A proposal for criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PM or PMT) substances registered under REACH

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Preamble

• Our ground- and drinking water need **highest level of protection**

• Sustainable Development Goal 6.3: “*by 2030 to improve water quality by reducing pollution [...] and minimizing release of hazardous chemicals*”

• EU drinking water directive: “*to protect human health from the adverse effects of any contamination of water*”

• EU groundwater directive: "*groundwater is a valuable natural resource and as such should be protected from [...] chemical pollution.*”

• EU water companies' memorandum:
  “*Nobody has a right to pollute water bodies*”
Introduction

• A growing threat to Europe's drinking water sources and aquatic environment
• By the increasing number and volume of chemical substances
• Europe's chemical industry needs to continue to innovate
• Aim of this initiative is to enable industry to easily identify substances that may contaminate the sources of our drinking water
Substances causing an irreversible threat to drinking water

• A substance that is emitted into the environment pose an irreversible threat to the quality of our drinking water if
  – it is persistent (P) in the environment and
  – mobile (M) enough to transport through river banks, groundwater aquifers, and natural and artificial barriers, over time scales of weeks or more, to reach a drinking water source

• If such a substance is toxic (T), it must be considered a serious threat to human health.
Intrinsic substance properties that cause a concern

• **PPOP** or **polar POPs**
  – polar persistent organic pollutant (Giger et al., 2005)

• **P³ substances** or **PPPs**
  – persistent polar pollutants (Reemtsma & Jekel, 2006)

• **NANA**
  – German: nicht abbaubar & nicht adsorbierbar (unknown)
  – [English: not degradable & not adsorbable]

• **PMOCs**
  – persistent mobile organic chemicals (Reemtsma et al., 2016)

Our proposal to call them:

• **PM and PMT substances**
  – persistent in the environment, mobile in the water cycle and toxic
    (Neumann, 2017)
Intrinsic substance properties that cause a concern

- PM and PMT substances can **recirculate within the water cycle** and are **difficult to remove** from the raw water in drinking water production.
- This is, because the **same intrinsic substance properties** that lead to persistence in the environment and mobility in the aquatic environment also **allow for breakthrough** in wastewater and sewage treatment plants as well as raw water treatment processes.
- Many PM/PMT substances **can withstand** ozonation, UV treatment, filtration by activated carbon, or even reverse osmosis.
- Therefore, **contamination** of the water cycle with PM/PMT substances **can be irreparable**.
The hazard of PM and PMT substances

The hazard posed by PM/PMT substances is of an equivalent level of concern to the hazard posed by PBT/vPvB substances

• Both
  – harmful effects not just nearby the point of emissions
  – can persist over time
  – can reach locations far from where they were initially emitted

Only difference: their pathways for environmental exposure and transport

• PBT/vPvB substances
  – human exposure via the diet
  – transport and accumulate via the food chain and biota

• PM/PMT substances
  – exposure through drinking water
  – transport and recirculate with the water cycle
Proposal to identify PM and PMT substances

Stepwise assessment procedure:

Applicability domain?

- NO → N/A
- persistent?
  - NO → No further action
- mobile?
  - NO → N/A

PM substance

- toxic?
  - NO → N/A

PMT substance

Applicability domain

- Inorganic substances, surfactants
  - => CURRENTLY EXCLUDED
- UVCBs and multi constituent substances
  - => ONLY INDIVIDUAL COMPONENTS
- Ionic, zwitterionic or ionizable organic compounds
  - => ONLY MEASURED $\log K_{OC}$

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Step 1: Assessment of P properties

- **Criteria** adopted from the Annex XIII of the REACH Regulation
- Same tiered approach includes screening and assessment steps
- PBT assessment is included in registration of uses > 10 t/year

=> NO ADDITIONAL WORKLOAD FOR REGISTRANTS

- **Focus on aquatic environment**, however, consistency with the PBT/vPvB assessment procedure: a *proof in any* environmental compartment is sufficient to fulfil “P”
- This has the intention to *reduce workload to the registrants* and to guarantee full consistency to the PBT/vPvB assessment procedure.

A substance fulfils the persistency criterion (P) if:

it fulfils the criteria for persistence in the Annex XIII of REACH

P criteria (half live at at environmentally relevant pH 6-8 and 12°C)

- marine water > 60 d
- fresh water > 40 d
- marine sediment > 180 d
- sediment > 120 d
- soil > 120 d
Mobility

• … is the ability to move **or to be moved**
• First guess: water solubility is extremely important
• **Not exactly** the opposite of potential to **accumulate**
• Second Thought: opposite of potential to **adsorb**

=> **WHICH SUBSTANCE PROPERTY ULTIMATELY DETERMINES MOBILITY IN THE WATER CYCLE?**
Modelling Approach

• common REACH model ECETOC TRA
• calculated concentrations in surface water and groundwater (maximum => drinking water)
• **64 substances**
  – **Identical concentrations** in the inlet of the sewage treatment plant
  – **wide range** of intrinsic substance properties
  – **No Degradation**

