Für Mensch & Umwelt

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Umwelt Bundesamt

SETAC Europe 25th Annual Meeting

A proposal for a chemical assessment concept for the protection of raw water resources under REACH

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Outline

Protection of Raw Water Resources

- In Europe drinking water is obtained mainly from groundwater, reservoirs or river bank filtration.
- If these environmental compartments are exposed to chemicals a contamination of drinking water is possible.

=› PRECAUTIONARY PRINCIPLE MUST APPLY TO PROTECT THE RAW WATER RESOURCES.

Overall in Europe water use is characterized by 65% ground water and 35% surface water (EU COM 2013)

- REACH Regulation (1907/2006 EG): registrant guarantees the safe use of chemicals throughout the whole life cycle.
- The risk assessment includes the evaluation of the hazardous substance properties and the exposure of the environment

=› WHICH SUBSTANCE PROPERTIES CAUSE A CONCERN TO RAW WATER RESOURCES?

REACH:
Regulation concerning the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals

Substance properties that cause a concern

- Fate and behaviour of polar substances have been investigated both scientifically and from a regulatory perspective.
- Hazard potential is maximised if chemicals are at the same time **mobile** in the water cycle and **persistent** in the environment

  => SEVERAL NAMES AND TERMS INDICATE THAT SUBSTANCE PROPERTIES AND HAZARD ARE COMPARABLE TO THOSE OF POPS AND PBTS.

- Consequently: Emission and impact are separated in time and space and remediation may not possible
- If those chemicals are **toxic:** No “save” emissions into the environment and No risk based assessment approach

  => NO STUDY YET HAS PROPOSED CRITERIA OR AN ASSESSMENT CONCEPT WITHIN REACH

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

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

NANA
nicht abbaubar &
nicht adsorbierbar

not degradable &
not adsorbable

PMT-substances
persistent in the environment and mobile in the water cycle and toxic

Step 1: Assessment of P properties

- Criteria adopted from the Annex XIII of the REACH Regulation; tiered approach includes screening and assessment steps
- Assessment of PBT properties is included in registration of uses › 10 t/year

P criteria (half live at 12°C)
freshwater › 40 d
sediment › 120 d
soil › 120 d
marine water › 60 d
marine sediment › 180 d

=› NO ADDITIONAL WORKLOAD FOR REGISTRANTS

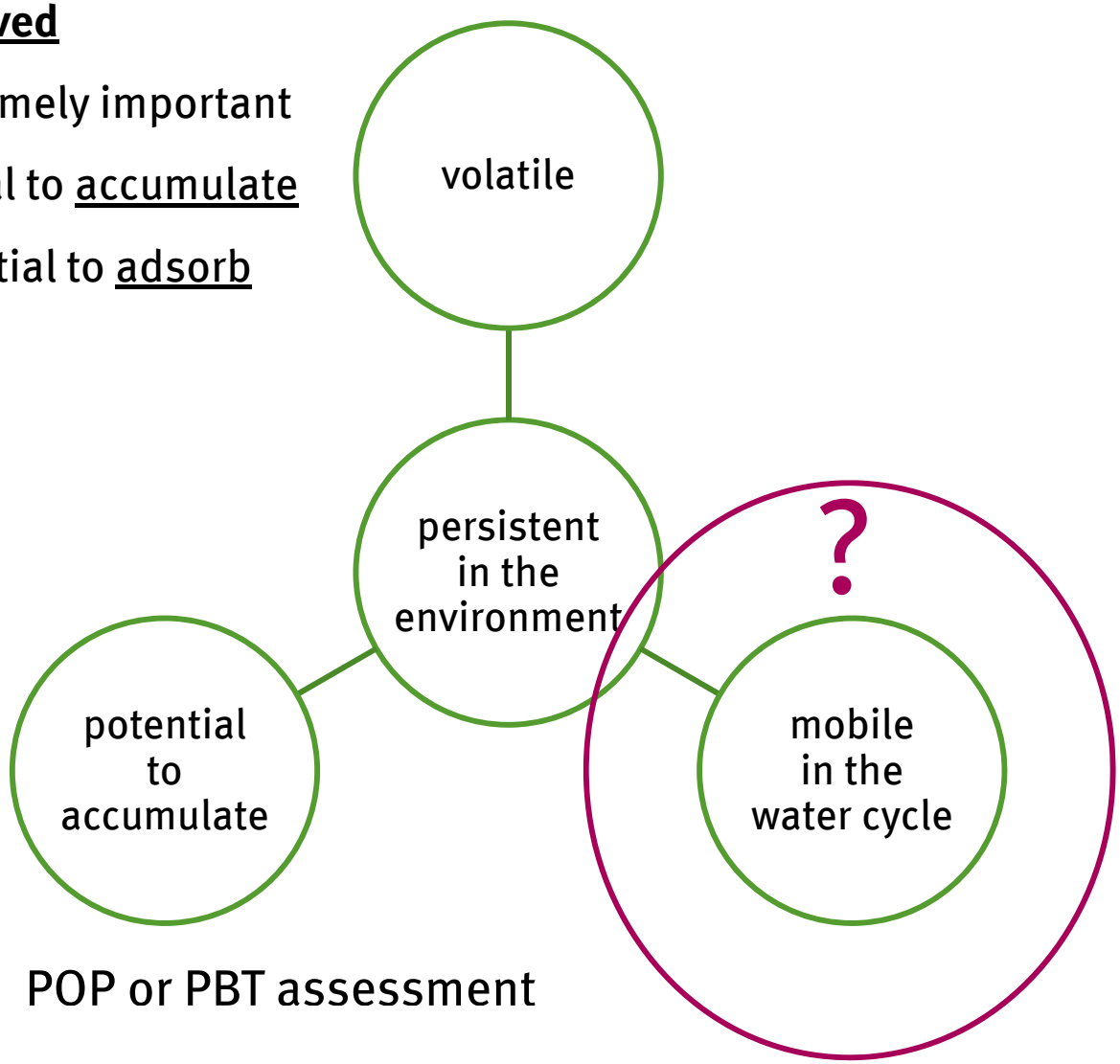
- Proposed decision tree focuses on the freshwater criteria, however, a proof in one environmental compartment is sufficient to fulfil "P"
- Proposed tiered approach address primary/ultimate degradation (coverage of transformation products)

