

**EDITORIAL ECETOC CONTRIBUTIONS TO THE REACH IMPLEMENTATION PROJECTS (RIPs)**

As the EU-chemicals law, REACH, approaches the final stages in the European Parliament and the European Council during the 4th quarter 2006 with entry into force expected during the 2nd quarter of 2007, it is appropriate to recount the involvement of ECETOC in the RIP activities so far. The major focus has been in RIP 3.2-2 and RIP 3.3-2 where specifically ECETOC's role in delivering a scientific input is clearly in keeping with the organisation's charter and has been facilitated by the dedicated contributions of member company scientific experts.

RIP 3.2 will develop a Guidance Document for manufacturers, importers and down-stream users of chemicals on how to carry out chemical safety assessment and document it in a chemical safety report; and how to communicate information using the safety data sheet (SDS) according to REACH.

Under the leadership of the European Chemicals Bureau (ECB) of the EC's Directorate General Joint Research Centre (DG JRC), a one-day workshop was organised on REACH exposure scenarios and exposure assessment at which the ECETOC developed Targeted Risk Assessment (TRA) methodology and web tool were presented. On-going discussions with the Commission and Member States (MS) continue to demonstrate that this scientific methodology, particularly for the human health risk assessment, is currently the most advanced on which to further develop an appropriate tool which will significantly improve the workability of the REACH regulations. The ECETOC Scientific Committee continues to fully support involvement of resources in this project.

In addition, ECB organised two drafting groups to which ECETOC nominees have participated namely: the working group (WG) on development of guidance for carrying out a PBT assessment and risk characterisation of

substances of very high concern (SVHC) in the environment and a WG on the setting of Derived No Effect Levels (DNELs) and assessment and risk characterisation of SVHCs for human health.

RIP 3.3 will develop a Guidance Document for industry on how they can fulfil the information requirements on intrinsic properties of substances. This should in particular give a better insight on how to use alternatives to *in-vivo* data such as (Q)SARs, chemical category approach, *in-vitro* data and how information on exposure can be taken into account.

Under the leadership of the European Centre for the Validation of Alternative Methods (ECVAM) of DG JRC (for the 'external' coordination with the decision making process and stakeholders) and Cefic (for the 'internal' running of the project), ECETOC is a member of a consortium comprising Member State agencies (Denmark, Netherlands, France, UK and Sweden), the Commission (DG JRC, DG Enterprise) and industry (Cefic, Eurométaux, Concawe and ECETOC) addressing the issues of information requirements.

Through its membership of the Product Management Group (PMG), ECETOC has coordinated the population and designation of the lead organisation of the Endpoint Working Groups (EWGs) with subject matter experts from the consortium partners that included major contributions of member company experts to the 11 EWGs covering both environmental and human health endpoints.

Specifically ECETOC has led the Degradation EWG and the Repeated Dose Toxicity EWG providing Secretariat support in addition to member company experts. The EWGs have been well supported by groups developing guidance on toxicokinetics, cross-cutting issues, non testing methods and non standard substances amongst others. Currently the EWGs are finalising the first draft reports, including the Intelligent Testing Strategies (ITS), for submission to the Stakeholder Expert Group (SEG) for review in a late December meeting. Following this review the reports will be finalised and used as the basis for drafting the Technical Guidance Document (TGD) for industry which will be implemented during 2007.

Through ECETOC, its members' employees and its archive of peer-reviewed papers, industry has contributed a significant scientific input to the RIP process to ensure sound chemical regulations based on robust science. It is hoped that these contributions will benefit both member companies as well as the industry at large to continue to operate safely in a highly competitive environment.

**SG CORNER**

**ECETOC 100<sup>th</sup> Technical Report**



A milestone for ECETOC was reached during the third quarter of this year with the publication of its 100<sup>th</sup> Technical Report entitled 'Contribution to the Methodology for the Development of Acute

Exposure Threshold Levels in Case of Accidental Chemical Release.'

The Task Force responsible for this paper had contributed to the three-year research project, ACUTEX that was funded within the EU 5th Framework Programme for Research and Technology Development. ECETOC was one of eight consortium partners that included government institutes, competent authorities, academia and industry. This group was charged to develop the methodology, software tools and a Technical Guidance Document (TGD) for establishing European Acute Exposure Threshold Levels (AETLs) in case of accidental chemical release. AETLs will support the harmonised implementation of the Council Directive 96/82/EC, known as the Seveso II Directive on the control of major-accident hazards involving dangerous substances. This achievement illustrates the benefits of ECETOC's pursuit of success through its scientific partnerships.

The publication of this 100th Technical Report has brought the balance of total reports published to 253 since 1978.



**Appointment of Dr. Neil Carmichael as Secretary General**

As of 1 November 2006, Dr. Neil G. Carmichael, previous Head of Toxicology at Bayer CropScience

will assume the role of new Secretary General, ECETOC.

