ClientEarth

September 2023

Comments on the Annex XV report proposing a restriction of PFAS

ClientEarth welcomes the well-documented Annex XV report proposing a restriction of the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFASs) due to the risk they pose to the environment and human health.

With our contribution, we hope to further support the dossier submitters and members of the RAC and SEAC in their assessment of the restriction proposal by providing some **legal clarifications**. More specifically, our comments focus on:

1. The hazard and risk assessments proposed by the dossier submitters articulated around the persistency concern;
2. The broad scope of the proposed restriction;
3. The justification of the restriction as the most appropriate risk management option under REACH;
4. The proposed derogations when justified by the existence of specific legislation, including:
    - Time unlimited derogations for active substances in biocidal, plant protection and medicinal products, and
    - Time limited derogations for uses of PFAS that are not sufficiently addressed in other pieces of legislation.
5. The overall assessment of the proportionality of the restriction.

1 Persistency sufficient to meet the risk threshold of Article 68.1

The main concern underlying the restriction proposal is the very high persistence of all PFASs, and therefore the likely irreversibility of the damage to the environment and health.

Persistency is in our view sufficient to meet the 'unacceptable risk' threshold required under Article 68.1, based on the text of REACH and its interpretation by the ECHA committees and the Court of the EU:

- Annex XV, which guides the preparation of a restriction proposal including the hazard and risk assessments, links back to Annex I REACH that confirms that, in relation to "particular effects", for example when quantitative risk characterisation or PBT/vPvB assessment are not practicable, it is possible to adopt a case-by-case approach.[1]
- In precedent cases, RAC has used the case-by-case approach mentioned in Annex I and found that persistency can give rise to a level of concern sufficiently grave to justify a restriction, e.g. in its evaluation of the microplastics[2], PFHxA[3] and PFAS in fire-fighting foams restrictions.[4]
- The General Court of the EU, in the GenX case, was clear on the fact that persistence is a concern as such, irrespective of whether the substance is also bioaccumulative or toxic.[5]

Major uncertainties, e.g., related to the concern posed by polymeric PFASs, should not serve as a justification to block ambition or delay regulatory action. First, because PFAS are almost all associated with environmental or health concerns[6] - if not during the use phase, at least at one stage of their lifecycle.[7] Second, where there are uncertainties, which are inherent to any scientific assessment, they are not of such magnitude to cast doubt on the existence of a risk. The focus should be on preventing the damage witnessed across Europe, rather than repairing it later on.

[1] REACH Annex I, 0.10.
[2] RAC Opinion on intentionally added microplastics restriction proposal, p. 46.
[3] Registry of restriction intentions until outcome - ECHA (europa.eu).
[4] RAC Opinion, see notably p. 16, 9a785928-3fbd-a230-cffa-7b8590240d69 (europa.eu).
[5] Judgment of the General Court of 23 February 2022, *Chemours Netherlands BV v. ECHA*, Case T-636/19, Paragraph 96: "Fourth, the applicant's interpretation is not consistent with the aim of Regulation No 1907/2006, as laid down in Article 1(1) of that regulation, which is to ensure a high level of protection of human health and the environment. Accordingly, that interpretation is also incompatible with the objective of Article 57(f) of Regulation No 1907/2006. That provision allows account to be taken of the intrinsic property of persistence for identification as a substance of very high concern, irrespective of whether that property is combined with very specific and limited properties, namely with bioaccumulation and toxicity. Persistence combined with other intrinsic properties of the substance in question may give rise to concerns of an equivalent level to those of CMR, PBT and vPvB substances. Consequently, the interpretation advocated by the applicant would preclude the identification as substances of very high concern of substances which are just as dangerous for human health and the environment as those referred to in Article 57(a) to (e) of Regulation No 1907/2006."
[6] PFAS: forever chemicals—persistent, bioaccumulative and mobile. Reviewing the status and the need for their phase out and remediation of contaminated sites | Environmental Sciences Europe | Full Text (springeropen.com).
[7] REACH does not exclude taking into account the risk related to the substance throughout its whole life cycle. This is even encouraged by the ECHA guidance on the preparation of an Annex XV dossier for restriction, for example pp. 44 and 50.

2 The broad scope of the proposed restriction

By targeting all PFASs without listing each individual substance, the proposal defines a broad scope for the future ban. We would like to support this approach, which is legally endorsed by the REACH text and furthers its main objective.

