Water treatment and disinfection by-products: A comparison of approaches for crop protection and biocidal products in the EU

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Water treatment for crop protection products

Regulation (EC) No 1107/2009 lays down the rules for the authorisation of crop protection products in Europe with the aim of protecting humans and the environment. During primary disinfection processes for central water treatment (e.g. ozonation, chlorination) certain active substances included in crop protection products and their metabolites have the potential to form **unwanted by-products with e.g. toxic, carcinogenic and genotoxic characteristics**. Notwithstanding that the EFSA (European Food Safety Authority), the scientific advisory body of the European Commission, has recently identified **data gaps** during the approval process of active substances, water treatment processes have **not (yet) been implemented in the European data requirements (Reg. 283/2013 or 284/2013)** relevant for the authorisation of crop protection products. Further, **no guidance document for experimental testing** is available. With this information pending, addressing water treatment processes successfully becomes a **challenge** for applicants of crop protection products [1].

Disinfection by-products

Biocidal Product Regulation (BPR) (EU) 528/2012 regulates the application of disinfectants for water treatment. **Disinfection by-products (DBPs)** are formed during the disinfection process using oxidizing, halogen-containing biocidal products. According BPR (2012), the effect of residues, which includes per definition also reaction products like DBPs, should be further evaluated in the **risk assessment**, as **known DBPs** like trihalomethanes and haloacetic acids can be **biologically active and stable in the environment**.
A recently published guidance document, **Guidance on the Biocidal Products Regulation, Volume V, Guidance on Disinfection By-Products (2017)** [2], defines a **stepwise approach** for an **environmental risk assessment (ERA)** of DBPs and provides further guidance for testing strategies, like whole effluent testing.

Comparison of approaches for crop protection and biocidal products in the EU

	Framework for crop protection products	Framework for biocidal products
Regulatory context	◗ EU Regulation (EC) No 1107/2009, Article 4 3(b) ◗ EFSA request to address water treatment	◗ Biocidal Products Regulation (BPR, 2012) ◗ Art 3 (1)(h) – residues include reaction products and Art 19 (1)(b)(iii) – risk assessment necessary for residues
Rationale for assessment	◗ Regulatory context & formation of unknown DBPs ◗ EFSA data gaps with request to provide assessment 2 years after adoption of guidance document	◗ Formation of DBPs due to disinfection of water with oxidising biocides ◗ DBPs may be biologically active and more stable than biocidal active substance itself
Relevant substances	◗ All active substances and their metabolites under approval/renewal [3] ◗ Varying likelihood of toxic properties of newly formed unknown compounds	◗ Oxidising substances (mainly halogenated ones containing chlorine or bromine) ◗ Main Product Types 2, 11 and 12 (1, 3, 4 and 5 also relevant)
Guidance documents	◗ None in force, draft guidance under development [4] ◗ Ozonation and chlorination to be considered for assessment	◗ Guidance on the Biocidal Products Regulation; Volume V – Guidance on Disinfection By-Products (2017) [2]
Relevant reactants / reaction products (DBPs)	◗ Ozone, OH-radicals, chlorine, hypochlorite, etc. ◗ No cut-off catalogue of by-products available	◗ Trihalomethanes (THMs), haloacetic acids (HAAs), haloaldehydes, haloketones, haloacetonitriles (HANs), bromate, chlorate/chlorite
Relevant environmental compartments	◗ Independently of environmental compartment all relevant metabolites to be addressed	◗ All environmental compartments, i.e. soil, surface water, sediment, groundwater ◗ Assessment triggered by exposure routes for the biocidal active substance itself
Risk assessment	◗ Laboratory studies (nitrosamines) ◗ Theoretical approaches based on chemical structure and predicted reactions with ozone and chlorine moieties via literature examples ◗ Calculation via quantum chemistry (R&D companies) ◗ Discussion on concentrations at raw water abstraction points *vs* ◗ Provide statement to waive request as no guidance available	◗ Stepwise approach (no tiered approach, all steps should be completed as required and necessary): ◗ Step 1: Worst case calculation for known markers with the highest toxicity assuming 100% conversion from active substance ◗ Step 2: Chemical assessment (changes of group parameters like AOX or TOX should be investigated alongside substance specific PEC/PNEC approach) → interrelationship to ecotoxicity should be established ◗ Step 3: Refined ERA for known marker DBPs (at least THMs, HAAs, HANs, bromate, halogenated phenols and halogenated amines) combined with whole effluent testing approach to cover unknown DBPs

References

[1] Agropages (2018): Dorn S. & Schnitzler F., Water treatment – Why is it a regulatory challenge for plant protection products in the EU?, 28.10.2018. http://news.agropages.com/News/NewsDetail---28186.htm
[2] ECHA (2017): Guidance on the Biocidal Products Regulation, Volume V, Guidance on Disinfection By-Products.
[3] ANSES (2019): AVIS de L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'évaluation de la pertinence des métabolites de pesticides dans les eaux destinées à la consommation humaine. Avis de Anses, Saisine n°2015-SA-0252.
[4] EFSA (2018): Minutes of the EFSA Network on Pesticide Steering meeting, Parma (12-13 June 2018).

Technical and regulatory challenges

Crop protection products

CP

- Water treatment processes not implemented in data requirements
- Currently no guidance document available for experimental testing
- Open question how to deal with the topic for product registrations
- Parent and metabolites to be addressed
- Handling of potential toxic DBP or new DBP findings – further assessment required?

Biocidal products

BP

- Grouping of substances difficult
- Endpoints not available (data availability crucial; QSAR, Reach data, literature data, etc. relevant)
- Derivation of reliable concentrations of different DBPs as input for environmental risk assessment
- Mixture toxicity
- Monitoring and testing is time and cost consuming

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