**COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS**

Substance name: 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)

CAS number: -

EC number: -

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: Equivalent level of concern having probable serious effects on the environment (Article 57f) Equivalent level of concern having probable serious effects on human health (Article 57f)

***Disclaimer:*** *Comments provided during public consultation are made available as submitted by the commenting parties. It was the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern.*

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

|  |  |  |  |
| --- | --- | --- | --- |
| Number / Date | Submitted by (name, submitter type, country) | Comment | Responses |
| 5275  2019/04/18 | Health and Environment Alliance (HEAL),  International NGO,  Belgium |  |  |
| *Attachment:* 5275\_HEAL-Comments-GenX.pdf |
| 5280  2019/04/25 | Germany,  Member State | -Environmental fate properties: Field data (3.2.5) Mobility HFPO-DA is very mobile in the aquatic environment, is widely distributed via waterways far from the point of emission and therefore reaches areas far away from direct emissions. This is clearly demonstrated by monitoring data. The German CA suggests to further summarize the monitoring data in a table to achieve a better overview. The maps illustrate well the spreading of HFPO-DA in the environment in North America, China and Europe. We suggest using geographical or political maps instead of maps based on satellite pictures in order to have a better orientation. This would improve the demonstration of the wide spread occurrence of HFPO-DA. Additionally we suggest to add a scale as the close ups of the maps differ.  3.5 Enrichments in plants Currently the section addresses three issues: 1. monitoring in plants, 2. enrichment in plants and 3. mobility in soil in comparison to PFOA. All these issues intertwine. Nevertheless it may help to add subheadings. This could specifically highlight the third issue. These findings are also important for mobility and should be referenced in the mobility section. We suggest to further summarize the monitoring data in a table to achieve a better overview.  -Human health hazard assessment: Chapter 4 – HH hazard assessment As stated in the general comments the German CA notes that data are available for several endpoints, including repeated dose toxicity and carcinogenicity. However, for neither of the endpoints discussed in the dossier a harmonized classification and labelling exists. Therefore, the German CA suggests merely using the presented data as additional argument in the equivalent level of concern assessment but not basing the SVHC identification on these properties in first place.  p. 87 ff 4.7 Carcinogenicity. A combined chronic and carcinogenicity study in rats was presented by the DS. However, it was stated (p. 88) that data are currently insufficient to conclude on the substance its full carcinogenic potential. During substance evaluation a lack of data has been identified and a request was issued on a carcinogenicity study in mice. This study is ongoing. At the moment, it is difficult to judge, if the concern on carcinogenicity is sufficiently substantiated to base the SVHC identification on these effects.  Therefore, the German CA is of the opinion that it would be more appropriate to wait for the outcome of the study and then initiate the CLH process if the data support this option. Nevertheless, as mentioned above, the available information can be used as supporting evidence to underpin the equivalent level of concern assessment.  Results of the recent evaluation by US EPA (https://www.epa.gov/sites/production/files/2018-11/documents/genx\_public\_comment\_draft\_toxicity\_assessment\_nov2018-508.pdf) could also be added.  -PBT/vPvB and equivalent level of concern assessment: p. 102 Section 6.3 The German CA suggests that the bullet point “adverse effects on human health” is removed from the first list as in our view the described effects could only be used as supporting evidence for the ELoC assessment due to the missing harmonized classification and labelling for the HH endpoints.  p. 108 6.3.1.10 Effects on human health – carcinogenicity The DS concludes that the substance possibly meets the CLP criteria for a category 2 carcinogen. Even if the substance would meet the criteria for a category 2 carcinogen, a harmonized classification and labelling should be the basis for SVHC identification according to Article 57 f based on human health effects.  p 111-112 6.3.2.2 ELOC assessment The German CA does not agree that the human health concern is sufficiently substantiated to identify the substances as SVHC based on adverse effects for human health. However, as the substances are very persistent and very mobile the human health data can be used as supporting evidence for demonstration of the equivalent level of concern. |  |
|  |
| 5281  2019/04/25 | KWR Watercycle Research Institute,  Other contributor,  Netherlands | 3 Comments on the decision on substance evaluation of GenX as SVHC (Milou M.L. Dingemans and Thomas ter Laak, KWR Watercycle Research Institute, Nieuwegein, the Netherlands).  It has been proposed to classify substances used in GenX technology (2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides; covering any of their individual isomers and combinations thereof) as a substance of very high concern (SVHC) via the REACH article 57f route. This proposal (in the form of a annex XV report) has been submitted in March 2019 by the EU memberstate the Netherlands. In response, ECHA has decided that the registrants are obliged to supply addition hazard and biomonitoring information to maintain the REACH registration for use of these substances. We have reviewed the decision on substance evaluation and would like to share the following comments:  1) Human relevant mechanisms may not be excluded based on the requested carcinogenicity study in mice. • The registrants argue that the effects observed in the submitted rat study are not relevant for humans. The registrants are to submit the results of a carcinogenicity study in a second species (mice) with the aim to be able to exclude human relevant mechanisms. It is important to design an adequate experimental plan (Testing Proposal) that is fit to obtain the needed information. ECHA has included guidance on the test methods that should be used in the decision on substance evaluation document. We strongly suggest to also include studies on cellular and molecular mechanisms using New Approach Methods (in vitro models). These methods have the potential to compare the activity of these substances on the PPAR-receptor and other, more human relevant, receptors potentially associated with carcinogenicity (the current knowledge gap for which the additional mouse study is requested).  2) The REACH status of these substances is unclear • The registrants should submit the additional hazard and biomonitoring information in March 2021 and November 2022. Until then, it is unclear whether this substance will remain on the list of chemicals that are proposed Substances of Very High concern, or whether they will be transferred to the Candidate List of Substances of Very High Concern. ECHA requests additional information on hazards and bioaccumulation of this substance to be able to exclude that these substances are unsafe (based on toxicology and bioaccumulation). In view of the precautionary principle the uncertainty on the absence of health effects and accumulation of internal exposure to these substances already urges risk management measures that need to be addressed by ECHA before the final outcomes of these studies are available. We suggest, based on the presented material and the precautionary principle, to transfer this substance on the Candidate List of Substances of Very High Concern until the additional research has proven that it is not a SvHC.  3) Persistence and mobility in the aquatic environment is not taken into account • As these substances are persistent, pass natural barriers, are poorly removed in wastewater treatment and are mobile in the aqueous environment, their permitted emission into surface water is a threat to drinking water sources. It is therefore recommended to include criteria for fate and behavior in the water cycle in the REACH registration process. These criteria have been developed in the scientific field of environmental chemistry and researchers stress the relevance of these polar and very polar persistant substances for the environment and human exposure (Reemtsma et al. Environ Sci Technol. 2016; RIVM [Versteegh and de Voogt] 2017). |  |
|  |
| 5282  2019/04/25 | Advisary Board Water Quality (AW) of the Dutch drinking water companies,  Other contributor,  Netherlands | 3 Comments on the decision on substance evaluation of GenX as SVHC (Milou M.L. Dingemans and Thomas ter Laak, KWR Watercycle Research Institute, Nieuwegein, the Netherlands).  It has been proposed to classify substances used in GenX technology (2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides; covering any of their individual isomers and combinations thereof) as a substance of very high concern (SVHC) via the REACH article 57f route. This proposal (in the form of a annex XV report) has been submitted in March 2019 by the EU memberstate the Netherlands. In response, ECHA has decided that the registrants are obliged to supply addition hazard and biomonitoring information to maintain the REACH registration for use of these substances. We have reviewed the decision on substance evaluation and would like to share the following comments:  1) Human relevant mechanisms may not be excluded based on the requested carcinogenicity study in mice. • The registrants argue that the effects observed in the submitted rat study are not relevant for humans. The registrants are to submit the results of a carcinogenicity study in a second species (mice) with the aim to be able to exclude human relevant mechanisms. It is important to design an adequate experimental plan (Testing Proposal) that is fit to obtain the needed information. ECHA has included guidance on the test methods that should be used in the decision on substance evaluation document. We strongly suggest to also include studies on cellular and molecular mechanisms using New Approach Methods (in vitro models). These methods have the potential to compare the activity of these substances on the PPAR-receptor and other, more human relevant, receptors potentially associated with carcinogenicity (the current knowledge gap for which the additional mouse study is requested).  2) The REACH status of these substances is unclear • The registrants should submit the additional hazard and biomonitoring information in March 2021 and November 2022. Until then, it is unclear whether this substance will remain on the list of chemicals that are proposed Substances of Very High concern, or whether they will be transferred to the Candidate List of Substances of Very High Concern. ECHA requests additional information on hazards and bioaccumulation of this substance to be able to exclude that these substances are unsafe (based on toxicology and bioaccumulation). In view of the precautionary principle the uncertainty on the absence of health effects and accumulation of internal exposure to these substances already urges risk management measures that need to be addressed by ECHA before the final outcomes of these studies are available. We suggest, based on the presented material and the precautionary principle, to transfer this substance on the Candidate List of Substances of Very High Concern until the additional research has proven that it is not a SvHC.  3) Persistence and mobility in the aquatic environment is not taken into account • As these substances are persistent, pass natural barriers, are poorly removed in wastewater treatment and are mobile in the aqueous environment, their permitted emission into surface water is a threat to drinking water sources. It is therefore recommended to include criteria for fate and behavior in the water cycle in the REACH registration process. These criteria have been developed in the scientific field of environmental chemistry and researchers stress the relevance of these polar and very polar persistant substances for the environment and human exposure (Reemtsma et al. Environ Sci Technol. 2016; RIVM [Versteegh and de Voogt] 2017). |  |
|  |
| 5283  2019/04/25 | VEWIN,  Other contributor,  Netherlands | 3 Comments on the decision on substance evaluation of GenX as SVHC (Milou M.L. Dingemans and Thomas ter Laak, KWR Watercycle Research Institute, Nieuwegein, the Netherlands).  It has been proposed to classify substances used in GenX technology (2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides; covering any of their individual isomers and combinations thereof) as a substance of very high concern (SVHC) via the REACH article 57f route. This proposal (in the form of a annex XV report) has been submitted in March 2019 by the EU memberstate the Netherlands. In response, ECHA has decided that the registrants are obliged to supply addition hazard and biomonitoring information to maintain the REACH registration for use of these substances. We have reviewed the decision on substance evaluation and would like to share the following comments:  1) Human relevant mechanisms may not be excluded based on the requested carcinogenicity study in mice. • The registrants argue that the effects observed in the submitted rat study are not relevant for humans. The registrants are to submit the results of a carcinogenicity study in a second species (mice) with the aim to be able to exclude human relevant mechanisms. It is important to design an adequate experimental plan (Testing Proposal) that is fit to obtain the needed information. ECHA has included guidance on the test methods that should be used in the decision on substance evaluation document. We strongly suggest to also include studies on cellular and molecular mechanisms using New Approach Methods (in vitro models). These methods have the potential to compare the activity of these substances on the PPAR-receptor and other, more human relevant, receptors potentially associated with carcinogenicity (the current knowledge gap for which the additional mouse study is requested).  2) The REACH status of these substances is unclear • The registrants should submit the additional hazard and biomonitoring information in March 2021 and November 2022. Until then, it is unclear whether this substance will remain on the list of chemicals that are proposed Substances of Very High concern, or whether they will be transferred to the Candidate List of Substances of Very High Concern. ECHA requests additional information on hazards and bioaccumulation of this substance to be able to exclude that these substances are unsafe (based on toxicology and bioaccumulation). In view of the precautionary principle the uncertainty on the absence of health effects and accumulation of internal exposure to these substances already urges risk management measures that need to be addressed by ECHA before the final outcomes of these studies are available. We suggest, based on the presented material and the precautionary principle, to transfer this substance on the Candidate List of Substances of Very High Concern until the additional research has proven that it is not a SvHC.  3) Persistence and mobility in the aquatic environment is not taken into account • As these substances are persistent, pass natural barriers, are poorly removed in wastewater treatment and are mobile in the aqueous environment, their permitted emission into surface water is a threat to drinking water sources. It is therefore recommended to include criteria for fate and behavior in the water cycle in the REACH registration process. These criteria have been developed in the scientific field of environmental chemistry and researchers stress the relevance of these polar and very polar persistant substances for the environment and human exposure (Reemtsma et al. Environ Sci Technol. 2016; RIVM [Versteegh and de Voogt] 2017). |  |
|  |
