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

Substance name: Perfluorobutane sulfonic acid (PFBS) and its salts

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 in 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

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| Number / Date | Submitted by (name, submitter type, country) | Comment | Responses |
| 5340  2019/10/18 | SEMI,  Industry or trade association,  Belgium | Concerning environmental hazard assessment: Experimental data are available for Bis(nonafluorobutyl)phosphinic acid, CAS 52299-25-9 . The substance was registered under REACH. The data are disseminated under https://echa.europa.eu/de/registration-dossier/-/registered-dossier/8036/1 (excluding the bioaccumulation study). This substance is considered as very similar to PFBS. A bioaccumulation study with a reduced number of fishes (compared to OECD 305) showed no significant update of the substance in fish. The BCF was < 12.  Concerning PBT/vPvB and equivalent level of concern assessment: A designation of PBT or vPvB should not be assigned to this substance as there is evidence that PFBS has a low bioaccumulation factor. See:  1) Int. J. Environ. Res. Public Health 2019, 16, 1692; doi:10.3390/ijerph16101692, Pan et al estimated the BAFs of 14 different PFAAs by measuring the concentration of the various PFAAs, including PFBS, in the water and the fish from Lake Chaohu in China. The greatest average log BAF for fish species was found for PFDA (3.50) followed by PFOS (3.35) and PFNA (3.31), whereas other PFAAs showed relatively lower average log BAF values, ranging from 1.45 to 2.85. This result agrees with the conclusions drawn by previous studies that PFCAs with ≤7 fluorinated carbons are not considered bioaccumulative, and the bioaccumulative potential is limited by the molecular size of PFCAs with ≥11–12 fluorinated carbons.  2) Chemosphere 167 (2017) 98-106, http://dx.doi.org/10.1016/j.chemosphere.2016.09.146 Zhou et al estimated BAFs in submerged plants and reported increasing BAFs with increasing chain length, suggesting the absorption of long-chain PFASs was stronger than short-chain PFASs. The mean BAFs of PFOS in submerged plants were almost the highest among all the PFASs, which were much more than BAFs of PFBS. BAFs of PFOA were also high, but lower than PFOS.  3) Environmental International 113 (2018) 1-9, https://doi.org/10.1016/j.envint.2018.01.011 Gomis et al 2018 modeled the bioaccumulation potential of 6 PFAAs in rats following a 10-day oral exposure to 1 mg/kg/day. The model showed that the AUCs in serum increased together with the chain-length among the PFCA and PFSA homologues. PFBA was the only exception due to a four-time longer elimination half-life compared to PFHxA (see Table S1 in the SM). In addition, the model simulation showed that PFBA, PFHxA, GenX and PFBS already reached steady-state conditions at the end of the first 24 h after the first dose. In contrast, PFOA and PFOS were still accumulating at the 10th day of the simulation. According to the authors, the binding affinity increased with chain-length and was also influenced by the functional group. For shorter-chain homologues (i.e. PFBS), the binding to the plasma protein fraction decreases as the concentration increases, indicating a potential saturation of the available binding sites  4) Chemico-Biological Interactions 281 (2018) 1-10, https://doi.org/10.1016/j.cbi.2017.12.021 Garcia et al 2018 looked at the cellular bioaccumulation potential and lipid binding of PFOS, PFOA, PFHxA and PFBS in vitro. The authors found that the cellular accumulation and retention correspond well to the phospholipid binding (CHIIAM7.4) and LogD7.4, whereas less so to LogP data. The shorter chain derivatives PFBS and PFHxA did not accumulate to any appreciable extent. Therefore, the authors concluded that the cellular accumulation potential of the four PFASs corresponded well to their respective half-life ranking in humans, monkeys and rodents.  5) https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/perfluorobutanesulfonic-acid-and-its-direct-precursors#KeyFindings See the Key Findings section where they talk to the low bioaccumulation potential.  6) https://rd.springer.com/chapter/10.1007%2F978-3-319-15518-0\_6#Sec9 Study showing the bioaccumulation levels relative to several mammal species. See Table 6.2 in Section 6.5 – Clearance. https://www.sciencedirect.com/science/article/pii/S0300483X08005192 Study showing bioaccumulation is much less in Humans, Rats, and Monkeys. See Conclusions. |  |
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| 5344  2019/10/18 | Netherlands,  Member State | p. 20 It is a strong feature of the dossier to compare the persistency of PFBS (C4) not only with its longer C8 homologue (PFOS), but also with its shorter C1 homologue (trifluoromethane sulfonic acid). However we do not understand your choice for including these two homologues only. Could you explain why you did not decide comparing this substance to its closer homologues (i.e. C6 or C3)? Especially for PFHxS an SVHC document including persistence data is already available.  p. 24. Third paragraph below equation 1: Please clarify which statement refers to which group (carboxylic acid of PFCAs).  Page 32. Third paragraph. The last sentence reads as if any experimental result leading to degradation of PFBS should be considered as unreliable on forehand. Please modify the wording.  Page 62. The suggestion that exposure of humans will continue after emissions stops due to sea sprays seems rather speculative. If this will happen it will be on such a scale that it should be considered negligible.  Page 63. On a local scale dispersion of the compound will play a major role (e.g. next to a emission source concentrations will drop once emissions stops). On a larger scale (regional, continental) concentrations are less affected by dilution.  Page 63. What is the origin of the half-lives used in the modelling? Further, because at neutral pH PFBS is almost fully deprotonated, it would be better to use Daw instead of Kaw.  Page 73. Attention is paid to the growth correction of the data. It could be argued that growth correction is not strictly necessary for a substance that is easily excreted from fish (and thus a fast equilibrium between fish and water is reached, although some half-lives tend to be rather long). At the same time the correction applied by Chen et al (2016) is not according to the guideline. According to the OECD 305 k1 and k2 are first determined from the untransformed data after which the k2 is corrected for growth of the fish (k2G). The effect of this alternative method could be shortly discussed.  p. 51 Could you add the findings of Brandsma et al. (2019) to Table 13?  p. 93 Please mention the recent findings by Brandsma et al. (2019) here.  pp. 94-95 It is very difficult to conclude from the field data presented in the SVHC dossier that “recent studies indicate that PFBS is one of the PFASs that show increasing concentrations in various environmental media, including in water and biota”, since these data are not covering a sufficiently dense measuring network. Is this statement therefore meant for specific regions, or worldwide? The latter statement might be too speculative based on the information available, and should therefore merely be presented as a hypothesis in the ELoC chapter. Also, there is no data presented in the SVHC dossier that allows for a comparison between PFBS concentrations and other PFAS concentrations over time.  pp. 95-96 This example mainly illustrates that PFBS is very mobile and rapidly spreads when released to the environment. To us the fact that the substance is detected at pristine areas is more illustrative of long-range transport than environmental distribution from one point-source. This example therefore does not add much to the dossier.  p. 101 Please consider removing the sentence “However no … mammalian data.” And changing it into the sentence “No cut-off values for human elimination half-lives for fulfilling the B or vB criteria have been defined.” As on p. 84. we agree that PFBS shows moderate bioaccumulation potential in humans based on the information provided by Olsen et al. (2009). We also agree that there is still discussion on the criteria for bioaccumulation data, however it seems incorrect to state that the data cannot be interpreted.  p. 102 Please consider inclusion of potential exposure via foods (such as edible fish or meat) as well as via food packaging and clothing in Section 4.2 to be more conclusive. Otherwise please consider revising this section, moving exposure to Part II of the SVHC dossier.  p. 109 Please consider incorporating the recent findings by Liu et al. (2019) in the section on in vitro findings. This study shows that PFBS exposure causes a decrease in CD90 in mesenchymal stem cells, which could stimulate adipogenesis. Furthermore, the authors report that short-chain PFASs, including PFBS, stimulated human mesenchymal stem cell adipogenic differentiation, evidenced by upregulation of several common adipogenesis marker genes. The effects of PFBS were however not as pronounced as for PFOS and PFOA. Liu et al. (2019) also report that four short-chain PFASs, including PFBS, did not affect human mesenchymal stem cell osteogenic differentiation, contrary to PFOA, which is able to do so.  p. 109 Could you also incorporate the spleen weight decrease reported in Lieder et al. (2009), with the side-note that the authors consider this effect not to be treatment related?  “Absolute and relative (to bodyweight and brain weight) spleen weights were lower than those of control males at all K+PFBS treatment levels. However, there was no trend in this reduction across the 10-fold dose range and no adverse histopathological effects were noted. Furthermore, the spleen weight to body weight percent values obtained for K+PFBS-treated males in this study were close to the central estimate of this parameter based on 16–24-week-old male Sprague–Dawley rats historical control data obtained from 19 studies conducted in the same laboratory between September 1994 and April 2008. In the study reported herein, mean spleen weight to bodyweight percents of 0.181, 0.158 (p≤0.01), 0.172, and 0.163±0.020 (p≤0.05) were obtained for the control, 60, 200, and 600mg/kg-day dose-group males, respectively. The mean (±S.D., range) for this parameter for controls from the 19 historical control studies was 0.159 (±0.015, 0.142–0.207). Therefore, the splenic weight effects were not considered to be of toxicological significance. The 200 and 600 mg/kg-day doses in the male rats were associated with increased adverse clinical observations and reductions in red blood cells, hemoglobin concentration, and hematocrit. Chloride was significantly increased at the 600mg/kg-day dose.”  p. 112 “The effects were … is not available”. What is meant by this sentence?  pp. 120-122 Could you please incorporate a short discussion on database uncertainty here, based on the conclusions made by the US-EPA (2018), who note that “the observation of decreased thyroid hormone is known to be a crucial element during developmental life stages, particularly for neurodevelopment, and the database is limited by the lack of developmental neurotoxicity studies. In addition, as immunotoxicity is an effect of increasing concern across several members of the larger PFAS family, the lack of studies evaluating this outcome following PFBS exposure is a limitation in the database.”  p. 122 “However, in general, … health challenges”. Gomis et al. (2018) did correct for the internal PFBS- concentration in the liver and noted that no robust conclusions could be drawn on the relative internal potencies of PFOS and PFBS. However, they state that “for PFBS, the administered dose should be up to 2000 times higher to achieve the same magnitude in serum and liver concentrations as PFOS, which is due to the higher bioaccumulation potential of PFOS in serum and in liver”. We think the main message of this paragraph should be that, however the toxicity of PFBS appears to be low, PFBS may contribute to mixture toxicity effects of PFAS. The unforeseen and unwanted health challenges are more closely interlinked with life-long exposure effects that cannot be tested for in traditional toxicity studies. The latter should however be part of the ELoC assessment and should not be discussed in Chapter 4.  p. 123. Some of the effect concentrations in the acute toxicity test are so high that it cannot be excluded that toxicity is caused by the couterion, e.g. potassium. Please add some remarks on the toxicity of the counterions in the dossier.  p.125. Nauplii is not a Latin name but a a lifestage of Artemia.  p. 126 Chen et al. (2018b). Could you please incorporate the dosages at which these effects occurred, or refer to Table 31 for this?  p. 128 It might be mentioned here that the studies for the marine medaka show effect concentrations that are orders of magnitude lower than the other effect concentrations. This can only be explained if the endpoint or the species is very sensitive. It might be the thyroid function related endpoints that are much more sensitive than other endpoints and are not included in the other tests, including the ELS with zebrafish.  p. 140 We specifically would like to note that according to the NL CA, it is no requirement for a substance to meet the “T” criteria for the environment as mentioned in Annex XIII of REACH. We agree with you that the ecotoxicological data showing developmental effects in fish are considered to fulfil the T criteria for the environment of Annex XIII of REACH, i.e. reduced body weight and length (NOEC of 1.0 μg/L), delay in hatching (LOEC 1.0 μg/L), reduced egg production (NOEC 1.0 μg/L) and a skewed sex ratio (NOEC of 2.9 μg/L). Other endpoint are not necessarily considered as population relevant.  p. 144 “No final conclusion … moderate bioaccumulation potential.” Consider removing these sentences for the reasons provided in the comment on p. 101.  p. 145 “Other effects of … data are insufficient.” What do you mean by this sentence? Data are insufficient to conclude on the toxic potential of the substance for these end-points?  p. 145 “In general, toxicological … to be lower.” Consider to include here the following sentence: “However, the observed adverse health effects observed for PFBS may contribute to mixture toxicity effects of PFAS.”  p. 148 “Monitoring data confirm … drinking water sources.” These sentences do not illustrate that the intrinsic properties of the substance result in irreversible and increasing contamination of surface water, marine water and groundwater. These points are captured under Section 6.3.2.3 and are not at place here.  p. 150 “Toxicological data obtained … in Section 6.3.1.8”. This summary sentence should also include the endocrine system and effects on development.  pp. 150-151 “PFBS has been … fulfilled for PFBS.” This paragraph should reflect more clearly which effects are applicable for classification, and which effects are taken up as supporting information. Consider to revise this section in the way as presented on p. 146:  The ecotoxicological data showing developmental effects in fish (reduced body weight and length (NOEC of 1.0 μg/L); delay in hatching (LOEC 1.0 μg/L); reduced egg production (NOEC 1.0 μg/L); and a skewed sex ratio (NOEC of 2.9 μg/L)) are considered to fulfil the T criteria for the environment of Annex XIII of REACH. This conclusion is supported by effects of PFBS on the visual system of marine medakas with a NOEC < 1.0 μg/L.  p. 152 “The relative toxic … in a study”. Could you be more precise here and explain why you mention this study, and what study this is? Or otherwise consider deleting this sentence.  p. 153 “The relative toxic … in a study”. See previous comment.  General comments regarding the ELoC assessment We largely agree with the ELoC assessment and the elements brought up motivating the concern for PFBS. However, we do see several points for further improvement.  