PFAS in Slovenia

General remarks

The Slovenian chemicals industry sees the need for more balanced regulatory measures for PFAS. With around 10,000 individual substances, the PFAS-group is extraordinarily large. Many of the individual substances in this group are important for our modern economy, technology, and the functioning of society. A number of PFAS are used for the production of high-tech products and with this part of many solutions needed for a green transition. It is self-speaking that the Slovenian chemicals industry is highly committed that chemicals including PFAS are used safely and intelligently.

The chemical industry utilizes certain PFAS to keep fugitive emissions low, to have an efficient and robust production apparatus, and above all, to provide safe operations for the workers on-site. Many of these targets are also required by law and necessary for the license to operate. Modern emissions regulations require lower emissions and thus more and more technically tight sections, with modern equipment fitted with many more valves, gaskets and other pressurized vessels are used in plants. As a result, the use of fluoropolymers increases with the new generation of plants. It is currently not possible to operate most chemical plants without PFAS-based sealings.

Furthermore, our customers use PFAS in numerous societally very valuable applications like high-performance lubricants in wind turbines, in components of modern medical technology or in public transportation. In any case, a restriction, as currently proposed, would be a fundamental pressure point for Slovenia's industrial community. Consequently, while we support a constructive regulatory approach for industrial uses of fluoropolymers and fluoroelastomers, we need to highlight the widespread lack of suitable alternatives with all negative consequences for safety, environmental protection, the economy, and society as a whole. In a safe industrial and stable economic context, however, it is important that availability of suitable alternatives for critical applications is established before restrictions or bans enter into force. Most industrial uses of PFAS as part of the production infrastructure have no drop in alternative as of now.

Input via public consultation

The dossier submitters are using the 6-months public consultation as a systematic collection of requests for exemptions. We disagree to this approach and do not consider it in line with a good administrative practice. It is also practically not suitable for an average Slovene company. Consequently, this will lead to a very incomplete picture of the actual situation. The documents, which are made available are not available in Slovene, we cannot work with this and raise awareness. Our association also does not have the necessary resources to translate these documents. While the EU's administration invites and expects a wide participation of all EU's companies, they practically do not enable them to do so and exclude the majority of SMEs from participation.

Hazard, Risk and Grouping

The restriction proposal builds on the assumption that all approx. 10.000 individual PFAS-substances are hazardous and cause a risk. In our view, this is far-fetched and not a sound scientific approach. This we do not consider to be in line even with the precautionary principle and goes far beyond an evidence-based approach. This becomes even more evident in some

parts of the Annex XV dossier, when general conclusions for all PFAS are based on individual cases or on very small and in our view non-representative samples. This view we underpin that even in the dossier the submitters a few times recognize that their samples do not allow or allow only to a limited extent - an extrapolation of the data to the entire EU or EEA is not possible or only possible to a very limited extent. In some cases, even data only from non-EU countries is used.

PFAS are not a homogeneous group in terms of hazard characterization and consequently risk assessment. Since PFAS are not equal, we consider that there is no scientific basis for regulating them all equally. Consequently, we think that the dossier submitters took a political decision when grouping 10.000 PFAS-substances in one group based on very small sample groups and this is out of their mandate in a REACH-restriction-process. On top, the applied very simplistic grouping approach was done despite that the Annex XV dossier emphasizes that there are many different classifications for certain groups of PFAS and that there is therefore no coherent hazard profile for all PFAS. A very good example are fluoropolymers, which are non-toxic, non-bioavailable, non-water-soluble, and non-mobile molecules. This makes it incomprehensible what their significant impact on the environment and human health could be that justifies practically their full ban.

The restriction

The restriction proposal is not functional in its current basic structure or is based on a very simplified supply chain model. Many PFAS, however, usually have a very broad and varied use. In this respect, supply chains are long and branched. This makes it practically impossible for an end-user or an actor in the middle of the chain to be able to comply with a limit value at the same time as the initial distributor, unless it is accepted that the initial distributor can take full advantage of transitional periods and place PFAS-containing products on the market and then all downstream actors have to dispose of these products disproportionately quickly.

To solve this problem, supply chains would have to be divided into different stages. Each of these stages would then have to be assigned its own transitional period or case specific PFAS concentrations. A practical problem also arises when suppliers have to declare ingredients only with concentrations above 1%, while at the same time a ban with limit values in the ppb range is introduced. This makes compliance for downstream actors extremely difficult or even impossible.

