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| **3124** | **Date:** 2020/09/25 11:14  **Content:**  Information on alternatives  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  **-** |
| **Answer to specific info request 1:**  treatment of nonwoven for the automotive industry, for engine compartment, wheelhouses,.. |
| **Answer to specific info request 7:**  yes we know fluorine free alternatives for hydrophobic treatment. |
| **Answer to specific info request 8:**  we know alternatives for hydrophobic treatment, but not for oleophobic. |
| **Answer to specific info request 9:**  At the moment we have no alternative for oleophobic treatment, we will loose this business completely, if the automotive industry keeps their requirements. we do not have any investments so far, but at the moment we have no solution or Idea how to solve that problem.  If the transitional period will be shorter, we will loose this business earlier. |
| **Answer to specific info request 10:**  the big difference is the oleophobic behavior. the hydrophic behavour is acceptable, for any application with no contact with oily substances. Additional we have in the engine compartment a temperature stability up to 150°C which we only full fill with fluorine carbon treated material. |
| **Dossier submitter response:**  Thank you for your comment. The DS discussed derogations for textiles in the automotive industry in the background document. Please note that DS proposes a derogation for textiles used in the engine bay. Other textile uses were not proposed to be derogated as only water-repellent properties are required that can be provided by non-fluorinated alternatives. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-fluorosurfactants are very effective for repellence of e.g. water, oil and grease. For certain uses alternatives appear to be available, but not for others. Derogation requests proposed by the Dossier Submitter or requested by stakeholders in the consultation, such as for technical textiles, have been evaluated by RAC from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that where oil repellence is required, based on the available information, suitable alternatives are not yet available. However, it is not clear that oil repellence is actually necessary for all related applications. We note RAC’s conclusion that a very 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. We agree that some derogations may be necessary (such as uses related to the engine room), but we will need more information to be able to propose a suitable scope and wording of a derogation. Information on the expected costs, emissions and availability of alternatives related to different sub-uses could be submitted in the consultation on the SEAC draft opinion. |
| **3125** | **Date:** 2020/09/25 09:12  **Content:**  Environmental emissions  Information on benefits  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Mitsubishi Gas Chemical Company, Inc.  **Org. country:** Japan | **Comment:**  Mitsubishi Gas Chemical Company, Inc. is a leading multi-national chemical company headquartered in Japan, and with presence in several EU countries.  One of its hero products for the food protection market is an oxygen absorber. Ageless®, an iron based oxygen absorber, has been widely used in the food packaging industry. It absorbs oxygen in a sealed container. By creating an oxygen-free environment, it prevents the oxidation of fatty acids and degradation of other food ingredients, thus extending the shelf-life of the packed food and keeping its freshness. Furthermore, our oxygen scavenging technologies also contribute to other industries outside the food protection. Ageless® is also used in order to extend the shelf-life of packed pharmaceuticals and medical devices. It absorbs oxygen to prevent degradation of pharmaceutical ingredients and of the composition of medical devices.  The innovative Oxygen Absorber technologies contain a PFHxA-coated paper layer as part of the laminated sachet structures that establish water repellency, air permeability, and allow only a very low level of oxygen to permeate into the inside of these sachets. The sachets act as packaging for several critical pharmaceutical and medical device products e.g. dialyzers, IV solutions, or prefilled syringes. An additional important function of the PFHxA-coating is to achieve a sufficient seal and delamination strength for the sachet packaging, so that it can’t disintegrate and break apart in use.  The Oxygen Absorber technologies add essential functionalities and fulfil pivotal roles in the mentioned areas of application. For food protection, they extend the shelf-life of the packaged food without the need for food preservation additives. For dialyzers, they prevent decomposition of resins during sterilization e.g. under gamma radiation. For IV solutions, they prevent discoloration and oxidation during retort sterilization, thus extending the shelf-life of the packaged IV solutions without additives.  Current C6 chemistry enables MGC to offer a wide range of highly functionalized paper sachet packaging solutions for food protection, pharmaceutical and medical device products. MGC are aware of potential alternatives, but they have not been explored in detail yet. Beyond, MGC believes that any alternatives to current PFHxA uses for Oxygen Absorbers will surely deteriorate current product performance standards.  If the proposed restriction of PFHxA substances is considered as ‘appropriate’, MGC would like to challenge the suitability of the restriction for articles, in particular the threshold value of 25ppb. Under normal use conditions, substances contained in articles have a significantly lower risk of being released, or of being exposed to the human body or the environment, unlike substances on their own or mixtures. Moreover, PFHxA is not used in large amounts in articles, which also limits the exposure.  If the proposed PFHxA restriction gets adopted without the suggested changes, MGC request significantly longer transition periods than the foreseen 18 months in order to develop technically comparable substitutes. Industrial chemical products for which alternatives currently already exist, are generally expected to need a transition period of at least 4 years for substitution in articles (even in the case of threshold values of the order of 1,000 ppm), and hence a much longer transition period is required for product groups with longer product life and design cycle such as adjacent products for pharmaceutical products and medical devices. |
| **Answer to specific info request 6:**  At least more than 30 million Oxygen Absorber packs are directly imported into the EU per year for use in pharmaceutical and medical device packaging, translating into the usage of >30 kg PFHxA per year. Furthermore, probably the same amount of Oxygen Absorber packs are indirectly imported into the EU every year through pharmaceutical and medical device products already equipped with Oxygen Absorber packs. |
| **Answer to specific info request 8:**  Theoretically available alternatives for the use of PFHxA in the mentioned Oxygen Absorber technologies (e.g. silicones, hydrocarbons) have not been assessed in detail, so it is premature to conclude whether substitution may be regarded as impossible. What can however be stated is that potential alternatives will very likely lead to inferior product performance of the functional paper packaging technologies. |
| **Answer to specific info request 10:**  While substitution may not be impossible, MGC holds the view that industry needs to be given sufficient time in order to identify and fully develop suitable alternatives to C6 chemistry. Alternative chemistries (e.g. silicones, hydrocarbons) would highly likely affect the performance of MGC’s coating solutions, so that customer expectations and specifications are at risk of still being met without access to PFHxA-based coatings. |
| **Dossier submitter response:**  Thank you for your comment. DS is not able to determine whether a derogation is justified based on the information submitted. You mention that your product has been widely used in the food packaging industry but only numbers for the use in pharmaceutical and medical device packaging are provided. The Dossier Submitter suspects that there are many types of oxygen absorbers available. In absence of more information, e.g. on the availability of non-fluorinated alternatives, how they compare to your product and how different products (fluorinated and non-fluorinated) differ in the protection of different products, the DS did not propose a derogation for this use. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain applications they are difficult or not possible to replace with retained function. Derogation requests, proposed by the Dossier Submitter or requested by stakeholders in the consultation (if associated with sufficient information on emissions and risk management measures), have been evaluated by RAC from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment and information provided on your specific product. Whilst SEAC acknowledges the advantageous properties of PFASs for many applications covered by the restriction, robust socioeconomic information is needed in order to evaluate and conclude on any derogation request. SEAC agrees to the Dossier submitter’s and RAC’s response above that more concrete information on your product would be needed and why PFAS are crucial respectively (e.g. information could be provided on potential alternatives and why these do not yet perform sufficiently well, costs of a restriction and any related impacts (e.g. reduced service life of articles and why that is seen problematic, any safety aspects, as applicable), time for transition to fluorine-free alternatives, etc.) in order for SEAC to consider a prolonged transition period/derogation. As to the general transition period of 18 months, SEAC agrees that this timeframe may be too short, and is currently considering proposing that it be extended to 36 months in order to give time for a balanced transition to alternatives in all sectors. |
| **3126** | **Date:** 2020/09/25 02:40  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** <redacted>  **Org. country:** South Korea  **Company name confidential:** Yes | **Comment:**  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 “About Semiconductor” we also strongly request for re consideration exemptions for semiconductor |
| **Answer to specific info request 1:**  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, and it will  cause huge economic impact. As automotive/transportation, medical 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.  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. |
| **Answer to specific info request 7:**  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:**  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.  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 p g , pp y g p p pp y 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, 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 9:**  Currently, 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.  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 category will be camera the affected camera, cell phone, automotive/transportation, security, medical, 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.  For repair parts related to automobiles/transportation, medical care, a PFHxA‐containing derogation period is  required for 20 years or more  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. |
| **Answer to specific info request 10:**  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, a PFHxAcontaining  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, 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. |
| **Answer to specific info request 12:**  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, 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.  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. |
| **Answer to specific info request 13:**  No information is available on the official analytical method for PFHxA at 25 ppb/1 ppm.  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. |
| **Dossier submitter response:**  Thank you very much for taking the time to prepare this extensive comment to this restriction proposal. DS agrees that no drop-in alternatives for all applications of PFHxA related substances in semiconductor manufacturing are available. DS considered the information you provided when reconsidering the proposed derogation for PFHxA and related substances in semiconductors and proposes a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years.  Regarding the 20-year maintenance guarantee the Dossier Submitter suspects that implications for medical devices and automotive/transportation are not comparable. While DS agrees that costs for re-approval would be potentially very high in the medical sector DS doubts the same applies to automotive/transport. More detailed information on the costs of recertification of repair parts in the sector would be needed to assess this aspect. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Proportionality and cost/benefit for derogating uses from the restriction are evaluated 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 participation! Please see reply to Comment 3062. |
| **3127** | **Date:** 2020/09/24 18:41  **Content:**  Scope or restriction option analysis  Information on alternatives  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Fire Rescue Service of the Czech Republic  **Org. country:** Czech Republic  **Attachment:**    <redacted> | **Comment:**  The Fire Rescue Service of the Czech Republic (FRS CR) appreciates the opportunity to provide input to the European Chemical Agency on the Annex XV Restriction Report on Undecafluorohexanoic acid (PFHxA), its salts and related substances. Information are provided in two attached documents: Comment on Restriction Proposal, and Confidential Attachment to the Comment. |
| **Answer to specific info request 5:**  As opposed to restriction of PFOA, its salts and related compounds, the proposed restriction of PFHxA, its salts and related compounds, would lead to a restriction of all fluorinated fire-fighting foams, i.e., AFFF and AFFF/AR. That is because the currently available “C6-based” fluorinated foams are based on PFHxA. We are not aware of any fluorinated foam based on shorter fluorinated chain than C6.  For other information about a stockpile, transition to fluorine free foams, and other related issues see attached documents. |
| **Answer to specific info request 7:**  See attached documents. |
| **Answer to specific info request 9:**  See attached documents. |
| **Answer to specific info request 10:**  See attached documents. |
| **Answer to specific info request 13:**  Analysis of Fluorinated Compounds in Foam Concentrates  To verify the content of fluorinated compounds in foam concentrates, an analysis of fluorinated compounds was conducted by two independent accredited analytical laboratories. The goal was to attest the content of PFOA and other fluorinated compounds in foam concentrates used by FRS CR, but also in other products available on the market. Both laboratories provided a range of analytes of fluorinated compounds including perfluorinated carboxylic acids (PFOA, PFHxA…), perfluorinated sulfonic acids (PFOS, PFHxS…), or fluorotelomer alcohols (6:2 FTOH...).  The challenge of analysing fluorinated compounds lies in a wide variety of compounds and their structures (as congeners). For some of them the standardized analytes do not exist, thus is not possible to determine their content using standard methods.  One of the laboratories offers the Total Oxidizable Precursor Assay (TOPA) which enables to determine the sum of fluorinated compounds in given sample using oxidation to decompose the complex molecules into easily detected ones.  On the other side, the TOPA method provides only a rough picture of content of fluorinated compounds, because the detection of simple molecules does not give any information about the wide variety original compounds which were present in sample before analysis. |
| **Dossier submitter response:**  Thank you for providing information to this restriction proposal and reporting on the different issues you see with a transition to fluorine free foams. DS is of the opinion that for most municipal fire brigades a switch to FFF is possible as challenges with the application of FFF only occur in cases of fires of large liquid fuels. Those usually only occur within facilities that have their own firefighting installations. For those cases DS anticipated proposing 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. DS agrees that a transition from AFFF to FFF is expensive but so is the remediation of contaminated soil or water. DS notes your concerns regarding the possibilities to purchase FFF via tenders. DS also considers your information that foam stocks contain trace amounts of PFOA making it likely that newer foams were mixed with foams purchased before 2015. Therefore, your stocks will most likely contain substances that fall under Regulation (EU)2019/1021 meaning stocks have to be replaced and systems will have to be cleaned until latest 2025. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that fluorine-containing foams are very efficient. For normal municipal fire-brigade use alternatives appear to be available. For other uses, such as for defence applications and for large tank fires, the Dossier Submitter has proposed derogations. RAC evaluated these proposed derogations from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC.  Regarding analytics, RAC considers testing at the proposed threshold of PFHxA of 25 ppb to be feasible, based on the input by ECHA in the consultation (comment 3115) although in the lower range of the reported LOQs for this matrix (Firefighting Foam ~ 20 - 50 μg/kg). A validated method to detect 29 PFASs (including PFHxA) to a limit of 10 ng/ml (ppb) in foam concentrates has been developed by the Fire Fighting Foam Coalition (FFFC) together with SGS AXYS Analytical Services Ltd. (AXYS) (Consultation comment 3010). RAC recommends developing a standardised method for analysis of PFHxA in firefighting foams. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Based on the information in the Annex XV dossier and the outcome of the consultation, we see that an adequate performance level of fluorine-free foams in some applications has not been proven yet. We also see that the development of FFF appears to be rapid and they perform better and better in more and more scenarios. Overall, we consider that an extended transition period will be needed for firefighting foams for class B fires. We support the transition periods proposed by the Dossier Submitter and we also highlight that the performance level of FFF in applications covered by the 5-year transition period should be reviewed during the transition period and before the restriction starts to apply. |
| **3128** | **Date:** 2020/09/25 02:33  **Content:**  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** ON Semiconductor  **Org. country:** United States  **Attachment:** | **Comment:**  **-** |
| **Answer to specific info request 1:**  See attachment (section IV) |
| **Answer to specific info request 2:**  See attachment (section IV) |
| **Answer to specific info request 6:**  Image Sensors, Semiconductors, See attachment (section IV) |
| **Answer to specific info request 8:**  See attachment (section IV) |
| **Dossier submitter response:**  Thank you very much for the information you provided to this restriction proposal. DS was not aware of semiconductors where PFHxA or related substances remain in the final product. This misconception was corrected in the background document for the restriction proposal. The information you provided was considered during the reconsideration of the proposed derogation for semiconductor manufacturing. DS is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. 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 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 respective transition period is likely not proportionate and therefore supports a transition period of 12 years as well. We note that claims were made 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 would be desirable. |
| **3129** | **Date:** 2020/09/25 08:49  **Content:**  Scope or restriction option analysis  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ACEM (Motorcycle Industry in Europe)  **Org. country:** Belgium | **Comment:**  ACEM supports in general the intention to limit the emissions of PFHxA, PFHxA salts and PFHxA-related substances into the environment. However, the proposed restriction only allows for very narrow derogations. It should be stressed that PFHxA is not an SVHC, it is not even classified under CLP. As for C6 fluorinated chemistry the current proposal would lead to far-reaching consequences for the motorcycling industry. This should be better taken into account. |
| **Answer to specific info request 1:**  Similar to the Automotive industry  - Textile/non woven: seat cover, insulating material in the engine area  - Fluoropolymers-coated/Fluoropolymers-containing parts: engine management systems, lambda sensors, pipes, fuel hoses, seals, cylinder head gaskets, valves, high temperature wire insulation in the motor compartment. |
