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EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

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ECETOC workshop addressed aquatic toxicity using species sensitivity distribution

Predicting the toxicity of chemicals to aquatic communities is an integral element in environmental risk assessment. It is therefore a major component in environmental protection strategies and in the process of managing the safe use and disposal of chemicals. Hazard (toxicity) is most frequently predicted using concentration–effect data from single species toxicity tests which measure effects on individuals. However, the protection goals are generally wider i.e. populations, communities and ecosystems. Species sensitivity distributions, SSDs, describe the statistical distribution of species sensitivity to a toxicant and so can predict hazardous concentrations (HCps) affecting a certain percentage (p) of all the species in a community. Estimated HCps for environmental protection are usually the 5th percentile of the distribution and are used to derive a protective threshold concentration for an ecosystem.

Group photo of the workshop participants

ECETOC and the Environment Agency for England organised a 3 day workshop to discuss and review current statistical SSD models, when and how they should be used in regulatory applications and their ecological significance. There were 41 attendees with experience in ecological risk assessment, ecology and statistics from academia, the chemical industry and the regulatory community. 18 presentations were given during the workshop which covered the broader aspects of the use of SSDs in environmental protection and management, recent developments and specific case studies. In addition there were 3 syndicate sessions (with 4 discussion groups each) which focused on ecological, statistical and regulatory considerations.

A number of recommendations were made on how SSD methods could be further developed to improve the quality of decisions needed from both the prospective risk and retrospective impact assessment of chemicals.

The findings of the workshop are published as ECETOC Workshop Report No.28: Estimating toxicity thresholds for aquatic ecological communities from sensitivity distributions. 11-13 February 2014.

The report can be freely downloaded via http://bit.ly/ecetoc-wr28

In addition to the Workshop Report, a special issue is going to be submitted in the coming months to the SETAC Journal "Integrated Environmental Assessment and Management (IEAM)"

In This Issue

Date announced for 2015 AGM and ATM

The 2015 Annual General and Annual Technical Meetings will be held at the Pullman Brussels Midi Hotel, Brussels, Belgium, on Tuesday, 3rd March 2015. The day will kick-off with the AGM (for Member Company Delegates only). The ATM, entitled "Science Approaches in Risk Assessment – Opportunities to Agree" will follow. Further details on the ATM will be published on the ECETOC website early in the New Year. Participation is by invitation only for both meetings.

The ECETOC Secretariat would like to wish all our readers Season's Greetings and a very Happy, Prosperous New Year!

Each December, ECETOC donates to charity the money saved by sending only electronic greeting cards. This year, we have donated Euro 1000 to "Samu Social" who help the homeless living on the streets of Brussels (www.samusocial.be).

Recent Events

Symposium on Environmental Risk Assessment of Non Extractable Residues

14–15.Oct.14, Brussels, Belgium, at SETAC Europe 10th Special Science Symposium: Bioavailability of Organic Chemicals: Linking Science to Risk Assessment and Regulation

This workshop focused on recent developments in the risk assessment of non extractable residues (NER) and discuss their environmental and regulatory significance. The workshop linked extractability with bioavailability within the context of environmental risk assessment and PBT (Persistence, Bioaccumulation and Toxicity) assessment. It also identified the immediate regulatory and research needs.

Eurotox 2014: ECETOC Christa Hennes Young Scientist Award

7-10.Sep.14, Edinburgh, Scotland

In 2014, the award has been renamed in memory of Dr Christa Hennes who sadly passed away in December 2013 and who was instrumental in organising this award. This is a Best Poster Award for toxicological research into mechanisms and risk assessment, selected by a panel in which ECETOC participates. The winner receives a monetary prize and a free invitation to the following year's EUROTOX meeting.

The 2014 winner is Dr Laura Pastor Castro of the University of Navarra, Spain, for her abstract "Sex-dependent gene expression of kidney transporters after ochratoxin A exposure in F344 rats".

