

## General Comments

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Submitted jointly by EEB and ClientEarth

### 1. Proportionality

We would like to support the DS conclusion on the proportionality of the restriction. The SEAC's draft opinion regarding the overall proportionality of the restriction incorporates qualitative assessments of costs, but fails to do so with benefits. With the existing data, however, a qualitative assessment and a conclusion on proportionality would have been possible, in the same way RAC concluded on risk.

We would also like to highlight benefits and costs that support the overall proportionality of the restriction that have not been fully assessed by the SEAC:

- Benefits (i.e. through reduced emissions), although qualitative, are likely *underestimated*, because
  - o The RAC's 2nd draft opinion numerically underestimated emissions through applied emission factors and neglecting mass balances, and by neglecting incineration as an end-of-life scenario as detailed in RCOM 3107, confidential attachment
  - o The arrow-head approach focussing on PFHxA as the final degradation product underestimates (eco)toxicity, as some precursors such as 6:2 FTOH and relevant degradation products such as 5:3 FT acid (from landfills) have higher toxicity than PFHxA.<sup>[1]</sup>
  - o As the recent scientific opinion by Cordner *et al.*<sup>[2]</sup> highlights, additional benefits to be considered include avoided costs from cleaning up and removing PFAS, decreased value of property or harvests, public expenses for legal enforcement and monitoring - on top of direct health cost and the more difficult to monetise environmental damage.
- Costs to companies, although based on little concrete data, are likely *overestimated* and minor, because:
  - o Fluorinated substances have been substituted without any regulatory pressure by many companies, indicating economic viability
  - o The assumption of generally lower performance of fluorine-free alternatives, proposed by the DS (BGD section 2.5.1) is cautiously followed by SEAC despite hard data (DO, p. 35 and elsewhere) and indications to the contrary (DO, p. 43).
  - o The draft SEAC opinion presents certain seemingly high estimations on costs (e.g. replacement costs are estimated to be 1 bn €) but fails to provide an adequate context and discussion on how to interpret these numbers. For example, the 1 bn estimate, if accurate, would be minor compared to total EU government expenditure for firefighting ca. 30 bn €/year<sup>[3]</sup> or 600 bn € over 20 years.

### 2. Labelling

Labelling of articles and mixtures containing the PFASs in scope during transition periods or for derogated uses, as proposed by us (RCOM 3077), was acknowledged but rejected (DO p. 30-31) without

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[1] Rice et al. (2020), doi.org/10.1016/j.fct.2020.111210, (MacDonald) Phillips et al. (2007), doi.org/10.1021/es070734c

[2] Cordner et al. (2021), Environmental Science and Technology, 55, 9630-9633. doi.org/10.1021/acs.est.1c03565

[3] <https://ec.europa.eu/eurostat/de/web/products-eurostat-news/-/edn-20210504-1>

much analysis. Especially given the Annex XV report's reduced consideration for end-of-life fates linked to recycling and incineration, this is a substantial oversight. This choice is even more surprising as ECHA's introductory website on restrictions explains that "[restrictions] can impose any relevant condition, such as [...] specific labels".

### **3. Transition time**

The standard transition time proposed by the DS of 18 months has been raised to 36 months in the DO (p. 9), even for sectors where short transition times are demonstrably feasible (such as outdoor wear and food packaging), especially considering the early notice by the restriction process, which takes itself a few years. Apparently, more consideration was given to uniformity across applications than to practical or risk aspects.

### **4. Broad derogations on PPE, high-vis clothing and medical devices**

The SEAC is proposing in its draft opinion to support a general sectoral derogation for all medical devices, contrary to RAC who has assessed only very specific derogations requested by industry stakeholders. The DS and SEAC justify their support to this wide derogation on the lack of information on all the uses of PFHxA in this sector. The burden of proof is on industry to provide justifications on the need for derogations to restrictions. If these justifications have not been provided and documented, the SEAC, should follow the legal text and guidance and abstain from supporting these wide derogations.

### **5. Uncertainties:**

The mere presence of uncertainties is not sufficient to question the overall proportionality of a restriction. To do so, a supported analysis of their nature and impact must be done.

Uncertainties are inevitable to risk assessment, in particular when it comes to complex chemicals covering multiple uses.<sup>[4]</sup> This is why the precautionary principle empowers EU institutions to act to prevent a risk even in the presence of considerable uncertainty.

SEAC's mandate is to formulate an opinion on the restriction and its related SE impacts with a view to inform the final decision (Art. 71 REACH). But that mandate should be exercised within the limits of the law and the related guidance, as well as in accordance with the principle of scientific excellence. Scientific excellence requires SEAC to present results that are thoroughly justified, logical and based on verifiable data.<sup>[5]</sup> The ECHA guidance makes clear that uncertainties in the context of a restriction proposal must be "identified and described throughout", and that their "importance to the outcome of the SEA" should be highlighted.<sup>[6]</sup> The "lack of account of uncertainties in drawing conclusions" constitutes a failure to properly explain the rationale for conclusions according to the guidance.<sup>[7]</sup> Hence simply refusing to conclude on proportionality without providing a thorough assessment of the uncertainties in presence is not acceptable.

In addition, it is striking that SEAC refused to consider the qualitative justification provided by the dossier submitter to estimate costs and benefits on account of "too many uncertainties".<sup>[8]</sup> The

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[4] See Case C-499/18, Bayer Crop Science AG v European Commission, Para. 81

[5] Case T-636/17, PlasticsEurope v ECHA, Para. 152. By analogy: judgment of 11 September 2002, Pfizer Animal Health v Council, T-13/99, Para. 172

[6] Guidance on SEA in restriction, p. 43

[7] Guidance on SEA in restriction, p. 46

[8] SEAC draft opinion, p. 54

qualitative assessment provided by Germany is indeed similar to the one used in the ECHA microplastics' restriction proposal and consistent with the Court's approach to the risk assessment of PBTs and vPvBs, or equivalents.<sup>[9]</sup> In a similar manner, the microplastics' dossier mentioned "considerable" uncertainties, including concerning the feasibility and availability of alternatives for some uses, the emissions to the environment or the socio-economic impacts.<sup>[10]</sup> Because the quantification of benefits is typically not possible for PBTs/vPvBs or substances of similar concern like PFHxA, the dossier submitter used a cost-effectiveness approach together with qualitative considerations.<sup>[11]</sup> The multiple uncertainties raised in that context, notably with regard to the calculation of emissions, did not prevent SEAC from concluding that adopting a restriction was necessary due to microplastics' extreme persistence and the irreversibility of the pollution<sup>[12]</sup> – concerns that are also clear from the PFHxA dossier.<sup>[13]</sup> Following, SEAC must thoroughly justify why uncertainties prevent the SEAC from concluding in the PFHxA case - despite the irreversibility of the pollution and the amount of qualitative information made available by the dossier submitter to justify proportionality.

