1. General comments and answers to specific information requests

1.1. Specific information requests

In addition to providing an opportunity for interested parties to submit general comments on the proposed restriction, SEAC Rapporteurs specified a series of information requests as part of the consultation on the following topics:

1. Reporting requirements and possible issues in collecting information by the actors indicated;
2. Concentration limits for PFHxA, its salts and related substances in fluoropolymers;
3. Coating of electronic devices;
4. Cladding of optical fibres;
5. Medical devices and medical textiles;
6. Antifog face shields;
7. Firefighting foam mixtures for class B fires used in large tanks;
8. Technical textiles used in engine bays;
9. Filtration and separation media;
10. Photographic coatings applied to papers and inkjet photo media coatings.

These requests were published in the 'SEAC DO info note' on ECHA's website[1].

1.2. Overview of comments received

SEAC received 161 comments on the draft opinion from companies (93), Industry or trade associations (44), NGOs (8), national authorities (6), individuals (6), civil society (2) and other contributors[2] (2) – see Figure 1.

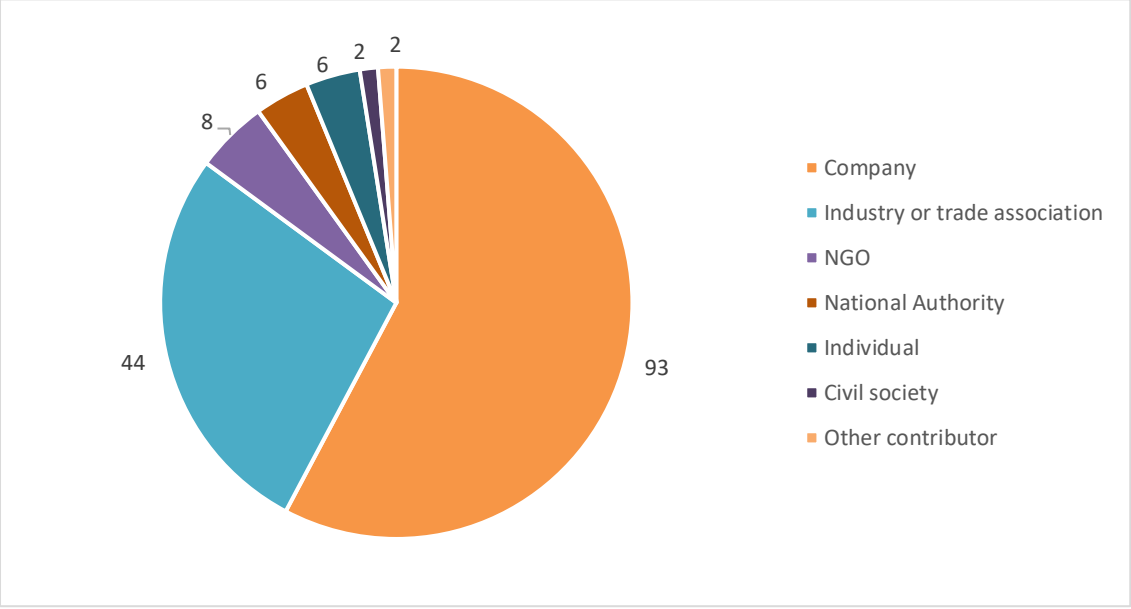

Figure 1. Number of comments received by respondent type

[1] See https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d accessed on 27.09.2021 at 10:03.
[2] One national fire brigade association, and the 'Global PFAS Science Panel'.

The comments received covered a wide variety of uses: textiles (60), filtration and separation media (45), fluoropolymers (35), medical devices[3] (33), electronic devices (25), fire-fighting foams (20), building materials (11), semiconductors (9) – see Figure 2.

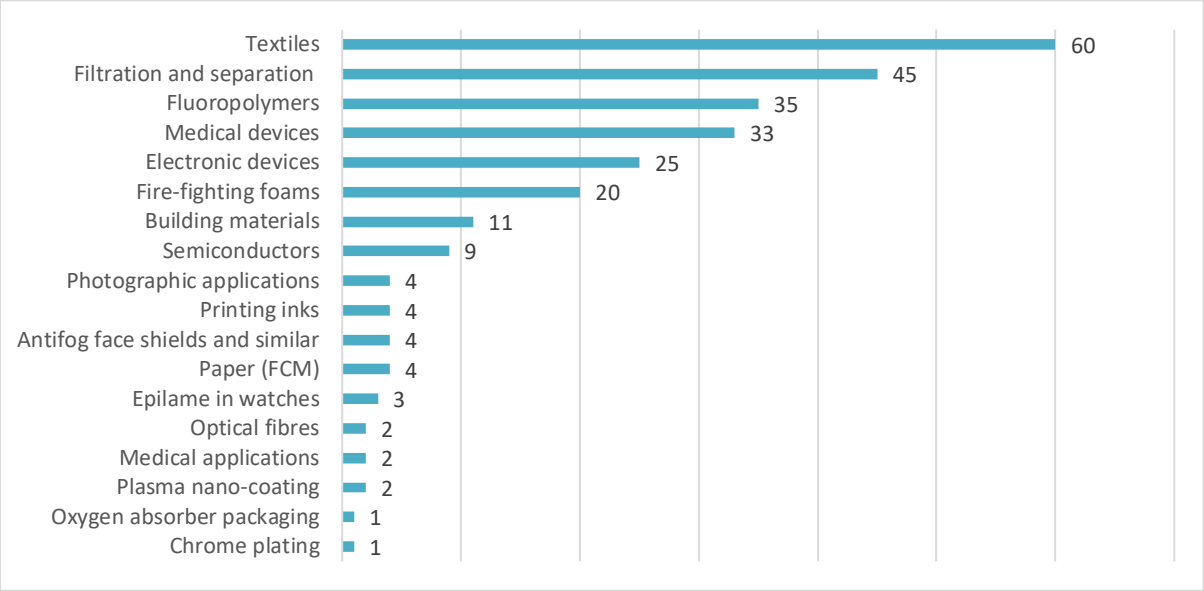

Figure 2. Number of comments received by use

2. SEAC rapporteurs' responses

The SEAC rapporteurs would like to thank the many interested parties that submitted comments and information to the consultation on the SEAC draft opinion.