| **Answer to specific info request 2:**  Similar to the Automotive industry |
| **Answer to specific info request 3:**  Similar to the Automotive industry |
| **Answer to specific info request 4:**  Similar to the Automotive industry |
| **Dossier submitter response:**  Thank you for your comment. The DS discusses derogations for textiles and fluoropolymers in the background document. Please note that DS proposes a derogation for textiles used in the engine bay. Other textile uses were not proposed to be derogated as only water-repellent properties are required that can be provided by non-fluorinated alternatives. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain applications they are difficult or not possible to replace with retained function. The Dossier submitter has proposed a derogation for textiles in engine bays. Derogation requests proposed by the Dossier Submitter or requested by stakeholders in the consultation, such as for technical textiles, have been evaluated by RAC from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC.  Fluoropolymers (incl. fluoroelastomers) as such 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. |
| **SEAC Rapporteurs comments:**  Thank you for your comments! We agree that where oil repellence is required, based on the available information suitable alternatives are not available. However, it is not clear that oil repellence is actually necessary for all related applications. We note RAC’s conclusion that a very 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. We agree that some derogations may be necessary (such as uses related to the engine room), but we will need more information to be able to propose a suitable scope and wording of a derogation. Information on the expected costs, emissions and availability of alternatives related to different sub-uses could be submitted in the consultation on the SEAC draft opinion.  As to fluoropolymers, 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 necessary. 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. |
| **3130** | **Date:** 2020/09/24 18:22  **Content:**  Hazard or exposure  Information on alternatives  Other socio economic analysis (SEA) issues  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Francéclat, the French Watch, Clock, Jewellery, Silverware and Tableware Committee and France Horlogerie - Time and Microtechnics Industries (FITHM)  **Org. country:** France  **Attachment:** | **Comment:**  Please find our comments in the attached document |
| **Answer to specific info request 1:**  Please find our comments in the attached document |
| **Answer to specific info request 7:**  Please find our comments in the attached document |
| **Answer to specific info request 8:**  Please find our comments in the attached document |
| **Dossier submitter response:**  Thank you for your contribution. DS was not aware of this field of use of fluorocarbon chemistry. Estimated total amounts of PFHxA per year used in epilamisation seems to be very low indeed. However, while emission of PFHxA during use of the articles is likely to be minimal and, hence, only negligible consumer exposure may occur, emission into environment will eventually occur at end of life of products. The DS considered all stakeholder information for this use and proposes a derogation in the background document.  The planned restriction proposal will also apply to imported products. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain applications they are difficult or not possible to replace with retained function. The Dossier Submitter has proposed a derogation for the use in epilames in watches. RAC can support the derogation for this use until suitable alternatives become available. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We note that there are specific requirements that the substance used must fulfil, and that the combination of properties is offered by the targeted substances but difficult to find in other substances. We note that RAC supports a derogation as emissions are minimised by other means than a restriction. Information on restriction-related costs indicates potentially high socioeconomic impacts, even though SEAC points out that cost information overall is scarce. SEAC therefore currently considers to concluding that restricting this use is likely not proportionate and supports a derogation as well. |
| **3131** | **Date:** 2020/09/24 18:23  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:** | **Comment:**  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.  In the absence of viable alternatives, international  competitiveness and operations of the entire European supply and value chain is put at risk.  Hence, we strongly advise to completely exclude the use of fluoropolymers and fluoroelastomers from the scope of this restriction! |
| **Answer to specific info request 6:**  Fluoroelastomers are used also in non-automotive application like oil and gas industry, chemical industry, pharmaceutical and food industry. Typical products are seals, hoses and membranes. Here, properties such as heat, chemical, oil resistance as well as low-permeability play a critical role. Please note: the fluoroelastomer industry will not maintain their capacity if the use in automotive applications gets restricted which in turn will have a serious impact on the applications mentioned above and might lead to their discontinuation in the EU. |
| **Answer to specific info request 7:**  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.  In the absence of viable alternatives, international competitiveness and operations of the entire European supply and value chain in high-technology industries is put at risk. |
| **Answer to specific info request 8:**  Fluoroelastomers are used in automotive and aerospace applications, oil and gas industry, chemical industry and maintain theri performance under harsh conditions (e.g. high temperature, aggressive media like acids, alkalines, oils etc). Typical products are:  Automotive industry - fuel lines and hoses, turbo charger hoses, particle filter hoses, seals and gaskets.  Non-automotive industry: seals and gaskets, hoses, membranes and diaphragms.  Due to the nature of the Fluoro-Carbon-bond high heat stability and flexibility of the material is given that cannot be matched by alternative materials.  Technical substitutions are not feasible with current knowledge , even with major investments and resources. The unique property spectrum of Fluoroelastomers is unmatched and cannot be substituted by thermoplastic (elasticity, low temperature behaviour), metallic or other elastomeric alternatives. |
| **Answer to specific info request 10:**  Fluoropolymers, including fluoroelastomers and fluoroplastics, 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. |
| **Dossier submitter response:**  Thank you for your comment. 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.  With regard to fluoroelastomers one stakeholder informed DS that 50 % of the EU fluoroelastomers market is produced without C6 polymerisation aids. Additionally, the stakeholder mentioned only one use (automotive) where the C6-fluoroelastomers are needed to meet certain EU standards.  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. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers (incl. fluoroelastomers) as such 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. |
| **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 necessary. 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. |
| **3132** | **Date:** 2020/09/24 17:53  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Protecion of intellectual property. Confidential data of licensor. | **Comment:**  **-** |
| **Answer to specific info request 1:**  Perfluorohexyloctane; F6H8, C14F13H17, CAS no: 133331-77-8 is used as non-active invasive medical device wih the intended use: "For lubrication of dry irritated eyes (ophtalmic use)". The substance is mentioned in the restriction proposal as related substance, but no experimental study/results are presented in the restriction dossier or in literature indicating that 1-(Perfluorohexyl)octane degrades to PFHxA under relevant environmental conditions. This assumption is only based on theoretical data from related substances.  All prominent examples of substances associated with health and environmental concerns (e.g. Perfluorooctanoic acid, Perfluorooctane sulfonic acid, Perfluorohexane-1-sulphonic acid) are partly water soluble and contain functional groups. This clearly differentiates them physically, chemically, and physiologically from 1-(Perfluorohexyl)octane.  The available ecotoxicological studies performed according to OECD guidelines do not indicate toxicity to aquatic invertebrates and algae (EC50 (48 h) > 100 mg/L; ErC50 (72 h) > 100 mg/L, NOErC (72 h) ≥ 100 mg/L, respectively). Since 1-(Perfluorohexyl)octane does not contain any functional groups responsible for a specific mode of action, low toxicity is expected for other taxonomic groups in the environment as well.  Detailed measured environmental concentrations related to 1 Perfluorohexyl)octane are not available.  1-(Perfluorohexyl)octane is considered as non-toxic for human health. Various toxicological studies showed no effects and human safety is confirmed in clinical trials. Furthermore, 1-(Perfluorohexyl)octane does not accumulate in the human body. Consequently, no immediate concern for human health can be identified and subsequently no impacts from continued use arise for human health. See confidential attachments. |
| **Answer to specific info request 8:**  No replacement is possible in the intended use: For lubrication of dry irritated eyes in cases where traditional water - or oil-based formulations do not bring sufficient relieve to patients.  The ban of the substance would mean stopping the marketing of the product and losing all sales. Estimated quantity: < 5 t/anno |
| **Dossier submitter response:**  Thank you very much for providing additional information on your use of PFHxA related substances. It was taken into account when considering the proposed derogation for implantable and non-implantable medical devices. |
| **RAC Rapporteurs comments:**  Thank you for your additional information. The Dossier has proposed a derogation for your use (as part of medical devices). RAC has evaluated this derogation request from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit for allowing this derogation is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you or your comments. Based on information received in the consultation on the dossier, the Dossier Submitter proposed a general derogation for medical devices. We expect that the products you discuss are covered by this derogation proposal. We support that derogation, however, we consider that the wideness thereof should be re-evaluated at a later point. |
| **3133** | **Date:** 2020/09/24 17:25  **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:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Gesamtverband Textil und Mode e.V.  **Org. country:** Germany  **Attachment:**    <redacted>  **Privacy comment:** The document is intellectual property of EURATEX (and its members). It should not be used for commercial purposes. The document could be shared with authorities. | **Comment:**  See t+m statement (non confidential Annex) including Annex I (confidential), II and III (non confidential) |
| **Answer to specific info request 1:**  See t+m statement (non confidential Annex) and Annex I (confidential) |
| **Answer to specific info request 6:**  See t+m statement (non confidential Annex) + Annex I (confidential) |
| **Answer to specific info request 7:**  See t+m statement (non confidential Annex) + Annex I (confidential) |
| **Answer to specific info request 8:**  See t+m statement (non confidential Annex) + Annex I (confidential) |
| **Answer to specific info request 9:**  See t+m statement (non confidential Annex) + Annex I (confidential) |
| **Answer to specific info request 10:**  See t+m statement (Annex) including Annex I (confidential) |
| **Answer to specific info request 11:**  See t+m statement (Annex) including Annex I (confidential) |
| **Answer to specific info request 12:**  See t+m statement (non confidential Annex) + Annex I (confidential) |
| **Dossier submitter response:**  Thank you for your valuable answers and comments.  First of all, DS agrees that for consumer outdoor apparel fluorochemistry is dispensable due to the presence of non-fluorinated alternatives. However, for other product sectors it is frequently stated that some materials might be replaced by products from sources outside Europe. DS emphasises that the restriction proposal will also cover imported articles.  DS further notes that decreased lifetime of certain articles due to the lack of dirt repellence is often mentioned. However, without concrete numbers it is difficult to estimate socioeconomic impacts as well as any effects on circular economy.  DS proposes derogations for some technical textiles in the background document: e.g. filtration, membranes, textiles used in engine bays.  Regarding your remarks on disposal of PPE and technical textiles DS notes that your comments only refer to Germany. Other stakeholder information points out that incineration with over 1 000 °C is not common in all parts of the EU. Therefore, in absence of legal requirements in most countries for collection and separation of technical textiles and PPE proper disposal is uncertain.  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 very 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 specific categories of PPEs that include some types of workwear, filtration and separation media and medical devices. RAC evaluated derogations proposed by the Dossier Submitter as well as derogation requests from stakeholders in this consultation from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction 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 such as the ongoing work for a CEN standard for analysis of PFAS in textiles. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that where oil repellence is required, based on the available information, suitable alternatives are not available. However, it is not clear whether oil repellence is actually necessary for all related applications. 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.  We agree that an extended transition period is needed for the transition to fluorine-free alternatives in PPEs and medical devices. We currently consider supporting the derogations proposed by the DS, now covering more categories of PPEs than in the original dossier.  We also find that considering the situation with alternatives and the operations necessary for the practical transition even where an alternative may be in sight, a general transition period of 18 months may be too short, and we think that 36 months might be more appropriate. |
| **3134** | **Date:** 2020/09/24 16:25  **Content:**  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** TEGEWA  **Org. country:** Germany | **Comment:**  General comment  The association TEGEWA submitted a first contribution to the public consultation on May 13th, 2020. We would like to complement our input with this document.  Proportionality of limits and of the restriction of uses without fluorine free alternatives  The association TEGEWA supports the intention to restrict the use of C-6 based fluorinated polymers as undecafluorohexanoic acid (PFHxA) related substances for the manufacturing of ordinary outdoor apparel for consumers. Fluorine free alternatives are available for this application.  But we question the proposed limits and their proportionality in view of the factual hazard of the substances and their actual risk for human health and the environment. In the dossier, no scientific data and reasoning is provided to derive thresholds. The thresholds seem to be copied from the PFOA and related substances regulation. The adoption of an equivalent concern approach for PFOA and PFHxA is not justified. The toxicological profile of PFHxA is much better than for PFOA, e.g. in view of half-life period in human bodies. There is sufficient toxicological data available for PFHxA to derive a suitable threshold. The equivalent concern approach is not necessary and not justified.  For applications with no suitable alternatives for C-6 side chain fluorinated polymers used in the textile supply chain we would question the proportionality of the restriction in principle. Most of these textile uses are essential for protecting, fishermen, police, armed forces, fire brigade, workers in chemical industry and in clinics etc. We want to stress one more time that, without C-6 chemistry, these protective clothes cannot be manufactured and used within the EU any longer. In addition, many technical textile applications are necessary for protecting the environment, e.g. textile filters in chimneys of industrial facilities. These applications are the basis for circularity and sustainability. Regarding these issues and for covering potential risks of such applications, a restriction is not the right legal instrument to apply. There are different, much more suitable legal instruments available or already in place, e.g. strict wastewater limits in water legislations and a ban in the Industrial Emissions Directive for a removal of residual liquors via wastewater treatment plants. Such measures could be refined in future, e.g. by defining Best Available Techniques for the use of side chain fluorinated polymers in the Textile BREF which is currently under review.  Factual release overestimated  The estimations in the dossier for release of PFHxA and related substances from textile manufacture and use of textile articles significantly overestimate the factual release. Incorrect assumptions lead to false release amounts and to contradictory statements in the dossier. The dossier submitters did not sufficiently consider the measures taken in the textile industry to avoid release in the environment. In their calculations, they did not take into account sufficiently that many globally active manufacturers of apparel are already doing without side chain fluorinated polymers. Even if outdoor textiles are provided with a water repellent finishing, that does not necessarily mean that fluoro chemicals are used. In the carpet sector the change to other types of fibres lead to a significant decrease of the use of side chain fluorinated polymers, which is not considered in the dossier, either.  So, the factual release is overestimated, and the environmental benefit would be overestimated as well. In fact, we could not recognize in the restriction dossier any comparison of the environmental benefits with the socioeconomic costs.  List of derogations in the annex XV dossier should be extended.  For protective clothing within the scope of professional use, medical devices, and technical textiles the use of C-6 based fluorinated polymers is essential. Therefore, the list of derogations in the annex XV dossier should be extended. A list of these applications developed together with our customer associations was attached to our first contribution from May 13th, 2020. Meanwhile the document has been updated. EURATEX already submitted the updated version with their second contribution (September 2020). We renounce to submit the document a second time.  Last but not least, we want to recall that the restriction of PFOA and related substances for ordinary apparel, for technical textiles and personal protective equipment (effective by 2023) was justified with the argument that functioning alternatives like C-6 side chain fluorinated polymers would be available. The dossier submitters of the current restriction proposal do not provide any information on available alternatives for such kind of personal protective equipment that in their view does not need C-6 side chain fluorinated polymers for its functioning.  But the lack of alternatives underlines the necessity that the list of derogations must be extended.  Specific Information Requests  In view of answers to specific information requests please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 1:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 7:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 8:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 9:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 11:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Answer to specific info request 13:**  Please refer to TEGEWA´s first contribution on May 13th, 2020. |
