ecetoc
e-NEWSLETTER
EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

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ECETOC Targeted Risk Assessment Tool: TRA VERSION 3 AND ASSOCIATED WORKSHOP

The newly improved TRA version 3 will be launched in early April along with updated user guides. In order to explain to users the differences between TRAv2 and TRAv3, ECETOC is organising a workshop to be held in Brussels 3rd May 2012.

REACH is the EU regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007. It streamlines and improves the former legislative framework on chemicals of the EU. One of the key challenges of REACH is that it envisages the registration and evaluation of approximately 30,000 chemicals by producers and importers. Many of these chemicals will be classified and will require Chemical Safety Assessments to support their registration. Faced with such a challenge, both practically and scientifically, suitable tools that are accessible to non-experts are a key need of the REACH process.

To achieve these aims, ECETOC has developed a tiered (step by step) approach for calculating the exposure to and risks from chemicals that might reasonably be expected in defined circumstances of use. The approach addresses exposure to consumers, workers and the environment. The general concept of ECETOC's targeted risk assessment (TRA) is based on the premise that, by making suitably conservative assumptions, broad exposure/risk models can be applied to determine where any further detailed assessment of risks may be required.

Since its launch in 2004, the ECETOC Targeted Risk Assessment Tool has proved to be an overwhelming success. Since the release of the TRA version 2 in July 2009, over 11,000 downloads of the tools have been made and many of the major consortia placed the TRA at the heart of their 2010 REACH Registrations.

Following the 2010 registrations, the core group of the ECETOC Targeted Risk Assessment task force has been seeking feedback from users of the tool in order to identify areas where the tools' functionality and accuracy might be further improved. At the same time, ECHA signalled its intent to update its Chesar CSA/ES tool. In this respect, updates to the worker and consumer tools have been developed in close co-operation with ECHA, who intend to incorporate the two human health components of the TRA into the new Chesar version 2. In addition to these two components, a spreadsheet implementation of EUSES is included in the integrated part of the TRA to facilitate environmental assessments. The integrated part of the TRA is also being updated. These new versions have been tested against the TRAv2 and other exposure models.

Attendance at the ECETOC workshop will be subject to a fee of Euro 200 per person to cover the costs of renting the venue and the catering.

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SG CORNER:

It is now 20 years since the seminal study by Niels Skakkebaek at the University of Copenhagen indicated a fall in sperm count over previous decades, based on analysis of published studies. Not long afterwards (1996), the book "Our stolen future" was published, with a foreword written by the then Vice-President of the United States of America, Al Gore. At that point we can consider that the "endocrine disruptors" really debate took off. ECETOC was immediately involved with the science publishing five ECETOC documents on this subject, all between 1996 and 1997.

By about the year 2000, the controversy seemed to have become less visible and more technical. However, the subject had not been forgotten. By the time a new series of chemical regulations started to appear in Europe, notably the revised pesticide directive and the REACH regulations, it was clear that the subject had matured. These regulations made clear that so called "endocrine disrupting chemicals" would face heavy restrictions or might even be banned. It seemed probable that this would be based on intrinsic properties, not on risk assessment. At this point no agreed definition that could be used for regulatory purposes existed.

ECETOC again took the lead on this and established a task force which has produced a report proposing a way forward. Two workshops were held with prominent academic experts and scientists from regulatory bodies in Europe, the most recent being last summer. In consequence ECETOC's proposals are the reference in this debate and we continue to have a seat at the table. The outcome will be known soon and is so far unpredictable. Whatever this outcome may be, we can be sure that our arguments have been heard and taken seriously. The years of investment by ECETOC experts to establish our reputation as a trusted scientific voice for the chemical industry has given us that right.

Neil Carmichael

Dr Neil Carmichael
Secretary General

SCIENTIFIC COMMITTEE NEWS

New Member
In November, the Scientific Committee welcomed as a new member Professor L. Maltby, Head of the Department for Environmental Biology at Sheffield University. Professor Maltby will strengthen the committee's expertise in environmental safety, particularly ecotoxicology and ecology.

