Für Mensch & Umwelt

Umwelt Bundesamt

16th International Conference on Chemistry and the Environment in 2017

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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Section IV 2.3 – Chemicals
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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)
- **P^3 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**

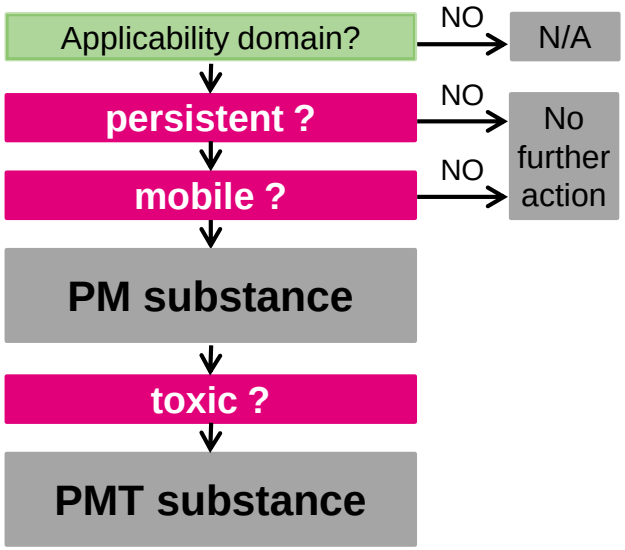
- Both
  - harmful effects **not** just nearby the **point of emissions**
  - can **persist over time**
  - can reach locations **far from where** they were **initially emitted**

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

- Inorganic substances, surfactants

  => CURRENTLY EXCLUDED

- UVCBs and multi constituent substances

  => ONLY INDIVIDUAL COMPONENTS

- Ionic, zwitterionic or ionizable organic compounds

  => ONLY MEASURED LOGK_{OC}

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.

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

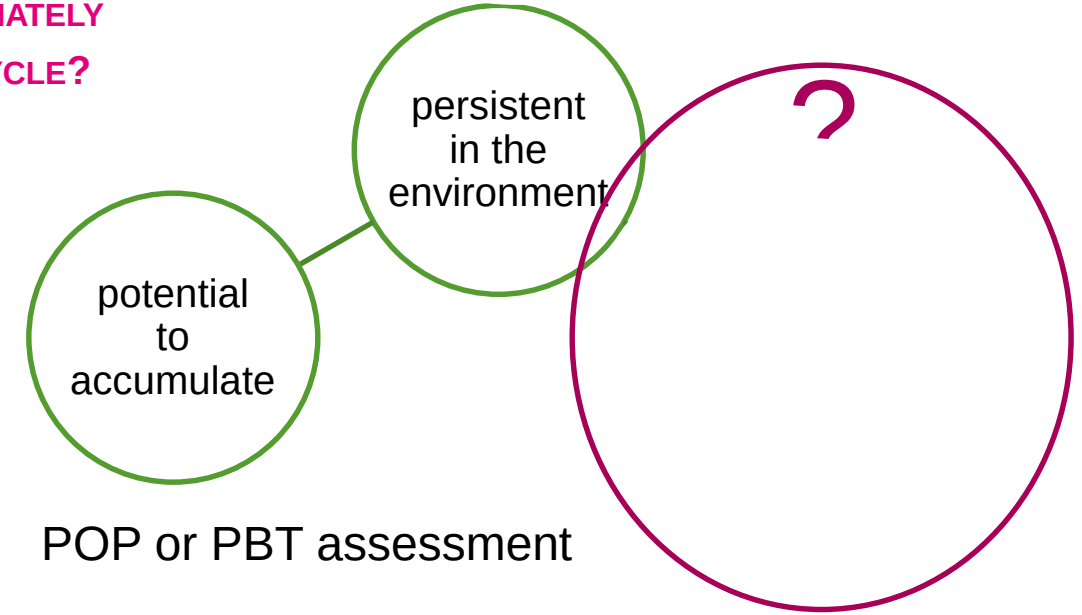
A substance fulfils the persistency criterion (P) if:

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

Mobility

- … is the ability to move **or to be moved**
- First guess: water solubility is extremely important
- Not exactly the opposite of potential to accumulat
- 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**

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.

