

KNCPC comments on the Annex XV restriction report on PFAS

September 25, 2023

1. Introduction

Korea National Cleaner Production Center (KNCPC) has been established in January 1999 by the Ministry of Trade, Industry and Energy (MOTIE), which is a ministry in charge of commerce, investment, industry and energy of the South Korean government. KNCPC focuses on finding solutions those help SMEs (Small and Medium-sized Enterprises) build their own strategies to solve the environmental issues they face. KNCPC provides various services to support small and medium-sized enterprises with three main functions: dissemination of cleaner production, improvement of resource efficiency and compliance with international environmental regulations. Recently, KNCPC has been researching on low-carbon technologies and circular economy to achieve carbon neutrality in South Korea by 2050.

As KNCPC was appointed as the REACH Business Support Center in December 2006 and the business service center for global environmental regulations from May 2009, KNCPC has been continuously monitoring EU REACH Regulation for supporting Korean SMEs exporting EU. Through the monitoring, KNCPC believes that EU REACH Regulation has greatly contributed to the investigation and spread of scientific chemical characteristics in accordance with the “No data, no market” Article 5 in this regulation, and plays a leading role in the global chemical policies.

We know that the Annex XV restriction report on PFAS published by ECHA in February 2023 is a part of the implementation of the Chemicals Strategy for Sustainability towards a toxic-free environment as mentioned in the European Green Deal. However, we would like to point out the mistakes that the restriction report on PFAS has failed to provide scientific evidence on the risk posed by PFAS mentioned at the European Green Deal, and the essential information in the REACH Regulation is missing.

2. Concerns about applying the generic approach to risk management on PFAS

The Chemicals Strategy for Sustainability (CSS) will gradually extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, or gene mutations, affect the reproductive endocrine system, or are persistent and bio-accumulative¹⁾. The Annex XV restriction report on PFAS seems to have applied the “P-sufficient” Approach²⁾ to managing all PFAS as a single group considered highly persistent in environmental media. Although the “P-sufficient” Approach of regulating highly persistent chemicals and micro-plastics is being explored within the EU, it seems insufficient to restrict all PFAS as follow reasons;

1) Grouping PFAS still under discussion with various methodologies

As reports of environmental and human impacts of PFASs have greatly increased, various researches related to grouping PFASs are also in progress. While the top-down type of grouping methodology may have advantages in terms of precaution, but the bottom-up type of grouping methodology is also being studied in terms of industry-side advantage. Bucks’s study³⁾ uses bottom-up approach to identify the 4,730 PFAS substances listed in a 2018 OECD/UNEP Report and suggests that grouping and categorizing PFAS using fundamental classification criteria based on composition and structure can be used to identify appropriate groups of PFAS substances for risk assessment.

Although the bottom-up grouping methodology should have been also considered in this restriction report on PFAS, it has limitations in the scope of the study that considered only top-down grouping methodology. The restriction report does not clarify its explanation, although it is necessary to select a methodology that is still being studied or discussed in the academic fields and explain sufficiently the validity of not considering other methodologies. Since there is not enough review process for multiple methodologies in the restriction report, the risk of errors based on uncertain theory may increased. We hope that the ECHA committees will

1) Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, 2020.10.14., European Commission

2) Ian T. Cousins *et al.*, *Environ. Sci: Processes impacts*, 2019, Vol. 21, pp.781-792

3) Robert. C. Buck *et al.*, *Integrated Environmental Assessment and Management*, Vol. 17, No. 5, pp. 1045-1055

carefully review the uncertainty, we submit the paper by Buck *et al.* as Attachment-1.

2) Insufficient data for most PFAS to facilitate chemical assessments

Cousins *et al.*⁴⁾ suggested that the most precautionary grouping approach is the “P-sufficient” approach phasing out PFAS based on their high persistence alone. The precautionary actions can be taken only when it is adequately, if not fully, supported by scientific evidence⁵⁾.

As many studies, as shown in the box below, refer that few scientific basis is currently available for conducting quantitative risk assessment, it is hard to accept that adequate scientific evidence has been presented on the restriction report on PFAS. Especially multiple studies maintains that fluoropolymers have unique properties and should not be grouped with other PFASs for hazard assessment or regulatory purposes. We submit the paper by Henry *et al.* as Attachment-2 for the evidence.