<table>
<thead>
<tr>
<th>Molecular Weight g/mol</th>
<th>Log K_{oc}</th>
<th>Water Solubility mg/L</th>
<th>Vapour Pressure Pa</th>
<th>Henrys Law Constant Pa m^3/mol</th>
<th>Log K_{ow}</th>
<th>Degradation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min</td>
<td>76</td>
<td>-0.32</td>
<td>7*10^{-8}</td>
<td>1*10^{-10}</td>
<td>-3.87</td>
<td>no</td>
</tr>
<tr>
<td>Max</td>
<td>781</td>
<td>10.2</td>
<td>910</td>
<td>7.263</td>
<td>17</td>
<td>no</td>
</tr>
</tbody>
</table>

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European Centre for Ecotoxicology and Toxicology of Chemicals: The Targeted Risk Assessment (TRA) tool for estimating exposures e.g. to the environment version 3 was launched in April 2012.

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Vapour Pressure: determinant of mobility?
Water Solubility: determinant of mobility?

Minimum water solubility > 150 µg/L

NOT mobile

mobile
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\[ \text{log } K_{ow}: \text{ determinant of mobility?} \]

2015 UFOPLAN Project FKZ 371265416
by Fritz Kalberlah, Jan Oltmanns, Markus A. Schwarz (FoBiG GmbH) & Joachim Baumeister, Albrecht Striffler (denkbares GmbH)
**log $K_{oc}$**: determinant of mobility?

![Graph showing the relationship between log $K_{oc}$ and the fraction of influent.](image)

- Increasing groundwater concentrations due to sludge application
- Decreasing groundwater concentrations due to strong soil adsorption
- Decreasing surface water concentrations due to removal by sludge adsorption

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log $K_{oc}$: determinant of mobility!

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Step 2: Assessment of M properties

- **Proposal to use** Soil Organic Carbon-Water Partitioning Coefficient as the criterion to identify substances to be mobile in the water cycle.
- Adsorption needs to be assessed in registration of uses > 10 t/year if ionisable or log $K_{ow} \geq 3$
  
  => **NO ADDITIONAL WORKLOAD FOR REGISTRANTS**
- For chemicals ionisable within environmental relevant pH-range: no calculation of $K_{oc}$ but experimental measurement

A **persistent substance fulfils the mobility criterion (M)** if:

(a) its water solubility is at environmental relevant pH 6-8 and $12 \ ^\circ C \geq 150 \ \mu g/L$
  
  and

(b) its log $K_{OC}$ at environmental relevant pH 6-8 and $12 \ ^\circ C$ is $\leq 4.5$.  

Step 3: Assessment of T properties

A substance fulfils the toxicity criterion (T) if:
- it fulfils the human health toxicity criteria from Annex XIII of REACH:
  - carcinogen Cat. 1A, 1B,
  - germ cell mutagen Cat. 1A, 1B
  - reproductive toxicant Cat. 1A, 1B, 2
  - STOT RE Cat. 1 or 2

Proposed additional criteria:
- meets the criteria for classification as
  • carcinogen Cat. 2, germ cell mutagen Cat. 2
  • category for effects on or via lactation"
- For oral exposure (long-term, general population) the (derived no effect level) DNEL is ≤ 9 µg/kg body weight and day

To discuss:
- should the T criteria in the PMT assessment also account for ecotoxicity?
Proposed Plan for Implementation 1/2

• The **long-term goal** of this initiative by the German Environment Agency (UBA) is that industry, through REACH and ECHA’s REACH guidance, will be able to more easily fulfil its obligation **to ensure that substances registered under REACH do not compromise the sources of our drinking water** by initiating voluntary measures **to minimize emissions into the environment**.

• This **proposal** of PMT criteria and assessment procedure to identify PM/PMT substances is available for **consultation, discussion and commenting**.

• A **research project** has been set up to include the expansion of the chemical **applicability domain**, data quality considerations and to **refine the T criteria**.
Proposed Plan for Implementation 2/2

• In late 2017 the German Environment Agency (UBA) intends to publish a first draft of a list of substances registered under REACH that are considered to fulfil the PM/PMT criteria or are candidate PM/PMT substances.

• In early 2018, the German Environment Agency (UBA) will hold a workshop in Berlin.

• If PMT criteria are agreed on, the German competent authority intends to propose the first PMT substances for candidate listing as substance of very high concern (SVHC) in 2018.
Announcements

• ICCE Poster 352
  Using REACH registration data for the identification of persistent, mobile and toxic (PMT) substances
  Ivo Schliebner et al.

• ICCE Oral Presentation 156
  by Thorsten Reemtsma
  Wednesday 11:15 in Auditorium 2

• Workshop “Persistent and Mobile Organic Chemicals in the Water Cycle:
  Linking science, technology and regulation to protect drinking water quality”
  23 - 24 November 2017, Leipzig, Germany organized by PROMOTE
Thank you for your attention

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