Verband der
Chemischen Industrie e.V.
Wir gestalten Zukunft.

VCI POSITION ON THE

REACH Restriction Proposal for PFASs

Summary

Background/Issue

- The proposal of 7 February 2023 for a restriction of per- and polyfluoroalkyl substances (PFASs) pursues a sweeping – and ultimately complete – ban of thousands of substances with an immensely wide range of different properties. This also concerns all articles that are made of or contain PFASs.
- Certain PFAS products are indispensable in all sectors and value chains
  - as key components in many modern, high-tech applications, such as e.g. semiconductor production, energy, climate or medical technology and biotechnology;
  - for the safe and efficient operation of production plants, inter alia, as seals, gaskets, valves, coatings, membranes, lubricants, electrical insulators or safety clothing;
  - for research and development of innovative and sustainable technologies.
- The restriction proposal does not provide for exemptions for most of these applications. Consequently, they would be banned only 1.5 years after entry into force. Temporary exemptions of 6.5 or 13.5 years are foreseen for just a few, narrowly defined uses. After expiry of those periods, these uses would be prohibited too. If any application would be politically allowed that point in time, companies would need to apply for temporary exemptions individually following a lengthy procedure – or they would be forced to relocate their productions outside the EU.

Evaluation/Proposals for Solutions/Necessary Measures

- The intended blanket bans would have fatal impacts on industrial production in all sectors, job security, reliable planning for businesses, innovations and almost all high-tech applications – and thus on the future viability and resilience of Germany and Europe as industry locations.
- PFAS products can withstand extreme conditions (including high temperature and pressure differences, resistance to acids and lyes) while permanently retaining functionality and performance.
- In certain cases, these indispensable properties (especially durability and resistance/persistence), which are often needed under aspects of safety technology too, could also pose risks to humans and the environment if handling or disposal is not done properly. However, the same equally applies to any alternative, which must have similar characteristics for the respective uses and in terms of the required performance and functionality. For this reason, the focus should be on safe handling.

- A more differentiated assessment and regulatory approach is called for. This approach should consider the safe and sustainable use throughout the whole product life cycle and ensure long-term reliability for applications, planning and innovation. In order to create such a basis, e.g. broad and long-lasting exemptions should be established for certain substance classes, products and, in particular, for professional and industrial uses.
- **A thorough revision or an entirely new version of the restriction proposal is needed.**

In this position paper, the VCI describes why the draft needs thorough revision so that undesirable impacts and serious consequences for the environment, safety and the industry location Europe with jobs in the EU can be averted.

Key messages at a glance:

Regulate non-manageable risks based on scientific assessment – instead of a sweeping ban of PFASs!

The special properties of PFASs are indispensable for a functioning, innovative industry and for sustainable high-tech products!

Therefore:

- **Prevent a blanket ban:**
  Regulate potential risks based on scientific assessment – instead of taking an entire product group from the market.
- **Check the range of what is impacted**:
  Ensure that all uses of PFASs are known before interrupting production processes or eliminating important applications.
- **Take a reality check**:
  Examine the enforceability of the restriction proposal so that productions do not relocate abroad or products using PFASs are manufactured elsewhere and imported into the EU.
- **Provide for exemptions**:
  Establish broad and long-term exemptions for certain substance classes and products, for example, for fluoropolymers and for professional and industrial uses.
- **Allow transition periods:**
  Allow time to develop adequate substitute products and thus sustainable solutions.
- **Make good use of the potential of chemistry**:
  Support the strong innovation potential of chemistry instead of obstructing it. This innovation potential is the key for alternatives and the transformation of the economy.

Detailed Points of Criticism and Demands

Scope of the Restriction Proposal – Group Approach

- The dossier for the restriction of per- and polyfluoroalkyl substances is the most comprehensive restriction project since the entry into force of the REACH Regulation.

  The restriction proposal covers over 10,000 individual substances whose common characteristic is a fully fluorinated alkyl group (-CF_3 or -CF_2-) and a postulated persistence associated with this. However, the real intrinsic properties of the individual substances, their effects on health and the environment, their mobility and uses are immensely different from one another.