Article 68.1 requires EU authorities to take measures "*when there is an unacceptable risk* to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis…". This provision does not suggest that the submitters of a restriction proposal should provide a substance-by-substance assessment when they have evidence that a broad group of chemicals, like PFAS, poses a grave risk. This might be the practice that has been adopted in many restriction proposals up to now, but that is neither dictated by the text nor the most recent EU commitments.[8]

Article 68.1 leaves it to authorities to assess the existence of that risk, based on a weight of evidence, and decide on the nature and scope of the measures adopted to address it.[9] In the face of uncertainties, the primary objective of the legislation, and its underpinning precautionary approach, shall guide the assessment.[10] That means any interpretation that would undermine the effectiveness of REACH should be set aside in favour of an interpretation that actively facilitates the realisation of its main aim.[11] The group approach is very effective in that regard.

Grouping was considered to be the most effective approach in the context of the proposal to restrict intentionally-added microplastics – it did not meet opposition during the restriction decision making process. More generally, grouping in the form of read across is recognized as valid in chemistry, widely used by companies in the context of registration and by authorities across processes, which was recently validated by the EU judges.[12]

3 Restriction as most appropriate measure and justified under REACH, Art. 68.1

Member States presenting a restriction proposal to ECHA must prove that the chemical "poses a risk to human health or the environment that is not adequately controlled and needs to be addressed".[13] The risk must be unacceptable[14] – a decision that involves an assessment of both scientific and social

[8] As confirmed by the Chemicals Strategy for Sustainability ambition to develop GRA and the group approach to chemical restriction.
[9] Judgment of the General Court of 14 November 2013, *International Cadmium Association (ICdA) and Others v European Commission (*T-456/11), Paragraph 45.
[10] Judgment of 7 March 2013, *Lapin*, C-358-11, Paragraph 37.
[11] See the judgments of the Court of Justice of 7 July 2009 in *S.P.C.M. and Others*, C-558/07, Paragraph 45, and *Bilbaína de Alquitranes and Others v ECHA*, T-93/10, Paragraph 116.
[12] Judgment of the General Court of 5 July 2023, *TIB Chemicals AG v European Commission*, Case T-639/20 (case related to the harmonized classification of organo-tin catalyst dioctyltin dilaurate (DOTL)).
[13] Article 69.4, REACH.
[14] Article 68.1, REACH.

factors[15] and is left to the European Commission at a later stage.[16] The aim of the RAC and SEAC opinions is to "identify (or refute) an unacceptable risk" in terms of the factual basis.[17]

There is little doubt that these prerequisites are met in the current case.

The dossier reports the use of PFASs in countless applications. This use has been associated with large emissions into the environment in the past years, most likely underestimated and with production numbers on the rise.[18] The persistency and oftentimes mobility of these chemicals lead to cross-border pollution that cannot be adequately managed nationally.[19] In various countries, concentrations of PFAS in some areas are way above the limit value for drinking water and extremely high levels have been found in human bodies, raising a number of health concerns.[20] Several affected communities across Europe have already brought legal action to prevent further damage and alerted officials to the cost of the pollution incurred.[21]

It is hence very clear from the current body of evidence that PFASs pose a substantial risk that is not merely hypothetical but scientifically recognized. This risk is not adequately controlled at the moment so that the States are right to answer the repeated calls to take action.[22] The criteria for a restriction under Article 69.4 and Article 68.1 are met.[23] It is in similar circumstances that the Court has established that a restriction on the placing on the market is **the most effective measure** for achieving the objective pursued by REACH.[24]

In the PFAS case, various arguments further support this conclusion (also considered in the dossier[25]):

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[15] The Court has consistently found that "it is for the institutions that are responsible for making political choices to determine the level of risk considered acceptable to society, that level of risk being determined not only on the basis of strictly scientific considerations but also taking account of social factors". In Judgment of 6 May 2021, Case C-499/18 P, *Bayer et al. v Commission*, Paragraph 155.

