Comments on the SEAC draft opinion and specific information requests

## Specific information request

1. During the public consultation on the restriction proposal, a manufacturer of fluoropolymers requested a less strict limit value for the sum of C9-C14 PFCAs and their salts. In addition, a semi-conductor importer has requested a time-limited derogation to enable it to meet the proposed limit values. The proposed limit values are 25ppb for the sum of C9-14 PFCAs and their salts and 260ppb for the precursors to C9-C14 PFCAs.

ECHA invites all producers or importers of fluoropolymers and electronic equipment to check they will be able to comply with the proposed restriction.

If the impacts of a restriction are so severe that you would like to request a (time-limited) derogation (or a higher threshold), please provide the following information:

* Concentrations and quantities of C9-14 PFCAs manufactured and/or placed on the market (including as impurities),
* Emissions of C9-14 PFCAs (and their precursors) from all the lifecycle steps,
* Information on alternatives or technical possibilities to avoid these substances, and the Socio-economic impacts of the proposed restriction on the company, downstream users and society.

Stakeholders are requested to be as specific as possible in their description of uses, that could potentially be covered by the derogation.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 387 | **Date/Time:** 2018/10/12 13:51  **Type:** BehalfOfAnOrganisation  **Org. type:**  Other contributor  **Org. name:**  Jones Day  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see the attached document 'PFCA\_public comment draft SEAC opinion\_Jones Day' |
| **Specific information 1:**  Please see the attached document 'PFCA\_public comment draft SEAC opinion\_Jones Day' |
| 388 | **Date/Time:** 2018/10/18 18:30  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European Automobile Manufacturers Association - ACEA  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  please see position paper attached |
| 389 | **Date/Time:** 2018/10/31 11:21  **Type:** Individual  **Country:**  Switzerland  **Attachment:** | **Comments on the SEAC draft opinion:**  Dear Sir / Madam,  I would like to draw your attention to the enclosed two documents recently adopted by the POPs Review Committee of the Stockholm Convention at its 14th meeting in September 2018 in Rome:  1) Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (UNEP/POPS/POPRC.14/6/Add.2)  2) Decision POPRC-14/2: Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex 1 of the Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting (UNEP/POPS/POPRC.14/6)  The two documents contain relevant information on the precursors to C9-C14 PFCAs, which are included in the definition of "PFOA-related compounds" under the Stockholm Convention. The SEAC Committee may wish to further take this newly available information into consideration.  Thanks,  <redacted> |
| 390 | **Date/Time:** 2018/11/06 09:18  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  3M Belgium bvba/sprl  **Org. country:**  Belgium  **Attachment:**    <redacted>  **Privacy comment:**  3M submits that details regarding production processes and related financial efforts, products involved, customer relationships, uses and market positioning, as well as production volumes, constitute commercial sensitive information and/or confidential business information, which are not publicly-available; nor has 3M previously disclosed such information vis-à-vis third parties. Therefore, 3M respectfully requests confidential treatment of the details set out in this Attachment. | **Comments on the SEAC draft opinion:**  Please see non-confidential attachment "Public comments 3M.zip". |
| 391 | **Date/Time:** 2018/11/12 12:07  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  United Kingdom  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  We are a manufacturer of PTFE lined hose products, where modified PTFE is a key component. We are working with our key PTFE suppliers to address the implications of new limits to C9-C14 PFCA's.  The specific information request section addresses the key points that we would like to raise in response to concentrations and quantities, Emissions, alternatives and socio-economic impacts of the proposed restrictions. |