| **Dossier submitter response:**  The DS does not consider your comment that use quantities and therefore emissions might be overestimated as relevant for the general conclusions of the socio-economic assessment. When use quantities are smaller than estimated DS expects substitution costs to be smaller, too. Functional losses are expected to be minor for most uses. Although a lot of stakeholders from the textiles sector claim functional losses to be significant DS received no robust quantitative or qualitative socio-economic information in the public consultation that supports this claim for apparel, home textiles or outdoor textiles.  With regard to PPE: Alternatives that provide water-repellence are available and discussed in the dossier. It is DS’s understanding that if additional repellence is required to prevent very serious consequences the manufacture and placing on the market of the PPE will be covered by the derogations proposed. 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 technical textiles discussion in the background document was expanded and additional derogations are proposed now.  As for PFOA DS is of the opinion that the risks of PFHxA are adequately controlled as outlined in chapter 1.37 Here the Dossier Submitter concludes that PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment (see chapter B.9) and environmental monitoring data (details in chapter B.4.2.4) regarded as a proxy for an unacceptable risk to the environment and human health. In theory a restriction with no concentration limit would bring all emissions to an end, however this is neither practical nor monitorable. Therefore, the proposed restriction has a concentration limit (please also see chapter 2.3). The concentration limit you refer to is therefore not reasoned by hazard or risk. 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. Regarding human health effects: 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 summarised 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 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. With regard to its half life in humans it should be noted that 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). Taking into account that exposure is continuous for instance via drinking water, half lives become of secondary importance. 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. 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. |
| **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 PPE and certain technical textiles. RAC evaluated these proposed derogations by the Dossier Submitter as well as requests for derogations from stakeholders in this consultation from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction is performed by SEAC.  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. Different options than the restriction have been discussed and evaluated by the Dossier Submitter and, subsequently, by RAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We currently consider supporting the derogations proposed for certain categories of PPEs and for medical devices. The scope of those derogations has been made wider compared to the original Annex XV dossier and now cover more products. We are also considering proposing that the general transition period be extended to 36 months in order to give time for a balanced transition in all sectors. |
| **3135** | **Date:** 2020/09/24 17:50  **Content:**  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Description of analytical methods  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exempt  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** MOL Group  **Org. country:** Hungary  **Attachment:** | **Comment:**  We agree with the intention of the Dossier Submitter, that fluorinated foam agents should be replaced in the future, and we would like to submit some statements and findings on the topic to facilitate the process. We see that this is mostly an environmental heavy proposal, which is only tangentially takes into account risk effects. We would like to highlight that we believe that both risk and environmental issues shall be evaluated equally during the analysis the supplemental part of the text the Dossier Submitter pays attention to petrochemical and defence related derogations, but in the legal text only defense derogations are listed in full scope, and petrochemicals are narrowed down to storage tanks only, despite the fact that this sector is the user of AFFF and AR-AFFF with a 59 % share. We think this raises safety and also proportional concerns.  Another main issue is the lack of coherence with similar valid restrictions. As many others, we are accomplishing and trying to adapt to the PFOA restriction presently. PFOA restriction also sets derogations for some subjects such as “already installed/loaded” and stockpiled foam agents. The current proposal ignores these conditions. Moreover, the conditions of application for training and testing purposes are not clear, and do not follow the same pattern as it declared in POP legislation for PFOAs. Because of the fact that the transition period of PFOA could overlap the entry into force of restriction on PFHxA, it would be beneficial to follow the same conditions in derogations. Our further comments can be found in the attached document. |
| **Answer to specific info request 5:**  A: YES  -Transition covers the entire activity of MOL Group (US, DS), where the application of foams is an obligation or necessary.  - Based on our rough estimate it takes circa 12 years.  - Testing the products, testing conformity with current systems, purchasing, modification, training, decontamination, disposal.  A: NO  - Providing information on current volume is a confidential information.  - No significant test results, or experiences can be found or shared in the oil and gas industry. Only being equivalent to Standards are displayed. No one can figure out what we can do without film forming foams, it could mean higher risk.  C:  It is crucial from a training point of view, that fire-fighters can train with the exact same quality foams which they use for intervention. |
| **Dossier submitter response:**  Thank you for your contributions to this restriction proposal. DS is aware of the issue with the current wording of the derogation proposal for large tank fires. The information from several different stakeholders (yours included) was considered when rewriting the proposed derogation and during the discussion of this derogation with RAC and SEAC. DS is of the opinion that a transition to FFF is generally possible and that foams, also for the application in large fire events, are available. An example for this is Statoil in Norway having transitioned to FFF foams throughout all of its operations[[1]](#footnote-1). Also, some larger scale tests with FFF have been performed e.g. by LASTFIRE. Furthermore, DS is of the opinion that for training purposes it is not necessary to use AFFF. DS was informed by different fire fighter organisations, that they completely moved away from testing with AFFF due to the high costs and great efforts that are linked to remediation of contaminated sites.  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 at present no viable alternatives to fluorine-containing foams are available for certain applications. The Dossier Submitter has proposed derogations for AFFFs for defence applications and for large tank fires. RAC evaluated these proposed derogations from an emissions/emission minimization perspective (proportionality and cost/benefit are evaluated by SEAC).  Regarding analytics, RAC considers testing at the proposed threshold of PFHxA of 25 ppb to be feasible, based on the input by ECHA in the consultation (comment 3115) although in the lower range of the reported LOQs for this matrix (Firefighting Foam ~ 20 - 50 μg/kg). A validated method to detect 29 PFASs (including PFHxA) to a limit of 10 ng/ml (ppb) in foam concentrates has been developed by the Fire Fighting Foam Coalition (FFFC) together with SGS AXYS Analytical Services Ltd. (AXYS) (Consultation comment 3010). RAC recommends developing a standardised method for analysis of PFHxA in firefighting foams. |
| **SEAC Rapporteurs comments:**  Thank you for your comments!  Thank you for pointing out the scale of tests discussed in the evaluation of performance level of FFF in the dossier. We have pointed the issue out in the draft opinion.  The proposed derogation for tank fires is considered to be widened and now should cover also other types of tanks than storage tanks. Furthermore, having considered all information received in the consultation, we are going to suggest that tanks exceeding 400 m2 in size and their bunded area would be included in the derogation.  We consider that an extended transition period will be needed for firefighting foams for class B fires also in other scenarios. We currently consider to support the transition period proposed by the Dossier Submitter, and we also highlight that the performance level of FFF in applications covered by the 5 years transition period should be reviewed during the transition period, before the restriction starts to apply. |
| **3136** | **Date:** 2020/09/24 17:06  **Content:**  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes | **Comment:**  Our company opposes the adoption of the proposed restriction due to the significant impacts to our company and our customers. We supply critical rubber seals made from fluorinated polymers designed for low temperature automotive applications. Many OEM and Tier 1 companies specify the low temperature fluorinated polymer. There are four primary manufacturers of this type of polymers. If PFHxA is restricted, the supply would be severely constrained resulting in reduced vehicle builds, reduced employment, and increased costs. |
| **Answer to specific info request 10:**  The performance attributes of low temperature fluorinated polymers include dynamic flexing and static sealing at -30 C, low permeability of hydrocarbon emissions, limited chemical attack from fuels, high temperature resistance, limited dimensional variation, and increased long-term durability in functional cycling. The alternative polymers of NBR, HNBR, and Fluorinated Silicone do not provide equivalent performance attributes. The cost to redesign and requalify an alternative would be significant. The attributes of each polymer are well documented and supports the need to maintain the commercial availability of the low temperature fluorinated polymers. |
| **Dossier submitter response:**  Thank you for your comment. DS proposes proposing 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.  With regard to fluoroelastomers one stakeholder informed DS that 50 % of the EU fluoroelastomers market is produced without C6 polymerisation aids. Additionally, the stakeholder mentioned only one use (automotive) where the C6-fluoroelastomers are needed to meet certain EU standards. DS already proposed a derogation for this use. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers (incl. fluoroelastomers) as such 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 minimization 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 necessary. 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. |
| **3137** | **Date:** 2020/09/24 16:04  **Content:**  Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on benefits  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** This consultation statement contains several information which are sensitive for this niche application of the described technology in the medical device market. Although many of the provided information is publicly available, the combination of the information could lead to a disadvantage for our company when it would become available to our competitors. For that reason, we claim that the documents that we attach to this statement will only be used by the authorities involved in the decision-making process on a potential restriction of PFHxA, its salts and related substances. | **Comment:**  Our company provided an initial comment (comment no. 3014) until the interim deadline 13.05.2020 to inform the legislators about an important niche application of PFHxA related substances which is not mentioned and considered for an exemption from the restriction proposal. With this initial comment we provided basic information on the use of PFHxA related substances in medical devices.  In the meantime, we have gathered further information and data in support of our request for an exemption from the proposed restriction of PFHxA, its salts and related substances. This comment supplements our already submitted comment no. 3014.  We suggest adding the following phrasing to the currently proposed exemptions under Number 9 (b) of the restriction proposal:  9. Paragraphs 1 and 2 shall not apply to any of the following:  […]  “(e) medical devices within the scope of Directive 93/42/EEC”. |
| **Answer to specific info request 1:**  Information on additional uses is provided in "Section V. Confidential Attachment". |
| **Answer to specific info request 2:**  Information on emissions of PFHxA from polymers is provided in "Section V. Confidential Attachment". |
| **Answer to specific info request 8:**  Information for uses where substitution is regarded as being impossible is provided in "Section V. Confidential Attachment". |
| **Answer to specific info request 10:**  Information for uses where substitution would be possible but is expected to lead to a lower quality of products or lower performance is provided in "Section V. Confidential Attachment". |
| **Answer to specific info request 12:**  Information on costs is provided in "Section V. Confidential Attachment". |
| **Dossier submitter response:**  Thank you for the additional information. The detailed information that clarifies the benefits of using your products was included in the socio-economic assessment. |
| **RAC Rapporteurs comments:**  Thank you for your additional information. The Dossier Submitter has proposed medical devices to be derogated from the restriction. RAC evaluated this derogation request by the Dossier Submitter from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction is performed by SEAC.  Also, Fluoropolymers (incl. fluoroelastomers) as such 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. |
| **SEAC Rapporteurs comments:**  Thank you for the information provided. We currently consider to support the derogation of medical devices now included in the restriction entry text. However, considering the wideness of the derogation and that there are applications that have not been assessed in detail, we think that the situation should be re-evaluated at a later point. At that time information on the availability and performance level of potential alternatives, on properties necessary for an alternative to work, and on realistic timelines for the implementation of the alternatives would be instrumental to ensure a suitable transition time. |
| **3138** | **Date:** 2020/09/24 15:39  **Content:**  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Lydall  **Org. country:** France  **Attachment:**  <redacted>  **Privacy comment:** The attached document contains sensitive business information. | **Comment:**  **-** |
| **Answer to specific info request 1:**  Please refer to the attached document. |
| **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.  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 the additional information. The Dossier Submitter has proposed a derogation for the use reported in your confidential comment. This RAC has evaluated from an emissions/emission minimization perspective, where your submitted information on emissions and risk management measures have been taken into account. Proportionality and cost/benefit for derogating uses from the restriction are evaluated by SEAC |
| **SEAC Rapporteurs comments:**  Thank you for the additional information. Please see our reply to comments 3024 and 3074. |
| **3139** | **Date:** 2020/09/24 10:40  **Content:**  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Italy  **Company name confidential:** Yes  **Privacy comment:** The current alternative materials available on market (e.g. silicon rubber, special polyester...) do not have the same performance as fluoropolymers compounds required in markets like automotive, electronics, electric motors, medical, oil & gas, aerospace, defense and others. These products can therefore not replace fluoropolymers and cannot be considered as viable alternatives.  During the past 40 years, the development of new and strategic materials based on fluoropolymers such as PTFE and FEP in the area of defense, electronics and transportation opened up new markets and applications. More recently, thanks to the ongoing development of new fluoropolymers (MFA/ETFE/PFA) higher performance and economic advantages were brought into these markets.  The use of these high performance materials brings a technological evolutions with tremendous advantages for producers, transformers and end- users. Furthermore, and beyond the economic impact of a restriction impacting the availability of fluoropolymers, it is crucial that these products remain accessible in the EU as they are critical elements for the implementation of recently discussed EU strategies such as the “Green Deal”.  Without the evolution made possible by the use of fluoropolymers, the cable market would be stuck in the past, whereas thanks to these technologies the former technical boundaries have been pushed and we can give improved performance with our cables to our customers who now benefit from using more durable and very high performing wire & cable products. | **Comment:**  **-** |
| **Answer to specific info request 6:**  Fluoropolymers are used in wire and cables insulations and jackets. Fluoropolymers are critical to this industry because of the unique combination of properties they offer such as resistance to chemical attack and high temperature, in critical applications and crucial EU industries such as the automotive, electronics, electric motors, medical, oil & gas, aerospace, and defense industry |
| **Answer to specific info request 7:**  At the moment there are no alternatives that could replace the use of fluoropolymers (PVDF / ECTFE / ETFE / FEP / MFA / PFA / PTFE) in these critical applications. Our company <redacted> has a turnover of approx. 14 million Euros, and 80% of it relies on products that require fluoropolymers. Any restriction impacting the availability to fluoropolymers in the EU would therefore have unmeasurable consequences on our company. Furthermore, it would put the EU automotive, electronics, electric motors, medical, oil & gas, aerospace, and defense industry at risk |
| **Answer to specific info request 8:**  Please refer to question 7: there are currently no alternatives to fluoropolymers for the range of products manufactured by our company |
| **Answer to specific info request 9:**  Please refer to question 7 above. Given the immediate impact on our business of a restriction impacting the availability of fluoropolymer, it is impossible to provide information on alternatives in the short/medium timeframe. Approximately 80% of our tailor-made cables and wire rely on fluoropolymers, and the consequences would be immediate and catastrophic for <redacted> |
| **Answer to specific info request 10:**  please see the final comments |
| **Answer to specific info request 12:**  To the best of our understanding, the table costs of the current version of Annex XV Report does not include any data relating to of our market (wires and cables). Please refer to question 7 for data specific to our company. |
| **Dossier submitter response:**  Thank you for your comment. 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 (incl. fluoroelastomers) as such 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 minimization perspective. Proportionality and cost/benefit for derogating uses from the restriction are evaluated 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 necessary. 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. |
| **3140** | **Date:** 2020/09/23 17:20  **Content:**  Information on benefits  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  **-** |
| **Answer to specific info request 6:**  C6 fluorochemicals have become the default choice for treatment of automotive textiles such as convertible cartop fabrics. |
| **Answer to specific info request 7:**  Non-fluorinated textile finish options exist, but offer severely compromised soiling resistance. This is a notable concern for outdoor fabrics such as convertible cartops. |
| **Answer to specific info request 8:**  Transition to non-fluorinated finishes would likely result in reduced lifespan of convertible cartop roofs, requiring more frequent roof replacement. |
| **Answer to specific info request 9:**  Transition in compressed timeframe risks compromised decisions based upon limited end-use application testing in vehicle assemblies. It would also be beneficial to allow more time for development of finishes with improved soiling resistance. |
| **Answer to specific info request 10:**  Application = DWR and soil release finish for convertible cartop fabrics. A reduction in soiling resistance performance will occur. |
| **Answer to specific info request 13:**  No known internationally recognized methods for chemical analysis of PFHxA. <redacted> has no intent to develop such a method. |