The SEAC rapporteurs note that many of the comments received were similar in nature and concerned common themes or uses. Given the large number of comments received, and to improve the clarity of the responses, the SEAC rapporteurs have prepared general responses to common themes. The SEAC rapporteurs took into account also comments that included only confidential information. However, no specific reference to confidential information can be made in these non-confidential responses. These general responses summarise the nature of the comments received and how the SEAC rapporteurs have responded to them, e.g. by undertaking revisions to the SEAC draft opinion where considered justified and necessary.

In some cases the SEAC rapporteurs have responded to comments by revising the wording of the 'conditions of the restriction' (i.e. the wording of the restriction as proposed by SEAC on pages 6-9 of the draft opinion). Respondents should note that the wording of the conditions of the restriction in the SEAC final opinion is intended to express the intention of SEAC. The European Commission would ultimately decide on the precise legal wording used to update Annex XVII of REACH in the event that a restriction was adopted.

The comments received have been grouped based on their content and the uses they discuss and one coordinated reply is given where the rapporteurs found that a subject-specific response might be helpful.

[3] Medical textiles are also counted in the 'medical devices' use.

Cross-cutting topics

1. Reporting requirements

#822, 840, 855, 868, 872, 884, 889, 891, 895, 897, 898, 907, 908, 910, 912, 913, 914, 916, 918, 919, 920, 921, 932, 937, 941, 947, 955, 964, 973

The SEAC rapporteurs would like to thank stakeholders for providing their view on the reporting requirement included in the restriction proposal by the Dossier Submitter. The reporting obligation should facilitate the gathering of data on derogated uses where there is limited information on use quantities in order to use this data in the course of a future review of the restriction. SEAC regards a reporting requirement in principle as a useful way to collect information that is currently not available to the decision maker but regarded as important to take informed decisions on future restrictions/derogations at the point in time of performing a review. However, SEAC notes from the numerous comments provided by stakeholders that the information may be difficult to gather and process due to several issues (e.g. long and complex supply chains; challenges specifically for importers; on which level of the supply chain the information is available and reporting should therefore be implemented (downstream user level, upstream actors, end-use level, etc.)). The details on the information available to SEAC from the restriction dossier and the consultations performed is available in SEAC's final opinion.

Overall, SEAC finds that it might be the most practical to set a communication requirement on the content of the substances in question for each actor in the supply chain and clarify that the reporting requirement is on the final downstream actor. That way the volumes used in the different applications could be made separate. Such a communication requirement could be comparable to the one currently included in the proposed restriction on intentionally added microplastics. SEAC notes that the microplastics restriction did not include an obligation to report the exact identity of the substance but that there are ways of dealing with the confidentiality aspect, for example by using unique identifiers (similar to what is done in poison centre notifications). SEAC underlines that the costs of such a measure have not been estimated. The committee expects that those could potentially be relatively low compared to other costs caused by the restriction, since the information should be already there (at the top and along the chain) and what is necessary would be mostly calculation and paperwork. The costs of the communication requirement discussed in the microplastics restriction may also give some indication of the possible magnitude. SEAC notes that it could be difficult for importers of articles to get the information on the presence of the substances since actors outside of the EU would not be bound by the communicating requirement.

2. General transition period

#844, 883, 884, 890, 897, 917, 929, 942, 957, 868

The SEAC rapporteurs would like to thank stakeholders for their comments on this subject, both those supporting the proposal of 36 months and those not supporting it.

Several industry stakeholders claimed in their comments that 36 months is the necessary minimum length of the general transition period. The arguments already brought up in the consultation on the Annex XV dossier were repeated and reinforced. The SEAC rapporteurs however note that industry actors often concentrated on the transition period needed specifically for the use they are involved in and did not comment on the general transition period as much. This is considered logical.

Parties from civil society claimed that 36 months is unnecessarily long and would come at the expense of human health and the environment. Reasoning for "unnecessarily"

was not provided. Related to “normal” textiles, cardboard and paper it was claimed that alternatives exist and are already used by some actors. As to food contact materials SEAC agrees that for some related applications and some users, alternatives appear to be already available, and SEAC considered whether it would be appropriate to exclude food contact materials from the proposed 36-month transition period. Considering that 1) alternatives are understood to be available only to a subset of the relevant applications, 2) alternatives are understood to generally work less well still at this point in time, such that more time for research and development is needed, 3- transition is already ongoing on a more voluntary basis, 4- complication of the scope of the restriction brought about by several “general” transition periods could make the measure less well understood, SEAC came to the conclusion that it is more appropriate to apply one general transition period.

Use-specific longer transition periods where no specific time limit is proposed: It was clarified in the opinion that SEAC considers that none of the derogations are proposed to be “eternal” (as was understood by some respondents, e.g., #844, 901). However, SEAC emphasises that it is not possible to define a time limit at this point in time based on the current poor availability of suitable alternatives and information provided.