=› A SUBSTANCE IS "P" IF IT FULFILS THE CRITERIA FOR PERSISTENCE IN THE ANNEX XIII OF THE REACH REGULATION

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

- We used the common REACH model ECETOC TRA
- We calculated concentrations in surface water and groundwater (maximum => drinking water)
- Default scenario
  - Identical concentrations in the inlet of the sewage treatment plant
  - No biodegradation
- 64 substances with wide ranges for all substance properties

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.

Table 12: Descriptive statistics for the sample used in ECETOC TRA modelling

	MW (g/mol)	log K_{oc}	WS (mg/L)	VP (Pa)	HLC (Pa m3/mol)	log K_{ow}	P/~~Not P~~
N	64	64	64	64	64	64	64
AM	315	3.67	75,198	340	6,249	3.13	100%
Median	293	3.23	36.1	0.00145	0.0168	2.80	P: 55% Not P: 45%
25th perc.	193	1.76	0.475	0.0000142	0.000094	0.678	
75th perc.	391	5.69	2,298	1.35	6.8	5.43	
MIN	76	-0.320	7.00E-08	1.00E-10	3.65E-13	-3.87	
MAX	781	10.2	910,000	7,263	266,000	17.0	

* HLC: Henry's law constant (calculated from molecular weight, water solubility and vapour pressure at 20-25 °C); P: Persistent; VP: Vapour pressure, WS: Water solubility