## Specific Information Requests

### 1: Reporting requirements

In line with the proposal by the Dossier Submitter, SEAC currently suggests reporting requirements *for the proposed uses to be derogated in PPEs, high visibility clothing, medical devices and their impregnation agents, epilames in watches, filtration and separation media, and fire-fighting foams (for class B fires in tanks >400m<sup>2</sup> and their bunded areas)*. For more details, please refer to paragraphs 9 and 11 of the conditions of the restriction as proposed by SEAC in the SEAC draft opinion.

*SEAC would like to receive feedback from stakeholders concerning the availability of information as required in paragraphs 9 and 11 to the actors indicated. In particular, if any issues in collecting this information is expected, a detailed explanation (including examples) should be provided.*

We applaud this measure and stress its importance to create transparency and inform future policy. Yet we criticise the absence of labelling of mixtures and articles, which would have allowed customers and users to make informed choices, and waste managers to ensure proper, specialised waste treatment.

### 2: Concentration limits for PFHxA, its salts and related substances in fluoropolymers[1]

*Based on the information provided during the consultation on the Annex XV report, the Background Document reports that fluoropolymers may contain PFHxA, its salts or PFHxA-related substances, as residues above the proposed specific concentration limits. To avoid the expected high societal costs of a restriction on the placing on the market of affected fluoropolymers, the Dossier Submitter proposed the following concentration limits for PFHxA and its salts or PFHxA-related substances in fluoropolymers:*

- 2000 ppb for the sum of PFHxA and its salts in fluoropolymers;
- 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers;
- 150 ppm for the sum of PFHxA and its salts in fluoropolymers used in the following usage groups: engine parts in automotive, aerospace and shipping industry;
- 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in the following groups: engine parts in automotive, aerospace and shipping industry;

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<sup>[9]</sup> Case T-226/18, Global Silicones Council v European Commission, Paras 190-191

<sup>[10]</sup> Annex XV restriction report for intentionally added microplastics, for example at p. 99

<sup>[11]</sup> Annex XV restriction report for intentionally added microplastics, p. 96

<sup>[12]</sup> See for example p. 63: "Even though a clear conclusion on proportionality is not possible, recognising the uncertainties (...) the irreversibility of microplastic emissions is a key argument in favour of proportionality of the proposed restriction. Even if the impacts of emission reduction are uncertain, early action can still be worthwhile from a social welfare perspective (...)"

<sup>[13]</sup> SEAC draft opinion, p. 52

- 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in coating of electronic devices until XX XX XX XX [7 years after entry into force];
- 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XX XX [7 years after entry into force].

SEAC currently notes in its draft opinion that higher concentration limits may be justified to allow for the continued use of fluoropolymers in a number of sectors. However, SEAC considers that more information is needed to understand the impacts of different potential concentration limits in order to guide any decision on setting appropriate concentration limits and requests specific and detailed information on:

- a. the sector/application in which respondents use fluoropolymers containing PFHxA, its salts and related substances (even as impurities), and the quantity of fluoropolymers used;
- b. the current concentration (in ppm/ppb) of PFHxA, its salts or related substances in fluoropolymers for specific applications/uses;
- c. the concentration of PFHxA, its salts or related substances necessarily needed in the fluoropolymer to reach an appropriate performance level (if at all necessary) for specific applications/uses;
- d. technical information on why it is not possible to use fluoropolymers that do not contain PFHxA, its salts or related substances in specific applications/ uses, including any technical information on why the performance level may not be satisfactory - does the presence of PFHxA, its salts or related substances in the fluoropolymer decisively affect the performance, or is it merely about the structure of the polymer itself (that would become different due to the presence of PFHxA, its salts or related substances during the manufacture of the fluoropolymer), or something else (please specify);
- e. why it is not feasible to reduce the concentrations below the general proposed concentration limits of 25 ppb (PFHxA and its salts) or 1000 ppb (PFHxA related substances), noting also that information was submitted about an existing technology to remove PFAS from fluoropolymers[2];
- f. existing technologies that allow the production of fluoropolymers without using PFAS (in particular, without using PFHxA, its salts or related substances) as processing aid;
- g. the concentration of PFHxA, its salts or related substances in purified fluoropolymer grades;
- h. the difference in price between fluoropolymers purified of PFHxA, its salts or related substances and non-purified grades, if that is considered a major impediment to transitioning to purified grades;
- i. possible difficulties of complying with different concentration limits for different sectors where fluoropolymers are used, as suggested by the Dossier Submitter;
- j. analysis to demonstrate and, if possible, quantify the negative impact of not proposing higher concentration limits (including corroborated information on the limit value that would help avoid the largest impacts)

[1] With the term fluoropolymers we refer to polymers where fluorine atoms are directly bound to the backbone (i.e. not to side chains). Fluoropolymers sometimes contain PFHxA, its salts or related substances as residuals from the manufacturing process but are not considered to be PFHxA-related substances themselves.

[2] Please see comment #2960 in the RCOM, part 1.

b-c) When establishing concentration limits, the priority should be to ensure the effectiveness of the restriction by avoiding releases of PFHxA. As explained in detail in our previous submissions to the PC (#3021, #3077, #3107), the DS proposed thresholds that had been agreed for other PFAS restrictions. Both the RAC and the SEAC should assess if these limits are the most effective in avoiding the risks and the costs posed by PFHxA that this restriction aims to address, and do so based on transparent and reliable test data.

d) We also encourage the SEAC to scrutinise whether such an exemption has any technical justification at all, irrespective of the threshold values proposed. Hitherto, no convincing indication of any presence of PFHxA, its salts and related substances in any fluoropolymers at all has been provided in this restriction procedure. Most major producers of fluoropolymers did not replace PFOA salts by PFHxA salts (or other C6 PFAS), but by perfluoro(poly)ether surfactants as processing aids in fluoropolymer

manufacture. In other words, they produce fluoropolymers that do not contain PFHxA, its salts and related substances, and their customers use them.

- Chemours substituted PFOA by Gen-X (EC 700-242-3), in their fluoropolymer manufacturing, to make both hard and elastomeric products (such as Teflon and Viton, respectively);
- 3M/Dyneon substituted PFOA by ADONA (EC 480-310-4);
- Solvay substituted PFOA by C6O4 (EC 682-239-6) in Europe<sup>[14]</sup>, and a chlorinated fluoropolyether (CAS 329238-24-6) elsewhere;
- Asahi substituted PFOA by perfluorinated diglycol acetate (EC 700-323-3).