Evaluation:

- In addition to the lack of degradation properties in the environment or the decomposition into persistent degradation products, REACH also requires the risk to be taken into account. So regulatory measures can be initiated as is really necessary. In our understanding, proof of an unacceptable risk to human health or the environment is mandatory to trigger the restriction procedure. A restriction of substances in uses that pose no risk goes beyond the fundamental principles of REACH and thus exceeds the existing legal framework.
- Especially where there is no environmental exposure in specific uses and in handling or where such environmental exposure can be strongly minimised, a ban is not justified.

Proposals:

- A more differentiated assessment and regulatory approach is needed which bans only critical uses. Uses that do not pose any risk must not fall in the scope of such bans, as a matter of principle.
- Stronger focus should be given on the uses with the strongest impacts on the environment, considering the entire – and possibly global – value chain. We think that the differentiation between monomers and polymers would make a first, well-targeted approach.

Scope of the Restriction Proposal – Exemptions

- The scope of the restriction proposal excludes certain structural elements, as these do not meet the criterion of persistence because of their complete degradability. Moreover, the explanations on the scope of the restriction proposal describe fully degradable PFASs as excluded in principle.

- The restriction proposal includes general exemptions for active substances in plant protection products, biocidal products and medicinal products as well as a derogation for the calibration of measuring instruments and as analytical reference materials. In addition, there are various time-limited derogations for which transition periods of up to 13.5 years are proposed.

Evaluation:

- We welcome the open-ended limited exemptions and derogations.
- However, it is important that the manufacture of products that are not covered by the restriction or temporarily exempted must remain possible in the EU. Here, not only products falling under the PFAS definition but also end products that no not contain any per- or polyfluorinated groups are relevant. In this connection, the necessary raw materials, all precursors and transported intermediates as well as agents and products required in production must be explicitly exempted too.
- Otherwise, the substance exempted from the scope would be allowed in its end use – while its manufacture would be prohibited inside the EU due to the ban of the precursors. Consequently, such substances or articles for exempted uses could exclusively be imported from non-EU countries. This would stand in contradiction to efforts to enhance the EU's resilience and to reduce the dependence on imports.
- The exemption of certain structural elements is understandable.

Proposals:

- The legal text must make perfectly clear that the entire manufacturing process of products exempted from the restriction does not fall under the restriction, either.
- In the legal text the raw materials, precursors and transported intermediates for exempted or time-limitedly derogated uses exemption must be explicitly excluded from the restriction.
- The exemption of fully degradable PFASs needs to be clarified in the legal text. The description in the explanations on the scope of the restriction proposal is not sufficient. Irrespective of their chemical structure, fully degradable PFASs must not fall under the restriction.

Scope of the Restriction Proposal – Possible Exemptions

- The current restriction proposal specifies certain uses as time-limited derogations for which transition periods from 6.5 to 13.5 years are proposed.
- Further derogations are described as optional. These uses were considered by the dossier submitters but not proposed as derogations due to the lack of sound data. It is anticipated that detailed information will be presented in the consultation, so that these exemptions can be included in the restriction.

Evaluation:

- The existing and eventual derogations identify many important uses. All the same, we are under the impression that many further, highly important uses should be named as derogations.
- We have concerns about the approach which leads to a situation where companies are required to provide information (preferably in a depth of detail corresponding to that of an authorisation dossier and considering the entire value chain) for a wide range of different applications within a very short time. This is not feasible for industry. We find this approach disproportionate. From our perspective, it contradicts the principle that for a restriction, the responsibility for relevant information lies with the competent authorities.
- Even though other substances might be used, or alternative processes could be applied in theory in some cases, this does not mean that such a potential technical alternative would be the "better alternative" in a holistic view.

Proposals:

- The optional derogations must be maintained as real exemptions, even if industry is currently unable to submit comprehensive data within the consultation.
- Well ahead of the end of a time-limited exemption, it should be carefully assessed whether suitable alternatives are really available and can be applied in due course. Where this is not the case, the exemption must be extended.
- Regardless of the fact that intensive research is ongoing into potential alternatives for specific applications and alternatives might be possible in some individual instances, it must be taken into account whether and to what extent a changeover of existing processes can be realistically implemented by the impacted companies and the public authorities involved. Especially in highly regulated fields (e.g. the health sector), changes to products are subject to complex validations and might make new approvals necessary, possibly worldwide. It is essential to give consideration to the immense input in terms of time.