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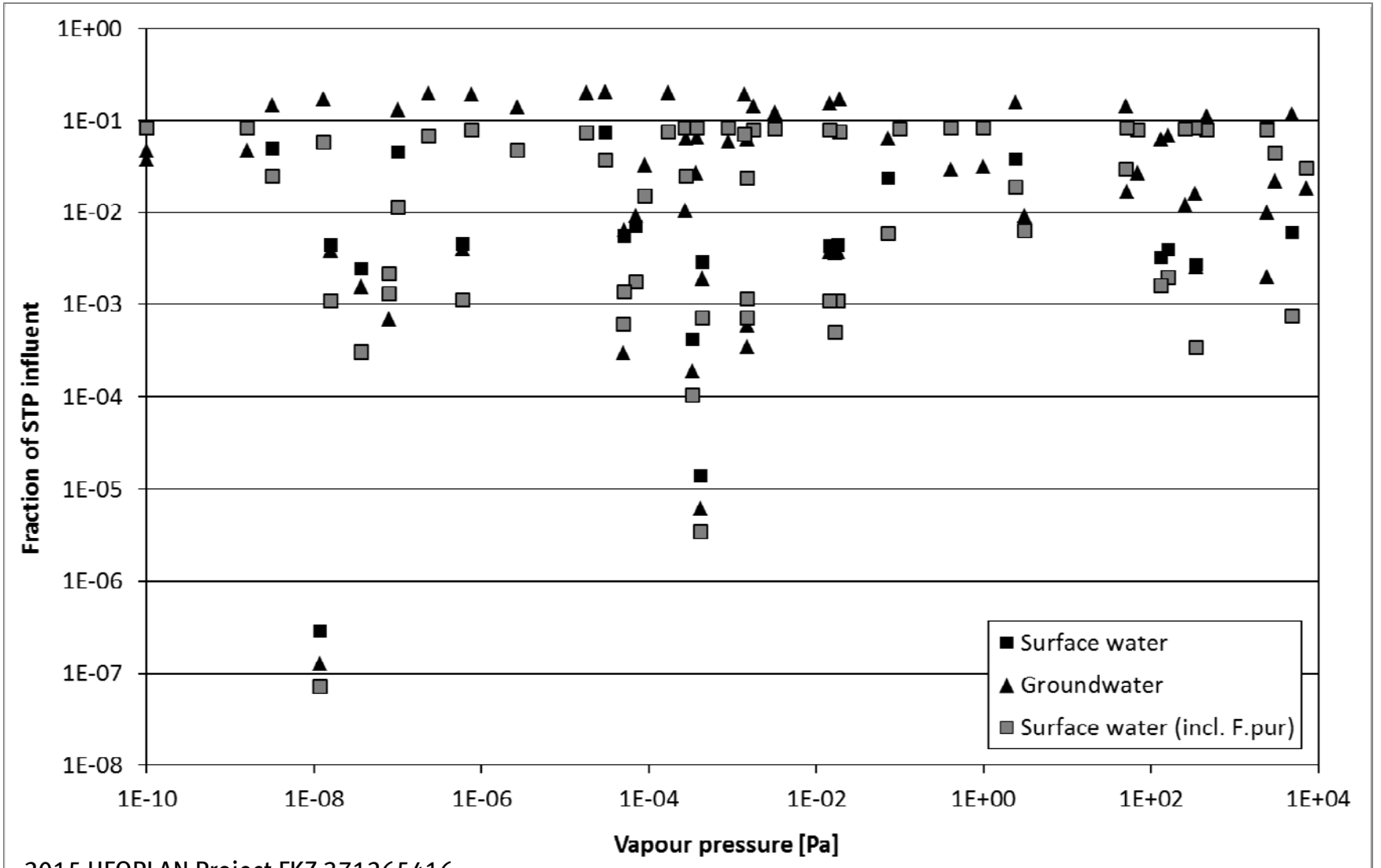
Vapour Pressure: determinant of mobility?