The reader may not infer the writer's preference for any of these perfluoroethers over C6 chemicals, but should read this as a neutral statement, taken from Wang *et al.* (2013)<sup>[15]</sup>. These five surfactants (the four above and PFHxA) play very similar roles and are likely interchangeable with minor adaptations in most polymerisation processes leading to fluoropolymers. Restricting the use of one of them would quickly lead to replacement by another one, without any major benefit for the environment or human health.

The derogation with its different detailed conditions appears to be tailor-made for Daikin, the remaining major manufacturer of fluoropolymers, who contributed to the earlier PubCons in comments #2988 and #3066, requesting a higher, confidentially communicated, threshold than the 150 ppb for PFHxA as a processing aid proposed in the restriction process. Daikin's use of PFHxA or its salts as a polymerisation aid is consistent with information in Wang *et al.* (2013), "some producers, such as Daikin (Iwai, 2011), may have used ammonium perfluorohexanoate (APFHx) as polymerization processing aids", which also mentions chemical pollution from a Daikin and Arkema site in Lyon, France.<sup>[16]</sup>

In spite of the limited practical implications in risk reduction expected if this derogation were not granted (for the easy substitution reasons explained above), we urge the SEAC to uphold aspects of good regulatory practice such as transparency of the technical justification given for the details of any derogation, as well as the necessary diligence in commercial neutrality where regulatory measures are tailored to one specific company.

### 3: Coating of electronic devices

*During the consultation on the Annex XV report, stakeholders requested a derogation for different types of coating of electronic devices. Based on those submissions, it remains unclear to SEAC if a derogation would be justified to avoid disproportionate impacts and how a possible derogation could be phrased in order to ensure that it is targeted only to specific uses. More information is needed before a derogation for coating of electronic devices can be fully evaluated by SEAC.*

*For **side-chain fluorinated polymers**, SEAC invites stakeholders to submit the following:*

- further information on the exact type of use, function provided, related emissions and costs of a restriction (including why alternatives are not available/technically or economically feasible);*
- proposals as to how to word a possible derogation such that it covers the necessary uses and only those uses;*
- information on whether the wording used in the PFOA restriction<sup>[1]</sup> ("pulsed plasma nano-coating") would also be appropriate for these uses (along with the related costs and emissions);*

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[14] Bernardini et al.(2021), Environment International, 152, 106484, doi: 10.1016/j.envint.2021.106484

[15] Z. Wang, I.T. Cousins, M. Scheringer, K. Hungerbühler (2013), Environment International, 60, 242-248, doi: 10.1016/j.envint.2013.08.021

<sup>[16]</sup> This passage is summarised in the background document to the original Annex XV document on p. 134 and also refers to a Chinese manufacturer using 6:2 FTCA mentioned in Wang et al. 2013. The latter seems not to have responded to the PubCon.

- d. information on the downsides of potentially including a derogation of pulsed plasma nano coatings (e.g. additional uses that have not been evaluated might be covered etc.);
- e. information on the extent to which a derogation for plasma nano coatings would also cover uses in filtration applications, medical devices/ medical textiles and technical textiles.

For **fluoropolymers**: please also see question 1 on “Concentration limits for PFHxA, its salts and related substances in fluoropolymers”

[1] Point 3e in the SEAC opinion on the PFOA restriction proposal: “Paragraphs 1 and 2 shall apply from (36 months after entry into force) with the exception of **pulsed plasma nano-coating produced using conditions that minimise emissions to the environment, for which the transition period is 6 years after entry into force**”.

a) Typical coatings for e.g. printed circuit boards (often referred to as conformal coatings) belong to three main categories, in all of which some fluorinated and many fluorine-free products exist nowadays.

- i. Liquid conformal coatings are transparent coatings applied in liquid state to a finished circuit board. They can in some respects (general chemical composition, curing, film thickness) be compared to traditional varnishes applied to wood or metal; they can be applied by dipping, brushing or spraying. As with more traditional coatings, different chemistries are employed: acrylic, polyurethane and polysiloxane coatings are commonplace; they can be solvent-borne or water-borne; they are cured by heat, reaction with a cross-linker or reticulation under UV light. Most conformal coating materials are fluorine-free; however, some side-chain fluorinated acrylates exist, e.g. Electrolube’s FPC, Daikin’s Optoace WP-140 and AI Technologies’ Fluoroseal SC7130. Producers generally offer different types of fluorine-free as well as fluorinated systems; the product overview by Electrolube is attached for illustration.<sup>17</sup>
- ii. Vapour-deposited conformal coatings, often referred to as “Parylene”. In this process, para-xylylene or a derivative thereof is deposited on the surface of the electronic component or assembly to be coated. The monomer (or sometimes its cyclic dimer) polymerises into a polymer made of alternating ethylene and p-phenylene units; the driving force for the polymerisation is the restitution of the aromaticity of the phenyl ring. The resulting film is very thin, on the nanometer scale; however it offers sufficient electrical insulation and protection against contamination against water, chemicals, oil etc. Differently substituted para-xylylenes exist: Parylene AF-4 is a fluorinated version; however, it does not bear a -C5F11 unit and hence does not fall under the scope of this restriction.
- iii. Plasma-deposited conformal coatings share some characteristics with the ones described in (ii). They offer broader chemical diversity as more varied (preferably gaseous or volatile) substances can be used as monomers; an excited state of the starting material is generated by a high temperature source in a low pressure environment. The excited species deposit on the substrate (i.e. the electronic assembly to be coated) and react into a thin polymeric film. Many different variations of this process exist, using many different types of monomers.  
Daikin’s patent EP0049884, filed in 1981, describes the use of fluoroalkyl acrylates (such as 6:2 fluorotelomer acrylate EC 241-527-8) for a plasma-deposited coating used as photoresists. It is unknown to us if this patent, now expired, has been used commercially by Daikin or other companies, nor if the use of a fluoroalkyl acrylate gives rise to any functions that fluorine-free materials cannot offer, as the patent does not

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<sup>17</sup> Also available here: <https://pdf.directindustry.com/pdf/electrolube/conformal-coatings/6210-736982.html>

provide any information on this. It should be stressed that such properties, within the uses described in that patent, do not include oil repellence: the film is used as a resist, i.e. parts of it are etched away after treatment with an electron beam, giving rise to a film with holes.

More recent patents on the same plasma-depositing technology using fluorinated substances, but not involving substances in the scope of this restriction, include Europlasma nv's WO11/089009 (see also part (c) of this answer), Standard Oil's US-4938995 and P2i's US2010/0203347.

Comment #2977 by Europlasma submitted in the PubCon to the present restriction proposal suggests industrial importance of C6-technology in plasma-deposited nanocoatings, but it does not transparently provide any hint to any function that cannot be fulfilled using fluorine-free technology.

