|  |  |  |
| --- | --- | --- |
| **3033** | **Date:** 2020/05/14 17:15  **Content:**  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Spain  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comment:**  <redacted> would like to underline that such impacts will be far reaching. If no derogation is granted, our German supplier will have to close down, resulting in direct job losses from production, R&D, marketing and sales of C6 chemistry. On the other hand, we will have to stop the production of the affected references.  <redacted>, as a sustainable and innovations-driven company, actively supports the movement to chemical alternatives with lower ecological impact wherever possible. <redacted> is currently working with other alternatives fluorine-free water repellents that are finding more and more acceptance in the outdoor and fashion apparel industry. However, many of our customers create advanced and highly specialised applications with C6 perfluorinated polymers that currently cannot be replaced with fluorine-free technology. Most of these applications will be banned under the proposed restriction and hence, essential product applications, markets and jobs in the European textile and shoe care industries are at stake. |
| **Answer to specific info request 7:**  <redacted> manufactures alternative fluorine-free products for applications for which only the water repellent finish is required. |
| **Answer to specific info request 8:**  \*All uses that demand chemical inertness towards aggressive chemicals and conditions or require repellency against oil, soil, blood and liquid chemicals cannot be fulfilled with fluorine-free technology. Please refer to our general response for more details and explicit applications.  \* From a physicochemical point, no fluorine-free alternatives are known that would reduce the surface energy/tension to a level which allows for repellency of oil, solvents, liquid chemicals, blood, etc.  \* <redacted> will not be able to provide a solution to the customers to protect their shoes, accessories, seats and outdoor clothing from oil, grease, and other stains such as sauces, wine, etc. |
| **Answer to specific info request 9:**  • What is the use?  Consumer water proofing sprays, water repellent agents for outdoor, sports and fashion apparel can be transitioned to fluorine-free alternatives within a short timeframe.  • What transitional period would be needed for this use?  A reasonable timeframe for transitioning the above applications would involve 2 to 3 years.  • Please describe the technical and economic consequences that would result from the proposed restriction if the transitional period were as requested, and provide information about the costs associated to these consequences.  If the timeframe was too short, it would be impossible to develop fluorine-free technologies for the technically more advanced and challenging applications and, ultimately, these applications would be lost as well as jobs and markets associated with them. We estimate that a quarter part of our business it is thanks to the use of C6 fluorinated polymers. For this reason, if <redacted> was not given enough time to transition the latter applications into fluorine-free solutions.  • What would be the consequences of a shorter transitional period? What would be the costs associated to that?  If the transitional period was too short, downstream users of the currently used C6 technology would not have the time to bring alternative fluorine-free technologies into harmony with their application, the marketing and customer expectation. Performance and, even worse, claims for product stability and performance would result.  • Would investments to enable new processes etc. be needed? If so, please provide information about the costs of these investments.  Additional resources would be needed along all business departments. For instance, human resources would be required in R&D, technical application labs, and marketing to develop, test and promote fluorine-free alternatives. Furthermore, investments in new production vessels and infrastructure would be essential, as fluorine-free alternatives demand as much as twice to four times the active substance and result in much short longevity of applications compared to C6  fluorinated polymers. These expectations would press <redacted> to investing into 3-5 man-years. |
| **Answer to specific info request 10:**  Please refer to our general response including a list of applications. |
| **Answer to specific info request 11:**  Alternative short-chain fluorotelomer substances do not provide the performance required. The alternatives' performance is comparable with our fluorine-free solutions. |
| **Answer to specific info request 12:**  Yes, human resources are needed to track C6 volumes for the applications exempted. |
| **Dossier submitter response:**  Thank you for the valuable information. The DS acknowledges your argument that current alternatives for C6 chemistry cannot fulfil demands for chemical inertness towards aggressive chemicals and conditions or for repellence against oil, soil, blood and liquid chemicals. Such potentially negative impacts will be weighed against the long-term risks of rising concentrations of PFHxA and related substances in the environment. Regarding clothing and footwear, the proposal in the background document foresees exemptions for personal protection and medical devices. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are very effective for repellence of water, oil, dirt, body fluids and liquid chemicals. For certain uses alternatives appear to be available, but not for others, and for water repellency alternatives appear to be available. Derogations proposed by the Dossier Submitter, or requested by stakeholders in the consultation and sufficiently substantiated with information on emissions and risk management measures, have been evaluated by RAC from an emission minimisation perspective only. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments! We agree that suitable alternatives are not yet available in cases where repellence to oil, dirt, chemicals or bodily fluids is required. An extended transition period is required where these properties are necessary. We support the derogation for certain categories of PPEs proposed by the Dossier Submitter. The scope thereof has been revised to cover more product categories. As to other textile products, we note that a large part of emissions of PFHxA-related substances originate from the textile sector, and therefore we consider that evidence on substantial negative socio-economic impacts is needed to support further derogations. We agree that a general transition period of 18 months may be too short, and we are currently considering proposing that it be extended to 36 months in order to give time for a balanced transition to alternatives in all sectors. |
| **3034** | **Date:** 2020/05/15 13:14  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes | **Comment:**  Our company uses PFHxA for water repellency finishing.  Their performances are the higher for repellency. The others products in the market have results really lower than PFHxA. If this product is forbidden we will lose many customers/markets. |
| **Answer to specific info request 7:**  Yes, but we try many others products and anyone aren't good results. |
| **Answer to specific info request 8:**  The tested products are not good water repellency. And the washing resistance and UV resistance are very lower than our specifications. |
| **Answer to specific info request 10:**  The substitution are lower performance for UV resistance (yellowing) and not compatible with our fire retardant product. |
| **Dossier submitter response:**  It would have been appreciated to get information on which kind of products you are manufacturing. Concerning outdoor clothing, data suggest that fluorine-free alternatives are comparable to C6 when only water repellence is needed. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are very effective for repellence of water oil and dirt. For water repellency only, functional alternatives appear to be available. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. According to the information available, alternative water repellents indeed appear to be available. With no information on the type of product you are manufacturing and the on socioeconomic impacts of a restriction it is not possible to suggest a derogation. Overall, we consider that a general transition period of 18 months may be too short, and we are currently considering to propose that it be extended to 36 months in order to give time for a balanced transition to alternatives in all sectors. |
| **3035** | **Date:** 2020/05/15 17:55  **Content:**  Information on alternatives  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** ALPEX PROTECTION  **Org. country:** France | **Comment:**  Alpex Protection is a SME, located in France. We employ 45 people, our turnover is 17M€. We produce and supply laminated fabrics for PPE (Personal Protective Equipment). These technical fabrics are treated in surface with resins made from PHxA. The laminated fabrics are used to make foul weather jackets, suits, especially for administrative markets (police, army, firefighters). Our customers request high performances in terms of waterand Oil repellency. At this stage, all the trials made on resin without C6 show poor values on these properties, especially for the oil repellency.  If the PFHxA are not any more available we will have no solution to reach the specifications of these administrative tenders. In the other hand, our competitors from other parts of the world will have the possibility to compete and obtain higher performances than ours, competition will not be fair.  The ban on the use of these components would be catastrophic for the future of our company |
| **Answer to specific info request 3:**  For personal protective Equipment, especially on garments used by administration (police, army, fire fighters), most of the technical fabrics with high performances are produced in Europe |
| **Answer to specific info request 7:**  on some synthetic fabric we could reach correct water reppellency level but oil repellency is the most critical. |
| **Answer to specific info request 8:**  at this stage substitution is impossible to reach the high oil repellency values requested for the garments used by the police men, soldiers, firefighters, industrial garments. The restriction could have dramatical consequences with the impossibility to supply our customers with the requested fabric properties |
| **Answer to specific info request 9:**  At this stage our chemical company suppliers did not supply or offer alternatives with good performances |
| **Answer to specific info request 11:**  Since PFOA restrictions, the oil repellency performances are lower but still at a good level. Before these restrictions we obtained good results with PFHxA. Today all the products tested show poor result on this property |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellence is essential to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The restriction proposal already derogates uses of PFHxA in products applied for the protection of professionals. The derogation refers to risk category III of Annex I (EU 2016/425) describing ”risks that may cause very serious consequences such as death or irreversible damage to health”. Based on received comments and further analyses the Dossier Submitter proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Furthermore, the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council whether the list of exempted uses of PPE can be further enlarged.  It is to be noted that also import of C6 treated articles will be covered by the proposed restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, such as water repellency only, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction, including specific categories of PPEs. Derogation proposed by the Dossier Submitter or requested by stakeholders in the consultation were evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that suitable alternatives are not yet available in cases where repellence to oil, dirt, chemicals or bodily fluids is required. Some transition time is required where these properties are necessary. We support the derogation for certain categories of PPEs proposed by the Dossier Submitter. The scope thereof has been revised to cover more product categories. |
| **3037** | **Date:** 2020/05/22 11:09  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Disclosure of this information would compromise our commercial interest including our intellectual property | **Comment:**  The appended confidential appendix is the translation of the report we referred to in submission 0717d180‐0805‐4ce7‐bafe‐7fb4b9bca044 |
| **Answer to specific info request 2:**  The appended confidential appendix is the translation of the report we referred to in submission 0717d180‐0805‐4ce7‐bafe‐7fb4b9bca044 |
| **Dossier submitter response:**  Thank you for providing the DS with your translated study of the degradation test report mentioned in #3002: "Physicochemical Study of KCR-100 According to Polymers Flow Scheme for Safety Evaluation. DS took it into account in the evaluation. |
| **RAC Rapporteurs comments:**  Thank you for the information on degradation of this particular C6 side-chain fluorinated polymer (SFP). Studies on the degradation of C6-SFPs are limited, however there are more studies available on SFPs for the homologue PFOA. In the restriction proposal for PFOA, its salts and related substances, RAC assessed and concluded that based on the available information, degradation rates of C8-SFPs in the order of 0.1-5% per year, a 1% degradation factor would be a reasonable estimated (acknowledging that this represents an overestimate for some SFPs and an underestimate for others). C6-SFPs are considered less stable than C8-SFPs, based on e.g. that re-impregnation needs to be conducted more often for C6-SFPs. Therefore, RAC concluded that based on the limited available data on the degradation of C6-SFPs, the same estimate of 1% as for PFOA would be appropriate. RAC do not consider this study to contradict the 1% estimate used by the Dosser Submitter and RAC for the degradation of C6-SFPs. |
| **SEAC Rapporteurs comments:**  Thank you for the information. |
| **3038** | **Date:** 2020/05/26 09:19  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes | **Comment:**  This would have a very big impact on our company. |
| **Answer to specific info request 4:**  Only my small company consumes 10 Tons per year. |
| **Dossier submitter response:**  Thank you for your response. DS does not understand which product group is addressed here. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Unfortunately, the information provided is too limited to be useful. |
| **SEAC Rapporteurs comments:**  Thank you for your participation. Information on the type of products, expected costs and emissions and availability of alternatives would be necessary to be able to evaluate whether any specific transition arrangements are justified. |
| **3039** | **Date:** 2020/05/26 10:29  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes | **Comment:**  Our company use a formulation with fluorinated polymers (C6) to bring oil and water repellency for few textile products. We are totally aware about the situation with REACh for this kind of product and we are conform regarding the quantity we used. But it's today the only substance which is enough efficient for PPE (protection gloves). So if it will be forbidden to use it in the futur we have no alternativ today. But we are ready to continue to be very conscious and follow the restrictions for the use of this formulation in our industry. |
| **Answer to specific info request 3:**  As specialized in technical yarns we are upstream for the textile chain. Today we only sell repellant yarn (fonctionnalized with C6 fluorinated polymers) in France, Spain and Portugal. |
| **Answer to specific info request 6:**  We buy PHOBOL formulation to AZELIS (HUNSTMAN distributor for France) : around 120kg / year (maximum) |
| **Answer to specific info request 8:**  All substances we have tested are not efficient enough regarding the oil repellency. Or this function is need for protection gloves. |
| **Answer to specific info request 10:**  The oil repellency effet bringed with C0 fluorinated polymer is really too low for gloves protection regarding the C6 fluorinated polymer. |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellency is necessary to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. It is to be noted that also import of C6 treated articles will be covered by the proposed restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are very effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction, including certain categories of PPEs. Derogation requests proposed by the Dossier Submitter or requested by stakeholders have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We support the derogation for certain categories of PPEs proposed by the Dossier Submitter. The scope thereof has been revised to cover more product categories. |
| **3040** | **Date:** 2020/05/28 12:46  **Content:**  Scope or restriction option analysis  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Moulinage du Solier  **Org. country:** France | **Comment:**  We are using C6-perfluorinated products for textile goods that are destined to aeronautic applications, both civilian and military. The main property aimed by treating textile articles with C6 products is the oleophobic protection they enable to confer.  At the moment, we have not been informed of any substitution products that can yield to the same level of protection of yarns. The removal and the complete restriction for the use of C6 products could have major and critical impact on the whole supply chain. Indeed, considering the strategic importance of the concerned applications, we cannot allow, both for our company and for the market, to cause a disruption of the supply of such products.  That is why, as long as any product of equivalent properties and efficiency would not have been found, it is clear, from our propective, that the restriction of C6 products need to be postponed. Otherwise, we will have to be granted an exemption to use those products. |
| **Answer to specific info request 1:**  a. Textile products destined to aernautic applications  b. Estimated annual quantity uses of 500 kg/year. No information available concerning risks to the environment as our yarns are further manufactured to create the final product of which we are not the final user. |
| **Answer to specific info request 6:**  See section 1. Additionnal uses |
| **Answer to specific info request 7:**  No there is no alternative available yet. |
| **Answer to specific info request 8:**  See section 1. Additionnal uses, and Section III. Non-confidential comments for uses, obstacles, and consequences related to the restriction of C6.  Concerning the global costs associated to thoses consequences, we are not able to provide a proper estimation. Indeed, as we are not the final user of the treated yarns, we have no insight on the financial loss that a stopping of aeronautic production lines would cause. |
| **Dossier submitter response:**  Thank you for your comment. Please note that the DS proposes in the background document to include into the restriction a derogation for textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of in particular oil and grease. Derogation requests proposed by the Dossier Submitter or requested by stakeholders, such as technical textiles, have been evaluated bt RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We note RAC’s conclusion that a large part of emissions of PFHxA-related substances originate from the textile sector and therefore we consider that evidence on substantial negative socio-economic impacts is needed to support any further derogations. Information on the expected costs, emissions and availability of alternatives (such as information on the necessary properties of C6 chemicals not found in fluorine-free alternatives, and on the type and wideness of the search made to find suitable alternatives) would be necessary to evaluate whether a derogation is justified. Such information could be submitted in the consultation on the SEAC draft opinion. |
| **3041** | **Date:** 2020/06/01 02:54  **Content:**  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  **Type:** Individual  **Country:**  Australia  **Attachment:**      **Privacy comment:** As explained earlier this document is NOT CONFIDENTIAL, is already published and in the public domain, available for download at http://www.fpaa.com.au/technical/technical-documents/information-bulletins/ib-06-v11-selection-and-use-of-firefighting-foams.aspx  so it can be made public, along with the other Australian Government Statement, also in the public domain. | **Comment:**  Please forward to <redacted> as this is a follow up to an existing submission, which has been published since 13th May 2020 deadline. I previously had problems of slow upload speed on our internet service, so the zip file did not arrive (recorded sent OK from here). Therefore I have supplied the attached information in the zip file as separate files using both submission and confidential boxes, which I am doing again now, although I hereby confirm the document in the Confidential box is NOT CONFIDENTIAL. Both are in the public domain. |
| **Answer to specific info request 5:**  As a Consultant I am concerned on the implications of this restriction proposal on foam users, the life safety of the public, emergency responders and site personnel, protection of critical infrastructure and protection of our environment. Swiftly getting the fires out is potentially the biggest advantage in achieving all these objectives, including minimised environmental harm from smoke, breakdown products of the fire in firewater runoff, excess creation of runoff from slow control and extinguishment ability of fluorine free foams which are not viable alternatives to C6 foams, and the consequent likely overflow of planned containment areas, most of which are designed to catch firewater from faster acting and more effective fluorinated foams. This particularly true in large flammable fuel fires in Major Hazard Facilities as defined in my earlier submission and the Fire Protection Association Australia's updated guidance on the Selection and Use of firefighting foams, which was published on 28th May 2020. Hence this additional information submission for your consideration along with a recently made public PFAS position Statement from the Australian Government. |
| **Answer to specific info request 7:**  Information provided here and previously in my full submission, provides extensive evidence that Fluorine Free foams considered adequate alternatives by this Restriction proposal are in fact NOT a viable alternative to high purity C6 foams which may contain or breakdown to PFHxA. Both attached documents confirm that position. |
| **Answer to specific info request 8:**  Substitution is impossible for large flammable liquid fires (eg. gasoline, E10 [10% ethanol in gasoline]; E85, Jet A1, Crude Oil, Industrial alcohols etc., particularly where stored and used in Major Hazard Facilities which includes:  Refineries and Chemical/Pharmaceutical Plants that handle flammable liquids.  • Storage and Distribution Facilities, Tank Farms & Terminals for flammable liquids including jetties/marine terminals.  • Flammable liquids in transit by rail, pipeline or road/ship tankers.  • Airports, helipads, offshore platforms and major transportation hubs.  • All military applications.  • Fixed foam systems and their re-charging to maintain designed safety protection levels.  Fluorine Free Foams have been shown by independent comparative testing to require at least 2-3 times more foam up to 6-7 times more foam on E10 than a C6 foam to adequately control and extinguish these fires. This foams are not interchangeable in different systems, each seems to have unique capabilities on specific fuels and are not suited to a broad range of fuels as is shown by C6 foams. Fluorine Free Foams are not "drop-in replacements" for fluorinated foams in fixed foam systems, as replacements for legacy C8 foams without extensive and expensive engineering design changes, which may not be possible due to constraints on space, water supply, pressures, foam storage volumes, propositioning system capability, all of which and more are likely to compromise the safety and fire protections intended by the original design of the system. it becomes very difficult to re-engineers these systems to allow F3s to be effective, yet most high purity C6 foam alternatives will be similarly effective without such major re-engineering, volume increases and operational duration extensions. |
| **Answer to specific info request 9:**  The updated guidance document recommends Flurine Free foams can be used on small flammable liquid fires where portable equipment allows high application rates to be used, also firefighter training, system testing and calibration using surrogate alternatives to fluorinated foams, but for large flammable liquid fires in Major Hazard facilities and other areas, there is no substitute for C6 foams, which should be accepted as an essential use to save lives, critical infrastructure, prevent unnecessary escalation, unnecessary extra smoke and toxic runoff generation, and prevent potential overflow into our environment which is likely to kill significant numbers of aquatic organisms and pollute water bodies, as has already occurred in a major chemical factory fire in Melbourne (Footscray) in Aug 2018 (detailed earlier) where Fluorine Free Foam was used and over 2,000 fish were killed, the local creek ecosystem destroyed and remediation work was still ongoing (confirmed by EPA Victoria) in January 2020. |
| **Answer to specific info request 10:**  Both attached documents confirm substitution would provide an unacceptably poor fir performance on large fires and those involving existing fixed systems. It is also clear there are no current design standards for fluorine free foams in fixed foam systems either for brand new builds or "upgrading" or substituting fluorine free foams into existing fixed foam systems, to ensure the designed system performance is not compromised, either in terms of speed and effectiveness, or protecting life safety of people (incl. emergency responders), or protecting critical infrastructure adequately, or minimising harm to our environment. |
| **Answer to specific info request 12:**  Both documents attached conclude that the socio-economic costs of using Fluorine Free foams in larger fires cannot be justified by currently available fluorine free products and C6 foams must therefore remain available as an essential use for large fires and Major Hazard Facilities. |
