Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. SEAC is not aware of any intentional or unintentional uses in the EEA covered by the proposed restriction. However, there are C&L notifications for the substance. Please provide information on environmental and economic impacts of restricting any possible uses that are not assessed in the report.
2. According to available information PFHxS is currently present in some imported articles. Please provide us with any further information on contents of PFHxS, its salts and related substances in imported articles.
3. It is possible that some economic impacts will occur as the proposed restriction would not allow companies to switch to PFHxS after the entry into force of the PFOA restriction in June 2020. Did your company plan any such substitution from PFOA to PFHxS?

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| **492** | **Date/Time:** 2020/05/25 17:44  **Type:** BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  CHEMTRUST, EEB and IPEN  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  The undersigning organizations support the restriction of PFHxS as part of the growing global  efforts to eliminate all PFAS. PFHxS is extremely persistent, it bioaccumulates and is likely to  lead to significant adverse human health effects. However, we consider that the proposed  restriction as currently under discussion will have a limited impact on the reduction of PFHxS  emissions given the high allowed concentration limits and the proposed derogations.  Concentration limits  Unfortunately, as with the previous REACH restriction decisions on PFAS (PFOA and C9-C14 PFCAs) SEAC’s draft opinion supports the concentration limits for mixtures or articles proposed by the Dossier Submitter (DS), 25 ppb for the sum of PFHxS and its salts or 1000 ppb for the sum of PFHxS related substances, as it considers that these values “provide a balance between the need to prevent intentional use and to m inimise emissions, and the availability of analytical methods ”. However, this is based on the PFOA restriction process initiated in 2014 and does not take the developments in analytical methods as well as the rapidly emerging evidence on the health hazard of PFHxS into account. The original PFOA restriction dossier proposed a 2 ppb limit as feasible already in 2014. The SEAC opinion does not provide any data or information as to why the proposed higher limits are relevant for PFHxS.  The SEAC opinion is based on claims by industry regarding the lack of analytical methods to enforce a lower value and does not include a technical or scientific justification on how these limits would best serve the purpose of the restriction such as addressing an unacceptable risk, REACH Art. 68(1), or indeed the higher-level conclusions of the Council of the EU of June 2019 (“to eliminate all non-essential uses of PFAS”). It should be noted that the opinion also states that “ There is no safe concentration for these substances”, a clear justification for the much lower threshold limit of 2 ppb originally proposed already for PFOA.  The SEAC opinion also states that “ The suitability of the proposed concentration limits was  not contested during the consultation of the Annex XV dossier.” Unfortunately, SEAC did not  consider the comments on this issue provided by our organisations during the Annex XV  dossier public consultation where we highlighted that:  - The limit is too high to avoid intentional use. The limited set of test results of PFHxS in consumer products presented in the dossier show that PFHxS has been detected in concentrations below 25 ppb/1000 ppb in several samples. The 25 ppb/1000 ppb value mirrors the opinion of the PFOA restriction. However, the DS of this restriction had originally proposed a value of 2 ppb for PFOA, its salts and PFOA-related substances on its own, in mixtures and articles to avoid intentional use. Lowering of 25/1000 ppb to 2 ppb would substantially reduce the total yearly PFHxS emissions from textiles from 6.3 kg to 0.5 kg, as RAC opinion concludes.  - Analytical methods to allow enforcement of lower limits are already available. As stated in the Restriction Report on page 38, “ Analytical methods for the detection of PFHxS are reported in the literature which can be used to measure PFHxS and PFASs in general in almost all environment all media .” Two methods are highlighted that have a level of quantification of 0.06 ppb. Testing methods have developed rapidly since the PFOA dossier was submitted and there are no constraints today for establishing a threshold of 2 ppb. To put this into perspective, the drinking water limits that have been established in the EU and the US for PFOS, PFOA and some other PFAS are in the 10- 100 ppt range. For example, several states in the US have a combined limit of 70 ppt for five PFAS (including PFHxS) that requires clean-up if exceeded.  Transitional period: The SEAC opinion agrees with the DS recommendation of a transitional period of 18 months after the entry into force of the proposed restriction. However, it states that “ no intentional uses of PFHxS, its salts and PFHxS-related substances have been identified in the EEA, and the exempted uses of PFOS will be derogated. Substitution activities would not be needed in the EEA”.... Furthermore, SEAC notes that “such transition period would not have negative impacts on the supply chain because articles already placed on the market would be exempted.”  Therefore, the need for a transitional period of 18 months is not justified and would only allow  importers to increase PFHxS stocks in the EU. In addition, importers have had already several  years to prepare for this regulatory action. The restriction intention was already announced  two years ago, in April 2018, and several months are still needed for this restriction to enter  into force. It was nominated to the Stockholm Convention for global elimination already in  2017. We therefore recommend to abandon the transitional period.  Derogation to concentrated fire-fighting foam: The Dossier Submitter estimated that the current EU stockpile of fire-fighting foams currently kept at refineries, tank farms, chemical plants and other installations contains around 0.5-3 kg PFHxS. Instead of proposing safe disposal of these foams in line with treatment of any other hazardous waste, SEAC ́s opinion is to allow their use. Use of fire-fighting foam is one of the most dispersive uses there is of PFAS and this proposal will undoubtedly lead to environmental contamination and increasing the body burden of PFHxS and PFAS overall of EU citizens. This is unacceptable and should be replaced by mandatory producer recalls and safe disposal.  