Dear Head of unit (5.1.2.e ),

With this letter The Netherlands would like to draw the attention on Trifluoroacetic acid (TFA) produced as a metabolite by several active substances in plant protection products and biocides.

TFA is considered as a PFAS-substance, is poorly degradable in the environment and has various sources, including coolants, propellants and medicines. Nevertheless, there is increasing scientific evidence of a link between the use of plant protection products and biocides and increased concentrations of TFA in groundwater (see appendix 1). Recent studies indicate that TFA is toxic to reproduction and therefore relevant to human health. According to European legislation, such relevant metabolites must meet a groundwater standard of 0.1 µg/L. At the same time, it has become clear that the standard studies for determining TFA formation have a number of shortcomings. In many cases it can therefore, based on the current studies, not be determined whether the groundwater standards are met in the risk assessment.

Currently, there are 30 active substances in plant protection products and 5 active substances in biocides approved in the European Union that may produce TFA as a metabolite (see Annex 2). The Netherland would like to emphasize the importance of a rapid and European harmonised approach to this issue. Therefore, The Netherlands welcomes the Commission's plan to mandate EFSA to further develop the methodology for determining TFA formation. This development should be prioritised and the updated methodology should be included in the risk assessment of both plant protection products and biocides as soon as possible.

In view of the above, The Netherlands considers it important that all active substances that may produce TFA as a metabolite are reviewed at European level as soon as possible, with specific attention to the leaching of TFA into groundwater. During this review, it should be tested on the basis of adequate studies whether TFA complies with the groundwater standard for relevant metabolites. Where possible, this review should be done within the framework of the ongoing renewal process. For substances for which this process has not yet been started, there are yet sufficient grounds to review the approval. The Netherlands, therefore, requests a review of the approval for all active substances for which the renewal process has not yet started, based on Article 21 of Regulation (EC) 1107/2009 and Article 15 of Regulation (EU) 528/2012.

For the active substances that are currently in the renewal process it should be determined, on a case-by-case basis, what the fastest and most suitable procedure is to include the most reliable scientific data on TFA formation. The Netherlands is well aware of the reasons why many active substances are already in the renewal process for a long period, but rapid decision making process should be considered of great importance.

For The Netherlands, where drinking water is largely extracted from groundwater, a robust European approach is crucial for the protection of the drinking water supply and public health.

Yours sincerely,

(directeur PAV)