Based on the above, it does not appear that any derogation is necessary. Although fluorinated conformal coatings (of types i and iii) may offer advantages over fluorine-free ones in very specific cases, no indication about any loss of function by resorting to fluorine-free coatings only is available to us, nor is there any indication in material hitherto available in the present restriction process. In case convincing evidence is submitted into this PubCon (by Daikin or other companies), justifying a specific derogation, technically accurate wording would have to be derived based on such information.

c) Supposing a solid justification for the derogation is made available, the wording taken from the PFOA restriction (restriction 68) is likely not appropriate. Based on comment #253 by ERM on behalf of their anonymous client into the public consultation on restriction 68, it can be inferred that the C6-based technology referred to here is very different from the C8-based technology referred to then; in other words, that C8-chemistry was not substituted by C6-chemistry – altogether the most obvious replacement in most technologies. The comment states “[studies put] in doubt [the company's] ability to move to a high performance alternative C6 chemistry within the 36 month transitional period”. Given that the PFOA restriction transition period of 3 years runs from 04/07/2020 to 04/07/2023, the anonymous company is unlikely to have accomplished the switch to C6 chemistry by the present date. Given that no C8-based substances are registered under REACH, it is unlikely however that that company (legally) keeps using C8 chemistry either at any industrial scale - given that mandatory REACH registration covers all substances used at volumes in excess of 1 t/y. Despite the very low film thickness, 1 t/y is a low amount for an industrial application with a broad use.

Unless there is both (1) a convincing rationale to a function achieved using C6-technology that cannot be achieved using fluorine-free technology, and that (2) impacts on society of not granting a derogation would be incommensurate, the downsides of a derogation appear obvious, especially as RAC and SEAC have so far disregarded end-of-life impacts of the fluorinated treatments.

Filtration media, technical textiles and medical textiles that are not medical devices (i.e. most of medical textiles) would only be covered in case they are incorporated in an electronic device to be coated with a pulsed plasma nanocoating.

#### **4: Cladding for optical fibres**

*During the consultation on the Annex XV report, one stakeholder (comment #3002) reported that cladding in optical fibres would be impacted by the proposed restriction and requested a derogation. However, the information provided was insufficient to evaluate the request for a derogation. In order for further consider this derogation, SEAC requests detailed and specific information on:*

- a. *the quantity of PFHxA related substances used in the EU per year for this use;*
- b. *how wide this use is in the EU (e.g. how many companies use PFHxA related substances for cladding in optical fibres);*

- i. *the claim that higher data rate transmission media will be mandatory in the near future for safe driving or auto-pilot system:*
- ii. *what is the timeframe in which this requirement is expected?*
- c. *what data rate will be required and what can alternatives achieve in this regard?*
- d. *alternatives that have been assessed, including information on the search for alternatives, and why they are considered not technically or economically feasible;*
- e. *the performance level of optical fibres potentially already being manufactured by other actors (using alternative substances or processes) in the use specified in comment #3002 (see RCOM, part 2)*

Standard optical fibres consist of a silica (i.e. glass) fibre core clad with doped silica, i.e. no fluorochemicals are involved. For this reason, no silica-based optical fibres should be derogated, and no request for derogation has been submitted.

The fibres referred to in comment #3002 are polymer optical fibres (POFs), i.e. only a subclass of optical fibres.<sup>[18]</sup> The fibre material is clad with a thin or thicker layer of a material with a lower refractive index. Advantages of POFs over silica (glass) fibres are higher flexibility, straightforward installation, resistance to vibration and lower cost, while long-range signal transportation and resistance to higher temperatures are inferior.<sup>[19]</sup>

Several types and designs of POFs exist, such as:

1. Fluoropolymer-based fibres “clad” with fluoropolymers (GI-OPFs); in reality these have a gradual change in refractive index rather than a layered design;<sup>[20]</sup>
2. PMMA fibres clad with fluoropolymers. A typical example are POFs coated with Cytop®, an amorphous (hence flexible) fluoropolymer commercialised by AGC. Cytop® could potentially be synthesised using APFHx as the surfactant. Such a case would, however, be the object of specific question 2 of this consultation.
3. PMMA fibres clad with (side-chain) fluorinated polymers; this is the type at hand here (see further explanations underneath)
4. PMMA fibres clad with silicone: this is the classical design across the POF market;
5. polycarbonate fibres clad with PMMA, polyolefins or silicone; polycarbonate is resistant to higher temperatures.

Types 1, 2, 4 and 5 are all likely used to some extent in such automotive applications. Although types 1 and 2 are not in the scope of this restriction (except in case APFHx is used as the polymerisation aid, see Q2), they would constitute regrettable substitution. Levels of C6 PFAS in the products would possibly increase, but the total amounts of PFAS (in the broad sense of the term, including fluoropolymers) would increase dramatically. Emissions from production would likely increase; emissions of fluorinated greenhouse-gases from end-of-life incineration would certainly increase, unless high-temperature (> 1000 °C) conditions are guaranteed.

Like many other requests for derogation, this one is a highly technical topic. A superficial analysis of the situation will lead to careless granting of derogation, at the detriment of the scientific quality of the committees’ output, the environment and public health. It will even lead to unintended market

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<sup>[18]</sup> A useful, if somewhat outdated introduction can be found here: J. Harmon (2001), *Polymers for Optical Fibers and Waveguides; an Overview*, in: *Optical Fibers ACS Symposium Series 795:1-23*, doi.org/10.1021/bk-2001-0795.ch001. Another useful reference is: O. Ziemann *et al.* (2008), *POF Handbook: Optical Short Range Transmission Systems 2*. ed. Berlin, Heidelberg: Springer-Verlag, doi.org/10.1007/978-3-540-76629-2

<sup>[19]</sup> A useful summary is provided by fibre manufacturer Lumitex: <https://www.lumitex.com/blog/optical-fiber-technology>

<sup>[20]</sup> Examples can be found here: <https://www.thorlabs.com/catalogPages/1100.pdf>

distortions by providing derogations to single companies. Like in most other cases, we recommend that SEAC nominates an expert devoid of any conflict of interest to shed light on such intricate questions.

