

# Regulatory Perspectives on Mobility

**Hans Peter H. Arp & Michael Neumann**

1 NGI Oslo, NTNU Trondheim

2 German Environment Agency (UBA)

Contact: [hpa@ngi.no](mailto:hpa@ngi.no)



ECO54

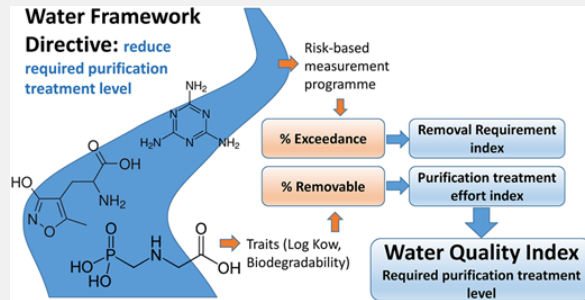
1st Stakeholder workshop on mobility concerns for  
chemical substances

# Agenda

- Need for a regulatory PMT/vPvM classification
- Recent history of the development of the PMT/vPvM criteria under REACH
- Thought starters for this workshop

# The need for hazard based criteria

- Persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM) substances are a threat to sources of drinking water
- Water suppliers have been raising concern, calling for stewardship by industry and regulatory action by authorities.
- Water quality is decreasing and treatment costs have been increasing largely due to more PMT/vPvM substances



Pronk et al. Water Supply (2021) 21 (1): 128–145.

ECO54 1st Stakeholder workshop on mobility concerns for chemical substances

6 August 2019  
Moving Forward on PMT and vPvM Substances



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## Briefing Note

### Moving Forward on PMT and vPvM Substances

#### 1. Introduction

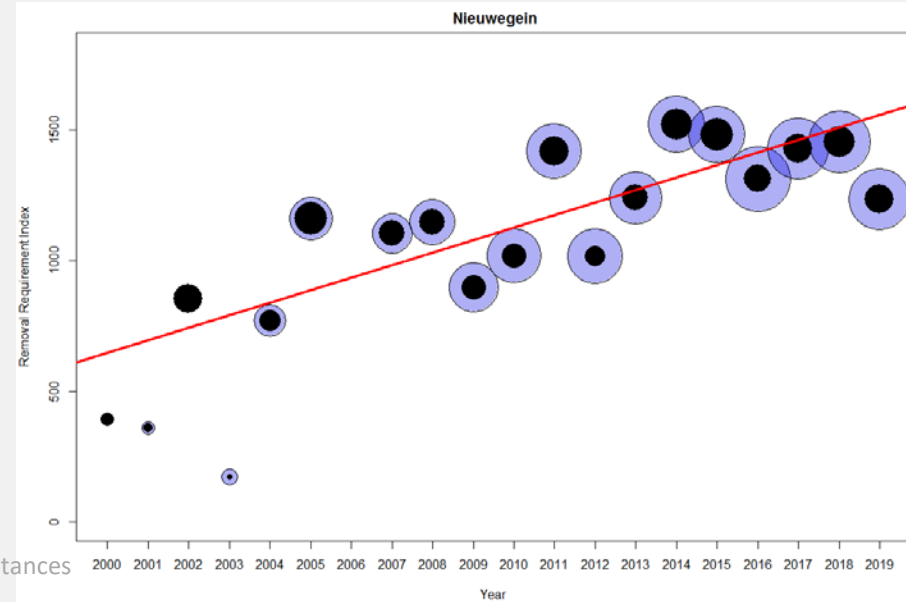
The purpose of this paper is to demonstrate the impact of persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM) substances on water services. We will describe possible regulatory approaches to restrict their use.

