ZVEI pager

For a risk-based approach to PFAS - no blanket ban

Competent authorities in five European countries earlier this year proposed a wide-ranging restriction on per- and polyfluorinated alkyl substances (PFAS) under the European chemicals regulation REACH. This is the EU's biggest chemicals restriction to date and is a key part of the EU Green Deal's chemicals strategy for sustainability.

The proposed ban on the manufacture, use and placing on the market of PFAS (in substances, mixtures, and articles) would have a massive impact on our member companies, whose technologies are essential for the energy transition, digitisation, European infrastructure, transport and logistics chains, healthcare, and process automation/measurement technology.[1]

We see the production, research, and development locations of the German and European electro and digital industries as well as their global competitiveness at serious risk in the event of a blanket ban and therefore call for a fundamental revision of the restriction proposal in key areas.

Our positions

On the restriction approach/procedure:

- The **ZVEI generally supports the objective of avoiding emissions of hazardous substances into the environment** and an appropriate regulation of individual substances posing uncontrollable risks. Our members are committed to continuously improving the environmental compatibility and safety of the products they place on the market.
- **Our society is facing major challenges in the energy transition**: Mobility and energy supply must become climate-neutral within a few decades. The electro and digital industry offers a wide range of solutions, such as semiconductors, lithium batteries, heat pumps and technologies for energy transmission and distribution. **All of these could not be produced today without the use of PFAS or would not work at all or work less efficiently.** Restricting substances should therefore not be done without a differentiated consideration of the uses and the consequences for them.
- What is needed is a **more differentiated regulatory approach** that is **risk-based** according to Article 68(1) REACH and **substance-based** according to Article 69 REACH. The proposed blanket ban of all PFAS, regardless of their toxicity and risk profile, does not meet this requirement. Given their enormous importance in industry, **the safe use of PFAS must remain possible** as long as their **risks can be well "managed"** by appropriate measures or **no suitable substitutes are available**.
  - It is important to distinguish between the different PFAS (groups) and the risks from each use.
  - It is also important to consider whether identified risks can be minimised through targeted measures, e.g., in occupational health and safety, emission control or waste legislation, rather than through a general ban under REACH.[2]
  - Only risky applications and those for which a technically suitable, economically justifiable, and less environmentally and health damaging alternative exists should be restricted. Otherwise, we risk having an unmanageably long list of very specific exemptions or excluding certain products and processes from the European market.
- Where substitution is possible, **appropriate transition periods of four to eight years** after entry into force (depending on sector, product life and development times) are needed, as provided for in other legislation, e.g. RoHS[3]. Even in the case of known substitutes, the 18-months period foreseen in the proposal is insufficient for the conversion of complex products and processes.
- Only the introduction of an **information obligation for "intentionally added" PFAS** (e.g. through inclusion in the REACH candidate list) prior to the introduction of targeted restrictions will allow all relevant uses to be included in the assessment in due time and any necessary derogations to be applied for. There is currently no legal basis for the dissemination and communication of information on PFAS in products along the supply chains. Most PFAS are neither classified in a harmonised way according to CLP nor included in the REACH candidate list. Information on PFAS in products is therefore only fragmentarily available in the complex international supply chains. It will take years to fill these information gaps.

Derogations

- In principle, a clearly defined **process for applying for new derogations and for renewing and reviewing those already granted** is necessary, especially in the case of a broad restriction of previously non-declarable substances. The **derogations currently envisaged are insufficient** and do not consider the relevance of PFAS for a wide range of uses and possible innovations in the electro and digital industry.
- **Spare parts and retreaded products must in principle be exempted** from the restriction. The **repair-as-produced principle** must be applied to the placing on the market of spare parts, wear parts and used parts for the purposes of sustainability and economic efficiency.
- **A general derogation is also needed for products that have already been placed on the market for the first time.**[4] Otherwise, they cannot be resold or further processed and placed on the market again as a component of more complex products/articles. The only option would be disposal.
- **Fluoropolymers** meeting the criteria for "polymers of low concern"[5,6] **and industrial applications in closed systems and equipment components** generally do not cause relevant emissions to the environment when used as intended. Due to the high industrial importance, general and long-term derogations are necessary, especially if no technically suitable and environmentally safer alternatives are known. Risks in the manufacturing and waste phase are better addressed in the relevant legislation (emissions/occupational health and safety, waste legislation).