Interplay with Other Pieces of Regulation

- The proposed restriction of PFASs is not intended to invalidate other pieces of regulation. The restriction of PFASs in firefighting foams and the F-gases regulation are mentioned as examples for this interplay.

Evaluation:

- Alongside the restriction of firefighting foams, there are further restriction projects under REACH and other items of regulation that might be undermined by the new PFAS restriction. Given the restriction in the use of firefighting foams, the launched restriction of PFHxA, the rules on PFHxS (perfluorohexane sulfonic acid, salts and compounds), PFOS and PFOA in the POPs regulation and the F-gases regulation, a regulatory framework is already in place which defines the provisions on certain PFASs. This framework is being implemented and will be expanded successively.

Proposal:

- There must be no double regulation. No contradiction nor inconsistency to existing restrictions may arise.

Use of PFASs in Plants and Releases

- Certain PFAS products are indispensable for the safe and efficient operation of production plants, e.g. as seals, valves, coatings, membranes, lubricants, electrical isolators or safety clothing. A restriction would have serious consequences on plants (safety, processes, emissions), plant permit and production processes.
- Numerous pieces of regulation must be obeyed for operating industrial plants. They cover the use of perfluorinated compounds and products in plants as well as the requirements to leak tightness.
- In Europe plants of the chemical industry are subject to work-intensive and enhancing permit processes where the competent authorities examine whether the plant is safe to operate. For this reason, changes to existing plants are not easily feasible.
- Technical regulations and laws impose strict conditions for emissions. Moreover, the industry is continuously working on further improving its processes.
- The F-gases regulation makes requirements to avoiding emissions of fluorinated greenhouse gases from cooling, climate and heat pump systems and their recovery.

Evaluation:

- In many plants it is very difficult or impossible to substitute fluoropolymers. Analyses of potential, technically feasible alternatives show major disadvantages.
- Prior to a ban, all applications and the availability of suitable alternatives must be considered entirely and comprehensively.
- Technical regulations and laws impose strict conditions for emissions. Moreover, the industry is continuously working on further improving its processes.[1]
- Even if an alternative is available, the switch of plants and production processes is highly time-consuming. It is necessary to make realistic assessments based on all framework conditions to be observed and to attune transitional periods to these.
- A ban of PFASs from the components of chemical plants would have no positive effect on PFAS emissions. Quite the contrary, such a step would considerably increase diffuse emissions of potentially hazardous substances.
- F-gases are already regulated by Regulation (EU) No 517/2014 (F-gases regulation) and Directive EU No. 2006/40/EC (MAC directive), which ensure their safe use throughout the entire life cycle.

[1] A more detailed substantiation is given in the annex to this document.

- In addition to the restriction of firefighting foams, REACH as well as other areas of legislation provide adequate options to minimise risks in the use of specific PFASs in a targeted manner.

Proposals:

- As a matter of principle, the use of fluoropolymers in plants should be exempted from the restriction.
- Production and use of plant components and necessary spare parts need to remain possible in the EU.

Chemical Synthesis

- There is no exemption for the use of PFAS in chemical synthesis.
- Due to their specific reactivity, certain fluoroalkyl compounds are used in chemical synthesis as reagents, solvents, intermediates, protective groups or catalysts to enable highly targeted reactions.

Evaluation:

- Certain – also non-polymeric – PFASs are used in production processes to achieve a high selectivity of a reaction or to allow the carrying out under mild conditions. Without PFAS reagents, for example, the manufacture of certain medicinal products is no longer possible, also in cases where such medicines themselves do not fall under the PFAS definition.

Proposal:

- Regarding the industrial use of PFAS it is, therefore, necessary to do inter alia a thorough socio-economic analysis before a ban. This analysis needs to include the end product as well as the entire production chain.

Research and Innovation

- The restriction proposal does not include an exemption for product and process-oriented research and development (PPORD).

