

*Best wishes from the Secretariat  
in Brussels for a  
happy holiday season  
and our sincere thanks  
for the loyalty and goodwill  
of our members  
throughout the year*



Dear Readers,

2016 has been another productive year for ECETOC. One of the highlights was the launch last May of the new ECETOC website, which introduces 'Topics' pages grouping information, publications and a series of [YouTube video interviews](#) with experts on some of the most important topics in the ECETOC Science Programme. Development of the website has continued and a series of language options have recently been added to spread the visibility of ECETOC even further afield.

The strong Asian interest in ECETOC and its activities over recent years continued in 2016 with Japanese and South Korean delegations visiting the ECETOC secretariat this year to learn more about the Targeted Risk Assessment (TRA) Tool and to present their national equivalents. ECETOC and its TRA Steering Group look forward to developing this collaboration as part of the ECETOC transformational programme to expand the use and applicability of the TRA Tool beyond Europe and REACH, and also welcome the translation into Japanese of the ECETOC Technical Reports supporting the current version of the TRA Tool by the Japanese Chemical Industry Ecology Toxicology & Information Center (JETOC). Meanwhile ECETOC is continuing to work with ECHA to address questions raised about the conservatism of the TRA model and to explore opportunities to protect workers' health in the workplace.

JETOC also published a Japanese translation of the series of papers on grouping of nanomaterials published by the ECETOC nano-grouping task force. Since the papers were published, ECETOC has been working to develop a nano-grouping risk assessment tool which is currently being adapted to coincide

with discussions at ECHA on nano grouping and read-across of chemicals. The tool should be ready early in 2017. Development has also started on a human exposure data app following the 2016 task force report on effective use of human exposure data in risk assessment of chemicals and associated workshop on advances in consumer exposure science: data, modelling and aggregate exposure assessment (see [Technical Report no.126](#) and [Workshop Report no.31](#)). These tools will be freely available on the ECETOC website when added to the 'Tools' section.

Over the course of 2016, ECETOC has published 8 ECETOC reports and 5 Papers in the Open Scientific Literature on subjects as diverse as: building a prenatal developmental toxicity ontology, human exposure data in risk assessment of chemicals, non-coding RNA in regulatory toxicology, freshwater ecotoxicity as an impact category in life cycle assessment, toxicity thresholds for aquatic ecological communities and assessing impacts of chemical exposures, assessment and application of adverse outcome Pathways (AOPs) relevant to the endocrine system, to name but a few.

During 2016, ECETOC also held 5 workshops, 2 review meetings, a workshop/round table at EUROTOX 2016 and participated in 7 international scientific symposia. Further details of these activities along with all the 2016 output will be published in the 2016 Annual Report which will be available on the ECETOC website towards the end of February 2017 to coincide with the Annual General Meeting and Annual Technical Meeting for Member Companies and invited guests on 8th March 2016.

## ECETOC Secretariat and Scientific Committee News

### Secretariat staffing

Dr Malyka Galay Burgos, Environmental Sciences Manager since September 2007, left ECETOC in July to follow a new course in her career. Malyka's expertise in environmental science combined with 'hands on' experience with genomics proved invaluable in creating the current impressive ECETOC Environmental Programme. Lucy Wilmot, Consultant with PFA-Brussels, will be managing the Environmental Sciences from January 2017.

Dr Madeleine Laffont, Human Health Scientist, will leave ECETOC at the end of 2016 to begin a new venture. Madeleine is a medical doctor by training and a consultant events moderator and project management specialist for environment & health issues by profession. Since May 2014, Madeleine has managed ECETOC's human health science area as contract agent and has become a highly valued member of the team. ECETOC is actively seeking a replacement for this position.

We also welcome Francesca Ugucioni to the secretariat as our new Office

Professional. Francesca replaces Agnieszka Harris who moved on to a new career in September 2016. The SC and Secretariat wish Malyka, Madeleine and Agnieszka well in their new careers.

