Advances in Mercury Science and Policy: Putting the Minamata Convention to Work

Chairs: Davide Vignati, Michael Bank, Bruce Vigon

With the increasing number of countries ratifying the United Nations Environment Programme's (UNEP) Minamata Convention on Mercury (Hg), the need to define science-based, effective, socially acceptable and economically viable strategies for Hg management is bound to garner significant interest from governments and other stakeholders worldwide. Although the Minamata Convention primarily focuses on human health, its implementation bears important environmental implications. The SETAC global mercury working group has been active in identifying key issues including the development of data and knowledge management networks, multi-tiered evidence based approaches to modeling, strategies for biomonitoring, international harmonization of management policies for contaminated sites, and rapid transfer of scientific advances related to the implementation of the Minamata convention. Still other important scientific and practical questions remain such as the definition of widely acceptable toxicity reference values, Hg source apportionment dynamics, interactions with global environmental change and Hg interactions with co-occurring contaminants such as selenium. Furthermore, the time-to-recovery of Hg contaminated ecosystem requires that possible management options are coordinated with strategies to mitigate climate change specifically those aspects related to global and local biogeochemical cycles of Hg and carbon. We welcome contributions illustrating data and scientific gaps in Hg science, limitations and solutions in current regulatory approaches, Hg bioaccumulation and biogeochemistry, data management approaches, development of interoperable monitoring networks and strategies for effective Hg risk exposure assessment and human health.

Preliminary session type: Platform and Poster

Biodegradability assessments of organic substances and polymers

Chairs: Thouand Gerald, Graham Whale

The biodegradation of organic substances is a natural yet poorly understood process. Given that biodegradation assessments form an integral part of chemical regulations to assess the persistent of substances this lack of knowledge needs to be addressed. Official references define the biodegradation process as "The biologically mediated degradation or transformation of chemicals usually carried out by microorganisms" (ECHA, 2012). The International Union of Pure and Applied Chemistry (IUPAC) expand this definition to include the breakdown of a substance in vitro or in vivo as catalysed by enzymes (IUPAC, 1993).

Biodegradability tests/assays are usually selected depending on chemical properties and the study objective. Most are designed to batch test a chemical substance (or polymer) as the sole carbon source in a mixed inoculum from different origins (river water, sea water, activated sludge and soil). Monitoring the biodegradation process remains a difficult task, ranging from the use of basic sensors to measure non-specific biodegradation parameters (oxygen or carbon dioxide) to sophisticated analysis to measure fate of the substance (Raman spectroscopy, Nuclear Magnetic Resonance, etc.). The data used from such assays is used in two ways. The first is to claim that the substance is degraded by a biological process (biodegradable), and the second is to predict the persistence of the substance in the environment. This classification assumes that the test would mimic one part of a complex environmental process.

The European REACH Regulation (Registration, Evaluation, and Authorisation of CHemicals) envisions a tiered approach to evaluate persistence. The first tier includes the use of cheap and simple test(s) of ready biodegradability corresponding to OECD (Organisation for Economic Co-operation and Development) 301 A to F guidelines. These stringent screening level tests were developed to identify chemicals that are readily biodegradable and are not considered to be persistent. A non-readily biodegradable substance is considered persistent unless it is shown to be inherently biodegradable (i.e. using OECD 302) or 'degradable' in more expensive and complex simulation tests (e.g. OECD 303, 307, 308 and 309 tests). The simulation test(s) used will depend on the potential receptor environments of (wastewater treatment plants, surface water, sediment, or soil).

Although there are several methods to assess biodegradation there are a number of critical issues which still need to be addressed (e.g. inocula, challenge of the mixture of substances, device for the testing, non-extractable residues, interpretation and use of the data for persistence assessment). This session will aim to address some of these issues and assess the validity/robustness of current biodegradation assays and approaches to provide relevant data in the context of the REACH regulation and environmental risk assessment.

Preliminary session type: Platform and Poster

Biomonitoring, bioindicators and bioassays for a relevant soil management

Chairs: Annette de Vaufleury, Benjamin Pauget, Erik Smolders

Currently no EU soil directive exits for soil protection and no EU-wide soil standards based on contaminant concentrations in soil are in place. Biological tools that characterize the impact of soil stressors (agricultural practices, contamination...) on soil biodiversity and functioning can be used as an alternative to soil contaminant standards. End-users expect a feasible toolbox based on terrestrial bioindicators to assess the impact of soil management methods that can be implemented in the field.

This session will focus on the use biomonitoring and/or laboratory bioassays to diagnose the ecological impact of contamination in soil and to measure effects of soil remediation thereon. In addition, there will be attention to other aspects of integrative and balanced field site management such as demographic and urbanization pressures, economic issues and legal aspects. W

We welcome presentations showing how terrestrial bioindicators, biomonitoring and/or laboratory bioassay can be implemented to assess risk of soil contamination of organic and/or metallic contamination, the effect of rehabilitation of brown fields, the impact of alternative agricultural practices (crop rotations, reduced tillage, organic and pesticides management) on soil functions. The scientific issues address the question if terrestrial bioindicators can be used to characterize / quantify ecosystem services, if terrestrial bioindicators may be integrated in LCA, and the role of terrestrial bioindicators in the TRIAD approach.