Substitution and Alternatives

Alternatives to PFAS are intensively researched in many sectors, especially in the chemicals industry. The development of alternatives with a comparable and sufficient performance takes a few years to a few decades to become ready for the practical use. The search for substitutes is particularly difficult in complex supply chains like we see them for many PFAS-based materials. **Therefore, it is essential that time-limited exemptions are granted until such substitutes are sufficiently available on the market at affordable conditions, what can be far beyond the maximum proposed deadline of 13,5 years. Furthermore, our companies need concrete financial support in this transition process.**

PFAS improve our lives

Many PFAS applications clearly have a positive contribution to society. They are relevant for important strategic goals, such as the EU Green Deal, the EU Chips Act, the CSS, 5G data transmission and electromobility. These and many other technologies are based on PFAS. These include critical areas such as medical technology or semiconductor manufacturing.

We should not oversee that fluoropolymers were identified as strategic materials in a recent report published by the JRC ("Supply Chain Analysis and Material Demand Forecast in Strategic Technologies and Sectors in the EU – A Foresight Study"). A regression to materials of the industrial past would be clearly irrational and irresponsible in these areas.

Therefore, careful handling of PFAS should be encouraged. Purification methods and destruction methods for PFAS should be supported. Ultimately, one should assume that there will be socially relevant PFAS-applications for a long time to come.

Global competitiveness

Globally such a broad and over-simplistic restriction proposal will put us into a massive competitive disadvantage. There are no indications that other economic areas will abandon PFAS technology so drastically and a global PFAS-restriction on the same scale is not realistic. We confront the real danger that investments in strategically important industries like semiconductor industry in Europe will be scaled back and production will be relocated to other parts of the world. After the current PFAS-restriction-proposal EU-companies have no long-term legal certainty. Consequently, the restriction runs counter to the EU's current efforts to strengthen green industrial policy. In this respect the EU is already today lagging behind compared to the USA or Asian countries.

For example, the US-IRA (Inflation Reduction Act) is massively supporting green technologies in the USA through subsidies. That way environmental technologies can be produced cheaper than in the EU, which in the past years is keeping itself busy with regulatory micro-management, instead of reducing its dependence on China. In a small country like Slovenia, we can feel the negative impacts even stronger. **Considering this, the EU should stop being a frontrunner no matter the costs and negative impacts. In our legal strategy we should also consider the legal developments of other major areas.**

Example: Influence on pharmaceutical industry

An example of the economic sectors where the use of PFAS is critical is certainly the use in pharmaceuticals. A fluorine atom has some unprecedented properties. It is very small, highly electronegative and has low-lying C-F bond orbital. In the case of pharmaceutical active substances (APIs), this is reflected in increased interaction with target enzymes and higher lipophilicity, which significantly improves the biological availability of active substances. Since fluorine atom forms a strong C-F bond with carbon, it is strategically attached in pharmaceuticals to certain sites of planned compounds, as metabolic enzymes have a harder time metabolizing such compounds. Thus, the active ingredient stays in the body for a longer

time before being excreted, which makes it more potent[1]. These properties of fluorine atoms make also compounds with CF_3- and -CF_2- structural moiety (which are actually PFAS) very useful as active pharmaceutical ingredients. The use of some APIs with a PFAS structure is especially important in areas where there are no or very few alternatives. Such an area is, for example, the area of anticancer medicines. Because of that many active substances with a PFAS structure, are also on the WHO Essential Medicines List. Such examples are aprepitant, bicalutamide, efavirenz, enzalutamide and nilotinib.

However, if we want to ensure the full availability of such medicines also in the EU area, it is necessary to ensure that the production of both medicines and the active ingredients needed for these medicines will also be fully enabled in this area. This is only possible if it is also possible to access and use the starting materials, intermediate compounds and reagents and could be processed to the final medicine.

The influence of the PFAS ban is even more drastic if we take in consideration that the unimpeded and high-quality production of both active substances and medicines is currently only possible by using equipment that contains key elements (gaskets, seals, filters, sometime even vessels or piping) made mostly of polymeric PFASs, which have become dominant due to their universal resistance, and therefore often also the only suitable material for making equipment.

Further, it is crucial to enable unhindered development of synthesis processes of reagents, intermediates and active substances. Obstructing any of these may make the production of such a medicine in the EU impossible, and the result will be that the production will be carried out outside the EU. The final effect may be periodic drug shortages or even complete unavailability of certain drugs, even further consequence would be a decline in inventiveness in the field of pharmacy in the EU. Some of these effects are well known to us from the recent times of the COVID epidemic.

[1] a) E. P. Gillis, K. J. Eastman, M. D. Hill, D. J. Donnelly, N. A. Meanwell: Applications of Fluorine in Medicinal Chemistry. *J. Med. Chem.* **2015**, *58*, 8315–8359. b) D. O'Hagan: Understanding organofluorine chemistry. An introduction to the C–F bond. *Chem. Soc. Rev.* **2008**, *37*, 308–319. c) T. Liang, C. N. Neumann, T. Ritter: Introduction of Fluorine and Fluorine-Containing Functional Groups. *Angew. Chem. Int. Ed.* **2013**, *52*, 8214–8264.