

Workshop: PMT and vPvM substances under REACH
Voluntary measures and regulatory options to protect the sources of drinking water
in Berlin, 13th to 14th March 2018

Welcome to day 2

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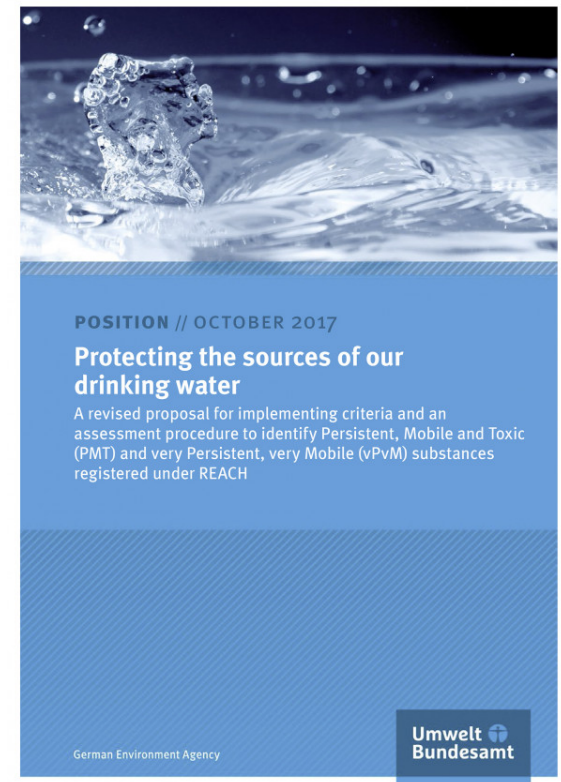
Our aim: protecting the provision of drinking water

- Our ground- and drinking water need the **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 [...] as such should be **protected from [...] chemical pollution.**”
- EU water companies' memorandum:
“**Nobody has a right to pollute water bodies**”



This workshop is part of the ongoing second consultation

- The **revised** proposal (“second version”) was published in October 2017
- As of today we have **received** over 30 written comments
- This workshop is the **final step** in the ongoing second consultation
- We will also take the discussion here in Berlin **into account**
- The revised (“**third**”) version of our proposal will be made available by **May 2018**



Discussion Starter I “How to establish ?”

- How could the PMT and vPvM criteria be **established** under REACH?
- Will CARACAL or MSC establish the PMT and vPvM criteria?
- Should there be new criteria under **Article 57** of REACH?
- Should there be new criteria for **classification** under harmonised CLP?



2006 EU chemical regulation REACH enters into force

- Aim of REACH: The safe use of chemicals
 - **High level of protection** for human health and the environment
 - **Precautionary principle**
 - **Substitution** of critical substances and critical uses
- New role for industry
 - Assessment of the **risk**
 - Identification of **hazardous substance properties**
 - **Communication** within the supply chain about safe uses
- New role for authorities & ECHA
 - **Supporting** industry with guidelines, tools and methods
 - Identification of those substances and uses that **require** a regulation
 - Initiation of **necessary** regulatory measures