| 5291  2019/04/26 | RIWA, Association of River Waterworks,  Industry or trade association,  Netherlands | RIWA, the Association of River Waterworks in the Netherlands and Belgium, welcomes the proposal by the Netherlands for the identification of HFPO-DA\* as a substance of very high concern on the basis of the criteria set out in REACH article 57. We support the conclusions of the proposal and would like to stress several of the specific findings in it, such as: • HFPO-DA is detected in finished drinking water at several locations downstream of the fluorochemical production plant in the Netherlands. This is of concern to the drinking water companies which are members of our association. Because HFPO-DA does not adsorb to sediment, soil and active coal, and does not show any (bio) degradation under environmental conditions, it is very difficult to remove HFPO-DA from water. Even advanced water purification techniques are mostly not able to remove HFPO-DA, or only to a very limited extent. RIWA would like to stress that one of the aims of the Water Framework Directive is to avoid deterioration of water quality in order to reduce the level of purification treatment required in the production of drinking water. As HFPO-DA is very difficult to remove from water with the current levels of purification treatment installed we strongly support to avoid any emissions to water. • HFPO-DA is very persistent, very mobile in the water environment and shows adverse effects in humans. The available information on toxicity shows that some of these effects can be considered irreversible (i.e. acting as a potential human carcinogen). The current uncertainty regarding bioaccumulation adds to the conclusion that adverse effects of HFPO-DA may occur at lower concentrations than the available toxicity data currently suggests. RIWA is of the opinion that for exposure through drinking water the precautionary principal should be in effect for substances like HFPO-DA. • In order to avoid similar situations such as with the presence of HFPO-DA in the water environment RIWA suggests looking at the criteria set in REACH for better protecting the sources of drinking water. We also support the comments submitted by Vewin and KWR Watercycle Research Institute in this public consultation.   \* 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) |  |
| *Attachment:* 5291\_RIWA Position on UBA proposal for PMT criteria REACH.docx |
| 5293  2019/04/27 | Vewin,  Other contributor,  Netherlands | Vewin welcomes the proposal by the Netherlands for the identification of HFPO-DA\* as a substance of very high concern on the basis of the criteria set out in REACH article 57. We support the conclusions of the proposal and would like to stress several of the specific findings in it: • HFPO-DA is detected in finished drinking water at several locations downstream of the fluorochemical production plant in the Netherlands. This is of concern to the drinking water companies. Because HFPO-DA does not adsorb to sediment, soil and active coal, and does not show any (bio) degradation under environmental conditions, it is very difficult to remove HFPO-DA from water. Even advanced water purification techniques are mostly not able to remove HFPO-DA, or only to a very limited extent. Vewin would like to stress that one of the aims of the Water Framework Directive is to avoid deterioration of water quality in order to reduce the level of purification treatment required in the production of drinking water. As HFPO-DA is very difficult to remove from water with the current levels of purification treatment installed, we strongly support to avoid any emissions to water. • HFPO-DA is very persistent, very mobile in the water environment and shows adverse effects in humans. The available information on toxicity shows that some of these effects can be considered irreversible (i.e. acting as a potential human carcinogen). Vewin is of the opinion that for exposure through drinking water the precautionary principal should be in effect for substances like HFPO-DA. • In order to avoid similar situations such as with the presence of HFPO-DA in the water environment Vewin suggests to incorporate criteria in the REACH registration and assessment processes for better protecting the sources of drinking water.  We also support the comments submitted by RIWA and KWR Watercycle Research Institute in this public consultation. \* 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) |  |
|  |
| 5297  2019/04/29 | Finland,  Member State |  |  |
| *Attachment:* 5297\_HFPO\_DA\_Annex\_to\_FI\_CA\_comments\_BIOWIN.docx |
| 5302  2019/04/29 | EurEau,  Industry or trade association,  Belgium | N/A |  |
| *Attachment:* 5302\_EurEau\_Public Consultation\_Ammonium 2333-tetrafluoro-2-(heptafluoropropoxy) propanoate.pdf |
| 5303  2019/04/29 | Chemours International Sàrl,  Company,  Switzerland | Please find comments for all Parts in the attached document. |  |
| *Attachment:* 5303\_20190429\_SVHC\_Comments\_Chemours\_HFPO-DA.pdf |
| 5305  2019/04/29 | United Kingdom,  Member State | page 8 (also p116): The statement “HFPO-DA adversely impacts human health at a daily intake that could be as low as 21 ng/kg bw/day (tTDI)” is misleading. A Tolerable Daily Intake (TDI) is an estimate of the quantity of a chemical contaminant to which a person may be exposed through environmental contamination, and which when found in food can be ingested daily over a lifetime without posing a significant health risk. Whilst the value calculated here is a ‘tentative’ TDI due to the various uncertainties having a daily intake of the TDI should not ‘adversely impact human health’. Please consider rephrasing.  Section 1.4 (page 17-18): Editorial – The vapour pressure of the dried ammonium salt is stated to be 0.0117 Pa and 0.017 Pa at different points in the text. Please confirm which value is correct.  Section 1.4 (page 18): Log Kow values are reported from QSAR predictions. Please provide an indication of the reliability of these predictions, and whether they are for the ionised or unionised form. Three different QSAR software packages were used, and it would be helpful to understand the differences and whether the training sets contain relevant substances/fragments. Please consider which value is most appropriate, also taking account of the pKa information.  Section 3.1 (page 21): HFPO-DA is compared to perfluorinated substances with a carbon chain length of 8 or higher (e.g. PFOA). Are data available for any per- or polyfluoroether carboxylic acids with similar chain lengths to HFPO-DA?  Section 3.1.1.3.2 (p 23): Data presented in the phototransformation in water study are not comparable to that produced in an OECD 316. The total Wm-2s-1 that the substance was exposed to should be provided, along with the temperature at which the study was performed. No extrapolation to daylight (as per OECD 316) at relevant latitudes has been performed. Additionally comparison to the AOP/ARP studies is irrelevant as these were not performed under environmentally relevant conditions.  Section 3.1.2.1.2 (page 24): It is noted that the toxicity of H-28397 to inoculum in a respiration inhibition test was measured. However, no results from the study are included. Please include these in the report.  3.2.1 The discussion of adsorption to powdered activation carbon and sub-bituminous granulated activated carbon is not relevant within the adsorption-desorption section. These are non-standard materials in the assessment of kd.  Section 3.2.2 (page 27): Editorial – The Henry’s Law Constant taken from the ECHA dissemination portal has the incorrect units (should be Pa·m3/mol not “mol Pa·m3/mol”). Please correct this.  Section 3.2.6 (page 38): Is it possible to provide a calculation based on a steady state emission and no removal mechanisms to estimate how long it would take for the concentration of HFPO-DA to reach levels in drinking water that would result in unacceptable risk to humans (e.g. using the FOCUS model)? It would be useful to have this hypothetical information to provide some further context to the proposal in terms of the urgency for action. This modelling could also be used to determine the effect of the emission reduction from the Dutch manufacturing plant.  Section 3.2.5 (page 38): If 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propanoyl fluoride (C3 dimer acid fluoride) is a known pre-cursor of HFPO-DA then should this substance also be included in this SVHC proposal as a “related substance”?  Section 3.2.6 (page 39): The dossier notes that HFPO-DA has been detected in areas large distances from known point sources, but that the concentrations that have been detected are very small. We think it would be helpful to provide some benchmark for comparison.  Section 3.3 (page 39): We do not consider that the summarised monitoring data support the statement that HFPO-DA “is wide spread over Europe, the US and China”. Only a small number of sampling programmes have been undertaken, generally around a known point source. The available data are not sufficient to conclude on the distribution of this substance in these areas. Please amend the text accordingly.  Section 3.3 (page 40 and 41): Based on the pKa, the log Kow and log Kaw used in the modelling should be for the ionised form.  Section 3.3 (page 40 and 41): The table and text states that the lower bounds of the vP criteria were used to set the DT50 for soil and water. However, the soil DT50 used is the lower bound of the P criteria (i.e. 120 days instead of 180 days). The justification for using either the P or vP criteria should be made clearer. As the DT50 values are unknown the dossier submitter could have modelled a number of half-lives ranging from the modelled ‘optimistic’ values to longer DT50 as this would have demonstrated the range of possible model outputs and the uncertainty associated with this. This would aid the discussion on page 41.  Section 3.3 (page 41): Please add the LRTP model boundary lines to Figure 11 to allow easier interpretation of the model output. What type of error results from compounding predicted values with a model? (See previous comment in Section 1.4 and 3.3 with regards to the reliability of QSAR predictions for ionised/non-ionised substances.)  Section 3.4.1 (page 42): Editorial – The SVHC report states “HFPO-DA could not be detected in fish at none of these two concentrations”. The meaning of this sentence is unclear as it includes a double negative. Do you mean that HFPO-DA was detected in fish at both exposure concentrations, or that it was detected in neither?  Section 3.4.1 (page 44): The final paragraph of this section states that there is “uncertainty in this [aquatic] bioaccumulation potential of HFPO-DA”. However, the reported BCF and BAF are so low that even if there is uncertainty associated with them this would have to be very high to result in values of concern. Please also move this paragraph to a separate section as it relates to human exposure via consumption of fish, rather than bioaccumulation.  Section 3.4.2 (page 44): Please document the range of BCF and BAF values reported in this summary section. It appears that even the higher BAFs observed at the lower exposure concentrations are extremely low when compared to B/vB thresholds and this comparison should be added to the report. The final sentence of this section suggests that bioaccumulation in fish could pose a high level of concern to humans via consumption. Please move this line as it relates to human exposure via consumption of fish, rather than bioaccumulation. It also needs to be clear why the level of concern arising from human exposure indicates ELoC.  Section 3.5 (page 46): The final sentence of this section suggests that accumulation in vegetables could pose a high level of concern to humans via consumption. We do not believe this is warranted as the BAF in vegetables is low and the clearance times of HFPO-DA in monkeys, rats and mice indicate it should be readily excreted after consumption by air-breathing mammals. We note that the human biomonitoring study requested under Substance Evaluation will provide more information on the half-lives in humans to allow a more detailed assessment of this. In addition, the dossier does not include an overall assessment of human exposure so the relative contribution from different sources cannot be assessed. Please remove or amend this text.  Section 3.5: The BAF calculation for plants does not document which part(s) of the plant HFPO-DA was located in. For example, it should have been possible to determine whether uptake was via air or water from the distribution in the plant. We do not agree that these BAF values reflect the mobile character of the substance. Enrichment really just demonstrates the solubility of the substance.  Section 4.11 (page 100): We are of the opinion that the need for a human health hazard classification for specific target organ toxicity or CMR endpoints that would meet the Annex XIII T criteria has not yet been demonstrated. We note that there is a self-classification of STOT RE 2 mentioned in Section 2, but in the RMOA the NL-CA states that this classification is not warranted. We also note that a carcinogenicity study has been requested under Substance Evaluation, so this may alter the classification. It would be helpful to include a clear statement about this within the dossier.  Section 6.3 (page 102): The SVHC dossier states that HFPO-DA shows “adverse effects on human health”. However, if a substance does not meet the Annex XIII T criteria, why should they be considered especially significant to justify an ELoC? We think that for consistency, a level of toxicity equivalent to the Annex XIII criteria should be used as an essential element of the ELoC argument, unless a very good justification is provided. Section 6.3 (page 102): The SVHC dossier states that HFPO-DA shows “a widespread occurrence in the Netherlands and in other EU Member States, in drinking water, fish and in home grown vegetable”. This statement is not supported by the data presented in the dossier, which only reports monitoring data from the Netherlands for these three media.  Section 6.3 (page 102): The SVHC dossier states that HFPO-DA is “ubiquitously present in the global environment at low background concentrations”. Although the summarised monitoring studies have detected HFPO-DA at low concentrations in the USA, China and Europe we do not consider that this is sufficient to state that this substance is ubiquitous globally.  Section 6.3 (page 102): The SVHC dossier states there is an “impossibility to remove the substance from the environment after release”. We do not think it is entirely fair to say that the substance is “impossible” to remove as Section 3.2.3 indicates that high pressure membranes can be effective. However, we agree that it may be difficult to remove in a cost-effective way using common treatment methods.  Section 6.3 (page 103): The SVHC dossier states that the hazard of these substances leads to a “societal concern for irreversible and intergenerational effects on humans and the environment for which as of yet no safe limit of exposure can be derived and which exposure cannot be predicted, controlled nor reversed”. If this statement is based on pre-empting the outcome of carcinogenicity and human biomonitoring studies that have been requested under Substance Evaluation then this should be made clear. In this case the ELoC argument would be based on the precautionary principle, rather than scientific data, and so this should be clearly stated and as a policy-based decision should be considered by the REACH Committee rather than the MSC.  Section 6.3.1.1 (page 103): We agree that this substance can be considered to meet the criteria for vP. It is stated that HFPO-DA is more persistent that PFOA. Neither HFPO-DA nor PFOA have data from definitive persistence studies in all compartments. There are not enough data from studies that trace transformation of these substances to make this statement.  However, the last sentence states that HFPO-DA has been found in remote areas with no indication of a point emission source, and so attributes these detections to long range transport. We do not know all the uses of the substance or non-European sites of use and manufacture, and so cannot state this conclusively. We would also not consider locations at which HFPO-DA has been detected to be ‘remote’, compared to the Antarctic for example.  Section 6.3.1.2 (page 103): Please summarise the range of BCF and BAF values reported in this summary section as they are extremely low when compared to B/vB thresholds and this comparison should be included in the report. Please also remove the text relating to human exposure via consumption of fish from this section on bioaccumulation.  Section 6.3.1.4 (page 104): See our previous comments where we disagree with the use of the term ‘ubiquitous’. We do not think that it surprising that a persistent and mobile compound is detected in monitoring programmes, and we see this monitoring data as further support for the persistence ELoC argument, not a separate point.  Section 6.3.1.4 (page 105): In the RMOA for this substance it is noted that the manufacturing plant in the Netherlands is adding measures to reduce its emissions by up to 99 % by 2020. Please add this information to the dossier.  Section 6.3.1.5 (page 105): We do not think that it surprising that a persistent and mobile compound is detected in monitoring programmes, and we see this monitoring data as further support to the persistence ELoC argument, not a separate point.  Section 6.3.1.7 (page 106): This section is largely a repeat of the bioaccumulation section 6.3.1.2, and as such should be removed if it does not add an additional ELoC argument. Has HFPO-DA been looked for or found in biota (especially mammals or birds) in monitoring programmes? Is there any evidence for HFPO-DA (not PFOA) that higher levels in biota would be observed than predicted based on the aquatic BCF and BAF?  