3. Labelling

#844, 884, 898, 911, 929

The SEAC rapporteurs would like to thank stakeholders for providing their clear view on both the advantages and difficulties of labelling products (e.g. articles, mixtures) that contain PFAS substances so that informed decisions can be taken by consumers, companies, waste managers, etc. over the whole lifecycle of products (e.g. consumption, waste stage). SEAC in its opinion acknowledges that improved flow of information would be beneficial in terms of achieving the aims of the restriction and also notes that in this way the purchasers would be better able to contribute to phase-down if they so wish, since the market would adapt to changes in behaviour. SEAC would like to emphasise that it is certainly not rejecting labelling requirements, as anticipated in comments provided during the consultation. However, it is SEAC’s task to evaluate information on costs and benefits of any such requirements. As no related concrete information was provided to SEAC (e.g. on how effective such labelling actually would be in promoting awareness and proper waste management, how much cost would be induced by the requirement, etc.), neither by the Dossier Submitter, nor during the two consultations, SEAC has no information at hand that would allow evaluating whether costs and benefits of a labelling requirement would be well balanced.

4. Analytical methods and enforcement issues

#840, 856, 873, 896, 917, 946

It was highlighted by stakeholders that poor availability of analytical methods is an impediment of effective implementation and enforcement of the restriction. It was underlined that it is very difficult if not impossible for downstream actors, including importers, to know whether PFHxA, its salts or related substances are included in products if suitable analytical methods are not available, given that currently there is no obligation to report the presence of these substances. It was pointed out that getting information from suppliers outside the EU requires contractual arrangements, which would require substantial efforts. Difficulties with extracting PFHxA from articles were specifically highlighted.

It is noted in the SEAC opinion that analytical methods for the different matrices are not yet well available, specifically for polymers and substances bound to matrices. The

necessity to further develop analytical methods was one factor underlying the decision to suggest the general transition period to be increased to 36 months.

5. Hazard assessment

#813, 815, 819, 832, 843, 858, 882, 896, 901, 911, 973

Some comments on hazard assessment were provided in the consultation. SEAC highlights that hazard assessment is in the RAC remit and SEAC cannot evaluate the related information. SEAC, however, notes that similar comments were made also in course of the consultation on the Annex XV dossier and respective replies were included in the RAC opinion and RCOM.

6. Emission estimates

#848, 878, 902, 926, 941, 973

Information on emissions is important for SEAC as the emission reduction expected is used as a proxy for benefits in a restriction case of this kind (e.g. PBTs, vPvBs, PBT-like substances). However, while there were some comments on emissions, no sufficiently substantiated data was provided that would have changed the evaluation of the emission estimates in the RAC opinion. Where relevant, SEAC has highlighted the comments on emissions in the opinion.

It was proposed in one comment to use the quantities of PFOA and its precursors provided in the SEA for the PFOA restriction as proxies for the quantities of PFHxA and its precursors to estimate the emissions of the latter. It was claimed appropriate because PFHxA and its precursors are drop-in replacements of PFOA and its precursors. SEAC notes that not all actors having used PFOA and related substances earlier switched to PFHxA and related substances; another respondent actually claimed that as to fluoropolymers, most major producers did not replace PFOA salts by PFHxA salts (or other C6 PFAS), but by perfluoro(poly)ether surfactants. SEAC agrees that due to differences in properties, such as lower surfactant activity, the levels of PFHxA and its precursors needed to provide for a certain property can be expected to be higher than those of PFOA and its precursors. However, SEAC has not seen any evidence implying that the effects raising PFHxA volumes relative to PFOA volumes and those lowering PFHxA volumes relative to PFOA volumes would in any way cancel each other or even be of a similar order of magnitude.

SEAC again underlines that the evaluation of emissions is in the RAC remit and SEAC will not discuss the issues further.

7. Review clause

#850, 893, 896, 911, 944

SEAC emphasises that the European Commission can initiate a review of a restriction at any time and considers that this could also be done in the context of future regulatory action on PFAS substances. SEAC considers that several aspects of the proposed restriction should be subject to a review in due course, especially the derogations proposed under paragraphs 5(c), 7(a) and 8(b) to 8(h), as large uncertainties are associated with these derogations and with this restriction proposal in general. SEAC notes that some of these derogations could result in relatively large releases and are not time limited. Furthermore, SEAC notes the potential need to also consider any new information, for example on analytical methods, and if appropriate modify the restriction conditions (e.g. concentration limits) accordingly. SEAC notes the Dossier Submitter's suggestion to carry out a first review six years after the entry

into force of the restriction and a subsequent review every three years if the above derogations are still considered necessary. However, based on the information available, SEAC cannot recommend any concrete timeframe for performing a review, but notes that this should be aligned with the timeframes of reporting in order to allow for the collation and evaluation of the information received. This recommendation is given to the Commission in the SEAC final opinion.

8. Spare parts

#841, 847, 853, 872, 881, 890, 905, 907, 917, 946, 953

SEAC notes that exemptions for spare parts were requested by the automotive industry (#847) as well as sectors dealing with the production of electrical and electronic equipment (#853, 872, 907, 912 and others). SEAC considers that derogations for spare parts could make sense from a circular economy perspective, as these would allow for the repair and maintenance and likely extend the lifetime of affected articles already on the market. However, in SEAC's view, the requested non-time limited character of any such derogations cannot be justified as the affected products would reach their end-of-life also at some point in time. SEAC also notes that overall, RAC does not support a derogation for the above products/sectors, as uses are wide and dispersive and emissions cannot be controlled by means other than a restriction. SEAC concludes that it will be important that both, the reduction of emissions and the principle of a circular economy need to be considered for the restriction at hand as they are relevant for the decision maker. However, SEAC does not have the information to assess the socio-economic impacts of specific (time-limited) derogations for spare parts for the automotive and EEE industry.

9. Substances requested to be excluded from scope

#861, 862, 883

#861: ECHA Substance Identification team has clarified that cyclic structures are not included in the scope of the proposed restriction. The same applies to the substance you mention: perfluoro-n-octane CAS 307-34-6; EC 206-199-2. It is, however, noted that your understanding that the restriction proposal is intended to cover only surfactants, is not fully correct. The proposal contains all related substances which are expected to degrade (regardless of the rate of degradation) into pefluorohexanoate/-hexanoic acid in the environment. Hence, many substances initially having no surfactant properties therefore belong to the scope of the proposal.

