**General comments and answers to specific information requests**

**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 >400m2 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.

1. **Concentration limits for PFHxA, its salts and related substances in fluoropolymers[[1]](#footnote-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;
* 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in **coating of electronic devices** until XX XX XXXX [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 XXXX [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:

1. the sector/application in which respondents use fluoropolymers containing PFHxA, its salts and related substances (even as impurities), and the quantity of fluoropolymers used;
2. the current concentration (in ppm/ppb) of PFHxA, its salts or related substances in fluoropolymers for specific applications/uses;
3. 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;
4. 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);
5. 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]](#footnote-2);
6. existing technologies that allow the production of fluoropolymers without using PFAS (in particular, without using PFHxA, its salts or related substances) as processing aid;
7. the concentration of PFHxA, its salts or related substances in purified fluoropolymer grades;
8. 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;
9. possible difficulties of complying with different concentration limits for different sectors where fluoropolymers are used, as suggested by the Dossier Submitter;
10. 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)
11. **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:

1. 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);
2. proposals as to how to word a possible derogation such that it covers the necessary uses and only those uses;
3. information on whether the wording used in the PFOA restriction[[3]](#footnote-3) (“pulsed plasma nano-coating”) would also be appropriate for these uses (along with the related costs and emissions);
4. 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.);
5. 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. **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:

1. the quantity of PFHxA related substances used in the EU per year for this use;
2. how wide this use is in the EU (e.g. how many companies use PFHxA related substances for cladding in optical fibres);
3. the claim that higher data rate transmission media will be mandatory in the near future for safe driving or auto-pilot system:
   1. what is the timeframe in which this requirement is expected?
   2. what data rate will be required and what can alternatives achieve in this regard?
4. alternatives that have been assessed, including information on the search for alternatives, and why they are considered not technically or economically feasible;
5. 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)
6. **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:

1. whether the definition of medical devices as specified in Regulation 2017/745 would also cover medical textiles (woven or non-woven);
2. if medical textiles are not covered by the proposed derogation for medical devices, please provide information on:
3. the type(s) of product(s) not covered;
4. the quantity of PFHxA related substances used in the EU per year for this application and the related emissions;
5. 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);
6. 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;
7. 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);
8. socio-economic impacts resulting from a restriction of this use.
9. **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:

1. the total quantity of PFHxA related substances used in the EU per year for this use;
2. 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);
3. 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);
4. 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;
5. antifog face shields not containing PFHxA-related substances potentially already on the market, their performance level and the alternatives used
6. **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 m2”. SEAC is currently supporting the Dossier Submitter’s rationale 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 m2, 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 m2 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.

1. **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[[4]](#footnote-4), 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:

1. 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;
2. clarification on the substances used, i.e. PFHxA-related (low-molecular) substances, side-chain fluorinated polymers, or fluoropolymers (see footnote 1) and their function;
3. a comprehensive overview of the end products (e.g. different types of vehicles) requiring this use;
4. the number/proportion of the related end products (cars etc.) requiring this use;
5. 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);
6. alternatives potentially already used by competitors, and their performance in general and in comparison with textiles containing PFHxA and/or related substances;
7. socio-economic impacts resulting from a restriction of this use;
8. proposed wording of a possible derogation, such that it would cover the intended use in terms of substances and end products;
9. 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.
10. **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:

1. Enforcement and compliance issues expected by industry stakeholders or enforcement authorities due to the current wording.
2. Applications that would not be covered by the proposed derogation with the current wording and, for these applications, information on:
3. 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);
4. 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.
5. 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).
6. The elements that a suitable wording for the derogation should contain.
7. 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
8. **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:

1. the type of products suggested to be derogated;
2. the quantity of PFHxA related substances used in the EU per year (non-confidential ranges) for this application and their function;
3. emissions taking place in the manufacturing, use (potentially by consumers) and end-of-life stages;
4. 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);
5. the timeframe needed to develop or implement suitable alternatives and the main impediments to develop a suitable alternative (if relevant);
6. 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.