Preliminary session type: Platform and Poster

Challenges in Environmental Assessment of Cosmetics and Personal Care Products

Chairs: Jacques L'haridon, Erwan Saouter, Iain Andrew Davies, James Lazorchak

Cosmetics and personal care products (CPCP) are applied to skin and hairs for cleaning, protecting, and enhancing personal beauty. After rinsing, many of these products flow down the drain to mix with wastewaters. In industrialized countries the drains lead to sewage treatment plants, but in developing countries, where there are few or no treatment plants, the drains flow directly into the rivers or sea shore. This is a typical scenario for rinse-off products such as shampoos, soaps and shower gels. But it is also true for leave-on products such as hair-care products and body lotions, which can be removed from the body by cleaning and bathing. As a consequence, many cosmetic products reach surface waters in a continuous manner, and certain products such as sun protection products may be released directly while bathing. But cosmetics and personal care products face significant methodology challenges when assessing their potential environmental impact:

•Extreme diversity of chemical families and complexity from single ingredients to complex mixtures.

-Specific ingredients such as nano-materials, microplastics, ionisable organics, permanently charged chemicals and super-hydrophobic substances, have physicochemical properties that are currently outside the applicability domain of standard test methods, making assessing their ecological risks uniquely challenging.

-Heterogenous complex mixtures such as natural extracts and essential oils are difficult to test with current environmental assessment methods which have been designed for single chemicals and homogenous mixtures. So there is a real need to develop relevant but easy to implement methodologies to assess the different types of heterogeneous complex mixtures used in personal care products.

•Emerging issue regarding marine exposure to plastic microbeads (present in face cleansers) or UV filters (present in sun care products) and their potential impact on aquatic life.

•Regulatory perspective in Europe on Consumer Products Environmental Footprint labelling, (including cosmetics and personal care products). Several environmental projects are under study at national (e.g. French) and international (e.g. EU) levels. They plan to assess the impact of products on aquatic ecosystems with the USEtox model, developed for Life Cycle Assessment (LCA). But on the other hand, the Critical Dilution Volume (CDV) calculation has to be applied to award the European Ecolabel for cosmetics products. So two methods (with some deviating results), could soon be requested in Europe to assess the cosmetic products environmental quality. It seems important to move toward a common relevant methodology.

The purpose of this session is to present the latest trends and advances in scientific tools that address some of these challenges to better assess the ecological risks of chemical ingredients used in cosmetics and personal care products.

Preliminary session type: Platform and Poster

Challenges in environmental read-across and grouping of substances - when fate, bioaccumulation and ecotoxicological properties are similar enough?

Chairs: Ulla Helminen, Jose Tarazona

Chemicals are regulated within a broad range of regulatory frameworks such as REACH Regulation, Biocidal Products Regulation and the Plant protection Products Regulation within the EU, with other chemical control schemes outside EU. There is a need to provide information on the intrinsic properties and hazards of these chemicals for their risk assessment. Grouping of the substances and read-across is one of the alternatives techniques to standard testing in order to fill data gaps.

According to the REACH Regulation, for example, those substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category'. Application of the group concept requires that physicochemical properties, environmental fate and human health and environmental effects are known and shown to be similar enough within the group that they may be predicted from the source substance(s) by interpolation to other substances within the group. In practise, the knowledge and the data that will be read-across from the source substance for the target substance(s) will need to be adequate and reliable and cover the key parameters and exposure duration for the endpoint in question. In addition, the data that is used in grouping and read-across needs to be adequate also for the classification and labelling and risk assessment purposes.

When developing a read-across approach, it is important to remember that the structural similarity between the chemicals alone is not enough and that supporting scientific arguments are necessary. The approach need to be well documented, justified and supported with adequate and reliable evidence. The considerations when building and assessing environmental grouping and read-across approaches should cover the following aspects: physico-chemical properties (e.g. water solubility, volatility), abiotic and biotic degradation (e.g. hydrolysis, biodegradation), bioavailability and behaviour in the different environmental compartments (water, sediment, soil, air) under different environmental conditions (e.g. pH, temperature), bioaccumulation potential, and the mode of action on target (for biocides and pesticides) and non-target species.

This session aims to provide an overview of the state of the art in the regulatory environmental risk assessment when using read-across data. We invite scientists from academia, regulatory bodies and industry to present their experiences on building or assessing the read-across approaches, and to discuss the challenges, advances and need for development in the different regulatory contexts. Presentations may focus on experiences in addressing the uncertainties in the environmental read-across approaches, in particular application of read-across to multi-constituents substances and UVCBs. In addition, we welcome presentations on new or improved methodologies to support grouping using novel technologies and approaches (e.g. OMICS, in vitro and AOPs).

Preliminary session type: Platform and Poster

Cross species extrapolation in ERA - how well does it work for fish?

Chairs: Charles Tyler, Andrew Ross Brown, Lina Gunnarsson Kearney, Anke Lange

Fish represent the planet's most diverse group of vertebrates, comprising more than 28 000 extant species, distributed between over 430 families (Nelson, 2006). Fish inhabit almost all of the world's marine and freshwater water bodies, exhibit a wide range of life history strategies and are fundamentally important for both ecosystem function and as a human food resource. Effects of pollutants are studied on relatively few species of fish, despite the fact that most, if not all, of our fresh and marine waters receive anthropogenic sources of pollutant discharges. International chemical regulatory test guidelines currently employ only a handful of fish species routinely including, in freshwater, fathead minnow and zebrafish (family: cyprinidae), rainbow trout (salmonidae), medaka (adrianichthyidae), and bluegill sunfish (centrarchidae), and, in saline water, sheepshead minnow (cyprinodontidae), silverside (atherinopsidae), turbot (scophthalmidae). A substantial source of uncertainty in environmental risk assessment (of chemicals) stems from the practical need to extrapolate toxicity data from tests with these few 'model species' to all other fish. There are some exceptions where empirical studies on a few classes of chemicals (e.g. endocrine disrupting chemicals, PAHs) in 'non model' fish species, including chronic exposures, have provided more certainty for these cross species extrapolations.