### New task force: Geospatial approaches to increasing the ecological relevance of chemical risk assessments

A task force is currently being established to review and inform on the use of geo-referenced data to increase the environmental relevance of chemical risk assessment. A key aspect of the task force's work will be to investigate the availability of geo-spatial data needed to derive scenarios based on combinations of data for describing European ecosystems and the services they provide in a range of environmental scenarios.

### ECETOC Environmental science related award

The ECETOC Best Platform Award honours the early career scientist with

the best platform presentation at the SETAC Europe Annual Meeting.

The Best Platform Presentation at SETAC Europe, Nantes 2016, went to Yuan Pan, of the University of Sheffield, United Kingdom, for her presentation on "Using the ecosystem services framework to link scientific research and policy-making: a case study of Lake Tai, China." More information on the SETAC Nantes meeting can be found at <http://nantes.setac.eu>

### ECETOC Christa Hennes young scientist award

At EUROTOX 2016, in Seville, Spain, the Christa Hennes Award for best poster for toxicological research into mechanisms and risk assessment was won by Marlon Jetten of Maastricht University for her abstract: "Development of short-term assay(s) to predict dermal cancer potential of petroleum streams".

The winner receives a monetary prize and a free invitation to the following year's Eurotox meeting. Eurotox 2016 website: <http://www.eurotox2016.com>

## Recent Events

### Improving chemicals risk assessment with refined exposure characterisation

Workshop at EUROTOX 2016, 05 September, 2016, Seville, Spain

For chemicals risk assessments to be reliable, they must combine both hazard and exposure assessment. However, in a number of circumstances it is difficult to predict exposure with any great certainty. New approaches to exposure assessment are now being implemented that seek to deliver more reliable risk assessments through the tiered and targeted acquisition and application of exposure information. This workshop/roundtable examined how the process of risk assessment is being improved through the implementation of tiering; the tools and databases being developed to further support such methodologies; together with the roles that different stakeholders can play in supporting the process and its governance. The focus of the discussion was on human health.

### Environmental and (eco) toxicological omics and epigenetics: science, technology and regulatory applications

SETAC/iEOS Joint Focused Topic Meeting 12-15 September 2016, Ghent, Belgium

*Session 6: Epigenetics in risk assessment: Academia, industry and regulatory perspectives*

There is a growing body of evidence that certain chemicals may affect epigenetic processes in organisms (e.g. DNA methylation, histone tail modifications, microRNAs, etc.) and subsequently alter the way an organism responds to a stressor. These epigenetic effects may result in long-term impact on phenotypes, fitness, health and disease in living organisms both within generations (from embryogenesis to adulthood) and in a trans-generational fashion. Despite the substantial amount of research published in this area, a number of questions remain to be answered, particularly in the context of long-term impact on human health and ecological risk assessment of chemicals. Three keynote speakers from Academia, Industry (Alan Poole, ECETOC) and Government addressed these questions and gave views on how epigenetic effects might fit into current tiered risk assessment frameworks.

### Applying 'omics technologies in chemicals risk assessment

10-12 October 2016, Madrid, Spain

'Omics technologies hold the promise of generating detailed information faster, more accurately and easier than ever before. These emerging technologies could help reduce animal testing, with the ultimate goal of replacing animal testing altogether. They could further increase the number of substances that can be accurately and efficiently tested in a given time. Finally, and importantly, they could identify new and emerging risks through toxicological screening and the provision of reliable biomarkers. Yet current methodological and analytical uncertainties limit the application of 'omics technologies in regulatory toxicology. Best practice for generating and storing, processing, and interpreting 'omics data is needed so that the outcomes of 'omics-based studies can be reliably verified and confidently integrated into regulatory hazard and risk assessment.

Against this background, ECETOC convened a workshop Applying 'omics technologies in chemicals risk assessment. Altogether 37 experts attended the workshop representing the European Commission; the Organisation for

Economic Cooperation and Development (OECD); national authorities from EU Member States, EU associated countries and the United States; academia; industry and independent consultants. An additional three experts contributed to the workshop in the form of video or dial-in presentations. A report on the workshop will be published in the Open Scientific Literature in due course.

