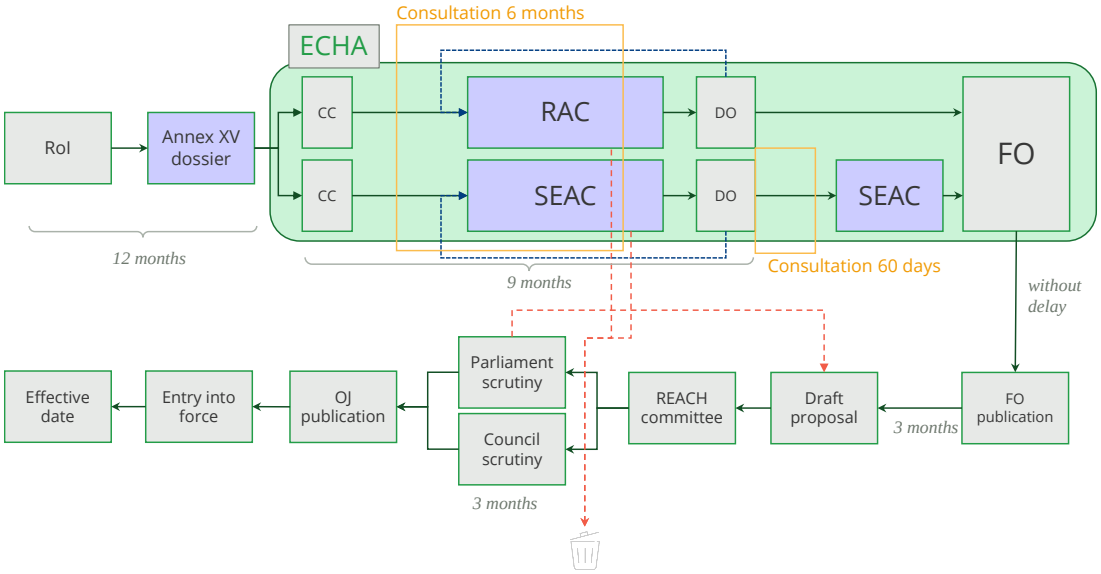
[2] See REACH Art. 73.

1. REACH restrictions[3]

1.1. Overall process

Banning a substance or a group of substances under REACH under the restriction procedure follows a well-defined logic and process (see Figure 1), with different roles and mandates for the different parties being defined in the legal text.

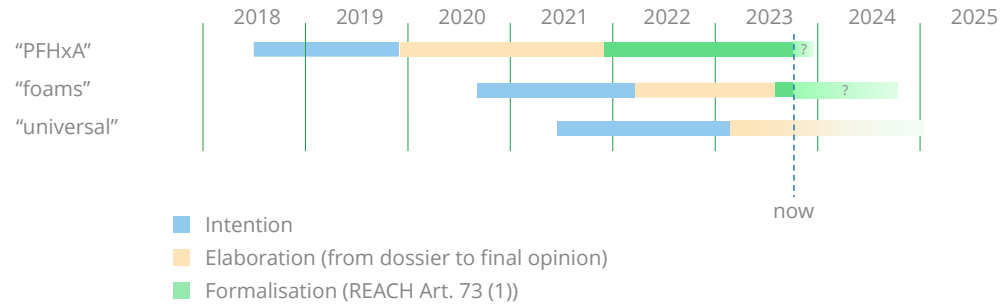
Figure 1: Schematic of the full restriction procedure in REACH. The purple shapes represent processes where substantial content is developed. Deadlines are legally established but do not correspond to real-life timing. RoI: registry of intentions, CC: conformity check, DO: draft opinion, FO: final opinion, OJ: official journal.



1.2. The process on PFHxA

Figure 2 shows the effective timing of the PFHxA and the overlapping restriction processes.

Figure 2: Simplified timeline of ongoing PFAS restriction processes.



The formalisation part so far of the PFHxA restriction can be summarised as three steps:

- The opinion by RAC and SEAC[4] was finalised in December 2021.
- ECHA submitted the opinion to the Commission in May 2022.[5]
- The Commission published the proposed legal text in June 2023.[6]

[3] We have provided an accessible description to the REACH restriction process in a recent report, available here.
[4] Available here.
[5] See recital (11) of the Commission's proposal. Art. 72(1) of REACH stipulates that ECHA should do this "without delay".
[6] Available here. Rather than the legal timeline of 3 months (Art. 73(1)), the Commission took 13 months.

1.3. Relation with other PFAS restrictions

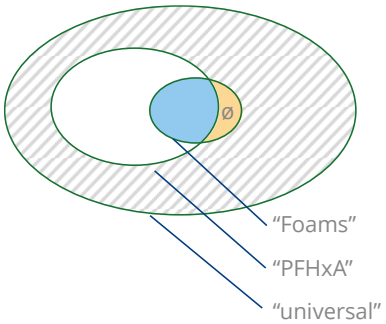
Earlier PFAS restrictions (on PFOS, PFOA, C9-C14 or PFHxS) banned substances that were industrially irrelevant by the time of the ban,[7] as can be corroborated by REACH registration data. Apart from the narrow restriction 73[8], the PFHxA restriction is the first restriction proposal covering PFAS in active use.