Comparative genomics studies have demonstrated conservation of many chemical targets across numerous taxa, including fish (Gunnarsson et al., 2008; Lalone et al., 2013; McRobb, 2014; Brown, 2014). In vitro studies comparing (for example) toxicant interactions with hormone receptors (Miyagawa et al., 2014), in vivo studies and species sensitivity distributions (Versteeg et al., 1999) have shown some strong commonalities for chemical effects across divergent fish species, compared to other phyla. Some studies, however, studying detoxification enzymes e.g. CYP1A (Eisner et al., 2015) have shown differences of up to 40-fold in their chemical activation between fish species. Very few studies have been conducted that consider commonalities and differences in adsorption, distribution, metabolism, and/or excretion across different fish species, which can fundamentally affect chemical potency. More empirical studies that consider these factors are much needed. Understanding potential exposure, and resilience of fish species is also key to understanding the overall ecological risks of chemicals to fish populations (Brown et al., 2014; Ibrahim et al., 2014).

In this session we encourage presentations that help advance our understanding of comparative chemical effects across fish species. We invite contributions spanning investigations into the evolutionary conservation of chemical targets, studies into differences in features of fish physiology, behaviour and/or ecological life-histories, which influence their susceptibility to chemicals. We welcome all approaches - in vivo, in vitro and in silico - for addressing these challenges. The session compliments, but is mutually exclusive of, a session on the practicality and applicability of model fish in ecotoxicology (lead - Jessica Legradi).

Key words: Fish, models, species, susceptibility, extrapolation

Preliminary session type: Platform and Poster

Endocrine Disruptors: Exposure, Hazard & Risk Assessment

Chairs: Gerd Maack, Henrik Holbech, Tom Hutchinson

Identification and assessment of endocrine disrupters has been of scientific interest for several decades, however, regulatory interest has grown significantly in recent years. A variety of natural and synthetic chemicals have been found to interfere with the hypothalamic-pituitary-gonadal/thyroidal (HPG/T) axes of laboratory animals. Extensive weight of evidence assessments indicate that fish and other wildlife species in the field have been affected by HPG/T-active toxicants, resulting in developmental and reproductive problems. Consequently, the US the Food Quality Protection Act (1996) was passed, requiring that the US Environmental Protection Agency (EPA) screen certain types of chemicals (e.g., pesticides) for their potential to affect HPG/T function. The EPA announced the initial list of chemicals to be screened for their potential endocrine effects (Tier I testing) in April 2009 and initial findings are now available to inform regulatory considerations. The Organisation for Economic Cooperation and Development (OECD) is also working to develop Test Guidelines to detect endocrine disrupters relevant to both human and wildlife health. Test guidelines for certain modes-of-action (e.g., oestrogens) are well established; however, there is a need to continue to address other less well known endocrine modes of action. Progress in exposure assessment is also an important challenge in order to address diverse inputs of endocrine disrupters into aquatic and terrestrial environments. Exposure assessments need to take into account complex mixtures (e.g., concentrated animal feeding operations, landfill leachate, runoff and wastewater effluents). Importantly, now that several OECD test guidelines have been adopted, and the US screening program is generating significant data, a key challenge involves the integration of hazard and exposure data. In Europe there is a need to provide scientific and regulatory advice on assessing the hazard of endocrine-active chemicals under the Biocides Regulation, Plant Protection Product Regulation and REACH. This session will provide a platform discuss the state of the science and key knowledge gaps regarding the fate, exposure and population-relevant effects of endocrine disrupters. Attention will also be given to innovative new research that uses a weight of evidence approach (combining bioassays, TIE and analytical chemistry) to support inform risk and hazard assessments in the context of recent regulatory discussions.

Sponsored by: Endocrine Disrupter Testing and Risk Assessment Advisory Group (Global)

Preliminary session type: Platform and Poster

Environmental chemistry, toxicity and Risk Assessment of Natural Compounds including Biopesticides

Chairs: Nina Cedergreen, Karina Knudsmark Jessing

Natural compounds may act as pollutants both if occurring naturally, as is for example the case with cyanobacterial toxins and aflatoxins leaching from fields, and if applied in large amounts as for example biopesticides. Little is, however, known on the environmental chemistry, toxicity and resultant risk of natural compounds. With the increased focus on turning away from conventionally produced pesticides to biologically produced, and supposedly more environmentally friendly, plant protection products there is an increased need for scientifically valid data on the environmental fate and toxicity of these compounds, which are often not very well chemically characterised. In this session we wish to present data on environmental fate, toxicity and risk of naturally produced bioactive compounds. The aim is to establish state of the art knowledge of the environmental risk of this group of chemicals in comparison with the more traditional chemicals for which risk assessments and legislations exists.

