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Contribution to the Consultation regarding the "Restriction on the manufacture, placing on the market and use of PFASs"

Dear Sir or Madam,

this paper is submitted on behalf of the companies AllessaProduktion GmbH, WeylChem Höchst GmbH and WeylChem InnoTec GmbH in contribution of the consultation regarding the "Restriction on the manufacture, placing on the market and use of PFASs". The companies all are part of the WeylChem Group of Companies.

The companies are, among other activities, manufacturer, importer, downstream- and end-user of PFAS intermediates, active ingredients and chemical end products and articles.

We manufacture and import PFAS-Intermediates, at the time being only such with one CF₃-Group at an aromatic ring, for further synthesis of other substances.

The other substances may also be intermediates, which are either further processed on site or at the site of a third party. They may also be directly exported.

Some of the intermediates are processed in the synthesis of active ingredients for agrochemicals (like Luna®, Zorvec®, Orondis®, Plenaris®, Lumisena® and others) or pharmaceuticals (Fluoxetine, Mefloquine, Leflunomide, Nulitamide, Dutasteride, Bicalutamide, Aprepitant, Celecoxib, Fipronil, Fluazinam, Penthiopyrad, Picoxystrobin, Fluridone, Norflurazon, Sorafenib, Trifluridin and more). PFAS are also used as intermediates or chemical end products in the manufacturing of novel batteries as power storage in electro mobility or for renewable energy as well as for the manufacturing of modern electronic high tech devices, such as display technology.

Some of them are produced in low tonnage bands or are still in R&D-stage. Most of the products require a sophisticated multistep-synthesis, with several PFAS as onsite intermediates. This fact gives the illusion of a higher number and tonnage of PFAS, while in fact it is a significant lower number of substances, which will really be brought to market.

Intermediates are in the current draft definitively not specifically exempted from the planned restriction. If this will not be changed, then as a consequence also the manufacturing of respective active ingredients, final products, articles etc. will get lost in Europe and will be manufactured outside the EU. Not even such products, which are foreseen as exempted, will then be kept in the EU, because the required raw materials may not even be imported.

We are also end-user of Fluoropolymers (PTFE, PVDF....) in our production equipment. We use PFAS-containing equipment, e.g. pipes, valves, pumps, seals, PFAS-coated reactors, equipment totally made of PFAS (e.g. Absorbers, tanks..), and many other. A lot of chemical equipment in the chemical industry is designed for multipurpose use. Therefore

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seals, coatings etc. must also be selected for such use and cover a wide range of applications. This use is crucial for our sites, because most of the processes need highly corrosive chemicals like sulfuric and hydrochloric acid, solvents which prevent usage of other polymers and high temperature resistance.

Fluoropolymers are used as seals and to protect non-resistant materials, like steel, by means of lining or coating. Most chemical productions could not be done at all without these materials. This includes, for example, all chlorination and bromination, all reactions in which hydrochloric acid or other aggressive substances, solvents or gases are used or formed or where higher temperatures are needed.

Therefore, e.g. almost all exhaust air pipes and scrubbers are made of these materials or at least lined or coated with it. Due to high demands on the tightness of systems to avoid emissions and leaks, other currently available materials can only be considered as substitutes to a very limited extent and are all no less persistent in the environment. This can be easily checked by looking at the material property and application tables available online from manufacturers of seals, hoses, drums, coatings and liners. As the new German TA-Luft has tightened the requirements regarding emissions from such equipment even more, this is even more difficult to achieve with other available materials.

If fluoropolymers will not be exempted from the restriction at least until suitable and permitted alternatives are found, then short term closure of many manufacturing facilities in the industry will result. It must be possible to continue the use of operating parts, which are already installed, for indefinite time, because replacing them without necessity would cost huge investments in a short time and would also entail production downtimes of months to years (for special equipment). No company can handle that. That would also exceed the capacities of the disposal and recycling industry as well as most manufacturer of alternatives.

If the use of such materials is no longer permitted without any substitutes available then the EU will face the most massive wave of de-industrialization ever. This will affect all branches of industry and not just the pharmaceutical and chemical industries.