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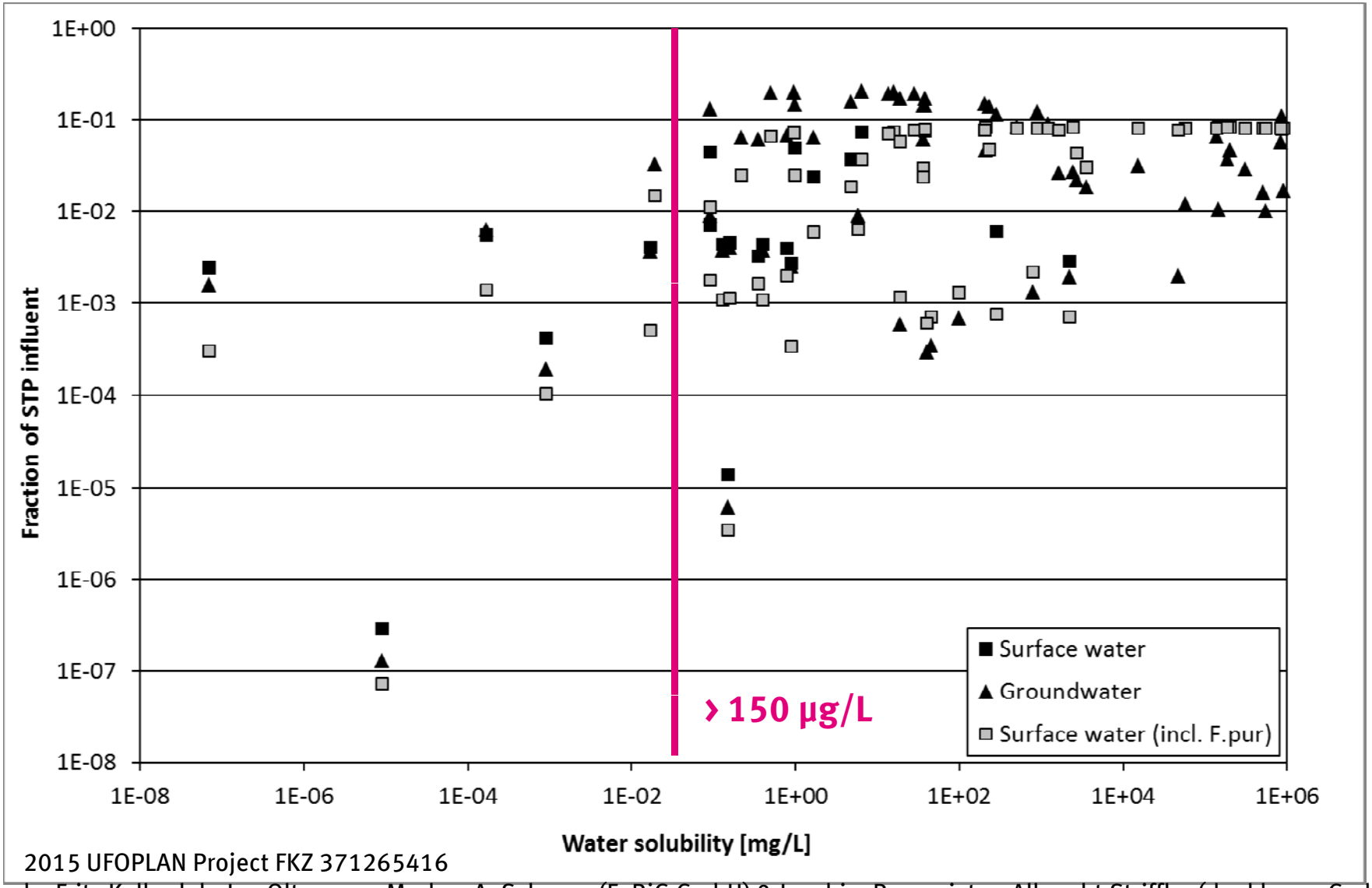
Water Solubility: determinant of mobility?