Section 6.3.1.8 (page 106): The SVHC dossier states that “Due to the considerable uptake in vegetables and fruits, consumption of these by humans contributes significantly to the total exposure to HFPO-DA”. This statement is not supported by the data presented in the dossier that reports BAF<1.62 gdwt/gfwt, and the dossier does not include an overall assessment of human exposure so that the relative contribution from different sources can be assessed.  Section 6.3.1.10 (page 107): As stated previously, we consider that a conclusion on human health effects should wait until the carcinogenicity and human biomonitoring studies requested under Substance Evaluation are available and can be considered together with the repeat dose toxicity data via the CLH process.  Section 6.3.1.12 (page 109): We do not think that co-exposure with similar substances is a relevant argument for ELoC. The relative importance of this will depend on a variety of factors, and we did not take co-exposure with other PBT/vPvB substances into account for previous SVHC cases.  Section 6.3.2.1 (page 111): Please remove the sentence on intergenerational effects from this section. No evidence has been provided that intergenerational effects will occur and this text is not relevant to this section on persistence.  Section 6.3.2.1: Please remove or re-word the sentence “Consequently, once HFPO-DA has entered the environment, it will not be removed by any natural processes e.g. bio- or photodegradation”. We do not agree that this statement can be made as not all natural processes of degradation are represented in the testing presented here. Additionally, photodegradation was observed as noted in Section 3.1.1.3.2.  Section 6.3.2.1 (page 111): See our previous comments on the use of the term ‘ubiquitous’.  Section 6.3.2.1 (page 111): The dossier states “The wide spread occurrence in the environment and the low background concentrations in water observed world-wide raise a concern for impact on migratory species and show that the substance has the potential to impair population level structure and recruitment or ecosystem function and stability at remote and pristine areas”. Again, we do not believe that the monitoring data presented allows for a conclusion of world-wide concern. In addition, exposure alone does not have the potential to cause effects – hazard would also have to be shown, which we do not believe to have been demonstrated for this substance.  Section 6.3.2.2 (page 111): This Section notes that the concern for carcinogenicity and the current uncertainty regarding bioaccumulation adds to the conclusion that “the effects of HFPO-DA on human health may be more severe than can be concluded on the basis of the currently available toxicity data alone”. However, a carcinogenicity study and human biomonitoring data have been requested under the Substance Evaluation of FRD-902 (and thus HFPO-DA). It would seem sensible to wait for the results of these studies before proceeding to SVHC identification,  Section 6.3.2.3 (page 112): The majority of chemicals enter the biosphere and humans via a variety of routes. This in itself is not a reason to identify a substance as an SVHC. Due to its persistence and mobility it is not surprising that HFPO-DA has been detected in monitoring programmes of environmental compartments, fish and vegetables. However, exposure alone is not sufficient to identify a substance as SVHC and we see this monitoring data as further support to the persistence ELoC argument, not a separate point.  Section 6.3.2.4 (page 114): The RMOA for this substance notes that the manufacturing plant in the Netherlands is adding measures to reduce its emissions by up to 99 % by 2020. Please add this information to the dossier together with details of how this is being achieved and whether this will reduce emissions to air or water.  Section 6.3.2.4 (page 114): The dossier states in Section 9 that the very high concentration (up to 3 mg/L) at a waste facility is being further investigated. It therefore seems premature to conclude that exposure is difficult to regulate when data to support this assertion have not yet been published and the sources not determined.  Section 6.3.2.5 (page 114): We do not consider that HFPO-DA is of equivalent concern to PBT/vPvB substances as T has not been demonstrated. |  |
|  |
| 5309  2019/04/29 | American Chemistry Council,  Industry or trade association,  United States |  |  |
| *Attachment:* 5309\_FINAL\_ACC Comments to ECHA 042919.pdf |
| 5314  2019/04/29 | European Chemical Industry Council (Cefic),  Industry or trade association,  Belgium |  |  |
| *Attachment:* 5314\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5315  2019/04/29 | FluoroCouncil,  Industry or trade association,  United States |  |  |
| *Attachment:* 5315\_FINAL FluoroCouncil response HFPO-DA SVHC consultation 29-4-19.pdf |

Specific comments on the justification

|  |  |  |  |
| --- | --- | --- | --- |
| Number / Date | Submitted by (name, submitter type, country) | Comment | Responses |
| 5269  2019/03/26 | Oasen drinkwater,  Other contributor,  Netherlands | P 28. Values of HFPO-DA were detected in our individual wells for drinking water with concentrations up to 120 ng/l downstream of the Chemour factory. Indicating that the substance is very persistent and mobile and is not degraded during river bank filtration. |  |
|  |
| 5270  2019/04/12 | European Environmental Bureau,  International NGO,  Belgium | EEB welcomes the SVHC dossier submitted by The Netherlands. The dossier provides a comprehensive motivation for the identification as SVHC of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof). EEB supports the proposal to identify HFPO-DA as a substance of equivalent level of concern (art 57f) to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation.  HFPO-DA should be identified as a substance of very high concern because of the combination of extreme persistency, high mobility and evidence of a wide range of toxicological effects on kidney, liver and immune system at low levels of exposure. In addition the substance may be carcinogenic. The substance is ubiquitously present in the environment, including pristine areas, groundwater and drinking water. It is difficult to remove from drinking water with current water treatment techniques. Its widespread occurrence in the environment and occurrence in drinking water, in combination with toxic effects at low exposure levels give rise to identification as SVHC according to Article 57f of REACH. |  |
|  |
| 5275  2019/04/18 | Health and Environment Alliance (HEAL),  International NGO,  Belgium | See full comments in attachment |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5275\_HEAL-Comments-GenX.pdf |
| 5279  2019/04/25 | ANSES,  National Authority,  France | ANSES agrees that these substances are very persistent and very mobile in the environment. The monitoring data presented in the dossier show a widespread occurrence of the substances. Indeed, it is found in freshwater systems such as groundwater, drinking water, tap water and marine water. It is proven by scientific data that removal of the substances in water is not possible by both conventional methods and by advanced water treatment processes. The substances exhibit a high long –range transport potential, which is supported by monitoring data and modelling estimations. Emissions of the substances or their precursors to the air compartment lead a subsequent wet and/or dry deposition into the environment (and their mobilization), where humans and biota can be exposed to the substance also by this route. This finding is supported by the concentrations found in rainwater and soils.  A range of serious effects are identified on the basis of experimental studies in rodents. - In repeated dose-toxicity studies, in particular in mice, the most sensitive effects appear to be significant adverse effects on blood cells (substantial decrease in haemoglobin, haematocrit, increase in reticulocytes) and on the liver (necrosis). These effects are observed at low dose (≤ 10 mg/kg in 90-day studies). Other effects are also identified (effects on kidney and immune system) but it is noted that they are less severe and/or occurring at higher doses. - HFPO-DA induces tumours in different organs in rats. In particular, liver, pancreas and testis are organs that have already been described as sensitive to carcinogenesis after PFOA exposure. This consistency brings further support to the identification of the carcinogenic potential of HFPO-DA. In addition, in contrast to PFOA that is classified Carc 2 because observed tumours are benign only, malignant tumours are observed after exposure to HFPO-DA in the liver and pancreas. Carcinogenic properties of HFPO-DA are therefore acknowledged. Harmonisation of carcinogenic classification will be justified once the ongoing study will be completed. - In addition, it is noted that one of the major effect of PFOA is developmental toxicity. PFOA is classified Repr 1B for development based on positive results mainly in mice but not in rats. For HFPO-DA, it is noted that effects on early deliveries and decreased foetal body weight in the rat PNDT study are observed from the mid-dose onward. No significant general toxicity is observed at this dose. Therefore, this effect cannot be attributed to general toxicity. In particular, the decrease in gravid uterine weight should not be seen as a sign of maternal toxicity as it can be consistent with the decrease of foetal body weight (magnitude of the two effects should be compared to confirm this). Unfortunately, no relevant developmental data on mice are available for HFPO-DA as only an OECD-421 screening study with insufficient dose is available. The potential of HFPO-DA to induce developmental toxicity is detected based on the findings in the rat study and may be underestimated by the lack of relevant mice data.  These data indicate that HFPO-DA has the capacity to induce serious health effects. Importantly, these effects are relevant for human health as well as for mammals of the environment. The relevance of the data gathered on rodents for their relatives in environment should be underlined in the rationale for the identification.  The main concern related to these substances is that due to their very important persistence and mobility, the continuous use of these substances will lead to an irreversible contamination of environment and result in uncontrolled sources of exposure for humans and biota at large (drinking water, food). As the substances will remain bioavailable for long periods of time due to their persistence in the environment, exposures of organisms (including humans) will occur across generations, even if the emissions have ceased. By itself, this concern is considered sufficient to support an SVHC identification according to 57(f) as it is not realistic to consider that a chemical substance can accumulate and disperse in the environment without ultimately generate risks. The level of concern is therefore not only driven by the level of severity of the effect in this case but also by the level of ability of the substance to persist and contaminate the environment.  In addition, because of their serious hazardous properties, the risks related to these substances are especially substantiated. On this basis, the dossier proposed by the Netherlands is supported.  The latter point supports an equivalent level of concern and should be discussed in more details. It is also consistent with the recommendation to discuss for HH ELoC the factor “is derivation of a safe concentration possible?”. In general, the dossier would benefit for a more structured presentation of the elements that are discussed in the introduction of the ELoC assessment and why some factors listed in introduction 6.3.2 are not discussed and/or considered relevant. |  |
|  |
| 5280  2019/04/25 | Germany,  Member State | The German CA supports the proposal to identify 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides as substances of very high concern (SVHC). Based on the information provided in the dossier we agree that the substances are very persistent and very mobile and meet the criteria of being of an equivalent level of concern to those substances mentioned in Article 57 a-e. The German CA would like to remind that in order to identify substances as SVHCs according to Article 57 (f) a demonstration of two aspects is necessary: 1. Demonstration of probable serious effects on human health and/or the environment 2. Demonstration of an equivalent level of concern to substances listed under points (a) (e) of Article 57 For the first part, the German CA agrees that the substances are very persistent and very mobile and therefore of high environmental concern. However, with regard to adverse effects on human health, the German CA notes that the substances are not listed in Annex VI of the CLP Regulation and no harmonized classification and labelling is yet available. Therefore, the German CA is of the opinion that the SVHC identification should not be based on these properties in first place. Nevertheless, the adverse effects described in the dossier can be used as supporting evidence to underpin the equivalent level of concern argumentation. |  |
|  |
| 5284  2019/04/26 | the city of Dordrecht,  Regional or local authority,  Netherlands | We welcome the proposal and can largely agree with the way the different properties of the substances are assessed. We particularly agree with the conclusion that the substances should be identified as SVHC. With respect to the applied criteria, we submit that persistency in the environment, or, in the case of these substances: the unability to degrade under ambient conditions, should in itself already be a reason to designate the substance as an SVHC. In that respect we refer to a recently published paper by Cousins et al (Environ. Sci.: Processes Impacts, 2019. DOI: 10.1039/C8EM00515J). The substances that are now proposed to be identified as SVHC have very long half-lives under environmental conditions, exceeding the vP criteria by far. When released into the environment, such substances will ultimately lead to human and environmental exposure, the effects of which may not yet be known. Furthermore, we would draw the attention of ECHA to the recent study by Conley et al (Env Health Persp., 2019. DOI: 10.1289/EHP4372). In this study, the effects of oral exposure to HFPO-DA in rat is compared to the effects of other known PFAS. The results of this study give additional evidence about the toxicity of HFPO-DA. |  |
|  |
| 5288  2019/04/26 | Ireland,  Member State | We understand that the proposal to identify HFPO-DA as a SVHC under Article 57(f) is based on a weight of evidence approach taking into account a number of hazard and fate properties, including that HFPO-DA adversely affects human health. Our comments relate only to the human health aspects of the proposal.  With respect to the effects on human health, the Annex XV report includes a number of repeated dose toxicity studies and a carcinogenicity study in rats. We note that in the discussion of this data, no conclusion is drawn regarding whether the data is sufficient to meet the classification criteria as STOT RE or carcinogenic under CLP. We appreciate that harmonised classification is not a requirement to identify a substance as an SVHC in accordance with Article 57(f). However, we consider that where classification criteria exist for the endpoints under consideration, as in this case, some discussion of whether the classification criteria are met would assist in assessing the severity of the effects observed and thus the impact on the equivalent level of concern assessment.  With respect to the carcinogenicity data in particular, there is some uncertainty regarding the weight applied to this potential hazard in the equivalent level of concern assessment. We note that on page 8 of the Annex XV report, the limitations of the available carcinogenicity data are noted: “HFPO-DA may also be a human carcinogen, but data are currently insufficient to fully determine its carcinogenic potential. The carcinogenicity of FRD-902 is currently under investigation in an ongoing Substance Evaluation.” However, the (potential) concern for carcinogenicity is used to justify an adverse effect on human health for HFPO-DA in various places in the Annex XV report, for example:  • Summary of how the substance meets the criteria set up in Article 57 of REACH (page 8): “The effect on human health may come with a possible delay between the moment of exposure and the onset of any observable adverse effect (i.e. cancer)…” (the same sentence is used on page 112) • Section 6.3.1.10 Effects on human health – toxicity (page 108): “Therefore, HFPO-DA is considered potentially carcinogenic to humans and the information available is concluded by the dossier submitter to possibly meet the CLP criteria for a category 2 carcinogen. Data are however currently insufficient to conclude on the full carcinogenic potential of HFPO-DA.” • Section 6.3.2.2 HFPO-DA causes adverse effects on human health (page 112): “Based on the effects on carcinogenicity it is concluded that HFPO-DA causes adverse effects on human health that can be considered irreversible.” • Section 6.3.3 HFPO-DA is of equivalent level of concern (page 115): “The available information on toxicity shows that some of these effects can be considered irreversible (i.e. acting as a potential human carcinogen).”  We note that the substance evaluation decision for FRD-902 includes a request for a carcinogenicity study in mice (OECD 451) which is justified as “the current data for the registered substance are not sufficient to conclude whether classification for carcinogenicity is triggered, and to differentiate between carcinogenicity classification in CLP Cat. 1B or Cat. 2”.  As the carcinogenicity of HFPO-DA is currently under evaluation, we consider that the proposal should be clearer regarding the weight given to the carcinogenicity concern in the equivalent level of concern assessment. |  |
