Für Mensch & Umwelt

Umwelt Bundesamt

ICCE 2015 Satellite Event

Using REACH registration data for the identification of persistent, mobile and toxic substances to protect raw water resources

Lena Vierke, Daniel Sättler and Michael Neumann

Outline

REACH

- Responsibility of industry
- Controlling and regulation by authorities

Database of registered substances

Persistent, mobile and toxic substances

- Definition of criteria and assessment concept
- Monitoring data

Substances critical for raw water

Ideas for identification of substances critical for raw water

REACH

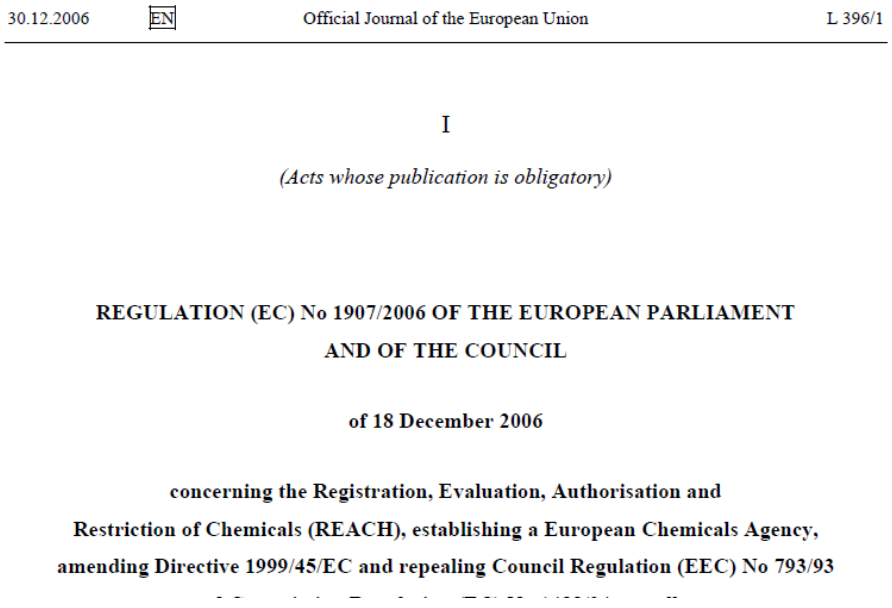
Registration, Evaluation, Authorisation and Restriction of Chemicals

European regulation on chemicals EG/1907/2006

Entered into force on 1st June 2007

"no data, no market“

- Registration of all substances produced or imported in amounts › 1t/a
- Responsible are manufacturer and importer
- Covers manufacturing, import and all uses



30.12.2006 EN Official Journal of the European Union L 396/1

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(Acts whose publication is obligatory)

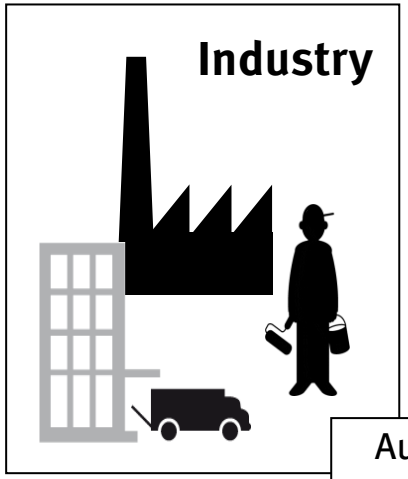
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

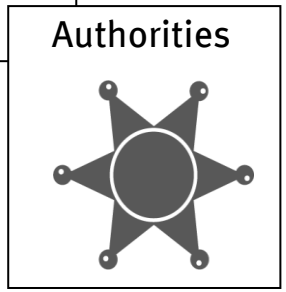
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93

REACH – Aims and tasks

- High Level of protection for human health and environment
- Enhancing competitiveness, achieving sustainable development and innovation
- Promote the development of safe products and processes in the chemical industry



- Industry is responsible for chemical safety assessment
- “no data – no market”: chemicals need to be registered



- Authorities assess single substances if there is a concern or if a concern can not be excluded
- Initiate regulatory measures if there is a risk

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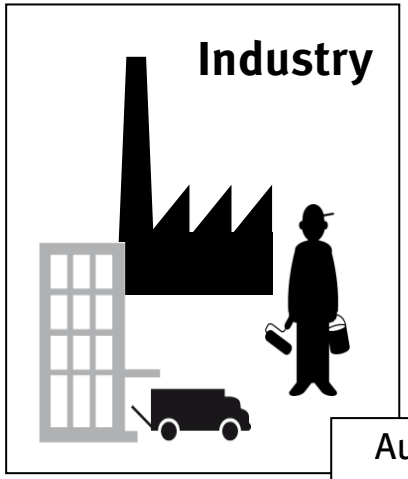

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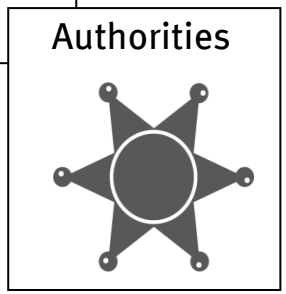

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REACH – Examples of data requests in registrations

≥ 1 t/a (Annex VII)

- Vapour pressure, water solubility, K_{OW}, K_{AW}, etc.
- Readily biodegradable
- Short-term tox daphnia, growth inhibition algae

≥ 10 t/a (Annex VIII)

- Abiotic degradation by hydrolysis
- Screening of adsorption/desorption
- Short-term tox fish

≥ 100 t/a (Annex IX)

- Simulation test degradation
- Bioconcentration; long-term tox fish and daphnia
- Dissociation

≥ 1000 t/a (Annex X)

- Further biotic degradation
- Further fate & behaviour
- Long-term tox sediment

If hazardous or PBT/vPvB

If toxic or CMR (incl. indirect exposure of humans)

