FluorTex GmbH
Polymer Technology

multiFlon® multidirectional PTFE
multiFlon® ePTFE Membranes
microFlon® sintered PTFE
monoFlon® ePTFE Gasketing

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To customers, business partners and users of
PTFE and PTFE-containing sealing and membrane
materials and other interested parties (stakeholders)

Our Contact: DR
Your Message:
Your Contact:
Date: 10th March 2023
230310 Information on PFAS Restriction Proposal

Dear Fluoropolymer Users,
dear business partners,

We would like to inform you about the current status regarding the PFAS restriction process.

On 7th February 2023, the European Chemicals Agency (ECHA) published a preliminary version of the restriction dossier for per- and polyfluoroalkyl substances (PFAS) on its website.

This initiative by 5 governmental organizations from Germany, the Netherlands, Sweden, Denmark and Norway proposes an EU-wide ban on the production, placing on the market and use of all substances defined as PFAS.

Contrary to the opinion of many users of Fluoropolymers and Fluoro- or Perfluoro-Elastomers, such as PTFE, FKM or FFKM, these materials are just as affected by the proposed ban as volatile and water-soluble fluorochemicals, which started the discussion on the restriction of PFAS in the beginning.

The reason for this is the definition of PFAS, namely the fundamental presence of fluorinated carbon atoms (CF2 or CF3) in a substance, regardless of its active hazard potential.

Thus, also non-toxic, inert plastics and elastomers with their special properties, such as the combination of chemical resistance, high heat and cold resistance, their unique pore structure or physiological safety, these polymers are also affected by the planned ban, although they are safe and are not substitutable in many applications in sealing technology, filtration, fuel cell technology or even medical technology.

When collecting the information on the submitted restriction dossier, the five implementing governmental organizations did not consider essential fields of applications of fluoropolymers and disregarded the related state of the art in many and essential parts.

The restriction proposals formulated in the dossier thus lead to a future ban on fluoropolymers. Accordingly there are no exceptions, apart from active substances in biocidal products, plant protection products and human and veterinary medicines.

In the dossier two restriction options are mentioned. Following the stricter restriction option 1 (RO1), all bans are to be effective 18 months after entry into force. The milder restriction option (RO2) provides derogation periods of 5, respectively 12 years for a small number of applications, including fuel cell membranes (5 years) or fluoropolymers in the petroleum and mining sector. Exceptions or time related derogations, e.g. for PTFE or FKM sealing materials in the chemical or pharmaceutical industry, are not foreseen.

Alternative substitute materials for many applications of fluoropolymers and fluoroelastomers are not physically viable or are orders of magnitude worse in performance or reliability. If this will change in the next 18 months, or within 5 or 12 years, cannot be estimated today. Therefore, an exemption for fluoropolymers and fluoro- or perfluoro-elastomers must be obtained, that ensures the continued use of these necessary high-performance materials in order to continue to give all users the opportunity to protect people and the environment with the best available technology.

As part of the restriction process, a public consultation will be conducted by the European Chemicals Agency (ECHA) from the 22nd of March to the 22nd of September 2023, to collect as much data and information as possible to assess the impact of a general ban.

We urge you as a distributor, processor or user of fluoropolymers and fluoroelastomers to participate in this consultation within the first 30 days, as the ECHA guidance gives earlier submissions a better chance. (see: *https://echa.europa.eu/documents/10162/17233/restriction_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c*).

Participation in the public consultation is only accepted online via ECHA's website and should be done by each independent company itself, as this process aims to present the individual uses of fluoropolymers in Europe, their economic and environmental benefits, as well as the social and economic impacts in the event of a proposed ban (including time-limited derogations), and/or regulation of the materials.

The submitted data can also be marked as confidential, so that ECHA and the involved committees RAC and SEAC (RAC: for Risk Assessment Committee and SEAC for Socio-Economic Analysis Committee) are obliged not to publish them.

Please prepare your data for online submission considering the following aspects:

- Scope or restriction options analysis
- Hazard or exposure
- Environmental emissions
- Baseline
- Description of analytical methods
- Information on alternatives
- Information on costs
- Information on the benefits of the restriction
- Other Socio-Economic Analysis (SEA) issues
- Transitional period/deferred entry into force
- Exemptions

Please note that only information that is submitted will be evaluated!
(Information and a guideline on this can be found in the attachment to this letter).

At the start of the consultation phase on March 22nd, 2023, a link will appear in the consultations section on ECHA's website, where you can actively participate in the process. *Consultations - ECHA (europa.eu)*

Fluoropolymers and fluoroelastomers must be excluded from the restriction. Therefore, please take this opportunity to influence the decision on the restriction to ensure the continued safe operation of your applications using the affected high-performance materials and to safeguard the future of your company and of any new technologies that require these materials.

