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and Mobility (defined as organic-carbon partitioning) do not 2 correlate to the detection of substances found in surface and 3 groundwater: Criticism of the regulatory concept of persistent 4 and mobile substances" 5 6 7 By 8 Hans Peter H. Arp,^{1, 2}* Raoul Wolf,¹ Sarah E. Hale,^{1,3} Sivani Baskaran,¹ Juliane Glüge,⁴ Martin Scheringer,⁴ Xenia Trier,⁵ Ian T. Cousins,⁶ Harrie Timmer,⁷ Roberta Hofman-9 10 Caris, 8,9,10 Anna Lennquist¹¹, André D. Bannink, ¹² Gerard J. Stroomberg, ¹² Rosa M.A. 11 Sjerps, ¹³ Rosa Montes, ¹⁴ Rosario Rodil, ¹⁴ José Benito Quintana, ¹⁴ Daniel Zahn, ¹⁵ Hervé Gallard, ¹⁶ Tobias Mohr, ¹⁷ Ivo Schliebner, ¹⁷ Michael Neumann ¹⁷* 12 13 14 15 ¹ Norwegian Geotechnical Institute (NGI), P.O. Box 3930, Ullevål Stadion, 0806 Oslo, Norway ² Department of Chemistry, Norwegian University of Science and Technology (NTNU), N-7491 16 17 Trondheim, Norway 18 ³ DVGW-Technologiezentrum Wasser, Karlsruher Str. 84, 76139 Karlsruhe, Germany 19 ⁴ Institute of Biogeochemistry and Pollutant Dynamics, ETH Zürich, 8092 Zürich, Switzerland 20 ⁵ University of Copenhagen, Thorvaldsensyei 40, DK-1871 Frederiksberg, Denmark 21 ⁶ Department of Environmental Science, Stockholm University, Stockholm, Sweden 22 Vewin, Association of Dutch water companies, Bezuidenhoutseweg 12, NL 2594 AV The Hague 23 ⁸ KWR Water Research Institute, Groningenhaven 7, Nieuwegein, the Netherlands 24 ⁹ University of Applied Sciences, Life Sciences and Chemistry, Heidelberglaan 7, Utrecht, The 25 26 ¹⁰ Wageningen University and Research, Environmental Technology, Droevendaalsesteeg 4, 27 Wageningen. The Netherlands 28 ¹¹ The International Chemical Secretariat, ChemSec, Första Långgatan 18, Gothenburg, Sweden 29 ¹²RIWA Association of River Waterworks, Groenendael 6, 3439 LV Nieuwegein, the Netherlands 30 ¹³ Oasen, Nieuwe Gouwe O.Z 3, 2801 SB Gouda, The Netherlands ¹⁴ Institute for Research on Chemical and Biological Analysis (IAQBUS), Universidade de Santiago de 31 32 Compostela, R. Constantino Candeira S.N., 15782 Santiago de Compostela, Spain 33 ¹⁵ Helmholtz Centre for Environmental Research - UFZ Permoserstraße 15, 04318 Leipzig, Germany 34 ¹⁶ Institut de Chimie des Milieux et Matériaux de Poitiers UMR CNRS 7285 1 rue Marcel Doré. 35 TSA 41105, 86073 Poitiers Cedex 9, France 36 ¹⁷German Environment Agency (UBA), Section IV 2.3 Chemicals, Wörlitzer Platz 1, 06844 Dessau-37 Roßlau, Germany 38 39 Keywords: 40 PMT and vPvM 41 **CLP** Regulation 42 Water protection 43 Drinking water 44 45 Corresponding author email: hans.peter.arp@ngi.no, michael.neumann@uba.de 46

Letter to the editor regarding Collard et al. 2023: "Persistence

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48 Dear Editor,

We wish to make readers of the recently published article by Collard et al. (2023) aware that it is based on several false claims in relation to the regulatory concept of introducing new hazard classes for persistent, mobile and toxic (PMT) substances and very persistent and very mobile (vPvM) substances. Specifically, these false claims misrepresent the underlying scientific justification and regulatory purpose of the PMT/vPvM criteria. The PMT/vPvM criteria were adopted in the European Union's CLP Regulation on April 20th, 2023, as part of the introduction of the new hazard classes PMT and vPvM. We feel it necessary to highlight these false claims, in view of the potential impacts these claims could have on the ongoing discussions regarding the adaptation of the new hazard classes PMT and vPvM in the Globally Harmonized System of Classification and Labelling of Chemicals of the United Nations (UN GHS).

