

Comments on the PFAS restriction proposal

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Executive Summary

This comment relates to the proposal for the restriction of PFASs submitted to ECHA on 7 February. The restriction proposal aims to restrict the production, use and placing on the market of PFAS in the future.

In terms of sustainable chemicals regulation, substances that pose unmanageable risks due to their properties and use profile should be regulated based on scientific assessments. However, the ZVO believes that a blanket regulation of entire substance groups, irrespective of the actual risk posed by individual substances, is inappropriate. Therefore, the ZVO rejects the current form of the restriction proposal. 10,000 various substances with different levels of risk are grouped together, and for most of them, a ban is proposed as the sole regulatory action. Nevertheless, the toxicology data is limited, and assessing the impact on industry and consumer goods is challenging.

Furthermore, the proposal is seen as contradictory to the basic idea of restriction. Instead of starting from a categorical authorisation of use and then restricting or regulating certain uses on the basis of relevant information, the present draft expresses a general prohibition of use and reverses the burden of proof for exemptions. This is highly problematic as it effectively amounts to an authorisation procedure and is not in line with the principles of REACH.

PFAS are also needed for the transition to a climate-neutral Europe. They are used in many areas and, due to their unique properties, are particularly important for innovation and technological progress in future technologies. In addition, technical solutions already exist to reduce or eliminate PFAS emissions to the environment during production, use and disposal. A far-reaching restriction of PFAS therefore risks removing urgently needed chemicals from the market and preventing the development of innovative future technologies, with massive consequences for Europe as a business location and for the achievement of environmental and climate protection goals.

Overall, the proposal for restrictions is deemed overly regulatory and has the potential to harm Europe's economy and its prosperity. It is strongly advised against adopting the proposal in its current form. Instead, a complete and thorough impact assessment, acknowledging scientific and economic factors, should be conducted.

In the following, each point of criticism is addressed in detail.

Group approach of the restriction proposal

The proposal covers about 10,000 substances that share only common chemical groups. However, this does not describe the specific properties of the individual substances. From a chemical point of view, large differences are to be expected, as even "identical" configurations can have different properties (e.g. enantiomers); the same applies to the equal treatment of low molecular weight substances and polymers.

The only criterion used in the grouping is the presumption of persistence or degradability to persistent derived products. However, persistence is not a hazard criterion without toxicological effects.

The toxicological properties of the individual substances are poorly documented. In the case of the (already existing) PFHxA restriction proposal, the dossier authors themselves stated that no risks to the environment and humans could be identified at present. They did not exclude the possibility that this might not be ruled out in the (distant) future, but this is a general statement and not a helpful, further-reaching finding. Such an assumption can be made at any time for any substance for which no risks are currently identified. This approach is therefore not helpful.

The substance group is almost omnipresent in industry as well as in consumer products. It has been and continues to be the basis of technological progress. To regulate or transform it in its entirety - especially in the relatively short timeframe of 18 months to 13.5 years - requires a complete overview of the uses and technical expertise on thousands of current and developing uses in complex interacting value chains; individual authorities will never be able to obtain an overall view to adequately assess the consequences of individual decisions.

Due to the numerous substances and uses impacted by the proposed restrictions, identification and assessment of possible substitutes must be carried out quickly. This will have to be accomplished by the same scientific resources, leading to obstacles and delays. Often, these procedures will depend on each other and take longer as a result. Although the economic repercussions are uncertain, they will undoubtedly be significant.

Restriction strategy

The proposed restriction is contrary to the basic idea of a restriction. Restrictions are based on a general authorisation of use; the authority excludes certain uses from the authorisation or imposes conditions (e.g. separate labelling or compliance with certain maximum levels) based on meaningful data. The current draft, though, upends two established paradigms. Firstly, it places an overall ban on usage, and secondly, it introduces a shift in the burden of proof for granting exemptions. Both criteria constitute an authorisation process. Restrictions in this form are the wrong regulatory instrument; the present draft amounts to a quasi-authorisation procedure. As far as authorisations are concerned, the experience with chromium trioxide shows that generic approaches are neither effective nor administratively and bureaucratically manageable for authorities and companies. The draft would create a "bureaucratic monster" similar to an ineffective authorisation procedure, especially as there are even fewer clear criteria for decision-making under the restriction regime than under the authorisation procedure.