# Removal Requirement Index increases for PMT/vPvM Substances

- Over the last 20 years water suppliers have to invest more and more effort to meet the requirements of the drinking water standards
- PMT/vPvM substances are the main driver

Harrie Timmer  
Dutch national association of water companies  
in the Netherlands VEWIN  
at Third PMT Workshop 2021

T. E. Pronk, R. C. H. M. Hofman-Caris, D. Vries, S. A. E. Kools, T. L. ter Laak, G. J. Stroomborg;  
A water quality index for the removal requirement and purification treatment effort of micropollutants.  
Water Supply 1 February 2021; 21 (1): 128–145. doi:  
<https://doi.org/10.2166/ws.2020.289>



# REACH: Equivalent Level of concern (ELoC) to PBT/vPvB substances

- PFBS, GenX and 1,4-dioxane identified by MSC as substance of very high concern (SVHC)
- Ongoing discussion: Restriction of PFHxA under REACH
- Under REACH assessed and compared 16 categories on health effects, environment effects and other effects
- Intrinsic substance properties cause hazard
- Result of this scientific paper: PMT/vPvM substances in general pose an ELoC to PBT/vPvB substances

Hale et al. *Environ Sci Eur* (2020) 32:155  
<https://doi.org/10.1186/s12302-020-00440-4>

Environmental Sciences Europe


RESEARCH Open Access

**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**

Sarah E. Hale<sup>1\*</sup>, Hans Peter H. Arp<sup>1,2</sup>, Ivo Schliebner<sup>1</sup> and Michael Neumann<sup>1</sup>

**Abstract**  
**Background:** Under the EU chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals, EC 1907/2006), registrants are not obliged to provide information related to intrinsic substance properties for substances that pose a threat to the drinking water resources. In 2019, perfluorobutane sulfonic acid (PFBS) and 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid (PFPO-DA trade name GenX) were demonstrated to have an equivalent level of concern (ELoC) to their persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT/vPvB) substances owing to their persistent, mobile and toxic (PMT) substance properties and very persistent and very mobile (vPvM) substance properties, respectively. They were both subsequently identified as substances of very high concern (SVHC) applying Article 57(f) in REACH. This work follows up on this regulatory decision by presenting a science based, conceptual level comparison that all PMT/vPvM substances pose an ELoC to PBT/vPvB substances. Using the two cases named above, as well as 1,4-dioxane, 16 categories were developed to evaluate a) serious effects on human health, b) serious effects on the environment and c) additional effects. 1,4-dioxane has recently been proposed to be classified as Carcinogenic 1B by the Committee for Risk Assessment (RAC). The aim was to enable an objective and scientifically justified conclusion that these classes of substances have an equivalent level of concern for the environment and human health.  
**Results:** In all of the categories related to human health, the environment and other effects, the PMT/vPvM case study substances exhibited comparable effects to PBT/vPvB substances. A difference in the human and environmental exposure pathways of PMT/vPvM and PBT/vPvB substances exists as they vary temporally and spatially. However, effects and impacts are similar, with PMT/vPvM substances potentially accumulating in (semi)-closed drinking water cycles and pristine aquatic environments, and PBT/vPvB substances accumulating in humans and the food chain. Both PMT/vPvM and PBT/vPvB substances share the common difficulty that long term and long-range transport and risk of exposure is very difficult to determine in advance and with sufficient accuracy.

\*Correspondence: [sah@ngi.no](mailto:sah@ngi.no)  
<sup>1</sup>Norwegian Geotechnical Institute (NGI), Ullevål Stadion, PO box 3930, 0403 Oslo, Norway  
Full list of author information is available at the end of the article

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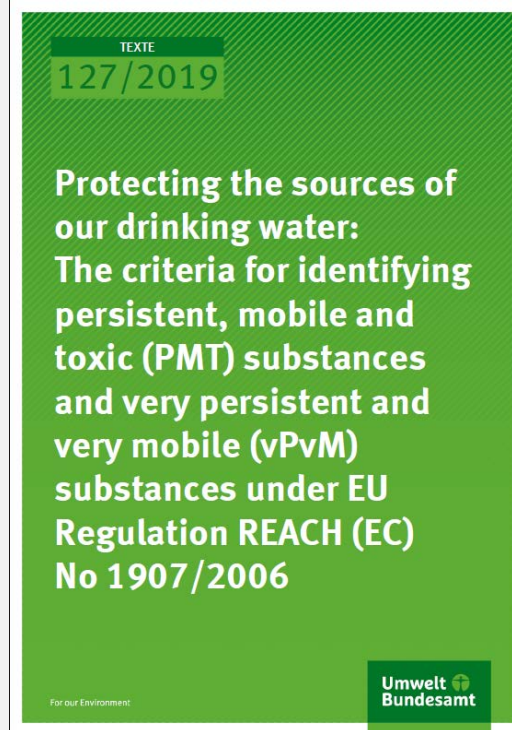
## Example categories used in the scientific paper

