Comments on the PFAS Restriction Proposal

Japan Chemical Industry Association (JCIA) appreciates the opportunity to provide the following comments in response to the proposal of this PFAS restriction. JCIA supports the EU's efforts to protect human health and environment. However, this proposal seems to have some defect, and not to take into account the impact on the wide range of industries appropriately. On the view of non-EU businesses, we provide comments as below with respect to this proposal.

1. Usefulness of PFAS and its Impact on Green Deals

As Cefic has already stated[1], the proposal would affect the value chain of products such as batteries, semi-conductors, electric vehicles and renewable energy production, and there are concerns that it would hinder the Green Deal's vision to achieve climate neutrality. Therefore, PFAS should be appropriately restricted depending on their application.

2. "Universal PFAS" restriction

The proposal considers all PFASs as one group and restricts them uniformly, which we believe is not appropriate in the view of risk assessment. This is as if to regulate all compounds with benzene rings as being as toxic as benzene. If the regulation is to be by restriction, the risk should be evaluated for each category of hazard. Substances with obvious toxicity, such as PFOA or PFOS, should be strictly regulated, which have been discussed also in Japan. However, not all PFASs with diverse structures should be regulated at the same level as PFOA and PFOS.

Some developmental toxicity studies and expert reviews suggest that a stepwise approach is needed to determine from multiple evidences, rather than one group of "all

[1] https://cefic.org/media-corner/newsroom/cefic-statement-on-the-pfas-restriction/

PFAS"[2,3]. The RMOA for PFAS in the UK[4] also suggests that from a regulatory perspective, and it may be more appropriate to consider regulatory approaches on the basis of particular PFAS groups and/or uses. Although it is not possible to identify appropriate subgroups for PFAS assessment at this stage, at least "Universal" cannot be assessed or managed, so group assessments that will allow for appropriate assessment and management should be discussed as soon as possible, and PFAS should be regulated after the agreement.

3. “Unacceptable risk" and the regulation by restriction

According to REACH Annex XV Part II-3, the risk addressed by the restriction must be in the form of a Chemical Safety Report based on the relevant hazard and risk assessment set out in Annex I. In REACH, persistence is subject to risk assessment only when combined with bioaccumulation and in some cases with toxicity. However, this restriction proposal is based on persistence alone, which is not considered a hazard endpoint, as if all PFASs are hazardous. In addition, while exposure assessments should be made for each use by creating exposure scenarios, all PFASs are grouped together, so the assessment for each use is insufficient and does not indicate the existence of unacceptable risks as required by Article 68. Therefore, we believe that this proposal does not meet the requirements for a restriction proposal as required by REACH, and it is not appropriate to discuss a restriction.

In addition to the exclusion of fully degradable PFAS, we think risk of PFAS with potential to degrade (soil remediation potential) would not be “unacceptable risk” and can be properly assessed in combination with the highest level of hazard. Also, should industrial uses that are recoverable and do not pose environmental leakage concerns be exempted, as is the case with microplastics, which are exempted from the restriction because of the possibility of controlled emissions within industrial sites[5]? We expect

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[2] Shaza Gaballah, Adam Swank, Jon R.Sobus, Xia MengHowey, Judith Schmid, Tara Catron, James McCord,Erin Hines, Mark Strynar, and TamaraTal(2020). Evaluation of Developmental Toxicity, Developmental Neurotoxicity, and Tissue Dose in Zebrafish Exposed to GenX and Other PFAS, Environmental Health Perspectives, 128(4) 047005

[3] J.K. Anderson, R.W. Brecher, I.T. Cousins, J. DeWitt, H. Fiedler, K. Kannan ,C.R. Kirman, J. Lipscomb, B. Priestly, R. Schoeny, J. Seed, M. Verner, S.M. Hays (2022): Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts, Regulatory Toxicology and Pharmacology 134 (2022) 105226

[4] UK HSE(2023): Analysis of the most appropriate regulatory management options (RMOA): Poly- and perfluoroalkyl substances (PFAS)

[5] 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

that these specific conditions will be explained in comments from JCIA member companies.

4. Derogation period

PFASs perform important functions in a variety of applications, and it is difficult to switch to alternatives listed in the proposal and develop alternatives within the derogation period, and specific development periods cannot be verified at this time. We request the addition of "a review clause" that would allow reconsideration at the end of the grace period if there is evidence that there is no suitable alternative and that development and verification is difficult within the proposed derogation period. For example, there are already regulated such as the review clause for extension requests for exemptions in RoHS Directive Article 5(3)[6]. In addition, since the restriction covers a very wide range of PFAS, even if alternative products can be used, it is highly unlikely that all transitions will be completed within the same transition period (18 months) as the existing restriction proposal, and should be extended to a realistic period. For example, the microplastics restriction has 4 to 8-year transition period for certain uses in addition to exemptions, and the CLP delegated law amendment has a 42-month transition period for reclassification and labeling of substances already on the market. Replacing a substance in a product takes more time than re-labeling, and an 18-month transition period is unrealistic.