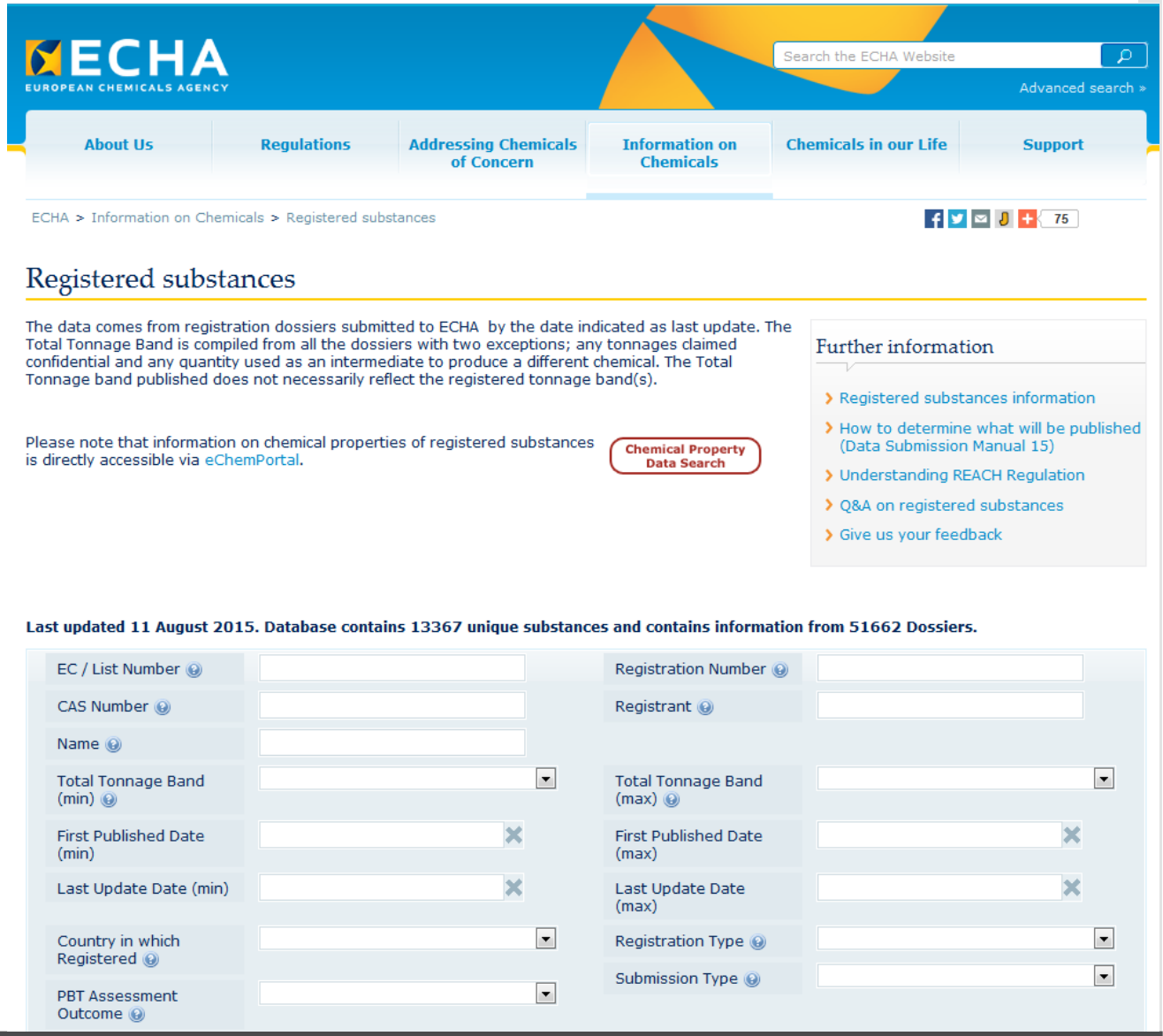
Incl. indirect exposure of humans

Exposure assessment

REACH – Registrations

August 2015
- 13381 substances
- 51719 dossiers

Database
http://echa.europa.eu/information-on-chemicals/registered-substances



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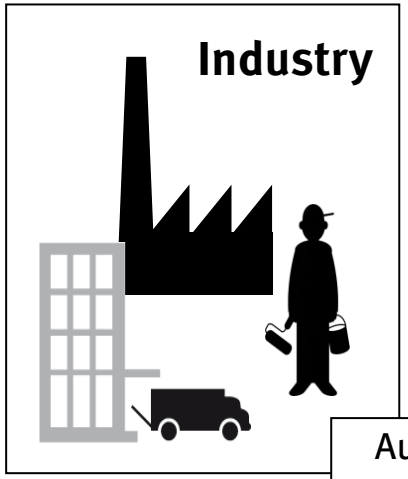

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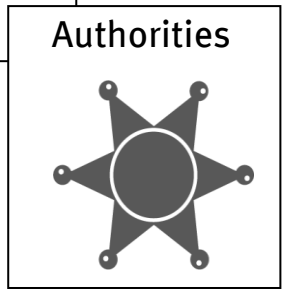
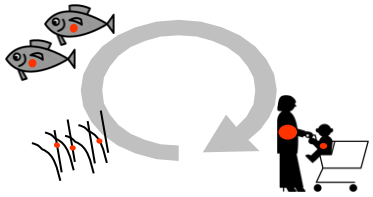


- **Authorities assess single substances if there is a concern or if a concern can not be excluded**
- **Initiate regulatory measures if there is a risk**

REACH – Substances of very high concern

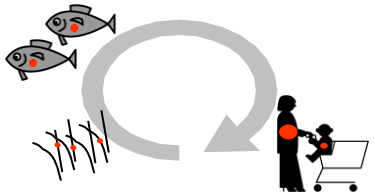
- carcinogenic, mutagen, toxic for reproduction (**CMR**)
- persistent, bioaccumulative, toxic (**PBT)**
- very persistent and very bioaccumulative (**vPvB**)
- **equivalent concern** e. g. substances with endocrine disrupting properties



REACH – Substances of very high concern

Persistent, bioaccumulative, toxic (PBT) substances

- Emission and impact are separated in time and space
- Remediation may not be possible
- Enrichment in the environment
- Long-term effects can not be foreseen

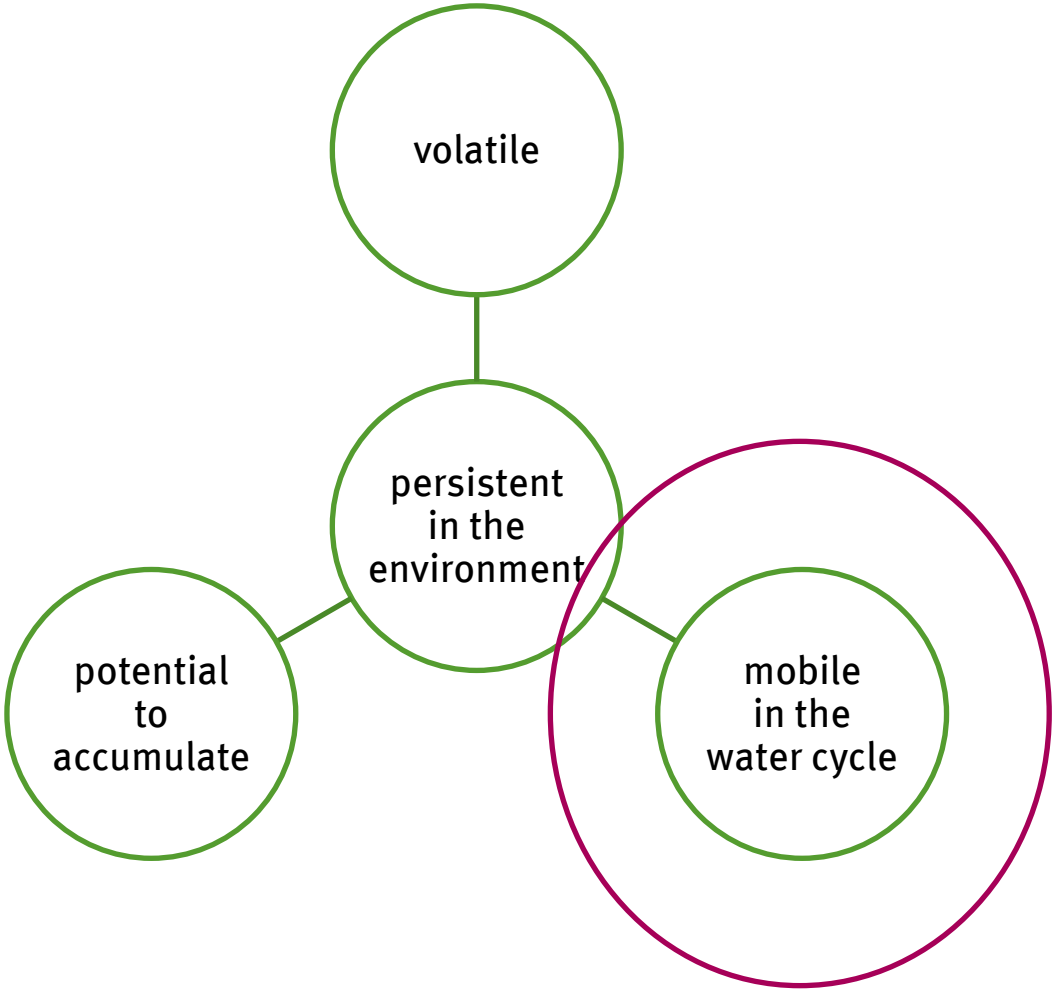


→ Emissions into the environment have to be avoided

→ Substitution is needed

Authorities initiate regulatory measures like authorization or restriction

Persistent substances in the environment



- Persistent substances with a high mobility in the aqueous environment might reach raw-water resources if release into the environment occurs
- Assessment of such substances so far not covered by REACH
- How to define the properties of these substances?

Research Project

Guidance for the precautionary protection of raw water destined for drinking water extraction from contaminants regulated under REACH

by
Fritz Kalberlah, Jan Oltmanns, Markus Schwarz
Forschungs- und Beratungsinstitut Gefahrstoffe (FoBiG)

in cooperation with
Joachim Baumeister, Albrecht Striffler
Denkbares

Financed by the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, Project *FKZ 371265416*

Substances which cause a concern for raw water

persistent ?

mobile ?

Persistent

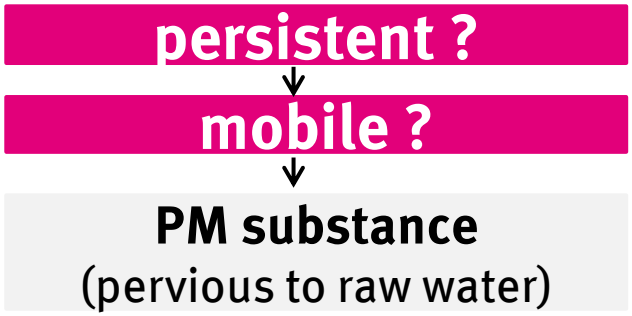
- already defined in REACH for PBT-assessment

Mobile: › 150 µg/L and log K_{OC} ‹ 4.5

- Modeling approach to find the determining properties (water solubility, vapor pressure, log K_{OW}, log K_{OC}) for high fractions in surface water and groundwater

(Kalberlah et al. 2015)