[16] Judgment of the General Court of 30 June 2021, *Global Silicones Council v Commission*, Case T-226/18: "It is apparent from those provisions that the notion of 'unacceptable risk' in Article 68(1) of Regulation No 1907/2006 is different from that of 'risk that is not adequately controlled and needs to be addressed' in Article 69 of that regulation. It is apparent more specifically from those provisions and, in particular, from the content to be covered by the opinions of the RAC, on the one hand, and of the SEAC, on the other, which guide the Commission in preparing the draft amendment to Annex XVII and in deciding whether or not a risk is unacceptable, that that risk depends on several factors. Those factors include, in particular, the risk assessment, in accordance with the relevant rules set out in Annexes XV and I, the appropriateness of a restriction in reducing the risks assessed and the socio-economic impact of such a restriction." (Paragraph 199).

[17] Avocate General Kokott, Opinion delivered on Judgment of 20 April 2023 in Case C-558/21 P, *Global Silicones Council and Others v European Commission,* Paragraph 48.

[18] Annex XV report, p. 2.

[19] Annex XV report, pp. 50 and 51.

[20] See notably the HBM4EU 2022 PFAS report: https://www.hbm4eu.eu/wp-content/uploads/2022/07/PFAS_Substance-report.pdf.

[21] See for example the recent challenge launched against Chemours in Dordrecht (Netherlands): https://cen.acs.org/environment/persistent-pollutants/Dutch-lawyers-sue-Chemours-DuPont/101/i30. A PFAS pollution case was also recently brought to the Swedish Supreme Court: Why high levels of PFAS should be a personal injury by law – ChemSec. Similar cases are pending in Belgium, France, Germany, Denmark and Italy.

[22] Zürich Statement on Future Actions on Per- and Polyfluoroalkyl Substances (PFASs) | Environmental Health Perspectives | Vol. 126, No. 8 (nih.gov).

[23] See also the clarifications provided by Advocate General Kokott on the notion of "unacceptable risk" under REACH, in the Opinion delivered on Judgment of 20 April 2023 in Case C-558/21 P*, Global Silicones Council and Others v European Commission*.

[24] Judgment of the General Court of 30 June 2021, *Global Silicones Council v European Commission*, Case T-226/18, Paragraph 170.

[25] Annex XV report, as of p. 68.

- A restriction is the quickest way to urgently address an uncontrolled source of chemical pollution and in a harmonised manner across Europe,
- All production, placing on the market and use are targeted,
- Restriction tackles the exposure to articles containing PFAS via imports,
- Restriction on the manufacture would avoid pollution resulting from exports of PFAS,
- Other possible risk management measures are either insufficiently protective (e.g. emissions control at site, CLH, SVHC identification), can only address part of the risk (e.g. authorisation, or specific EU legislation like the Water Framework Directive, the Industrial Emissions Directive, the EU Soil health law etc.) or involve further, long decision making implying significant burden on both authorities and companies (e.g. authorisation).

Opting for mere emissions control measures, such as the implementation of strictly controlled conditions for specific PFASs like fluoropolymers, is not recommended. The benefit of an EU wide restriction is first and foremost the creation of a harmonised level of protection across Europe for the regulation of a pollution that is known to be extremely hard to monitor and contain. The control of PFAS emissions at sites is already challenging for industry and might pose further enforcement issues.[26] Overall, risk control measures on their own are not satisfactory from a prevention point of view as they are unlikely to ensure a significant minimisation of the current and future risk posed by PFAS, and do not incentivise the substitution to safe chemicals – which are clear objectives pursued by the REACH Regulation.[27]

4 Proposed derogations based on the existence of adequate legislation

The restriction proposal currently provides for two types of exemptions:

- ➔ **Time unlimited derogations** (e.g. for active substances in plant protection products).
- ➔ **Time limited derogations** that will enable the continued use of PFAS for a certain period of time (e.g. when used in certain personal protective equipment), and therefore allow continued emissions of the chemicals into the environment during that period and beyond.

Time-unlimited exemptions and some of the transition periods are justified by the existence of other applicable EU legislation. The restriction is not meant to affect other prohibitions, e.g,. under the POPs Regulation, or rules that would already sufficiently reduce the risk associated with PFAS in the EU.

However, in most cases, the instruments in place do not afford the same level of environmental and health protection as an EU wide restriction. 'Double regulation' should only be considered as a valid argument to the extent that the risk associated with PFAS is addressed to a level at least similar to the one afforded by a restriction.

Our analysis of the existing legislation shows that: `

[26] https://www.oecd.org/chemicalsafety/risk-management/Risk_Reduction_Approaches%20for%20PFASS.pdf.
[27] REACH, Article 1.