One important element of the ELoC is to argue the presence of probable severe adverse effects for environmental health or human health. For environmental health, this has been done to some extend but for human health this is much less elaborated on. We suggest to make this more explicit in naming the different effects observed and indicating how these contribute to the weight of evidence. Furthermore, in our opinion the observed indication for some bioaccumulation potential in humans is an important argument in de ELoC assessment, which is currently not so well addressed as a possible ELoC element.  A second important element is the combination of high persistency with high mobility and the presence of multiple “precursor” substances that degrade to PFBS resulting in an irreversible environmental presence and an increasing overall environmental abundance even after cessation of use of these substances. However, this increase is not endless and it is not so that locally exposure will occur to “the whole released mass”. We agree that the persistency and mobility and degradation of precursor substances is of high concern, but suggest that the way this is described is somewhat further detailed at the appropriate places in the discussion to reflect these nuances.  Another more general comment is the statement that PFBS cannot be easily removed from drinking water or the environment, where it lacks a reference to efficiency studies on water remediation techniques. If possible, we would suggest that this is further substantiated.  Last, consider separating the facts from the interpretation of facts, i.e. present the scientific data in Chapter 1-5 and leave the interpretation of data to the ELoC chapter. Removing statements from specific places in the latter chapters has been indicated in our previous comments.  Specific comments related to the ELoC assessment pp. 155-156 “PFBS has due … impairment at large”. As stated in our main comment, we believe that the persistence and mobility of the substance are the main properties of concern leading to irreversible contamination, and supporting elements of concern are adverse effects to human health and the environment and mixture toxicity. Could you try to reflect the weight of evidence of elements of concern in this paragraph?  p.155 last sentence on the page: concentrations refers to environmental concentrations?  p. 160 par.2 “all part of the same equilibrium” is an unclear statement. Consider rephrasing; par. 3 consider deleting “several concerns”; par. 5 specify the different concerns for HH effects and how they are included in the weight of evidence; par. 7 consider to add uncertainty of effects as a consequence of long-term low dose exposure (especially in the light of the endocrine effects observed this may be of high relevance); par 9. The current paragraph on bioaccumulation is very concise, please consider to add more information and to put these observations in further perspective, stating that the limited data shows that the substance at least has a moderate bioaccumulation potential in humans.  Table 40: consider adding the possible signals for mild bioaccumulation to at least the elements of intergenerational effects and uncertainty in quantifying exposure and uncertainties in deriving safe exposure levels. Consider adding that co-exposure to other PFAS is not a hypothetical concern but is based on current monitoring data.  Section 6.3.4. general comment: there is still relatively much repetition in this section. Possibly this can be further optimized by changing the structure of the written texts somewhat. References:  Brandsma, S. H., Koekkoek, J. C., van Velzen, M. J. M., & de Boer, J. (2019). The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. Chemosphere, 220, 493-500.  Gebbink, W. A., van Asseldonk, L., & van Leeuwen, S. P. (2017). Presence of emerging per-and polyfluoroalkyl substances (PFASs) in river and drinking water near a fluorochemical production plant in the Netherlands. Environmental science & technology, 51(19), 11057-11065.  Gomis, M. I., Vestergren, R., Borg, D., & Cousins, I. T. (2018). Comparing the toxic potency in vivo of long-chain perfluoroalkyl acids and fluorinated alternatives. Environment international, 113, 1-9.  Lieder, P. H., Chang, S. C., York, R. G., & Butenhoff, J. L. (2009). Toxicological evaluation of potassium perfluorobutanesulfonate in a 90-day oral gavage study with Sprague–Dawley rats. Toxicology, 255(1-2), 45-52.  Liu, S., Yang, R., Yin, N., & Faiola, F. (2020). The short-chain perfluorinated compounds PFBS, PFHxS, PFBA and PFHxA, disrupt human mesenchymal stem cell self-renewal and adipogenic differentiation. Journal of Environmental Sciences, 88, 187-199.  US-EPA. (2018). Human health toxicity values for perfluorobutane sulfonic acid (CASNR 375-73-5) and related compound potassium perfluorobutane sulfonate (CASNR 29420-49-3). EPA Document Number 823-R-18-307. https://www.epa.gov/sites/production/files/2018-11/documents/pfbs\_public\_comment\_draft\_toxicity\_assessment\_nov2018-508.pdf Zafeiraki, E., Gebbink, W. A., Hoogenboom, R. L., Kotterman, M., Kwadijk, C., Dassenakis, E., & van Leeuwen, S. P. (2019). Occurrence of perfluoroalkyl substances (PFASs) in a large number of wild and farmed aquatic animals collected in the Netherlands. Chemosphere, 232, 415-423. |  |
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| 5346  2019/10/18 | Cefic,  Industry or trade association,  Belgium |  |  |
| *Attachment*: 5346\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5348  2019/10/18 | 3M Belgium,  Company,  Belgium |  |  |
| *Attachment*: 5348\_3M comments.pdf |
| 5349  2019/10/18 | SABIC Innovative Plastics BV,  Company,  Netherlands |  |  |
| *Attachment*: 5349\_PFBS rebuttal to SVHC categorisation.pdf |
| 5350  2019/10/18 | LANXESS Deutschland GmbH,  Company,  Germany | Please find comments for all Parts in the attached document. |  |
| *Attachment*: 5350\_LANXESS\_Comments\_SVHCproposalPFBSandsalts.pdf |
| 5351  2019/10/18 | ASD-EUROSPACE,  Industry or trade association,  France |  |  |
| *Attachment*: 5351\_ASD-Eurospace comments on PFBS and its salts-18102019-Final.pdf |
| 5352  2019/10/18 | American Chemistry Council,  Industry or trade association,  United States | 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. |  |
| *Attachment*: 5352\_FINAL\_ACC Comments to ECHA PFBS 101819.pdf |
| 5354  2019/10/23 | FluoroCouncil,  Industry or trade association,  United States | Attached are the comments of the FluoroCouncil re: the PFBS SVHC proposal consultation. |  |
| *Attachment*: 5354\_FINAL FluoroCouncil response PFBS SVHC consultation 18-10-19 .pdf |
| 5357  2019/11/04 | Sweden,  Member State |  |  |
| *Attachment:* 5357\_Nyberg et al 2018 (003).pdf |

Specific comments on the justification

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| Number / Date | Submitted by (name, submitter type, country) | Comment | | Responses | |
| 5322  2019/10/08 | Germany,  Member State | The German CA supports this proposal to identify PFBS and its salts as substances of equivalent level of concern to Art. 57 a-e.  Identity of the substance: it is very clearly and understandably described which substance or group of substances is addressed in the report.  ELoC assessment: Chapter 6 clearly depicts the equivalent level of concern and follows a case-by-case approach using the weight of evidence evaluation. The DE CA strongly supports this case-by-case approach. The DE CA supports the approach how the ELoC has been shown. The DE CA agrees that the concerns address the same key concerns as for PBT substances i.e. effects are unpredictable in the long-term, and difficult to reverse as cessation of emission will not necessarily result in a reduction in substance concentration and the potential of contamination of remote areas. In fact, persistency and ecotoxic effects fulfill the criteria of Annex XIII.  Once released, PFBS stays in the environment, and is distributed on a wide scale because PFBS is an extremely persistent and mobile substance. Future generation will be faced with these contaminations. There are no natural barriers. Sediment and soil do not function as sink for the substance in similar manner as for, e.g., heavy metals or most of persistent organic pollutants. As made clear in the dossier, removal is difficult due to its low adsorption potential. Effects will not only occur on the point of release but also far away from its point of release due to potential for wide spreading especially via the aqueous compartments. As outlined in the dossier PFBS bioaccumulates to a lesser extent. However, non-reversible environmental background concentrations lead to long-term continuous exposure and could lead to toxic effects in the same way as for bioaccumulative substances. As outlined in the dossier either mobile or bioaccumulative substances would seem to share the same concern for the development of high internal concentrations, which trigger effects. Furthermore, a high protein binding potential leads to a facilitated tissue distribution. In several studies the dossier has listed, it is shown that PFBS accumulates in plants and is found in drinking water. If emissions continue, concentration in environmental media relevant for human nutrition (e.g. vegetables and drinking water) will increase and these resources cannot be used for human consumption anymore. In consequence, PFBS will effect the health of the general population in the future. Therefore, emissions need to be reduced.  Human health hazard assessment: It could be useful to cite the EFSA/ECHA guidance document on endocrine disruptors and the effects of ED on the thyroid (doi: 10.2903/j.efsa.2018.5311).  p. 101, Toxicokinetics 4.1.2 Human information: Please replace the citation Olsen et al. 2009a with Olsen et al 2009b. Olsen et al 2009b represents the paper on the pharmacokinetics of PFBS. Olsen et al. 2009a deals with a review on human fetal development.  p. 102. Toxicokinetics – table 27, row humans. Replace the citation Olsen et al. 2009a with Olsen et al 2009b. Olsen et al 2009b represents the paper on the pharmacokinetics of PFBS.  P 106. 4.3. Levels of PFBS in humans – table 28. Please include the paper of Calafat et al. 2019 (Calafat AM, Kato K, Hubbard K, Jia T, Botelho JC, Wong LY, 2019 Legacy and alternative per-and polyfluoroalkyl substances in the U.S. general population: Paired serum-urine data from the 2013-2014 National Health and Nutrition Examination Survey. Environmental International 131, 105048). The study proved the presence of PFBS in 9.1 % serum samples of children aged 6 to 11 years (n = 148). | |  | |
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| 5325  2019/10/09 | ChemSec,  International NGO,  Sweden | ChemSec agrees to the identification of PFBS and its salt as SVHCs of equivalent level of concern both for the environment and for human health. The dossier is impressive, proving the hazardous properties as well as the wide-spread occurrence in humans, wildlife and the environment. The intrinsic properties very Persistent and very Mobile are clearly presented referring to relevant and convincing data. Additionally, the shown endocrine disrupting effects, targeting the thyroid system in fish and rodents give reason for high concern for both human health and wildlife. We welcome further regulatory actions on this substance. |  | |
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| 5333  2019/10/11 | EEB,  International NGO,  Belgium | EEB thanks Norway for submitting the SVHC proposal on Perfluorobutane sulfonic acid and all of its salts (PFBS and its salts). The dossier provides a comprehensive motivation for the SVHC identification of PFBS and its salts. EEB supports the proposal to identify PFBS and its salts as SVHC according to Article 57(f) of the REACH Regulation.  EEB would like to point at a new in vitro study reporting developmental effects at low doses of PFBS. Whereas the SVHC dossier reports in vitro effects in the μmol/L range, a new study reports effects in human mesenchymal cells at human relevant doses (in the nmol/L range). PFBS exposure caused amongst others perturbation of cell self-renewal, stimulation of adipogenesis and effects on adipogenic differentiation resulting in more lipid accumulation, similar to PFOS and PFOA but with milder effects. This study is a mechanistic study shedding more light on the similarities, differences and trends in the perfluorinated acids families. As such it advantageously complements the more empirical standardised studies by considering aspects that might otherwise be overlooked. Liu et al., 2020: The short-chain perfluorinated compounds PFBS, PFHxS, PFBA and PFHxA, disrupt human mesenchymal stem cell self-renewal and adipogenic differentiation. Journal of environmental sciences 88 (2020) 187 - 199.  The scientific evidence of the toxic effects of PFBS on man and the environment will accumulate in the future and contribute further to the already existing evidence of toxic effects by PFBS that are reported at low concentrations in a wide variety of species, including amphibians, fish, rodents and man. Developmental effects in fish are reported at low concentrations (< 10 μg/L), including reduced body weight and length, delay in hatching, reduced egg production and skewed sex ratio. Furthermore effects have been reported in liver, kidneys, stomach and hematological systems in repeated dose toxicity studies with rats. Reproductive toxic effects have been reported in mice following prenatal exposure to PFBS, including delay in perinatal growth and pubertal onset and changes in reproductive organ development. Endocrine effects are reported for amphibians, fish and mammals. The reported effects are of particular concern for vulnerable species, sensitive life stages and future generations.  PFBS can be considered extremely persistent and mobile in the environment. The substance has a high long-range transport potential and has been found ubiquitously in the aqueous environment, including remote areas and groundwater. Due to its extreme persistency, the substance will remain in these compartments for decades or even centuries. PFBS has been detected widely in drinking water across Europe, including France, Germany, Italy and Spain. PFBS is also found in biota across the globe, such as whales, dolphins, and threatened species like polar bears and green turtles. The findings of PFBS in sensitive life stages, such as fetus of whales and bird eggs is of serious concern. It is furthermore detected in a wide variety of human tissues, including human blood, lung, bone, kidney, urine, and hair. Findings of PFBS in human cord blood indicate prenatal exposure of the unborn child. Increasing trends are reported for concentrations of PFBS in water, biota and human blood over the years, indicating an increasing accumulation in the environment. The combination of these properties will lead to continuous and irreversible exposure of future generations via food and drinking water.  In conclusion, PFBS and its salts should be identified as substances of very high concern because of evidence of serious adverse effects on human health and the environment in combination with irreversible and prolonged exposure of man and the environment, giving rise to an equivalent level of concern to substance properties listed in points (a) to (e) of Article 57 of the REACH Regulation. |  | |