| **Dossier submitter response:**  Thank you very much for taking the time to prepare such an extensive comment to this dossier. DS agrees, that the question how to restrict the use of PFAS containing firefighting foams is a very sensitive topic and considerations have to be made carefully. That is why DS discussed with RAC and SEAC proposing derogations from the restriction proposal for applications where the use of fluorinated foams is critical e.g. for defence applications or large storage tanks for liquid fuels. But DS believes that some alternatives even for those applications are available (e.g. Solberg Re-healing foam RF3x6 ATC fluorine-free foam. All tests (ICAO foam test and test according to the US Mil-Spec protocol, including the NFPA 403) were passed[[1]](#footnote-1)) and received information on successful transitions to fluorine free foams, e.g. from the Danish royal air force[[2]](#footnote-2) or some refineries with large storage tanks in Norway[[3]](#footnote-3) . |
| **RAC Rapporteurs comments:**  See response to comment 2978. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that the performance level of FFF may not yet be at an adequate level for certain scenarios and we find that a prolonged transition period is necessary. However, due to the type of use and the level of potential emissions this period should be as short as possible. Based on all the information available, we expect that alternatives suitable for the rest of the problematic scenarios but not covered by the tank fire exemption will be available within 5 years and therefore we support that as the length of the period. Anyhow, we regard that performance level of FFF will have to be reviewed during the transition period and necessary measures taken before the restriction will be applied. We note the difficulties with potentially insufficient capacity of water containment areas in case higher flow rates are necessary, and we have highlighted the issue in the draft opinion. |
| **3042** | **Date:** 2020/06/01 03:54  **Content:**  Hazard or exposure  Information on alternatives  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Fire Protection Association Australia (FPA Australia)  **Org. country:** Australia  **Attachment:** | **Comment:**  Further to our original submission (8af427b3-53d1-45ef-8bd7-b2c5ac8f8df8) this submission is simply to provide the now published version of our supporting document Information Bulletin IB-06 Selection and use of firefighting foams. In our original submission on 13 May, we provided the draft of this updated Information Bulletin and we are now fulfilling our commitment to provide ECHA with the now published version. |
| **Answer to specific info request 5:**  Further to our original submission (8af427b3-53d1-45ef-8bd7-b2c5ac8f8df8), please see in Section IV our now published version of our supporting document Information Bulletin IB-06 Selection and use of firefighting foams (provided as per our commitment in the original submission on 13 May). |
| **Dossier submitter response:**  Thank you for providing the new version of your information bulletin. |
| **RAC Rapporteurs comments:**  Thank you for the updated attachment. |
| **SEAC Rapporteurs comments:**  Thank you for the information submitted. |
| **3043** | **Date:** 2020/06/02 14:12  **Content:**  Scope or restriction option analysis;  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Umweltbundesamt GmbH (Environment Agency Austria)  **Org. country:** Austria | **Comment:**  PFHxA has been measured and detected in environmental media and in 100% of urine samples of Austrian volunteers (Hartmann et al. 2019: https://doi.org/10.1515/bimo-2017-0001).  A comprehensive compilation of data from Anderson et al. demonstrates widespread human and environmental exposure with PFHxA (Anderson et al. 2019: https://www.sciencedirect.com/science/article/pii/S0273230019300200). It can be assumed that concentrations in humans and the environment will increase with continued (and increasing) use.  The recent assessment of EFSA (2020) on the risks to human health related to perfluoroalkyl substances in food demonstrates concern at very low levels of exposure (EFSA, 2020). There is still a lack of data concerning the respective selected sensitive endpoints for PfHxA (e.g. immunotoxicity in children).  Moreover, on page 8, we would propose to include “and environmental species” after “human health” in the following sentence: “PFHxA may cause adverse effects on human health such as relevant reduction in thyroid hormones.”  The indicative list of substances covered by the restriction is of high importance and should be as comprehensive as possible including updates once new PFHxA related compounds are identified.  Regarding the above mentioned risk-related aspects, we therefore fully support a restriction of PHFxA, its salts and related substances. |
| **Dossier submitter response:**  DS thanks the Austrian Environment Agency for the support and the provided information. References have been considered.  The text on page 8 has been changed accordingly: “and environmental species” after “human health” has been included in the following sentence: “PFHxA may cause adverse effects on human health such as relevant reduction in thyroid hormones.”. The Study conducted by Hartmann et al, is already included. Anderson et al have conducted a Risk assessment for PFHxA and have concluded that PFHxA and related fluorotelomer precursors currently appear to present negligible human health risk to the general population. As highlighted in this dossier current exposures and emissions to the environment from manufacture and use do not pose a risk for human health at the moment. However, the extreme persistency of PFHxA and any release that occurs contributing to the environmental stock over time, imply uncertainties regarding long-term risks to human health and for the environment. At the point of time the effects are triggered, it will be very difficult to negate the consequences due to the irreversibility of the exposure. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC agrees that there is a hazard and risk posed by PFHxA, its salts and related substances, warranting a restriction of their uses. RAC supports adding a non-exhaustive list of substances within the scope of the proposed restriction. An exhaustive list is not deemed possible since 1) there may be data gaps in the Dossier Submitter’s identification of substances falling under the scope of the restriction, and 2) new substances may have been/will be invented that will also be covered by the scope of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. |
| **3044** | **Date:** 2020/06/15 13:31  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Federation of the European Sporting Goods Industry  **Org. country:** Belgium  **Attachment:**  <redacted> | **Comment:**  The Federation of the European Sporting Goods Industry (FESI) represents approximately 2,000 sports manufacturers and retailers (85% of the European market) through its twelve national sporting goods associations, its special groupings, and its directly affiliated member companies. FESI’s constituency accounts for a European turnover of 81 Billion Euro Annually and employs approximately 700.000 EU Citizens.  The sporting goods industry, as mediator between the users (sports people), the regulatory and standardisation world and the global supply chain has a natural interest in robust and reliable standards and protocols as this improves the public’s confidence in and positive perception of the sector. This ultimately helps to elevate consumer satisfaction.  Therefore, FESI welcomes the opportunity to provide general comments on the Annex XV restriction report on undecafluorohexanoic acid (PFHxA), its salts and related substances. The proposal raises several important issues, and FESI seeks to contribute information and insight to aid in ECHA’s deliberations.  FESI members understand the importance of reducing and working toward eliminating intentional use of fluoropolymers in textile and footwear manufacturing whenever it is non-essential. We believe that an incrementally phased-in limit based on feasibility and socio-economic assessments will support all industries in this challenging undertaking. At present, FESI members manage and monitor C6 chemistry through their respective Restricted Substance Lists (RSLs) and are working with suppliers to replace their use and decrease concentrations of them in manufacturing and finished products where feasible. Some members have been restricting and testing for PFC in their products since 2006. The result has been the accumulation of data and experience concerning the extent to which these chemicals are utilized in different stages of the supply chain, their existence as unintended contaminants in apparel and footwear materials, and the challenges that exist in decreasing their wide use and incidental occurrence. The main conclusion so far is that current exposure to PFHxA specifically is unlikely to increase to a level that is critical to human health based on its limited use.  In addition we would like to stress that currently all our members (big companies and SME’s) are under drastic liquidity shortages despite remaining fixed costs and rising safety costs to be applied at retail and office level. In addition to this most of our member’s technical teams are currently overstretched in compliance activities related to PPE equipment and other short-term priorities linked to their companies’ subsistence and the safety of their employees and customers, if they are not on temporary unemployment or leave. This situation does not allow FESI and its members to provide the amount of data requested on such short notice and ECHA should take this into consideration when assessing the input. |
| **Answer to specific info request 1:**  - Hi-Visibility for work wear will be inhibited in lack of oil repellence, with risks of health and safety as a consequence.  - Maintenance of products for example ski resorts workers which can be exposed to oil, dirt, seebum and wax  - Extending life span (durability) of products (keeping them clean, water repellent and performing for a longer time and less need to wash products (i.e sleeping bags and outdoor jackets) detergents contaminate the DWR if the oil repellence is lacking  - Oil repellence. Often a requirement for certain PPE (personal protective equipment), emergency service workers (firefighters, police, ambulance, etc) and military  - Extended water repellence in “tough” weather conditions and exposed to high levels of precipitation with user or products being exposed for a longer time (jackets, tents, sleeping bags…): PFAS based DWR is known to endure much longer under extreme and extended conditions. In essence: Any uses in harsh conditions over 2 hours, which covers a large amount of professionals who will be expected to work outside for 2+ hours independent of the weather, and for any consumer/ professional sport users who are exposed beyond 2 hours with no access to accommodation or need to stay out for longer periods of time. Also any multi-day uses with over-night stays, such as off-shore sailing or alpine expeditions, under potentially harsh conditions require this type of extended protection. This group is highly important, yet estimated to be a very small part of the market.  - Breathability. For any lower temperatures, where people need to move, there will be body humidity / sweat, which condenses under garments if it is not breathable, and will cause serious risks of cold injuries, hypothermia, etc  - chemical / biological run-off needed for many technical uses  - Flame retardance |
| **Answer to specific info request 3:**  Unfortunately, we only have the information in values and not volumes. . According to Eurostat 10.9 billion EUR (in 2018) of sport products are produced in the EU. 60 % of it is for intra-EU trade 6.5 Billion EUR is therefore produced and sold in the EU. However, the data needs to be taken with caution because EUROSTAT definitions are very narrow and do not include many products and data and are an underestimate of the reality. We estimate the intra EU trade of sport goods to be closer to 12 Billion of which 5.8 Billion if purely Outdoor products (see attached report. Source European Outdoor Group).  • Estimate of what % of products contain C6 substances  The product range of our members varies a lot. Some companies specialised in sports practiced in potential “rougher” circumstances and with longer exposure to weather and atmospheric conditions such as Outdoor sports, water sports, snow sports and so on, generally have more need for the DWR properties of the wide range of PFASs substances. While some specialised companies have reported that up to 50% their products contain some form of fluoropolymers (especially Down jackets) for most sport/leisure companies (the cast majority of our membership) the use is far lower and can be around or below 1 %. According to the data received we would estimate that between 5 and 10 % the total of our members products contain C6 Chemistry of some sort.  • Typical levels of PFAS substances present in products, if known  Very difficult to evaluate. No clear data from the members of this. We know the vast majority does not use long-chain perfluorinated chemicals. For apparel, they tend follow the Bluesign RSL or AFIRM RSL for usage ban levels on fluorinated substances.  Most textiles treated with a fluorinated DWR coating will contain app. 0.5 - 1 % w/w of perfluorinated functional groups (moieties) that could be regarded as precursors for PFCs of concern. This portion represents only approximately one third of the weight of the coating polymer that is applied. The remaining two thirds are essentially non-fluorinated hydrocarbon building blocks. The concentration of free, extractable PFASs such as FTOHs, FTAs, FOSEs, PFCAs, or PFSAs is measured in µg/kg or parts-per-billion. Cost of restriction can potentially be loss of life. |
| **Answer to specific info request 8:**  - Hi-Visibility for work wear will be inhibited in lack of oil repellence, with risks of health and safety as a consequence.  - Maintenance of products for example ski resorts workers which can be exposed to oil, dirt, seebum and wax  - Extending life span (durability) of products (keeping them clean, water repellent and performing for a longer time and less need to wash products (i.e sleeping bags and outdoor jackets) detergents contaminate the DWR if the oil repellence is lacking  - Oil repellence. Often a requirement for certain PPE (personal protective equipment), emergency service workers (firefighters, police, ambulance, etc) and military  - Extended water repellence in “tough” weather conditions and exposed to high levels of precipitation with user or products being exposed for a longer time (jackets, tents, sleeping bags…): PFAS based DWR is known to endure much longer under extreme and extended conditions. In essence: Any uses in harsh conditions over 2 hours, which covers a large amount of professionals who will be expected to work outside for 2+ hours independent of the weather, and for any consumer/ professional sport users who are exposed beyond 2 hours with no access to accommodation or need to stay out for longer periods of time. Also any multi-day uses with over-night stays, such as off-shore sailing or alpine expeditions, under potentially harsh conditions require this type of extended protection. This group is highly important, yet estimated to be a very small part of the market.  - Breathability. For any lower temperatures, where people need to move, there will be body humidity / sweat, which condenses under garments if it is not breathable, and will cause serious risks of cold injuries, hypothermia, etc  - chemical / biological run-off needed for many technical uses  - Flame retardance |
| **Answer to specific info request 9:**  For most leisure and “lighter” – “shorter” outdoor activities (for example water repellency) successful alternatives have been applied which represents the vast majority of products on the market. For most specialized outdoor companies, we estimate that between 5 and 20 % of DWR treated products have switched to a PFC free substance/technology. |
| **Dossier submitter response:**  Thank you for your detailed response.  Regarding human health effects, you stated in Chapter 4: “The main conclusion so far is that current exposure to PFHxA specifically is unlikely to increase to a level that is critical to human health based on its limited use. “This is a hazard-based assessment approach. There is no evidence for severe risks for human health effects of PFHxA at current environmental exposure levels. However, substantial toxic effects have been documented in several studies as summarized in the Chapter B.5. “Human health hazard assessment” of the restriction report. These include endocrine effects, such as decreased levels of thyroid hormones, nasal lesions, decreased fetal body weight gain, and kidney papillary necrosis. The corresponding DNELs range between 0.03 - 1 mg/kg bw/d. As stated in Chapter 2.5.2, exposure estimates are still below these levels. PFHxA has been demonstrated to accumulate in the human body leading to comparable levels as PFOS (Perez et al., 2013). In fact, PFHxA the most prevalent PFAS in human brain, reaching higher levels than PFHxS or any other PFAS. PFHxA was also the dominant perfluorinated compound in human liver, showing a higher median concentration (68.3 ng/g) than PFOS (41.9 ng/g). High levels have also been detected in the human lung (207 ng/g). Without the proposed restriction on PFHxA, precursors and related substances, an increased production, environmental burden and human exposure are expected, because long-chain PFAS might be replaced by C6-compounds. Since consequences of continued (and extended) use and both, increased human and environmental exposure will not be reversible by regulatory action later on, it is important that releases are reduced to a minimum.  DS agrees that for uses where safety of the user depends on C6 containing treatments, derogations should be possible – such as for PPE etc. With regard to the extended product service life due to the C6 treatment, there is a lack of data to compare the service life of C6 and fluorine-free textiles.  DS agrees, that when oil and dirt repellence is necessary to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council.  For other uses (sailing, alpinism) alternatives are available.It is to be noted that also import of C6 treated articles will be covered by the proposed restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction, including specific categories of PPEs and high visibility clothing. Derogations proposed by the Dossier Submitter, or requested by stakeholders in the consultation and sufficiently substantiated with information on emissions and risk management measures, have been evaluated by RAC from an emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. RAC agrees with the Dossier Submitter that there is a hazard and risk posed by PFHxA, its salts and related substances, based on a combination of properties of concern (persistency, mobility, difficulties of removal) although no risk at present can be identified at current exposure levels and with the current knowledge on hazard. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that suitable alternatives are not yet available in cases where repellence to oil, dirt, chemicals or bodily fluids is required. An extended transition period is required where these properties are necessary to avoid high societal costs. We support the derogation for certain categories of PPEs proposed by the Dossier Submitter. The scope thereof has been revised to cover more product categories, and also high visibility clothing is now proposed to be derogated. We note RAC’s conclusion that a large part of emissions of PFHxA-related substances originate from the textile sector and therefore we consider that evidence on substantial negative socio-economic impacts is needed to support any further derogations. |
| **3045** | **Date:** 2020/06/17 10:59  **Content:**  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes | **Comment:**  We are producing reinforcement for roofing membranes - this reinforcement exists out of a fabric that is coated with C6 to avoid any water absorption which is a high safety requirement. Unless there is no alternative - we cannot eliminate flourcarbon. |
| **Answer to specific info request 4:**  In our current business we use 40 metric tons/year, this only in Belgium - not taking US in to account. |
| **Answer to specific info request 7:**  Please share this information asap to all stakeholders |
| **Answer to specific info request 10:**  There are no real substitutes given the fact that there is a high risk of safety. |
| **Dossier submitter response:**  Thank you for the information. Nevertheless, details on why you consider your product as an essential use and why there is no alternative for C6 for hydrophobic coating were not described. Based on the available information a derogation is not justified. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are very effective repellents. For water repellence only, functional alternatives appear to be available. Derogations proposed by the Dossier Submitter or requested by stakeholders, for e.g. construction, were evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC evaluates a proposed restriction in terms of its socioeconomic benefits to its socioeconomic costs, considering also derogations suggested by the Dossier Submitter and requested in the consultation. In order for SEAC to consider your comment for its opinion making, more detailed information on the costs of a restriction, emissions and alternatives and why they are not regarded as appropriate yet (and any related impacts such as e.g. safety aspects, as mentioned in your comment) need to be provided. |
| **3046** | **Date:** 2020/06/26 12:09  **Content:**  Baseline;  Information on alternatives;  Information on benefits;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**    <redacted>  **Privacy comment:** We have divided our input in public and confidential parts. The parts marked as confidential allow to disclose both our identity and an individual’s protected data (Art. 4(1)(b) of Regulation (EC) No 1049/2001) and contain a detailed breakdown of life-cycle costs which may allow competitors to draw conclusions on our profitability (Art. 4(2) of Regulation (EC) No 1049/2001). In addition, data on potential damage in the scenarios investigated may give hints on suitable targets for sabotage (Art. 4(1)(a) of Regulation (EC) No 1049/2001). We, therefore, request confidential treatment. | **Comment:**  Please find attached document Objection PFHxA. |
| **Answer to specific info request 5:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 7:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 8:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 9:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 10:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 11:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 12:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Answer to specific info request 13:**  Please find attached document Answers\_rest\_pfhxa\_rcom. |
| **Dossier submitter response:**  Thank you very much for providing information on your use of fluorine free firefighting foams (FFF) and estimates on the costs and time needed for a substitution of fluorinated firefighting foams (AFFF) with fluorine free foams. This was considered very helpful for reconsidering the derogation for the use of AFFF for large storage tanks. DS agrees that this is a critical application where a reliable performance of the firefighting equipment is crucial. Therefore, the DS proposed a 12 year derogation under the consideration that in facilities with large tanks releases from firefighting action will be contained and can be disposed of properly. The proposed derogation was also discussed with RAC and SEAC. However, DS wants to highlight cases where a successful transition to FFF was realised (Information from EC DG ENV/ECHA Report “The use of PFAS and fluorine-free alternatives in fire-fighting foams” (2020)):   * Aviation sector - Copenhagen Airport in Denmark:   + Solberg Re-healing foam RF3x6 ATC fluorine-free foam is used for training and emergency response.   + All tests (ICAO foam test and test according to the US Mil-Spec protocol, including the NFPA 403), were passed.   + Optimal efficiency was found at a 6% foam concentration (ICAO Level C) instead of 3% (ICAO Level B). * Petrochemical sector: Offshore production in Norway (Equinor):   + At most facilities, Re-healing RF1, 1% foam from Solberg is used, while some older facilities use Re-healing RF1 3% foam. For a few installations (where there is risk of methanol fire), alcohol resistant foam was used.   The annual discharge of PFAS based foams to the sea was reduced from 3-4 t to (almost) zero. |
| **RAC Rapporteurs comments:**  Thank you for your input. RAC is aware that at present no viable alternatives to fluorine-containing foams are available for certain applications, and several time-limited and unlimited derogations have thus been proposed by the Dossier Submitter. For example, based on a recommended transition period of up to 10 years for further testing of alternatives for large atmospheric storage tanks (COM/ECHA (2020) “The use of PFAS and fluorine-free alternatives in fire-fighting foams”), a 12-year derogation period has been proposed by the Dossier Submitter. RAC evaluated the proposed derogations from an emissions/emission minimisation perspective (proportionality and cost/benefit are evaluated by SEAC). |
| **SEAC Rapporteurs comments:**  Thank you for your comments! We agree that the performance level of FFF may not yet be at an adequate level for certain scenarios. We acknowledge that moving from C6 to FFF is fundamentally different from just changing one ingredient. We consider that an extended transition period will be necessary. However, due to the type of use and the level of potential emissions, this period should be as short as possible. Based on all the information available, we expect that alternatives suitable for the rest of the problematic scenarios but not covered by the tank fire exemption will be available within 5 years and therefore we support that as the length of the period. As to the tank farm derogation, having considered all information submitted in the consultation, we are considering suggesting that the bunded areas be included in the derogation.  Thank you for providing underpinned estimates on the financial consequences of the proposed restriction in the firefighting area. |
| **3047** | **Date:** 2020/07/03 18:02  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Italy  **Company name confidential:** Yes | **Comment:**  We are the Italian distributor for AGC Chemicals who make fluoropolymers and our customers do not have alternatives to the product ETFE (ethylene tetra fluoroethylene) which is produced by AGC Chemicals using a fluorinated process media.  Therefore ETFE is included within the scope of this proposed restriction and we would like to request an exception so that we can continue to sell to our customers who are active in many market segments including automotive, aerospace, pharmaceutical, industrial, chemical, architectural, & electronics. Our customers tell us that they do not have alternatives offering similar performance in terms of extremely high temperature resistance, durability, chemical resistance, UV resistance, lightweight properties etc. |