Registration, Evaluation,
Authorisation and Restriction
of **C**hemicals

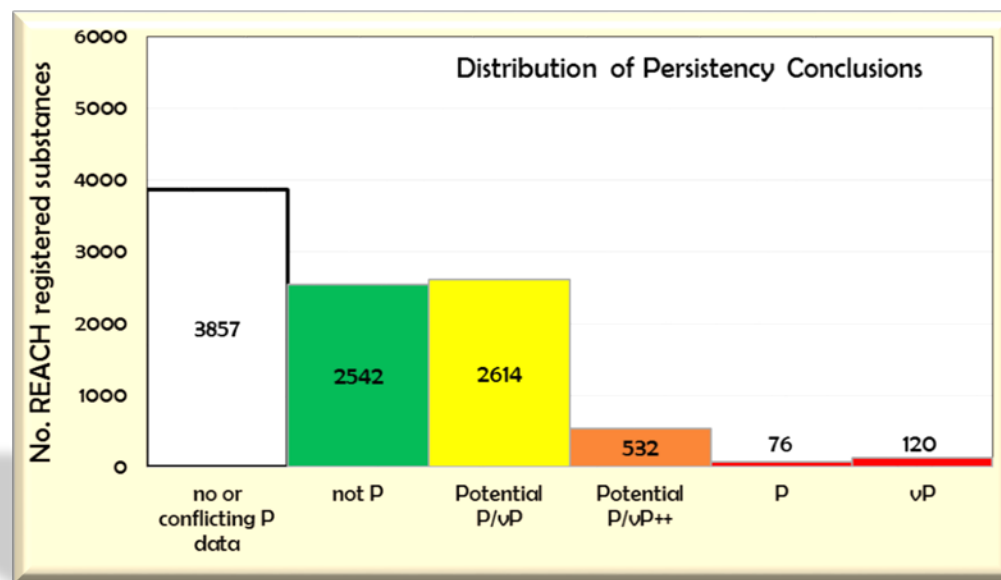
Enters into force on
18.12.2006

Substitute previous individual
chemical laws

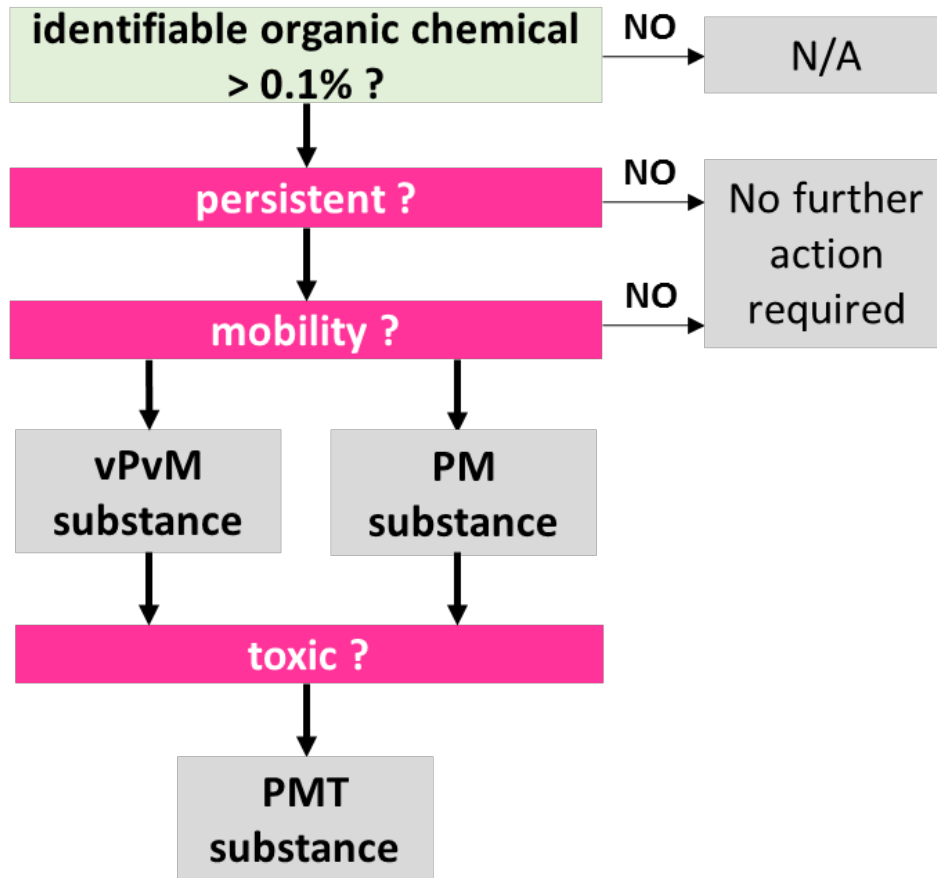
We propose a two step approach

- **Identify** all PMT and vPvM substances during registration under REACH
- Registration data are used to carry out an accurate PMT or vPvM **assessment**.