#862: The use as intermediate is derogated for the transported isolated intermediates (see the entry table, para 8 of SEAC opinion). Furthermore, on site intermediates are not covered by the restriction.

#883: CAS no 132182-92-4 is not covered in the scope of the restriction proposal. It is noted that the proposed entry of the final RAC and SEAC opinion is the binding part of the opinion, whereas the indicative list of substances is not formal. ECHA has indicated that they intend to remove the substance from the indicative list of substances when it is next time updated.

10.Essential use concept:

#833, 838, 891, 942

The SEAC rapporteurs note that some stakeholders in their comments referred to the "essential use" concept and that it is important to apply such a concept in regulatory decision making, specifically for substances such as PFAS. The Dossier Submitter initially included a discussion on essentiality in its assessment but removed it during

the opinion making phase. Additionally, SEAC would like to emphasise that no agreed criteria are currently available in EU chemicals legislation in order to apply such a concept in the evaluation of a restriction proposal. Therefore, currently, and at this stage of the process, SEAC cannot further consider a discussion on essentiality in its opinion.

Use-specific topics

11.Textiles

a. Protective clothing and PPEs (including for armed forces)

This response covers the following comments: #814, 816, 818, 819, 823, 824, 834, 836, 839, 843, 863, 852, 864, 892, 900, 918, 927, 928, 938, 940, 956, 957, 958, 962

Information on further product categories that would need to be derogated was received from a lot of respondents. With respect to protective clothing for military and law enforcement and also other emergency response workers, the reasons behind the necessity of the C6 treatment were well explained and SEAC rapporteurs support also covering these by a derogation. For other types of articles, the information was less conclusive and further derogations are not supported. It was proposed in the consultation that the exemption relating to emergency response workers would be limited to equipment purchased by governmental or government recognised organisations. SEAC rapporteurs do not have information on the impacts of such a limitation e.g. on enforceability and practicality and therefore, while agreeing that derogations should be as limited as reasonably possible, do not propose to make this limitation.

It was suggested that in relation to equipment intended/ specifically designed for armed forces, the derogation should cover not PPE but “personal equipment”, or that it should cover “PPE and articles”. The relevant article types were not fully elucidated (some examples were mentioned by one respondent). SEAC does not have sufficient information on the type or any information on the volume of the intended articles. Also, information on the reasons why C6 treatment would be necessary and whether alternatives are available is very scarce, and the SEAC rapporteurs hence do not support such extension of the derogation. Stain resistance and repellence against flammable liquids were highlighted as specific virtues of C6 treatment in textiles for the army. SEAC rapporteurs acknowledge that these are advantageous properties. However, increased washing is one approach available if sufficient dirt repellence cannot be achieved with alternatives. As to repellence against flammable liquids and flame retardance, other flame retardant agents seem to be available and could be applicable at least in some cases.

The SEAC rapporteurs also note the request that the derogation should cover PPE not only in risk category III but also those in risk category II and furthermore those in category I when normative requirements demand compliance with 27,5 mN/m² surface tension. SEAC rapporteurs consider that the supporting information submitted related to these articles specifically was scarce and does not allow a respective evaluation of the costs of restriction, potential emissions or the availability of alternatives.

It was reported in the consultation that fluorine-free alternatives for use in the manufacture of articles addressing risks in category III(g) are available and already used. SEAC has therefore proposed excluding the respective articles

from the derogation.

Related to high visibility clothing, concern on the derogation only covering articles fulfilling the requirements of standard EN ISO 20471 was voiced by several stakeholders. SEAC rapporteurs note that this demarcation could lead to a situation where large sizes of a specific item would be covered by the derogation while small sizes would not and agree that this would be peculiar. However, in the absence of information on the related volumes it is not clear to the SEAC rapporteurs how much wider the derogation would become with such a change. Overall, information on the costs of the restriction, the expected emissions and the availability of alternatives would be needed to be able to evaluate whether it would be appropriate to cover new articles by the derogation.

For medical textiles, please see SEAC's response under the heading "*10. Medical devices and other medical applications (including medical textiles and IVD equipment)*".

b. Home textiles, consumer apparel, outdoor textiles, upholstery

#819, 843, 845, 915, 924, 949

The SEAC rapporteurs consider that, contrary to PPE and similar, any significant impacts on health and safety from potentially lower performance levels of articles manufactured using alternatives are not as evident.

Alternatives for water repellent properties appear to be available. For these product types it was not well established that oil repellent properties would be necessary. The SEAC rapporteurs note the claims that good repellent properties would be necessary in some products due to environmental pollution or bird droppings, but the added value of C6 treatment was not further underpinned.

Increased washing could be used as an alternative to treatment for stain resistance. The SEAC rapporteurs note that re-design of upholstered articles could be needed to allow easier removal of the textiles. As an advantage the rapporteurs expect that the lifetime of the upholstered articles could be made longer in some cases this way.

The SEAC rapporteurs agree that a longer lifespan of products is as such a desirable property of fabrics (as for most other products as well, mainly from a circular economy point of view). A shorter lifespan could be considered an indication of costs related to the restriction. However, overall, considerably more information on the costs of the restriction and the expected emissions, and underpinning of the non-availability of alternatives, would be needed to support derogations.

c. Technical textiles

i. In engine bays

#819, 821, 822, 830, 838, 847, 855, 867, 875, 877, 891, 895, 896, 920, 921, 929, 939, 940, 941, 955, 964

The SEAC rapporteurs would like to thank stakeholders for the comments provided, specifically, but not limited to, information related to the questions made by the committee. The consultation yielded relevant further information on the functions and aims of C6 treatment

in the products in question. Also, the role of noise regulations is now better covered in the underpinning of the derogation proposal. SEAC rapporteurs now agree that a derogation appears to be justified.