Substances which cause a concern for raw water



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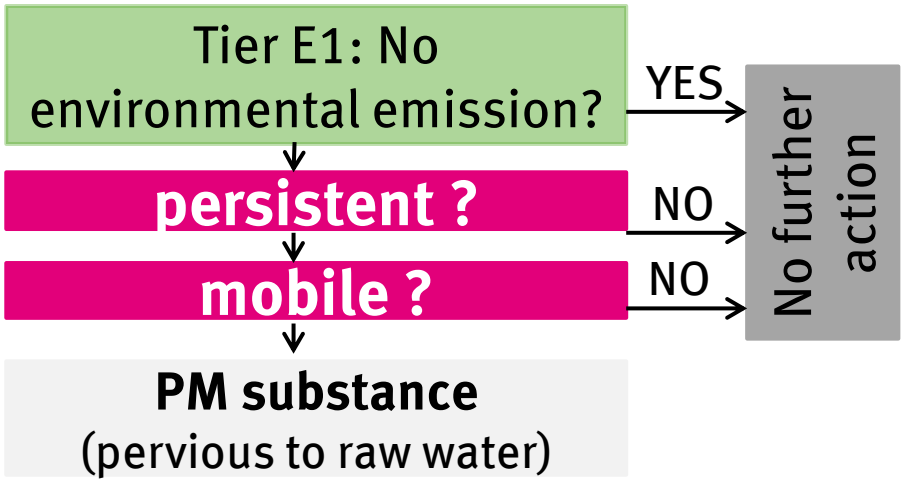

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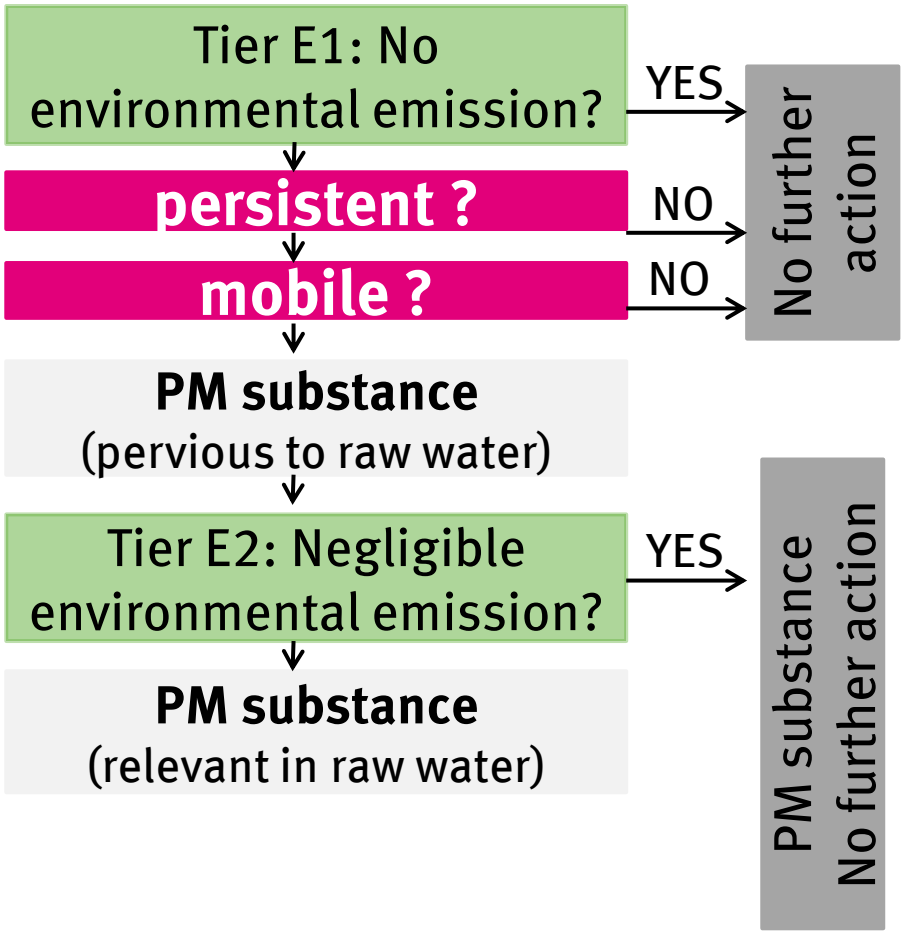

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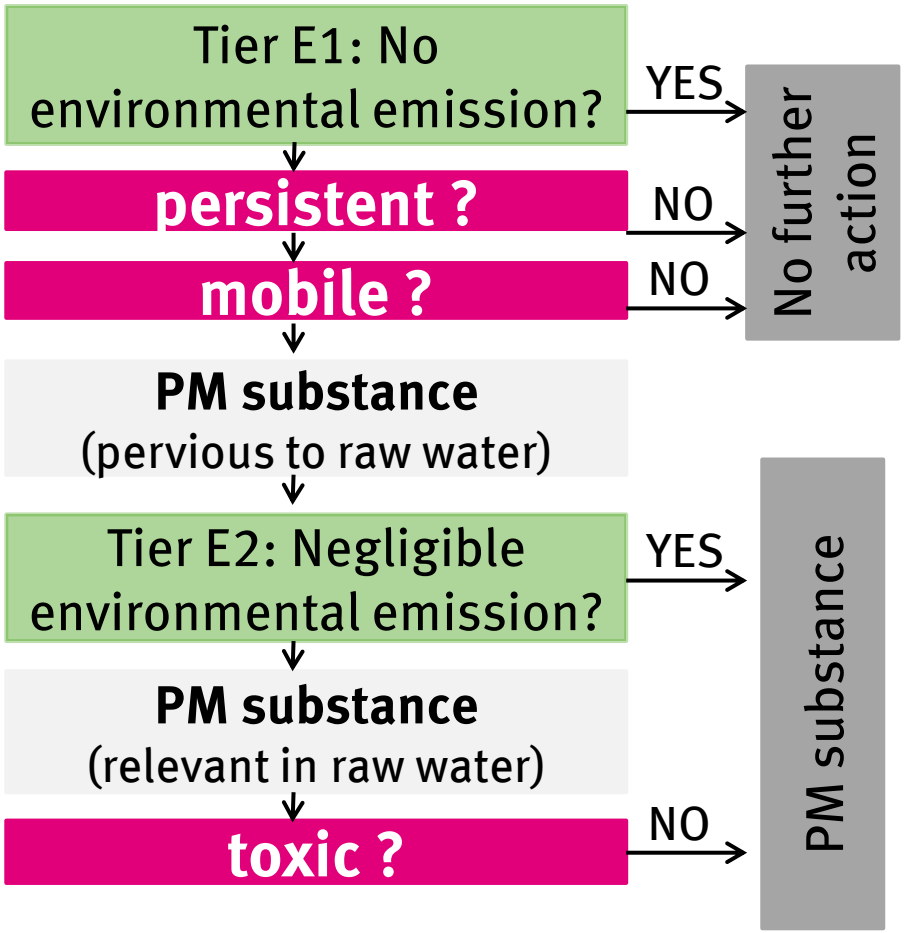
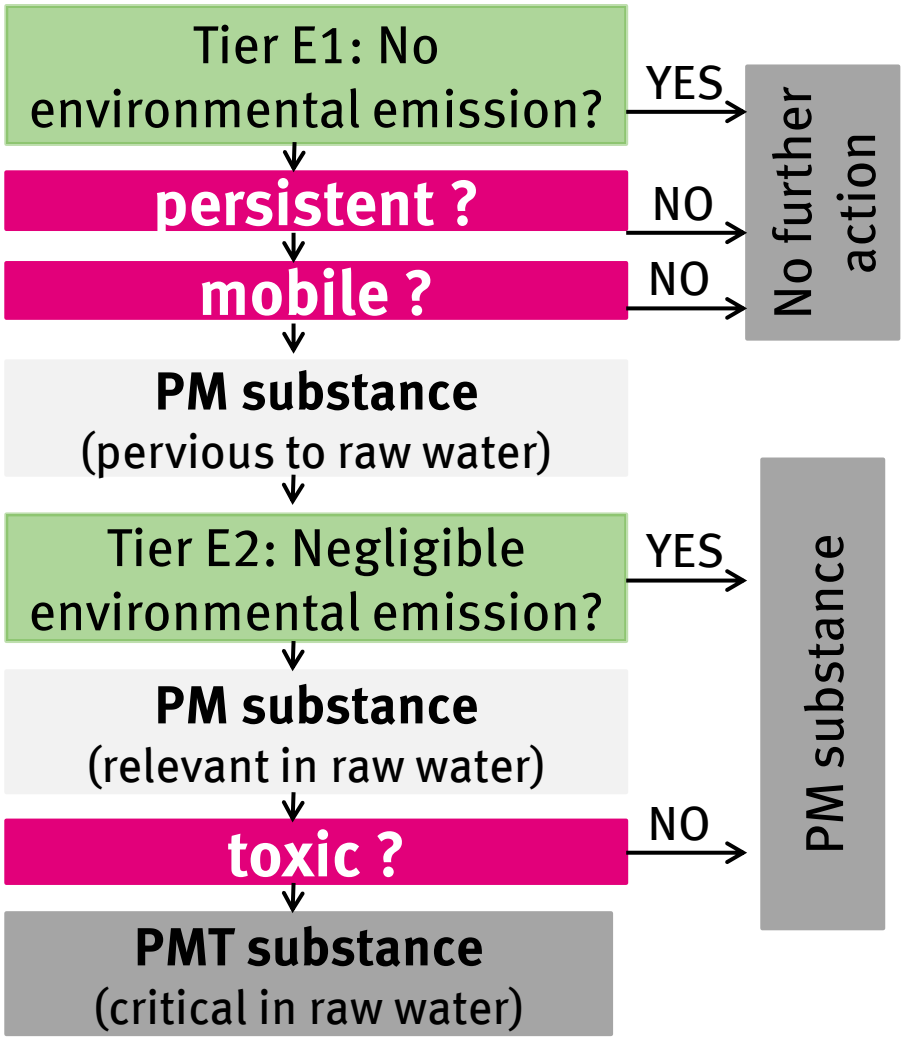


