

## **Are we going about chemicals risk assessment for the aquatic environment the wrong way?**

Andrew Johnson, John P. Sumpter, Valeria Dulio, Dean Leverett

Wednesday May 25, 2:00 PM - 4:00 PM, Salle R2

The aim of this session is to provoke debate over the current direction of ecotoxicology and risk assessment for chemicals in the aquatic environment. The aim of ecotoxicology is to protect wildlife in the natural environment from our chemicals. The major focus of this discipline has been to identify which synthetic chemicals represent the greatest threat from the many thousands out there. In 1980 Richard Schoettger stated 'frankly, the US scientific community does not have the time, research facilities, trained personnel, experimental animals, nor financial resources to provide the additional data needed for comfortable predictions of the possible environmental effects of a broad spectrum of chemical contaminants'. Despite such a warning, scientists have continued to attempt this. Many published studies now report changes in gene expression, protein profiles and metabolite profiles, without linking them to any phenotypic change relevant to the wellbeing of the animal. Have we become too caught up in detail and lost sight of the wider picture? The task of testing thousands of chemicals against hundreds of aquatic species with thousands of end-points is daunting enough, but it has become even more challenging as we realise chemicals mixtures may harm wildlife.

What is surprising is that, whilst we rely more and more on laboratory ecotoxicity studies for our risk assessments, what is actually happening to wildlife in the river is receiving little attention. There are, however, some who have taken an interest and used the large monitoring datasets collected by regulators to link biodiversity with local pressures. What has received less attention from these approaches, however, are the trends in wildlife over time. Perhaps we need to ask if the aquatic wildlife populations that are most exposed to wastewater are the ones in decline?

Despite our concern over reductions in fish fertility associated with endocrine disruption, there is little evidence that fish populations are in peril. Indeed, fish biologists suggest that UK cyprinid populations have been recovering since reaching a low-point in the 1950s-1970s. What we may consider in our laboratories to be the worrying effect of a chemical on an individual organism may be irrelevant in relation to the more important factors controlling reproduction and recruitment in the wild. The central assumption key to current risk assessment, that effects observed in the laboratory or predicted by models are readily transferrable to the population level, is therefore questionable. If we don't know whether our wildlife species are declining or increasing, how valuable are our other ecotoxicological activities?

## **Consensus building in life cycle impact assessment: experiences, achievements and challenges**

Olivier Jolliet, Rolf Frischknecht, Llorenç Mila i Canals, Serenella Sala

Wednesday May 25, 2:00 PM - 4:00 PM, Auditorium 450

Improving life cycle impact assessment models to be applied in the integrated environmental assessment of products is crucial. Several efforts are ongoing to address this need of improvement.

To answer this, the UNEP-SETAC Life Cycle Initiative (2012-2017) has launched a flagship project to provide global guidance and build consensus on environmental LCIA indicators (see <http://www.lifecycleinitiative.org/>). The flagship project is focusing on building consensus for different impact categories.

A Pellston workshop (to be held in January 2016) will be devoted to find consensus on a first set of impact categories, namely: land use impact on biodiversity, water depletion, respiratory inorganics, climate change. The overall LCIA framework as well as several cross cutting issues will be also discussed. A common case study is being developed and serves to test and evaluate the harmonised impact indicators and to ensure their practicality.

The aim of the special session is to report the result of the Pellston workshop and to discuss the way forward, e.g. in policy and business related contexts.

Regarding the European policy context, the European Commission is aiming at a similar process covering land use related impact at midpoint, water related impact, respiratory inorganics and resource depletion to be used in the context of the Product Environmental Footprint studies. Progress on this impact assessment harmonization process will also be presented in this session.

Acceptability and applicability of the methods will be discussed aiming at improving the use of the models in practice and the interpretation of the results. The session will also place some emphasis on the balance between continued methodological development and the need for stability and consensus for more efficient use of life cycle approaches in policy and private sector, supporting decision-making and communication.