Event website:
http://www.eurotox2014.com

Upcoming Events

Annual ECETOC Environmental Progress Review

12-13.Feb.15, Brussels, Belgium

The Annual ECETOC Environmental Progress Review will be held in Brussels on 12th and 13th February 2015 and will be attended by environmental experts within ECETOC Member Companies. An update on current ECETOC and LRi environmental projects will be presented on the first day. On the second day, ECETOC Member Company scientists will participate in a brainstorming session to generate new ideas for the 2015 ECETOC activities and for RfPs within the LRi programme. This is an opportunity for Member Companies to propose ideas and to provide input directly into ECETOC and Cefic LRi scientific programmes.

Workshop on the improvement of the OECD 306 screening test

17-18.Feb.15, CEFAS laboratories, Lowestoft (UK)

Recent ECETOC workshops recommended a series of modifications and enhancements to existing OECD biodegradation screening tests to deliver more robust methods for assessing persistence [1]. This reflects the high variability and poor reliability previously reported in OECD biodegradation screening tests such as the OECD 306 [2,3,4]. The Cefic-LRi funded Eco11 [5] investigated and validated these enhancements, producing a framework for selecting the most suitable inocula cell concentration method for improved enhanced activated sludge (c.f. OECD 301) and marine tests (c.f. OECD 306). The plan is that these improvements will lead to a ring test of an enhanced OECD 306 test.

[1] ECETOC 2013. Assessing Environmental Persistence. Workshop Report No. 24.
[2] ECETOC 2003. Persistence of chemicals in the Environment. Workshop Report No. 90.
[3] ECETOC 2007. Workshop on Biodegradation and Persistence. Workshop Report No. 10.
[4] Goodhead et al., 2013. Standard inocula preparations reduce the bacterial diversity and reliability of regulatory biodegradation tests. Environmental Science and Pollution Research, 21 (16); 9511-9521.
[5] Cefic 2014. Cefic LRi Eco11. http://www.cefic-lri.org/projects

This workshop will introduce the concepts and hands-on lab-based training so that any facilities interested in participating in a ring test will have the knowledge to do so, consisting of:

- Half a day of the theory, concepts and scientific evaluation of cell concentration methods and enhanced tests.
- Half a day of a practical demonstration of a cell concentration method for aqueous inocula (e.g. an enhanced OECD 306 test).

The workshop is aimed at lab-practitioners and those with a specific interest in this area; further information can be obtained from info@ecetoc.org

Latest Publications

New information and weight-of-evidence in PBT/vPvB assessment of chemicals

An ECETOC task force has reviewed the new information and 'weight-of-evidence' approach set out in Annex XIII of REACh as amended in 2011, to better assess whether a chemical substance is persistent, bioaccumulative and toxic (PBT), or very persistent /very bioaccumulative (vP/vB). An integrated evaluation strategy is proposed with focus on P and B assessment (on T sufficient guidance exists). In principle, if the available screening information indicates the absence of PBT or vPvB properties, there is no need or obligation for higher-tier assessment and/or further testing. Weight-of-evidence analysis depends on the available information and may include several hypotheses and lines of evidence. Further research is recommended on several topics (endpoints), to fill gaps in knowledge before developing new criteria and specific guidance that allow regulatory conclusions to be drawn, in particular for terrestrial B assessment.

The document is published as ECETOC Special Report 18: Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH).

The Summary and free PDF of the report are available at http://bit.ly/ecetoc-sr18

Evaluating existing concepts for the grouping and safety assessment of nanomaterials

It is well-accepted that nanomaterials need to be safe. However, conducting a full testing scheme for each and every variant of each nanomaterial will lead to an enormous amount of data that may not be necessary for risk assessment. This would be a waste of time, money, and even worse, laboratory animals. A solution to this dilemma is the so-called 'grouping of chemicals'. Science-based grouping approaches allow the prediction of a substance's toxicity by comparing it to other similar substances. For conventional non-nanosized substances, grouping is already allowed, for example by European Chemicals Regulation. However, grouping nanomaterials is more complex as it requires the consideration of physical, chemical and biological properties and, although various agencies and consortia have made proposals, there is currently no unified global grouping concept.