	Molecular Weight g/mol	Log K_{oc}	Water Solubility mg/L	Vapour Pressure Pa	Henrys Law Constant Pa m^3/mol	Log K_{ow}	Degradation
Min	76	-0.32	$7*10^{-8}$	$1*10^{-10}$	$3.65*10^{-13}$	-3.87	no
Max	781	10.2	910	7.263	266	17	no

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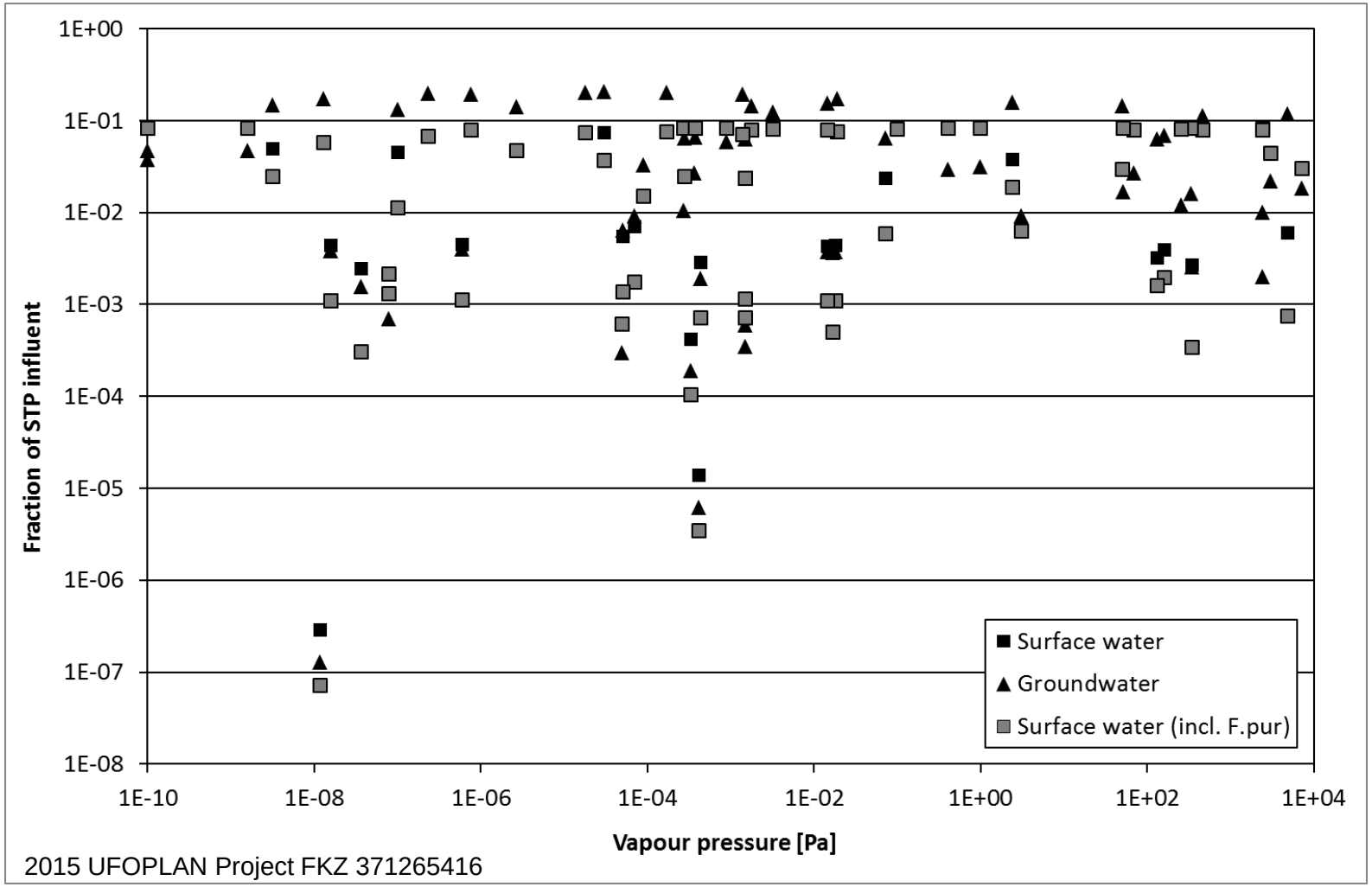
Vapour Pressure: determinant of mobility?



