

Persistent chemicals and water resources protection:

Conclusions from the ECETOC Task Force

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Disclaimer: The Task Force's Technical Report is still in preparation and the conclusions presented here should be considered preliminary and subject to change [09 April 2020]

Background

- Protecting ground- and drinking water resources is an important common goal
- A PMT/vPvM hazard-based concept within the REACh context has been proposed to improve the protection of these resources
- Available groundwater monitoring data showed:
 - P/M criteria are not predictive of the occurrence of substances in groundwater – questioning the proposed criteria
 - Substances detected in groundwater are not only REACh-regulated substances – questioning the PMT-concept under REACh
- This indicates the need for further adjustment of the concept

P/vP – Persistent/very Persistent
M/vM – Mobile/very Mobile
T – Toxic

Material & Methods

The ECETOC Task Force is elaborating on the following relevant topics:

- Review of existing legislation
- Appropriateness of the proposed PMT-criteria
- Review of existing monitoring data (case study)
- Level of relevant metabolite concentrations
- Applicability of an alternative risk-based approach

Results: Existing EU Legislation

Water Protection

- Water Framework Directive
- Groundwater Directive
- Drinking Water Directive

GOALS:

- *Protection of all waters; surface, ground, bathing & drinking water sources*
- *Protection of aquatic ecology & habitats*
- *Improve quality of drinking water*

Chemical Regulations

- Plant Protection Products
- Biocides
- Medicinal products
- REACH

GOALS:

- *Safe use of chemicals*
- *As part of the environmental risk assessment, some regulations cover groundwater and/or risk to humans via consumption of drinking water*

Results: Appropriateness of the fate criteria (PM)

- Combination of P & M preferable?
 - Very low or non-sorbing (vM) substances may break through to a water compartment even if they do not meet the P criteria => **false negatives**
 - Substances classified as P may still be degraded sufficiently fast in soil during transport processes if they are low M, thus not reaching ground water => **false positives**
 - Therefore, alternative approaches such as GUS-index, screening, modelling making use of the combination of both P and M are more appropriate
- More refined P and M metrics, e.g. as part of a modelling approach?
 - The output of modeled emission data very much depends on the quality of input parameters
 - Higher tier and compartment specific data on degradation and adsorption typically improves the quality of the modelled data

Results: Appropriateness of additional Toxicity (T) Criteria

- Category 2 carcinogens or mutagens: They are not SVHCs under REACH and in addition, under BPR and PPPR they still can be approved. Cat 2 substances are still allowed in consumer products as they are not within the scope of the Carcinogens & Mutagens Directive
- Effects via lactation: For the three substances which are currently solely classified with H362 (“effects via lactation”) => the classification for the first one is not justified, the other two are pesticides (i.e. not REACH related)
- DNEL of $\leq 9 \mu\text{g}/\text{kg bw}/\text{d}$: This approximates with the cut-off limits of STOT RE 1 and 2 category substances (already part of existing “T”)
- Endocrine disruptors (ED): For human health, ED aspects are covered within the REACH Annex testing requirements and effects would lead to Reprotoxic Cat 1 or 2 or STOT RE 1 or 2 classification
- **Work is on-going to define and set information requirements under REACH**

