Assessment of PBT and vPvB chemicals: Requirements, challenges and policy implications

Monika Nendza, Silke Gerda Margaret Gabbert, Stefan Hahn

May 9, 14:20 - 16:00, The Arc

Substances with persistent, bioaccumulating and toxic (PBT) or very persistent and very bioaccumulating (vPvB) properties can accumulate in environmental media with unpredictable long-term effects. PBT and vPvB chemicals are, therefore, of primary regulatory concern. Several European legislations, for example REACH (EC No 1907/2006) and the regulations on plant protection products (EC No 1107/2009), biocidal products (EC No 528/2012) or medicinal products (EC No 726/2004) aim to identify PBT and vPvB chemicals and to adopt effective regulatory measures for minimal use of such substances. The need for harmonizing and improving existing approaches for identifying PBT and vPvB chemicals has been recognized. Generally, the identification of PBT and vPvB chemicals is based on defined (screening) criteria using more or less conservative thresholds. Evidence-based approaches to PBT/vPvB assessments may include, for example, the use of monitoring data, environmental exposure modelling or computational methods such as quantitative structure-activity relationships (QSARs) and read-across (RAX). Recent recommendations refine in particular the persistence and bioaccumulation assessments. Further important properties are the long-range transport potential (LRTP) and the long-term damage (stock pollution) potential. Adequate consideration is needed for substances with potentially similar concern such as pseudo-persistent (continuously present) chemicals or substances that are persistent, mobile and toxic (PMT). Closely related to the challenges of the identification of PBT/vPvB chemicals is the question how to translate PBT/vPvB properties into effective, concern-based regulatory strategies. In particular, REACH links regulatory decisions on the authorisation and restriction of PBT/vPvB chemicals with a socio-economic analysis (SEA), which requires balancing all positive against negative impacts from chemicals' use and non-use. So far, it is unclear how to adequately translate information, and the absence of information, about the properties of PBT/vPvB chemicals into an SEA. The aim of this session is to offer a platform to scientists, regulators and stakeholders for presenting and discussing the diverse issues related to the improvement of PBT/vPvB identification and regulation. Contributions comparing existing concepts for PBT-identification are of interest as well as presentations addressing challenges in the determination of the individual properties, for example novel and integrated testing and assessment strategies for persistence, bioaccumulation and toxicity. We also invite conceptual and applied research addressing the implications of improving PBT/vPvB assessment for regulatory decision-making, including approaches for socio-economic assessment, impact assessment and impact valuation. Interdisciplinary research projects, illustrating the nexus between natural and social sciences, are also explicitly encouraged.

Development and validation of standardised methods and their use in regulatory frameworks

Adam Lillicrap, Sebastian Buchinger, Kirit Wadhia

May 11, 8:35 - 10:15, Meeting Studio 314 & 316

The importance of standardisation, within the context of environmental sciences, is that it provides a level of International harmonisation for the generation and interpretation of data and ensures that tests fulfill internationally established minimum criteria . With the increasing need for more targeted hazard assessment strategies that will be required for risk assessment in the future both for aquatic and soil ecotoxicology, standards from a regulatory perspective are likely to play a significant role to ensure that robust and reliable data are generated subject to valuation based on internationally accepted concepts. Beside others, the Organisation for Economic Co-operation and Development (OECD) and the International Organisation for Standardisation (ISO) make significant contribution to meeting the regulatory demand for standardized test methods; OECD focusing on the assessment of chemicals while ISO dealing with the determination of water and soil quality. Over the last few years significant milestones have been accomplished or developments are currently in progress for new standards in environmental sciences. This session aims to explore some of these advances by presenting instructive examples from both, aquatic and soil ecotoxicology. Additionally, the process involved with ISO and the development of new standards will be discussed. Within this session, we also welcome new ideas for test methods, biomarker endpoints, and standards relating to sampling and characterisation procedures (e.g. nano-materials, microplastics), chemical analysis and statistical approaches which may be of future relevance for assessing soil, sediment as well as fresh and marine water quality. This session is being led by representatives from International Organisation for standardisation within ISO technical committee 147 (Water Quality) and technical committee 190 (Soil Quality).

Environmental risk assessment of biocides: regulatory requirements, challenges and consequences