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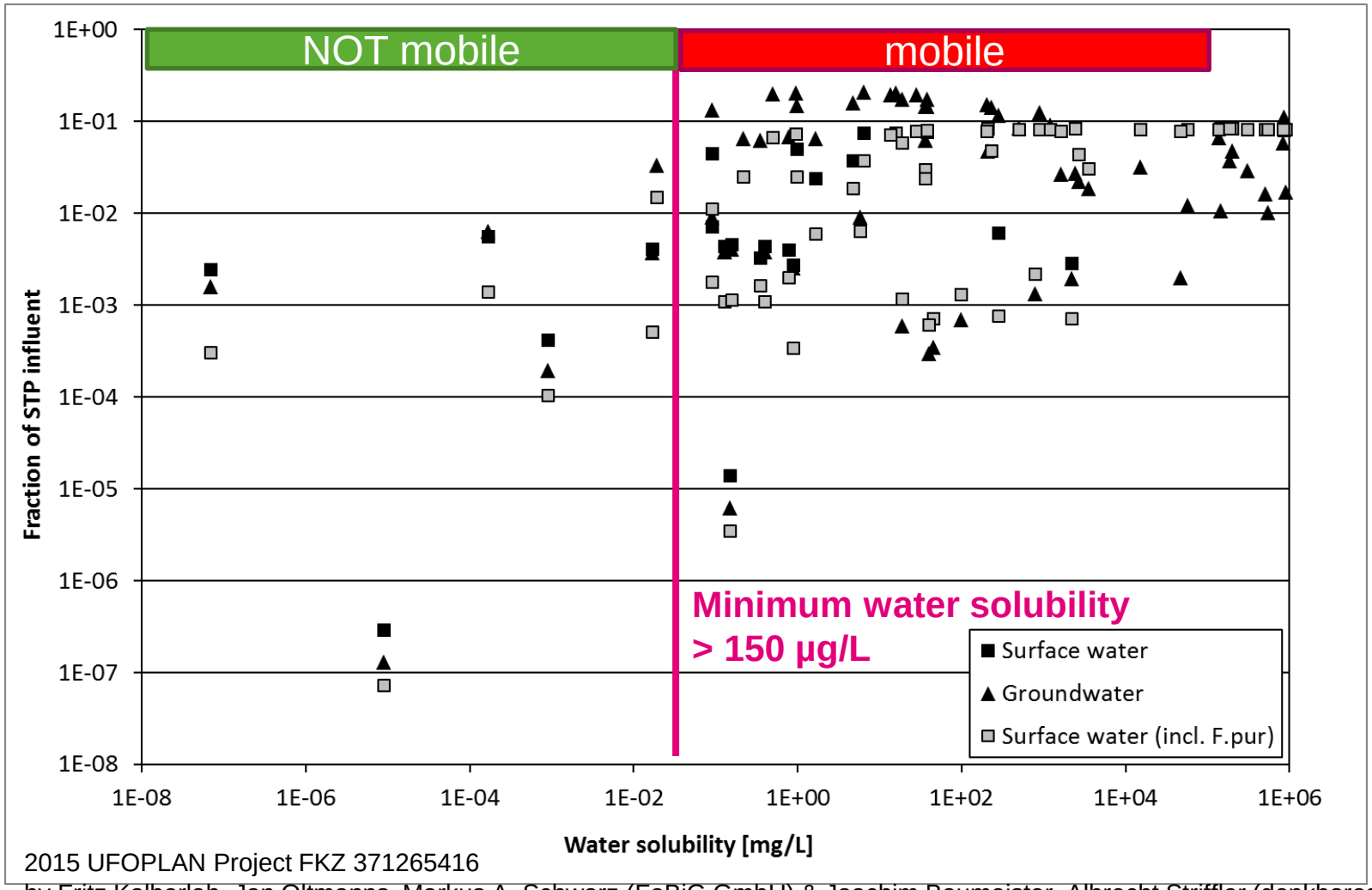
Water Solubility: determinant of mobility?