2012 Work Programme
At its December meeting, the Scientific Committee looked at the year ahead in terms of requests for new task forces and proposals for workshops. There are a number of interesting and relevant projects are in the pipeline. The committee discussed how this challenging programme could be managed and planned for 2012 and beyond. However, the committee was keenly aware that any new activity needs to be prioritised against important existing activities on ECETOC's portfolio of projects and with a view on available resources. This is a process which will need regular review and management.

WHO renews NGO status of ECETOC
The World Health Organisation (WHO) has decided to maintain ECETOC in official relations with them for another 3 years. This means that ECETOC continues to be recognised as a non-governmental organisation (NGO). It continues to strengthen ECETOC in its mission to promote the use of best scientific principles in human and environmental risk assessment of chemicals, biomaterials and pharmaceuticals. The cooperation with WHO in the past has promoted this ideal. The WHO decision is based on a collaborative work plan that was agreed with the WHO under their International Programme on Chemical Safety (IPCS). For general information and a list of NGOs, see
www.who.int/civilsociety/relations/en

IARC Monograph 106: Trichloroethylene and some chlorinated agents. Lyon, France 2–9 October 2012
IARC is planning its next Monograph on the Evaluation of Carcinogenic Risks to Humans. Any ECETOC Member Companies interested in sending a suitable observer and/or specific data (details via web links below) are invited to contact their ECETOC Delegate to nominate their candidate before 16 April, for consideration/appointment by the SC meeting on the following day.

Preliminary list of agents (CAS numbers)
Trichloroethylene (79-01-6)
Tetrachloroethylene (127-18-4)
Trichloroacetic acid (76-03-9)
Dichloroacetic acid (79-43-6)
Chloral (75-87-6)
Chloral hydrate (302-17-0)
Some other chlorinated agents

http://monographs.iarc.fr/ENG/Meetings/index.php
Preliminary list of agents to be reviewed
Call for Data *(closes 2 September 2012)*
Request for Observer Status *(closes 2 June 2012)*
WHO Declaration of Interests for this volume

Dr Fraser Lewis
Scientific Committee Chairman

Lead article, continued from front page...

There are a few places left which will be issued on a first-come first-served basis.

TRA Tool users who would like to attend this event should register their interest by completing the form at this link: http://bit.ly/ecetoc-TRAv3ws_registration

Dr Malyka Galay Burgos
Environmental Sciences Manager

Dates announced for 2012 ANNUAL MEETINGS

The 2012 **Annual General Meeting**, which is open to Delegates representing ECETOC Member companies only, will be held at the Sheraton Brussels Airport Hotel on 22nd May. ECETOC members can find more information at http://members.ecetoc.org/en/annual-meetings/annual-general-meetings-agm.aspx

The 2012 **Annual Technical Meeting** for Experts from ECETOC Member companies and some invited guests will be held in Brussels on 6th June. The topic will be 'Chemical exposure for risk assessment: Present problems and future solutions'. Dr Jose Tarazona will be one of the key speakers. Further details and the venue will shortly be announced on the ECETOC website: http://www.ecetoc.org/2012-atm

Latest PUBLICATIONS

JACC Report:

JACC No. 55: Linear Polydimethylsiloxanes
CAS No. 63148-62-9 (Second Edition)
(December 2011)
http://bit.ly/ecetoc-jacc55

All ECETOC reports are freely available from our website: www.ecetoc.org/publications

Scientific Articles:

Lavelle KS, Schnatter RA, Travis KZ, Swaen GM, Pallapies D, Money C, Priem P, Vrijhof H. 2012. Framework for integrating human and animal data in chemical risk assessment. *Regul Toxicol Pharmacol* 62:302-312. doi: 10.1016/j.yrtph.2011.10.009

Hennes EC, Galay Burgos M, Hamer M, Pemberton M, Travis K, Rodriguez C. 2012. Workshop: Combined exposure to chemicals. *Regul Toxicol Pharmacol* 63:53-54. doi: 10.1016/j.yrtph.2012.02.008

ECETOC publishes Technical Report No. 111 on
DEVELOPMENT OF GUIDANCE FOR ASSESSING THE IMPACT OF MIXTURES OF CHEMICALS IN THE AQUATIC ENVIRONMENT

The potential risk from combinations of chemicals in the environment has recently moved up the scientific, regulatory and political agenda as a result of the increasing concern about the potential impact on the environment from a 'cocktail effect' and the perception that current risk assessment procedures are inadequate.

