Position Paper

Environmental Affairs and Sustainability

PFAS restriction under the REACH Regulation

Background:

German authorities in cooperation with authorities of the Netherlands, Denmark, Norway and Sweden prepared a restriction dossier for per- and polyfluoroalkyl substances (PFAS) under the REACH Regulation. After a first public consultation phase at the end of 2021, the European Chemicals Agency (ECHA) pre-published the restriction proposal on 7 February 2023. On 22 March 2023, the six-month public consultation phase provided for in the REACH Regulation was launched. According to the systematics of Annex XVII of the REACH Regulation, the potential future restriction would affect the manufacturing, placing on the market and use of PFAS.

The very high persistence, high mobility, bioaccumulation potential, long-distance transport potential, global warming potential and ecotoxicity of some PFAS substances are primarily cited as reasons for possible restriction. Without targeted protective measures, PFAS can enter the environment throughout the entire product life cycle during the manufacturing, use and disposal phases and thus further increase global concentrations.

On the restriction proposal:

In the present restriction proposal, PFAS are defined as a substance containing at least one fully fluorinated methyl or methylene carbon atom (without H/Cl/Br/I attached). This includes about 10,000 different PFAS.

Two different regulatory options (restriction options RO1 and RO2) are proposed in the restriction dossier. A complete ban on all PFASs without exemptions (RO1) and a ban with application-specific, largely time-limited derogations (exemptions). The latter option is currently favoured by the dossier submitters.

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Under the RO2, exemptions are provided for various uses. Some examples are given below:

- Unlimited exemptions: active substances in plant protection products, biocidal products, human and veterinary medicinal products; refrigerants in HVACR[1]-equipment in buildings where national safety standards and building codes prohibit the use of alternatives; PFAS for calibration of measurement instruments and as analytical reference materials.
- Time-limited exemptions (examples): refrigerants in refrigerated centrifuges (13.5 years after entry into force of the restriction); refrigerants in low temperature refrigeration below -50 °C (6.5 years after entry into force of the restriction).
- Exceptions still to be discussed (examples): non-stick coatings in industrial and professional bakeware (6.5 years)

All applications not covered by an exemption would be affected by a direct ban of all PFAS after a transition period of 18 months (approx. 2026 / 2027). In summary, both options aim at a complete ban on the production, import and use of all PFAS in the European Economic Area (EEA) in the long term.

Affect on mechanical and plant engineering sector:

Based on the current PFAS restriction proposal all manufacturers in the mechanical and plant engineering industry would be affected either in their products or in their production line. For example, hydraulic components, pumps, motors and valves, as well as fittings and compressors are highly affected and widely used in the industry. PFAS, mostly fluorinated polymers, are often used, for example, in seals, hoses, wires and coatings. While in some cases "only" the performance of products would deteriorate immensely, other products could no longer be manufactured, imported and placed on market, so that companies would be completely or partially deprived of their business basis by a PFAS ban.

Evaluation of the restriction proposal:

The chemical scope of the proposal is very broad. Different substances with different properties and risk profiles are grouped together based on their chemical structure. Thereby, for the majority of the 10 000 different PFAS, a hypothetical risk is derived solemnly on the basis of their chemical composition. A well-founded risk assessment of the individual PFAS, which takes into account not only the hazard properties but also the exposure of the various uses, has not been carried out. Article 68 of the REACH Regulation stipulates that substances posing an unacceptable risk to human health or the environment may be regulated under restrictions. Following this logic, applications of PFAS for which no risk could be identified must also remain possible in the future.

F-gases fall under the universal PFAS restriction as well. At the same time, certain F-gases are regulated in the F-Gases Regulation. In this context, F-gases that are used in industrial refrigeration process technology (especially in buildings), among other things for safety reasons, are also largely subsumed as PFASs in the sense of the PFAS dossier. These F-gases are thus subject to double regulation.

[1] HVACR- Heating, ventilation, air conditioning and refrigeration

Mechanical and plant engineering companies are often in the middle of the supply chain. Therefore, the identification of an affected party is a major challenge. The insufficient harmonised classification of PFAS in the CLP Regulation means that no information is passed on along the supply chain (e.g. via the safety data sheet), which makes the analysis of the affectedness time-consuming and in many cases impossible. In order to obtain information along the supply chains on which substances are contained e.g. in formulations or intermediate products, final lists of PFAS of very high concern (classified as CMR, PBT, vPvB, PMT, vPvM or as ED[2]) (with CAS numbers) are needed.

Many uses of certain PFASs that are important for machinery and equipment manufacturing companies are not mentioned in the restriction proposal, although extensive information has been provided in previous consultations. The use of PFAS-containing gaskets, hoses, wires, valves and coatings is only temporarily exempted in the restriction proposal and only in certain industrial uses (e. g. industrial and commercial food and feed production). Yet these parts have a very high relevance for the entire industry (chemical plants, tool, printing, paper, textile machines, etc.).

Industrial applications mainly involve the use of fluoropolymers. Some of them have been scientifically evaluated as "polymers of low concern" (PTFE, ETFE, FEP, PFA, PVDF and VDF-co-HFP). They have been shown to be chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile[3]. For these reasons, the fluoropolymers are also approved, for example, as materials for food contact or in medical technology. Furthermore, Henry et al. (2018) declare all fluoropolymers to be polymers of low concern. A deviating classification should be scientifically justified.

When assessing possible alternatives, it must be carefully examined within the framework of a holistic approach whether there are actually suitable, equivalent substitution options for the uses affected by the restriction. In addition to existing technical regulations (e.g. legal requirements or standards), the degree of technological maturity, safety-relevant aspects, energy consumption, service life and other factors must be taken into account.