|  |
| 5290  2019/04/26 | Sweden,  Member State | General comments The Swedish CA is concerned about the following properties of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof), further denoted HFPO-DA: • the extreme persistence, which results in that HFPO-DA will remain in the environment for indefinite time and background concentrations will increase. • the mobility in water and soil, which may result in, among other things, further contamination of drinking water resources and together with the extreme persistency and other physicochemical properties result in potential long-range transport and contamination of pristine areas. • difficulty of remediation, which means that contaminated compartments, such as e.g. drinking water resources, will remain contaminated for very long periods of time and attempts to remove HFPO-DA, from e.g. drinking water resources, will be costly and inefficient. • the toxicity-profile, which is similar to that of PFOA, and includes liver toxicity (incl. necrosis) at dose levels relevant for STOT RE1-classification, and tumours in the liver, pancreas and testes. |  |
|  |
| 5291  2019/04/26 | RIWA, Association of River Waterworks,  Industry or trade association,  Netherlands |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5291\_RIWA Position on UBA proposal for PMT criteria REACH.docx |
| 5292  2019/04/26 | CHEM Trust Europe,  National NGO,  Germany | CHEM Trust supports the identification of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) as SVHC. The group of substances has been shown to be of high persistence, very high mobility and having adverse effects on human health. The very good dossier makes a convincing case that there is scientific evidence of probable serious effects to the environment and humans, which gives rise to an equivalent level of concern according to article 57(f) of REACH.  The high persistence of HFPO-DA combined with its high mobility means that potential impacts will continue even after cessation of emissions, thus presenting a threat also to future generations. The intrinsic properties and connected uncertainties in the assessment regarding the potential serious and irreversible effects makes it unlikely that deriving a safe concentration is possible.  Taken together with the evidence of adverse effects provided on human health, the potential for long-range transport and the fact that structurally similar perfluorinated substances have already been included as PBT or vPvB chemicals in the REACH candidate list this dossier convincingly identifies this compound group as SVHC according to REACH 57 f.  On the issue of high persistence we would note that scientists have argued for decades that high persistence in itself is a major concern as highly persistent chemicals accumulate in the global environment and have the potential to reach critical concentrations at which negative unexpected effects can be triggered (Cousins et al., Environmental Science: Processes & Impacts, 2019, DOI:10.1039/C8EM00515J.) The paper emphasizes that “these increasing concentrations will result in increasing probabilities of the occurrence of known and unknown effects and that, once adverse effects are identified, it will take decades, centuries or even longer to reverse contamination and therefore effects.”  To demonstrate the very high mobility the dossier has compiled important studies reporting findings in drinking water and surface water and has highlighted results illustrating the ineffective removal of the substances in water treatment steps. It is indeed very concerning that the environmental occurrence of HFPO-DA has developed over just a few years (2012-2018) since the start of using these compounds in Europe. The increased exposure via drinking water mobility should be considered of equivalent concern to bioaccumulability (see also Reemtsma, et al., 2016. Mind the Gap: Persistent and Mobile Organic Compounds – Water Contaminants that Slip Through. Environ. Sci. Technol., 50, pp. 10308-10315. http://doi.org/10.1021/acs.est.6b03338) In CHEM Trust`s view it would be important to pursue a general policy discussion to ensure that the identification and regulatory controls of PMT/vPvM chemicals under REACH are improved (see also proposal by the German Environment Agency UBA (UBA, 2017. Protecting the sources of our drinking water: A revised proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances registered under REACH. German Environment Agency, 20pp. https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/171027\_uba\_pos\_pmt\_substances\_engl\_2aufl\_bf.pdf |  |
|  |
| 5294  2019/04/27 | Individual,  Finland | The report produces a commendable effort to provide an overview of the available data on GenX. Unfortunately, the authors allow themselves speculations and unfounded statements, present hypotheses and raise questions. With some cleaning of the text this report could be a reasonable proposal to fund further research to address the scientific questions raised. However, the available substance specific facts presented may raise a (societal) concern but not an alarm. It is premature to take regulatory risk management actions at this moment, and there is sufficient time to address the outstanding scientific questions by appropriate data generation on the substance itself. The identification of GenX as an SVHC should therefore not be supported for the moment. Several arguments are presented that underpin this position.  1) Some of the questions raised are currently under investigation with data being generated on human biomonitoring (which will address uncertainties in the human half-life of GenX) and a mice carcinogenicity has been requested under the substance evaluation process (to follow-up on mode of action uncertainties). 2) The dossier heavily relies on a read-across based on structural similarity, but does not produce a hazard data matrix to compare different endpoints, their effects and potencies of the substances used in the read-across. This violates the approach advocated in the ECHA’s RAAF. Furthermore, the physico-chemical fate and behaviour information presented introduces a circular argumentation. The model calculation (e.g. EPIWIN) are based on the premise that structural components contribute to the calculated property value. However, for PFASs these values have not been independently derived, and the model calculations are speculative (as acknowledged in the dossier) since they are outside the models’ domain of applicability. If the read-across is accepted by MSC then the approach used here for the SVHC identification of GenX introduces a discrepancy in the standards applied to registrants and regulators regards read-across. ECHA uses a slightly leaner approach in substance evaluation, since this results in data generation and a possible confirmation of the read-across concern, however, it is dis-proportional to take regulatory action mainly on the basis of structural similarity. 3) Some of the data on occurrence mentioned (Expertise centrum PFAS, 2018) are non-peer reviewed, not published and thus untraceable. This is a violation of the right of the public to be heard since they cannot be commented upon. 4) The limit value derived by the Janssen et al (2017) is not necessarily directly comparable to the DNEL value derived by the Registrants according to the REACH methodology and uses an additional assessment factor for additional uncertainty on the substance’s half-life in humans. Firstly, the introduction of an additional assessment factor in the DNEL derivation would be an unprecedented move by ECHA The assessment factors provided in the REACH guidance documents already cover many uncertainties and are considered to provide a reasonable worst-case approach for DNEL or toxicological limit value derivation. Secondly, it is highly speculative that the GenX half-life in humans is analogous to that of PFOA, and data are currently being generated to further follow-up on that speculation. 5) The protection target for the SVHC identification of GenX are humans. As mentioned, key elements of the hazard database for GenX are still under development (see above). The human exposure routes presented are exposure through drinking water and food (e.g. plants and fish), and some data are presented on the occurrence of GenX in these exposure sources. Several questions arise on the topics presented. 5a) The authors speculate on the dependence of bioaccumulation in aquatic organisms on the exposure concentration. The general concern is that in such instances the bioaccumulation increases with increasing exposure concentrations due to saturation of active elimination processes. In effect, the substance specific data presented suggest an exposure concentration dependence, however, somewhat unexpectedly this goes in the opposite direction. An average BAF in muscle of carp of 4.1 L/kg at a median concentration of 369 ng/L in water (Pan et al, 2017) whereas at a significantly higher exposure concentration of 6800 ng/L a BAF in muscle of carp of 0.31 L/kg is reported (Van Bentum et al, 2017). This dependence of the bioaccumulation in aquatic organisms on the exposure concentration will lead to an overestimation of the human exposure via fish if the more conservative BAF value is used and should therefore not be an element of concern. 5b) Enrichment in plants is not an element of concern as such, and criteria for when plant accumulation is to be considered as an independent assessment element are not available. The authors do not provide comparative information from other substances to further benchmark the substance’s accumulation. Therefore, this information can only be used in a quantitative risk assessment with realistic assumptions on the plant food basket contribution. 5c) Both properties are fate and behaviour related, not intrinsic hazard properties, and similarly degradation is not a hazard property. In the context of ED-identification ECHA excludes fate and behaviour properties from case-by-case equivalent level of concern assessments. Including them here suggests an inconsistent approach taken. 6) The aquatic mobility and long-range transport potential (LRTP) are based on monitoring in the aquatic (marine) environment from sources with significant direct releases. The LRTP provides support for the mobility in aqueous environments, but it subsequent occurrence in pristine and remote areas is not a relevant element in this SVHC identification as the protection targets are humans (exposed via the food and water. If the protection targets were organisms living in those pristine and remote environments the LRTP could be considered in a weight of evidence approach, however, the dossier does not contain an environmental hazard assessment. 7) No information is provided on soil mobility, other than screening level studies, and higher tier leaching studies are not available/presented. 8) A comparison with PBT/vPvB substances is not relevant for this case. Environmental food-chain transfer to higher trophic levels would require that the dossier contains an environmental hazard assessment. 9) Irreversibility of effects has not been demonstrated. 10) Continuous exposure to a substance with toxicological effects that act through threshold mechanisms is not an element of equivalent level of concern. Humans are always and continuously exposed to different types of natural and man-made substances. This a general issue that can be addressed through the established risk assessment methodologies. The monitored upper-level exposure concentration in drinking water is 30 ng/L. Even when taking the extremely low TDI of Janssen et al (2017) of 21 ng/kg bw/day as a worst case DNEL, then a human of 70 kg would need to drink 42 liters of water per day to arrive at a risk characterisation ratio (RCR) of 1. Please note that the average intake of water by humans is 2 liters of water, and also that water has an LD50 in the range of 5.4-6.3 liters per day. 11) The dossier lacks information on (expected) time trends in substance concentrations. No increase over time has been reported. Hence, it can only be speculated that cessation of emissions do not lead to a reduction in environmental or the more relevant drinking water concentrations.  In conclusion, it is acknowledged that there is a high public and political concern, specifically in the Netherlands, fueled by media coverage of the general press. However, based on the above arguments there is no scientific argumentation to consider this alarming and requiring an immediate regulatory risk management. It is still unclear how the substance affects human health, and the body of science is not robust enough as it needs to be. The data generation processes of REACH should, specifically in this case, be finished first before moving onwards with irreversible regulatory actions. The costs and benefits need to be carefully balanced. |  |
|  |
| 5295  2019/04/29 | Norway,  Member State | General comment: We thank the Dutch authorities for the SVHC-dossier for HFPO-DA, its salts and its acyl halides, and appreciate the opportunity to comment on the dossier. We share the concern for the findings of HFPO-DA in the environment and for the properties of the substance which represent a risk to human health and the environment. HFPO-DA is highly persistent and is not expected to degrade under environmentally relevant conditions. It is highly mobile in the aqueous environment, and contamination of water resources and drinking water has been observed. Furthermore, HFPO-DA has a potential for long-range transport. In our opinion HFPO-DA exhibits properties that taken together are of an equivalent level of concern as PBT/vPvB substances. According to the REACH PBT Guidance the specific concerns related to PBT/vPvB substances is due to their potential to accumulate in parts of the environment and to the fact that the effects of such accumulation for human health or wildlife may be unpredictable in the long term. With continuous emissions of HFPO-DA, environmental concentrations will increase, including the levels in drinking water sources and even an enrichment in edible plants. An increasing human exposure will be accompanied by increasing HFPO-DA levels in human blood and organs. At some point a concentration may be reached at which the currently known and unknown health effects of the substance may be realized. HFPO-DA should therefore be identified as a substance of Very High Concern (SVHC) according to REACH article 57 f) and included in the Candidate List.  Detailed comments: We suggest adding a recent study by Conley et al. (2019) on developmental toxicity; The study is a combined in vitro and in vivo study in Sprague-Dawley rats concerning potential maternal and postnatal toxicities of oral HFPO-DA. The study demonstrated that HFPO exposure produced higher maternal liver weights, lower maternal serum thyroid hormone and lipid profiles, and up-regulated gene expression related to PPAR-signaling pathways in maternal and fetal livers during gestation. The pilot postnatal study indicated lower female body weight and lower weights of male reproductive tissues in F1 animals. Reference: Conley, Justin M., et al. "Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats." Environmental health perspectives 127.3 (2019): 037008. We also suggest including another recent study by Cousins et al. (2019) on persistency and the concern on high persistent compounds: This paper argues that the higher the persistence of a chemical, the greater emphasis should be given in chemicals assessment and decision making. The study demonstrates that if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination irrespective of the chemical's physical-chemical properties. Thus, increasing concentrations, will result in increasing probabilities of the occurrence of known and unknown effects and that, once adverse effects are identified, it will take decades, centuries or even longer to reverse contamination and therefore effects. Reference: Cousins, Ian T., et al. "Why is High Persistence Alone a Major Cause of Concern?." Environmental Science: Processes & Impacts (2019). The substance FRD-902 (CAS no 62037-80-3) was included in a Norwegian environmental monitoring study in 2016. Samples were collected from locations within the Oslofjord area, Lake Mjøsa and in the vicinity of the City of Oslo. Samples were taken from a STP (VEAS), seawater and sediments near the outlet from VEAS, moreover samples from snail and shore crabs and cod liver (Gadus morhua) were analysed. Also from a lake (Mjøsa) samples from a STP (HIAS), sediments in the vicinity and liver samples from several fish species in the lake (perch (Perca fluviatilis), roach (Rutilus rutilus), bream (Abramis brama), grayling (Thymallus thymallus) and whitefish (Coregonus lavaretus)) were analysed. Moreover, liver samples from rats captured from the sewage system of Oslo, from the streets of Oslo and from indoor areas at a waste treatment plant and dust and air samples from a hotel and two shopping centres were analysed. The substance was not quantified in any of the samples. However, it should be recognized that there are no known companies producing or using the substance (or the acid (HFPO-DA) or other of its salts) in this area. Reference: The Norwegian Environment Agency. Screening programme 2016: Suspected PBT compounds. M-806 | 2017 |  |