Preliminary session type: Platform and Poster

Environmental risk assessment of chemical mixtures: the steps ahead

Chairs: Thomas Backhaus, Rolf Altenburger

While approaches for the assessment, management and mitigation of the impacts of local pollution from singular events and point sources are largely agreed upon and widely applied on a routine basis, the assessment of diffuse complex pollution scenarios is still a major challenge for science, environmental policy and chemical management. Meeting this challenge will require a move away from a narrow focus on individual pollutants, coarse acute individual or population level end points, the exclusive consideration of single emission sources and exposure routes towards a broader, more holistic approach. Standard instruments for chemical risk assessment and management, such as Environmental Quality Standards (EQS) or Predicted No Effect Concentrations (PNECs) need to be modernized and embedded into mixture-aware regulatory frameworks. Also, the current strategy for priority setting is too often focused on identifying individual priority pollutants. There is therefore an urgent need to identify "archetypal" mixtures that result from common emission scenarios, in order to develop more realistic priorities for chemical management.

The session aims to provide an overview and critical reflection of the current debate, to identify gaps and bottlenecks. On the one hand, the session aims to present and analyze the specific situations in the different regulatory arenas (e.g. REACH, the Biocide and Pesticide Regulations or the Water Framework Directive), using conceptual analyses or evaluations of specific case studies. On the other hand, cross-cutting, conceptual analyses are also highly welcome. The session focusses on the hazard and risk assessment as well as the management of chemical mixtures, but also encourages contributions that cover issues that go beyond chemicals and discuss the issue of multiple stressors in general. We invite presentations that analyze the issue from the perspective of all the different stakeholders (academia, industry, regulators, NGOs).

The session has be successfully run at previous SETAC meetings, always attracting a sizable crowd, indicating that the topic is of particular relevance for the SETAC community - which is hardly surprising, given the fact that even preliminary monitoring data over and over confirm that organisms are typically exposed to a complex mixture of various toxicants from various sources.

Preliminary session type: Platform and Poster

Fate and Effects of Metals: Regulatory and Risk Assessment Perspective

Chairs: Ilse Schoeters, Nathalie Dom

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.

Sponsored by: Metals Advisory Group (Global)

Preliminary session type: Platform and Poster

'Focal species' in terrestrial & aquatic risk assessments for pesticides. Concepts & practicalities of their inclusion in lab & field experiments

Chairs: Steve Norman, Seamus Taylor, Gabriel Weyman

In higher-tier bird and mammal risk assessments for agricultural pesticides, species having the potential to be exposed in a particular crop are identified. Worst case examples in terms of food intake to bodyweight ratio are selected from each feeding guild. These species are generally referred to as 'focal species'. For example, in orchards the Great tit is a focal species representing the guild of small insectivores. When initially estimating exposure of these focal species, conservative assumptions are used (according to EFSA Guidance) in terms of the proportion of diet which contains residues. A particular active substance may have an inherent moderate to high acute toxicity in standard lab tests or a conservatively-selected reproduction NOEC (perhaps influenced by a widely-spaced dose range). Coupled with the aforementioned exposure estimate this usually triggers a requirement for additional higher-tier data. Often, realistic 'effect studies' have to be conducted, escalating in scale from higher-tier lab studies, to outdoor enclosure studies, up to large-scale field studies conducted in agricultural crops. At the core of such experiments is the challenge of assessing focal species directly. This raises all sorts of conceptual and practical questions about how best to design and conduct such experiments, especially if reproduction needs to be studied. In aquatic risk assessment, the term 'focal species' is not often used. However, it seems that the process is moving in that direction. For example, for insecticides a need to address the so-called 'EPT' species (Ephemeroptera, Plecoptera, Trichoptera) and Amphipod crustaceans is now often highlighted by regulators (none of these species is included in a test guideline). The choice is then between 1: accepting increased uncertainty factors upon endpoints from other species (perhaps leading to a negative outcome), or 2: to actually conduct studies which include these focal species. As for the bird and mammal situation, this raises many questions regarding choice of species, study design, test conditions, monitoring methods and relevant endpoints, especially when the focal species are univoltine or even semivoltine. Presentations and posters are kindly invited on your own experiences and challenges in these areas, in order to facilitate discussion and increased understanding.

Preliminary session type: Platform and Poster

Future challenges for the effect and risk assessment of plant protection products with respect to sediment organisms

Chairs: Daniel Faber, Henry Krueger, Theo Brock, Paul Sibley

The sediment compartment is globally receiving more and more interest by the scientific community. In Europe the "Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water" was published by the European Food Safety Authority (EFSA)1. This scientific opinion is addressing the Environmental Risk Assessment (ERA) for the sediment compartment. At the moment, only tier 1 RA for sediment organisms is covered in the existing aquatic guidance document published in 2013 by EFSA2.

The number of currently available standardized and validated OECD test guidelines is limited. Aquatic invertebrates are covered by the OECD technical guidelines (TGs) 218/219/233 for chironomids (Chironomus riparius) and the OECD TG 225 using the oligochaete Lumbriculus variegatus. Aquatic macrophytes are addressed by Myriophyllum spicatum (OECD TG 239).

The guidelines which have been developed by the OECD differ substantially from ASTM and US-EPA guidelines. In North America a higher number of test methods with sediment organisms are available (e.g. Hyalella azteca, Chironomus dilutes, Leptocheirus plumulosus)3. The test guidelines which have been developed in North America were created to simulate chronic sediment exposure. Therefore the application of test substances and the ageing of the sediment and the exposure differ markedly from OECD test guidelines. One major difference for example is the use of natural sediment in ASTM and US-EPA guidelines instead of artificial sediment in OECD TGs. The longer ageing period as well as the flow through conditions used according to ASTM and EPA guidelines result in a totally different exposure due to bioavailability and water concentrations of the investigated test substances.

