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PTFE micropowders production in the EU after 2022 – questions and scenarios

Scenarios and regulatory framework for the production of compliant PTFE micropowders in the EU post-2022

In this presentation, Heroflon (a subsidiary of Daikin), firstly, outlines a business model for the production of compliant PTFE micropowders in the EU after July 2022.

Secondly, the presentation poses a number of questions to better understand whether the different steps of this production process would be possible after July 2022 under the conditions currently set by the EU POP Regulation on PFOA and the upcoming REACH Restriction on C9-C14.

HEROFLON

- Joined the Daikin group in 2017.
- It is a leading Italian company with 30 years of experience processing fluoropolymers and technical compounds
- Established in 1986 as a start-up of the production of PTFE micropowders
- Has 3 production plants in Italy and sales offices in USA and Brazil.



Background – Regulatory state of play

- The Delegated Regulation amending the Annex I o the EU POP Regulation 2019/1021 on perfluorooctanoic acid (PFOA) entered into force on 4 July 2020.
- The Regulation includes a time-limited **exemption for PTFE micropowders** as well as mixtures and articles containing PTFE micropowders with a PFOA impurity level up to 1 ppm. This exemption will be subject to review within the two years after its entry into effect (by July 2022).
- In addition, the EU's legislative procedure for the adoption of a C9-C14 REACH restriction is in its final stages. The restriction is expected to include an exemption for C9-C14 PFCAs in PTFE micropowders that would be subject to a review by the Commission after 36 months.

Background – Current exemption for PTFE micropowders production

Exemption for PTFE micropowders in Annex I, Part A:

“For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0,0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micropowders produced by ionising irradiation or by thermal degradation as well as in mixtures and articles for industrial and professional uses containing PTFE micropowders. All emissions of PFOA during the manufacture and use of PTFE micropowders shall be avoided and, if not possible, reduced as far as possible. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022.”

- **PFOA is NOT used for producing HEROFLON's PTFE micropowders.**
- At present, HEROFLON purchases various forms of high molecular weight PTFE to transform these PTFE materials into low molecular weight PTFE micropowder.
- However, during the production process PFOA may be generated unintentionally, in a concentration presumably above 25ppb for PFOA.
- HEROFLON will be in a position to supply its customers with compliant PTFE micropowders by 4 July 2022. These PTFE micropowders will have PFOA impurity levels below 25ppb. To ensure compliance with the POP Regulation and C9-C14 Restriction, these micropowders will be made subject to an additional treatment step after the first processing step (which is irradiation).

However, for after 4 July 2022,
it is unclear whether **the intermediary steps for the manufacturing of compliant PTFE micropowders in the EU** will require an additional exemption under the EU POP Regulation and the C9-C14 Restriction.

The production of PTFE micropowders process consists in two main steps:

