General comments and answers to specific information requests

Introduction

We are not a manufacturer of PFAS, but are a plant operator in the chemical Industry and therefore use essential equipment that contains or is made of PFAS. Especially Fluoropolymers and Fluoroelastomers give technical characteristics that are relevant in terms of safety aspects for our production process.

Fluoropolymers and Fluoroelastomers are used in our production units in sealants, o-rings, fittings, diaphragms coatings in pipes, hoses, valves, instrumentation and all kinds of machines and equipment, as well as in gaskets, filter materials etc. Within this equipment, they feature essential technical characteristics.

Polymer of low concern

The proposed PFAS regulation covers about 10.000 substances, whereas about 50 substances of these are Fluoropolymers and Fluoroelastomers.

Fluoropolymers and Fluoroelastomers can be classified as PFAS based on their molecular structure. However, their toxicological and eco-toxicological profile is essentially different from the majority of PFAS substances.

Fluoropolymers and Fluoroelastomers are recognized by the OECD as safe materials: "PLC" = polymer of low concern (OECD, 1993 and 2009). They are non-toxic, non-bioavailable, non-water soluble and non-mobile molecules and therefore, of low concern from a human and environmental health standpoint. According to literature, they do not generate microplastics. Recent publications have demonstrated that Fluoropolymers and Fluoroelastomers are justifiable identified as PLC by looking at the criteria of polymer composition, molecular weight, weight percentage of oligomers, electrical charge, reactive functional groups, water solubility, particle size, polymer stability, thermal stability, to name a few (Henry, B. 2018), (Stephen H. 2022).

Unique technical characteristics

Fluoropolymers and Fluoroelastomers provide unique technical characteristics. In general they show far higher resistance against many chemical substances including acids, bases and organic solvents than non-fluorinated polymers and elastomers. In addition, Fluoropolymers and Fluoroelastomers can be used at much higher temperatures. Especially for combinations of strong or highly concentrated acids and bases with temperatures above 60°C or the combination of different hazardous chemicals, currently only fluorinated polymers and elastomers are suitable materials. For these applications no alternatives are available (see attached table for an overview). The reason for this unique characteristic is the chemical structure of the Fluoropolymers: The strong bond between Fluor- and Carbon-atoms in combination with a complete Fluorine cover of the long Carbon-chain provides high resistance against chemical attacks and high temperatures.

In order to provide the highest level of workers and plant safety, we are obliged to use Fluoropolymers and Fluoroelastomers for technical applications with hazardous substances by different regulations. Another example are the requirements to be met when producing Food or Pharma material in our plant. Equipment that is in compliance with Food and Pharma requirements, needs to be used. Suitable and approved materials are often fluoropolymers only.

The high stability of Fluoropolymers and Fluoroelastomers is also the reason for the long lifetime of gaskets, sealants, o-rings, coatings, diaphragms and filter materials etc. made of these substances. Emissions are neglectable during the lifetime of the material due to the high stability. Also, the amount of waste is low due to the long lifetime.

Dependency on new developments and approvals

Users as we would depend on new developments by the manufacturers of the equipment. At first, an alternative substance must be found, which provides the same resistance against chemicals, temperatures and pressure as well as similar mechanical properties. Once an applicable substance is found to substitute Fluoropolymers and Fluoroelastomers, the new part must be (re)designed. For the future it would be required that tailor-made solutions would be available. Several of our suppliers indicated that such tailor-made solutions would be difficult to develop due to the unique technical characteristics of Fluorpolymers and Fluoroelastomers.

In case those materials cannot be developed and validated within the timeframe intended by the regulation, a safe handling of those hazardous substances would not be given anymore. Subsequently we would need to stop manufacturing at our manufacturing site in Europe due to safety reasons. Continuity of our business would depend on the invest and the success of PFAS manufacturers make towards developing replacement material.

Given the condition that producers of PFAS would be able to develop replacement materials that express similar characteristics as e.g. Fluoropolymers and Fluoroelastomers, additional time would be required for approval of the materials by authorities and subsequent validation by users, before the materials can be implemented in manufacturing processes. The approval of the material by the authorities is seen as problematic, since only a certain number of applications per year can be processed by the authorities.