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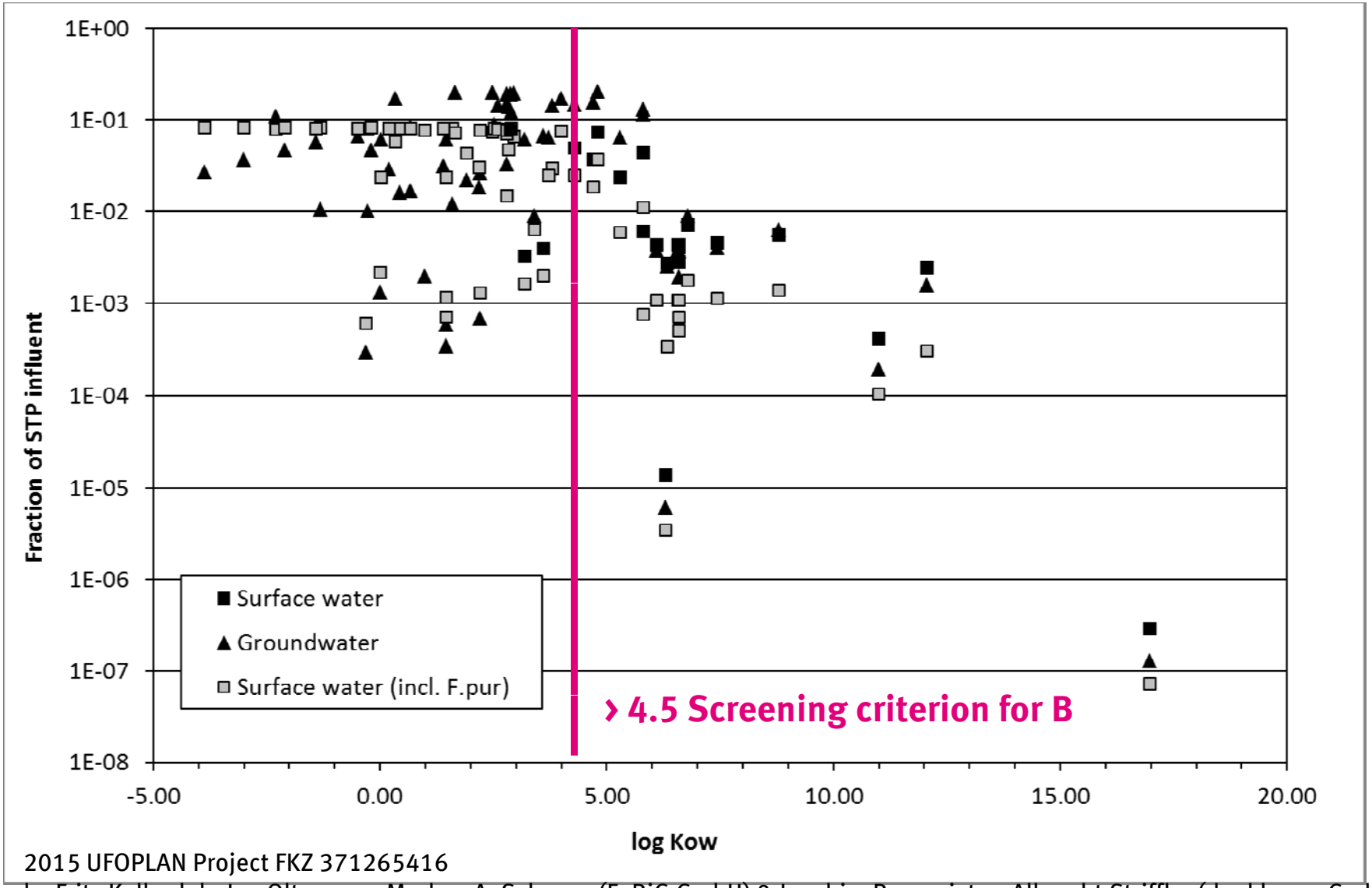
log K_{ow}: determinant of mobility?



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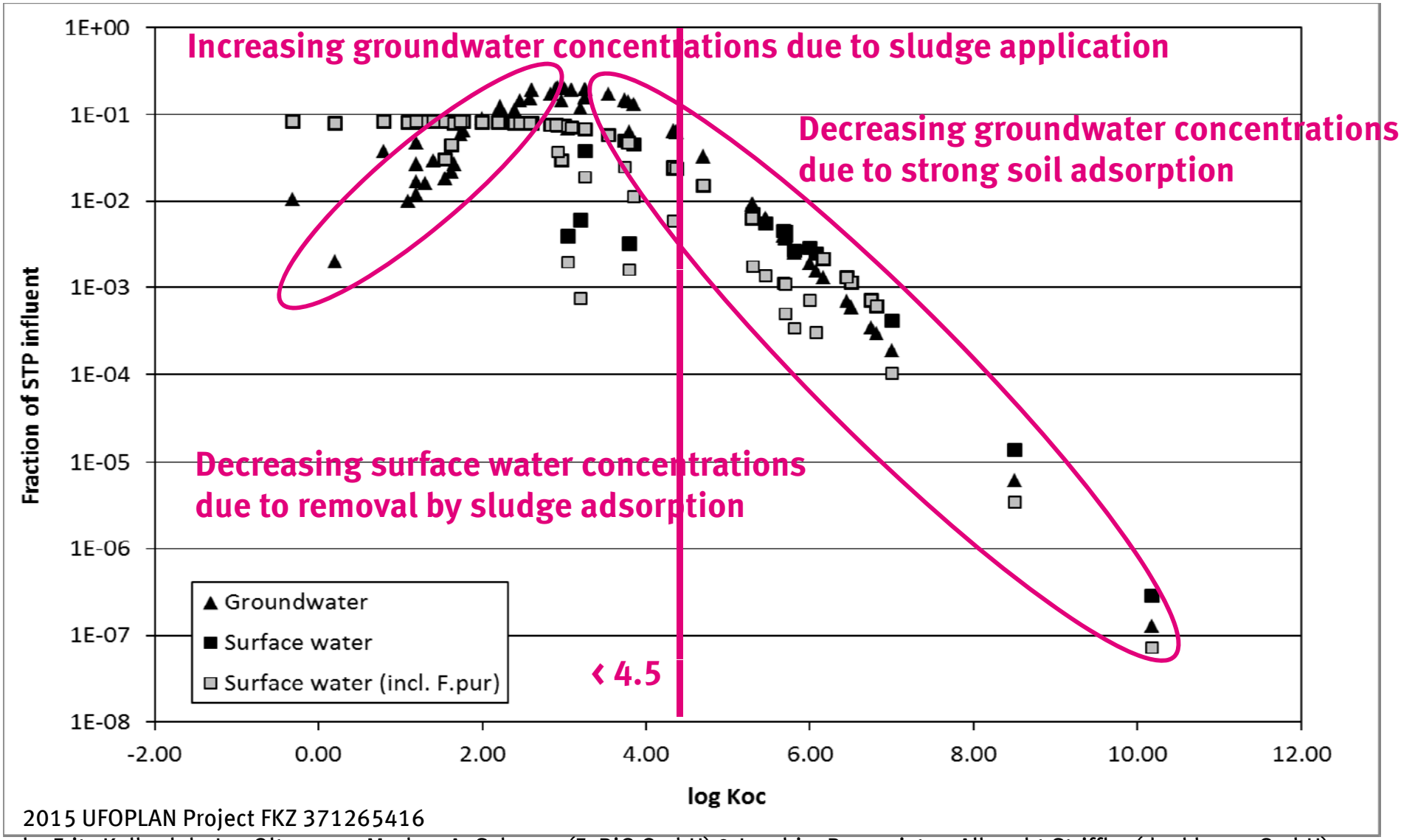
log K_{oc}: determinant of mobility!



