

PER- AND POLYFLUOROALKYL SUBSTANCES ("PFASs")

Annex XV Restriction Report Proposal for a restriction for PFAS ("EU REACH proposal") versus UK HSE Analysis of the most appropriate regulatory management options for PFAS ("UK RMOA")

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Comparison

I INTRODUCTION

The "Annex XV Restriction Report Proposal for a restriction for PFAS" and its Annexes (the "EU REACH proposal") aimed at restricting a wide range of PFAS under Regulation (EC) No 1907/2006¹ ("REACH Regulation" or "REACH"), was submitted to ECHA by the competent authorities of Germany, Sweden, the Netherlands, Denmark and Norway ("the Dossier Submitters"). The EU REACH proposal was officially published on 22nd March 2023 on ECHA's website, inviting interested parties to submit comments within six months, i.e. until 25 September 2023. This document proposes a restriction of PFAS under EU REACH and will be later evaluated by ECHA and the Commission. For the time being, the Commission Regulation amending Annex XVII to REACH inserting a new restriction entry for PFAS is expected to enter into force around 2026.

The "UK HSE Analysis of the most appropriate regulatory management options for PFAS" ("UK RMOA") was drafted by the Health and Safety Executive ("HSE"), acting in its role as the Agency for UK REACH in close cooperation with the UK Environment Agency, and published in April 2023. This document examines the nature of the risks posed by PFAS and the most appropriate options for management of these risks. This document will be used by HSE to take further regulatory action within the context of the 2023-2024 UK Reach work programme, which should be published around June 2023.

We have reviewed and compared some of the **key aspects** of the two regulatory proposed measures as follows.

I DEFINITION

In the **EU REACH** proposal, the Dossier Submitters do not specify the IUPAC name, nor EC number nor CAS number of PFAS substances. Instead, they use the following definition "any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it)",² based on the 2021 OECD definition, with only an exception for fully degradable PFASs subgroups that only contain some specific structural elements.³ In their view, this definition should cover more than 10,000 PFAS substances.⁴ By relying on the 2021 OECD definition of PFAS,⁵ they do not however consider that this does not represent a legally binding accepted legal definition and that the 2021 OECD report,⁶ from where the definition was taken, was only conceived as a working paper.⁷

In contrast, the **UK RMOA** recognizes that "there is no single globally adopted definition of per- and polyfluoroalkyl substances (PFAS) for human health or environmental regulation"⁸. As such, the UK RMOA adopts a "working definition"⁹ which appears narrower as, compared to the OECD definition used under the EU REACH proposal, removes the criterion that a single isolated methylene group (-CF₂-) is sufficient for classification as a PFAS.¹⁰ Consequently, many fluorinated chemicals in potential use are not considered PFAS in the UK assessment. Hence, there are fewer fluorinated chemicals represented and considered for risk assessment and potential risk management measures compared to the EU REACH proposal.¹¹

¹ Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1.

² EU REACH proposal, p. 4 Column 1.

³ Ibid. "A substance that only contains the following structural elements is excluded from the scope of the restriction: CF₃-X or X-CF₂-X, where X = -OR or -NRR and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(=O)-), -OR-, -SR- or -NRR-, and where R/R'/R'' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(=O)-)".

⁴ Ibid., p. 21, p. 181.

⁵ Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it) (OECD, 2021

Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances Recommendations and Practical Guidance. OECD Series on Risk Management, No. 61. OECD Publishing, Paris. <https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO/2021/25&docLanguage=En>.

⁶ Ibid.

⁷ Ibid., p. 7.8.

⁸ UK RMOA, p. 12.

⁹ Ibid., p. 12, 13.

¹⁰ Ibid.

¹¹ Ibid., p. 21.

