2nd submission - Comment on Proposed Restriction of PFAS

Conference of Fluoro-Chemical Product Japan (FCJ)

On behalf of chemical manufacturers, we, Conference of Fluoro-Chemical Product Japan (FCJ), have been working tirelessly to comply with national chemical regulations. We have supported EU's ambitious attempts to reduce risks from hazardous substances and have sincerely responded to actual measures to meet the requirements of EU chemical regulations such as REACH. However, we believe that the proposed restriction of PFAS (Per- and Polyfluoroalkyl substances) proposed by 5 European countries is an excessive measure because it restricts more than 10,000 of organofluorine compounds (PFAS) on the grouping basis that they are persistent as substances of concern equivalent to the already regulated PFOS and PFOA.

In addition to our opinion submitted on 18 May, reference # 4149, we would like to submit our opinion on the following matters:

【Positioning of intermediates】

Intermediates (transported isolated intermediates) are used in strictly controlled conditions under the current REACH to convert to target compounds. As the above proposed restriction is unclear as to the positioning of intermediates, we hereby offer our opinions in this proposal.

1. The importance of intermediates

Restriction does not apply for some uses under the proposed EU PFAS restriction, and 5 and 12 year grace periods for the application of restriction are being proposed for uses that are both socio-economically important and difficult to substitute. That said, the proposed restriction does not address the handling of intermediates required to produce PFAS substances for these uses.

In order to use PFAS substances for exempted or deferred applications and apply them to their social functions, it is essential to use the intermediates in manufacturing, even if they fall under PFAS by definition. In addition, maintaining the production of PFAS and the using of intermediates in Europe will not only facilitate securing a stable supply of exempted or deferred substances in Europe, but also lead to the development of related industries and maintain employment. We would like to emphasize these points and argue for the proper positioning of intermediates in the proposed restriction.

2. Handling of intermediates in REACH

Under the REACH regulation, intermediates are defined as substances that are manufactured and used for chemical processing in order to be transformed into another substance, and are classified as either non-isolated intermediates, on-site isolated

intermediates, or transported isolated intermediates. Among these, non-isolated intermediates are not applied to REACH (Article 2 of REACH). The registration requirements for on-site isolated intermediates and transported isolated intermediates are described in Articles 17 and 18 of REACH, respectively, and reduced registration is in operation when they are used under strictly controlled conditions.

As can be seen from the above registration measures, intermediates are expected to be handled by appropriately skilled workers at controlled manufacturing sites and are substances for which environmental emissions and exposure risks can be controlled.

With regard to PFAS restriction, Article 68 of REACH states that on-site isolated intermediates are not subject to the adoption of new restrictions on manufacture, use, or placing on the market, or to the revision of existing restrictions in Annex XVII. On the other hand, transported isolated intermediates are not exempt from the adoption of new restrictions, and their positioning in the proposed restriction is unclear. Article 18(4) of REACH provides specific strict conditions for the use of transported isolated intermediates, and on that basis, the previous restriction proposals for PFOA[1)] and PFHxA[2)] were both considered to exempt transported isolated intermediates from the restrictions.

A similar approach should be considered with the proposed PFAS restriction.

3. Suggestions for countermeasures

Based on the socio-economic importance of the intermediates as described above and the perspective of the risk of environmental impact, we propose the following regarding the positioning of transported isolated intermediates in the proposed EU PFAS restriction:

Transported isolated intermediates used in the manufacture of substances involved in exempted or deferred applications under the proposed PFAS restriction should be subject to the same restriction treatment (exemption or deferral of restriction) as the substances involved in exempted or deferred applications if subject to the control of Article 18(4).

4. Active substances in plant protection, biocidal products, and human and veterinary medicinal products

From the Q&A responses[3)] to the webinar held on April 5, 2023, we recognized the intention of the authorities in the five countries that "the proposed derogation also cover all preceding steps that are necessary to produce the product" with respect to these active substances.