## 5: Medical devices

*During the consultation on the Annex XV report, stakeholders provided information on the use of PFHxA related substances in some medical devices (e.g. hearing aid devices, eye drops). SEAC is currently considering whether to support the derogation proposed by the Dossier Submitter for the use of PFHxA, its salts and related substances in medical devices as specified in Regulation 2017/745. To be able to support it in the final opinion, SEAC would like to receive more information on:*

- a. *whether the definition of medical devices as specified in Regulation 2017/745 would also cover medical textiles (woven or non-woven);*
- b. *if **medical textiles** are not covered by the proposed derogation for medical devices, please provide information on:*
  - i. *the type(s) of product(s) not covered;*
  - ii. *the quantity of PFHxA related substances used in the EU per year for this application and the related emissions;*
  - iii. *alternatives that have been assessed, including information on the search for alternatives, and why they are considered not technically or economically feasible (including their difference in price, if economic feasibility is considered to be an issue);*
  - iv. *the substitution timeline, in case alternatives are currently available, but more time than the 36-month general transition period currently proposed by SEAC (from entry into force of the restriction) is considered necessary for substitution;*
  - v. *the extent to which the relevant applications would be covered by a derogation of plasma nano coatings similar to what was suggested by SEAC in the PFOA restriction case (see footnote 3);*
  - vi. *socio-economic impacts resulting from a restriction of this use.*

The term “medical textile” lacks a legal or technical definition, very much like the term “technical textile”. “Medical textile” may be understood as “textile material used in a medical setting”; in that case it would cover medical gowns, bed linens, gauzes, masks, wipes, materials used in sutures etc. A useful systematic classification has been published by Azam Ali and Shavandi.<sup>[21]</sup> Art. 2 (1) of regulation 2017/745 defines “medical devices” (complemented by Chapter III of Annex XVIII) and importantly specifies “in or on the human body” and thereby limits the scope of medical devices. For example, bed linen does not fulfil any of the four sub-elements of Art. 2 (1). Surgical gowns, when supposed to protect the personnel, are PPE, not medical devices, as they do not meet any of the four sub-elements of Art. 2 (1).

Tellingly, PFAS producer 3M confirm that none of their products for the health sector contain PFAS (see confidential attachment).

## 6: Antifog face shields

*SEAC considers that the socio-economic impacts of a restriction for the use of PFHxA related substances on face shields used in medical settings may merit the same considerations as personal protective equipment, although they are not covered by Regulation (EU) 2016/425. However, in order to complete their evaluation of the impacts of a restriction for this use and be able to support a derogation in the final opinion, SEAC requires additional information on:*

- a. *the total quantity of PFHxA related substances used in the EU per year for this use;*
- b. *how widespread this use is in the EU (e.g. how many companies use PFHxA related substances for treating antifog face shields and the function they provide);*

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[21] M. Azam Ali, A. Shavandi (2016) Performance Testing of Textiles: Methods, Technology and Applications. Woodhead Publishing Series in Textiles, p. 129-153

- c. alternatives that have been assessed, including information on the research for alternatives made, and why they are considered not technically or economically feasible (including their difference in price, if economic feasibility is considered to be an issue);
- d. the substitution timeline, in case alternatives are currently available, but more time than the 36-month general transition period currently proposed by SEAC (from entry into force of the restriction) is considered necessary for substitution;
- e. antifog face shields not containing PFHxA-related substances potentially already on the market, their performance level and the alternatives used

- a. The total quantity of relevant substances used is likely very low, if existent at all, for the reasons explained in the next sub-points of this question;
- b. To the best of our knowledge, there is no substantiated indication on such uses. The Annex XV dossier and DO dossier merely refer<sup>[22]</sup> to one company using “C6 fluorosurfactants [...] as anti-fog coatings”. The RCOM compilation provides no hints to the existence of such an application. It is difficult to understand on what basis SEAC considered this application for a derogation, as no analysis of alternatives has been conducted.

Anti-fog coatings are indeed used in many types of PPE protecting among others the eyes and susceptible to fogging from the humidity of the wearer’s breath, which can condense on the colder surface of the shield (or goggles or glasses, for that matter). The inside of many such articles is coated with such a coating; the outside may be coated with other materials, depending on the use.<sup>[23]</sup> Anti-fogging properties can be certified and tested according to EN 166 and EN 168 to be used as PPE in medical settings. Not all face-shields certified as PPE in medical settings, however, are certified for anti-fogging properties (letter N in the EN 166 conformity description).<sup>[24]</sup>

- c. The anti-fogging properties are based on the following principle:<sup>[25]</sup> a hydrophilic coating prevents the build-up of droplets upon condensation, by providing a high surface tension material that can compete with water’s own surface tension. This way, a thin uniform film of moisture is formed.
  - a. The cited review lists polyvinyl acetate, polyvinyl alcohol, cellulose derivatives and acrylic resins as some of the suitable polymers and provides literature references. Uses of fluorinated substances are not mentioned; they may however exist.
  - b. This strongly indicates that all relevant functions of anti fog face masks (and related PPE) can be reliably fulfilled without the use of fluorinated treatments.
- d. In case any fluorinated treatments exist on the market, conversion to any of the already existing alternative technologies should be easily achievable in 36 months.
- e. This is a reversal of the burden of proof: it is up to the applicant for a derogation to prove (among others) that face-shields with fluorine-free treatments (own products and competitors’ products) do not fulfil their intended function – as so often, lab test results should not be mistaken for an indication on function.

## 7: Firefighting foam mixtures for class B fires, large tanks

*The Dossier Submitter proposed a 12-year derogation with a reporting requirement for “concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m<sup>2</sup>”. SEAC is currently supporting the Dossier Submitter’s rationale*

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[22] Section 2.5.1.12 of the Annex XV dossier and section E.2.13.8 of the BD to the DO.

[23] See the attached technical data sheet by Uvex for an example.

[24] See the attached technical data sheet by Brigo for an example.

[25] Authoritatively explained in A. Nasar (2018), Smart Polymers and Composites, Materials Research Foundation Volume 21, p. 85f, and references therein.

for a derogation for this use but is considering suggesting that the minimum size of tanks to qualify for the derogation would be set at 400 m<sup>2</sup>, and that the bunded areas of those tanks are also included in the derogation. However, SEAC would like to receive information on the **number of sites and the total surface area that would be covered by the derogation as phrased by SEAC** (tanks larger than 400 m<sup>2</sup> and bunded areas). In addition, information on the size of bunded areas (including an average size) and the possibility to fully contain the fire-fighting foams in case of an accident would be welcome.

The DO goes in the right direction in not granting derogations for class B uses where fluorine-free foams are not needed (such as in aviation or military uses). However, the transition time of 5 years for use and 3 years for selling (condition 5c of the DO) is overly long and unnecessarily extends the time during which emissions can continue to occur.

However, most importantly, the exception for tanks with a surface area above 400 m<sup>2</sup>, granted for 12 years (condition 7a of the DO) is neither needed nor justified.