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| Ref. | Date/Type/Org. | Comments |
| 957 | Date/Time:  2021/09/07 19:28  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  W. L. Gore & Associates GmbH  Org. country:  Germany  Attachment:    <redacted>  Privacy statement:  commercial interests of a natural or legal person, including intellectual property would be undermined | General Comments:  See attachments |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 958 | Date/Time:  2021/09/07 19:27  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  AGC Chemicals Europe, Ltd  Org. country:  United Kingdom  Attachment:    <redacted>  Privacy statement:  Protection of confidential business information (e.g. AGC fluoropolymers produced with C6 fluorotelomers as process media) | General Comments:  Please see attachments: - Non-confidential document from AGC on fluoropolymers - Non-confidential document from AGC on fluorotelomers |
| Specific information 2:  See non-confidential and confidential documents from AGC. |
| Specific information 3:  See non-confidential and confidential documents from AGC. |
| Specific information 5:  See non-confidential and confidential documents from AGC. |
| Specific information 8:  See non-confidential and confidential documents from AGC. |
| Specific information 9:  See non-confidential and confidential documents from AGC. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 959 | Date/Time:  2021/09/07 19:31  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  commercial interests of a natural or legal person, including intellectual property would be undermined | General Comments:  See attachment |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 960 | Date/Time:  2021/09/07 19:33  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  commercial interests of a natural or legal person, including intellectual property would be undermined | General Comments:  Our submission is attached. |
| Specific information 2:  See confidential attachment |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 961 | Date/Time:  2021/09/07 19:39  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  Filtration and Separation Coalition consisting of Ahlstrom-Munksjö, Hollingsworth & Vose and Lydall  Org. country:  Belgium  Attachment: | General Comments:  Please refer to the joint industry statement submitted as attachment. |
| Specific information 9:  Please refer to the joint industry statement submitted as attachment. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 962 | Date/Time:  2021/09/07 19:49  Type:  BehalfOfAnOrganisation  Org. type:  National Authority  Org. name:  <redacted>  Org. country:  France  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  The information is related to the defence sector. | General Comments:  See attached document in Section V. |
| Specific information 2:  See attached document in section V. |
| Specific information 9:  See attached document in section V. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 963 | Date/Time:  2021/09/07 19:48  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  ALKEMYA SOLUTION SARL  Org. country:  France  Attachment:    <redacted>  Privacy statement:  The confidential dossier include confidential datas on our company : its commercial strategy, its technical knowledge, different commercial informations, etc … a public access on those datas shared with you would undermined our commercial interests | General Comments:  Through our participation to this consultation we want to bring to your attention the importance of the use of fluoro telomers in our application field : the protection of stones in the building industry. The benefits of this technology and the control on the eventual releases let us very confident on the opportunity to get a derogation of use ; this specific application has been under evaluated perhaps due to a low level of communication from our raw materials supplier and we try to correct it via our participation and the ones of several companies working on the same technology. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 964 | Date/Time:  2021/09/07 20:00  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  EDANA  Org. country:  Belgium | General Comments:  n/a |
| Specific information 1:  We are of the opinion that any reporting requirements should be as efficient and accurate as possible. For example, it could occur that a natural and legal person placing a mixture on the market and a natural and legal person placing an article on the market exist in the same supply chain which benefits from one of the specified derogations. In this case, there is a risk of double counting of the quantity of PFHxA, its salts and related substances for one use (= used in mixtures which will be incorporated in an article). This situation will lead to overestimation of the total volume of this substance. To avoid a potential double counting and overestimation, the industry needs to have clear guidance on whom, within the supply chain for a specific derogation, is obliged to fulfil the legal requirement. EDANA would like to highlight that the absence of a standard analytical method would pose serious implementation and enforceability challenges to both industry and regulators. The scope of the draft standard CEN/TR 16741 “Textiles and textile products - Guidance on health and environmental issues related to chemical content of textile products intended for clothing, interior textiles and upholstery” doesn’t include nonwovens. It specifically addresses: “2.1 textile clothing and accessories clothing and accessories (such as handkerchiefs, scarves, bags, shopping bags, rucksacks, belts etc.) consisting of at least 80 % by weight of textile fibres 2.2 interior textiles, textile products for interior use textile products for interior use: textile products for interior use consisting of at least 80 % by weight of textile fibres; wall and floor coverings are excluded 2.3 fibres, yarn and fabric intended for use in textile clothing and accessories or interior textiles”. Nonwovens are defined by ISO standard 9092 and CEN EN 29092 “engineered fibrous assembly, primarily ]planar, which have been given a designed level of structural integrity by physical and/or chemical means, excluding weaving, knitting or paper making”. Nonwovens are designed for their specific application, ranging from thin, light weight nonwovens to strong and durable ]nonwovens, be it consumer or industrial applications. The combination of their specific characteristics through the raw materials selection, the formation and bonding methods used or the applied finishing treatments, such as printing, embossing, laminating etc. allow to deliver high-performance products. |