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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

- Potential to adsorb is **not** correlated with BCF-value and consequently an overlap of criteria for "M" and "B" is justified
- For chemicals ionisable within environmental relevant pH-range: no calculation of K_{oc} but experimental measurement

=› A PERSISTENT SUBSTANCE IS "M" IF IT FULFILS THE CRITERIA
WATER SOLUBILITY › 150 µG/L AND LOG K_{OC} ‹ 4.5

Ionisability: The property to ionise in water, determined by the **pK_a**-value

Neutral, non-ionisable chemicals: **K_{OC}** positively correlated with **K_{OW}**

Triclosan has log K_{oc} of 4.2 and BCF of 2532 and is found at the same time in the water cycle and in biota and humans (Health Canada, 2012)

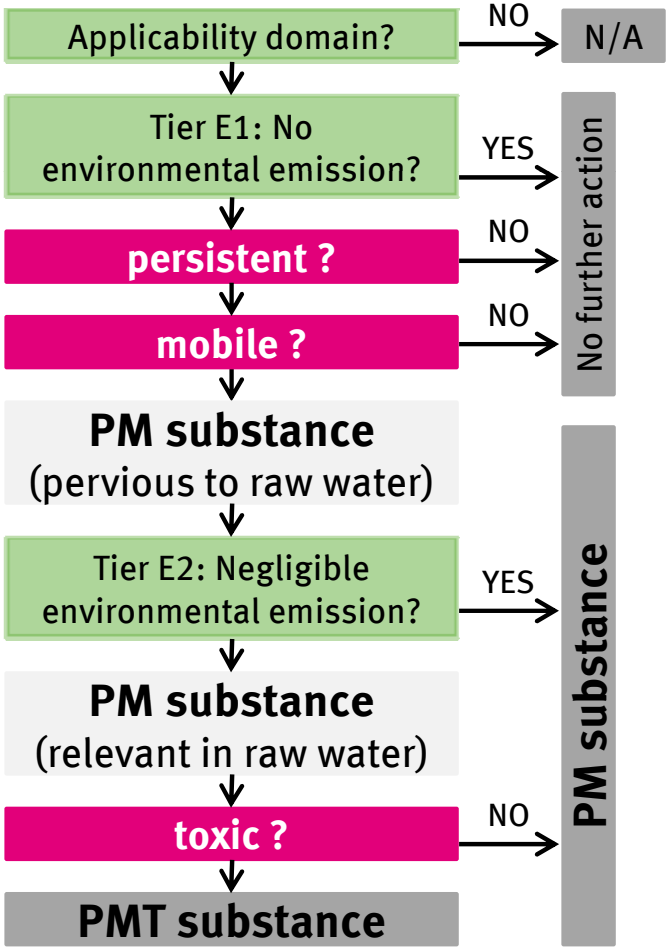
Proposal: **Ionisable** chemicals: if pK_a for acidic functionality ‹8.5 or pK_a for alkaline functionality ›5.5

