

ECETOC GIVES GUIDANCE FOR SETTING OELs FOR DATA-POOR SUBSTANCES

In October 2006, ECETOC published its 101st Technical Report, entitled 'Guidance for Setting Occupational Exposure Limits (OELs): Emphasis on Data-Poor Substances.' This was the result of 2 years work by an ECETOC task force chaired by Dr. Will ten Berge of DSM at the time.

The task force's objectives were to capture current practice in deriving OELs and arrive at a broad consensus; and to develop a set of simple algorithms to achieve a new paradigm in OEL setting. After seven one-day meetings and two steward sessions later, the report was approved for publication by the scientific committee.

The report reviews existing procedures for setting OELs, that, in the absence of sound human exposure data for chemical substances, are generally based on a no observed adverse effect level from repeated dose animal studies, with application of appropriate assessment factors to account for uncertainty and variability in the data set.

Contrary to these 'data-rich' substances, for which adequate data are available, no clear procedures exist for the derivation of OELs of 'data-poor' substances.

In this report, six methods for setting OELs for such substances have been proposed and evaluated, and worked examples have been provided. These methods are as follows:

- **Hazard banding** seems to be a promising method to set OELs for data-poor substances with EC risk phrases. These risk phrases are grouped following ECETOC criteria into four categories or hazard bands for gases/liquids and solids, each corresponding to a specific OEL range.
- The **maximum tolerated dose** in long-term studies can be used to derive an OEL. If not known, the maximum tolerated dose can be predicted from the acute oral toxicity (lethal dose in rats) and the octanol-water partition coefficient.
- **Four-hour lethal concentrations** from rat inhalation studies can be used directly for calculating OELs.
- Current (quantitative) **structure-activity relationships** for predicting toxicity are insufficiently reliable, and therefore of limited value for setting OELs. It is recommended to search for substances with similar structures and known toxicity, and then read the data across.
- If an OEL is to be based on sensory irritation, it can be predicted from the so-called **respiratory dose**, i.e. the concentration in air which reduces the breathing rate of mice by 50%. If not available, the respiratory dose can be calculated from the octanol-air partition for substances from a homologous series.
- Finally, the principle of **threshold of toxicological concern** (normally for food contaminants) can be used for deriving OELs if less conservative safety factors are applied.

The ECETOC task force found that for certain substances none of the proposed methods will be applicable. For others, one or more of the methods might be appropriate, but could lead to different results.

In conclusion, therefore, it is proposed that an integrated approach based on the six methods proposed can be used to set a provisional OEL for the data-poor substance concerned. However, for the value to be reliable, experienced toxicological expertise is required in the interpretation of the results.

SG CORNER

My first two months at ECETOC were in Tandem with Mike Gribble, so it is appropriate that I start by thanking Mike for his help getting started as Secretary General. He has handed over a very well organised and efficient Secretariat. A healthy balance sheet is also part of my inheritance.

During 2006, the Scientific Committee has grown with the objective to broaden its areas of expertise. We were happy to welcome seven new members to the committee. Six were company scientists: Dr Eckhard von Keutz, Bayer HealthCare; Dr David Farrar, Ineos Chlor Ltd; Dr Stuart Marshall, Unilever; Dr Giuseppe Malinverno, Solvay; Dr Carlos Rodriguez, Procter and Gamble and Dr Mark Pemberton of Lucite.

We also welcomed a new external member: Prof. Saskia van der Vies from the Free University, Amsterdam. This is a particular pleasure as she is the first ever female member of the Scientific Committee.

The process is not yet complete as we are currently inviting two new members with environmental expertise. The aim is to re-invigorate the environmental portfolio of activities, which has been less active the last year or two following the sudden and much regretted death of Tom Feijtel, the retirement of Chris d'Hondt and Peter Douben's move to Cefic. A workshop was held at the close of the year which came up with a very ambitious package of future projects flowing mostly from the REACH Endpoint Working Group (EWG) process.

In fact, the Scientific Committee will be re-evaluating it's entire workplan as a result of the Futures Workshop held last summer. A comprehensive science strategy is under construction and will be presented at the AGM in May.

With the ending of the EWG document writing there are opportunities to pick up a new momentum in our scientific activities. I am looking forward with pleasure to working again with my many old friends in the ECETOC network and to making new ones as the year progresses.

Neil Carmichael

Dr. Neil Carmichael
Secretary General

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ECETOC Activities

2007 ECETOC Science Awards

Each year, ECETOC sponsors three awards for young scientists.

This year, it will repeat its relationships with:

- The Society of Environmental Toxicology and Chemistry (SETAC) Europe Annual Congress (Porto, Portugal, 20-24 May 2007) to sponsor an environmental science related award, and
- The European Societies of Toxicology (EUROTOX) Annual Congress (Amsterdam, The Netherlands, 7-10 October 2007) to sponsor a human health related science award.

For the first time in 2007, ECETOC will sponsor an award for epidemiology related science. This will be in association with the International Commission on Occupational Health's Scientific Committee on Epidemiology in Occupational Health (EPICOH) on the occasion of their Annual Congress (Banf, Canada, 9-12 October 2007).

2007 Award for Environmental Science Research

The SETAC Young Scientists Awards will honour the best platform presentation by a junior scientist under the age of 30 at the SETAC Europe Annual Meeting that will take place 20-24 May 2007 in Porto, Portugal.

The platform presentation will be evaluated by 3 senior scientists on the basis of originality of the approach; quality of the work (e.g. appropriate methodology, interpretation of results, conclusiveness); quality of the presentation (e.g. clarity, response to questions); and self-reliance and independence (not one of co-authors, but the most active, if more than one author).

For more information on how to submit an abstract for consideration for the SETAC Young Scientist Award, please visit:

www.setaceumeeting.org/porto/awards/YS.htm

New Members

During 2006, ECETOC was pleased to welcome the following new member companies: They were Nanogate, who became an Associate Member as of 1 August 2006 and Total Petrochemicals, who became a Full Member as of 1 November 2006.

As of 2007, ECETOC is pleased to welcome Albermarle as an Associate Member. Also as of this time, previous full members Petresa and Borax have become Associate Members.

Refinement of Mutagenicity/Genotoxicity Testing Workshop

23-24 April 2007, Malta

ECETOC will be organising an invitation-only workshop on the aforementioned subject this April in Malta to focus on reviewing the challenges of current *in vitro* testing and developments for future *in vitro* type tests for mutagenicity and genotoxicity, as well as refinements of *in vivo* test protocols.

For more information, contact christa.hennes@ecetoc.org

2007 ECETOC Annual Technical Meeting

10 May 2007, Brussels, Belgium

The 2007 Annual Technical Meeting will take place in Brussels on 10 May. This year, the meeting will be a members-only event and will focus on new science areas of nanomaterials and 'omics'. In addition, it will serve to present ECETOC's long-term science strategy.

To be notified when the programme has been finalised, please send an e-mail to info@ecetoc.org

NEW Reports



Technical Report

No. 101: Guidance for Setting Occupational Exposure Limits (OELs): Emphasis on Data-Poor Substances (October 2006)

Workshop Report

No. 8: Societal Aspects of Nanotechnology 9 November 2005, Barcelona (October 2006)



JACC Report (Joint Assessment of Commodity Chemicals)

No. 55: Trifluoroethane (HFC-143a) CAS No. 420-46-2 (October 2006)



See www.ecetoc.org/publications for all executive summaries.

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.

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