STEP 1: COMPARISON WITH THE PMT AND vPvM CRITERIA



Step 1: Comparison with the PMT and vPvM criteria



Project 2016: Application of the proposed criteria

- UBA funded Research Project No 74925 (Berger et al. 2018)
- First time ever potential PMT substances under REACH were **identified**
- Assessment of P_{water} , M and T of 167 REACH registered substances
 - 9 substances assessed as P_{water} MT substances
 - 20 substances assessed as P_{water} M substances with suspected T
 - 93 suspected P_{water} MT substances were identified

P _{water}	64						69						11	23					
M	29		31			4	28		37			1	3	11	7	16			
T	9	20	2	27	2	4	12	16	7	29	1	1	3	11	4	3	2	13	1

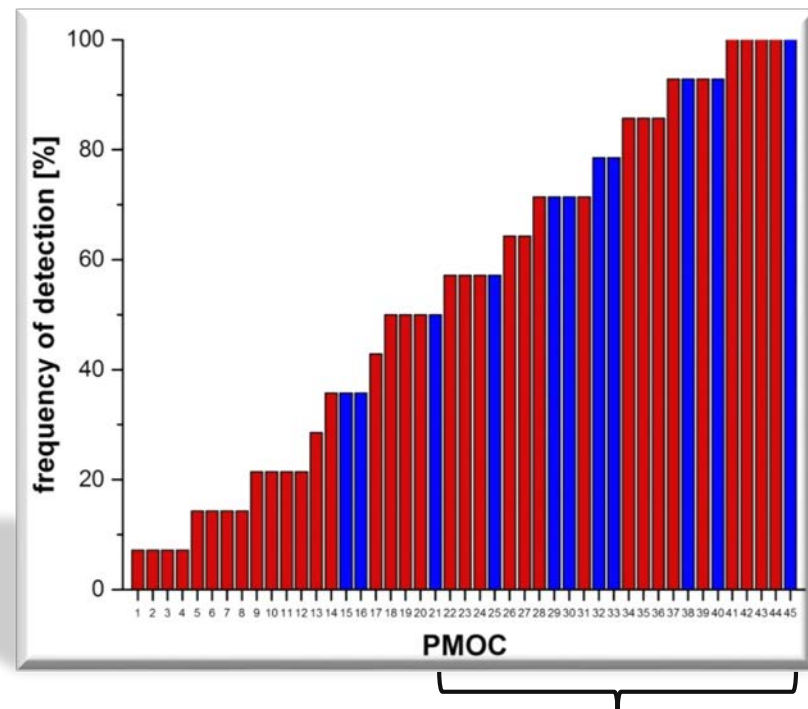
Application of the proposed criteria

- UBA funded Research Project No 74925 (Berger et al. 2017)
- 9 substances assessed as P_{water} MT substances

ID	CAS No.	EC No.	Substance name	Emission ranking
1	107-06-2	203-458-1	1,2-Dichloroethan	1
2	127-18-4	204-825-9	Tetrachloroethene	4
3	79-01-6	201-167-4	Trichloroethene	10
4	123-30-8	204-616-2	4-Aminophenol	37
5	288-88-0	206-022-9	1,2,4-Triazole	51
6	123-91-1	204-661-8	1,4-Dioxane	52
7	1671-49-4	430-550-0	4-Mesyl-2-nitrotoluene	88
8	87-62-7	201-758-7	2,6-Dimethylaniline	137
9	2896-70-0	220-778-7	2,2,6,6-Tetramethyl-4-oxopiperidinoxy	145

Proof of Concept: New Monitoring data

- 14 water samples analysed by EU project PROMOTE
- **65%** PM substances (45 of 70 analysed) detected
- Majority „**novel**“ PM substances

