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Umwelt 
Bundesamt

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

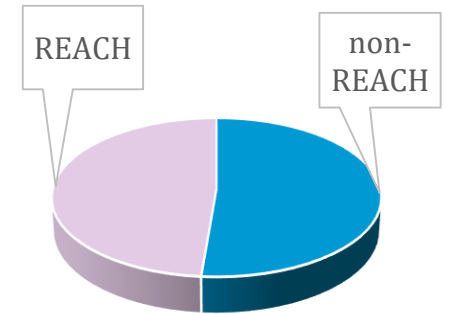
- UBA since 2009 worked on the scientific justification and regulatory implementation of the PMT/vPvM criteria
=> 2012 the term “PMT” was first presented at German SETAC in Leipzig
- The new CLP hazard classes PMT and vPvM have a lower mobility criterion and therefore are less stringed than the original 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)

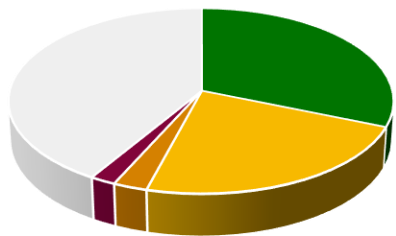
Literature Review of 55 water monitoring studies between 2000 and 2019

- 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

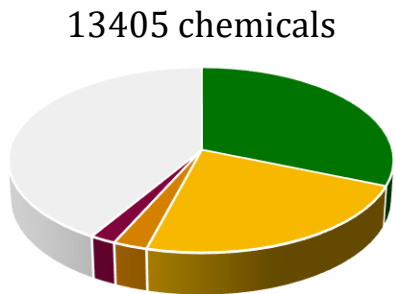


only 1.9 % of the unique chemical structure in the REACH registration database fulfil the CLP criteria for PMT and/or vPvM

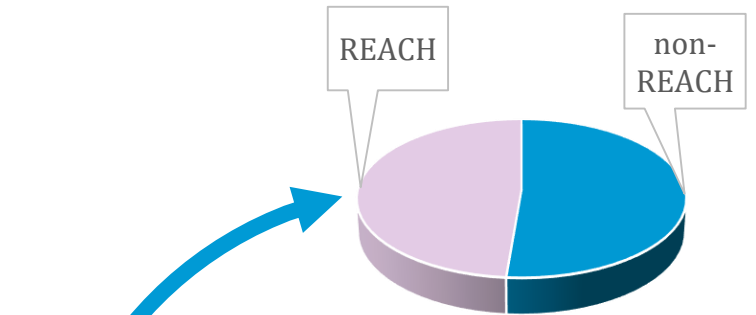
[2] Arp & Hale (2023), [3] Arp, Hale & Neumann (2023)

Literature Review of 55 water monitoring studies between 2000 and 2019

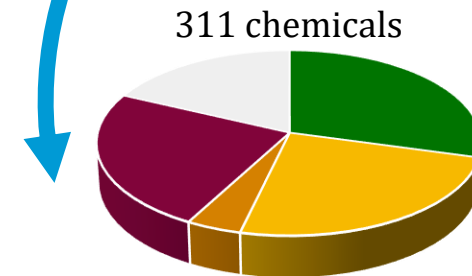
- 639 chemicals have been detected in drinking water relevant media (bank filtration, groundwater, raw water, drinking water)
=> **49 % are REACH registered**
- 311 REACH registered chemicals have been detected in drinking water relevant media
=> **18 % have insufficient data for a PMT/vPvM assessment**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