I GROUPING

In the **EU REACH** proposal, the Dossier Submitters decided to cover more than 10,000 PFAS substances by grouping PFAS substances on grounds of their structural similarities (primarily related to the alleged "very persistent" property of the substances).¹² According to the Dossier Submitters, this approach would allow to avoid the regrettable substitution and prevention of future exposure of those PFAS, which are not currently in use.¹³ With this approach, the Dossier Submitters however failed to conduct a proper case-by-case assessment as required under REACH¹⁴ and failed to explain the combination of persistency with other concerns, which is a requirement under REACH and Regulation 1272/2008 ("CLP").¹⁵

The **UK RMOA's** grouping approach is similarly based on structural similarity, on the assumption "that structurally similar substances are likely to pose similar hazards",¹⁶ to avoid regrettable substitution and improve manageability.¹⁷ However, it recognizes several challenges and shortcomings with grouping, as "groups will usually have trends in one or more properties which influence chemical bioavailability, and it can be challenging to identify an appropriate group boundary in the absence of comprehensive data"¹⁸ and that "members of some groups may transform to arrowheads that are members of other groups".¹⁹ As such, the UK RMOA proposes to divide PFAS in two primary PFAS families, i.e. non-polymeric PFAS (perfluoroalkyl substances, polyfluoroalkyl substances, fluorotelomer based substances) and polymeric PFAS (side-chain fluorinated polymers, fluoropolymers, fluoroelestomers and perfluoropolyethers) as further specified in Tables 1.2.1 and 1.2.2 of the UK RMOA.²⁰

I HAZARD ASSESSMENT

In the **EU REACH** proposal, the Dossier Submitters use data mostly relating to a few PFAS (most notably PFOA and PFOS),²¹ unduly extending them to all other PFAS using a "specific-to-general" approach, which does not appear scientifically and legally sound.²² In addition to that, by stating that "all" PFAS are persistent, while "some" or "most of" are mobile/accumulate in biota/carcinogenic/endocrine disruptors, etc.,²³ they failed to explain which hazard properties pose specific PFAS and in turn, which properties lead to risks for specific PFAS substances and related uses.

In that respect, the **UK RMOA** recognizes that "the majority of the data for human exposure is centred on PFOS and PFOA"²⁴ and that the "limited exposure data for the majority of PFAS poses a significant challenge and a potential barrier to effective risk management".²⁵ By acknowledging that PFAS have "unique properties that make them challenging to analyze",²⁶ HSE focuses the hazard assessment on the subgroups identified to establish if conclusions could be reached on the PBT, PMT and vP/vB or vPvM status of substances in the assessed groups.²⁷

I SCOPE OF THE RESTRICTION MEASURES

In the **EU REACH** proposal, the Dossier Submitters propose to prohibit the manufacture, use and placing of the market of PFAS as substances on their own and the placing on the market in another substance, as a constituent, a mixture, or an article in a concentration of or above (i) 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) (ii) 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) (iii) 50 ppm for PFASs (polymeric PFASs included). It further specifies that if the total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.²⁸

On the contrary, the **UK RMOA**, being an earlier analysis of the possible regulatory options, consider four scenarios: (i) preparation of Annex XV dossiers to potentially support one or more restrictions of PFAS under UK REACH; (ii) UK REACH authorisation of PFAS used in processing aids in the manufacture and processing of fluorinated polymers; (iii) further evaluation and investigation of substances that have been highlighted to be of concern and (iv) continued collaborative work across government and with external stakeholders to bring together work on PFAS strategically.²⁹ Interestingly, the first option includes, *inter*

¹² EU REACH proposal, p. 20.

¹³ Annex B to the EU REACH proposal, p. 5.

¹⁴ ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), p. 32.

¹⁵ REACH, Annex XIII, CLP, Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ L 93, 31.3.2023, p. 7–39.

¹⁶ UK RMOA, p. 14.

¹⁷ Ibid, p. 21.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid, p. 16, 20.

²¹ Annex B to EU REACH proposal.

²² EU REACH proposal, p. 13, p. 33.

²³ EU REACH proposal, p. 13.

²⁴ UK RMOA, p. 86.

²⁵ Ibid, p. 90.

²⁶ Ibid.

²⁷ Ibid, p. 118.

²⁸ EU REACH proposal, p. 4 Column 1.