| **Dossier submitter response:**  Thank you for your comment. In order to discuss whether a derogation is justified it would be necessary to consider more detailed information regarding a possibly reduced lifespan. DS also would like to consider more information regarding possible alternative materials (e.g. PVC).  Thank you for your valuable answers and comments.  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 very effective for repellence of e.g. water, oil and grease. For certain uses alternatives appear to be available, but not for others. RAC evaluated derogations proposed by the Dossier Submitter or requested in the conslutation by stakeholders, such as for technical textiles, from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments! We agree that where oil or dirt repellence is required, based on the available information, suitable alternative substances are not well available. However, it is not clear whether oil or dirt repellence is actually necessary for all related applications. Alternatives could be available at least for some of them (not only referring to substances, but also other processes such as increased washing etc.). 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 would be necessary to evaluate whether a derogation is justified. Such information could be submitted in the consultation on the SEAC draft opinion. |
| **3141** | **Date:** 2020/09/24 13:31  **Content:**  Scope or restriction option analysis  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:** DIGITALEUROPE  **Org. country:** Belgium  **Attachment:** | **Comment:**  See attached document |
| **Answer to specific info request 1:**  Fluoropolymers (fluoroplastics and fluoroelastomers) are used in products and production processes in the digital industry.  See attached document for more information. |
| **Answer to specific info request 8:**  Fluoropolymers are unique in their chemical and heat resistance. Examples are sealing and tubing in conditions where chemical (and temperature) resistance is essential and applications where low friction is essential in combination with requirements on temperature and moisture resistance, PTFEs in wiring insulation, Li Ion batteries and gasket where the semi/lubricating properties needed.  See also attached document. |
| **Answer to specific info request 9:**  Complex electronic products consist of many hundreds or thousands unique parts, often with a long supply chain. There is no information available yet from these supply chains on the use of PFHxA and the related substances. After publication of the restriction it can take more than a year to identify the uses. After that it will take time for our suppliers to find alternatives.  See attached document. |
| **Answer to specific info request 13:**  See attached document. |
| **Dossier submitter response:**  Thank you for your comment and the information you provided. DS considered the information you provided when considering a derogation for PFHxA and related substances in electronic devices and is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. DS is not responsible for the information availability along the supply chain. This is the task of the registrant of a substance / manufacturer / importer of articles and the subsequent downstream users. Analytical methods for PFHxA and related substances are generally available, however DS is aware that extraction methods are still under development.  DS will consider proposing 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.  With regard to fluoroelastomers one stakeholder informed DS that 50 % of the EU fluoroelastomers market is produced without C6 polymerisation aids. Additionally, the stakeholder mentioned only one use (automotive) where the C6-fluoroelastomers are needed to meet certain EU standards.  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. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers (incl. fluoroelastomers) as such 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, such as electronic devices, which have been evaluated by RAC from an emissions/emission minimization perspective. Proportionality and cost/benefit for derogating uses from the restriction are evaluated 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 necessary. 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.  We are also considering proposing that the general transition period be extended to 36 months in order to give time for a balanced transition in all sectors. |
| **3142** | **Date:** 2020/09/24 00:31  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes | **Comment:** |
| **Answer to specific info request 1:**  Annex XV dossier 2.5.1.5 requires that “Short-chain perfluorinated substances not becoming part of the final product (the microchip)”. In fact, the PFHxA containing materials remain in some final products of semiconductors. For example, CMOS image sensor has three color films (Red, Green and Blue) which are formed by the photolithography process and remain in the products, and these films contains PFHxA as a surfactant. Some black coating layers also contain PFHxA and remain in the semiconductor products. As a result, supplying components such as CMOS imaging sensors would become very difficult, and the economic impact would be significant on a very wide range of industries in which we serve, automotive, computing, consumer electronics, IoT/Emerging, mobile device and security.  Because automotive and medical industries require 20 years of repair parts support, 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, if this official gazette were issued without any amendment. 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 7:**  PFHxA has been widely used by the semiconductor industry, and it is difficult, if not impossible, that a replacement can be identified, qualified, mass produced and approved by customers in 7 years. We strongly request that the regulators consider appropriate exemption for the semiconductor industry. We also strongly request that that no deadline be set for the PFHxA removal from use before an alternative is fully qualified and approved.  Even if an alternative is found, the following consideration shall be given.  1. The alternative cannot be replaced instantly because the characteristics of the alternative must be identical to the existing one, quality and reliability testing must be passed, and technical process for obtaining the applicable safety standard certification must be taken when required.  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 take a considerably long time.  3. The time period for the PFHxA removal from use for semiconductor products containing PFHxA must be more than 20 years because of the 20-year repair part support requirement for automotive and medical industries. |
| **Dossier submitter response:**  Thank you very much for the information you provided to this restriction proposal. DS was not aware of semiconductors where PFHxA or related substances remain in the final product. This misconception was corrected in the background document for the restriction proposal. The information you provided was considered during the reconsideration of the proposed derogation for semiconductor manufacturing and DS is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available Proportionality and cost/benefit for derogating uses from the restriction are evaluated by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your participation! Please see reply to Comment 3087. |
| **3143** | **Date:** 2020/09/23 15:15  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ETRMA - European Tyre & Rubber Manufacturers Association  **Org. country:** Belgium  **Attachment:** | **Comment:**  The European Tyre & Rubber Manufacturers Association (ETRMA) represents nearly 4.400 companies in the EU, directly employing about 370.000 people. The global sales of ETRMA’s corporate members represent 70% of total global sales and 7 out of 10 world leaders in the sector are ETRMA Members . We have a strong manufacturing and research presence within the EU and candidate countries, with 93 tyre-producing plants and 17 R&D centres.  Use of Fluoropolymers in the rubber industry:  General Rubber Goods are used in a large variety of sectors and applications. Rubber parts are essential pieces in automotive, aviation, off-shore oil and gas industry and food contact materials. It is estimated in 2.8 million tonnes the annual production of rubber goods in Europe, that has been stable over the lasts years. Approximately 67% of the production of these rubber parts is for the automotive and transport industry, 10% is for household applications, 4-5% are products for the food contact and drinking water sector and up to 2% is estimated for the leisure and sport equipment.  The particularities of rubber, with strength, resistance to temperatures and flexibility have made rubber parts essential in many complex goods. For some applications, rubber goods are requested to perform in extreme and hard environments. For instance, rubber seals and O-rings inside motors, where rubber is in contact with oils at high temperature and extreme pressures. Other example are hoses used in oil and gas industry where working temperature could reach -50ºC degrees in the case of Offshore LPG transfer. In this specific applications, rubber needs to be reinforced with cross-linked fluoropolymers. Those Fluoropolymers, such as FKM or PTFT are chemically, thermally and biologically stable; they do not present significant toxicological concerns and cannot degrade into other PFAS.  ETRMA calls authorities to secure the use of fluoropolymers in rubber goods and avoid disturbances in the current value chain: The following modifications to the propped restriction on paragraph 11 shall be included:  The concentration limit referred to in paragraph 2 shall be 150 ppm for the sum of PFHxA and its salts in fluoroelastomers used in the following usage groups: Automotive and aerospace industry. This derogation shall not apply to articles referred to in paragraph 2(c).  • Paragraph 11 shall enlarge the scope to rubber articles containing fluoropolymers. The derogation shall apply to articles referred in paragraph 2c too.  • Paragraph 11 shall enlarge the scope to cover all the sectors were rubber articles containing fluoropolymers are used, and not exclusively automotive and aviation  The restriction proposal on PFHxA would disturb rubber value chain, modification on paragraph 11 are needed:  It is estimated that 14-50 kilotons of rubber goods require the use of fluoropolymers, accounting for 0,5 to 2% of the overall production of rubber goods in Europe. Rubber goods containing fluoropolymers are used in automotive, aviation, oil and gas sectors, construction, food contact materials, machinery and medical devices. The use of fluoropolymers in rubber is essential to meet technical expectations on product performance. To date there are not chemicals, nor technological alternatives, that could substitute the use of fluoropolymers in our industry.  Rubber goods containing fluoropolymers are used inside other complex objects, such as aviation or automotive, in industrial controlled environments or construction sites. Their use is essential to fulfil a modern society needs and cannot be substituted by other alternatives as it would create a breach in rubber goods performance and ultimately, an impact on safety and welfare.  The restriction proposal forbids the use of PFHxA. A list of substances meeting the definition is provided. PFHxA are not directly used by the producers of rubber goods containing fluoropolymers. However, it is our understanding that, in order to produce fluoropolymers, PFHxA substances are used as process substances. Traces of PFHxA might remain in fluoropolymers.  The producers of fluoropolymers, our suppliers, consider that those potential traces would not pose a risk for the environment under normal conditions of use (see PlasticsEurope Fluoropolymers Group answer). We voice those claims, as rubber goods containing fluoropolymers are used when rubber has to perform in extreme and hard conditions, usually as part of complex products, no accessible by consumers.  We welcome the dossier submitter efforts to allow the use of PFHxA for the production of fluoropolymers. Paragraph 11 of the proposed restriction is a large step towards supporting the European rubber industry. However, there current exceptions need to be modified in order to cover all the value chain and all uses by the rubber industry as explained hereunder.  Currently, all the burden of compliance is for producers of final articles, such rubber goods producers. This places the industry in very difficult situation:  Firstly, downstream users of fluoropolymers, as rubber goods producers, get little information on the content of impurities, such as PFHxA, in the fluoropolymer. None of the PFHxA listed is included in the SVHC, therefore there is no obligation to communicate the presence of those substances across the value chain. Further, the potential presence of PFHxA as impurities is in such little quantities that does not reach the required thresholds to be communicated in Safety Data Sheets; therefore, there is no obligation to communicate the presence of those PFHxA on the value chain. The inclusion of PFHxA in Annex XVII of REACH would not change the communication obligations.  Secondly, there are not in place tests methods that are trustable, reliable and enough sensitive to be used for compliance. We are extremely worried about the lack of method. It could hamper rubber industry´s ability to show compliance.  In order to secure that the proposed restriction supports the use of fluoropolymers in key industrial sectors and that there a are not disturbances in the rubber value chain. Paragraph 11 shall enlarge the scope to rubber articles containing fluoropolymers. The derogation shall apply to articles referred in paragraph 2 c too.  We would also point that the use of fluoropolymers is not restricted to the sectors automotive and aerospace. Other key sectors are construction works, oil and gas industry, offshore industry, food contact materials, to mention some. Those sectors are equally relevant and strategic for Europe. Rubber goods containing fluoropolymers are essential in the hereunder sectors and cannot be substituted. The derogation shall enlarge the scope to cover all the sectors were rubber articles containing fluoropolymers are used.  List of sectors were rubber goods containing fluoropolymers are used  • Food contact materials and non-stick kitchenware,  • Construction products  • Medical devices and applications  • F-gases e.g. (PFC, HFC, HCFC, HFE, HFO) in air-conditioning, heat-pump equipment  • Semiconductors  • Transportation (automotive, aviation etc.)  • Petroleum activities, Oil, gas and mining  • Personal protection equipment  • Machinery  • Off shore  It shall be noted that rubber goods containing fluoropolymers are used in food contact materials and drinking water applications when rubber goods are required to work at hard pressures and extreme conditions. Regulation on (EC) No 1935/2004 on food contact materials, the Drinking Water Directive, 98/83/EC, currently under revision, and national regulations, have in place systems to control the risk that substances may pose to the human health or the environment. Migration limits for targeted substances are set for rubber goods. There are test methods already in place to meet the requirements and are used and known by industry. |
| **Answer to specific info request 6:**  See document attached |
| **Dossier submitter response:**  Thank you for your comment.  DS is not responsible for the information availability along the supply chain. This is the task of the registrant of a substance / manufacturer / importer of articles and the subsequent downstream users. Analytical methods for PFHxA and related substances are generally available, however DS is aware that extraction methods are still under development.  DS will consider proposing 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.  One stakeholder informed DS that 50 % of the EU fluoroelastomers market is produced without C6 polymerisation aids. The stakeholder mentioned only one use (automotive) where the C6-fluoroelastomers are needed to meet certain EU standards.  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.  Therefore, the DS argues that a general derogation with higher concentration limit for fluoropolymers is justified. For fluoroelastomers a derogation (with higher concentration limit) is justified for specific uses only. For example, fluoropolymers have highly valuable properties as food contact materials. The stakeholder emphasises the importance of fluoropolymers in rubber goods. Alternatives with equal performance are not available, yet. According to industry, release of PFHxA and related substances due to these uses is negligible. DS agrees. In addition, fluoroelastomers are not listed in the BfR recommendation XXI on rubber food contact materials nor has there ever been an application for the inclusion of respective substances into this recommendation. Hence, DS is not aware of widespread use of fluoroelastomers for food contact materials.  The stakeholder requests that the current derogation for fluoroelastomers (restricted to automotive and aerospace industry) shall apply also for articles. DS is not aware that fluoroelastomers are really needed in food contact materials since they are not listed in the respective BfR recommendation (see above). If fluoroelastomers are actually used for food contact, DS would like to ask the stakeholder to provide data on usage, migration etc.  The stakeholder points out that there are regulations on FCM which are already in place. This is correct with regard to the framework regulation (EC) No. 1935/2004 on food contact materials. However, no specific measure (regulation) for rubber food contact materials exists on a European level. In the BfR recommendation XXI on rubber food contact materials, fluoroelastomers or respective starting materials are not listed nor was there ever an application for listing of these substances. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Fluoropolymers (incl. fluoroelastomers) as such 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 minimization perspective. Proportionality and cost/benefit for derogating uses from the restriction are evaluated 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! 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 necessary. We consider that the derogation should also cover articles.  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. |
| **3144** | **Date:** 2020/09/23 17:10  **Content:**  Information on alternatives  Information on benefits  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes | **Comment:**  **-** |
| **Answer to specific info request 6:**  C6 fluorochemicals have become the default choice treatment of automotive textiles such as convertible cartop fabrics. |
| **Answer to specific info request 7:**  Non-fluorinated textile finish options exist, but offer severely compromised soiling resistance. This is of notable concern for outdoor fabrics such as for convertible cartops. |
| **Answer to specific info request 8:**  Transition to non-fluorinated finishes would likely result in reduced lifespan of convertible cartop roofs, requiring more frequent roof replacement. |
| **Answer to specific info request 9:**  Transition in compressed timeframe risks compromised decisions based upon limited end-use application testing in vehicle assemblies. It would also be beneficial to allow more time for development of finishes with improved soiling resistance. |
| **Answer to specific info request 10:**  Application = DWR and soil release finish for cartop fabrics. A reduction in soiling resistance will occur. |
| **Answer to specific info request 13:**  No known internationally recognized methods for chemical analysis of PFHxA. <redacted> has no intent to develop such a method. |
| **Dossier submitter response:**  Please refer to DS response to stakeholder comment number 3140. |
| **RAC Rapporteurs comments:**  Please see our response to comment 3140. |
| **SEAC Rapporteurs comments:**  Please see reply to comment 3140. |
