BDI

POSITION | CHEMICAL POLICY | RESTRICTION

PFAS-Restriction

Evaluation of the restriction proposal

24 April 2023

Background

On 13 January 2023, the competent authorities from Germany, the Netherlands, Denmark, Sweden and Norway submitted a restriction dossier to restrict all PFAS (per- and polyfluoroalkyl substances). This was published in advance on 07.02.2023. On 22.03.2023, the conformity of the restriction proposal was confirmed by the ECHA Committees, and a public consultation was launched. The dossier is very comprehensive and consists of an Annex XV report with 7 annexes and 4 appendices.

Scope of the restriction

The restriction is intended to ban the production, placing on the market and use of all PFAS as such or in mixtures and articles (above certain concentration limits, see below).

The scope of the restriction proposal refers to the OECD definition of PFAS. It includes all substances containing at least one fully fluorinated methyl group (-CF3) or methylene group (-CF2-) without further H, Cl, Br or I atoms (more than 10,000 substances in total). This also includes fluoropolymers and polymers with fluorinated side chains.

Two restriction options are assessed in the restriction dossier:

I. Full ban on all PFAS with a transition period of 18 months (no derogations)

II. Full ban on all PFAS with use-specific and time-limited derogations (6.5 years or 13.5 years after entry into force) and otherwise a transitional period of 18 months

The restriction dossier assesses Option II as the preferred option.

For mixtures and articles, the following concentration limits are proposed for the full ban of all PFAS:

- ≥ 25 ppb for each PFAS determined by targeted analysis (polymeric PFAS are excluded from quantification).
- ≥ 250 ppb for the sum of PFAS measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFAS excluded from quantification)

- ≥ 50 ppm for PFAS (polymeric PFAS 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 PFAS or non-PFAS.

Intended Derogations

In the restriction dossier - in addition to the general derogation of fire extinguishing foams and degradable PFAS - three types of derogations are provided for:

- Small number of time-unlimited derogations for
  a. PFAS used as active substances in plant protection products, in biocidal products and in human and veterinary medicinal products (with 2-yearly reporting obligation to ECHA). The derogation is limited to the active substances themselves and does not include their manufacturing processes. The PFAS ban applies, for example, to transported isolated intermediates needed for the manufacturing of the active substances. Therefore, despite the proposed derogations, significant consequences are to be expected for the areas of plant protection products, biocidal products, and pharmaceuticals. This also contradicts ongoing efforts towards European sovereignty and the goal of being less dependent on global supply chains;
  b. PFAS used for the calibration of measurement instruments and as analytical reference materials.
  c. PFAS in Refrigerants in HVACR equipment in buildings where national safety standards and building codes prohibit the use of alternatives.
- Time-limited use-specific derogations for which sufficient information has already been provided (6.5 or 13.5 years after entry into force).
- Time-limited use-specific derogations still to be discussed, for which further information is needed (6.5 or 13.5 years after entry into force).

All not mentioned sectors and applications without derogation would be subject to a direct ban of all PFAS after the transition period of 18 months.

Intended derogation (with sufficient information; selection)

Use-specific derogations are mentioned under both point 5 and point 6 (derogation for fluoropolymers and perfluoropolyethers) of the restriction proposal. Two different time periods (deadlines) for derogations are provided in the restriction dossier. The time period granted for derogations depends on the availability of alternatives. A period of 6.5 years is foreseen if appropriate alternatives are not yet or not yet sufficiently available on the market, but these are already under development. A transition period of 13.5 years, on the other hand, is granted for uses where technically and economically feasible alternatives are not yet available and where it is unlikely that PFAS-free alternatives will be available in the near future. The temporary derogations do not include exemptions for the manufacturing process. This would allow uses exempted from the scope, but the ban on precursors would prohibit the manufacture of the respective substances within the EU.

The proposed derogations are very detailed and formulated in a "small-scale" manner - broader derogations are not foreseen. It is also noticeable that many applications which were submitted by industry in the two "Call for Evidence" as uses without suitable alternatives are not considered in the restriction

dossier (e.g., use of PFAS in lithium-ion batteries, in industrial plants, in hydrogen electrolysis, chlorine electrolysis, etc.).