| Specific information 5:  a) To the extent to which products are used in medical settings, they fall under the definition of medical devices according to the Regulation 2017/745 (EU). b) ii) C6 fluoropolymer-treated repellent medical nonwovens are used in hospitals to avoid cross­ contamination of fluids for the health of the clinician and the patient. Medical apparel such as gowns and drapes are constructed with repellent-treated medical nonwovens. The addition of C6 fluoropolymer to the nonwoven fabric provides water repellency, body fluid repellency (i.e. blood, lung fluid, amniotic fluid, etc.) and fat repellency. Manufacturers currently use the lowest amount of C6 possible on surgical fabrics to ensure safety and efficacy of the product. The repellent nonwoven fabric creates a barrier between the wearer of the garment and low surface tension fluids (i.e. blood, body fluids, fat, alcohol based and surfactant based prep solutions, etc.). Without the addition of the fluoropolymer, the nonwoven will not provide this barrier. This barrier is critical to human health by protecting both the patient and the clinician from low surface tension fluids which have the potential to contain viruses and bacteria, from passing between the patient and clinician(s). Fluoropolymer-treated repellent medical nonwovens provide superior barrier, comfort (breathability, hyperthermia, perspiration) and range of movement without negative effects on human health per cytotoxicity, primary skin irritation and skin sensitization testing. Risk management measures include: - Minimizing the amount of fluoropolymer applied to the nonwoven to achieve specific barrier performance properties as required by fitness for use in medical apparel. - The addition of non-fluorinated auxiliary chemistry allows for a reduction of fluoropolymer by at least 30%, while still achieving barrier performance properties. - The chemical application process is designed, and constantly monitored through automated controls, to minimize fluorine emissions via air or water. - Barrier performance requirements are routinely reviewed with customers in order to determine if any reduction in performance is acceptable, thereby reducing overall fluoropolymer need. (Note: to date, no performance reduction has been accepted due to the potential negative consequences to human health.)] b)iii) Global chemical suppliers have been actively working to find an alternative finish that provides the same level of protection as the fluoropolymer finish. Until that occurs, the industry believes it is critical to continue use of C6 fluoropolymer on fabrics exposed to low surface tension fluid. b) iv) Considering the safety and efficacy critical features of the products needed to comply with stringent requirements of Medical Devices Regulation in regards to conformity assessment, we suggest a transition period of at least 7 years, after an acceptable alternative is commercially available. Such a change of technology to go FC-free will require: 1/ Meeting all the regulations requirements before adjusting hospital agreed specifications related to the blood and body fluid barrier performance if needed. Currently, due to pandemic, hospitals are not willing to do any testing. That initiative is on hold since 2020. 2/ changing a significant component in a medical device depending on the risk class takes minimum 5/7 years. It took 4 years from start to finish to succeed the transition from C8 to C6. The complexity is much higher when going to “FC free” solution. Such new technology qualification includes, amongst others, all the validation testing, aging testing, CE Marking … b) v) Please refer to the individual members submissions. b) vi) Without repellency to low surface tension fluids, viruses and bacteria could transfer between the patient and clinician(s) through the medical apparel. |
| Specific information 8:  a) To the best of our knowledge, C6 is embedded in the fabric and there are, therefore, no emissions during service life. Moreover, end-of-life removal and disposal are covered by Directive 2000/53/EC, the ELV Directive, which ensures proper handling and treatment. b) Although the performance requirements may depend on the final applications, C6 side-chain fluorinated polymer provide unique performance benefits to the sector: • Low surface tension resulting in unique water-, oil- and stain-repellency; • Exceptional chemical stability leading to long lifetime of products; • Soil release properties; and • High heat and chemical resistance. c) We would like to point out that the term ‘automotive’ covers only certain categories of vehicles (e.g., passenger cars), but not motorcycles nor non-road mobile machinery that are used for construction and agriculture. In our view, the term ‘automotive’ should be reconsidered. Moreover, the proposed derogation should apply to cover other applications that require oil- and stain- repellency. Some examples of these applications are provided below: • C6-treated nonwoven fabrics are used under the engine shield to protect the compartment, preventing fuel absorption and promoting temperature resistance due to its oil-and stain- repellent properties. This constitutes a key safety feature in case of accident, which provides more time to rescue people before the vehicle starts to burn out. • C6 is also used to provide strong fuel/oil-repellency and heat resistance to nonwovens used as sound insulation material in various parts of vehicles, e.g. in the moulded bonnet linner, the rear wheel arch liner (https://www.edana.org/nw-related-industry/nonwovens-in-daily-life/automotive). This helps increasing the safety of the vehicle by insulating the components and reducing noise, vibration, and harshness (NVH). We also would like to point out that, due to EU Regulation 540/2014 on the sound level of motor vehicles, all types of vehicles are required to be equipped with sound absorption parts. Without the C6 chemistry, compliance with this Regulation would be challenging. • A similar NVH application is in the insulation of compressors for industrial machinery