²⁹ UK RMOA, p. 174.

alia, a restriction on the manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water or soil, or directly transferred to humans.³⁰ Also, the fourth option considers to explore a review of the F-gas regulations to determine whether additional PFAS registered under UK REACH should be brought within scope and the development of statutory standards for PFAS in drinking water in England and Wales.³¹

DEROGATIONS / EXEMPTIONS

In the **EU REACH** proposal, the Dossier Submitters propose a single exemption for fully degradable PFAS by stating that "a substance that only contains the following structural elements is excluded from the scope of the restriction: CF₃-X or X-CF₂-X', where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-, -OR", -SR" or -NR"R"; and where R/R'/R"/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-)".³² Furthermore, they propose several derogations that fit under three macro-categories: time-unlimited³³ (for active substances in biocides, plant protection products and human and veterinary medicines), five-years long³⁴ (e.g. polymerisation aids in the production of polymeric PFASs etc) and twelve-years long³⁵ (e.g. tubes and catheters in medical devices). The three types of derogations entail conditions, such as reporting obligations to ECHA. While these are proposed derogations, the Dossier Submitters also propose "potential derogations" in square brackets, asking stakeholders to provide more information during the public consultation.

While the **UK RMOA** does not propose already a restriction, in full consistency with the criteria of the OECD for polymers of low concern,³⁶ it recognizes that fluoroplastics or fluoroelastomers represent low hazard groups. As such, it proposes to exempt them from a possible restriction,³⁷ along with "intermediates, uses in sealed/contained systems (including use as heat exchange fluids in heat pumps and refrigeration systems), (low risk uses)".³⁸

CONCLUSION

This analysis has shown several differences between the EU and the UK approaches. First, the definition under UK REACH appears narrower as, compared to the OECD definition used under the EU REACH proposal, it removes the criterion that a single isolated methylene group (-CF₂-) is sufficient for classification as a PFAS. Secondly, while both use the grouping approach, the UK one recognizes that there are indeed several challenges and shortcomings, thus it further divides PFAS into two sub-groups, i.e. non-polymeric and polymeric PFAS. Thirdly, both recognize that the majority of data comes from the two mostly-studied PFAS, i.e. PFOS and PFOA. However, while the former extend these data to other PFAS in a specific-to-generic approach, the latter focuses the hazard assessment on the subgroups identified to establish if conclusions could be reached on the PBT, PMT and vP/vB or vPvM. Fourthly, while the EU REACH proposal proposes a restriction with specific requirements, the UK RMOA analyses four possible future regulatory actions. Lastly, while the EU REACH proposal proposes only an exemption for fully degradable PFAS and three macro types of derogations, the UK RMOA analyses the possibility to exempt fluoropolymers, intermediates, uses in sealed/contained systems (including use as heat exchange fluids in heat pumps and refrigeration systems).

Overall, the UK RMOA's approach appears more pragmatic and effective than the EU REACH proposal. This would indeed attract more business to the UK, as companies will be incentivized to move their business where less restrictive measures will apply. This would have a major impact from a socio-economic point of view in the EU market.

In addition to that, if adopted as they currently stand, these disparities will likely create illegal barriers to trade in the future, in breach of the international trade rules laid down in the General Agreement on Tariffs and Trade ("GATT"),³⁹ the Agreement on Technical Barrier to Trade ("TBT")⁴⁰ and the Agreement on Sanitary and Phytosanitary Measures ("SPS").⁴¹

³⁰ Ibid.

³¹ Ibid., p. 176.

³² EU REACH proposal, p. 4 Column 1.

³³ Ibid., Conditions of restriction 4.

³⁴ Ibid., Conditions of restriction 5 and 6.

³⁵ Ibid., Conditions of restriction 5 and 6.

³⁶ Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, Buxton LW, Fiedler H, Seed J, Hernandez O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integr Environ Assess Manag* 2018 May;14(3):316-334. doi: 10.1002/ieam.4035. Korzeniowski SH, Buck RC, Newkold RM, Kassimi AE, Laganis E, Matsuoka Y, Dinelli B, Beauchet S, Adamsky F, Weilandt K, Soni VK, Kapoor D, Gunasekar P, Malvasi M, Brinati G, Musio S. A

critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. *Integr Environ Assess Manag* 2023 Mar;19(2):326-354. doi: 10.1002/ieam.4646.