Toxic

- Criteria from REACH Annex XIII
  - carcinogen Cat. 1A, 1B,
  - germ cell mutagen Cat. 1A, 1B
  - reproductive toxicant Cat. 1A, 1B, 2
  - STOT RE Cat. 1 or 2
- 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

(Kalberlah et al. 2015)

Substances which cause a concern for raw water



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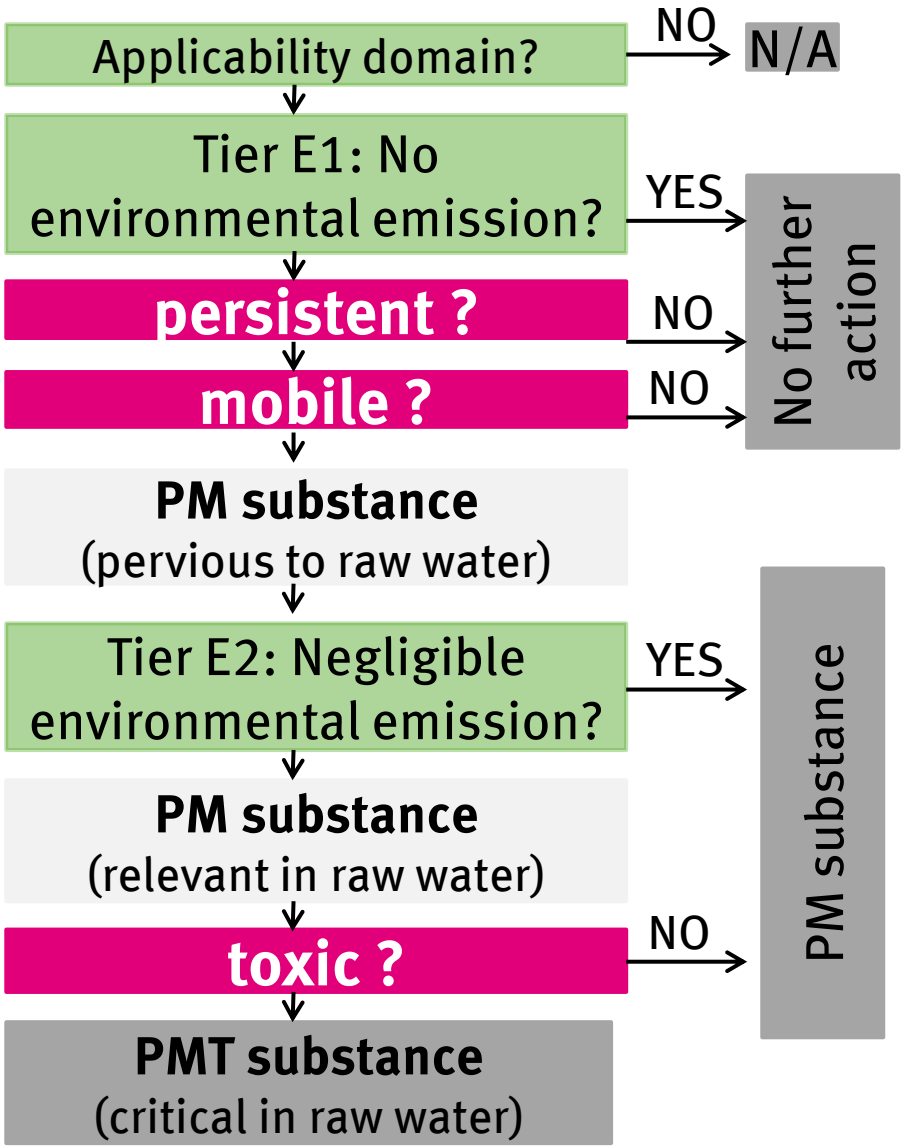

Applicability domain

- Inorganic substances, organometallic compounds, surfactants
  =› currently excluded
- UVCBs and multi constituent substances
  =› only individual components
- Ionic, zwitterionic or ionizable organic compounds
  =› only measured log K_{OC}

(Kalberlah et al. 2015)

Substances which cause a concern for raw water

Proposal for PMT-criteria and assessment concept is available – what next?

- Provide guidance for industry
  - Industry is responsible for the save use of their substances
  - Proposed criteria and an assessment concept is compatible with obligations for registrations › 10 t/year

- Screen REACH-registered substances for PMT-substances critical in raw water
  - Might be substances of very high concern
  - Might be of interest for environmental screening and monitoring programs

Monitoring data

Very few monitoring data from the aqueous environment for REACH-registered substances

=› 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

=› P & M criteria proven for 6 out of 8 in monitoring

Environmental exposure may also be caused by high and continuous emissions

(Kalberlah et al. 2015)

Monitoring data

Very few monitoring data from the aqueous environment for REACH-registered substances

=› 9 substances vs. ~ 13 000 registered substances

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=› 8 substances

Lack of analytical methods?

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(Kalberlah et al. 2015)

PROMOTE
Protecting Water Resources from Mobile Trace Chemicals

Coordination

Helmholtz Centre for Environmental Research - UFZ, Germany, Thorsten Reemtsma, Urs Berger, and Stefanie Schulze

Partners

Fresenius University of Applied Sciences, Germany, Thomas Knepper et al.

Norwegian Geotechnical Institute, Norway, Hans Peter Arp et al.

University of Santiago de Compostela, Spain, Assoc. José Benito Quintana et al.

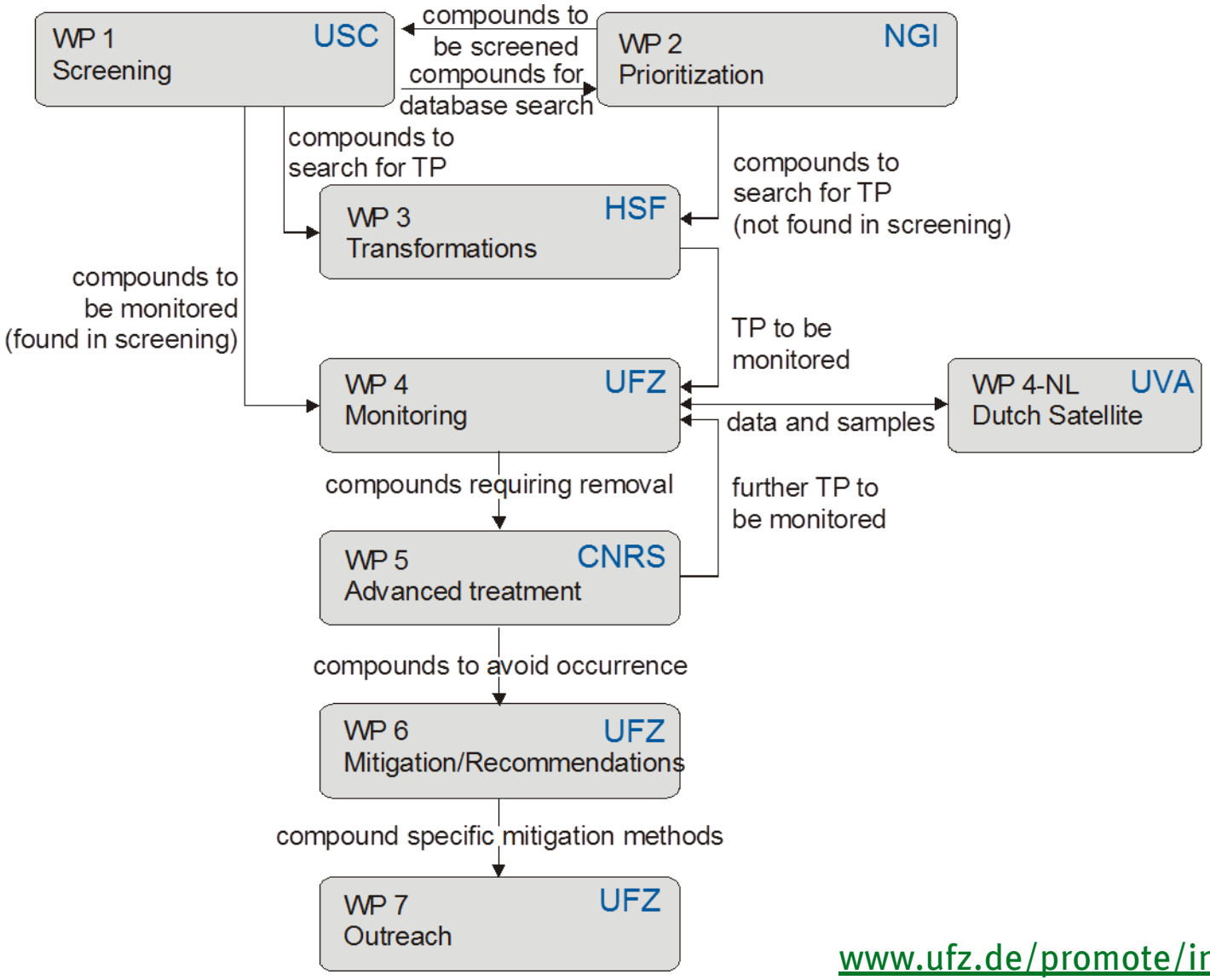
National Center for Scientific Research, France, Hervé Gallard et al.