The PFHxA restriction has since been followed by two other restriction proposals:

- The restriction on PFAS in fire-fighting foams or "foams restriction";[9]
- The well-known universal PFAS restriction or "uPFAS".[10]

There are substantial overlaps in substance scope between these three restriction proposals, as shown in Figure 3. The foams restriction generally proposed broader derogations and longer transition periods than the PFHxA restriction.

Figure 3: Overlaps in substance scope. The orange area is void regarding current production.[11]



1.4. What is PFHxA again?

The PFHxA family is an important subfamily of PFAS, and industrially the most relevant type of small-molecule PFAS.[12] These substances are used in a broad range of applications, mostly as surfactants (in fire-fighting foams) or in side-chain fluorinated polymers (SCFPs), which are used e.g. in food contact paper or as surface treatment in clothing and on other materials.[13]

Fire-fighting foams are by design likely to be released into the environment. Likewise, while SCFPs[14] are not intended to be thus discharged, they lead to emissions: partially fluorinated monomers are reacted into a comb-like structure, with a non-fluorinated backbone and fluorinated teeth. The latter can break off the backbone via cleavage of ester linkages, being released into the environment.

Both the surfactant and the SCFP use are therefore important sources of emissions, the most impactful uses being in firefighting foams, textiles (in the broad sense) and food contact paper.

[7] See section 2.3 of this report for a more detailed discussion and references.
[8] Restricting the use of two C6 substances in spray applications; information available here.
[9] Details and documents available here.
[10] ECHA's webpage here; EEB recently released a 10-page explainer report on the topic, available here.
[11] The pale orange area is an empty set: all chemically suitable and REACH-registered substances are of the C6 type, as justified in section 12 of EEB's contribution #3566 to the consultation on the PFAS-in-foams restriction.
[12] As opposed to gaseous PFAS or fluoropolymers, to use a simple classification proposed in the uPFAS restriction dossier. See this report, section 3.3. for further explanations.
[13] See report "Avoiding the streetlight effect", section 3.2, 5 and 6, for non-specialist explanation.
[14] An in-depth study of the different architectures in SCFPs was published by the OECD in 2022.

2. Analysis of changes and inconsistencies

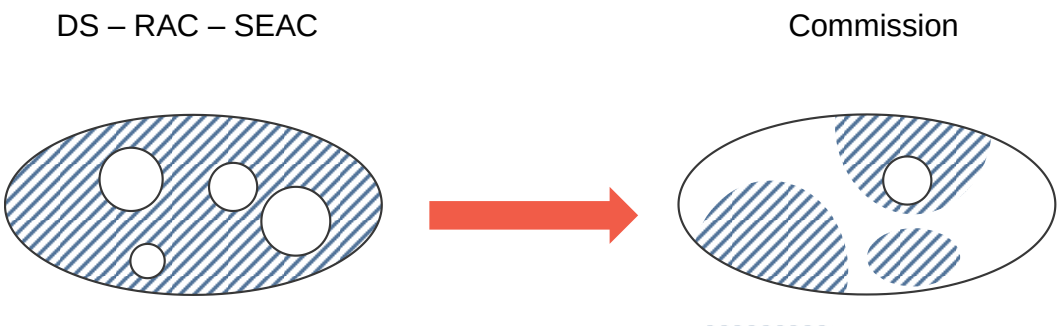
The Commission's proposal was published in June 2023 in the Comitology register[15] and sent to the REACH Committee. The draft regulation consists of two documents:

- The proposed Commission Regulation amending Annex XVII. It contains 24 recitals and two articles formally amending Annex XVII and clarifying the entry into force.
- An Annex containing the conditions of the proposed restriction in the format suitable for insertion into Annex XVII.

2.1. Broad vs. targeted approach

Probably most crucially, the Commission radically changed the approach to the restriction, shifting from a broad restriction with derogations as proposed by the DS, RAC and SEAC to a targeted restriction, as illustrated schematically in Figure 4.

Figure 4: Schematic representation of a broad (left) vs. a targeted (right) restriction:



A broad restriction with derogations is written as "generally banned, except …", whereas a targeted restriction is written as "banned where explicitly stated".

While a targeted restriction may look tidier or even clearer, the Commission's shift in approach leads to not restricting many specific uses for which the DS, RAC and SEAC proposed restricting, and possibly other unrecognised ones.

The following overview table shows differences between the measures proposed by the DS, RAC, SEAC and the Commission. Red crosses indicate no restriction.

[15] As Draft Implementing Act D090483/01, available here.

Figure 5: Overview table[16] of restriction conditions between the DS, RAC, SEAC and Commission texts.

