Challenges in Environmental Assessment of Cosmetics and Personal Care Products

Jacques Lharidon, Erwan Saouter, Iain Andrew Davies, James M. Lazorchak

Wednesday May 25, 8:15 AM - 10:15 AM, Salle R0-B

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.

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

Ulla Helminen, Jose Tarazona

Tuesday May 24, 8:10 AM - 18:30 PM, Exhibition hall (poster only session)

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).

Endocrine Disruptors: Exposure, Hazard & Risk Assessment

Gerd Maack, Henrik Holbech, Tom Hutchinson

Wednesday May 25, 8:15 AM - 12:50 PM, Salle 300

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.

Environmental risk assessment of chemical mixtures: the steps ahead

Thomas Backhaus, Rolf Altenburger

Tuesday May 24, 10:50 AM - 4:00 PM, Salle 150

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.

Fate and Effects of Metals: Regulatory and Risk Assessment Perspective

Ilse Schoeters, Nathalie Dom

Tuesday May 24, 10:50 AM - 12:50 PM, Salle 200

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.

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

Katja Knauer, Christine Kula

Tuesday May 24, 5:30 PM - 6:00 PM, Exhibition Hall (Poster corner session)

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!

Higher tier tests in the risk assessment of plant protection products

Eric Bruns, Seamus Taylor, Veronique Poulsen, Ivo Roessink

Tuesday May 24, 8:15 AM - 12:50 PM, Auditorium 450

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?

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

Werner Brack, Jaroslav Slobodnik, Jos van Gils

Thursday May 26, 8:15 AM - 12:50 PM, Auditorium 450

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.

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

Silke Gerda Margaret Gabbert, Monika Nendza, Stefan Hahn, Heinz Ruedel

Thursday May 26, 10:50 AM - 12:50 PM, Salle R0-B

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.

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

Christopher S Warren, Ketil Hylland

Tuesday May 24, 8:10 AM - 6:30 PM, Exhibition Hall (Poster and Poster corner session)

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.

Pollutant risks to amphibians and reptiles: how much we know and what we need

Manuel Ortiz Santaliestra, Isabel Lopes, John M. Brausch

Wednesday May 25, 2:00 PM - 4:00 PM, Salle G+H

Amphibian and reptile toxicity data have not been traditionally taken into account when assessing risks of man-made chemicals that are released to the environment. Historically, amphibians and reptiles are considered to be protected by data retrieved from other vertebrate taxa. In consequence, no standardised guidelines for toxicity assessment in these groups exist and ecotoxicological information is still limited compared to other vertebrates. The recent inclusion of amphibians and reptiles in the terrestrial ecotoxicological risk assessment, required for the authorisation of plant protection products, according to the European legislation (Regulation 284/2013), has focused the spotlight on the scarcity of information about these animals, and in turn on the necessity of using the little available information and conducting studies to generate new, relevant data. The European Food and Safety Authority has announced the development of a Guidance Document on pesticide risk assessment for amphibians and reptiles for the upcoming years, and is already involved in a process to compile useful information with this purpose. This session aims to create the environment for scientist from all sectors, as well as for regulators, to share novel information and to raise issues related to the development of a new ecological risk assessment framework for European amphibians and reptiles. Some examples of major themes to be tackled in this session are: (i) effects of pesticides and emerging pollutants on different life stages of amphibians and reptiles; (ii) identifying and understanding the role of major exposure pathways in observed effects, (iii) establish possible associations between in vitro versus in vivo responses and among different life stages/biological organisational levels targeting the substitution of animal experimentation in these two taxa. The session is promoted by the SETAC Global Advisory Group of Ecotoxicology of Amphibians and Reptiles.

Prospective and retrospective soil risk assessment of chemical stressors

Patrick Kabouw, Juliska Princz, Mark Maboeta, Silvia Pieper

Monday May 23, 2:00 PM - 4:00 PM, Salle 150

Soils are a non-renewable resource that provides a habitat for an extremely diverse range of organisms, thereby delivering unique ecosystem services. However, soils should not be taken for granted. Soils need care, maintenance, protection, and in some cases, restoration, to ensure the sustainability and continued delivery of these unique ecosystem services. Although soils are important they are often described as "a black box".

Ecologists are slowly unraveling this complex "black box" with its interactions and dependencies. Although research is aided by novel innovations and more holistic approaches, there is still a long way to go in understanding how soils are able to sustainably deliver ecosystem services.

Soils need protection but how to protect and restore soils when the processes, species, and functions are so diverse and little understood? In this session, we aim at linking scientific innovations to regulatory developments. These developments include the recent scientific workshop1 on soil risk assessment for chemical substances (i.e., industrial chemicals, pesticides and biocides), guidance on the characterisation of exposure of soil organisms to, e.g. pesticides2, and ongoing work on risk assessment. In addition, the session addresses ongoing discussions on the use of NOEC vs. ECx values, the design of higher tier effect studies, statistical power of laboratory and field tests, appropriate soil test species, and how to address the protection of biodiversity and soil ecosystem services.

In this session, we welcome work related to current soil risk assessment schemes - both prospective and retrospective - for different chemical substances. This session aims to contribute to the protection of soil biodiversity and important related ecosystem services. Therefore we welcome presentations on innovative methods in effect assessment, new methodologies in the statistical evaluation of data, and theoretical and practical suggestions on how to improve soil risk assessments.

1) http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-soil-risk-assessment

2) EFSA (European Food Safety Authority), 2015. EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2015;13(4):4093, 102 pp., doi:10.2903/j.efsa.2015.4093

Risk Assessment of Biocides - latest developments

Anja Kehrer, Anja Coors

Monday May 23, 10:50 AM - 12:50 PM, Salle 150

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.

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

Reinhard Laenge, Bryan W. Brooks, Caroline Moermond, Daniel J. Caldwell

Wednesday May 25, 10:50 AM - 12:50 PM, Salle R0-B

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

Standards - an essential link between environmental science and regulation

Sebastian Buchinger, Adam Lillicrap, Kirit Wadhia, Cecile GRAND

Thursday May 26, 8:15 AM - 10:15 AM, Salle R0-B

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).