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



639 chemicals detected in drinking water relevant media

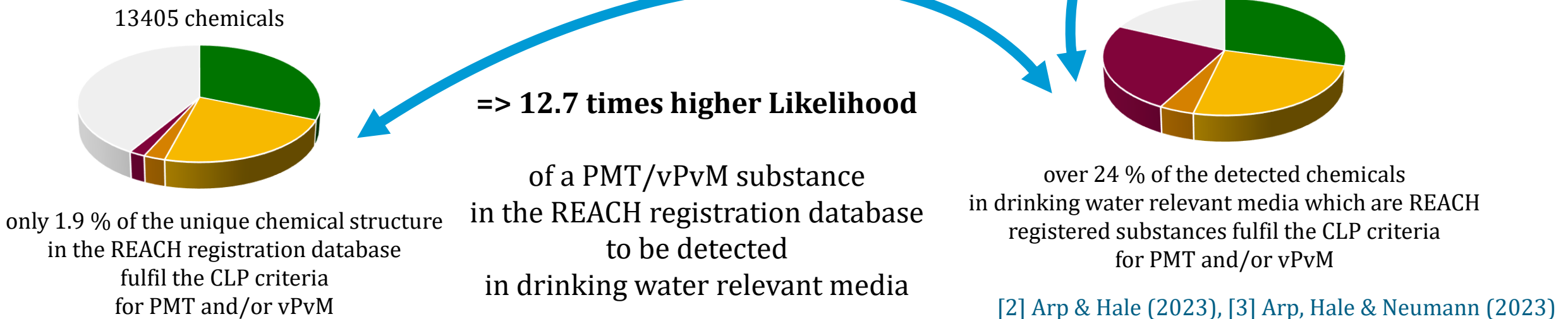


over 24 % of the detected chemicals in drinking water relevant media which are REACH registered substances fulfil the CLP criteria for PMT and/or vPvM

[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**
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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

	 22400 REACH registration database assessable 13405	 639 detected only DW relevant media (BF, GW, RW, DW) 49% REACH registered 311	
Insufficient data	41 %	18 %	
PMT/vPvM criteria	UBA vs CLP	UBA vs CLP	Likelihood UBA vs CLP
Not PMT/vPvM	27 % vs 31 %	23 % vs 29 %	0.9 vs 0.9
Potential PMT/vPvM	26 % vs 23 %	26 % vs 24 %	1.0 vs 1.0
PM (incl. PvM and vPM)	3.1 % vs 2.6 %	3.9 % vs 4.2 %	1.3 vs 1.6
PMT and/or vPvM	2.6 % vs 1.9 %	29.6 % vs 24.1 %	11.4 vs 12.7

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

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

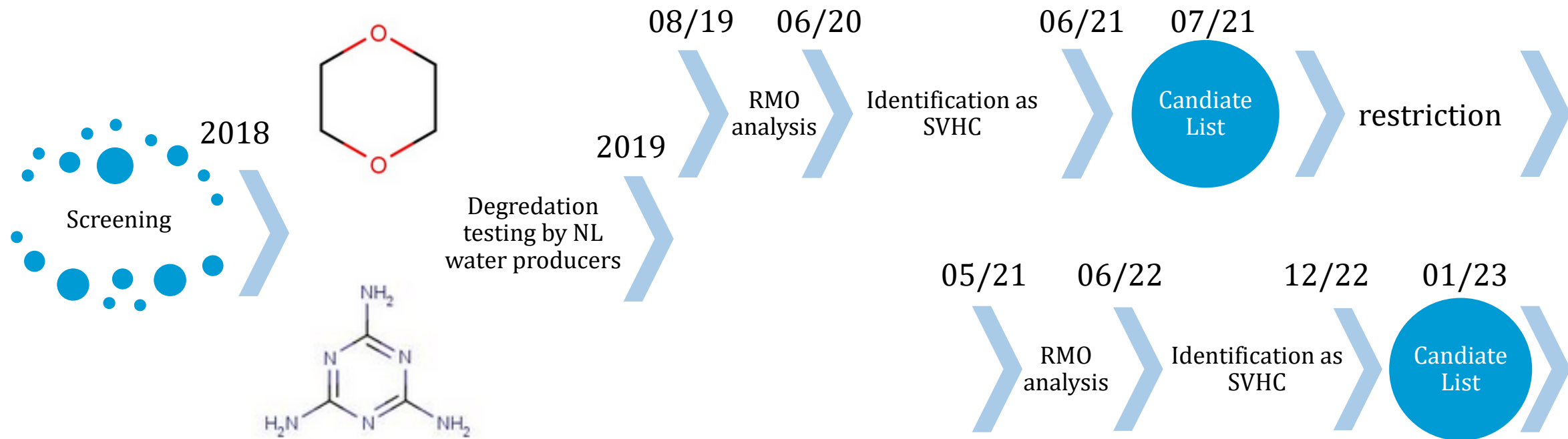
- Survey of water labs throughout Germany: of 150 PMT/vPvM substance (UBA criteria) 17% have an **analytical gap** and additional 58% have a **monitoring gap**
- The **remediation gap** was confirmed for 52% of 150 PMT/vPvM substances (UBA criteria), additional 15% only ozonation and additional 21% only activated carbon
- PMT/vPvM substances are **substances of very high concern (SVHC)** 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)