1. Theory does not justify the size limit of 400 m<sup>2</sup> (nor the initially proposed one of 500 m<sup>2</sup>). The performance of a foam can actually be linked to three parameters:
  - a. spreading: This is the foam's ability to cover a surface uniformly by flowing freely over the surface of the fuel; this is mostly relevant for gentle application (i.e. where a foam is projected onto a wall or vertical surface) since there is no forward momentum when the foam meets the fuel. Where fixed deluge and spray systems are used, minor differences in spreading rates can be accommodated by adapting the design of such equipment which is tightly regulated in standards such as EN 13565 and NFPA 11. Where forceful application is used, spreading rates have limited relevance as the foam is projected directly onto the fuel's surface with an inherent forward momentum. This momentum pushes the foam across the fuel surface, smothering the fire, irrespective of inherent spreading capacity.
  - b. extinguishment, i.e. the propensity to quench the fire. This property is assessed in a routine and standardised manner according to EN 1568 (specifically parts 3 and 4). The rapid control and extinguishment of a fire is a key element to all international standards, such as the ones by the International Civil Aviation Organisation (ICAO), Underwriters Laboratories (UL), Factory Mutual (FM) and Lastfire.
  - c. burnback resistance (i.e. avoiding that a fire can start again after being extinguished). Once a fire has been extinguished, the foam layer is required to hold back any vapours which may reignite above the foam surface. EN 1568 requires a foam to resist flames for a set period of time in order to achieve an acceptable rating. This is also required in all of the listed standards, mentioned above.

A foam's performance on parameters (b) and (c) are usually indicated on technical data sheets, a IA rating (EN 1568 part 3 and 4) being a top rating. High-quality fluorine-free foams routinely meet those specifications; it should be kept in mind that many lower-quality AFFFs also exist and are used. A few examples:

- fluorine-free foams with a top IA rating include Solberg's Versagard AS-100, Angus Fire's Respondol ATF and Bioex' Ecopol Premium;<sup>[26]</sup>

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[26] Technical data sheets available from [https://www.perimeter-solutions.com/wp-content/uploads/2021/02/SOLBERG-VERSAGARD-AS-100\\_datasheet-VF.pdf](https://www.perimeter-solutions.com/wp-content/uploads/2021/02/SOLBERG-VERSAGARD-AS-100_datasheet-VF.pdf), <https://angusfire.co.uk/wp-content/uploads/6833-Respondol-ATF3-3-1.pdf> and <https://www.bio-ex.com/en/our-products/product/ecopol-premium/>, respectively

- C6-based foams with a IIIB or IIIC rating (EN 1568 part 3) include Dr. Sthamer's Moussol®-FF 3/6 F-5 and 3F's Chemex.<sup>[27]</sup>

These are merely a few examples to illustrate that both types of foam exist in many different grades and qualities and hasty generalisations and unfair comparisons (such as "fluorinated foams perform better than fluorine-free ones"), although regrettably commonplace, should be avoided.

What's more, European Standards such as EN 13565, require lower performing foams to be applied at higher rates in order to compensate for the lower performance, but they do not preclude or limit their use. These ratings and associated fire performance are especially important in extinguishing fires for large storage tanks, as site operators may rely on other sites' supplies of foams (and equipment) in their disaster management plans – this means they will have to work with many different qualities of foam in practise.

Finally, it should be noted that not all fires can or should be extinguished; in the aftermath of the Buncefield fire (see also part 3 of this response), the UK's Health and Safety Executive issued a final report regarding fuel storage sites.<sup>[28]</sup>

Recommendations 18 and 19 in part 2 of this report provide high-level summaries on cases where a controlled burn strategy is better than extinguishing the fire. This should be kept in mind against any impression that AFFFs can extinguish any type of fire.

2. Practice does not justify this size limit either. Existing legislation (e.g. in the US) banning the use of fluorinated foams usually only grants case-by-case exemptions, and the general ban does not contain any reference to surface areas. Many states in the US have recently passed such legislation;<sup>[29]</sup> time limits to exemptions are often much shorter than in the DO: California 2032, Washington State 2028, Illinois 2027, Vermont 2025, Connecticut 2023. Tank farms in the scope of these bans are, among many others, Motiva's site in New Haven, Connecticut and the Exxon refinery in Joliet, Illinois, which both host numerous tanks in excess of 400 m<sup>2</sup>, and even up to 2000 m<sup>2</sup>.<sup>[30]</sup> The DO remains below the ambition and technical possibilities demonstrated by legislation elsewhere.

Regarding ECHA's request on the possibility to fully contain AFFFs in the event of an accident, we provide the following information:

3. Containment by the bunded area: In a best-case scenario, bunded areas are built to retain leaks of fuel or chemicals until the leak can be dealt with, but their resistance to fires has proven to be insufficient. The Buncefield Fire in the UK in 2005, one of the major fire events in tank farms, showed failures in the bunded areas, releasing large quantities of fluorinated foams (actually still C8-based) to the environment. Due to the fire burning for several days in bunded areas of three different construction types, leakages were observed because of heat damage to the concrete walls, movements of concrete slabs, and joints and sealants damaged by the heat.

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[27] Technical data sheets available from [https://www.sthamer.com/en/pdf/Produktdatenblatt/PD-7942-V06-MOUSSOL-FF\\_3x6\\_F-5-EN.pdf](https://www.sthamer.com/en/pdf/Produktdatenblatt/PD-7942-V06-MOUSSOL-FF_3x6_F-5-EN.pdf) and [https://www.3fff.co.uk/wp-content/uploads/2020/06/CHEMEX\\_FT\\_UK-1.pdf](https://www.3fff.co.uk/wp-content/uploads/2020/06/CHEMEX_FT_UK-1.pdf)

[28] HSE 2009, Safety and environmental standards for fuel storage sites, Process Safety Leadership Group, Final report, available at: <https://www.hse.gov.uk/comah/buncefield/fuel-storage-sites.pdf>

[29] a useful summary is provided by the Fire Fighting Foam Coalition, AFFF Update June 2021, available from: [www.ffff.org](http://www.ffff.org), also attached.

[30] Aerial views of relevant sites attached as .pdf files.

The attached expert report<sup>[31]</sup> summarises the lessons learnt; we have highlighted relevant passages for the readers' convenience.

In a worst-case scenario, bunded areas are not even protected by an impermeable layer in the soil. Although bunds can be retrofitted,<sup>[32]</sup> many bunded areas in the EU have probably not been equipped with such linings, allowing fuel and foam to seep through the ground after the event. In addition, some tanks may even not be equipped with concrete or brick-and-mortar bunds, but only rely on earth dikes.

A long-term derogation for use of fluorinated foams may therefore not rest on the assumption that bunded areas can reliably retain foams. Controlling the risk of such releases would entail independent detailed checks of the installations, as a minimum against all failure modes described by Tarada and Robery.

Another major fire incident, currently still under investigation, took place at ITC in Deer Park, Texas, US in March 2019. In this event, major environmental pollution was caused by foam being discharged outside of the bunded area<sup>[33]</sup>, by the failure of secondary (i.e. bunds) and of tertiary physical barriers (a dike)<sup>[34]</sup> designed to contain fuel and foam.<sup>[35]</sup> Subsequent environmental monitoring<sup>[36]</sup> documented high concentrations of 6:2 FTS (i.e. PFHxA-related substances) in the waterways around the site.

