

Water Treatment – A Regulatory Challenge for Crop Protection Products in the EU

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Water Treatment – Why a Regulatory Challenge?

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. It is known that 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]

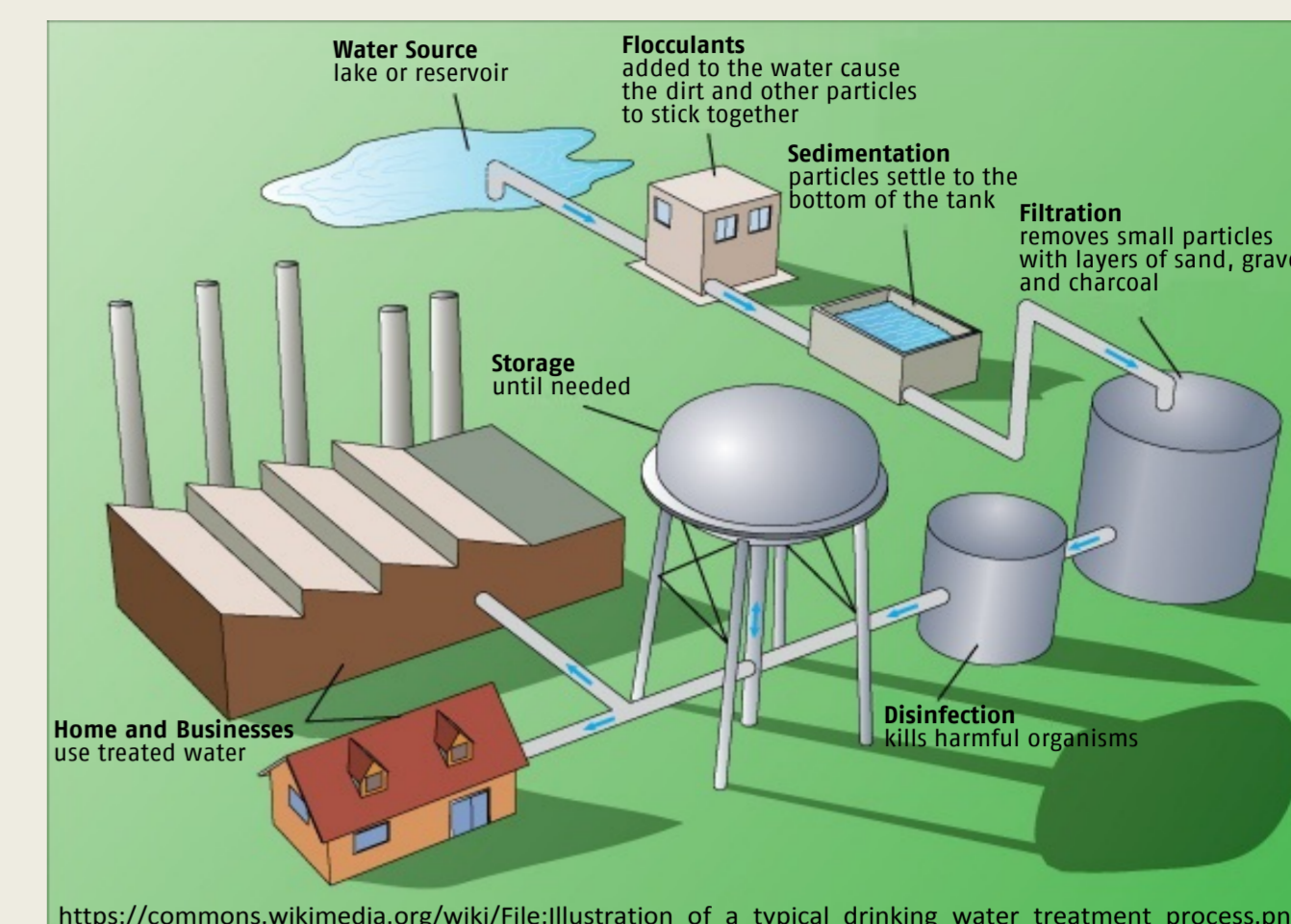
Regulatory relevant Treatment Processes

Primary disinfection:

- Ozonation (ozone)
- Chlorination (chlorine)

Trend away from these processes – known to bear risks – towards:

- Nano-filtration
- Inverse osmosis
- Activated carbon adsorption (powder, micro-grains)



Drinking water treatment process [2;3]

Treatment processes linked to country level

How successful are current Attempts to address the Issue?