Results: Relevant metabolite concentrations

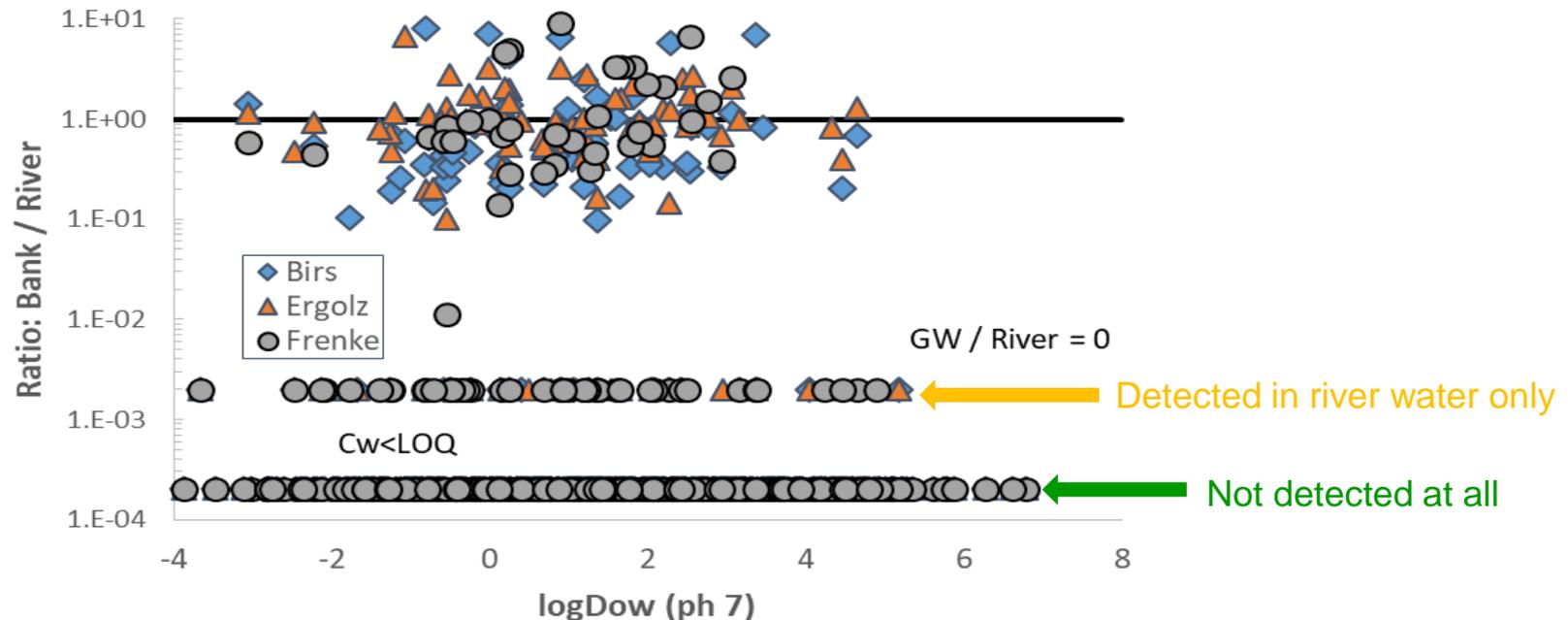
- Existing frameworks have established approaches for metabolites (e.g. PPPR), which could be applied to REACh substances
- Identification and quantification of metabolites is limited to OECD 307, 308 or 309 TGs using environmentally relevant concentrations
- Expected metabolite concentrations based on measured environmental concentrations (MECs) and predicted environmental concentrations (PECs):

Data source	Type of value	Parent concentration [µg/L]	Metabolite concentration (0.1% of parent) [ng/L]	Optimal Limit of Quantification [ng/L]
REACh	PEC	0.01 – 10	0.01 – 10	0.001 - 1
EU WFD*	MEC	0.01 – 0.1	0.01 – 0.1	0.001 – 0.01

*Carvalho et al., 2016. Monitoring-based exercise: second review of the priority substances list under the Water Framework Directive. <https://circabc.europa.eu/w/browse/52c8d8d3-906c-48b5-a75e-53013702b20a>

Results: Review of monitoring data

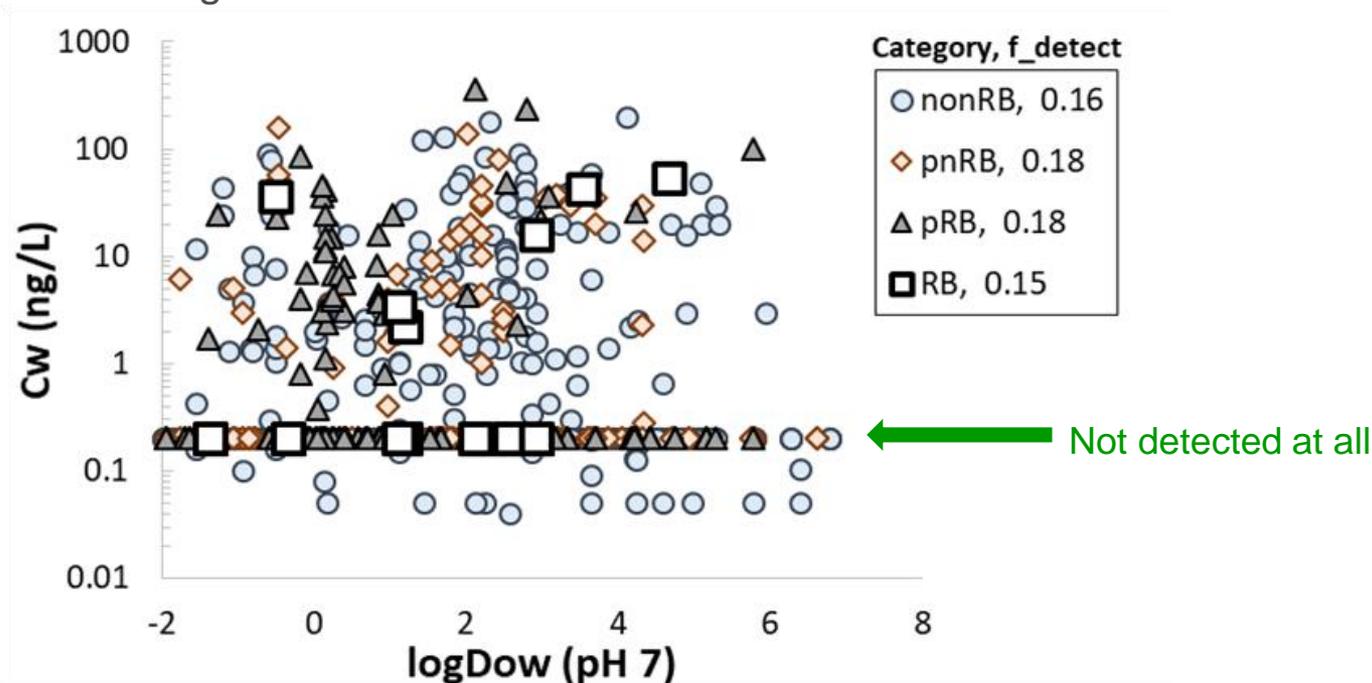
River bank filtration systems (river *versus* ground water concentrations; Swiss study)