Evaluation:

- In practice, a ban of more than 10,000 PFAS substances from the chemical “toolbox” would mean that these substances and fluorochemistry in general are no longer available for innovation in the EU. In several areas (high-tech, medical devices, pharmaceuticals, chemical synthesis, …) PFASs are also used for research purposes in order to develop innovative products – irrespective of whether the end products contain PFASs or not. Research opportunities, which are important especially for making the transformation and the success of the European Commission’s Green Deal initiative, would be severely hampered by the non-availability of PFASs. It is also worth noting that PFASs are frequently used for materials in equipment, devices and plants for research, such as routine analysis – because these require high compatibility with an extremely broad spectrum of chemicals and a low contamination potential for the substances to be analysed.

Proposals:

- R&D and innovation must remain possible in Europe.
- In order to keep innovative developments in Europe, it must also to be possible to further use substances and articles, which fall under the PFAS definition, in both R&D and PPORD.
- The use in equipment and devices required for research and testing/analysis must remain permitted.
- The restriction proposal must include a specific exemption of PPORD.

Annex: Background Information

1. Examples of necessary exemptions for the chemical-pharmaceutical industry

The restriction proposal contains a listing of use sectors for which time-limited exemptions are being planned. In our perception, however, the use of PFAS in industry is taken into account only insufficiently so that further additions become necessary. From the perspective of the chemical-pharmaceutical industry, inter alia, the following sectors are of major importance:

Use of Substances:

- **Synthesis:** Given their specific reactivity, certain fluoroalkyl compounds are used in chemical synthesis as reagents, solvents, intermediates or protective groups to bring about targeted reactions and avoid unwanted by-products. This can also be essential in processes that do not generate PFASs as end products, for example, in the synthesis of peptides.

- **Catalysis:** Certain fluoroalkyl compounds can support specific reactions as catalysts. For example, catalyst systems containing triflate can result in esters and acids of any long-chain and highly branched olefins. At present, there are no alternative production processes for this. Furthermore, the process is characterised by mild conditions, high yield and high selectivity. It contributes to resource conservation, requires low energy and helps reduce waste. The catalyst system is not in the end product but remains in the reaction system.

Articles used:

- **Gaskets:** Fluoropolymer-based gaskets have an important role in the entire processing industry, e.g. in the manufacture of foods, medicines, semiconductors, basic chemicals or certain chemical and pharmaceutical products. Due to their chemical resistance (safety aspect) and physiological safety (FDA license/USP class), fluoropolymer-based gaskets are used in the chemical-pharmaceutical environment as standardised industrial products. PFAS-based seals are mandatory in many cases to enable the safe and license-compliant operating of plants for the manufacture of basic chemicals under extreme conditions or where high purity is required. Other than manufacturing, fluoropolymer-based seals and gaskets are also used in plants for the transshipment of chemicals and in the relevant means of transport (rail tank cars, road tankers, tankships, containers etc).

- **Fittings (general) and pressure-bearing accessories (e.g. valves, strainers)**: In plants of the chemical, pharmaceutical and semiconductor industries, fittings and pressure-bearing accessories are frequently exposed to aggressive and corrosive media which they need to

withstand reliably and permanently. Materials that do not withstand these forms of stress pose immense safety risks.
Practically all valves with high requirements to tightness consist of fluoropolymers entirely, are lined with them or at least need fluoropolymer gaskets. In many cases, the non-availability of PFAS-based materials will lead to a situation where the use of alternative materials can no longer meet the very high tightness requirements under environmental law (e.g. German technical instruction air on quality control with regard to diffuse emissions "*TA Luft*"). Moreover, membrane valves with PTFE membranes are prescribed and specified in numerous pharmaceutical processes because of their chemical resistance.