4. **Containment for atmospheric losses:** Whoever has seen a smoke plume from a major fire incident knows of the forceful upwards movements of hot air, and knows that soot can be deposited many kilometres away. A sizeable fraction of the foam projected by monitors onto fire will not end up in the bunded areas (even if they withstand the fire), and more will be dragged into the smoke plumes and deposited elsewhere. The fire itself may not be supposed to break up the PFAS from the foam to inorganic fluoride: even dedicated (but certainly insufficiently effective) incinerators fail to destroy PFAS effectively<sup>[37]</sup>, let alone a fire burning at lower temperatures in most parts of the fire. Effective minimisation of releases through the air can in practice only be achieved by using fluorine-free foams.

## 8: Technical textiles: textiles used in engine bays

*In the Background Document, and, in response to a comment received during the consultation on the Annex XV report<sup>[1]</sup>, the Dossier Submitter proposed a permanent (i.e. without a time-limit) derogation for textiles used in engine bays in the automotive and aerospace industry. However, SEAC considers that the information available in the Background Document and provided during the consultation on the Annex XV report is insufficient to conclude on a derogation. Therefore, SEAC requests additional information on:*

*use quantities of PFHxA, its salts and related substances used and associated emissions to the environment from the manufacture, the service life and the end of life of vehicles;*

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[31] F. Tarada, P. Robery (2014) Containment for petroleum products - lessons learnt from Buncefield, UK, Civil Engineering, 167 (CE4), 167-175, dx.doi.org/10.1680/cien.14.00016, attached with highlights of relevant passages.

[32] See e.g. the materials and services offered by Rawell: <https://www.rawell.co.uk/sectors/?i=1>

[33] Aerial views illustrating the failures can be found here: <https://www.youtube.com/watch?v=dTiTrUNE61E>

[34] <https://www.chron.com/neighborhood/deerpark/article/Spill-from-ITC-Deer-Park-plant-fire-threatening-13723602.php> and <https://www.icis.com/explore/resources/news/2019/03/22/10338392/dike-at-fire-hit-itc-chemical-tanks-in-us-la-porte-partially-collapses/>

[35] News Release on 23rd March 2019 by the Texas Commission on Environmental Quality, attached

[36] N.A. Aly et al. (2020) Temporal and spatial analysis of per and polyfluoroalkyl substances in surface waters of Houston ship channel following a large-scale industrial fire incident, Environmental Pollution, 265, 115009, doi.org/10.1016/j.envpol.2020.115009

[37] An example of such incorrect disposal is described here: <https://theintercept.com/2020/04/28/toxic-pfas-aff-upstate-new-york/>

clarification on the substances used, i.e. PFHxA-related (low-molecular) substances, side-chain fluorinated polymers, or fluoropolymers (see footnote 1) and their function;

- a. a comprehensive overview of the end products (e.g. different types of vehicles) requiring this use;
- b. the number/proportion of the related end products (cars etc.) requiring this use;
- c. alternatives (for the textile product or for the PFAS treatment) that have been assessed, including information on the search for alternatives, and why they are considered not technically or economically feasible (including their difference in price, if economic feasibility is considered to be an issue);
- d. alternatives potentially already used by competitors, and their performance in general and in comparison with textiles containing PFHxA and/or related substances;
- e. socio-economic impacts resulting from a restriction of this use;
- f. proposed wording of a possible derogation, such that it would cover the intended use in terms of substances and end products;
- g. the extent to which other possible derogations proposed, such as the one proposed by the Dossier Submitter for filtration and separation media, would also cover the use of technical textiles in engine bays.

[1] Please see comment #2996 in the consultation on the Annex XV report for information on the referred use (RCOM, part 2).

Regarding aspects e, f and i: Textile auxiliaries supplier CHT recommends their fluorine-free repellent Ecoperl<sup>[38]</sup> along the C6-based Tubiguard as suitable repellent coatings for filters used in engine bays; however without any reference to nonwovens used as liners (which is mentioned in comment #2996). A use such as the one mentioned by CHT would indeed mean that uses in engine bays would be covered by the (not sufficiently justified, see Q9) derogation on filtration and separation media.

Based on the explanations in comment #2996, it is difficult to understand what areas of the engine bay of a combustion engine would be meant, and what the exact function of such a textile material could be. Ignition-prone areas (and thereby safety-relevant ones) would have to be areas where fuels or oil can accumulate and ignite through a spark or high temperature. Adding to our surprise, an inspection of real engine bays revealed no conspicuous textile materials (e.g. under the hood of a Renault Twingo) or some nonwovens, which however repelled neither water nor oil (Mazda CX-5).

Although repelling oil could arguably be a useful feature of materials used in such areas, one should wonder how less lipophobic surfaces such as rubber, plastics or metals fare in such circumstances in the nearby surroundings.

## 9: Filtration and separation media

During the consultation on the Annex XV report, several stakeholders requested a derogation for filtration and separation media. The Dossier Submitted proposed a permanent (i.e. without a time limit) derogation for "filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellence".

SEAC is currently considering whether to support this derogation, since enforcement of and compliance with this derogation may be difficult due to the current wording. More information could be submitted on:

- a. Enforcement and compliance issues expected by industry stakeholders or enforcement authorities due to the current wording.
- b. Applications that would not be covered by the proposed derogation with the current wording and, for these applications, information on:
  - i. alternatives that have been assessed, including information on the research for alternatives made, and why they are considered not technically or economically feasible (including their difference in price, if economic feasibility is considered to be an issue);

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<sup>[38]</sup> Brochures and technical datasheets attached.

- ii. *the substitution timeline, in case alternatives are currently available, but more time than the 36-month general transition period currently proposed by SEAC (from entry into force of the restriction) is considered necessary for substitution.*
- c. *The extent to which the relevant applications would be covered by a derogation of plasma nano coatings similar to that suggested by SEAC in the PFOA restriction case (see footnote 3).*
- d. *The elements that a suitable wording for the derogation should contain.*
- e. *Industrial or other national or international performance standards for filtration and separation media that can be met only with the current performance of combined water- and oil-repellence provided by PFHxA related substances. Evidence on the failure of alternatives to meet these standards should also be provided. Information on the performance standards will help SEAC to understand how to word any proposed derogation*
- a. Independently of any technical justification for the proposed derogation, the wording “high performance” is bound to cause trouble by its unspecific and vague nature.
- b. (+e) Based on the technical information provided in the DO and in comment 3024, the function of a C6-treated or C6-containing filter remains unclear. Many filters, including HEPA filters (air filtration only, performance classes defined in EN 1822), which serve in many of the application sectors mentioned in comment 3024), rely on an affinity of the particles to the filter fibre: the particles are removed not only by size exclusion (like in a sieve), but also by affinity for the fibre. By sticking to the fibre, the particle does not travel further into or through the filter. For this reason, many such filters are made from glass fibre or polyolefins. Lowering the surface energy of the fibre to very low values by a fluorinated treatment appears counterproductive, as the capacity to stick to the fibre is lost; the filter would then only act by size separation, like a sieve. When the treatment is applied in process step 1 or 4 (as defined and described in the attachment to comment 3024, p. 5), this problem appears obvious - therefore with the currently available description, the PFAS treatment sounds counterproductive.