applications. Here the C6-SFP treated nonwoven materials are also used to deliver sound insulation performance in an environment where they are exposed to oil- and water-based contamination. The repellency effect of the C6 treatment minimizes the impact of these environmental hazards. e) Nonwovens help reduce the weight of the car, lowering fuel consumption, provide advanced insulation, fire retardancy and resistance to water, fuels, extremes of temperature and abrasion. They contribute to extending the product lifetime and making cars safer, more cost-effective and more sustainable. The combination of the abovementioned properties can only be granted with fluorinated compounds. g) Nonwovens help reduce the weight of the car, lowering fuel consumption, and provide advanced insulation, fire retardancy and resistance to water, fuels, extremes of temperature and abrasion. They contribute to extending the product lifetime and making cars safer, more cost-effective and more sustainable. The combination of the above-mentioned properties can only be granted with fluorinated compounds. h) We believe that a derogation for technical textiles is necessary to cover all those uses for which durability as well as oil- and stain- repellency are required. Technical textiles can be defined, as stated in the Opinion of the European Economic and Social Committee on Growth Driver Technical Textiles, in the following manner: Textile fibres, materials and support materials meeting technical rather than aesthetic criteria, even if, for certain markets, both types of criteria are met. Technical textiles bring a functional answer to a wide range of specific requirements: lightness, resistance, reinforcement, filtration, fire-retardancy, conductivity, insulation, flexibility, absorption and so on (Opinion (CCMI/105-EESC-2012-1966) of the European Economic and Social Committee on Growth Driver Technical Textiles, https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/technical-textiles). In addition, we propose to extend the proposed derogation to all means of transport, professional mobile equipment, large scale industrial tools and fixed installations, in line with the definitions provided in the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, also known as RoHS. Based on the RoHS 2 – Frequently Asked Questions provided by the Commission, this would allow to cover not only cars, commercial vehicles or aircrafts, but also hydraulic excavators, fork-lifts, road maintenance equipment and harvesters, as well as compressors for industrial machinery applications (https://ec.europa.eu/environment/system/files/2021-01/FAQ%20key%20guidance%20document%20-%20RoHS.pdf, p. 17). Consequently, our proposal reads as follows: Paragraphs 1 and 2 shall not apply to high performance technical textiles used for NVH (noise, vibration, harshness) insulation and engine ignition protection in means of transport, non-road mobile machinery as defined in Regulation 2016/1628, as well as large scale industrial tools and large-scale fixed installations as defined in Directive 2011/65/EU. i) It is our understanding that the currently proposed derogation for filtration and separation media does not cover the use of technical textiles in engine bays, nor the other uses listed hereinabove (see section c). |
| Specific information 9:  c) We refer here to individual submissions made by member companies. d) In view of the concerns expressed by SEAC regarding the enforceability of the current wording of the proposed derogation, we suggest the conditions of the restriction in the SEAC opinion (https://echa.europa.eu/documents/10162/c33c8359-ceee-ab6d-c205-af1b1516e8eb) be read as follows: “(8) Paragraphs 1 and 2 shall not apply to (h) air and liquid filtration and separation media that require a combination of water and oil repellency for filters used in industrial settings or by professionals”. Currently point h) reads: “filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency”. In our opinion, the derogation aims to cover filtration and separation media which require a combination of water and oil repellency. This combination of properties, which can only be achieved by C6 fluorotelomer chemistry, provides critical benefits including optimal pressure drop, barrier properties against airborne harmful pollutants and microbiological contaminants, high dust holding capacity, durability, and the required level of glue-repellency to ensure optimal converting. Water and oil repellency performance can be verified through a variety of standards (e.g. AATTC118, 3M kit test, TAPPI 599 or ISO 14419) that are well known within our sector and can be conveniently performed by our industry and enforcement authorities alike. e) We refer here to individual submissions made by members companies. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 965 | Date/Time:  2021/09/07 20:14  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  CREE SA  Org. country:  France  Attachment:    <redacted>  Privacy statement:  The confidential dossier include datas on our company : Its commercial strategy, its technical knowledge, commercial informations, etc … a public access on those datas shared with you would undermined our commercial interests | General Comments:  Through our participation to this consultation we expect to bring to your attention the importance of the use of fluoro telomers in our application field : the protection of porous substrates like natural stones in the building industry. The benefits of this technology and the control on the eventual releases let us very confident on the opportunity to get a derogation of use. We work on this technology for more than 30 years and have invested a lot to make it good. This specific application has been under evaluated per SEAC due to a low level of communication from fluoro telomers suppliers on this topic and we try to correct it via our participation and the ones of several companies working on the same technology. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 966 | Date/Time:  2021/09/07 20:18  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  ALKEMYA SOLUTION SARL  Org. country:  France  Attachment:    <redacted>  Privacy statement:  The confidential dossier include datas on our company : Its commercial strategy, its technical knowledge, commercial informations, etc … a public access on those datas shared with you would undermined our commercial interests | General Comments:  2nd submition ... To replace the confidential part ... the "dossier" had an issue on one file. Through our participation to this consultation we expect to bring to your attention the importance of the use of fluoro telomers in our application field : the protection of stones in the building industry. The benefits of this technology and the control on the eventual releases let us very confident on the opportunity to get a derogation of use ; this specific application has been under evaluated perhaps due to a low level of communication from our raw materials supplier and we try to correct it via our participation and the ones of several companies working on the same technology |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 967 | Date/Time:  2021/09/07 20:35  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  SEMI Europe  Org. country:  Germany  Attachment: | General Comments:  SEMI Europe is the European affiliate of SEMI, the industry association representing more than 2,400 semiconductor and electronics manufacturing companies worldwide, including nearly 400 EU headquartered businesses. SEMI Europe welcomes the opportunity to provide comments on ECHA’s Socio-Economic Committee (SEAC) draft opinion on the proposed restriction on undecafluorohexanoic acid (PFHxA), its salts and related substances.  For reasons provided in our response (in attachment in Section IV), SEMI Europe suggests an amendment on the conditions of the restriction proposed by SEAC. |
| Specific information 2:  We support the thresholds supported by the Fluoropolymers Product Group (FPG): (a) 500 ppm for the sum of PFHxA and its salts in fluoropolymers; (b) 2500 ppm for PFHxA related low molecular substances in fluoropolymers. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 968 | Date/Time:  2021/09/07 20:57  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  SEMI Europe  Org. country:  Germany  Attachment: | General Comments:  SEMI Europe is the European affiliate of SEMI, the industry association representing more than 2,400 semiconductor and electronics manufacturing companies worldwide, including nearly 400 EU headquartered businesses. SEMI Europe welcomes the opportunity to provide comments on ECHA’s Socio-Economic Committee (SEAC) draft opinion on the proposed restriction on undecafluorohexanoic acid (PFHxA), its salts and related substances.  For reasons provided in the response (in attachment in Section IV), SEMI Europe suggests an amendment on the conditions of the restriction proposed by SEAC. |
| Specific information 2:  SEMI Europe supports the thresholds suggested by the Fluoropolymers Product Group (FPG): (a) 500 ppm for the sum of PFHxA and its salts in fluoropolymers (b) 2500 ppm for PFHxA related low molecular substances in fluoropolymers |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 969 | Date/Time:  2021/09/07 21:18  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Public access cannot be granted to our confidential attachment as it would compromise our company's commercial interests and / or public safety due to the details about our assets and safety concepts. | General Comments:  please refer to our confidential attachment |
| Specific information 7:  please refer to our confidential attachment |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 970 | Date/Time:  2021/09/07 21:31  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  ALGIMOUSS S.A.S  Org. country:  France  Attachment:    <redacted>  Privacy statement:  The confidential dossier include datas on our company : Its commercial strategy, its technical knowledge, commercial informations, etc … a public access on those datas shared with you would undermined our commercial interests | General Comments:  Through our participation to this consultation we expect to bring to your attention the importance of the use of fluoro telomers in our application field : the protection of porous substrates like natural stones in the building industry. The benefits of this technology and the control on the eventual releases let us very confident on the opportunity to get a derogation of use. We work on this technology for more than 25 years and have invested a lot to make it good and to prepare the future with it. This specific application has been under evaluated per SEAC due to a low level of communication from fluoro telomers suppliers on this topic and we try to correct it via our participation and the ones of several companies working on the same technology. |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 971 | Date/Time:  2021/09/07 23:45  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United States of America  Company name confidential:  Yes | General Comments:  Please see the response in section 2 |
| Specific information 2:  The sector is Medical Device products. The primary applications in the Healthcare Market that utilizes the C6 fluoropolymer for protection against Blood Borne Pathogens (low surface tension fluids) are Surgical Gowns and PPE apparel. These protective products are produced with nonwoven materials utilizing the Spunbond-Meltblown-Spunbond technology, commonly referred to as SMS. C6 Fluoropolymer treated Surgical Gowns are used in the majority of Surgical Procedures in Europe and globally to reduce the risk of exposure to pathogens carried in low surface tension fluids. The C6 treatment provides the fluid protection of the fabric needed to resist penetration of surgical preparation fluids and body fluids into the nonwoven materials. Our Company produces several million square meters per year of SMS Nonwovens for the Surgical Gown and PPE applications. The committee should consult with EDANA to understand the overall European market size which would be significantly higher for total volume of materials for this category of C6 treated materials. Additional applications with C6 treated nonwovens materials are Wound Care (tapes), Ostomy (skin interfacing), and Surgical (tapes). The nonwoven technologies utilized are carded chemically bonded polyester & polyester/viscose materials. The C6 treatment provides dry interface surfaces, repellency of body fluids and oils in order to maintain skin health. In addition, the treatment allows for the processing of adhesives to prevent blocking or adhesive strike through when manufacturing the tape with various adhesive systems. Nonwovens treated with C6 and produced