- **Lined piping systems and hoses**: Many processes in the chemical and pharmaceutical environment make high demands to the materials to be used (e.g. regarding corrosion and reaction resistance). In these cases, inter alia, there are lined piping systems made of fluoropolymers (PTFE/PFA) to prevent corrosion or other reactions with the material of the piping or the tubes and thus to avoid impurities in products. In addition to these special requirements, piping and packaging materials must fulfil the legal requirements to tightness to the outside (WGC, BREF ex IED). The production and transport of hydrogen is just one example of the use of sealing and lining polymers. In this area, the safety requirements are particularly high. Fluoropolymers (ETFE products) are stipulated without alternative for reasons of operational reliability, the above-mentioned legal requirements to tightness (German "TA-Luft") and the additional rules under explosion protection. Especially with regard to the energy transition and the demand for hydrogen, this use is becoming even more important.
  Tubes made of fluoropolymers (e.g. PTFE) are used, for instance, in the pharmaceutical industry and in the filling of substance-based medical devices. They are also relevant for the filling of chemicals, sampling and analysis technology. Mainly the high requirements to purity make their substitution impossible.

- **Membranes**: Membranes/diaphragms made of fluoropolymers are used, inter alia, in electrolysis processes. For example, their use in chlorine production largely substitutes asbestos and amalgam processes – modernising matters up to mercury-free, asbestos-free and less energy-intensive processes for the manufacture of basic chemicals. If suitable membranes can be no longer used in this process, in the future the production could not continue. Over 95% of the European chlorine production as well as caustic soda production would be eliminated and, consequently, almost the entire value chain based on this. Membranes made of fluoropolymers are also needed in electrolytic hydrogen production.

  Beside the uses in electrolysis, membranes made of fluoropolymers are used as filter membranes for micro- and ultrafiltration in the purification of drinking water and wastewater, for sterile filtration in the manufacture of medical devices and medicines, and in

biotechnology. They are also important components in diaphragm pumps and (pressure) sensors.

- **Flame protection in sensitive areas**: For reasons of safety technology, certain construction components must be equipped with flame retardants. Many electrical and electronic applications are necessary for realising digitalisation and the energy transition. The grid infrastructure, digital end devices and electric vehicles are just a few examples. Flame-retardant cables, plastic casings and components can be necessary for the functionality and service life of the said products. A restriction must not make it impossible to comply with fire safety rules or the conditions of insurers. Also, productions in Europe might be abandoned.

- **Semiconductors and chips**: To produce semiconductors, PFASs are needed as process chemicals and materials in plant construction – with extremely high purity requirements. Very strong acids (hydrofluoric acid and nitric acid) are used in the production of high-purity silicon. This is only possible in plants with fluoropolymer lining and plant components made of fluoropolymer materials that can permanently withstand the extremely corrosive properties of the acids – while completely excluding metallic impurities even in the ultra-trace range. Plant components, holders, sealing materials and special formulations containing PFAS are also used for evaporation deposition and etching processes, photolithography, the central process step in semiconductor production. The required high purity and the tightness of the plant can only be ensured by using perfluoro-based components. Chip production is not possible without using PFAS and fluoropolymers. The production of high-purity polysilicon (ca. 50% of the world market) and semiconductors in the EU would have to be abandoned. This contradicts the ambitious EU Chips Act which wants to reduce the Union's dependence on semiconductor production outside Europe.

- **F-gases**: In most cases, F-gases are intended for use in closed systems and end-of-life recovery. They are not intended for release into the environment, except in highly specific applications such as metered-dosed aerosols for the administration of pharmaceutical active ingredients (e.g. for asthma treatment).

In addition to the above-described uses which would directly impact the chemical-pharmaceutical industry, there are many further applications (for example, in protective equipment, medical technology or the building sector) that might also affect the industry. In this respect, we would refer especially to the overview given by the Federation of German Industries (BDI).

Appraisal / Impact:
The uses of per- and polyfluorinated alkyl compounds are complex, diverse and vary in character. All of them need to be examined according to the existing legal provisions before deciding on their ban or exemption. Here, it is essential to also check carefully whether there are

suitable alternatives for individual applications that might be affected by a PFAS ban: In our view, this is not the case for the above-mentioned examples, due to the given requirements to materials. The submitting authorities, too, state in the dossier that no alternatives are available, for example, for PFAS gaskets. However, this is ignored in the draft legal text. Even though other substances might be used, or alternative processes could be applied theoretically in some instances, this does not mean that such potential technical alternatives are “the better” ones. This subject needs a precise analysis which includes, first and foremost, the safety-relevant aspects (plant safety, emissions into the environment etc) but also energy consumption, service life, product purity and further factors. When assessing technical and industrial uses, special consideration should also be given to future-oriented technologies such as the production of hydrogen as an energy source or the demand for digitalisation. The energy and transport transition and the entire transformation of the economy call for new plant technologies. While it was still possible to seal piping systems for fossil fuels with simple elastomers such as acrylonitrile-butadiene rubber (NBR) or even hemp, the hydrogen industry and battery production need much lower diffusion rates and higher product purities in the sealing material. This can be achieved only with PFAS polymers.