		DS	RAC	SEAC	Commission
Actions		manufacture use placing on the market			(X) use placing on the market
General transition period		18m		36m	24m
Reporting to ECHA		efforts quantities	identity quantities		(X)
Food contact paper		18m	18m	36m	24m
Textiles, leather, hides, fur	Clothing, for GP	18m	18m	36m	24m
	Others, for GP	18m	18m	36m	36m
	Other than for GP	18m	18m	36m	(X)
Personal protection equipment		(X)	18m	(X)	(X)
Textiles in engine bays		(X)	18m	(X)	(X)
High-visibility clothing class 3		(X)	18m	(X)	(X)
Epilames		(X)	(X)	(X)	(X)
Medical devices		(X)	18m/(X)	(X)	(X)
High performance filtration media		(X)	18m	(X)	(X)
Fire-fighting foams (use)	Municipal	5y	18m	5y	18m
	Civil aviation	5y	18m	5y	5y
	Training and testing	5y	18m	5y	18m
	large tanks	12y	18m	12y	(X)
	Defence	(X)	18m	5y	(X)
	all others	5y	18m	5y	(X)

m=months, y=years, GP=general public

2.2. Missing annex

As mentioned in section 3.3, the Commission must annex detailed explanations of the reasons for diverging from the dossier and opinion.

No such annex has been published; however, the recitals in the Commission Regulation document contain some information. **The present analysis** (see the annex in section 4) **rests solely on the content of the 24 recitals of the proposed regulation as no other information was made available by the Commission.**

3. Obligations and prerogatives of the different parties

In this section, we provide the reader with a few selected and relevant examples of legal background, to save the reader the hassle of checking the text in the official journal.

3.1. RAC

REACH describes the RAC's tasks in Art. 70.[17] It requests RAC to do carry out two tasks:

- **Assess if the restriction is an appropriate measure**, i.e. if it can be assumed that it does what it is intended to do, i.e. reduce the risk. It must do so based on the data, information and reasoning in the dossier, which can be complemented and refined;

[16] This table is not exhaustive.

[17] Generally, in this report article numbers refer to REACH and recital numbers to the Commission proposal on the PFHxA restriction.

- Formulate an opinion containing this assessment and taking into account views submitted into the consultation.[18]

In other words, **RAC is not requested to assess if the restriction is "the most appropriate"** measure, but only whether it is appropriate.

This contrasts with Annex XV, part 3, which requires the DS to provide justification that "a restriction is the most appropriate Community wide measure" regarding effectiveness, practicality and monitorability in the DS's assessment of different risk management options. Such a justification is sensible, as the restriction process should not be pursued if another measure is identified by the DS as more appropriate.

However, the information needed to make that assessment is one that RAC is not meant to look at in the context of its mandate. RAC should only assess the validity of the DS's analysis about the risk. Quite obviously, the RAC opinion on whether the measure proposed is appropriate in reducing the risk plays a big part in the assessment of the most appropriate action to take.

Article 70

Agency opinion: Committee for Risk Assessment

Within nine months of the date of publication referred to in Article 69(6), the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the Member State dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in Article 69(6)(a).

3.2.SEAC

Art. 71 describes the role of SEAC in formulating its opinion, next to describing the process of the 2nd consultation in paragraphs (1) and (2). Generally, SEAC should carry out its analysis considering:

- relevant parts of the dossier,
- the socio-economic impact based on the (optional) Socio-economic Analysis (SEA),
- and input into the second consultation.[19]

Article 71

Agency opinion: Committee for Socio-economic Analysis

1. Within 12 months of the date of publication referred to in Article 69(6), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

[18] The reference to Art. 69(6)(a) corresponds to "comments on dossiers and the suggested restrictions".
[19] Surprisingly, SEAC is not requested to consider views submitted in the 1st consultation (defined in Art. 69(6)).

2. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Article 69(6)(b) and under paragraph 1 of this Article.

3. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested, the Agency may postpone the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.

3.3. The Commission

The Commission's mandate is defined in an equally simple way in Art. 73 (1).[20] The Commission is requested to carry out one or two tasks:

- Prepare a proposal for the legal text of the restriction within three months,
- **Provide reasons where the proposal diverges** from the dossier or does not take the RAC and SEAC opinion into account.

In other words, the Commission has far-reaching discretion in proposing legal text, but also the obligation to explain the reasons for diverging from the dossier or opinion. EU judges have confirmed this interpretation.[21]

Article 73

Commission decision

1. If the conditions laid down in Article 68 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 71 if that Committee does not form an opinion, whichever is the earlier.

Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences.

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[20] Paragraph 2 of the article refers to the comitology procedure to accept the Commission's proposal.

[21] T-456/11, International Cadmium Association (ICdA) and Others v European Commission, para. 45 and 46: 'the European Union authorities have a **broad discretion**, in particular as to the assessment of highly complex scientific and technical facts, **in order to determine the nature and scope of the measures which they adopt** (...). **However**, even though such judicial review is of limited scope, it requires that those authorities which have adopted **the act in question must be able to show before the European Union judicature that in adopting the act they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate**.'