University of Amsterdam, The Netherlands, Pim de Voogt et al.
Federal Environment Agency, Germany, Michael Neumann, Daniel Sättler and Lena Vierke

and further associated partners

Identification and monitoring of persistent, mobile organic contaminants (PMOC)

PROMOTE
Protecting Water Resources from Mobile Trace Chemicals



www.ufz.de/promote/index.php?en=33910

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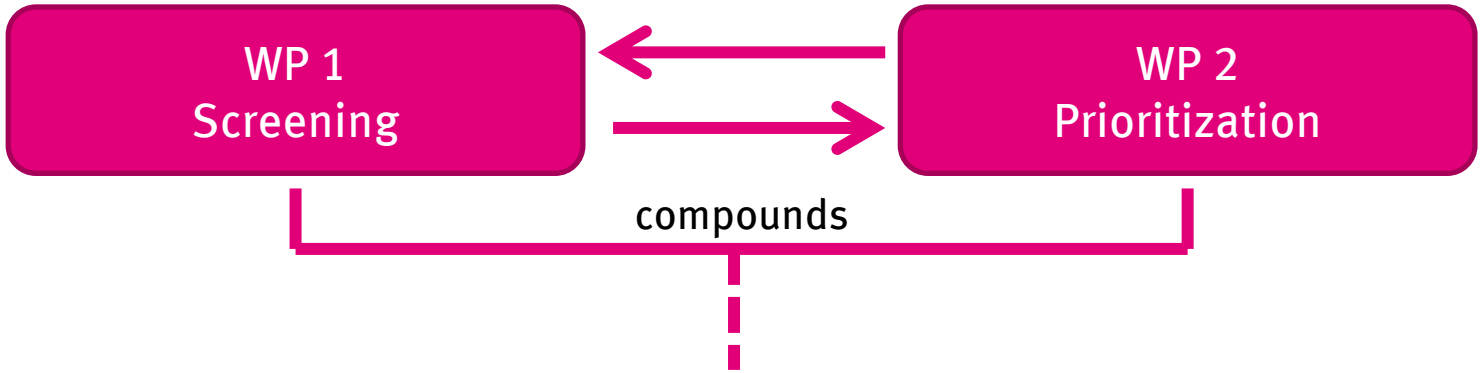


Analytical screening for polar pollutants of industrial origin

- Development of analytical screening methods
- Screening in water samples

Prioritization based on REACH registration data

- Prioritize PMOC from REACH-registered substances
- Develop criteria to identify uses under REACH that may cause a contamination of source waters, based on volume emitted and emission release category

www.ufz.de/promote/index.php?en=33910

Conclusion

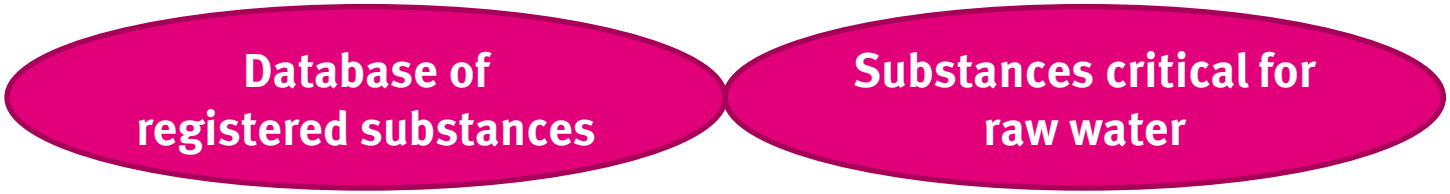
REACH

- Industry is responsible for safety of chemicals throughout the lifetime
- Possibilities for different measures by authorities, e.g. SVHC identification of PBT substances

→ Protection of raw water so far not considered

Persistent, mobile and toxic (PMT-)substances

- definition of criteria and assessment concept to be used by industry and authorities
- Only very few monitoring data available



Identification of substance in raw-water by monitoring

→ Search in REACH registrations for further information or address substances by regulatory measures

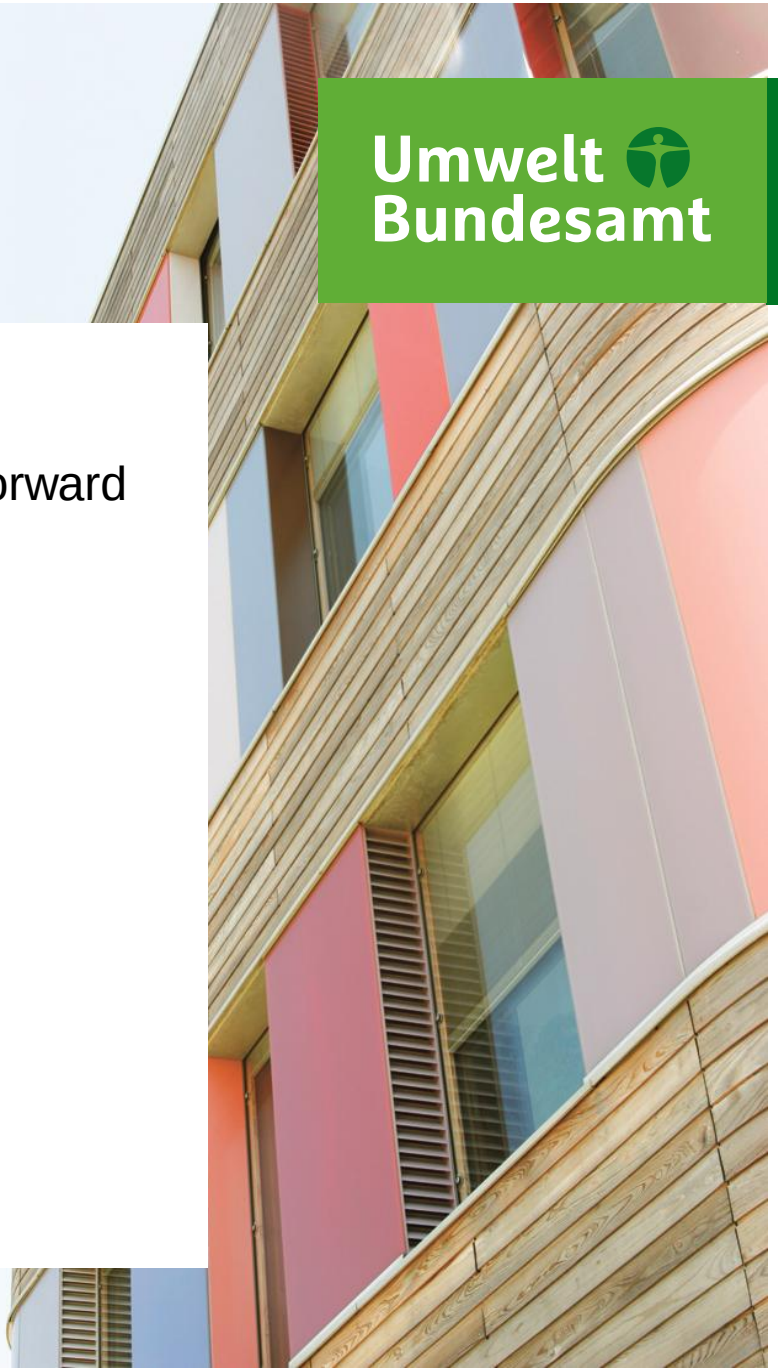
Identification of PMT-substances in REACH registrations

→ Performance of monitoring

Thank you for your attention and I am looking forward to our discussion!

