



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food Safety, Sustainability, and Innovation
Pesticides and biocides

Brussels,
SANTE/E4/MGP/ai(2023)11845961

Dear

Subject: Your e-mail of 4 April 2023 on Commission's interpretation of Article 44 of Regulation (EC) No 1107/2009

I refer to your above-mentioned e-mail in which you ask the Commission for an interpretation of Article 44 of Regulation (EC) No 1107/2009¹ (the 'PPP Regulation') as regards the interaction with Directive 2000/60/EC (the 'Water Framework Directive' or 'WFD').

Article 44(1) of the PPP Regulation states: "*A Member State shall review an authorisation where it concludes that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved*".

In your interpretation, an authorisation of a PPP can be reviewed pursuant to Article 44(1) based on the non-fulfilment of WFD requirements, but the authorisation of the PPP cannot be amended or withdrawn pursuant to Article 44(3) based solely on the non-fulfilment of the WFD requirements, as this requires non-fulfilment of the requirements referred to in Article 29 of the PPP Regulation, which do not refer to the WFD.

You also mentioned that the WFD's environmental quality standards (EQS) are derived in a different methodological way and are in general lower than the regulatory acceptable concentrations (RACs) in surface waters identified in the context of approval of active substances used in PPP, and that, as a result, it is common to see cases where exceedance of the WFD-EQS is reported but there are no (or far fewer) exceedances of the RACs set out as end-points of active substances.

As regards how EQS are established in the context of the WFD, whether at EU level for the list of priority substances (of EU-wide concern) set out in Annex I to Directive 2008/10/EC on

¹ Regulation (EC) No 1107/2009

Environmental Quality Standards (the 'EQSD'), or at national level for the so-called 'River Basin Specific Pollutants' (of national concern), a detailed guidance document² has been developed under the Common Implementation Strategy for the WFD. This guidance explains in more detail the similarities and conceptual differences between an EQS, a Predicted No Effect Concentration (PNEC), and a RAC for a pesticide (see point 1.3 of the guidance document).

In summary, it concludes that a PNEC or RAC derived as part of a risk assessment will provide an important step in the derivation of an EQS and, in some cases, the PNEC from a risk assessment may be identical to the EQS. However, it will not be sufficient to simply adopt the PNEC as the EQS as a matter of course for several reasons. These reasons include the following:

- WFD EQS are intended to protect all receptors (including humans) from all routes of exposure;
- The risk assessment for PPPs allows for short term impacts from which recovery is possible. This is not a feature of the WFD.

The differences between the risk assessment procedure under the PPP Regulation and the WFD are also explained in the EFSA guidance on tiered risk assessment of pesticides (EFSA, 2013³) (see chapter 11.5.2). In particular, that guidance states:

"The protection goals underlying the WFD refer to human and ecosystem health. Within the context of ecosystem health and the EQS setting it is assumed that (1) ecosystem sensitivity depends on the most sensitive species (population) and (2) protecting ecosystem structure protects community functioning. EQSs are derived on the basis of predicted no effect concentrations (PNECs) for all relevant populations of water organisms (comparable to the ETO⁴). Although the generic protection goals of the WFD and PPP Regulation do not differ substantially, the SPGs⁵ of the Plant Protection Product Regulation do not exclude that under certain conditions short-term effects followed by recovery are acceptable (ERO)⁶, while EQS setting within the context of the WFD in principle is based on the ETO."

An important point to note is that the same toxicological data should (as far as possible given differences in the timing of regulatory processes) be used to derive EQS and RACs. Indeed, Commission Regulation (EU) No 283/2013⁷, point 7 of the introduction to Section 8 of Part A of the Annex states that *"All of the aquatic toxicity data shall be used when developing a proposal for environmental quality standards (Annual Average EQS, AA-EQS; Maximum Acceptable Concentration EQS, MAC-EQS). The methodology for derivation of these endpoints is outlined in the 'Technical Guidance for Deriving Environmental Quality Standards' for the Water Framework Directive 2000/60/EC of the European Parliament and of the Council."* In other words, the data generated for the purpose of a PPP authorisation should be considered when setting the EQS under the WFD.