81 EFSA conclusions for AIR3 substances available
(Status: 09 May 2019)

25 a.s. no data gap

12 a.s.
not addressed
but no data gap

13 a.s.
successfully
addressed

56 a.s. with data gap

32 a.s.
waived or
ignored

24 a.s.
addressed
without success

- 1-methylcyclopropene (gas – plant growth regulator)
- ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) (biofungicide)
- *Ampelomyces quisqualis* Strain: AQ 10 (fungal isolate)
- Azadirachtin (Margosa extract – insecticide)
- *Bacillus subtilis* strain IAB/BS03 (soil bacterium – fungicide)
- *Beauveria bassiana* strain PPRI 5339 (fungal isolate – insecticide)
- Benzoic acid (use: disinfection)
- *Coniothyrium minitans* Strain CONIM/91-08 (DSM 9660) (fungal isolate)
- *Glodiadium catenulatum* (fungal isolate)
- *Pasteuria nishizawae* Pn1 (soil bacterium – nematocidal)
- *Pseudomonas chlororaphis* (soil bacterium)
- *Verticillium albo-atrum* strain WCS850 (fungal isolate)

- 2,4-DB (no further information available)
- Clodinafop (variant evaluated clodinafop-propargyl) (discussion on concentrations)
- Ethofumesate (experimental study + theoretical assessment)
- Fenamiphos (oxidation addressed only, however no detailed information available)
- Florpyrauxifen (variant assessed florpyrauxifen-benzyl) (no further information available)
- Forchlorfenuron (discussion on concentrations + theoretical assessment)
- Imazosulfuron (no further information available)
- Laminarin (discussion on concentrations + literature search)
- Mecoprop-P (no further information available)
- Methiocarb (discussion on concentrations + literature search (only chlorination))
- Propanil (no further information available)
- Sodium hydrogen carbonate (discussion on concentrations)
- Tolclofos-methyl (no further information available)

EFSA:

... a data gap was identified for information on the effect of water treatment processes ...

... gap leads to the consumer risk assessment from the consumption of drinking water being not finalised ...

... consideration of the processes of ozonation and chlorination would appear appropriate ...

The data gap identified by EFSA arises from Article 4 (approval criteria for active substances) 3(b) of Regulation (EC) No 1107/2009:

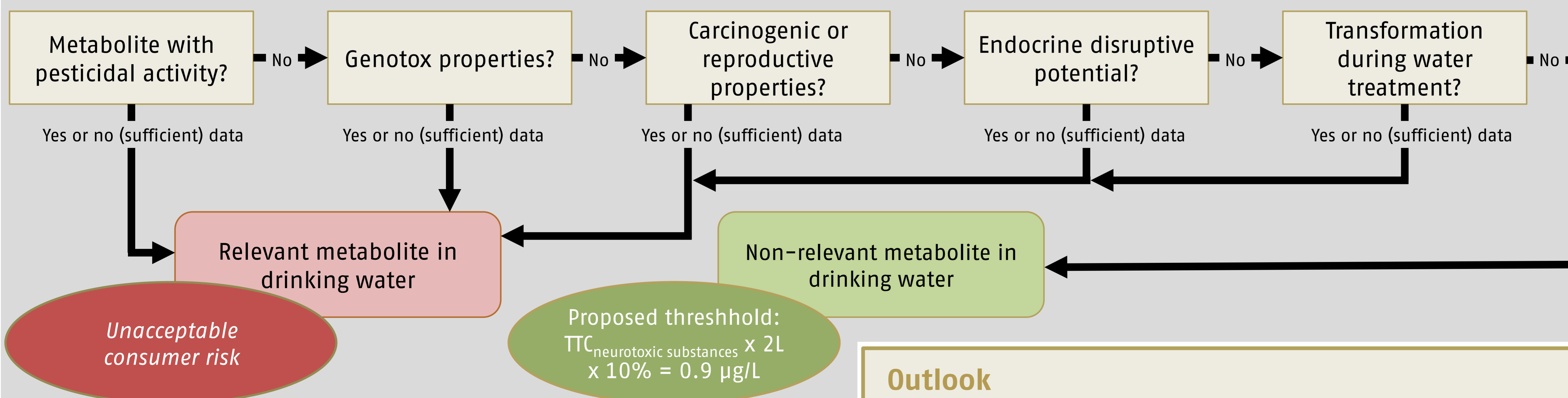
3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:
(b) it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater; ...

Current EU Position

The applicant shall submit (confirmatory) information to the Commission, the Member States and the Authority within two years after adoption of a guidance document on evaluation of effects from water treatment processes on the nature of residues present in surface- and groundwater.

Recent Developments

- At EU level: Guidance development regarding evaluation of effects from water treatment processes on nature of residues in treated water initiated [4]
- Meanwhile: Persistence definition and persistence criteria for metabolites in drinking water established [3]
 - „A metabolite with pesticidal activity is evaluated as persistent in drinking water in case it is suspected to cause an unacceptable risk for human health“



Outlook

- Considerations of effects from water treatment processes need implementation into the regulation for plant protection products
- A guidance document for experimental testing is required
- How to deal with issue for product authorizations needs addressing
- Parent and metabolites have to be addressed

[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] WHO (2011): Guidelines for drinking-water quality – 4th ed., ISBN 978 92 4 154815 1.

[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 persistance 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).