Dr. Lena Vierke
Lena.Vierke@uba.de

www.reach-info.de



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% P: 55% Not P: 45%
Median	293	3.23	36.1	0.00145	0.0168	2.80	
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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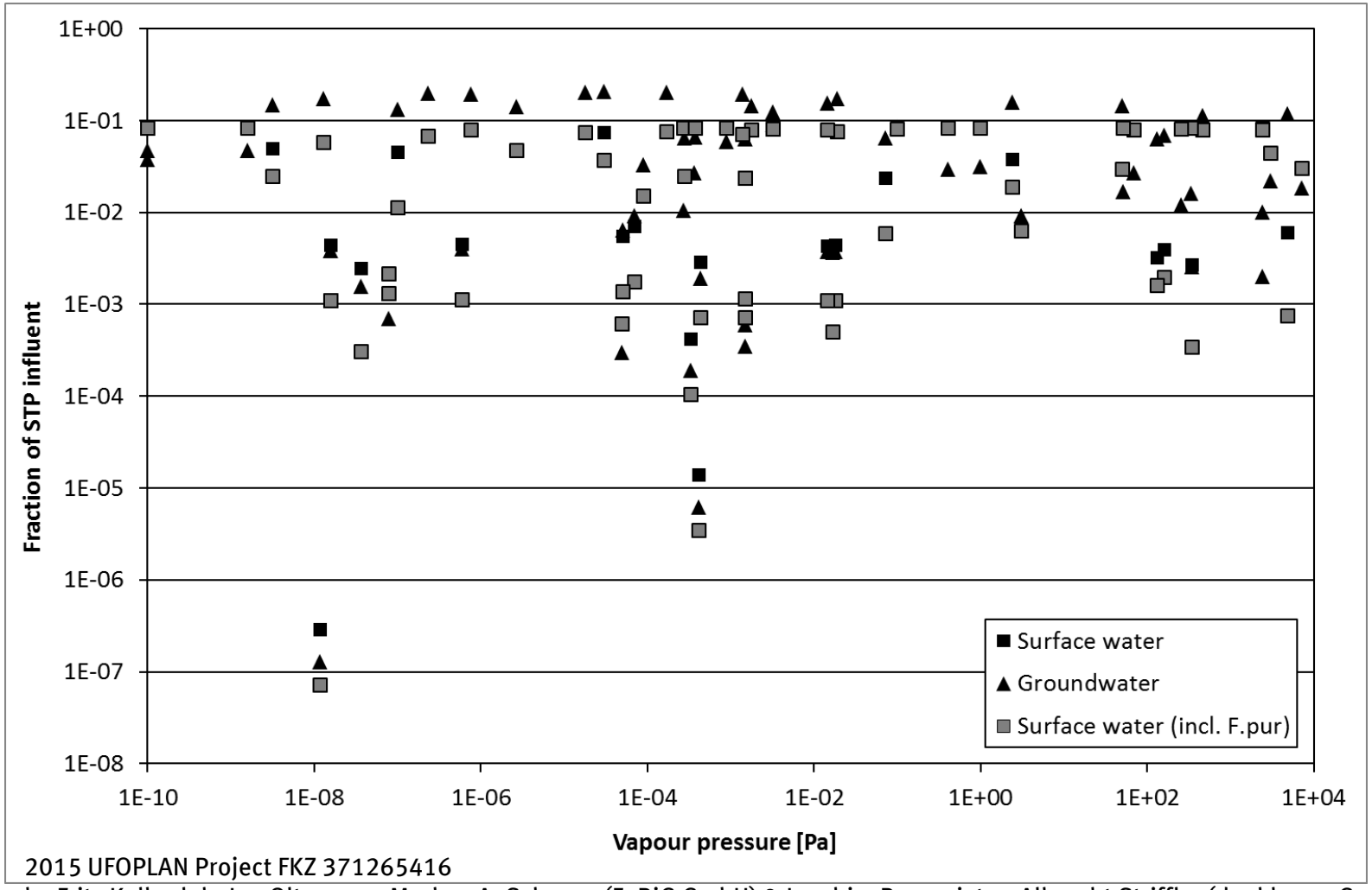
by Fritz Kalberlah, Jan Oltmanns, Markus A. Schwarz (FoBiG GmbH) & Joachim Baumeister, Albrecht Striffler (denkbares GmbH)

Vapour Pressure: determinant of mobility?



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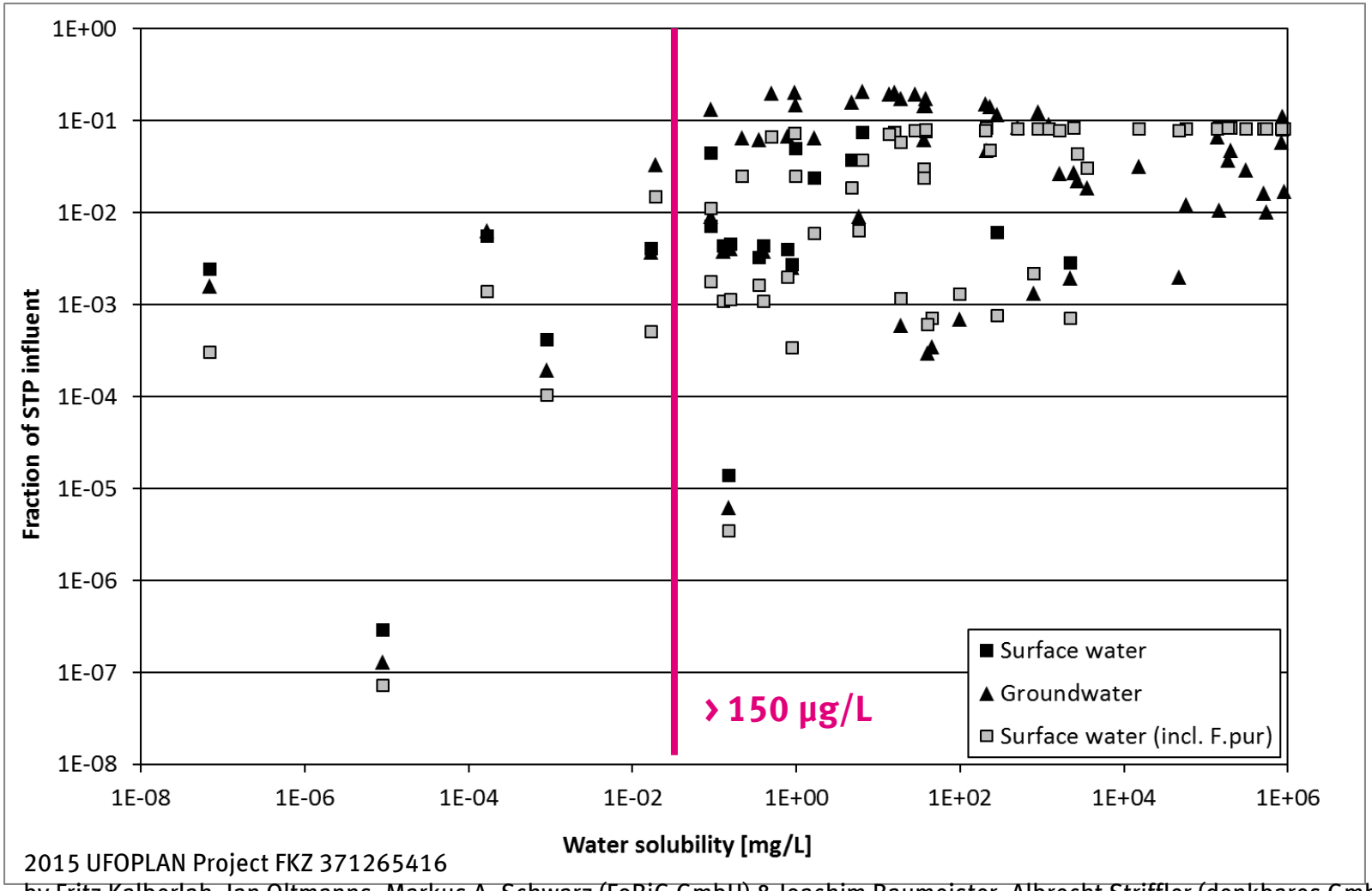
Water Solubility: determinant of mobility?



