Muddy waters. Navigating the EFSA / ECHA drinking water treatment guidance for biocidal products: Impacts, challenges and uncertainties

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Introduction

The EFSA/ECHA guidance document[1] on the impact of water treatment processes on residues in water abstracted for drinking water production applies to both active substances and products under Regulation (EU) 528/2012 from April 1, 2026[2]. In many cases, the biocidal product application stage will represent the first time the active substance(s) involved will be evaluated against this guidance. The guidance broadly consists of three parts: (i) environmental exposure, (ii) water treatment transformation product (tTP) testing, (iii) human health hazard assessment. Understanding the environmental exposure is therefore critical as it triggers subsequent tTP testing and human health hazard assessment. Using the publicly available data from the active substance approvals process, an assessment of the proportion of biocidal products likely to require tTP testing was made based on the environmental risk assessments conducted for the representative products. In considering the environmental exposure pathways and models across the different product types, uncertainties come to light in the application of the guidance and consideration of further impacts and challenges on the stewardship of biocidal products through the regulatory process is made.

Data set

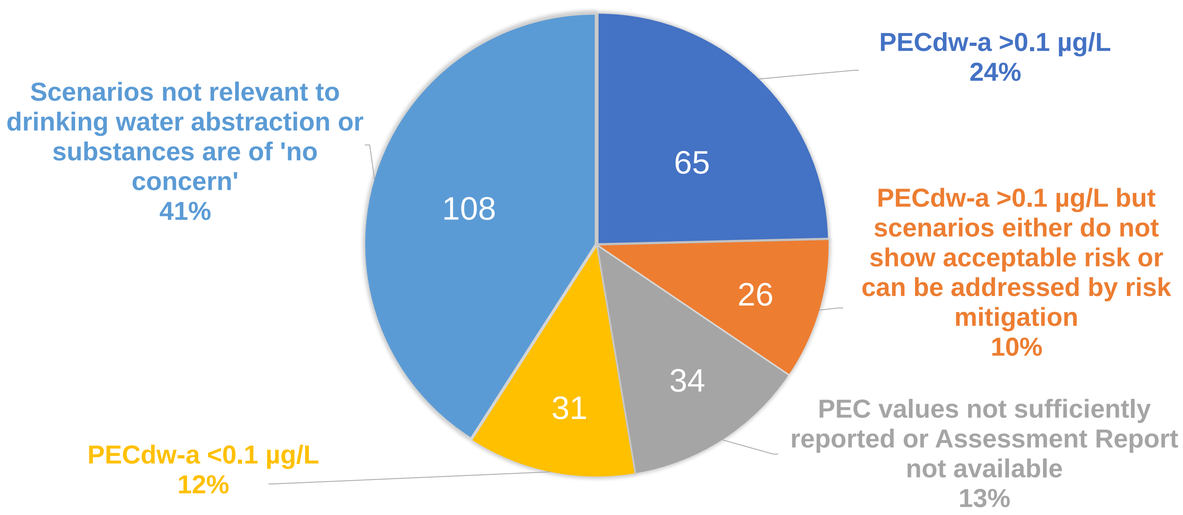
A list of all EU approved active substance-product type (a.s.-PT) combinations was obtained from the ECHA database in July 2024[3]. The database contains 294 approved a.s.-PT combinations, 30 of which are for Annex I (low risk) substances. Excluding Annex I substances, there were 139 individual active substances approved on the EU market.

Screening approach

For each of the approved a.s.-PT combinations (excluding Annex I), the associated Assessment Report or Competent Authority Report (CAR) was downloaded. Data was available for 252 of the remaining 264 a.s-PT combinations (12 a.s-PT combinations (5%) did not have assessment reports available). The environmental risk assessments for the representative products were screened against the following criteria:

- Relevance of water bodies in the emission scenario(s) to drinking water abstraction
- Reported PEC_{dw-a} >0.1 µg/L (based on PEC_{sw} and PEC_{gw})
- $PNEC_{sw}$ <0.1 µg/L
- Quantitative assessment of metabolites

Screening of representative product exposure assessments for PEC_{dw-a}



Impacts

Scenario relevance to drinking water abstraction points

Although the guidance acknowledges that some scenarios will not result in exposure of water bodies relevant to the abstraction of drinking water, this must be considered on a case-by-case basis:

- 217 a.s-PT assessments (82%) include scenarios with emission to water bodies clearly relevant to drinking water abstraction (e.g. emission via the sewage treatment plant (STP), groundwater exposure following sludge application to soil)
- For 20 a.s-PT assessments (19%), exposure of relevant water bodies could be excluded based on negligible exposure (e.g. indoor use of solid baits) or the exposed water body being small scale (such as garden ponds)
- For 15 of the assessments (6%) it is uncertain if the exposed water bodies would be considered relevant for drinking water abstraction, e.g. for coastal waters or marinas. Taking a cautious approach and including these scenarios as relevant potentially triggers tTP formation, and subsequent toxicity, testing that may not be warranted, however excluding these scenarios may result in requests for further data late in the evaluation process if a Regulator concludes the opposite

PEC_{dw-a} >0.1 µg/L

91 a.s-PT combinations (34%) with scenarios relevant to drinking water abstraction report PEC values >0.1 µg/L and therefore would potentially trigger tTP testing:

- For 26 of these, the scenarios did not show acceptable risk (PEC_{sw}/PNEC >1 or active substance PEC_{gw} >0.1 µg/l) or could be addressed by risk mitigation measures
- For the remaining 65 a.s-PT combinations (24%) tTP testing would be unavoidable

34 a.s-PT combinations (13%) were insufficiently reported, or the Assessment Reports were unavailable, to assess PEC_{dw-a}.