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| 5334  2019/10/11 | Health and Environment Alliance (HEAL),  International NGO,  Belgium | The Health and Environment Alliance (HEAL) thanks Norway for proposing the identification of Perfluorobutane sulfonic acid (PFBS) and its salts as SVHC based on article 57(f) and fully supports this identification.  The present supporting dossier is well structured and justified.  PFBS is a short-chain PFAS, which has been increasingly used as a replacement to longer-chain ones. PFBS has been reported to be used as a replacement of PFOS – e.g. in stain-repellent materials used in industrial and consumer products and applications.  PFBS is structurally similar to PFOS. Although it is less bioaccumulative, it is still very persistent. According to HEAL, high persistence alone should be a sufficient reason for SVHC identification under article 57(f). Due to high persistence, high mobility (particularly in the aqueous environment) and potential for long-range transport, as long as emissions of PFBS will continue in the environment, the serious effects for health and environment already visible from existing data will remain and potentially increase to become irreversible.  PFBS has been detected in human blood, lung, bone, kidney, urine and hair. It is found in surface waters in remote areas such as the Arctic and Antartic, confirming its potential for long-range transport. According to IPCHEM data, we also know that the substance is present in surface and waste waters in Europe (such as the North of Italy). On the other hand, it is acknowledged that removing the substance from drinking water is challenging due to low adsorption potential and costly. This increases concerns about the impossibility to avoid human exposure to the substance.  Evidence well-described in the dossier already reports adverse effects of PFBS exposure at low concentrations in several species, including amphibians, fish, rodents and man.  Animal studies suggest that the thyroid seems to be a potential target organ for PFBS toxicity in animals as well as humans. Endocrine disturbances, such as decrease in T3 and T4 levels, have been shown after prenatal PFBS-exposure of mice, both in mother and their offspring, and supported by ecotoxicity studies. This suggest that PFBS is a potential endocrine disruptor – it is in fact already listed as such by the US platform Endocrine Disruption Exchange (TEDX).  According to recent animal studies conducted in the US by the National Toxicology Programme (NTP), short-chain PFAS (including PFBS) affect the same organs as long-chain PFAS, including liver and thyroid. During the studies, the rats who were administered PFBS showed reduced survival rates and lower body weight. For more information, see TOX 96, August 2019, https://ntp.niehs.nih.gov/publications/reports/tox/000s/tox096/index.html?utm\_source=direct&utm\_medium=prod&utm\_campaign=ntpgolinks&utm\_term=tox096abs  Taken together, these elements point to severe effects of PFBS for human health and the environment and support the identification of PFBS and its salts as SVHC under article 57(f). |  | |
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| 5335  2019/10/11 | ClientEarth,  International NGO,  Belgium | ClientEarth thanks Norway for submitting this thorough proposal establishing without doubt that PFBS and its salts are a substance of very high concern under Article 57 f). ClientEarth supports the identification of PFBS and its salts as proposed by Norway, and commends Norway in particular for the care with which it explained the reasons why these substances were considered as having an equivalent level of concern. |  | |
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| 5339  2019/10/17 | European Semiconductor Industry Association  Industry or trade association  Belgium | ESIA represents the European Semiconductor manufacturing Industry sector and is a downstream stream industrial user of PFBS in small but technologically critical quantities. As such ESIA is not in a position to comment on the identity and properties of PFBS and its salts as outlined in the SVHC dossier. |  | |
| 5341  2019/10/18 | ANSES,  National Authority,  France | ANSES generally support the analysis of the properties of PFBS and its salt and the rationale that concludes that it raises an equivalent level of concern relevant for SVHC identification according to 57f. ANSES considers that the concerns raised by PFBS and its salts are mainly articulated on 3 aspects: - Persistence and mobility of PFBS and salts is expected to lead to irreversible and increasing contamination of the environment. The monitoring data reported at different locations (even in remote locations as artic and antartic) and systems (freshwater, marine, groundwater, ice, snow etc.) also show the global water contamination around the world. - PFBS is not readily removed with conventional water purification techniques, leading to a contamination of water (including human drinking water). This in combination with the fact that contamination is also found in food through enrichment of plants raise a concern for an increasing exposure of biota and humans. This includes sensitive windows of exposure to sensitive life stages as transfer to eggs in birds or through placenta in mammals is observed. PFBS has been measured in different wildlife species including threatened/vulnerable species. PFBS and its salts exert toxicity relevant for humans and environment. In particular, disruption of thyroid hormone raises specific concern as thyroid hormones regulates a number of important physiological function (growth, metabolism, brain). The effects of PFBS and its salts via thyroid disruption on these functions are not fully characterised, due to their possible large scope as well as to the poor capacity of regulatory tests to explore these functions in details. There is therefore a concern that a safe level cannot be established with a sufficient certainty due to ED properties of PFBS and its salts. Considering the information from marine fish medaka the substance exerts several toxic effects that may have serious implications on a population level. - This, in conjunction with the difficulty to control and restrain exposure levels indeed raise major concerns.  More specific comments are provided below. In relation to mutagenicity, it is noted that results of in vitro as well as in vivo (micronucleus study) studies are presented in the recent NTP report (Tox 96) and confirm the absence of mutagenic potential of PFBS. https://ntp.niehs.nih.gov/ntp/htdocs/st\_rpts/tox096\_508.pdf?utm\_source=direct&utm\_medium=prod&utm\_campaign=ntpgolinks&utm\_term=tox096  In relation to immunotoxicity, the paragraph in section 4.10.1.2 does not provide information that are very specific of a possible immunotoxic response. The immunotoxic potential of PFBS remains therefore largely unexplored in vivo.  In relation to endocrine disruption, a consistent decrease in thyroid hormones (TH) is observed in the two studies that measure TH, in rats and mice. It is accompanied in the study by Feng 2017 by an increased level of TSH. This attempt to compensate the decrease of TH indicates that the decrease of TH is sufficient to induce a physiological response. No direct effects are observed on thyroid weight or histopathology. However, increased thyroid weight and proliferative changes are induced by a sustained compensatory activity. They may therefore need longer exposure to appear and are therefore not essential to demonstrate adversity of the dysregulation of thyroid hormones.  The offspring of mice exposed during gestation to PFBS (dams that experienced decreased TH levels), exhibit decreases in serum estrogen and progesterone levels with the elevation of luteinising hormone levels and deficits in perinatal growth, pubertal onset, and reproductive organ development female (Feng 2017). Thyroid hormones are essential for normal development and the regulation of basal metabolism (Jomaa 2015 ) and the biological plausibility that the delay in offspring growth can be related to developmental hypothyroidy is therefore strong. Although the possible link with low maternal thyroid hormones is not clear, the pattern of effects of the development of female reproductive function and organs together with alteration of E2 and P4 levels points toward an alteration of hormonal control linked to sexual function. In addition, the review Choksi et al. (2003) concludes that developmental hypothyroidism alters female reproductive tract development in rats.  The absence of understanding of the specific mechanism of action (or mechanisms that may superimpose) of disruption of thyroid hormones is not a prerequisite in the identification of an endocrine disruptive mode of action, as required to fulfil the JRC criteria to define an ED.  The decrease in TH is quite well established in this regard and it is noted that ECHA/EFSA guidance (2018) on identification of ED in Biocides and Plant Protection Products considers that “Using the current understanding of thyroid physiology and toxicology (European Commission, 2017), it is proposed that the following be applied when interpreting data from experimental animals: […] 2) Substances that alter the circulating levels of T3 and/or T4 without histopathological findings would still present a potential concern for neurodevelopment.” (emphasis added). This is consistent with AOP 42 (“Inhibition of Thyroperoxidase and Subsequent Adverse Neurodevelopmental Outcomes in Mammals ”) that have been endorsed by TFHA/WNT, that considers that the relationship between decreased T4 in serum and decreased cognitive function (relationship 403 ) is considered to be documented with a high level of evidence, relevant for rats, mice and humans. It is acknowledged that the SVHC identification is not based on the ED properties of PFBS. However, it is considered that alteration of TH by PFBS is well established and it raises concern on that the ED potential can have potential and under-investigated implications on the multiple functions regulated by thyroid hormones and in particular neurodevelopment. This is an additional argument to be added or developed in the overall rationale to demonstrate an ELoC.  In page 142, the paragraph concerning to the persistence, we believe that it is more appropriate to remove the parenthesis regarding the comparison of the hydrolytic half- life with P criteria. According to guideline R 11 PBT assessment: « … the degradation half lifes obtained in a hydrolysis test cannot be compared to the persistence criteria of annex XIII…. ». Based on the information presented in the dossier (Stability of bond C-F, read across and experimental data) it is clear that the substances is vP.  References not present in Annex XV report: Jomaa, B., de Haan, L., Peijnenburg, A., Bovee, T., Aarts, J. and Rietjens, I. (2015) “Simple and rapid in vitro assay for detecting human thyroid peroxidase disruption”, ALTEX - Alternatives to animal experimentation, 32(3), pp. 191-200. doi: 10.14573/altex.1412201. Choksi NY et al. (2003). Role of thyroid hormones in human and laboratory animal reproductive health. Birth Defects Res B Dev Reprod Toxicol. 2003 Dec;68(6):479-91. doi:10.1002/bdrb.10045. JRC (2013). Key Scientific issues relevant to the identification and characterisation of endocrine disrupting substances – Report of the Endocrine Disruptors Expert Advisory Group (ED EAG). Eds. Munn S. and Gourmenou M. Pp 32. Available at: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/key-scientific-issues-relevant-identification-and-characterisation-endocrine-disrupting |  | |
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| 5342  2019/10/18 | CHEM Trust Europe,  National NGO,  Germany | CHEM Trust supports the identification of perfluorobutane sulfonic acid (PFBS) and its salts as SVHC. We would like to thank the dossier submitter for the thorough job in compiling all relevant information. The excellent summary of scientific evidence demonstrates that PFBS is highly persistent, very mobile and fulfils the T criteria for ecotoxicity. Moreover, it shows widespread occurrence of the substance in humans, wildlife and the environment, including in remote regions. The potential for endocrine disrupting properties, targeting the thyroid, highlights the concern for potential adverse effects on humans and wildlife. Thus the 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.  PFBS is one of the dominating and increasing PFAS in various environmental compartments away from point sources: Occurrence was reported in surface water, groundwater, drinking water (including tap water and bottled water), marine water and biota. Studies also found the substance in house dust and in human blood and tissue samples, in particular near hot spots.  PFBS has been detected in different species across the globe such as marine mammals including in endangered or vulnerable populations. In whales it was shown that PFBS transfers from mother to foetus. PFBS was also found in birds` eggs, passed on from the mother bird. The findings of PFBS in sensitive life stages and in endangered species are of special concern.  Due to its high-water solubility, PFBS is bioavailable to plants. Enrichment in plants especially in its edible parts like leaves, vegetables and fruits, has been demonstrated by studies and field data. If releases of PFBS to the environment are not minimised, concentrations in vegetables and drinking water relevant for human nutrition will increase further. The high persistence of PFBS combined with its high mobility, its ability to transfer from mother to the offspring, indications for inter-generational effects and the difficulties and high costs in removing PFBS using end-of-pipe treatment means that potential impacts will continue for decades and centuries even after cessation of emissions, thus presenting a threat also to future generations.  Taken together with the additional evidence on 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. |  | |
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| 5343  2019/10/18 | Sweden,  Member State | The Swedish CA agrees with the reasoning presented in the dossier. The most important elements of the ELOC assessment of Perfluorobutane sulfonic acid (PFBS) and its salts are in our view: • The extreme persistence, which results in that PFBS will remain in the environment for indefinite time and background concentrations will increase. Consequently, this leads to continuous (life long) and most probably increasing exposures of wildlife and humans. • The mobility in water and soil, which already has resulted in contamination of ground water and drinking water resources. The mobility together with the extreme persistency and other physicochemical properties also leads to a potential for long-range transport and contamination of pristine areas. • The difficulty of remediation, which means that once drinking water resources have been contaminated with PFBS it will be difficult to remove. Currently, commonly applied remediation methods are not efficient in removing PFBS from wastewater or in drinking water production. The need for future remediation may potentially be very costly to the society.  We consider these elements of concern enough to consider that PFBS fulfils the provisions of article 57(f). In addition, a number of studies show that PFBS also has effects on biota including mammals. The acute toxicity to aquatic organisms seem to be low but long term fish studies indicate effect levels that fulfils the T criterion for the environment of REACH Annex XIII. The available mammalian toxicity data points to similar effects as for longer chain PFAAs but with a lower potency. |  | |
