

Third PMT Workshop: Getting control of PMT and vPvM substances under REACH

A brief history of the PMT/vPvM criteria

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Welcome,
vitejte, welkom, tere tulemast, tervetuloa,
bienvenue, willkommen, kalos irthate, üdvözöljük,
fáilte, benvenuta, velkommen, witamy, bem-
vinda, bienvenidas, välkommen,
欢迎, ようこそ

Third PMT Workshop: world wide participation ...



Für Mensch & Umwelt



Umwelt
Bundesamt

Third PMT Workshop: Getting control of PMT and vPvM substances under REACH

The organizing committee



Michael



Jona



Ivo



Sarah



Hans Peter

10 year success of the PMT workshop series

- 2011 First PMT Workshop

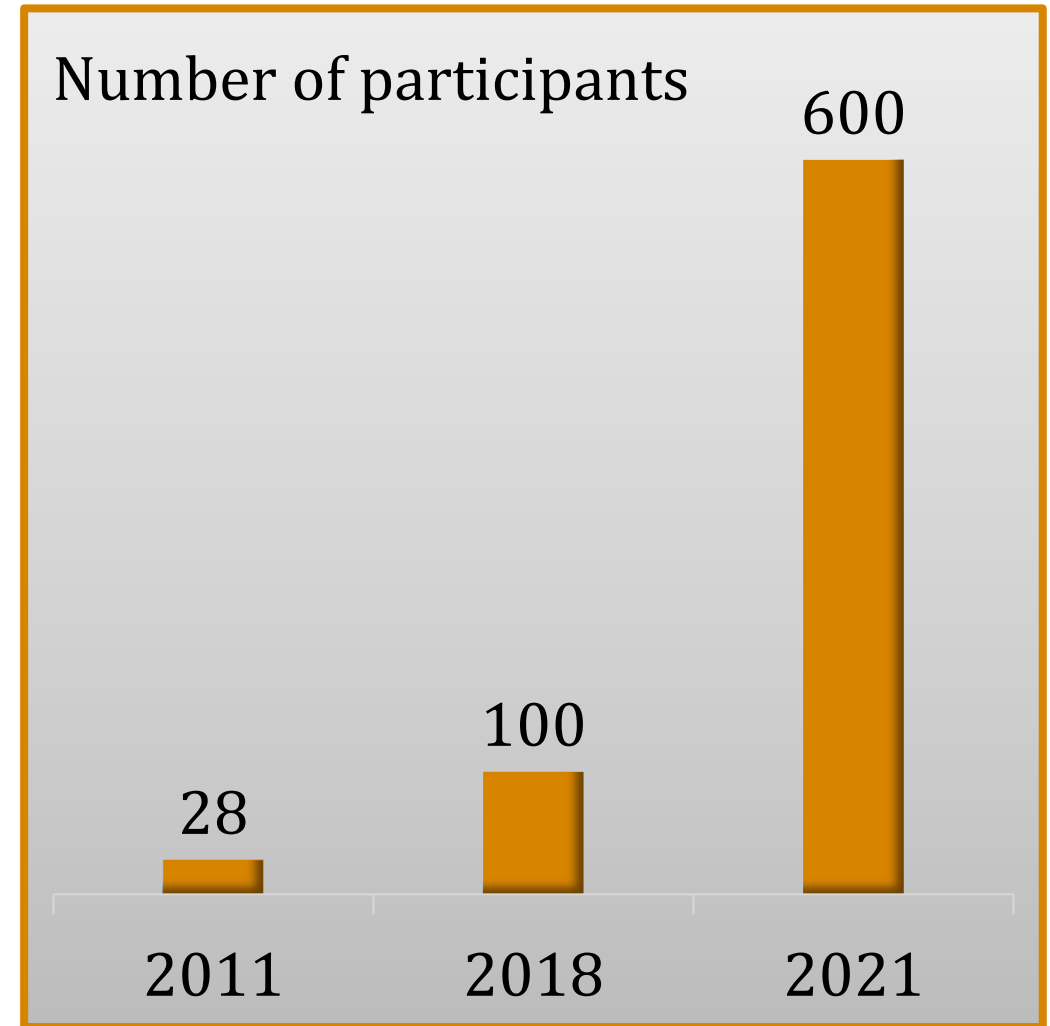
"Evaluation of the relevance of substances to raw water
in the context of the REACH regulation"

- 2018 Second PMT Workshop

"PMT and vPvM substances under REACH.
Voluntary measures and regulatory options
to protect the sources of drinking water"

- 2021 Third PMT Workshop

"Getting control of PMT and vPvM substances under REACH"



It all started 2009 with an idea ... and ... with a poster ...