Anja Kehrer, Anja Coors

May 11, 11:05 - 12:45, Meeting Studio 314 & 316

Biocides are a very diverse group of 22 different product types used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism. These effects are caused by any means other than mere physical or mechanical action. Harmful organisms in this context are e.g. rodents, algae, fungi, bacteria or aufwuchs. Examples of biocidal products are insecticides, rodenticides, disinfectants or anti-fouling paints for ships. Because they are designed to affect organisms, biocides can also pose risks to humans and non-target organisms in the environment. Thus, they need to be authorized. Their authorization is a complex procedure which is regulated by the Biocidal Products Regulation 528/2012 (BPR) and subdivided in two central areas: the active substance procedure on EU-level and the product procedure on national level. For both procedures extensive data have to be submitted which enable the evaluating member states to conduct a comprehensive risk assessment. This requires, among other things, extensive studies on the influence of the active substance (a.s.) on the environment. Risk has to be determined for every a.s. in the product separately as well as for at least one biocidal product containing the a.s.. Only if the a.s. has passed the evaluation process and is included in the union list of approved active substances, the risks to man and environment posed by the product is assesed in the product procedure. Besides the environmental risk assessment also several other aspects have to be covered like e.g. the assessment of disinfection-by-products (DBPs), endocrine disrupting- and PBT-properties of active substances or the mixture toxicity assessment of products and aggregated exposure assessment. Not for all of these aspects guidance documents or even procedures agreed between the member states are available, making the assessment sometimes complex and requires discussion and coordination between the member states. This session aims to provide an overview of the state of the art in the regulatory environmental risk assessment (ERA) of biocides and associated emerging challenges and possible consequences. We invite scientists from academia, regulatory bodies and industry to present their experiences within the field of the ERA of biocides, and to discuss possible challenges, knowledge gaps or needs for further developments in the regulatory context. Possible topics might be the comparative assessment of biocidal products, the use of bio-pesticides or micro-organisms as biocides or the development of resistance in target organisms. A similar session has been successfully run at the previous SETAC Europe Meeting in Nantes providing an overview on the latest developments in the ERA of biocides including an introductory talk form ECHA, talks on the fate of biocides in the environment and their monitoring as well as the sustainable use of biocides, the mixture toxicity assessment of biocidal products and the effects of anticoagulant rodenticides of non-target animals in the environment. As the feedback from the audience of the previous session was consistently positive, it should be continued at the next SETAC Europe Annual Meeting in 2017 in Brussels.

Fate and Effects of Metals: Regulatory and Risk Assessment Perspective

Koen Oorts, Olivier Perceval

May 9, 14:20 - 16:00, Copper Hall

Regulations in Europe as REACH, CLP and WFD have been a trigger during the last 15 years of research on hazards and risks of metals in the environment. This has resulted in the development of new approaches to reduce the uncertainty associated with estimates of metal fate and toxicity in soils, sediments and aquatic environments (e.g. bio-availability models, fate models). The application of these significant advances in science and modeling of metals in aquatic and terrestrial environments can contribute to pollution prevention, better regulations, improved environmental quality setting and improved risk management decisions. More recently, the focus of research on metals has expanded to assessment of mixture toxicity, prediction of toxicity in tropical environments, bioaccessibility in humans. This session will review, through case studies, the significant advances in the science related to metals in the context of risk assessment and regulatory initiatives.

Fate, risk assessment and management of natural toxins: state-of-the-art, challenges and future prospectives

Gemma Giménez Papiol, Hans Christian Bruun Hansen, Karina Knudsmark Sjøholm

May 8, 8:30 - 18:30, Exhibition Hall (Poster & Poster Corner session)

Natural toxins are compounds produced by organisms, other than human beings, with toxic effects on human and other organisms. Both plants, fungi, bacteria and microalgae produce natural toxins covering a huge chemical diversity, modes of action and often with continous production in large quantities in proximity or within vulnerable ressources such as food, feed and drinking water. Risk assessment and management of a number of natural toxins has led to a set of regulations and legislation accepted and implemented at world level, which are revised regularly based on the existing data, technical advances, and new evidences and challenges. However, for many natural toxins there are no analytical methods, no monitoring data and no regulation despite that toxicity has been documented. Despite the differences between compounds and sources, the risk assessment strategy is quite similar to the one for xenobiotics: it is based mainly on the prevention of the exposure to the toxic compound by regular monitoring of the toxin presence in food, feed and water (typical intoxication vias) as well as the presence of the producing organism in the environment. The diversity of sources, temporal and spatial variation in release from the sources, and diversity of compounds demands for analytical methods and research fields involved in their monitoring and fate. The main technical challenges are related to the improvement of the methods in order to get faster, cheaper and more reliable results, leading to portable, screening, on-line, real-time or remote sensing data; and including lower limits of detection and quantification. Natural toxins are a worldwide challenge due to the numerous and high-production sources, the increase of travel and toxin transfer due to toursim, and the trade (of food etc) between separated geographical regions. Limited knowledge has been gathered about the effects of climate change, spreading of invasive species (producing natural toxins) and emission of new and more agressive natural toxin organims - in particular microorganisms. The aim of the session is to update and compare the methods used to analyse, monitor and study different natural toxins, sources and fate in order to learn from this experience, discuss common challenges and establish future goals and prospectives related to research, management and social impact of natural toxins.