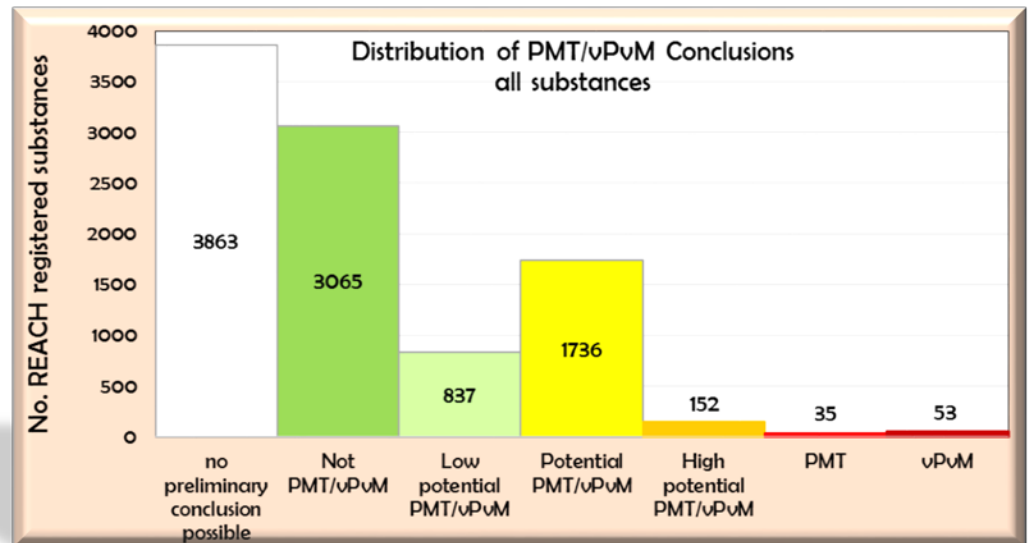


<http://www.ufz.de/promote/>

28 PM substances

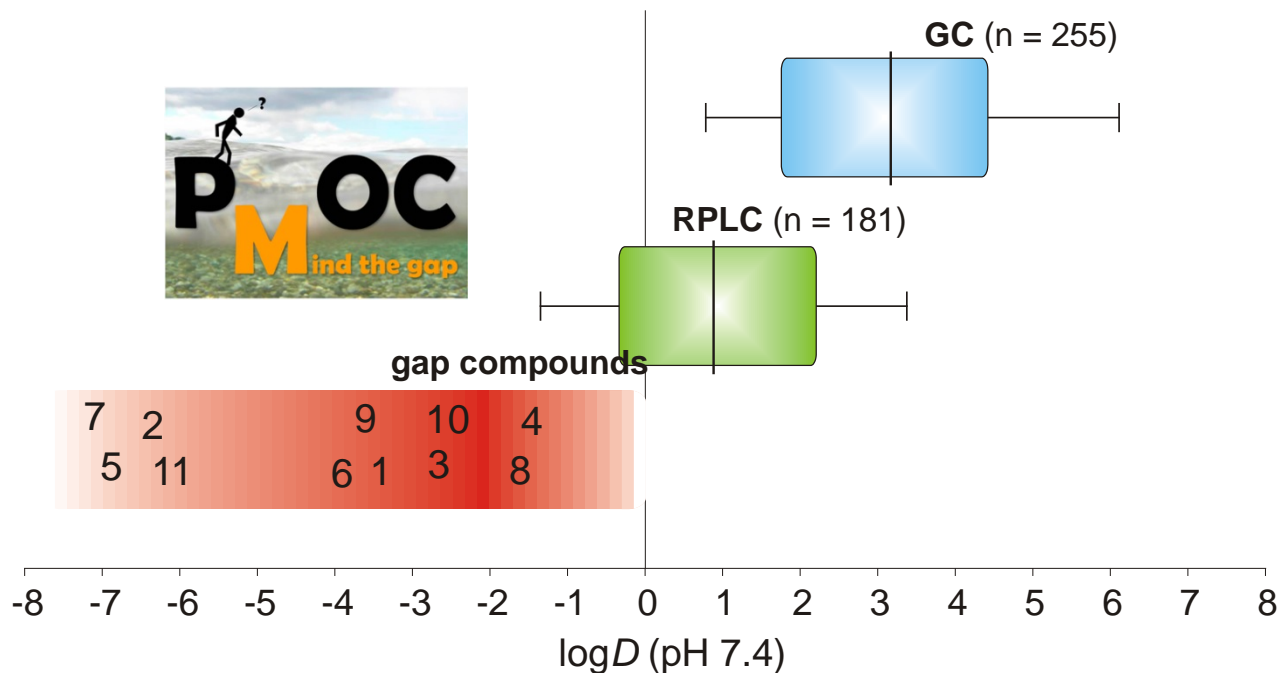
Project 2018: Application of the proposed criteria