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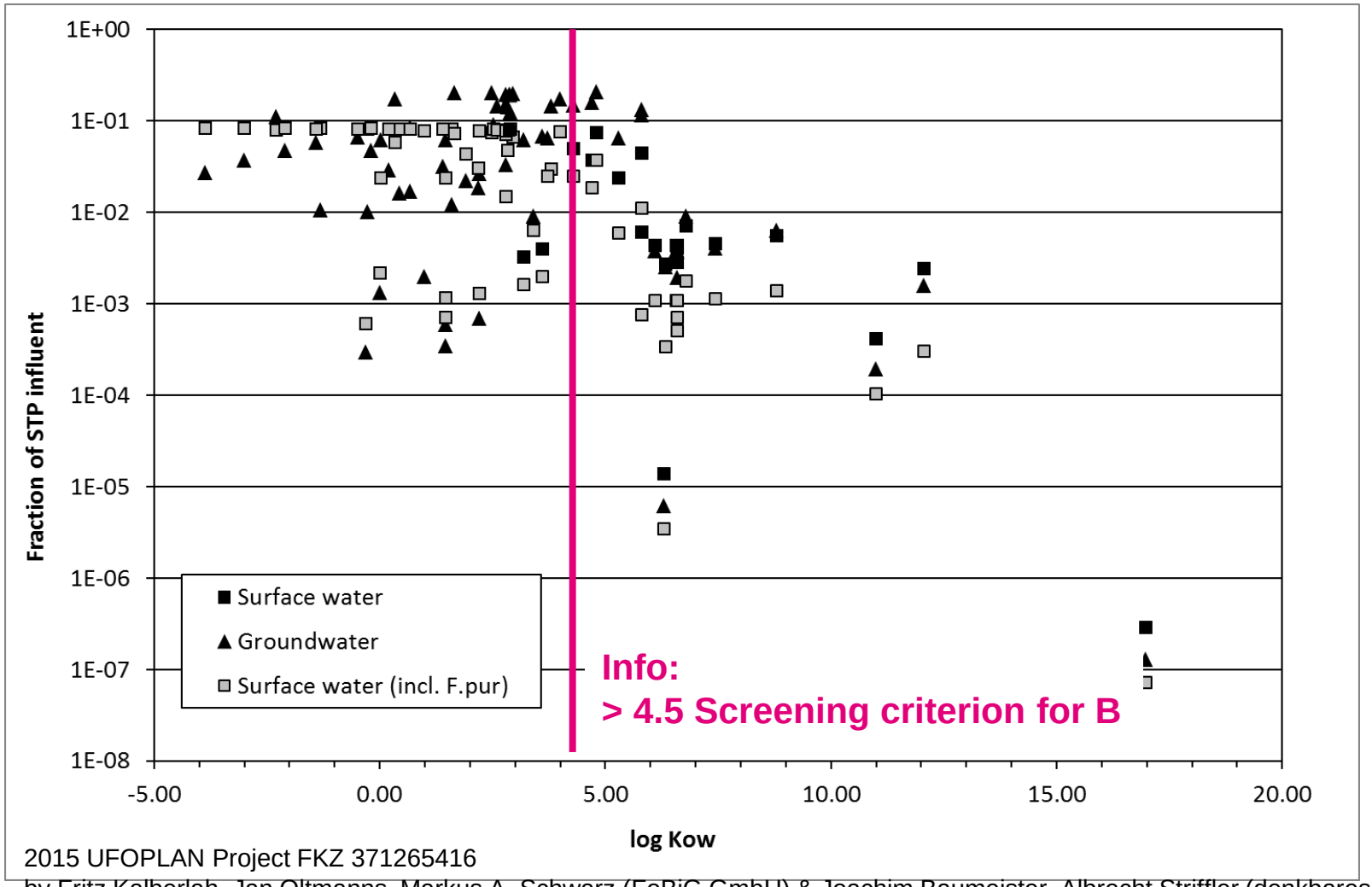
log K_{ow}: determinant of mobility?