1) The risk posed by PFAS used as active substances in plant protection products, biocidal products and medical products is not sufficiently addressed in the dedicated legislations.

- **The Plant Protection Products (PPP) Regulation** (No 1107/2009)

A first noticeable gap in this legislation, compared to the proposed restriction, is that it provides rules for the placing on the market, use and control of plant protection products including the active substances contained in those products, but not the manufacture.[28] Secondly, active substances may not be approved at EU level if harmful to health and/or with unacceptable effects on the environment, but a derogatory regime applies for active substances other than certain CMRs which may be harmful to health or the environment but are considered "necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods (…)".[29] Persistency is not an exclusion criterion which means very persistent substances may still be approved as candidates for substitution. Article 24 of the regulation specifies that substances meeting two of PBT criteria, e.g. many of the long-chain perfllluoroalkyl acids, may be approved for a period of 7 years - renewable.[30] Finally, the substance by substance approach under this regulation fundamentally conflicts with the environmental and health protection objective pursued by the Annex XV report under assessment.

- **The Biocidal Products (BP) Regulation** (No 528/2012)

This regulation also focuses on the placing on the market and use of biocides, not their manufacture. Similarly to the regime of the PPP regulation, active substances used in biocidal products undergo extensive risk assessment and shall not be approved if they meet certain exclusion criteria specified under Article 5 of the regulation - that includes PBT and vPvB substances but not very persistent chemicals as such. They are, like active substances in plant protection products, assessed individually instead of as a group. By way of derogation, hazardous substances including PBTs may be approved for a period of 5 years if certain conditions are met, e.g. if "not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance".[31] In addition to this derogation, some substances may be approved as candidates for substitution for a period up to 7 years. Article 55 of this regulation provides for more derogations, for example in case the "active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available" (paragraph 3).

- **Medicinal products (MP) Regulation** (Directive 2001/83; Regulation 726/2004)

Little account is made of the environmental impact of active substances used in medicinal products, whether human or veterinary, during the marketing authorisation process. The focus is mostly on the health of humans even though applicants are required to submit information concerning the environmental risk.[32] The fact that a REACH restriction might hinder the availability and security of supply of PFAS containing medicines[33] needs further explanation from the dossier submitter. From a legal point of view, there is little ground for excluding the PFAS used as active substances in these

[28] Article 1(1) Regulation 1107/2009.
[29] Article 4(7).
[30] E.g. difeconazole (approval regulation here).
[31] Article 5(2)(c).
[32] Article 8(3)(g) Directive 2001/83.
[33] Annex XV report, p. 74.

substances given that the more specific legislation for these products fails to take this type of risk into consideration and may therefore not support the objective of phasing out PFAS.

To conclude, PFAS used as active substances in biocidal, plant protection or medicinal products are released into the environment and contribute to the overall risk, and, by law, they are not excluded from the REACH restriction chapter. Moreover, it was shown above that there is a regulatory gap at the moment. The dossier submitters themselves acknowledge that "the predominant concern for the restriction, i.e., persistence, is not sufficiently taken into account during the current authorization processes following PPP, BP and MP regulations".[34] As a consequence, there is no valid – legal - reason to exclude these specific uses of PFAS from the scope of the current restriction proposal. The reporting requirements proposed for the placing on the market, applicable to manufacturers and importers of PFAS active substances in plant protection, biocidal and human and veterinary medicinal products are unlikely to address the current gaps in the legislation given the magnitude of the PFAS pollution. Finally, asking for further action from the EU Commission under the specific legal frameworks seems unreasonable given the need to act urgently, in one unique and coordinated manner. Contrary to what the dossier submitters suggest in their proposal, there is no objective reason to wait and "discuss the necessity and proportionality of further (EU) action or measures" for these sectors when the seriousness of the problem and options for remedy are already well identified.[35]

2) The lack of adequate regulatory frameworks for some of the derogated uses should be taken into account in setting the appropriate transition period.

Some applications, such as cleaning fluids for use in oxygen-enriched environments, appear not to be subject to any specific legislation regulating the composition of specific articles, meaning the presence of PFAS in those uses and possible releases may be left uncontrolled during the transition time.

Other applications, in particular personal protective equipment and food contact materials, are subject to specific legislation setting out requirements on the presence of hazardous substances; but these requirements are unlikely to be as protective as the measures provided in the PFAS restriction proposal.