- The ratio between river and ground water does not correlate with Log D_{ow} (pH 7)
- Many substances were detected in river water only or were even not detected at all
- The proposed threshold for mobility could not be confirmed by measured data

Results: Review of monitoring data

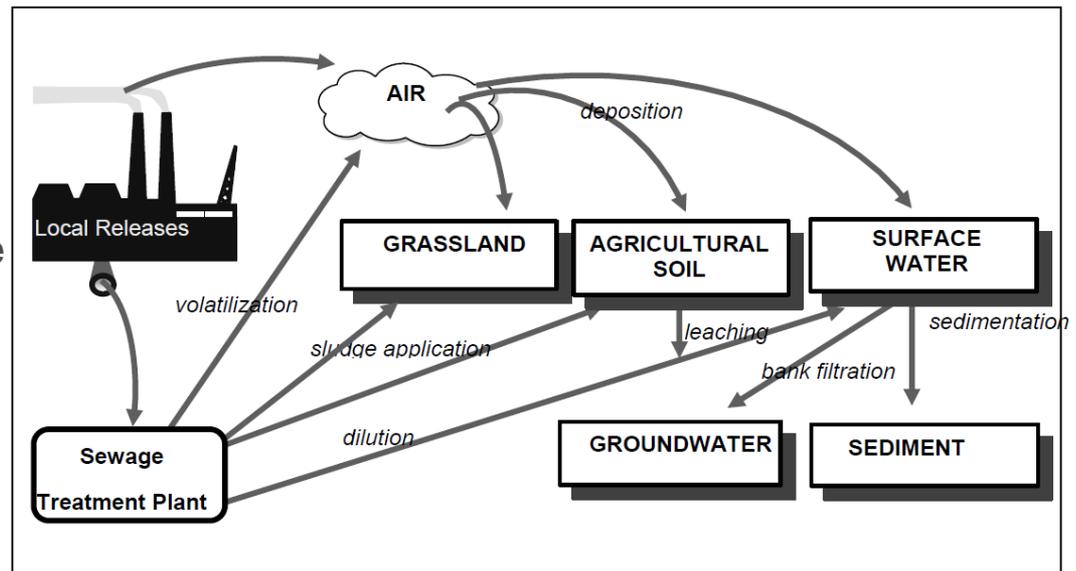
Detection of readily (RB) and non-readily biodegradable (non-RB) substances in groundwater from available monitoring data



- Measured groundwater concentrations do not correlate with biodegradability
- The 'P' and 'M' criteria are not predictive of local concentrations creating both false positives and negatives
- Tonnages, other fate processes (e.g. photolysis, hydrolysis), use pattern and emissions determine actual exposures, rather than P & M

Results: Risk-based approach for protecting drinking water

- Persistence (P) and Mobility (M) cannot be used alone as indicators of a chemical's probability of being present in drinking water
- A risk-based approach is recommended as it includes information on uses, release patterns/routes of exposure, fate & partitioning properties that included P and M metrics
- The protection goal is safe drinking water, and use of predicted drinking water concentrations compared with toxicological endpoints (where available) is recommended instead of applying cut-off concentrations