| **3145** | **Date:** 2020/09/23 12:01  **Content:**  Environmental emissions  Information on alternatives  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ANIE Federazione  **Org. country:** Italy | **Comment:**  PFHxA-related substances are reported in Annex XV Restriction proposal report to be used in semiconductor manufacturing step called photolithography. The Italian semiconductor industry currently understands that based on recent supply chain communication some PFHxA related substances, potentially are included in the “non exhaustive list scope” of the “PFHxA, its salts and related substances restriction proposal” can be used as specialty chemicals in photolithography processes. These materials are used in the manufacturing of semiconductors specifically for imaging semiconductor components. These specific semiconductor components are incorporated into many products across many sectors including cameras, medical equipment, video displays, smart phones, automotive, and monitoring instruments. It is currently understood that the total quantity of PFHxA related substances used by semiconductor manufacturing sector in Europe can be less than 200 grams/per year. Unlike typical photolithography processes where the material is removed, some of these substances due to the function of these specialty substances concerned, are remaining within the final imaging semiconductor component.  There is currently no ability to replace the PFHxA its salts and related substances within the time frame currently allocated in the restriction proposal draft text – 7 years. The exemption would need to be in the range of 15 years. The photolithography process is the fundamental basis of semiconductor manufacturing, and therefore the continued access to the PFHxA its salts and related substances containing specialty photolithography formulations is a prerequisite for continuing semiconductor manufacturing and innovation in Europe. Additionally , the industry would request that in this case the exemption should include the semiconductor component.  PFAS containing specialty formulations are used in semiconductor manufacturing essential process called photolithography due to their high technical functionality. The photolithography process is the fundamental basis of semiconductor manufacturing, and therefore the continued access to PFAS containing speciality photolithography formulations is a prerequisite for continuing semiconductor manufacturing and innovation in Europe. There are no PFAS-free alternatives for semiconductor manufacturing photolithography use. Photolithography specialty formulations in semiconductor manufacturing process have transitioned from longer chain per-fluorinated chemistries (PFOS, PFOA) and are now dependent upon the use of other chain per-fluorinated chemistries including in this case ;PFHxA its salts and related substances. These per-fluorinated substances are an essential constituent of the formulation (mixture/preparation), due to their specific surfactants’ properties. There are no general per-fluorinated free substance alternatives that can adequately provide the functional properties for the critical high-tech applications required within the semiconductor manufacturing process. Any development in this area would require first novel chemistries to be identified. Then, after validation of the processes and the products at equipment manufacturers, industrial processing and manufacturing is required at both suppliers’ and semiconductors’ manufacturing premises.  Photolithography is the process which generates the patterns on the silicon wafer forming the circuit after several manufacturing step. Photolithography processes are the most critical process steps of the whole semiconductor manufacturing process flow. Photolithography processes are repeated several times (in the range between 20 and 60, according to technology) with the manufacturing process to build up the layers of features of the transistors and interconnects that finally becomes an array of semiconductors on the silicon wafer.  The specific color filter materials photolithography process pattern will permanently stay on the semiconductor. This is very different to the normal photolithography process where the resist is removed. In the “photo-patterning “, the color resists of Red, Green and Blue are formed on the imaging semiconductor component by the photolithography process and the resist remains on the semiconductor surface. Due to the specific function of these specialty chemicals concerned, those substances are remaining on the semiconductor surface. It can be estimated that the concentration is going to exceed 1000 ppb for the semiconductor component. Therefore, the industry would request that the exemption should include the semiconductor component.  The substance potentially included in the restriction is currently understood to be contained above 1000ppb, but below the threshold for MSDS disclosure. Detailed substance’s identification is not available since directly related to the supplier’s intellectual property.  During the manufacturing process and due to the strictly controlled measures implemented in the semiconductor manufacturing premises all emissions are minimized. Air and Waste water treatments are in place at all locations and, for this specific use, of products dedicated to imaging sector, all spent solvents are sent for incineration.  The sentence reported on the Annex XV Draft Restriction Report: Thus, the possible emissions of PFHxA from the process of semiconductor manufacture and by the subsequent service life of semiconductors is considered as very low, while being vague, over estimates the emissions into the environment in Europe. The total PFHxA related substance consumption is very minimal (at less than < 0.2 kg/per year ) and most of the substances are transferred in the solvent phase (sent for incineration). |
| **Answer to specific info request 7:**  There is no evidence currently that per-fluorinated free substances alternative exists for the replacement of PFHxA its salts and related substances in the specialty chemicals used” specifically for manufacturing imaging semiconductor component. Moreover, in case an alternative is identified, several successive steps must be completed (including qualification and verification of the final component’s behavior) before it can be implemented in an industrial setting. Once the substitute is identified at supplier R&D level, it must be validated at product development phase and in semiconductor industrialization settings. Assuming that the specialty chemicals industrialization process and commercialization may take till 5 years, a typical time line for implementing new materials in the semiconductor manufacturing is typically above 15 years, depending also on the time required for the whole qualification and industrialization of the component in the final product.It is considered that the sentence reported on the Annev XV restriction draft report is very much under estimating the reality for the industry:  “A transitional arrangement of seven years is considered appropriate to give industry sufficient time to substitute and enable industry to continue production in the EU.” |
| **Answer to specific info request 8:**  The use of PFHxA its salts and related substances in specialty photolithography chemicals used in the ”photo-patterning” processes for semiconductor manufacturing for imaging semiconductor components is regarded as being impossible to substitute. There is no fit for purpose alternative available and the manufacturing processes complexity makes evaluation of new chemistry almost impossible. The photolithography process is the fundamental basis of semiconductor manufacturing. In case the PFHxA its salts and related substances containing specialty photolithography chemicals become not available in Europe, the continuation of semiconductor manufacturing and innovation in Europe would be seriously hampered whilst competitors in other regions do not face similar regulations. The Italian Semiconductor Industry, losing its fundamental process would progressively be in the condition of exporting those processes to non European Manufacturing locations therefore reducing innovation, growth and giving competitive advantage to non EU Manufacturing semiconductor Companies.  Despite the fact that there is no prospect of alternatives to PFHxA from material suppliers at present, if the substances are restricted as currently proposed there will a be a potential tremendous negative impact on the very wide range of downstream user industries in which imaging semiconductor components are used. This means the affected category will be camera, mobile phone, automotive/transportation, security, medical, production equipment and management/control system. As automotive/transportation, medical and management/control system requires 20-years repair parts support, the current proposal would have serious consequences for the supply of semiconductor components and for end product maintenance and both would stop in Europe. This current restriction approach of PFHxA for semiconductor components will adversely effect EU social infrastructure. The industry does not find this the appropriate risk management approach or proportionate for 200grams per year used. |
| **Answer to specific info request 9:**  In case perfluoro compound free alternative for the use of PFHxA its salts and related substances in specialty photolithography chemicals used in the manufacturing of imaging semiconductor components is identified in the future, the Industry would need to go for a profound manufacturing process redefinition. Re-definition of the process would potentially imply new manufacturing equipment and relevant investment as a completely new manufacturing line set up.  The identification of an alternative is a lengthy process and devoting resources to replacement activity only would divert resources for innovation would reduce European ability to compete. Once an alternative is identified, it must be validated both during processing and during the work life of the component in the final product . Once validated, both at supplier and at the semiconductor component manufacturing level the industrial process must start. Therefore, the proposed derogation period of 7 years is not enough, and 15 years derogation would be required. In this case =however a deadline with exemption deadline would be more proportionate and appropriate. A Review could be conducted after 12 years. A time limited derogation would imply for the industry to start R&D activities devoted to alternatives search, only, therefore hampering the semiconductor Industry to innovate. |
| **Answer to specific info request 10:**  No substitution would be approved in the semiconductor sector, if not able to maintain the same products quality and or products performance. Example a medical imaging machine |
| **Answer to specific info request 11:**  Yes, on topic. However no generally suitable per-fluorinated substances free alternatives are used in the semiconductor manufacturing processes in photolithography specialty chemicals, or for imaging semiconductor components |
| **Answer to specific info request 12:**  Is opinion of the Italian semiconductor industry that the dossier submitter has not done a concrete cost/ impact assessment. Moreover for the specific use of PFHxA its salts and related substances in specialty ”photo-patterning” chemicals used in the manufacturing of imaging semiconductor components the PFHxA related substances are remaining on the final article (contrary to what it is reported on the draft Annex XV restriction report). In case the derogation is not given the consequences maybe very high in terms of:  1) Loss of billing -  2) Employment reduction  3) Loss of competitive advantage: the EU based semiconductor company may lose the market share of the imaging sector in favor of non EU based competitor  As far as the semiconductor uses are concerned it is our understanding the proposed reporting is not due. Should reporting be completed the semiconductor sector is reliant on their suppliers, there is no direct control on the data to be provided. |
| **Dossier submitter response:**  Thank you for your comment and the information you provided on the use of PFHxA related substances in the photolithography process. DS considered the information you provided when reconsidering the proposed derogation for PFHxA and related substances in semiconductors and is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. DS is especially grateful for bringing to DS’s attention the misconception that PFHxA related substances do not remain in the final product. This was corrected in the Background Document. DS is of the opinion that analytical methods for PFHxA and related substances are generally available. However, DS is aware that extraction methods are still under development. DS considers the restriction proposal proportionate given the fact that PFHxA will remain in the environment for decades and emissions will add up over that time. Effects of PFHxA and related substances might occur with delay and are not limited to the present time, but will also be an issue for future generations. 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. An extensive cost assessment was not possible due to missing information. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available Proportionality and cost/benefit for derogating uses from the restriction are evaluated by SEAC. |
| **SEAC Rapporteurs comments:**  Please see reply to Comment 3087. |
| **3146** | **Date:** 2020/09/23 12:54  **Content:**  Hazard or exposure  Information on benefits  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** EUROFEU  **Org. country:** Germany  **Attachment:** | **Comment:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 5:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 7:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 8:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 9:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 10:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 12:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Answer to specific info request 13:**  Our comments are summarized in attached Document named "200923 ECHA-RAC\_SEAC-EUROFEU\_Restriction proposal PFHxA\_ submission II.pdf" extending earlier submission "EUROFEU-PFHxA-Comments-final-20200512.pdf" |
| **Dossier submitter response:**  Thank you for your contribution to this restriction proposal. DS agrees that a transition to fluorine free foams will be challenging. DS is of the opinion that for most municipal fire brigades a switch to FFF is possible as challenges with the application of FFF only were reported in cases of large fires of liquid fuels. Those usually only occur within facilities that have their own firefighting installations. For those cases DS anticipated proposing 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. DS agrees, that a transition from AFFF to FFF is expensive but so is the remediation of contaminated soil or water. Regarding the availability of AFFF DS had the proposed derogation checked by legal experts and it was stated that also manufacture, placing on the market and import are covered by the proposed derogations. With regard to the analytical methods for detecting PFHxA and related substances DS is of the opinion that they are available. However, DS is aware that extraction methods are still in development.  DS thanks you for the cost data. However, DS does not agree with your conclusions on proportionality. First all replacement costs are one-off costs. Over 20-50 years the cost to society is considerably smaller. Secondly, the example described in your comment does not support socio-economic estimates as long as representativeness remains completely unknown. Public consultation comment 3158 provides detailed data on AFFF users in Germany. Although representativeness of this data is unclear, too, it demonstrates the large variance in use patterns in Germany. Comparable data for the EU is not available.  Additionally, your conclusions do not factor in the impact of the amended EU-POP-regulation (EU)2019/1021 and the potential for users to substitute early.  Regarding incineration capacities DS refers to the recent report by ECHA and DG Env on firefighting foams which comes to the conclusion that most likely capacities will be sufficient.  DS appreciates the provided data regarding the environmental emissions. This information was considered in amending the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for your comment. 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 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. A time-unlimited derogation for AFFFs in defence applications has also been proposed by the Dossier Submitter. RAC evaluated the proposed derogations from an emissions/emission minimization perspective (proportionality and cost/benefit are evaluated by SEAC).  Thank you for your information related to emissions which has been considered by RAC.  Regarding analytics, RAC considers testing at the proposed threshold of PFHxA of 25 ppb to be feasible, based on the input by ECHA in the consultation (comment 3115) although in the lower range of the reported LOQs for this matrix (Firefighting Foam ~ 20 - 50 μg/kg). A validated method to detect 29 PFASs (including PFHxA) to a limit of 10 ng/ml (ppb) in foam concentrates has been developed by the Fire Fighting Foam Coalition (FFFC) together with SGS AXYS Analytical Services Ltd. (AXYS) (Consultation comment 3010). RAC recommends developing a standardised method for analysis of PFHxA in firefighting foams. |
| **SEAC Rapporteurs comments:**  Thank you for these additional comments! We note the practical challenges of a 5-year transition period for the industry and we have pointed those out in the draft opinion. We agree that it is important that AFFFs will be available in practice for the derogated uses. We welcome that, according to the Dossier Submitter, this should indeed be the case. |
| **3147** | **Date:** 2020/09/23 12:10  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Electronics and Information Technology Industries Association  **Org. country:** Japan | **Comment:**  Display Device Environment Committee is a committee under Display Device Board of JEITA (Japan Electronics and Information Technology Industries Association), members of which are display device manufacturers in Japan. We are working on various environmental issues common to display device industry.  We understand importance of regulation for PFHxA. But as it was found by recent survey that PFHxA related substances remain in display devices, etc., we request exemption as follows.  Request for exemption  We request exemption of products using display devices, etc.  Here, display devices, etc. is special term defined as display devices and other devices which use thin-film transistors (TFT) formed on glass or plastic substrate.  This request aims to exempt all the products in which PFHxA related substances possibly remains, as explained later in “Specific Information Requests 1: Additional uses”. Therefore, more explanation will be done there. |
| **Answer to specific info request 1:**  a. Description of the use  PFHxA related substances (hereinafter called PFHxA RS) is used as surfactant of some insulating material (mixture) for insulating layer of display devices, etc (metioned later). This material is solidified and remains in display devices, etc. and then in final display products. Note that though called insulating layer, its function is not limited to insulation and can include planarization, protection (over coat), pixel separation and so on.  Source of this information is an answer of one manufacturer in a recent survey to resist manufacturers done by JEITA. As this survey must have done anonymously, name of manufacturer, material and PFHxA RS etc. are not specified. According to the answer, concentration of PFHxA RS in the material is over 1000ppb. At solidifying process, as solvents are usually more volatile than PFHxA RS, its concentration is expected to become higher for solidified layer. Thickness of insulation layer is usually of the order of 10 micro meter. Thickness of display device, etc. is of the order of 0.1 to 1 mm. Supposing denominator of concentration is weight of display device, etc. (elemental article comprising complex product), concentration of PFHxA RS can be over 1000 ppb.  Display devices includes Liquid Crystal Display (LCD) and OLED (Organic Light-Emitting Diodes) Display.  Recently non-display devices using common process, material to display devices has appeared and is expected to extend their market. Some non-display device uses same principle as touch sensing function built in recent display devices to realize sensor such as fingerprint sensor, biometric sensor and so on. There will be other possibility for non-display device. Then extended definition for display devices, etc. limited by common feature using TFT on substrate is introduced in the “Request for exemption”.  Range of products using these display devices, etc. are very wide and essential to our society, as shown below.  TV, Notebook PC, PC monitor, automotive display, medical display, display for industrial use, smartphone, tablet, wearable display, digital camera, goggle for VR (Virtual Reality), security product using fingerprint sensor, healthcare product using biometric sensor, etc.  Another relating information exists in already submitted comment No.3056 by DIC. According to this, PFHxA RS are used as surfactant for materials for Flat Panel Displays(FPD). They are sold to makers located in Japan, Korea, Taiwan and China, which are all the limited countries currently manufacturing the display devices. This showed that the use of PFHxA is not minor but general.  Moreover, it is shown that other uses as coating solutions for polarization films exist, which cannot be caught by the survey explained above.  DIC is requesting exemption of FPD, which means some of the material is possibly remained in final products with concentration over 1000ppb.  Note that though, in general, term resist means material used temporally as a mask for photolithography and then removed, photosensitive material used to form layer, such as insulating layer, color filter layer is also sometimes called resist. So it should be avoided to suppose that material termed resist does not remain in the products.  b1. Quantities used  Display devices, etc. are manufactured in only Korea, China, Taiwan and Japan. Annual total area of substrate for display device manufactured in these countries is of the order of hundred km2. Assuming the total thickness of the layer using PFHxA RS is 10 micrometer, specific weight is 1, weight of the layer is of the order of a thousand t. Assuming concentration of PFHxA RS remained in layer is 1000ppb, weight of PFHxA RS is of the order of 1 kg. Ratio of products manufactured in or imported to EU will be 1 order below. Then annual weight of PFHxA RS remained in the products is of the order of 0.1 kg.  Although we do not have detailed statistics on final products, order estimation as above shows that PFHxA RS in requested exemption is rather small in overall use of PFHxA RS.  Example of products using display devices, etc. are already shown in a). As PFHxA RS is used in all the countries manufacturing them, restriction to products without exemption will lead to very serious impact to EU. Though information for detailed socio-economic analysis is lacking, we think restriction to the products using display devices, etc. is not acceptable.  b2. Information regarding the potential risks to the environment  Over the display devices, etc., there exist a cover glass or film. Therefore, in usual use of the products, emissions of PFHxA RS are essentially zero.  Wastes of the products are basically appropriately treated by relevant law. They are treated at high temperature to PFHxA RS be decomposed or landfilled to controlled disposal site　and highly isolated from environment. Actually, some of the products will be inappropriately disposed. But, as the PFHxA RS is confined in solid layer with low solubility, their emission to environment is expected to be very small.  Considering the order estimation shown in the b1 and the information above, though detailed quantitative analysis cannot be shown, we think that risks to the environment increased by the requested exemption is very small. |
