Water Treatment – A Regulatory Challenge under Regulation (EC) No 1107/2009

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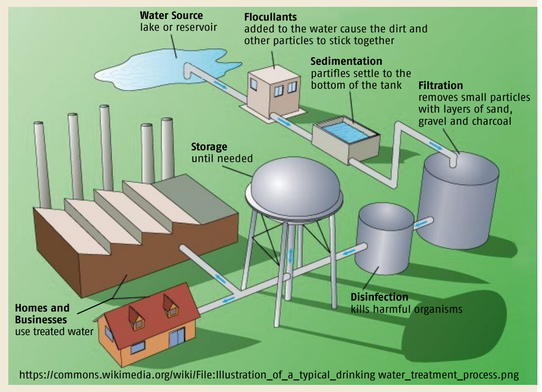
Water Treatment – Why a Regulatory Challenge?

Regulation (EC) No 1107/2009 lays down the rules for the authorisation of plant protection products with the aim of protecting humans and the environment. It is known that certain active substances which are included in plant protection products and their metabolites react during primary disinfection processes for central water treatment (e.g. ozonation, chlorination) to form by-products with e.g. toxic, carcinogenic and genotoxic characteristics. Notwithstanding that EFSA has recently identified data gaps during the approval process of active substances, water treatment processes are not (yet) implemented in the data requirements (Reg. 283/2013 or 284/2013) relevant for the authorisation of pesticides and no guidance document for experimental testing is available. With this information pending, addressing water treatment processes successfully becomes a challenge for applicants.

What Are the Main Processes Applied for Central Water Treatment?

- Primary disinfection:
  - **Ozonation (ozone)**
  - **Chlorination (chlorine)**
  - Chloramination (chlorine dioxide)
  - UV radiation
- Filtration (rapid gravity filters, roughingfilters, pressure filters, slow sand filters, bank filtration)
- Aeration
- Membrane processes (high-pressure, low-pressure)
- Chemical coagulation
- Activated carbon adsorption
- Ion exchange

Used individually or in combination

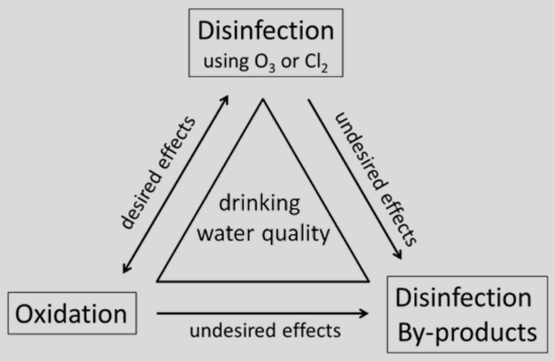


Drinking water treatment process

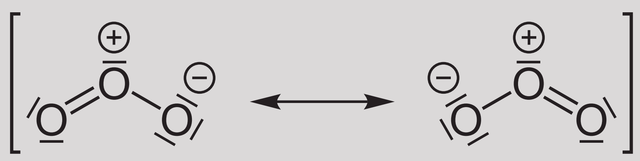
Treatment processes linked to country level

[5]

Regulatory Relevant Treatment Processes

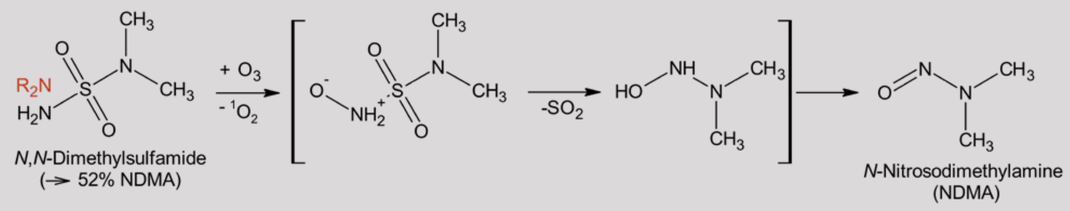


Ozonation



https://upload.wikimedia.org/wikipedia/commons/d/d7/Ozon_Mesomerie.svg

Example for formation of undesired by-product [1]:



N,N-Dimethylsulfamide (→ 52% NDMA)

As NDMA is characterized to be carcinogenic, genotoxic and toxic for reproduction [2] its presence in drinking water should be avoided [3]. The German UBA e.g. sets a guidance value for drinking water (GOW) of 10 ng NDMA/L [4].

