

ZeroPM Workshop: Achieving Zero Pollution of Persistent and Mobile Substances: Prevention through Chemical Alternatives, Policy Action and Market Transition

Regulatory Options for PMT/vPvM substances in the REACH registration database

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PMT/vPvM assessment of all substances in the REACH registration database

- UBA since 2009 worked on the scientific justification and regulatory implementation of the PMT/vPvM criteria
 - => 2012 the term "PMT" was first presented at German SETAC in Leipzig
- The new CLP hazard classes PMT and vPvM have a lower mobility criterion and therefore are less stringed than the original proposal by UBA from 2019
 - => From all P/vP substances ca. 24 % less are identified as PMT/vPvM substances

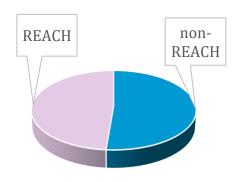
- 22400 substances are in the REACH registration database
 and for 13405 unique chemical structures a PMT/vPvM assessment was performed
 - => 41 % have insufficient data for a PMT/vPvM assessment
 - => only 260 or only 1.9 % are PMT/vPvM substance (CLP criteria)



[1] Neumann (2012), [7] Neumann & Schliebner (2019) [2] Arp & Hale (2023)

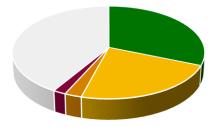
Literature Review of 55 water monitoring studies between 2000 and 2019

- 639 chemicals have been detected in drinking water relevant media (bank filtration, groundwater, raw water, drinking water)
 - => 49 % are REACH registered



639 chemicals detected in drinking water relevant media

13405 chemicals



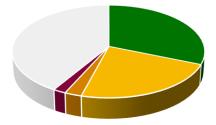
only 1.9 % of the unique chemical structure in the REACH registration database fulfil the CLP criteria for PMT and/or vPvM

[2] Arp & Hale (2023), [3] Arp, Hale & Neumann (2023)

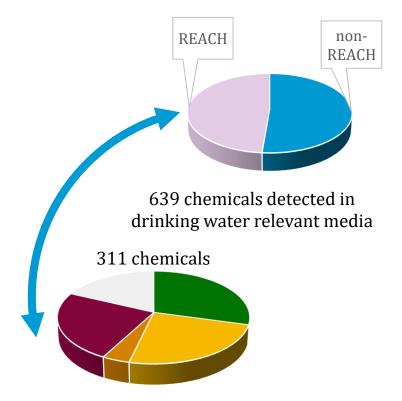
Literature Review of 55 water monitoring studies between 2000 and 2019

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 - => 49 % are REACH registered
- 311 REACH registered chemicals have been detected in drinking water relevant media
 - => 18 % have insufficient data for a PMT/vPvM assessment
 - => over 24 % are PMT/vPvM substance (CLP criteria)

13405 chemicals



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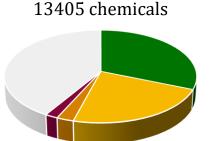


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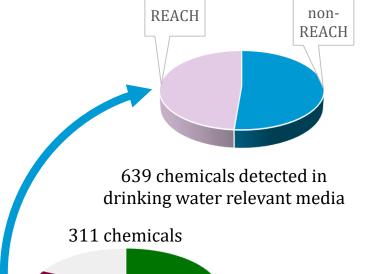
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only 1.9 % of the unique chemical structure in the REACH registration database fulfil the CLP criteria for PMT and/or vPvM

=> 12.7 times higher Likelihood

of a PMT/vPvM substance in the REACH registration database to be detected in drinking water relevant media



over 24 % of the detected chemicals in drinking water relevant media which are REACH registered substances fulfil the CLP criteria for PMT and/or vPvM

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REACH registration database: Likelihood of a PMT/vPvM substance to be detected

- 70.3 % of the detected REACH registered substance should be further evaluated and handled with scrutiny
- 46.2 % of the detected REACH registered substance need P, M and/or T assessment
- Every third PMT/vPvM substance in the REACH reg. database has already been detected
- For Not PMT/vPvM substances the Likelihood to be detected is reduced to 0.9