It is therefore necessary to carefully assess whether suitable alternatives are available in good time before the end of a time-limited exemption. Even though intensive research on potential alternatives for specific applications is ongoing, it must be considered whether a changeover is realistically possible in the remaining time or whether an exemption should be extended.

Furthermore, it should be considered to what extent a change in existing processes is realistically feasible for the impacted companies and the public authorities involved. Especially in highly regulated areas (e.g. the health sector) changes to products are subject to complex validations and might require new approvals, possibly worldwide. This input in terms of time needs to be taken into account in the implementation of potential alternatives.

The consequences – such as the lack of basic chemicals and raw materials, the necessary supply of spare parts for running, repair and maintenance of existing plants – to the entire downstream value chain should not be forgotten, either. An ensuing early decommissioning and disposal would cause disproportionate and avoidable burdens on the environment and society.

Moreover, the extremely wide scope of the restriction, low thresholds and the manifold different PFAS applications in diverse fields of industry and society result in a very high risk of missing essential uses of PFAS in the definitions of much needed exemptions. Complete identification, assessment and communication of each individual case is extremely difficult for complex products and multi-stage process and supply chains. There is the great risk of not identifying essential uses in due time.

Demand: The use of fluoropolymers in industrial applications/plants, including the necessary spare parts, must be fully exempted from the restriction. It must be possible to continue operating plants. We urge the legislator to recognise the expertise of impacted companies regarding further necessary exemptions and to give special consideration to the specific feedback received in the consultation.[2]

Regarding possible exemptions for which detailed information is to be submitted in the consultation so that these exemptions could be incorporated in the restriction, we have concerns about the course of action: Ultimately, companies are required to apply within a very short period of time for exemptions for their manifold uses – preferably in a depth of detail that corresponds to an authorisation dossier with regard to the entire value chain but without being able to anticipate the likelihood of success. Firstly, this is an impossible effort for industry. Secondly, in our understanding the said approach contradicts the principle that, in the event of a restriction, the responsibility for the relevant information lies with the competent authorities. This course of action is disproportionate.

We propose that the named exemptions remain in the restriction proposal for the time being.

2. Use of PFAS in plants

Numerous pieces of legislation must be observed for the operation of plants in industry. These cover the use of perfluorinated compounds and articles in plants as well as the requirements to tightness.

Industrial processes must be sealed safely and reliably to the outside, so that chemical and pharmaceutical products and foods can be produced with safety for consumers and the environment. In many cases, fluoropolymers are used for this purpose, with several decades of operating experience.

Several fields of chemical plant construction depend on perfluorinated alkyl compounds. Existing analyses of technically feasible alternatives identify the following risks, even though quite often materials with much more favourable pricing would be used:

- Not “proven-in-use”
- Reduced usage phase of plant components
- Poorer possibilities to clean plant components (GMP) and thus increased waste generation and impurities in production
- Higher leakage rates and diffuse emissions, resulting in rising emissions of chemicals into the environment

[2] In particular, we would refer to the positions and the information contributed by the Federation of German Industries (BDI), the German Mechanical Engineering Industry Association (VDMA) and CEFIC / FFP4EU.

- More maintenance effort
- Costly construction with disadvantages for energy (bellows seal instead of PTFE packing)
- Higher fire hazards due to friction and leakage risks
- Higher insurance premiums
- Higher total costs
- Non-compliance with legal requirements

The restriction dossier does not give consideration to the above points.