| **Dossier submitter response:**  DS proposes a broad derogation for fluoropolymers for this restriction proposal in the background document but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional information available these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for the restricted substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are in general warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3048** | **Date:** 2020/07/08 18:26  **Content:**  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes | **Comment:**  We would like underline that such impacts will be far reaching for all manufacturing of electrical cables insulated with fluoropolymers, if no derogation is granted. To date, there is no technical alternative which could replace ETFE - Ethylene tetrafluoroethylene. Some programs are underway for the next 30 years with automobile or aeronautical manufacturers. |
| **Answer to specific info request 1:**  Electrical cables insulated :  Fluoropolymer thermoplastics have a very high electrical insulation characteristic. They are generally used for their chemical and physical resistance properties, this is the reason why they are used to make electrical cables with low radial thickness of insulation. These cables are qualified in the automotive and aeronautical sectors for the next 20 to 30 years. Cables insulated with fluoropolymers must meet very demanding standards around the world such as : UL758 (US), NF C 93-524 (FR), SAE AS22756 ans SAE AS22759 (US), DIN VDE 0250-106 (AL), DIN VDE 0881 (AL), ...  For our company the consumption of fluoropolymer represents 50 tonnes per year. Fluoropolymer cables are also used for their excellent abrasion resistance and their thermal resistance (between 150 ° and 250 ° C), these characteristics are found in the requirements of automotive standards such as ISO 6722. |
| **Answer to specific info request 8:**  Substitution of fluoropolymers is not possible in the construction standards for electric cables. To date, there is no thermoplastic insulation having the same technical characteristics (chemical, electric, physic, ...). Substitution is not possible, for our company it represents several million Euros and dozens of jobs |
| **Answer to specific info request 9:**  Where the substiton is possible, the quality of the electric cables in thermal resistance, in mechanical resistance and in resistance to insulation would be degraded. The costs and risks to the aviation and automotive industry (for example) would be catastrophic. Products qualification programs are extremely expensive and take several years. |
| **Answer to specific info request 10:**  Where the substiton is possible, the quality of the electric cables in thermal resistance, in mechanical resistance and in resistance to insulation would be degraded. The costs and risks to the aviation and automotive industry (for example) would be catastrophic. Products qualification programs are extremely expensive and take several years. |
| **Dossier submitter response:**  Thank you very much for providing information on your use of PFHxA related substances. DS was not aware of this application.  ETFE itself is not targeted in this restriction proposal. The interlink between the use of ETFE and PFHxA, its salts and related substances is not clear for the DS. DS assumes, that PFHxA, its salts or related substances may occur as residue in the ETFE-fluoropolymer. More information on this issue would have been needed to allow for further discussions regarding the C6 thresholds in polymers. DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With available additional information these proposals might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the proposed restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for the restricted substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3049** | **Date:** 2020/07/09 18:53  **Content:**  Scope or restriction option analysis;  Information on alternatives;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** RUDOLF GmbH  **Org. country:** Germany  **Attachment:**  <redacted>  **Privacy comment:** This is confidential, because it is sensitive business know-how. | **Comment:**  Rudolf GmbH submits the following comments to participate in first discussions in ECHA`s Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). Rudolf GmbH actively supports a regulation concerning PFHxA, it’s salts and PFHxA-related substances only for uses, which can be readily covered by available alternatives. However, Rudolf GmbH is very much concerned about consequences that might result from the restriction proposal in its current state. Before we go into the details of our worries, we want to briefly highlight only those features that are unique to C6 perfluorinated polymers and which currently cannot be substituted by fluorine-free alternative technologies. Repellence Against Blood, Oils, Solvents and other Liquid Chemicals with Low Surface Energy: By their physico-chemical properties, perfluorinated polymers are currently and most likely will ever be the only class of substances able to repel liquids such as blood, solvents, petrol and other liquid chemicals with low surface energy. This is key feature for many protective fibres treated including firefighting jackets, medical gowns and other workwear for individuals likely to come in touch with hazardous material. - Low Flammability: Due to their inherent chemical structure, perfluorinated polymers exhibit low flammability features that is superior to all alternative fluorine-free water repellents. In fact, C6 perfluorinated polymers have specifically been designed and are state-of-the-art treatments that assist the low flammability of flame retardant fibres. Flame retardant fibres treated with C6 perfluorinated fibres are nowadays found in many public buildings e.g. furnishings or the textile covering of motor compartments of cars in which the treated textiles additionally exhibit diesel repellence.-Chemical Inertness: The exceptional strength of the carbon-fluorine bond provides perfluorinated polymers with the best inertness towards challenging chemicals and conditions. For instance, (C6-) perfluorinated polymers are the only substance class available for filtration media that are chemically resistant to toxic and most aggressive hydrogen fluoride arising in industrial waste incineration. The latter air pollutant is kept in control along with other emissions by treated high-temperature gas filters installed in these facilities. - Soil Repellence: Though perfluorinated polymers are best known for their oil repellency, they also exhibit repellence towards dry soil as the only class of repellent polymers. In fact, some fluorine-free alternatives attract dry soil actively resulting in treated articles being shortened in their life-span and thus leading to more waste. Moreover, quick dirt build-up on surface of treated articles leads to the water repellent performance being broken down much faster. - Low Dosage Actives: Although various fluorine-free alternative technologies are available that can almost match the performance of C6 perfluorinated polymers if only water repellence is required e.g. for outdoor apparel, all of these alternatives have to be dosed at least at three times the actives amount to achieve comparable results. This finding again makes C6 perfluorinated polymers the more sustainable solution as fossil fuels are saved.  - Best Laundry Wash Resistance: Due to their strong adherence to substrates, C6 perfluorinated polymers show the best resistance to laundry washes thus extending the lifetime of treated articles. This property allows for long-lasting sustainable solutions and saves from unnecessary waste. - Beneficial Ecological and Toxicological Profile Compared with Long-Chain C8 Perfluorinated Polymers: Unlike long-chain C8 PFAS such as PFOS and PFOA, the short-chain PFHxA is neither a substance of very high concern (SVHC) nor a PBT or CMR substance under REACH. Hence, C6 perfluorinated polymers were adopted as the more favourable industrial standard in terms of environmental and toxicological profile. It is important to know that there is no direct use for PFHxA and their salts and this compound occurs only as an impurity in ranges in the ppb region in our emulsion concentrates containing C6-perfluorinated polymers. Recent published studies also show that human exposure to PFHxA is low and infrequent. As seen from the characteristics list above, C6 perfluorinated polymers are essential for many advanced and start-of-the-art technical applications of modern human life. Their unique features have led to many uses not only in articles in which their protective character is well apparent e.g. the firefighting jacket but also to applications which are vital for our society and in which this type of substances is not replaceable. Due to the aforementioned importance of C6-perfluorinated polymers Rudolf is deeply concerned that the restriction proposal in its current state may a) ban many essential textile uses, for which fluorine-free alternative technologies are not available yet and will therefore lead to unreasonable consequences such as industrial norms involving safety and reliability of applications not being met anymore b) If the proposal becomes adopted in its current state, we fear it will shut down the production and commerce of C6 perfluorinated polymers for all textile applications in the EU including the ones exempted under the current proposal. Manufacture for the proposed exemptions only will become completely uneconomical forcing EU-based producers including Rudolf to shut down their production of C6 fluorinated polymers altogether. c) In the best case scenario, production of C6 fluorinated polymers will be shifted to Far East countries with less controlled industrial and environmental standards resulting in more uncontrolled PFHxA emissions and contradicting EU's efforts for less global pollution. In this case, the EU would heavenly depend on supply of technology which is used for the manufacture of protective gear such as face masks, medical gowns, firefighting jackets, etc. The Corona virus pandemic is now showing us how vulnerable our society is with the EU completely depending on supply of personal protective equipment such as face masks from Far East countries.  However, the more realistic and worrying scenario involves global shut-down of the short-chain C6 chemistry and resurrection of the environmentally and toxicologically harmful long-chain C8 chemistry. This assumption is based on the experience that in Far East countries the C6 technology is currently used only for exporting treated articles into the European market, while for the domestic uses the better performing C8 technology is still the state-of-the-art treatment. So, if the nowadays widely accepted C6 chemistry, recently introduced as the new industrial standard with a more favourable environmental and toxicological profile compared to C8 chemistry, is now abandoned, then manufacturers in the Far East will have no incentive to discontinue their production of C8 perfluorinated polymers. In fact, we already see Asian manufacturers scaling up their production capacity for C8 perfluorinated polymers today. This effect will contradict EU’s efforts for less global pollution with long-chain C8 PFAS. In summary, both scenarios describe that exempted applications and articles involving C6 fluorinated polymers under the current restriction proposal will be extremely difficult or even impossible to sustain. d) Many European companies have invested significant resources into transitioning their products and applications from C8 to C6 perfluorinated polymers to sustain their business models on an environmentally more favourable technology. These investments were made on the perspective of future earnings. If these efforts become shattered by the proposed restriction, jobs in the European textile industry, which is heavenly focussed on producing advanced technical textiles, will be lost and companies will be shut down. In this respect, the present restriction proposal will not achieve its desired effect to the extent of even contradicting REACH restriction principles according to which a restriction “shall take into account the socio-economic impact of the restriction, including the availability of alternatives” (Art. 68 (1)). Rudolf GmbH would like to underline that such impacts will be far reaching. If no derogation is granted, the German plant will have to close down, resulting in direct job losses from production, R&D, marketing and sales of C6 chemistry. Currently we achieve a substantial part of our turnover with the manufacture and commerce of C6 fluorinated polymers at our headquarters in Geretsried. Detailed figures have been provided separately in our confidential business information. Rudolf, as a sustainable and innovations-driven company, actively supports the movement to chemical alternatives with lower ecological impact wherever possible. Rudolf GmbH is currently working on its 4th generation of fluorine-free water repellents that are finding more and more acceptance in the outdoor and fashion apparel industry. However, many of our customers create advanced and highly specialised applications with C6 perfluorinated polymers that currently cannot be replaced with fluorine-free technology. Most of these applications will be banned under the proposed restriction and hence, essential product applications, markets and jobs in the European textile industry are at stake. Hence, we ask the committees RAC and SEAC to consider the following points: - Review and grant exemptions for further applications that provide essential safety aspects to textiles treated with C6 perfluorinated polymers. For instance, personal protective equipment as specified in regulation EU 2016/425 is exempted for risk category III (a), (c), (d), (e) and (f). However, there is no exemption planned for III (l) concerning PPE targeting the risks of bullets wounds and knife stabs. We find this very controversial as this means that bulletproof vests e.g. for police will not be available with the most reliable treatment though it has been shown that firearm bullets can penetrate wet aramid fibres like a knife through butter.- Review the resulting availability of products and applications involving C6 fluorinated polymers for the proposed exemptions in case no amendments are made to the current restriction proposal. In above paragraph b) we had already outlined in detail that the proposed restriction will almost certainly restrict the availability of C6 products and applications for exempted uses in the EU or, in the best case scenario, make the EU depended on supply of life-saving C6 technology from Far East countries. This point is of particular importance in this current Corona virus crisis. - Review and grant exemptions for further textile applications involving C6 perfluorinated polymers that are essential for the benefit of our community and which currently cannot be replaced with fluorine-free alternative technologies. To determine, which applications are essential, a reasonable approach would involve screening all industrial norms that can currently be met only by perfluorinated polymers. - Review the feasibility of controlling the end-of-life-time of articles treated with C6 perfluorinated polymers and avoiding their widespread disposal. - Review the possibility of extending the transition time of technical textile applications up to 10 years until fluorine-free alternative textile treatments become available. Extension of the transition period would also allow textile associations to develop new norms based on performance that can be achieved with fluorine-free technology. - Review the feasibility of monitoring the import of products and articles commonly treated with fluorinated polymers. If the EU decided to terminate the production and commerce of products and articles involving C6 chemistry for most applications within EU, it would be wise to install monitoring measures for articles imported into the EU. It would have to be ensured that EU-based companies using fluorine-free technology are not competing with imports using better performing perfluorinated polymers. In this regard it must be highlighted that analysis and detection of fluorinated polymers in treated articles is complex and time-consuming. To emphasise our concerns following application examples are attached in more detail. Rudolf GmbH is active and markets C6 perfluorinated polymer emulsions in the following areas: Personal protective equipment (PPE) Personal protective equipment is treated with C6 perfluorinated polymers to ensure the highest level of protection and comfort to individuals that are often faced with extreme and life-threatening situations. Such incidents may expose the wearers of PPE to all sorts of harmful substances, such as petrols, chemicals or bioorganic spills that would otherwise penetrate the textiles and pose a serious health hazard. Firefighting jackets for instance have to feature low flammability and be repellent against solvents and firefighting water. If firefighting jackets became wet during operation they would lose their breathability and the risk for individuals overheating would unreasonably increase. In another instance medical textiles require the highest level of repellency against infections bodily fluids to keep medical staff as well as patients protected from bacteria and virus. The respective standard DIN EN 13795 explicitly refers to textiles being resistant against dry and wet microbial penetration. Currently there are no technical alternatives for C6 treatments that would meet the standards for PPE as specified in EN ISO 6530 (protection against liquid chemicals), EN 13795 (surgical drapes), EN 469 (protective clothing for firemen) Reproofing of Personal Protective Equipment (PPE) Textiles that must exhibit particular protective functions are heavily regulated by European standards. C6 perfluorinated polymers are used as reproofing agents to restore the repellency against chemicals such as water, solvents and other chemicals of PPE including clothing for firefighting as specified in EN 14325 and EN 469. Additionally, the articles reproofed must exhibit low flammability. There is currently no alternative fluorine-free chemistry available that would restore the aforementioned specified protective features. Though C6 perfluorinated polymers are exempted from the restriction proposal, it is highly unlikely these protective reproofing agents will still be available once the restriction is in place, as the production and commerce for this niche market will become very uneconomical. Due to the latter fact, there is a highly probable risk C6 perfluorinated polymers will not be available in the EU even for the applications exempted from the restriction. Medical Textiles: Medical textiles treated with C6 perfluorinated polymers e.g. drapes, gowns, etc. make the substrates repellent to bodily fluids and thus avoid the transmission of infectious bacteria and virus from and to patients and medical staff. Unlike other repellent treatments, C6 perfluorinated polymers can be used in very low dosages and hence exhibit highest breathability of textiles and by this allowing not only for a high level of protection but long wear comfort. In summary, there are no technical alternatives for C6 perfluorinated polymer treatments that would meet the standards for medical textiles as specified in DIN EN 13795 (resistance against dry and wet microbial penetration) and EN 20811(resistance to water penetration). Filter Media: Filter media treated with C6 perfluorinated polymers guarantee safe and durable operation of various applications, in which e.g. constant retention of bacteria in liquids or gases under harsh conditions (alkaline, acidic, solvent-based) is achieved such as clean air supply of bioreactors in the food, beverages and pharmaceuticals industry as specified in ASTM F-838-05 (bacterial retention of membrane filters utilized for liquid filtration). Non-Wovens for Technical Applications: Technical non-woven materials e.g. in the automotive industry are subject to extreme wear and soiling. Hence, the materials used must be resilient, highly durable and easy to clean but also allow for light-weight constructions that lower the consumption of fossil fuels at the same time. The aforementioned expectations can currently be meet only by textile treatments with C6 perfluorinated polymers offering cost-effective and sustainable articles that are appealing over their entire life span. All these requirements are reflected in various test standards of the car manufacture industry. Carpets:To meet the industrial testing standard ASTM 6540, carpets are treated with C6 perfluorinated polymers to equip them with high resistance against soiling and thus exhibit long-lasting appeal. Fluorine-free alternative treatments are only water repellent but do not repel dry or oily soils. In fact, many fluorine-free water repellents do attract dry soils shortening the carpet’s lifetime as they become unsightly much quicker. The durability and lifetime of the carpet treated with C6 perfluorinated polymers is clearly improved. Carpets are not only used for residential environments but also in automotive industry. Most automotive producers have specifications which require a fuel, diesel and oil repellency. This can only be achieved with C6 perfluorinated polymers. Awnings: Awnings are heavily exposed to rain, wear, soiling and UV irradiation. C6 treatments render the articles durable and resistant to these extreme weather conditions. Especially bird droppings and tree sap are extremely tenacious that can only be completely removed if the awnings had been treated with C6 perfluorinated polymers. Fluorine-free alternatives do not achieve comparable performance and durability and are hence the less economic and sustainable solution. Upholstery applications: Upholstery in home textiles and automotive is subject to intensive stress, abrasion and reoccurring soiling. To meet the expectancy for durable and long-lasting appeal, the articles must render easy-to-clean and soil repellent properties. These expectations can only be met by C6-treated upholstery as envisioned in various automotive test protocols. As mentioned before, fluorine-free alternative treatments provide only water but no oil or soil repellency. Actually, some fluorine-free treatments can attract dry soils and lead to unsightly furniture and seating quickly making these solutions less sustainable. Construction Industry: C6 perfluorinated polymers are used as durable state-of-the-art protecting agents on hard surfaces against all kinds of stress and influences. Outdoors, they act as a barrier against extreme weathering including alternating temperatures, UV irradiation, wear, etc. on substrates such as concrete, marble, stone and tiles. By their great stability and strong substrate adherence, they form an effective repellent film against soil, solvents and oil-based stains including graffiti. Due to these unique features they allow for quicker cleaning, less use of aggressive detergents and longer intervals between cleaning cycles thus being very sustainable protection solutions. Indoors, C6 perfluorinated polymers protect floorings and walls in garages, workshops and public buildings against oil and solvent-based stains accordingly. No other chemistry is currently available that provides the same level of protection. Alternative silane/siloxane-based agents do not provide stain and oil repellency and, moreover, are less durable due to their poor UV resistance. Fabric Coatings: For creating bifunctional fabrics i.e. a fabric that is hydrophilic on one side and hydrophobic on the other, solvent-borne and aqueous textile chemicals are often applied single-sided. For this purpose a C6 base coating is essential for preventing the solvent-borne chemical from migrating through the fabric to the other side. Consumer and Professional Reproofing Applications: C6 perfluorinated polymers are used as very effective reproofing agents to extend the lifetime of shoes and garments by retaining their water, oil and soil repellent protective features. They are established low dosage products with a known toxicity profile. While reproofing products contain C6 perfluorinated polymers in ranges between 0.2 to 0.5 % actives content, for fluorine-free alternatives 2.0 to 5.0 % actives content is typical. The fluorine-free alternatives do only provide less durable and less pronounced water repellency and no soil or oil repellency. The latter feature is an essential protection from dirt that would otherwise decrease the life-time of e.g. shoes drastically. Outdoor apparel: C6-treated outdoor fabrics have the unique feature of repelling all kinds of oily soil. Hence, C6 fabrics must not be washed as frequently and save energy and resources compared to non-fluorinated fabric treatments. Furthermore, C6 treatment is more laundry durable extending the service life significantly. Reproofing with after care products is also unnecessary. |
| **Answer to specific info request 1:**  No use of PFHxA and related substances is known to Rudolf for applications other than the ones included in our general response. |
| **Answer to specific info request 2:**  Please refer to our confidential submission part for detailed information. |
| **Answer to specific info request 3:**  C6 fluorinated polymers are usually applied by pad application onto the textile fibre. In this application a roll of untreated fibre is led through a bath with C6 fluorinated polymer solution. Upon pick-up of the finishing liquor, the excess water is squeezed out by padding.From our experience, textiles applied by this method contain about 1.0 wt% C6 fluorinated polymer relative to the textile fibre weight. Please refer to our confidential submission part for detailed information on how this number converts to potential emissions of PFHxA-related substance. However, it has to be taken into account that treated articles are usually made up of more than one fabric layer. So, it is expected that less than half of an outdoor jacket consists of fabric material treated with C6 fluorinated polymer. Furthermore, C6 fluorinated polymers are tightly bound to the textile fibres by cross-linkers in washable articles. Hence, only a small fraction of the C6 fluorinated polymer can be extracted by chemical methods. |
| **Answer to specific info request 4:**  Please refer to our confidential submission part for detailed information |
| **Answer to specific info request 6:**  Please refer to our confidential submission part for detailed information. |
| **Answer to specific info request 7:**  Rudolf Group manufactures alternative fluorine-free polymers for applications for which only the water repellent finish is required. |
| **Answer to specific info request 8:**  All uses that demand chemical inertness towards aggressive chemicals and conditions or require repellency against oil, soil, blood and liquid chemicals cannot be fulfilled with fluorine-free technology. Please refer to our general response for more details and explicit applications. From a physicochemical point, no fluorine-free alternatives are known that would reduce the surface energy/tension to a level which allows for repellency of oil, solvents, liquid chemicals, blood, etc. |