For further information please do not hesitate to contact us

References:

European Chemicals Agency “ECHA”: https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

Annex to the information letter of FluorTex/AK Dichtungen of March 2023

PFAS restrictions - public consultation, start 22.03.2023, end 22.09.2023

In the following, we have listed and explained some points from the ECHA guidance to you as a company affected by the planned PFAS restrictions. Please note that you should provide as much information as possible, which must also be verifiable.
Attention: No data submitted will be considered as acceptance of the restrictions!

You will have the opportunity to upload detailed information as electronic documents in ECHA's public consultation. Therefore, please prepare your data for participation already before joining this online procedure, taking into account as many of the following aspects as possible:

The ECHA guidance „Inputting to the consultation phase of an Annex XV restriction report and SEAC draft opinion under REACH" is the basis for the following information. You can find the ECHA guidance in the Annex to this document or on the Internet:
https://echa.europa.eu/documents/10162/17233/restriction_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c

Scope or restriction options analysis
Comments can be made here on the feasibility or appropriateness of specific concentration or migration limits proposed by the dossier submitter.

In particular, please evaluate the appropriateness of banning non-hazardous substances, such as PTFE, that do not pose an active hazard during their intended use. Products or applications not mentioned in the dossier should also be presented here, with a detailed evaluation of a ban or restriction. In doing so, please present the effects on society, the economy and the environment.

Hazard or exposure
Information on the specific property(ies) of the substance(s) addressed in the restriction dossier may be submitted. If the respondent provides a study on a specific property (e.g. biocompatibility) that was not assessed by the submitter of the dossier in its risk assessment, it would be helpful if a more comprehensive analysis of the hazard was also provided during the consultation.
However, it is also useful, for example in the case of the use of fluoropolymers, to submit studies describing the safety and harmlessness of these substances. Please note that a risk analysis by the RAC will only be carried out if data are submitted! These must clearly demonstrate that substances affected by the restriction proposal are to be excluded because they are safe and do not pose a risk.
If the dossier submitter has provided a study on a certain hazard property (e.g. toxicity), you can contradict this by submitting a corresponding more comprehensive analysis of the lower hazard potential, or present the lower overall hazards, compared to alternative materials or to the non-use of the substance concerned.

Environmental emissions
Attention: Fluoropolymers are harmless in their use and have no emissions themselves during their intended use. They do, however, prevent emissions of hazardous substances from industrial facilities and thus contribute significantly to environmental protection. Please demonstrate with provable data how little fluoropolymer you need to prevent against very much emissions!

Baseline
This may also reveal demonstrable errors in the basic data. Please provide evidence for the submitted corrected data.

Description of analytical methods
Please ensure that the information provided is verifiable. If you have given material to an accredited laboratory for analysis (e.g. analysis of PTFE to determine the extractable PFAS content), please name this laboratory, stating the accreditation number (e.g. DAKKS in Germany) and the analysis report number.

Information on alternatives
Please describe the impact of alternatives vs. fluoropolymers e.g. in relation to TA Luft and the emission minimization requirement. Information on alternatives discussed in the restriction dossier or on their reasonableness is welcome here (e.g. EPDM or silicone as alternatives to FKM or FFKM). Please note that "lack of alternatives" is not an argument, and your information will not be considered if you do not provide a substantiated evaluation of alternatives. Not using substances can also be an alternative!

Information on costs
Please note that health system costs should also be considered as social impacts. For example, the non-use of high quality PTFE membrane filters, for the filtration of particulate matter from industrial processes, significantly increases these emissions and thus has a direct impact on the cancer incidence proven to be caused by particulate matter and the health care costs directly related to it.

Information on benefits
Information may be submitted on benefits of the restriction with regard to harmful chemicals. Attention: Please consider that the restriction of inert fluoropolymers can also cause harm (negative benefits) and bring disadvantages, which must be equally considered by the RAC and SEAC evaluation panels. Please describe the disadvantages of a restriction in a provable way, as precise and understandable as possible.

Other Socio-Economic Analysis (SEA) issues
Please describe any potential impacts to the community, development and future projects, site closures, or other issues that may result from a restriction. Please keep in mind that only a time derogation does not prevent a ban on fluoropolymers!

Transitional period / deferred entry into force
When proposing a transition period/deferred entry into force, you should provide sufficient evidence on risks (e.g., emission levels) and socioeconomic impacts to justify your proposal. Please propose transition periods only if you can actually implement equivalent or better alternatives for fluoropolymers and elastomers within those transition periods.

Exemptions
Information may be submitted suggesting new exemptions or oppose or modify exemptions proposed by the dossier submitter. Further supporting information on previously proposed exemptions related to risks and costs is also welcome.

In order to request an additional exemption, sufficient evidence must be submitted during the consultation that addresses the issues noted above and subsequently justifies the requested exemption.

Examples of the required information can be found in the annex of the attached ECHA guidance document – „*Addendum: Good practice examples of information submitted in the consultation for exemptions*“.

Please take this opportunity to continue the safe operation of your current applications and secure the future of new technologies, your business and our modern society.