Brussels, 25.09.2023

2nd EEB submission to the "universal PFAS REACH restriction" (uPFAS)

This submission is the second contribution of the European Environmental Bureau (EEB) to the public consultation on the proposal for universal PFAS restrictions. As the largest European network of environmental NGOs, EEB advocates for a future where people and nature thrive together. This vision is threatened by the past and current use of PFAS.
We appreciate the work done by the submitters on this exceptionally comprehensive dossier to address the inadequately managed risk posed by PFAS, and we support the overall conclusion that a restriction is the right measure to address this problem at the EU level.

General comments

We recognise that some individual applications are not yet at a point where PFASs are dispensable, but we would emphasise that these cases need to be very well defined and supported by evidence provided. Essential use criteria as defined by the Montreal Protocol offer here a solid guideline for predictable decisions. This implies that we disagree with derogations that do not meet these criteria and broad derogations based on unavailable information. Our comments and additional information below are therefore intended to help clarify the individual uses and alternatives and to clarify further aspects, based on comments from other contributors to this consultation.
In many restriction procedures, comments submitted into the consultation deal with the non-availability of alternatives, rather than highlighting alternatives in use or explaining their suitability. As so often, socioeconomic actors likely to financially suffer from a restriction are more vocal than those likely to benefit from it. As an example, many comments in the public consultation (mostly rightly) highlight the outstanding stability and inertia of fluoroelastomers, but somewhat superficially conclude from this to the irreplaceability of fluoroelastomers in general.
With this contribution, we aim to strengthen the knowledge base that should enable the adoption of a restriction that is as protective and holistic as possible and as flexible as necessary to reach a smooth and rapid implementation.
As an environmental NGO, we wish to share our understanding of the situation, and bring more nuance into this discussion. We bring to the attention of ECHA's scientific committees a number of practical uses of non-fluorinated elastomers as alternatives to fluoroelastomers. We would also like to point out some inconsistencies and contradictions, in order to help the scientific committees to make an informed decision on potential derogations.
In the following two sections of the general comments, we present arguments and information on the legal situation around food contact materials and the Industrial Emissions Directive to bring additional nuance to the discussions.

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Food contact approvals

Surface treatments used on paper and board have largely been covered by the restriction on PFOA (for the C8-based materials)[1] and the pending restriction on PFHxA.[2] Use of C4 substances for such purposes is not documented to the best of our knowledge, and e.g. the German BfR's lists of recommended substances[3] contains several C6 materials, but no C4 materials. However, a few potentially suitable C4 monomers are registered under REACH, e.g. methacrylate EC 266-737-7 and alcohols 252-044-7 and 252-043-1. Similarly, the German list contains perfluoropolyethers, which are not covered by earlier restrictions or restriction proposals and should be covered under the present restriction.

Plastics and rubbers, both fluorinated and fluorine-free, used for sealing, for conveyor belts etc. are covered by and mentioned in the restriction dossier (section 1.3.2.3 and A.3.4). Mentions (in this consultation and in meetings or the press) of the importance of PFAS for the food industry are rife; yet they are often unspecific, making the reader believe that PFAS generally cannot be missed and that non-fluorinated materials generally cannot be used.

We would like to confront this with some information not contained in the dossier. The dossier only mentions the Food Contact Materials Regulation[4] (FCMR) in section 2.2.2, for what it could potentially do, rather than for what it already covers. Annex I of the FCMR lists 17 groups of materials that *may be covered by specific measures* at the EU level.

One of the few groups covered at the European level[5] is group 10: it covers plastics, excluding rubbers and silicone materials (and ion exchange resins). It defines an exhaustive "positive list" of substances that may be used in food contact plastics. It lists several substances used to make PFAS: monomers[6] for many fluoropolymers as well as several processing aids. Although it surprisingly allows the use of GenX[7], a still popular polymerisation aid for PTFE listed as an SVHC, or even of PFOA[8], it also includes many safer chemicals and materials that can be used as alternatives to PFAS.

Like paper and board (group 9), rubbers (group 5) and silicones (group 13) are not regulated at the European level. Member States are *not prevent[ed]* (by virtue of Art. 6 of the FCMR) to maintain or adopt national rules.