### Guidance on the selection of cohorts for extended one-generation reproduction toxicity study (OECD 443)

Presentation by Alan Poole (ECETOC) at 7th Euro-Global Summit on Toxicology and Applied Pharmacology 24 October, 2016 Rome, Italy

The extended one-generation reproduction toxicity study (EOGRTS; OECD test guideline 433) is a new and technically complex design to evaluate the putative effects of chemicals on fertility and development, including effects upon the developing nervous and immune systems. In addition to offering a more comprehensive assessment of developmental toxicity, the EOGRTS provides important improvements in animal welfare through reduction and refinement of use of experimental rodents in a modular study design. The challenge to the practitioner however is to know how the modular aspects of the study should be triggered on the basis of prior knowledge of a particular chemical, or on earlier findings in the EOGRTS itself, requirements of specific regulatory frameworks notwithstanding.

### Human evidence for chemical respiratory sensitisation – How to use it and how to improve it

27-28 October 2016, Madrid, Spain

In 2015, an ECETOC taskforce published the results of its review of the available data considering the relevant endpoints that can be used to describe Chemical Respiratory Allergy (CRA) and to inform our understanding of threshold effects<sup>[1]</sup>. The task force publication concluded that while the acquisition of sensitisation to chemical respiratory allergens is a dose-related phenomenon, and that thresholds exist, currently the mechanisms involved in CRA are not fully elucidated, there is uncertainty regarding routes of exposure and no validated models exist for identification of respiratory sensitising substances. Neither are there any methods suitable for the routine assessment of threshold values for sensitisation of the respiratory tract by chemicals. As a result, human thresholds of induction and elicitation are poorly characterised which creates uncertainty surrounding the safe use of H334 (previously assigned the risk phrase R42) classified substances.

Therefore, ECETOC organised a workshop to develop best practice guidance on how to assess and use available human data for the identification of respiratory sensitisers and to drive discussions on identifying human biomarkers for respiratory sensitisation to chemical allergens and the use of such tests in prospective monitoring of workforces to identify more accurate threshold data. A workshop report will be published in due course.

<sup>[1]</sup> Cochrane SA, Arts JH, Ehnes C, Hindle S, Hollnagel HM, Poole A, Suto H, Kimber I. 2015. Thresholds in chemical respiratory sensitisation. *Toxicology* 333:179-94.

### Developing a strategy to improve the hazard and risk assessment of difficult to test multi-component substances

02-04 November 2016, Gaylord Palms, Kissimmee, Florida, USA, preceding the SETAC World Congress

International regulatory frameworks (specifically REACH, Environment and Climate Change Canada's DSL Categorisation, and USEPA's PMN process) have highlighted the complexities of registering, characterising fate and ecotoxicity, and risk assessing complex chemical mixtures whether from manufacturing environments or plant derived materials. Several industrial sectors (e.g., petrochemicals, personal care) have developed frameworks for characterisation and analysis of these complex substances.

The RIFM/ECETOC Workshop provided a platform for key sectors and regulators to identify best practices and key research needs to support environmental risk assessment of these complex substances. Initial outcomes from this workshop were presented at SETAC's World Congress in Orlando, and will be presented at the SETAC EU meeting in Brussels in May as part of a jointly organised session: Improving the environmental assessment of complex composition substances and mixtures for Chemicals Management.



**Group photo of the participants at the RIFM/ECETOC Workshop on difficult to test multi-component substances**

## Upcoming Events

### 2017 Environment Progress Review

02-03 February 2017, Brussels, Belgium

This annual review is an opportunity for Member Companies to propose ideas and to provide input directly into ECETOC and Cefic LRI scientific programmes. Recommendations from this meeting are taken into account by the ECETOC Scientific Committee and Cefic LRI when deciding their respective future scientific work programmes.

### 2017 Annual General Meeting followed by 2017 Annual Technical Meeting

08 March 2017, Brussels, Belgium

The Annual General Meeting (open to Member Company Delegates only) will start the day and be followed by the Annual Technical Meeting which will bring together ECETOC scientists and other invited experts.