## **Ecotoxicological assessment and water quality monitoring in support of marine and freshwater legislation in Europe**

Olivier PERCEVAL, Ketil Hylland

Tuesday May 24, 2:00 PM - 4:00 PM, Salle R0-B

Despite having shown their usefulness in environmental risk assessment and in monitoring programmes over the past couple of decades, biomarkers, bioassays or other bioanalytical tools have not been widely implemented in current European marine and freshwater legislation, such as the Water Framework Directive and the Marine Strategy Framework Directive. Effect-based methods have further been used in promising new approaches to assess the potential hazards of industrial chemicals and to evaluate the quality of effluent discharges. Again, such methods have not yet been widely used in a regulatory context, e.g. in support of REACH and the Industrial Emissions Directive (IED). This session will focus on papers that show the use of ecotoxicological (effect-based) methods in contexts relevant to current environmental legislation in Europe, either environmental assessment, chemical risk assessment or effluent assessment. Studies focusing on the requirements for successful applications, for instance through the standardisation of bioassays and biomarkers and the implementation of QA/QC procedures, will be also covered by this session. In addition to invited platform presentations, poster presentations are also welcome.

## **Improving the usability of ecotoxicology in regulatory decision-making: findings from a SETAC Pellston® Workshop**

Marlene Agerstrand, Jane P. Staveley

Monday May 23, 8:15 AM - 10:15 AM, Salle G+H

A SETAC Pellston workshop was convened in September 2015 with the goal of developing guidance on steps that can be taken to improve the use of all ecotoxicity data in prospective risk assessments, whether the data are from guideline studies conducted under Good Laboratory Practices or from research studies published in the literature. A main aim of the workshop was to increase understanding between those conducting studies to be published in the peer-reviewed literature and regulatory institutions assessing those studies. This includes an understanding of the advantages and limitations of guideline, GLP studies. The workshop addressed processes to 1) improve the reliability and reproducibility of ecotoxicity studies; 2) improve the use of peer-reviewed studies in regulatory risk assessment of chemicals; and 3) improve the methods used in risk assessments when evaluating single pieces of evidence or lines of evidence. Recommendations on good practices for study design, establishment of minimum requirements for reporting the methodology, performance and results, and proposals for improving consistent use of the information during the regulatory processes were discussed. Other issues of importance were: regulators' view of academic research; the role of scientific journals in promoting reliability and reproducibility of studies; actions industry can take to increase the transparency of studies; methods for enabling transfer of knowledge between stakeholders; and tools for improved risk assessment. This session will be constructed to include opportunities for discussion with the audience.

## **Science Integrity and Publication Bias**

Maurice Zeegers

Tuesday May 24, 2:00 PM - 4:00 PM, Auditorium 800

There is a broad consensus among academic institutions, government and industry that more systematic and explicit attention should be paid to scientific integrity. Responsible Conduct of Research (RCR) is not only an ethical responsibility. It is also a relevant operational priority in times when there is increased scrutiny from government, regulatory authorities stakeholders and the public, and the reproducibility of research findings appears to be low. Previous studies have shown that on average 2% of scientists conduct fraud and 34% are involved in Questionable Research Practices (QRP), which due its high frequency may have a larger organizational impact. Surveys have shown that the most common QRP is not to publish a valid study. If the likelihood of publication is related to the study outcome (often negative) Publication Bias occurs. This conference addresses this topic with a special session and an associated poster session.

The special session will include plenary contributions on Research Integrity and Publication Bias from different angles: academia, science institutes, academic journals, industry and government and will conclude with a forum discussion on the topic. The aim of the poster session is to provide a platform to authors to present valid studies, regardless their sample size or reported outcomes and not likely to be published elsewhere because of less desired outcomes or other reasons. The only criteria for inclusion in the poster session will be that the study should be conducted with a reasonable study design. This session and subsequent similar poster sessions at future SETAC meetings will be included in a web-based database and published by SETAC to bring this research into the public domain and contribute to an unbiased availability of study results.