for advanced wound care & medical tapes utilizes lower volumes of nonwovens, but it is still in the millions of square meters per year. Again it would be recommended that the committee consult with EDANA to understand the overall European market size which would be significantly higher for total volume of materials for this category of C6 treated materials. As our Company’s market share size, specific formulations with add on levels and resulting annual quantity of the C6 formulations are proprietary and extremely confidential, these questions would be best discussed directly with our Company once the level of confidentiality of this information is better understood. Based on information from our Suppliers the nonwoven products would exceed the proposed limits, and there are concerns from the Suppliers that the salts / substances have not been completely defined for the limit requirements or characterized for detection. Specific to the wound care and tape products it is our understanding that the C6 fluoropolymer in the solution that we receive prior to blending our formulation would contain >300ppm PFHxA related substances. Actual values in the finished nonwovens we produce would require analytical analysis. Specific to the nonwoven Surgical Gowns and PPE finished materials it is our understanding that these would contain < 1000 ppb, but the Suppliers have stated that the salts/substances have not been defined in a list to the Suppliers, and analytical detection capability is a significant concern at the proposed limits of the salts/ substances. Additional performance information, the C6 fluoropolymer treatments on the nonwoven Surgical Gown materials are used to repel low surface tension fluids, this is a critical performance requirement. The surface tension of commonly used Surgical Preparation and irrigation fluids can range from as low as 22 Dynes to 45 Dynes. The treatment of the nonwoven material with the C6 fluoropolymer works in conjunction with the barrier properties of the SMS materials to protect the wearer against Blood Borne Pathogens. The primary concern with the surgical prep fluids (22 -40 Dynes) is the breakdown of the fluid resistance causing pathways for Blood/Fluid Borne Pathogens to penetrate through the fabric. The C6 fluoropolymer treatment prevents the penetration. Repellency to low surface tension fluids is specified by our Healthcare customers. The test specified is, Alcohol Repellency, with a typical target 7-8 meaning that the nonwoven will repel fluids as low as 20 Dynes. There is no treatment formulation or system known at this time that can meet or come close to the performance levels needed for the Surgical Gown Barrier Specifications or the requirements needed for the Wound care and medical tape applications. Research of alternate formulations to replace the fluoropolymer chemistry has been investigated over the last several years that included mechanical surface modification technologies and chemical alternatives. None of these technologies have been successful in achieving the low surface tension repellency and the oil repellency requirements for these medical material applications. Defining a timeline to replace the C6 fluoropolymer for these applications is difficult to estimate since the replacement to this chemistry will need a breakthrough invention. |
| Specific information 5:  Please see information provided in section 2, the answers in section 2 relate to the Nonwoven materials (disposable medical textiles) used in Surgical Gowns & other Medical Devices |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 972 | Date/Time:  2021/09/07 23:57  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  Werkfeuerwehrverband Deutschland (WFVD)  Org. country:  Germany | General Comments:  We would like to comment on the SEAC draft opinion as follows: Comments specifically on §5c of the opinion of SEAC Unfortunately our comment specifically on this issue from 13th May 2020 (#3031) was not sufficiently considered in the opinion of the SEAC (although with an increase from 18 to 36 months as proposed in the SEAC draft opinion this issue would be only for 2years instead of 3.5years). Therefore I would like to reiterate it here. §5c of the SEAC opinion on the PFHxA restriction proposal reads:  “5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to: [..] (c) concentrated fire-fighting foam mixtures that were placed on the market before [date – 36 months after the entry into force of this Regulation] and are used or are to be used in the production of other firefighting foam mixtures”. This would result in a situation where PFAS-based foams can be used for general firefighting purposes for a period of 2 years but cannot be manufactured. For PFHxA this would result in a difficult and unfavourable situation. A similar approach was used when restricting PFOS and PFOA. However these restriction were of a different type, than the restriction of PFHxA from an end-user perspective. In case of PFOS it was a change from one PFAS-based foam to another (PFHxA precursor based). In case of PFOA it is a change from a foam containing impurities to a more pure version of PFHxA-based foams. Therefore a transition was easier and more or less a drop-in approach could be taken. In case of a transition from PFAS-based foams to fluorine free foams (as a consequence of the proposed PFHxA restriction), this is not the case. Such a transition takes a considerable amount of planning and changes (performance assessment, different physical characteristics like viscosity, cleaning equipment, equipment changes, …). On the other hand an end-user (e.g. fire brigade) needs always the possibility to quickly fill up foam tanks. After the foam was used in an incident it is necessary to rapidly restore the operability of safety systems. It is not possible to use fluorine free foam as a drop-in replacement and it is not feasible to transition to fluorine free foam just after the incident. If one would continue to use PFAS-based foams and the manufacturing of these foams is not possible anymore, fire brigades are likely to prepare for it by building up stocks of PFAS-based foams. This could result in an, otherwise unnecessary, increased purchasing and hence manufacturing of PFAS-based foams. To prevent this situation, manufacturing should be allowed as long as use is allowed. In this case manufacturing should also be allowed for the proposed period of five years.  