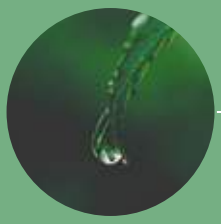
# Annual Report '17



ecetoc

EUROPEAN CENTRE FOR ECOTOXICOLOGY
AND TOXICOLOGY OF CHEMICALS

# Contents

# ① About ECETOC

## ECETOC AT A GLANCE

**FORUM FOR EXPERT COLLABORATION** from world-wide industry, academia and regulatory bodies who work together to develop an agreed understanding on how the State of the Science can be used to improve Risk Assessment by developing novel Tools, Guidance and Frameworks. This is achieved through Task Forces, Expert Meetings and Workshops

**HARNESSES CROSS-SECTORIAL CHEMICAL INDUSTRY EXPERTISE** from the leading companies representing industrial chemicals, agrochemicals, consumer products, biomaterials and pharmaceuticals

**IDENTIFIES RESEARCH NEEDS** selects proposals and monitors progress of research projects for the Cefic Long-range Research Initiative (LRI)[1]

**SHARES KNOWLEDGE** through freely available Scientific Publications: reviews, articles and workshop reports

**SCIENTIFIC REPRESENTATION** for its member companies through presentations at specialist meetings and scientific activities with international agencies, government authorities and professional societies

[1]http://cefic-lri.org/

Since 1978 ECETOC, an Industry-funded, scientific, not-for-profit think tank, strives to enhance the quality and reliability of science-based chemical risk assessment.

## BACKROUND

An independent, non-profit, non-commercial and non-governmental organisation, ECETOC was established in 1978 to provide a scientific forum through which the extensive specialist expertise of manufacturers and users of chemicals could be harnessed to research, review, assess and publish studies on the ecotoxicology and toxicology of chemicals.

## FINANCING

ECETOC is financed by its membership, which is comprised of the leading companies with interests in the manufacture and use of chemicals, biomaterials and pharmaceuticals.

## PURPOSE

Put science at the heart of decision making to protect human health and the environment.

## VALUES

Providing the best science to help ensure risk management decisions are grounded in science.

## VISION

ECETOC is recognised as the reference source for industry expertise in regulatory decision making.

## MISSION

Developing and communicating best science practices for risk assessment.

## STRUCTURE

ECETOC is governed by a Board of Administration comprising senior executives from member companies. The Board is responsible for the overall policy and finance of the organisation. The Board appoints the Secretary General and the members of the Scientific Committee which defines, manages and peer reviews the ECETOC work programme. The Board and the Scientific Committee are supported by the ECETOC secretariat which is managed by the Secretary General, who oversees the day to day running of the organisation.

# ② Membership

## BENEFITS OF MEMBERSHIP

**HARNESS THE COLLECTIVE EXPERTISE OF THE CHEMICAL INDUSTRY**
to contribute to the science of regulatory risk assessment

**HAVE A VOICE**
in shaping Industry's Science Agenda

**CAPACITY SHARING**

- Keep informed of current and future regulatory science challenges
- What's hot, what's new, what's affecting other companies/ sectors
- Access to ECETOC Expert meetings attended by top academic, industry and regulatory agencies from around the world
- Train staff through participation in ECETOC Task Forces and Research Monitoring Teams
- Member companies and regulatory authorities gain understanding and knowledge to apply within their organisations

**REPRESENTATION IN EU AND INTERNATIONAL ORGANISATIONS**
ECHA (RAC, MSC), WHO (Risk Assessment Network) and OECD

**PROPOSE THE DEVELOPMENT OF TOOLS TO STREAMLINE CHEMICAL REGISTRATIONS**
such as SSD Tool and the TRA (Targeted Risk Assessment Tool) which is used in the vast majority of REACH dossiers

Membership is open to companies who manufacture or use chemicals (see **www.ecetoc.org/membership** for more details). To apply for membership, contact the ECETOC Secretary General, Mr Olivier de Matos: Telephone: +32 2 675 3600, Email: info@ecetoc.org or write to: ECETOC, Avenue E. van Nieuwenhuyse 2, bte.8, B-1160, Brussels, Belgium.