So far, only a few and mostly very specific time-limited exemptions for industrial uses have been proposed. Many uses have not been considered so far. PFAS-containing materials are needed in machinery and equipment whenever extreme conditions (high or low temperatures, high frictional resistance, aggressive/corrosive/toxic chemical conditions or a combination of these) prevail. Therefore, most existing industrial plants and applications - also in the field of future technologies (e.g. fuel cell, water electrolysis, heat pump, solar system) - often do not have equivalent alternatives to the expensive PFAS, which - due to their high price alone- are not used carelessly.

Another problem is that machines and plants are built to last for decades. Against this background, it is important that spare and used parts are taken into account in the restriction proposal. Neither fundamental exemptions from the regulation nor longer transition period are planned. This means that after the transitional period of 18 months, repairs or the regular replacement of wear parts in long-lasting products, such as the replacement of seals or hoses in industrial plants, would no longer be possible.

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[2] CMR- carcinogenic, mutagenic, toxic for reproduction; PBT- persistent, bioaccumulative and toxic; vPvB- very persistent and very bioaccumulative; PMT- persistent, mobile and toxic; vPvM- very persistent, very mobile; ED- endocrine disruptors, substances with endocrine-disrupting properties.

[3] Henry, B. J; Carlin, J. P; Hammerschmidt, J. A; Buck, R. C; Buxton, L W.; 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. Manage. 2018, 14 (3), 316-334.)

Even where there are exemptions, they are proposed for only five and twelve years. It is not clear whether and, if so, how an extension of the existing exemptions can be applied for.

Due to the lack of standardized, simple analytical methods, it is not possible to control how the implementation of the restriction proposal can be ensured by market surveillance in the future, e.g. in particular with regard to imported products containing PFAS. This would result in products containing PFASs no longer being manufactured in the EU, but possibly continuing to find their way into the EU. An uncontrolled import of products containing PFASs would lead to considerable competitive disadvantages.

VDMA demands:

The machinery and equipment manufacturing industryfully supports the goal of no longer allowing PFAS classified as very hazardous (for example: CMR, PBT, vPvB, PMT, vPvM or as ED) to enter the environment. In this respect, regulation of these PFASs classified as very hazardous is fundamentally correct when there is a risk of exposure. It is also understandable to group the PFASs sensibly and in terms of their risk potential in order not to have to regulate each of the 10,000 substances individually. But:

- **Broadness of the regulation**
  The restriction proposal includes F-gases, low-molecular compounds as well as fluoropolymers and thus several thousands of substances. Regulation must be more differentiated. A comprehensive scientific risk assessment must be carried out for the restricted substances, and groups of substances must be shown to have the comparable hazardous properties. The risk-based approach must be maintained so that uses that do not pose a relevant risk remain possible.
- **Industrial applications are not consumer goods**
  - **The general exemption of fluoropolymers, which are considered "polymers of low concern" according to the OECD definition**
    Fluoropolymers and substances, such as monomers and processing aids, which are necessary for fluoropolymer production must be exempted from the ban, provided that safe use is ensured. This is also what the study by the British Health and Safety Executive (HSE) envisages. In short, low risk groups (e.g. fluoroelastomers, fluoropolymers assessed as "polymers of low concern") or uses without relevant risk (e.g. contained uses) must be exempted[4] .
  - **Substitutes**
    In applications with extreme conditions (high or low temperatures, high pressures, UV radiation, high frictional resistance, aggressive chemicals or a combination of these), there are no suitable alternatives to products containing PFAS. The high price of fluoropolymers minimises their use anyway. These unique materials are generally only used in industry when necessary. The use of PFAS in industrial applications (seals, hoses, wires, valves, compressors and coatings) contributes to the safety, resource efficiency and durability of industrial equipment, among other things.
  - **Input pathway into the environment**
    Some PFAS are mobile and enter the environment. The environmental pathway of different PFAS subgroups must be considered. Exceptions must apply where there is no relevant (environmentally hazardous) entry into the environment. For example, a

[4] Analysis of the most appropriate regulatory management options (hse.gov.uk)

fluoropolymer seal located in the enclosed space of a machine does not pose a relevant risk.

- **Exception of the industrial sector**

  It is necessary to distinguish applications in the consumer sector (B2C) from those in the B2B sector. Industrial actors can ensure that PFAS, PFAS-containing materials and products are handled professionally throughout the entire life cycle through professional risk management.

- **Longer transition periods**

  The 18-month transition period envisaged in the restriction proposal is too short for industrial applications; a period of several years is needed to test the possible alternatives for functionality and safe use, as well as to qualify them for series use and, in many cases, to approve them within the framework of EU legislation. Thus, the general transition period would also have to be several years.

- **Unbureaucratic application for new exemptions and extension of existing exceptions**

  In order to avoid possible unconsidered applications, a simple and unbureaucratic process for future exemptions should be made possible. In addition, an extension of the exceptions must be ensured.

- **List of substances concerned**

  The chemical scope of the restriction must be communicated transparently by means of a list of affected substances (including IUPAC names, CAS numbers, EU numbers) so that companies can collect the information along the international and extensive supply chain.

- **Exemption for spare and used parts**

  For the placing on the market of spare, wear and used parts, exceptions to the restriction are necessary for the purpose of sustainability and economic efficiency (repair as produced principle). These are to be granted for an unlimited period or at least for a significantly longer period than the transitional periods currently provided for.

- **Avoid double regulation**

  It is unclear how the universal regulation for PFASs will correlate with other regulations currently under discussion (in particular the new F-Gases Regulation, (EU) No 517/2014). Consistency and coherence with other EU regulations must be ensured.

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