### Advances in high tier environmental exposure modelling: Bridging the gaps between research and practical application

ECETOC Workshop, 04-05 May 2017, Brussels, Belgium

Over the past 35 years, a variety of exposure modelling concepts have been developed, each with a series of specific objectives, processes, compartments and/or chemical classes in mind (e.g. generic multimedia models versus spatially explicit models, models for metals, models for pesticide application, waste water treatment and river models, etc.). This workshop aims to (1) Review recent advances in exposure models; (2) Identify and assess feasibility of models and research capable of being representative of harmonized approaches for assessing exposure between the different industry sector groups; (3) Address applicability domain challenges, including chemical, spatial, and temporal.

## Latest Publications

### Special Report no.19: Building a prenatal developmental toxicity ontology

(Published August 2016)

This ontology provides a way for data and information on developmental toxicology from different sources to be structured and shared in an understandable way. By using a common vocabulary and a user friendly structure, it is envisioned that this particular ontology will allow scientists to make connections and understand relationships between common pathways resulting in adverse reproductive health outcomes. Such a tool will help scientists and toxicologists predict the possibility of a substance producing developmental toxicity without the need for comprehensive animal testing.

This ECETOC Special Report no.19: *Building a Prenatal Developmental Toxicity Ontology*, can be freely downloaded at <http://bit.ly/ecetoc-sr19>. A paper is also in preparation to be published in the Open Scientific Literature.

### Workshop Report no.29: Defining the role of chemical activity in environmental risk assessment within the context of mode of action: practical guidance and advice

29-30 October 2015 Snowbird, Utah, USA (Published August 2016)

At its most basic level, chemical risk assessment involves an assessment regarding both the toxicity and exposure mechanisms associated with a specific chemical. It is well understood that the toxic effects of a given chemical depend on the dose (how much), frequency of exposure (how often), and the route by which the chemical enters the body. Mechanisms that influence toxicity and exposure of chemicals are governed by thermodynamics. As such, understanding these mechanisms can be useful in identifying chemicals that represent unacceptable risks to humans and the environment.

ECETOC in collaboration with RIFM organised a two-day workshop to assess the feasibility and applicability domain of the chemical activity concept within chemical risk assessment. The workshop reviewed the use of chemical activity as an applied tool for assessing the environmental risks of neutral hydrophobic chemicals known to act as baseline toxicants,

and worked towards identifying data gaps. The accompanying workshop report summarises a research strategy defined to address existing data gaps needed to expand the applicability domain to miscible and ionisable organic chemicals with specific modes of action, and application of the concept to chronic toxicological endpoints.

A description and findings of the workshop have been published as ECETOC Workshop Report No. 29: *Defining the role of chemical activity in environmental risk assessment within the context of mode of action: Practical guidance and advice*. 29-30 October 2015, Snowbird, Utah, USA. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-wr29>

### Workshop Report no.30: The role of epigenetics in reproductive toxicity

12-13 November 2015, Brussels (Published August 2016)

Building on the success of an earlier ECETOC workshop in December 2011: Epigenetics and Chemical Safety (See ECETOC Workshop Report no.23), this November 2015 workshop brought together scientists from around the world to discuss and explore if environmental exposure-induced epigenetic changes that occur during foetal development in utero as a response to external factors such as chemical exposure, might be responsible for diseases in adults. The ability to understand and measure epigenetic changes occurring in the developing embryo offers the possibility of predicting and preventing disease states in later life. Experts from a range of disciplines including epidemiology, toxicology, epigenomics and regulatory science met over two days — first to share knowledge and then to brainstorm research needs in the field.

The workshop offered ideas and suggestions for applied research to address this question. These are being pursued through the CEFIC Long Range Research Initiative (LRI).

The findings of the Workshop have been published as ECETOC Workshop Report no.30: *The Role of Epigenetics in Reproductive Toxicity*. 12-13 November 2015, Brussels. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-wr30>

## Workshop Report no.31: Advances in consumer exposure science: data, modelling and aggregate exposure assessment

26 January 2016, Brussels (Published August 2016)

The workshop provided the opportunity for experts from industry, academia and the regulatory community to review and discuss the landscape of the various tools and methods currently available to estimate consumer exposures. Also, by using case studies, they examined the strengths and weaknesses of the various tools and methods for assessing consumer exposures to different classes of substances.