Neil has a B.Sc. in Zoology from the University of Newcastle on Tyne and a Ph.D. in Toxicology at the University of London. His Ph.D and later academic research concerned heavy metals and their toxic effects in both vertebrate and invertebrate models. (continued overleaf..)

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# ECETOC Activities

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Neil is also a member of several scientific or professional societies and is the Chairman of Toxicology Expert Group of ECPA. He is chairman of the ILSI – HESI technical committee "Agricultural Chemicals Safety Assessment".

He is already a familiar face at ECETOC having served on its Scientific Committee during the period 1991 to 2003, the final four years of which, as Vice-Chairman.



## From ECETOC to the Swiss Society of Chemical Industries (SGCI)

Effective 1 January 2007 and following my retirement from Dow, I will start a part-time position with SGCI Chemie Pharma Schweiz based in Zurich, Switzerland. In this new role I hope to leverage my extensive involvement in the chemicals industry over 30 years with my most recent experience gained during this tenure with ECETOC to provide robust science to the chemicals regulatory environment.

Dr. Michael Y. Gribble  
ECETOC Secretary General

## Winners of the ECETOC 2006 Science Award for research into health sciences



On the occasion of the 2006 EUROTOX (European Societies of Toxicology) Annual Congress this 20-24th September in Croatia, ECETOC was pleased to present one of its Young Scientist Awards to Sabine Langie of the University of Maastricht, The Netherlands for her poster entitled: '*Redox-dependent regulation of nucleotide excision repair*'.

This project was selected for the award under the broad theme of 'toxicological research into mechanisms and risk assessment'.



In addition, ECETOC was pleased to be able to recognise the work of Vlatka Filipovic Marijic of the Ruder Boškovic Institute, Zagreb, Croatia. Her poster, entitled '*Metal exposure assessment in native fish, *Mullus barbatus* L., from the Eastern Adriatic sea*' was agreed by the judges to be 'Highly Commended'.

For more details, visit [www.ecetoc.org/science\\_award](http://www.ecetoc.org/science_award)

## News on ECETOC's annual workshop collaboration with EEMS (European Environmental Mutagen Society)

ECETOC and EEMS (European Environmental Mutagen Society), co-sponsored by LRI (the CEFIC Long-range Research Initiative), have held two symposia at this year's annual general meeting of EEMS in Prague on 3 July 2006.

The symposia, on '*Molecular epidemiology: New knowledge from biomarkers of effects*' and on '*Biomarkers for the evaluation of children's health*', were well attended by some 150/100 participants, mostly from academia, government, contract research organisations and pharmaceutical industry.

The audience, including many key scientists, showed a high level of interest, and there was a lively discussion after each presentation, often continuing into the breaks.

The organising Task Force supplied the 4 chairmen and 3 of the 11 speakers.

The suite of papers based on the presentations made in Prague will be published as a special issue of Toxicology Letters (Elsevier Science) in 2007.

The Prague symposia were the fifth organised by ECETOC in collaboration with EEMS since 1998. CEFIC-LRI has been co-sponsor since 2004.

For more information, visit [www.ecetoc.org/newsroom](http://www.ecetoc.org/newsroom) or download the [symposia conclusions](#)

## NEW Reports



### Technical Report

No. 100: Contribution to the Methodology for the Development of Acute Exposure Threshold Levels in Case of Accidental Chemical Release (Published July 2006)

### Workshop Report

No. 7: Testing Strategies to Establish the Safety of Nanomaterials (Published August 2006)



### JACC Report (Joint Assessment of Commodity Chemicals)

No. 51: Synthetic Amorphous Silica (CAS No. 7631-86-9) (Published September 2006)



See [www.ecetoc.org/publications](http://www.ecetoc.org/publications) for all executive summaries!

## FORTHCOMING Meetings

### November

- 9 Toxicogenomics and Male Reproductive Health Workshop Bayer CropScience, Sophia Antipolis, France
- 22 Board meeting, ECETOC Offices, Brussels, Belgium
- 22 Cyanides Antidotes task force meeting Venue tbc, Brussels, Belgium
- 23 EEMS 2006 Editorial Board, ECETOC Offices, Brussels, Belgium

### December

- 12 Scientific Committee meeting, ECETOC Offices, Brussels, Belgium
- 14-15 Assessing mixtures of chemicals task force meeting ECETOC Offices, Brussels, Belgium

### January

- 16 LRI HEMT meeting ECETOC Offices, Brussels, Belgium

### February

- 23 Fluoroalkanes task force meeting ECETOC Offices, Brussels, Belgium

## ECETOC In Brief

ECETOC, European Centre for Ecotoxicology and Toxicology of Chemicals, was established in 1978 as a scientific, non-profit, non-commercial association, financed by 51 of the leading companies with interests in the manufacture and use of chemicals. A stand-alone organisation, it was established to provide a scientific forum through which the extensive specialist expertise in the European chemical industry could be harnessed to research, review, assess and publish studies on the ecotoxicology and toxicology of chemicals.

## Website

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