|  |
| 5297  2019/04/29 | Finland,  Member State | We thank the Netherlands for this proposal. Please note that in addition to the comments to the Annex XV report listed below there is a separate document regarding the biodegradation predictions using the BIOWIN models (file name: HFPO\_DA\_Annex\_to\_FI\_comments\_BIOWIN.docx). This document gives additional information to the comments below. Comments: We would like to draw your attention to the recent publication by Conley et al. Please discuss these findings in relevant sections of the document. Conley, Justin & S. Lambright, Christy & Evans, Nicola & Strynar, Mark & McCord, James & Mcintyre, Barry & Travlos, Gregory & Cardon, Mary & Medlock-Kakaley, Elizabeth & Hartig, Phillip & S. Wilson, Vickie & Gray Jr, Leon. (2019). Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats. Environmental Health Perspectives. 127. page 6. List of abbreviations. Please include “HFPO” in the list page 8. (summary): ”HFPO-DA adversely impacts human health at a daily intake that could be as low as 21 ng/kg bw/day (tTDI).” Please, rephrase this sentence to: HFPO-DA may adversely impact human health at a daily intake…”. Reasoning: The wording gives impression that there are reported cases of people suffering from HFPO-DA toxicity. page 8: “which will become irreversibly affected”: Comment: This refers to concentrations and distribution. Therefore, we think that “affected” should be replaced by “exposed” as effects are not discussed in this paragraph  page 8: “chronic background concentrations” (used also in other parts of the document): Comment: The word “chronic” seems to be redundant and misleading as it is often associated with effects and here it is used in relation to exposure. An alternative wording could be e.g. “expected continuous presence in the environment”.  page 9. Please extend the summary to include reasoning why there is considered to be an ELoC to the environment and humans, taking into account that there are no indications that the T criterion of PBT assessment would be fulfilled and that information on environmental hazards is not included in the proposal at all. In our view this should include considerations related to PBT/vPvB substances. This is discussed in more detail in our other comments (e.g. comments regarding pages 111 and 114). page 9: “effects will not only occur at the point of release…”. Comment: This sentence is about distribution and not effects. Therefore, it could be replaced by “the substance will not only be present at the point of release but…”. In addition, “will affect a very large number of people” should be changed, e.g. to “a very large number of people may be exposed to the substance”.  page 9: “…such as PFOA, PFHxA and PFBS present in the environment lead to combination effects on human health, which add further onto the societal concern for this substance.” Please modify to: …may lead to combination effects on human health,… Reasoning: as stated on page 113: “Effects resulting from combined exposure are of concern but are as of yet unknown.”  page 21: ”For HFPO-DA there are no studies on its degradation potential available that follow a standardized and generally accepted study design, such as the OECD test guidelines” Comment: “HFPO-DA” apparently refers here to the dimer acid of HFPO. Please specify this in the sentence because based on the list of abbreviations (page 6) and Chapter 1.1. (page 11) HFPO-DA can also refer to the group of 2,3,3,3-tetrafluoro-2- (heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof).  page 21: “A number of studies for the PFOA confirm that this substance is very persistent and does not undergo abiotic or biotic degradation at all under environmental conditions (ECHA, 2013b).” Comment: Please modify to:“…and does not undergo abiotic or biotic degradation at all in studies conducted under environmentally relevant conditions (ECHA, 2013b).”. Reasoning: there are studies indicating biodegradation of PFOA conducted in optimised conditions, i.e.:  Luo, Q. et al. 2015. Laccase-Catalyzed Degradation of Perfluorooctanoic Acid. Environ. Sci. Technol. Lett., 2015, 2 (7), pp 198–203 https://pubs.acs.org/doi/10.1021/acs.estlett.5b00119 Luo, Q. et al. 2017. Factors controlling the rate of perfluorooctanoic acid degradation in laccase-mediator systems: The impact of metal ions. Environmental Pollution. Volume 224, May 2017, Pages 649-657 https://doi.org/10.1016/j.envpol.2017.02.050 Yi et al. 2016. Isolation, identification, and degradation performance of a PFOA-degrading strain. Genetics and Molecular Research 15 (2): gmr.15028043. http://dx.doi.org/10.4238/gmr.15028043. https://www.geneticsmr.com/articles/6361.  page 21: “The difference between these PFCAs and HFPO-DA is the ether bond in the perfluoro chain (see also Annex II). This ether bond is not expected to lower the persistence substantially. QSARs included in BIOWIN v4.10 of EpiSuite generally have a negative fragment contribution of the ether bond on the degradation included. Further, also the length of the perfluorochain does not influence the degradability of the substances” Comment: We propose to modify and extend this, for example as follows: “There are structural similarities between HFPO-DA and PFCAs, such as the high degree of fluorination, the carboxylic acid group, steric conformation, and bond angles (see Annex II). One difference between HFPO-DA and PFCAs is the HFPD-DA’s ether bond which is located between two C3 moieties. Due to the ether bond the fluorinated carbon chains in HFPD-DA are shorter than in e.g. perfluorohexanoic acid (PFHxA) which has the same number of fluorine atoms. There are no indications available in the literature that the ether bond or other differences between these compounds would have an influence on the degradability/stability of these substances in the environment. QSARs included in BIOWIN v4.10 of EpiSuite generally have a negative fragment contribution of the aliphatic ether bond on the degradation included (see ‘Comparison of BIOWIN QSAR results for HFPO-DA, PFHxA, and PFOA’). This indicates that ether bond in HFPO-DA is not expected to lower the persistence substantially. BIOWIN results suggest that HFPO-DA, PFHxA, and PFOA have a low biodegradability and that there may be some differences in biodegradability between these compounds. However, the reliability of the BIOWIN models to predict differences between these compounds is questionable (see ‘Comparison of BIOWIN QSAR results for HFPO-DA, PFHxA, and PFOA’). Reasoning: This change is proposed to take into account that there is no information on long-term degradation rates of perfluorinated substances with different chain lengths or with different functional groups (such as carboxyl or ether) in environmentally relevant conditions. Also other differences between HFPO-DA and PFCAs than the ether bond may be significant and therefore are briefly discussed in the proposed text. Regarding BIOWIN models we agree that (aliphatic) ether fragments in BIOWIN are mostly negative indicating that an addition of an aliphatic ether to a molecule generally decreases the predicted degradability according to BIOWIN. However, as the purpose here is to estimate the effect of an ether fragment in relation to PFCAs (that are considered vP) we do not think that the fact that ether bond has a negative coefficient in BIOWIN is a sufficient argument for equal persistence of HFPO-DA to PFCAs. All structural differences should be considered as well as the values of the coefficients. Therefore, we suggest to include the comparison of BIOWIN results (submitted here as separate document, file name: HFPO\_DA\_attachment\_to\_FI\_comments\_BIOWIN.docx) e.g. as an appendix.  page 24: “In particular, the perfluorinated carbon chain is counted as four units of “carbon with 4 single bonds & no hydrogens”, while only BIOWIN 1-4 and 7 predictions include an additional fragment for a trifluoromethyl group. Comment: Please modify e.g. to “In particular, there is no fragment coefficient for a subterminal perfluorinated carbon in the BIOWIN models. For example, for EC 236-236-8 the perfluorinated carbon chain is counted as three units of “carbon with 4 single bonds & no hydrogens”, while BIOWIN 1-4 and 7 predictions include an additional fragment for a trifluoromethyl group and BIOWIN 5-7 include a fluoride fragment. It should also be noted that in BIOWIN 1-4 the trifluoromethyl fragment is based on only one compound in the training set. In the case of BIOWIN 1-2 the amount of trifluoromethyl fragment exceeds the maximum number of fragments in the training set compounds and in this situation the predictions may be less accurate according to BIOWIN User’s Guide.”.  Reasoning: There are three (not four) units of “carbon with 4 single bonds & no hydrogens” in HFPO-DA. In addition, BIOWIN 5-7 in principle cover the whole perfluorinated chain as they include also a fluoride fragment (in addition to the “carbon with 4 single bonds& no hydrogens”).  page 24: “The toxicity of H-28397 (88% ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate, 13.3% water and an impurity of 3.4 ppm perfluorooctanoic acid) to inocula was tested separately in a respiratory inhibition test according to OECD TG 209.” Comment: Please include an explanation and the results or move to microbial toxicity section or delete the sentence. It is not clear why this information is included in the degradation section. In addition, the toxicity results are not given.  page 25: Please specify in the report whether the screening studies by Kawashima and Lili include toxicity controls.  page 25: “Based on the predictions on biodegradation by BIOWIN and the lack of any primary degradation in the screening tests available on biodegradation, it is concluded that HFPO-DA does not biodegrade.” Comment: In line with the arguments presented above, we propose to modify, e.g., to: “Based on the lack of any primary degradation in the screening tests available on biodegradation, predictions on biodegradation by BIOWIN, and the very high degree of fluorination it is concluded that the biodegradation of HFPO-DA in the environment is likely to be very slow or negligible”.  page 26: Please include discussion of reliability of KOCWIN 2.00 prediction for HFPO-DA.  page 39, last paragraph of 3.2.6. Comment: Please modify to take into account that there are many uncertainties in the use of monitoring data in P/vP assessment. According to the ECHA guidance R.11. “conclusions should be drawn on the basis of monitoring data only when there is sufficient understanding of the substance distribution and transport behaviour and under the condition that the uncertainties in the monitoring data presented are adequately addressed.”. We note that in the degradation section monitoring data is not used as the main argument. The same considerations may be relevant for mobility as well.  page 41: first paragraph:”lower boundary of the half-life criterion for very Persistent (vP substances)” : Please delete “lower boundary of the” as there are no lower boundaries for vP (for each of the compartments the vP criterion is indicated by one half-life value).  page 41: last paragraph. “This makes these estimations less reliable.” Comment: please specify, what are these estimates (the same ones as in Table 8 or other?) and what is the comparison point meant by “less reliable than”?  page 42: last paragraph. Please specify “aqueous exposure concentrations”; what is the difference between this parameter and “water concentrations” in the same paragraph? Is it the same measurement but only on different sampling date?  page 43: “Other data for BCF and BAF of PFOA in carp (Verbruggen et al., 2017) show that the expected BAF value for PFOA is higher than what as observed for HFPODA at the same external water concentration.”. Comment: This is a difficult sentence. Would the following modification be in accordance to the meaning of the sentence?: “Other data for BCF and BAF of PFOA in carp (Verbruggen et al., 2017) show that at the same external water concentration a higher BAF would be expected for PFOA than for HFPO-DA”?  page 43: Figure 12. In the figure caption, could you explain what is the meaning of “Arrows denote values smaller than indicated”? What values does it refer to? and what does it mean (e.g., that the values are out of the scale of the graph?). There is only one arrow that is linked to a data point.  page 43: “The water concentrations of PFOA in the studies cited by Verbruggen et al. (2017) were always amongst the highest observed in the field studies (roughly about half of the total concentration of PFASs or more).”. Comment: What does “amongst the highest observed” refer to (highest of PFASs studied?). Please specify.  page 44: “Taking into account the uncertainty surrounding the joint exposure of PFAS, the aquatic bioaccumulation of HFPO-DA might still be very similar to that of PFOA.”. It could be explained why the BCF study by Hoke et al. 2016) (with FRD-903 only) seems to be given a low weighting in this assessment and instead the effect of joint exposure of PFAS is emphasised. Are the BCFs reported in that study (<30 and <3 L/kg) considered reliable? Is there any information on biotransformation in fish and whether it could affect the result?  Page 86: “Decreased globulin and corresponding increases in A/G ratio are considered early signs of potentially reduced immune function.” This effect was reported quite consistently and at already low dose levels in both rats and mice in repeated dose toxicity studies and is thus interesting. Moreover, the lowest reference values for humans (tTDI) were derived from this effect. Could you please elaborate briefly in the document (possibly including literature references) why you consider this finding as early signs of potentially reduced immune function.  page 87 (carcinogenicity). The tumour findings are important part of the dossier. This section would benefit of more detailed information which would enable the reader to conclude on carcinogenic properties of the substance. Please modify the section as follows:  The Table 32 is difficult to read since different dose levels were used for males and females. Please modify the table 32 by including dose levels as mg/kg bw/day. Moreover, incidences for males and females could be in separate columns for clarification. The tumor findings are compared with historical control data but no information on historical control data is given. Thus, it is not possible to judge the relevance of the historical data. Please include in the text the necessary information on historical control data, i.e. whether the data is from the same laboratory that conducted the study in question, strain and origin of the animals (same breeder?), how many studies and animals, from what time period (preferably within 5 years to study in question). Second paragraph. Please consider modifying accordingly: “The incidence of Leydig cell tumours was not statistically significant, amongst others due to a relatively high incidence of these lesions in the controls. However, the incidence of interstitial cell hyperplasia was increased at 50 mg/kg bw/day and outside the historical control range suggesting that increased incidence of Leydig cell tumours in high dose males was treatment-related.  