| **Specific information 1:**  -> Concentration and quantities of C9-C14 PFCA's  We have consulted with 3M Dyneon regarding their modified PTFE material. Please refer to their confidential comments on this point, since we do not have the specific details.  -> Emissions of C9-14 PFCAs (and their precursors) from all the lifecycle steps  We have consulted with 3M Dyneon regarding their modified PTFE material. Please refer to their confidential comments on this point, since we do not have the specific details.  -> Alternatives or technical possibilities to avoid these substances, and the Socio-economic impacts of the proposed restriction on the company, downstream users and society.  We manufacture hose products that are lined with a modified PTFE and this is the main business of the company, which currently employs 300 people in the UK and has a turnover of £30M. These hose products are used within many demanding applications where only a modified PTFE material is appropriate. We have provided industrial hoses for over 40yrs and has a very wide well established customer base around the world.  We do not manufacture PTFE and we understand that addressing these new proposed limits can only be solved by the material manufacturer. However, if we are not able to purchase modified PTFE there will be a significant socioeconomic impact upon the business and the industries served by our products.  Examples of hose applications and consideration of the related key material properties are:  Chemical transfer: highly corrosive chemicals that would severely corrode steel or other polymer materials require the excellent chemical resistance of PTFE. The modified versions of PTFE are more resistant to chemical permeation than unmodified, which is of key importance for chemical release in the vicinity of the hose. We provide a product that is key to the safety of chemical transfer through the resistance to corrosion and has contributed significantly to raising safety standards for the use of flexible pressure vessels (hose) within the chemical industry. A key hose standard is BS EN 16643 for this industry.  Pharmaceutical and Biotechnology transfer: The high purity of PTFE prevents contamination of very sensitive pharmaceutical and biotechnology products that are used to combat disease and other medical conditions. The cleanability of PTFE is critical along with the high purity derived from the excellent chemical resistance of the PTFE, which must meet FDA and USP VI <87>, <88>, <661.1>, BS EN 16643 and other key industry recognised technical standards and regulations. Cleaning and sterilisation is typically achieved through high temperature steam cleaning on the internal bore of the hose. Our products are validated for these processes in a heavily regulated industry, which means an inability to supply hoses would cause a serious problem for pharmaceutical production.  Food transfer: The high purity and excellent cleanability of PTFE is crucial to ensure food is not contaminated from previous batches of food product. Cleaning is typically achieved through internal steam clean leading to high temperature range capability. Our PTFE liners meet the requirements of EU 1935/2004 and EU 10/2011 at the highest temperature testing thresholds. Automated systems with high cycle food transfer (e.g. filling systems) require excellent hose flexibility and reliable flex life, which is derived from the use of modified PTFE hose liner.  Aerospace: PTFE hoses are used in many areas of an aircraft and our hose supply into this marked – <redacted> are Aerospace AS9100 accredited. Reliability is extremely important in aerospace applications and PTFE is used for many demanding applications, such as engine, landing gear, flight control surface actuation and fuel systems. The temperature extremes for aircraft hoses are wide and are typically -55°C to +232°C (e.g. AS 1946 hose) and must satisfy full pressure and other demanding conditions over this full range. The low permeability of modified PTFE is important to prevent vapour release in confined spaces. Flexibility and high flex life is needed in applications where flexing is significant (flight control surfaces, landing gear) and where high cycle vibration damping is critical (engine piping). There are many PTFE hose technical standards that are relevant to the aerospace industry (AS1946, AS620, AS1339, AS1975, etc.) and we are engaged with the SAE G3D committee to ensure that hose safety is maintained.  Automotive: Many safety critical components within automotive applications require modified PTFE hoses. Brake hoses on motorcycles and cars have low volumetric expansion (prevents brake softness) and the PTFE is resistant to corrosive brake fluids. In addition, the demanding low emissions thresholds for fuel vapours (safety, environmental VOC’s) and other hydrocarbon fluids requires a modified PTFE hose liner. Standards that govern this industry are SAE J1401 and VMSS.  Our products have to meet many technical standards across many different industries. The Chemical, food and pharmaceutical/Biotech industries recognise BS EN 16643:2016, which is a hose specification standard. This standard requires low levels of permeation to minimise vapour release for PTFE liners that are internally smoothbore (cleanliness and good flow) and externally convoluted (good flexibility and flex life). A modified PTFE material is the only version of material that can meet these permeation levels. Similarly, flex life requirements under the rolling-U testing and fluid permeability through weep testing requirements can only be achieved using a modified PTFE. |