- Sufficient information to conduct quantitative risk assessment is currently available for only a relative few PFAS. A well-founded, scientific basis on which to evaluate their combined toxic potential does not yet exist (by Suzanne E. Fenton *et al.*⁶⁾)
- fluoropolymers are a distinct and different group of PFAS and should not be grouped with other PFAS for hazard assessment or regulatory purposes. (by Stephen H. Korzeniowski *et al.*⁷⁾)
- Fluoropolymers, high molecular weight polymers, have unique properties that constitute a distinct class within the PFAS group. This review concludes that fluoropolymers are distinctly different from other polymeric and nonpolymeric PFAS and should be separated from them for hazard assessment or regulatory purposes. (by Barbara J Henry *et al.*⁸⁾)

4) Ian T. Cousins *et al.*, *Environ. Sci: Processes impacts*, 2020, Vol. 22, pp.1444-1460

5) Viktoria Obolevich, *European Journal of Risk Regulation*, 2023, pp.1-7

6) Suzanne E. Fenton *et al.*, *Environmental Toxicology and Chemistry*, 2021, Vol. 40, No. 3, pp. 606-630

7) Stephen H. Korzeniowski *et al.*, *Integrated Environmental Assessment and Management*, 2022, Vol. 19, No. 2, pp. 326-354

8) Barbara J Henry *et al.*, *Integrated Environmental Assessment and Management*, 2018, Vol. 14, No. 3,

3. Review derogation period based on Annex XV of REACH Regulations

According to Annex XV in REACH Regulations, the proposal shall include the information on alternatives as follows:

- information on the risks to human health and the environment related to the manufacture or use of the alternatives,
- availability, including the time scale,
- technical and economical feasibility.

However, it should be totally reviewed derogation period because some or all of the essential information has not been provided in the restriction report on PFAS.

1) Feasibility of alternatives those do not consider the risks to human health and environment

The information on alternatives in the restriction report is presented only with information on environmental impacts, and information on human health and environmental hazards required by Annex XV in the REACH Regulation is missing.

Insufficient risk assessment of human health and environment may result in a more harmful working environment for workers or users than PFAS due to spills of harmful chemicals, fuels and so on han handling and using PFAS. Moreover, PFAS alternatives may increase environmental load due to increased waste volume with shorter replacement cycles or reduced product life compared to using PFAS.

Since the applicability of the alternatives has been estimated without sufficient risk assessment of the alternatives to human health and environment, the derogation periods in the restriction report might be difficult to trust.

2) Feasibility of alternative availability that does not include time scales

Table E.113 in Annex E of the restriction report shows Alternatives for PFAS substances used in transportation products and articles. Although the application of PFAS in transportation products has presented only 6 sub-groups, it is estimated that more than hundreds of parts are used with PFAS substances in the actual automotive industry. The industry also realizes the limitations of substitute materials

and expects that it will take more than 10 years to develop most substitutes. (For example, an alternative like nitrile rubber has approximately only 10% of the lifetime of PFAS in Table E.114 in Annex E.) However, the transportation sector with the derogation period allowed is very limited in Table E.116 in Annex E.

These discrepancies seem to be due to a lack of time scale analysis on the availability of alternatives required by REACH Regulation Annex XV. When the regulation of PFAS apply precautionary actions methodology, it is necessary to investigate and analyze the availability of alternative on a time scale more precisely.

4. Conclusions

The restriction proposal on PFAS as a single group may be a good theoretical study on the regulatory efforts to implement far-reaching and ambitious targets amid a high level of scientific uncertainty. However, we think there are a lot of vacancies in scientific evidence to apply regulations to all PFAS as a single group.

The Chemicals Strategy for Sustainability has been announced as a plan for the detailed implementation of the European Green Deal, and requires mutually consistent and complementary progress with other initiatives such as carbon neutrality or circular economies. However, there is much concern in the industry that restricting all PFAS as a single group will rather disturb the green and digital transitions.

Finally, we trust that the EU's experience in establishing chemical policies based on scientific data, and we hope that ECHA Committees will produce a credible conclusion reflecting the position of all stakeholders on the PFAS regulation proposal.

References

- 1) Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, 2020.10.14., European Commission
- 2) Ian T. Cousins et al., Environ. Sci: Processes impacts, 2019, Vol. 21, pp.781–792

- 3) Robert. C. Buck et al., Integrated Environmental Assessment and Management, Vol. 17, No. 5, pp. 1045–1055
- 4) Ian T. Cousins et al., Environ. Sci: Processes impacts, 2020, Vol. 22, pp.1444–1460
- 5) Viktoria Obolevich, European Journal of Risk Regulation, 2023, pp.1–7
- 6) Suzanne E. Fenton et al., Environmental Toxicology and Chemistry, 2021, Vol. 40, No. 3, pp. 606–630
- 7) Stephen H. Korzeniowski et al., Integrated Environmental Assessment and Management, 2022, Vol. 19, No. 2, pp. 326–354
- 8) Barbara J Henry et al., Integrated Environmental Assessment and Management, 2018, Vol. 14, No. 3, pp.316–334

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