| **Answer to specific info request 9:**  To date, we have no specific information on alternative for the material explained in 1. But in general, problem with alternative in display devices is basically common to semiconductor or other electrical device and is explained in detail in already submitted comment No.2989, 3062. |
| **Dossier submitter response:**  Thank you very much for your additional comment on the restriction proposal. DS was not aware of your application of PFHxA and related substances in the manufacture of flat panel displays. DS considered the information you provided when reconsidering the derogation proposal for semiconductors and electronic devices and is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed time-limited derogations for PFHxA and its related substances in fluoropolymers for coating of electronic devices as well as for semiconductors. RAC evaluated these derogation requests from an emissions/emission minimization perspective. Proportionality and cost/benefit for derogating uses from the restriction are evaluated by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and the information on this use. It is important that 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. Overall, the information gained remained scarce. 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). |
| **3148** | **Date:** 2020/09/23 10:24  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** FUJIFILM Electronic Materials Co.,Ltd.  **Org. country:** Japan  **Attachment:**  <redacted> | **Comment:**  FUJIFILM Electronic Materials Co., Ltd. and our group companies (we call “FFEM”)　is a supplier of the photo-patterning materials to form the Color Filters (CF: Red, Green and Blue, and other colors, such as Yellow, Cyan, Magenta, Black, and Infra-red) and planarization films on the image sensor (IS) devices. These products are also applied to micro display (MD) devices. Our products are being sold in the world including European market.  FFEM is now using a surfactant containing PFHxA related substance for the most photo-patterning products for keeping the high quality of IS and MD devices.  And these photo-patterning materials, containing the PFHxA related substance remain on the final products as CFs, or planarization films, on IS or MD devices after the photo-patterning process.  Therefore, the restriction of PFHxA for semiconductor products will be strongly impacted for the global IS and MD market.  This time, FFEM fully supports the public comments (No.3062) that were submitted from JEITA to ECHA on July 17, 2020.  By referring to the comments from JEITA, we submit the comments as follows.  Currently, 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 have informed that they did not register CAS number in some cases. Therefore analytical institutions cannot perform a quantitative analysis due to the absence of standard samples and PFHxA content amount cannot 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 are established.  Threshold and Analytical method:  However, no information is available on the official analytical method for PFHxA at 25 ppb/1 ppm.  Therefore, it is inappropriate to set the threshold value for PFHxA without establishing a content analysis method, and absence of PFHxA measured content information may cause huge confusion to the whole supply chain when lower streams of the supply chain require the information.  Where no alternative is available:  Although it is recognized in Annex XV that there are 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 the semiconductor 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:  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“.  However, the PFHxA containing materials remains in the final product in the following cases;  CMOS IS or OLED MD has three color filters (Red, Green and Blue, or Yellow, Cyan, and Magenta) which are formed by photo-patterning process and remain in the products, and these filters contain PFHxA as a surfactant. Some planarization film for IS or semiconductor devices also contain PFHxA based surfactant and remains in the products.  Thus we strongly request exemption for semiconductor products (including compound semiconductor) itself and no-time-limited derogation for the various use of semiconductor processes such as process agents for the photo-patterning and photolithography process. |
| **Answer to specific info request 1:**  Please see the confidential attachment. |
| **Answer to specific info request 7:**  Please see the confidential attachment. |
| **Answer to specific info request 8:**  Please see the confidential attachment. |
| **Answer to specific info request 9:**  Please see the confidential attachment. |
| **Answer to specific info request 10:**  Please see the confidential attachment. |
| **Answer to specific info request 12:**  Please see the confidential attachment. |
| **Answer to specific info request 13:**  Please see the confidential attachment. |
| **Dossier submitter response:**  Thank you for your comment and the information you provided on the use of PFHxA related substances. DS considered the information you provided when reconsidering the proposed derogation for PFHxA and related substances in semiconductors and is proposing a derogation for the use of PFHxA and related substances for semiconductors and semiconductor related equipment for twelve years. DS is especially grateful for bringing to DS’s attention the misconception that PFHxA related substances do not remain in the final product. This was corrected in the Background Document.  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.  However, DS is aware that extraction methods are still under development. Furthermore, DS would like to state, that SVHC identification is not an issue in regard to the restriction proposal but the risks which are not adequately controlled. 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. Also, DS is not responsible for the information availability along the supply chain. This is the task of the registrant of a substance / manufacturer / importer of articles and the subsequent downstream users. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Proportionality and cost/benefit for derogating uses from the restriction are evaluated 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! 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 respective transition period is likely not proportionate and therefore supports a transition period of 12 years as well. |
| **3149** | **Date:** 2020/09/23 06:37  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** DIC Corporation  **Org. country:** Japan  **Attachment:** | **Comment:**  Please see the attached file. |
| **Answer to specific info request 1:**  Please see the attached file. |
| **Answer to specific info request 8:**  Please see the attached file. |
| **Dossier submitter response:**  Thank you for your comment and the information you provided on the additional uses of PFHxA related substances in semiconductors. DS considered the information you provided when reconsidering the proposed derogation for PFHxA and related substances in semiconductors. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Proportionality and cost/benefit for derogating uses from the restriction will be assessed by SEAC. |
| **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 respective transition period is likely not proportionate and therefore supports a transition period of 12 years as well. We note that claims were made 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 would be desirable. |
| **3150** | **Date:** 2020/09/22 11:27  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Eurovent Association  **Org. country:** Belgium  **Attachment:** | **Comment:**  **-** |
| **Answer to specific info request 9:**  High efficiency air filters for HVAC industry. Expected transition period up to 10 years. Deterioration of filters performance in terms of energy efficiency. Increased energy consumption in ventilation, air-conditioning and industrial applications resulting in higher CO2 emission. |
| **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.  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. RAC is aware that C6-fluorosurfactants are effective for water and oil repellency. The Dossier Submitter has proposed filtration and separation media to be derogated from the restriction. Also, fluoropolymers (incl. fluoroelastomers) 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. These proposed derogations have been evaluated by RAC from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction will be done by SEAC. |
| **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 as requested by the Filtration and Separation Coalition and supported by you. Considering all information received in the consultation on the dossier we are currently considering supporting the derogation. |
| **3151** | **Date:** 2020/09/21 23:07  **Content:**  Information on alternatives  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Information on recipies and volumes of membranes used per year included. Intellectual property and commercial interests have to be protected. | **Comment:**  PFHxA, its salts and related substances are widely used for the hydrophobic and oleophobic surface treatment of polymer membranes and other filter materials for use as venting units for automotive and transportation applications (sensors, gear boxes, head lamps, batteries, electrical motors, connectors, etc.), for packaging solutions for degassing hazardous liquids (acids, caustic solutions, agricultural fertilizers, surfactants, etc.) and liquid foods, for cell culture equipment, for diagnostic cartridges for rapid micro diagnostic solutions (p.e. Corona PCR testing solutions), for medical devices and various industrial applications. For most of these products it is essential to have a surface treatment stable against aggressive chemicals and repellent to water based liquids as well to oil based liqiuds. The content of PFHxa and related products in hydrophobic / oleophobic membranes treated with PFHxA containing systems normally is found in a range below 100 ng/g.  For water based liquid repellency alternativ solutions without PFHxA may exist for some applications, especially in the field of textile treatment. For polymer membrane surface treatment until now now systems without PFHxA were found to replace the PFHxA concerning performance parameters (water entry pressure requested by applications). The oleophobic treatment of polymer membranes is not possible without systems containing fluorinated groups shorter than PFHxA and related substances. Alternativ solutions for metals and glass based on nano particle deposition on the surfaces are not applicable due to low binding forces of the nano particles to the surfaces. Especially for medical applications there is a high risc of pollution by nano particles removed from the surfaces, especially for applications with blood contact.  That's why it is necessary to allow the use of PFHxA for described applications in automotive, life sciences and analytics, medical devices, packaging of hazardous liquids and industrial venting fields in applicable concentrations. |
| **Answer to specific info request 1:**  a) PFHxA and related substances are in use for surface treatment of polymer filters and membranes to achieve hydrophobic and oleophobic properties. These PFHxA relating systems mostly contain teleomeric fluorinated side chain polymers covalently bound to the surface of the base polymer.  The hydrophobic and oleophobic membranes are used for venting applications in automotive and transportaion field where water and oil containing liquids have to be repelled to protect eletronic and electrical parts. Venting of batteries for electrical cars and bikes is realized by membranes also.  In the fields of biological and medical analytics and diagnostics as well as of life sciences several systems need sterile venting by membranes to protect them from bacterial pollution. Sterile venting is necessary also for many medical devices, for example tube systems for dialyzer units, surgery systems and ostomy bags.  Packaging solutions with oleophobic membranes in container closures prevent environment pollution by degassing hazardous liquids. Also liquid foods often requires packaging solutions with integrated venting membranes.  Industrial and consumer good applications often require membrane venting to protect electronical and electrical parts and products against moisture and oily liquids. There is a wide range of applications from smart phones to outdoor lamps and devices to house hold goods as electrical tooth brushes and many more. |
| **Answer to specific info request 7:**  Instead of fluorinated side chain polymer systems analogous systems with non fluorinated side chanes with polymer backbone are available. These systems do not allow an oleophobic treatment of polymer membranes and filters due to their chemical nature. We found that these non fluorinated side chain systems are not able to fulfill application requirements (water entry pressures and chemical substance repellency).  Systems with nano particles used for hydrophobic and oleophobic surfaces of glass, metal and some polymers are already on the market. Since the nano particles are mostly to big inner surfaces of filters and pore walls cannot be coated with these systems. Furthermore most of the nano particles are not connected to the surfaces via covalent binding. So the release of nano particles to environment and human body cannot be avoided. |
| **Answer to specific info request 8:**  The use are all applications described in specific info request 1 answer.  Especially all membrane venting applications requesting oil and related liquid (also biological liquid) repellency will not be possible anymore with dramatic consequences to the use of electronic and electronical parts in automotive and transportation, industry and household devices as well in medical devices requiring sterile venting. Also the safe transportation of degassing hazardous liquid goods will be affected very negative with huge danger of environment pollution.  The alternative fluorine free systems on the market are not able to create oil repellent membrane surfaces (also inner surfaces) due to their chemical nature or the size of nano particles. Since nano particles are not connected to the surfaces environmental pollution and transition into human body is possible. |
| **Answer to specific info request 10:**  All uses requiring oil repellency will not be possible with non fluorinated systems.  For applications requiring just hydrophobic properties where might be solutions in principle. But these systems were not able to fulfill technical application and protection requirements (water entry pressure of membranes and chemical substance repellency). So fare for a lot of current membrane venting applications in automotive and transportation, industry and house hold as well as in life science and diagnostics and for medical devices where will not be an adequate technical solution.  If some applications would allow hydrophobic properties only change of system would require development , testing and validation of new systems and products. Time and costs expences for these processes cannot be estimated. From our experience such processes can take 3 and more years, even for medical products. |
| **Answer to specific info request 11:**  Yes we are. Shorter fluorinated side chains will significantly reduce the oleophobic grade of the membrane surfaces and the water entry pressure as well. Summerized: shorter fluorinated side chains will reduce the venting membrane performance and make it very hard to fulfill requested technical parameters for many applications. |
| **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.  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. 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, filtration and separation media and medical devices. RAC evaluated these proposed derogations, as well as requested derogations from stakeholders in this consultation, from an emissions/emission minimization 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 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 are currently considering supporting the derogation. In case the formulation of the derogation text is considered not appropriate by stakeholders, more information on the use, the related costs, alternatives and suggestions of a more suitable wording could be sent in the consultation on the SEAC draft opinion. |
| **3152** | **Date:** 2020/09/22 17:47  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  **-** |
| **Answer to specific info request 1:**  PFHxA related chemicals are used for hydrophobic/oleophobic treatment of filtration and separation media that are used in filters intended for equipment in i.e. following applications:  • Gas turbines  • Industrial dust removal (i.e. food, polymers, pigments, chemicals, metals and minerals)  • HVAC  • Home and professional vacuum cleaners  • Medical applications  • Fuel filtration  • Cabin air Filtration  In all of the above applications C6 fluorotelomer chemistry provides filters with superior properties like  • Durable water and oil repellency due to unique low surface tension of fluorine to ensure safe operation  • Good cleanability of filter surface which leads to extended lifetime  • Reduced pressure drop even in difficult operating conditions also increases lifetime and therefore reduces waste due to deferred filter exchange.  • Extreme high efficiency, with an absolute smooth surface, where no particles will be able to penetrate pores, nor in any other way get stuck and be able to contaminate.  Apart from these properties C6 fluorotelomer treated filter/filtermedia ensure  • Higher productivity for system operators due to longer filter life / less downtime  • Resistance against microbiological pollutants  • Better chemical resistance  • Compatibility with other chemistries, final applications, and processes like EC1935; FDA; EN1186-2 & 3; and several others  • Glue-repellency and controlled wicking of compounding material during manufacturing |
| **Answer to specific info request 2:**  Filtration and separation media manufacturers add C6 fluorochemistry during the pulping step or in the chemical finishing treatment, in both cases in very small amounts. In Addition media plants usually have a closed water treatment therefore, PFHxA releases to the environment from the production process are expected to be either non-detectable or very limited.  Moreover, it is worth noting that C6 is well embedded in the filtermedia matrix and, therefore, no environmental releases are expected at the stage of filter manufacturing and during use of the finished equipment.  At end of life, filters (especially in Germany) are usually disposed by incineration. Such incineration plants are again equipped with filter systems that ensure the removal of any harmful compound that could occur during the well observed incineration process. Therefore we consider the potential of PFHxA release in the whole loop of the filtration application as very low. |
| **Answer to specific info request 8:**  As discussed in the Filtration coalition’s contribution, there are no available alternatives able to provide the required performance levels of hydrophobicity and oleophobicity and other properties. If adopted in its current form, the restriction proposal would not allow the filtration industry to ensure the required levels of performance. In turn, this would pose significant risks in terms of safe operations of applications relying on high performance filtration and separation media. |