| 393 | **Date/Time:** 2018/11/15 01:19  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  SEMI  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see the attachment. |
| **Specific information 1:**  Please see the attachment. |
| 394 | **Date/Time:** 2018/11/15 22:32  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  PlasticsEurope Fluoropolymers Product Group  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  To Whom It May Concern:  The fluoropolymers product group of PlasticsEurope and its members appreciate this opportunity to comment on the draft opinion of the European Chemicals Agency’s (ECHA) Committee for Socio-economic Analysis (SEAC) regarding the proposed restriction on the manufacturing, use and placing on the market of PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, their salts and precursors (collectively, C9-C14 PFCAs).  PlasticsEurope’s Fluoropolymer member companies do not intentionally manufacture, process or use C9-C14 PFCAs (or their salts or precursors) in any of their respective operations or products, within the EU or elsewhere. However, C9-C14 PFCAs can result as unintentional impurities at extremely low-levels during fluoropolymer production.  The fluoropolymers product group of PlasticsEurope supports EU-wide measures to limit the presence of C9-C14 PFCAs in fluoropolymers, including manufacturing process impurities, provided those measures are proportionate, effective, practical (i.e., implementable, enforceable and manageable) and monitorable, as REACH requires. Any C9-C14 PFCA restriction should be carefully drawn to minimize unnecessary harm to society, and to fluoropolymer manufacturers and their customers, that would be disproportionate to the anticipated risks and benefits of the proposal. Fluoropolymers are used in numerous applications of high socioeconomic value, as the following publication describes:  http://www.plasticseurope.org/en/resources/publications/socio-economic-analysis-european-fluoropolymer-industry-executive-summary  The fluoropolymers product group of PlasticsEurope has serious concerns about the scope and content of the proposed restriction. Neither ECHA’s restriction proposal, nor any subsequent opinion of ECHA’s Risk Assessment Committee (RAC) or of the SEAC, draws any risk threshold-based conclusions in support of the proposed restriction and its 25-ppb maximum concentration limit, whether for single component or even more so for their sum. Furthermore, the restriction has been proposed before a reliable, validated and commercially-available test method for C9-C14 PFCAs has been established for fluoropolymers. Setting a maximum concentration limit for C9-C14 PFCAs where no reliable, validated and commercially-available analytical method yet exists to confirm or enforce compliance with that limit would qualify as a manifestly-inappropriate regulation and would, thus, be disproportionate (at least without appropriate derogations for fluoropolymers containing trace amounts of C9-C14 PFCAs solely as manufacturing impurities).  Looking back, the EU set a maximum concentration limit (at the ppm level) for PFOS before a reliable, validated and commercially-available test method existed to monitor and enforce that limit. Several years elapsed after the addition of PFOS to REACH Annex VXII before the EU undertook a study to investigate whether reliable and replicable analytical test methods existed for PFOS in solid matrices. The outcome of that study revealed a wide variability in test results among many reputable commercial laboratories. We hope that the EU will proceed differently in restricting C9-C14 PFCAs. |
| 395 | **Date/Time:** 2018/11/16 11:35  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Netherlands  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Dear Sir, Madam,  I herewith request that the regulations as sugested will not be implemented until a workable alternative is available.  Due to the critical applications for which we use hoses with this base material it is imperative that there is a viable alternatieve available.  Thank you for your understanding!  If needed i am available for comments.  Best Regards,  <redacted>  Managing Director |
| 396 | **Date/Time:** 2018/11/16 12:38  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  United Kingdom  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  The product supply chain related to this submission involves two external companies who have intellectual property related to the material, its processing and use and this should not be released into the public domain in-line with our confidentiality and disclosure agreements with these parties. | **Comments on the SEAC draft opinion:**  Please find attached comments on the SEAC draft opinion dated 13/9/18 |