Similar reasoning holds for filtration media for liquids.

The information in the attachment to comment 3024 is similarly cryptic in other respects: Table 1 lists the following as oil resistance standards – oil resistance being the only feature that generally cannot be matched with non-fluorinated treatments:

- the Tappi T559 standard, which tests oil resistance, not oil repellence,
- ISO 14419, which assesses (oil) stain resistance of textiles, rather than oil repellence,
- the DuPont kit test (without further details; however what is generally meant with the DuPont kit test is a test to assess pressure tightness of protective suits),
- the 3M kit test (again without further details; “3M kit test” normally refers to a tightness tester for masks and respirators).
- ISO 29461-4 and -7 provide little of a hint as to the function (let alone necessity) of a fluorinated treatment, not least as they are under development. The already existing parts 1, 2, 3 and 5 of the same standard do not help either. ISO 29461-1:2021, hot off the press, provides a classification system of air intake filters for engines and turbines, depending on the need to filter coarse or fine dust – other classification systems for filters have existed before (such as ISO 16890, for general ventilation). Yet, no information is provided justifying the use of fluorinated treatments.

In other words, the tests listed appear not to correspond to the (vague) description of relevant functional performance linked to the use of C6 treatments.

The request for this derogation comes from three companies from the filtration media market, which encompasses many more actors. At least two out of the three companies hold potentially relevant patents incorporating SCFPs into filtration media:

- Hollingsworth&Vose hold US patent 2011/0147320, describing combinations of dendrimers and an optional fluorinated material, whereby the latter functions as a water repellent - the combination with oil repellence is at most optional, therefore materials falling under this patent would likely not qualify for the derogation.
- Hollingsworth&Vose also hold the more relevant and recent US patent 2018/0001244, wherein one layer of a filter material is fluorinated. According to paragraph [0041], the fluorinated species (which may correspond to an acrylic SCFP) “may impart a certain level of oil repellency”, without mentioning the technical function of the oil repellence.
- Lydall holds US patent 10,003,34, which describes the use of fluoropolymers (which also refers to fluorinated polymers in this patent) in insulating materials, imparting high mechanical strength. Example 6 describes the use of Daikin’s Unidyne TG-5502 water and oil repellent, a fluorinated acrylate; however, the invention does not rely on oil repellence, mentioning only water repellence.
- Lydall also commercialises LyPore(R) media intended to separate oil and water,<sup>[39]</sup> the performance of which rests on (unidentified) “proprietary fluoropolymer [sic] repellency”.

Based on the above, it appears that only the second and possibly the fourth (if indeed corresponding to a fluorinated polymer, rather than a fluoropolymer), are relevant for this proposed derogation. Affected technology includes two recent patents only, and their holders and potential licence grantees as well.

We urge SEAC to consider that:

- the functions have so far been very vaguely described;
- the functions have so far been excessively broadly described;
- there is no information yet on the necessity of the fluorinated treatment for the intended function, nor any indication on performance loss on leaving out the fluorinated treatment;
- there is no indication on how the related needs were covered without fluorinated materials prior to the granting of the two patents;
- no information is available yet how any performance potential translates into any societal benefits;
- no information is available yet how any such societal benefits compare to the risks related to their use;
- RAC neglected all risks from end-of-life scenarios other than landfilling. Especially any risks from the release of fluorinated substances (potentially strong greenhouse gases) from incineration at standard temperatures have been disregarded.

## 10: Photographic coatings applied to papers and inkjet photo media coatings

*During the consultation on the Annex XV report, some stakeholders argued that the proposed derogation for photographic coatings on films should be extended to also cover photographic coatings applied to papers and inkjet photo media. SEAC currently does not support the derogation proposed by the Dossier Submitter for these uses and requests more information on:*

- the type of products suggested to be derogated;*
- the quantity of PFHxA related substances used in the EU per year (non-confidential ranges) for this application and their function;*

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<sup>[39]</sup> <http://lydallpm.com/products/liquid-filtration/lypore-unity-coalescing-media/overview/>

- c. *emissions taking place in the manufacturing, use (potentially by consumers) and end-of-life stages;*
  - d. *alternatives that have been assessed, including information on the research for alternatives made, and why they are considered not technically or economically feasible (including their difference in price, if economic feasibility is considered to be an issue);*
  - e. *the timeframe needed to develop or implement suitable alternatives and the main impediments to develop a suitable alternative (if relevant);*
  - f. *the socio-economic impacts of not being able to use PFHxA related substances, including if/how a loss of performance would result in any concrete cost for society.*
- a. The only entry in the RCOM documents matching this description is entry 2991 by a single company, Schoeller Technocell. That entry mentions, in the public part, “surfactants” used in “coatings for Photo Inkjet” media. This description falls under “inkjet photo media coatings”. Surprisingly, none of the earlier policy documents (Annex XV and RCOM of the C8-restriction, studies by Fraunhofer[40] and Defra[41], academic papers by Buck et al.[42] or the very comprehensive review by Glüge et al.[43] ) mentions such a use for any PFAS. We therefore urge SEAC not to conclude favourably on granting such a derogation, except if compelling evidence were provided in the present public consultation, indicating that the C6 substances involved fulfil a function that cannot be achieved otherwise, and which present an obvious societal advantage. We also urge SEAC to take into account that RAC disregarded risks from end-of-life scenarios such as recycling or incineration, thereby underestimating the risks.
- f. Given that only a single company requested this derogation, SEAC should not only weigh societal function (let alone a single company’s financial concerns) against environmental and health risk, but also potential distortion of market forces.

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<sup>[40]</sup> [https://www.isi.fraunhofer.de/content/dam/isi/dokumente/ccn/2012/PFOA-PFOS\\_1.pdf](https://www.isi.fraunhofer.de/content/dam/isi/dokumente/ccn/2012/PFOA-PFOS_1.pdf)

<sup>[41]</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/183154/pfos-riskstrategy.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/183154/pfos-riskstrategy.pdf)

<sup>[42]</sup> R.C. Buck et al. (2011), Integrated Environmental Assessment and Management, 7 (4), 513-541, doi.org/10.1002/ieam.258

<sup>[43]</sup> J. Glüge et al. (2020), Environmental Science: Processes & impacts, 22, 2345-2373, doi.org/10.1039/D0EM00291G