It was proposed by several respondents that the derogation should cover also other types of vehicles than those proposed by the Dossier Submitter (i.e. automotive and aerospace industry). It was claimed that "automotive" can be understood to refer to only certain types of passenger cars and suggested that the wording would be changed to "transport and non-road mobile machinery" SEAC rapporteurs agree that similar arguments seem to be relevant for all of these product types and supports the proposed wording.

ii. In other parts of automotive and other machines

It was requested in some of the comments received that the derogation should also cover textiles in other parts under the bonnet, in parts under the body of the vehicle or even in all of the vehicle, including vehicle interior materials. SEAC rapporteurs consider that the necessity of oil repellence is not as evident in these parts. For some parts, exposure to lubricant oils could be a plausible scenario, however, such parts were not specified.

The SEAC rapporteurs find that applying a derogation to all textiles used in all vehicles would make the derogation very wide and could have a large impact on emissions. More information on the availability of alternatives, costs of restriction and expected emissions would be needed to support a derogation of any of these applications.

iii. For uses related to construction/building (e.g. fabric based coated construction material, flexible composite membranes), see the relevant section of this document

12. Medical devices and other medical applications (including medical textiles and IVD equipment)

#822, 835, 849, 855, 861, 862, 865, 867, 872, 875, 877, 886, 887, 888, 895, 896, 898, 901, 907, 908, 910, 912, 913, 916, 917, 918, 919, 929, 930, 933, 938, 940, 958, 964, 971

The SEAC rapporteurs would like to thank the stakeholders for their numerous contributions during the consultation on the SEAC draft opinion as regards medical devices, medical textiles and related products such as in-vitro-diagnostic medical devices. The rapporteurs note that comments are diverging as regards their content, specifically whether or not derogations should be applied and how these should be best framed. Whilst some stakeholders request a broad derogation for medical devices, incl. medical textiles (this is also the proposal of the Dossier Submitter) and *in-vitro* diagnostic medical devices, several stakeholders stress that any such derogation is too broad as alternatives are partly already in use and substitution takes place continuously. These stakeholders request tailored product-specific derogations where alternatives are not yet performing sufficiently well.

The Dossier Submitter notes that a broad derogation, as suggested in the Annex XV restriction proposal, is most probably not justified based on the fact that alternatives might be readily available or already in use for some products. Still, as the necessary

information to perform a product-specific assessment was missing and as most products affected provide health- and life-protecting functions and alternatives are overall not yet available, this broad derogation is suggested. Otherwise, negative socio-economic impacts to society are to be expected. SEAC agrees to the before mentioned aspects specifically as key aspects could not be clarified during the opinion development process, such as:

- what exactly falls under the term “medical device”;
- are medical textiles indeed covered by the term medical device as specified in the Medical Device Regulation 2017/745 (MDR) and, if yes, which ones;
- for which products are alternatives already on the market and for which products are derogations still necessary;
- the exact timeframe for the development and implementation of alternatives and many more.

The above open issues could not be clarified, neither during the development of the restriction proposal, nor during the consultation on the Annex XV report or the consultation on the draft SEAC opinion. A broad derogation is therefore supported by SEAC. SEAC concludes that the derogation should comprise medical devices (as suggested by the Dossier Submitter), medical textiles (of which the Dossier Submitter did conclude that these are anyhow covered by the MDR) as well as *in-vitro* diagnostic medical devices defined under the respective Regulation 2017/746.

For medical textiles, SEAC recommends following the definition brought forward by EURATEX (comment #940) and supported by several stakeholders, requesting a derogation for “woven, knitted and nonwoven medical textiles as specified in Medical Device Regulation (EU) 2017/745 with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795”.

SEAC notes that imposing the proposed condition for reporting (see paragraphs 9 and 11 in the entry) could help to refine this broad derogation in future.

13.Filtration and separation media

#840, 854, 856, 866, 868, 876, 892, 899, 903, 920, 921, 941, 951, 955, 961

The SEAC rapporteurs would like to thank the stakeholders for submitting information requested by SEAC in the note accompanying the call for comments. Information was received, i.a., on the factors affecting the possible substitution timeline, applications where filter media are applied, use volumes, and specifically on the elements that a suitable wording of a derogation should contain. Also, further explanation on why water and also oil repellence is necessary in the products was received and considered useful by SEAC. SEAC used the information received to finalise the evaluation and the scope of the proposed derogation.

Some of the respondents supported the wording proposal by the Dossier Submitter, while some considered that “high-performance” could be deleted as it appears redundant. SEAC originally suspected the term “high-performance” to be redundant and found it potentially confusing, and therefore considered deleting it. However, seeing the explanation received stating that this term actually does limit the derogation to the most relevant applications (#840) SEAC considers that the term should not be deleted but rather defined.

It was proposed by stakeholders that the derogation should be limited to filters used in industrial settings or by professionals. SEAC notes that alternatives for filters

intended for consumer use were reported to be available, agrees with the proposal and took it forward in the proposed SEAC entry text.

Stakeholders also highlighted that more than one of the derogations proposed may be applicable for some of these uses. SEAC agrees that this is indeed the case and considers that the legal interpretation of the interplay between the different derogations and the assessment of overall impact on the operations of an individual company is up to each actor.

14.Fire-fighting foams

#831, 832, 839, 850, 858, 880, 889, 896, 911, 925, 927, 935, 944, 952, 962, 969, 972

The SEAC rapporteurs would like to thank stakeholders for the comments provided, specifically, but not limited to, information related to the questions made by the committee.

It was stressed by several stakeholders that they strongly prefer firefighting issues to be handled under one dedicated restriction proposal for all PFAS. SEAC notes all the complications reported relative to separate restrictions and fully agrees that one restriction would be a preferable approach. Such a restriction proposal is currently under preparation by ECHA and will be evaluated in SEAC in due time. However, for the purpose of the present opinion, SEAC evaluated the current restriction proposal as it is.

