Deriving Environmental Quality Standards for chemical substances in surface waters

Background

Under the EU Water Framework Directive (WFD), Environmental Quality Standards (EQS) are used as regulatory values to verify whether the risk of substances regulated under the WFD is acceptable. The risk is considered acceptable if the measured environmental concentration (MEC) is lower than the EQS. The derivation of EQS is laid down in the CIS guidance document 27 [1] by the European Commission. Like other EU guidance documents for assessing the risk of chemical substances for surface waters, e.g. under REACh or the Biocidal Products Directive (BPD), it is largely based on the Technical Guidance Document on Risk Assessment [2].

What are environmental quality standards?

Environmental Quality Standards are substance-specific concentrations of individual chemicals in the aquatic environment below which no harmful effects on aquatic organisms are expected. In general, the more toxic a substance is, the less of it can be tolerated in a waterbody. Two separate values are determined in each case. The acute EQS (MAC-EQS) is intended to provide protection against short-term exposure peaks. Short-term pollution levels occur, for example, after rain events that flush applied plant protection products into water bodies. Chronic EQSs (AA-EQS) are intended to provide protection against prolonged exposure, which can result, e.g., from the continuous emission of pollutants via municipal wastewater treatment plants. Under REACh and the BPR, the term PNEC is used instead of EQS. Despite different terminology, PNECs are derived according to the same methods and principles (Tab 1).

EQSs and PNECs are derived on the basis of the current state of knowledge, so they should be reviewed at regular intervals.

Table 1 Terminology of effect values in EU environmental risk assessment

	Long-term	Short-term
WFD	AA-EQS	MAC-EQS
REACh, BPD	PNEC	$PNEC_{intermittent}$

How are acute and chronic EQS derived and updated?

First, ecotoxicological data from all available sources (public literature, accessible approval studies, databases, other substance evaluations, etc.) are compiled. All studies are evaluated for their reliability and relevance [3]. Finally, only values from reliable and relevant studies are being used for the derivation of EQS.

There are three methods to derive MAC-EQS and AA-EQS. Firstly, the assessment factor (AF) method, secondly, the species sensitivity distribution (SSD) method, and thirdly, the derivation based on effect concentrations, which were determined by means of micro- and mesocosm studies (model ecosystems). The latter represents a more realistic exposure scenario compared to laboratory tests, with multiple species. Since mesocosms are complex, they are not often available.

The choice of the derivation method depends mainly on the number of existing effect data. The AF method has the lowest data requirements, which is why it is also the most commonly used method. Data must be available for at least three aquatic species, representing three trophic levels in the food chain: primary producers (e.g. algae), primary consumers (e.g. water fleas) and secondary consumers (e.g. fish). If all three are available, this is referred to as a complete base set. The AF method assumes that the entire ecosystem can be protected by protecting the weakest link in the food chain.

The SSD method takes a different approach. It assumes that the sensitivity of the different species in the ecosystem can be described with the help of a statistical distribution. For an SSD to be sufficiently robust, relatively high data requirements apply: At least ten, but ideally more than fifteen toxicity values must be available for different species from at least eight defined plant and animal groups. From the SSD, an EQS is determined according to WFD Guidance Document 27 [1].

To derive EQS based on micro- or mesocosm studies is often not possible. If available at all, many of these studies were carried out for the authorisation of plant protection products. They are often not relevant for EQS derivation, because they do not meet the requirements of the Guidance on EQS derivation [1].

Assessment factors are used in all three derivation methods, because it is assumed that communities in the environment may react more sensitively to a substance than the available toxicity data suggest. Basically, the less data available, the higher the assessment factor.

When deriving an AA-EQS based on the AF method, an AF of 10 is used when the chronic data set is complete. If data are missing, higher AFs (50 to 1000) are applied (Tab 2). For the MAC-EQS the default AF is 100. This can be reduced to 10 if it can be assumed that the most sensitive taxonomic group is represented in the data set.

The SSD method also uses an assessment factor in the end. This is usually lower than for the AF method (MAC-EQS: 5-10; AA-EQS: ≤ 5), assuming that the uncertainty is smaller. The data in the SSD have to be normally distributed, if the EQS is derived based on this method. Assessment factors ≤ 5 are used for mesocosm studies.

If possible, EQS should be derived according to all three methods. In the end, the risk assessor is choosing the final EQS. EQS derived from SSDs and mesocosms are usually preferred. However, it is accepted that there might be cases where the final EQS is based on the AF method.

Table 2 Assessment Factors for the derivation of the AA-EQS for freshwater ecosystems

Available data	**Assessment Factor**
At least one **short-term** L(E)C50 from each of **three trophic levels** (fish, invertebrates (preferred Daphnia) and algae) (i.e. base set)	**1000**
One long-term EC10 or NOEC (either fish or Daphnia)	**100**
Two **long-term** results (e.g. EC10 or NOECs) from species representing **two trophic levels** (fish and/or Daphnia and/or algae)	**50**
Long-term results (e.g. EC10 or NOECs) from at least three species (normally fish, Daphnia and algae) representing **three trophic levels**	**10**

Bioaccumulation and secondary poisoning

Substances with a log Kow >3 or a BCF >100 are considered to have the potential of accumulating in the food chain of ecosystems. For those substances the risk from secondary poisoning to fish eating birds like herons and mammals like otters has to be assessed as well [1]. The resulting EQS for secondary poisoning is compared to the AA-EQS. If the AA-EQS for direct aquatic toxicity is higher, the EQS for secondary poisoning is chosen as the final AA-EQS.