PMT and/or vPvM	2.6 % vs 1.9 %	29.6 % vs 24.1 %	11.4 vs 12.7
PM (incl. PvM and vPM)	3.1 % vs 2.6 %	3.9 % vs 4.2 %	1.3 vs 1.6
Potential PMT/vPvM	26 % vs 23 %	26 % vs 24 %	1.0 vs 1.0
Not PMT/vPvM	27 % vs 31 %	23 % vs 29 %	0.9 vs 0.9
PMT/vPvM criteria	UBA vs CLP	UBA vs CLP	Likelihood UBA vs CLP
Insufficient data	41 %	18 %	
	13405	311	
red substance	assessable	49% REACH registered	
led with scrutiny	REACH registration database	only DW relevant media (BF, GW, RW, DW)	

22400

[2] Arp & Hale (2023), [3] Arp, Hale & Neumann (2023)

639 detected

PMT/vPvM substances pose an Equivalent Level of Concern to PBT/vPvB substances

- Survey of water labs throughout Germany: of 150 PMT/vPvM substance (UBA criteria)
 17% have an <u>analytical gap</u> and additional 58% have a <u>monitoring gap</u>
- The <u>remediation gap</u> was confirmed for 52% of 150 PMT/vPvM substances (UBA criteria), additional 15% only ozonation and additional 21% only activated carbon
- PMT/vPvM substances are <u>substances of very high concern (SVHC)</u> caused by serious effects on human health (4 categories) and on the environment (9 categories) and other effects (3 categories)
- => a safe level of exposure that would be protective cannot be determined and any emissions into the aquatic environment over the whole lifecycle must be minimised

[7] Neumann & Schliebner 2019, [5] Arp et al. (2023), [6] Hale et al. (2020)

The UBA list of PMT/vPvM substances in the REACH registration database

- The UBA list is fit for purpose and ready to use
 - Manufacturers, importers and downstream users
 can immediately act to minimise emissions throughout the whole life cycle with appropriate risk mitigation measures (RMM) and start preparing self-classification under CLP
 - Local authorities at the watershed scale and drinking water producers
 can monitor the substances and can identify emitters within their jurisdiction and
 can oblige the plant operator to derive conditions for safe use and minimise emissions
 - Member State Competent Authorities (MS CAs), ECHA and the European Commission (EC)
 can identify SVHCs under article 57 (f) of REACH and
 start preparing harmonized classification under CLP
- NGOs

 can inform their members and can encourage changes that lead to lower use, lower
 environmental emissions and the use of less hazardous alternatives
- => 344 prioritised PMT/vPvM substances (UBA criteria); only 260 (CLP criteria)

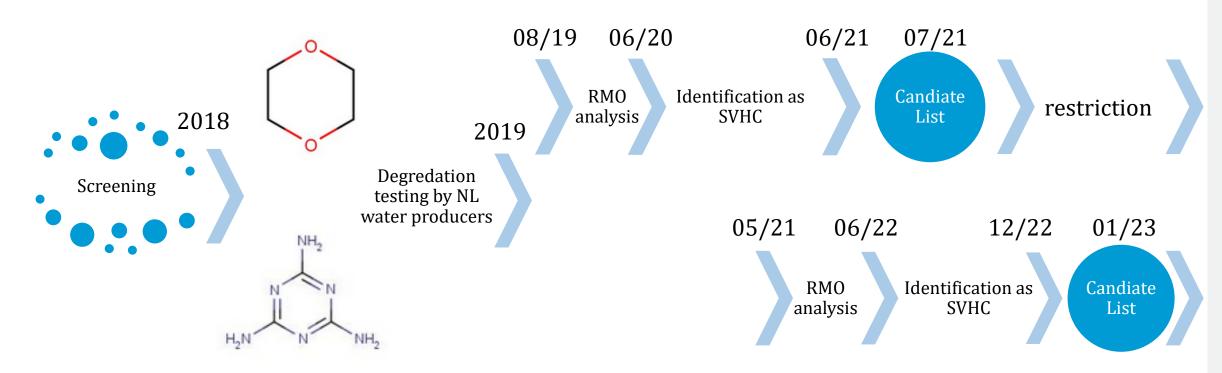
First update since 2019:

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EC-No.H	Full Name II	Other #EACH + substances &- precursorsit	_	ac aura	1 -	M+* Rationales	Te ² Rationales		Detections* (ref-index)s
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203-444- Se	1,2-dibromoethanes	THE STATE OF THE S	UPANE- PMTs	PMTs	Posential PJ vP++; wf estimated 11/2-(error factor 50) = 30d, weight- of-evide non-by-discovery in monitoring statisti- (SBA, 2019), and consistent indications of P- across tested-QSARsa	UBAUVMer EC:VMer exp log Koc=0.1	(CarcTab) (SNInt: Classified CMR- according to Assex- Vi of Regulation 1272/2008) (Pro.S.P(D)s	wery high	WW:-=* SW:-=* SW:-+* GW:max 500 ng/L (G06)=* SW:-+*
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204-661- 8x	1,4-dioxanex			under- PMTs	אפיליי Ne degradation in g-0000-TG 309 (Hofman Carin and Claden, 2029), calculated half-life LL- discase: >10,000 days. No significant biodegradation in 301F test.ii	UBA:vMer EC:vMer min Down G.4- (2a)s	(Carc2)s	weryttigfu	WW
204-337- 6s	Bezophenonell	76	VPMAN SE PMAN	PMT- (uh-Wod, M-BT)s	screening tests are wide upnead. There is nove- discussion on this from WAC WHO. (https://www.graphs.lam.who.lam/wp- costext/uploads/2018/06/mons.001.007.pdf). From this study, estimated 41/2 (error factor 00).	EC:Me/	have been reported, it is- potentially- persistent and has-	werphight	WW** Sit
301-152- 2m	1,2-dichloropropanet	(p)301-152-3; (p)904-304-21	PMIN.	unus di PATE	Potential P/uP++;=+ P-data-for-this-substance is variable and difficult to-conclude; however, its identification in-	EC:yMe/	(Carclab) (SNInt- Classified CMR- according to Annex- Viof Regulation 1272/2008)#	werytigh	WW:-+' SW:-max 6-ng/L (505)=' DW:-max 6-710-ng/L (505)=' GW:-max 50-000-ng/L (506)=' #W:-max 670-ng/L (505)=' BE:-e
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[7] Neumann & Schliebner 2019, [8] Arp & Hale 2019, [4] Arp, Hale, Schliebner & Neumann (2023)

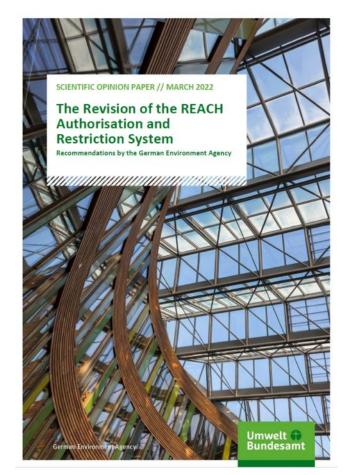
1,4 Dioxane (EC 204-661-8) and Melamine (EC 203-615-4)

- UBA was a pioneer in developing the ELoC of Article 57 (f) under REACH and in identifying PMT/vPvM substances as SVHC
- Standardised assessment procedures and harmonised criteria are needed to reduce work load,
 to speed up decisions and to increase reliability for the chemical industry



The Revision of the REACH Authorisation and Restriction System

- Under REACH the simplified procedure for identifying SVHC that have a harmonised classification should be extended to PBT, vPvB, PMT, vPvM and ED substances.
 - => separate letters for PMT, vPvM, and ED should be added to REACH Article 57
- The generic approach to risk management (GRA) currently applies to the restriction
 of 1A/1B CMR and should be extended to PBT, vPvB, PMT, vPvM and ED substances
 => should also be extended to professional and industrial uses
- Derogations from restrictions for PBT, vPvB, PMT, vPvM and ED substances should only permitted for strictly controlled conditions or when uses are <u>necessary</u> for health and safety or are critical for society and no alternatives are available



https://www.umweltbundesamt.de/en/publikationen/the-revision-of-the-reach-authorisation-restriction