Time required on users site to validate if replacement material is comprehensively supporting the same application as PFAS did, or if further safety measures need to be installed, might be underestimated. Once newly developed replacement material is approved the manufacturer of equipment for industrial plants as well as the plant operator will need to verify if the material fits the equipment and purpose and is in line with the regulatory requirements on e.g. emissions (clean air act etc.). Hence we expect that the industry will need more time and a critical review of feasibility must be carried out in the future.

Market situation and future risks

Not only user of such hazardous substances as raw materials for the manufacturing process would have safety issues, but also our suppliers that produces those substances. If those would not be able to manufacture under safe conditions in Europe anymore, they most likely will end their business here (or in worst case close this business segment) and we would have to purchase our raw materials from outside of Europe. This would raise questions on sustainability (we have set up our supply chain to be able to purchase within a radius of mainly 500km), emission and environmental protection (in Europe the legislation and controls are by far the most restrictive ones already today) and security of the supply chain (we have seen the impact during Covid pandemic and the importance of purchase and manufacturing within Europe).

In respect to the supply chain, also our customer would be impacted by the regulation. We are supplier to customers in various market segments, such as Construction, Paint, Ceramics but also Pharma, Food, Nutraceuticals and Feed. The materials are used as excipients in the production of pharmaceuticals, as food additives in food and beverages, in semiconductors, photovoltaic cells and many other industrial applications.

Our company is within the top 3 suppliers delivering in the business segments Construction, Paint, Food and Pharma/Nutraceuticals worldwide. We have > 1000 customers worldwide, offering them several hundred of final products. At our site in Wiesbaden we employ a total of approx. 550 persons and generated a turnover superior than 550 Mio € in 2022 all businesses combined.

It is the goal of the EU commission to strengthen the industries that are relevant to the system and wellbeing of society, such as Pharma and Food businesses. With the current set up of the proposed legislation, we fear that the EU would move away from this goal.

Sustainability aspects

Replacement of existing equipment

Fluoropolymers and Fluoroelastomers are very robust materials which feature durability and longevity. Therefore, most equipment made or including Fluoropolymers and Fluoroelastomers are constructed to withstand 30 – 40 years or even more years within the manufacturing process. If now we would be required to exchange this equipment for other, Fluoropolymers and Fluoroelastomers free equipment, it would not only

have a strong economic impact but would also counteract the idea of sustainable usage of resources. Use of currently installed equipment should not be restricted, as those already existing materials have no additional impact on pollution by Fluoropolymers and Fluoroelastomers manufacturing nor would the dismantling support the reduction of emission. Solely the usage time would be reduced, which counteracts the goal of most efficient usage of resources.

Waste management and recycling of material

In the chemical industry, materials containing PFAS are disposed according to established and monitored processes, so that e.g. thermal recycling ensures that PFAS are converted into their harmless, non-persistent form, comparable to the thermal recycling of other polymers.

Even full recycling of Fluoropolymers can be conducted and by this circular management implemented (https://www.invertec-ev.de/projekte/umwelt-ressourcen-schonung/ptfe-recycling/ and https://www.element9.de/). Therefore Fluoropolymers and Fluoroelastomers do not pose an irregular concern to the environment.

Currently PFAS materials are only used where no alternatives are available (due to technical requirements, regulatory requirements etc.) since other material are less expensive. Therefore even in big plants the amount of PFAS materials installed in equipment is low. We are operating several production lines generating a maximum of 300kg of waste of Fluoropolymers and Fluoroelastomers per year.

Conclusion

Given the aspects mentioned above, we request for an exemption for the use of equipment made of or containing Fluoropolymers and Fluoroelastomers in the chemical Industry when handling the following substances or materials:

- Hazardous chemicals e.g. acids, bases and organic solvents
- Pharmaceutical Excipients
- Food Additives

This exemption is necessary for the listed applications as those rely on proper new developments. Otherwise a continuity of production in several areas is impossible. We therefore request that a re-evaluation should take place after 10 years to assess if suitable replacement materials have been developed by the manufacturers. If materials are available, a transfer period shall be set. For the time being however, already installed equipment should not fall under the regulation and shall not be removed, but shall be allowed to continue to be used until technically safe replacement material is available. The material currently in operation shall be used according to its foreseen lifetime before exchanging to the replacement material.

The proposed measures would generate the best benefit for producers and customers sustainability aspects.

References

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