REACH: Assessment concept of PMT properties

- Applicability domain
  - Inorganic substances, organometallic compounds, surfactants
    =› CURRENTLY EXCLUDED
  - UVCBs and multi constituent substances
    =› ONLY INDIVIDUAL COMPONENTS
  - Ionic, zwitterionic or ionizable organic compounds
    =› ONLY MEASURED LOGK_{OC}
- Criteria for P & M are independent of uses and emissions
- If exposure assessment was already performed
  all necessary data for P & M assessment are available
- Otherwise, emission related assessment steps
  reduce work load

- If criteria for P and M and emissions is fulfilled
  =› ASSESSMENT OF T PROPERTIES IS NECESSARY

Proposal for a stepwise assessment concept of PMT properties including emission related assessment steps



Step 3: Assessment of T properties

- Criteria from Annex XIII of REACH regulation:
  - classified as
    - 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:
  - QSAR or screening indications for CMR or endocrine disrupting properties
  - classified with H362 (“may cause harm to breast-fed children”)
  - listed in e.g. drinking water directive
  - For oral exposure (long-term, general population) the (derived no effect level) **DNEL is ≤ 9 µg/kg body weight and day**

STOT RE: specific target organ toxicity upon repeated exposure

TTC (Threshold of toxicological concern) approach was used to derive a **DNEL** (general population, oral, long term) of 9 µg/kg x d as precautionary cut-off

=› PRECAUTIONARY PRINCIPLE MUST APPLY TO PROTECT DRINKING WATER

Validation with data from monitoring

- Literature review of monitoring data
  - water bodies or STP effluent
  - high frequency and / or relevant concentration
  - full registration under REACH

=› 9 SUBSTANCES

1 no data “P”&“M”: 4-Benzophenon

=› 8 SUBSTANCES

2 PMT-substances: 2,4,6-Trinitrotoluol, Diuron

4 PM-substances: Trichloropropylphosphat, Benzotriazol, Tolyltriazol, Acesulfam K

2 high emissions: Bisphenol A, NTA

Monitoring data only available for a small fraction of chemicals registered under REACH