pages 92-93. In rat developmental toxicity study early deliveries and reduced pup weights were observed at 100 and 1000 mg/kg bw/day while also maternal toxicity was evident at these doses. Please include brief comparison of maternal toxicity and foetal effects/early deliveries and discuss whether you consider these effects (foetal effects, early deliveries) to be a secondary non-specific consequence of other toxic effects (maternal toxicity) or not. Consider also findings of the mice reproduction/developmental screening study and the findings of the recent publication by Conley et al and conclude on developmental toxicity (i.e. whether you consider that the data currently available fulfils CLP criteria for Category 2/Category 1B developmental toxicant. When appropriate, please include this conclusion also in section 4.8.3 (summary and discussion of reproductive toxicity), section 4.11 (summary and discussion on human health hazard assessment, page 100), section 6.3.1.10, pages 108-109, section 6.3.2.2  page 100. First paragraph: “In summary, the data illustrate that HFPO-DA induces tumours in the liver, pancreas, and testes in rats upon chronic exposure.” Please conclude clearly on carcinogenic potential based on the currently available data. For example: This indicates that HFPO-DA may also be a human carcinogen… the data is considered to fulfil CLP criteria for Category 2 carcinogen. Please include this conclusion also to section 6.3.2.2 page 112.  page 101: “The environmental health hazards…”. Comment: apparently, “health” should be deleted (as the title of the Chapter is Environmental hazard assessment).  page 101: “The environmental health hazards of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid,its salts and its acyl halides (covering any of their individual isomers and combinations thereof) are considered not relevant in the context of the present Annex XV proposal to motivate the very high concern for these substances that lead to propose these substances as SVHC according to art. 57(f) of REACH. Subsequently, no environmental hazard assessment has been performed.” Comment: The report states on page 116 that there is scientific evidence of probable serious effects to the environment and humans, which gives rise to an equivalent level of concern according to article 57(f) of REACH. The text on page 101, claiming that environmental hazards are not relevant, therefore seems inconsistent with the proposed SVHC identification. Please consider including a justification why environmental hazards are not considered relevant.  page 102: 6.3. “All publicly available information was taken into account and no information was given additional weight in relation to other information”. Comment: Please check whether this statement is correct. At least based on the degradation section there were differences in the relevance of the studies as it is stated: “All studies and publications are considered relevant to evaluate the degradation of HFPO-DA, and are used in the weight of evidence assessment of persistence. Despite the fact that some studies are not conducted according to OECD guidelines, or may not be considered highly relevant as standalone studies to assess the persistence, the study results show an overall consistent pattern of degradation for HFPO-DA. Hence, the dossier submitter sees no reason to discard any study on the basis of reliability.”  page 102: “…are irreversibly present in the environment due to the absence of degradation and the impossibility to remove the substance from the environment after release…” Comment: Please modify to “…are irreversibly present in the environment due to the absence of degradation in environmentally relevant conditions and the impossibility to remove the substance from the environment after release…”  page 103: “The Substance Evaluation decision addresses concerns of carcinogenicity which could lead to a potential classification and the half-life in humans (bioaccumulation potential) which could lead to identification of the substance as PBT/vPvB and/or a different DNEL for workers and consumers.”. Comment: Please clarify whether it means that different DNEL might be derived for workers compared to consumers, or whether it means in general a refinement of DNEL for workers and consumers.  page 103: 6.3.1. The title refers to “hazardous properties” whereas many of the subtitles are more related to observations that are related emissions and distribution of the substance. “Summary of the data on the identified concerns” could be more suitable.  page 110: In Section 3.1 it is shown that HFPO-DA is so very persistent that the substance practically does not degrade in the environment. Comment: Please modify to be consistent with 3.1.4, e.g. to: 1 “it is shown that degradation potential of HFPO-DA in all compartments can be concluded to be very low or negligible.”  page 110: “Based on the available experimental and QSAR information on HFPO-DA and on the information of structurally related substances, it is expected that HFPO-DA will meet the P and vP-criteria of REACH Annex XIII.”: Comment: Perhaps the words “expected” and “will” can be deleted as it is already said in the subtitle 6.3.2.1 (and in summary section of the report) that the substance is very persistent.  page 110:” it will not be removed via any natural process such as e.g. bio- or photodegradation.”. Comment: we propose to modify “its removal via any natural process such as e.g. bio- or photodegradation will be negligible or very slow.”  Page 111: “Due to the very high persistence of the substance, the exposure will remain over multiple generations and hence will lead over time to inter-generational effects.” and “Irreversible concentrations in the environment will furthermore lead to inter-generational effects”. Comment: Please modify to “Due to the very high persistence of the substance, the exposure will remain over multiple generations and hence can lead over time to inter-generational effects.” and later “Irreversible concentrations in the environment can furthermore lead to inter-generational effects”. No certain predictions can be done for inter-generational effects with current knowledge, but as a precaution there is a concern that inter-generational effects might occur in the future.  page 111: “The wide spread occurrence in the environment and the low background concentrations in water observed world-wide raise a concern for impact on migratory species and show that the substance has the potential to impair population level structure and recruitment or ecosystem function and stability at remote and pristine areas.” Comment: Please delete or modify the sentence. Reasoning: It is unclear from the present text why the occurrence in the environment is of particular concern to migratory species compared to other species and what evidence there is for impairment of population level structure and recruitment or ecosystem function and stability at remote and pristine areas, considering that no data on environmental hazards is included in the document at all. If the available mammalian toxicology data is considered relevant for the environment this should be explained in the report. If a similar argumentation as for vPvB substances (i.e. that regulatory action is warranted even though the T criterion is not fulfilled) is considered relevant here, it should be described.  Page 111: “once released any amount will persist and environmental occurrence will only increase with continued production, use and emission of HFPO-DA and any of its precursors.“ Comment: Please modify to: “once released any amount is likely to persist and environmental occurrence will increase with continued production, use and emission of HFPO-DA and any of its precursors”. Reasoning: There are studies indicating that degradation of perfluorinated substances is possible in optimised conditions. Therefore, it is not completely excluded that some degradation would occur in the environment. We also note that the environmental half-lives of HFPO-DA or other perfluorinated componds in the environment are not known and there are no standard simulation tests available for these compounds.  Page 111: “Irreversible concentrations in the environment will furthermore lead to inter-generational effects ”. Comment: Please modify to: “High persistence and continuous presence in the environment can furthermore lead to inter-generational effects”. Reasoning: As discussed in comments above.  page 112: “HFPO-DA enters the biosphere and humans via several routes” Comment: Please change the term biosphere to biota or for example “HFPO-DA enters the biosphere via several routes”. We think that biosphere, by definition, would also include humans.  page 112: Second paragraph: “Based on the effects on carcinogenicity it is concluded that HFPO-DA causes adverse effects on human health that can be considered irreversible.” Please modify to: “Based on the currently available data on carcinogenicity it is concluded that HFPO-DA may cause adverse effects…”  page 113: ”Independent of the half-lives in humans, irreversible background concentrations of HFPO-DA in water, which may lead to the contamination of drinking water and food and feedstuff, lead to long-term continuous human exposure, that can be expected to be inter-generational.” Please modify to: “Independent of the half-lives in humans, irreversible background concentrations of HFPO-DA in water may lead to the contamination of drinking water and food and feedstuff and hence to long-term continuous human exposure, that can be expected to be inter-generational.”. Reasoning: as discussed in comments above.  page 113: “bioaccumulation in humans cannot be ruled out due to the absence of data in humans”: Comment: We do not think that a concern which is not confirmed can be used as an argument for EloC. This would not be appropriate for SVHC identification under 57 (a) to (e).  page 114:, 6.3.2.5 “The environmental abundance of HFPO-DA is considered to be impossible to reverse in practice, and hence exposure of humans and the environment will continue after cessation of use.” Comment: “The environmental abundance” is unclear. In addition, as indicated in comments above, the possibility for degradation in the environment cannot be completely excluded. We propose to change to “Once released and distributed to the environment, the presence and amount of HFPO-DA in the environment are expected to be long-lasting, and hence exposure of humans and the environment will continue after cessation of use”.  page 114, 6.3.2.5. We think that this section is crucial for the report and should be more informative. To justify an ELoC it should be explained why the combination of environmental fate properties and other properties, together with the documented level of toxicity, causes a concern that is of equivalent level to a PBT and/or vPvB substance. The only explanation in 6.3.2.5 currently is that the environmental concentrations of HFPO-DA will increase in the aquatic environment when the use continues (and also for remote and pristine environments) and that the environmental abundance is considered to be impossible to reverse in practice. We think that the relationship between environmental half-life, bioaccumulation, environmental concentrations and internal concentrations should be discussed in more detail to evaluate whether there is an exposure potential comparable to PBT/vPvB substances which would be supportive of ELoC.  Reasoning: We think that the potential ELoC of HFPO-DA should be compared to PBT and vPvB substances because the exposure of humans is via the environment and because the justifications for ELoC to humans have similarities to PBT and vPvB substances. There is no proper explanation why the substance is considered an ELoC to the environment.  Currently, there are no generally agreed principles in the EU on what level of evidence of toxicity in combination with high persistence (vP) and mobility is considered to form an ELoC under REACH. We note that the toxicity properties of HFPO-DA are not equivalent to Art. 57 points (a) to (d) as neither the classification criteria for CMR Category 1 nor the T criteria of PBT assessment are fulfilled based on currently available information. As the level of toxicity of HFPO-DA is lower than that of PBT substances based on currently available information, it should be explained why it is still considered that there is an equivalent level of concern to PBT substances.  It might be more straightforward to justify a comparison of HFPO-DA to vPvB substances than PBT substances. We note that according to ECHA guidance R.11, “In the case of vPvB substances, there is concern that even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since high but unpredictable levels may be reached in man or the environment over extended time periods.”. Therefore, it should be explained why very persistent and mobile substances will reach similar levels in humans or in the environment over extended time periods as vPvB substances.  The internal concentration (and exposure) of PBT/vPvB substances can be expected to increase in organisms along the food chain due to the persistence in the environment and accumulation in lipids. Regarding a very persistent and mobile substance (but with no significant bioaccumulation potential) the concentrations may increase in water and in food, which may lead to increasing exposure to the substance based on the lines below:  -assuming continuous emissions there will be an increase in environmental concentrations (e.g. due to the lack of degradation or adsorption) which leads to a continuous exposure of environmental organisms, as well as humans via environment, drinking water, or food -assuming that there is no bioaccumulation the internal concentrations in organisms will depend on the concentrations in the environment, drinking water, or food -therefore, the internal concentrations will increase with increasing environmental/drinking water/food concentrations -it should be further discussed whether the expected increase in internal concentrations of HFPO-DA will lead to similar levels as expected for PBT/vPvB substances We propose these issues to be included in more detail in the report.  page. 115. first paragraph: ”…shows adverse effects in humans.” Could you please rephrase this sentence: shows potential for adverse effects in humans / may cause adverse effects in humans. Reasoning: the sentence gives impression that there are reported cases of people suffering from HFPO-DA toxicity.  page 115: “The current uncertainty regarding bioaccumulation adds to the conclusion that adverse effects of HFPO-DA may occur at lower concentrations than the available toxicity data currently suggests.”. Comment: It is not clear from this sentence how the bioaccumulation might explain that effects may occur at lower concentrations (e.g. does it refer to internal concentrations or concentrations in the environment). In addition, we do not think that a concern which is not confirmed can be used an argument for EloC. This would not be appropriate for SVHC identification under 57 (a) to (e). page 115: “Further concern also arises as a consequence of the very high persistence and chronic background concentrations in the environment, resulting in continuous exposure that may lead to the irreversibility of adverse effects that are normally considered reversible upon the removal of exposure in standard toxicity studies.” Comment: Please clarify whether this refers to effects in humans or in environmental species. Page 115: “The combination of very persistent and very mobile characteristics means that with continuous emission into the environment, the concentrations of HFPO-DA in the environment will increase, the substance will be distributed world-wide and pristine areas and groundwater will become irreversibly affected.”. Comment: Please consider clarifying whether this refers to the presence of the substance or to the effects of the substance, or both. As no environmental hazards are included in the report, meaning of “affected” is unclear here in the environmental context. One option would be to consider only the presence of the substance, e.g.”…the substance will be distributed world-wide, including pristine areas and groundwater.”  Page 115: 2nd paragraph, “As HFPO-DA adversely affects human health, continuous exposure …” Please modify the sentence by deleting “As HFPO-DA adversely affects human health..”. Reasoning is the same as for the sentence considering HH effects in first paragraph of page 115.  Page 115 and 116: please modify to: “may lead to combination effects”. Reasoning: As stated on page 113: “Effects resulting from combined exposure are of concern but are as of yet unknown.” |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5297\_HFPO\_DA\_Annex\_to\_FI\_CA\_comments\_BIOWIN.docx |