Category	PBT/vPvB	PMT/vPvM
<b>Irreversible health effects?</b>	Yes - Substances can bioaccumulate in humans; chronic and acute effects possible	Yes - Continuous exposure through drinking water and remote aquatic ecosystems over long time scales possible, despite potential rapid excretion rates; chronic and acute effects possible
<b>Irreversible exposure?</b>	Yes - Once the contamination is in the environment it cannot be removed and impacts cannot be mitigated by reducing pollution levels. - Emissions from contaminated areas can be ongoing long after phase-out.	Yes - Once the contamination is in the environment it cannot be removed, particularly due to the lack of water treatment facilities or difficulty to remediate soil and groundwater. - Emissions from contaminated areas, such contaminated soil and groundwater, can be ongoing long after phase-out.

# Development of PMT/vPvM criteria under REACH

- Started already in 2009 by German Environment Agency (UBA)
- Based on latest available science, as evaluated by expert committees (e.g. ECHA's PBT expert group, dedicated workshops)
- Is consistent with existing chemical regulations (e.g. REACH, Ground water directive), or at least does not conflict with them
- Is practical, transparent, and feasible for compliance or enforcement

## Derived Criteria



Neuman & Schliebner, 2019

# 2017 to now: From scientific to policy level discussion

PBT Expert Group of ECHA (**PBT EG**)  
Risk Management Expert Meeting (**RiME**)

Meeting of Competent Authorities  
for REACH and CLP (**CARACAL**)

The  
PMT/vPvM  
criteria

2017 Risk Management  
Expert Meeting (RiME-2  
and RiME-3 2017)  
and 15<sup>th</sup> and 16<sup>th</sup>  
PBT Expert Group

2019 final PMT/vPvM  
criteria presented to  
CARACAL-30

2018 second public  
consultations and UBA  
and UFZ Workshops

The Member State  
Committee (MSC)  
identifies PFBS and  
GenX as substance of  
very high concern  
(SVHC)

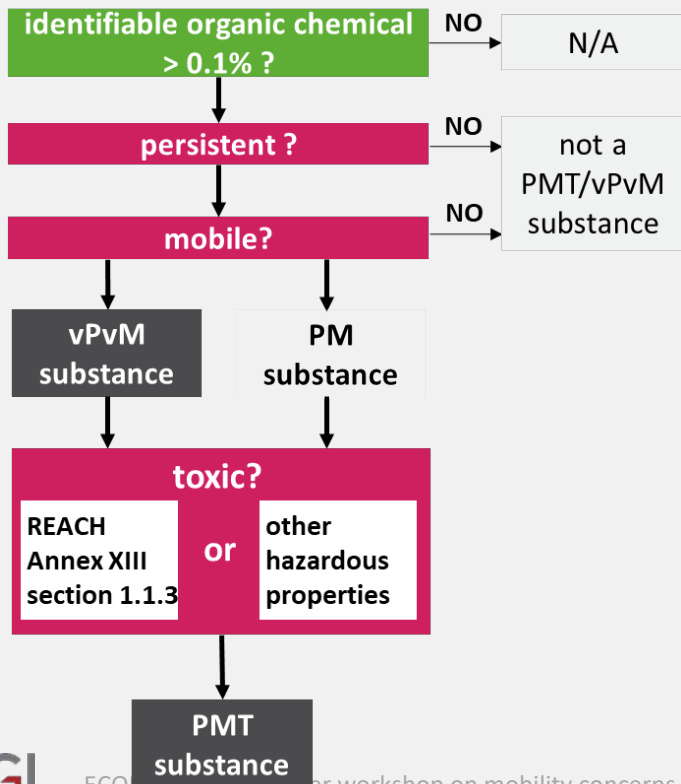
Implementing PMT/vPvM  
criteria into CLP and REACH  
regulation