## **Tendency towards higher complexity in environmental risk assessment of Plant Protection Products: to accept or to avoid?**

Tobias Frische, Veronique Poulsen

Tuesday May 24, 2:00 PM - 4:00 PM, Auditorium 450

The environmental risk assessment for the authorisation of Plant Protection Products (PPP) in the context of Regulation EC 1107/ 2009 is a complex and demanding science-based process. Decision making according to Regulation (EC) No 546/2011 requires that no authorisation shall be granted if standard criteria (i.e. trigger values for the acceptability of risk assessed at a more generic Tier 1 level) are failed. However, the Regulation opens for a refined risk assessment by the additional sentence: "unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the PPP in accordance with the proposed conditions of use". This means that when the evaluation aims at reflecting more realistic "higher-tier" conditions - both in terms of exposure and effect - the risk assessment approaches tend to become more complex and more open to expert judgment. This development is questionable in several ways e.g.

- Increasing the realism only of individual aspects of the risk assessment might result in new uncertainties and thus questionable protectiveness of the regulatory decisions
- Increasing the realism of risk assessment means a higher demand for expertise in industries and authorities and time in processing of applications for authorisations
- Increasing the realism of risk assessment means increasing of complexity of risk assessment and decision making and is therefore a challenge for risk communication

The aim of this session is to initiate a broader discussion on this issue of "increasing complexity in ERA" in terms of both the scientific and regulatory perspectives and to explore the implications and achievable benefits for environment and society. Therefore we invite various stakeholders (industry, academia, regulatory authorities, NGOs) to present their experience and opinions, discuss the benefits and drawbacks of this development. In order to enable for more discussion time during the session, it is proposed to reserve the last time slot of the session for an open discussion by the audience.

## **The sustainability of wine production in Europe**

Fabrice Martin-Laurent, Sabine Elisabeth Apitz, Serge Delrot

Wednesday May 25, 2:00 PM - 4:00 PM, Salle R0-A

The value of sustainability, ecosystem services and footprint concepts are best demonstrated with examples. Following sessions on the sustainability of Whiskey, Chocolate and Olive Oil, a special session on the Sustainability of wine production, covering both the production of sparkling (Champagne) and still wines is proposed. Viticulture has a major economic importance in France, Europe and over the world, but this industry must face several challenges including the need to decrease phytochemical treatments and to adapt to climate change and competition with new wine producing countries. Economic and biological constraints are diverse and depend on the type of wines produced and its area of production. For example, these constraints markedly differ for the production of sparkling wines (Champagne), spirits (Cognac) and still wines (Bordeaux).

The viticulture sector, with a long tradition as part of French and other European cultures and landscapes, is in some places being modernized by intensifying production and creating bigger farms whilst in other regions traditional or intermediate approaches are being used. Depending upon how practices are changed, this may lead to lower prices due to overproduction, loss of biodiversity at farms and an increase of soil erosion. Wine production has environmental impacts at many stages of the lifecycle; the most important drivers include irrigation, agrochemical applications (including fertilizers and pesticides); as well as impacts from production, packaging and shipment. Toxic impacts include environmental and public health impacts from use of agrochemicals during grape cultivation. Since 2001, the Champagne and Bordeaux wine producing areas have worked towards more sustainable production and distribution. Goals include: Participation of several thousands of farmers in both regions, and reduction in use of agrochemicals by 50% using integrated crop management, the cleaning up of vineyards to promote the natural ecosystems and soil function, waste management and sustainable transport. Life Cycle and ecosystems thinking and approaches and assessment methods have increasingly been applied to agricultural systems. This session will carry on from previous sessions and explore how these concepts can be adapted and integrated to provide better insights.

The production of wine is an ideal topic within which to examine the integrative dimensions of sustainability and ecosystem services concepts. The session will examine champagne production in terms of following topics:

- Ecosystem services dependencies and impacts
- Life Cycle Assessment and Environmental footprints
- Waste management
- The socioeconomic importance
- Sustainability, and its links with ES flows

The session is planned for 120 minutes and will consist of 3-4 presentations and a discussion. We believe this special session should attract participants in the fields of sustainability, systems ecology, ecosystem services, environmental footprints, land degradation, biodiversity, and life cycle analysis.