| 5298  2019/04/29 | Austria,  Member State | PFAS compounds are resistant to degradation and the degradation potential of HPFO-DA is negligible. The Austrian REACH CA supports the vP status of the substance. Additionally, the substance in its anionic form is very mobile based on the very high water solubility and the calculated log KOC for HFPO-DA (2.48 and 1.92), hence the substance can be widely distributed via water. With conventional methods during drinking water treatment, no substantial removal for HPFO-DA is possible. A special concern is the presence in drinking water.  The LRTP tool from OECD indicates that the substance has a potential for long range transport. The properties of the substance in combination with the toxicity (concerns related to potential carcinogenicity, immunotoxicity and developmental toxicity as well as endocrine disruption) leads to a very high concern for human health and the environment and therefore qualifies the substance to be identified as 57 (f). Therefore the Austrian CA strongly supports the Dutch proposal to identify 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) as Substance of very high concern as a substance of equivalent level of concern according to Article 57 (f) of the REACH Regulation, also to prevent undesired substitution of other PFASs. |  |
|  |
| 5301  2019/04/29 | Provincie Zuid-Holland,  Regional or local authority,  Netherlands | We welcome the proposal and can largely agree with the way the different properties of the substances are assessed. We particularly agree with the conclusion that the substances should be identified as SVHC. With respect to the applied criteria, we submit that persistency in the environment, or, in the case of these substances: the unability to degrade under ambient conditions, should in itself already be a reason to designate the substance as an SVHC. In that respect we refer to a recently published paper by Cousins et al (Environ. Sci.: Processes Impacts, 2019. DOI: 10.1039/C8EM00515J). The substances that are now proposed to be identified as SVHC have very long half-lives under environmental conditions, exceeding the vP criteria by far. When released into the environment, such substances will ultimately lead to human and environmental exposure, the effects of which may not yet be known. Furthermore, we would draw the attention of ECHA to the recent study by Conley et al (Env Health Persp., 2019. DOI: 10.1289/EHP4372). In this study, the effects of oral exposure to HFPO-DA in rat is compared to the effects of other known PFAS. The results of this study give additional evidence about the toxicity of HFPO-DA. |  |
|  |
| 5302  2019/04/29 | EurEau,  Industry or trade association,  Belgium | N/A |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5302\_EurEau\_Public Consultation\_Ammonium 2333-tetrafluoro-2-(heptafluoropropoxy) propanoate.pdf |
| 5303  2019/04/29 | Chemours International Sàrl,  Company,  Switzerland |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5303\_20190429\_SVHC\_Comments\_Chemours\_HFPO-DA.pdf |
| 5305  2019/04/29 | United Kingdom,  Member State | We thank The Netherlands for producing this dossier and have the following comments;  We agree with the proposed grouping of the substances presented in this SVHC dossier, based on the formation of HFPO-DA in the environment at relevant pH.  We agree that even though no simulation studies are available, the available evidence indicates that HFPO-DA can be considered to be a very persistent (vP) substance. It is likely to significantly exceed the Annex XIII criterion by analogy with similar substances.  We agree that it is mobile and likely to move from terrestrial to aqueous compartments. We also agree that it may be difficult to remove significant amounts of HFPO-DA from waters using many current treatment technologies.  However, we do not agree that the data presented in the dossier allow us to state that HFPO-DA is ubiquitous in the environment. The monitoring data presented are from a relatively small number of studies, from a limited number of countries, generally around known point sources.  The SVHC dossier also notes that there are numerous CLP notifications of FRD-902, FRD-903 and 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoyl fluoride, and Section 9 refers to unknown sources of HFPO-DA in the environment. There is also the potential that HFPO-DA or the parent compounds are present as an impurity in fluoro-polymers. It is therefore unclear whether the monitoring data truly indicate long-range transport from known point source industrial sites, or are due to other unknown point or diffuse sources. On the other hand, highly persistent substances are likely to be able to reach remote environments eventually. Whether this might be in sufficient amounts to cause harm over relevant timescales is a different question.  There is currently no clear evidence that HFPO-DA is significantly toxic in either aquatic or mammalian studies and there is no evidence of significant bioaccumulation potential in humans or wildlife. Scientific evidence of a high degree of likely harm to the environment or human health is therefore lacking. All other SVHCs have demonstrated high toxicity potential as shown by their classification or by meeting the criteria to be considered T (the vPvB category exists because the physico-chemical properties of such substances may prevent toxicity being observed in the relatively short durations of laboratory experiments, e.g. due to the time needed to reach steady state); this does not seem to be the case for HFPO-DA.  The SVHC dossier states “Based on the information available, it is concluded that the effects of HFPO-DA [on human health] are severe”. However, HFPO-DA does not currently have any human health classifications that would trigger regulatory action. We agree that the key target organs in repeat dose studies are the liver, blood, and to a lesser extent the kidney. There are some indications of effects on the immune system, although this is less convincing. The registrants apply the self- classification STOT RE 2 (liver, blood) however, the data are not consistent across the studies. For example, necrosis is reported in the liver in the 28 day study in rats, but not at higher doses in the 90 day study. Furthermore, effects on haematological parameters which are seen in male rats after 28 days and 90 days are not seen after 12 months (in the carcinogenicity study). Ideally, the repeated dose toxicity needs to be properly assessed (i.e., through the CLH process), with full consideration given to whether the effects are relevant to humans (some of the liver effects are consistent with PPARα). In the associated RMOA the NL-CA dismisses this classification. A guideline carcinogenicity study is available in rats in which tumours were seen in the liver, pancreas and testes. In our opinion, this could support classification in Carc Cat 2 at most (the substance is non-genotoxic, and there is evidence for a PPARα MoA).  The dossier refers to a tentative Tolerable Daily Intake (tTDI) which has been calculated using various uncertainty factors including an additional uncertainty factor of 66 to cover the unknown differences between bioaccumulation in humans and animals. This is based on data from PFOA but no justification for using this, rather than any other analogous substance, is given. A second carcinogenicity (in mice) and human biomonitoring studies have been requested under Substance Evaluation. These studies may provide evidence of toxicity that could be taken into account in future (or it could confirm a low level of toxicity). It could also allow for a more realistic TDI to be calculated. We therefore consider that it would be more appropriate to wait for this information, prepare a CLH proposal to thoroughly assess the human health data, recalculate TDIs and then assess whether the ELoC criteria are met.  Turning to other points made in support of the “equivalent level of concern” (ELoC) argument:  • Long-term exposure of organisms: This argument could apply to any substance that is emitted continuously into the environment. Whilst an uncertainty, we do not think this is a good ELoC argument.  • Co-exposure with other per- and polyfluoroalkyl substances: We do not think this is a relevant argument for ELoC. The relative importance of this will depend on a variety of factors, and we did not take co-exposure with other PBT/vPvB substances into account for previous SVHC cases.  • Plant enrichment: There is no benchmark provided to indicate how HFPO-DA compares with non-PFAS substances, or description of the levels that can be achieved in edible plant tissues. Unless such enrichment leads to a toxic effect in plants (not described), we do not see how this can be a particular concern for a substance that does not accumulate in consumers and is of relatively low toxicity. What level of plant bioaccumulation should constitute ELoC and why? (For example, in fish, regulatory triggers are only met at 500 L/kg or higher.) Why is plant bioaccumulation not part of the PBT assessment, but relevant here? We are not convinced that bioaccumulation or occurrence in plants demonstrates “mobility” in the usual sense. The data presented do not clarify how the substance entered the plant, e.g. via uptake through groundwater/irrigation, through respiration in the gaseous phase or a mixture of both.  The main concerns seem to be around the release of this substance from known industrial point sources, which could be controlled in other ways. Proposing this substance as an SVHC appears premature, given that key data have been requested under Substance Evaluation. The ELoC argument in this case therefore appears to be governed by the precautionary principle in the absence of significant toxicity from the substance itself. There is no prior EU-wide policy agreement on the use of this principle for low toxicity perfluoroalkyl substances (PFAS) or any agreed scientific criteria on which to base the decision. It is therefore questionable whether the MSC is an appropriate forum to take this type of decision, especially given the precedent that this would create for other (non-PFAS) substances and the resulting uncertainty that would entail for industry stakeholders. We therefore believe that such a policy-based decision should be taken by the REACH Committee, with an understanding of the uncertainties involved and (ideally) an impact assessment. |  |
|  |
| 5306  2019/04/29 | Denmark,  Member State | DK CA would like to thank the NL CA for submitting this Annex XV dossier. The dossier submitter proposes to identify 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides as substances of equivalent level of concern according to Article 57 (f) of the REACH Regulation. The DK CA supports the proposal and believes that the dossier presents sufficient evidence for the identification of these substances as being substances of very high concern.  We would like to draw your attention to two recently published studies on persistency and on toxicity relevant for the evaluation of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid which can be used to further strengthen the argumentation used in the dossier. A recently published study by Cousins et al. (2019) argues why high persistency alone may cause a major concern. The authors uses model predictions to demonstrate that if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination irrespective of the chemical's physical–chemical properties. Based on this the authors argues that high persistency, without considering any other hazardous properties, is a sufficient basis of regulation of a chemical. Another recently published study has identified maternal, fetal, and postnatal effects of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid following oral exposure in Sprague-Dawley rats (Conley et al., 2019). A reference to this study can be used to strengthen the argumentation for the toxic properties of this substance. References: Cousins, I. T., Ng, C. A., Wang, Z. and Scheringer, M. (2019): Why is high persistence alone a major cause of concern? Environ. Sci.: Processes Impacts, 2019. DOI: 10.1039/c8em00515j Conley, J. M., Lambright, C. S., Evans, N., Strynar, M. J., McCord, J., McIntyre, B. S., Travlos, G. S., Cardon, M. C., Medlock-Kakaley, E., Hartig, P. C., Wilson, V. S. and Earl Gray Jr, L. (2019): Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats. Environmental Health Perspectives 127(3). https://doi.org/10.1289/EHP4372. |  |
|  |
| 5309  2019/04/29 | American Chemistry Council,  Industry or trade association,  United States | 1. The Proposal Does Not Demonstrate That Conditions Have Been Met for SVHC Identification on the Basis of Equivalent Level of Concern (ELoC) to PBT/vPvB  The Proposal argues that HFPO-DA should be identified as a SVHC under REACH on the basis that the materials represent an ELoC to other substances identified in Article 57(a) through (e), that is, ELoC to carcinogens, mutagens, reproductive toxicants, persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances, respectively, for having “probable serious effects to human health and the environment.” This Proposal argues that for HFPO-DA, “there is scientific evidence of probable serious effects to human health” due to a combination of properties, including extreme persistence and mobility, which will result in contamination of drinking water sources. However, the Proposal does not provide sufficient policy or technical justification to warrant the conclusion that the materials demonstrate an ELoC.  The persistence and mobility information presented in the Proposal are not equivalent to the vPvB criteria in Article 57(e). The comparison of persistence and mobility to persistence and bioaccumulation suggests that mobility is of equivalent concern to bioaccumulation. A case has not been made in the Proposal that “M” and “B” are equivalent; rather that both criteria are elements of potential exposure. There is no consensus in the scientific community regarding this point, nor have there been sufficient policy discussions of it in Europe, to establish common understanding.  Artificially limiting the mobility criteria to intrinsic substance properties, such as soil adsorption coefficient (Koc), may misclassify a large range of substances that present no concern for exposure from sources of drinking water, which will then create a potentially unnecessary burden for both authorities and industry.  2. Assessment of Mobility and Exposure Via Drinking Water Can Be Achieved Using Existing Risk Assessment Methods and Tools.  As discussed above, the Proposal’s underlying rationale for identifying HFPO-DA as persistent and mobile is to address concerns for exposure to the substance from drinking water. However, it is possible to use existing risk assessment and risk management to address mobility and potential exposure via drinking water. Therefore, additional screening criteria for SVHC ELoC that would lead directly to restriction or authorization under REACH are not warranted.  The concept of mobility is currently assessed as part of the exposure assessment required under REACH. The environmental risk assessment aims to evaluate the exposure from the uses registered by the applicant, which includes consideration of release rates and environmental transport in the environment. As such, the mobility of a substance is already incorporated in the exposure assessment, since properties such as environmental fate and partitioning to and between different media are key input parameters. Narrowing the evaluation of mobility to a single intrinsic property, such as Koc, may generate false positives inadvertently implicating many substances that are not a real-world concern for exposure from sources of drinking water.  Environmental risk assessment under REACH addresses all environmental compartments, including the groundwater compartment, as illustrated in the ECHA guidance for predicted environmental concentration (PEC) derivation. In particular, predicted exposure in groundwater (PEClocalgrw) is used in the exposure modelling for humans with indirect exposure via the environment. As indicated by the guidance, monitoring information may be used when it is representative and within the scope of the risk assessment. These points should be addressed in Section 3.2.4 of the Proposal.  In addition, there are existing regulatory frameworks outside of REACH that should be utilized for protection of drinking water, including the Water Framework Directive. This allows for environmental monitoring to be used to determine if chemicals are present in drinking water at levels that raise concern.  ACC supports the use of tiered, risk-based approaches for assessment of chemicals. Regulatory action should not be based solely on screening-level, hazard criteria or intrinsic properties without the opportunity for risk assessment. Based on the above considerations, including the possibilities for addressing concerns for drinking water with existing risk assessment tools and methods, in general, the combination of properties including mobility should not be considered as ELoC for SVHC.  4. Need for General, Agreed-Upon Criteria  Finally, before identifying any ELoC for the environment, general criteria should be developed. These criteria should include demonstration of how a substance being proposed as ELoC for the environment has serious and irreversible effects on human health or the environment. Before any substance-specific case based on ELoC for the environment is assessed, a policy discussion on the applicability of ELoC criteria to the environment is required, and agreement needs to be reached on any relevant assessment methodologies. In general, where possible, hazard information must be put into appropriate context of realistic exposures.  The EU Commission recently addressed this issue in response to the Parliamentary question for written answer E-000641-19. In response to questions regarding if there is a mutual agreement and understanding of what constitutes an equivalent level of concern under Article 57(f), the EU Commission indicated that while criteria have been agreed upon in the case of sensitizers, criteria have not been agreed upon for other effects. The EU Commission states:  "Due to that, the Commission announced in 2018 in the REACH Review that it will ensure together with ECHA and Member States that criteria for the identification of substances of very high concern (SVHC) requiring an assessment of ELoC are developed and applied in a consistent manner."  ACC supports the adoption of clear criteria before Article 57(f) can be used for evaluating substances based on environmental criteria. |  |