Within the session, we would like to address the differences between the OECD and US-EPA/ASTM guidelines and the consequences of the different approaches for an ERA using data from both sources. As the bioavailability in the different test systems is not directly comparable and different main uptake pathways exist for the different taxonomic groups and species, it should be discussed whether approaches as lined out in the scientific opinion are practically feasible.

References:

1"Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water" EFSA, 2015

2"Guidance on tiered RA for plant protection products for aquatic organisms in edge-of-field surface waters" EFSA, 2013.

3"Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates" US-EPA, 2014

Preliminary session type: Platform and Poster

Grouping and read-across in environmental risk assessment of nanomaterials: possible approaches, knowledge gaps and regulatory challenges

Chairs: Birgit Sokull-Kluettgen, Stefania Gottardo, Eric Bleeker

The continuous development of nanotechnology and increasing use of nanomaterials in consumer products combined with gaps in knowledge and data have led to concern about their safe use and possible negative impact on human health and the environment, which needs to be addressed in the regulatory context. Internationally, nanomaterials are regulated within a broad range of regulatory frameworks for chemicals, such as REACH in the EU or the TSCA in the US. These frameworks require that the environmental safety of nanomaterials is demonstrated by industry or the competent authorities through the assessment of information on physicochemical properties, potential exposure, fate and behaviour in the environment, and observed ecotoxicological effects. Despite the exponential increase in the number of scientific publications on ecotoxicity and environmental fate of nanomaterials, it has, so far, not been possible to identify general mechanisms of toxicity for these materials, nor to determine their fate and behaviour in complex media. On top of this, small variations in a few physicochemical properties may potentially lead to significantly different risk profiles for nanomaterials. However, at present the knowledge regarding whether or not variation(s) in physicochemical properties would lead to variation(s) in ecotoxicity and/or environmental behaviour for nanomaterials is limited. Industry and regulatory authorities are therefore faced with the challenge of efficiently gathering sufficient information for environmental risk/safety assessment of a large number of chemically different nanomaterials as well as nanoforms with the same chemical composition but differences in other physicochemical properties (e.g. size, surface treatment, surface charge, shape). This challenge could be addressed by considering possibilities for grouping and read-across of nanomaterials in line with regulatory requirements and associated guidance in this area. This field is in its infancy but some proposals are already available in the scientific literature and regulatory authorities are also studying this possibility to address data requirements.

The session therefore aims to provide a description of the state-of-the-art development of approaches for grouping and read-across of nanomaterials with focus on environmental endpoints and links to regulatory needs. We particularly encourage case studies that discuss the applicability of these approaches. Scientists from research organisations, industry and authorities are invited to present their experience and difficulties with regard to grouping and read-across of nanomaterials and to share lessons learnt. Last but not least, we invite views on future research needs for addressing uncertainties and data gaps in current and future approaches for grouping and read-across of nanomaterials.

Sponsored by: Nanotechnology Advisory Group (Global)

Preliminary session type: Platform and Poster

Habitat improvement in the agricultural landscape to assure the protection goal "biodiversity"

Chairs: Katja Knauer, Christine Kula

The protection of non-target species has always been a requirement of pesticide regulation (directive 91/414/EEC), however, under the new regulation 1107/2009/EC the protection goal was broadened and biodiversity is defined as a new protection goal stating that "impacts on biodiversity and the ecosystem" must be avoided. "Biodiversity" is defined as "variability among living organisms ... and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems".

Several MS set risk mitigation measures to protect non-target aquatic and terrestrial life when authorising plant protection products. Most often restrictions were stipulated to protect aquatic organisms, bees and birds. However, also the protection of mammals, other arthropods than bees and plants dwelling outside cropped fields contributes considerably to the protection of biodiversity in agricultural landscapes. The situation for those non-target species living in the treated field is less clear, but usually impacts are accepted if recovery can be expected to occur. In regulatory decision-making also beneficial organisms (in-crop) like insects and earthworms according to the principles of Integrated Pest Management have been considered.

The decline of biodiversity (e.g. birds, amphibians) in the agricultural landscape is of concern and some measures have been undertaken in European countries to implement ecological compensation areas to reduce the impact of agriculture on ecosystems via the Common Agricultural Policy. It was demonstrated that ecologically diverse areas gain higher resilience against effects of pesticide use on the treated fields than less diverse areas.

For this session we invite abstracts on:

•Risk assessment schemes which allow to differentiate between impact of pesticide and other stressors

•Measures to improve biodiversity or habitat structure in the agricultural landscape in the light of interactions between in- and off-field habitats

•Linking risk mitigation (or habitat improvement) to decision-making for the approval of pesticides.

Measures discussed in this session can be ecotoxicologically driven (reduction of chemical stress), or be related to land or water management, or other stressors. They may refer to protection of plants, invertebrates or vertebrates. Reports of successful or unsuccessful attempts to achieve the above goals are equally welcome!

Preliminary session type: Platform and Poster

Higher tier tests in the risk assessment of plant protection products

Chairs: Eric Bruns, Seamus Taylor, Veronique Poulsen, Ivo Roessink

In recent years, new non-standard effect and exposure assessment approaches have been developed in order to keep pace with the evolving regulatory framework for plant protection products. Recommendation for the conduct of established higher tier tools, e.g. aquatic mesocosm studies, are being or have already also been refined in this context. These complex study designs are required to be practically applicable to the regulatory risk assessment process in order to be able to draw sensible conclusions from the scientific evidence available. One of the challenges scientists face is how to improve the ecological and contextual realism of effects assessment approaches in order to enhance our ability to account for the complexity of communities and ecosystems, whilst employing more realistic exposure scenarios. This complexity is real and can lead to difficulties in reaching an appropriate regulatory balance based on current scientific evidence. As a result, it is strongly debated how the endpoints from these studies link to protection goals relevant to the agricultural landscape where pesticides are used.