To develop a consistent approach for grouping nanomaterials, the ECETOC Nano Task Force first reviewed the available schemes but concluded that none cover all aspects relevant to nanomaterial safety assessment. In a second step, the Task Force will identify the best available concepts to combine into a comprehensive unified framework that can be applied internationally for the grouping of nanomaterials. As described above, if the scheme is accepted, it will save time, money and animal experimentation.

The Task Force review of available proposed schemes is published as an Open Access article in *Regulatory Toxicology and Pharmacology* and a proposed unified framework is expected in 2015.

Arts J, Hadi M, Keene A, Kreiling R, Lyon D, Maier M, Michel K, Petry

Continued on page 4

Latest publications (continued)

T, Sauer U, Warheit D, Wiench K, Landsiedel R. 2014. A Critical Appraisal of Existing Concepts for the Grouping of Nanomaterials. *Regulatory Toxicology and Pharmacology 70(2):492-506. Doi: 10.1016/j.yrtph.2014.07.025* Download this Open Access article from the publisher's website: http://bit.ly/ecetoc-art2014-arts-et-al

Incorporating potency into classification for carcinogenicity and reproductive toxicity

Classification should give guidance on the potential hazards of chemicals. Once the nature of the hazard is known, potency is the most important indicator of the degree of the hazard. Classification for carcinogenicity and reproductive toxicity does not distinguish between chemicals with up to 7 orders of magnitude difference in potency. This can cause problems in communication and has downstream consequences for the use of chemicals which may be inappropriate. There is methodology in the EU guidelines for assessing potency which is scientifically valid and should be used more widely. Classification schemes which incorporate potency have been developed. These would promote clarity of communication and more relevant downstream risk management for chemicals. It is hoped this work will start a discussion on changing the GHS criteria.

Hennes C[†], Batke M, Bomann W, DuHayon S, Kosemund K, Politano V, Stinchcombe S, Doe J. 2014. Incorporating potency into EU classification for carcinogenicity and reproductive toxicity. *Regulatory Toxicology & Pharmacology* 70(2):457-467. Download this Open Access article from the publisher's website: http://bit.ly/ecetoc-art2014-Hennes-et-al

[Footnote: [†] Deceased]

Contribution of New Technologies to Characterisation and Prediction of Adverse Effects

A taskforce was set up to investigate how newly developed methods in toxicity testing contribute to hazard and risk assessment of chemicals. The taskforce aimed at identifying the opportunities and current limitations of these new methods in comparison with traditional studies in laboratory animals.

Identification of the potential hazards of chemicals has traditionally relied on studies in laboratory animals where changes in clinical pathology and histopathology compared to untreated controls defined an adverse effect. More recently, a paradigm shift in toxicity testing has been proposed, mainly driven by concerns over animal welfare but also thanks to the development of new methods.

Currently, technologies based on computer modelling, isolated cell systems and genetics, are available to provide detailed insight in toxicological Mode of Action (MOA) of adverse effects observed in laboratory animals.

The vision described as Toxicity Testing in the 21st century (Tox21c) aims at predicting toxic effects in animals, based on these above-mentioned new technologies.

At present, a practical application of the Tox21c vision is still far away. While moving towards toxicity prediction based on these new technologies, a stepwise reduction of animal testing is foreseen by combining animal tests with new technologies. Furthermore, newly developed methods will also be increasingly applied, in conjunction with established methods in order to gain trust in these new methods. This confidence is based on a critical scientific prerequisite: the establishment of a causal link between data obtained with new technologies and adverse effects manifested in animal studies. It is proposed to apply the principles described in the WHO/IPCS framework of MOA to obtain this link. Finally, an international database of known MOAs obtained in laboratory animals using data-rich chemicals will facilitate regulatory acceptance and could further help in the validation of the adverse outcome pathway concepts.

Rouquié D, Heneweer M, Botham J, Ketelslegers H, Markell L, Pfister T, Steiling W, Strauss V, Hennes C. 2014. Contribution of New Technologies to Characterization and Prediction of Adverse Effects. Accepted for publication in *Critical Reviews in Toxicology*.

The current full catalogue of ECETOC publications can be downloaded at http://bit.ly/ecetoc-catalogue

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