Even with the derogations already provided in the dossier, it will be important for industry to contribute further information and data to the public consultation, as these are also not guaranteed at this stage and can be removed from the restriction at any time.

Use (exceptions according to number 5 with sufficient evidence)	Dead-line
Polymerisation aids in the production of polymeric PFAS: This exemption does not apply to the production of PTFE, PVDF and FKM.	6,5
Textiles used in personal protective equipment (PPE) intended to protect the users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c)	13,5
Textiles used in personal protective equipment (PPE) in professional firefighting should protect users from risks as specified in Regulation (EU) 2016/425, Annex I, risk category III (a) - (m)	13,5
Impregnating agent for the reimpregnation of articles according to paragraph 5b and 5c	13,5
Textiles for use in filtration and separation media used in industrial and commercial applications in high performance air and liquid applications in industrial and professional settings that require a combination of water and oil repellence	6,5
Refrigerant in low temperature refrigeration below - 50 °C	6,5
Refrigerant for laboratory tests and measurement equipment	13,5
Refrigerants in refrigerated centrifuges	13,5
Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exists	13,5
Industrial precision cleaning fluids	13,5
Cleaning fluids for use in oxygen-enriched environments	13,5
Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health	13,5
Diagnostic laboratory testing	13,5
Additives to hydraulic fluids for anti-erosion/corrosion protection in hydraulic systems (incl. control valves) in aircraft and aerospace industry	13,5
Refrigerants in mobile air conditioning systems in combustion engine vehicles with mechanical compressors	6,5
Refrigerant in transport refrigeration other than in marine applications	6,5
Insulating gases in high-voltage switchgear (over 145 kV)	6,5
Lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment	13,5

Use (derogations according to Number 6 (fluoropolymers and perfluoropolyethers) with sufficient evidence)	Deadline
Food contact materials for the purpose of industrial and commercial food and feed production	6,5
Implantable medical devices (not including meshes, wound treatment products, tubes and catheters)	13,5
Tubes and catheters in medical devices	13,5
Coatings of Metered Dose Inhalers (MDIs)	13,5
Proton-exchange membrane (PEM) fuel cells	6,5
Fluoropolymer applications in petroleum and mining industry	13,5

Potential Derogations (for which further information is needed; selection)

In addition to the foreseen derogations, the dossier mentions potential derogations for uses where sufficient evidence is not yet available. These derogations are only to be granted if industry provides further information and data during the public consultation. However, it remains open which information and proof points exactly would have to be provided by industry in the consultation to achieve sufficient evidence.

Use (Potential derogations according to point 5, if further information provided)	Deadline
Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry	13,5
Hard chrome plating	6,5
Foam blowing agent in expanded foam sprayed on site for building insulation	6,5
Industrial and professional use of solvent-based systems in 3D printing	13,5
Industrial and professional use of smoothing agents for polymer 3D printing applications	13,5
Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required.	13,5
Preservation of cultural paper-based materials	13,5
Cleaning and heat transfer: engineered fluids for medical devices	13,5
Membranes used for venting of medical devices	13,5
Use as refrigerant and for mobile air conditioning in vehicles for military applications	13,5
Semiconductor manufacturing process	13,5

Use (Potential derogations according to item 6 (fluoropolymers and perfluoro-polyethers), if further information provided)	Dead-line
Non-stick coatings in industrial and professional bakeware	6,5
Hernia meshes	13,5
Wound treatment products	13,5
Coating applications for medical devices other than MDI inhalers	13,5
Rigid gas permeable contact lenses and ophthalmic lenses	13,5
PCTFE-based packaging for medical preparations, medical devices and medical molecular diagnostics	13,5
PTFE in packaging for ophthalmic solutions	13,5
Packaging of terminally sterilised medical devices	13,5
Applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods	13,5

For these derogations that are still open (to be discussed), further information on the type, functional relevance and socio-economic importance of the respective PFAS use must urgently be provided within the public consultation. The same applies to uses for which no derogations are foreseen in the dossier, and currently no alternatives exist (see *BDI recommendation for action*).

