

Persistent Chemicals

Background

An important topic of focus within the current landscape of risk and hazard identification in chemicals is that of persistency. One concern raised by some authorities regards their presence in drinking water resources, and consequently the effectiveness of existing regulatory frameworks has been questioned. Persistent chemicals are generally defined as having the ability to stay unchanged in the environment for a long time. There is a growing perceived concern that because they resist degradation, they can cause harm when continuous exposure occurs in humans, wildlife, soil and the aquatic environment. These same properties however can be useful in various industrial applications. We see for example that UV stabilisers are expected to be stable for 12-15 years and some substances are designed to be persistent in order to work (e.g., rodenticide, flame retardants, polymeric materials).

Persistence is expressed in the regulatory context as the degradation half-life (T1/2) of a substance in soil, water, and sediment. The concept of half-life describes the time it takes for half the initial amount of the chemical to be removed from the environment by degradation. When deciding upon appropriate regulatory action the Chemical Industries Association (CIA) advocates that this should not be based on persistence alone as other properties (bioaccumulation, toxicity) and factors (carbon footprint and lifecycle analysis) need to be considered along with the weight of scientific evidence on the risks posed.

Current status

The last few decades have seen a varying number of persistent chemicals in high profile cases of environmental contamination such as in the case of CFCs (chlorofluorocarbons), PFAS (perfluoroalkyl substances), etc. Under the EU's Green Deal zero-pollution agenda, the European Commission as part of its EU Chemicals Strategy for Sustainability has noted that the regulatory framework will need to rapidly reflect the scientific evidence on the risk posed by very persistent chemicals.

In the UK and EU, the regulation of persistent chemicals is anchored by the REACH (Registration, Evaluation and Authorisation of Chemicals) Regulation and the Persistent Organic Pollutants (POPs) Regulation. Other regulatory frameworks including Plant Protection Products Regulation (PPPR), Biocidal Products Regulation (BPR), and the Directives on medicinal products for human use (HMPD) or for veterinary use (VMPD) provide regulatory frameworks for very persistent chemicals.

Persistent chemicals are not regulated by persistency alone. Under both EU and UK REACH, they also need to be bio-accumulative (B) and toxic (T) (referred to as PBT chemicals where P refers to Persistent) to be subject to regulatory action via being identified as Substances of Very High Concern (SVHCs). Those that meet the REACH criteria for being Very Persistent (vP) must also be very Bioaccumulative (vB)- these are referred to as vPvB chemicals – to meet the SVHC criteria. Other international jurisdictions have different criteria on how the persistency of a chemical is assessed (these are not discussed further here).

Recently a new EU-REACH category PMT/vPvM has been proposed by the German Environment Agency, where the M represents Mobility to account for potential risks to drinking water. The UK is also considering this in terms of future chemicals management policy. This proposed category is also included in the EU Chemicals Strategy for Sustainability which lays out proposals for including PMT in Article 57 of the REACH regulation and setting a new hazard category under the Classification, Labelling and Packaging (CLP) regulation. The EU also intends to propose it for discussion at the global level for inclusion under the Globally Harmonised System (GHS) classification system.

Additionally, consumer and media opinions continue to gain popularity, accelerating potential regulatory action for persistent chemicals. The case of Perfluoroalkyl substances chemicals (PFAS) or the recent EU-REACH restriction proposal on microplastics are such examples.

Our opinion and actions

- It is of note that intrinsic properties found in metals such as lead, and those with stable and resistant Carbon-Fluorine bonds found in certain chemicals mean they are resistant to degradation within organisms and the environment. The assumption that persistency is always a negative attribute cannot be used in isolation to determine policy and regulatory decisions. Where this property has and continues to be both beneficial and essential for certain applications e.g., in the manufacturing of equipment and machinery whereby stability and durability is a requirement, socio economic

analyses need to be made to determine whether continued use brings benefits.

- Persistency on its own is not meaningful for informing decisions on regulatory action. CIA thereby supports the current process of identifying persistent substances in combination with other properties, as is the case under the UK and EU REACH regulations. Chemicals that are Persistent and Bio accumulative and Toxic (referred to as PBTs) are identified as Substances of Very High Concern (SVHC), which in the REACH authorisation process are progressively replaced by substances without PBT properties or technologies where technically and economically feasible alternatives are available.
- CIA notes that although persistence of a chemical in the environment may trigger a certain level of potential concern, it is our view that this is not enough on its own to assess present or future risks to human health and the environment. Once a



concern is identified, further risk assessment measures should be taken, such as additional testing, hazard analysis etc. to characterise the risk and, if confirmed, adopt risk management measures. We thereby encourage an evidence based/science driven policy making decision process for evaluating persistent chemicals.

- CIA recognises there are various challenges with undertaking persistency assessments for a chemical, most notably how to measure the half-life.
- Whilst industry initiatives to address persistent chemicals have focussed on their biodegradability, it is recognised that there is a wide variation in the extent of biodegradation observed between the various tests presently available. Biodegradation testing is complex and issues such as the samples used, the environmental matrix under study (e.g. water or sediment) as well as the pre-treatment of the test substance can affect the regulatory credibility of tests. It is also worth noting environmental conditions play a key role in the persistency of a substance. Another challenge when assessing the persistence of a substance is that the properties of a substance will need to be well characterised. However, complex compositions, low solubility, and also volatility can make a substance difficult to test and thereby the assessment needs careful consideration. Therefore, rather than focussing on persistency alone in testing a substance, consideration of the combined environmental fate characteristics of a substance and its interaction with the environment should be considered.

Conclusion

CIA recognises the evolving debate on persistent chemicals in the UK, EU, as well as globally and thereby encourages any future policy measures to be both evidence-based and science driven. We fully support co-operative working with relevant authorities to ensure this.

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