# Chemicals Strategy for Sustainability (CSS)

- On 14.10.2020 EU COM publishes the CSS
  - “For a Pollutant-Free Environment”
- Strengthening the chemical legislation i.e. REACH and CLP
- Focus more resources on hazard identification
- Ensure that the most harmful chemicals are not contained in particular in consumer products
  - food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textile
- ‘One substance, one assessment’
- CLP regulation with central role for hazard assessment
  - new hazard classes
  - Endocrine disruptors; PBT, vPvB; PMT, vPvM; terrestrial toxicity

# State-of-the-Art PMT/vPvM hazard assessment

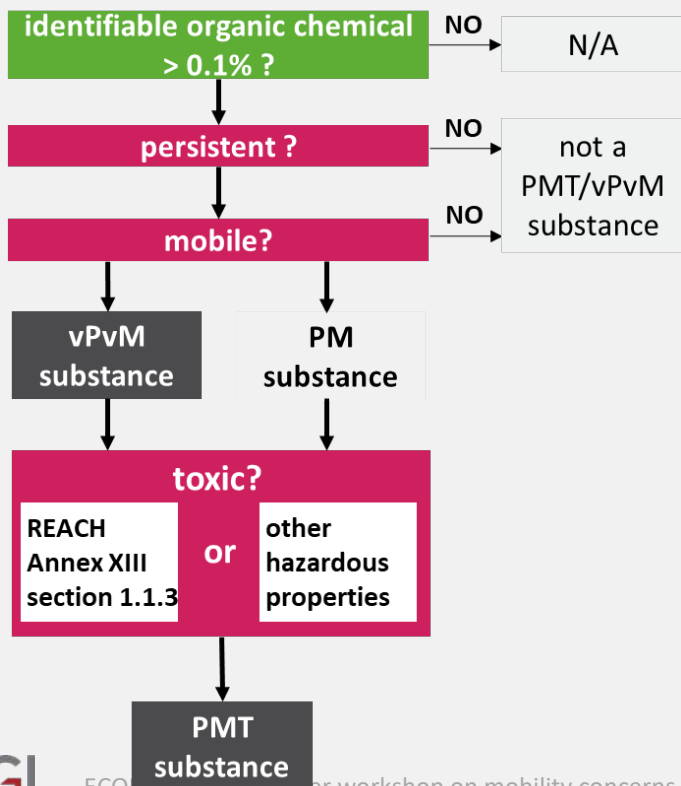


Scientific background and guidance



Arp & Hale, 2019

# First Step: Assessing persistency (P and vP)

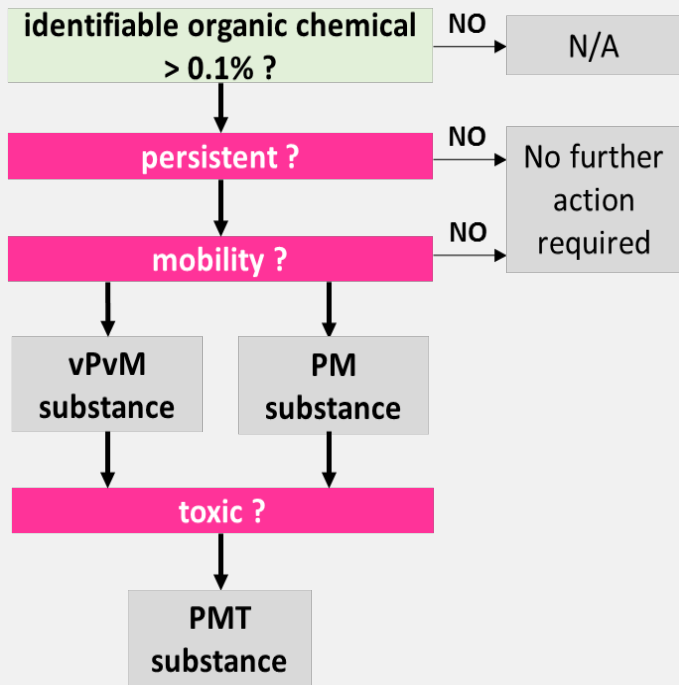


## P and vP criteria identical to Annex XIII of REACH

	<b>persistent (P)</b> in any of the following situations	<b>very persistent (vP)</b> in any of the following situations
marine water	half-life > 60 days	half-life > 60 days
fresh water	half-life > 40 days	half-life > 60 days
marine sediment	half-life > 180 days	half-life > 180 days
fresh water sediment	half-life > 120 days	half-life > 180 days
soil	half-life > 120 days	half-life > 180 days