PFAS-Consultation

Follow-up analyses of a short-term ban on PFAS need to take into account the following aspects:

- Where is the current environmental pollution from this group of substances coming from?
- Where and in what quantities are these substances currently entering the environment?
- What is the measurable impact of the proposed restrictions?
- Use in production or manufacturing itself
- Use in the production of precursors
- Use in the production of article precursors
- Use in means of production
- Use in further processing of the article
- Use in the final product

Each of these aspects can affect the others. Changes in precursors, including means of production, lead to changes in chemical properties that may require adjustments throughout the supply and value chains. Repercussions are likely. In addition, the ability to execute specific production steps with the necessary standard may no longer be feasible. The consequences are unpredictable.

Changes in the further processing of the product - especially in the case of the surface technology of the coated product - can affect quality requirements or the technologies required in the preliminary stage (see above). It is very likely that different technologies will be used instead of one (the previous surface treatment).

These complex structures cannot be transformed in a few years without causing collateral damage and unintended consequences, such as supply chain disruptions whose long-term implications have become evident since the corona pandemic. It is already easier to order semi-finished PVDF from China than to wait for materials produced in Europe. Further restrictions would make the industry entirely dependent on China.

Specifically, hundreds, if not thousands, of production tools would have to be tested for alternatives by the user and then replaced. Examples include:

Fields of application: Fluoropolymers

In electroplating and surface treatment, the following areas have been identified (without claiming to be exhaustive) where fluoropolymers are used:

Means of Production

- Chemical-resistant, mechanically stable production containers (including PVDF)
- Exhaust air purification systems and exhaust air ducts
- Bath warmer
- Water treatment plants for production
- Water recirculation systems
- Cable sheathing in aggressive liquids
- Air hoses
- Diaphragm valves
- Air-operated diaphragm pumps
- Various seals
- Wet area of filter pumps
- Temperature and level probes
- Moisture protection in electronic control systems
- Protective clothing

Surface Treatment

- Coating additive (e.g. for defined tightening torques for screws for permanent "seating"; i.e. safety criteria)
- Coating additive for enhanced corrosion protection (e.g. zinc lamella coatings)
- Self-lubricating plain bearings
- Valve coatings

Fields of application: low-molecular PFAS

In electroplating, wetting agents are necessary as surface-active substances for achieving uniform and efficient coating and to prevent the formation of aerosols (health and safety!). PFAS surfactants represent a special class of wetting agents, as they possess exceptional stability even in highly oxidising media, such as chromic acid electrolytes. They are used in the electroplating of plastics to prepare the plastic for the coating process and partly for the final coating. Fluorinated surfactants are almost completely replaced in this process. While modern chrome plating processes can function without fluorinated or partially fluorinated wetting agents, certain geometries or base materials in the preparation of plastics for the coating process necessitate fluorine-free wetting agents, which do not have the necessary properties to guarantee fault-free production, despite technological advancements in plant operations. In these cases, wetting agents based on partially fluorinated alkyl sulphonic acids, which also belong to the PFAS group of substances, must still be used. The employment of wetting agents has already been substantially decreased through advancements in plant technologies, but it is not yet feasible to completely eradicate them. However, in numerous production stages where it is technically viable, wetting agents have been effectively substituted. At the same time, highly effective measures have been employed to decrease the already minuscule and almost indiscernible waste water residues by 80-90%.

In surface technology, 6:2 FTS is mainly used as a suppressant. The annual quantity for Germany is less than 10 tonnes. Since this chemical is only partly stable in highly oxidising electrolyte solutions, it is partially broken down into smaller fluoroorganic compounds, which are problematic to eliminate in waste water treatment.

While previous retention technologies existed for its precursor PFOS, they are now outdated. For 6:2 FTS, a similar development has not yet taken place and is not widely used due to its questionable future.

Non-fluorinated alternatives are not nearly as stable and usually lead to severe bath contamination by degradation products, resulting in higher rates of defective production and wasted resources.