Chlorination

When dissolved in water, chlorine converts to an equilibrium mixture of chlorine (Cl_2), hypochlorous acid (HOCl), and hydrochloric acid (HCl):

$$Cl_2 + H_2O \longleftrightarrow HOCl + HCl$$

In acidic solution, the major species are Cl_2 and HOCl, whereas in *alkaline solution*, effectively only ClO^- (hypochlorite ion) is present:

$$Cl_2 + 2\ OH^- \longrightarrow Cl^- + ClO^- + H_2O$$

Very small concentrations of ClO_2^-, ClO_3^-, ClO_4^- are also found.

How Successful Are Current Attempts to Address the Issue?

49 EFSA conclusions for AIR3 substances available
(Status: 16 April 2018)

12 a.s. no data gap

5 a.s. not addressed but no data gap

- ***Ampelomyces quisqualis* Strain: AQ 10** (fungal isolate)
- **Benzoic acid** (use: disinfection)
- ***Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660)** (fungal isolate)
- ***Gliocladium catenulatum*** (fungal isolate)
- ***Pseudomonas chlororaphis*** (soil bacterium)

7 a.s. successfully addressed

- **2,4-DB** (no further information available)
- **Ethofumesate** (experimental study + theoretical assessment)
- **Forchlorfenuron** (discussion on concentrations + theoretical assessment)
- **Imazosulfuron** (no further information available)
- **Laminarin** (discussion on concentrations + literature search)
- **Mecoprop-P** (no further information available)
- **Tolclofos-methyl** (no further information available)

37 a.s. with data gap

18 a.s. waived or ignored

19 a.s. addressed without success

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; …*

Applied Ways of Addressing Ozonation and Chlorination

- Providing **laboratory** studies
- **Theoretical** approaches based on
  - chemical structure and expected reactions with ozone and chlorine via literature examples
  - calculation via quantum chemistry
- Discussion on **concentrations** at raw water abstraction points
- **Waiving** as no guidance available

The Regulatory Challenge

- Water treatment processes are **not implemented in the data requirements** (Reg. 283/2013 or 284/2013)
- Currently **no guidance document available** (for experimental testing)
- Open question how to deal with for **product registrations**
- **Parent *and* metabolites** have to be addressed

EU Position and Recommendations

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

DEVELOPMENTS: No major focus on guidance development at the moment

CONSULTANCY RECOMMENDATIONS: For active substance dossiers,

(I) do not address the issue at all as data waiving does not result in non-approval

(II) try to avoid data gap and potential request for confirmatory data by addressing the issue on EU level alongside the submission

[1] Schmidt, C. K. and Brauch, H.-J. (2008): N,N-Dimethylsulfamide as Precursor for N-Nitrosodimethlyamine (NDMA) Formation upon Ozonation and its Fate During Drinking Water Treatment. Environ. Sci. Technol., 42 (17), 6340-6343; DOI: 10.1021/es7030467.
[2] Gefahrstoffdatenbank Uni Hamburg (2018): NDMA; visited 26 April 2018. https://www.chemie.uni-hamburg.de/claks/gefahrstoffe/62-75-9.htm
[3] EU Commission (2007): Official Journal of the European Union [webpage on the internet] COMMISSION DECISION of 4 May 2007 laying down protective measures concerning uses of plant protection products containing tolylfluanid leading to the contamination of drinking water (notified under document number C(2007) 1865) (Text with EEA relevance) (2007/322/EC) [published 9 May 2007].
[4] UBA (2017): Gesundheitliche Orientierungswerte (GOW) für nicht relevante Metaboliten (nrM) von Wirkstoffen aus Pflanzenschutzmitteln (PSM). Status of January 2017.
[5] WHO (2011): Guidelines for drinking-water quality - 4th ed., ISBN 978 92 4 154815 1.