- UBA funded Research Project No FKZ 3716 67 416 0
- Assessment of P, M and T of all (May 2017)
REACH registered substances
 - 210 substances assessed as PMT
 - 30 substances assessed as vPvM (not PMT)



The Analytical Gap for mobile (polar) compounds

- Monitored substances



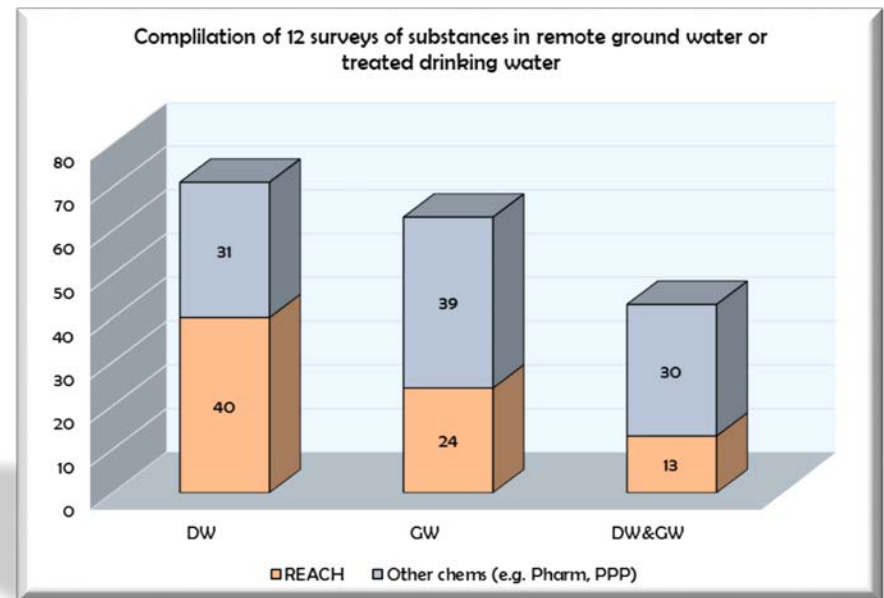
1: AMPA, 2: Paraquat, 3: Cyanuric acid, 4: DMS, 5: Diquat, 6: 5-Fluorouracil, 7: Glyphosate, 8: Melamine, 9: Metformin, 10: Perfluoroacetic acid, 11: EDTA

Reemtsma et al. (2016) *Environ. Sci Technol.* 50, 10308-10315



Proof of Concept: Existing Monitoring data

- NGI performed a literature survey:
groundwater (**GW**) and drinking water (**DW**)
- Already today at least **77 REACH-registered substances** were detected in Europe
- **55%** (42 of 77) are confirmed or potential persistent and mobile (PM substances)
- the remaining are all either just P or just M,
with **large production volumes and emission likelihood**
(via uses within or outside of REACH)



We propose a two step approach

- **Identify** all PMT and vPvM substances during registration under REACH
- Registration data are used to carry out an accurate PMT or vPvM **assessment**

STEP 1: COMPARISON WITH THE PMT AND vPvM CRITERIA

STEP 2: EMISSION CHARACTERIZATION

- **Minimize** emissions into the environment
 - Risk Mitigation Measures (RMM)
 - Safer alternatives
- **Only** if voluntary measures are not effectively protecting the sources of drinking water, regulatory instruments would need to be applied

- [illegible]

Substances of very high concern (SVHC)

- Article 57 of REACH defines the criteria for

Substances of very high concern (SVHC)

- carcinogenic, mutagenic and reproductive toxic substances (**CMR**)
- persistent, bioaccumulative, toxic substances (**PBT**)
- very persistent, very bioaccumulative substances (**vPvB**)
- **equivalent level of concern**
 - Substances with **endocrine** disrupting properties
 - Sensitisers
 - **PBT-like**



Regulatory options 1/2

- Authorization regime following the “equivalent level of concern” criteria referred to in Article 57 (f) of REACH:
 - **Both** PBT/vPvB and PMT/vPvM substances
 - persist in the environment and survive the route of transport and of exposure to humans, to remote areas and to pristine environments
 - main **difference** is their pathways of exposure and transport
 - For PBT/vPvB substances, human and animal exposure is primarily via the diet, as these substances transport and accumulate via the food chain and biota.
 - For PMT/vPvM substances, exposure is primarily through water sources, as these substances transport with and recirculate and enrich within the water cycle, accumulate in remote water sources, and thereby could contaminate the sources of drinking water.