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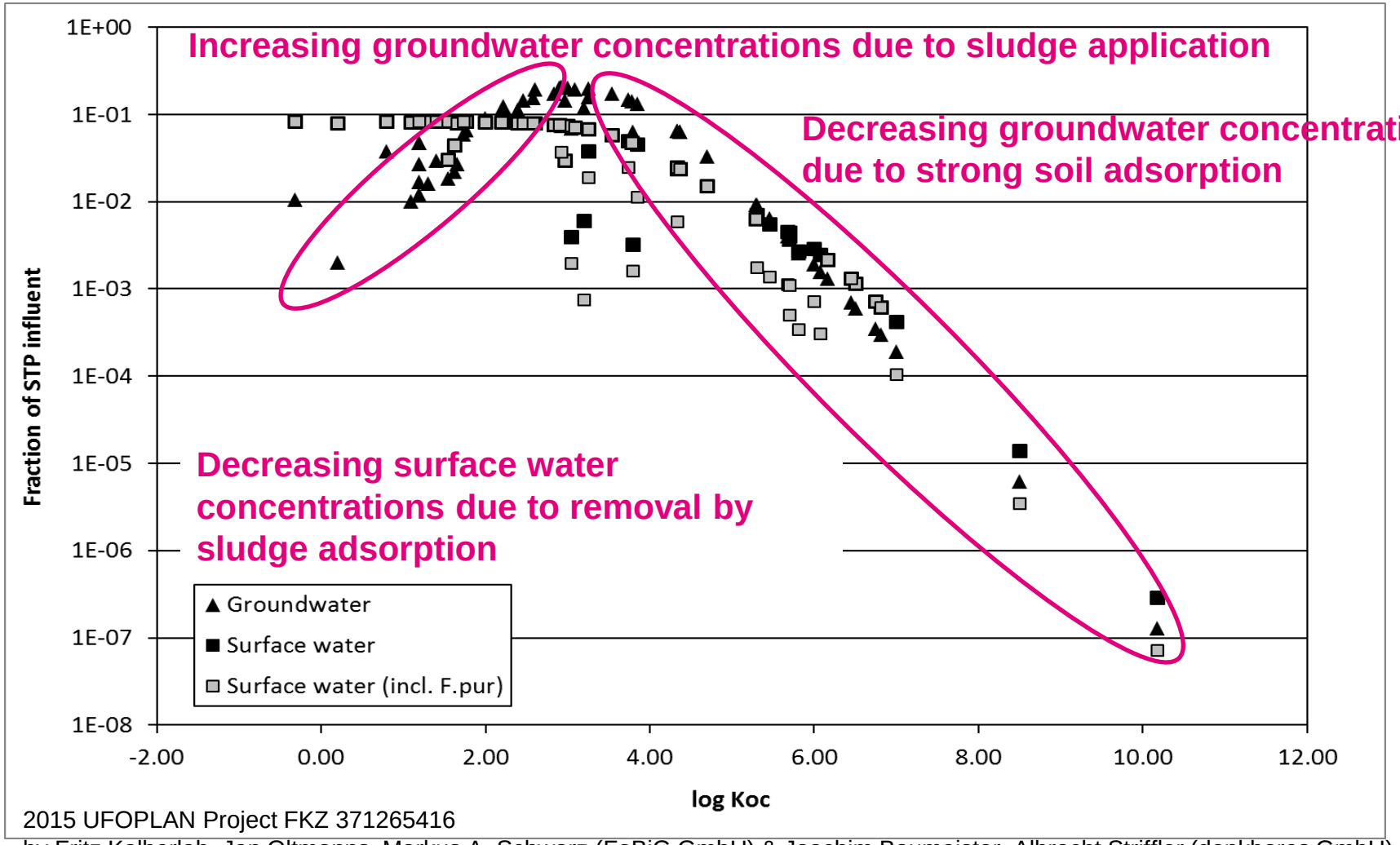
log K_{oc}: determinant of mobility?