The difficulties caused by the placing on the market of certain foams being derogated only for 3 years while the use of the same foams would be derogated for 5 years were stressed by several respondents. It was claimed that related supply problems would force actors into an almost immediate replacement of the foams or to build up a potentially excessive stock during the transition period. Also, the peculiarity of allowing manufacture for export longer than manufacture was pointed out. SEAC agrees with these arguments and has proposed to apply the transition period of 5 years also to the placing on the market of these foams.

One industry stakeholder reported that in their opinion a longer transition period is not needed for testing and training but the restriction could be implemented upon entry into force (comment #935). SEAC agrees that superfluous derogations should not be included in the conditions of the restriction. However, noting that the respondent in question is situated in the US, it is not clear to SEAC if stakeholders within the EU agree that this derogation is not necessary and has not reflected this in the proposed entry text.

a. Fire-fighting foams for defence applications

   SEAC notes and appreciates the comments from three Member States saying that a derogation of defence uses in the entry of the restriction would be more practicable than the separate application of REACH Art. 2(3) for national exemptions in the interests of defence. SEAC considers however that as only few parties claimed that a derogation would be necessary, a derogation may not be needed by most Member States. Also, based on some comments received, there seem to be differences in the practices followed by different Member States (e.g., different fuels used), and SEAC considers that this implies that a separate assessment per Member State may be appropriate.

b. Fire-fighting foams for class B fires in large tanks

The tank size limit of 400 m^2 was based on information received in the consultation on the Annex XV dossier; it was confirmed by several parties that according to experience, fluorine free fire-fighting foams are able to extinguish fires up to 400 m^2 and requested the size limit to be set at that level.

Considering that fires of >400 m^2 can take place also outside of tanks, SEAC considered whether the derogation should be made wider to cover more such areas and at least bunded areas of >400 m2. SEAC concluded that such a change would make the derogation completely different from that proposed by the Dossier Submitter, and the available information is not sufficient for the evaluation of such a derogation.

SEAC notes the statements that a derogation should cover all types of fires inside a refinery or a petrochemical site, or all Major Hazard Facilities, or be based on the provisions laid down in the SEVESO-II-Directive. SEAC finds these interesting proposals but considers the related information available for this case as insufficient for evaluation.

SEAC again highlights that an evaluation of how to control risks related to PFAS in general in firefighting foams is ongoing. A related restriction proposal is being prepared by ECHA (as reported in the Registry of Intentions web page[4]) and may come to different conclusions than the PFHxA restriction proposal. SEAC will evaluate that proposal on its own merits in due time.

15. Fluoropolymers (including fluoroelastomers)

#837, 841, 842, 847, 857, 865, 867, 871, 872, 873, 875, 877, 881, 883, 886, 894, 907, 908, 910, 912, 913, 917, 919, 922, 929, 934, 936, 946, 947, 950, 953, 957, 958, 959, 960

The SEAC rapporteurs would like to thank stakeholders for having provided further information on this topic, specifically on the points raised by SEAC in their list of specific information requests. SEAC appreciates the views on potential suitable limit values for fluoropolymers. It was useful also to receive signals of support of the limit values proposed by some actors from the rest of the industry. Unfortunately, the underpinning of the values proposed was very limited in the SEAC rapporteurs' opinion. Based on the available evidence it is not possible to fully evaluate the suitability of and support any specific threshold values.

SEAC recalls that while fluoropolymers as such may not be the target of the restriction proposal, all emissions of PFHxA, its salts and related substances are. That is, also emissions of the substances from fluoropolymers (amounts used as process agents and remaining in the fluoropolymer product, amounts produced during the manufacturing process, and alike) would be under the scope. Given that the reduction of emissions is the goal, any limit values set would need to be lower than the contents currently routinely encountered. Limit values higher than the current contents would appear useless (or equal to complete derogation).

SEAC also appreciates the confirmation made by actors in the field that PFASs are only needed during the manufacture of the fluoropolymer and the residue left behind in the finished fluoropolymer product does not affect the performance.

Information on the content of PFAS needed in the process media to achieve the

[4] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6

necessary performance level of the product for some key applications could have helped further evaluation.

Reports on the applicability and limitations of methods for the purification of fluoropolymers were noted, appreciated, and used to update the opinion.

Generally, SEAC notes that for carrying out substitution/ moving to less-PFAS-containing or PFAS-free products, it may be necessary to make further changes to the design of final products or to the practices followed. Finding a direct drop-in substitute with identical characteristics may not be realistic.

Some stakeholders claimed that the proposed restriction would entail a complete ban of fluoropolymers in practice. To this end it is to be noted that only the types of fluoropolymers that contain PFHxA, its salts or related substances will be covered by the restriction. Other types of fluoropolymer products will be allowed. It was confirmed in comments by other respondents that a large part of fluoropolymer products is currently manufactured without PFASs.

The SEAC rapporteurs note the strong preference for only two limit values (one for PFHxA and its salts, one for PFHxA-related substances) expressed by industry stakeholders. After evaluating the supporting argumentation, SEAC rapporteurs agree that at this point in time setting application-specific concentration limits appears not to be possible.

Based on the comments received it appears that the same fluoropolymer products are supplied to different kinds of uses with varying performance level. To achieve optimal reduction of emissions, it would seem useful to further differentiate between products and use for each application a fluoropolymer grade that contains the least possible amount of PFASs but still works appropriately in that application. Improvement of communication in the supply chain as well as development of analytical methods would be necessary to this end.

Overall, SEAC notes that some kind of special arrangement for fluoropolymers is definitely needed (i.e., derogation, higher concentration limits or alike) but given the situation in the field and based on the available information it is not possible for SEAC to propose any specific limit values.