ECHA Chapter R.11. Version 3.0 (June 2017)  
Neumann & Schliebner (2019)

## Second Step: Assessing Mobility (M and vM)



### Currently two proposals for M and vM criteria

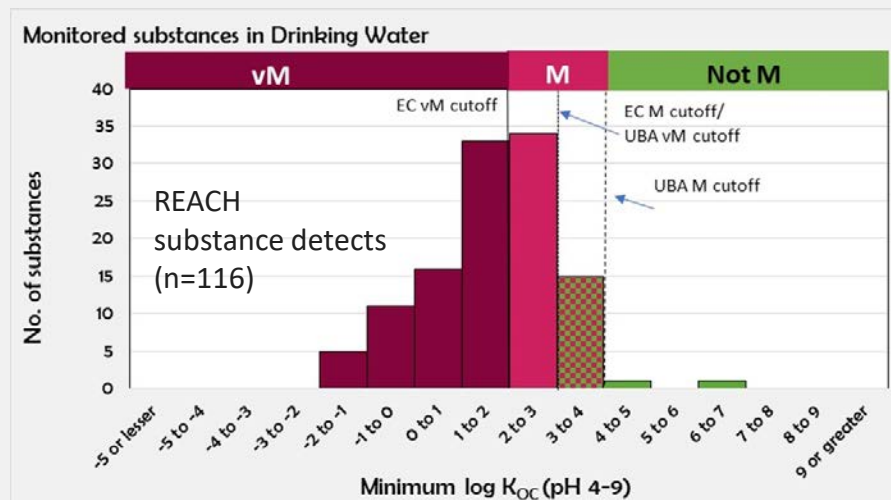
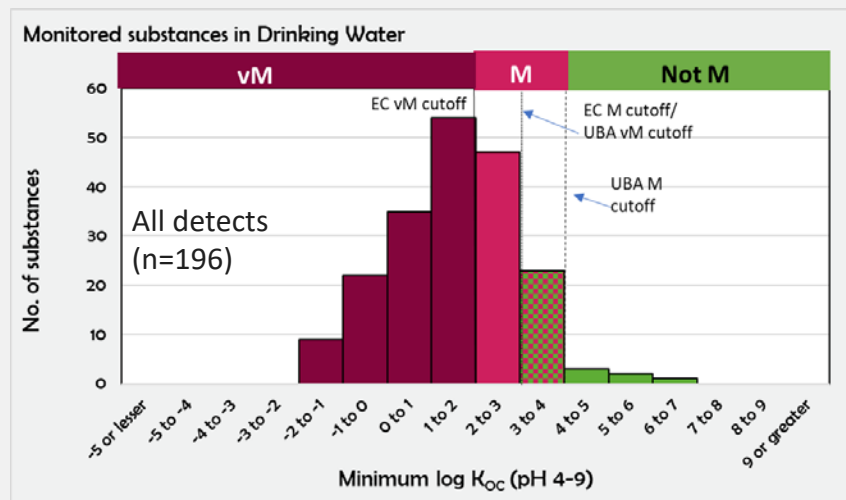
	<b>Mobile (M)</b> if it fulfills P or vP and the following situation	<b>very mobile (vM)</b> if it fulfills P or vP and the following situation
Neumann & Schliebner (2019)	< 4.0	<3.0
lowest experimental <b>log K<sub>oc</sub></b> (pH 4-9)		
EC proposal for CLP at CARACAL	< 3.0	<2.0
<b>log K<sub>oc</sub></b>		

# Mobility: Rationelle for log K<sub>oc</sub> and cutoff values

- Annex II section 12.4 of REACH
  - log K<sub>oc</sub> is a way to describe soil mobility
- Half-lives combined with log K<sub>oc</sub> used by many organizations for mobility
  - Groundwater Ubiquity Score (1979)
  - EU Common Implementation Strategy Working Group (log K<sub>oc</sub> < 3.0)
  - Biocide regulation (log K<sub>oc</sub> < 2.7)
  - UNEP FAO (different categories)
- Simulation Model: If M (log K<sub>oc</sub> = 4.0) and P (soil half-life = 120 day)  
8% of river concentrations could penetrate bank filtration (sandy soil) to drinking water extraction points

