Regulation (EC) No. 1907/2006 (REACH)

Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs) submitted by

BAuA - Federal Institute for Occupational Safety and Health

Bureau REACH, National Institute for Public Health and the Environment (RIVM)

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Dear Sir or Madam, this is the corrected version and refers to number:

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We welcome the opportunity to contribute to the public consultation initiated by the European Chemicals Agency regarding potential restriction of Per- and polyfluoroalkyl substances (PFASs) according to Regulation (EC) No. 1907/2006 ("REACH").

1. What are the uses of PFASs?

In many, if not all, important industrial sectors such as the automotive, biotech, chemical & pharmaceutical, electrical & electronic, food, steel & metal, construction, mining and water industries, professional users in established analytical laboratories use products with PFASs for quality control and product safety. Many laboratory instruments and assemblies made of fluoropolymers (e.g. PFA, FEP and others) are used there. Instrumental analytical applications ensure that components meet requirements and do not pose a risk in use, that pharmaceutical products can be administered to patients and that food and water can be consumed by society without risk.

2. Which products, applications and which PFASs are involved?

We have to cover instrumental analytical applications in various industrial sectors (e.g. ICP-MS, HPLC-MS, GC-MS) which use laboratory equipment and assemblies made of fluoropolymers (e.g. PFA, FEP and others) to ensure that produced articles meet requirements and products do not pose a risk in use.

For example, the laboratory products are used in sample preparation (digestion and extraction procedures) of solid samples for trace analysis by ICP-MS and other methods and for sample handling in analytical autosampler systems. In many cases, vessels made of fluoroplastics (PFA) are even prescribed by national and international standards for analytical questions, such as metal cation trace analysis, because only the special properties of the fluoropolymer material make it possible to work with low contamination and high precision in the trace analytical (ppt level) pg/l range. Laboratory products made of fluoropolymers are also used in the production and storage of low-concentration standards for various analytical procedures.

Instrumental analytical applications also ensure that suitable, efficient and safe pharmaceutical ingredients can be developed and processed without risks to patients. Therefore, USP replaced chapter 231 (a more than 100 years old used wet chemical screening subjective visual method in which metal sulphides are precipitated out of an aqueous solution by colour) with chapters <232> elemental impurities-limits and <233> elemental impurities-procedures to regulate more strictly the detection of trace elemental impurities in pharmaceuticals by inductively coupled plasma–mass spectrometry (ICP–MS) to be able to perform a speciation analysis.

The ICP-MS technique is also used for food and water analysis to ensure that both can be consumed by society without risk. An example here is the ISO 17294 series, which sets out a procedure for the simultaneous determination of 63 trace elemental impurities by ICP-MS for water quality control.

Guideline for chemical analysis - digestion of environmental samples. This guideline also refers to the regulation for the determination of element traces in food L 00.00 19/1 by means of pressure digestion (DIN EN 13805) and specifies vessels made of perfluoroalkoxy plastic (PFA), hexafluoroethylene propylene (FEP) or quartz, depending on the solvent used, for use.

3. Why are products made of PFASs used and why is there no other way?

Fluoropolymers are used because only these materials have such high chemical and heat resistance and can thus contribute to safety in analytical work. In addition, fluoropolymers have only weak interactions with other substances and low permeability, thus preventing chemicals/analytes from adsorbing on the surface and being absorbed into the material. Only by this way carry-over can be reduced and precisely repeatable accurate measurement results in the lower pg/l range (ppt level) is possible at all. For many questions, only the use of fluoropolymers is possible and alternative materials with equally good chemical properties do not actually exist.

4. What would be the effects of restricting the use of PFASs?

Without laboratory products made of fluoropolymers, safe, precise analysis, in quality control, research and development of new active pharmaceutical ingredients as well as environmental analysis for a wide range of questions would no longer be possible.

Also control of food and water quality or the suitability, efficacy and safety of pharmaceutical products would no longer be possible to the usual and required level. The safety of consumers and patients would be at risk if routine analysis in these areas had to be abandoned. Today established reference limits would be shifted upwards again.

5. What influence does laboratory equipment made of PFASs have on ecological systems?

The fluoropolymers used to manufacture the laboratory equipment, in the form of granulates, are shaped into their final form by hot moulding. Any wastes (sprues, slugs, ...) are returned to the running process after being crushed, so that only a small amount of waste is produced during the manufacturing process itself. The remaining waste parts that can no longer be used are not disposed of with household waste, but rather sent to defined waste channels.

The disposal of the used laboratory equipment is also not done via household waste. The educated users in

the laboratory are obliged to use defined waste paths for this process, so that no risks for the environment can be identified. Due to the special chemical properties, the articles are extremely durable and thus save frequent disposal for replacement purchases.

6. Alternatives?

There is no alternative material with equally good properties. That is the case and it is very likely that there will be no such material in future.

As downstream users, we process the available material, which is produced by the chemical polymer industry, we have no data or indications as by now whether the polymer manufacturers are already researching alternative materials and whether and when an alternative material can be expected. So, the availability of alternative materials is not yet given and whether and when such a material will be available, it is also not yet possible to estimate whether supply problems with the potential alternative materials could be expected.

As a laboratory equipment manufacturer, we need much more time to find alternative materials for the products that currently still require the use of PFA material. Not all fields of application can be served with the materials currently available on the market. A material qualification for the existing products will take considerably more time, especially since it is also possible that the existing tools cannot be used with other materials for the manufacture of the products and a new construction will be necessary.

The envisaged time of 18 months from EIF will not be sufficient, even if we start already now to convert the entire product range. We need a transitional period that is extended to 6,5 years after entry into force of the restriction for the use of fluoropolymers for the production of special laboratory equipment and to be able to find possible alternative materials.

We would be happy to assist in case there are any further questions. Please do not hesitate to contact us, in case specific contributions might be considered helpful.

VITLAB GmbH

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