Diclofenac in recycled fertilisers:

Screening risk assessment identifies low risk but there are various uncertainties and need for monitoring

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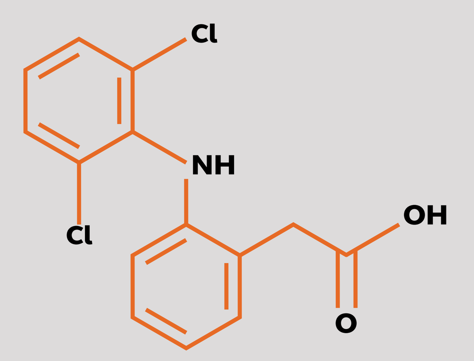
Identification of contaminants/impurities of potential concern → Longlist of contaminants/ impurities → Prioritised shortlist of contaminants/impurities* → Risk assessment → Pre-RMOA (Regulatory Management Options Analysis) / AoA (Analysis of Alternatives)

** Taking into account intrinsic hazards, existing regulations, occurrence in fertilisers, exceedances of existing limits in fertilisers, concentrations in environment, existing risk assessments, etc.*

Methods

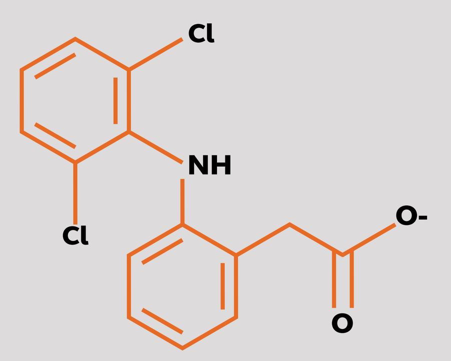
Q: Which compound to assess?

A: Diclofenac (two forms, pKa 4.18)



Unionised

Dominant form under most environmental conditions



Ionised

Increasingly occurs in low pH environments

Q: Which fertiliser to assess?

A: Comparison of concentrations in different source materials and removal efficiency of different nutrient recovery methods

Q: Exposure calculations?

A: Freshwater, sediment and soil → FEE tool Fertilizers Europe (for tool selection see our SETAC EU 2022 poster)

Secondary poisoning + humans via the environment → output of FEE tool + equations EUSES

Q: Which scenario to assess?

A:
- Single annual application of 100 kg P_2O_5/ha
- spERC1 Fertilizers Europe (outdoor use – direct application of solid fertilisers to soil, surface spreading)
- Generic crop, application to bare soil
- No crop offtake
- No specific risk management measures

Near-Future-Needs

Further research and/or measurement campaigns would be needed with regard to:

- Diclofenac **removal efficiency** of different **nutrient recycling techniques** resulting in material that may be used in/as fertilisers
- Diclofenac in different **environmental compartments** → especially poor data availability for soil and sediment
- Presence of diclofenac in **manure**, especially for countries where diclofenac is approved for use as veterinary medicine
- **Local/regional differences** of diclofenac concentrations in **sewage sludge**
- **Local/regional differences** in the use of **sewage sludge, anaerobically digested sludge**, and **irrigation water**

Results

Fertiliser type assessed

- Fertilisers based on/containing precipitated P-salts derived from sewage sludge

Scenarios

- 2 scenarios with 1 and 10% transfer of diclofenac to recovered material (based on literature data showing highly variable removal efficiencies depending on the nutrient recovery technique → overall, 66-100% removal reported)
- 2 sub-scenarios at low and neutral pH (with separate log Kow and log Koc)

Concentrations in recovered P-salts

Input material: 70.0 µg/kg dw (90th pct measured in JRC survey – Tavazzi et al., 2012) → **Recovered P-salts:** 0.7 and 7.0 µg/kg dw in 1 and 10% transfer scenario, respectively → 1.67 or 16.7 µg/kg P_2O_5, respectively (average P_2O_5 content of precipitated P-salts = 42%; STRUBIAS, Huygens et al., 2019)

General findings

- No **risks** were calculated except for **soil** in the scenarios at **pH 7** and for **secondary poisoning** in **all scenarios**.
- The environmental concentrations used as **PECregional determined the outcome** of the assessment. **Contribution of recycled fertiliser use** was **very small** (always well below 1%), and **no build-up** was predicted **over time**.
- **Source contribution analysis** was hampered due to **insufficient data** (see Near-Future-Needs). **Raw or anaerobically digested sewage sludge** and **irrigation water** are likely **important contributors** to environmental concentrations.

Results diclofenac after 1 and 10 years of application – scenario pH 7

Assessment endpoint	Clocal - 1 yr *	PECregional	Total exposure - 1 yr *	PNEC/TDI	RCR – 1 yr *	RCR – 10 yrs *
Freshwater [A] µg/L	1.2E-02 0.1	40	40 40	50	0.8 0.8	0.8 0.8
Sediment [B] µg/kg dw	6.1E-05 6.1E-04	0.9	0.9 0.9	1.2	0.8 0.8	0.8 0.8
Soil [B] µg/kg dw	3.3E-05 3.3E-04	0.3	0.3 0.3	0.21	1.4 1.5	1.4 1.5
Secondary poisoning **C – Aquatic pathway – Terrestrial pathway µg/kg			2.8 1.6	0.35		7.9 4.6
Humans exposed via the environment **D µg/kg bw/day			0.01	0.5		0.02

* Upper and lower values in the cells for freshwater, sediment and soil are for the 1 and 10% transfer scenario, respectively

** RCR values shown are for the 10% transfer scenario only

[A] PNEC = AA-EQS pelagic community (UBA, 2018)

[B] Calculated using equilibrium partitioning

[C] PNEC = Quality standard secondary poisoning (UBA, 2018)

[D] TDI = ADI derived by EMEA (2003)

Take home message

When stimulating the use of recycled nutrients from sewage sludge in agriculture, efficient removal of pharmaceuticals or their residues during nutrient recovery needs to be guaranteed.

For diclofenac, in case efficient removal can be guaranteed, regulatory measures may need to be taken at other levels to reduce environmental concentrations (e.g., use of sewage sludge and anaerobically digested sludge in agriculture, use as veterinary medicine, …)

Acknowledgement

The results presented were generated in view of the project "Contaminants in fertilisers: Assessment of the risks from their presence and socio-economic impacts of a possible restriction under REACH" (European Commission – DG Environment). The project team was composed of Arcadis, DHI, Arcadia International and Vander Straeten Consulting Services. Presented work was performed by Arcadis.

The report can be requested via e-mail

Check out our SETAC EU 2022 posters on our virtual booth (QR)