During 2017, the ECETOC Membership comprised the following 31 full Member Companies and 7 Associate Member Companies...

## ECETOC MEMBER COMPANIES

# ③ Message from the **Chair of the Board**

**MARTIN KAYSER**
Chair of the Board of Administration

On the eve of the 40th Anniversary of ECETOC, we can look back with great pride on the accomplishments of our association in actively supporting its Membership in the safe manufacturing and use of chemicals, pharmaceuticals and biomaterials through sound science. Furthermore, thanks to the dedication, goodwill and personal involvement of the scientists who donate their time to the Science Programme, ECETOC is widely recognised and respected for its meaningful role in placing science at the heart of decision-making to protect human health and the environment.

Right from the early years, ECETOC cooperated with the International Agency for Research on Cancer (IARC) and participated in the World Health Organisation (WHO) International Programme on Chemical Safety (IPCS). The 1990s saw cooperation begin with the European Commission for the first technical guidance document, the European Centre for the Validation of Alternative Methods (ECVAM), the United Nations Environment Programme (UNEP) and the International Register of Potentially Toxic Chemicals (IRPTC) partnership in the European Commission project 'FAME'[2] and the granting of official NGO status with the WHO.

With the new millennium came cooperation with the European Commission on implementation of the White Paper on the Strategy for a future Chemicals Policy[3], on ACUTEX, a project to develop a methodology for acute exposure values (ACUTEX) and on the scoping of REACH technical guidance documents.

On the occasion of its 25th Anniversary in 2003, ECETOC started to sponsor young scientist awards with the objective of recognising and promoting young scientists.

2004 saw the launch of ECETOC's biggest success story to date – the Targeted Risk Assessment (TRA) Tool which has been identified by the European Commission's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as a preferred approach for evaluating consumer and worker health risks. The TRA is now being applied for the

ECETOC is widely recognised and respected for its meaningful role in placing science at the heart of decision-making to protect human health and the environment.

... let us celebrate the many achievements of these past 40 years and look ahead to supporting our members and other stakeholders by providing the best science to help ensure risk management decisions are grounded in Science for many years to come.

vast majority of EU REACH registrations and is also being closely examined for use by regulators outside the EU. Indeed, during the past decade, ECETOC has grown to become an International reference source for science-based chemical risk assessment and in 2013 Sumitomo Chemical became its first Japanese Member Company.

Speaking of Membership, during 2017 we welcomed 2 new Members: Arkema and The Lubrizol Corporation. The Arkema Group is a specialty chemicals global major with 3 business segments – High Performance Materials, Industrial Specialties, and Coating Solutions – and globally recognised brands, operating in close to 50 countries. The Lubrizol Corporation, headquartered in Wickliffe, Ohio, USA, is a subsidiary of Berkshire Hathaway and provides specialty chemicals for the transportation, industrial and consumer sectors.

Job changes and retirements in 2017 led my fellow Board Members, Drs. Petra Hanke-Baier (Procter & Gamble), Thomas Jostmann (Evonik Industries), Carole Langrand-Lerche (Bayer CropScience) and Karen Niven (Shell) to step down from the Board. I would like to thank all four of them for their dedication and contributions over the years and wish them well in the future. At the 2017 AGM, we welcomed new Board Members Dr. Patrick Masscheleyn (Procter & Gamble) and Dr. Heiko Rieck (Bayer). Drs Steve Maund (Syngenta Crop Protection), Chantal Smulders (Shell International) and Volker Soballa (Evonik Industries) will be proposed for Board Membership at the 2018 AGM to bring us back up to a full complement.

I am also very happy to have Olivier de Matos on board as the new Secretary General following the retirement of Dr. Alan Poole in September 2017. I would like to thank Alan for his excellent work and commitment over his 5-year tenure. Previously, Olivier was Managing Director at Burson-Marsteller in Brussels, Leader of the Environment and Energy Practice and member of the Brussels Leadership Team. Olivier's expertise and experience will be vital for the continued leadership of ECETOC on independent scientific developments and to address future challenges.