Chemical industry plants in Europe are subject to a licensing procedure where the competent authorities examine whether the plants meet the legal requirements. Involving a major effort, this procedure is lengthy and must be repeated in the event of relevant changes and planning. Therefore, changes to existing plants cannot be made without considerable input in terms of time and money. It must be ensured and substantiated that even without using PFAS polymers, the necessary protection of humans and the environment from gaseous and liquid leakages is safeguarded by alternative sealing and ventilation systems and, for example, that the requirements under the TA Luft can be complied with. Where no suitable alternatives are available, plants might need to be shut down or, if possible, converted to other processes should PFAS-containing spare parts be needed.

The time-intensive licensing procedure means that changes to processes in the chemical and pharmaceutical industry, should they be technically feasible, necessitate a sufficiently long planning phase and very high investments. Such a conversion can be implemented only if application-specific substitutes are available which have at least the same performance and service life, particularly in demanding conditions – so that plants can continue to be operated safely. The longevity, i.e. the persistence, of materials is an important property for the safety of processes. Moreover, process changes in chemical reactions usually lead to changes in the composition of the resulting reaction products. Intermediates and end products must be respecified in tedious testing and released for their respective intended use.

According to experts, there are currently no adequate substitutes to continue operating the numerous impacted plants in a manner that is fit for the future and would justify the expense of once more going through the plant licensing procedure.

In cases where no alternatives are available, a completely new development of materials would become necessary even though their success is not guaranteed in any way. Chemical and pharmaceutical production plants, which depend without alternative e.g. on piping systems and reactors with PTFE inside lining, would be shut down in the EU – with complete productions being relocated to countries outside Europe. That would result in a stronger dependence of the EU on imports and counteract the efforts for European sovereignty.

A restriction of PFAS must consider the impacts on plants and production processes imperatively and include appropriate exemptions. Furthermore, it is important to have spare parts available for plants so that their long utilisation phase can be ensured – also with a view to sustainability.

3. Emissions and Releases/Discharges

The handing of chemical substances is comprehensively regulated by law in Europe. Manufacturers and importers of substances are subject to extensive legal provisions on chemicals. Furthermore, supplementary national requirements exist.

In Germany, a comprehensive set of technical legal rules is in place to prevent the release or discharge of substances. These include, inter alia, the German regulation on plants for the handling of water-hazardous substances and the hazardous incidence ordinance. The German wastewater ordinance governs the discharge of PFAS-containing wastewater in Germany, implementing the provisions of the European Industrial Emissions Directive (IED). Under the IED, emissions into water bodies must always be kept as low as technically possible.

In addition, for some time now there have been requirements to the use, restriction and ban of individual substances or applications such as, for example, PFAS-containing fire extinguishing foams during firefighting operations and drills. This considerably reduces or already fully avoids PFAS releases which caused soil contaminations in the past. The IED includes elements of precautionary soil protection too.

The same holds true for emissions to air. Extensive EU legislation (IED) and, in particular, national ordinances (e.g. the German *TA-Luft*) serve to void PFAS emissions. The *TA-Luft* additionally stipulates that components (such as flanges or pumps) must not exceed certain leakage rates. Thus, complex tests of components become necessary. At present, alternative components are not available at all or they do not meet the same requirements. This creates a conflict between avoiding diffuse emissions and phasing out of substances.

The non-leakage requirements of *TA Luft no. 5.2.6* cannot be achieved without fluoropolymers in combination with exacting chemical and physical conditions. It must be prevented that the requirements of the *TA-Luft* regarding the demanded rehabilitation of plants until the end of 2025/2026 and new stricter technical standard specifications to the non-leakage of media-transporting construction components – together with a general substance ban – result in a forced shutdown of plants due to a lack of alternative sealing materials. Moreover, the “Sevilla Process” and the ensuing BAT reference documents formulate requirements to avoid emissions from occurring in the first place or to limit them to an absolute minimum in an environmentally compatible manner. For example, the LVIC[3] BREF[4] is currently collecting information on emissions in water and air. The existing TXT[5] BREF prescribes to examine the substitution of PFAS in textile manufacture.

Nothing points to the use of PFAS in components (e.g. franges or PTFE-lined piping) to cause PFAS emissions into air or water. Emissions of PFAS are excluded even in the case of damage or when using very corrosive substances.

[3] Large Volume Inorganic Chemicals

[4] BAT reference document

[5] textile

Laws and technical regulations impose strict requirements to prevent emissions. Moreover, industry is working continuously to further improve its processes.