This also applies to future technologies, such as energy storage and battery technology, modern electronics and displays, high-performance materials, climate and heat pump systems, electro mobility, mechanical engineering etc., as well as pharmaceuticals and crop protection. Even R&D will be hit, because many equipment and synthetic building blocks will no longer be available. R&D on the field of PFAS will no longer be required, because that will then take place in third countries in future.

The socio-economic impact will be extreme in Europe, which then will be fully dependent on foreign countries with all environmental and political implications this will have. And all this will take place with no benefit for the environment at all. In the opposite, it's going to get rather worse than better, because the majority of known alternatives usually show poorer performance, higher attrition and lower durability, which leads to shorter maintenance intervals, system failures and higher waste volumes.

From a psychological point of view, this draft regulation is already devastating. Investment projects are postponed or completely reconsidered. Obviously, in Europe one can no longer be sure that one's investments will pay off when the floodgates are open to such arbitrariness.

We fully agree that PFAS, which have been shown to be very harmful and for which a suitable and equivalent alternative is available, should be substituted. However, this must be done on the basis of an individual case by case decision or for small groups of substances and defined applications, like in case of PFOAs and firefighting foams, but not by a blanket ban on an entire class with many thousands of substances and countless applications and articles.

In addition, the justification should explain exactly why the individual substance or group should be banned and what alternatives are available, using scientifically sound studies. Otherwise, the fatal suspicion arises that chemicals policy wants to ignore scientific and economic facts for reasons of convenience or political expediency. "We don't know anything, so it must be banned" is not a confidence-inspiring approach. This will lead us back to the Dark Ages. That is exactly the message of this draft.

2. Emissions in the end-of-life phase:

Regarding the PFAS-intermediates the manufacturing and use takes place under strictly controlled conditions as stipulated in Art. 17 and 18 of REACH. The end-of-life phase is the next reaction step, where it is totally consumed in the synthesis of another substance. Emissions like waste water, air emissions, waste are minimized and controlled according to the national and European regulations and the permissions of the authorities.

In the case of active ingredients for the agricultural and pharmaceutical industries, the risk management and the estimation of the end of life phase is considered for approvals according to these regulations.

The manufactured substances for electronic devices, displays and batteries are in our company at the time being produced in small quantities and/or are at R&D-stage. Because these substances are toll manufactured for customers, we have no information about the end of the life cycle. Most likely most of these substances will no longer be manufactured in the EU when reaching the commercial scale, if the restriction gets in force.

3. Emissions in the end-of-life phase (Recycling and deposition):

The handling of waste is regulated comprehensively by law and is subject to extensive waste legislation in both Europe and Germany. The same applies to waste management, waste recycling, waste disposal and waste shipments across national borders. Of course, this also applies to all waste containing PFAS.

Waste containing PFAS that cannot be recycled, especially e.g. non-polymeric PFAS, is incinerated in the chemical industry in hazardous waste incinerators (SAV). The efficiency of such systems in Germany and Europe is very high, even municipal systems achieve well over 90% destruction of such compounds. In these plants, the fluoropolymers are fully mineralized and/or emitted as HF and CO₂. The requirements of waste legislation and related areas of law already ensure a high level of protection for people and the environment for the handling and disposal of material flows containing PFAS at all levels of the waste hierarchy (further use as a product, preparation for reuse, recycling, other recovery or disposal).

Scrapped equipment made of PFAS-coated or -lined steel this is normally recycled by the steel industry. The temperature of such process is more than 1.500°C. Under such conditions, the PFAS content will be destroyed completely.

5. Proposed derogations – Tonnage and emissions:

None of the proposed derogations is applicable for our uses. The fluoropolymers (PTFE, PVDF...) are not exempted, which means that manufacturing or import will no longer be possible if the restriction is set in force.

No derogation for intermediates is foreseen, which means, that also products, which are made from them can no longer be produced within the EU. That will also affect products, which itself are object of derogations, like the active ingredients.

6. Missing uses – Analysis of alternatives and socio-economic analysis

The use as intermediate in the synthesis of another substance is not considered in the restriction draft. In the main part of the draft, the term "intermediate" can be found three (!) times, but not in context of derogation. The only derogation of fluoro compounds as intermediates is found at page 65 and concerns substances, which are explicitly not PFAS. In Annex A, which concerns manufacturing and uses, the term is used twice, but also not in context with a derogation for PFAS intermediates. This makes it clear that obviously important uses of PFAS were not considered. In the case of the intermediates, it hardly can be assumed that this happened accidentally.