| **Answer to specific info request 9:**  Consumer water proofing sprays, construction and coated building applications, water repellent agents for outdoor, sports and fashion apparel can be transitioned to fluorine-free alternatives within a short timeframe. A reasonable timeframe for transitioning the above applications would involve 2 to 3 years.If the timeframe was too short, it would be impossible to develop fluorine-free technologies for the technically more advanced and challenging applications and, ultimately, these applications would be lost as well as jobs and markets associated with them. We estimate that more than half of our business with C6 fluorinated polymers goes into technically advanced applications. Hence, if Rudolf was not given enough time to transition the latter applications into fluorine-free solutions we estimate business losses to the number provided in the confidential submission part. If the transitional period was too short, downstream users of the currently used C6 technology would not have the time to bring alternative fluorine-free technologies into harmony with their application, the marketing and customer expectation. Performance and, even worse, claims for product stability and performance would result.Additional resources would be needed along all business departments. For instance, human resources would be required in R&D, technical application labs, and marketing to develop, test and promote fluorine-free alternatives. Furthermore, investments in new production vessels and infrastructure would be essential, as fluorine-free alternatives demand as much as twice to four times the active substance and result in much short longevity of applications compared to C6 fluorinated polymers. These expectations would press Rudolf to investing into 10 man-years at least and 3 - 5 Mio € for additional production capacity. |
| **Answer to specific info request 10:**  All known applications which involve C6 polymers today.Check general response for more details (e.g. fluorine-free alternatives do not provide oil, blood, liquid chemicals repellency, low dosage, durability, etc.). This is hard to estimate. Consumers will determine whether lower quality of fluorine-free applications and products will be accepted.Product costing is not an issue. Fluorine-free alternatives are less expensive but need to be used more quantitatively. Performance of fluorine-free alternatives will be the issue and must fulfil the current norms. Please refer to our general response including a list of applications. |
| **Answer to specific info request 11:**  Alternative short-chain fluorotelomer substances do not provide the performance required. The alternatives' performance is comparable with our fluorine-free solutions. |
| **Answer to specific info request 12:**  Yes, human resources are needed to track C6 volumes for the applications exempted. |
| **Dossier submitter response:**  Thank you for the valuable information. DS is aware that currently there are no fluorine-free alternatives providing oil and stain repellence. It is stated (also by other stakeholders) that using fluorine-free alternatives will decrease the service life of many products, such as outdoor furniture, awnings, carpets and upholstery. However, DS has no information to what extend the reduction of life time will amount to for the product categories above. It is stated that: “Extension of the transition period would also allow textile associations to develop new norms based on performance that can be achieved with fluorine-free technology.” DS wonders how long it would take to alter norms or develop new norms so that they will be fulfilled by textiles treated with non-fluorinated alternatives. Concerning upholstery, designing furniture with changeable coverings might increase life time of furniture. Concerning awnings, it is the opinion of the DS that – although being difficult to remove - bird droppings and tree sap will not impair the actual purpose of an awning: protection against sun and rain.  DS would have been interested to know which percentage of C6 fluorinated polymers is used in the different sectors (for example, if PPE are included in ‘technical advanced applications’ as mentioned in answer 9).  DS agrees, that when oil and dirt repellency is essential to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. It is to be noted that also import of C6 treated articles will be covered by the proposed restriction.  DS notes the request for a derogation of use in the construction sector but is not able to discuss the request without additional specific information on the uses. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction, including specific categories of PPEs and high visibility clothing. Derogations proposed by the Dossier Submitter or requested by stakeholders, for e.g. technical textiles and construction, have been evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that suitable alternatives are not yet available in cases where repellence to oil, dirt, chemicals or bodily fluids is required. Extended transition time is required where these properties are necessary to avoid high societal costs. We support the derogation for certain categories of PPEs proposed by the Dossier Submitter. The scope thereof was revised based on information received in the consultation and now covers more product categories. Also, high visibility clothing is now proposed to be derogated. As to medical textiles, there is now a general derogation for medical devices proposed. According to our understanding, woven and non-woven medical textiles are widely covered by this derogation. Further information relating to products that this does not apply to but that are considered to require a derogation from the restriction can be submitted in the consultation on the SEAC draft opinion.  Overall, noting that RAC concludes that a large part of emissions of PFHxA-related substances originates from the textile sector, we consider that evidence on substantial negative socio-economic impacts is needed to support any further derogations. A similar situation as regards socioeconomic implications and the lack of respective information applies for the construction sector. Whilst SEAC notes the concern brought forward by stakeholders during the consultation, it has no such information at hand that would allow assessing whether a derogation is justified from a socioeconomic perspective (costs, consequences (i.e. impacts) of using alternatives, emissions, etc.).  We agree that a general transition period of 18 months may be too short, and we currently consider to propose that it be extended to 36 months in order to give time for a balanced transition to alternatives in all sectors.  Imports will fall under the proposed restriction, hence import of fluorinated products will not be possible in the EU. |
| **3050** | **Date:** 2020/07/10 12:22  **Content:**  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Italy  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Protection of commercial interests of a legal person, including intellectual property | **Comment:**  - |
| **Dossier submitter response:**  Thank you for providing follow up information to your original comment. The DS disagrees that the transition period should be extended in general. Alternatives are available and used for several applications. In order to evaluate the need for use-specific derogations it would be helpful to receive more detailed substitution plans for individual uses. |
| **RAC Rapporteurs comments:**  Thank you for your complementary information. RAC is aware that C6-fluorosurfactants are very effective for repellence of water, oil and grease. For certain uses alternatives appear to be available, thus for these no extensive prolongation of the transitional period would be needed. Derogations proposed by the Dossier Submitter, or requested by stakeholders in the consultation and sufficiently substantiated with information on emissions and risk management measures, have been evaluated by RAC from an emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for the information provided. In order for SEAC to evaluate any specific derogation request/proposal, information on socioeconomic impacts that justifies the request needs to be provided (costs, emissions, consequences (in terms of impacts) of using alternatives, etc.) to the Committee. For the current restriction proposal, SEAC agrees that a general transition period of 18 months may be too short, and we currently consider to propose that it be extended to 36 months in order to give time for a balanced transition to alternatives in all sectors. |
| **3051** | **Date:** 2020/07/10 15:35  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Marubeni Europe Plc, Duesseldorf Branch  **Org. country:** United Kingdom | **Comment:**  We are using ETFE for plastic Sheets for the semiconductor Industry where chemical resistance, purity, low leaching-out and fire resistance are essential. |
| **Answer to specific info request 2:**  Data will be provided by AGC |
| **Answer to specific info request 8:**  Other materials like PVC sheets are highly contaminated by metal and can't be used in the wafer processing (semi-conductor chip production). |
| **Dossier submitter response:**  The information you provided on the use of ETFE in the semiconductor industry have been considered when reconsidering the derogation proposal for semiconductors. ETFE itself is not targeted in this restriction proposal. The interlink between the use of ETFE and PFHxA, its salts and related substances is not clear for the DS. DS assumes, that PFHxA, its salts or related substances may occur as residues in the ETFE-fluoropolymer. More information on this issue would have been appreciated. This information would be beneficial for further discussions regarding the C6 thresholds in polymers or possible derogations.  DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With available additional information, these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimization perspective. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested a general time-limited derogation of semiconductors for 12 years based on the information provided. SEAC notes that RAC supports this derogation as emissions are expected to be minimised by other means than a restriction. Furthermore, SEAC notes that information on restriction-related costs indicates potentially high socioeconomic impacts. Even though uncertainties remain, SEAC considers that a restriction for this use without a respective transition period is likely not proportionate at present and therefore supports a transition period of 12 years as well.  The Dossier Submitter also proposed specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3052** | **Date:** 2020/07/14 08:55  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  ETFE-powder is used as a rotolining material for many pipes and tubes in the chemcial Industry. The heat and chemical resistance is exceptional and the processing is far better than all potential, more expensive materials. |
| **Answer to specific info request 2:**  Please consult AGC |
| **Answer to specific info request 13:**  Please consult AGC |
| **Dossier submitter response:**  ETFE itself is not targeted in this restriction proposal. The interlink between the use of ETFE and PFHxA, its salts and related substances is not clear for the DS. DS assumes, that PFHxA, its salts or related substances may occur as residues in the ETFE-fluoropolymer. More information on this issue would have been appreciated. This information would be beneficial for further discussions regarding the C6 thresholds in polymers or possible derogations.  DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With available additional information, these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3053** | **Date:** 2020/07/15 07:42  **Content:**  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Chemical Fibers Association  **Org. country:** Japan | **Comment:**  Japan Chemical Fibers Association (JCFA) much appreciates the opportunity to reply to this public consultation, and submit our opinion on the proposal to restrict PFHxA, its salts and related substances under REACH.  Indeed, JCFA are all for the activities to protect human health and the environment from toxic chemical substances. However, JCFA thinks there are some concerns about the proposed restriction on the following grounds:  (1) According to the proposal, “Mobility” and “Long-range transport potential” of PFHxA types are mentioned as one of the reasons for the regulatory action, but these properties are not subject to regulations as the hazards justifying the restriction in REACH. As for PBT (Persistent, Bio-accumulative and Toxic), these three properties are required to be restricted in REACH, the requirement for the restriction is applicable only to “Persistent”, and not applicable to “Bio-accumulative” and “Toxic”. Also, it appears there has been no progress in collecting and verifying scientific knowledge since a proposal for SVHC (Substances of Very High Concern) was withdrawn in 2018. There is scientific grounds needed to justify putting stricter restrictions on PFHxA types, which weren’t allowed to be listed in SVHC.  (2) One of the alternatives to PFOA types (C8) determined to be restricted is C6, and there is currently no alternative substances found for C6. With regard to the products which can meet required properties using non-fluorination technology among a wide range of product applications, manufacturers have been making efforts to develop the alternative technology. However, such products are limited as things stand, and most products couldn’t meet the market’s required properties without fluorination technology to impart water and oil repellence. The water and oil repellence is closely related to the safety to the human, and is a crucial function for outdoor clothing as well as individual protective tool. JCFA is concerned that if C6 chemicals were forbidden to use for products needed the water and oil repellence as the essential function, the production would stop and which might cause confusion for our society as well as the supply chain. Actually, there are lots of SMEs in a textile processing industry, which will bring about the increase in their workload. |
| **Answer to specific info request 8:**  Please see the comment |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellency is essential to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. Concerning outdoor clothing, it is the opinion of the DS that it is possible to switch to non-fluorinated alternatives as many textile brands already did.  It is to be noted that also import of C6 treated articles will be covered by the proposed restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comment.  According to Article 67 of the REACH Regulation[[4]](#footnote-4), a new restriction can be introduced “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis […]”.  This proposal explains why persistence and mobility in combination with other properties, including adverse effects, justify the proposed restriction and why risks are not hypothetical based on the properties of the substance.  The risk assessment of PFHxA contained in this proposal applies the ‘case-by-case’ approach described in paragraph 0.10 of Annex I to the REACH Regulation[[5]](#footnote-5), i.e. where a standard risk assessment is not considered to be appropriate. The Background Document of the restriction proposal has provided justifications why a conventional quantitative risk assessment approach has not been applied. RAC agrees with the approach in its opinion. A REACH restriction is not limited to substances having legally set hazard properties, such as those underpinning SVHC or CLH. Other hazards and risks can be considered (e.g. for mobility), where justified.  RAC is aware that fluorinated polymers are effective for repellence of e.g. water, oil and grease. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction such as PPE and high-visibility clothing. Derogations proposed by the Dossier Submitter or requested by stakeholders, e.g. for technical textiles, have been evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree that suitable alternatives are not yet available in cases where repellence to oil, dirt, chemicals or bodily fluids is required. Extended transition time is required where these properties are necessary in order to avoid high societal costs. We support the derogation for specific categories of PPEs proposed by the Dossier Submitter. The scope thereof was revised based on information received in the consultation and now covers more product categories. Overall, noting RAC’s conclusion that a large part of emissions of PFHxA-related substances originates from the textile sector, we consider that evidence on substantial negative socio-economic impacts is needed to support any further derogations. |
| **3054** | **Date:** 2020/07/15 12:23  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  ETFE is one of the most important insulation material for automotive cables. Based on outstanding properties such as flex life, stress cracking resistance, temperature resistance, chemical resisdance their is nearly no alternative grades. Our cables are specified and delievered to all European car manufacturer. |
| **Answer to specific info request 2:**  please consult AGC |
| **Answer to specific info request 8:**  cable insulation for automotive applications from 150°C to 180 °C |
| **Answer to specific info request 13:**  Please consult AGC |
| **Dossier submitter response:**  ETFE itself is not targeted in this restriction proposal. The interlink between the use of ETFE and PFHxA, its salts and related substances is not clear for the DS. DS assumes, that PFHxA, its salts or related substances may occur as residue in the ETFE-fluoropolymer. More information on this issue would have been appreciated. This information would be beneficial for further discussions regarding the C6 thresholds in polymers or possible derogations.  DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional available information, these proposals might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3055** | **Date:** 2020/07/15 15:56  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The attachment contains sensible company information | **Comment:**  Medical and toxicological data are summarized in the confidential attachment to underline the request for exemption of 1-(Perfluorohexyl)octane (CAS 133331-77-8) for the use in medical and pharmaceutical applications. |
| **Answer to specific info request 1:**  Products containing 1-(Perfluorohexyl)octane are certified as class IIb medical devices (see attachment) according to the Medical Device Directive (MDD) and are marketed in several European countries. |
| **Dossier submitter response:**  Thank you for providing the toxicological information. As stated in response to your earlier comment, DS proposes a derogation for this use and for medical applications in general. |
| **RAC Rapporteurs comments:**  Thank you for your additional information. The Dossier has proposed a derogation for your use (as part of medical devices). RAC evaluated this derogation request from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for allowing this derogation is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments! Please see reply to Comment 2997. |
| **3056** | **Date:** 2020/07/15 17:20  **Content:**  Hazard or exposure;  Environmental emissions;  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** DIC Corporation  **Org. country:** Japan  **Attachment:**  <redacted>  **Privacy comment:** Contains technical details on the manufacture of flat panel screens and details on supply chain that would be detrimental to DIC Corporation's interests if widely disseminated. | **Comment:**  DIC Corporation is a maker of fluorochemical and acrylic polymer based surfactants having C6 telomer groups.  Our products are not PFHxA itself but fall into the definition of PFHxA precursors.  DIC Corporation is a major supplier of fluorine-based surfactants in the market of materials for Flat Panel Displays (FPD) such as positive/negative type of photoresists and coating solutions for polarization films. DIC Corporation sells the surfactants to makers of these materials who are located in east-Asia (Japan, Korea, Taiwan, China), not in the EU.  Because almost all of display products are made outside of the EU, DIC’s surfactant is imported to the EU market as components of “Articles” of LCD products.  The quantity of our products imported to the EU region as a component of FPD panels is not so large: approx. 2 MT/year.  There is no concern that PFHxA and/or its related compounds should be generated or released from FPD products during use as the substance is firmly bound into the display screen layers. Furthermore, FPD panels are under strict regulatory management in the EU to avoid exposure during disposal (e.g. Directive 2012/19/EU on waste electrical and electronic equipment), and FPD panels are collected, decomposed and recycled or otherwise properly incinerated.  There is great concern that the availability of FPD products in the EU will be affected by the proposed restriction. There is considerable technical difficulty with replacing C6 telomer-based surfactants and any alternative will require a long period of time to establish the performance through the supply chain. This process is likely to affect the supply of displays and monitors for airplanes, automotive, medical devices many other industrial applications.  For the reasons given, an exemption from the current proposed restriction of PFHxA in the EU is requested for FPD panels manufactured using PFHxA related compounds and imported into the EU. |
| **Dossier submitter response:**  Thank you very much for your comment on the restriction proposal. DS was not aware of your application of PFHxA and related substances. DS considered the information you provided when reconsidering the derogation proposal for semiconductors and electronic devices and is proposing a derogation for semiconductors and semiconductor related equipment for twelve years.  In order to justify a derogation, it would be helpful to learn whether all FPD contain C6 telomers. Additionally, DS notes that you confirm the general availability of alternatives. In order to propose an adequate transition period DS would appreciate additional information, preferably a detailed substitution plan. |
| **RAC Rapporteurs comments:**  Thank you for your comment. The Dossier Submitter has proposed a 7-year derogation (increased threshold for PFHxA and its salts and PFHxA-related substances) for fluoropolymer coating of electronic devices. RAC evaluated the proposed derogation from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and the information on this use. It is important that all uses that will be impacted by the restriction are identified. We note that information on this use was submitted only by very few respondents in the consultation on the dossier. Hence is not clear how wide this use is and whether suitable alternatives may have been found already. To be able to evaluate whether a derogation is justified, it would be necessary to have information on the socioeconomic impacts expected from the restriction and the availability of suitable alternatives for the use of the substance (including why it may be specifically difficult to find alternatives in this use, and what is the extent of search made). |
| **3057** | **Date:** 2020/07/16 12:18  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  ETFE fulfills required chemical and temperature resistance on our products. |
| **Dossier submitter response:**  ETFE itself is not targeted in this restriction proposal. The interlink between the use of ETFE and PFHxA, its salts and related substances is not clear for the DS. DS assumes, that PFHxA, its salts or related substances may occur as residue in the ETFE-fluoropolymer. More information on this issue would have been appreciated. This information would be beneficial for further discussions regarding the C6 thresholds in polymers or possible derogations.  DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional available information, these proposals might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers such as ETFE are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3058** | **Date:** 2020/07/17 03:17  **Content:**  Environmental emissions;  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Japan  **Company name confidential:** Yes | **Comment:**  We propose the following regulations regarding PFHxA and related substances contained in water-based ink products for inkjet printing equipment.  Suggestion  1. Water-based ink products for inkjet printing equipment are not subject to regulation (same as LATEX ink) human impact, environmental impact is nil  2. When regulated, non-conforming ink products have a switching grace period of 10 years or more  Development element 1, An alternative ink development: more than 5 years  Development element 2, Printing equipment development supporting alternative ink: 3 years or more  ~Explanation~  □Overview of the use of PFHxA related substances  　· One raw material of the water-based ink for ink-jet printing equipment, PFOA used as replacements for such  　- The target substance content rate in ink is less than 0.05%  -The substance of Law required test results in persistent ( P) has been confirmed,  but bioaccumulation (B), toxic (T) is low  ・Ensure the reliability of ink jet printing equipment and control the density unevenness of the media.  □Human body effect 　-No effect  Target substances are transferred to paper, which is a medium, by inkjet printing  - 1, printing at the time >> human body contact risk of name not Never touch the ink directly during printing  - 2, maintenance, service of time >> human body contact risk is low  　　Low risk of exposure due to automatic maintenance and work by service personnel wearing  　　 protective equipment    □Environmental impact-developed countries of the affected by the recycling system is none  　　　Printing equipment (residual ink inside the printing equipment)  　　　　· For discard disposal of printing equipment we have implemented the appropriate  　　　　　recycling and incineration disposal by a professional collection agency  　　　　・The ink cartridge ( residual ink in the cartridge ) is suitable as a plastic product.  　　　　　Since it is incinerated, there is no concern about environmental pollution of rivers and soil.  　　　Printed matter  　　　　・For the method of discarding printed materials, use an appropriate collector or recycler  　　　　　Since incineration and recycling are the mainstream, the impact on soil and rivers is extremely low.    □ Response to non-conforming products  　　Need grace period for replacement of printing equipment  　　If sales of non-compliant ink products that are not compliant with the relevant laws and regulations are  prohibited  Large amount of machine waste occurs due to replacement of printing equipment (impact on the environment)  　~ Market trend forecast ~  　　Step1 Sales regulations  You can no longer purchase incompatible ink products  Step2 Utilization of non-genuine ink  　　　　Expensive use of non-genuine products in order to continue to use the printing equipment to  Printer-Because it is out of the manufacturer's warranty category,  Because the printer is out of the manufacturer's warranty category, the printer cannot receive quality  maintenance services from the manufacturer.  　 Step3 Product life of the printing device will be shortened and replacement of the device (discarding the old  printing device) will be accelerated.  　　　　　　　　Concerns about impact on exhaust pollution  □ Need a grace period for the development period  　　System required to follow the regulations switching of the grace period:10 years (below 1 + 2 )  　　1. New development of compatible ink (more than 5 years)  　　2. Development of printing equipment that matches compatible ink (3 years or more)    (Current situation)  Material examination for compatibility of reliability of inkjet printing equipment and image quality in ink products  　　As alternative materials we are studying materials other than fluorine-based compounds, but at the moment there are no materials with similar functions.  　( Multi-product more , hurdle of the technical aspects also high, prospects of development review period can’t be planning ) |