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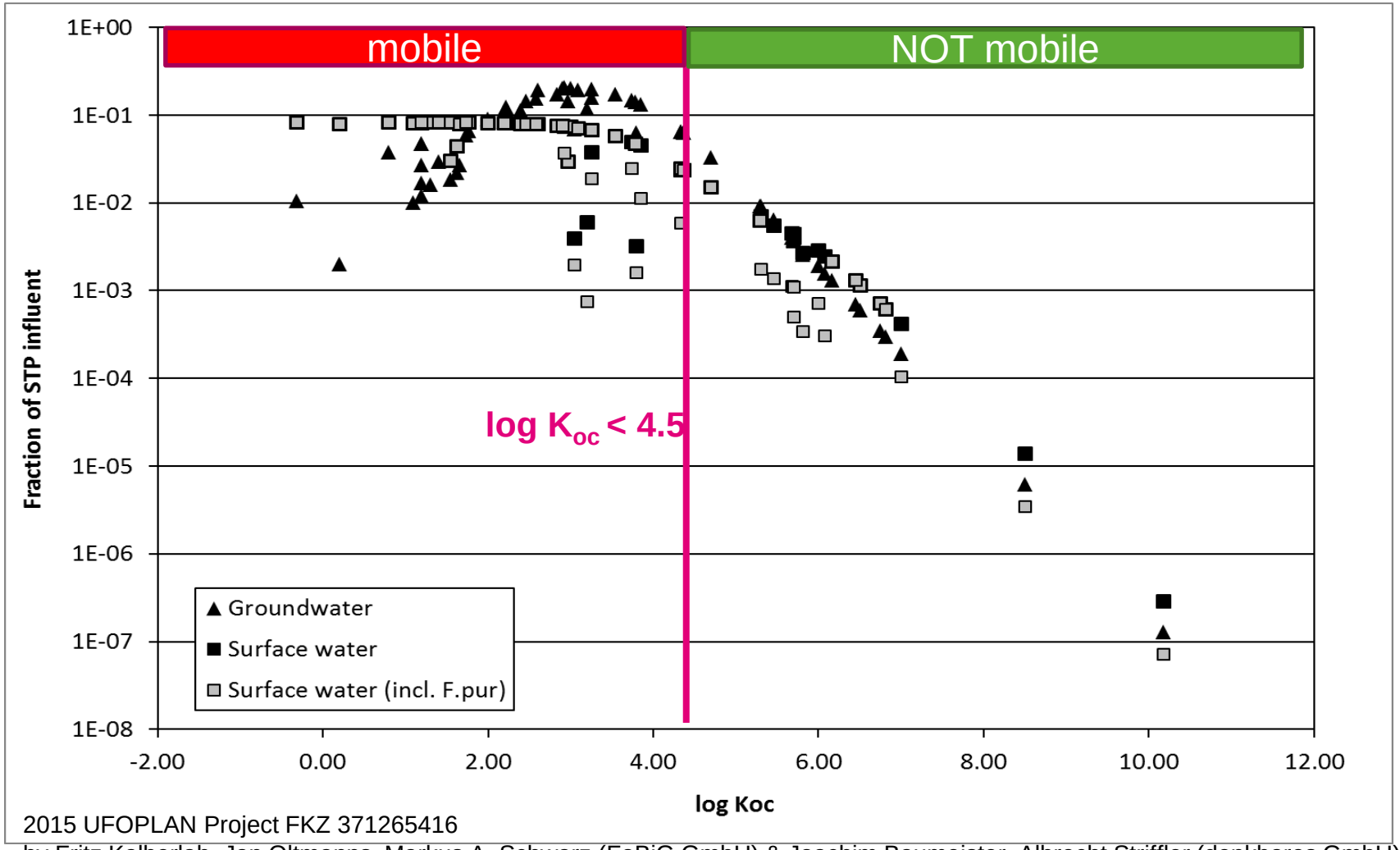
log K_{oc}: determinant of mobility!