16. Electronic devices

a. Coating of EEE

#838, 848, 872, 896, 901, 907, 908, 910, 912, 913, 916, 917, 919, 929, 933, 946

The SEAC rapporteurs would like to thank stakeholders for the comments provided, specifically, but not limited to, information related to the specific information requests made by the committee. Specific thanks for explaining the applicability of the different coating techniques and for clarifying the meaning that the terms "functional coating" including "conformal coating" have in the field. Also, further underpinning of why it is difficult to find suitable alternatives was useful. SEAC rapporteurs acknowledge that where the aim is that EEE will be smaller in size, it is useful that the coatings applied (specifically inside the devices) are thin.

It was highlighted in comments that derogating only pulsed plasma nano coatings (which was supported previously in SEAC opinions on PFOA) would not be sufficient in this case but important applications would be missed. Unfortunately, robust information on the expected emissions over the entire life cycle (including manufacture) relating to the different applications, which might have enabled the

limiting of the derogation to a subset of uses, was not submitted and hence not evaluated by RAC. Overall, considering all the information submitted, SEAC rapporteurs think that restricting these uses at this point in time may not be proportionate and support a 7-year transition period for functional coating used in electrical and electronic equipment.

We note the claim that the use of PFAS substances in electronic devices makes any electrical or electronic device no longer recyclable, and we now also point this out in the opinion.

b. Lubricants for EEE

#872, 896, 907, 917, 919, 946

Lubricants for EEE were mostly addressed by six respondents. The lubricants were reported to be critical for EEE that has precision machinery. It was explained that PFHxA-related substances give lubricants the ability to stay in the fine moving parts of precision instruments. Lubricating components getting wetted and diffuse was claimed to lead to significant reduction of the durability and the performance of the product. It was reported that only fluorine compounds with low surface free energy can provide oil repellency and are difficult to replace. SEAC rapporteurs agree that this could imply that alternatives may be difficult to find, however, based on the very scarce information submitted it is not possible to make conclusions. SEAC rapporteurs overall agree that the restriction would induce some costs to industry, however, no information on the order of magnitude is available.

It was highlighted in some of the comments that this relates to the same application and function as "Epilame in watches" and it was claimed that the amount used is similarly very low. However, no corroborating evidence or even scoping information related to the volume of possible emissions is available. Overall, the available information is unfortunately not sufficient to allow proper evaluation.

c. Displays

#846, 870, 904, 905, 909, 923

A request to derogate flat panel displays was made in the consultation by several stakeholders. Costs of the restriction and the emissions expected were described largely on a qualitative basis only, however, to such an extent that it was possible for SEAC rapporteurs to get a rough understanding of the overall situation. Also, the difficulties with finding suitable alternatives and the underlying reasons were described to some extent.

A transition period of up to 12 years was requested. The underpinning of lack of alternatives was not completely elucidated though. It appears as if alternatives performing somehow but not allowing a similar performance level/ a sufficient performance level for some product types would be available and could potentially be further developed. SEAC rapporteurs also note that the restriction appears to only apply to part of the respective products (impacts on 25% of FPD imports into EU market was estimated by one respondent). This could imply that alternatives are already available for some products vis-à-vis the proposed restriction. The availability of alternatives for different functions in the different layers of the display was unfortunately not elucidated in the comments.

Some actors claimed that at least a 7-year transition time would be needed. SEAC rapporteurs proposed a derogation of 7 years based on the information on alternatives and the socio-economic costs of the restriction but highlighted that

there are high uncertainties about the emissions.

17.Semiconductor microelectromechanical systems (MEMs)

#860, 893

The SEAC rapporteurs note that it was highlighted in the consultation that a derogation of anti-adhesive coatings for semiconductor microelectromechanical systems would be necessary. Their importance with regard to the appropriate functioning of safety and comfort systems in vehicles and in consumer applications such as smartphones, tablets and wearables was highlighted. The amount of PFHxA-related substances used for this application was reported to be approximately 10 kg per year. Some indications of the reasons behind the difficulties to find alternatives were provided.

SEAC considers that it would be appropriate to derogate this use for 12 years either via the more generic derogation of semiconductors or separately.

The SEAC rapporteurs note the concerns that a 12-year transition period would be too short. A note has been added to the opinion stating that a review should be made also relating to semiconductor-related uses at a later point.

18.Photographic applications

#906, 943

The SEAC rapporteurs would like to thank the stakeholder for the comments provided.

New information was submitted relating to use in instant cameras and instant films. The SEAC rapporteurs note that in this use volumes are rising, in contrast to other related uses where volumes are decreasing due to the ongoing transition to digital techniques. Some information on use volumes was submitted and statements relating to the availability of alternatives made. An estimation of the socio-economic costs of non-use was not provided. SEAC rapporteurs do not consider a derogation justified based on the available information.

19.Printing inks and printers

#890, 945

The SEAC rapporteurs would like to thank stakeholders having provided further information on this topic, e.g. on important socio-economic information such as the number of printers potentially requiring early replacement due to a restriction, information on remaining lifetimes, on emissions, economic impacts, etc. (some information was claimed confidential, some was non-confidential). SEAC notes that in the consultation on the SEAC draft opinion, stakeholders specifically requested derogations for water-based printing inks, components of electrophotographic printers and for oiling web cassettes used in xerographic printing presses for transactional and MICR printing. SEAC appreciates the additional information provided and notes that for some specific applications, such as the above, longer transition periods might be needed, specifically from the perspective of avoiding early disposal of products already on the market. However, SEAC notes that RAC did not support a derogation for wide-dispersive uses that cannot be controlled other than by means of a restriction. For the specific uses highlighted during this consultation, SEAC has no indication on the magnitude of related emissions and on the respective socio-economic impacts of different longer transition periods. SEAC expects that some products will reach their end-of-life already within the 36 months transition period, which would reduce any related costs of early disposal, at least for parts of the products affected. In the absence

of further comments requesting longer transition periods (assuming that only limited engagement in the consultation processes indicates that other actors may not deem longer transition periods necessary), only limited socio-economic information related to these specific uses and due to RAC's recommendation to restrict the uses as soon as possible from an emission reduction perspective, SEAC does not support a specific longer transition period.