- However, the idea of the PMT concept and the name “PMT” was first presented in
 - 2012 at the German SETAC GLB and
 - 2015 at the SETAC Europe
- From the beginning, the PMT concept was designed to be **hazard based**

M. Neumann et al.: A proposal for a chemical assessment concept for the protection of raw water resources under REACH

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 be 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

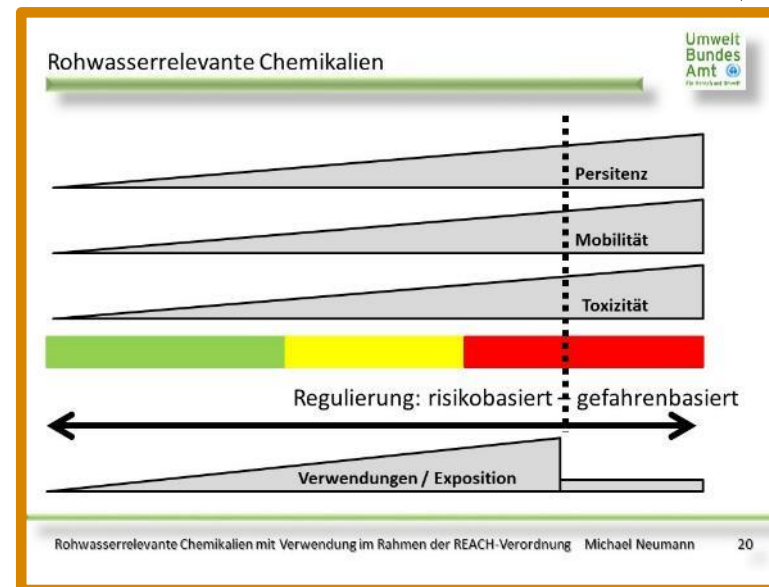
PPOP or polar POPs
polar persistent organic pollutant
(Giger et al., 2005)

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

05.05.2015 SETAC Europe 25th Annual Meeting 4



Originalbeiträge

Bewertung trinkwasserrelevanter Chemikalien im Rahmen der REACH-VO

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Zusammenfassung
Ziel von REACH ist, ein hohes Schutzniveau für Mensch und Umwelt durch das Vorsorgeprinzip bei der Verwendung von Chemikalien zu erreichen. Die Bewertung der Trinkwasserrelevanz von Chemikalien ist unter REACH jedoch nicht explizit geregelt. Durch ein Sachverständigengutachten werden jetzt Empfehlungen erarbeitet. Wesentliche Ziele sind es, den Expositionspfad „man via the environment“ bzgl. Trinkwassers im Sinne der REACH-VO zu definieren und die daraus resultierenden Konsequenzen und Verpflichtungen für Industrie und Behörden zusammen zu stellen. Es sollen Screening-Kriterien erarbeitet werden, anhand derer die Behörden trinkwasserrelevante Chemikalien aus dem Pool der Registrierungsdossiers identifizieren können. Für das Vorsorgeprinzip ist es wichtig, potentiell trinkwasserrelevante Chemikalien schon frühzeitig zu identifizieren, um einen Eintrag ins Trinkwasser zu vermeiden.

arbeitsintensive Aufgabe darstellen. Die Behörden werden sich dabei auf die Identifizierung regulierungsbedürftiger Stoffe, z. B. von besonders besorgniserregenden Stoffen, konzentrieren und dadurch Vorschläge für die Regulierung durch Kandidatenlisten, für die Zuweisung einer Zulassungspflicht oder für Beschränkungen erarbeiten.

Der Schutz der menschlichen Gesundheit stellt für Hersteller, Importeure und Verwender auch unter REACH eine hohe Verantwortung dar. Wie in der Abb. 1 dargestellt, muss für registrierungspflichtige Stoffe über 10 t/a, eine Expositionsbeurteilung erstellt werden. Erst für Stoffe ab 1000 t/a und für Stoffe mit kritischen Stoffeigenschaften ab 100 t/a muss bei der Bewertung des Risikos einer Verwendung auch die indirekte Belastung des Menschen über eine Kontamination der Umwelt (man via the environment) berücksichtigt werden. Dabei stellt die Kontamination des Trinkwassers durch Chemikalien ein besonders zu beachtender indirekter Expositionspfad dar.