Higher tier approaches in the risk assessment of plant protection products and their links to protection goals

Frances Pickering, Eric Bruns, Veronique Poulsen

May 8, 8:35 - 10:15, Silver Hall

The risk assessment of plant protection products is becoming increasingly complex in the face of new guidance documents and data requirements. One of the consequences of this is that emerging and new non-standard effect and exposure assessment approaches have been required to be developed in order to keep pace with the evolving regulatory framework. These can be either desk-based theoretical approaches or complex and novel study designs or a combination of both. One of the challenges scientists face is identifying practical and scientifically justifiable solutions to improve the ecological and contexual representativeness of risk assessments in order to meet the requirements of the protection goals and regulatory authorities. This is amplified as the acceptability of higher tier approaches in regulatory risk assessment is more and more challenged. Scientists must be able to communicate complex risk assessments in a clear and robust manner that can be understood, and thus correctly interpreted, by all stakeholders. The natural ecosystem is complex and variable, and thus a balance must be struck between the level of realism of the risk assessment and designing practical solutions. Field studies represent the most relevant tools for risk assessment, providing the most realistic data sets. However, their lack of acceptability by regulators, particularly the use of recovery endpoints, could lead to us losing these most valuable tools from the risk assessment. Ecological models also have a promising future within higher tier risk assessments, potentially able to bridge the gaps between experimental data and real world scenarios. However, again, the acceptability of these models by regulators currently limits their use in regulatory submissions. Abstracts are welcomed from industry, government bodies and academics for this session which aims to provide a forum for the sharing of knowledge and experience in linking higher tier approaches to protection goals and the regulatory acceptability of such approaches. Abstracts on either experimental (laboratory, semi-field or field based) or theoretical approaches, or a combination of both, are welcomed. We also welcome presentations looking to the future, addressing possible future data requirements and risk assessment issues. If sufficient abstracts are received, it is anticipated that the session will be organised into aquatic and terrestrial themes.

Regulatory Best Practices for Assessment of Endocrine Active Substances

Ellen Mihaich, Gerd Maack, Katherine Coady

May 10, 14:20 - 16:00, Copper Hall

Regulatory assessment and proposed management of endocrine active substances (EAS) varies in different jurisdictions across the globe. Irrespective of the regulatory process, most jurisdictions use the World Health Organization International Programme on Chemical Safety definition of an endocrine disruptor requiring that a substance is demonstrated to cause a change in endocrine function that consequently leads to an adverse effect in an intact organism. Based on this common understanding of what constitutes an endocrine disruptor, harmonization of best practices for the assessment of endocrine active substances should be promoted where possible. This session will discuss various aspects of endocrine active substance assessments including data quality and relevance of various endocrine endpoints for hazard and risk assessment. Additionally, tools and approaches that can be used to help identify endocrine activity and disruption will be discussed. Topics may also include: use of emerging high through-put tools related to endocrine pathways, methodologies for deciphering systemic toxicity from endocrine activity, and weight of evidence approaches that include both exposure and potency of endocrine active substances. To illustrate best practices in endocrine assessments, case studies of endocrine active substances in different regulatory programs may be presented.

Risk assessment and management of waterbodies (ground, fresh, marine and drinking waters)

Mario Carere, Henner Hollert, Armelle Hebert

May 10, 8:35 - 10:15, Meeting Studio 313 & 315

This session will focus on risk assessment and risk management of ground, fresh and marine water bodies. It intends to bring together scientists from academic research, industry, regulatory authorities and policy makers and to provide a platform for knowledge transfer on recent tools and approaches for monitoring and assessing the chemical and biological status of surface waters. A core question is how newly developed tools can be applied in implementing water quality legislations. Especially welcome are studies demonstrating the application of in vitro bioassays, biomarkers or other bioanalytical tools for determining the risk resulting from the simultaneous presence of multiple chemicals in water bodies, or field studies linking chemical and biological methods. The identification of the relevant chemicals modes of action and the derivation of effect-based trigger values would be of particular interest. Studies on the practical costs of routine implementation would also be welcome. This session further seeks contributions linking exposure of chemicals in water bodies to human health concerns Key words: Water Framework Directive (WFD), Ground Water Directive (GWD), Marine Strategy Framework Directive (MSFD), Drinking Water Directive (DWD), mixtures, risk assessment

Science communication and citizen science - strategies for successful stakeholder engagements

Leonie Nuesser, Thomas-Benjamin Seiler, Jan Brant

May 9, 14:20 - 16:00, Meeting Studio 314 & 316

Nowadays, science communication and interactions with non-scientists is widely recognized as an important responsibility of scientists. When successful, these interactions can be a powerful tool and have the potential to provide a better understanding of your field of research and its relevance to society - which is beneficial for all participating sides. Within environmental and ecotoxicological science and research this is of particular interest since our field is linked to many levels of everyday life. We should not rely on science journalism or the initiatives of a distinguished group of scientists to be solely responsible for the understanding of our research. However, acknowledging the importance of communication does not make us good communicators. So how do we learn skills and how do we choose the right communication strategy depending on our audience and the information we want to disseminate? How do we avoid misunderstanding and raising wrong concerns? Together with you we want to develop and demonstrate concepts of good communication for our community. Today, non-scientists may collaborate on establishing hypotheses, project design, interpreting data, and disseminating results. Citizen science has the potential to provide a wide range of benefits, not least of which is uniting and leveraging the expertise of multiple disciplines to further scientific investigations. This session will collect experiences and expertise on different strategies for the engagement with specific stakeholders, how to tackle risk and uncertainty communication and the inclusion of non-scientists in sampling campaigns and decision finding processes. The presentations include different case studies where the dissemination of scientific information was implemented via conceptual strategies. We seek to initiate a lively discussion between the presenters and the audience. Listeners are encouraged to report their own cases, issues or experiences.