Finally, I would like to express my thanks to the members of the Secretariat team, past and present, who have supported and facilitated the Science Programme over the past 40 years. During 2018, let us celebrate the many achievements of these past 40 years and look ahead to supporting our members and other stakeholders by providing the best science to help ensure risk management decisions are grounded in Science for many years to come.

[2] Fisheries and Aquaculture Monitoring and Evaluation under the European Maritime and Fisheries Fund (EMFF)

[3] COM (2001)88. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52001DC0088:EN:NOT

# ④ ECETOC Board of **Administration**

The Board of Administration, composed of at least six member-company representatives

Two Board Members are entitled to represent the Associate members

Board members have a two-year mandate and are responsible for the overall policy and finance of the association

The Board is also responsible for appointing the members of the Scientific Committee

**The Board of Administration, composed of at least six member-company representatives, is empowered by the Annual General Meeting with the management and administration of ECETOC, and delegates these tasks on a daily basis to its Secretary General. Two Board Members are entitled to represent the Associate members. Board Members have a two-year mandate and are responsible for the overall policy and finance of the association. The Board is also responsible for appointing the members of the Scientific Committee.**

**Member companies may propose candidates for the Board; these candidates must have managerial duties within their company and possess scientific and technical experience.**

## ELECTION OF BOARD MEMBERS AT THE 2017 ANNUAL GENERAL MEETING

- **Lorraine Francourt** (Dow Europe)
- **Peter Hertl** (Syngenta Crop Protection)
- **Martin Kayser** (BASF)

and

- **Craig Nessel** (ExxonMobil Biomedical Services Inc.)

were unanimously re-elected to the ECETOC Board.

Proposed new Board Members:

- **Patrick Masscheleyn** (Procter & Gamble)

and

- **Heiko Rieck** (Bayer)

were both unanimously elected to the ECETOC Board.

It was also announced that:

- **Petra Hanke-Baier** (Procter & Gamble)

and

- **Thomas Jostmann** (Evonik Industries),

recently retired from their respective companies and stepped down from the Board,

and

- **Carole Langrand-Lerche** (Bayer CropScience)

and

- **Karen Niven** (Shell)

had both accepted new positions and also stepped down from the Board.

## ECETOC BOARD MEMBERS DURING 2017

- **Martin Kayser** (Chair)
  BASF
- **Lorraine Francourt** (Treasurer)
  Dow Europe
- **Peter Hertl**
  Syngenta Crop Protection
- **Patrick Masscheleyn**
  Procter & Gamble
- **Craig Nessel**
  ExxonMobil Biomedical Sciences
- **Heiko Rieck**
  Bayer

The following nominees attended Board Meetings as guests while awaiting approval by members at the 2018 AGM)

- **Chantal Smulders**
  Shell International
- **Volker Soballa**
  Evonik Industries
- **Steve Maund**
  Syngenta Crop Protection
  (To replace Peter Hertl who retired at the end of 2017)

# ⑤ Report from the **Secretary General**

**OLIVIER DE MATOS**
Secretary General

It is with great pleasure that I share with you ECETOC accomplishments in 2017 and provide a sneak preview of our ambitions for 2018.

In 2017 ECETOC launched the Human Exposure Assessment Tools Database (heatDB). This free public directory allows risk assessors to quickly review what data sources and exposure tools are available for given purposes and to have guidance on their appropriate use.[4]

The year was also productive with the publication of 2 Technical Reports (#129 and #130) and 2 Workshop Reports (#33 and #34). Last but not least, 8 articles were published in peer-reviewed journals; one of the highlights is related to ECETOC's ongoing work on Omics which also led to a Workshop Session on data standardisation across 'Omic platforms in regulatory toxicology held at the US SOT Annual Meeting in March 2017 and an ECETOC Workshop Session on Omics in regulations held at EUROTOX in September 2017. ECETOC also organised a 2-day workshop and modelling tools fair in May 2017 on advances in exposure modelling, resulting in a Workshop Report which is in press at the time of writing this review. A complete publication list can be found later in this report under 'Communicating the Science'.