National rules for industrial sites, in particular emission limits, are similarly not sufficient to address the risk at stake and should therefore be put aside in favour of a more restrictive approach. In accordance with the principle of subsidiarity, less protective national standards, for instance regarding refrigerants in HVACR equipment in buildings, should be overruled by EU action if considered more effective, given the magnitude and transnational nature of the pollution, in reaching the objective pursued by the EU community.[36]

The restriction proposal should clarify how the residual risks associated with the use of PFAS in the derogated applications are or would be sufficiently controlled by existing or upcoming legislation. Without further explanation, the risks associated with these uses remain serious and need to be addressed within the scope of the current restriction.

[34] Annex XV report, p.74.
[35] See for example: https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.4786.
[36] Article 5(3) of the Treaty on European Union (TEU).

5 The assessment of the proportionality of the restriction

In assessing how to tackle an unacceptable risk under REACH, the Commission must apply the principle of proportionality.

Article 68.1 integrates the demand for proportionate action by instructing policy makers to "take into account the *socio-economic impact* of the restriction, including the availability of alternatives". The work done by SEAC provides the main support for this proportionality exercise.

The socio-economic analysis of the restriction is key to the final decision making as it enables the policy makers to decide whether the restriction of a chemical under REACH is the right measure to manage an unacceptable risk appropriately, and if yes, under which conditions. It should be broad enough and consider all the potential disadvantages and costs but also economic gains, health and environmental benefits expected from the restriction, a broad approach visible from the reading of Annex XVI and that Advocate General Kokott confirmed as necessary under REACH.[37]

The primary aim of the REACH Regulation to achieve a high level of environmental and health protection must be particularly borne in mind in the proportionality exercise.[38] The Court has recalled on several occasions that the financial burden for companies of a restrictive measure should not alone take precedence over the broader protection of health and the environment.[39]

In the current Annex XV report, the dossier submitters provide a detailed picture of the substantial risk at stake, together with the related costs and benefits associated with a potential ban. In particular, they show that the undeniable short-term costs for the industry should be looked at in the light of the long-term costs of a continued use of PFAS, which might be even greater. By nature, PFAS will continue to accumulate and therefore have effects that are unpredictable and potentially irreversible. In similar situations, the Court of Justice has recognised that, due to the difficulty of establishing the critical threshold for a serious risk, a general prohibition on the use of a chemical can be justified.[40] It is therefore not necessary to determine precisely the threshold between acceptable and unacceptable.[41]

In such context, the standard of proof that relies on those requesting exemptions is high - any request for derogation should be either thoroughly substantiated or rejected. Given the overarching aim of the restriction proposal, derogations should be interpreted as narrowly in scope as possible and short-lived.[42] Economic actors will need to provide sufficiently strong evidence that their use of PFAS is not only critical for society, but that it is also impossible to substitute it in the current state of technical knowledge available. They should also prove that the costs for them are greater than the overall societal

[37] Opinion delivered on 25 February 2021 on Case C-458/19 P, *ClientEarth v European Commission*.
[38] "It is nevertheless clear from Articles 35 and 37 of the Charter of Fundamental Rights of the European Union, Article 114(3) TFEU and Article 1(1) and recital 1 of the REACH Regulation that the aim of a high level of protection of human health and the environment is to be pursued. This must also be borne in mind in taking the decision on restrictions." – Avocate General Kokott, Opinion delivered on 20 April 2023 in Case C-558/21 P*, Global Silicones Council and Others v European Commission*, para. 36.
[39] See for example in authorisation case, Judgment of 20 April 2023, *Commission v Parliament* (Case C-144/21), Paragraph 126.
[40] Judgment of 11 July 2000, *Toolex*, C-473/98, Paragraph 45.
[41] Advocate General Kokott, Opinion delivered on Judgment of 20 April 2023 in Case C-558/21 P, *Global Silicones Council and Others v European Commission*, paragraph 80.
[42] The Court has confirmed on multiple occasions that as exceptions to a necessary restrictive measure that aims to protect health/the environment, derogations must be given a strict interpretation. Judgment of 7 March 2013, *Lapin*, C-358-11, Paragraph 42.

benefits that a restriction would bring, including in terms of reduced costs (related to clean-up, health care etc.) and economic gains (e.g., for alternative providers).

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