4. Annex: examples

Text: Dossier, RAC and SEAC opinion[22]	EEB analysis
RAC opinion, p. 6: proposed by **RAC** are: PFHxA), its ched 1) Shall not be manufactured, used or placed on the market as substances on their own. SEAC opinion, p. 11: **proposed by SEAC** are: ity) | Conditions of the restriction xA), its ed 1. Shall not be manufactured, used or placed on the market as substances on their own. Commission proposal, annex: 07/2006, the following entry is added: 1. Shall not, from ***[PO: please insert the date = 24 months from the date of entry into force of this Regulation]*** be placed on the market, or used, in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the Commission proposal, recital 14: (14) Despite the existing uncertainties on the data available, the Commission concurs with RAC that releases to the environment and exposure to humans have been confirmed by a large set of environmental and human monitoring data, and that the manufacture of PFHxA, its salts and PFHxA-related substances, and the uses of those substances that result in releases to the environment that are not adequately controlled, should be minimised. Instead of a broad restriction, the Commission considers a targeted	Topic: Manufacturing The DS proposed restricting the manufacture of the substances in scope, and RAC and SEAC both confirmed this proposal. The Commission text leaves out the restriction on manufacturing, and provides little of an explanation. However, recital 14 recognises the risk stemming from manufacture and describes the Commission's consideration that the restriction should be limited to uses where adequate control of emissions is not given (see also the analysis of recital 14). It is no clear why the Commission estimates that emissions from manufacturing are adequately controlled. Of course, restricting manufacturing for certain end-uses but not for others becomes substantially more difficult to enforce and monitor as the approach shifts from a broad to a targeted approach.
RAC opinion, p. 7:	Topic: Reporting requirement The RAC and SEAC proposed reporting the types and quantities of PFAS used under derogations yearly to ECHA, thereby refining the proposal of the dossier submitter. The Commission proposal simply ignores this proposal. Very strictly speaking, one could argue that the condition is not applicable when there are no formal derogations, as in the

[22] The page numbers refer to the joint opinion published by RAC and SEAC; "RAC opinion" means that the passage in question refers to the RAC opinion, and likewise for SEAC.

8) From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraphs 7 (b) and (c) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. The European Chemicals Agency shall forward the data to the Commission by 31 March every year. Similar text in SEAC's opinion, p. 13.	Commission text; however, a similar condition could have applied to cases not restricted by any condition at all, but within the substance scope. The reporting requirement has various benefits: it would allow developing data over market uptake of non-fluorinated alternatives, create an incentive to substitute, and improve the information on emissions without causing much administrative burden to companies. Such a reporting requirement already exists in the microplastics restriction and could be generalised for future restrictions.
RAC opinion, p. 52: **RAC conclusion(s):** RAC agrees that a broad EU-wide restriction with targeted and carefully selected derogations and transition periods is the most appropriate measure to reduce the risks of PFHxA, its salts and related substances. However, RAC does not agree that the entire scope of the restriction proposed by the Dossier Submitter has been sufficiently justified, including for some of the proposed derogations. Commission proposal, recital 4: (4) On 3 June 2021, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that it has not been demonstrated that the restriction on PFHxA, its salts and PFHxA-related substances as proposed by Germany is the most appropriate Union-wide measure to address the identified risks. Nevertheless, RAC considers that a broad Union-wide restriction with carefully considered targeted derogations and transition periods is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness, practicality and monitorability.	Topic: "most appropriate" RAC concludes very clearly that an EU-wide restriction is 'the most appropriate measure to reduce the risk of PFHxA' – but it expresses some doubts on the scope. The Commission reads this opinion erroneously by concluding that RAC does not think a restriction is the most appropriate EU wide measure. It also misunderstands the role of the RAC foreseen under Art. 70, by relying on its assessment of what is 'most appropriate' in the light of effectiveness, practicality and monitorability considerations. However, the first sentence (although a direct quote from p. 6[23]) appears to imply that RAC should have made such a conclusion, or that the absence of such a conclusion would invalidate the dossier or the opinion. This cannot be the case, as RAC's mandate is only to conclude whether the restriction is "appropriate", not "the most appropriate" (see section 3.1). The 2nd sentence of the Commission proposal translates the RAC conclusion faithfully. The second sentence of the RAC opinion expresses especially that in their opinion, the DS did not sufficiently justify some of the proposed derogation: indeed, RAC substantially shortens the list of derogations in their proposed conditions (e.g. the DS's conditions 5a, 6, 8a, 9b-e) on grounds of their insufficient justification.

[23] On p. 6, this passage is closely followed by the table of conditions proposed by RAC, which are substantially more far-reaching than the Commission's proposal. The spatial closeness rather suggest that RAC proposed their conditions in spite of uncertainties, and that they modified the DS proposal to make it the most appropriate one.

<table>
<tr>
<td>RAC opinion, p. 39:

Therefore, RAC considers that it is not possible to conclude quantitatively on the magnitude (or likely range) of emissions of PFHxA, its salts and related substances from the different uses within the scope of the proposed restriction (with the exception of some sectors[9]). In addition, for several uses, there is insufficient information to conclude on the effectiveness of operational conditions and risk management measures to control releases.