The German authority BfR[9] compiles and updates twice a year lists of recommended substances for food contact materials.[10] These lists are not exhaustive lists nor positive lists, nor do the lists free the user of their legal obligation to ensure safe use. Rather, manufacturers desiring to have a material listed can apply

[1] Commission Regulation 2017/1000, subsequently recalled because of listing under the POPs Regulation.
[2] Commission proposal available here.
[3] List XXXVI, available here.
[4] Regulation 1935/2004, available here.
[5] By Regulation 10/2011, available here.
[6] Such as tetrafluoroethylene, hexafluoropropylene, perfluorohex-1-ene, perfluoromethyl perfluorovinyl ether and perfluoropropyl perfluorovinyl ether.
[7] Entry 861.
[8] As its ammonium salt, entry 468. One should not be too surprised that chemicals banned and phased out for their hazards are still on this list, as even phthalates DBP and DEPH are still listed.
[9] Bundesinstitut für Risikobewertung or Federal institute for Risk Assessment, the competent authority for food safety, product safety and chemicals safety.
[10] All lists are available here.

for inclusion and provide the authority with relevant test data.[11] The most relevant list regarding fluroroelastomers is list XXI/1[12], collating "commodities based on natural and synthetic rubber in contact with food". Four categories of materials are distinguished:

- Category 1, including but not limited to sealing rings for cans and jars,
- Category 2, including but not limited to hoses for conveying food, lid seals and valve balls,
- Category 3, including but not limited to diaphragms, pistons, conveyor belts and aprons,
- Category 4, including but not limited to seals for pipelines, pumps, taps and angle seat valves.

Table 1 then lists the rubbers and latices recommended: the list includes most of the classical rubber types, such as natural rubber, polybutadiene, isoprene rubber, chloroprene rubber, styrene butadiene rubber, EPM and EPDM. However, the list does not mention FKM or any other name of a fluoroelastomer.
This suggests that, while they may be used in the food industry,[13] **fluoroelastomers likely play a less predominant role than suggested by many contributions to the public consultation, and their non-fluorinated alternatives are (still) very well established**. We assume that inclusion of a material in the BfR's lists provides a convincing sales argument, as the customer would feel reassured by the BfR's approval seal.

Industrial Emissions Directive

The interplay of REACH with other European legislation is a matter of importance, but also of confusion.
Every piece of legislation has its own remit and scope, its own objective, its own mechanisms and procedures. Some laws are more coercive than others. Some may enact bans, others monitoring requirements, others technical minimum standards, others obligations for transparency. Two pieces of legislation may address two different aspects of a substance, e.g. its access to the market and its treatment in the waste stage.
Input into this consultation contains several surprising claims that appear at odds with the regulatory situation in Europe. Contributions by several companies and lobby organisations ascribe mechanisms to the Industrial Emissions Directive (IED)[14] that it does not have.
Examples include:

- VCI Nord (#4503): *Gemäß IED sind Emissionen in die Gewässer immer so gering wie technisch möglich zu halten*.[15] In reality, the IED (Art. 1) aims *to prevent or, where that is not practicable, to reduce emissions*. The IED (Art. 14) sets via the BREFs[16] binding ranges for emission limits (generally expressed as concentrations) for some pollutants and requires permitting authorities to set emission limits for other parameters. The ranges of the BREFs (so-called BAT-AELs) are based on

[11] The BfR's English FAQ page on the topic is a useful resource.
[12] Available here. It should be noted that XXI/1 is a sub-list of XXI, "commodities based on natural and synthetic rubber". Statements made here on XXI/1 hold equally for list XXI.
[13] Use of a fluoropolymers is not forbidden by their non-inclusion in these lists.
[14] Directive 2010/75, available here. The ongoing revision of the IED is unlikely to change any of these aspects.
[15] According to the IED, emissions to water must always be kept as low as technically possible.
[16] Overview and BREF texts are available here.

Best Available Techniques (as defined in Art. 3 (10)) – these may not be equated to the lowest *technically possible* levels.[17]

- Arkema (#4424): *The potential emissions as well as the end of life can be effectively managed through alternatives regulations such as the Waste directive, the Landfill directive and the industrial emissions directives.* The Waste Framework Directive[18] does not contain any provisions specific to PFAS, nor does its set[19] any waste codes for PFAS-containing waste. The Landfill Directive[20] does not either. For the IED, at last, see the previous bullet point.
- Alzchem Trostberg (#4588): *The stringent environmental regulations on industrial emissions (IED) and in European waste legislation (WFD) ensure that no significant release occurs from industry.* Art. 11.c of the IED sets the principle that installations should be operated in such a way that *no significant pollution is caused* – rather than *no significant release occurs.* The principle is not always abided by, let alone the result of "no significant release" occurring.
- the French federation of mechanical engineering industries (#6203): *releases from production sites could be minimized by regulating industrial emissions, for example under the [IED].* Indeed this *could* theoretically be achieved. However, the relevant BREFs (POL, CWW, WGC) do not contain a single BAT-AEL on PFAS, i.e. no binding elements exist. None of the relevant BREFs are scheduled for an update anytime soon.
- DuPont (#4530 and #6212): *The [IED, ELV[21] and WFD] constitute a strong regulatory system that could be used to enforce containment of fluorosilicone emissions arising from the manufacture of or disposal of military vehicles* (#6212)*/vehicles of all types* (#4530)*.* Manufacture of (military or other) vehicles is not an activity in the scope of the IED. The ELV does not attempt to contain emissions from disposal, but *encourage* (indeed with minimum targets) *reuse and recovery*. Nor does the WFD.