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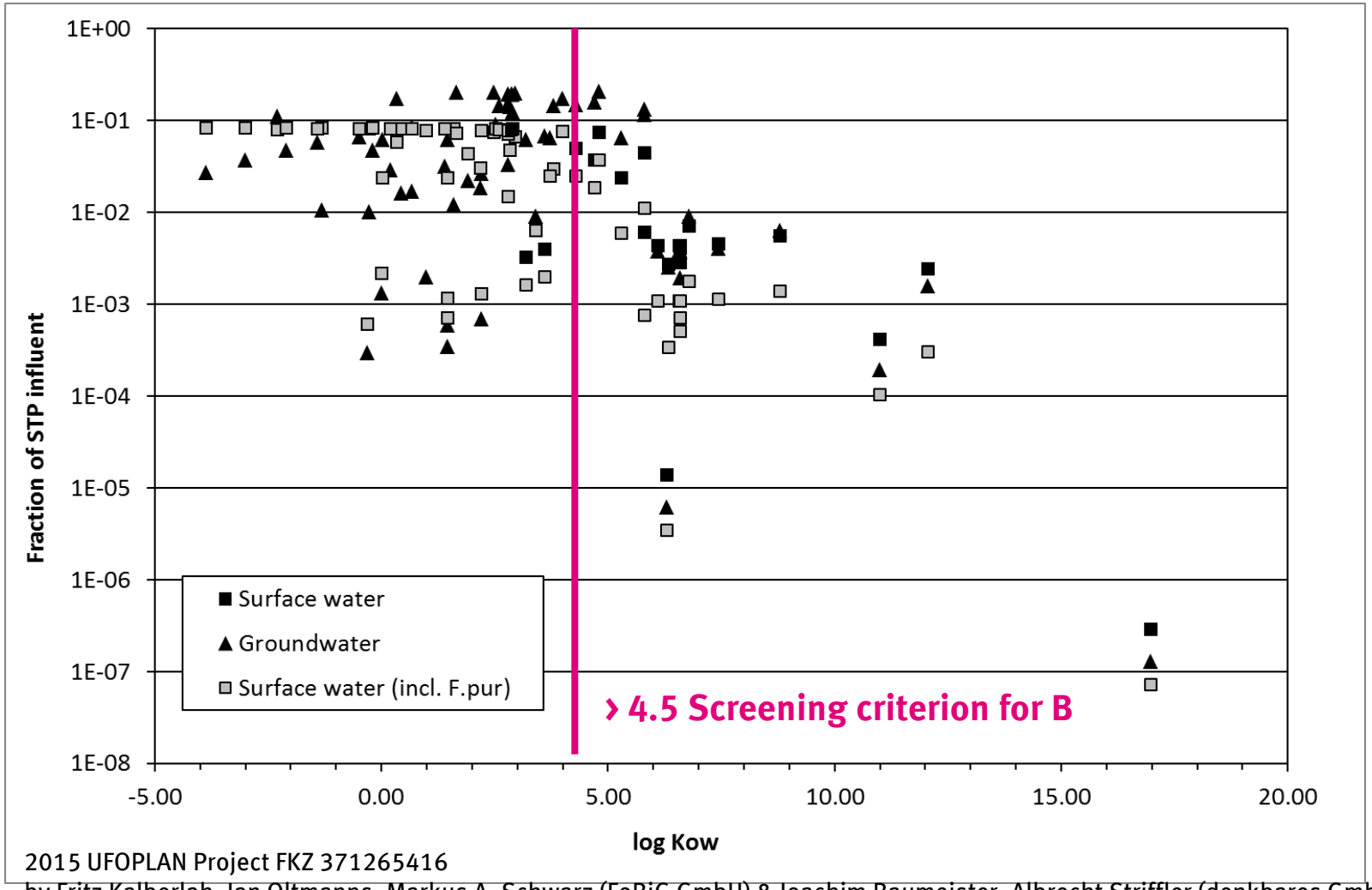
log K_{ow}: determinant of mobility?



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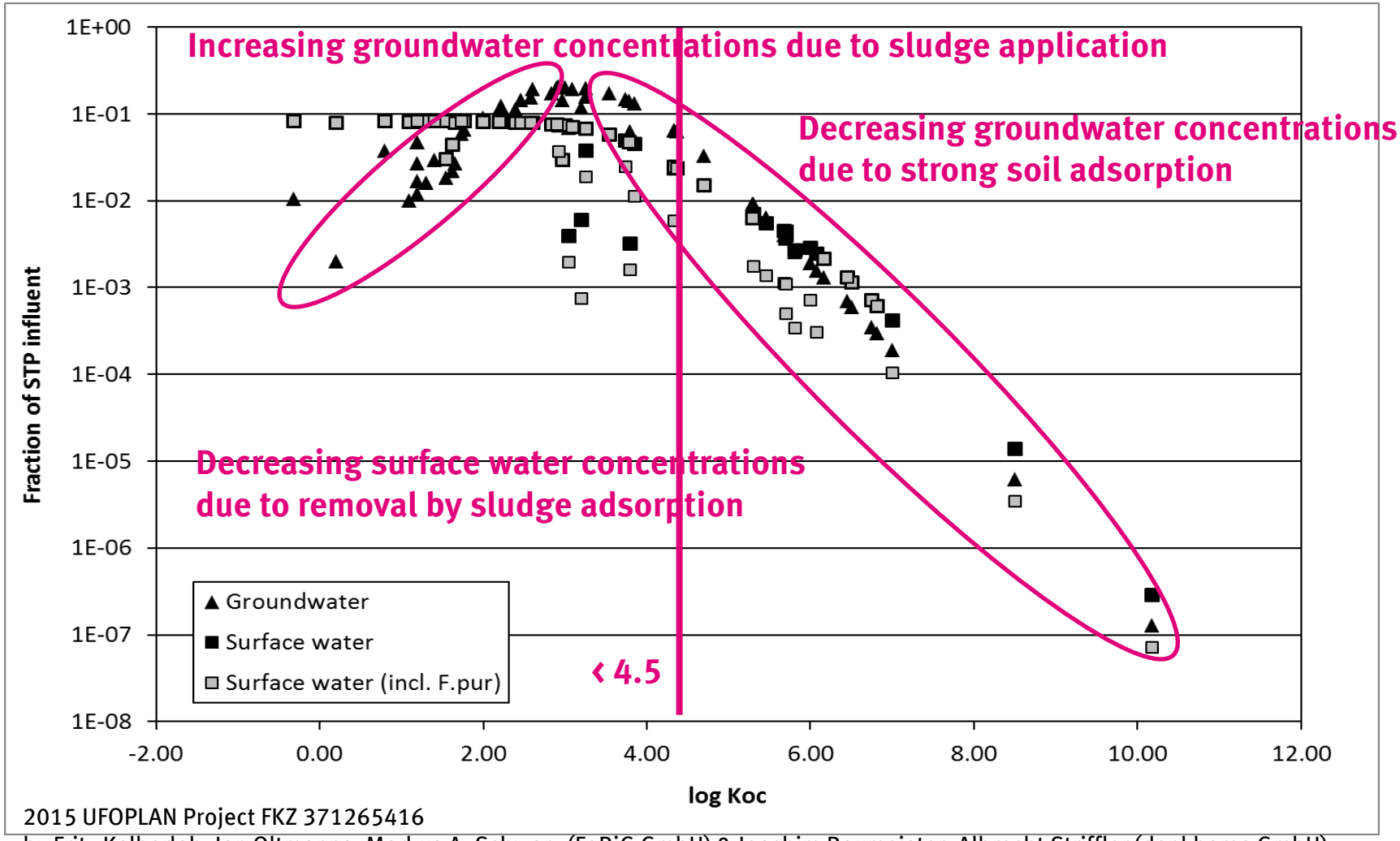
log K_{oc}: determinant of mobility!



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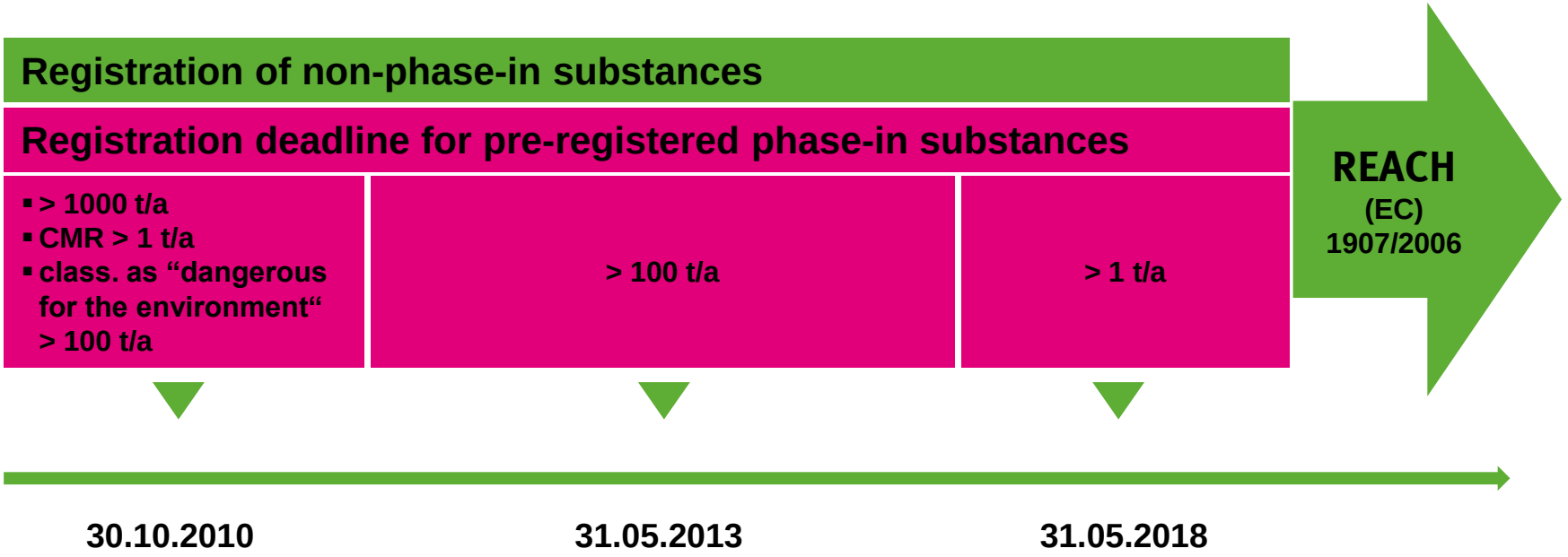