20.Oxygen absorber packaging

#885

The SEAC rapporteurs note that a request to derogate this use was made by one actor only. Therefore, it is expected that other actors may have found other solutions. SEAC rapporteurs understand that the alternatives applicable to technologies for food contact materials and food packaging do not apply to this use. However, considerably more information on the reasons for the difficulty to find alternatives and specifically on the expected costs of the restriction would be necessary to justify a derogation.

21.Chrome plating

#896, 950

It was requested that the transition period for this use should be aligned with the review periods granted under authorisations. The SEAC rapporteurs acknowledge that this might be useful for some actors. However, since there is no universal latest substitution date for Cr-VI authorisations, but the review period varies per specific case, it is not possible to set the end date of the transition period for phasing out PFHxA, its salts and related substances on such date.

22.Photovoltaics

#896, 958

A request to apply a derogation to crystalline silicon photovoltaic modules was made in the consultation. Some limited information on use volumes and emissions was provided. It was claimed that alternatives are not available, but the reasons why no alternatives could provide the same performance characteristics were not elucidated. An evaluation of socio-economic impacts related specifically to this use was not included.

The request came from stakeholders outside of the EU, and it is not clear if the reason behind is that there may not be any related manufacture in the EU or that EU manufacturers do not consider a derogation necessary. Also, it could not be fully clarified if this use will actually be covered by other proposed derogations such as the proposed longer transition period for coatings for electronic devices.

23.PFHxA-based fluorosilicones defoamers

#976

Thank you for the comment. The SEAC rapporteurs note that the products in question are used widely in different sectors and applications. This could imply that emissions may be wide; however, no specific RAC-assessment on emissions is available to SEAC.

The SEAC rapporteurs note that some of the associated applications may already be covered by use-specific derogations. Other than that, more concrete information on costs of the restriction for these specific uses, the emissions expected and the

availability of alternatives and why these do not function sufficiently well would be needed to evaluate whether a dedicated derogation would be justified.

24.Paper and cardboard / Food contact material

#897, 926, 934, and others

The SEAC rapporteurs would like to thank stakeholders for the comments provided, mainly referring to the length of the general transition period of 36 months, which is also applicable for this sector. Comments mainly state that the extension of the general transition period is regarded as not justifiable as alternatives are already on the market and in use and there are plenty of examples where transition has already succeeded and companies have fully phased-out PFAS in FCMs. However, SEAC also received some contradictory information, mainly confirming that while the transition is ongoing, this will still require some time to fully replace PFAS in all relevant applications. With this information at hand and noting that RAC did not support a derogation for wide-dispersive uses that cannot be controlled other than by means of a restriction, SEAC finds that no specific transition period is needed for this sector, but that the general transition period should suffice. SEAC's reasoning on why a general transition period of 36 months is recommended and why this should also cover food contact materials, can be found in SEAC's answer dealing with the general transition period comments.

25.Building / construction products

#817, 825, 949, 963, 965, 966, 970, and others

The SEAC rapporteurs would like to thank the several stakeholders that have provided comments referring to the importance of PFHxA, its salts and related substances for the building and construction industry. SEAC notes that the comments are mainly referring to the use of the substances for the protection of porous substrates like natural stone and assimilated substrates in the construction industry. Surfaces that need these treatments include roofs, walls, facades, terraces, interior and exterior grounds. Furthermore, stakeholders report on uses in fabric based coated materials within construction (e.g. tent warehouses, roofs of shopping malls, roofs of indoor tennis courts, etc.) and in flexible composite membranes for different applications (solar protection, façade, furniture, etc.). SEAC notes the information provided by stakeholders, mainly on potential alternatives and why these are not performing sufficiently well and possible socio-economic impacts, all qualitatively described. SEAC wants to emphasise that RAC did not support a derogation for wide-dispersive uses that cannot be controlled other than by means of a restriction. SEAC notes that both the emissions of continued use and the socio-economic impacts of a restriction could be substantial for this industry, but SEAC has no information at hand to make any quantitative or qualitative comparison in order to conclude on proportionality. SEAC therefore considers that the information provided on costs, emissions, techniques applied and the availability of alternatives (where this information was included in the comment) is not sufficient to allow a conclusion on whether a derogation or a longer transition period would be appropriate for any of the product groups covered.

26.Epilames used in watches

#931, 937

The SEAC rapporteurs note that more concrete information on social and economic costs, such as job losses, loss of revenues for the EU market, etc. was provided during the consultation on the SEAC draft opinion. SEAC appreciates the type of information received, but notes that it is difficult to verify the provided figures without these being explained in more detail (e.g. assumptions taken and how the results have been derived, etc.). Still, SEAC considers that these figures serve as confirmation to what

was already assumed during the opinion development i.e. that restricting this use would most probably induce high economic and social costs. RAC supports a derogation as emissions are minimised by other means than a restriction. With the information at hand, SEAC concludes that restricting this use is likely not proportionate.

27.Cladding for optical fibres

#923, 929, 946

The SEAC rapporteurs would like to thank stakeholders for the comments provided, specifically, but not limited to, information related to the questions made by the committee. The SEAC rapporteurs consider that most of the information submitted overlaps with information already submitted previously. Some further information was received related to the requirements for alternatives. However, more information on the costs of non-use and the wideness of the use would be needed to be able to fully evaluate the necessity of derogating. Noting that only one respondent reported a need to derogate this use, SEAC rapporteurs expect that other actors may have found alternatives, and therefore regard that a dedicated derogation is not justified.