Evaluation of the restriction proposal

The restriction proposal is very broad. A structuring or subdivision of the more than 10,000 substances, which have very different intrinsic properties, is not recognisable. A differentiation that considers the different risk profiles of the substances is not made. Instead, a comprehensive ban of the entire substance class is proposed.

While in the framework of previous restriction procedures mostly individual uses, for which an unacceptable risk is known according to Article 68 (1) of the REACH Regulation, were specifically banned, in the proposed PFAS restriction for the first time a generic approach is chosen, in which - apart from production and placing on the market - any type of use (apart from a few, time-limited derogations) is banned.

Such a comprehensive and undifferentiated ban on PFAS substances would have a massive impact on European companies and the innovative capacity of industry in Europe. Due to the reduced availability of substances in Europe for which there are currently no suitable alternatives existing, the transformation of industry and the goals of the Green Deal would not be achievable in the time envisaged. The fact that certain PFAS substances are necessary for this transformation has been noted by many expert bodies, most recently for example by the German Hydrogen Council. [1]

[1] *National Hydrogen Council -Effects of the ban on per- and Polyfluorinated chemicals (PFAS)*

The restriction proposal would also challenge European sovereignty in several areas as dependencies on imports would increase (e.g., semiconductors, feedstock for exempted PFAS uses/products, chemical industry intermediates and end products, production of pharmaceuticals, pesticides and biocidal active ingredients).

German industry supports the aim of the Chemicals Strategy for Sustainability to improve the protection of human health and the environment from risks posed by chemicals while increasing the competitiveness of European industry. BDI is committed to the existing and well-established mechanisms of the REACH Regulation. As provided for in Art 68 of the REACH Regulation, substances posing an "unacceptable risk" should be regulated under restrictions.

For PFAS the aim must be to substitute uses that are associated with risks and to prevent emissions into the environment by taking appropriate measures. In recent years, industry has already made considerable efforts and established comprehensive environmental protection measures. Toxic and particularly harmful substances from the PFAS group (e.g., PFOA and PFOS) have been substituted and production processes have been changed.

However, assessments of many sectors show that a complete substitution of PFAS in many applications is currently not feasible. PFAS are used in many industries whenever extreme conditions such as high or low temperatures, high frictional resistance or aggressive chemical conditions require it. They therefore play an important role in most existing industrial plants (see below) and in the field of future technologies (e.g., fuel cells, hydrogen electrolysis, heat pumps, solar plants).

In a position paper in 2021, the BDI identified the areas in which there are no suitable alternatives for PFASs and the applications in which they are used (*BDI position paper 2021*).

With the present position paper, the BDI is commenting on the PFAS restriction proposal and addressing the relevant aspects, critical points and proposed solutions from the point of view of German industry.

General aspects

- Many substances with very different properties and risk profiles are affected by the proposed restriction. Many of the substances are not classified as hazardous substances according to the CLP Regulation. Many fluoropolymers relevant to industry, such as PTFE, meet the OECD criteria for "polymers of low concern" (PLC). This means that they are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile. For these reasons, fluoropolymers are also suitable, for example, as materials for food contact, in medical applications or in the production of high-purity active pharmaceutical ingredients (e.g., vaccines).
- Consumer products for which the specific concentration values are exceeded could no longer be imported and placed on the European market with the foreseen restriction. Since the concentration limits are very low, it can be assumed that many products, which cannot be dispensed for social reasons, would be affected. This would have a serious impact on the daily life of every individual. It must be clear that the availability and safety of products without the use of PFAS will no longer be given in the required technical quality.
- The restriction proposal will also have a significant impact on industrial installations in many industries. In these, fluoropolymers are widely used. Industrial production facilities and pipelines are often subject to conditions that require special properties of the materials (e.g., corrosion resistance, resistance to acidic or alkaline substances, gas tightness, non-conductive properties, temperature resistance). Most industrial production plants and infrastructures are therefore equipped with highly standardised components made of fluoropolymers. Examples

are columns, vessels, pumps, compressors, blowers, filters, process control instruments, valves, flaps, process analytical equipment in pipelines as compensators or inliners, but especially as seals. A lack of these plant components would have a considerable influence on the service life, functionality, and safety of industrial plants. The requirements of the TA-Luft regarding leakage rates as well as plant safety can be met in certain temperature and pressure ranges only with PTFE seals or liners. By using resistant PFAS-based materials, an operational safety/operational reliability is achieved that is necessary for process plants with a high hazard potential for humans and the environment.