Nevertheless, based on a qualitative evaluation of the available information[10], RAC concludes that releases to the environment from wide-dispersive uses[11] within the scope of the proposed restriction are inevitable (i.e. the conditions of use mean that releases cannot be controlled by specifying operational conditions and risk management measures) and that the largest emission sources are from textiles, paper and cardboard (food contact materials) and municipal firefighting foams. Other wide-dispersive uses also contribute to releases.</td>
<td rowspan="2">Topic: "wide dispersive uses" (WDUs)
RAC made two distinct statements, neither of which is rendered faithfully by the Commission's wording:
Operational conditions and RMM's are not sufficient to avoid emissions from WDUs in general.
The three WDUs mentioned are the largest emission sources.
The RAC opinion can be summarised as follows: there isn't enough information to quantify emissions, nor, in many cases, to conclude that measures in place are sufficient. Therefore, and based on available information, it is concluded that they are not sufficient. It can be concluded that textiles, food contact paper and municipal firefighting are the top emission sources.
The Commission statement suggests that RAC only supported measures on the three uses mentioned. However, RAC obviously proposed much more far-reaching measures.
RAC certainly did not suggest restricting these three WDUs only (see their proposed conditions) and implementing RMM in other uses (which the Commission proposal does not even propose).
The Commission wording rather suggests that RAC concluded: The DS's proposal is useful for textiles, food contact paper and municipal firefighting (but not for others).
(see also the next entry)</td>
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<td>Commission proposal, recital 5:(see also the entry after the next)

(5) RAC supported the restriction as proposed by Germany regarding the uses where it is not possible to implement risk management measures to minimise emissions, especially wide dispersive consumer uses in food contact materials, in textiles as well as in firefighting foams used for municipal firefighting, which comprise three major emission sources. However, based on the limited information available on the conditions of use and the effectiveness of risk management measures, RAC could not conclude on whether certain other uses contribute to the identified risks, such as chrome plating and firefighting foams used at industrial installations. For those other uses, the uncertainties around the current conditions of use and effectiveness of risk management measures are too large to conclude that the restriction as proposed by Germany was the most effective risk management option.</td>
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<td>RAC opinion, p. 45:

RAC conclusion(s):

RAC concludes that there is insufficient scientific data to completely evaluate whether implemented operational conditions and risk management measures are sufficient to address the risks, specifically for hard (functional) chrome plating and for firefighting at industrial installations. Nevertheless, for widespread uses, such as in paper and cardboard, textiles and municipal firefighting foams, operational conditions and risk management measures are clearly not appropriate and effective to control the identified risk. This conclusion is elaborated in the section of the opinion on the "Effectiveness to address the identified risk".</td>
<td rowspan="2">Topic: "hard chrome plating and industrial firefighting" (see also previous entry)
Here the difference between the RAC conclusion and the Commissions' rendering is obvious: RAC approximately stated that with available information they could not conclude that RMM's are sufficient. Nevertheless, they propose to delete the DS's derogations on hard chrome plating (5a) and industrial firefighting (large tanks, 8a), i.e. to restrict these uses This is an implicit application of the precautionary principle[24], in the Commission's official reading of the principle.[25]</td>
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<td>Commission proposal, recital 5:

(see previous entry)</td>
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[24] Which underpins REACH, as per Art. 1(3).

[25] See the Commission's report *The precautionary principle: decision-making under uncertainty*, available here. Although the title says it all, a useful quote may be: "Where there is scientific uncertainty about the full extent of possible harms but 'doing nothing' is also risky, decision-makers may use the precautionary principle."

<table>
<tr>
<td>RAC opinion, p. 9:
management measures, RAC could not conclude on whether certain other uses[3] contribute to the identified risk. This was on the basis that the uncertainties around the current conditions of use and effectiveness of RMMs are too large to conclude that the proposed restriction (a ban on use) was the most effective risk management option. Furthermore, RAC does not support the justification for most of the derogations proposed by the Dossier Submitter as

[2] Textiles (all categories), paper and cardboard, municipal firefighting foams, firefighting foams for defence applications, printing inks, photographic applications, building materials, impurities/constituents in fluoropolymers (incl. fluoroelastomers), medical devices (with the exception of coating for hearing devices and implantable medical devices), cosmetic products, and mixtures for consumer uses.
[3] Chrome plating, firefighting foams used at industrial installations/sites with containment, optical fibres.

Commission proposal, recital 5: (see also the entry before the previous)
conditions of use and the effectiveness of risk management measures, RAC could not conclude on whether certain other uses contribute to the identified risks, such as chrome plating and firefighting foams used at industrial installations. For those other</td>
<td>Topic: "hard chrome plating and industrial firefighting"
The Commission text in recital 5 draws on the RAC opinion's text on p. 9; however, it crops the RAC text. RAC stated that they could not conclude on a contribution from firefighting foams used at industrial installations/sites with containment, as well as from optical fibres.
RAC nevertheless proposed to restrict the use of firefighting foams at industrial sites (with or without containment) and to delete the DS's temporary derogation condition 8a. SEAC was more closely aligned with the DS: both proposed to restrict uses on industrial sites in general, and to grant a transition time of 12 years only for uses on tanks larger than 500 m^2 (DS condition 8a) or 400 m^2 (SEAC condition 7a).</td>
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<td>RAC opinion, p. 7:
5) Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to:
(a) semiconductors and semiconductor-related equipment.