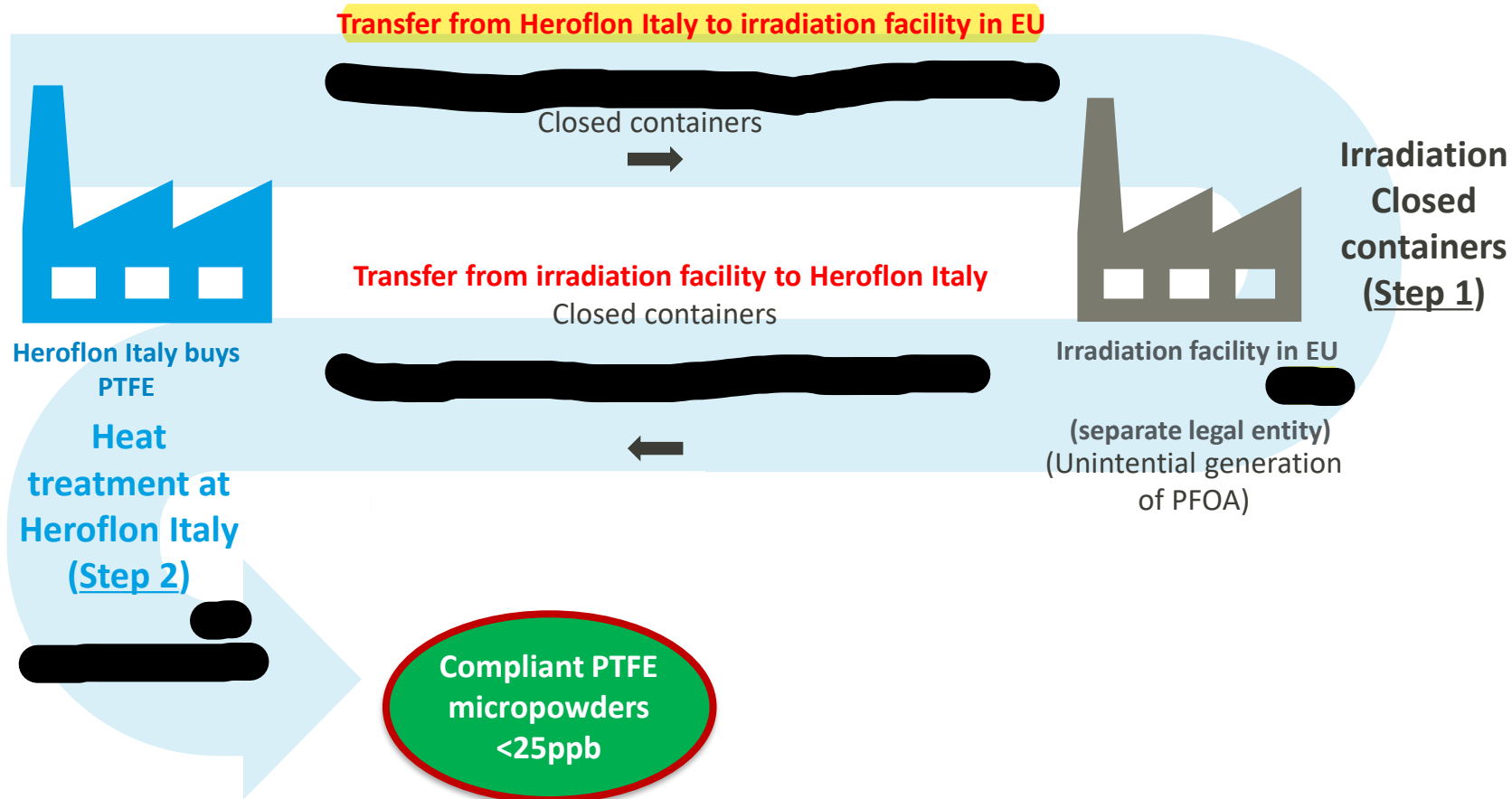
Step 1: Irradiation

- This process results in the unintentional generation of impurities of PFOA in PTFE micropowders, above the allowed UTC level (above 25 ppb).

Step 2: Post treatment (Heat treatment)

- That step is conducted in order to reduce the level of impurities of PFOA in PTFE micropowders below 25 ppb.
- After completion of step 2, PTFE micropowders are compliant.

Scenario



Main questions regarding intermediary steps of the production process

Transfer to a facility located in the EU:

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- The transfer from an EU-based company to another legal entity in the EU for Step 1 (irradiation) and the transfer from this facility back to the company for Step 2 (heat treatment) are intermediary steps in the process to produce compliant PTFE micropowders.
- Would these transfers be regarded as “placing on the market” under POP Regulation and REACH?

Heat treatment

- Step 2/heat treatment (further processing) is also an intermediary step in process to produce a compliant end-product. Would the heat treatment be regarded as a “use” under the POP Regulation and REACH?

Supplementary question regarding intermediary steps of the production process

Irradiation process:

- Our understanding is that the Stockholm Convention (Annex A) only covers intentional manufacturing (unintentional presence in products is regulated separately by UTC levels). Does the definition of „manufacturing” in REACH also only cover intentional manufacturing?

What is at stake? Production of compliant PTFE micropowders in the EU

- HEROFLOX welcomes the exemption granted under the POP Regulation until July 2022. By then, HEROFLOX will be in a position to produce PTFE micropowders with lower levels of impurities and that are compliant with the EU POP Regulation.
- HEROFLOX would like to maintain its operations in the EU, in compliance with relevant EU and local regulations after July 2022.
- It is important that HEROFLOX and other European producers are able to produce compliant PTFE micropowders in EU after July 2022 by means of post-treating the irradiated material.
 - If this production method (irradiation and post-treatment) is not allowed, there is the risk that European PTFE micropowders producers, such as HEROFLOX, will have to cease their local production, forcing Heroflon and its customers to rely on imports of PTFE micropowders from outside the EU.
 - To the best of our knowledge, the imported PTFE micropowders would also be produced by irradiation and a post-treatment step.
- Legal clarity is needed on what business models are allowed under the EU POP Regulation (and the C9-C14 REACH Restriction) or whether additional derogations are needed to safeguard production in the EU.