For example, in aquatic mesocosm studies the realisation of realistic worst case exposure situations and the exposure of many species from different taxonomic groups and trophic levels, including species interactions, allow the assessment of effects on and recovery of affected populations as well as the analysis of indirect effects. In recent years, however, the focus of aquatic (semi-)field studies has shifted from a community perspective to the assessment of threshold concentrations for individual sensitive species, while the recovery assessment is seen more critically due to the presence of just one stressor (the test item) in such tests. The same can be said of terrestrial field studies (e.g. on non-target arthropod or soil invertebrate communities). However, to some extent, effects on population abundance and biomass are considered acceptable (Draft EFSA Guidance Document to define protection goals for environmental risk assessment in relation to biodiversity and ecosystem services). Also, functional redundancy (a key-feature of communities), and recovery of ecosystem functions and services are regarded as essential components of the environmental risk assessment of PPP (Draft EFSA Scientific Opinion on the temporal and spatial ecological recovery of non-target organisms for environmental risk assessments).

Abstracts are welcomed from industry, researchers, regulators, and CRO's for this session which aims to provide a forum for the sharing knowledge and experience in linking higher tier studies to protection goals. Questions to be addressed could be: how to deal with the requirement to have at least eight potentially sensitive populations present in sufficient numbers in a mesocosm study? How to assess recovery of vulnerable species considering the different protection goals and the issue of multiple stressors? How can we better link our experiments to the reality in the field / landscape? How can the results be used to reach balanced evidence-based decisions?

Preliminary session type: Platform and Poster

Identification and prioritisation of hazardous pollutants in the aquatic environment - the role of effect-directed analysis, monitoring and modelling

Chairs: Werner Brack, Jaroslav Slobodnik, Jos van Gils

About 100 million of different chemicals are known and registered in the Chemicals Abstract System, more than 100.000 of chemicals are in daily use and ten thousands of chemicals (including many unknowns) are typically detected as complex mixtures in aquatic environments such as sediments, soil, water and biota. Thus, hazardous pollutants need to be identified and prioritised from the site via the basin till the European scale. A train of complementary approaches is required to address this need including 1) site-specific toxicant identification by effect-directed analysis (EDA), 2) effect-based and multi-and non-target chemical screening together with multivariate tools to identify River Basin Specific Pollutants and 3) modelling- and scenario-based approaches to prioritise chemicals that are produced and used in Europe based on fate, transport, (mixture) effects and risk models.

This session wants to present innovative tools and approaches for toxicant identification and prioritisation and interesting case studies on different scales and in different matrices (water, sediment and biota). Particularly welcome are integrated approaches and new attempts to combine EDA, monitoring and modelling for a more consistent prioritisation of emerging pollutants and mixtures in aquatic ecosystems and water resources relevant for human health via drinking water abstraction or fishery.

Preliminary session type: Platform and Poster

Identifying and regulating PBT and vPvB chemicals: Requirements, challenges and policy implications

Chairs: Silke Gabbert, Monika Nendza, Stefan Hahn, Heinz Ruedel

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 for humans and ecosystems. PBT and vPvB chemicals are, therefore, of primary regulatory concern. Several European legislations, for example REACH (Regulation EC No 1907/2006), the Plant Protection Product Regulation (EC No 1107/2009), or the Biocidal Products Regulation (EC No 528/2012) aim to identify PBT and vPvB chemicals and to trigger effective regulatory measures in order to minimize the use of such substances.

The need for harmonization and improving existing approaches for identifying PBT and vPvB chemicals has been recognized by scientists, policy-makers and stakeholders. Generally, the identification of PBT and vPvB chemicals is based upon defined (screening) criteria using more or less conservative thresholds. Furthermore, it is assumed that existing criteria take a too narrow perspective on PBT/vPvB assessments, ignoring other important properties such as their long-range transport potential (LRTP) and their long-term damage potential (stock pollution property), which applies also to pseudo-persistent chemicals. As a consequence, some PBT/vPvB chemicals may be ignored. Evidence-based approaches to PBT/vPvB assessments may additionally include, for example, the use of monitoring data (e.g. to prove LRTP or biomagnification in food webs) or computational methods such as quantitative structure activity relationships (QSARs) and read-across (RAX). Closely related to the challenges around 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 account for the complex properties of PBT/vPvB chemicals in an SEA for coherent regulatory decision-making.

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 equal interest as presentations addressing challenges in the determination of the properties themselves, or approaches using environmental monitoring data. 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.

Preliminary session type: Platform and Poster

Innovative techniques for monitoring chemicals in the environment

Chairs: Lorraine Helen Youds, Chris Metcalfe, Yelena Sapozhnikova

Innovative technologies and new analytical techniques for pollution monitoring are fast increasing in usage by researchers, regulators and policy-makers in the field of ecotoxicology. Technological innovations in pollution monitoring include devices such as: mobile phones; passive samplers; miniaturised sensors; and robotics. New technologies provide a number of advantages over current monitoring methods in that they allow us to: quantify levels of pollution at greater frequencies and spatial resolutions than is currently possible; monitor locations that in the past have been difficult to sample (e.g. hostile environments or systems with accessibility issues); and characterise human and ecological exposure to the plethora of chemicals that have never been monitored before.