SEAC considers that restricting existing stocks of these foams would be disproportionate,  however it states that “Concerning the costs and benefits of replacing fire-fighting foams  containing PFHxS in stock, SEAC notes that the costs have not been estimated in the  Background Document of this restriction proposal ”. SEAC bases its opinion on the claim that  “earlier experience on costs of replacing AFFF based on PFOA were estimated taking into  consideration the amount of fuel needed for the destruction of the foam by incineration.”It is unclear how SEAC and the DS come to the conclusion that restricting these  foams still in stock would be disproportionate, noting that SEAC does not quantify the benefits  of avoiding these releases, for example by estimating the remediation costs for cleaning up  the emissions of PFHxS and the significant health costs related to PFAS exposure.  By only looking at industry cost of replacement without taking the wider societal costs, these  costs will instead be externalized, which means that it will always be cheaper to release  hazardous waste than to destroy or treat it. This is a perspective that hardly fits in the 21 st  century at a time of the European Green Deal and Europe`s ambition to establish a clean  circular economy without PFAS!  Exempted uses in the PFOS restriction: SEAC supports the derogation of the exempted uses in the PFOS restriction (use of PFOS in mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems). However it recognizes that “in accordance with paragraph 9 of Article 8 of the Stockholm Convention, the POPs Review Committee recommended to the Conference of the Parties to the Convention to consider listing and specifying the related control measures for PFHxS, its salts and PFHxS-related compounds in Annex A (elimination) without exemptions. ” “In line with the view of the Commission, SEAC considers that the proposed restriction, and accompanying RAC and SEAC opinions, will contribute to the discussions on the global regulation of PFHxS”.  It should be noted that the EU was represented at the POPs Review Committee meeting that  came to the conclusion that no exemptions were needed. By following the proposed approach  in the Draft Opinion, derogations adopted at the EU level would be promoted at a global level.  This would weaken the international controls of PFHxS as well as undermine the Stockholm  Convention, currently the only legally binding means of controlling unmanageable, hazardous  chemicals similar to the EU restriction process. Furthermore, SEAC states in its draft opinion  that “during the consultation, the German Competent Authority indicated that on the market  there are fluorine-free, chemical alternatives, e.g. alkane sulfonates, for hard chromium (VI)  plating available, as well as effective technical solutions to minimize aerosol emission, e.g.  galvanic bath covers or air extraction systems.”  This makes it very clear that the proposal to derogate this use has no technical/economic  justification and should be abandoned. Otherwise, it will further allow a highly polluting and  dangerous industrial sector such as the chromium VI platers, to continue business as usual,  hindering the market for safer alternative providers both at EU and global level. |
| **SEAC Rapporteurs response:**  Thank you for your comments. All your arguments were considered carefully and some changes were introduced to SEAC opinion justification.  Concentration limits:  The SEAC rapporteurs did a lot of work during opinion making to find further information on the availability of new analytical methods. We consider that, at this moment in time, the best available evidence seems to indicate that analytical methods are not yet sufficiently developed for a lower limit value. There may exist methods in the possession of individual parties, however, we highlight that from a monitoring and enforcement viewpoint, analytical methods have to be widely available for the affected stakeholders and preferably standardised.  There appear to be a couple of projects going on for the development of standardised methods for PFASs, reported on the CEN web pages, but the progress appears relatively slow.  We note that methods with much lower LOQs exist for some matrices, however, they are not applicable to all matrices. We find one clear concentration limit preferable compared to a large set of individual limits for different media.  25 ppb and 1000 ppb limit values are, according to the information we have, sufficiently low to prevent intentional use. Based on the information available, we conclude that a content at that low a level does not bring about the desired functions. Analytical tests may reveal lower contents in present samples, but that could be due to unintentional contamination.  Moreover, we consider that the 2 ppb limit value could have negative practical implications for enforcement while we note that the enforceability of the limit values proposed by the Dossier Submitter has not been questioned during the consultations.  As regards our reporting in the draft opinion of the outcome of the consultation of the Annex XV dossier, indeed it was badly formulated. Thank you for pointing this out. Our intention was to say that the feasibility of the limits was not contested. We will make sure that the final opinion will not state that the limits were not contested.  Transitional period:  We consider that the 18 months transition period is very short in view of initiating import activities. At the moment imports of the relevant substances or mixtures containing them do not appear to take place. Also contents in imported articles are, according to the dossier, currently low and diminishing.  We therefore see no drawback of a transition period of 18 months, but we expect it to give enforcement authorities and laboratories, in addition to industry actors, some time to develop the necessary methods and practices.  Derogation to concentrated fire-fighting foam:  From the socio-economic point of view, 0.5-3 kg of emissions in the big picture looks relatively low considering the costs associated with the replacement and demolition of the respective firefighting foam. Also considering the recent (compared to the shelf-life of these products) replacement of PFOS by the actors in the field, an obligation to replace the substiutive materials could be easily seen as disproportionate.  Exempted uses in the PFOS restriction:  The outcome of the Consultation on the Annex XV dossier implies that the availability of alternatives is becoming better and better, however, there was no indication in the submission that alternatives would be suitable for use in all the different relevant circumstances and applications at this point in time.  In our opinion, uses of PFOS have to be regulated under the PFOS restriction instead of the PFHxS restriction. PFOS is understood to be not less harmful than PFHxS, which also seems to support the thought that regulation under PFOS restriction is sufficient/ appropriate. However, in the revised opinion we underlined that the exemptions in this restriction are strictly linked to the presence (or not) of an exemption under the PFOS restriction. |