6) Paragraphs 1 and 2 shall not apply until XX XX XXXX [10 years after the entry into force] to:
(a) Coating for hearing aid devices.

7) Paragraphs 1 and 2 shall not apply to any of the following:
(a) a substance that is to be used, or

Commission proposal, recital 6:
(6) Furthermore, RAC did not support the justification for most of the derogations as proposed by Germany as there was insufficient information available to conclude that releases from those uses were minimised. However, in the event that a restriction would be imposed, RAC supported derogations for the following uses as credible information on the minimisation of releases from those uses was available: semiconductors and semiconductor related equipment, epilame in watches, coating for hearing devices, implantable medical devices and transported isolated intermediates.</td>
<td>Topic: "insufficiently justified derogations"
Superficial reading of this text will not reveal what is left out: that RAC proposed not derogating, i.e. restricting uses for which there was insufficient information. As opposed to this, the Commission proposes not restricting these uses.
For the uses for which there was sufficient information, RAC supported time-limited derogations for 12 years for semiconductors and semiconductor related equipment (RAC condition 5a), 10 years for coating for hearing aid devices (6a) and open-ended derogations (7a-c) for the others.</td>
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<td>RAC opinion, p. 10:
uses may have not been identified and assessed. RAC also notes that standard analytical methods for the substances and matrices within the scope of the proposed restriction need to be developed. However, RAC concludes that, in general, analytical methods are commercially available to monitor exposures and the implementation of the restriction. In summary, although there are uncertainties, RAC is of the opinion they do not

RAC opinion, p. 143:</td>
<td>Topic: standard analytical methods
Most of recital 7 is a literal quote of the RAC opinion (p 10); however, the Commission changed "need to be developed" to "are required to be developed". While the latter sounds like a precondition, the former may simply mean that they unfortunately do not exist yet. A more careful consideration of p. 143 confirms this intention: RAC strongly recommends</td>
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Since no EU-standardised analytical methods are yet available to analyse PFHxA, its salts and related substances, RAC strongly recommends the development of standardisation of such methods (analysis of PFHxA and TOP assay), including the extraction process, in line with the recommendations and activities for previously regulated PFASs. RAC takes note that a standardised method for analyses of PFASs, including PFHxA, its salts and related substances in textiles is under development by CEN (European Committee for Standardization) within the technical committee TC248/WG26, "EC restricted substances in textiles". RAC agrees with the Dossier Submitter that a lack of standard methods for the substances in the restriction should not be considered a hindrance to the enforceability or monitorability of the restriction as the situation mirrors the same circumstances as for the previously adopted PFAS restrictions. SEAC opinion, p. 23: SEAC considers that the proposed restriction is in general practicable, enforceable and monitorable. However, SEAC notes Forum's opinion that the restriction can be regarded as enforceable, as long as it is clear which substances are in the scope of the restriction and that reliable normative test methods are defined covering all types of regulated substances. SEAC agrees that these are relevant points to clarify to improve the enforceability. Commission proposal, recital 7: (7) RAC agreed with the concentration limits and general transition period as proposed by Germany. RAC also noted that standard analytical methods for the substances and matrices within the scope of restriction as proposed by Germany are required to be developed. However, RAC concluded that, in general, analytical methods are commercially available to monitor exposures and the implementation of the restriction as proposed by Germany. Commission proposal, recital 10: (10) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1), point (f), of Regulation (EC) No 1907/2006, was consulted during the restriction process and its opinion has been taken into account. SEAC noted the Forum's opinion that the restriction as proposed by Germany can be regarded as enforceable, as long as it is clear which substances are in the scope of the restriction and that reliable normative test methods are defined covering all types of regulated substances.	standardisation of methods such as the analysis of PFHxA and the TOP assay.[26] They also clarify that non-availability of standard methods[27] should not be considered detrimental to enforceability[28] – and that the same drawback holds for restrictions finalised years ago (such as that on PFOA and related substances). In recital 10, the Commission quotes the SEAC opinion (the document), while eliminating SEAC's opinion (the view), keeping solely the Forum's opinion. Thereby recital 10 can be read as if the prior standardisation of analytical methods were a *sine qua non* for enforceability. SEAC actually makes the explicit statement that the proposed restriction is "practicable, enforceable and monitorable", and that development of reliable normative test methods would improve enforceability – thereby toning down the Forum's opinion. Imperfect enforceability must not be mistaken for lack of enforceability.
SEAC opinion, p.23: SEAC considers, however, that it has not been demonstrated that the restriction as initially proposed by the Dossier Submitter is the most appropriate Union wide measure to address the identified risks. Even if SEAC cannot conclude whether the conditions of the proposed restriction, as modified by SEAC, are the most appropriate measure to address the identified risks either, SEAC proposes conditions based on the currently available information.	Topic: "most appropriate" Recital 8, in analogy with recital 4, states that SEAC could not conclude that either the DS proposal, or their own modified version were the "most appropriate" measure. As explained in section 3.2, SEAC is not legally not explicitly required to conclude positively on whether the measure is appropriate or the most appropriate. The opinion acknowledges the relative