Einleitung
Die europäische Verordnung REACH (registration, evaluation, restriction and authorization of chemicals) hat zum Ziel, ein hohes Schutzniveau für Mensch und Umwelt durch das Vorsorgeprinzip bei der Verwendung von Chemikalien zu erreichen. Durch das Schaffen einer vergleichbaren Informationsbasis für alle Chemikalien – basierend auf harmonisierten Methoden und Verfahren – sollen innovative und risikoarme Chemikalien und Verwendungen gefördert werden. REACH führt neue regulatorische Instrumente ein und etabliert eine Neuverteilung der Aufgaben und Verantwortung zwischen Behörden und Unternehmen.

Hersteller und Importeure müssen in den nächsten Jahren ihre Stoffe registrieren (ab einer Menge von > 1 t/a, no data -> no market) und dabei das Risiko für Mensch und Umwelt in einem Stoffsicherheitsbericht (> 10 t/a) bewerten. Dabei ist der gesamte Lebenszyklus zu berücksichtigen. Die Unternehmen garantieren die sichere Verwendung und die angemessene Kontrolle der Risiken und sind verantwortlich für die Einstufung und Kennzeichnung der Chemikalien. Informationen werden innerhalb der Lieferkette u. a. durch ein Sicherheitsdatenblatt weitergegeben.

Die ECHA (European Chemical Agency) und die Behörden haben vor allem beratende und koordinierende Aufgaben. Sie unterstützen die Ausschüsse (Risk Assessment Committee [RAC], Socio-Economic Analysis Committee [SEAC], etc.) und entwickeln Leitfäden, Tools und Methoden. Zukünftig wird auch die Dossierbewertung und die Stoffbewertung eine

Rechtliche Vorgaben unter REACH
Art. 14 REACH-VO: Daten für langfristige Expositionen (regulierungsbedürftige Stoffe > 10 t/a)
Stoffcharakterisierung + Stoffcharakterisierung
Gefahr! Stoffgem. RL 67/450/EG bzw. PBT/vPvB
↓
Verteilende Expositionsbeurteilung inkl. Expositionsannahmen (ES) - basierend auf Abschätzung
↓
Risikoermittlung für den CTD
Bewertung der indirekten Exposition (man via the environment)
Registrierung muss sichere Verwendung des Stoffes über gesamten Lebenszyklus nachweisen
Expositionen für alle spezifischen Verwendungen werden dem BfR und anderen Risikomanagementbehörden (BfM) abgeleitet
Unterstützung bei der Bewertung der Belastung des Menschen über die Umwelt (man via the environment)

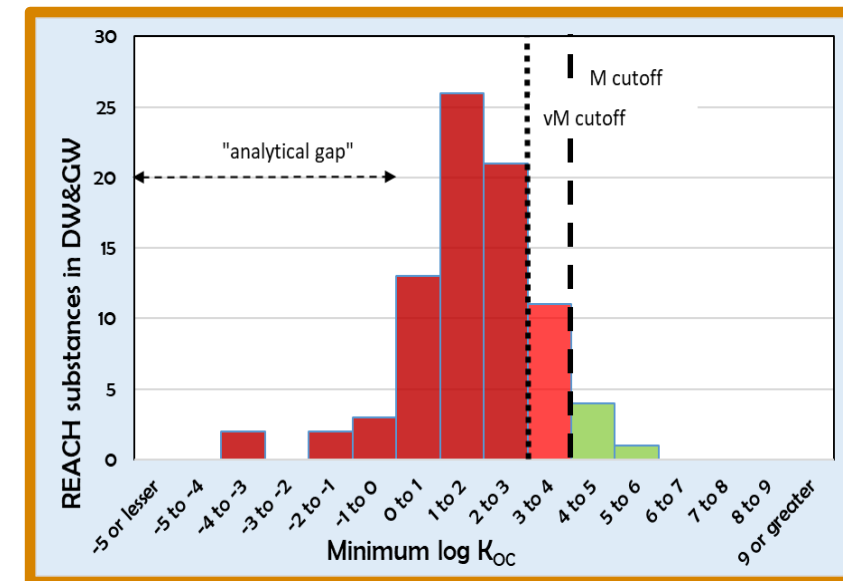
Abb. 1 Rechtliche Vorgaben der REACH-Verordnung

Mitt Umweltchem Ökotox 82 15. Jahrg. 2009/ Nr. 2

... and ended 2019 with the finalised PMT/vPvM criteria

- The PMT/vPvM criteria presented in 2019 to CARACAL-30 are scientifically well justified by monitoring data, simulation models, impact assessment and regulatory justification
- Since 2009 the process was communicated openly and transparently with over 40 scientific talks, poster and publications
- Three year scientific discussions at several workshops and three public consultations involved over 100 scientists and institutions and we received 66 written comments