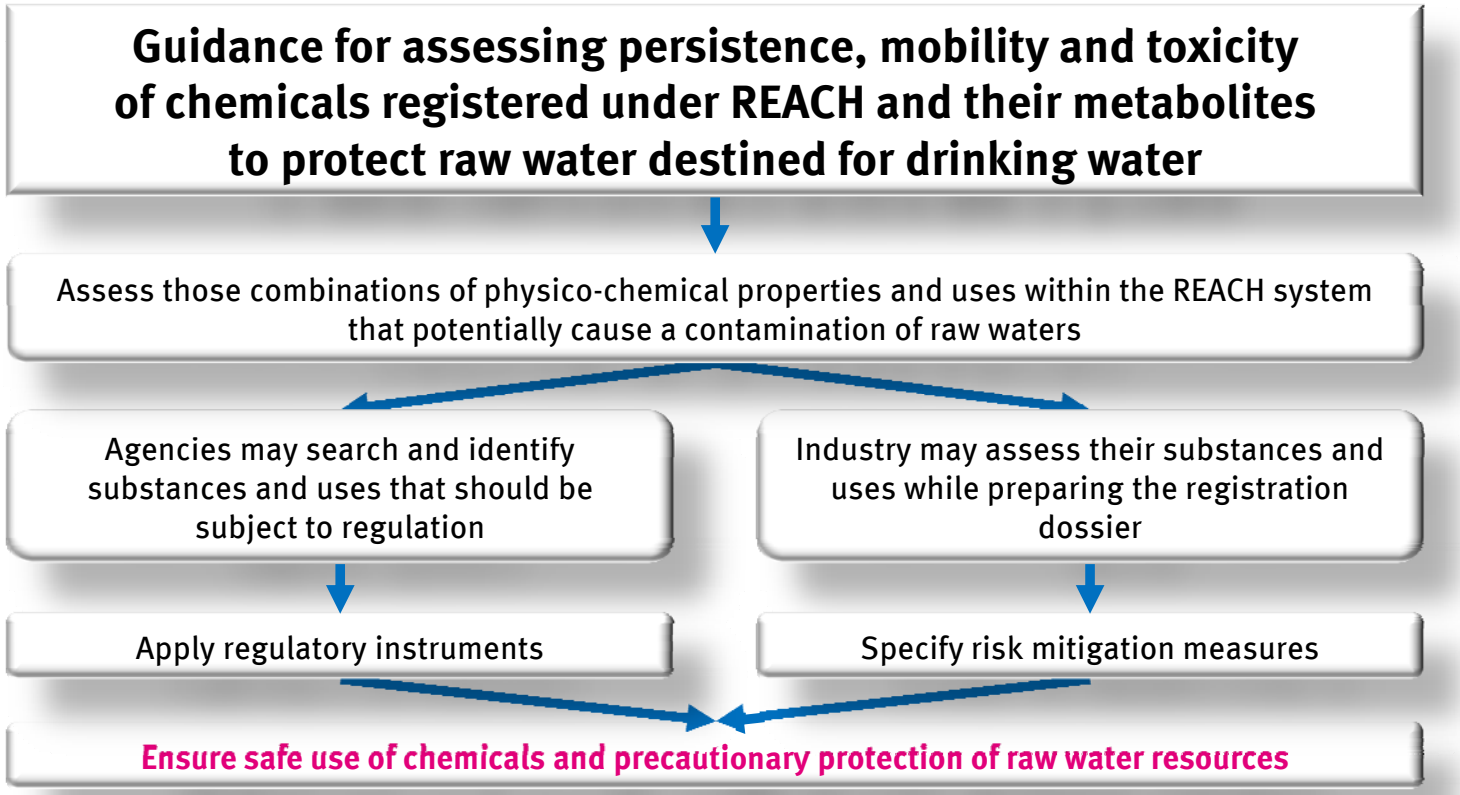
Chemicals found in monitoring often with data gabs in the registration dossier

=› P & M CRITERIA PROVEN FOR 6 OUT OF 8 IN MONITORING.

HOWEVER, ENVIRONMENTAL EXPOSURE MAY ALSO BE CAUSED BY HIGH AND CONTINUOUS EMISSIONS =› QUANTITATIVE RISK ASSESSMENT

Outlook: Risk Management

- The Federal Environment Agency (UBA) aims at supporting industry to fulfil their responsibility by providing guidance.
- In addition, we aim at identifying chemicals for which regulatory action may be necessary.



Outlook: Regulatory Options

- Ground- and drinking water need highest level of protection.
- Remediation is costly, if possible at all.
- Substances that are persistent in the environment, mobile in the water cycle and toxic cause a concern.
- The same substance properties may hinder the degradation by ozone and UV and the filtration by activated charcoal during the water treatment process.

=> PROPOSAL: PMT-SUBSTANCES MIGHT BE IDENTIFIED AS SUBSTANCES OF VERY HIGH CONCERN (SVHC)

Authorization: The use of a chemical is prohibited, unless a specific use is authorized.

Restriction: The use of the chemical is generally allowed, unless a certain (or all) use is restricted.

Conclusions

- REACH Regulation (1907/2006 EG): Precautionary principle needs to be considered to protect the raw water resources.
- Substances that are persistent in the environment, mobile in the water cycle and toxic cause a hazard comparable to POPs and PBTs.
- We propose criteria and an assessment concept which is compatible to the obligations of registrations of uses › 10 t/year
- The Federal Environment Agency (UBA) aims at supporting industry to fulfil their responsibility by providing guidance.
- PMT-Substance may cause a contamination of raw water resources and intrinsic substance properties hinder the water treatment process
  => identification as substances of very high concern (SVHC)

Propose criteria:

P = PBT-assessment and Annex XIII of the REACH regulation

if P than M = Water solubility › 150 µg/L and logKoc ‹ 4,5

T = Annex XIII or indications or precautionary cut-off DNEL is ≤ 9µg/kg body weight and day

Stepwise approach:
Emission related assessment steps shall reduce work load

Thank you for your attention

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