COMMENTS TO THE PUBLIC CONSULTATION ON THE REACH RESTRICTION PROPOSAL ON PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

PUBLIC VERSION

Submitted by: Solvay Special Chem

Date: 22.09.2023

Executive Summary

Solvay's Special Chem business unit manufactures intermediates used by the pharmaceutical and agrochemicals in the EU.

The products manufactured are Trifluoroacetic acid (TFA) and its derivatives. TFA is an organofluorine classified as PFAS according to the OECD definition, however, it is not a fluorinated surfactant molecule and it contains very few carbon atoms. This substance does not accumulate in the human body.

Due to the unique nature in which the pharmaceutical and agrochemical markets have been covered in the PFAS restriction proposal, the following submission will discuss Solvay's position on these specific sectors alone.

While recognizing the importance of science-based regulatory measures, Solvay expresses concerns about the current scope of the PFAS REACH restriction proposal. Though certain products are exempt from the proposed ban (biocidal products, plant protection products, and human and veterinary medicinal products), the synthesis and use of PFAS intermediates required for manufacturing these products would still be affected. This would have a tremendous impact on different actors and industries in the EU, as not only the industrial production of PFAS precursors intended for derogated products would have to cease, but also all EU pharmaceutical, chemical and agrochemical industries manufacturing PFAS products and co-products derogated under the PFAS restriction proposal would have to move the production in non-EU countries, in lieu of the provisions currently included in the proposal. The detrimental consequences for the EU economy, industries and society would be enormous and the dependence related to the import of essential products (such as medicines made with or containing compounds that fall under the PFAS definition set forth in the restriction proposal) from non-EU countries would have striking effects. Solvay agrees with Industry associations, such as the EFPIA, AnimalHealth Europe, and Croplife Europe, and calls for full derogation for PFAS raw materials, intermediates, and auxiliaries required for the manufacturing of exempt products such as active pharmaceutical ingredients (API) and agro active ingredients (AI).

Solvay's commitment to responsible manufacturing across its sites in Bad Wimpfen (Germany) and Salindres (France) has led to improved production processes, reduced emissions, and overall environmental safety. The company continuously invests (about several million euros, respectively) in best available techniques, ensuring a responsible approach to managing and reducing emissions from its production activities.

The socioeconomic impacts of the planned PFAS restriction would be significant and would go far beyond foregone profits to Solvay itself and social cost of unemployment for its employees. The supply chain for short-chained PFAS molecules involves numerous manufacturers, downstream users, and end applications within the pharmaceutical and agrochemical sectors. Solvay's Trifluoroacetic acid (TFA) and derivatives are essential to various industries and they play a crucial role in peptide synthesis for drugs like diabetes treatments, COVID treatments, anti-cancer and anti-HIV medications. TFA and derivatives are indispensable in the healthcare and agricultural sectors, as they serve as intermediates, solvents, and raw materials in numerous applications.

The restriction could result in an increased EU reliance on Asian producers. Currently Solvay is the only European supplier of PFAS small molecules for the pharmaceutical and agrochemical sectors. In case of the restriction, the goal of the EU to support an independent and strong pharmaceutical sector will be jeopardized. As further elaborated in the present submission, should the current proposal be adopted without further changes, such a restriction may lead to shortages of essential medicines, financial and political challenges, and increased costs for public and private health insurance given in detail below. Further impacts on DUs have also been examined by Ricardo in a study on the economic impact of a universal PFAS restriction on behalf of the European Chemical Industry Council (CEFIC).

In conclusion, Solvay calls for a full and time-unlimited derogation comprising all PFAS raw materials, intermediates and auxiliaries required for the manufacturing of products proposed for a derogation under RO2. The derogation should be extended to the complete supply chain, from the synthesis of PFAS raw material / intermediates / auxiliaries to their end use for the production of APIs, biocidal products and PPPs.