Source: Arp et al. 2019



Product Stewardship and Risk Governance for PMT/vPvM substances

- From the beginning, consultation with industry was important. Already in 2017 we presented the idea for the PMT/vPvM criteria to 150 representatives from IND and DU
- An impact assessment was always part of our considerations. The finalised PMT/vPvM criteria are a ready-to-us-tool for IND and DU to identify critical substances
- We want to support industry with their challenges for developing sustainable products and with their aim to minimise emissions of PMT/vPvM substances into the environment
- Safe alternatives to hazardous chemicals and Sustainability by Design is a tremendous opportunity for designing the new chemistries of tomorrow

Day 1

Anna Lennquist from ChemSec

Day 2

Marie Collard from CEFIC

Sascha Pawlowski from BASF & Thomas Kullick from VCI

Ninja Reineke from CHEM Trust

Xenia Trier from the European Environment Agency (EEA)



Source: Elisseeva / Thinkstock

Drinking water suppliers are raising concerns about PMT/vPvM substances

- PMT/vPvM substances pose a great risk to drinking water sources and water suppliers call for ambitious regulatory measures to restrict their use under REACH
- We see raising numbers and amounts of REACH-registered chemicals detected in ground and drinking water
- Placing the burden of removing persistent and mobile substances from drinking water resources on water suppliers is an unsustainable use of chemicals
- Mobility combined with Persistency means these chemicals do not adsorb to activated carbon (AC) filtration and are resistant to degradation
- Reverse osmosis would for the average household in Europe per year add €200 to the water bill. (EurEau)

Day 1

Gabriel Sigmund from the University of Vienna

Martin de Jonge from Vitens

Juliane Hollender from EAWAG

Luisa Rabe & Pia Schumann from UBA

Claudia Castell-Exner from EurEau

Day 2

Roberta Hofman-Caris from KWR

333 substances detected
in ground and/or drinking water



Source: Arp et al. 2019

PMT/vPvM substances registered under REACH

- 2019 UBA published a list of 119 PMT/vPvM substances for further investigation related to the need for introducing risk management measures
- End of 2021 UBA will publish an update of this list to further support: Getting control of PMT and vPvM substances under REACH

Day 1

Ivo Schliebner from UBA

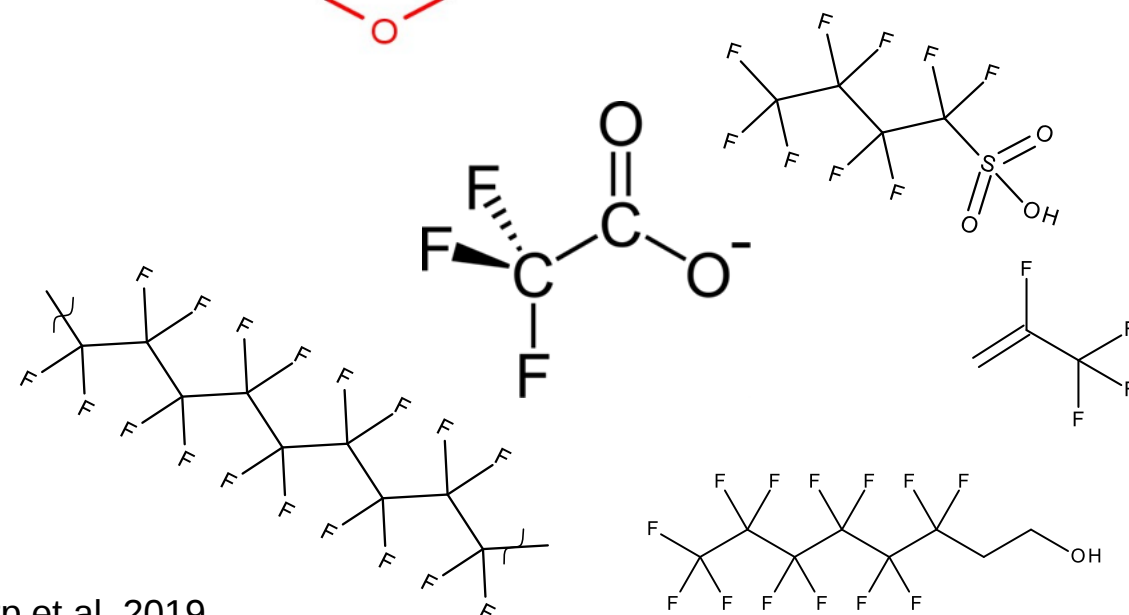
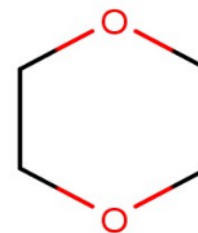
Karsten Nödler from TZW