| **Answer to specific info request 9:**  Any changes in filtermedia and respectively filters will require the requalification of filters themselves as well as the equipment in which they are integrated.  Please see below a short, non-inclusive list of the types of sectoral performance standards that these materials are subject to:  • ISO 29463-1: 2017 (High efficiency filters and filter media for removing particles from air)  • EN1822-1:2019  • ISO 16890-1:2017 (Air filters for general ventilation)  • EN 60335-2-69-AA (Professional vacuum cleaner) |
| **Answer to specific info request 10:**  An absence of derogation for filtermedia / filter applications will result in a supply interruption of filters within the current technical specifications until adequate alternative candidates are identified and products have completed the subsequent requalification process.  This will not only affect a filter supplier but also major customers that use i.e. filter for power generation in gas turbines, filters for removal of harmful substances in industrial processes or professional vacuum cleaners. Even if the qualification of alternatives would come to a positive solution the requalification of new products could implement a delay in supply.  Together with the current pandemic situation the economic burden will put a risk on manufacturing facilities located in the EU. If the PFHxA restriction will not be a global topic there is the danger of transferring manufacturing capacities to non EU countries and open a grey market for imports from other parts of the world where filters can be produced with available high performance materials. |
| **Dossier submitter response:**  Concerning home vacuum cleaners: DS was not aware that SFP treatment of filters for home vacuum cleaners was necessary.  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.  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. RAC is aware that C6-fluorosurfactants are effective for combined water and oil repellency. The Dossier Submitter has proposed filtration and separation media to be derogated from the restriction. RAC has evaluated this derogation request from an emissions/emission minimization perspective. Evaluation of proportionality and cost/benefit of restricting or derogating a use from the restriction are done by SEAC. |
| **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 currently consider supporting the derogation. |
| **3153** | **Date:** 2020/09/21 18:11  **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:**  A socio-economic analysis and supportive documents are forwared as confidential attachments to support 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:**  please see socio-economic analysis and supportive documents (confidential attachment) |
| **Answer to specific info request 8:**  please see socio-economic analysis and supportive documents (confidential attachment) |
| **Dossier submitter response:**  Thank you for providing additional information on the properties of the substances used and the socio-economic analysis. |
| **RAC Rapporteurs comments:**  Thank you for the additional information. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and the socio-economic analysis provided! This is very useful for the evaluation of the necessity of derogating.  We are currently considering supporting the derogation of medical devices proposed by the Dossier Submitter. Considering the wideness of the derogation now proposed and that there are applications that have not been assessed in detail, we consider that the situation should be re-evaluated at a later point. We note that you have already compiled a lot of information useful for that assessment. Some updating of the information at least relating to the availability of alternatives and realistic substitution timelines may be needed for an assessment later on. |
| **3154** | **Date:** 2020/09/21 18:57  **Content:**  Environmental emissions  Information on alternatives  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Switzerland  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comment:**  **-** |
| **Answer to specific info request 1:**  Please refer to the attached document. |
| **Answer to specific info request 8:**  Please refer to the attached document. |
| **Dossier submitter response:**  Thank you for providing additional information regarding the level of C6 fluorinated polymers in coated internal watch parts and on Stearic acid as an alternative to the used fluorinated polymers, which is in your view not suitable. |
| **RAC Rapporteurs comments:**  Thank you for the additional information. |
| **SEAC Rapporteurs comments:**  Thank you for the information. Please see reply to Comment 2976. |
| **3155** | **Date:** 2020/09/18 16:02  **Content:**  Scope or restriction option analysis  Information on alternatives  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Dafo Fomtec AB  **Org. country:** Sweden  **Attachment:** | **Comment:**  **-** |
| **Answer to specific info request 1:**  If or when there will be a restriction of PFHxA this will mean the end of fluorine containing foam in general in Europe. There is a huge market outside EU (e.g. Middle East and Asia) that is supplied by Eurpoen based foam manufacturers. These markets have not yet any discussions going on regarding regulation of PFHxA. A regulation in Europe will mean that it is not possible for European based manufacturers to supply these markets anymore. This will put them in a difficult situation where they are forced to buy from less serious manufacturers from their regions that have products containing both PFOS and PFOA. |
| **Answer to specific info request 5:**  a) Have you already shifted from PFHxA, its salts and/or related substances to fluorine-free foams or are you planning to shift to those alternative foams?  First of all, a regulation of PFHxA will mean a ban to all fluorine containing foams. Yes, partly. In application areas where it is possible we offer FFF:s. Primarily, the installation must be protected with a foam that is capable of handling the risks. FFF:s are well known to have serious problems with fuel compatibility that is not covered by international standards. The test fuels normally used are heptane, acetone, and isopropyl alcohol. For AFFF:s it is sufficient to test with these since they give good picture of fire performance due to the AFFF:S are not as sensitive to different fuels. For FFF:s the picture is completely different due to fuel intolerance and especially on polar solvents. Hence, the application and the risk assessment with the customer decides what foam type to use.  If yes:  • In which area did you or are you planning to shift to fluorine-free foams (e.g.: seagoing units, storage of fuel)?  Full swing can be made with fire fighting departments, training with foam, and testing and commissioning of foam systems. Furthermore, foams for class A fires, such as wild fires FFF:s are recommended to be used. In certain sprinkler applications where the FFF has been evaluated with the used sprinkler heads and the fuel to protect.  How long did the transition to fluorine-free foams take you or how long will it approximately take to perform the transition?  The development of FFF:s to the point where we are today is about 8-10 years of active R&D. Today’s FFF:s are fully acceptable in certain well defined application areas, but in other more demanding areas they do not have the performance needed. R&D-work continues and we are getting improvements all the time, but have FFF:s that are fully capable of replacing AFFF:s will take up to 10 years still.    • What are/were the challenges when performing such a transition? E.g., when using the same equipment, are the residues of PFHxA, its salts and/or related substances in the equipment posing a technical challenge in relation to the concentration limit proposed?  Fixed systems needs to be assessed in detail and upgraded to use FFF:s. It will be common to replace the whole system with a completely new installation that is designed to work with the increased application densities of foam that will be needed.    Find suitable FFF:s that are more fuel tolerant and work with a broad spectra of different fuel types.    Make sure that the industry is doing their risk assessments thoroughly and go for the safe solution and not trust all you hear. The problem here is that the European standards for firefighting foam installations is very poor and basically makes you favors a poor solutions just because it does not cover testing on different fuel types but just give the recommendation that the foam manufacturer shall give the proper recommendations and those are mainly based on fire tests that are not very relevant.    If no:  • Please, specify whether you have moved from PFHxA, its salts and/or related substances to a foam containing other fluorinated substances.  No, you cannot change to other fluorinated substances. If you move away from PFHxA the only alternative is go fluorine free. And fluorine free foams are capable of providing safe solutions with current technology and design standard for fixed extinguishing systems.    Please, provide information on the volumes and value of the stocks you may have on fluorinated foams in general and more specifically on foams containing PFHxA, its salts and/or related substances.  This is not a relevant question to us as a foam manufacturer. But we as a manufacturer have quite large stock of fluorinated surfactants containing PFHxA    • Please, provide information on the volumes of fire-fighting foams containing PFHxA, its salts and/or related substances currently in use in your equipment? Please, provide any information on the handling, release mitigation and waste management instructions relevant for estimating the releases and evaluating the socio-economic impacts.  This is not a relevant question to us as a foam manufacturer. But the socio-economic impact can be severe if a hasty and non-fact based transition to fluorine free foams is pushed through without having proper design standards that reflects the performance of fluorine free foams.    Why did you decide not to shift to fluorine-free foams or, more specifically, to foams free of PFHxA, its salts and/or related substances?  It impossible to change in all kinds of installations due to lack of proper design standards    • What changes are necessary to allow the transition to fluorine-free foams from PFHxA, its salts/related substances? Are you already taking measures to achieve such changes? How long will it take until respective measures are in place to allow a transition to fluorine-free foams?  Changes to design standards and test methods that will provide safe data enabling the installation of system using fluorine free foam that will actually function.    b) Hand-held fire extinguishers: please, provide information on the volumes and concentrations of PFHxA, its salts or related substances you use in the extinguishers, the use sectors using extinguishers containing these substances, current handling, release mitigation and waste management instructions, and any other information which would be relevant for estimating the exposures and the socio-economic impacts of the proposed restriction?  Handheld extinguishers with fluorine free foams generally have a performance are so reduced in comparison with AFFF-based extinguishers that it is a question of it is even worth having them. As an example, a 6 liter extinguisher using AFFF can easily extinguish a fire of 7,3 m2 but a fluorine free can barely extinguish a fire of 3,5 m2.  c) Are you using aqueous film-forming foams (AFFF) containing PFHxA, its salts and/or related substances for training purposes? If yes, please specify why.  es, there are no fluorine containing foams that does not contain PFHxA. We are using AFFF because a transition to fluorine free foams is impossible due to lack of adequate design standards enabling a safe installations of systems using fluorine free foam that will actually function.  d) Are you using AFFF containing PFHxA, its salts and/or related substances for testing purposes? If yes, please specify why.  No not generally, all R&D-activities today are focused on developing fluorine free foams in order to improve its properties. However, some fire testing with fluorine containing foams are conducted now and then for customer related issues. In such cases the fire tests are conducted in very controlled conditions were all fire water is collected and handled according to local regulations. |
| **Answer to specific info request 8:**  The lack of design standards that is based on up to date test data on fluorine free firefighting foams makes it impossible to safely design extinguishing system. The design parameters in current standards is not based on actual test data. Tests performed by us and others shows that when adapting the current standards in their curent format will lead to non-functional system designs. |
| **Answer to specific info request 9:**  Fluorine free foams can today be used at municipal fire brigades in non-industrial firefigting situations. They can adjust their equipment and tactics to accomodate for the lower performing fluorine free foams. Also training should be accomplished with fluorine free foam, this is more or less in practice today. |
| **Dossier submitter response:**  Thank you very much for your contribution to this restriction proposal. DS is of the opinion that a restriction of the use of PFAS containing foams could in the long run also have a positive impact outside of Europe by giving examples, that show, that a transition is possible. DS agrees that there are some critical applications for which the use of AFFF is still necessary and that no drop-in alternative is available right now. 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[[2]](#footnote-2)) and received information on successful transitions to fluorine free foams, e.g. from the Danish royal air force[[3]](#footnote-3) or Statoil in Norway having transitioned to FFF foams throughout all of its operations[[4]](#footnote-4). DS anticipated proposing a 12-year derogation for the use of PFAS containing foams on large liquid fuel fires 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.  The Dossier Submitter notes the information with regard to exports and the associated concern that regrettable substitution might take place in some regions. Additional information from European manufacturers on export quantities would have been helpful. |
| **RAC Rapporteurs comments:**  Thank you for your comment. Although FFFs have proven to be functional alternatives to AFFFs for many applications, RAC is aware that for certain applications AFFFs cannot yet be replaced, and time-limited and unlimited derogations have therefore been proposed by the Dossier Submitter for defence applications and for fighting fires in large tanks. RAC evaluated the proposed derogations from an emissions/emission minimization perspective. Proportionality and cost/benefit analysis for restricted and derogated uses are performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and for the introduction into test standards.  We agree that more research and development is needed to ensure that appropriate FFF are available for all market sectors and fire scenarios. We also see that the European foam design standard need further development to adapt it to FFFs.  We consider that an extended transition period will be needed for firefighting foams for class B fires. However, due to the type of use and the level of potential emissions, this period should be as short as possible from a risk-point of view. Based on all the information available we expect that alternatives suitable for the rest of the scenarios problematic but not covered by the tank fire exemption will be available within 5 years and therefore we consider supporting that as the length of the period. We also highlight that the performance level of FFF in applications covered by the 5 years transition period should be reviewed during the transition period, before the restriction starts to apply. As to the tank farm derogation, having considered all information received in the consultation we are currently considering suggesting that tanks exceeding 400 m2 in size and their bunded areas would be covered by the derogation. |
| **3156** | **Date:** 2020/09/18 16:47  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Camfil AB  **Org. country:** Sweden  **Attachment:**  <redacted>  **Privacy comment:** Protection of our commercial interests, as the document contains non-publicly available details about our company. | **Comment:**  Camfil values the opportunity to submit comments to the ongoing public consultation on the REACH restriction proposal for PFHxA, its salts and related substances.  Camfi shares the concerns identified by the Filtration and Separation Coalition (submission number 3014) regarding the use of C6 fluorotelomer chemistry for filtration and separation applications. We therefore wish to express our support to their derogation request:  "Paragraphs 1 and 2 shall not apply to filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellancy." |
| **Answer to specific info request 1:**  1. Description of the use  The Camfil Group uses filtration and separation media in the manufacturing of air filters intended for equipment in the following applications:  • Healthcare including hospital isolation stations as well as operation theaters  • Cleanrooms in life science, food & beverage as well as microelectronics & optics  • Nuclear power plants  • Biosafety laboratories  • Gas turbine applications  • Industrial dust control  • General ventilation of commercial & public buildings  • Protection of cultural heritage in museums, libraries and galleries  • Transportation incl. railway, airplanes, cruise ships and automotive industry  C6 fluorotelomer chemistry provides air filters with the following properties:  • Durable water and oil repellency due to unique low surface tension of fluorine;  • Glue-repellency and controlled wicking of compounding material;  • Reduced pressure drop even in difficult operating conditions, extending the lifetime of filters and ensuring optimal operating conditions; and  Apart from these properties, C6-treated filters ensure:  • High dust holding capacity;  • Resistance against microbiological pollutants;  • High mechanical strength ;  • High filtration efficiency;  • Compatibility with other chemistries, final applications, and processes; |
| **Answer to specific info request 2:**  Filtration and separation media manufacturers add C6 during the pulping step or in the chemical finishing treatment, in both cases in very small amounts. Therefore, PFHxA releases to the environment from the production process are expected to be either non-detectable or very limited.  Moreover, it is worth noting that C6 is well embedded in the filter matrix and, therefore, no environmental releases are expected at the stage of filter manufacturing or during use of the finished equipment. |
| **Answer to specific info request 8:**  1. Absence of suitable alternatives  As discussed in the coalition’s contribution, there are no available alternatives able to provide the required performance levels of hydrophobicity and oleophobicity and other properties. If adopted in its current form, the restriction proposal would not allow the filtration industry to ensure the required levels of performance. In turn, this would pose significant risks in terms of safe operations of applications relying on high performance filtration and separation media.  2. Requalification process  The abovementioned properties are not the only parameter to consider. Any changes in filters will require the requalification of filters themselves as well as the equipment in which they are integrated.  Please see below a short, non-inclusive list of the types of sectoral performance standards that these materials are subject to:  • DIN 1946-4, Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care  • ISO 14644, cleanrooms and associated controlled environments  • EN17141:2020, Cleanrooms and associated controlled environments - Biocontamination control  • ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control  • ASME AG-1-2019, Code on Nuclear Air and Gas Treatment  • KTA 1401, General Requirements Regarding Quality Assurance (Nuclear)  • EU GMP Annex 1, Manufacture of Sterile Medicinal Products  • FDA, Aseptic Processing guide  • DIN 10505, Food hygiene - Ventilation equipment for sales arrangements of foodstuffs - Requirements, testing  • VDI 6022 - Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)  • EN ISO 846, Plastics - Evaluation of the action of microorganisms  • EN ISO 29461, Air intake filter systems for rotary machinery  • EN ISO 16890, Air filters for general ventilation  • ISO 16891, Test methods for evaluating degradation of characteristics of cleanable filter media  • EN ISO 29463, High-efficiency filters and filter media for removing particles in air  • EN 1822, High efficiency air filters (EPA, HEPA and ULPA)  • VDI 3803-4, Air-conditioning - System requirements - Air filter systems, (VDI Ventilation Code of Practice) |
