

SEMI Europe Comments on

“Amendment of Annex XVII REACH and its Appendices regarding CMRs, liquid substances or mixtures and testing methods.”

May 2020

SEMI Europe welcomes the opportunity to provide its feedback on “Amendment of Annex XVII REACH and its Appendices regarding CMRs, liquid substances or mixtures and testing methods.”

An action is proposed in the EU to, among other things, remove the PFOA restriction (Entry 68) from REACH Annex XVII. The draft regulation titled “COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants”

The specific impact to Entry 68 is given in the Annex to the amending regulation, in point (6), as “Entry 68 is deleted;”

A very small amount of justification for this action is given in the preamble to the amending regulation as follows:

(9) Deletion of entry 68 of Annex XVII to Regulation (EC) No 1907/2006 should apply from the date of application of the relevant provision of Commission Delegated Regulation (EU) .../... [10] , including perfluorooctanoic acid and its salts in Annex I to Regulation (EU) 2019/1021.

...

[10] Commission Delegated Regulation (EU) .../... of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (OJ L ..., ..., p...).

Which clearly anticipates an amendment to the EU POPs Regulation to add a PFOA restriction.

We have our understanding of the PFOA restriction proposed for EU POPs Regulation from the Commission document C(2020)1973/F1 Annex.

We have analyzed the new restriction proposed to be added to POPs against the restriction proposed for deletion from REACH, and we note that the derogation for “equipment used to manufacture semi-conductors” [sic] which was set to expire 4 July 2022 (Ref REACH Entry 68, Restriction point 3(a)(i)), has not been carried forward into the EU POPs PFOA restriction exemptions.

Our main concern with this difference centers on a scenario where fluoropolymer and fluoroelastomer (together ‘fluoromaterials’) articles might be in components purchased for assembly into semiconductor manufacturing and similar equipment. Our understanding is that it is possible fluoromaterial articles can

contain PFOA above 25ppb, but, if so, the PFOA is an unneeded, unrequested, and unintended residue. Under the Stockholm Convention this scenario requires no specific exemption because the PFOA would be exempted from Annex A by Note (i) "Except as otherwise specified in this Convention, quantities of a chemical occurring as unintentional trace contaminants in products and articles shall not be considered to be listed in this Annex".

However, EU POPs brings specific definitions to what a UTC is, and with differing threshold values, depending on the restricted substance. The draft EU POPs amendment sets a UTC value for PFOA at 25 parts per billion. Thus, a threshold is set that is equivalent to the REACH restriction, but the REACH exemption is not provided.

Therefore, we request that the REACH PFOA restriction not be removed unless an equivalent exemption with at least the same time frame is provided in the POPs PFOA restriction.

While requesting at least the same time frame, we think an unlimited exemption would provide for a more proportional and practicable regulation based on the following points of rationale:

1. While our industry is high tech, annual equipment sales are quite low, and about 50% of the components in the manufacturing equipment we build are off the shelf parts and assemblies bought in low annual quantities. We do not have a strong economic influence on the related distributors and suppliers. This is in stark contrast to high tech companies which manufacture consumer products.
2. A single product in our industry can have thousands to tens of thousands of off-the-shelf components (designed by other companies), and with consideration of 'once an article, always an article', there can be millions of articles.
3. Fluoromaterials are ubiquitous in electro-technical components because of their chemical resistance, low friction, heat resistance, etc.
4. The decision to add PFOA as a fluoromaterial production aid, or not, is made by fluoromaterial manufacturers far upstream in our supply chain and outside of our practical economic influence.
5. Some assurances have been made by some fluoromaterial manufacturers in the world, for example under the EPA Stewardship program, but the assurances, different for each company, had limits and did not always cover their full product lines, and it seems that at best, the assurance of 'made without PFOA' is given, which is not the same thing as assuring conformance to a 25ppb threshold.
6. There are fluoromaterial suppliers that could have input to our supply chain that were not part of the EPA Stewardship agreement, such as many operating in China.
7. Generally speaking, any fluoromaterial (and thereby fluoromaterial article) made prior to approximately 2015 probably has high amounts of PFOA residue from the production process. There could be assemblies and parts from this era still in warehouses globally that could enter our supply chain.
8. There is little knowledge in the supply chain of whether PFOA could be present in a fluoromaterial beyond the point of fluoromaterial manufacturing, mainly because there are no regulations in

place that would require the residue to be mentioned, for example, in SDSs or other transactional documents.

9. There is no nationally, much less internationally, recognized test method for determining if PFOA might be present on the order of 25ppb in a solid fluoromaterial matrix. The Commission has received some input from a test company claiming they could do an effective test for ~400 Euro, but this was not relevant to a solid fluoromaterial matrix. The best efforts we have been able to identify are labs which use a modified EPA 537 or a modified CEN/TS 15968. These effort are not sufficient for reliable reporting.
10. Re-using used electro-technical (e.g., EEE) products is an important aspect of a circular economy, and any such product is likely to contain some sort of fluoromaterial article, and yet there is no practical way to investigate such articles because information is unavailable (due to records never being collected under an earlier version of regulations, companies out of business, parts without source markings etc....) and there is no possibility to test components and have a product that could then be sold on at a profit (the test methods are either destructive or too costly to implement, or inaccurate). Therefore used EEE sales in the EU cannot be supported because compliance cannot be demonstrated. This somewhat disrupts the goal of a circular economy.
11. There are no robust studies which demonstrate PFOA residues that might be contained (trapped) in a fluoromaterial matrix are free to migrate into the natural environment. Additionally it is expected that electro-technical (e.g., EEE) waste parts from industry will be captured in an appropriate waste stream that can identify fluoromaterials and recycle them safely.
12. As the PFOA restriction in the Stockholm is implemented globally with regards to fluoromaterial manufacturing, this will have the most effective impact at any possible source of PFOA in our supply chain and thereby our equipment (and other industrial equipment).

In light of these points we think an article restriction at 25 ppb is disproportionate to both to the potential risks and the practical ability of investigating related supply chains for manufacturers of highly complex industrial equipment.

We recommend the deletion of the text in [brackets] in the following proposed EU POPs PFOA restriction exemption point 4, if/when the REACH PFOA restriction is removed:

Specific exemption on intermediate use or other specification
... 4. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0,0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micropowders produced by ionising irradiation of up to 400 kilograys or by thermal degradation as well as in mixtures and articles for industrial and professional uses [containing PTFE micropowders] . All emissions of PFOA during the manufacture and use of PTFE micropowders shall be avoided and, if not possible, reduced as far as possible. This exemption shall be reviewed and assessed by the Commission no later than [... <i>Publications Office: please insert date that is 2 years after entry into force of this amending Regulation</i>]. ...



Further rationale: Our understanding is that PFOA might be residual in a variety of fluoromaterials, not just PTFE, and when considering a fluoromaterial article at the time a component is selected for integration into industrial machinery it will be impractical to determine if it was originally made from a fine powder or some other grade of material.

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