In this report, field-based approaches for assessing impacts on the aquatic environment and developing guidance on suitable methods are reviewed; case studies are used to identify research needs, including how methods can be implemented and what diagnostic tools are required; and the value of retrospective assessment in assessing environmental capacity for future industrial development is considered. Finally, a framework is presented which will retrospectively allow the evaluation of the potential impact of chemicals or chemical mixtures in the environment.

Strategic Science Areas:
Mixtures and co-exposure
Biodiversity and ecosystems

The report can be downloaded from the ECETOC website free of charge.
Direct link to summary and PDF download:
http://bit.ly/ecetoc-tr111

ECETOC publishes Technical Report No. 112 on
REFINED APPROACHES FOR RISK ASSESSMENT OF PBT/VPVB CHEMICALS

Many national or regional regulations and regional or global conventions exist that identify and prioritise substances of concern based on their hazardous properties. The criteria for identifying such substances under these various instruments are not the same, but have many similarities through cut-off values associated with a chemical's persistence (P), bioaccumulation (B) and toxicity (T). Criteria for PBT first came on the agenda within the EU in the revision of the Technical Guidance Document (TGD) on risk assessment (EC, 2003). This document assigned criteria to identify substances of concern as PBT or very persistent and very bioaccumulative (vPvB) based on their half-lives in selected environmental media, their bioaccumulation in biota and their long-term ecotoxicity.

This hazard based approach to chemical management was argued on the basis that 'safe' environmental concentrations for such substances cannot be established with sufficient reliability due to the unacceptably high level of uncertainty associated with quantitative risk assessment, the concerns that accumulation of such substances would be practically difficult to reverse, and the need to protect pristine (marine) environments. These concerns were then reflected in the EU REACH legislation which effectively removed risk assessment as the regulatory decision making tool for substances classified as PBT or vPvB.

Building upon a previous ECETOC report to develop a framework for the risk assessment of PBT chemicals (TR 98, 2005), this report reviews the scientific developments that have been made and details the on-going research that is being carried out with the specific aim of reducing the uncertainty of risk assessments of PBT/vPvB chemicals.

Several case studies have been analysed and the literature on newly developed methodologies has been reviewed. The task force has concluded that the use of refined methodologies, which include the use of appropriate and/or improved test procedures, is strongly dependent on the nature of the respective chemical and its exposure characteristics. Therefore the choice of methodologies needs to be made on a case by case basis.

Strategic Science Areas:
Integrated testing strategies
Risk, hazard and precaution

The report can be downloaded from the ECETOC website free of charge.
Direct link to summary and PDF download:
http://bit.ly/ecetoc-tr112

Keep up to date with the latest ECETOC news by following our Twitter feed http://www.twitter.com/ecetoc, or by subscribing to our RSS news feeds at http://bit.ly/ecetoc-rss-news and http://members.ecetoc.org/en/news.aspx

ECETOC publishes JACC Report No.55 on LINEAR POLYDIMETHYLSILOXANES (PDMSs)

The report presents a critical evaluation of their toxicity, physico-chemical properties, and environmental fate and effects. PDMSs are a type of non-volatile (odourless), fluid (viscous) "silicones" that are virtually insoluble in water and are widely used in industrial, consumer, food and medicinal or pharmaceutical applications. It is concluded that, overall, PDMS does not present a risk to the environment or to human health. The report has been produced as part of the ECETOC Joint Assessment of Commodity Chemicals (JACC) programme and updates an earlier JACC report from 1994 (JACC No. 26).

Strategic Science Area:
Risk, hazard and precaution

The report can be downloaded from the ECETOC website free of charge.
Direct link to summary and PDF download:
http://bit.ly/ecetoc-jacc55

ENVIRONMENT PROGRESS REVIEW

At the end of February, ECETOC hosted its annual 2-day scoping meeting to inform member company scientists of progress in current and recently completed environmental Cefic LRI projects, ECETOC task forces and workshops. The first day, with a large turn-out of 29 participants, reviewed existing and recent activities whilst the second day focussed on identifying new ideas for ECETOC or Cefic LRI activities.