It is therefore vital that the proposed REACH restriction does what it is supposed to do: to ensure that the manufacture, placing on the market and use of the substances *do not adversely affect human health or the environment*. No other piece of legislation is currently doing it in the stead of REACH, not least because e.g. the IED does not cover imported goods.

We appeal to RAC and SEAC to conduct thorough legal analyses before discarding any aspect of the restriction on the claim of "double regulation"[22] or the like.

[17] Neither in theory (the law does not contain any such wording), nor in practice: a recent report by EEB and CREA (available here) lists several examples where legislation in other parts of the world is substantially stricter than the IED.
[18] Directive 2008/98, available here.
[19] Via Decision 2014/955, available here.
[20] Directive 1999/31, available here.
[21] End-of-life vehicles directive, Directive 2000/53, available here.
[22] Which most often merely refers to another piece of legislation applying to the same object or activity, instead of its literal meaning: the same aspect of an object of activity being covered by two (not necessarily conflicting) pieces of legislation.

Specific Information Requests

Question 1: Sectors and (sub-)uses

- Other: Textiles for use in engine bays in automotives (for noise and vibration insulation)
- Paper & board packaging
- Plastic packaging

Question 6: Missing uses – AoA and SEA

Seals, joints, and gaskets

It is sometimes claimed[23] that fluoroelastomers are only used where absolutely needed because of their higher cost. While they are doubtlessly more expensive because of higher production and raw material costs, the cost difference should be put into perspective. A search in a professional online shop[24] gives unnegotiated prices of 3.04 € for a bag with 50 NBR O-rings against 8.63 € for 50 FKM O-rings of identical dimensions.[25] While this is a threefold difference, the low overall cost and high longevity of O-rings means that they represent only a negligible share of the overall production costs.
It therefore appears more likely that fluoroelastomers are mostly used for convenience, as they generally withstand tough physical and chemical conditions. Why bother selecting an appropriate non-PFAS seal when a fluorinated allrounder is available at a slight premium?

Chemical resistance
Chemists and physicists will easily comprehend that fluoroelastomers are chemically resistant and inert. They will also comprehend that other, non-fluorinated elastomers are not especially reactive or unstable molecular structures either, and that many of them can fulfil functions necessary to specific applications in which fluoroelastomers can be, and are, used.
As an example, comment #4505 claims that *Fluoropolymers are used […] due to their […] resistance to high temperature and aggressive chemicals. In detail, these are: • Ozone, […] • Steam (with temperatures ranging between 140 and 200°C) • Solutions of sodium hydroxide and citric acid used for cleaning purposes*
While this statement is probably correct, it does not address the question whether there are suitable non-PFAS alternatives under these conditions. The often-quoted Bürkle tables of chemical resistance[26] provide the following, contrasting, information:

[23] Composite seals, on the other hand, appear to be even costlier than fluoroelastomer ones, according to contribution #4389.
[24] RS online, accessible here.
[25] In this case, O-rings with an outer diameter of 8 mm and a thickness of 2 mm. For other sizes, relative differences up to a factor 5 have been found.
[26] Waste Gas from the Chemical Industry; free download available here.

Chemical	Resistance[27] (20/50 °C)	
	FKM[28]	Non-PFAS
Ozone	1/0	EPDM 1/0
Sodium hydroxide (≥30%)	2/4 to 4/4[29]	EPDM 1/0
Citric acid 10%	1/1	NBR 1/1

- With ozone, EPDM would give similarly good resistance
- According to Bürkle, fluoroelastomer FKM is only moderately suitable (at best) with more concentrated sodium hydroxide solutions, whereas non-PFAS EPDM has excellent resistance. With dilute solutions (1%), both FKM and EPDM show good resistance.
- With citric acid, NBR has similar performance to FKM.

This illustrates that there are likely many cases where fluoroelastomers are used because of their rather broad resistance spectrum, although they can likely be replaced by non-PFAS alternatives in most specific, practically occurring cases.
In some limited cases, the elastomer will be potentially exposed to a broader range of chemicals, e.g. in gas sensors. As these are relevant for safety reasons, such uses may warrant a derogation (akin to the Montreal Protocol's concept of essential uses) in case the absence of technically suitable alternatives can be convincingly demonstrated.