5. Impact on the chemical industry

According to Annex A of the proposal, this proposal states that "chemical industry" has not been fully considered, and if sufficient information is not provided at this consultation, it may be restricted without a derogation period. The characteristics of PFAS are essential for equipment and fixtures that support the chemical manufacturing process, and there is no doubt that the impact is significant. However, because they are essential, there are areas where alternative substances have not been studied and impact assessments have not been sufficiently conducted. Under such circumstances, if restrictions are imposed without a derogation period despite insufficient evaluation, the chemical industry itself may come to a halt. Therefore, there should be a derogation period, similar to that indicated for other manufacturing

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Chemicals (REACH) as regards synthetic polymer microparticles
https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/7/consult?lang=en

[6] DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011
on the restriction of the use of certain hazardous substances in electrical and electronic equipment

and energy industries in paragraphs 5 and 6. In order not to disrupt the supply of chemicals necessary for society, even if some restrictions are placed on PFASs, their use in manufacturing facilities with strictly controlled emission should not be prohibited.

If the current proposal is adopted as is, there is a concern that the wide range of PFASs to be restricted will result in significant time and financial costs for analysis to prove non-inclusion in products, and that the economic activities of the industry as a whole will stagnate. Although PFASs are listed in the GADSL, which is a list of substances regulated by the automobile industry to which the chemical industry makes a significant contribution, declarations on "Other PFAS Substances" (other than substances individually regulated by POPs, etc.) are limited to "Intentionally added including degradation byproducts"[7]. Therefore, in many cases, it is possible to confirm that substances are not intentionally added or not contained as degradation byproducts through raw material surveys, so the actual cases where product analysis is required are limited. On the other hand, in this restriction proposal, since it is not limited to "Intentionally added" and furthermore the threshold is as low as 25 ppb, an order of magnitude lower, it is assumed that the assurance at the entrance (raw material survey) is limited and the proof of non-inclusion at the exit (final product analysis) is required. Besides, since the scope of coverage is very wide, we believe that the difficulty in complying with this proposed restriction is not comparable to that of GADSL.

Regarding the monetary cost, we estimate that if we were to subcontract the analysis of 10 samples for 100 PFAS substances, the cost would be approximately 10 million yen/test. Considering new products and customer requirements, as well as repeated measurements at a certain frequency, we believe the financial/time cost would be enormous.

6. Harmonizing with the Green Deal

If all PFAS-containing products were to be banned from the market after 18 months of the restriction enter into force, there is concern that a large amount of PFAS-containing waste would be generated from what used to be sales stock in all industries. Is there any effective plan for the disposal of these stocks? It has been over 50 years since the production and import of PCBs was banned in Japan, and even now a dedicated system is in place for the disposal of PCB waste[8]. On the other hand, it

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[7] https://www.gadsl.org/

[8] https://www.jesconet.co.jp/eg/index.html

requires new resources and manufacturing capacity to produce alternative components. In the EU, which is trying to increase resource efficiency under the Green Deal policy, it is unlikely that restricting all PFAS-containing products would be consistent with the policy. At the very least, the restriction should be limited to highly hazardous PFASs and products with high exposure is expected.

Furthermore, if all the piled-up sales stock were to be disposed of, it would be inconsistent with the aim of the eco-design regulation, and the economic burden on many industries would be extremely large and have a significant impact on society.

7．Analysis and thresholds

The concentration thresholds prohibiting the placing on the market are set at extremely low, but specific analytical methods are not specified. A very wide range of PFASs is subject to restriction, and if no analytical method is specified, PFAS manufacturers and users will not be able to determine if the concentration threshold is exceeded, which may cause a great deal of confusion. The subject of analysis should be clarified and internationally recognized analysis methods should be specifically specified. Analytical methods are also necessary for conducting enforcement.

The thresholds for PFOA and PFOS are based on hazard, but this “all PFAS” restriction set at a threshold of 25 ppb without any evidence, which is inconsistent with other limits (e.g. 0.1% for SVHC articles). It should be reviewed.

In light of the above, our request for the proposed restriction are as follows

1）Limit to only hazardous PFAS subgroups and high-risk uses, rather than restricting all PFASs as a single group

2）Since it is unclear whether the study of switching to non-PFAS alternatives will be completed within the derogation period, a review clause to reconsider before the end of the derogation period will be established.

3）Provide the threshold consistent with those of highly hazardous PFOA and PFOS already regulated, and analytical methods to control within the thresholds

We support the idea that the EU should ensure human health and the environment in the EU region through its Green Deal policy, and strongly request that appropriate chemical regulations be implemented to this end.