1. Collard et al. (2023) incorrectly claim that surface water monitoring data are relevant to the PMT/vPvM criteria.

Collard et al. (2023) incorrectly state "Cut-off criteria for M were derived from a benchmarking exercise comprised of a large dataset of surface and groundwater monitoring data". Rather, the PMT/vPvM criteria were developed in relation to subsurface transport, in the context of groundwater and drinking water protection (Arp and Hale, 2022). The PMT/vPvM criteria were not developed to predict water contamination, particularly not surface water contamination. Surface water monitoring data were not considered during the development of the PMT/vPvM criteria (Neumann and Schliebner, 2019). The aim of protecting groundwater and riverbank filtration was a central scientific reason for using the

73 log organic carbon-water partition coefficient (log $K_{\rm OC}$) as the parameter to base the 74 classification criteria for mobile (M) and very mobile (vM) substances, as stated in the CLP 75 regulation: 76 77 "The classification criteria for M/vM relate, in particular, to the log K_{OC} (soil 78 adsorption coefficient) value. The K_{OC} value is the organic carbon-water partition 79 coefficient and reflects the ability of a substance to be adsorbed on the organic fraction of solid environmental compartments such as soil, sludge and sediment, and is 80 81 therefore inversely related to the substances' potential of entering into groundwater. It 82 is therefore appropriate to assess the mobility criterion against the log K_{OC} value of a substance, a low Koc implying a high mobility." (EC, 2023) 83 84 85 Therefore, any critique of the PMT/vPvM criteria that is based on surface water monitoring data is irrelevant. 86 87 88 89 2. Collard et al. (2023) incorrectly imply that the M/vM criteria were derived exclusively 90 from benchmarking of monitoring data. 91 92 The quote from Collard et al. (2023) above is also incorrect in its implication that the cut-off 93 criteria for M and vM were derived exclusively from the benchmarking of monitoring data. 94 The cut-off criteria for M and vM were developed to protect sources of drinking water, such 95 as groundwater and riverbank filtration, from receiving and accumulating persistent (P) and 96 very persistent (vP) substances. The $\log K_{\rm OC}$ cut-off values for this purpose, presented in the

CLP delegated act (EC, 2023), were derived through multiple lines of evidence and several

rounds of consultations with international experts over several years (Arp and Hale, 2022, 2019; EC, 2023, 2021; Neumann and Schliebner, 2019). Though some of the technical documents used to develop these criteria referred to groundwater and drinking water monitoring data (Arp and Hale, 2019), it was not the sole consideration. Alternative lines of evidence included: i) the intrinsic ability of PMT/vPvM substances to travel long distances and over long time scales in the subsurface based on groundwater models (e.g. Gustafson, 1989), ii) the difficulty in removing PMT/vPvM substances from wastewater, raw water, and drinking water using standard and advanced treatment processes (Gollong et al., 2022; Neuwald et al., 2023), iii) the historic acceptance of similar criteria to protect groundwater in the EU biocide regulation (EU 528/2012), iv) the methodology of the EU groundwater watch group (Lapworth et al., 2019), v) the methodology of the UN FAO (FAO, 2000), vi) the economic impact analyses published by the German Environment Agency (Arp and Hale, 2019), and vii) the recent impact assessment performed by the European Commission (EC, 2022). Collard et al. (2023), in their critique of the PMT/vPvM criteria, excluded all mentions of these considerations related to subsurface modelling and breakthrough in river bank filtration of PMT/vPvM substances, difficulty in water treatment processes to remove such substances, existing regulations and guidelines using similar criteria, as well as socioeconomic impacts of using PMT/vPvM substances, much of which were described by Hale et al. (2022).

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The primary purpose of the PMT/vPvM criteria is not to prevent all water contamination. Rather, it is to prevent emissions of the persistent substances that have the greatest potential to be problematic water pollutants. These water pollutants would have a substantial impact on society, and owing to their intrinsic properties, may also be considered substances of very high concern (SVHC) (Hale et al., 2020). Substances that are not PMT/vPvM substances may

also contaminate water but are collectively considered less problematic from a water quality management point of view because they are relatively less likely to reach drinking water resources (Arp and Hale, 2022). They are also easier to remove with conventional technology, including natural attenuation, and easier to detect using traditional methods (Hale et al., 2022).