A ban of PFAS in the components of chemical and pharmaceutical plants would have no positive effect on PFAS emissions. Quite the contrary, such a ban would significantly increase diffuse emissions of potentially hazardous substances.

4. Waste and Recycling in Industry

The handling of waste is comprehensively regulated by law. Waste producers, owners, transporters, collectors, brokers, and traders are subject to extensive waste legislation both in Europe and Germany. The same applies for waste management, recovery, disposal and shipment across national borders. These legal rules apply, of course, to PFAS-containing waste too.

The central waste legislation is the EU Waste Framework Directive in the European Union and the Circular Economy Act (*Kreislaufwirtschaftsgesetz/KrWG*) in Germany. This is supported by comprehensive subordinate sets of legal rules. In particular, WFD and KrWG stipulate that waste disposal must be carried out in such a way that the well-being of humans and environment is not affected and that it does not cause any harm. Waste disposal is divided into waste recovery (material or energy) and waste elimination. As a matter of principle, waste recovery has priority over waste elimination. Section 7 KrWG explicitly states the following: *"The recovery of waste, especially via the binding of waste within products, shall take place properly and safely. Recovery shall be deemed to take place properly if it is effected in compliance with the provisions of the present Act and with other provisions of public law. It shall be deemed to take place safely when, given the nature of the waste, the level of its contaminants, and the type of recovery, no adverse effect on the public interest can be expected, and in particular when no accumulation of harmful substances occurs within the substance cycle."* This applies, of course, to PFASs too. Should the protection of humans and the environment not be adequately safeguarded in waste recovery, waste must be disposed according to the "waste hierarchy" prescribed in sections 4 and 6 KrWG.

One way of removing organic pollutants – and thus also PFAS – from the substance cycle is waste incineration. In the chemical industry, this is usually done in hazardous waste incineration plants. In the municipal sector, waste incineration takes place in municipal waste incineration plants. Regarding waste incineration, EU environmental law lays down clear rules through the Waste Incineration BREF, according to which plants must comply with existing limit values and, consequently, need to have the necessary POP destruction efficiency.

Waste of fluoropolymers are disposed in suitable waste incineration plants with appropriate waste gas purification systems according to the state-of-the-art and without strains on the environment caused by persistent PFASs, so that negative environmental impacts can be demonstrably excluded according to the current state of knowledge.

The transition from the waste regime to the product regime is clearly regulated, too. Here, the following is laid down in section 7a KrWG *"Natural or legal persons using or placing on the market for the first time substances and objects with end of-waste status shall ensure that such*

substances or objects satisfy the applicable requirements under chemical and product legislation.“ Further details on the end-of-waste status can be found in Article 6 WFD and section 5 KrWG.

These provisions of the waste legislation and neighbouring fields of the law already now ensure a high level of protection for humans and the environment in the handling and disposal of PFAS-containing waste streams at all levels of the waste hierarchy (continued use as product, preparing for reuse, recycling, others, recovery, elimination). If necessary, additional measures should be prescribed applying scientific criteria and in a targeted manner for individual substances and substance streams – on the basis of a risk assessment and within the existing legal framework.

This means for the circular economy and waste disposal that there is no reason for an overall further tightening of product law requirements for the entire substance group of PFASs.

However, there is the danger of a PFAS ban significantly impairing the circular economy as regards the usability of recycling products from mechanical recycling. Here, it is a challenge that the composition of waste is often not fully known.

Due to the existing diverse uses, PFAS-containing waste streams cannot be avoided in the future, either. Further research efforts are needed for the recycling of PFAS-containing waste. This is difficult because material purity cannot be guaranteed in most cases. Implementation of the planned PFAS restriction puts at stake the research efforts in this area.

For fluoropolymer articles, the additional problem would arise that the product uses for recycling products would cease to exist. The recycling industry would then abandon the relevant recycling processes. Moreover, this would adversely affect the closed loops for plastics.

Just like other facilities of the process industry (see above), waste treatment plants and parts of hazardous waste incineration plants cannot be operated without materials made of fluoropolymers (e.g. PFTE, PVDF, PVA).

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