| **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.  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. RAC is aware that C6-fluorosurfactants are effective for combined water and oil repellency. The Dossier Submitter has proposed filtration and separation media to be derogated from the restriction. RAC evaluated this derogation request from an emissions/emission minimization perspective.  Also, 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 minimization 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 filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellence as requested by you and the Filtration and Separation Coalition. Considering all information received in the consultation on the dossier we are currently considering supporting the derogation. |
| **3157** | **Date:** 2020/09/18 12:58  **Content:**  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Netherlands  **Company name confidential:** Yes | **Comment:**  Dirt and oil resistance is very important to make outdoor fabrics weather resistant.  An alternative product for FC is not available, even though we would like to have this.  Without FC we have no product. If FC use is not (anymore) allowed,  we will have to stop production and deliveries. We then have no right to exist.  There will also be consequences in the supply chain because we are market leaders in a number of tent and tent market segments.  Purchasing outside the EU (certainly with FC, possibly C8 technology) will then be the only option for the European confectioners (our current customers). |
| **Answer to specific info request 1:**  Our articles are used for Outdoor applications; tent fabric, sun awnings and outdoor upholstery fabrics. The quantities of FC used in 2020 from januari-september are in the range of 14.000 KG. |
| **Answer to specific info request 2:**  The potential risk to the environment is considered low. This is based on extensive research conducted in 2017. The initial concentration of FC on the fabric was tested. After two years of outdoor weathering the concentration was measured again. These levels where equal, meaning that the FC doesn’t wash of the fabric. |
| **Answer to specific info request 3:**  The amount of Fluorcarbons (C6) applied on the fabric lies between 1000-3000 ppm. |
| **Answer to specific info request 7:**  Yes, we have tested several alternatives. The results are negative, since they bring a water repellence but no oil repellence. Also on tent fabric we need repellence to dirt of different origins. With tested alternatives we cannot reach the desired low surface tension. |
| **Answer to specific info request 8:**  On tent fabric we need repellence to dirt of different origins. With tested alternatives we cannot reach the desired low surface tension. They bring a water repellence but no oil repellence and dirt repellence. The consequence would be that we can’t fulfil the market expectancy on dirt and oil repellence. Experience in the past has learned that in our business this will result in a lot of complaints and claims.  Without FC we have no product. If FC use is not (anymore) allowed,  we will have to stop production and deliveries. We then have no right to exist.  A direct consequence is 75 FTE layoffs and write-offs of stocks and the dismantling of the company.  An excessive cost item (> € 10 million) |
| **Answer to specific info request 9:**  At this moment there is no alternative available. That is why a time schedule cannot yet be issued. We have no prospect of a possible substitution in the short term. In addition to ageing tests in the lab, fabrics must be placed outside for a longer period after which it is tested. The standard period to thoroughly test fabrics (in outdoor weathering) is 2 years. |
| **Answer to specific info request 10:**  See remarks on last questions, there is no substitution or technical sufficient solution at this moment. |
| **Answer to specific info request 11:**  Yes, we are aware of that. A step from 6: 2 FTOH to 4: 2 FTOH means a loss in efficiency and a great risk of complaints and claims.  Note: this must be tested extensively, expectations are that results will not be good enough. But, it could be better than PFOH-free alternatives. |
| **Answer to specific info request 12:**  We are not aware of a cost assessment made by our sector’s Dossier Submitter. We need the information to be able to evaluate this question. |
| **Answer to specific info request 13:**  We are aware of a method for chemical analysis for PFHxA but we do not do this analysis ourselves. A matrix on this topic is unknown to us. We are working with multiple suppliers/partners on the subject of PFHxA where this information could be available. |
| **Dossier submitter response:**  Thank you for your comment.  DS wants to highlight that the restriction proposal also covers import from non-EU countries. DS is aware that to date there are no oil and dirt repellent non-fluorinated alternatives available. However, for tent fabrics water repellence seems to be the most critical issue. Information on the consequence of losing dirt repellence for those outdoor articles and if decreased product lifetime is an issue including quantification would have been appreciated. Especially tents usually are not outdoors all the time; thus, the decrease in lifetime might not be dramatic. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain applications they are difficult or not possible to replace with retained function. 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. Proportionality and cost/benefit analysis for restricting or derogating uses from the restriction is performed by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We agree that where oil or dirt repellence is required, based on the available information, suitable alternative substances are not very available. However, it is not clear whether oil or dirt repellence is actually necessary for all related applications. Also, alternatives could be available at least for some of them (not only referring to alternative substances, but also other processes, such as increased washing).  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 justified. Such information could be submitted in the consultation on the SEAC draft opinion.  We are considering proposing that the general transition period be extended to 36 months in order to give time for a balanced transition in all sectors. |
| **3158** | **Date:** 2020/09/17 11:19  **Content:**  Baseline  Other socio economic analysis (SEA) issues  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Werkfeuerwehrverband Deutschland (WFVD)  **Org. country:** Germany  **Attachment:** | **Comment:**  Further to my comment from 13th May 2020 I would like to submit the results from on a survey on the use of fire-fighting foam by industrial fire services in Germany. It provides background information on foam stocks and use of fire-fighting foam as well as the status of transitioning to fluorine-free alternatives at industrial fire services in Germany. |
| **Answer to specific info request 5:**  See attachement |
| **Dossier submitter response:**  Thank you very much for contributing to this survey. The provided information was considered very helpful during the reconsideration of the proposed derogations for the use of fluorinated firefighting foams. |
| **RAC Rapporteurs comments:**  Thank you for the additional information. |
| **SEAC Rapporteurs comments:**  Thank you for the very interesting information. It helped to better see the complete picture when evaluating whether and what kind of derogations are necessary for uses of firefighting foams. |
| **3159** | **Date:** 2020/09/17 07:48  **Content:**  Transitional period  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** The Japan Federation of Medical Devices Associations (JFMDA)  **Org. country:** Japan  **Attachment:** | **Comment:**  Please refer to documents submitted at the SECTION IV. Non-confidential attachment. |
| **Answer to specific info request 1:**  a. Medical Devices   Contained in fluororesin used in medical devices   Part that contacts inside or outside of the patient's body (liquid repellent effect)   Printed circuit board (liquid repellent effect)   Medical non-wovens to prevent medical personnel from infection (liquid repellent effect)   Medical film (surfactant effect)   Contained in the color film of image sensors such as CCD/CMOS used in medical devices such as endoscopes (surfactant effect)  b. Please refer to documents submitted at the SECTION IV. Non-confidential attachment. |
| **Answer to specific info request 8:**  Medical Devices  In order for a medical device manufacturer to identify PFHxA-containing parts and switch to alternative substances, it takes a period of time for investigation of PFHxA-containing parts, search of alternative substances and development, quality confirmation, and application to administrative organs for manufacturing and sales. In particular, the long period of quality confirmation and application to administrative organs is a characteristic of the medical device industry. Regarding the investigation of the PFHxA contained, since there is a possibility of unintentional use and contamination by medical device manufacturers, a large-scale investigation is required for the supply chain of parts. In addition, biological evaluation of parts containing alternative substances that contact patients may require animal experiments or clinical trials, resulting in enormous costs and long evaluation periods. Even alternative substances with reduced environmental impact cannot be judged to be biologically compatible and must be thoroughly evaluated. Since medical devices are required to have high level of safety, it takes a long period of time to examine the quality and obtain approval for manufacturing and sales from administrative organs and third-party organizations.  Please also refer to documents submitted at the SECTION IV. Non-confidential attachment. |
| **Dossier submitter response:**  Thank you for providing information on the use of PFHxA and related substances in medical devices. DS has taken your information into account for the proposal to derogate medical devices from the 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, such as medical devices. RAC evaluated this derogation request from an emissions/emission minimization 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 very much for the information on uses in medical devices! We are currently considering supporting the derogation of medical devices now included in the restriction proposal. However, considering the wideness of the derogation and that there are applications that have not been assessed in detail, we consider that the situation should be re-evaluated at a later point. |
| **3160** | **Date:** 2020/09/17 18:19  **Content:**  Other socio economic analysis (SEA) issues  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** STMicroelectronics  **Org. country:** Netherlands | **Comment:**  PFHxA-related substances are reported in Annex XV Restriction Proposal Report to be used as a surfactant in semiconductor manufacturing step called photolithography.  Photolithography is the process which generates the patterns on the silicon wafer forming the circuit after several manufacturing step. Photolithography processes are the most critical process steps of the whole semiconductor manufacturing process flow. Photolithography processes are repeated several times (in the range between 20 and 60, according to technology) with the manufacturing process to build up the layers of features of the transistors and interconnects that finally becomes an array of microchips on the silicon wafer.  Specialty chemicals are specifically designed and engineered by the suppliers and the device engineering teams to achieve the required function and performance.  In details, as declared by our (non-EU based) supplier a C6 telomer derived polymeric material, potentially included in the “PFHxA, its salts and related substances restriction proposal” is present above 1000 ppb, in almost all pigmented materials (applied as color filters) used as specialty chemicals in the photolithography processes for specific manufacturing of semiconductor components dedicated to the imaging sector. The final applications concerned are almost in all video applications from Cameras to Video Display, Monitoring and Control Instruments, Automotive, Medical (endoscope cameras) and Mobile Phones. Components are essential for Automotive Safety and Medical Monitoring.  The specialty chemicals are used for a specific photolithography processes called “photo-patterning” which include coating, soft-bake, exposure, development, and cure.  The specific Color Filter Materials process implies that the pattern will permanently stay on the semiconductor component, on the contrary of the standard photolithography process where resist is removed. In the “photo-patterning “for the image sector, the color resists of Red, Green and Blue (RGB) are formed on the semiconductor by the photolithography process; the resist remains within the semiconductor component.  The substance potentially included in the restriction (C6 telomer derived polymeric material as currently declared by our non EU based supplier) is contained above 1000ppb in the specialty chemicals, but below the threshold for MSDS disclosure and – based on supplier’s communication - estimated average concentration is < 200 ppm (20 – 400 ppm).  Total quantity of the concerned C6 telomer derived polymeric materials used by STMicroelectronics premises located in France is < 200 grams per year.  Detailed substance’s identification is not available since directly related to the original supplier’s intellectual property (STMicroelectronics’ tier 2 supplier). More over there is no evidence the substance would degrade to PFHxA.  Due to the specific fit for purpose function of the specialty chemicals concerned, some of the substance is remaining within the semiconductor component. For the time being, according to the supplier, an effective measurement method is not available, therefore the concentration on the semiconductor component cannot be measured. However, it can be estimated that the concentration is going to exceed 1000 ppb for the semiconductor component. Therefore, the industry would request that the exemption should include the semiconductor component, as well.  No emissions arise from the components into the environment and final consumers are not exposed to those substances, being the semiconductor component embedded into inert resin and the component included in equipment safely closed.  During the manufacturing process and due to the strictly controlled measures implemented in the semiconductor manufacturing premises all emissions are minimized. Air and Waste water treatments are in place at all locations and, for this specific use, for the manufacturing of semiconductor products dedicated to imaging sector, all spent solvents are sent for incineration.  The sentence reported on the Annex XV Draft Restriction Report: Thus, the possible emissions of PFHxA from the process of semiconductor manufacture and by the subsequent service life of microchips is considered as very low, while being vague, over estimates the emissions into the environment. As said before the total PFHxA consumption is minimal (< 200 g/y) and being most of the substance transferred in the solvent phase the potential discharge in the environment is estimated to be < 10 grams per year. Moreover, all sewer waste are treated in a waste water treatment plant.  Photolithography specialty formulations in semiconductor manufacturing process have transitioned from longer chain per-fluorinated chemistries (PFOS, PFOA) and are now dependent upon the use of other chain per-fluorinated chemistries including PFHxA its salts and related substances. These per-fluorinated substances are an essential constituent of the formulation (mixture/preparation), due to their specific surfactants’ properties. There are no general per-fluorinated free substance alternatives that can adequately provide the functional properties for the critical high-tech applications required within the semiconductor manufacturing process. Any development in this area would require first novel chemistries to be identified. Then, after validation of the processes and the component at equipment manufacturers, industrial processing and manufacturing is required at both suppliers’ and semiconductors’ manufacturing premises.  For the time being there is no forecast of being able to replace the PFHxA its salts and related substances within the time frame currently allocated in the restriction proposed draft text – 7 years. The exemption would need to be in the range of 15 years. |
| **Answer to specific info request 12:**  For the semiconductor sector the dossier submitter has not provided a detailed cost assessment. Moreover for the specific use of PFHxA its salts and related substances in specialty ”photo-patterning” chemicals used in the manufacturing processes of semiconductor products dedicated to the imaging sector, the PFHxA are remaining on the final article (contrary to what it is reported on the draft Annex XV restriction report – “It is important to consider that PFHxA-related substances are used as manufacturing chemicals and are not present in the final articles”). However due to missing analytical tests methods to detect the telomeric substance in the polymer matrix, precise detection is not possible.  For the time being the STMicroelectronics billing depending on the C6 telomer derived polymeric material is equivalent to 3,95 million $ per gram of substance per year.  Due to the specificity of this specific photopatterning material, being solvent based and not water based, and therefore sent for incineration, the cost of emission is estimated to be 70 million $ per gram of substance sent to waste water treatment plant per year.  The ”photo-patterning” process, so far, involves one STMicroelectronics manufacturing site located in France, only, therefore the impact would be concentrated in this unique Region, only.  In case the derogation is not given the consequences maybe very high in terms of  1) Loss of billing - 790 million $ per year lost  2) Employment reduction - site being mostly dedicated to those products for the image sector – an important possibly temporary reduction of direct and indirect employment could be expected  3) Competitive advantage: the EU based semiconductor company may lose the market share of the imaging sector in favor of the bigger non EU based (Japanese) competitor |
| **Dossier submitter response:**  Thank you very much for providing this additional information. It was considered during the process of further drafting the restriction proposal. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC is aware that C6-perfluorinated substances have desirable functional properties and that for certain specialized uses they are difficult or at present not possible to replace with retained function. The Dossier Submitter has proposed a 12-year derogation period for semiconductors and related equipment. RAC supports a time-limited derogation for a maximum of 12 years until alternatives are available. Proportionality and cost/benefit for derogating uses from the restriction are evaluated by SEAC. |
| **SEAC Rapporteurs comments:**  Thank you for adding some quantification. Please see our reply to Comment 3087. |
| **3161** | **Date:** 2020/09/17 18:39  **Content:**  Environmental emissions  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** EURATEX  **Org. country:** Belgium  **Country:**  Belgium  **Attachment:**    <redacted> | **Comment:**  The Database provided in Excel file is meant to be shared with all relevant authorities and it is not meant to be disclosed to the public |
| **Answer to specific info request 3:**  Information provided in the enclosed text and Database |
| **Answer to specific info request 8:**  Information provided in the enclosed excel file Database |
| **Answer to specific info request 9:**  Information provided in the enclosed excel file Database |
| **Answer to specific info request 10:**  Information provided in the enclosed excel file database |
| **Dossier submitter response:**  Thank you for submitting the table. Based on information provided by stakeholders in the public consultation. 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. Additional derogations for technical textiles (in engine bay and filtration and separation media) are proposed in the background document. |
| **RAC Rapporteurs comments:**  Thank you for the additional information. |
| **SEAC Rapporteurs comments:**  Thank you for this information. We support the derogations proposed by the DS for some technical textiles and some categories of PPEs (please refer to the opinion for more details).  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 further derogations are justified. Such information could be submitted in the consultation on the SEAC draft opinion. |

1. <https://ipen.org/documents/global-pfas-problem-fluorine-free-alternatives-solutions> [↑](#footnote-ref-1)
2. <https://www.solbergfoam.com/Foam-Concentrates/RE-HEALING-Foam.aspx> [↑](#footnote-ref-2)
3. <https://ipen.org/sites/default/files/documents/IPEN_F3_Position_Paper_POPRC-14_12September2018d.pdf> [↑](#footnote-ref-3)
4. <https://ipen.org/documents/global-pfas-problem-fluorine-free-alternatives-solutions> [↑](#footnote-ref-4)