| **Answer to specific info request 9:**  Use: Printing for textiles  Transition period: 10 years or more |
| **Dossier submitter response:**  Thank you for your comment. There are alternatives for water-based inks available (e.g. siloxanes and solvent based or UV curable mixtures). Therefore, a prolonged transition period is not justified.  Release of PFHxA-related substances from printing inks can occur during the whole life cycle. These substances are then degraded to PFHxA under environmental conditions. Effects of PFHxA might occur with delay and are not limited to the present time, but will also be an issue for future generations as PFHxA will remain for decades to centuries. At the point of time the effects are triggered, it will be, however, very difficult to reverse the effects due to the irreversibility of the exposure. Since consequences of an underestimation of adverse effects are not reversible by regulatory action later on, it is important that releases are reduced to a minimum. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants have very functional properties for various applications, including printing inks. Your derogation request has been considered by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogating this use is performed by SEAC.  RAC agrees with the Dossier Submitter that there is a hazard and risk posed by PFHxA, its salts and related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. According to the information provided in the restriction dossier, alternatives for water-based printing inks are available. We surmise that the existing alternatives may not be fully suited to different processes, however full information on the lack of performance is missing. To propose a derogation, we would need information on the properties necessarily required but not found in alternatives, i.a. why suitable alternatives are specifically difficult to find in each specific use, and/or how wide the search for alternatives has been, to fully evaluate the case.  Since RAC concludes that the use is wide dispersive and emissions cannot be minimised by means other than a restriction, we consider that evidence on substantial negative socio-economic impacts is needed to support any derogations. |
| **3059** | **Date:** 2020/07/17 09:20  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Auto Parts Industries Association (JAPIA)  **Org. country:** Japan  **Attachment:**    <redacted> | **Comment:**  The Japan Auto Parts Industries Association (JAPIA) was established in August 1969 as a “public interest incorporated association” aimed at working to promote the auto parts industry of Japan.  Since its reorganization in December 2011 as a “general incorporated association”, JAPIA has been engaging in various activities for the further development of the industry.  For automobile safety and comfortable driving, the high quality of each automobile part is a great contribution. The environmental situation in the auto parts industries ran into unprecedented difficulties such as structural change, promotion of international corporations, etc. However, JAPIA actively makes an effort towards these problems together with JAPIA member companies.  The number of Japanese Automotive Suppliers are 6,700 companies with 686,000 people directly employed. The yearly sales is 290.2 billion euros. Automobile industries accounts for 17.5% of the total manufacturing shipment value in Japan. Automobile parts account for more than 50% of total automobile industry shipment value and half of them are from JAPIA member companies.  1. Japan Auto Parts Industries Association (JAPIA) is concerned about the consequences of the current PFHxA restriction proposal.  Regarding the consequences of the current PFHxA restriction proposal, JAPIA supports the comments on the restriction proposal that Daikin Industries, Ltd submitted in their comment (No.2988) to ECHA on May 13, 2020. Please refer to paragraph 5.  Fluoropolymers, which include both fluoroelastomers and fluoroplastics, are generally prepared by emulsion polymerization using an emulsifier, which used to be PFOA.  According to the regulation of PFOA, the downstream makers understand that the substances used in emulsifier are shifted to fluorchemicals substances having lower carbon numbers, and PFHxA is mainly used in the substances.  At the present, we confirm with our downstream makers that it is not possible to replace with an alternative technology to fluorchemicals free. It is necessary to discuss the alternative technology with upperstream makers, not from downstream makers such as JAPIA.  The PFHxA restriction proposal has a huge impact to the Automobile Industry, Construction and Machinery Industry as well as many other sectors.  The transitional period of 18 months is too short to give a chance to the Chemical Industry to develop new technologies comparable to the existing fluoropolymers. A certain period of evaluation time is needed even if the Chemical Industry succeeds to develop new technologies in this case. A minimum of 10 to 15 years is required.  In order to restrict PFHxA and fluorchemicals substances, alternative substances should be safe and environmentally-friendly. Therefore, the restrictions should compare between PFHxA and fluorchemicals substances and the environmental impact of alternative substances, and also should take into consideration for the usage stage of vehicles, not only for alternative substances and production of materials.  The threshold value of the current PFHxA restriction proposal for automobile is too low. It should be 1000ppm for the fluoropolymers in a similar manner to SVHC (Substance of Very High Concern) substances. Exempted materials should provide a wide range for continuing the production of PFHxA and fluorchemicals in automobile parts that are needed for the Automobile Industry such as high-performance fluoroplastics and it also should water and oil repellents as well as fluoroelastomers and greases in the very least. Additionally, the exemption also needs to be extended to articles manufactured with the above materials.  2. PFHxA used in automobile parts  Fluoropolymers, which include both fluoroelastomers and fluoroplastics, are widely used in automotive parts because they have excellent heat resistance and electrical properties, as well as non-adhesive and non-abrasive properties. In addition, the Fluoropolymers make a great contribution to improving combustion efficiency and automobile safety.  The main applications of fluoropolymers used in automotive parts can be found in about 78 products such as Drive unit, Hose, O-ring, Oil seal, Gasket, O2 sensor, Power cable, Break pad, Seat, Pinwheel, Bonnet and Acoustic absorbent material among others. Please see the attached “Parts list using PFHxA by JAPIA2”.  3. Purpose of PFHxA used in automobile parts  The main materials and its purpose of use of PFHxA in automobile parts are as follows; Fluoroelastomers used in parts that require heat resistance and chemical resistance, low permeability and fuel/oil resistance, Fluoroplastics used in parts that require heat resistance and chemical resistance, Greases used in parts that require heat resistance and combustion prevention  at contact point, and Water and oil repellents Used in parts that require abrasion resistance and chemical resistance.  4. Total amount of production volume and use of PFHxA  Please see the attached "Japan Auto Parts Industries Association (JAPIA) Response to ECHA Public Consultation".  5. Reference  Please see the attached "Japan Auto Parts Industries Association (JAPIA) Response to ECHA Public Consultation". |
| **Dossier submitter response:**  See response to comment 2988 from Daikin Industries, Ltd.  DS proposes a derogation for the use of fluoroelastomers in automotive parts. DS proposes a broad derogation for fluoropolymers for this restriction proposal now but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional available information, these proposals might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration limits for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. With regard to the issues raised in comment 2988, please see our responses there. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal.  Please also see our reply to comment 2988. |
| **3060** | **Date:** 2020/07/17 10:20  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Japan  **Company name confidential:** Yes | **Comment:**  I would like to know the definition of LATEX ink.  Reason: LATEX ink is exempt from regulation  I can not understand the reason why water-based ink is not excluded |
| **Answer to specific info request 1:**  Aqueous ink containing PFHxA is used for textile printing |
| **Dossier submitter response:**  (see also DS response to previous comment (comment 3058))  DS has information that for latex printing inks no alternative is available at the moment but in the process of development. Therefore, a temporary derogation was proposed. For water-based inks no derogation is justified as alternatives are available. |
| **RAC Rapporteurs comments:**  Please see the reply provided by the Dossier Submitter. RAC has no further comments. |
| **SEAC Rapporteurs comments:**  We agree to the reply by the Dossier Submitter. Please see also our reply to Comment 3058. |
| **3061** | **Date:** 2020/07/17 10:29  **Content:**  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  Some applications can just run with this products because their mutual technical, electrical properties + its chemical resistance is unique in this combination.  This Polymers are very stable that allows us to reprocess this product in a very often without loosing its properties. |
| **Dossier submitter response:**  Thank you for your comment. Unfortunately, the information you provide is to unspecific to grant an additional derogation on polymers. |
| **RAC Rapporteurs comments:**  The comment is not specific enough. Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your participation. Unfortunately the comment is too unspecified to perform an evaluation and support any specific derogation request. |
| **3062** | **Date:** 2020/07/17 11:06  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Description of analytical methods;  Other socio economic analysis (SEA) issues;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Electronics & Information Technology Industries Association (JEITA)  **Org. country:** Japan | **Comment:**  General comments:  -The enforcement of PFOA's POPs regulations has just begun on July 4, 2020. As one of the alternatives to PFOA, PFHxA is used at various stages of many supply chains, regulation of PFHxA immediately after the initiation of PFOA regulation has a great impact.  PFHxA should not be a candidate of REACH regulation because PFHxA matches only one of three restriction criteria of REACH regulation, and also chemical content information is not provided to its supply chains as it is not listed on the SVHC list. Moreover, the time allowance to the enforcement is shorter and the exemptions are less than PFOA despite the proposal has same thresholds to PFOA.  In addition to that PFHxA is not in the SVHC, the use amount of PFHxA is very small and the information of content to products (dispensing, mixtures, etc. ) is not currently provided to its supply chains as it is considered company’s know-how and/or confidential information. Upper suppliers has informed that they did not register CAS number in some case. Therefore analytical institutions can not perform a quantitative analysis due to the absence of standard samples and PFHxA content amount can not be known.  It is hard to believe that there will be realistic controls to the content of PFHxA which is used at various stages of many supply chains, because no PFHxA in SVHC list and no analytical method for 25ppb/1ppm threshold is established.  Threshold and Analytical method:  The propose regulation adopted the same threshold as PFOA, however there was no evidence of justification.  Also, no information is available on the official analytical method for PFHxA at 25 ppb/1 ppm.  In particular, in the case of PFHxA related substances, we are in a situation where major analytical institutions can not perform analysis to the materials due to no standard samples to identify the chemicals and quantitative value.  It is inappropriate to set the threshold value for PFHxA without establishing content analysis method, and absence of PFHxA measured content information may cause huge confusion to whole supply chain when lower stream of supply chain require the information.  Conducting risk assessment to define appropriate threshold values which match to the risk and practical analysis method is strongly requested. Further, the analysis method and the threshold values need to be assessed by Socio-Economic Assessment.  Where no alternative is available:  Although it is recognized in Annex XV that there is no alternatives for semiconductor uses, a time-limited derogation for seven years for semiconductors is set in the proposal. The Annex also mentioned quote “efforts are undertaken by industry to identify fluorine-free alternatives and to integrate them into production processes”, however since PFHxA has various uses in semiconductors industry, and there is no reason to expect a replacement in 7 years. We strongly request no-time-limited derogation for semiconductor uses as there is no alternative available as of now. As described below in “About Semiconductor”, we also strongly request for re-consideration for exemptions for semiconductor.  Regarding Semiconductor device:  There is a fundamental misunderstanding in Annex XV dossier 2.5.1.1 Semiconductors quote “Because PFHxA-related substances are only used in manufacturing and are not present in the final product, it would be reasonable to expect that parts of the production would be replaced by imported articles“.  The PFHxA containing materials remains in the final product in the following cases;  (Note : Not all cases are listed below as there are so many semiconductor applications.)  In some semiconductor products such as CMOS image sensor has three color films (Red, Green and Blue) which formed by photolithography process and remain in the products, and these films contains PFHxA as a surfactant. Some planarization film for semiconductor also contain PFHxA based surfactant and remains in the products.  Thus we strongly request exemption for semiconductor(including compound semiconductor) itself and no-time-limited derogation for the various use of semiconductor process such as process agents for the photolithography process, etching process and cleaning fluids. |
| **Answer to specific info request 1:**  There is a fundamental misunderstanding in Annex XV dossier 2.5.1.5 Semiconductors quote “Short-chain perfluorinated substances are not becoming part of the final product (the microchip)“.  The PFHxA containing materials remains in some final product of semiconductor and correctively the sentence should be “Short-chain perfluorinated substances are sometimes becoming part of the final product (the microchip)”  The PFHxA containing materials remains in the final product in the following cases;  (Note : Not all cases are listed below as there are so many semiconductor applications.)  In some semiconductor products such as CMOS image sensor has three color films (Red, Green and Blue) which formed by photolithography process and remain in the products, and these films contains PFHxA as a surfactant. Some planarization film for semiconductor also contain PFHxA based surfactant and remains in the products.  Further, semiconductor industry uses PFHxA for various purposes as be described in ‘2.5.1.5 Semiconductors', quote “The semiconductor industry uses PFASs as process agents for the photolithography process, etching process and furthermore in cleaning fluids.”  As be described in the same session, quote “Moreover, even within the semiconductor industry technologies are not consistent. Alternatives that work for one application or one company, will not necessarily work for another application or another company. Currently the semiconductor industry does not see an option to substitute the fluorine chemistry from their processes immediately.”, it means the alternative might be found for a particular application, however this doesn’t mean that the alternative applicable to other applications. All different applications need to have fine tuning and certifications for each dedicated alternatives. Thus it is difficult to foresee when replacement will complete.  Socio-economic aspects;  In the session “ANNEX XV RESTRICTION REPORT E.2.2.5. Economic and other impacts”, it’s said that “Currently the semiconductor industry does not see an option to substitute the fluorine chemistry from their processes immediately. If uses in the manufacturing of semiconductors are included in the scope of the restriction severe economic impacts are expected.”  As be quoted, despite the fact that there is no prospect of alternatives to PFHxA from material suppliers at present, if the substances are subject to the restricted substances as proposed this time and the regulation is enforced 18 months after the publication of the official gazette, Supplying components upstream in the supply chain, such as imaging sensors semiconductors, becomes difficult and has a tremendous impact on the very wide range of industries in which they are used.  This means the affected category will be camera, cell phone, automotive/transportation, security, medical, production equipment and management/control system, and it will cause huge economic impact. As automotive/transportation, medical and management/control system requires 20-years repair parts support, If this official gazette were issued without any amendment, the supply for maintenance of the products would be cut off, and it would inevitably have a serious adverse effect on traffic safety and human life. In other words, the restriction of PFHxA for semiconductor products will give a serious adverse effect on entire EU social infrastructure.  The monetary impact of this regulation on socio-economics is expected to be enormous because it covers a wide range of industrial fields and the degree of impact is uncertain, but it is difficult to estimate.  In case of semiconductor, even if an alternative is found, the following things need to be considered;  1. The alternative can not be replaced instantly because the characteristics of the alternative must be identical to the existing one, and quality/reliability test must be passed, and the technical process for obtaining the applicable safety standard certification must be taken if necessary.  2. It takes a lot of time and money to guarantee the reliability and robustness of the semiconductor product. Management processes and costs are also incurred to manage these technical processes. Such technical processes occur in each of the relevant long supply chains and such processes are not only expensive, but also takes a considerably long time.  3. The derogation period for semiconductor products which containing PFHxA must be more than 20 years due to its 20-years repair parts requirement for automotive/transportation, medical and management/control system.  Risk（Human Health or Environment）  1. All semiconductor manufacturing processes using PFHxA containing materials are performed within the closed environmental infrastructure, thus the risk of “the release is considered as very low” as be described in section ‘B.9.12.2’.  It also wrote that “The release of PFHxA, its salts and related substances from semiconductors during the service life is considered as very low.”  2. Because the semiconductor is sealed by the package, and the total content is very small, exposure to humans from packaged semiconductors is usually unthinkable even if PFHxA is contained in the final product semiconductor itself.  Therefore, it is reasonable to consider that the use of PFHxA in semiconductors has an acceptable effect on the human health and environment.  Possibility of substitution:  ‘E.2.2.5. Economic and other impact’ describes as follow;  “This substitution process takes also time and can only be done once the well-defined chemical structure, that is seen as the alternative, has been identified (hence, only after the step of an identification of a clear chemical alternative on a chemical level, real feasibility testing can be initiated). It is assumed that this process will take more than five years. If no such substitute is found to be available, R & D will have to look for alternative chemistry or processes and the time period needed for an invention cannot be estimated.“  As stated above, be quoted from ‘E.2.2.5. Economic and other impact’, in the semiconductor industry, alternative products having the same technical properties (characteristics, quality, etc.) as they are now available are not available. For this reason, a substitute for mass production is currently unavailable, and the prospect is not even clear.  In “E.2.2.5. Economic and other impact”, there is only a description of “more than 5 years” without any evidence. Despite the recognition that "the time period needed for an invention cannot be estimated," it is inappropriate to propose a limited period of seven years for semiconductors in view of the situation of the above substitutes.  In the case of PFOS, the switching period could be estimated because there was already an alternative PFOA, but there is no reason to find that this switching period is appropriate because no alternative has been found in PFHxA.  Even if semiconductors could be replaced, it would be insufficient in 5-7 years to reach every corner of the long supply chain.  Furthermore, if a semiconductor alternative is made but the performance is not exactly the same, the downstream final product manufacturer needs to start over from the design, and even if it has the same performance, it takes a long time to verify it.  For repair parts related to automobiles/transportation, medical care, manufacturing equipment, and management/control, a PFHxA-containing derogation period is required for 20 years or more.  Require additional exemption:  As PFHxA application for semiconductor industry varies widely, we strongly request that no limiting intended use and also request exemption for semiconductor(including compound semiconductor) itself and no-time-limited derogation for the various use of semiconductor process such as process agents for the photolithography process, etching process and cleaning fluids, like as the following exemptions;  COMMISSION REGULATION (EU) 2017/1000  “6. Point 2(c) shall not apply to:  (a) articles placed on the market before 4 July 2020;  (b) implantable medical devices produced in accordance with point 4(d)(i);  (c) articles coated with the photographic coatings referred to in point 4(d)(ii);  (d) semiconductors or compound semiconductors referred to in point 4(d)(iii).’ “ |
| **Answer to specific info request 7:**  Please refer the comment in ‘1:Additional uses’ in above.  In semiconductors, there are many cases where PFHxA substitute substances are not in sight because properties such as performance and quality cannot be obtained. We strongly request that the regulators consider appropriate exemption and their derogation from a socio-economic point of view, and that no deadline be set if alternatives are not clear. |
| **Answer to specific info request 8:**  Please refer the comment ‘1:Additional uses’ in above.  Semiconductor industry uses PFHxA for various purposes such as process agents for the photolithography process, etching process and furthermore in cleaning fluids, and the PFHxA containing materials remains in some final product of semiconductor.  The PFHxA containing materials remains in the final product in the following cases;  (Note : Not all cases are listed below as there are so many semiconductor applications.)  In some semiconductor products such as CMOS image sensor has three color films (Red, Green and Blue) which formed by photolithography process and remain in the products, and these films contains PFHxA as a surfactant. Some planarization film for semiconductor also contain PFHxA based surfactant and remains in the products.  In the semiconductor industry, alternative products having the same technical properties (characteristics, quality, etc.) as they are now available are not available. For this reason, a substitute for mass production is currently unavailable, and the prospect is not even clear.  Despite the fact that there is no prospect of alternatives to PFHxA from material suppliers at present, if the substances are subject to the restricted substances as proposed this time and the regulation is enforced 18 months after the publication of the official gazette, Supplying components upstream in the supply chain, such as imaging sensors semiconductors, becomes difficult and has a tremendous impact on the very wide range of industries in which they are used.  This means the affected category will be camera, cell phone, automotive/transportation, security, medical, production equipment and management/control system, and it will cause huge economic impact. As automotive/transportation, medical and management/control system requires 20-years repair parts support, If this official gazette were issued without any amendment, the supply for maintenance of the products would be cut off, and it would inevitably have a serious adverse effect on traffic safety and human life. In other words, the restriction of PFHxA for semiconductor products will give a serious adverse effect on entire EU social infrastructure. The monetary impact of this regulation on socio-economics is expected to be enormous because it covers a wide range of industrial fields and the degree of impact is uncertain, but it is difficult to estimate. |