Comment on Paragraph 7 of the opinion of SEAC: inclusion of secondary containment The WFVD welcomes the inclusion of secondary containments of tanks to the derogations described in paragraph 7, which was asked for in our comment from 13th May 2020 (#3031). In this regard we would like to underline the importance of a careful wording in this context to clearly communicate what tanks and what bunded areas of what size are covered by this derogation.  Comment on Paragraph 7 of the opinion of SEAC: tank size In the Explanatory notes for changes and clarifications, SEAC writes that “during the consultation on the Annex XV report, industry stakeholders requested that the minimum tank size of 500m2 was reduced to 400m2 or that the tank size limit was removed altogether. The choice of 500m2 as minimum surface area of the tank for the derogation was not justified in the Annex XV report. The limit of 400m2 proposed in the consultation was not justified in detail either. However, it was confirmed that experience shows that fluorine free fire-fighting foams are able to extinguish fires up to 400m².” The initially suggested 500m² as proposed by the Dossier Submitter is not just “industry experience” but justified by scientific data. In a large research project carried out by the DGMK for the German refineries (DGMK 1985) more than 1000 test were conducted. They contained different pool sizes, fuels and firefighting foams. Among them were 16 tests of 500m². 8 of them were carried out with fluorine-free foam (protein and synthetic foam) of which 7 were successfully extinguished (DGMK 1985:83-84). Although PFAS-based foams tested under same circumstances showed a better extinguishing time (between 8 to 90 seconds quicker), these tests demonstrate that a successful extinguishment of fuel size up to 500m² with fluorine free foam is possible. The fact that 35 years ago fluorine-free foams were not as developed as they are today, and that PFAS-based foam used in this test contained PFOS (which is said to had a better performance than todays short chain “C6” AFFFs), give additional safety margin to justify a 500m² tank size limit.  DGMK (1985): DGMK- Projekt 230-01 - Untersuchungen zur Optimierung des Brandschutzes in Großtanklägern (accessible via https://dgmk.de/publikationen/untersuchungen-zur-optimierung-des-brandschutzes-in-grosstanklaegern/) |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| 973 | Date/Time:  2021/09/09 21:39\* (submission after the consultation deadline was agreed by ECHA recognising that a technical issue had affected the ability of the respondent to submit within the consultation deadline)  Type:  BehalfOfAnOrganisation  Org. type:  Other contributor  Org. name:  Global PFAS Science Panel  Org. country:  Switzerland | General Comments:  We as scientists from different academic and regulatory institutions in Europe and the US welcome the opportunity to comment on the draft SEAC opinion concerning the proposed restriction of PFHxA, its salts and related substances. We have been studying the class of substances known as PFAS for decades. We strongly support the proposal to restrict PFHxA, its salts and related substances. This initiative is very important because of the shift within industry towards the so-called short-chain perfluoroalkyl chemistries as replacements for the increasingly restricted long-chain perfluoroalkyl chemistries. PFHxA and the other replacement substances pose similar problems as their predecessors, due to their extreme persistence, mobility, long-range transport potential and the difficulty to treat remove them after they have been released into the environment. PFHxA is in fact more technically challenging, and costly, to remove from drinking water and wastewater than its long-chain analogs. As our scientific publications (attached) have set forth, high persistence alone is already a sufficient reason for controlling emissions of a synthetic organic chemical. If a chemical is highly persistent, its use and release into the environment will lead to accumulation and therefore increasing contamination, even if the amounts used at a particular time are low. This increasing stock of contamination will result in the increasing probability of known and unknown effects. Once adverse effects are identified, the contamination and therefore the effects will be very difficult (and expensive) or even impossible to reverse. In its draft opinion on the proposed restriction of PFHxA, the SEAC itself notes the high persistence of the chemical, and how continued use will lead to increasing contamination. Regrettably, the SEAC has not concluded that the overall conditions of the proposed restriction are the most appropriate and proportionate for addressing the identified risks, due to the limited available information on socio-economic impacts and emission estimates.  We are concerned about and respectfully disagree with the approach taken by the SEAC. Instead, we would like to recommend a robust approach for estimating emissions of PFHxA and its precursors based on existing knowledge and data. We would also like to recommend additional considerations for estimating socio-economic impacts in relation to drinking water. We further suggest incentives for ensuring that producers and downstream users of PFHxA provide the information needed for regulators to decide on appropriate actions. 1. A robust approach to estimating emissions of PFHxA and its precursors As SEAC noted in its 2015 opinion on the Annex XV dossier for the PFOA restriction and again in its draft opinion on the current restriction proposal, PFHxA and its precursors are drop-in replacements of PFOA and its precursors. Molecular structure-wise, PFHxA and its precursors are often shorter-chain homologues to PFOA and its precursors. Therefore, we propose 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. This approach is most likely a very conservative estimate for the following two reasons: (1) As shown in the scientific literature, PFHxA and its precursors have much lower surfactant activities than their longer-chain homologues PFOA and its precursors (https://doi.org/10.1016/j.colsurfa.2021.127313). Thus, in a given application, for the same surfactant activity requirements, it is expected that much higher levels of PFHxA and its precursors will be needed than for PFOA and its precursors. (2) The quantities of PFOA and its precursors are