Frauke Averbek from the DE CA

Day 2

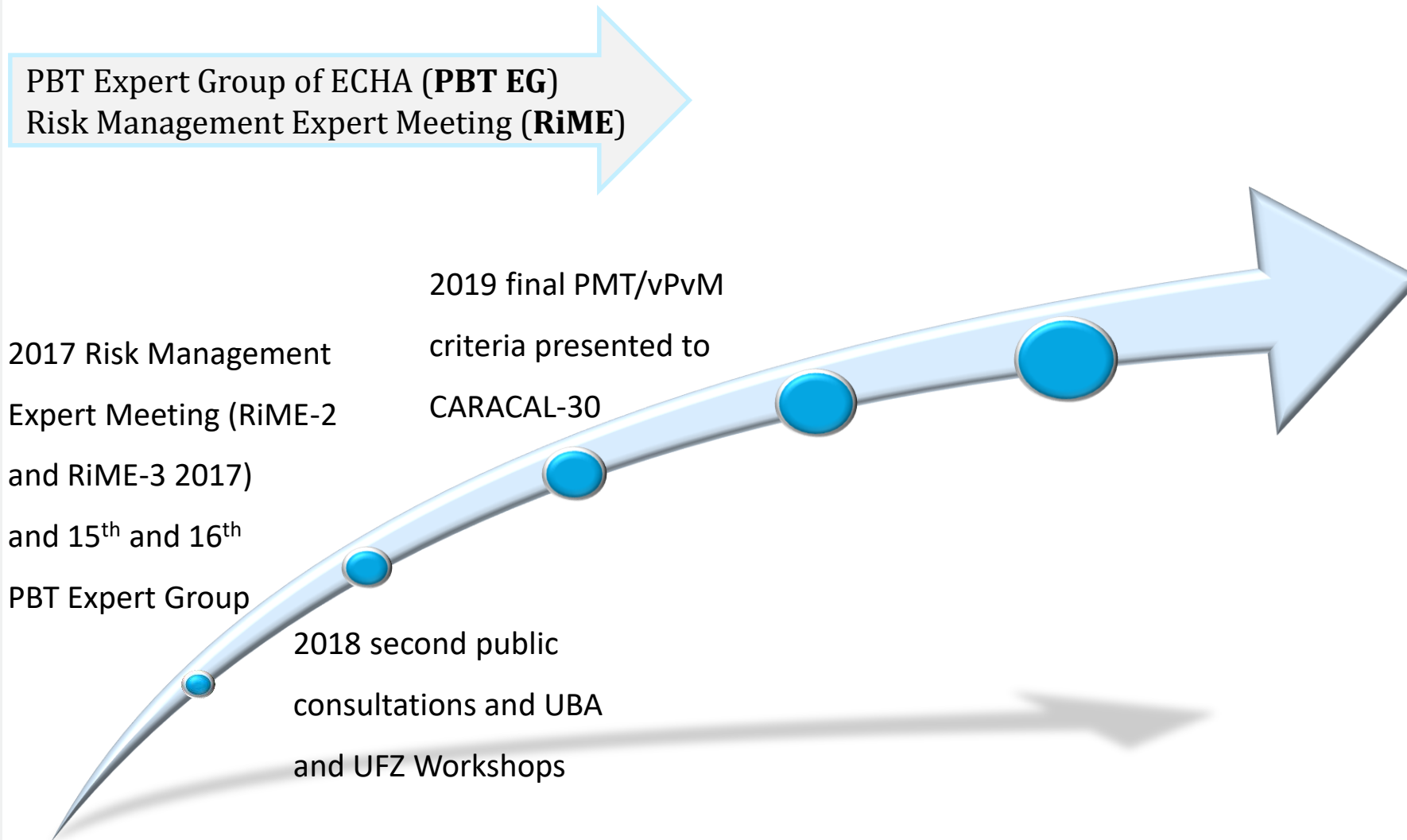
Julia Hartmann from RIVM

CAS	Name	tonnage per annum	P	P rationale	M	M rationale	T	T rationale	detected in GW or DW
108-78-1	melamine	100000 - 1000000	vP	All biodegradation results in 301C and 302B tests imply no significant biodegradation. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Dow/Kow = -2.3 (ionizable compd.)	T	Carc_2 STOTRE_2	DW
123-91-1	1,4-dioxane	1000+	P	No significant biodegradation in 301F test. The PBT assessment evaluates the substance to be persistent. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = -0.5 (neutral compd.)	T	Carc_2 STOTRE_1 STOTRE_2	DW
288-88-0	1,2,4-triazole	1000 - 10000	P	All biodegradation results in 301A and 302B tests imply no significant biodegradation. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = 1.6 (ionizable compd.)	T	Rep_2	DW
80-08-0	Dapsone	100 - 1000	vP	No significant biodegradation in 301D tests. The PBT assessment evaluates the substance to be persistent. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = 1.8 (neutral compd.)	T	STOTRE_1 STOTRE_2 Suspected ED	DW
127-18-4	Tetrachloroethene	100000 - 1000000	vP	No significant biodegradation in 301 C tests. The PBT assessment evaluates the substance to be persistent. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = 2.2 (neutral compd.)	T	Carc_1b Carc_2 Rep_2 STOTRE_2 Suspected ED	DW
330-54-1	Diuron	100 - 1000	vP	measured half-life = 2 241 d (soil)	vM	exp. min. log Doc/Koc = 2.1 (neutral compd.)	T	ecotox Carc_2 STOTRE_2 Suspected ED	DW&G W
56773-42-3	PFOS	0 - 10	vP	on SVHC list - vPvB substance	vM	exp. min. log Doc/Koc = 0.0 (single anion compd.)	T	SVHC	DW&G W
62037-80-3	GenX	10 - 100	vP	All biodegradation results in 301B and 302C imply no significant biodegradation. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = -5.1 (single anion compd.)	T	STOTRE_2	DW
127-18-4	Perchloroethene	100000 - 1000000	vP	No significant biodegradation in 301 C tests. The PBT assessment evaluates the substance to be persistent. Therefore this substance is assessed to be persistent in water. (Berger et al. 2018)	vM	exp. min. log Doc/Koc = 2.2 (neutral compd.)	T	Carc_1b Carc_2 Rep_2 STOTRE_2 Suspected ED	GW

