

# Background Document on PFAS and Plant Protection Products (NL)

Document for discussion in HLM, 11 December 2024

## Background and context

Per- and polyfluoroalkyl substances (PFAS) are widely recognised for their persistence in the environment. This property, combined with growing evidence of their adverse health and environmental effects, have led national authorities in Germany, Denmark, Sweden, Norway and the Netherlands to propose a total ban on the sale, use and manufacturing of PFAS under REACH. This restriction proposal is currently under discussion in ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).

## Derogation for plant protection products

Around 35 approved active substances in plant protection products (PPP) fulfil the PFAS definition.<sup>1</sup> These substances commonly include one or more CF<sub>3</sub>-groups in their chemical structures to enhance properties such as stability and lipophilicity. The PFAS-restriction proposal includes a permanent derogation for these active substances, as well as for biocides and (human and veterinary) medicines. The rationale for the derogations is that these active substances – in contrast to other chemicals – are regulated by a system requiring individual substance approval and product authorisation before market entry. At the same time, the restriction proposal states that the predominant reason for restricting PFAS – their persistence – is not sufficiently considered in the current authorisation processes for the derogated substances. Therefore, the proposal includes a recommendation to the European Commission to address this concern.

## Trifluoroacetic acid (TFA)

Trifluoroacetic acid (TFA) is a potential degradation product (metabolite) of different PFAS, including active substances in PPP. TFA – itself a PFAS – is a highly persistent and mobile substance. Recent data on TFA reveal significant concerns about its acute toxicity and its toxicity for reproduction. This is reflected in a proposal for harmonised classification submitted by Germany.<sup>2</sup> To address these findings, the European Commission mandated EFSA to establish new toxicological reference values for TFA, which can be used in the risk assessment of substances producing TFA as a metabolite.

In several Member States the high concentrations of TFA found in groundwater have been raised as an issue of concern, for example for drinking water production. Even though TFA has multiple sources beyond PPP, scientific findings (e.g. from Germany) reveal that PPP are a significant source of TFA in groundwater. The PPPR prescribes a groundwater limit of 0,1 µg/L for toxicologically relevant metabolites like TFA. The European Commission has stated that TFA can be regarded as a relevant metabolite, given the available data. It is therefore necessary to find out whether the currently approved substances meet regulatory requirement of the groundwater limit. However, due to methodological issues around the detection of TFA it is still unknown which substances produce TFA in which quantities. It is probable that additional data will be required for all active substances capable of producing TFA as a metabolite to enable a comprehensive groundwater risk assessment. Considering the number of active substances involved, this undertaking is expected to demand significant time and resources.

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<sup>1</sup> The actual number of approved active substances is liable to change because of non-renewals, approvals or withdrawal of substances.

<sup>2</sup> The proposal includes the following classifications: Repr. 1B, Acute Tox. 3, Skin Corr. 1A, Aquatic Chronic 3, PMT, vPvM.

### **Implications for the regulation of Plant Protection Products**

The derogation in the restriction proposal is accompanied by a recommendation to address persistence more rigorously within the PPP regulatory framework. The emerging scientific knowledge on TFA highlights the need for a proactive and adaptive approach.

One key challenge is addressing the unknowns in TFA formation, especially with regards to groundwater, while balancing the urgency of this matter with the need for thorough regulatory assessment and constraints regarding time and resources. Another key challenge is to improve the regulatory framework to be more suitable for persistent substances and metabolites.

### **Questions for Discussion**

#### *TFA*

- How can the issue of TFA formation by PPPs be effectively addressed within the existing PPP assessment framework, considering the resource-intensive nature of evaluating active substances individually?
- Are there alternative, more efficient approaches to tackle this issue?

#### *Improving the regulatory framework for the future*

- What lessons can the TFA issue provide for improving the regulatory framework to better assess and manage risks from persistent substances like PFAS, including their metabolites?
- What specific changes, such as a revision to Annex II of the PPPR, are needed to integrate persistence considerations and prevent similar challenges?