In the meantime, 2018 has got off to a flying start with several new activities in particular our Review and Scoping meetings covering Environment and Human Health. These meetings provide an open, collaborative environment where scientists from the public and private sectors work together to find solutions to global challenges. They will feed ECETOC's scientific agenda and the Cefic Long-range Research Initiative (LRI). We are conscious that discussions will be very productive and that the wish list will be extensive. ECETOC activities are very popular indeed and we will need to prioritise to ensure that we do not commit to more than our resources can support.

ECETOC will celebrate its 40th Anniversary in 2018. 40 years promoting quality and reliability of science-based chemical risk assessments. It is a real honour to have the opportunity to build upon this heritage.

We aim to continue building the collaborative space where top scientists from academia, government and industry can meet, exchange ideas and knowledge and work together to develop meaningful research and build a knowledge-bank of scientific solutions that protect human health and safeguard the environment.

The year 2017 was one of change for ECETOC as I have the privilege of having replaced Dr. Alan Poole upon his retirement as Secretary General since 1st September 2017. During his tenure, Dr. Poole has streamlined ECETOC to bring best scientific practices to the industry and the global regulatory community in the area of chemical risk assessment - we thank him for his contribution to ECETOC's legacy.

ECETOC will celebrate its 40th Anniversary in 2018. 40 years promoting quality and reliability of science-based chemical risk assessments. It is a real honour to have the opportunity to build upon this heritage. For the past 40 years, we have championed scientific excellence and science-based decision-making by providing a forum for top scientists from industry, government, and academia to work together.

We aim to continue building the collaborative space where top scientists from academia, government and industry can meet, exchange ideas and knowledge and work together to develop meaningful research and build a knowledge-bank of scientific solutions that protect human health and safeguard the environment.

For the coming years, we are dedicated to creating a diverse organisation and collaborative environment, with a shared commitment to scientific excellence with a public purpose.

We will further develop the visibility of ECETOC and our dialogue with stakeholders to amplify the voice of science and actively contribute to critical scientific topics with top quality scientific output. But that is for next year's report.

[4] http://www.ecetoc.org/tools/ecetoc-heat-db

# ⑥ Science **Programme**

## Foreword from the Scientific Committee Chair

**BENNARD VAN RAVENZWAAY**
Chair of the Scientific Committee

In the week from 30 January until 02 February 2018 ECETOC held its Environmental, Human Health and Exposure Science Progress Review and Scoping meetings. Four days of looking back on what has been achieved, but more importantly breakout sessions, discussions and prioritisation of what we should do in the future. A total of slightly over 100 people attended these meetings. It was a pleasure and satisfying to note that there was very active exchange and participation from scientists representing academia, regulators and industry. I believe that the tripartite principle should continue being one of the core values of ECETOC. Industry is not the only party bringing sound science to the table, we must listen to our colleagues from academia. Equally important, we must take into account how to translate sound science into proposals that find their way into the regulatory community, because without our work they will be of limited relevance. Listening to the needs and advice of regulators is an essential start. To be truly effective, this requires a higher level of engagement with representatives of regulatory entities.

We need to overcome fears and perception within our own membership, as well as with our colleagues from regulation that working together could be perceived as inappropriate influencing. Public campaigns by certain NGOs to discredit and thus prevent such tripartite engagement have been more successful than we may think and are a true threat to advancing regulatory science towards the protection of human health and the safeguard of the environment. The only answer that I can give to address that perception is to be transparent in our goals and actions and to always remain at the level of solid science. Again, this is the true core of ECETOC and as such we have built a reputation that all of us can be proud of, and that we should preserve and nurture. Additionally, we do need to be more vocal in our communication.

I believe that the tripartite principle should continue being one of the core values of ECETOC. Industry is not the only party bringing sound science to the table, we must listen to our colleagues from academia.

If we have the science right, then it is appropriate and necessary to communicate our position with passion!

Another core value of ECETOC is its ability to address topics of longer term scientific relevance

... the Transformational Programmes that usually run for a period of 3 to 5 years are a perfect illustration. This year has seen several important developments demonstrating that ECETOC is able to deliver!

and shape the scientific agenda. In that respect, the Transformational Programmes that usually run for a period of 3 to 5 years are a perfect illustration. This year has seen several important developments demonstrating that ECETOC is able to deliver!