Regulatory aspects

- The group approach of the restriction proposal is legally questionable. According to Art. 69 of the REACH Regulation, a substance-based approach is prescribed for restrictions. This objection remains relevant even though various other restrictions on groups of substances are included in Annex XVII of the REACH Regulation.
- The restriction proposal is not risk-based, as no risk assessment of individual substances or (at least) individual groups of substances with homogeneous properties has been carried out. Thus, the chosen restriction approach does not meet the requirements of Article 68(1) of the REACH Regulation, which provides that restrictions may be adopted in the presence of "unacceptable risks". Therefore, a restriction of substances in applications that do not pose a risk exceeds the legal framework provided by the REACH Regulation.
- The lead authorities justify the chosen approach (for all PFAS) primarily with the persistence of the substances and possible hazard properties such as mobility or bioaccumulation. However, the actual risk assessment required by Art. 68(1) of the REACH Regulation, which considers not only hazard properties but also exposure, does not take place.
- A differentiated approach is required for a lawful, appropriate, and proportionate regulation of PFAS. This must take into account the different properties of the substances and an assessment of whether a PFAS substance or its use poses an unmanageable risk to the environment or human health. In particular, if no environmental exposure occurs in specific applications, a ban is not justified. Safe uses of certain PFAS that cannot be replaced by appropriate alternatives must continue to be possible in Europe. Otherwise, the restriction proposal is disproportionate.
- Since derogations are only provided for if it has been assumed that no alternatives exist, the identification and assessment of alternatives are of particular relevance in the context of the restriction procedure. When assessing possible alternatives, it must be carefully examined within a holistic approach whether there are suitable and available substitution options for the uses affected by the restriction. In doing so, it is necessary to review the alternatives against the background of existing technical regulations (e.g., legal requirements or standards) and the level of technological maturity. Even if in some cases other substances can be used or alternative processes applied, this does not mean that such an alternative is suitable for the entire range of similar applications, let alone that it is sufficiently available on the market or economically feasible. Only a precise analysis that also includes safety-relevant aspects, energy consumption, service life and other factors can provide sufficient information here.
- Due to the broadness of the approach chosen, already the analysis of the affectedness is very difficult for the companies. To obtain information along the supply chains about which substances are contained in formulations or intermediates, for example, lists of relevant substances (with CAS numbers) would be helpful. It remains to be considered that even this would

not be sufficient for polymers, for example, as many have the same CAS number despite different production and substance properties. However, since only some PFAS are classified according to the CLP Regulation and since there is no information obligations within the supply chain (e.g. via the safety data sheet), even if such a list of substances would be available, the analysis of the affectedness remains time-consuming and difficult.

- In order to be able to provide all relevant information for a derogation - in particular on PFAS applications for which no alternatives currently exist or are even foreseeable - within the consultation, the affected sectors and companies need a reasonable amount of time. Since, for example, data on socio-economic impacts of the restriction must first be collected within comprehensive studies, a period of 6 months is not sufficient. Although industry has been intensively engaged in data collection since the announcement of the restriction plans, it remains an impossible task to identify all PFAS applications and compile solid data material on them in the given timeframe.
- It remains unclear how the proposed PFAS restriction relates to ongoing or completed restriction procedures. For example, PFOA and PFHxS are already regulated under the POPs Regulation, while the procedure to restrict PFHxA under REACH is still ongoing. To enable an impact assessment, the scope of application or the demarcation from other regulations urgently needs to be clarified.