| *See the corresponding embedded attachment in table 1 of Part I:* *5309\_FINAL\_ACC Comments to ECHA 042919.pdf* |
| 5312  2019/04/29 | ChemSec,  International NGO,  Sweden | ChemSec´s agrees with the identification of this substance as an SVHC.  The dossier well summarizes the evidence showing extreme persistency and high mobility in, resulting in widespread and concerning occurrence in the environment. In addition the substance has shown an array of toxicological effects, including being a potential carcinogen.  ChemSec supports the idea of identifying substances that are persistent, mobile and toxic (PMT) or very persistent and very mobile (vPvM) as SVHCs. This is an important and problematic group of substances that need more regulatory attention in order to halt and prevent further pollution of valuable water resources. |  |
|  |
| 5314  2019/04/29 | European Chemical Industry Council (Cefic),  Industry or trade association,  Belgium | Cefic comment relates to the general approach proposed and not on sustance specific aspect. |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5314\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5315  2019/04/29 | FluoroCouncil,  Industry or trade association,  United States | See attached contribution. |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5315\_FINAL FluoroCouncil response HFPO-DA SVHC consultation 29-4-19.pdf |
| 5316  2019/04/30 | Swedish Society for Nature Conservation,  National NGO,  Sweden | 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid (HFPO-DA), its salts and its acyl halides (covering any of their individual isomers and combinations thereof)  Swedish Society for Nature Conservation welcomes the SVHC dossier submitted by The Netherlands. The dossier provides extensive background information for the identification of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) as a SVHC. SSNC supports the proposal to identify HFPO-DA as a substance of equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 (REACH) according to Article 57(f) of the REACH Regulation.  HFPO-DA should be classified as a substance of very high concern due to the combination of extreme persistency, high mobility and evidence of a wide range of toxicological effects on kidney, liver and immune system at low levels of exposure. In addition there is some evidence that the substance may be carcinogenic. The substance is ubiquitously present in the environment including groundwater and drinking water and current water treatment techniques are not capable of removing HFPO-DA. Since HFPO-DA is used in the production of fluoropolymers, there is a risk that it could be present in consumer products such as cosmetics. Also, scientific data shows that fluoropolymer manufacturing is a source of emission of per- and polyfluoroalkyl substances such as HFPO-DA into the environment (Song et. al 2018 ). The widespread occurrence together with the documented toxic effects at low exposure levels is evidence that HPPO-DA meets the criteria as SVHC according to Article 57f of REACH. |  |
|  |
| 5317  2019/05/02 | Belgium,  Member State | Belgian comments to the Annex XV SVHC report for GENx --------------------------------------  Belgium would like to thank the NL CA for submitting this Annex XV dossier. We recognize that the dossier submitter proposes to identify GENx:  2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)  as a SVHC according to Article 57(f) of REACH Regulation.  Belgium, as a Member State, is of the opinion that enough evidence is available in the Annex XV dossier to identify GENx as being of equivalent level of concern, because amongst others:  a) Regarding the toxicity of the substance, effects seen in liver are severe and irreversible (Haas 2008a, MacKenzie, 2010 and Edwards, 2010a), and could warrant a classification as STOT RE1. Moreover the concern is further supported by effects seen in the available carcinogenicity study. We draw the attention on the fact that new information is available in Conley (2019).  b) GENx fulfils the persistent (P) and very persistent (vP) criterion of Annex XIII to REACH. This is based on its structural properties, QSAR estimates, read-across, screening test, and monitoring.  c) GENx gives rise to an equivalent level of concern to the bioaccumulation (B) criterion of Annex XIII of REACH. This can be shown by recalling that the legislator included B in REACH as a concern because irreversible or poorly reversible internal exposures to a substance can potentially lead to toxic effects that are not already known, as it appeared in several historical cases. GENx indeed raises equivalent concerns regarding internal unavoidable exposure: (1) GENx is a very mobile substance (low adsorption to organic matter / soil) with a high distribution towards aquatic systems, and can be transported over long distances in short timeframes, and is currently already found in surface water, groundwater and oceans, and (2) if emissions are not reduced, concentrations will only increase in the aquatic compartment due to the high persistence of the substance, and due to the residence time in aquifers and the lack of water treatment methods available at large scale for drinking water, such exposures can be considered irreversible in practice (as shown by existing cases of tap water contamination with other PFAS where the only solutions found in the midterm are the change of water sources or providing bottled water). This concern is further substantiated more generally in Cousins (2019) for compounds that are persistent and poorly adsorbed in organic matter and sediments.   REFERENCES ---------  CONLEY et al, 2019. Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats. Environmental Health Perspectives. https://doi.org/10.1289/EHP4372  COUSINS et al 2019, Why is high persistence alone a major cause of concern? Environmental Science: Processes & Impacts  EDWARDS, T. L. 2010a. An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice  HAAS, M. C. 2008a. A 28-day Oral (Gavage) Toxicicty Study of H-28397 in Rats with a 28-day Recovery.  MACKENZIE, S. A. 2010. H-28548: Subchronic Toxicity 90-Day Gavage Study in Mice. |  |
|  |

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

|  |  |  |  |
| --- | --- | --- | --- |
| Number / Date | Submitted by (name, submitter type, country) | Comment | Responses |
| 5269  2019/03/26 | Oasen drinkwater,  Other contributor,  Netherlands | Both US-EPA and RIVM derived drinking water standards for HFPO-DA in the same order of magnitude as PFOA. Both extremely low (around 0,1 microgram/liter)which indicates that this is a substance with a high toxicity. Added to the Persistency and Mobility of this substance, it is very clear that HFPO-DA is a threat for the public through drinking water and should be classified as SVHC. |  |
|  |
| 5275  2019/04/18 | Health and Environment Alliance (HEAL),  International NGO,  Belgium |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5275\_HEAL-Comments-GenX.pdf |
| 5284  2019/04/26 | the city of Dordrecht,  Regional or local authority,  Netherlands | As a local government, we are responsible for the health and well-being of our citizens. At the same time, we have to deal with the emissions, among which HFPO-DA, from a major fluorochemical plant. The proposal already takes into account a number of studies about environmental concentrations that were measured in the vicinity of this plant. We find HFPO-DA in soil, ground water, surface water, drinking water and in crops in vegetable gardens, often along much higher concentrations of PFOA, the predecessor of HFPO-DA which was used and emitted for over 40 years from the same fluorochemical plant. We are still facing the consequences of these PFOA-emissions. People living near the plant still have elevated levels of PFOA in their blood even though emission ended in 2012. The similarities between HFPO-DA and PFOA, including the health concerns and their behaviour in the environment, urge for swift action and justify designation of HFPO-DA as a SVHC. We have to prevent the long-term effects we are facing now because of the emission of PFOA that went on for decades. We owe our citizens and the future generations the best protection and have to learn from the past. Therefore we shouldn’t delay the designation of HFPO-DA as a SVHC. |  |
|  |
| 5285  2019/04/26 | Gemeente Sliedrecht,  Regional or local authority,  Netherlands | As a local government, we are responsible for the health and well-being of our citizens. At the same time, we have to deal with the emissions, among which HFPO-DA, from a major fluorochemical plant. The proposal already takes into account a number of studies about environmental concentrations that were measured in the vicinity of this plant. We find HFPO-DA in soil, ground water, surface water, drinking water and in crops in vegetable gardens, often along much higher concentrations of PFOA, the predecessor of HFPO-DA which was used and emitted for over 40 years from the same fluorochemical plant. We are still facing the consequences of these PFOA-emissions. People living near the plant still have elevated levels of PFOA in their blood even though emission ended in 2012. The similarities between HFPO-DA and PFOA, including the health concerns and their behaviour in the environment, urge for swift action and justify designation of HFPO-DA as a SVHC. We have to prevent the long-term effects we are facing now because of the emission of PFOA that went on for decades. We owe our citizens and the future generations the best protection and have to learn from the past. Therefore we shouldn’t delay the designation of HFPO-DA as a SVHC. |  |
|  |
| 5286  2019/04/26 | Unie van Waterschappen,  National Authority,  Netherlands | The Unie van Waterschappen from the Netherlands supports the proposal for identification of HFPO-DA and its salts/Acyl Halides as SVHC on the basis of the criteria set out in REACH article 57  The Dutch water boards have many problems with HFPO-,also known as GenX . GenX is found in increased concentrations in the surface water, in effluent from WWTPs , groundwater, aquatic soils. GenX has similar properties to substances that are on the SVHC list. The waterboards have high economic costs because of stopping work by the presents of GenX. There are also concerns about the health of the people who come into contact with GenX due to, among other things, air deposition. Through air deposition , GenX deposits on soil and water and affects people in their living environment who swim, eat fish, live in, consume vegetables and dairy products. Temporary standards have been derived because of the lack of information. GenX is the substitute for PFOA which is already identify as an SVHC substance. GenX have persistent, mobile en toxic characterics( PMT). Substances with PMT characterics are defined bij their inabiltiy to break down under environmental conditions, their affinity for water, and, when toxic their adverse impacts to human health and the environment. It has been proven that these substances have harmful effects on the environment and human health. That is why we support the proposal to put GenX on the SVHC list to prevent harmful effects of GenX on the environment and public health. |  |
|  |
| 5291  2019/04/26 | RIWA, Association of River Waterworks,  Industry or trade association,  Netherlands |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5291\_RIWA Position on UBA proposal for PMT criteria REACH.docx |
| 5292  2019/04/26 | CHEM Trust Europe,  National NGO,  Germany | The dossier provides ample evidence of exposure via diffuse emissions to the general population via drinking water, fruits and local air emissions which is very concerning. The fact that the registrant has replaced the use of PFOA by FRD-902 as processing aid in the so-called GenX technology points to a bigger, very common problem: restricted hazardous chemicals are replaced by similar substances which are often identified as harmful some time later. It is clear that a more systematic solution needs to be found to prevent this failure of human health and environment protection. CHEM Trust has highlighted this topic in the report From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them (https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf).  The dossier addresses a group of structurally related substances which is a very welcome approach for this SVHC identification. However, we do see the urgent need to apply more effective regulatory approaches, such as covering an even larger group of substances in the subsequent control measures to break the vicious circle of moving from one to the next PFAS. (see also Wang et al, Environ. Sci. Technol. 2017, 51, 2508−2518, A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)? DOI: 10.1021/acs.est.6b04806). |  |
|  |
| 5297  2019/04/29 | Finland,  Member State |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5297\_HFPO\_DA\_Annex\_to\_FI\_CA\_comments\_BIOWIN.docx |
| 5301  2019/04/29 | Provincie Zuid-Holland,  Regional or local authority,  Netherlands | As regional government we are the competent authority for a major fluorochemical plant where release of HFPO-DA is a concern. The proposal already takes a number of studies into account about environmental concentrations that were measured in the vicinity of this plant. We find HFPO-DA in soil, ground water, surface water, drinking water and in crops in vegetable gardens, often along much higher concentrations of PFOA, the predecessor of HFPO-DA which was used and emitted for over 40 years from the same fluorochemical plant. We are still facing the consequences of these PFOA-emissions. What remains a concern to us is the co-exposure of humans and the environment to several PFAS simultaneously. As there is not yet an agreed scientific approach on how to assess such exposure, we consider this an additional argument to designate HFPO-DA as SVHC. |  |
|  |
| 5302  2019/04/29 | EurEau,  Industry or trade association,  Belgium | N/A |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5302\_EurEau\_Public Consultation\_Ammonium 2333-tetrafluoro-2-(heptafluoropropoxy) propanoate.pdf |
| 5303  2019/04/29 | Chemours International Sàrl,  Company,  Switzerland |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5303\_20190429\_SVHC\_Comments\_Chemours\_HFPO-DA.pdf |
| 5305  2019/04/29 | United Kingdom,  Member State | Section 11 (page 120): The Dutch manufacturing plant appears to be a key source of the substance in the European environment. It would be useful to describe the level of emission from the plant to air, wastewater, etc., and if possible the historical trends. This would then help to explain (or not) the findings around the vicinity of the plant and beyond. It would also be useful to understand what risk management has been put in place to reduce emissions. The RMOA stated that the site operator is taking steps to reduce emissions by up to 99 % by 2020. Can additional details be provided?  Section 11.2: Please provide further information to support your statement that the potential alternatives to these substances will “most likely be similar in their properties with regard to persistence, mobility and possibly toxicity”. |  |
|  |
| 5309  2019/04/29 | American Chemistry Council,  Industry or trade association,  United States |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* *5309\_FINAL\_ACC Comments to ECHA 042919.pdf* |
| 5314  2019/04/29 | European Chemical Industry Council (Cefic),  Industry or trade association,  Belgium |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5314\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5315  2019/04/29 | FluoroCouncil,  Industry or trade association,  United States |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5315\_FINAL FluoroCouncil response HFPO-DA SVHC consultation 29-4-19.pdf |