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| 5344  2019/10/18 | Netherlands,  Member State | The Netherlands CA fully supports the identification of PFBS as SVHC under Article 57 (f) of REACH based on the following:  Firstly, PFBS is very persistent, as indicated by the lack of abiotic or biotic degradation under environmental conditions. Secondly, PFBS is very mobile, as indicated by its high solubility in water and its low sorption potential. Thirdly, the high persistency of PFBS in combination with the high mobility of the substance in the aqueous phase, the evidence for long-range transport and the substance its widespread occurrence at present, albeit at low concentrations, leads to the conclusion that potential impacts to human health and the environment will proceed long after cessation of emissions, hence posing an irreversible threat to future generations and illustrating the urge to act now.  These three main issues in combination with the supporting evidence of observed adverse effects to human health and the environment, supporting evidence of moderate bioaccumulation in humans, and the fact that several other perfluoralkyl acids have been identified as SVHC based on PBT, vPvB or ELoC properties leads to the conclusion that PFBS clearly meets the criteria for SVHC under ELoC. The Netherlands CA specifically wants to add to this that in their view meeting the ‘T’ criterion as defined in Annex XIII of REACH is no prerequisite for PFBS to be identified as an SVHC under ELoC; rather it is the combination of the elements of concern that give rise to ELoC to those of other substances listed under points (a) to (e) of Article 57 REACH.  As follow-up of Gebbink et al. (2017), PFBS is still reported to be ubiquitously present in drinking water samples in the Netherlands with concentrations ranging from 2.5-11 ng/L and in/on plant leaves at a concentration of <0.1 - 1.1 ng/g ww (Brandsma et al. 2019). Moreover, PFBS is detected in eels caught between 2010-2016 in several Dutch waters, with tissue sample concentrations ranging from <0.3 – 7.1 ng/g ww, often in presence with other PFASs (Zafeiraki et al. 2019). These data, in combination with the data already present in the SVHC dossier, corresponds to the overall image of persistence, mobility, long-range transport, and widespread occurrence of PFBS in the environment, identifying PFBS in the environment not only as a Dutch but as a worldwide problem. |  | |
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| 5345  2019/10/18 | Finland,  Member State | We thank Norway for this proposal. The FI CA acknowledges that SVHC identifications based on the equivalent level of concern (ELoC) in relation to the Art. 57 (f) are made on a case by case basis. Our comments on the proposal are listed below. We question some of the arguments which are used to support the proposed identification of PFBS as an SVHC.  Comments: page 11 & 160: “It is particularly concerning that PFBS prefers and persists in the aqueous environment, while severe effects of PFBS have been demonstrated for fish, which belong to this particular environmental compartment” Comment: We suggest to modify “prefers” to “is mainly distributed to” to address the environmental distribution of PFBS more scientifically.  page 12 & 161: (bullet point): “ecotoxic effects fulfilling the T criteria in Annex XIII of REACH …”. Comment: Particularly as these results are based on a non-guideline study, we think that the proposed fulfilment of the T criterion may still need to be considered and discussed, taking into account the possible comments in the public consultation.  page 12 & 161 (bullet point): “high societal concern”. Comment: It could be clarified where the high societal concern refers to e.g. “high societal concern for contamination of drinking water sources”.  page 13&161: “The high persistence and high mobility of PFBS together lead to a concern for co-exposure with other contaminants with similar effects on human health and the environment. Coexposure may last for a very long time, because natural degradation processes for these substances are slow or negligible. This is brought into the weight-of-evidence as supportive information.” Comment: The wording of REACH on ELoC (Art. 57 (f)) refers to substance specific scientific evidence as a basis of SVHC identification. Thus, wording of Art. 57 (f) does not explicitly refer to considerations of other substances to which the organisms may be exposed simultaneously but it seems to refer to substance specific effects. Since co-exposure is dependent on other substances potentially causing similar effects, co-exposure as an ELoC argument does not seem to be in line with the wording of Art. 57 (f).  Moreover, the concern for co-exposure arises from intrinsic properties of PFBS such as high persistence, mobility and toxicity. These properties as such are already elements of the proposed SVHC identification. We agree that high persistence and mobility can contribute to the concern for co-exposure. However, please consider whether co-exposure with other contaminants with potentially similar effects is necessary and appropriate argument for SVHC identification.  page 28” Brendel et al. (2018) recently summarized the current knowledge on the environmental stability of short chain PFASs and concluded that perfluoroalkyl acids (including PFBS) are extremely persistent, and that they do not undergo abiotic or biotic degradation at all under environmental conditions.” Comment: Please consider specifying what carbon chain length range is referred to in this publication (if indicated) and what data is used for this conclusion.  page 28” Brendel et al. (2018) recently summarized the current knowledge on the environmental stability of short chain PFASs and concluded that perfluoroalkyl acids (including PFBS) are extremely persistent, and that they do not undergo abiotic or biotic degradation at all under environmental conditions.” Comment: Please consider specifying what carbon chain length range is referred to in this publication (if indicated) and what data is used for this conclusion.  page 28: “Ateia et al. (2019) point out that the short-chain PFASs are equally persistent as their long-chain counterparts, and that the high solubility of short-chain PFAS in water, low/moderate sorption to soils and sediments and resistance to biological and chemical degradation has resulted in their widespread presence in various aquatic environments.” Comment: Please consider specifying what carbon chain length range is referred to in this publication (if indicated) and what data is used for this conclusion.  page 32: “Since biodegradation of the test substance is calculated as the decrease in DOC in the test bottles, corrected for the DOC in the blank control, the unusual values from the blank control can explain what initially looks like biodegradation of KPFBS, which justifies for a Klimisch reliability 3. In conclusion, there is no reliable evidence for biodegradation of KPFBS in this study.” Comment: Based on ECHA web page, (https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/22432/5/3/2/?documentUUID=54b32b65-8a6a-4af7-bf1e-d61a398a815b), DOC in bottles with test item plus inoculum was 22.0-22.5 mg/l on day 0 and 19.5 mg/l on day 28. The DOC in inoculum blanks was 1.0-3.0 mg/l during the study. OECD 301E does not include specific validity criteria for inoculum blank. According to OECD 301 E, a test is considered valid if the criteria given in "Data and Reporting" (p. 7) are met. The validity criterion of less than 20% difference of extremes of replicate values of the test chemical at the end of the test seems to be fulfilled as degradation was 13% and 15% in the replicates. Also, the validity criterion regarding the percentage degradation of the reference compound is fulfilled (the pass level reached by day 7). If possible, we recommend checking and reporting whether toxicity, abiotic and adsorption controls were included in the test (not mentioned in Annex XV report or ECHA web page). We note that there is no specific validity criterion for DOC in inoculum blank (or its variation). Therefore, we are not convinced that the variation in inoculum blanks justifies that the study is not reliable. We note that the inoculum blank values are exactly the same (at least within the number of digits used in the web page) among the replicate measurements and flasks within the same day, and it could be speculated that there might be a systematic error/sensitivity difference contributing to the differences between each measurement day. However, even if this was the case, we do not see this as a reason to consider the study not reliable. We also note that there is a strikingly deviating result for one of the replicate measurements for the test plus inoculum flask B (30 mg/l) but this does not affect the calculation of biodegradation after 28 days. Based on substance properties volatilization or adsorption seem unlikely reasons to explain the DOC removal in this case.  Bourgeois et al. (2015) reported that three fluorinated fire-fighting foams fulfilled the pass level for ready biodegradability in a DOC die-away test. The article also states: “Fluoride liberated during AR-AFFF and FP 28-day biodegradation testing were found to be 40.4 and 19.5 µg L-1, respectively, or 0.009% and 0.010% with respect to initial foam mass. These levels are one to two orders of magnitude lower than estimated organic fluorine (0.15–3%). And, no free fluoride was detected in AFFF samples. Thus, biodegradation of AFFF, AR-AFFF, and FP foams has not led to significant defluorination despite all three meeting the criteria for ‘‘ready biodegradability.’ As the substances studied by Bourgeois et al. have a considerably lower fluorine content than PFBS, and as they include more readily degradable materials in addition to the fluorinated components, a considerable DOC removal percentage could be possible even without defluorination. Thus, in our view, the findings by Bourgeois et al. (2015) regarding DOC measurement do not seem directly applicable to perfluorinated substances (and thus do not invalidate the use of DOC measurement for PFBS).  Reference: A. Bourgeois, J. Bergendahl, A. Rangwala. 2015. Biodegradability of fluorinated fire-fighting foams in water. Chemosphere. Volume 131, July 2015, Pages 104-109. https://doi.org/10.1016/j.chemosphere.2015.02.042  page 32: ”Another experimental study is available on ECHAs dissemination webpage for KPFBS where Quinete et al. (2010) tested KPFBS for biodegradation in conventional screening tests. Biodegradation of <1% after 40 days based on oxygen consumption was observed in a manometric respirometry test (OECD 301 F; OxiTop) using domestic non-adapted sludge of a sewage treatment plant (STP). According to the registrants, the study was deemed as not reliable due to significant methodological deficiencies.” Comment: We would recommend to present dossier submitter’s view on the reliability of the study, instead of (or in addition to) registrant’s view. Please specify what are the mentioned methodological deficiencies. According to ECHA web page there is no information on validity criteria and, in addition, it is indicated that there are inconsistencies in the reporting of the results. We note that based on Fig. 5. of the original paper it seems that the validity criterion for reference substance would be fulfilled. We recommend checking this and adding this information to the report. In addition, we recommend mentioning whether there is any information on toxicity and abiotic controls.  page 32: “Furthermore, a closed-bottle test (OECD 301 D) using inoculum from the Rhine River demonstrated < 3% biodegradation (based on oxygen consumption) of PFBS within 28 days. This study was deemed as reliable with restrictions by registrants since detailed documentation was missing.”. Comment: We would recommend to present dossier submitter’s view on the reliability of the study, instead of (or in addition to) registrant’s view. Please include more details of the study, at least what information is available regarding the validity criteria, and toxicity and abiotic controls.  page 33: ” If the sulfonic acid group was to have an influence on the perfluoroalkyl chain, it would be on the neighboring CF2-group, and this is common for all the PFSAs.”. Comment: Please correct the sentence as CF3SO3H does not have a CF2-group.  page 33: “Hence, the persistence of the members in this class of substances is highly comparable, and an evaluation of the persistence of PFBS in comparison with trifluoromethane sulfonic acid and PFOS in a read-across approach is justified.”. Comment: Saez et al. (2008) studied degradation of PFBS and PFOS, as well as other fluorinated compounds. Bacterial communities from sewage sludge were exposed to a mixture of PFAS under aerobic or anaerobic conditions. Individual PFAS concentrations were determined in the experiment media at different exposure times. The authors state that “Based on the results presented in this paper, it can therefore be concluded that the PFAS tested in these experiments are non-biodegradable under the experimental conditions used in this study, despite using municipal sewage sludge, which presumably has a history of exposure to PFAS. Similar experiments with sediment contaminated with PFAS also showed no evidence for biodegradation of any of the PFAS tested (data not shown).”. Please include this study in the document (or, if it is not considered relevant, please indicate the reason). As it contains information on both PFBS and PFOS, it could be used also in the discussion on read-across.  We agree that ready biodegradability and hydrolytic stability is likely to be highly comparable between the members in this class of substances. However, regarding biodegradation, for trifluoromethane sulfonic acid only a ready biodegradation test is available and therefore only “potentially P or vP” can be concluded based on that test. In addition, there is a considerable difference between trifluoromethane sulfonic acid and PFBS, for example between molecular dimensions, which may be important for enzymatic attack. This should be taken into account in the argumentation. Particularly, as there are no data available on environmental half-lives, we consider that it is appropriate to take into account the available information on microorganisms and enzymes capable of transforming these substances, in addition to the chemical structure considerations which are already included. Information sources on biodegradation of fluorinated compounds, which may be useful, are included below.  Neilson and Allard (2002) provided a review of the degradation and transformation of organic fluorine compounds by aerobic and anaerobic bacteria, yeasts, and fungi. Natarajan et al. (2005) gave on overview on the microbial cleavage of C-F bond in aliphatics and aromatics. Ang et al. (2018) reviewed information available on fluoroacetate dehalogenase, which catalyses the hydrolysis of C-F bonds.  Chan et al. (2011) studied fluoroacetate dehalogenase RPA1163 (originating from the bacterium Rhodopseudomonas palustris and produced in E. coli). Structural and biochemical characterization was presented. The authors mention, e.g., that “enzymatic defluorination requires a halide pocket that not only supplies three hydrogen bonds to stabilize the fluoride ion but also is finely tailored for the smaller fluorine halogen atom to establish selectivity toward fluorinated substrates.”.  Li et al. (2019) reported in silico and in vitro studies on fluoroacetate dehalogenase RPA1163. They reported that the enzyme showed no activity toward 2,2,3,3-tetrafluoropropionic acid and pentafluoropropionic acid while is capable of degrading 2,3,3,3-tetrafluoropropionic acid.  Key et al (1998) studied degradation of difluoromethane sulfonate (DFMS), trifluoromethane sulfonate (TFMS), 2,2,2-trifluoroethane sulfonate (TES), perfluorooctane sulfonate (PFOS), and 1H,1H,2H,2H-perfluorooctane sulfonate (H-PFOS) by a laboratory isolate designated Pseudomonas sp. strain D2. The article states, e.g.: “Growth and defluorination were only observed for those compounds containing hydrogen (TES and H-PFOS). TFMS and PFOS were not degraded. TES was completely defluorinated, and H-PFOS was partially defluorinated.” and “This study demonstrates that hydrogen-substituted fluorinated sulfonates are susceptible to biodegradation and defluorination and that they can support growth under sulfur-limiting and aerobic conditions. The sulfur inhibition studies establish a link between defluorination and sulfur metabolism.”