EEMS

Symposium at EEMS on EPIGENETICS AND CHEMICAL SAFETY

Following last December's Rome workshop organised by ECETOC on epigenetics and chemical safety, a symposium on the subject will be held by ECETOC and EEMS, the European Environmental Mutagen Society, on 17th September at the 42nd meeting of EEMS in Warsaw, Poland. Speakers will include: B. van Ravenzwaay (ECETOC / BASF, Germany), J. Goodman (Michigan State University, USA), R. Meehan (Medical Research Council, UK), S. Guibert (Institut de Génétique Moléculaire de Montpellier, France), J. Cadet (Grenoble University, France), M. Benahmed, (Nice University, France) and J. Kleinjans (University of Maastricht, Netherlands).

EEMS website: http://www.eemseu.org/

ECETOC Session at EUROTOX 2012

At this year's annual meeting of EUROTOX (European Societies of Toxicology) in Stockholm, Sweden, ECETOC will hold a session on 'Dose-response relationship and receptor-mediated toxicology' on 20th June. It addresses an on-going debate which is controversial when exploring the nature of the dose-response curve and the effect at the low end of this curve. More specifically, the concept of threshold in receptor-mediated toxicity is currently being challenged, particularly in the field of endocrine toxicity.

The session will be chaired by Remi Bars of BayerCropScience and Ben van Ravenzwaay of BASF. Scientists invited to present their latest research in the field are Earl Gray (US EPA), Russell Thomas (Hamner Institutes for Health Sciences), Remi Bars, Cliff Elcombe (CXR Biosciences) and Dieter Schrenk (University of Kaiserslautern).

For more information, please visit http://www.eurotox2012.org

Workshop planned to discuss
THE EFFECTIVE EVALUATION OF THE PERSISTENCE OF CHEMICALS IN THE ENVIRONMENT

ECETOC has been actively involved in developing the scientific understanding of factors that affect the persistence of chemicals in the environment for over 15 years. In 2007, ECETOC and the Environment Agency (EA) of England and Wales co-hosted a Workshop on "Biodegradation and Persistence" at Holmes Chapel in the United Kingdom (WR 10). Attendees, from academia, regulatory agencies and industry discussed the challenges and uncertainty faced with persistency assessments at the screening and confirmatory testing level. The following recommendations made during the workshop have been acted upon:

- Development of a validation set of chemicals for biodegradation research (funded by CEFIC/LRi and completed in 2010);
- Development of new persistency screening tools with biodegradation studies using enhanced biomass levels (funded by CEFIC/LRi and due for completion in 2012);
- Demonstrating the environmental significance of microbial adaptation (funded assigned by CEFIC/LRi in 2011);
- Measuring biodegradation half-lives and identifying sources of variability and uncertainty (funded by CEFIC/LRi and project due to begin in 2012);
- Addressing the uncertainty associated with bound residues or non-extractable residues formed in higher tiered persistency assessments. This resulted in a subsequent ECETOC Workshop (WR 17, 2010) and two current ECETOC Task Forces.

It is now considered to be the right time to follow up the Holmes Chapel workshop with a further workshop to (i) discuss the progress and output of the activities conducted as a result of the 2007 workshop, (ii) discuss other scientific developments within the field of persistence, and (iii) learn from the chemical industry and environmental regulators experience of persistency assessments conducted within the initial phases of REACH.

UBA (Germany), the Environment Agency (England and Wales), and ECHA have expressed an interest in being part of the organising committee for this workshop. The technical programme will address the following themes through a combination of invited and submitted keynote presentations (using case study measured data where possible) and syndicate sessions:

- Regulatory effort to harmonise persistency criteria and its evaluation across the EU;
- Validation of biodegradability tests for persistency evaluation and the development of appropriate quality assurance/ quality control standards;
- Effective prioritisation on persistence at the screening level including the role of QSBRs, modified and enhanced biodegradation test;
- Biodegradability assessments with 'difficult' substances;
- Assessment of non-extractable residues associated with sludge, soils and sediments within high tiered studies;
- Predication, detection, identification and evaluation of degradation products;
- Microbial adaptation and its relevance to exposure and persistency assessment.

The workshop is planned to take place in the autumn of 2012.