In 2014 we started our first Transformational Programme called "using data from developing technologies wisely" and "increasing the relevance of ecotoxicological risk assessment". This programme has now been completed with a series of 5 publications in a special issue of Regulatory Toxicology and Pharmacology, 91, Suppl. 1 (2017).

This Transformational Programme has also proven a series of best practices: (1) tackling a scientific challenge at an early stage, (2) working together with academia and regulators (3) good preparation and execution of a 2.5 day workshop (4) effective and timely writing of reports and (5) bringing the best science and top scientists together. With respect to the points (3) and (4), it should be noted that ECETOC has adapted its way on how to deal with the limited resources that are available. All participants were highly engaged; however, we should be aware that we have our limitations with respect to the amount of time that we can dedicate to ECETOC activities. In that respect the ad-hoc involvement of dedicated consultants to organise and help in writing first drafts has been essential to deliver good work in a short period of time.

This new way of working was also adapted to rapidly develop a position document for the identification of compounds which interact with the endocrine system "endocrine disruptors - ED". The first draft was prepared by a small dedicated group with the help of two consultants, and subsequently discussed and amended with the input of a large number of companies and participants. Within 3 months we produced a scientifically sound, step wise approach for ED identification, which was submitted to the EU authorities and published on our website. Recently we have used a similar approach to provide comments to the final draft ED document.

In exposure sciences, the Targeted Risk Assessment (TRA), which is the second Transformational Programme, is continuously being expanded and has been used in the majority of REACH dossiers submitted to ECHA already. I have no doubt that this tool will continue to evolve further in the future and beyond Europe.

The third Transformational Programme is called "Ecological relevance of toxicity assessment schemes". Its objective is to achieve a more realistic scenario of the environment in risk assessment procedures. ECETOC's work in this area in 2016 focused mainly on role of ecosystem services in environmental risk assessment resulting in a Technical Report 125 on Chemical Risk Assessment – Ecosystem Services and support of 2 LRI sponsored Workshops on this topic.

Last but not least, the Guidance on "Grouping of nanomaterials" finalised in 2016 has been largely taken up by ECHA as well as Health Canada and is highly likely to lead to the reduction of animal testing.

2017 has also been a year of profound internal changes. First, I would like to thank our former Secretary General, Alan Poole, for the 5 years of dedicated work and leadership of ECETOC. Alan was essential in bringing about several changes, which allowed our organisation to become more efficient and able to adapt to new requirements. He also managed the transition of the ECETOC offices and staff in an excellent way, safeguarding productivity as well as scientific excellence during

this transition period. Above all, dear Alan, for me it was always a great pleasure to work with you – thanks! Here I would also like to express my gratitude to Christine Yannakas, who served ECETOC in the most loyal way for many, many years. To the members of the Scientific Committee she was the face of ECETOC. Christine, enjoy your well-deserved retirement.

And now it is time to welcome the new team! Lucy Wilmot was contracted by ECETOC in 2017 to manage the Environmental Sciences Programme. Lucy has a B.Sc. in Chemistry from the University of Sheffield, and an M.Sc. in Environmental Geochemistry from the University of Leeds. Since 2008, Lucy has worked as an environmental scientist and project manager for the regulatory consultancy Peter Fisk Associates Ltd (PFA), working on projects relating to risk assessment of chemicals under EU legislative regimes, including REACH. Alice Brousse, responsible for the Human Health Programme, has a PhD from the University of Pharmacy in Poitiers with a specialisation in Toxicology, Environment and Health. At the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) she worked on the 'Harmonisation between threshold and non-threshold methodology in human health risk assessment'. Like Lucy, Alice also works as a scientist and project manager for PFA-Brussels.

Before being appointed as our new Secretary General, Olivier de Matos was Managing Director at Burson-Marsteller in Brussels, Leader of the Environment and Energy Practice and member of the Brussels Leadership Team. His work has focused on advising clients on EU environmental and chemicals policies, in particular REACH. Olivier has also led the implementation of Burson-Marsteller's work on agrochemical issues (pesticides, biocides and fertilisers). He also served for more than 10 years in several meetings of UN conventions as an industry observer. Olivier has a Masters Degree in International and EU Law from La Sorbonne (Paris). For me and the whole Scientific Committee I can say that we are all excited to work with a new dedicated team, full of energy and new ideas.