A particular application for new technologies includes (but is not limited to) the monitoring of contaminants of emerging concern (CECs) in the environment. New sensing technologies may also reduce barriers to CECs' sample collection and analysis through the application of real-time sensing and data provision. Furthermore, use of newly-developed and reliable analytical techniques (such as time of flight mass spectrometry and developments in biological assays) allow us to determine the occurrence, behaviour and fate of CECs. Newer CECs that have not previously been recognised require novel analytical methods for their characterisation, identification and detection.

Effective application of the myriad pervasive technologies provides a better understanding of the degree of exposure of humans and wildlife to pollutants and hence the risks of these pollutants to ecosystem and human health. Use of state-of-the-art analytical methods is required to detect and quantify newer CECs, which have proven difficult to analyse due to their susceptibility to degradation and transformation.

Innovative technologies and new analytical methods can also be used to inform mitigation measures both in the short term and over longer timescales. However, significant barriers to use of the data and information provided by new methods of assessment exist. For example, users of pollution data (general public and decision-makers) are often hindered by a lack of understanding of the information provided and/or a knowhow related to integration of new data into current regulatory and policy frameworks. This session will promote an open discussion inclusive of representatives from the academic, industrial, governmental and regulatory sectors, who are interested in the development of new technologies and methodologies for pollution monitoring.

Implications for human health and wellbeing, ecosystem health, big data management and stakeholder involvement and the use of new pollution data will be explored.

Preliminary session type: Platform and Poster

Large data sets in environmental analysis and assessment - let's start to ride the wave

Chairs: Tobias Schulze, Peter Haglund, Michael Andrej Stravs

State-of-the-art analytical instrumentation used in environmental analysis, especially that equipped with mass spectrometry detectors, and high-throughput bioassays produce a huge amount of primary and secondary research data in the range from some hundreds of gigabytes up to pentabytes per year. These large datasets are challenging in terms of their storage, handling, curation, evaluation, data exchange and data sharing. With regard to the Horizon 2020 Open Data Pilot, most of the European Community funded projects are obliged to share primary and secondary research data with their community and beyond. Hence, the aim of this session is to start the discussion how the environmental community will face the upcoming ever larger datasets challenge. In this session, all contributions are welcome that focus on

(1) community data sharing,

(2) data storage and long-term archiving in databases and repositories,

(3) tools for evaluation and modelling of data in large datasets,

(4) interoperability and integration of environmental data with other communities and existing platforms (e.g. metabolomics), and

(5) establishment of common standards and ontologies (terminologies).

Preliminary session type: Platform and Poster

Management and Control of Pharmaceutical Manufacturing Effluent

Chairs: Daniel Caldwell, Robert Kase, Ad Ragas

Pharmaceuticals have been detected in the environment in trace quantities, most at less than 1 µg/l. While patient use and excretion accounts for over 90% of the environmental load of pharmaceuticals, another pathway to the environment is through wastewater discharged from pharmaceutical manufacturing sites. Pharmaceuticals have been measured downstream of manufacturing plants in China, India, Denmark, France, Germany, Spain, Switzerland, and in the United States, often at higher concentrations. While the overall contribution of pharmaceutical manufacturing activities to the levels of pharmaceuticals in the environment is low when compared with the amount excreted by patients consuming the drugs, manufacturing discharges are one source that can be readily controlled. This session will discuss methods to evaluate pharmaceutical discharges from manufacturing to determine potential risk to aquatic life and impacts on ecosystem services, and identify appropriate risk mitigation measures.

Preliminary session type: Platform and Poster

Oil and Gas Extraction: Ecological Effects and Science-Based Management

Chairs: Suhur Saeed, Christopher Warren, Ketil Hylland

Oil and gas extraction activities require effective management and oftentimes mitigation to avoid significant impact to the surrounding environment. For example, the co-production of potentially enormous volumes of water with varying quality, commonly referred to as 'produced waters', provides one such environmental challenge. However, in an area with scarce water resources, efforts to re-use produced water may help turn a challenge into an opportunity. There are many other examples of how scientific research can help shape environmental management and regulation within the petroleum industry through better understanding of impacts and innovative approaches to addressing their mitigation.

This session will focus on practices for environmental monitoring, environmental impact/risk assessment, impact/risk mitigation and technology development approaches related to oil and gas exploration and production activities. Scientists, regulators and industry representatives are invited to present their latest achievements in the field of e.g. offshore and inshore oil and gas extraction regulations, environmental risk assessment, oil spill impact assessment, produced water treatment, re-use and impact mitigation, environmental effects monitoring and modeling. Abstracts are especially welcomed on integrated assessments and management techniques for operations in the Arabian Gulf region and the Arctic.

Preliminary session type: Platform and Poster

Passive sampling and toxicity profiling

Chairs: Timo Hamers, Ron van der Oost

In recent years, many monitoring initiatives have been undertaken in which passive sampling techniques were combined with toxicity profiling, such as the Joint Danube Survey (ICPR), the Toxicity as Ecological Key Factor project (STOWA) and the TIPTOP project (CEFIC). Whereas traditional chemical monitoring is based on compound-by-compound target analyses of time-point grab samples, these initiatives try to use more ecologically relevant monitoring techniques for environmental quality assessment. Passive sampling has the advantage that it integrates concentrations of pollutants over time while accounting for bioavailability. Toxicity profiling has the advantage that it directly reflects the toxicity of the complex mixture present in the sample, including unknown substances, transformation products, and compounds present at levels below their analytical limit of detection. Moreover, a test battery can be used for effect-based monitoring consisting of in vitro bioassays covering a spectrum of different mechanisms of action, in vivo bioassays covering different trophic levels, or a combination of the two. The test battery can be regarded as a safety net for microcontaminants , which can signal the presence of potentially toxic compounds in the environment at low concentrations.