High integrity equipment

Occasionally, stakeholders mention the necessity to use fluoropolymers or -elastomers for "high-integrity equipment" (HIE) or related concepts. It is generally hinted that for safety reasons, e.g. flanged connectors in industrial pipe line systems require seals and gaskets made from fluoropolymers. We would like to provide more background on the meaning of such statements, and the relevant technical and legal references.
It should be mentioned that none of the contributions (up to #6420 included) uses this term; however, contribution #4503 contains relevant mentions.
The term "high integrity equipment" is officially mentioned in the IED's WGC BREF,[30] the EU's reference document to avoid or reduce gaseous emissions from production installations in the chemical sector. Its most crucial reference in BAT 23 (technique 1b): *BAT is to use a combination of the techniques given below with the following order of priority. […] [1a] limiting the number emission sources […], [1b] use of high-integrity equipment[.] High-integrity equipment includes, but is not limited to:*

- *[…] bellow valves or double packing seals or equally effective equipment;*
- *Magnetically driven or canned pumps/compressors/agitators, or pumps/compressors/agitators using double seals and a liquid barrier;*

[27] 0= no data, ratings range from 1 (very good) to 4 (not resistant).
[28] The Bürkle tables only list FKM as a fluoroelastomer, whereas the authors of comment #4505 may very well be using another, non-disclosed fluoroelastomer.
[29] This low level of suitability FKM should be contrasted with a high suitability of other fluoroelastomers, e.g. FFKM.
[30] Available for download here.

- *certified high-quality gaskets (e.g. according to EN 13555), […].*

The wording "a combination […] with the following order of priority" is not very coercive and using equipment other than HIE would not be considered "not BAT" by many permitting authorities.
It should be noted that neither the descriptive nor the legally binding part of the BREF provides a definition of the concept of HIE.
National legislation also sometimes mandates performance levels e.g. for gaskets, most famously the German TA Luft,[31] which (somewhat uncommonly) mandates use of the 2012 standard VDI 2290[32]. The use of VDI 2290, however, is only specified for flanges (and their gaskets) in section 5.2.6.3, i.e. it does not apply to other seals outside flanges, e.g. in valves or pumps. Leakage rates for valves and metering devices are described in section 5.2.6.4 in a similar way as for flanges, but without reference to VDI 2290.
It is also important to understand that VDI 2290's scope is defined as follows: *It applies without restriction to metal flanges […]. VDI 2290 is not applicable […] for flanges for that* (sic) *no sealing constants can be determined, e.g. enamelled flanges made of glass, plastic materials or with plastic liners* (emphasis added).

As a conclusion, **we recommend to RAC and SEAC to thoroughly check scope and applicability, as well as alternatives fulfilling the same function, whenever legally binding requirements are invoked**.

Question 7: Potential derogations marked for reconsideration – AoA and SEA

Technical textiles (automotive)

This use, corresponding to the non-proposed derogation 5.u, is reminiscent of a question addressed in the restriction of PFHxA, its salts and related substances. In the final consultation on the Annex XV dossier (Q3-Q4 2021), SEAC requested information on such uses, as they found available information insufficient to conclude positively on a derogation.
We would like to bring to the attention of the scientific committees EEB's contribution #929 to the said consultation. We have copy-pasted here the submitted text for convenience.

Regarding aspects e, f and i: Textile auxiliaries supplier CHT recommends their fluorine-free repellent Ecoperl[33] along the C6-based Tubiguard as suitable repellent coatings for filters used in engine bays; however without any reference to nonwovens used as liners (which is mentioned in comment #2996). A use such as the one mentioned by CHT would indeed mean that uses in engine bays would be covered by the (not sufficiently justified, see Q9) derogation on filtration and separation media.

Based on the explanations in comment #2996, it is difficult to understand what areas of the engine bay of a combustion engine would be meant, and what the exact function of such a textile material could be. Ignition-prone areas (and thereby safety-relevant ones) would have to be are as where fuels or oil can accumulate and ignite through a spark or high temperature. Adding to our surprise, an inspection of real engine bays revealed no conspicuous textile materials (e.g. under the hood of a Renault Twingo) or some nonwovens, which however repelled neither water nor oil (Mazda CX-5).

Although repelling oil could arguably be a useful feature of materials used in such areas, one should wonder how less lipophobic surfaces such as rubber, plastics or metals fare in such circumstances in the nearby surroundings.

[31] Legal text available here. English versions of the text also exist.
[32] A bilingual 4-page introduction can be downloaded here.
[33] Brochures and technical datasheets attached.