Beyond efficiency and processes, the future of ECETOC is very much related to the spirit, enthusiasm and creativity of the ECETOC office as well as to our membership participating in Task Forces and Workshops. ECETOC will celebrate its 40th anniversary in March 2018, I hope to see many of you at the occasion of our annual meeting, to share with me our passion for this wonderful organisation.

In exposure sciences, the Targeted Risk Assessment (TRA), which is the second Transformational Programme, is continuously being expanded and has been used in the majority of REACH dossiers submitted to ECHA already. I have no doubt that this tool will continue to evolve further in the future and beyond Europe.

# HIGHLIGHTS OF 2017 COMPLETED TASK FORCES

## ECETOC DEVELOPS SEVEN STEPS FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTING PROPERTIES (ECETOC 7SI-ED)

**In response to the 'Outline of draft Guidance Document for the implementation of the hazard-based criteria to identify endocrine disruptors', published by ECHA and EFSA in December 2016 with support from the JRC, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) has developed science-based guidance showing how the ECHA and EFSA outline to identify endocrine disrupting properties may be put into practice.**

The Outline of Draft Guidance Document states its intention is to '… provide guidance for the implementation of the scientific criteria concerning the hazard-based identification of endocrine disruptors in the context of [the plant protection products and biocidal products] Regulations (EC) No 1107/2009 and (EU) No 528/2012. The Guidance is intended be suitable for both applicants and regulatory authorities.' The Outline goes on to say that '…the endocrine disruptors identification step will be based exclusively on the evaluation of the relevant hazardous properties of a substance.'

Therefore, ECETOC has focused its expertise on providing input for consideration under

Section V of the ECHA and EFSA outline 'Hazard identification strategy for endocrine disrupting properties'. This has resulted in the development of the ECETOC Seven Steps for the Identification of Endocrine Disrupting properties (ECETOC 7SI-ED).

The ECETOC 7SI-ED, that covers human and environmental health, focuses on how to use a weight-of-evidence (WoE) approach to assess available information, to integrate it and determine its sufficiency to conclude on the endocrine disrupting properties of a substance. For this conclusion, the ECETOC 7SI-ED builds on the WHO/IPCS (2002) definition of an endocrine disruptor (ED) and its three components. It offers guidance on how to evaluate and integrate information on each of the three components of the definition of an ED, i.e. how to consider:

**1 -** available apical studies to identify adverse effects that may be endocrine mediated;

**2 -** (non-) endocrine activity data and

**3 -** the biological plausibility that these are linked by a specific endocrine mode-of-action (MoA).

The ECETOC 7SI-ED is based on robust scientific principles and has been designed to be practical and transparent in its utility with the framework being presented as a series of discrete logical steps, each of which is supported by a clear set of questions and considerations to guide decision-making. The ECETOC 7SI-ED applies existing relevant scientific concepts and established best practice frameworks and methodologies e.g. OECD EDTA CF (2012); OECD GD No. 150 (2012); the WHO/IPCS MoA Frameworks, the JRC ToxR Tool and ECETOC TR 106 (2009).