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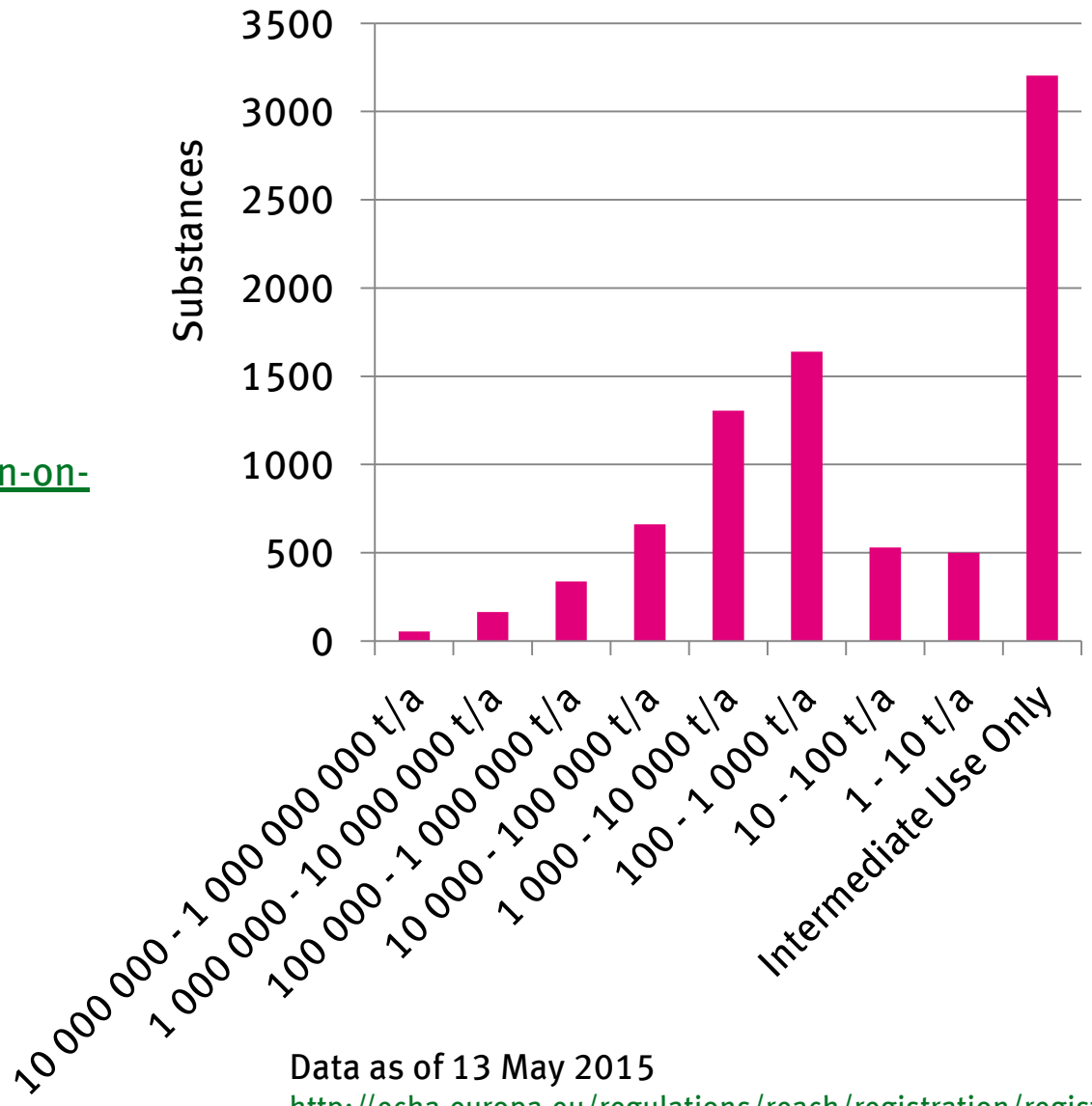

Data as of 13 May 2015
http://echa.europa.eu/regulations/reach/registration/registration-statistics/registered-substances-tonnage-band

REACH – Registrations

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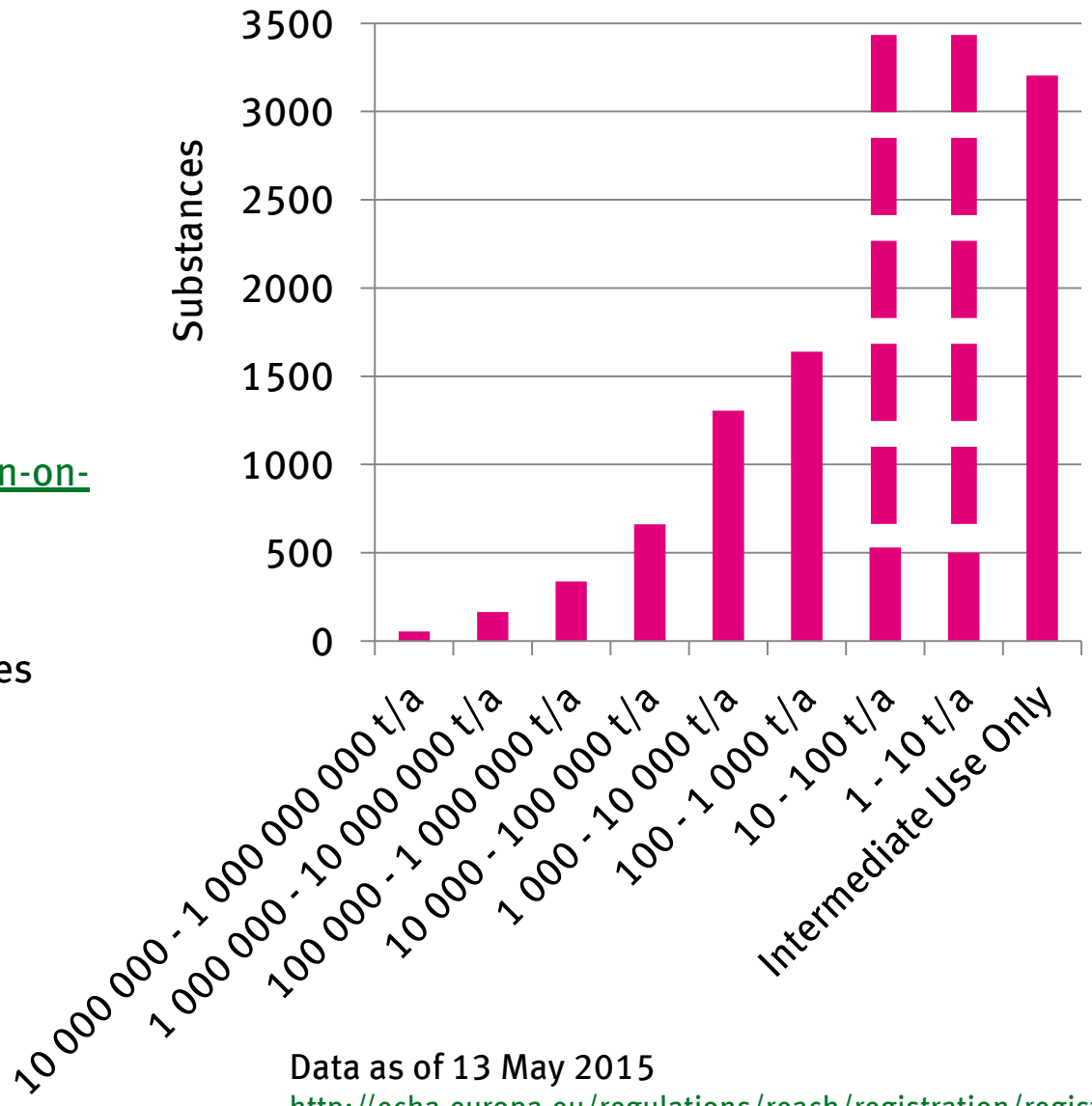
http://echa.europa.eu/information-on-chemicals/registered-substances

Registration of phase-in substances
‹100 t/a until 05/2018

- 25000 substances
- 70000 dossiers

expected by ECHA



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