Quantitative assessment of metabolites

102 a.s-PT combinations (39%) report metabolite formation at concentrations sufficient to trigger inclusion in the environmental exposure assessment. However, only 54 of these (20%) reported a quantitative assessment for the metabolites.

In most cases a quantitative risk assessment was considered unnecessary based on lower ecotoxicity compared to the parent substance, but a quantitative assessment would now be required to determine PEC_{dw-a}. Often minimal environmental fate data are available for the metabolites in question, so the environmental exposure assessment would be conducted based on worst-case defaults, increasing the likelihood of PEC_{dw-a} exceeding 0.1 µg/L. Additional environmental fate data may therefore be necessary for the metabolites in order to refine the PEC_{dw-a} to avoid triggering tTP formation testing.

EFSA / ECHA Guidance (2023) for Biocides

Exposure

Step 1: Identify substances >0.1 µg/L at drinking water abstraction points (PEC_{dw-a}) including active substances, environmental transformation products (eTP) and substances of concern
PEC_{dw-a} = PEC_{sw} or PEC_{gw} where the waterbody is relevant for drinking water abstraction

tTP formation

Step 2: Literature search and modelling
Step 3: Testing at high concentrations (1000 x LOQ)
Step 4: Testing at low concentrations (1 – 10 µg/L)
Step 5: Identify treatment transformation products (tTPs) ≥0.075 µg/L

Hazard assessment

Step 6
- Tier 1: Genotoxicity
- Tier 2: General toxicity assessment
- Tier 3: General toxicity assessment other than genotoxicity and repeat dose toxicity

Challenges

Limited options for refinement

The guidance notes that where a PEC_{sw} exceeds the 0.1 µg/L threshold, it may be preferable to refine the exposure assessment before carrying out tTP formation testing. Surface water emissions for most biocides occurs indirectly via the sewage treatment plant (STP) in which the STP effluent is diluted by a factor of 10 in the receiving water body (ECHA, 2017)[4]. Under the drinking water treatment guidance for biocides PEC_{sw} = PEC_{dw-a}, meaning no further dilution or removal processes in the water body are considered between emission from the STP and abstraction for drinking water treatment. This does not align with the approach described for Plant Protection Products in which a 4d-PEC_{sw} is recommended for PEC_{dw-a}.

Refinement options for the exposure assessment are limited. Conducting STP simulation studies may result in a reduction of the PEC_{sw} for the active substance but have the potential to identify additional metabolites that would then require inclusion in the exposure assessment.

$PNEC_{sw}$ <0.1 µg/L

39 a.s-PT assessments (15%) report $PNEC_{sw}$ <0.1 µg/L, therefore if PEC_{sw} (PEC_{dw-a}) exceeded the trigger for tTP testing, unacceptable risk to surface water would be demonstrated. In many cases, additional ecotoxicity data could be submitted to improve (increase) the $PNEC_{sw}$ to demonstrate acceptable use, however, this has the potential to trigger the need for tTP testing adding additional complexity to the stewardship of the product through the regulatory process.

Substances of Concern

The criteria for identification of substances of concern (SoC) are primarily based on toxicity and the recent addition of new hazard classes to the CLP regulation[5] are likely to draw additional substances into scope. However, there is no evidence that these substances pose an inherent risk for tTP formation compared to other 'non-hazardous' co-formulants, raising the question of how relevant these criteria are for inclusion in the drinking water treatment assessment.

Data availability for SoC is often limited, therefore exposure assessments are frequently conducted based on worst case defaults, compounding the conservatism of the exposure assessments. The costs of conducting tTP formation testing and subsequent toxicity testing for multiple SoC within a formulation are likely to be prohibitively expensive and time consuming. Early screening of formulations for SoC and preliminary environmental exposure assessments are therefore critical to allow sufficient time to find mitigations before applications are submitted.

Uncertainties

Substances of No Concern

49 active substances (approved in 106 a.s-PT combinations) may potentially be considered as 'substances of no concern' based on rapid reactivity, natural occurrence at higher levels, the criteria specified in SANCO/221/2000[6] or are microbes. However, such substances are only omitted from the formal tTP formation assessment on a case-by-case basis, leading to uncertainty as to exactly where the line is drawn between 'concern' and 'no concern'.

Whilst disinfectants such as active chlorine, which are themselves used in the drinking water treatment process, would not trigger tTP testing under the current guidance, an assessment of the formation of disinfection by-products from their use in biocidal products will be required once guidance on this subject is finalised and implemented.

Aggregated exposure

Although formal guidance on the subject is still under development, aggregated exposure is currently considered in the environmental risk assessment of biocidal active substances and products. Aggregated exposure is not discussed in the drinking water treatment guidance so it is uncertain how, or if, this must be considered in the assessment of PEC_{dw-a}.

References

1 Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water. EFSA Journal 2023; 21(8): 8194
2 CA-June24-Doc.7.2 - Applicability Impact of water treatment guidance_final.docx (available on CIRCABC)
3 https://echa.europa.eu/information-on-chemicals/biocidal-active-substances (accessed on 29/07/2024)
4 Guidance on the Biocidal Products Regulation. Volume IV Environment – Assessment and Evaluation (Parts B + C), Version 2.0, ECHA, 2017
5 Commission delegated regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures
6 Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No. 1107/2009. SANCO/221/2000-rev. 11, European Commission 2021

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