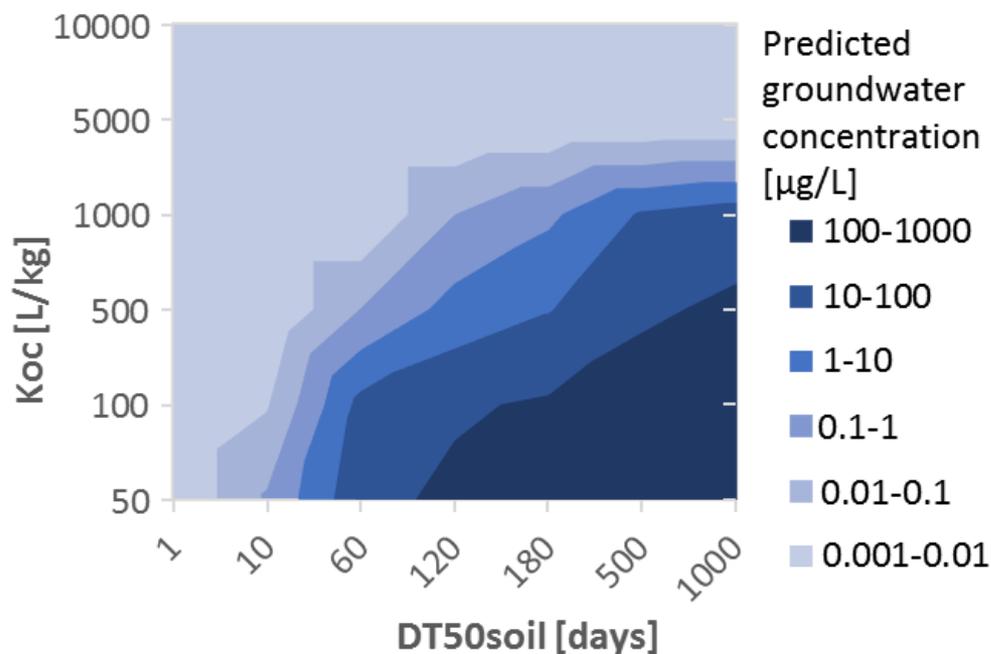


ECHA (2016). Guidance on information requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment. Version 3.0. February 2016

Results: Risk-based approach for protecting drinking water

- The figure below shows predicted concentrations in groundwater ($\mu\text{g}/\text{l}$) of representative chemicals (e.g. PPPs) having varying persistence and mobility values, for an annual application rate of 1000 g/ha, calculated using the EU crop protection model FOCUS PEARL

- The figure clearly shows that for a defined route of exposure and given application rate (direct application to land), degradation and partitioning in soil further inform on the potential level of exposure in groundwater



- Future areas of research to extend the risk assessment identified
 - The interaction of ground and surface water close to drinking water abstraction points via bank infiltration

Discussion and Conclusion

- Existing EU frameworks including REACH, already provide some measures (prospective and reactive) to protect drinking water resources
- Using P and M metrics in combination as part of an exposure assessment is recommended rather than a hazard-based P & M assessment alone
- The criteria for 'T' as in Annex XIII of REACH already fulfil the protection goal to ensure a high level of human and environmental safety
- The (PM)T criteria should focus on human health aspects only in order to align with the protection goal of safe drinking water for humans
- The threshold for identification of metabolites should follow the recommendations as set within the OECD 307 – 309 test guidelines
- Available groundwater monitoring data do not match with P and M profiles of substances, questioning the proposed criteria
- Annual volumes, use patterns and emissions with routes of exposures are considered as the drivers for groundwater appearance of substances
- Therefore, a risk-based (modelling) approach, using chemical properties combined with information on emissions and use pattern, provides a more suitable alternative to identify potential substances of concern

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Abbreviations

BPR: Biocidal Product Regulation

D_{ow} : Octanol-water distribution coefficient

DNEL: Derived No Effect Level

DT50: Disappearance Time 50 (time within which the concentration is reduced by 50%)

ED: Endocrine disruptor

GUS-index: Groundwater Ubiquity Score (GUS) index

GW: Groundwater

K_{oc} : Organic carbon-water participation coefficient

MEC: Measured Environmental Concentration

non-RB: non-Readily Biodegradable

PEC: Predicted Environmental Concentration

PPP: Plant Protection Product

PPPR: Plant Protection Product Regulation (Regulation (EC) No 1107/2009)

RB: Readily Biodegradable

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)

STOT RE: Specific Target Organ Toxicity - Repeat Exposure

SVHC: Substance of Very High Concern

TG: Test Guideline

WFD: Water Framework Directive (Directive 2000/60/EC)