| **Answer to specific info request 9:**  Please refer the comment ‘1:Additional uses’ in above.  In the semiconductor industry, alternative products having the same technical properties (characteristics, quality, etc.) as they are now available are not available. For this reason, a substitute for mass production is currently unavailable, and the prospect is not even clear.  In “E.2.2.5. Economic and other impact”, there is only a description of “more than 5 years” without any evidence. Despite the recognition that "the time period needed for an invention cannot be estimated," it is inappropriate to propose a limited period of seven years for semiconductors in view of the situation of the above substitutes.  Even if semiconductors could be replaced, it would be insufficient in 5-7 years to reach every corner of the long supply chain. Furthermore, if a semiconductor alternative is made but the performance is not exactly the same, the downstream final product manufacturer needs to start over from the design, and even if it has the same performance, it takes a long time to verify it.  For repair parts related to automobiles/transportation, medical care, manufacturing equipment, and management/control, a PFHxA-containing derogation period is required for 20 years or more.  If PFHxA is restricted as current proposal, supplying components upstream in the supply chain, such as imaging sensors semiconductors, becomes difficult and has a tremendous impact on the very wide range of industries in which they are used.  This means the affected category will be camera, cell phone, automotive/transportation, security, medical, production equipment and management/control system, and it will cause huge economic impact. As automotive/transportation, medical and management/control system requires 20-years repair parts support, If this official gazette were issued without any amendment, the supply for maintenance of the products would be cut off, and it would inevitably have a serious adverse effect on traffic safety and human life. In other words, the restriction of PFHxA for semiconductor products will give a serious adverse effect on entire EU social infrastructure. |
| **Answer to specific info request 10:**  Please refer the comment ‘1:Additional uses’ and ‘9: For uses where substitution is possible now, or uses where substitution is not possible now, but it is expected to become possible within a short to medium timeframe:’ in above.  In the semiconductor industry, alternative products having the same technical properties (characteristics, quality, etc.) as they are now available are not available. For this reason, a substitute for mass production is currently unavailable, and the prospect is not even clear.  Even if semiconductors could be replaced, it would be insufficient in 5-7 years to reach every corner of the long supply chain. Furthermore, if a semiconductor alternative is made but the performance is not exactly the same, the downstream final product manufacturer needs to start over from the design, and even if it has the same performance, it takes a long time to verify it. For repair parts related to automobiles/transportation, medical care, manufacturing equipment, and management/control, a PFHxA-containing derogation period is required for 20 years or more.  In case quality degradation occurs, it will give huge impact on wide range of industries which use image sensing semiconductor because they are placed in upper stream of long supply chain for various of electronic products. Namely the affected category will be camera, cell phone, automotive/transportation, security, medical, production equipment and management/control system, and it will cause huge economic impact.  As automotive and medical requires 20-year maintenance guarantee, if this official gazette were issued without any amendment, the supply for maintenance of the products would be cut off, and it would inevitably have a serious adverse effect on traffic safety and human life. In other words, the restriction of PFHxA for semiconductor products will give a serious adverse effect on entire EU social infrastructure. |
| **Answer to specific info request 12:**  Please refer the comment ‘1:Additional uses’ and ‘9: For uses where substitution is possible now, or uses where substitution is not possible now, but it is expected to become possible within a short to medium timeframe:’ in above.  Despite the fact that there is no prospect of alternatives to PFHxA from material suppliers at present, if the substances are subject to the restricted substances as proposed this time and the regulation is enforced 18 months after the publication of the official gazette, supplying components upstream in the supply chain, such as imaging sensors semiconductors, becomes difficult and has a tremendous impact on the very wide range of industries in which they are used. Namely the affected category will be camera, cell phone, automotive/transportation, security, medical, production equipment and management/control system, and it will cause huge economic impact. Furthermore as automotive and medical requires 20-year maintenance guarantee, if this official gazette were issued without any amendment, the supply for maintenance of the products would be cut off, and it would inevitably have a serious adverse effect on traffic safety and human life. In other words, the restriction of PFHxA for semiconductor products will give a serious adverse effect on entire EU social infrastructure. The monetary impact of this regulation on socio-economics is expected to be enormous because it covers a wide range of industrial fields and the degree of impact is uncertain, but it is difficult to estimate.  In case of semiconductor, even if an alternative is found, the following things need to be considered;  1. The alternative can not be replaced instantly because the characteristics of the alternative must be identical to the existing one, and quality/reliability test must be passed, and the technical process for obtaining the applicable safety standard certification must be taken if necessary.  2. It takes a lot of time and money to guarantee the reliability and robustness of the semiconductor product. Management processes and costs are also incurred to manage these technical processes. Such technical processes occur in each of the relevant long supply chains and such processes are not only expensive, but also takes a considerably long time.  3. The derogation period for semiconductor products which containing PFHxA must be more than 20 years due to its 20-years repair parts requirement for automotive/transportation, medical and management/control system. |
| **Answer to specific info request 13:**  Please refer the comment ‘1:Additional uses’ in above.  No information is available on the official analytical method for PFHxA at 25 ppb/1 ppm.  In particular, in the case of PFHxA related substances, we are in a situation where major analytical institutions can not perform analysis to the materials due to no standard samples to identify the chemicals and quantitative value.  It is inappropriate to set the threshold value for PFHxA without establishing content analysis method, and absence of PFHxA measured content information may cause huge confusion to whole supply chain when lower stream of supply chain require the information.  Conducting risk assessment to define appropriate threshold values which match to the risk and practical analysis method is strongly requested. Further, the analysis method and the threshold values need to be assessed by Socio-Economic Assessment. |
| **Dossier submitter response:**  Thank you very much for further commenting on this restriction proposal. With regard to your remarks about the missing SHVC identification of PFHxA, its salts and related substances please refer to the answer to your first comment. Furthermore, thank you for bringing to DS’s attention, that in some cases PFHxA related substances in fact do remain in the semiconductor product. This was adjusted in the background document for the restriction proposal. The new information you provided and your request for a 20 years derogation for spare parts have been considered when reconsidering the derogation proposal for semiconductors.  DS is aware on difficulties in analytical investigation of complex matrices, especially over the supply chain. However, there are reliable analytic methods already available to analyse content of PFHxA its salts and related substances. The analytical methods itself are not substantial different from analysing PFOA its salts and related substances (see last table in Annex of Background Document Part 2, Appendix E.1.(Overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental compartments as in products and articles)). DS is aware that especially extraction methods and sample processing influence the analytical results significantly. DS also sees the need of standardisation of these methods and appreciates any efforts going into that direction. |
| **RAC Rapporteurs comments:**  Thank you for your comment.  According to Article 67 of the REACH Regulation[[6]](#footnote-6), a new restriction can be introduced “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis […]”.  This proposal explains why persistence and mobility in combination with other properties, including adverse effects, justify the proposed restriction and why risks are not hypothetical based on the properties of the substance.  The risk assessment of PFHxA contained in this proposal applies the ‘case-by-case’ approach described in paragraph 0.10 of Annex I to the REACH Regulation[[7]](#footnote-7), i.e. where a standard risk assessment is not considered to be appropriate. The Background Document of the restriction proposal has provided justifications why a conventional quantitative risk assessment approach has not been applied. RAC agrees with the approach in its opinion. A REACH restriction is not limited to substances having legally set hazard properties, such as those underpinning SVHC or CLH. Other hazards and risks can be considered (e.g. for mobility), where justified.  RAC agrees with the Dossier Submitter that there is a hazard and risk from PFHxA, its salts and related substances (degrading to the terminal end-product PFHxA) warranting a minimization of emissions (see opinion). Due to the difficulties to remediate contaminated matrices such as water and soil, any effects would be very difficult to reverse. A derogation for 12 years for semiconductors has been proposed by the dossier submitter. RAC evaluated derogation requests proposed by the Dossier Submitter or raised by stakeholders in the consultation from an emissions/emission minimisation perspective. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Evaluation of proportionality and cost/benefit for restricting or derogating a used is performed by SEAC. RAC is aware of the technical challenges related to analysis of certain matrices and in particular for analysis of PFHxA-related substances, and acknowledges the lack of standardised methods (including the sample extraction process). This issue, however, applies for all so far regulated PFASs and should not hinder a restriction specifically for PFHxA. RAC supports the development of standardised protocols for analysis of PFHxA and PFHxA-related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that a prolonged transition period is necessary for semiconductors. After the consultation on the dossier, the Dossier Submitter suggested a general time-limited derogation of semiconductors for 12 years based on the information provided. SEAC notes that RAC supports this derogation as emissions are expected to be minimised by other means than a restriction. Furthermore, SEAC notes that information on restriction-related costs indicates potentially high socioeconomic impacts. Even though uncertainties remain, SEAC considers that a restriction for this use without a longer transition period is likely not proportionate at present and therefore supports a transition period of 12 years as well.  We note your claim that the transition period should be even longer than this. We consider that the available information on alternatives and possible timelines does not support such conclusion at this point. We note that the Dossier Submitter recommends the European Commission to monitor the situation after the entry into force of the restriction and we agree that this would be desirable. |
| **3063** | **Date:** 2020/07/17 13:41  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Netherlands  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Reason for confidentiality is protection of commercial interests as well as intellectual property. | **Comment:**  We have recognized that ECHA will start public consultation for the draft of undecafluorohexanoic acid (PFHxA), its salts and related substances restriction.  We emphasize the specific ink cartridges for printing to be exempted to avoid supply stop for the printers which have already been imported in the European Union.  Supplemental information will be attached as confidential. |
| **Answer to specific info request 1:**  Provided as supplementary confidential information. |
| **Answer to specific info request 7:**  Provided as supplementary confidential information. |
| **Answer to specific info request 8:**  Provided as supplementary confidential information. |
| **Dossier submitter response:**  Thank you for the confidential information on printing inks and ink cartridges.  DS notes the request for a derogation of specific ink cartridges but is not able to discuss the request without additional specific information. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants have very functional properties for various applications, including printing inks. Time-limited derogations for certain printing inks have been proposed by the dossier submitter. RAC evaluated these proposed derogations as well as derogations requests raised in the consultation by stakeholders from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree to the reply by the Dossier Submitter. |
| **3064** | **Date:** 2020/07/17 19:14  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Information on benefits;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Alliance for Telomer Chemistry Stewardship  **Org. country:** United States  **Attachment:** | **Comment:**  Please refer to our attachment. |
| **Answer to specific info request 1:**  Please refer to our attachment. |
| **Answer to specific info request 12:**  Please refer to our attachment. |
| **Dossier submitter response:**  Thank you for your comment, the DS has considered your information.  With regard to the listed requests for derogations (response to question 1):  It is unclear why for awnings in addition to water repellence (which can be achieved with fluorine-free alternatives) oil repellence is needed. DS acknowledges that dirt repellence might be beneficial for aesthetic reasons but there is a lack of data on decrease of lifetime. For some outdoor applications as well as interior textiles, also non-textile solutions might be considered. For interior textiles such as furniture also alternative designs resulting in removable and washable textile parts could result in an increase of lifetime.  In order to decide on additional derogations more information is needed than presented in section III. Other stakeholders have submitted more information on uses in section III which have been added to the background document.  Regarding your discussion of the essential use concept DS would like to clarify that the term is used in the background document but no derogation has been proposed or denied with recourse to the concept.  Regarding your request for derogations due to lack of alternatives with equivalent functional performance please note that availability of alternatives is only one of several aspects to be considered for a restriction. Secondly, alternatives with less functional performance might still be suitable for users.  Substantial toxic effects have been documented in several studies as summarized in chapter B.5. “Human health hazard assessment” of the restriction proposal report. These include endocrine effects, such as decreased levels of thyroid hormones, nasal lesions, decreased foetal body weight gain, and kidney papillary necrosis. The corresponding DNELs range from 0.03 – 1 mg/kg bw/d. As stated in chapter 2.5.2, exposure estimates are still below these levels. PFHxA has been demonstrated to accumulate in the human body leading to comparable levels as PFOS (Perez et al., 2013). In fact, PFHxA is the most prevalent PFAS in human brain, reaching higher levels than PFHxS or any other PFAS. PFHxA was also the dominant perfluorinated compound in human liver, showing a higher median concentration (68.3 ng/g) than PFOS (41.9 ng/g). High median concentrations have also been detected in the human lung (207 ng/g). Thus, with a rising environmental concentration of PFHxA serious human health impacts cannot be excluded. Without the proposed restriction on PFHxA, precursors and related substances, an increased production, environmental burden and human exposure are expected as emissions add up from past present and future. PFHxA is efficiently distributed in the environment and can be found in remote areas. Contamination is not restricted to the point of source of contamination. End of pipe solution such remediation are therefore not efficient. Drinking water and food crop can be a constant source for human exposure. Effects of PFHxA might occur with delay and are not limited to the present time, but will also be an issue for future generations as PFHxA will remain for decades to centuries. At the point of time the effects are triggered, it will be, however, very difficult to reverse the effects due to the irreversibility of the exposure. Since consequences of continued (and extended) use and both, increased human and environmental exposure will not be reversible by regulatory action later on, it is important that releases are reduced to a minimum.  Concerning the manageability of emissions and several techniques to remove PFHxA mentioned in your comment, please see chapter B 4.6. where DS discusses several techniques for the removal from the environment. Please note that despite its effectiveness, reverse osmosis is the most costly method for removal. Also disposal of the remaining concentrate, which will contain the rejected PFASs, adds to the cost of operation of these systems. For municipal wastewater treatment plants for instance as a source of PFHxA and PFHxA related substances this is hardly implementable. Please note that PFHxA and its related substances are emitted from several diffuse sources. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Our response is similar as to the response to your previous comment (3018).  According to Article 67 of the REACH Regulation[[8]](#footnote-8), a new restriction can be introduced “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis […]”.  This proposal explains why persistence and mobility in combination with other properties, including adverse effects, justify the proposed restriction and why risks are not hypothetical based on the properties of the substance.  The risk assessment of PFHxA contained in this proposal applies the ‘case-by-case’ approach described in paragraph 0.10 of Annex I to the REACH Regulation[[9]](#footnote-9), i.e. where a standard risk assessment is not considered to be appropriate. The Background Document of the restriction proposal has provided justifications why a conventional quantitative risk assessment approach has not been applied. RAC agrees with the approach in its opinion. A REACH restriction is not limited to substances having legally set hazard properties, such as those underpinning SVHC or CLH. Other hazards and risks can be considered (e.g. for mobility), where justified.  RAC agrees with the Dossier Submitter that there is a hazard and risk from PFHxA, its salts and related substances (degrading to the terminal end-product PFHxA) warranting a minimisation of emissions (see opinion). Due to the difficulties to remediate contaminated matrices such as water and soil, any effects would be very difficult to reverse. Different options than the restriction have been discussed and evaluated by the Dossier Submitter and, subsequently, by RAC. The proposed restriction has by RAC been considered the most efficient measure to minimise emissions to the environment. Your comments related to emissions have been considered by RAC. Evaluation of proportionality and cost/benefit is performed by SEAC. Regarding remediation, please see response to comment 3018. RAC is aware of the technical challenges related to analysis of certain matrices and in particular for analysis of PFHxA-related substances, and acknowledges the lack of standardised methods (including the sample extraction process). This issue applies for all so far regulated PFASs and should not hinder a restriction specifically for PFHxA, its salts and related substances. RAC supports the development of standardised protocols for analysis of PFHxA and PFHxA-related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. In addition to RAC’s response above, SEAC notes that comments provided are referring to costs of the restriction having been largely underestimated. SEAC is aware that the socioeconomic assessment in the dossier is incomplete, this being valid also for cost information. We find that this is partly due the wide scope of the restriction proposal, but we note that the Dossier Submitter has made considerable efforts to collect information. Further relevant information was submitted in the consultation and SEAC was not confined to the dossier in its evaluation. These aspects are reflected in SEAC’s opinion. |
| **3065** | **Date:** 2020/07/20 15:06  **Content:**  Hazard or exposure;  Environmental emissions;  Information on alternatives;  Information on benefits;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** AGC Chemicals Europe, Ltd.  **Org. country:** United Kingdom  **Attachment:**    <redacted>  **Privacy comment:** Confidential Business Information | **Comment:**  Please see non-confidential attachment. |
| **Answer to specific info request 1:**  Please see non-confidential and confidential attachments. |
| **Answer to specific info request 8:**  Please see non-confidential and confidential attachments. |
| **Answer to specific info request 9:**  Please see non-confidential and confidential attachments. |
| **Answer to specific info request 10:**  Please see non-confidential and confidential attachments. |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellence is essential to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. DS is aware on difficulties in analytical investigation of complex matrices. However, there are reliable analytic methods already available to analyse content of PFHxA, its salts and related substances. The analytical methods itself are not substantial different from analysing PFOA, its salts and related substances. DS refers to the last table in the Annex of BD part 2 (overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental compartments as in products and articles). DS is aware that especially extraction methods and sample processing influence the analytical results significantly. DS also sees the need of standardisation of these methods and appreciates any efforts going into that direction. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction, such as specific categories of PPEs and filtration and separation media. Derogations proposed by the Dossier Submitter or requested by stakeholders, e.g. for technical textiles, have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC.  Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. RAC is aware of the technical challenges related to analysis of certain matrices and in particular for analysis of PFHxA-related substances, and acknowledges the lack of standardised methods (including the sample extraction process). This issue applies for all so far regulated PFASs and should not hinder a restriction specifically for PFHxA, its salts and related substances. RAC supports the development of standardised protocols for analysis of PFHxA and PFHxA-related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see our reply to Comment 2999. As to PPEs, we support the derogation for some categories of PPEs proposed by the DS. The scope thereof has been revised to cover more product categories. We note that PPE specifically designed for use by the armed forces or in the maintenance of law and order are not covered by Regulation (EU) 2016/425; we agree that they should not be prevented from containing the targeted substances where necessary and we currently recommend a specific derogation for this use. We note the requests for derogation for automotive applications. We agree that there may be applications where derogating is justified, however, the information available is not sufficient to draw conclusions. Also, some of the issues seem to relate to fluoropolymers and we reckon that setting higher concentration limits for PFHxA, its salts and related substances in fluoropolymers as proposed may solve some of the related issues. We will look for more information on concentration limits of PFHxA, its salts and related substances in fluoropolymers in the consultation on the SEAC draft opinion. |
| **3066** | **Date:** 2020/07/22 12:07  **Content:**  Environmental emissions;  Description of analytical methods;  Information on alternatives;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Daikin Industries, Ltd.  **Org. country:** Japan  **Attachment:**    <redacted> | **Comment:**  Daikin Industries, Ltd. is a leading multinational air-conditioning and chemical company headquartered in Japan, and with a presence in several EU member states. Its chemicals division is specialized in the production of fluorochemicals, such as fluoropolymers, fluorotelomers, as well as fluorocarbons.  In addition, Daikin is a member of PlasticsEurope’s Fluoropolymer Group (FPG), the Performance Fluoropolymer Partnership (PFP), as well as the Alliance for Telomer Chemistry Stewardship (ATCS). Daikin supports the comments on the restriction proposal that these three organisations have submitted to this public consultation.  As expressed in our first contribution in May 2020, Daikin questions the restriction proposal’s legal and scientific validity due to deficiencies in the dossier’s risk justification. PFHxA is not PBT or vPvB. In addition, a proposal to identify PFHxA as SVHC based on equivalent level of concern to PBT/vPvB did not reach a consensus with ECHA Member State Committee and was withdrawn. Finally, alternatives and socio-economic implications are not sufficiently assessed.  Daikin welcomes the opportunity to reply to this consultation with a second individual contribution and submit further details and input on our recommended changes to the proposal to restrict PFHxA, its salts and related substances under REACH. Confidential information is contained only in the confidential version, separated from this non-confidential version.  Daikin has also identified significant gaps in the currently proposed exemptions. These gaps demonstrate that the restriction proposal lacks an appropriate assessment of the dossier’s socio-economic consequences and available alternatives. |
| **Answer to specific info request 1:**  Daikin holds serious concerns about significant gaps in the currently proposed exemptions. These gaps demonstrate that the restriction proposal lacks an appropriate assessment of the dossier’s socio-economic consequences and available alternatives.  1. Fluoropolymers  We advise to completely exclude the production, placing on the market and use of fluoroplastics and fluoroelastomers from the scope of this restriction, including mixtures and articles. However, in the case that it should nevertheless be decided to set and implement a more specific exemption with thresholds and conditions, the current scope and wording of the exemption point 11 for fluoroelastomers requires significant modifications.  1-1 Need for extension of exemption 11 to whole fluoropolymers, including fluoroplastics.  1-2 Need to include import and use of processing aid for the production of fluoroelastomers  1-3 Higher threshold needed  1-4 Need for exemption to cover articles  1-5 Wider range of industry sectors need to be covered  2. C6-side chain Fluorinated Polymers (Repellents)  Recommendations for 5 additional exemptions for textiles to protect workers properly.  2-1 Medical woven textiles  2-2 Wider exemption for PPE  - Oil/fuel – Gas station, oil&gas drilling/production site, chemical/fire fighters, kitchen, etc  - Body fluids, chemicals – Emergency service (Fire fighters, ambulance crews, police etc),  - Outdoor/extreme conditions (cold/snow/heavy rain) – Professional athletes, rescue staff  2-3 Automotive  2-4 Filtration – industrial filters against fuel, chemicals, coal, nuclear, water, automotive paint etc  2-5 Military textile – Soldiers and police uniforms etc  For more detail, please find out attachment. |
