Orgalim Position Paper on the restriction of PFAS

Executive summary

Orgalim, representing Europe’s technology industries, welcomes the opportunity to comment on the proposed restriction for the group of PFAS (per- and polyfluoroalkyl substances). The competent authorities for REACH of the Netherlands, Germany, Denmark, Sweden and Norway are currently preparing a REACH Annex XV Restriction Dossier. They are considering proposing EU-wide measures covering all PFAS.

Our technology industries, major downstream users and article manufacturers are fully committed to reducing the content of hazardous substances in their products to support a more circular economy.

Here are our key messages on the proposed restriction:

➢ A general regulation of thousands of PFAS substances as one group does not have sufficient scientific basis and would therefore be disproportionate.

➢ The grouping of thousands of PFAS substances carries the risk that regulation would be too complex for enforcement authorities and thus not feasible.

➢ The PFAS regulatory approach being planned is contrary to generally accepted REACH principles, such as that there should only be restrictions in the case of unacceptable risks. Policymaking and decisions regarding chemicals should be risk-based, not hazard-based.

➢ The impact of a broad PFAS regulation on industry and product diversity would be significant. A ban on the production and use of a broad range of PFAS, but also of specific PFAS, would considerably restrict the innovative capacity of industries. Safe and durable products already on the market would no longer be allowed to be marketed. The European Union’s economic goals as well as the goals of the EU Green Deal would be hindered or endangered. The safety of products and their production processes (e.g., in aggressive environments) as well as occupational health and safety and environmental protection would have massive disadvantages in many areas as a result of a broad ban on PFAS. For instance, it would hinder the manufacturing of electrolyzers, which may prevent the goals of the EU’s Hydrogen Strategy and the proposed revision of the Renewable Energy Directive from being achieved. Moreover, the surface treatment industry (galvanic industry) would be highly impacted because PFAS are used for safety reasons, to reduce worker exposure.

➢ A lack of viable alternatives to PFAS substances means high socio-economic costs when trying to replace them. Exemptions should therefore be granted where no appropriate substitute is available.

➢ Due to the often highly complex international supply chains and the associated difficulty in analysing and preparing for the realistic impact of a ban on many thousands of substances, there is a great risk of unforeseen disruptions to supply chains with all the associated economic impacts. A sufficient amount of time is needed to analyse the precise impact of the ban per substance; this time has unfortunately not been granted.

➢ Double regulation should be avoided. For instance, F-gases are already covered by the F-gas Regulation and the Montreal Protocol.
Europe’s technology industries are fully committed to reducing the content of hazardous substances in their products to support a more circular economy. Our position and recommendations on the circular economy can be found here, and our comments on the REACH revision roadmap can be found here.

Moreover, we fully support the Chemicals Strategy for Sustainability published by the Commission. We also believe that substances posing an unacceptable risk due to their properties and use profile should be restricted or regulated, based on scientific assessment.

However, the current proposal to implement EU-wide measures covering all PFAS is not feasible for our industries.

First of all, the group of PFAS is not a single substance, but a class of substances containing more than 4,500 individual chemicals. Most PFAS are not classified as “hazardous” under the CLP Regulation. The planned comprehensive restriction of PFAS is primarily justified by the high persistence of many representatives of the substance group. Other reasons cited are the high mobility and the bioaccumulation potential of some PFAS substances. But not all PFAS are equally persistent nor equally mobile or bioaccumulative. Their hazard profiles differ considerably.

**A general ban based on the persistence of PFAS only would thus contradict the risk-based approach.** We support a risk-based approach instead of moving towards a hazard-based approach (which is the precautionary principle) because the risk-based approach is based on scientific evidence of how the environment and people are affected. As stressed by the Commission, the precautionary principle may only be invoked in the event of a potential risk and it can never justify arbitrary decisions. We reject the broad regulation of entire groups of substances irrespective of their actual risk – in the case of PFAS, several thousand substances.

**We also perceive a risk that restricting entire groups of substances to “essential uses” would violate the principle of proportionality.** According to this principle, only such measures may be taken that are suitable and necessary for the achievement of the objective (here: health and environmental protection) and do not result in disproportionate effects. This excludes prohibiting uses that do not lead to relevant exposures, even if they are not considered “essential”. These include, for example, uses of PFAS as process chemicals, intermediates under strictly controlled conditions, and substances in closed systems that can be disposed of properly. Furthermore, it does not seem necessary to ban the entire group of PFAS except for essential uses. Individual environmental protection measures and disposal strategies can be used to prevent their entry into the environment. Restricting the permitted use solely to uses that are necessary for the functioning of society (a concept that is hardly tangible) would exclude uses that are of great benefit to society (e.g. by increasing the durability, safety and resource and energy efficiency of products and articles).

**Fundamentally, the political limitation on essential applications leads to an inhibition of future developments, as it is not an objective scientific method and does not allow for planning security.** What is considered non-essential today has no chance of being developed further within the context of essential applications at a later date, as internal company compliance requirements would prevent research and development in this area. If the EU wants to continue to be a driver of innovation together with its industry, such a static concept cannot be effective.

Moreover, an article can only be substituted after the upstream chemical manufacturers have completed its substitution with viable alternatives, based on the needs and standards applied in each sector. There are many industrial applications for PFAS or PFAS-based materials (e.g. polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF, fluororubber), alternatives for SF6, aerosol suppressants, etc.). For a large number of these applications, there are no known substitutes in the short term. or for the foreseeable future, that have the unique combination of properties (chemical inertness, resistance to extreme temperatures, physiological compatibility) and outstanding technical performance, which is caused

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1 According to the OECD, Per- and polyfluoroalkyl substances (PFAS) are a large group of chemicals widely used in industrial and consumer applications since the 1950s, most usually where extremely low surface energy or surface tension and/or durable water- and oil-repellency is needed, e.g., chromium metal plating, various fire-fighting foams, or for surface treatment of textiles, carpets and papers. PFAS consist of a fully (per) or partly (poly) fluorinated carbon chain connected to different functional groups. (https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/)
by the very robust C-F binding. In the event of a broad PFAS ban, not only new, but also state-of-the-art technology and products will be restricted or become impossible to develop.

Thus, almost all of our technology sectors would be affected: mechanical engineering, electrical engineering, batteries, electrolysis, metalworking, aerospace, food contact materials, piping, cables, water treatment, clean room equipment...

Even if potential alternative substances to PFAS are identified, they might not always become a real and viable alternative. A substitute has to show the same level of performance after such a design change. Many industries have to comply with chemical and environmental regulations, but also with sector-specific stringent product-related regulations as well as performance and safety standards. There are many critical applications in our sectors for which PFAS are essential. Therefore, EU-wide measures covering all PFAS would also include substances that cannot be replaced today. In the event of a ban on all PFAS in the EU, huge disadvantages in health and safety, lifetime, resource and energy saving requirements would result. Sales markets would be lost for many EU goods, since they could no longer compete with non-EU goods in terms of quantity, quality, durability, resource efficiency, safety, technification and miniaturisation.

Finally, PFAS also have a crucial role to play in helping our industries move towards a decarbonised economy. Many PFAS are needed in high-tech applications. Such a broad restriction will be very likely to hinder future innovation. The foreseen restriction does not only address production or manufacturing, but also “use”. In many products with long lifetimes, PFAS are used and require maintenance over their lifetime. With such a restriction, this would become impossible.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.