The amended CLP regulation summarises this as follows:

"PMT and vPvM substances pose concerns as, due to their high persistence together with a high mobility that is a consequence of their low adsorption potential, they can enter the water cycle, including drinking water, and spread over long distances. Many PMT and vPvM substances are only partly removed by wastewater treatment processes and can even break through the most advanced purification processes at drinking water treatment facilities. Such incomplete removal coupled with new emissions mean that the concentration of those PMT and vPvM substances in the environment increase over time. Once released into the environment, exposure to PMT and vPvM substances is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment. Any effects from this exposure are unpredictable in the long-term." (EC, 2023)

3. Collard et al. (2023) imply that emission information should be linked to the PMT/vPvM criteria.

One of the three questions Collard et al. (2023) asks is, "What could possibly drive the presence of these chemicals in these potential sources of drinking water?". This is answered later in the paper with statements such as "emissions and vicinity to emissions sources are driving the detection rate of chemicals in surface water". This is an obvious conclusion that is more related to exposure and risk assessment than to the PMT/vPvM criteria, which addresses the potential of a chemical to enter drinking water resources if emitted.

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Risk is defined as hazard (i.e. the toxic effect) combined with exposure, whereas the PMT/vPvM criteria describe a combination of problematic intrinsic properties of the substance related to hazard and exposure that are independent of emissions or use. The PMT/vPvM criteria, thereby, indicate that continuous emissions will lead to increasing exposure and risk over time, and that an effects threshold will eventually be exceeded (Cousins et al., 2019). This is similar to the case of persistent, bioaccumulative and toxic/very persistent bioaccumulative (PBT/vPvB) substances, in that given continuous release there will be increasing exposure and risk in the food chain (Hale et al., 2020). PMT/vPvM criteria alone do not provide an indication of the level of exposure, only the potential. For a risk assessment, one needs the substance property data used in the PMT/vPvM assessment, along with emission and scenario parameters. For instance, in the case of a river bank filtration or groundwater pollution scenario from a source to a drinking water well, the concentration of the substance in the well water will depend on the substance properties determined in the PMT/vPvM assessment (degradation half-life – persistency, adsorption potential – mobility, and toxicity), as well as the exposure parameters (emission volumes, vicinity to well, aquifer depth, groundwater flow rate, hydraulic conductivity, time since emissions). A substance that degrades quickly or has a high adsorption potential would need to be emitted in larger quantities or emitted in closer proximity in order to contaminate a specific site, relative to a

substance that does not degrade or has a low adsorption potential. Therefore, non PMT/vPvM substances can contaminate wells, but would require more emissions or shorter travel distances from the source to the well relative to PMT/vPvM substances. It is also worth mentioning that it is difficult to measure well contamination of many PMT/vPvM substances, as traditional analytical approaches are not always suitable for many mobile substances (Hale et al., 2022; Reemtsma et al., 2016).

Requiring an emission characterization to be part of the PMT/vPvM criteria would be the equivalent of requiring information on the proximity to a flame as part of a flammable substance hazard assessment. As it is essential for users of flammable substances to know they should avoid emissions near combustion sources; it is also essential for users of PMT/vPvM substances or PBT/vPvB substances to know that any emissions will lead to environmental accumulation leading to the contamination of drinking water resources or in food-chains, respectively. These accumulation processes are difficult and near impossible to reverse (Cousins et al., 2019; Hale et al., 2020). The PMT/vPvM criteria, therefore, allow for precaution in the use and emissions of PMT/vPvM substances.

4. Concluding remarks

Collard et al. (2023) is not the first study co-authored by scientists affiliated with chemical manufacturers that have made similar false premises regarding the PMT/vPvM criteria; similar claims can be found Pawlowski et al., (2023). The hazard classes for PMT and vPvM are relatively new, and therefore some misconceptions about their purpose or justification can occur. However, it is important to recognize that these misconceptions are being put forward by those that may be affiliated with companies that may produce PMT/vPvM substances. The

introduction of the new hazard classes PMT and vPvM supports the precautionary principle, so that the use of these substances on the market is compatible with the protection of water resources.

One section in the paper by Collard et al. (2023) that is worthy of further consideration is the in-depth reassessment of P and vP conclusions for several substances. Many of the persistence assessments in the cited literature were based on a weight-of-evidence assessment using the best available data; however, the weight-of-evidence was often not of sufficient quality to definitively conclude P or vP. The type of statistical analysis conducted by Collard et al. (2023) could only be done correctly if harmonised, high-quality P and vP assessments based on the CLP criteria, were available. For P and vP assessments, this would require half-life data from simulation tests (OECD 307 for soils (OECD, 2002a), OECD 308 for sediments (OECD, 2002b) and OECD 309 for water (OECD, 2004)), as well as batch sorption experiments for mobility following OECD 106 (OECD, 2000). More high-quality data on this front is encouraged, particularly since the PMT/vPvM criteria are fit for purpose to protect drinking water resources.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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