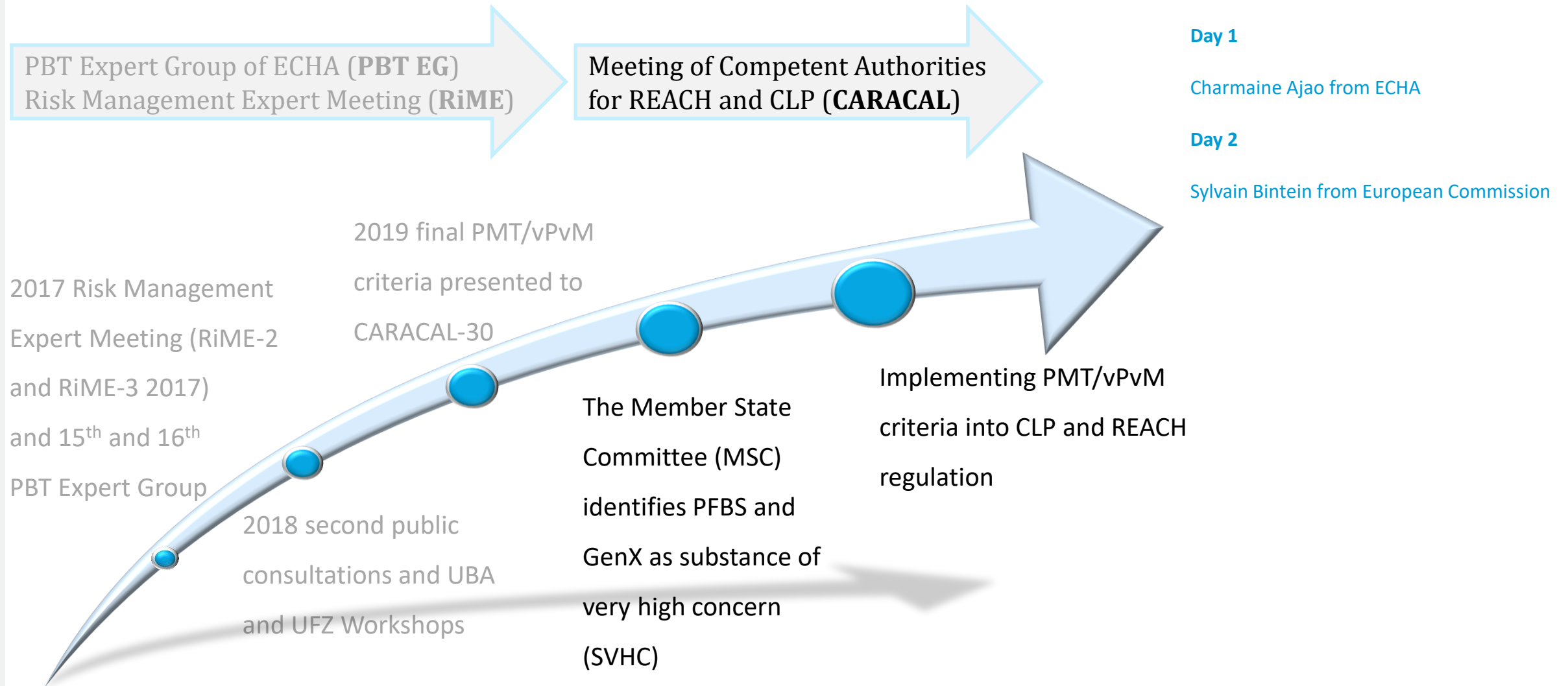


Source: Arp et al. 2019

2017 to now: From scientific discussion of the PMT/vPvM criteria to ...



2017 to now: ... to policy level discussion on the PMT/vPvM criteria



Closing the gaps for PMT/vPvM substances ...

- In the last years, many gaps for PMT/vPvM substances were discussed and identified
- Most prominent gaps are the "analytical gap" and the "monitoring gap"
- Both gaps may lead to a "regulatory gap"