For this session, we invite participants to present the results from monitoring studies applying passive sampling in different environmental matrices (water, sediment, air), toxicity profiling with in vitro and/or in vivo bioassays, and preferably a combination of passive sampling and toxicity profiling. Contributions addressing the ecological relevance or cost-effectiveness of such monitoring strategies for environmental quality assessment purposes, if possible compared to traditional chemical monitoring, are especially welcomed.

Preliminary session type: Platform and Poster

Risk Assessment of Biocides- latest developments

Chairs: Anja Kehrer, Anja Coors

Biocides are very diverse group of 22 different product types used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. Harmful organisms in the context of biocides are e.g. rodents, algae, fungi, bacteria or aufwuchs. Examples of biocidal products are insecticides, rodenticides, disinfectants, insect repellents or anti-fouling paints for ships. Because of their intrinsic properties biocides can pose risks to humans, animals and the environment.

Biocides are regulated by the Biocidal Products Regulation 528/2012 (BPR), which entered into force on 1 September 2013. It repeals Directive 98/8/EC (BPD) and aims to provide a high level of protection for humans, animals and the environment. However, with the new Regulation several new aspects have to be covered by the applicants as well as the evaluating member states like e.g. the assessment of the mixture toxicity of products, aggregated exposure assessment or comparative assessment - and there also open questions which have not been solved under the "old" Directive e.g. how to cover Disinfection-by-Products.

The session will provide an overview of the latest developments in the assessment of biocides including risk assessment and risk mitigation options as well as their sustainable use.

Preliminary session type: Platform and Poster

Science based strategies for the environmental assessment and management of pharmaceuticals and veterinary medicines

Chairs: Reinhard Laenge, Bryan Brooks, Todd Davidson, Caroline Moermond

Strategies to evaluate and, if required, mitigate the impact of human and veterinary pharmaceutical compounds are being developed and advocated within the European Union and its member states. The current system of environmental risk assessment (ERA) for medicines as part of the authorization process for new products contributes substantially to the knowledge of the potential risk that these compounds may pose to the aquatic and terrestrial environment. However, a number of aspects of the present procedures and the transparency of data limit the application of these data resources for more general purposes beside the authorization of a new, specific product. First of all, many active pharmaceutical ingredients (APIs) which were introduced to the market before the currents ERA requirements were adopted, lack sufficient environmental data to perform a comprehensive assessment of their potential environmental risk. Secondly, the information on environmental risks for compounds authorized for marketing is rarely updated during the life cycle of the product and thus, increasing scientific knowledge and updating of testing and assessment methodology is not applied to marketed compounds. As a consequence the regulatory risk assessment can become dated. Additionally, the responsibilities and ownership of data can be split amongst several or many enterprises, once an API loses exclusivity. This makes the development and maintenance of a single, overarching compilation of environmental data difficult. Last but not least, for human pharmaceuticals the potential environmental impact of an API should not be evaluated in isolation, but the therapeutic benefit for human patients needs to be considered and potential environmental risk mitigation measures should not impede free access to medicines for patients. For veterinary medicines, regulations allow mitigation measures at several levels based on environmental concerns, the effectiveness of those measures is sometimes debated. Comprehensive impact assessments for environmental risk mitigation measures need to be prioritized that deliver effective, quantifiable and pragmatic environmental protection whilst maintaining access to medicines and the societal and economic benefits. Considering these aspects, a thorough evaluation of the potential impact of pharmaceutical compounds is required based on available scientific information, and new strategies for developing data on fate, effects and distribution pathways of APIs, implementation of options for regulatory use of this data bases, the development of options for mitigation of any environmental risks, socio-economics and development of new processes for a cooperative approach between all stakeholders are needed.

Session keywords: Science- Prioritizing risks, communicating the science, science-based policy / Current procedures for environmental risk assessment of human and veterinary pharmaceuticals in the EU and elsewhere / Regulatory schemes, efficiency and effectiveness / Environmental concerns and therapeutic needs / Impact assessment, communicating risk, keeping the issue in perspective / Socio-economics / Future perspectives / Direction, improvements

Preliminary session type: Platform and Poster

Standards - an essential link between environmental science and regulation

Chairs: Sebastian Buchinger, Adam Lillicrap, Kirit Wadhia, Cecile Grand

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 environmental risk assessments in the future both for aquatic and soil ecotoxicology, standard test methods are likely to play a substantial role to ensure that robust and reliable data are generated.

Beside others, the Organisation for Economic Co-operation and Development (OECD) and the International Standards Organisation (ISO) make significant contribution to meeting the regulatory demand for standardized test methods; OECD focusing on the assessment of chemicals while ISO is dealing with the determination of water and soil quality in both chemical analysis and biological testing. Over the last few years, important milestones have been accomplished or developments are currently in progress for new standardised test methods 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 the development, validation and regulatory acceptance of new standardised test methods 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 ISO technical committee 190 (Soil Quality).

Preliminary session type: Platform and Poster