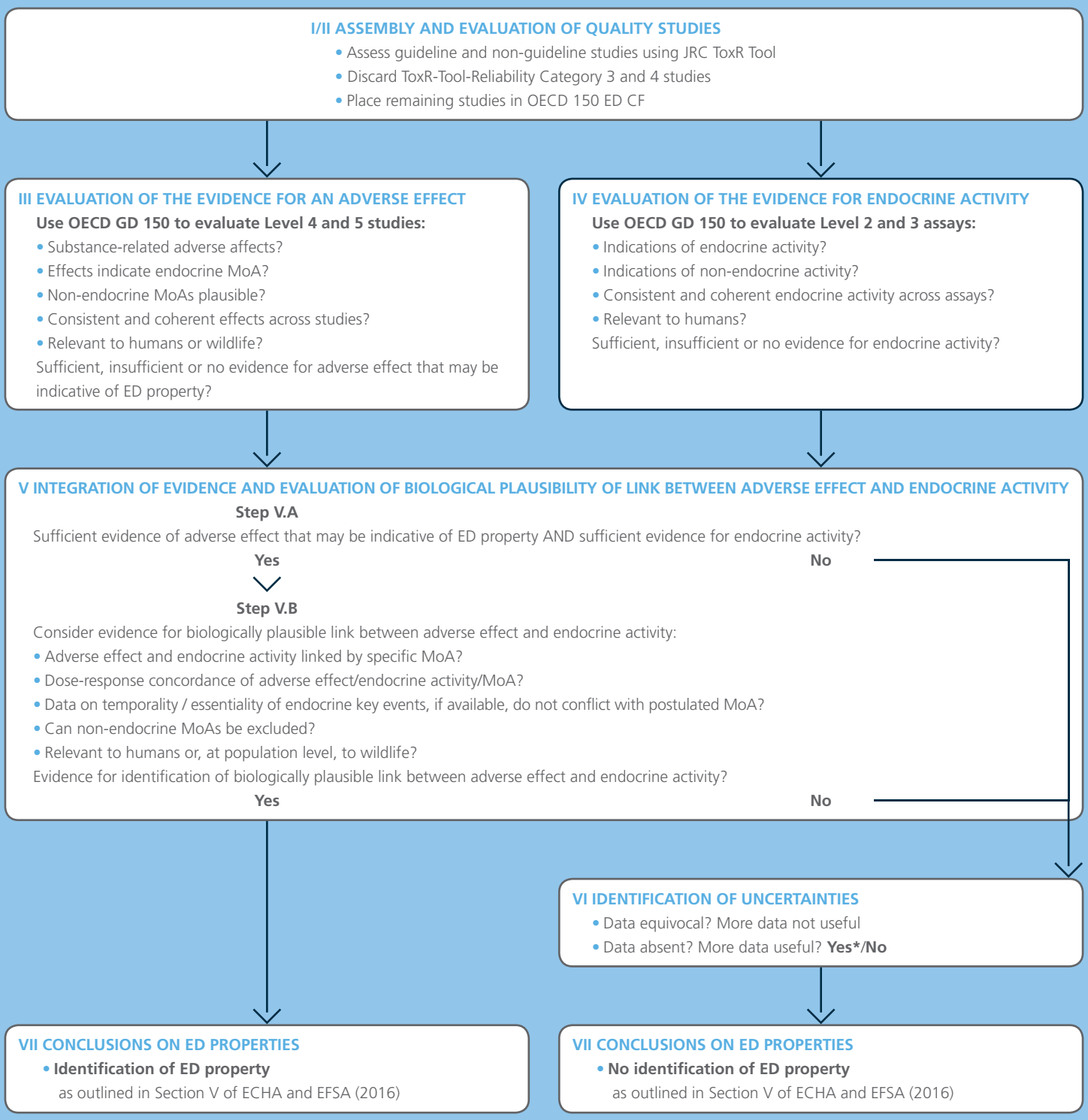
In the Technical Report, the seven steps of the ECETOC 7SI-ED are presented as both text and schematically with further guidance on how to address each step. By following this process, the data for any regulated substance can be transparently organised and evaluated to reveal the WoE available, its strengths and uncertainties, to compare with the WHO/IPCS (2002) definition of an ED. This enables a conclusion to be drawn on whether, or not, a substance meets the regulatory definition.

The next step for any substance that meets the ED definition criteria is to undergo a comprehensive hazard and risk assessment, including potency and exposure assessment, for which guidance already exists yet is beyond the scope of this document.

The Task Force findings were published in March 2017 as ECETOC Technical Report no.130: The ECETOC Seven Steps for the Identification of Endocrine Disrupting Properties (ECETOC 7SI-ED)[5].