A synopsis of the meeting together with recommendations for improving quality and reducing variability in consumer predictions are found in ECETOC Workshop Report no 31: *Advances in Consumer Exposure Science: Data, Modelling and Aggregate Exposure Assessment*. 26th January 2016, Brussels. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-wr31>

## Workshop Report no.32: Noncoding RNAs and risk assessment science

3 – 4 March 2016, Málaga (Published August 2016)

ECETOC organised a workshop in collaboration with the Cefic Long-range Research Initiative (LRI) to discuss the state-of-the-art research on Noncoding RNAs as potential biomarkers in regulatory toxicology for the assessment of product safety. A promising avenue is using measurements of ncRNAs as markers of toxicity, particularly tumour induction, which is usually examined in high-tiered studies requiring the use of many experimental animals. Thus, such measurements hold the potential to significantly reduce animal testing for the carcinogenic potential of chemicals. It was however agreed that while significant progress has been achieved careful evaluation is still required to determine the utility of such biomarkers in assessing product safety.

The findings of the Workshop have been published as ECETOC Workshop Report no.32: *Noncoding RNAs and Risk Assessment Science*. 3 – 4 March 2016, Málaga. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-wr32>

## Technical Report no.126: Guidance for effective use of human exposure data in risk assessment of chemicals

(Published November 2016)

To understand and predict health risks posed by exposure to substances it is necessary to interpret both the toxic properties and the potential exposure to that substance:

### **Risk = Fn(Hazard, Exposure)**

This task force reviewed the landscape of the various tools and methods available currently to estimate consumer exposures and, by using case studies, the strengths and weaknesses of the various tools and methods for assessing consumer exposures to different classes of substances were examined. A workshop was also organised to review and discuss the task force output (see Workshop report no.31 above). It is hoped that the task force report will be of use to both regulatory bodies and industry in providing guidance on the appropriate use of different exposure tools and data for different purposes. Additionally, the task force output should provide a path forward with regards to further research and data that can be gathered by the broader risk assessment community in order to facilitate better exposure assessments in the future.

The task force report has been published as ECETOC Technical Report no.126: *Guidance for Effective Use of Human Exposure Data in Risk Assessment of Chemicals*. The

Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-tr126>

## Technical Report no.127: Freshwater ecotoxicity as an impact category in life cycle assessment

(Published November 2016)

Freshwater is a vital component in the global ecosystem. Freshwater is a unique environmental habitat and also essential for human life. Freshwater pollution not only poses a risk to the environment, but it can also impact human health as well. Therefore, it is important to maintain anthropogenic pollution below a threshold that would characterise a risk.

Life cycle assessment (LCA) is a methodology that strives for the assessment of environmental burdens along an entire (product) value chain. This means, for example, a consumer product assessment starts at the extraction of raw materials and it ends with the disposal of the product. All environmentally relevant intermediate stages such as transport, manufacturing steps and product use are accounted for, considering even secondary resources such as energy consumptions and their associated values chains in full.

ECETOC established a task force to investigate the method employed in the LCA context of PEF. The report includes an extended discussion of the options that could move forward the discussion of the relevance and practical aspects of assessment of ecotoxicological effects in the framework of LCA.

The document has been published as ECETOC Technical Report no.127: *Freshwater Ecotoxicity as an impact category in life cycle assessment*. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-tr127>

## Technical Report no.128: Guidance on assessment and application of Adverse Outcome Pathways (AOPs) relevant to the endocrine system

(Published December 2016)

Various European chemical regulations do not allow the marketing or use of substances known to have endocrine disrupting properties – chemicals that induce adverse effects in humans and/or wildlife as a result of interaction with the endocrine system.

Adverse outcome pathways (AOPs) have the potential to be important tools for the assessment of endocrine disrupting properties as they can help identify if an adverse effect observed in an in vivo (animal based) study can be plausibly linked to a change in the endocrine system. AOPs could potentially be used to help predict the potential for an adverse effect in humans and/or wildlife from the results of in vitro (non-animal based) assays, potentially reducing the requirement for animal testing.