The closed production systems recommended as an alternative technology release the aggressive aerosols. Therefore, the exhaust air areas require special chemical resistance, which can only be reliably provided by using piping and system components made of fluoropolymers. Neglecting to do so will lead to high maintenance requirements and resource consumption due to the frequent need for replacement parts. Leakage becomes more likely, increasing the risk to the environment and people through increased exposure.

Conclusions

Precautionary principle makes a comprehensive impact analysis necessary:

The very far-reaching approach of this restriction proposal requires a comprehensive impact analysis in line with the precautionary principle¹. This includes examining the costs and benefits of taking

¹ <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52000DC0001>

action or not (through an economic cost-benefit analysis). Furthermore, the REACH Regulation's mandate to maintain the economic strength of the EU must also be considered.

The precautionary principle requires a thorough assessment of the proportionality of measures, which is absent from the document. Additionally, there is no explanation of how the measures align with the desired level of protection.

According to its own statement, the Commission will apply the precautionary principle in its risk analysis only "in cases where the scientific basis is insufficient or there are uncertainties..."². However, in the case of unobservable risks, particularly for fluoropolymers and low molecular weight in PFAS such as PFHxA³, there is ample data available.

This document obviously contradicts the rules that the European Commission has set for itself to ensure adequate regulation!

A classification of the current inputs of the individual substances into the environment and their effects must be made

The significant environmental contamination at present is largely due to the uncontrolled use of PFAS in the past. To evaluate the effects of further use of PFAS, conducting a risk analysis on its use and the likelihood of release is crucial. This is essential to determine whether a ban would prevent or even cause harm.

The group approach is not chemically founded

The CF₂ group alone cannot describe the properties of the substances. The restriction approach completely ignores the other functional groups. In particular, equating low molecular weight PFAS with fluoropolymers is scientifically untenable.

The general group ban misapplies the restriction procedure

A total ban with the option to apply for exemptions actually results in an authorisation procedure, as it relies on authorisation-equivalent exemption applications. The proposed restriction thus deliberately bypasses the required rules of an authorisation procedure, such as review periods. This is not provided for in REACH, creates legal and market instability and discriminates against SMEs in particular by shifting the burden of proof again and creating high bureaucratic costs. The approach opens the way to an incalculable number of legal disputes over exemptions that have not been granted - because there are no generally applicable criteria for this in REACH.

The sometimes extremely low input quantities do not justify short transition times

In these cases (e.g. 6:2 FTS in surface technology), a ban procedure with fixed deadlines is not justified. Instead, targeted incentives for research into substitution options would be appropriate, without risking collateral damage to the economy and the market (in particular supply chain disruptions such as during and after the Corona crisis).

² CONSUMER HEALTH AND FOOD SAFETY, COM (97) 183 final, 30.04.1997

³ ANNEX XV RESTRICTION REPORT, PROPOSAL FOR A RESTRICTION, SUBSTANCE NAMES:

Undecafluorohexanoic acid (PFHxA), its salts and related substances, BAuA Federal Institute for Occupational Safety and Health Division 5 - Federal Office for Chemicals Friedrich-Henkel-Weg 1-25 D-44149 Dortmund, Germany, VERSION NUMBER: 1.0 DATE: 20.12.2019

Persistence is not a stand-alone risk criterion

Persistence describes the long-term fate of substances in the environment. This criterion applies to numerous natural substances, including salt, limestone (entire mountain ranges), petroleum, natural gas, coal, nitrogen, all ores and rocks, sand and various metals such as gold. Clearly, persistence is not directly related to "harmful" and "must be eliminated". This is true for the vast majority of PFAS, particularly - but not exclusively - fluoropolymers. Regulation under REACH cannot be justified unless there are clearly demonstrated health and environmental risks that are unacceptable.

Conclusion

For the above-mentioned reasons, the ZVO does not consider the proposal to restrict PFAS appropriate. The ZVO therefore urgently appeals to the decision-making bodies not to consider such a regulatory approach, the extensive consequences of which cannot be foreseen.

The criticisms are:

- A blanket regulation of all PFAS without individual risk assessment is rejected.
- The proposal is considered contradictory as it proposes a general ban and reverses the burden of proof.
- PFAS are important and necessary for innovation and technological progress.
- A far-reaching ban could be detrimental to the economy and environmental goals.
- A comprehensive impact assessment is recommended.