available only until the early 2010s. As the chemical industry has rapidly expanded over the past decades (https://cefic.org/app/uploads/2021/02/FactsFigures2021\_Leaflet\_V05.pdf), it is expected that the quantities of PFHxA and its precursors have also increased over time. 2. Additional considerations for estimating socio-economic impacts in relation to drinking water The draft SEAC opinion for the proposed PFHxA restriction recognizes the potential for contamination of drinking water but does not consider the future socio-economic impact of the recast Drinking Water Directive (EU/2020/2185). In addition to a parameter of 500 ppt for total PFAS, it provides a ‘Sum of PFAS’ parameter of 100 ppt for 20 PFAS substances associated with adverse health impacts based on current knowledge. We wish to note that PFHxA is one of the 20 PFAS listed as associated with adverse health impacts based on current knowledge. Within five years (as of 12 January 2026), Member States will need to ensure that water supplied for human consumption complies with the ‘Sum of PFAS’ parameter of 100 ppt, which will include PFHxA. If water supplied for human consumption does not meet the ‘Sum of PFAS’ parameter, water suppliers will need to take measures to reduce the levels of the 20 PFAS to the summed level of 100 ppt. PFHxA has been found in sources used for drinking water. The potential is high that PFHxA will contribute to bringing overall PFAS contamination to levels requiring significant investments in remediation technologies, along with ongoing costs for operation and maintenance for years to come. The projected costs for ensuring safe drinking water do not appear to have been considered in the SEAC’s review of the potential benefits of the proposed restrictions on PFHxA. 3. Human health concerns for PFHxA, its salts and related substances should be weighed more carefully The Background Document to the Opinion, Section 2.5.2 on human health impacts, begins “The human exposure to PFHxA, its salts and related substances has the potential to cause adverse health effects.” While existing data suggest that human exposure to PFHxA is unlikely to increase to levels that cause risks to human health, the persistence of PFHxA, the lack of reversibility of its releases, the lack of certainty of the magnitude of future exposures, and intergenerational nature of its exposure indicate that serious health concerns related to PFHxA-exposure are expected to arise in the future. The section notes that “…with a rising environmental concentration of PFHxA serious human health impacts cannot be excluded.” We therefore disagree with the approach taken by the SEAC as it appears contradictory to evidence presented in the Background Document that PFHxA poses serious human health concerns. 4. Time to rightfully reverse the onus to producers The lack of information from the stakeholders that produce or use PFAS is a constant problem for public scrutiny over these problematic chemicals. We agree that more data on tonnages, uses and emissions of PFHxA would be highly useful. However, too often the stakeholders that produce PFHxA and other chemical substances invoke their right to keep such information confidential for business reasons. Or they avoid disclosing the data they hold. It is difficult not to view this as a tactic to delay control measures. With the principle “no data, no market”, the REACH Regulation should place the burden of proof on industry to show that their uses of a substance are safe for human and environmental health. It makes sense that the producers and industrial users of PFAS should similarly shoulder the burden of providing the information that regulators need to decide on the appropriateness of a proposed action. The SEAC has the opportunity here to provide incentives for industry to deliver data, e.g. by applying worst-case scenarios or boundary conditions when industry has not provided the data needed for better analyses. The principles of the REACH Regulation should not be undermined, simply because industry has not made this information available.  We urge the SEAC to incorporate our recommended approaches in its assessment and to consider the proposed restriction on PFHxA in its entirety as proportionate.  On behalf of the Global PFAS Science Panel: Martin Scheringer, Institute of Biogeochemistry and Pollutant Dynamics, ETH Zürich, Switzerland Zhanyun Wang, Chair of Ecological Systems Design, Institute of Environmental Engineering, ETH Zürich, Switzerland Ian Cousins, Department of Environmental Science, Stockholm University, Sweden Juliane Glüge, Institute of Biogeochemistry and Pollutant Dynamics, ETH Zürich, Switzerland Dorte Herzke, Norwegian Institute for Air Research (NILU), Institute for Arctic and Marine Biology, Tromsø, Norway Jamie DeWitt, Department of Pharmacology & Toxicology, Brody School of Medicine, East Carolina University, Greenville, NC, USA Carla Ng, Department of Civil & Environmental Engineering and Environmental and Occupational Health, University of Pittsburgh, Pittsburgh, PA, USA |
| SEAC Rapporteurs response:  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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| **976** | **Date/Time:**  2021/09/20 13:38\* (submission after the consultation deadline was agreed by ECHA recognising that a technical issue had affected the ability of the respondent to submit within the consultation deadline)  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential:**  Yes  **Attachment:**    <redacted>  **Privacy statement:**  the protection of our commercial interests, including intellectual property, could be undermined if the attached information would be publicly available | **General Comments:**  Beside the technology fields mentioned below, the use of PFHxA in coatings is not consudered. PLease find our documents attached accordingly. |
| **SEAC Rapporteurs response:**  Thank you for your comment. The SEAC rapporteurs’ responses to the comments submitted in the consultation can be found in the ‘ORCOM responses’ document. |

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. [↑](#footnote-ref-1)
2. Please see comment #2960 in the RCOM, part 1. [↑](#footnote-ref-2)
3. 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”**. [↑](#footnote-ref-3)
4. Please see comment #2996 in the consultation on the Annex XV report for information on the referred use (RCOM, part 2). [↑](#footnote-ref-4)