. It is stated that the studied strain originated from an enrichment that fortuitously contaminated a laboratory stock solution a medium containing DFMS as the sole source of sulfur. The origin of the enrichment is not indicated. To our knowledge, this study is the only one where biodegradation results for perfluorinated sulphonates with chain lengths below and above that of PFBS are available for the same organism/test system. Also, the differences reported between perfluorinated and partially hydrogenated sulphonates are interesting.  References: Ang, T.H. et al. 2018. Dehalogenases: From Improved Performance to Potential Microbial Dehalogenation Applications. Molecules 2018, 23, 1100; doi:10.3390/molecules23051100  Key et al. 1998. Defluorination of Organofluorine Sulfur Compounds by Pseudomonas Sp. Strain D2. Environ. Sci. Technol. 1998, 32, 2283-2287  Li, Y. et al. 2019. Harnessing fluoroacetate dehalogenase for defluorination of fluorocarboxylic acids: in silico and in vitro approach. Environment international · July 2019 DOI: 10.1016/j.envint.2019.104999  Natarjan, R. Azerad, R., Bader ,B., Copin, E. 2005. Microbial cleavage of C-F bond. Journal of Fluorine Chemistry 126, 425-436.  Neilson, H. and Allard, A.-S. Degradation and Transformation of Organic Fluorine Compounds. In: The Handbook of Environmental Chemistry Vol. 3, Part N Organofluorines (ed. by A.H.Neilson). Springer-Verlag Berlin Heidelberg 2002.  Saez et al. 2008. Persistence of perfluoroalkylated substances in closed bottle tests with municipal sewage sludge. Environ Sci Pollut Res (2008) 15:472–477 DOI 10.1007/s11356-008-0020-5  page 34: “However, no biodegradation has been observed for trifluoromethane sulfonic acid in screening tests, see Table 8.”. Comment: Please clarify in the text whether the tests in Table 8 were measuring mineralization only (please indicate the parameter monitored (CO2, O2, DOC) or whether also primary degradation and transformation products were measured). page 34:”PFOS is considered extremely stable in the environment and does not hydrolyse, photolyse or biodegrade under any environmental conditions tested (OECD,2002).” Comment: New information relevant to PFOS biodegradation has been published after 2002: Chetverikov et al (2017) reported on isolation of a bacterium (Pseudomonas plecoglossicida 2.4-D) able to use perfluorooctanyl sulfonate (PFOS) as the only source of carbon and energy. The strain was isolated from soil contaminated by waste from petrochemical production in a factory area (Bashkortostan republic, Russia). It is stated that P. plecoglossicida 2.4-D transforms PFOS to perfluoroheptanoic (perfluoroenanthic) acid, while free fluorine ions are released into the medium. The transformation of PFOS (a molecular ion with an m/z of 499 аmu), is presented. It is stated that the presence of a component with a molecular ion with an m/z of 419 аmu is possible when performing oxygenogenic or monooxygenase removal of a sulfonate group from PFOS (m/z of 80 аmu) in the form of sulfite. Further transformation was accompanied by active growth of the culture and release of fluoride ions into the medium. A compound previously absent in the medium with a molecular ion equal to an m/z of 363 amu was found, which was identified as perfluoroheptane (perfluoroenant) acid. The authors note that the concentration of the fluoride ions correlate with the transformation pathway presented in their Fig. 5, in which four fluoride ions are released into the medium. It is mentioned also that the release of fluoride ions into the medium probably caused an inhibiting effect on the process of further destruction of intermediate fluoride compounds by the studied strain.  Chetverikov and Loginov (2019) isolated a bacterium (Ensifer adhaerens Strain M1) from soil collected at the site for storage and testing of fire-fighting equipment (Maldive Republic). The bacterium is reported to use PFOA and PFOS as sole sources of carbon and energy with production of perfluoroheptanoic acid as a metabolite and release of fluoride ion. It is reported that, in the variant with PFOS, a component was detected with m/z 419 Da for the molecular ion, which was possible in the case of removal of the sulfonate group from PFOS (m/z 80 Da) as sulfite. A compound with m/z 363 Da for the molecular ion, which was not originally found in the medium, was detected after 72 h of cultivation and its concentration increased during the following day, while the compounds with m/z 499 and 419 Da (indicated as PFOS and perfluorooctane, respectively) were not detected in the medium after six days of cultivation. The compound with m/z of 363 Da was identified as perfluorohaptanoic acid. In the variant with PFOA, a compound with m/z = 369 Da was detected after 24 h. It is mentioned that this was possible as a result of the reaction of carbon dioxide (m/z 44 Da) elimination from the carboxyl group and that this compound (indicated as perfluoroheptane) was subsequently completely transformed to perfluoroheptanoic acid. It is also reported that conversion of perfluorinated substrates was accompanied by release of free fluoride ions, with the beginning of release correlating with the beginning of linear decrease in the substrate concentration in the medium. The authors consider that fluoride ions probably have an inhibitory effect on further degradation of the intermediate fluorinated compounds.  Kwon at el. (2014) reported on identification of an aerobic bacterium (99% similarity to Pseudomonas aeruginosa strain HJ4) which was reported to decompose approximately 67% over a range of concentrations for PFOS in 48 hours. However, the formation of fluoride ion from PFOS biodegradation was not observed. It should be noted that the conclusion that PFOS was biodegraded in the study by Kwon et al. (2014) has been questioned (Avendaño t al. 2015) as it was considered that no convincing evidence tracking potential PFOS degradation products was given, e.g., due to lack of abiotic controls. According to the comment, the conclusion was drawn mostly based on the observation that levels PFOS in a liquid bacterial culture were decreasing over 48 h. Also a response to the comments is available (Kwon 2015).  Luo et al. (2018) investigated the degradation of PFOS by laccase-induced enzyme catalyzed oxidative humification reactions (ECOHRs) using 1-hydroxybenzotriazole (HBT) as a mediator. The authors report for example the following conclusions: “ECOHRs induce PFOS degradation via a radical chain reaction by directly attacking the C−C bond of PFOS and generating the perfluoroalkyl or acid radicals followed by formation of partially fluorinated products via radical rearrangement and cross-coupling. Products formed during ECOHRs having less fluorine and more hydrogen atoms are expected to be less toxic and more available for microbial degradation. The ECOHR mechanism may be effective in natural water and soil systems to transform and incorporate PFOS into the natural organic matter, thus detoxifying and immobilizing PFOS.”  Ochoa-Herrera et al. (2016) reported that “PFOS was not reductively dehalogenated by the anaerobic microbial consortium even after very long periods of incubation (3.4 years). Similarly, the tested short chain perfluoroalkyl substances (i.e., PFBS and trifluoroacetic acid) and a polyfluoroalkyl PFOS analogue, 6 : 2 fluorotelomer sulfonic acid (FTSA) were also resistant to anaerobic biodegradation. Likewise, no conclusive evidence of microbial degradation was observed under aerobic conditions for any of the short-chain perfluoroalkyl and polyfluoroalkyl carboxylic acids tested after 32 weeks of incubation. Collectively, these results indicate that PFOS and its alternatives such as short chain perfluoroalkyl sulfonates and carboxylates and their polyfluorinated homologues are highly resistant to microbial degradation.”  References: Mejia Avendaño, S., Zhong, G., Liu, J.. 2015. Comment on "Biodegradation of perfluorooctanesulfonate (PFOS) as an emerging contaminant". Chemosphere 138, 1037-1038 https://www.sciencedirect.com/science/article/pii/S0045653515002222?via%3Dihub  Chetverikov, S.P., Sharipov, D.A., Korshunova, T.Y., Loginov, O.N. .2017. Degradation of perfluorooctanyl sulfonate by strain Pseudomonas plecoglossicida 2.4-D. Applied Biochemistry and Microbiology. https://link.springer.com/article/10.1134/S0003683817050027  S. P. Chetverikov, O. N. Loginov. 2019. A New Ensifer adhaerens Strain M1 is Capable of Transformation of Perfluorocarboxylic Acids. Microbiology. January 2019, Volume 88, Issue 1, pp 115–117. https://link.springer.com/article/10.1134/S0026261718060085  Bum Gun Kwon a, b, Hye-Jung Lim a, Suk-Hyun Na a, Bong-In Choi a, Dong-Soo Shin c, Seon-Yong Chung. 2014. Biodegradation of perfluorooctanesulfonate (PFOS) as an emerging contaminant. Chemosphere. Volume 109, August 2014, Pages 221-225. https://doi.org/10.1016/j.chemosphere.2014.01.072 Bum Gun Kwon. 2015. Reply to comment on “Biodegradation of perfluorooctanesulfonate (PFOS) as an emerging contaminant”. Chemosphere Volume 138, November 2015, Pages 1039-1044. https://www.sciencedirect.com/science/article/pii/S0045653515002210?via%3Dihub#  Qi Luo, Xiufen Yan, Junhe Lu, and Qingguo Huang. 2018. Perfluorooctanesulfonate Degrades in a Laccase-Mediator System.Environ. Sci. Technol. 2018, 52, 10617−10626  Valeria Ochoa-Herrera,\*ab Jim A. Field,a Antonia Luna-Velascoac and Reyes Sierra-Alvareza . 2016. Microbial toxicity and biodegradability of perfluorooctane sulfonate (PFOS) and shorter chain perfluoroalkyl and polyfluoroalkyl substances (PFASs). Environ. Sci.: Processes Impacts, 2016,18, 1236-1246. https://pubs.rsc.org/en/content/articlelanding/2016/em/c6em00366d/unauth#!divAbstract  page 34: “The persistence of PFSAs similar to PFBS has been confirmed.”. Comment: Please consider revising the sentence to take into account that PFHxS and PFOS have longer perfluorinated chains than PFBS.  Page 36: “PFBS has been demonstrated to have a half-life in water of more than 1 year.”. Comment: Please specify that this is a hydrolytic half-life. Biodegradation half-life in water has not been determined for PFBS.  page 101: 2nd paragraph: “PFBS may also bind to several different transporter polypeptides (NTCP, ASBT and OATPs) which are all capable of contributing to the enterohepatic circulation and…” Comment: This sentence is unclear. Please consider rewording: “…enterohepatic circulation. Thus, enterohepatic circulation of PFBS may contribute to… “  page 104: paragraph 6, 7 row Comment: editorial: samles => samples. paragraph 7. extra ng/ml  page 109, last paragraph: “In a repeated oral dose toxicity study for 28-days performed by NTP, a significant decrease in serum phosphorus and potassium levels in male rats treated at 300 mg/kg bw/day and 900 mg/kg bw/day was observed, giving NOAEL values of 100 mg/kg bw/day for males and 300 mg/kg bw/day for females (NTP, 2019).” Comment: This sentence lacks information. If decrease in serum phosphorus and potassium levels was observed in males only, what is the basis for NOAEL value of 300 mg/kg bw/day for females? Please clarify.  page 111, Summary of repeated dose toxicity: “These data together with human data linking PFAS to an increased BMI or changes in blood cholesterol or triglycerides, points towards a possible metabolic effect related to PFBS-exposure. However, other data in the literature may be less clear.” Comment: The conclusion on metabolic effects remains unclear from this wording. Please state clearly e.g.: The currently available data is insufficient for conclusion. Please see also the comment to page 122.  page 112: Section 4.6.1.1. Comment: This section may give wrong impression on the indication of current data for carcinogenic potential. Please clarify e.g. “There are no two-year carcinogenicity studies available with PFBS. A few repeated dose toxicity studies have reported hyperplastic changes in kidney and necrosis in forestomach at high doses ... which may indicate…”  page 112, 2nd paragraph: “There were no treatment-related microscopic changes in sex organs of males although a decreased number of spermatids per gram testes and increased incidence of abnormal sperm were noted at the highest dose, although this was not seen in the F1-generation and was within historical variations.” Comment: Could you please state whether these effects were statistically significantly different from the control group. Moreover, since decreased number of spermatids and increased incidence of abnormal sperm were within historical control range and were not observed in F1-generation, it could be concluded that these findings appear incidental.  Page 112, 2nd paragraph: “In this study, no alterations in fertility, estrus cycling, or histological alterations in female reproductive tissues were observed. However, exposure to 100 but not 300 or 1000 mg/kg bw/day through gestation showed a significant increase in diestrus cycling (>6 consecutive days).” Comment: According to tabulated data of Lieder et al 2009b publication the number of rats with ≥6 consecutive days of diestrus was statistically significantly increased (p≤0.01) in the 100 mg/kg/day dose group and significantly decreased (p≤0.05) in the 1000 mg/kg/day dose group. At 30 mg/kg bw/day and 300 mg/kg bw/day there were no differences to control group in number of animals with ≥6 consecutive days of diestrus (7/30, 10/30, 15/30, 7/30, 0/29, at 0, 30, 100, 300 and 1000 mg/kg bw/day, respectively). Please correct this to relevant sections in the document. Since there are no dose dependence and the result seem spurious, we do not consider appropriate to include this data in Table 29. Please also modify the text in other relevant sections e.g. page 118, 5th paragraph.  Page 112: “…the study was terminated 3 weeks after their birth, in which rats were exposed to gavage doses of potassium PFBS as high as 1,000 mg/kg bw/day.” Comment: The last sentence seems spurious/unnecessary. Please delete or modify.  Page 113, 2nd paragraph Comment: The results of the rat two-generation study by Lieder et al., 2009b seem to contradict with the reported effects in the mice study by Feng et al. 2017. Although treatment-related microscopic changes in kidney and/or liver were reported for both sexes in F1 generation, a slight body weight reduction was observed in males only but no effects on maturation or development of sex organs in either sex although dose as high as 1000 mg/bw/day was used. The study by Leader et al is assessed as Klimisch 1 (well documented guideline study), whereas Feng et al is Kimisch 2. Since reduced serum thyroid hormone levels have been reported in both rats (28-day NTP study, 2019) and mice, this diverge in results should be discussed as a part of weight of evidence assessment. In case the similar endpoints for maturation and development for sex organs were not assessed in the study by Lieder et al., this should be stated. We further note that unlike some other PFASs, based on Rumpler et al. (2016, study abstract) half-life of PFBS in mice would be short, similar to that of rats (page 100 and table 127).  Page 113, 3rd paragraph: “…found that offspring mice, orally exposed before pregnancy to potassium PFBS (50, 200 and 500 mg/kg bw/day) from gestational day (GD)1-GD20…” Comment: The exposure window remains unclear form this sentence i.e. whether mice were exposed before pregnancy or during GD1-GD20 or both. Please clarify.  Page 113 - 114: reporting of the Feng et al. 2017 study. Comment: This study is the prime study reporting effects potentially relevant for human health. Please report this study more accurately e.g. % differences of means to control, state whether the effects were statistically significant compared to controls, preferably in tabular format.  