Aspects of content (evaluation of the foreseen derogations)

- The restriction proposal provides for various use-specific derogations to allow sufficient time for the search for alternatives and the changeover of all products. However, for many uses, the time required for conversion cannot be reasonably determined due to the lack of feasible or technically mature alternatives. Even if alternatives already exist, the proposed period for derogations is too short for many uses. The development and conversion of production processes as well as the development, approval and certification of products require a very long period in many areas (e.g., medical devices, plant engineering).
- Many uses in which certain PFAS play a central role are not mentioned in the proposed restriction, although extensive information on these was provided by industry in the two "calls for evidence". In particular, the use of plant components containing PFAS in industrial plants is not even considered in the restriction proposal, although this is highly relevant for the entire industry and no suitable alternatives currently exist for this (see above).
- For spare parts and used parts, neither general derogations from the ban nor longer transition periods are foreseen, i.e., the same periods as for new parts/products are foreseen. The reuse of used parts (e.g., components of industrial plants) would no longer be possible after the expiry of the transitional period, as they would no longer be allowed to be supplied to third parties (note: according to Art. 3 No.12 of the REACH Regulation, every supply, not only the first one, is a "placing on the market"). The repair or regular replacement of wearing parts in long-life products, e.g., the replacement of seals in industrial plants or the installation of spare parts in motor vehicles, would also no longer be possible after the transition period.
- In general, there is a risk that due to the rigid factual and temporal requirements and due to the complexity of the supply chains, derogations for relevant uses can be missed and subsequently no longer granted. This aspect is particularly relevant for innovations that are currently being developed and could no longer be used without certain PFAS (e. g. hydrogen electrolysis; see also the statement of the National Hydrogen Council).

- Against this background, the question also arises as to whether and according to which procedure extensions of the transitional periods are possible or whether there will be a possibility to apply for new derogations even after the delegated regulation has entered into force. In order not to exclude future innovations that require the use of PFAS from the outset, a possibility should be created for this. Moreover, this should be possible if no suitable alternative has been found even after a transitional period of 13.5 years and considerable effort in the search.
- The proposed restriction is associated with locational and competitive disadvantages for European industry, which would lead to increased dependence on non-European markets. For example, products in which PFAS are required in the manufacturing process but are not contained in the product itself or in which the intended limit values are not exceeded in the (end) product could no longer be manufactured in the EU in future. However, imports from abroad would still be possible. This applies, for example, to the production of semiconductors after the envisaged transitional period of 13.5 years.
- Even though the restriction proposal provides for some temporary derogations for the use of fluoropolymers, these are partly in vain, as no (sufficient) derogations are provided for the required starting materials and intermediate products (processing aids and monomers) or they are not formulated in a legally secure and unambiguous manner. In the restriction proposal, this is justified by the fact that non-PFAS-containing processing aids can also be used to produce certain fluoropolymers (PTFE, PVDF and FKM PFA etc.). However, this approach does not consider that this has been shown not to apply to all uses of fluoropolymers. For the production of certain high molecular weight, very pure, high-quality fluoropolymers (fine powder or dispersion) which are used in many high-tech applications, there is no alternative to fluorinated polymerisation aids. Only these create reaction conditions that allow the formation of the very high molecular weight chains during the polymerisation process. The very derogation for polymerisation aids foreseen in the restriction proposal would mean that after the expiry of the transitional period of only 6.5 years, the production of end products containing high molecular weight fluoropolymers (e.g., medical devices and future technologies) would no longer be possible in the EU. However, it would still be possible to import these products into the EU (due to the exemptions). Thus, also in this respect, the restriction proposal would run counter to the EU's objective of shortening supply chains and strengthening industrial value creation in the EU. The proposal should be revised to ensure that all products that can or must be used in the EU can also be manufactured in the EU. A migration of European industry to third countries because of the European PFAS restriction must be avoided.
- It also remains open how the proposed restriction can be adequately implemented by enforcement regarding imported products that contain PFAS. Since there is currently no single standardised analytical methods for all PFAS available and there are information obligations in the supply chains only for the fewest PFAS, these will be difficult to execute. This would mean that products containing PFAS could no longer be manufactured in the EU but would continue to enter the EU due to the import ban, which is impossible or difficult to control. For example, it is completely unclear how it can be checked whether components (such as seals or hoses) contain PFAS in imported vehicles or other complex end products.