| **Answer to specific info request 2:**  This section is disclosed only on confidential basis. |
| **Answer to specific info request 3:**  This section is disclosed only on confidential basis. |
| **Answer to specific info request 8:**  Please refer our answers to Question 10. |
| **Answer to specific info request 10:**  1. Fluoropolymers  Fluoropolymers, including both fluoroelastomers and fluroplastics, are the only materials available that combine all the necessary properties and performance criteria – such as heat, chemical, oil resistance as well as low-permeability – that the downstream industries require in their applications.  Non-fluorinated materials are often referred as alternatives to PFHxA grades. However, they result in significantly lower-performing products that do not meet users’ safety and quality standards. Even fluorinated, Daikin currently has no alternative substance to manufacture fluoroelastomers which would provide a better hazard profile as well as an equivalent performance.    In the absence of viable alternatives, the current restriction proposal iteself and the proposed exemptions put international competitiveness and operations of the entire European supply and value chain at risk.  2. C6-side chain Fluorinated Polymers (Repellents)  Non-PFC is often named as alternatives of C6. However, there is no non-PFC available that offer the same properties with C6. In this section, gap of performance between C6 and non-PFC is discussed. The applications where only water repellency is needed can be substituted by non-PFC. However, where other properties i.e. oil/fuel/alcohol repellency and/or durability are needed, non-PFC cannot be alternatives to C6. In consequence, non-PFC is not sufficient to protect worker’s safety.  For more detail, please find out attachment. |
| **Answer to specific info request 13:**  As fluorochemical industry, former FluoroCouncil (now FPG with respect to European fluoropolymers) submitted each company’s methods during discussions on PFOA restriction. In addition, CEN/TS15968 (2010) and US FDA method C-010.01(Version 2019) can be used for both fluoropolymers and C6 side-chain fluorinated polymers.  Daikin would like to reiterate that there is currently no harmonised/established analytical method to measure PFOA/PFHxA impurities. In the absence of a standard analytical method, the setting of impurity level thresholds is very challenging. Moreover, lack of harmonised analytical method causes serious implementation / enforceability challenges on both industries and regulators, in case the restriction proposal is adopted in its current form.  For more detail, please find out attachment. |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellence is necessary to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, derogations should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. DS proposes a broad derogation for fluoropolymers for this restriction proposal but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional available information these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions.  During the preparation of the restriction proposal dossier your company informed the DS that 50 % of the polymers of the EU fluoroelastomer market is produced without the use of C6 polymerisation aids. There is only a very limited number of uses where the C6-fluoroelastomers are needed to meet certain EU standards. You also informed the DS about measured quantities of C6 in your products which enabled DS to propose the limit value of 150 ppm. In order to review this value DS would appreciate an explanation why a higher threshold is required now.  Another stakeholder provided information that he does not require a derogation for the production of his fluoroelastomers, i.e. he can meet the 1 000 ppb threshold.  DS is aware on difficulties in analytical investigation of complex matrices. However, there are reliable analytic methods already available to analyse content of PFHxA, its salts and related substances. The analytical methods itself are not substantial different from analysing PFOA, its salts and related substances. DS refers to the last table in the Annex of BD part 2 (overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental compartments as in products and articles). DS is aware that especially extraction methods and sample processing influence the analytical results significantly. DS also sees the need of standardisation of these methods and appreciates any efforts going into that direction. |
| **RAC Rapporteurs comments:**  Thank you for your comment.  According to Article 67 of the REACH Regulation[[10]](#footnote-10), a new restriction can be introduced “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis […]”.  This proposal explains why persistence and mobility in combination with other properties, including adverse effects, justify the proposed restriction and why risks are not hypothetical based on the properties of the substance.  The risk assessment of PFHxA contained in this proposal applies the ‘case-by-case’ approach described in paragraph 0.10 of Annex I to the REACH Regulation[[11]](#footnote-11), i.e. where a standard risk assessment is not considered to be appropriate. The Background Document of the restriction proposal has provided justifications why a conventional quantitative risk assessment approach has not been applied. RAC agrees with the approach in its opinion. A REACH restriction is not limited to substances having legally set hazard properties, such as those underpinning SVHC or CLH. Other hazards and risks can be considered (e.g. for mobility), where justified.  RAC agrees with the Dossier Submitter that there is a hazard and risk from PFHxA, its salts and related substances (degrading to the terminal end-product PFHxA) warranting a minimization of emissions. Due to the difficulties to remediate contaminated matrices such as water and soil, any effects would be very difficult to reverse. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction. Derogations proposed by the Dossier Submitter or requested by stakeholders RAC have evaluated from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC.  Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities is within the scope of the restriction. The Dossier submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. RAC is aware of the technical challenges related to analysis of certain matrices and in particular for analysis of PFHxA-related substances, and acknowledges the lack of standardised methods (including the sample extraction process). This issue applies for all so far regulated PFASs and should not hinder a restriction specifically for PFHxA, its salts and related substances. RAC supports the development of standardised protocols for analysis of PFHxA and PFHxA-related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see reply to Comment 2988.  Thank you for explaining very clearly why chemicals can repel liquids. We agree that suitable alternatives are not currently available in cases where repellence to oil, alcohol etc. is required. We also recognize that there are challenges to the work to find suitable alternatives in the future. Accordingly, we agree that derogations/ extended transition periods are required where these properties are necessary. We support the derogation for some categories of PPE proposed by the DS. The scope thereof was revised based on information received in the consultation and now covers more product categories. We note that PPE specifically designed for use by the armed forces or in the maintenance of law and order are not covered by Regulation (EU) 2016/425; we agree that they should not be prevented from containing the targeted substances where necessary and we currently recommend a specific derogation for this use. As to medical textiles, there is now a general exemption of medical devices proposed. According to our understanding, woven and non-woven medical textiles are widely covered by this exemption. Further information relating to products that this does not apply to but that are considered to require a derogation from the restriction can be submitted in the consultation on the SEAC draft opinion. |
| **3067** | **Date:** 2020/07/24 12:29  **Content:**  Baseline  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Italy  **Company name confidential:** Yes | **Comment:**  - |
| **Answer to specific info request 1:**  Amongst the broad group of PFAS, fluoropolymers such as ETFE (ethylene-tetrafluorethylene) are used for the insulation of electrical cables due to their stability and high electrical insulation properties and mechanical and thermal resistance. |
| **Answer to specific info request 10:**  At the moment we are not able to say with certainty whether there are fluorine-free substances alternatives to fluorinated polymers that guarantee the same level of quality performance for applications in our sector.  A possible restriction on the use of fluoropolymers would oblige stakeholders to radically redefine their business objectives. |
| **Dossier submitter response:**  Thank you for your comment. Detailed information is necessary for DS to be able to deal with your comment in a systematic way.  DS proposes a broad derogation for fluoropolymers for this restriction proposal but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional information available these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities is within the scope of the restriction. The Dossier submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances in fluoropolymers for different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for derogations from the restriction is done by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3068** | **Date:** 2020/07/24 16:54  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** W. L. Gore & Associates GmbH  **Org. country:** Germany  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 7:**  See attached document |
| **Answer to specific info request 10:**  See attached document |
| **Answer to specific info request 11:**  See attached document |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellence is necessary to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others, and the Dossier Submitter has therefore proposed certain uses to be derogated from the restriction, such as for specific categories of PPEs. Derogations proposed by the Dossier Submitter or requested by stakeholders, e.g. for technical textiles, were evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC.  Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities is within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see the reply to Comment 3015.  We agree that further types of PPEs compared to the original dossier need to be derogated. The scope of the derogation has been revised by the Dossier Submitter. We note that PPEs specifically designed for use by the armed forces or in the maintenance of law and order are not covered by Regulation (EU) 2016/425; we agree that they should not be prevented from containing the targeted substances where necessary and we currently recommend a specific derogation for this use.  We appreciate that oil repellence confers benefit to water repellence. However, related to the discussion on performance in a cold environment, noting that where it is very cold it is generally only limited humidity, it is not completely clear why the performance of fluorine-free alternatives is not sufficient in protection against cold.  Finally, thank you very much for the information on the current situation relating to textile recycling. The information was very interesting and helpful for SEAC’s evaluation and opinion making process. |
| **3069** | **Date:** 2020/07/27 16:24  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** DRAKA FILECA SAS, PRYSMIAN Group  **Org. country:** France | **Comment:**  DRAKA FILECA is a major cable supplier in Aerospace market worldwide. Our main business is based roughly in totality on the manufacturing of fluoropolymer insulated cables.  Aerospace application represents very harsh environment. The range of temperatures, the chemical resistance and more widely the highest resistance to any stress bring the industry to select the highest performance materials.  This policy is totally applicable to cable manufacturing. The materials used are chosen for their outstanding stability and inertia to their environment. The target is : To sustain high level of performances during the whole aircraft lifetime and not comprise in any way the safety of the aircraft and of passengers indeed.  For this reason, and for more than 50 years, all types of fluoropolymers such as : PTFE, FEP, PFA, ETFE and PVDF have been used for cable insulation for power supply and for data transmission.  Today, 100% of the wiring installed in aircraft worldwide are based on fluoropolymer insulated cables. We don’t find any alternative materials for such applications  The major standards of cables used in AEROSPACE business explicitly request the use of fluoropolymer for insulation and dielectric purpose. |
| **Answer to specific info request 1:**  Fluoropolymer materials are purchased with different configurations :  • PolyTetraFluoroEthylene (PTFE) is mainly purchased as unsintered films dedicated to be taped then transformed with temperature.  • PolyTetraFluoroEthylene (PTFE) and Fluorinated Ethylene Polypropylene (FEP) are also purchased as aqueous dispesion for topcoat applications.  • Fluorinated Ethylene Polypropylene (FEP); Ethylene Tetra Fluoro Ethylene (ETFE) ; PolyVinyliDene Fluoride (PVDF); PerFluoroAlkoxy (PFA) are purchased as thermoplastic pellets to be fused during Extrusion operation.  The global volume of such purchased fluoropolymer is around 150 tons per year for our company. |
| **Answer to specific info request 10:**  So far today, No alternative materials have demonstrated equivalent performances and properties able to cope with Aerospace requirements.  No solution exists unless degrading significantly the level of performances of the current cables with a very probable increase of risk of accident.  The restriction of the use of Fluoropolymers will have a serious impact on EU aerospace value chain, in terms of supply interruption, competitiveness, jobs, requalification costs. |
| **Dossier submitter response:**  DS proposes a broad derogation for fluoropolymers for this restriction proposal but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional information available these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions.  PTFE, FEP, PFA, ETFE and PVDF are not targeted in this restriction proposal. The interlink between the use of e.g. ETFE and PFHxA, its salts and related substances is not fully clear for the DS. The DS assumes that PFHxA, its salts or related substances may occur as residue in the ETFE-fluoropolymer, but more information on this issue would have been needed. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities is within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3070** | **Date:** 2020/07/28 17:00  **Content:**  Scope or restriction option analysis;  Environmental emissions;  Description of analytical methods;  Information on alternatives;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** EDANA  **Org. country:** Belgium | **Comment:**  With this document, EDANA would like to contribute to this public consultation on the REACH restriction proposal to PFHxA, its salts and related substances (hereinafter collectively ‘PFHxA’ unless otherwise indicated). Independently from EDANA’s contribution, some of our members will be submitting individual comments on the public consultation, dealing with their respective circumstances.  Our members, leading companies in the nonwovens and related industries, will be seriously impacted by this restriction proposal if it is accepted as intended, as currently there are no viable alternatives to the use of PFHxA and related substances– hereinafter C6 chemistry.  Nonwovens are innovative, high-tech, engineered fabrics made from fibres used in a wide range of consumer and industrial products either in combination with other materials or alone.  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. An overview of the nonwovens that illustrate the many benefits they bring to the consumers can be found on the EDANA website (https://www.edana.org/nw-related-industry/nonwovens-in-daily-life ).  PFHxA chemical properties and applications  PFHxA shows lower toxicity than PFOA and other long-chain substances, fact admitted by the Dossier Submitter. The supply chain is trying to minimise the emission of substances from their plants with their voluntary actions. Given the lower toxicity and the voluntary emission control (in nonwoven industry at least), the balance between the loss of performance, safety, conformity with applicable standards, and the benefits to be obtained by the restriction should be considered.  C6 chemistry can provide for virtually all nonwoven substrates:  • Barrier performance throughout the entire medical sector, i.e. for surgical apparel, filters, liners, etc.  • Diesel, oil and grease repellency  • Solvent repellency  • Stain release / soil release / easy to clean properties  These chemicals can be used in:  • Medical: surgical gowns, medical drapes, packs, protective masks (face masks, FFP2 masks, FFP3 masks), sterilization wipes, ostomy bag, etc.  In hospital gowns, drapes and divider curtains, certain fluorinated polymers create a barrier that provides life-saving protection against infections and transmission of diseases in hospitals. Wall and floor paints employing fluorochemical technology allow for the aggressive use of biocides for cleaning, helping to prevent infections in hospitals and laboratories.  • Filtration: medical device filters, energy efficient HVAC filters, automotive fuel and oil filters, swimming pool filters, air-conditioning filters, etc.  C6 chemistry provides durable water and oil repellency, essential properties upon which high-performance filtration and separation media applications depend in order to provide health, safety, and energy efficiency benefits.  • Automotive: molded bonnet liners, battery separators, headliner backers, fluorotelomer-based surface protection treatments protect automobile carpets and seats against stains, soil, oil, and water.  Critical properties  These properties relate to the unique low surface tension of fluorine. Water and oil repellency provide a strong chemical barrier which is crucial to allow the superior functionality of some applications. Oil-repellency is furthermore strongly correlated with the glue-repellency property, without it the glue would penetrate inside the media with the risk of clogging the pores that will result in an increase of pressure drop properties as well as a reduced lifetime. Pressure drop means loss of pressure across a filter device in an air (or liquid) flow, due to resistance to flow, which can be caused by filter media, humidity, or contamination. Keeping pressure drop at a low level is key for the good functioning, extended lifetime of filters and maintaining low energy consumption. Additional benefits include higher dust holding capacity, prevention of microbiological growth, high mechanical strength even in highly humid or rainy environments as well as protection against corrosion and damages. These critical properties also contribute to life- and energy-saving technologies on which many industries depend.  Critical applications  Filtration and separation media treated with C6 fluorinated polymers consist primarily of nonwovens composed of manmade fibres, natural fibres (or a combination of both), with resins that contribute to the structural or physical properties of the media. Filtration and separation media manufactured with C6 fluorinated polymers play a critical role in the following applications, among others: medical devices, PPE, HVAC (including EPA/HEPA/ULPA), Air Pollution Controls (APC), dust collectors, hydraulic systems, coalescers, gas turbines, and fuel systems.  Plasma nano-coating technology used by the nonwoven media suppliers for air and liquid filtration applications adds essential functionalities to medical devices, electronic devices, and technical textiles. High oil repellence is critical for mouth masks or HVAC for hospitals and cleanrooms to achieve their protection function. In many industrial applications oil repellent nano-coatings allow to boost filter efficiency while adding the functionality to the media without affecting the pressure drop.  Currently there are no other chemicals available than PFHxA to achieve such high oil repellency (level 4 or higher according to ISO 14419).  Manufacturing process:  The manufacturing process of nonwovens typically needs only small amounts of fluorinated polymers. More information will be submitted individually by our members.  Wet-laid processing is used to produce filtration and separation media. According to this process, fibres are initially suspended in an aqueous solution (1) and then formed into a sheet on a moving screen where the water is removed (2). The web is then further dewatered and dried (3). After drying, filtration media undergo relevant mechanical and/or chemical finishing treatments (4) to be tailored or functionalised to meet specific properties. Finally, the media manufacturing ends with large rolls of product. Converters transform these large rolls into smaller rolls to be later assembled as part of a final filter article by filter manufacturers. C6 fluorinated polymers can be used at different stages of the process, e.g. during stage (1) or (4), depending on the process and performance requirements  Wastewater from the process is recovered and treated in wastewater treatment plants according to environmental legislation, for example Annex 28 Regulation in Germany. Those wastewater treatment plants can be equipped with e.g. physicochemical treatments and/ or biological treatments.  No air emission releases are expected from the drying process since fluorinated side-chain polymers are very stable chemicals and the temperature remains below degradation possibility.  Regarding solid waste from the process – e.g. media production, filter manufacturing–, it should be noted that residuals are fully captured, including the ones containing C6, and then disposed according to their corresponding waste code.  It is worth noting that C6 is well embedded in the filter matrix and, therefore, based on physical-chemical data available to the member companies it should not be expected that C6 gets airborne downstream in the value chain.  The application of the substance can be also done running a nonwoven media (e.g. a spunbonded nonwoven) through a liquid solution (foulard type) and subsequently drying the nonwoven in a thermal dryer/oven. As water evaporates, the active substance remains as a thin film on the nonwoven’s fibre/filament surfaces. Just like for the wet-laid filter manufacturing process, no emissions are expected to occur during the drying process as the temperatures applied are below degradation temperatures.  The production process of plasma nano-coating is operated in a closed chamber, similar to dry etching processes used in the semiconductor industry. Any residual process gases are captured through a scrubber, only purified exhaust gases are emitted to the environment.  The process is completely dry allowing for important reductions in CO2 emission and process chemicals used. Nano coatings are only 10-s of nm thin.  Assessment of alternatives  Any alternative should ensure following specifications must be met:  - Water repellency (Hydrostatic head, Hydrodynamic resistance);  - Oil repellency;  - Compatibility with glue / glue repellency;  - High durable filtration efficiency (against viruses, bacteria, oil, water, dust, etc.) in all types of environments.  - Resistance against microbiological contaminants.  - Performance in difficult operating conditions (high moisture content at high temperatures).  - Compatibility with other chemistries, final applications, and processes.  The key alternative fluorine-free repellents that are most widely used in the EU and which could be regarded as potential alternatives include flat modified polymers, hyperbranched functionalized polymers, paraffin, silicones, polymeric compounds.  However, these candidate alternatives show a lower level of water repellency and no oil repellency. Therefore, there are no alternatives available to provide filtration and separation media with a combination of these two essential properties. Additionally, paraffin does not provide sufficient temperature resistance. Silicones cause damage to the air fume treatment in RTO systems and are not accepted in certain applications. On top of that both paraffin and silicones have been identified as paint wetting impairment substances by the German Mechanical Engineering Industry Association (VDMA), they are also not allowed for HVAC filters. Due to their interference with paint adhesion, silicones are restricted by the automotive industry and their absence is verified in all air supply equipment through specific test methods. Silicones also may degrade to D4, D5, D6 which are listed as SVHCs, and are subject to a separate REACH restriction proposal.  Substitution to shorter side-chain fluorinated polymers (C4) could not achieve the same performance as C6 would do. The loss of performance caused by the switch from C6 to C4 is larger than the one from C8 to C6. The production cost to switch from C6 to C4 would go up and the quantity to be used in the downstream would be increased in order to try achieving the similar performance made by C6-based products. It would consequently lead to production cost of some chemical products that will increase significantly, which would naturally be carried onto the selling price and the downstream production costs (please refer to members individual contributions).  In addition, undertaking a similar transition from C6 to C4 as it was done for C8 to C6 is not a realistic option. With all PFAS being under regulatory scrutiny, C4 is not seen as a long-term potential replacement, which is what our industry and downstream users require.  