Page 114, first paragraph: “However, the study did not correlate the observed effects for the statistically significant decrease in pup body weight at the relevant dose levels”. Comment: This sentence is confusing and the reasoning for the statement made is unclear. Do you mean that it was not analyzed whether there was a correlation or that it was analyzed but there was no correlation? We note that in publication of Feng et al 2017 (Toxicological sciences 155(2), 2017, 409-419) pup body weights are shown only in figure not in tabular form and there are no data or statements whether individual PFBS-exposed pup body weights correlated with hormone levels or with effects on maturation. Neither it is stated whether this was assessed from the individual data or not. Please clarify this.  Please explain importance of body weight data of dams and pups (and clinical findings) for interpretation of the reported effects. For example: “No effect on body weight gain of dams exposed to PFBS was observed indicating that PFBS did not cause remarkable general toxicity in dams.” Preferably the body weight data of dams and pups should be presented in the document, but it seems to be missing from the publication as well, which is a shortcoming in reporting. We also note that no data on male pups is reported in the publication, which is also a shortcoming. General toxicity in pups could cause reduced body weights, delay in development and maturation, as well as hormonal effects. Therefore, it should be elaborated further in the document why observed effects in maturation of female pups are presumably not a secondary consequence of general toxicity but may be rather caused by permanent hypothyroxemia.  page 114, first paragraph: “These results together with the effects mentioned above (under fertility), indicate that prenatal PFBS exposure (≥200mg/kg/day) causes permanent hypothyroxinemia accompanied by deficits in perinatal growth, pubertal onset, and reproductive organ development in female mice.” Comment: It remains unclear what are the effects under fertility section. As discussed in comments above neither data on sperm effects or diestrus are robust enough for this conclusion. Please consider modifying.  page 121, Table 29: Overview of PFBS-induced health effects Comment: Please modify to e.g.: “overview of the PFBS-induced effects in rodents potentially relevant for humans.”  page 121: ”…provide evidence for adverse health effects…” Comment: Please amend to: “…provide evidence for potential adverse health effects.”  page 121: last sentence: ”A dose dependent decrease in hemoglobin and hematocrit levels was observed in male rats with a NOAEL determined to be 60 mg/kg bw/ day (90 days) as the most sensitive.” Comment: Please clarify the sentence. Does it mean that decrease in haemoglobin and haematocrit was the most sensitive endpoint….?  page 122: “A study on mice indicated modest changes in lipid metabolism after 4-6 weeks daily exposure to PFBS (30 mg/ kg bw/day). Only a few studies have, as of yet, seen similar effects on lipid metabolism. Together with human data indicating that PFBS, as well as other PFAAs, have been associated to increased BMI or changes in blood cholesterol and triglycerides, these data may point towards an effect of PFBS on metabolic disorder or disturbance of the lipid metabolism.” Comment: Considering how scare and low-confidence the data available is and the potential bias in toxicology not to publish negative results, this seems too strong statement. Please consider adding: “However, the current data is insufficient for conclusion”.  page 122: “In addition, the combinatorial effect when exposed to a mixture of PFASs is of concern. The co-exposure of PFBS and other very persistent fluorochemicals present in the environment may lead to a combination of effects on human health. Comment: Please see our previous comments on pages 13 and 161 on co-exposure.  page 127: “PFBS exposure was also shown to result in a skewed sex ratio in fish toward male dominance (LOEC 9.5 μg/L, NOEC 2.9 μg/L). Furthermore, the gonado somatic index and the oogenesis of female fish was lowered (LOEC 9.5 μg/L, NOEC 2.9 μg/L) and decrease in egg production (LOEC 2.9 μg/L, NOEC 1.0 μg/L)”. Comment: We suggest to clarify in the text which generation (F0/F1) these effects apply. This comment is also relevant to page 137 where Chen et al. 2019 is discussed.  page 132: “In conclusion, these results show that PFBS have adverse effects on hepato-histology and sexual development on X. laeveis”. Comment: Please modify this to “…PFBS have adverse effects on hepatohistology and potential to alter the sexual development on X. laevis”. The study Lou et a. 2013 only showed promoted expression of estrogen and androgen receptor activity without any effects on growth/metamorphosis/sex ratio etc. It is mentioned on the same page earlier that the authors only indicated potential for adverse effects on sexual development. Thus, we see that results of this study only showed potential of PFBS to alter the sexual development on X. laevis. Please check if this is also relevant to the other parts of the dossier concerning the study Lou et al. 2013.  page 140:.” There are indications that PFBS may have endocrine disrupting properties.” Comment: We note that earlier on page 140 it is stated in a more confident way: “PFBS led to marked and persistent disturbances in the thyroid endocrine system…”, and “endocrine disturbances caused by PFBS have been show in in tadpoles and in avian neuronal cells”. Therefore, please consider whether these wordings are consistent and sufficiently accurate.  page 141: “There is experimental evidence that the shorter chain trifluoromethane sulfonic acid is non-degradable,…”. Comment: We propose to modify the sentence because regarding biodegradation there is only one test available for trifluoromethane sulfonic acid. That test indicates that the substance is not readily biodegradable but does not tell about primary degradation or about degradation half-life in the environment.  page 141: “For PFOS no biodegradation has been demonstrated (UNEP, 2006).”. Comment: Please see the comments on page 34 regarding new information relevant to biodegradation of PFOS.  page 142: “Based on experimental data and read-across with relevant perfluoroalkane sulfonic acids like PFOS and trifluoromethane sulfonic acid, PFBS should be identified as a very persistent (vP) substance (hydrolytic half-life, t1/2 at 25 °C of more than 1 year) that by far fulfils the P and vP criteria in REACH Annex XIII.”. Comment: As indicated in our comment on page 33, we have some remarks regarding the argumentation for the read-across and therefore some changes might be needed in this sentence, too. In addition, it should be discussed whether it is appropriate to state that the vP criterion is by far fulfilled (as there is no data available on biodegradation half-life), in such a definitive way as in the current text. At least, the current text should be changed taking into account the lack of information on biodegradation half-life. It can also be discussed whether the fulfilment of P and/or vP criterion without the “by far” addition, or, potentially, with a remark that on the basis of available information, the half-life may be substantially higher, is sufficient to substantiate ELoC in the present case together with the other concerns. In addition, regarding the shorter chain analogues such as trifluoromethylsulphonate, we do not see the need to any definitive statement regarding P/vP criterion for the purpose of SVHC identification of PFBS.  page 147: “PFBS is stable towards both abiotic and biotic environmental degradation and has been shown to by far exceed the trigger values of being a very persistent (vP) substance, see Section 3.1.”. Comment: There is only a hydrolytic half-life that can be compared to the criteria. Therefore, please consider modifying.  page 147: “The P/vP assessment is supported by read-across with relevant perfluoroalkane sulfonic acids like PFOS and trifluoromethane sulfonic acid.”. Comment: This sentence may need to be modified as indicated in other comments regarding the read-across.  Page 150: “It is not possible to reverse the exposure, and effects on human health and the environment are to be considered irreversible”. Comment: Should it be continued by ”… unless emissions are stopped”?.  page 152 & 158 (chapter Concern related to co-exposure) and table 40 Comment: Please see our previous comments on pages 13 and 161 on co-exposure.  page 152, 4th paragraph: ”The relative toxic potency of individual PFASs to liver…”. Comment: Which study? Please add reference.  Page 152: “Degradation of precursor compounds with formation of PFBS represents a future source of PFBS, even if the emissions are stopped immediately”. Comment: It could be specified whether this refers to the emissions of the precursors or of PFBS.  Page 152: “Consequently, once effects become apparent, it may be too late to take measures to protect us from exposure.”. Comment: As ELoC is also proposed to be fulfilled for the environment, and the paragraph refers also to emissions reaching the environment as it mentions control of emissions from industry and purification of wastewater, please consider modifying the sentence to also take into account environmental protection (e.g., “..to protect humans and the environment”)  Page 152: Regarding the way the Brendel et al. (2018) study is discussed Comment: It might be preferable to avoid the unnecessary use of very definitive expressions like “everlasting“ and “permanent”. The environmental half-life is not exactly known (there are no standard studies to determine the biodegradation half-life for PFBS or any of the analogues) and it has been reported that degradation of perfluorinated sulphonates may occur in certain conditions, as indicated by comments above.  Page 152: “The concerns brought forward in Sections 6.3.2.1 to 6.3.2.5 lead to a concern for co-exposure with other contaminants with similar health effects.”. Comment: We have reservations for the use of co-exposure as ELoC argument. However, in the event that this chapter/sentence is kept, we propose to consider whether it should mention effects on the environment.  Page 153: “Considering the irreversibility of the environmental contaminations and the continuously increasing background levels, estimation of acceptable releases is not possible.”. Comment: We propose to rephrase as: “Considering the poor irreversibility of the environmental contaminations and the continuously increasing background levels when the substance is released to the environment, estimation of acceptable releases is not possible.”  Page 155: “PFBS which is less readily adsorbed to soil, sediment and suspended matter compared to the classic PBT/vPvB substances due to its properties, will likely have a higher proportion of the emitted substance bioavailable for organisms.”. Comment: This comparison does not take into account that PBT/vPvB substances will have a higher proportion of the substance accumulated in organisms (and thus bioavailable).  Page 155: “Irreversible, bioavailable, increasing exposures of both wildlife and man via environment will maintain as long as emissions continue, and even if emissions are stopped, the concentrations will not start to decrease immediately.”. Comment: Please consider deleting “increasing” because exposure depends on rate of emission as well as many environmental factors. Please consider changing “stopped” to “decreased” (at least if this is based on the citation from Cousins et al. in 6.3.2.8). Even assuming that no degradation occurs, the concentrations could start to decrease (at least in local scale), if emissions are stopped due dilution and distribution.  Page 156: “it can be concluded that the degradation potential of PFBS in all environmental compartments is very low or negligible.”. Comment: We propose to change to “…is likely to be very low or negligible”.  Page 156: “Its high persistency implies that PFBS will remain in the environment much longer than most other substances that are identified as exhibiting P or vP properties. PFBS by far exceeds the criteria for P and vP as laid down in Annex XIII of the REACH regulation.”. Comment: This may need modification, as indicated in comments above.  Page 156: “Exposures are not expected to decrease upon cessation of releases because of the high persistence of the substance.”. Comment: Please see comment on page 155 regarding cessation of emissions.  Page 158: “... as degradation of PFBS and other PFASs in the environment is extremely slow or negligible”. Comment: We propose deleting “extremely” or changing to “is likely to be very low or negligible”.  page 160: “This is supported by read-across to perfluoroalkane sulfonic acids with both shorter and longer chain lengths, which also have a very high environmental stability.”. Comment: This may need modification, as indicated in comments above. |  | |
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| 5346  2019/10/18 | Cefic,  Industry or trade association,  Belgium | Thank you for giving us the opportunity to provide comment on this Annex XV proposal for SVHC identification based on Article 57f of REACH. Cefic comment is not directly related to substance specific parameters but on the general APPROACH taken to identify an SVHC based on equivalent level of concern for environmental effects. The enclosed file reiterates previous submitted comments on similar files. Comments refer to the LACK of an agreed and broadly accepted methodology on how to assess equivalent level of concern for environmental effects. In our view it’s important to first set this assessment methodology before taking any decisions on newly submitted dossiers. |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5346\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5347  2019/10/18 | United Kingdom,  Member State | 1. We appreciate the amount of detailed work that has been put into producing this well written dossier and we thank the authors for taking on board many of the suggestions we made on the earlier draft submitted to the PBT EG. We think this has strengthened the arguments made, although we still have reservations regarding the overall outcome (see points 14 and 15).  2. Section 1.3.3 p22 and 1.4 p23, plus other later sections (e.g. Section 3.4.4 on LRT and p152/3), and Conclusions: Whilst the focus of this SVHC proposal is now on PFBS itself, it still refers to precursors and co-exposures with other PFAS as supporting arguments. Although we agree that these are important considerations for managing the long-term exposure and risks from PFBS, we do not think they are relevant in terms of the hazard posed by an individual substance. The grouping of PFAS compounds and combination effects are currently being discussed (including a paper for MSC-66). We think that this discussion should take place (and a conclusion reached) before applying these ideas to specific substances.  3. Section 3 p28 and response to the PBT EG RCOM: You imply that ‘studies published in scientific journals which have already been peer reviewed are reliable’. We do not agree with this. Published papers require a different standard of peer review, for a different purpose, than establishing reliability and relevance for regulatory purposes. The majority of studies used in this proposal are from academic literature sources rather than regulatory studies performed in accordance with standardised (ring-tested) guidelines and appropriate quality assurance (e.g. GLP). We cannot accept that publications in a peer reviewed journal are accepted for regulatory purposes without critical appraisal of their reliability and relevance. We thank you for proposing validity scores for some of the key studies but the reliability is still not always clear (methodologies, analytics and reporting standards in particular are unclear) for many of the published papers relied upon).  4. Section 3.1 p28 & 29: At the bottom of p28 and third paragraph of p29 when referring to the papers by Brendel et al. (2018) and Cousins et al. (2016), you use the words ‘pointed out’ as if extreme persistence in itself is now an established reason for managing chemicals and that all PFAS pose the same risk. These opinions are not established in regulation and so we would prefer use of the word ‘proposed’ in relation to these authors’ suggestions.  