- In this workshop we will also observe and discuss the status of gaps and how to close them

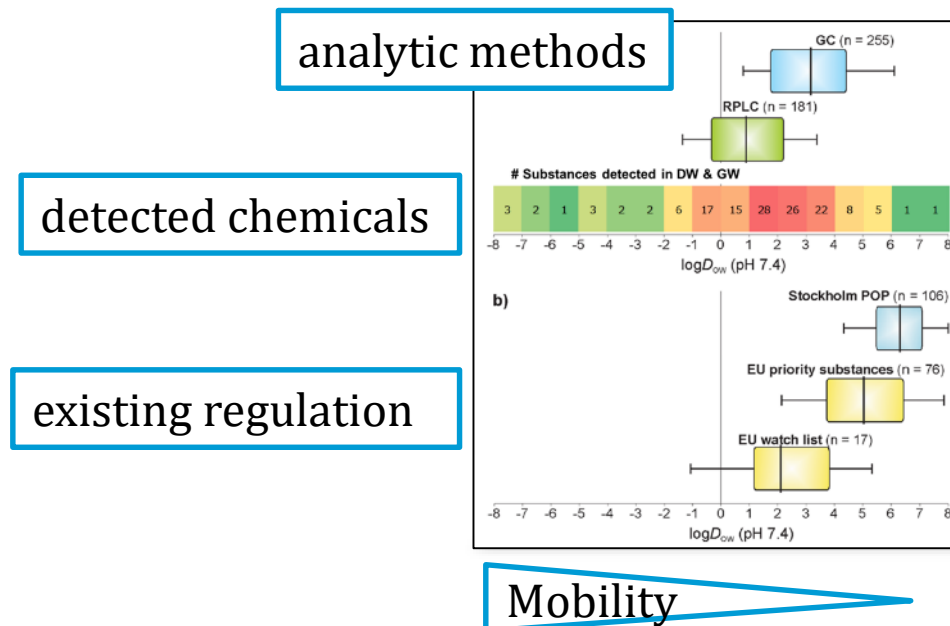
Day 1

Thomas Letzel from the Technical University of Munich and AFIN-TS GmbH

Day 2

Harrie Timmer from Vewin

Hans Peter H. Arp from NGI



Source:
Reemtsma et al. 2016

Let's have a poll ... what is your view? What is the current status of the following gaps?

Which are the **three** most concerning gaps from your personal point of view?