As regards the consequences of non-compliance with the EQS under the WFD for PPP authorisations, Article 7a(3) of the EQSD states that *"Where the results of the report show that additional measures at Union or Member State level may be necessary in order to facilitate compliance with Directive 2000/60/EC in relation to a particular substance approved pursuant to Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012, Member States or the Commission shall apply Articles 21 or 44 of Regulation (EC) No 1107/2009 or Articles 15 or 48 of Regulation (EU) No 528/2012, as appropriate, to that substance, or products containing that substance"*.

² [Guidance No 27 - Deriving Environmental Quality Standards - version 2018.pdf \(europa.eu\)](#)

³ [Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters \(wiley.com\)](#)

⁴ Ecological Threshold Option

⁵ Specific Protection Goals

⁶ Ecological Recovery Option

⁷ [CL2013R0283EN0020020.0001_cp 1..1 \(europa.eu\)](#)

This means that in case of non-compliance with the EQS under the WFD, there must be a review of the PPP authorisation and the uses deriving from it, and that, where it can be established that the use of the PPP in accordance with the authorisation is responsible for, or contributes significantly to, that non-compliance, an authorisation under the PPP Regulation must be withdrawn or amended.

Article 44(1) of the PPP Regulation confirms this requirement for a review of an authorisation, as noted at the beginning of this letter. Article 44(3) specifies the circumstances requiring withdrawal or amendment of an authorisation, including point (a) on failure to satisfy the requirements of Article 29(1), point (c), on authorisation conditions not having been met, and point (d) on modifying the manner of use and amounts used on the basis of developments in scientific and technical knowledge. The reference to Article 44(3), point (a), leads back to Article 29(1), point (e), which in turn refers to Article 4(3) which requires a PPP to have, amongst others, no unacceptable effects on the environment. Non-compliance with the WFD deriving solely or substantially from the correct use of the authorised PPP uses would constitute such a unacceptable effect.

It is obviously important, when assessing the status of water bodies on the basis of monitoring results collected under the WFD, to bear in mind that some of the PPP residues measured may have come from a source unrelated to authorised use as a PPP in agriculture in the surrounding agro-ecosystem. Other relevant sources could include use in forestry, in public areas (e.g. roadsides), on amenities (e.g. golf courses), private gardens, or – depending on the active substances - for other purposes (e.g. as a biocide or veterinary medicine). Furthermore, consideration should be given to whether exceedances are sustained or occasional, how significant they are, and whether they are linked to particular environmental or seasonal conditions, or linked to incorrect use of the product or accidents.

Any exceedance of EQS deserves, therefore, to be analysed on a case-by-case basis to understand the reasons for the exceedance in order to be able to define appropriate follow up. Under the WFD, investigative monitoring can be carried out for this purpose. It is also helpful to recall that Article 67 of the PPP Regulation obliges professional users to keep records of their PPP uses with details which include the area, the crop, and the product and rates used, and to make these records available to authorities on demand. Such records will be available electronically by 1 January 2026, as defined by the recently adopted Implementing Regulation (EU) 2023/564⁸ for Article 67, and this is expected to facilitate the tracing of the sources of such EQS-exceedances.

Furthermore, measures that can be taken to reduce chemical pollution to achieve the objectives of the WFD include those in the Directive on the Sustainable Use of Pesticides (SUD). In relation to PPPs, such measures may include, e.g.: advisory services, lower dose rates and the establishment of buffer zones. The National Action Plans under the SUD could cover increased monitoring and inspections by water authorities. A Guidance Document on monitoring is available under the SUD⁹, and monitoring can also be set as condition under the PPP Regulation, if considered appropriate. The Water Safety Plan approach under the Drinking Water Directive can be supported by riparian buffer strips, fencing of riparian areas, or installation of biobeds.

Please note that this position represents the opinion of the concerned services of the European Commission. It is not legally binding and without prejudice to any interpretation given by the Court of Justice of the European Union.

⁸ Commission Implementing Regulation (EU) 2023/564 of 10 March 2023 as regards the content and format of the records of plant protection products kept by professional users pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 74, 13.3.2023, p. 4)

⁹ Commission Notice of 10.10.2017 Guidance on monitoring and surveying of impacts of pesticide use on human health and the environment under Article 7(3) of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (referred to as the Sustainable Use Directive)

Yours sincerely,

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