5. Section 3.1.1.2, p30: In the second paragraph of this section, the dossier states that ‘...the degradation half-life of PFBS in the atmosphere is above the threshold of two days, which proves that the substance has a potential for long-range transport.’ However, it says previously that the results of the AOPWIN model should be interpreted with caution. We would therefore prefer the word ‘indicates’ instead.  6. Section 3.2.5/6, p42-60: We agree that PFBS has properties that make it highly mobile, and it is therefore widely detected in numerous environmental compartments and regions. This could be a cause for concern if levels are approaching those where harm to humans or other organisms is envisaged (accounting for uncertainties). As the dossier notes, in many cases current concentrations are very low (in the ng/L or kg level) or not detected. Higher (µg) levels can be found in some instances, mostly in east Asia with a few occurrences in the EU. However, almost all of these elevated levels are associated with proximity to PFAS production facilities, industries using PFAS, other hot spots such as waste-water treatment plants or landfill sites and those affected by fire-fighting foams or similar direct sources of contamination. Away from these sites, levels are generally low. Specifically on p53 (last paragraph) we would not use the word ‘substantial’ in relation to drinking water contamination as this is a relative term implying that concentrations are especially high (in relation to some safety limit?) whereas they are in the tens of ng/L range (an order of magnitude below the limit set under the European Drinking Water Directive of 0.1 μg/L for individual pesticides for example) and not related to a particular toxicological concern. It could say ‘widespread’ instead.  7. Section 3.4.2/3, p 63 - modelling of Long Range Transport potential and occurrences in remote regions: The location of PFBS in Figure 4 on p64 does not clearly imply (as suggested, also at 3.4.5) an especially ‘high LRT potential’ in relation to other ‘POP-like’ substances. We think benchmarking this against some known POPs would be useful. Regarding the occurrence in ‘remote’ areas and biota, our comments on these monitoring data are similar to those made above. We note that some of the occurrences in ‘remote’ regions could actually also be due to local sources of contamination. Specifically in this Section, use of the word ‘considerable’ in relation to levels in Polar Bears (p70) is a relative and potentially misleading term when levels of 0.08-0.69 ng/g (µg/kg) ww in plasma may be of little or no toxicological significance. Unless you intend to conduct a thorough quantitative risk assessment, we would suggest using the word ‘higher’ or ‘elevated’ instead.  8. Section 3.5, p71 on Bioaccumulation: In general the information presented indicates a low potential for PFBS to bioaccumulate in most organisms. Levels found are usually proportionate to and reflect those in the surrounding environment or feed (which were often from areas of high contamination) and this would not strictly be considered indicative of significant levels of accumulation. The study by Numata et al. (2014) (Section 3.5.1.4) where pigs were fed contaminated food (at a mean PFBS concentration of 132 µg/kg dw) is of potential interest as it gave a BMF value in whole pig of 1.2 (compared with 17.9 for PFOS). However we note there was high individual variation in elimination half-lives. You quote this BMF value widely in the conclusions but it is unclear from the summary how the data were generated or how reliable this study was (no limit of detection or validity score is given). The summary mentions further data analysis undertaken by ECHA in 2017 - could these be provided (e.g. in an Annex?). We note that the elimination half-lives indicated for PFBS in human blood (Section 3.5.3.2, p83) appear longer than for rodents, although these are also variable, based on a very small sample size and do not necessarily relate to whole body elimination half-lives. As this is also a key weight of evidence (WoE) argument used in the overall SVHC proposal, and ECHA apparently examined this in 2017 too, could more detail please be provided in an Annex? It is important, when using arguments that such BMF and elimination half life values pose an ‘equivalent level of concern’ (e.g. to B/vB substances) that there is benchmarking against those where that concern has previously been established, e.g. the other SVHC PFAS, which in each case do have notably greater values.  9. In the study on birds (Newsted et al, 2008) at Section 3.5.1.3, you quote the apparent maternal transfer to eggs in your WoE conclusion. However, few details are available for this study and its reliability is unclear. The dossier mentions the egg-to-serum ratio was approximately 1.0 and that concentrations of PFBS in eggs were directly proportional to dietary concentrations, so it is unclear what the elevated concentrations in eggs relate to or whether this could even include the shell. PFBS concentrations in 14-day old offspring were less than in adults or eggs (‘at least 480-fold less than those measured in eggs from the seventh week‘) so there does not, in any case, appear to be subsequent transfer from eggs to the offspring. We think the use of this information as part of the overall WoE requires further justification.  10. From Section 3.5.3 a mean ‘BAF’ from five crab species of 110 from a study in Korea by Naile et al. (2013) is quoted in the overall conclusion and, although low in BCF terms, it stands out as higher than other aquatic values for PFBS. The study seems reliable (you have given it a validity score of 2) and the water and biota sampling appear to be concurrent; although as you note it would have benefitted from measuring BAF for individual crab species. It is also supported by the subsequent study in the same area by Hong et al. (2015) where a BAF crab of 200 is determined. The values are for whole homogenised crab and it would be interesting to know whether the PFBS is concentrated in the shell or other edible body tissues. We also note a comment in these papers of PFBS behaving differently in saline to fresh water; as one concern expressed is LRT via ocean currents, we think it could be relevant to investigate this further.  11. In Section 3.5.2, p76 and Annex II: The highest BAF value from crabs (110) is used along with an assumed water half-life of 10 years in modelling based on the report by Crookes and Fisk (2018). This paper indicates how concentrations of PFBS in aquatic biota might be expected to exceed the biota concentrations for a persistent and bioaccumulative substance over time - and it has been used in the overall WoE conclusion to support an equivalent level of concern (ELoC) to PBT/vPvB substances (e.g. at Section 6.3.2.1-4). The calculations provided in Annex II use generally worst case assumptions taken from studies of uncertain relevance to EU conditions. The BAF value used is less than a BCF of 500 usually triggering a bioaccumulation concern and we would question whether estimations using on such a low value follow the normal assumed linearity of increasing hazard. Our reading of the Crookes and Fisk paper is that such (crude) predictions should be used as an initial screen only, not as demonstration of a concern. The same comments apply to the modelling undertaken in Cousins et al., 2019.  12. Further to point 11 above, one of the main ELoC arguments used in the PFBS SVHC proposal is that substances with a low bioaccumulation potential could potentially reach similar levels in biota as substances that are known to bioaccumulate, provided they are sufficiently persistent and mobile in the environment when considered over a longer time-scale. If this is set against a trend of increasing concentrations of PFBS in the environment (as set out in Section 3.9) we can understand the reasons behind this concern. However, we also think that more detailed modelling than that initially proposed by Crookes and Fisk (2018), using a wider range of relevant (and more realistically worst case) input parameters for the specific substance in question, could usefully be developed to more accurately predict the likelihood of this concern ever being realised. At present we do not consider it sufficiently predictive of there being a probable future very high concern for PFBS.  13. Given the inconclusive evidence of toxicological significance (at relevant exposure levels) in mammalian studies and low acute toxicity to aquatic wildlife, the case for PFBS potentially reaching levels of concern relies on the long-term toxicity studies by Chen et al on Marine Medaka (Section 5.1.1.2, p125-128). These studies appear to relate to a single experiment performed in a single academic laboratory (with different end points reported in different journals). Can it be confirmed that this is indeed the case? We note that the study has been rated as ‘reliable with restrictions’. However, we are not convinced that it has been critically reviewed. For example, analytical monitoring is stated to be carried out ‘regularly after the renewal of the sea water’ but there is no discussion of what regularly means; whether this implies it is only fresh solution that was tested and there is no mention of whether the report authors have been contacted for further information. In addition, several of the results in the discussion in Section 5.1.1.2 and 5.6 are either not dose-dependent, not statistically significant or the concentration at which the effects are seen is not stated.  The potential for PFBS to pose an ED hazard based on these fish and other studies is now emphasised in the overall WoE conclusion. However, this has not been considered by the ED EG and we do not think it appropriate to speculate about whether the reported effects are related to endocrine disruption in the absence of clear mechanistic information for the substance or supporting information from mammalian studies. If the Chen et al. study is indeed valid, the Annex XIII ‘T’ criterion is met based on the NOEC for F0 fecundity and F1 hatching regardless of the mode of action. Given the importance of this in any overall SVHC Conclusion and the lack of quality assurance or consideration against standard guidelines, we feel there should be further in-depth analysis of the Chen et al. studies.  The dossier also concludes that the potential for serious long term-effects (including known, ‘unknown’ and ‘irreversible’ ones) might not be observed in standard tests (p12 & p157), though little evidence is provided to support this assertion. Deriving (eco)toxicological endpoints from a range of relevant standard tests, and accounting for uncertainty in these, is currently the basis of most chemical regulations. Non-threshold concerns have not been clearly established for PFBS and taking such an (overly) precautionary stance on the utility of standard studies effectively undermines the very regulations we are working to.  14. Section 6, p141 and the overall SVHC conclusions (wherever these appear in the dossier): The dossier takes an overall WoE approach rather than relying upon individual elements of concern for PFBS meeting the Article 57(f) ELoC criteria. We believe that each of the elements making up this WoE need to be considered for their individual veracity and contribution (weighting) to the whole ELoC argument. When we look at each one in turn, we do not see that they are individually conclusive or compelling of PFBS posing a probable serious adverse effect on human health or the environment. Whilst we agree the substance is likely to be extremely persistent and mobile and hard to remove once in the environment, the information on bioaccumulation does not equate to the concerns from a B/vB substance. Currently the potential ‘adversity’ of effects and meeting of the ‘T’ criterion is also not demonstrated by the mammalian or environmental toxicity data without there being further detailed scrutiny of the original published papers.  We do understand the dossier is taking a precautionary approach to PFBS being an SVHC due to concern over its increase in environmental and biological compartments/media globally. However, outside of particular industries and hot-spots in the EU, production, usage and contamination levels are generally low in relation to any clear toxicological concern. Referring to our point 12, such a precautionary approach looking at the potential for future harm could be better supported by more detailed, substance-specific and realistically worst case modelling than currently provided in Annex II. We would welcome ECHA and MS developing (and validating where possible) such modelling approaches to better support precautionary ELoC cases based on uncertain future hazards of PMT substances.  15. Overall we remain to be convinced that there is sufficient evidence to indicate that PFBS is an SVHC through meeting Article 57(f) ELoC criteria. It is not clear either for each element of the WoE, or collectively, that a threshold has been reached to describe how PFBS is a substance of very high concern, rather than one just of concern or even high concern. We feel that a more strategic solution to managing the emissions and risks from PFAS generally could prove more effective than attempting their case-by-case SVHC identification. |  | |
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| 5348  2019/10/18 | 3M Belgium,  Company,  Belgium | Please find our comments in attachment. |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5348\_3M comments.pdf |
| 5349  2019/10/18 | SABIC Innovative Plastics BV,  Company,  Netherlands | The attached document (Section IV) provides substantive scientific reasoning in the overall determination that the elements for concern, as postulated in the Annex XV report, cannot be justified to the extent required in the determination and identification of a substance as an SVHC according to the requirements of Article 57(f) of Regulation (EC) 1907/2006. Specifically, the following sections demonstrate there is insufficient “scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those other substances listed in points (a) to (e)". Indeed, there is no evidence the PFBS meets the persistent (P) or very persistent (vP) criteria, and insufficient evidence of long-range transport. The current monitoring data does not support the conclusion that there is high potential for wide geographic scale contamination of PFBS. There is no evidence that PFBS is bioaccumulative and no reliable evidence of environmental hazard. Available toxicological data do not provide evidence of serious effects to human health. Measured PFBS concentrations in the environment, and in the human body are far lower than the effect levels determined in reliable (eco)toxicity studies. Overall, there is insufficient scientific evidence on PFBS and its salts to support any conclusion on probable serious effects to human health or the environment which give rise to an equivalent level of concern. Read-across to shorter (C1) and longer (C8) chain perfluoroalkane sulfonic acids (PFSAs) is not justified and no formal rationale is presented in the Annex XV report. In many instances, the evidence used in the Annex indicates that shorter and longer PFSA substances are not good analogues for hazard or behaviour predictions. Furthermore, the manufacture and use of PFBS is limited. The PFBS substance group represent a low overall EU volume and their uses are not widely dispersed. |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5349\_PFBS rebuttal to SVHC categorisation.pdf |
| 5350  2019/10/18 | LANXESS Deutschland GmbH,  Company,  Germany |  |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5350\_LANXESS\_Comments\_SVHCproposalPFBSandsalts.pdf |