That is a severe gap in the proposal, since this would lead to total loss of all PFAS production in Europe no matter if derogations were applicable or not. That would affect pharmaceutical uses (active ingredients, devices) as well as agrochemicals and other uses. Some of such substances have only one CF₃-group, often bound to an aromatic ring. If the final product of the synthetic route is a molecule with a CF₃-group, then this must be introduced at any step in the chemical synthesis. It might be that in a multistep synthesis several PFAS intermediates must be manufactured to achieve this. There is obviously no possibility of substitution of the intermediates.

Sometimes a protection group must be used in the synthesis of another chemical substance. The Triflate-Group (trifluoromethanesulphonic acid) is an important protection group and processing aid in organic synthesis. This substance and the intermediates made from it also are not exempted, which would infringe even the manufacturing of non-PFAS compounds.

There is also no derogation for substances, which are produced solely for export outside the EU, e.g. as intermediates or monomers.

The use as monomer is also not exempted, which would also lead to a total ban of the manufacturing of fluoropolymers in Europe. This is most likely not that important, because the production of such substances already takes place widely outside the EU.

As described above the most important gap is, that the use of fluoropolymers in equipment of the process industry and in devices is not exempted. That is also the application with the lowest environmental impact, because the equipment is fixed and enclosed in the instalment and used for many years. At the end of the live cycle, it may be recycled or disposed as waste according to applicable legislation.

Conclusion:

This restriction, if it were to come into force unchanged, has the potential to cause lasting damage to the entire industry in Europe. The resulting socio-economic damage can hardly be quantified and will permanently and significantly reduce the economic power of Europe. The damage affects almost all sectors of the economy, including those that are urgently needed for the purpose of ecological conversion and in the fight against climate change. Urgently needed investments will certainly be questioned very critically under such framework conditions. The idea of bringing production of sensitive products such as pharmaceuticals, chemicals, high-tech, electricity storage technology and others back to Europe then can completely be abandoned.

We therefore demand

1. Manufacturing and production in the EU must continue to be possible.

Import and use of PFAS intermediates are essential for the manufacturing of different end products, e.g. active ingredients and other derogated products.

Especially fluoropolymers are important for the entire chemical and pharmaceutical industry as integrated parts of the production equipment, devices and machines.

2. Resilience in the EU must be ensured.

It is very likely that production sites will have to be shut down and investments in new plants will no longer be made in Europe under the condition of this restriction. It must be ensured that Europe's dependence on imports is not increased and that the European economy is protected. Important considerations here are both the availability of products and the preservation of jobs.

3. The use of fluoropolymers in the chemical process industry should generally be exempted.

The proposed restriction, in its current form, will inevitably shut down significant parts of Europe's chemical industry, which relies on fluoropolymer materials for which there are currently no alternatives. This not only affects the processes associated with the production of fluoropolymers, but almost the entire chemical production including all downstream manufacturing processes in other sectors as well.

4. Functional systems must be able to continue operations.

It must be taken into account that wearing and maintenance material must be made available over a sufficiently long period of time. In many cases there are currently no alternatives.

5. Safe handling and transport conditions must be guaranteed.

The use of hoses, valves or coatings made of PFAS can also be important when transporting products under certain conditions. It must be ensured that the restriction does not have any negative safety-related effects when goods are transported on road, rail, plane or ships.

6. A holistic approach is required when it comes to evaluating alternatives.

PFAS often have advantages in terms of energy consumption, environmental protection, plant safety or occupational safety. The evaluation of alternatives must consider all variables including durability, energy and resource consumption, waste, hazardous properties, etc. Also economic factors must be taken into account, because without competitive conditions, the plants cannot continue to operate.

7. Research, development and innovation must continue to be possible in Europe.

In order to keep innovation developments in Europe, it must be possible to continue to use substances that fall under the PFAS definition in the context of research and development but also in product and process-oriented research and development (PPORD). This requires a specific exemption from PPORD in the restriction proposal.

Kind Regards

Allessa GmbH, Product Safety on behalf of AllessaProduktion GmbH, WeylChem Höchst GmbH and WeylChem InnoTec GmbH



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