New Task Force:
MODE OF ACTION & IDENTIFICATION OF ADVERSE VERSUS NON-ADVERSE EFFECTS

At its December meeting, the Scientific Committee agreed the terms of reference for a new task force on Mode of Action and Identification of Adverse vs. Non-adverse Effects. This topic was prioritised at last year's workshop on REACH-driven science needs, and after having initiated a number of other activities that derived from it, it was now decided to send out a call for nominations for this new task force. It will hold its first meeting in April. Details can be found on the ECETOC website under "Ongoing Task Forces".

Strategic Science Area:
Integrated testing strategies

NANOGENOTOX have announced a workshop that will bring together stakeholders and partners of the Joint Action in order to discuss the progress of NANOGENOTOX and in particular stakeholders' expectations regarding knowledge transfer and use of the final results. ECETOC is represented by Dr Maria Donner (DuPont). The workshop will take place 3rd May in Brussels.

For more information on this project, please visit http://www.nanogenotox.eu

ECETOC at a glance

Established in 1978, ECETOC is Europe's leading industry association for developing and promoting top quality science in human and environmental risk assessment of chemicals. Members include the main companies with interests in the manufacture and use of chemicals, biomaterials and pharmaceuticals, and organisations active in these fields.ECETOC is the scientific forum where member company experts meet and co-operate with government and academic scientists, to evaluate and assess the available data, identify gaps in knowledge and recommend research, and publish critical reviews on the ecotoxicology and toxicology of chemicals, biomaterials and pharmaceuticals.

ECETOC also provides scientific representation for its member companies through presentations at specialist meetings and by participation in the scientific activities of international agencies, government authorities and professional societies. A non-profit, non-commercial and non-governmental organisation, ECETOC prides itself on the objectivity and integrity of its work programme, the output of which is published in the form of peer-reviewed reports and articles in peer-reviewed journals, or as specialised workshops.

EUROECOTOX
European Network for Alternative Testing Strategies in Ecotoxicology

EUROECOTOX NETWORK

announces conference on the future of alternative testing for eco-toxicity safety assessment

ECETOC is a partner in EUROECOTOX (the European network for alternative ecotoxicology testing strategies in Ecotoxicology) which will hold the "First European Conference on the future of alternative testing for eco-toxicity safety assessment" on 28th-29th June 2012 at Eawag, Dübendorf, Switzerland.

EUROECOTOX is a two year project which was officially launched in 2011. A co-ordination action funded by the FP7 Environmental programme, it has as its main objectives the integration of European activities on the replacement, refinement and reduction of animal experiments in ecotoxicology, and the promotion of the validation of new alternative testing methods.

A dedicated website (www.euroecotox.eu/) has been set up as part of the network promoting activities and to aid in the dissemination of the co-ordinating action results.

Agenda

Dates and times are subject to change.
Please check our website for the latest information.

April

02 Task Force on poorly soluble particles (PSP) and lung overload. Meeting in Brussels, Belgium

04-05 Task Force on development of interim guidance for the inclusion of NER in the risk assessment of chemicals. Meeting in Bracknell, UK

16 Task Force on Mode of Action and identification of adverse vs. non-adverse effects. Meeting, Brussels, Belgium

17 197th Scientific Committee meeting, Brussels, Belgium

23 Task Force on cyanides antidotes. Meeting in Darmstadt, Germany

May

02 Task Force on category approaches, read-across, (Q)SAR. Meeting in Brussels, Belgium

03 ECETOC Workshop on TRA Tool version 3, Brussels, Belgium. *See front page*

03 NANOGENOTOX Workshop, Brussels, Belgium. *See page 5*

21 ECETOC Board of Administration meeting Brussels, Belgium

22 ECETOC Annual General Meeting, Brussels, Belgium *See page 2*

June

06 ECETOC Annual Technical Meeting. Brussels, Belgium *See page 2*

20 ECETOC Session at EUROTOX 2012, Stockholm, Sweden. *See page 4*

26 198th Scientific Committee meeting. Brussels, Belgium

28-29 EUROECOTOX Conference on the future of alternative testing for eco-toxicity safety assessment. Eawag, Dübendorf, Switzerland *See article on this page*

September

17 Symposium on epigenetics and chemical safety. Warsaw, Poland. *See page 4*

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