| 5351  2019/10/18 | ASD-EUROSPACE,  Industry or trade association,  France | Page 17: Such a broad and unspecific group entry ("any salt form of PFBS, either currently existing or developed in the future") appears to be not feasible from a compliance point of view, even more so considering the long and widely distributed industrial supply chains leading to the production of very complex hardware in our sector. The first analysis reveals more than 1,000 CAS substances which are corresponding to this group.  Such a broad listing also raises legal concerns with regard to the substance identification requirement and general principles of EU law.  Further details are elaborated in the enclosed contribution (PFBS-2019-C1-18102019). |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5351\_ASD-Eurospace comments on PFBS and its salts-18102019-Final.pdf |
| 5352  2019/10/18 | American Chemistry Council,  Industry or trade association,  United States | The Proposal argues that PFBS 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 PFBS, “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. |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5352\_FINAL\_ACC Comments to ECHA PFBS 101819.pdf |
| 5354  2019/10/23 | FluoroCouncil,  Industry or trade association,  United States |  |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 5354\_FINAL FluoroCouncil response PFBS SVHC consultation 18-10-19 .pdf |
| 5357  2019/11/04 | Sweden,  Member State | The Swedish Chemicals Agency has one additional comment in the consultation of the Annex XV dossier of PFBS and its salts, submitted by Norway.  We would like to inform the Dossier Submitter about the recent article of Nyberg et al 2018 (see attachment). We propose that this study be included in the SVHC proposal for PFBS. |  | |
| *See the corresponding embedded attachment in table 1 of Part I:* 357\_Nyberg et al 2018 (003).pdf |

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

Specific comments on use, exposure, alternatives and risks

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| Number / Date | Submitted by (name, submitter type, country) | Comment | Responses |
| 5329  2019/10/10 | BOMA BOHEMIA spol. s r.o.,  Company,  Czech Republic | Perfluorobutane sulfonic acid (PFBS) is used as wetting agent in the production of photographic films. The maximum volume of PFBS contained in these products is 0,0168 % of weight. |  |
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| 5339  2019/10/17 | European Semiconductor Industry Association,  Industry or trade association,  Belgium | The European Semiconductor Industry Association (ESIA) should like to thank the Norwegian Authorities for their dossier and the opportunity to input some information to this consultation on SVHC properties. ESIA will comment briefly regarding the use and how the potential risks are managed.  PFBS is used in low concentrations and minor quantities in speciality formulations for their critical properties in photolithography processes in semiconductor manufacturing. This includes critical use in photoresists and in antireflective coatings for photolithography, the highly important step of patterning in semiconductor manufacturing.  Photolithography materials in semiconductor manufacturing are now dependent upon the use of shorter chain chemistries, including shorter chain chemistries with a C4 carbon chain length. There are no known non-perfluorinated substance alternatives that can adequately provide the functional properties for the critical high tech applications required within the semiconductor manufacturing process. Any development in this area would require first a future invention. The potential risk to the environment and human health is managed in semiconductor manufacturing through stringent risk management measures and safety practices to prevent release of chemicals during all stages of the manufacturing process. There is no exposure to the employee at the work place during production due to the use of closed systems. This potential risk is well controlled through the application of closed system manufacturing equipment which are installed in a cleanroom environment. Automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment. The European semiconductor industry has a long history of responsible use of perfluorinated substances and has made significant voluntary commitments and efforts to progress the transition to perfluorinated substances of lower chain lengths. The global semiconductor manufacturing industry has eliminated the use of (C8) PFOS and is also taking substantial efforts for many years to remove the use of PFOA. The transition of semiconductor industry towards the shorter chain homologues for critical manufacturing uses has taken many years and much investments to realise.  The modern world is based on the enabling capabilities of semiconductor technology across many sectors of activity. Semiconductors enable the more efficient use of electrical energy in lighting, computing, data storage centres, intelligent transport systems, electric vehicles and in industrial manufacturing systems. Innovations in semiconductor devices enable sustainable developments in automotive safety, more secure communications and banking payments systems, improving medical devices and they play a key role in the realisation of the smart grid. |  |
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| 5340  2019/10/18 | SEMI,  Industry or trade association,  Belgium | Overall feedback:  PFBS can be used in low concentrations as a part of specialty chemical formulations in semiconductor manufacturing processes, in particular due to their critical properties in photolithography processes. This includes critical use in photoresists and in antireflective coatings for photolithography, which is the highly important step of patterning in semiconductor manufacturing.  Photolithography materials in semiconductor manufacturing are now dependent on the use of shorter chain chemistries, including those with a C4 carbon chain length. There are not known non perfluorinated substance alternatives that can adequately provide the functional properties for the critical high-tech applications required within the semiconductor manufacturing process. Any development in this area would require first a future invention.  The potential risk to the environment and human health is managed in semiconductor manufacturing through stringent risk management measures and safety practices to prevent release of chemicals during all stages of the manufacturing process. There is no exposure to the work place employee during production due to the use of closed systems. This potential risk is well controlled through the application of closed system manufacturing equipment which are installed in a cleanroom environment. Automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment.  The semiconductor manufacturing supply chain has a long history of responsible use of perfluorinated substances and has made significant voluntary commitments and efforts to progress the transition to perfluorinated substances of lower chain lengths. The global semiconductor manufacturing industry has eliminated the use of (C8) PFOS and is also taking substantial efforts for many years to remove the use of PFOA. The transition of semiconductor industry towards the shorter chain homologues for critical manufacturing uses has taken many years and much investments to realize.  Specific feedback: Inputs on p. 195 that provides information on use KPFBS, which states that the main application of KPFBS is as a flame retardant in polycarbonate, and also on p. 199 that provides information about alternatives of KPFBS as flame retardancy additives.  According to a major PFBS related products manufacturer’s catalogue and some Polycarbonate resin manufacturer’s catalogues, potassium perfluoro butyl sulfonate (KPFBS) has been widely used for providing additional flame retardancy to polycarbonate (PC) resin without deteriorating PC’s mechanical strength and transparency.  Due to the specific characteristics of KPFBS, there is a non-negligible possibility that KPFBS is used as an intentional additive in the PC resins used to construct some parts of semiconductor manufacturing and related equipment (SMRE). PC resin is widely used to compose special containers for semiconductor device wafers. The containers are called ‘FOUPs’ or ‘SMIF pods’, depending on their structure. PC resin is also widely used to compose the equipment front-end interface module that consists of FOUP or SMIF load/unload interface(s) and an enclosure containing wafer handling mechanism for loading and unloading wafers from FOUP or SMIF pod to processing part of the semiconductor processing equipment. The front-end interface module of semiconductor processing equipment is called ‘EFEM’. FOUPs and SMIF pods as well as the enclosure part of EFEMs are used where the semiconductor device wafers need to be protected from organic, inorganic, and particulate contaminations present in the manufacturing clean-room environment. They are mainly used as a ‘mini-environment’ at the loading point (known as the EFEM -Equipment Front End Module) of semiconductor manufacturing and related equipment, and as a mini-environment in overhead transport and storage systems (known as AMHS –Automated Material Handling Systems, or OHTs – OverHead Transports) used to stage and temporarily store the device wafers, and move them from equipment to equipment. The in-process semiconductor devices which are present on the device wafers are extremely sensitive to ambient environmental conditions. Therefore, materials from which the FOUPs, SMIF pods, and the enclosure part of EFEMs are composed, and many components of the processing equipment, are critical to the quality of the manufactured semiconductor devices. Even removing a KPFBS additive, or replacing it, could have significant impact to the yields of the semiconductor device manufacturing process. Qualifying any alternation in the item materials requires both intensive experiments and tests by the FOUP, SMIF pod, and semiconductor manufacturing equipment suppliers, and the semiconductor device manufacturers (i.e., the end user of the equipment) to prove that the alternative materials meet all the required performance criteria such as substance outgassing (both quantity and quality), water adsorption/desorption performance, mechanical strength, flame retardant characteristics, and other factors.  At this time, we don’t have sufficient information to prove whether or not the PC resins used in SMRE contain KPFBS. FOUP, SMIF pod, and SMRE suppliers generally specify only base materials (e.g. PC resin) with some performance criteria (e.g., mechanical strength, transparency, flame retardancy grade) for components they purchase to make their products, and sometimes they just select components which contain articles that just happen to be made from PC resin. They do not specify the complete composition of the PC material they acquire from the upstream supply chain, especially with regard to additives. Also, complete composition details are often confidential business information (in part because of the R&D investment required to make materials that meet the stringent performance requirements in the industry). We have just raised this possibility of KPFBS applications in the semiconductor sector. It will take a lengthy period to discover actual uses, where in the supply chain the decision-to-use originates, possible alternatives, qualification testing of the possible alternatives, and for alternatives that pass the qualification testing – enforcing their use at the required suppliers in the supply chain. |  |
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| 5342  2019/10/18 | CHEM Trust Europe,  National NGO,  Germany | The dossier provides ample evidence of exposure to the general population via increasing diffuse emissions from sources like drinking water, fruits and local air emissions. Given that potential adverse effects due to life-long exposure are largely unknown and considering the irreversibility of the environmental contaminations and the continuously increasing background levels, estimation of acceptable releases is not possible. Hence, the risks cannot be adequately controlled and thus it is necessary to minimise the emissions. CHEM Trust therefore calls for swift regulatory measures following the identification as SVHC. Otherwise these chemicals keep recirculating in the water cycle and will lead to increasing exposure levels in humans and wildlife via environmental exposure (including drinking water, bottle water, edible plants, animal feed, food).  The fact that PFBS and its salts were introduced into the market as a replacement chemical for PFOS-substances 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 covers PFBS and its salts which is a 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 which is a group of over 4,000 substances. (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).  In the recent CHEM Trust briefing we advocate for stringent global regulation of PFAS as a group under the Stockholm Convention: PFAS – the ‘forever chemicals’, Invisible threats from persistent chemicals. CHEM Trust, 2019. https://chemtrust.org/wp-content/uploads/PFAS\_Brief\_CHEMTrust\_2019.pdf |  |
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| 5345  2019/10/18 | Finland,  Member State | The following monitoring data between 2014-2019 are available for PFBS in Finnish surface waters: 222 water samples has been analysed from 47 different sites around Finland with the concentrations of PFBS ranging from <0.1–4030 ng/L (56 % > LOQ). Highest measured concentrations of PFBS are from firefighting training sites or ditches and streams near airport area. In all river samples, which were not from the point sources, concentrations were between <0.1-3.6 ng/L (unpublished data, available in database) (Finnish Environment Centre 2018).  Refence: Finnish Environment Institute 2018. Open information. Ympäristötiedon hallintajärjestelmä Hertta. Pintavesien vedenlaatu (VESLA). Available at https://wwwp2.ymparisto.fi/scripts/kirjaudu.asp (registration required) (in Finnish). |  |
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| 5346  2019/10/18 | Cefic,  Industry or trade association,  Belgium |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5346\_2019 04 29\_Cefic updated reflection on SVHC\_ELoC for env.pdf |
| 5348  2019/10/18 | 3M Belgium,  Company,  Belgium | Please find our comments in attachment. |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5348\_3M comments.pdf |
| 5349  2019/10/18 | SABIC Innovative Plastics BV,  Company,  Netherlands |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5349\_PFBS rebuttal to SVHC categorisation.pdf |
| 5350  2019/10/18 | LANXESS Deutschland GmbH,  Company,  Germany |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5350\_LANXESS\_Comments\_SVHCproposalPFBSandsalts.pdf |
| 5351  2019/10/18 | ASD-EUROSPACE,  Industry or trade association,  France |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5351\_ASD-Eurospace comments on PFBS and its salts-18102019-Final.pdf |
| 5352  2019/10/18 | American Chemistry Council,  Industry or trade association,  United States | As discussed above, the Proposal’s underlying rationale for identifying PFBS 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. |  |
| *See the corresponding embedded attachment in table 1 of Part I:* 5352\_FINAL\_ACC Comments to ECHA PFBS 101819.pdf |
| 5354  2019/10/23 | FluoroCouncil,  Industry or trade association,  United States |  |  |
| *See the corresponding embedded attachment in table 1 of Part I:*5354\_FINAL FluoroCouncil response PFBS SVHC consultation 18-10-19 .pdf |
| 5357  2019/11/04 | Sweden,  Member State |  |  |
|  |  | *See the corresponding embedded attachment in table 1 of Part I:*5357\_Nyberg et al 2018 (003).pdf |  |