| 397 | **Date/Time:** 2018/11/16 15:13  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Netherlands  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  On behalve of our organisation <redacted> we want you to know that PTFE hoses are a very important part of our turnover. Besides that it's also very important for our customers in de food- and chemical industry that they can rely on lasting deliveries in the future. Especially the PTFE Co-polymer grades,that will ensure more flexibility and a long life performance. So, in our opinion, the powder manufacturers need more time to develop an alternative for the current PTFE co-polymers that are needed for the PTFE hoses we are delivering to our customers. We hope you will give them more time to develop a good alternative for the co-polymers.  Best regards,  <redacted>  Account/Product manager |
| 398 | **Date/Time:** 2018/11/16 20:03  **Type:** Individual  **Country:**  France | **Comments on the SEAC draft opinion:**  Bonjour,  Je suis le directeur d’une société de construction de flexible.  Je viens d’apprendre qu’en raison d’une nouvelle réglementation européenne en matière d’environnement sur les PTFE qui entrerait en vigueur début 2020 les producteurs ne seraient plus en mesure de fournir un produit de qualité équivalent. Que dans l’état actuel de leurs connaissance et de leurs recherchent, ils espèrent pouvoir faire bénéficier le marché de nouvelle poudre conforme à la réglementation fin 2020. Dans ce laps de temps, la seule alternative serai un PTFE d’ancienne génération avec des qualités mécanique très inférieur…  Vous devez être informé que ces produits sont couramment utilisés en tant que flexibles pour dans l’industrie et notamment dans l’industrie chimique pour le transfert de divers produits corrosifs, toxiques… et que si les qualités de ces produits sont dégradés vous faite courir au personnels des sociétés utilisatrices et des riverains de ces site industriel de gros risques pour leurs intégrités physique pouvant même aller jusqu’à la mort.  Vous devez savoir que ce qui sera modifié momentanément est l’essence même du flexible en PTFE, la capacité à résister aux mouvements sans casser ou fissurer.  Je comprends toutes les avancer en matière de réglementations sur l’environnement. Je suis une personne responsable, père de famille, tout à fait conscients de la nécessité de réduire notre impact écologique. Je vous demande juste un peu de raison et de bon sens en accordent un délai supplémentaire pour permettre aux fabricants de proposé un produits plus sûr, conforme a la nouvelle réglementation et aux attentes du marché pour que personne ne soit mis en danger.  Cordialement. |
| 399 | **Date/Time:** 2018/11/19 08:58  **Type:** BehalfOfAnOrganisation  **Org. type:**  Other contributor  **Org. name:**  Tokyo Electron U.S. Holdings  **Org. country:**  United States | **Comments on the SEAC draft opinion:**  Because of the possibility of articles containing substances or mixtures for which C9-C14 PFCAs have occurred as an unintended byproduct of some manufacturing process, add a derogation to the effect of: “(New paragraph) Paragraph 2(c) shall not apply to a substance that occurs as an unavoidable, unintentional by-product in the manufacture of a fluorochemical.” |
| **Specific information 1:**  We are aware that fluorochemicals can undergo certain manufacturing processes to adjust their monomer chain lengths that could produce C9-C14 PFCAs in low (ppb) quantities, but because of our position in the supply chain, it is very difficult to gain any specific information on more details. |
| 400 | **Date/Time:** 2018/11/19 09:00  **Type:** Individual  **Country:**  United States | **Comments on the SEAC draft opinion:**  Because of the possibility of articles containing substances or mixtures for which C9-C14 PFCAs have occurred as an unintended byproduct of some manufacturing process, add a derogation to the effect of: “(New paragraph) Paragraph 2(c) shall not apply to a substance that occurs as an unavoidable, unintentional by-product in the manufacture of a fluorochemical.” |
| **Specific information 1:**  We are aware that fluorochemicals can undergo certain manufacturing processes to adjust their monomer chain lengths that could produce C9-C14 PFCAs in low (ppb) quantities, but because of our position in the supply chain, it is very difficult to gain any specific information on more details. |
| 401 | **Date/Time:** 2018/11/19 18:44  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Xtraflex NV  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  <redacted> | **Comments on the SEAC draft opinion:**  Please find confidential comments |
| **Specific information 1:**  Please find confidential comments |
| 402 | **Date/Time:** 2018/11/19 21:50  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Beltec bvba  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  Please see confidential comments from Xtraflex nv. | **Comments on the SEAC draft opinion:**  Please find confidential comments |