Possible solutions and demands of BDI

To achieve sustainable regulation of PFAS in Europe, which on the one hand protects people and the environment from unacceptable risks and on the other hand continues to ensure the availability of

substances for technological developments and innovative applications, the following aspects must be taken into account from the industry's point of view:

- The restriction of PFAS must be **substance-related and risk-based** (Art. 68 (1) of the REACH Regulation). Not all PFAS pose an unacceptable risk that would justify a full ban of PFAS.
- The restriction must **differentiate** between the **various PFAS categories,** and the risks posed by their uses and **exclude individual substance groups from the restriction proposal (including fluoropolymers).** Risks in the manufacturing and waste phases must not lead to an immediate broad ban on fluoropolymer applications but can be addressed through IED and occupational health and safety measures.
- **Appropriate transition periods** are necessary. The general period of 18 months is clearly too short for the conversion of all uses for which no derogations are provided. Even for uses where suitable substitutes are already available (or can be identified), the conversion of processes requires a longer period. The development, release and certification periods for regulated products must also be considered (both in general and for exceptions). Otherwise, there is a risk of disproportionate consequences for supply chains in many key industries.
- To allow all sectors and companies a legally secure assessment of their affectedness, the **scope of the restriction must be communicated in a transparent manner**. A list of relevant substances containing IUPAC names or CAS numbers is required for the analysis of affectedness along global supply chains.
- The establishment of a comprehensive **information obligation for "intentionally added" PFAS for** at least five years prior to a comprehensive PFAS restriction could, from the industry's point of view, be a suitable approach to control PFAS emissions and prepare for a more targeted regulation. This would also enable the targeted definition of risk minimisation measures,
- Regarding the **derogations provided for**, the following points should be implemented:
    - **Comprehensive derogations are** needed for highly important social applications such as medical technology, as well as for **high-tech and central industrial applications,** in order not to endanger the operation of numerous industrial plants, the continued existence of entire value chains in Europe, the green transformation of industry and the goals of the Green Deal.
    - The possibility to **review, renew and reapply for derogations** is needed due to the technical importance of PFAS.
    - For the placing on the market of **spare parts, wear parts and used parts,** derogations are necessary for the purpose of sustainability and economic efficiency (repair as produced principle). These should be granted for an unlimited period or at least for a significantly longer period than the transitional periods currently provided for.
    - **Products** already placed on the **market for the first time are to be exempted from the restriction**. Otherwise, existing stocks of substances, mixtures and articles at downstream users would have to be disposed, since under REACH every process of making available to third parties is considered as placing on the market.
- In order not to drastically increase dependencies on non-European markets and to ensure that the production of the products exempted from the restriction will still be possible in the EU, there must be clearly described **derogations also for raw materials, processing aids and**

intermediate products in the supply chain. The consideration of the whole supply chain should be formulated in the restriction dossier in a clear and legally secure way. Otherwise, relevant uses would be exempted from the restriction, but production would no longer be possible within the EU due to the ban on precursors etc.

- The use of PFAS often offers advantages over alternative processes or substances in terms of energy consumption, raw material consumption (especially rare raw materials), environmental protection or occupational safety. When **evaluating alternatives, therefore, a holistic approach is** required which ensures the inclusion of all relevant technical, functional and regulatory criteria.
- Incorrect technical assumptions regarding the availability of alternatives need to be corrected in the restriction proposal. This concerns e.g., unfounded assumptions about the availability of alternatives for fluoropolymers in certain applications and the invalid assumption that fluorinated polymerisation aids are not necessary for many of those fluoropolymer-containing products exempted in the current proposal.
- In general, care must be taken to ensure that the restriction is implementable and **verifiable for enforcement.** Enforcement must be strengthened to effectively prevent non-compliant imports from non-EU countries. For this purpose, among other things, measurement methods for the detection of PFAS in articles must be developed and standardised before the restriction comes into force.
- In addition, **coherence with existing or emerging EU legislation must** be ensured. For example, it is currently very unclear how the proposed dossier relates to the ongoing restriction procedure for PFHxA.

Imprint

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