Regulatory options 2/2

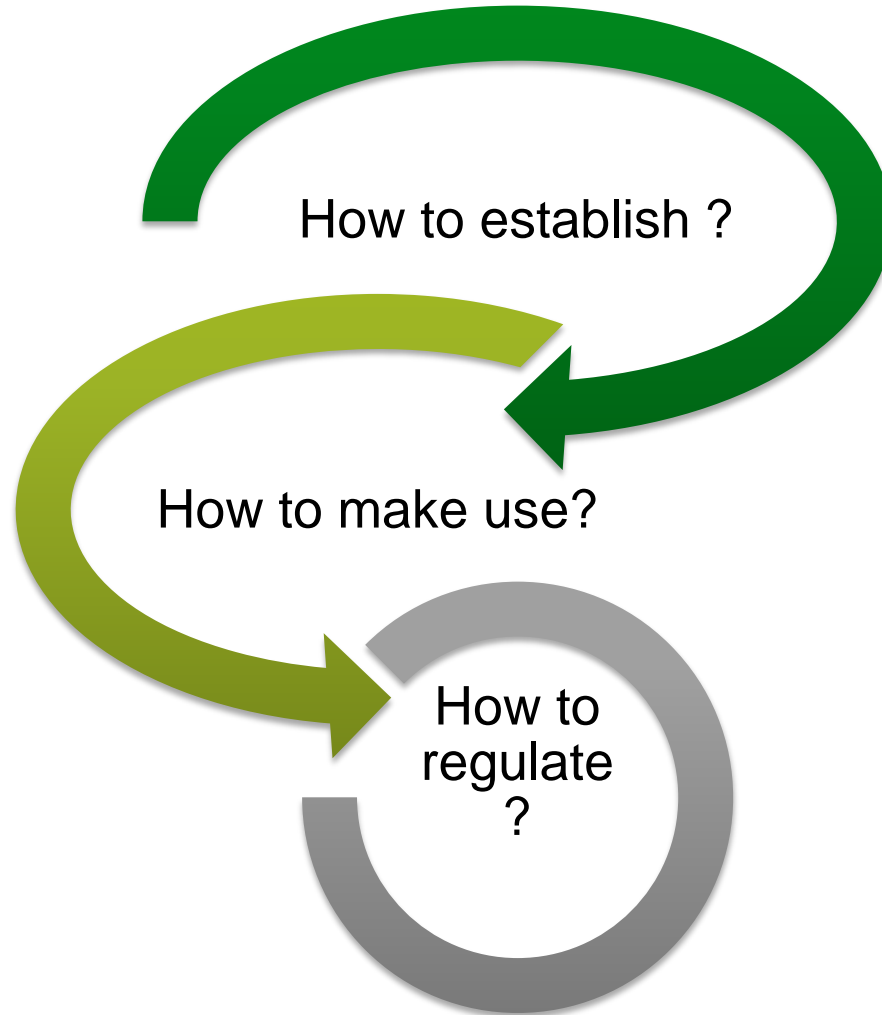
- Identification as substance of very high concern (SVHC) following the Article 57 (f) is a **case by case** decision
- If PMT criteria are agreed on within the member state competent authorities (MSCAs), the German MSCA intends to propose the **first PMT substances for candidate listing** as SVHC in 2018.
- Second regulatory instrument could be the restriction of critical uses under REACH

Discussion Starter III “How to regulate?”

- What are the **regulatory options** for PMT and vPvM substances?
- What is the **way forward** under the EU chemical legislation REACH?



Discussion starter



We are looking forward to day two

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<https://www.umweltbundesamt.de/mobile-chemikalien>