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

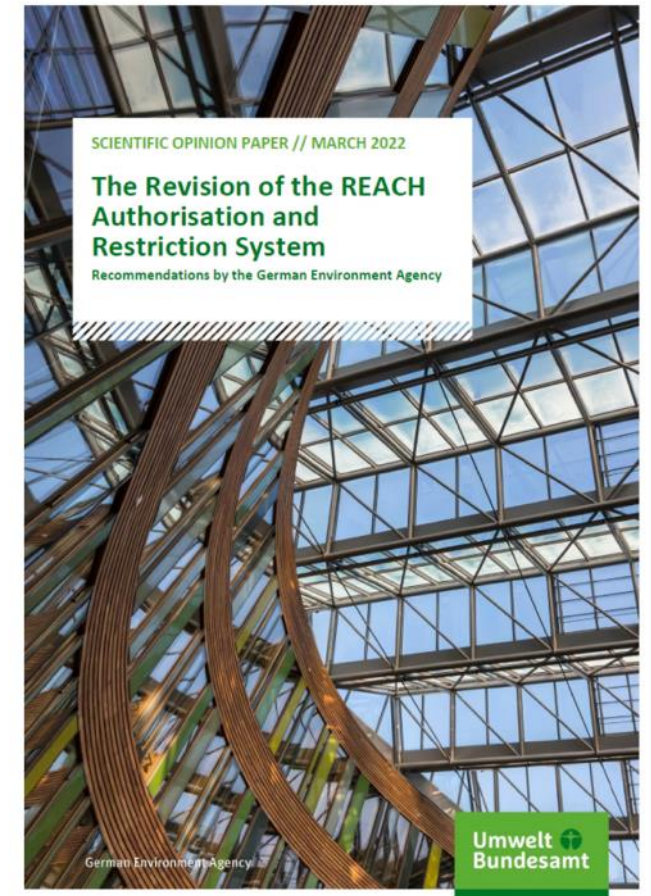
- UBA was a pioneer in developing the ELoC of Article 57 (f) under REACH and in identifying PMT/vPvM substances as SVHC
- Standardised assessment procedures and harmonised criteria are needed to reduce work load, to speed up decisions and to increase reliability for the chemical industry



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 be permitted for strictly controlled conditions or when uses are **necessary** 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

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



Literature

- [1] Michael Neumann (2012) Rohwasserrelevante Chemikalien mit Verwendung im Rahmen der REACH-Verordnung. Vortrag auf der Gemeinsame Jahrestagung von SETAC-GLB und der Fachgruppe „Umweltchemie und Ökotoxikologie“ der GDCh: „Erkennen, Untersuchen, Modellieren – Vom Nutzen des Verstehens“, 10. – 13. September 2012 in Leipzig
- Acknowledgement: Environmental Research of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) Project No. (FKZ) 3719654080
- [2] Hans Peter H Arp and Sarah E Hale (2023). REACH: Guidance and Methods for the Identification and Assessment of PMT/vPvM Substances: 2'nd Edition, Texte | 19/2023, edited by Michael Neumann and Ivo Schliebner, IV 2.3 Chemicals, German Environment Agency (UBA), Dessau-Roßlau, Germany. ISBN: 1862-4804 xxx pages
- [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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- [5] Hans Peter H Arp; Sarah E Hale; Ulrich Borchers, Vassil Valkov, Laura Wiegand; Daniel Zahn, Isabelle Neuwald; Karsten Nödler, Marco Scheurer (2023). PMT/vPvM Substances under REACH: Prioritization approaches for registrants, regulators, researchers and the water sector Final report, Texte | 22/2023, edited by Michael Neumann and Ivo Schliebner, IV 2.3 Chemicals, German Environment Agency (UBA), Dessau-Roßlau, Germany. ISBN: 1862-4804 xxx pages
- [6] Sarah E Hale, Hans Peter H. Arp, Ivo Schliebner and Michael Neumann (2020). Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH. Environmental Sciences Europe, 32(1), 1-15. <https://doi.org/10.1186/s12302-020-00440-4>
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- [8] Hans Peter H Arp and Sarah E Hale (2019). REACH: Improvement of guidance and methods for the identification and assessment of PMT/vPvM substances, Texte | 126/2019, German Environment Agency (UBA), Dessau-Roßlau, Germany. ISBN: 131 pages

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“PMT/vPvM substances: Occurrence, Assessment, Management and Regulation”

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- **33rd SETAC Europe** 30 April – 4 May 2023 in Dublin (Ireland)

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“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>