ZeroPM identified 44 regulations and directives relevant for PMT/vPvM substances

- Self or harmonised classification of a substance under CLP has an impact on a wide range of regulatory measures
 - => a link to the new hazard classes must/should be implemented and established to prevent emissions
- Industrial Emissions Directive (IED)
 - use less hazardous substances and reduce releases of hazardous substances to the environment
- RoHS
 - Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- Food Contact Materials (FCM)
 - Regulation on material and articles intended to come into contact with food and repealing
- Waste Framework Directive
 - Directive on waste and repealing certain Directives
- POP Regulation
 - The Stockholm Convention on Persistent Organic Pollutants

ZeroPM identified 44 regulations and directives relevant for PMT/vPvM substances

- A large number of substances are present in the water cycle, consequently a substance-by-substance approach is not sufficient
 - => link to the new hazard classes PMT and vPvM must/should be implemented and established
- Water Framework Directive (WFD)
 - Priority (hazardous) substances
- Groundwater Directive
 - GW is less monitored than surface water
 - The Groundwater Watch List (GWWL) should be made mandatory
- Drinking Water Directive
 - The first watch list was adopted
- Marine Strategy Framework Directive (MSFD)
- => Monitoring data must/should lead to pollution prevention at source measures



Source: Elisseeva / Thinkstock

Voluntary Emission Reduction Measures Taken by IND

- European Chemical Industry should be the leadership on chemical safety
- A shift is needed towards a proactive approach of demonstrating safety and sustainability in pre-commercial innovation
- Self or harmonised classification of a substance as PMT or vPvM under CLP should trigger a wide range of voluntary measures
- Branch specific list of unwanted substances (e.g. textiles, automotives, ...)
- Accelerating chemical innovation and "Safe And Sustainable-By-Design"
- Eco-label
 - Regulation on the EU Eco-label
 - Blauer Engel by UBA (https://www.blauer-engel.de/)
- SIN List by ChemSec (https://sinlist.chemsec.org/)
- German Spurenstoffdialog (https://www.umweltbundesamt.de/das-spurenstoffzentrum-des-bundes)



Source: Neumann

Conclusion

- 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
- 17 % of PMT/vPvM substances have an analytic gap and 52% have a remediation gap
- The UBA list with PMT/vPvM substances is fit for purpose and ready to use by all stakeholders and UBA will support ECHA in developing guidance for an PMT/vPvM assessment under CLP
- UBA will continue to support IND in identifying PMT/vPvM substances in the REACH registration data base and to close data gaps and non-compliance
- 41 % REACH registered substances have insufficient data and
 25.2 % have only screening data for a PMT/vPvM classification
- UBA will support water producers to prioritise REACH registered substances for monitoring and for assessing contaminants with an OECD TG 309 degradation test



Neumann et al. "Regulatory Options for PMT/vPvM substances in the REACH registration database"

Literature

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- Acknowledgement: Environmental Research of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) Project No. (FKZ) 3719654080
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 - [3] Hans Peter H Arp, Sarah E Hale and Michael Neumann (2023). PMT/vPvM assessment of REACH registered Substances Detected in Wastewater treatment plants effluent, Freshwater Resources and Drinking Water, Texte | 20/2023, edited by Michael Neumann and Ivo Schliebner, IV 2.3 Chemicals, German Environment Agency (UBA), Dessau-Roßlau, Germany. ISBN: 1862-4804 xxx pages
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Abstract submission deadline 3rd March 2023

https://icce2023.com/

• 33rd **SETAC Europe** 30 April – 4 May 2023 in Dublin (Irland)

Session 3.22

"PMT/vPvM substances: Assessment, Management and Regulation" Late poster submission possible

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Thank you for your attention

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