- Substance Assessment
 - Availability of persistency data
 - Availability of mobility data
 - Availability of toxicity data
 - Availability of analytical methods
 - Availability of monitoring data
- Risk Governance
 - Missing knowledge about transformation products and mixture composition
 - Missing risk assessment tools/models
 - Missing water remediation infrastructure
 - Missing chemical legislation
 - Missing safe and sustainable substitutes

The poll starts now and runs for 40 minutes

You find the poll in the lower right corner behind the three dots

Take your time and click the **three** most concerning gaps

press "send" to submit

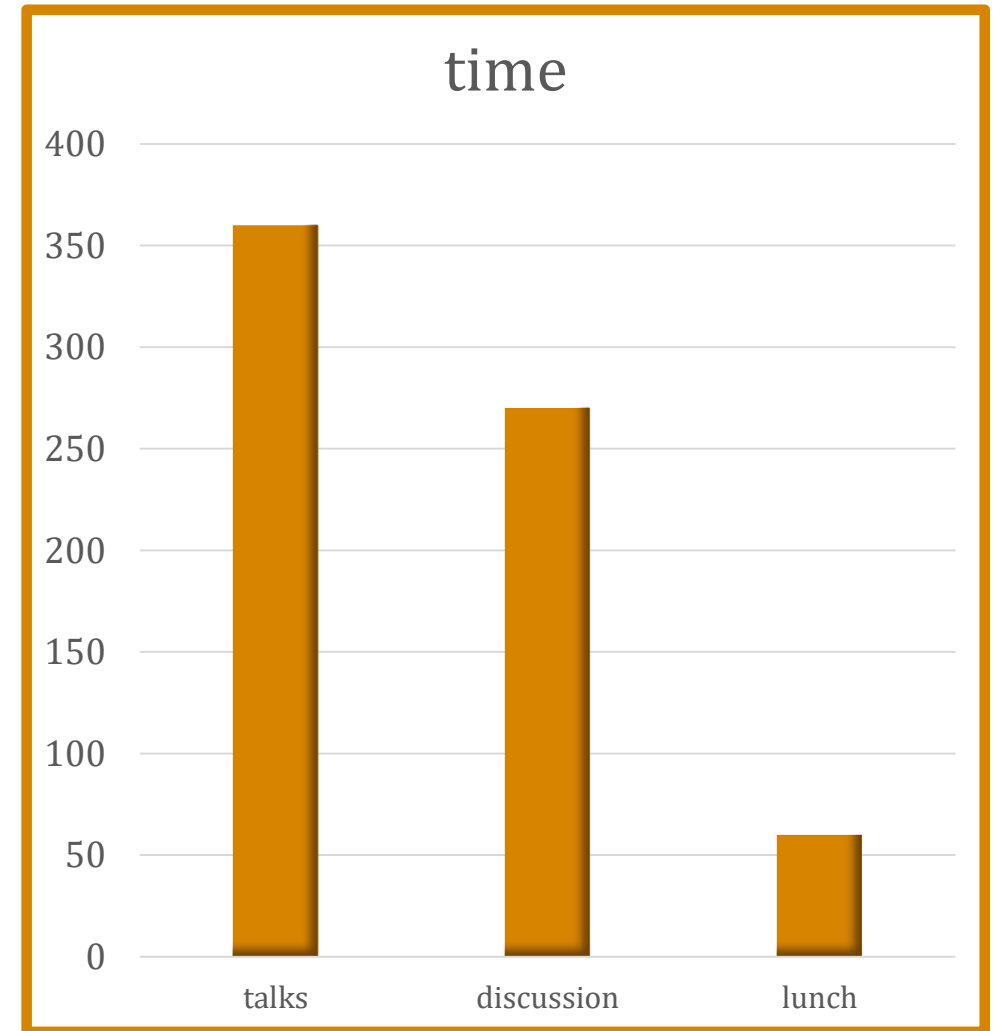
Conclusion

- The PMT and vPvM criteria are well justified by monitoring data, by regulatory justification and have been developed involving over 100 scientist and institutions in Europe
- In the last years we switched from the scientific discussion of the PMT/vPvM criteria to the policy level discussion on the PMT/vPvM criteria
- From REACH perspective the implementation of the PMT/vPvM criteria into CLP and into REACH regulation is an essential step to the protection of Europe's drinking water resources
- The German Environment Agency will continue to propose PMT/vPvM substances for the identification as substance of very high concern (SVHC) under REACH



Please be active ...

- We do have time for questions and discussions...
- If you would like to ask a question please **raise your hand**.
 - Turn on your camera and microphone when you are speaking
 - Afterwards please lower your hand and turn off microphone
- If you would like to make a comment please use the chat
- If you would like to clap your hand please use the “reaction” button



Thank you for your attention

Michael Neumann

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Dessau-Rosslau

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<https://www.umweltbundesamt.de/en/PMT-substances>