This guidance will be a useful tool for 1) those looking to develop new AOPs helping to identify the key elements that need to be considered during construction, and 2) those considering applying existing AOPs by providing a list of key elements to be considered to facilitate a critical review and ensure it is fit for the intended purpose.

The document has been published as ECETOC Technical Report no.128: *Guidance on assessment and application of Adverse Outcome Pathways (AOPs) relevant to the Endocrine System*. The Executive Summary and free PDF of the report are available at <http://bit.ly/ecetoc-tr128>

## Latest Publications (continued)

### Published Articles:

Struijs J, van de Meent D, Schowanek D, Buchholz H, Patoux R, Wolf T, Austin T, Tolls J, van Leeuwen K, Galay-Burgos M. 2016. Adapting SimpleTreat for simulating behaviour of chemical substances during industrial sewage treatment.

*Chemosphere* 159:619-27 (Open Access in preparation)

Doi: [10.1016/j.chemosphere.2016.06.063](https://doi.org/10.1016/j.chemosphere.2016.06.063)

Aigner A, Buesen R, Gant T, Gooderham N, Greim H, Hackermüller J, Hubesch B, Laffont M, Marczylo E, Meister G, Petrick JS, Rasoulpour RJ, Sauer UG, Schmidt K, Seitz H, Slack F, Sukata T, van der Vies SM, Verhaert J, Witwer KW, Poole A. 2016.

Advancing the use of noncoding RNA in regulatory toxicology: Report of an ECETOC workshop.

*Regul Toxicol Pharmacol* 82:127-139 (Open Access)

Doi: [10.1016/j.yrtph.2016.09.018](https://doi.org/10.1016/j.yrtph.2016.09.018)

Belanger S, Barron M, Craig P, Dyer S, Galay-Burgos M, Hamer M, Marshall S, Posthuma L, Raimondo S, Whitehouse P. 2016.

Future needs and recommendations in the development of species sensitivity distributions: Estimating toxicity thresholds for aquatic ecological communities and assessing impacts of chemical exposures.

*Integr Environ Assess Manag* (Open Access in preparation)

[Epub 29 September 2016 ahead of print]

Doi: [10.1002/ieam.1841](https://doi.org/10.1002/ieam.1841)

Moore NP, Beekhuijzen M, Boogaard PJ, Foreman JE, North CM, Palermo C, Schneider S, Strauss V, van Ravenzwaay B, Poole A. 2016.

Guidance on the selection of cohorts for the extended one-generation reproduction toxicity study (OECD test guideline 443).

*Regul Toxicol Pharmacol* 80:32-40 (Open Access)

Doi: [10.1016/j.yrtph.2016.05.036](https://doi.org/10.1016/j.yrtph.2016.05.036)

Brown AR, Whale G, Jackson M, Marshall S, Hamer M, Solga A, Kabouw P, Galay-Burgos M, Woods R, Nadzialek S, Maltby L. 2016.

Towards the definition of specific protection goals for the environmental risk assessment of chemicals: A perspective on environmental regulation in Europe.

*Integr Environ Assess Manag* 2016 Aug 10

Doi: [10.1002/ieam.1797](https://doi.org/10.1002/ieam.1797) (Open Access)

Thomas P, Mackay D, Mayer P, Arnot J, Galay Burgos M. 2016.

Response to comment on "Application of the activity framework for assessing aquatic ecotoxicology data for organic chemicals".

*Environ Sci Technol* 50(7):4141-4142

Doi: [10.1021/acs.est.6b00864](https://doi.org/10.1021/acs.est.6b00864)



### In the pipeline

Technical Report no.129: *Biodegradation default half-life values in the light of environmentally relevant biodegradation studies. Analysis of the ECETOC biodegradation data base.*

Technical Report: *Sufficiency of aquatic hazard information for environmental risk assessment*

Paper reporting on Workshop: *Applying 'omics technologies in chemicals risk assessment. 10-12 October 2016, Madrid, Spain*

Workshop Report: *Chemical respiratory allergy: clinical information and how to use it and improve it. 27-28 October 2016, Madrid*



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