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Lavorazioni Plastiche

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UNI EN ISO 9001:2015



CERT N.245

To all INTERESTED PARTIES

Grumello del Monte, 20 April 2023

SUBJECT: Communication on RESTRICTION PROPOSAL OF PFASs (Per- and polyfluoroalkyl substances)

Dear Customer,

The European Chemicals Agency (ECHA), on 7 February pre-issued the UE restriction proposal of PFASs, notified by national Authorities of Germany, Denmark, Netherlands, Norway and Sweden, targeted to reduce or eliminate the environmental PFASs presence.

The final version of restriction - "Restriction on the manufacture, placing on the market and use of PFASs" - was issued on 22 March, with the Annex XV report, 7 Attachments and 4 Appendixes. Support documents available at the following link: <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

The restriction proposal defines PFASs (Per- and polyfluoroalkyl substances) as substances which "contain at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I atom attached to it)", on the base of definition expressed by OECD (Organisation for Economic Co-operation and Development) in 2021 for those substances.

The restriction proposal does NOT distinguish between FLUOROPOLYMERS, as PTFE and PVDF, and other PFASs: Fluoropolymers have unique properties and constitute a distinct class within the PFASs group, as they don't show the toxicological and environmental characteristics related to other PFASs considered of concern.

96% of Fluoropolymers available on the market, including the 18 major Fluoropolymers manufactured and used worldwide in innumerable applications, divided as Fluoroplastics, included PTFE and PVDF, and Fluoroelastomers, meets, themselves and in-use, the OECD criteria as "PLC - Polymers of Low Concern" for the health and the environment.

FLUOROPOLYMERS have unique and outstanding combination of stability, resistance and durability properties: they are regarded as irreplaceable to ensure optimal performance in many important applications, and basic to provide functionality to a broad range of products; they are used in food, pharmaceutical, and medical sector, and they are indispensable for critical applications in the chemical, electronic, and semiconductors industry. They are the preferred choice in many applications, because other materials are not able to achieve the combination of requested functionalities.

This makes FLUOROPOLYMERS fundamental in our society. ⁽¹⁾ ⁽²⁾

The proposal restriction aims to BAN the transformation, importation and use of PFASs in the whole EU, without differentiate FLUOROPOLYMERS from the rest of PFASs: even fluoropolymers will be covered by this restriction, with consequences on use possibility and impacting on application and manufacturing sectors.

About that, on the base of Art. 69 and 70 of Title VIII (Restriction) of Reg. CE 1907/2006 - REACH, regarding the Registration, Evaluation, Authorization, and Restriction of Chemical substances, ECHA opened a 6 months public consultation, with deadline established on 25 September 2023, to gather opinions, suggestions and information from all parties interested by this proposal restriction: all stakeholders and all interested parties can participate, through this official route.

Each participation to the consultation can process via restriction proposal dedicated page on ECHA website, going at the following link:

<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

and then selecting the option "Give Comments", at the voice "Consultation on restriction report".



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The participation to the consultation is crucial to ensure the Fluoropolymers application continuity in EU: The main goal is to obtain a complete exemption for fluoropolymers from PFASs restriction. Although the restriction proposal establish the possibility to have derogations for individual industries and/or applications, this option becomes really hard to be followed because of the supply chain complexity and the broad variety of applications which Fluoropolymers are involved in.

Consultation consists of 6 sections:

- Header
- Section I. Personal information
- Section II. Organisation
- Section III. Non-confidential comments:
this section has a subsection with specific questions related to restriction proposal (Specific Information Requests): in this section comments and information on Fluoropolymers are insertable.
- Section IV. Non-confidential attachment:
this section gives the opportunity to insert via attachments the comments related to the specific questions of the previous section.
- Section V. Confidential attachment:
in this section can be inserted the information classified as confidential with a separated document, explaining the reason of confidentiality.

After the submission of contribution, it will be sent an automatic reply about the correct submission of that.
For an effective contribution, the following tips are recommended:

- Quantitative data is more appreciated than qualitative comments
- Scientific/technical based data is given higher priority than business information (except if specifically required)
- If the case, clearly state that there are no alternatives to Fluoropolymers for own specific use
- If possible, clearly indicate why the continued use of Fluoropolymers is relevant, not only for own company but also for the European society as a whole
- If possible indicate, when requested, relevant economic data in terms of revenue and profit obtained that own company obtains from Fluoropolymers

The participation to the consultation is crucial: without the engagement of every level of the value chain of Fluoropolymers, severe business impacts across different sectors are expected.

Robecchi Articoli Tecnici Srl guarantees to constantly monitor the evolution of the implementation phases of REACH legislation and offers maximum cooperation to all interested parties, in order to maintain continuous exchange of information, that will lead to work in absolute safety for people and for environment.

(1) Henry B., Carlin J., Hammerschmidt J., Buck R. C., Buxton L., Fiedler H., Seed J., and Hernandez, O. (2018); "A critical review of the application of polymers of low concern and regulatory criteria to fluoropolymers". *Integrated Environmental Assessment and Management*, Vol. 14(3), pp. 316-334.

(2) Korzeniowski H., Buck R. C., Newkold R. M., El kassmi A., Laganis E, Matsuoka Y., Dinelli B., Beauchet S., Adamsky F., Weilandt K., Soni V. K., Kapoor D., Gunasekar P., Malvasi M., Brinati G., and Musio S. (2022); "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers". *Integrated Environmental Assessment and Management*, Vol. 19(2), pp. 326-354.

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