Monitoring/Conformity

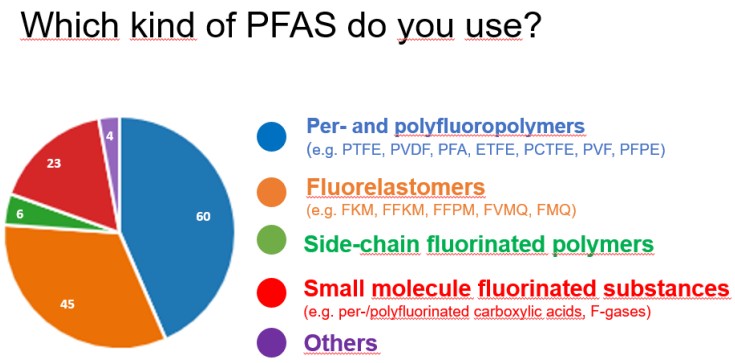
- When **setting transition periods** the existing **laboratory capacity, availability/usability of analytical methods and the burden on businesses** (staff, time, equipment) must be considered.
- Compliance with the proposed restriction cannot be verified for all uses with currently available methods and in the absence of a complete substance list. **Practical and standardised analytical and extraction methods must be available for all restricted substances and applications** before a legal restriction is imposed.
- To create a **level playing field** for all market participants and to reliably identify any infringements **market surveillance needs to be strengthened**, especially at external borders, but also within the EU.

Current status

- A **public consultation**[7] on the restriction proposal at the European Chemicals Agency (ECHA) is open until **25 September 2023**. Important information on uses and necessary exemptions and transition periods can be submitted.
- The **legislative proposal is expected to be published in 2025** and **the bans on the manufacture, use and placing on the market of substances, mixtures and articles containing PFAS are expected to enter into force in 2026-2027**, in line with the REACH restriction process.
- The dossier only provides for a **small number of mostly temporary derogations**, which ZVEI considers **insufficient**. In particular, the proposal lacks broad exemptions for fluoropolymers and important PFAS uses in the electro and digital industry.
- The subgroup of **fluoropolymers** in particular is used in many products, production processes and equipment in our industry because of its outstanding properties (e.g. resistance to extreme conditions (temperature, pressure or chemically aggressive media), low dielectric constant and low coefficient of friction). As a result of decades of development towards smaller, more efficient, and safer products, it is usually **the unique combination of several of these properties** that requires the use of PFAS.
- For many uses, **no suitable substitutes** are known. Consequently, no timeframe can be given for when substitutes will be available. A temporary derogation would therefore send the wrong investment signal for key technologies which should be strengthened in Europe (e.g. semiconductors, lithium-ion batteries, CO2-neutral energy production and distribution, etc.).[8]
- Where PFAS-free alternatives are known, they are **often no drop-in alternatives**: the specific combination of properties of PFAS materials can often only be replaced by a combination of materials or components, which requires more development effort and time than a 1:1 replacement. Changes to product dimensions, design and possibly the entire manufacturing process may be required.
- Electronic devices are often made up of **thousands of individual components** sourced through **complex international supply chains**. Changes to key components or product design require intensive testing, requalification and, where necessary, recertification of products through sometimes complex testing procedures. The time-consuming redesign of products and subsequent testing must be carried out at every stage of the value chain. If the tests are not passed, the whole process starts all over again. Such iterations can take years. For products that require certification or (mandatory) conformity assessment, limited testing capacity (both in terms of personnel and laboratory equipment) is often the speed-determining step.

Background: Numbers, data, facts

- The current restriction proposal regulates over 10,000 individual substances, all of which have a fully fluorinated carbon atom according to the PFAS definition, and some of which vary widely in their chemical, physical (solid, liquid, gaseous) and toxicological properties and risk profile.



Source: ZVEI internal survey on PFAS uses, summer 2021 / nominations of uses by 65 responding companies.

- According to an internal ZVEI survey from 2021, **fluoropolymers** account for **more than 75 % of PFAS uses known to ZVEI members**. Considering the companies' production facilities, we estimate that **almost 100% of our member companies will be affected** by the planned PFAS restriction, although the overall impact will vary from company to company.
- The lifespan of electro and digital industry products varies greatly and can be up to **40 years** (e.g. infrastructure for the transmission and distribution of electricity).
- According to the restriction dossier and the German UBA, the electronics/semiconductors and energy sectors currently contribute less than 2 % of total PFAS emissions in the EU.[9]

6 July 2023

[1] BDI position on the restriction of PFAS, 2021, publication (bdi.eu)
[2] Report: Government Risk Management Approaches Used for Chemicals Management
[3] cf. amending Directive 2015/863/EU to RoHS Directive 2011/65/EU, inclusion of four phthalates in Annex II with a transition period of 4 or 6 years, depending on the category.
[4] In contrast to the RoHS Directive, a substance restriction under REACH regulates every further transfer of an article in the supply chain, not only the "first placing on the market", cf. REACH Art. 3.12.
[5] Henry, B. J; Carlin et al., 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.)
[6] Korzeniowski SH, Buck RC et al., A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag. 2023 Mar;19(2):326-354. doi: 10.1002/ieam.4646. epub 2022 Aug 9. PMID: 35678199.
[7] https://echa.europa.eu/de/restrictions-under-consideration/-/substance-rev/72301/term
[8] "The general restriction of PFAS endangers the semiconductor industry in Europe and the goals of the European Chips Act as well as the ecological and digital transformation in Germany and Europe!", ZVEI e. V., Position Paper, 08.05.2023
[9] UBA, Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFAS), ECHA, 5 April 2023

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