[26] The latter (total oxidisable precursors) is a method that allows detaching the fluorinated side-chains from the SCFPs by oxidation, and thereby quantifying them. The standard under development at CEN, however, rests on extraction after alkaline hydrolysis or methanolysis, a milder and more general method, as explained in contribution #878 to the consultation. Both methods could also be used for the PFOA or the C9-C14 restriction.

[27] i.e. methods defined by e.g. an ISO or EN standard, as opposed to standardised methods used commercially, described in the open literature etc.

[28] On the same p. 143, RAC also explains that the TOP assay, like other analytical methods including a blank sample, may underestimate true concentrations, but will not overestimate them. In other words, potential shortcomings of the method would be in favour of the infringing actor.

<table>
<tr><td>Commission proposal, recital 8:

(8) On 8 December 2021, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion concluding that it has not been demonstrated that the restriction on PFHxA, its salts and PFHxA-related substances as proposed by Germany is the most appropriate Union-wide measure to address the identified risks, taking into account its socio-economic benefits and costs. SEAC considered that a restriction on PFHxA, its salts and PFHxA-related substances is, in general, an appropriate measure to address the identified risks. However, based on the limited available information on socio-economic impacts and emission estimates, SEAC could not conclude whether the conditions of the restriction, as modified by SEAC, are, as a whole, the most appropriate measures to address the identified risks. Nevertheless, SEAC concluded on the socio-economic benefits and costs of a restriction for certain uses, where information on socio-economic impacts was less uncertain. SEAC took into account RAC's conclusions on effectiveness of risk management measures and the minimisation of emissions, the irreversibility of emissions of PFHxA to the environment, the information available on alternatives, the possible functional losses and socio-economic impacts. SEAC concluded that restricting the uses in consumer apparel textiles, firefighting foams in municipal and mobile firefighting, paper and cardboard as food contact materials and consumer mixtures is likely not an inappropriate measure, in terms of its socio-economic benefits and its costs, to address the risk, and that restricting the use in cosmetic products is likely an appropriate measure, in terms of its socio-economic benefits and its costs, to address the risk.</td><td>irrelevance of the conclusion on "most appropriate" as they state that it did not keep them from proposing conditions – this aspect, however, did not find its way into the Commission text.
Regarding specific measures, it goes without saying that the word "inappropriate" was not used by the SEAC, as opposed from what the Commission text suggests. However, in SEAC's overview table on p. 127 and following, SEAC notes that restricting the four uses mentioned by the Commission is "likely not disproportionate", and that for cosmetics, restricting is "likely proportionate". SEAC uses the proportionality assessment to decide whether to grant time-limited derogations, not to decide whether to restrict. SEAC indeed proposes to restrict in all five cases without a time-limited derogation. However, overall SEAC proposes restrictions (with or without time-limited derogations) for many other uses rejected by the Commission, e.g. for uses of fire-fighting foams.</td></tr>
<tr><td>(Recital 9 appears to be a truthful rendition of the opinion.)</td><td></td></tr>
<tr><td>RAC opinion, p. 43:[29]

RAC conclusion(s):

RAC agrees that threshold approaches may underestimate the risk of PFHxA to the environment and human health due to the continuous increase in environmental stocks and, subsequently, increases in environmental and human exposure. While PFHxA does not seem to have high bioaccumulation potential, and therefore does not meet the criteria for a PBT/vPvB substance, RAC agrees that the properties of PFHxA warrant a case-by-case risk assessment approach where, in analogy to PBT/vPvB substances, any releases and exposures should be regarded as a proxy for a risk to the environment and human health. Therefore,

Commission proposal, recital 12:

(12) Taking into account the Annex XV dossier and the opinions of RAC and SEAC, the Commission considers that an unacceptable risk to human health and the environment arises from the use and placing on the market of PFHxA, its salts and PFHxA-related substances in certain mixtures and in certain articles, which needs to be addressed on a Union-wide basis.</td><td>Topic: unacceptable risk
In recital 12, the Commission states what it considers unacceptable risk: namely the risk linked to certain mixtures and in certain articles: the ones for which the Commission proposes a restriction.
This in turn suggests that the Commission considers the risk acceptable when linked to the same substances, but arising from other mixtures and articles. For this deviation from the RAC and SEAC opinion, no explanation of the detailed reasons (as per the legal provisions, see section 3.3) is provided either.
RAC (and SEAC) both state that releases and exposures all contribute to risk, which is overall unacceptable. They did not provide a distinction between unacceptable and acceptable parts of the risk, nor of what fraction of the unacceptable risk would be considered acceptable (nor of course any explanation for their reasoning).</td></tr>
<tr><td>(Recital 11 appears to be factually correct.)</td><td></td></tr>
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[29] The highlighted text exists with identical wording in the SEAC opinion, p. 118.