During the EQS derivation also an assessment of human health is being made. If triggered by the toxicological and chemical characteristics of the substance under evaluation, EQS for drinking water consumption as well as for the consumption of fisheries products are derived. These EQS will replace other AA-EQS, if they are lower [1].

EQS for the protection of sediment species

Sediment dwelling organisms require their own effect assessment. WFD guidance document 27 [1] describes the methodology of deriving sediment EQS.

Ideally, the sediment EQS is derived based on ecotoxicity data from long-term tests with sediment dwelling organisms in which the sediment was spiked with the substance. Often the EQS are derived based on the AF method because not enough data are available to apply the SSD method. Like for the pelagic species an AF of 100 is used if only one chronic datum is available, 50 if two and 10 if three data from long term tests with species representing different living and feeding conditions are available.

For many substances no sediment toxicity data are available. Under these circumstances sediment EQS are calculated from data for pelagic species using an extrapolation based on equilibrium partitioning.

Effect assessment for Plant Protection products

Whether a particular plant protection product (PPP) poses a risk to aquatic organisms must be assessed in the EU and other countries like Switzerland and Norway as part of the authorisation procedure for the individual product [4]. From the risk assessment during authorisation, so-called Regulatory Acceptable Concentrations (RAC) can be derived, below which no unacceptable adverse effects on aquatic organisms are expected.

The determination of RAC values is not regulated under the plant protection products Regulation (EC) No 1107/2009 [4], but is based on recommendations of the European Food Safety Authority (EFSA) [5]. Some countries publish their RAC values, e.g. Germany, Switzerland and the Netherlands. These values serve as a guideline for the review of PPPs in the context of the authorisation procedure and for assessing the effectiveness of risk reduction measures during their application.

Methodological differences between RAC and EQS

The three methods (AF, SSD and Mesocosm) used for EQS or PNEC derivation also serve as the basis for deriving the RAC value. However, they are used in a tiered approach in such a way that the less complex methods are applied first (assessment factor method -> SSD method -> micro- or mesocosm method). In the first tier, it is tested whether the TER values (comparable to assessment factors) are met. The TER are the ratios between effect concentrations for fish, water fleas and algae and the predicted environmental concentration (PEC) required under 1107/2009 [4]. The other methods are described in a technical document of EFSA [5] and are used in practice to check whether the use of the plant protection product under the proposed conditions does not have unacceptable effects on the viability of aquatic organisms. If this is the case, a permit can be granted. At each stage, the risk is determined by comparing the result of the effect assessment with the PEC. Only if the risk is not acceptable, i.e. the PEC value is greater than the RAC, the next tier of the risk assessment is carried out.

Even though EQS and RAC are basically based on the same methods, there are methodological differences in detail that can lead to different values. These are, for example:

- Consideration of temporary negative effects: In the context of PPP authorisation, short-term negative effects on algae or invertebrates observed in mesocosm studies may be accepted under certain conditions and if the organisms recover within a few weeks.

- Greater tolerance for effects on algae and aquatic plants: In the EQS derivation, chronic toxicity to aquatic plants and algae is assessed using concentrations at which only 10% of the test organisms are affected (EC10), or even no difference to the control can be determined, i.e. at the no observed effect concentration (NOEC). For the RAC derivation, on the other hand, the endpoint of the EC50 is used, at which 50% of the test organisms are already affected. RACs for substances which mainly affect plant and algal species are thus higher than AA-EQS even if the same data set and derivation method is used.

Quantitative differences

Due to different methodologies used for PPP approval and water protection legislation, there are more or less significant differences between chronic AA-EQS, acute MAC-EQS and RAC. For herbicides and other substances, for which plants are most sensitive, the RAC is likely to be in a similar concentration range as the MAC-EQS. If the RAC is based on invertebrate or vertebrate ecotoxicity data, it is likely to be within the range or even identical to the AA-EQS. If the RAC is based on a mesocosm study, and recovery is accepted, it is possible that the RAC is even higher than both AA-EQS and MAC-EQS.

Substances without experimental data

If experimental data are partially or completely lacking, e.g. for REACh substances, transformation products or ingredients in personal care products, no formal AA-EQS or PNEC can be derived. Even if these compounds are frequently found in the environment, there is often no legal requirement to generate new ecotoxicity data. Hence, the evaluation of their environmental risks would not be possible.

In such cases, the use of in silico methods, such as quantitative structure activity relationships (QSAR), have been suggested and successfully used to assess and prioritize the risk of these compounds [6]. In the NORMAN network, these threshold values are referred to as provisional PNECs (P-PNEC) and are used to compare the risk of compounds in environmental mixtures in a stepwise approach, i.e. identified risks based on P-PNEC result in the evaluation of these compounds and the need to verify the potential risk based on experimental studies.

Bibliography

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