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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} ≥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 °C ≥150 µg/L and

(b) its log K_{OC} at environmental relevant pH 6-8 and 12 °C is ≤ 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
  • “additional 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**

based on a study that derived "thresholds for toxicological concern" (TTC), and found that 9 µg/kg/d was the DNEL cut-off for 95% of substances exhibiting "moderate or low biological activity" (i.e. CRAMER class II)

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.

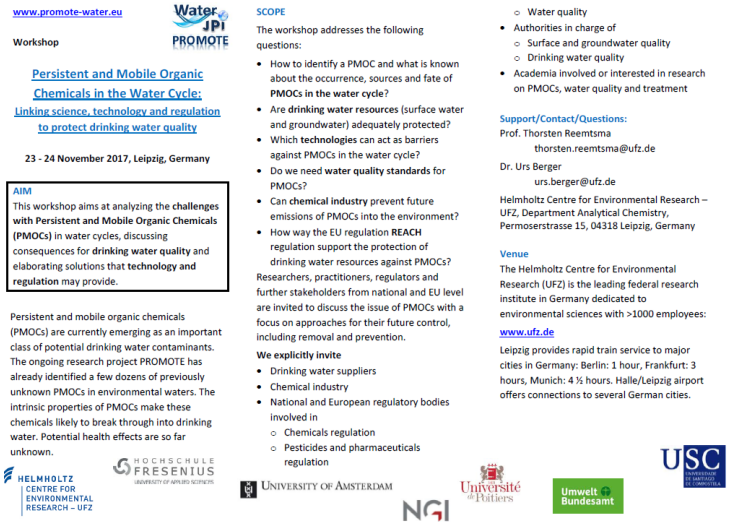
Announcements

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

- 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

  http://www.ufz.de/**promote**/



www.promote-water.eu

Water JPI PROMOTE

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

AIM

This workshop aims at analyzing the **challenges with Persistent and Mobile Organic Chemicals (PMOCs)** in water cycles, discussing consequences for **drinking water quality** and elaborating solutions that **technology and regulation** may provide.

Persistent and mobile organic chemicals (PMOCs) are currently emerging as an important class of potential drinking water contaminants. The ongoing research project PROMOTE has already identified a few dozens of previously unknown PMOCs in environmental waters. The intrinsic properties of PMOCs make these chemicals likely to break through into drinking water. Potential health effects are so far unknown.

HELMHOLTZ CENTRE FOR ENVIRONMENTAL RESEARCH – UFZ

HOCHSCHULE FRESENIUS UNIVERSITY OF APPLIED SCIENCES

SCOPE

The workshop addresses the following questions:

- How to identify a PMOC and what is known about the occurrence, sources and fate of **PMOCs in the water cycle**?
- Are **drinking water resources** (surface water and groundwater) adequately protected?
- Which **technologies** can act as barriers against PMOCs in the water cycle?
- Do we need **water quality standards** for PMOCs?
- Can **chemical industry** prevent future emissions of PMOCs into the environment?
- How way the EU regulation **REACH** regulation support the protection of drinking water resources against PMOCs?

Researchers, practitioners, regulators and further stakeholders from national and EU level are invited to discuss the issue of PMOCs with a focus on approaches for their future control, including removal and prevention.