Commission proposal, recital 13: (13) The Commission considers that it is not demonstrated that the proposed restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks, taking into account that the data presented on emissions, risk reduction and socio-economic impacts are uncertain and important data are missing. RAC clearly indicated that the reported quantitative release estimates are unreliable due to numerous inconsistencies between different sections of the Background Document to the Opinion on the Annex XV dossier[5], insufficient justifications for the assumptions made and significant gaps in the information presented or in the reporting of the underlying calculation methodology for the different use sectors.	Topic: uncertainties In the crucial recital 13, the Commission reiterates the argument of "non-demonstration" of "most appropriate". Such a demonstration is not required from either RAC or SEAC, and certainly not from the Commission. While the Commission is obviously at leisure to add tasks to their own legal obligations, it is difficult to conceive how the outcome of such a task can legally be used to diverge from the Committees' opinion. The Commission then uses the argument of uncertain or missing data as a justification to diverge from the RAC and SEAC opinion, while the two Committees clearly made their proposals for conditions considering the situation, and in spite of uncertain or missing data.[30] The Commission's disregard for the RAC opinion is made clear in the second half of recital 13: the fact that the RAC proposed conditions for the restriction, after all, is not even mentioned. The Commission's wording is inspired from the RAC's opinion (p. 38-39), where the statements about uncertainties are followed by a "nevertheless", leading to the statement on the insufficiency of operational controls and risk management measures (see also the analysis of recital 5).
(Conditions proposed by the DS, RAC and SEAC, see the overview table in section **Error! Reference source not found.**) Commission proposal, recital 14: (14) Despite the existing uncertainties on the data available, the Commission concurs with RAC that releases to the environment and exposure to humans have been confirmed by a large set of environmental and human monitoring data, and that the manufacture of PFHxA, its salts and PFHxA-related substances, and the uses of those substances that result in releases to the environment that are not adequately controlled, should be minimised. Instead of a broad restriction, the Commission considers a targeted restriction as the most appropriate Union-wide measure to address the identified risks. The Commission considers that the restriction should be targeted to those uses for which RAC concluded that it is not possible to implement risk management measures to minimise emissions and SEAC concluded that restricting that specific use is likely appropriate or likely not inappropriate in terms of socio-economic benefits and costs. For those uses, the Commission considers that the risk is not adequately controlled, alternatives are available and socio-economic costs are likely to be limited in comparison to the human health and environmental benefits.	Topic: broad or targeted? The equally crucial recital 14 is the Commission's word of command towards a targeted restriction (see section 2.1), with limited targets, and an own consideration of adequate control despite the proposals of the DS, RAC and SEAC. The Commission is clear about their deviation from the proposal, yet no explanation -let alone detailed reasons – are provided. The misquote of "appropriate" and "inappropriate" (see analysis of recital 8) is repeated another time.
Commission proposal, recital 16: would lead to functional losses with significant negative impacts. Given the possible socio-economic impacts related to functional losses where alternatives do not provide sufficient oil and stain repellence, a longer transition period for textiles other than in clothing and related accessories for the general public is considered to be justified.	The text appears mostly correct, although it does not explain the deviations of the Commission proposal from dossier and opinions. Only the last sentence is inconsistent with the conditions proposed: the highlighted text should have been rephrased as follows to correspond to the watered-down condition (2): *a longer transition period for textiles for the general public other than in clothing and related accessories is considered to be justified*.

[30] Concluding only on fully certain and complete data is often colloquially referred to as "paralysis by analysis".

Commission proposal, recital 17: (17) On 14 January 2022, the Agency submitted on behalf of the Commission a dossier[6] pursuant to Article 69(1) of Regulation (EC) No 1907/2006, proposing to restrict the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS) in firefighting foams. PFHxA, its salts and PFHxA-related substances are in the scope of that restriction proposal. The Commission considers that a decision on restricting the use of PFHxA, its salts and PFHxA-related substances in most firefighting foams uses is more appropriately reached based on the restriction dossier for all PFAS in firefighting foams. However, given that alternatives are widely available and already in use for PFHxA, its salts and PFHxA-related in firefighting foams used for training and testing, for municipal fire services and for civil aviation, the Commission considers that restricting those uses should not be delayed.	Topic: fire-fighting foams This recital deals with the scope overlap between the PFHxA and the foams restriction (see also section 1.3). The Commission carves out several important uses of firefighting foams from the PFHxA restriction, arguing that restricting them can be done "more appropriately" in the firefighting foams restriction. This statement can hardly count as a *detailed explanation of the reasons* for diverging from the dossier and the scientific opinions. The Commission then states that restricting the remaining uses should not be delayed – but why should the others be delayed?
(The remaining recitals 18-24 do not appear to contain noteworthy inconsistencies with the dossier, the opinions, or the legal requirements.)	