³⁷ Ibid.

³⁸ Ibid.

³⁹ GATT Agreement, articles Art. I, III, XI, XX.

⁴⁰ TBT Agreement, article 2.

⁴¹ SPS Agreement, articles 2, 3 and 5.

ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION FOR PFAS ("EU REACH PROPOSAL") VERSUS UK HSE ANALYSIS OF THE MOST APPROPRIATE REGULATORY MANAGEMENT OPTIONS FOR PFAS ("UK RMOA")

Table Comparison

KEY ASPECT	EU REACH PROPOSAL	UK RMOA
DEFINITION	Do not specify IUPAC name, nor EC number nor CAS number of PFAS substances "Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF₃-X or X-CF₂-X, where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-); - Relies on OECD definition - Does not consider that the OECD paper is only "working paper", i.e. work in progress.	"Fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (-CF₂-)"; - Formulates its own "working" definition"; - Removes the criterion that a single isolated methylene group (-CF₂-) is sufficient for classification as a PFAS.
GROUPING	Use the grouping approach (persistence is key), not in line with REACH requirements Aim: avoid the regrettable substitution and prevention of future exposure of those PFAS, which are not currently in use.	- Aim: avoid regrettable substitution and improve manageability; - Further sub-divides into two macro-groups: (i) non-polymeric PFAS (perfluoroalkyl substances, polyfluoroalkyl substances, fluorotelomer based substances) and (ii) polymeric PFAS (side-chain fluorinated polymers, fluoropolymers, fluoroelastomers and perfluoropolyethers).
HAZARD ASSESSMENT	Recognize that most data concerns two well-studied PFAS, i.e. PFOS and PFOA - Unduly extends PFOA and PFOS data to other PFAS ("specific-to-general" approach); - Fail to explain which hazard properties pose specific PFAS (e.g. which are PM, PT etc); - Fail to explain which properties lead to risks for specific PFAS substances and related uses;	- Recognize that specific PFAS have specific properties; - Focuses the hazard assessment on the two identified subgroups; - Establish if conclusions could be reached on the PBT, PMT and vP/vB or vPvM status of substances in the assessed groups.

SCOPE OF THE RESTRICTION MEASURES	Proposes to prohibit the manufacture, use and placing of the market of PFAS as substances on their own and the placing on the market in another substance, as a constituent, a mixture, or an article in a concentration of or above: (i) 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) (ii) 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) (iii) 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.	Considers four possible regulatory scenarios: (i) Preparation of Annex XV dossiers to potentially support one or more restrictions of PFAS under UK REACH; ● The use and disposal of FFF where non-PFAS alternatives are available; ● Other wide dispersive uses such as the application of coatings or use of cleaning agents; ● The manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water or soil, or directly transferred to humans. This includes textiles, upholstery, leather, apparel, rugs and carpets, paints, varnishes, waxes and polishes, cleaning products. Consideration may be given to other consumer articles if other gaps are identified in consultation with other legislative regimes such as food contact materials. (ii) UK REACH authorisation of PFAS used in processing aids in the manufacture and processing of fluorinated polymers; (iii) Further evaluation and investigation of substances that have been highlighted to be of concern; (iv) Continued collaborative work across government and with external stakeholders to bring together work on PFAS strategically. ● A review of the F-gas regulations to determine whether additional PFAS registered under UK REACH should be brought within scope; ● Development of statutory standards for PFAS in drinking water in England and Wales; ● This is likely to be considered by a future drinking water advisory board on standards.
DEROGATIONS/ EXEMPTIONS	● Proposes only one exemption for fully degradable PFAS; ● Proposes three macro types of derogations: ● Time-unlimited; ● Five years long; ● Twelve years long.	Analyses the possibility to propose an exemption for fluoropolymers, intermediates, uses in sealed/contained systems (including use as heat exchange fluids in heat pumps and refrigeration systems)