We explicitly invite

- Drinking water suppliers
- Chemical industry
- National and European regulatory bodies involved in
  - Chemicals regulation
  - Pesticides and pharmaceuticals regulation
  - Water quality
- Authorities in charge of
  - Surface and groundwater quality
  - Drinking water quality
- Academia involved or interested in research on PMOCs, water quality and treatment

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Venue

The Helmholtz Centre for Environmental Research (UFZ) is the leading federal research institute in Germany dedicated to environmental sciences with >1000 employees:

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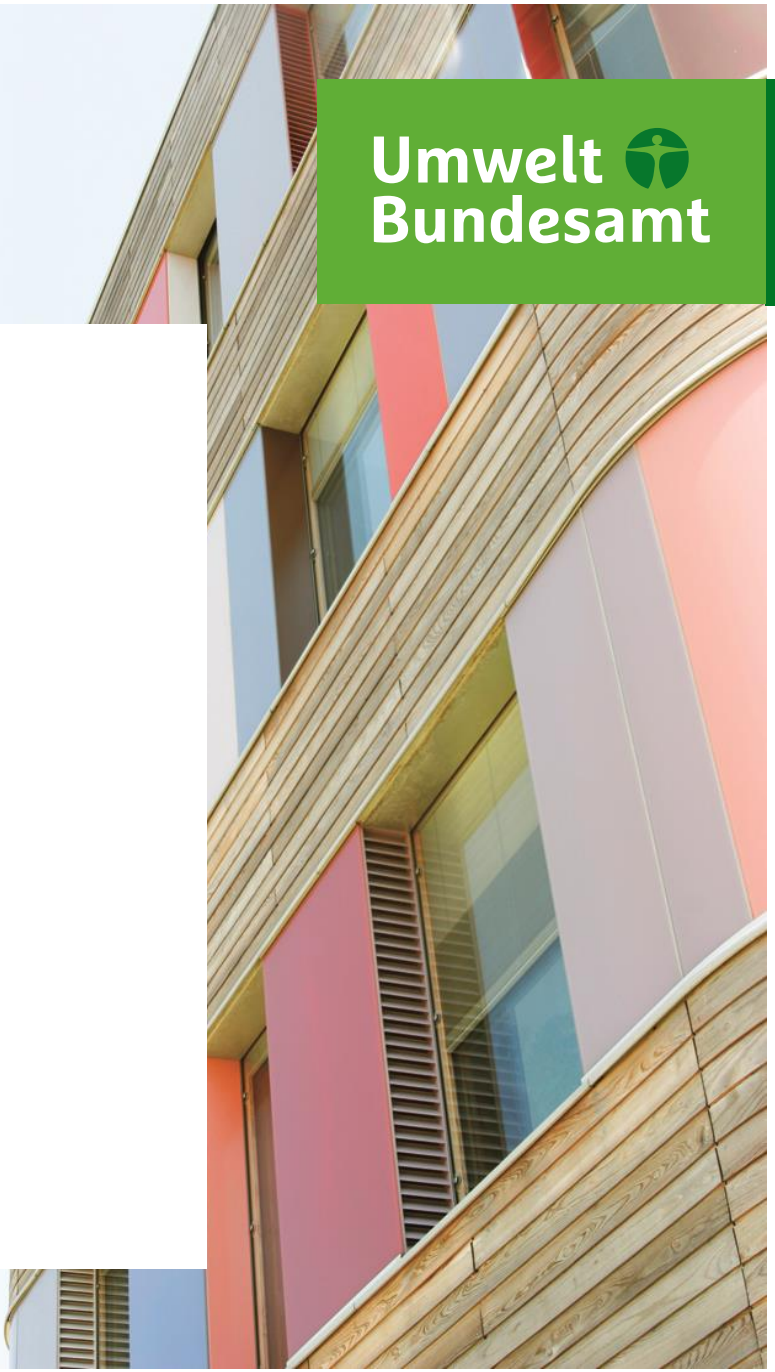
Leipzig provides rapid train service to major cities in Germany: Berlin: 1 hour, Frankfurt: 3 hours, Munich: 4 ½ hours. Halle/Leipzig airport offers connections to several German cities.



Thank you for your attention

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