Requalification process  High performance air and liquid filtration and separation are used in safety-critical applications which require requalification of equipment including third party certifications, in some cases for both producers and their customers. There are common sectoral standards which need to be met in a requalification process, some of them relate specifically to performance in terms of repellency, for filtration and separation media as well as filters. Some examples are illustrated below:  • Oil repellency – ISO14419:2010  ISO 14419:2010 is applicable to the evaluation of a substrate's resistance to absorption of a selected series of liquid hydrocarbons of different surface tensions. The standard is intended to provide a guide to oil stain resistance. It can provide a rough index of oil stain resistance as, generally, the higher the oil repellency grade, the better resistance to staining by oily materials, especially liquid oil substances.  There are no alternatives available to PFHxA to reach oil level >= 4.  • Filter efficiency and durability of filter efficiency of charged nonwoven media – ISO16890  Filter efficiency and durability of filter efficiency of charged nonwoven media – ISO16890  ISO16890 makes classification of fine air filters based upon initial and discharged efficiency for PM1, PM2.5 and PM10 particles. Measurements must be performed before and after discharging in iso-propyl-alcohol (IPA).  Linked to this standard exists an energy classification standard of filter elements: Eurovent RS4/C/001-2019.  This standard assigns an energy rating to filters based upon its filtration efficiency (ISO16890) and its dust loading characteristics over time.  • Strong antibacterial effect according to ISO 20743 §8.2 (2013)  ISO 20743:2013 specifies quantitative test methods to determine the antibacterial activity of all antibacterial textile products including nonwovens. ISO 20743:2013 is applicable to all textile products, including cloth, wadding, thread and material for clothing, bedclothes, home furnishings and miscellaneous goods, regardless of the type of antibacterial agent used (organic, inorganic, natural or man-made) or the method of application (built-in, after-treatment or grafting). Based on the intended application and on the environment in which the textile product is to be used and also on the surface properties of the textile properties, the user can select the most suitable of the following three inoculation methods on determination of antibacterial activity: a) absorption method (an evaluation method in which the test bacterial suspension is inoculated directly onto specimens); b) transfer method (an evaluation method in which test bacteria are placed on an agar plate and transferred onto specimens); c) printing method (an evaluation method in which test bacteria are placed on a filter and printed onto specimens). The colony plate count method and the ATP (ATP = Adenosine Tri-phosphate) luminescence method are also specified for measuring the enumeration of bacteria.  There are no alternatives available to PFHxA to reach antibacterial value A >= 3.  At present, there is no substance candidate that can meet all the current performance and industry requirements. Other standards relate to the overall performance or other aspects of media / filters. They nonetheless belong to the requalification process, contributing to the complexity and costs of this process.  Socio-economic impact  The absence of derogation for these applications will put at risk manufacturing facilities located in the EU. It would furthermore result in a supply interruption of filtration and separation media within the current technical specifications until adequate alternative candidates are identified and completion of subsequent requalification. It must be noted that more than 80% of applications that require requalification have a link to other industrial activities – e.g. medical, pharmaceutical, food and nutrition, protective equipment electronics, energy, chemistry.  In terms of timeline, there is no certainty at this stage on when suitable alternatives will be found despite R&D work being conducted for years now. The sector just completed its transition from C8 to C6 which already took 5 to 10 years depending on applications and represented a heavy economic burden on the industry – in terms of tens of millions of euros (please refer to members individual contributions). As mentioned above, transitioning to non-fluorinated chemistry will take even more time, be significantly costlier and can only start once a good candidate has been identified by producers. The duration of the requalification by customers (customer internal testing/ field testing) might also take longer depending on the sector, the value chain, and the intended applications. There are sectoral standards that need to be met in a requalification process, certain of them relate specifically to performance in terms of a critical property (e.g. repellency for filtration and separation media as well as filters) for which at present, there is no candidate that can meet all the current performance and industry requirements. Other standards relate to the overall performance or other performance requirement per application. They all belong to the requalification process, contributing to the complexity and costs of this process.  Analytical method  The few analytical methods provided by the Dossier Submitter do not cover the array of products falling under the scope of the restriction proposal. Additionally, in case the restriction proposal is adopted in its current form, the absence of a standard analytical method would pose serious implementation and enforceability challenges to both industry and regulators.  Conclusion:  We are confident that the above facts clarify that the absence of a derogation would be disproportionately costly. It also represents significant risks in terms of safe operations of applications relying on high performance filtration and separation media.  We therefore suggest that Table 5 (page 37) in the Annex XV dossier, paragraph 9 (c) be amended for clarity as follows:  (c) non-woven medical textiles, “which are critical to health of workers in the medical field, patients and general public, including but not limited to surgical gowns, medical drapes, packs, protective masks (face masks, FFP2 masks, FFP3 masks), sterilization wipes.”  We also suggest that the following uses be considered for a derogation:  - Filtration: Filtration for industrial application, including but not limited to, medical device filters, energy efficient HVAC filters, coalescer, automotive fuel and oil filters, swimming pool filters, air-conditioning filters.  - Automotive applications which are critical to functionality and safe operation of automobiles, including but not limited to, molded bonnet liners, battery separators and headliner backers.  About EDANA  EDANA helps its members to design their future, serving more than 275 companies in the nonwovens and related industries, across over 40 countries. Its mission is to create the foundation for sustainable growth of the nonwovens and related industries through active promotion, education, and dialogue. |
| **Answer to specific info request 2:**  please refer to section III above |
| **Answer to specific info request 6:**  please refer to section III above |
| **Answer to specific info request 7:**  please refer to section III above |
| **Answer to specific info request 8:**  please refer to section III above |
| **Answer to specific info request 9:**  please refer to section III above |
| **Answer to specific info request 10:**  please refer to section III above |
| **Answer to specific info request 11:**  please refer to section III above |
| **Answer to specific info request 12:**  please refer to section III above |
| **Answer to specific info request 13:**  please refer to section III above |
| **Dossier submitter response:**  Thank you for your response. DS agrees, that when oil and dirt repellence is necessary to ensure safety for professionals, including protection from potentially infectious body fluids such as blood, exceptions should be granted. The DS proposes in the background document to include into the restriction a derogation for personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h), (l); and high visibility clothing fulfilling the requirements of EN ISO 20471 Class 3. Further the DS proposes to derogate medical textiles when used as a medical device as specified in Regulation 2017/745 of the European Parliament and of the Council. It is to be noted that also import of C6 treated articles will be covered by the proposed restriction.  DS is aware on difficulties in analytical investigation of complex matrices. However, there are reliable analytic methods already available to analyse content of PFHxA, its salts and related substances. The analytical methods itself are not substantial different from analysing PFOA, its salts and related substances. DS refers to the last table in the Annex of BD part 2 (overview of methods for extracting and analysing PFHxA, its salts and related substances as well in environmental compartments as in products and articles). DS is aware that especially extraction methods and sample processing influence the analytical results significantly. DS also sees the need of standardisation of these methods and appreciates any efforts going into that direction. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil, grease, blood and liquid chemicals. For certain uses alternatives appear to be available, but not for others. The Dossier Submitter has proposed certain uses to be derogated from the restriction such as specific categories of PPEs and filtration and separation media. Derogations proposed by the Dossier Submitter or requested by stakeholders, e.g. for technical textiles, have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC.  RAC is aware of the technical challenges related to analysis of certain matrices and in particular for analysis of PFHxA-related substances, and acknowledges the lack of standardised methods (including the sample extraction process). This issue applies for all so far regulated PFASs and should not hinder a restriction specifically for PFHxA, its salts and related substances. RAC supports the development of standardised protocols for analysis of PFHxA and PFHxA-related substances. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The Dossier Submitter has proposed derogation of filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellence. Considering all information received in the consultation on the dossier, we support this derogation. In case the formulation of the derogation text is considered not appropriate, more information on the use, related costs and alternatives could be sent in the consultation on the SEAC draft opinion.  As to medical textiles, there is now a general derogation of medical devices proposed. According to our understanding, woven and non-woven medical textiles are widely covered by this derogation. Further information relating to products that this does not apply to but that are considered to require a derogation from the restriction can be submitted in the consultation on the SEAC draft opinion.  We note the derogation requests relating to the automotive sector and we note that the Dossier Submitter has proposed to derogate textiles for the use in engine bays in automotive and aerospace industry. However, we consider that the information received in the consultation on the dossier is not sufficient to allow a conclusion on whether and what kind of derogation would be justified. We are looking for more information on the availability of alternatives and the related societal costs from the consultation on the SEAC draft opinion. |
| **3071** | **Date:** 2020/07/29 12:50  **Content:**  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Italy  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comment:**  We are buing ETFE product since 20 years from AGC CHEMICALS. The properties of ETFE such us high temperature resistance, high chemical and corrosion resistance, UV resistance, lightweight nature, high mechanical strenght, electrical and high-rediation reistance poprerties mean that these materials can not be reflected by an other product. The performance of others material will be not sufficient. (Please see AGC CHEMICAL comments about ETFE already submitted to this consultation). |
| **Answer to specific info request 2:**  We have installed a fume extractor on the extrusion line to remove the hydrofluoric acid which is added during the processing of ETFE. |
| **Answer to specific info request 7:**  Not I'm not aware of any fluorine-free substances. |
| **Dossier submitter response:**  Thank you for your comment. Detailed information is necessary for DS to be able to deal with your comment in a systematic way.  DS proposes a broad derogation for fluoropolymers for this restriction proposal but would like to remind you that in future restriction proposals for PFAS the issue of fluoropolymers will come up again. With additional available information these might come to different conclusions on certain fluoropolymers or certain uses and with regard to the negligibility of emissions. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers are outside the scope of the restriction. However, residual levels of PFHxA, its salts and related substances as impurities are within the scope of the restriction. The Dossier Submitter has proposed higher concentration thresholds for PFHxA, its salts and related substances for fluoropolymers in different uses, which have been evaluated by RAC from an emissions/emission minimisation perspective. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. After the consultation on the dossier, the Dossier Submitter suggested specific higher concentration limits for PFHxA, its salts and related substances present in fluoropolymers. Considering the wide dependence of businesses in many industry sectors on high-performance fluoropolymers, and the magnitude of the expected impacts on the economy in case they were suddenly not available, we find that higher concentration limits are warranted. However, we do not currently have enough information to evaluate the most suitable level of those specific limit values and we will need more information from the consultation on the SEAC draft opinion before we can confirm our proposal. |
| **3072** | **Date:** 2020/07/30 20:42  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The attachment contains sensitive company information. | **Comment:**  - |
| **Answer to specific info request 1:**  Please refer to the attachment. |
| **Answer to specific info request 8:**  Please refer to the attachment. |
| **Answer to specific info request 10:**  Please refer to the attachment. |
| **Answer to specific info request 11:**  Please refer to the attachment. |
| **Answer to specific info request 12:**  Please refer to the attachment. |
| **Dossier submitter response:**  DS appreciates your comment regarding the use of PFHxA related substances, including fluoropolymers and fluorinated side-chain polymers in filter and membrane technologies. DS was not aware of this use in detail so far but received additional information from several stakeholders during this consultation. DS also sees the need for effective and reliable filter systems in a wide range of applications touching nearly every market sector in the global economy. DS is also aware that many of today’s technologies cannot function without high quality filtration. Therefore, DS proposes a possible derogation for industrial applications on the basis of your comment in the background document.  The DS notes that some stakeholders suggested derogations only for specific use categories and not filter and membrane technology in general. However, the DS does not fully understand the consequences of different proposals to derogate ‘all industrial uses’ or ‘high-performance applications” for example. DS would have appreciated more information on enforceability, for example if standards are available to identify uses that are ‘industrial’ or ‘high-performance’. |
| **RAC Rapporteurs comments:**  Thank you for your comment. The Dossier Submitter has proposed the use described in your comment to be derogated from the restriction. Derogation requests proposed by the Dossier Submitter or requested by stakeholders have been evaluated by RAC from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The Dossier Submitter has proposed a derogation for the use mentioned in your comment. Considering all information received in the consultation on the dossier, we currently consider supporting this derogation. Considering the confidential status of your submission we refrain from a more specific reply in order not to reveal the content. |
| **3073** | **Date:** 2020/07/31 13:09  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Japan  **Country:**  Japan  **Company name confidential:** Yes  **Attachment:**  **Privacy comment:** a reason could be that the protection of our commercial interests, including intellectual property, would be undermined | **Comment:**  Please see the confidential attachment |
| **Answer to specific info request 6:**  Please see the confidential attachment |
| **Answer to specific info request 8:**  Please see the confidential attachment |
| **Dossier submitter response:**  No confidential attachment was submitted, but a further comment was submitted by this organisation (see comment 3080). |
| **RAC Rapporteurs comments:**  Thank you for your comment. Please see our response to comment 3080 containing the attachment. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Please see our response to comment 3080. |
| **3074** | **Date:** 2020/07/31 15:11  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** LYDALL PERFORMANCE MATERIALS SAS  **Org. country:** France  **Attachment:**  <redacted>  **Privacy comment:** The attachment includes sensitive company information | **Comment:**  - |
| **Answer to specific info request 1:**  Please refer to the attachment |
| **Answer to specific info request 8:**  Please refer to the attachment |
| **Dossier submitter response:**  DS appreciates your comment regarding the use of PFHxA related substances, including fluoropolymers and fluorinated side-chain polymers in filter and membrane technologies. DS was not aware of this use in detail so far but received additional information from several stakeholders during this consultation. DS also sees the need for effective and reliable filter systems in a wide range of applications touching nearly every market sector in the global economy. DS is also aware that many of today’s technologies cannot function without high quality filtration. Therefore, DS proposes a derogation for industrial applications on the basis of your comment in the background document.  The DS notes that some stakeholders suggested derogations only for specific use categories and not filter and membrane technology in general. However, the DS does not fully understand the consequences of different proposals to derogate ‘all industrial uses’ or ‘high-performance applications” for example. DS would have appreciated more information on enforceability, for example if standards are available to identify uses that are ‘industrial’ or ‘high-performance’. |
| **RAC Rapporteurs comments:**  Thank you for your comment. The Dossier Submitter has proposed the use described in your confidential comment to be derogated from the restriction. RAC evaluated derogation requests proposed by the Dossier Submitter from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The Dossier Submitter has proposed a derogation for the use described in your confidential comment. Considering all information received in the consultation on the dossier we currently consider supporting the derogation. Considering the confidential status of your submission we refrain from a more specific reply in order not to reveal the content. |
| **3075** | **Date:** 2020/07/31 17:13  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Ahlstrom-Munksjö  **Org. country:** Finland  **Attachment:**  <redacted>  **Privacy comment:** The attachment contains sensitive company information | **Comment:**  - |
| **Answer to specific info request 1:**  Please refer to the attachment |
| **Answer to specific info request 8:**  Please refer to the attachment |
| **Dossier submitter response:**  DS appreciates your comment regarding the use of PFHxA related substances, including fluoropolymers and fluorinated side-chain polymers in filter and membrane technologies. DS was not aware of this use in detail so far but received additional information from several stakeholders during this consultation. DS also sees the need for effective and reliable filter systems in a wide range of applications touching nearly every market sector in the global economy. DS is also aware that many of today’s technologies cannot function without high quality filtration. Therefore, DS proposes a derogation for industrial applications on the basis of your comment in the background document.  The DS notes that some stakeholders suggested derogations only for specific use categories and not filter and membrane technology in general. However, the DS does not fully understand the consequences of different proposals to derogate ‘all industrial uses’ or ‘high-performance applications” for example. DS would have appreciated more information on enforceability, for example if standards are available to identify uses that are ‘industrial’ or ‘high-performance’. |
| **RAC Rapporteurs comments:**  Thank you for your comment. The Dossier Submitter has proposed the use described in your confidential comment to be derogated from the restriction. RAC has evaluated derogation requests proposed by the Dossier Submitter from an emissions/emission minimisation perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The Dossier Submitter has proposed a derogation for the use described in your confidential comment. Considering all information received in the consultation on the dossier we currently consider to supporting the derogation. Considering the confidential status of your submission we refrain from a more specific reply in order not to reveal the content. |
| **3076** | **Date:** 2020/08/04 11:39  **Content:**  Scope or restriction option analysis;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes | **Comment:**  Restriction option for consumer goods treated with PFHxA:  - People have been spoiled in the last decades with super performing materials at low prices, whether this performance is needed is not questioned and without this performance you simply make no sales. Unfortunately, performance and ‘eco-friendly-ness’ are still contradictory.  - People should be forced to consider if the performance is really needed and be aware of the impact of their demands. In this case easy-clean, soil or water repellency.  - This can be done via a compulsory label or tax. This tax should then be used for R&D towards suitable alternatives which in the case of C6 fluoro-chemistry do not exist yet.  Request for exemption:  1/ Printed wallcoverings with extra washable, scrubbable or extra scrubbable performance  2/ Textile wallcoverings  - In printed wallcoverings, fluorocarbons are used to prevent staining during installation (glue) and to prevent dust to agglomerate (particularly on textile wallcoverings). Dust has a proven impact on house dust mite allergies.  - For high-trafic areas, (Contract) Market demands on washable, cleanable and rub-fast wallcoverings are high and can only be met with the use of PVC if FC will be banned. It is questionable that PVC is a more eco-friendly and safer product than traces of PFHxA. Also in domestic use and in hospitals, the demand on cleanable wallcoverings in hygiene areas (kitchen, bathroom, sanitary, ...) is rising.  - Since COVID-19, the request for surface sterilization or disinfection in public, crowed or sanitary places has boomed. The latest health crisis has also demonstrated the need for disinfection of solid surfaces in both public and private areas. The only wallcovering that is resistant to such chemicals will have FC chemistry incorporated or is based on PVC. It is questionable that PVC is a more eco-friendly and safer product than traces of PFHxA. |
| **Answer to specific info request 7:**  Several reseach projects have demonstrated that both water, soil and oil repelency cannot be achieved other than with FC chemistry. Some alternatives are emerging, but are not available in quantities for industrial production or are simply too expensive. (Duratex, Centexbel) |
| **Answer to specific info request 8:**  Situations where both oil and water repelency is required.  If banned, textile wallcoverings will not be marketable, all efforts to provide alternatives to pvc wallcoverings with scrubbable and stain repelent properties will have been in vain. |
| **Answer to specific info request 11:**  We are aware, but short chain FC (<6:2) are not performing enough |
| **Dossier submitter response:**  Thank you for your comment. The benefits are described very generically making it impossible for the Dossier Submitter to justify a derogation.  DS notes that ‘printed wallcoverings’ are high-end articles. The DS therefore considers other wallcoverings manufactured for that market segment as suitable and affordable alternative. For high-traffic areas there are non-textile solutions for wall coverings. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are effective for repellence of e.g. water, oil and grease. For certain uses alternatives appear to be available. Derogations proposed by the Dossier Submitter, or requested by stakeholders in the Consultation and sufficiently substantiated with information on emissions and risk management measures, have been evaluated by RAC from an emission minimisation perspective only. Evaluation of proportionality and cost/benefit for restricting or derogating a use is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We note RAC’s conclusion that a large part of emissions of PFHxA-related substances originate from the textile sector and we consider that in view of the effectiveness of the restriction, evidence on substantial negative socio-economic impacts is needed to support any further derogations. Information on the expected costs, emissions and availability of alternatives (such as information on the necessary properties of C6 chemicals not found in fluorine-free alternatives, and on the type and wideness of the search made to find suitable alternatives) would be necessary to evaluate whether a derogation is necessary and justified. Such information could be submitted in the consultation on the SEAC draft opinion. |

1. https://www.solbergfoam.com/Foam-Concentrates/RE-HEALING-Foam.aspx [↑](#footnote-ref-1)
2. https://ipen.org/sites/default/files/documents/IPEN\_F3\_Position\_Paper\_POPRC-14\_12September2018d.pdf [↑](#footnote-ref-2)
3. https://ipen.org/sites/default/files/documents/the\_global\_pfas\_problem-v1\_5\_final\_18\_april.pdf [↑](#footnote-ref-3)
4. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [↑](#footnote-ref-4)
5. Paragraph 0.10 of Annex I to REACH: “In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.” [↑](#footnote-ref-5)
6. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [↑](#footnote-ref-6)
7. Paragraph 0.10 of Annex I to REACH: “In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.” [↑](#footnote-ref-7)
8. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [↑](#footnote-ref-8)
9. Paragraph 0.10 of Annex I to REACH: “In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.” [↑](#footnote-ref-9)
10. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [↑](#footnote-ref-10)
11. Paragraph 0.10 of Annex I to REACH: “In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.” [↑](#footnote-ref-11)