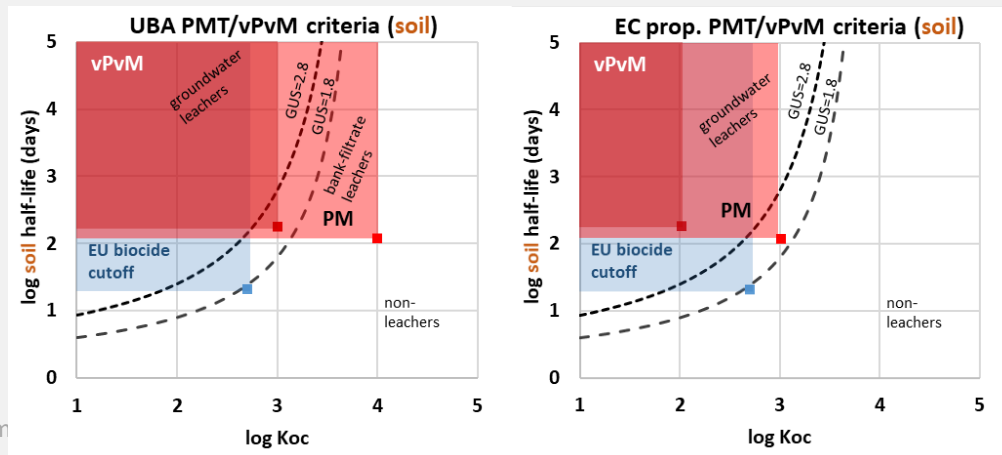
# Empirical Data compared with proposed log K<sub>oc</sub> cutoff values

- 196 chemicals (including 116 REACH substances) **detected** in drinking water **and** an **experimental log K<sub>oc</sub> value** is available
- Less detected substances are classified as PMT/vPvM if log K<sub>oc</sub> cutoff is lowered



# Thought starter: discussion topic 1: What are we really talking about when talking about the mobility of chemicals?

- Significance of the analytic gap (very few labs monitor for the most mobile substances)
- Which is the protective  $\log K_{OC}$  cutoff value for P/vP substances considering diverse, vulnerable emission pathways
  - urban surface water -> bankfiltrate -> drinking water (limited treatment)
  - factory soil contamination -> groundwater extraction well -> drinking water
- Groundwater protection e.g.  $GUS = \log DT_{50soil} (4 - \log Koc)$  (Gustafson, 1979)
- Subsurface mobility vs LRTP



## Thought starter:

### discussion topic 2: Is mobility a concern for hazard or risk?

- Intrinsic hazard of mobility of a chemical (regardless of use) vs. risk assessment of a specific use of a chemical
- Keep it simple:  
PMT/vPvM criteria under CLP and goal of «One Substance, One assessment»
- Hazard classes in CLP, REACH and UN-GHS need to apply **to all vulnerable uses in all vulnerable (global) regions**. Consider, e.g. regions experiencing draught
- Current risk assessment models used in Europe do not include relevant transport pathways to drinking water, like bank filtration, waste water re-use



## Thought starter: discussion topic 3: What data gaps did you encounter, or are you plagued with, when assessing the hazard of chemical substances?

- ↗ Again: analytical gap and monitoring gap  
Do we really know how many mobile substances are in the water cycle?
- ↗ Persistency data is the largest data gap.  
Is there a simplified method considered equivalent to OECD TG 307 to 309 ??
- ↗ Complexity and variability of Koc data regarding ionic compounds.  
Use of minimum experimental value as proxy vs weight of evidence in special cases
- ↗ Hydrolysis data
- ↗ Photolysis is a data gap – subsurface mobility of photolysis transformation products is of interest, but not photolysis half-lives (subsurface mobility vs LRTP)

# Thank-you!

- Funding from the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety of Germany (FKZ 3719 65 408 0)
- The EU research project **ZeroPM** funded by Horizon 2020 (No 101036756)
  - WP3 Policy – “regulatory watch” will track and develop guides for EU Green Deal regulations for PMT/vPvM substances as they develop!



➤ [zeropm.eu](https://zeropm.eu)



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#påsikkergrunn