We recognize and endorse that this would exempt intermediates, as well as raw materials, solvents, catalysts, etc. used in their production, with respect to the aforementioned active substances.

【Concentration Limits under Paragraph (2) of the Proposed Restriction】

In the proposed Restriction, 25 ppb for 1 PFAS, 250 ppb in total, and 50 ppm for polymeric PFAS are proposed as concentration limits for all PFAS except for polymeric PFASs.

However, the underlying risk is not clearly stated for each limit proposed. In the proposed Restriction, the only common rationale for restriction of all PFASs is persistency. Therefore, we believe concentration limits commensurate with the risk should be established.

As an example, PFOA is a compound regulated by EU-POPs due to bioaccumulation and toxicological effects in addition to persistence. While the concentration limit for PFOA and its salts is 25 ppb, the limit for PFOA-related substances, defined as those that can convert to PFOA, is 1,000 ppb.

Furthermore, for SVHCs such as PBT and vPvB that fall under the provisions of Article 57 REACH, the concentration limit as a criterion for providing data is set at 0.1%.

For pharmaceutical products, the IMPURITIES IN NEW DRUG SUBSTANCES Q3A (R2) [4], which was established based on the agreement at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in the US, EU, and Japan, set the reporting threshold for impurities at 0.05% (when the maximum dose is 2g/day or less) or 0.03% (when the maximum dose is over 2g/day). For highly toxic impurities, a lower concentration limit may be set as appropriate.

Thus, other regulations appropriately set concentration limits according to risk level. Therefore, in this proposed Restriction, PFASs with only persistence risk and PFASs with bioaccumulation and toxicological risks in addition to persistence risk should be considered separately, and appropriate thresholds should be set according to the risk level.

【Review of Period and Exemptions】

The proposed Restriction proposes grace periods of 5 or 12 years besides the 18-month transition period. The rationale is limited to an assumed assessment of the availability of alternatives in the future EiF (at the time of publication in the Official Gazette) based on some information provided in the CfE as of 2021, with no mention of a review provision in case such alternatives prove to be impractical. In the consultations that began on March 22, ECHA requested that information on the Evidence base be provided. After careful investigation of these submitted opinions and information on the availability of alternatives, an appropriate conversion time should be reestablished, taking into account the time required for demonstrations and evaluations. In addition, research and development will need to be conducted in the future for applications where no alternative has been identified. A framework should be considered to allow for a postponement of the transition period if several essential functions/roles cannot be achieved within 12 years.

We also believe a process should be established to consider new exemptions for technologies and applications that are currently unknown and for which PFAS is recognized as essential for social implementation. Without careful and periodic review provisions, trade restrictions and other restrictions on PFASs used in a wide variety of fields and applications will not only cause market disruption, but will also deny the use of technologies that will contribute to the attainment of a European Green Deal in the future.

Reference:
1) Report on the request to review a derogation request (entry 68 of Annex XVII to REACH) https://echa.europa.eu/documents/10162/7268a482-33bb-3686-7fdc-4a32f560394e#https://echa.europa.eu/documents/10162/dd905dfc-fb1e-42b1-f1a5-a705bb487d44
2) ANNEX XV RESTRICTIONREPORT https://echa.europa.eu/documents/10162/7268a482-33bb-3686-7fdc-4a32f560394e#https://echa.europa.eu/documents/10162/dd905dfc-fb1e-42b1-f1a5-a705bb487d44
3) Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH, Questions and answers https://echa.europa.eu/-/restriction-of-per-and-polyfluoroalkyl-substances-pfass-under-reach#:%7E:text=Download%20Q%26A%20%28part%20II%20%2D%20content%20of%20the%20proposed%20restriction%29
4) ICH Q3A (R2) Impurities in new drug substances https://www.ema.europa.eu/en/ich-q3a-r2-impurities-new-drug-substances-scientific-guideline