[5] Available at https://goo.gl/75uWn4

## SIMPLIFIED FLOW CHART OF THE ECETOC 7SI-ED THAT FOLLOWS THE OUTLINE PRESENTED IN SECTION V OF ECHA AND EFSA (2016)




Abbreviations: CF: Conceptual Framework; ED: Endocrine disrupting; GD: Guidance Document; MoA: Mode-of-action.
*cf. Explanatory note to Step VI on page 24 of the Technical Report.

# TASK FORCES ESTABLISHED

## SPECIAL TASK FORCE ON ENDOCRINE DISRUPTION

**In response to the 'Outline of draft Guidance Document for the implementation of the hazard-based criteria to identify endocrine disruptors', published by ECHA and EFSA in December 2016 with support from the JRC, in December 2016 ECETOC set up a Special Endocrine Disruption Task Force to develop within a 3-month timeframe science-based guidance showing how the ECHA and EFSA outline to identify endocrine disrupting properties may be put into practice.**

**Details of the results of this activity can be found in this report under 'Completed Task Forces'.**

## DNEL DERIVATION GUIDANCE

The ECETOC DNEL Derivation Guidance (2010) – which provides the technical underpinnings by which many/most of industry DNELs (derived no-effect levels) were developed in 2010 and post-2010 – are using guidance factors that differ from those in ECHA REACH guidance, and Member States and ECHA generally challenge these when used. In many cases, the ECETOC guidance factors have been applied but with insufficient supporting documentation (only citation to ECETOC report, rather than substance specific data to support).

Within ECETOC, several companies have formed a Task Force aimed at updating the original guidance on assessment factors based on the latest scientific data and experience both internationally and with the REACH Regulation.

REACH is a precautionary regulation that is intended to provide a high level of protection for human health (and the environment) while maintaining cost of the competitiveness and sustainability of the EU chemicals' market. It achieves this high level of protection in substance risk assessment by calling for the use of conservative, default Assessment Factors (AFs) when developing Derived No Effect Levels (DNELS) for non-cancer endpoints, first-tier exposure assessment tools. Individually these conservative assumptions are reasonable. However, when used in combination in the risk assessment they are multiplicative resulting in a significant over prediction of the actual risk for many substances. This significant over prediction results in the need for additional resources from industry experts and regulators in order to refine these assessments. These refinements include the development and use of chemical specific AFs and the use of higher tier exposure assessment tools to more accurately predict risk.

Experience gained during registration has demonstrated that the burden of proof necessary to justify to ECHA the use of chemical specific AFs is set so high that justification of these factors will be unachievable for all but a few data rich substances. This situation is compounded by the lack of clear and practical guidance on how to develop chemical specific AFs and a lack of such expertise within the chemical industry.

While higher tier exposure assessment tools are available and experience with these is growing it is unlikely that these alone will be sufficient to correct the conservative AFs that are recommended today, particularly for substances of the lower volume bands which attract the highest default AFs (based on e.g. study duration).

The development of guidance by a scientific body such as ECETOC would help to increase the quality and consistency of dossiers thereby leading to a reduced burden in both parties, but would also indirectly contribute to maintaining EU competitiveness.

### ASSESSING THE HUMAN HEALTH AND ENVIRONMENTAL SAFETY OF POLYMERS

In an attempt to tackle the question of how the safety of polymers for man and the environment can be assessed, this task force will devise a framework for the risk assessment of polymers. This risk assessment framework will address the following three general issues which make it difficult to address the potential impact of polymers using conventional risk assessment methodology for organic chemicals, i.e. the EU TGD/ECHA REACH Guidance:

**1 -** Polymers are by default mixtures of substances. Hence, they can be seen as complex reaction products which require a differentiated risk assessment approach.

**2 -** The limited information available on polymers reveals that many are not intrinsically toxic to man and environmental organisms, most likely because they are not biologically available for systemic uptake.

**3 -** A major issue in the environmental assessment of polymers is polymer degradability. Limited information is available on biodegradation of polymers. The precautionary assumption in conventional risk assessments is that polymers are persistent which adds significant uncertainties for the environmental risk assessment and challenges for risk communication.

The objective of the Task Force is to devise a framework for human health and environmental safety assessment of polymers as resource for industry to achieve a common level of understanding and to establish a basis for a discussion with regulators and policy makers. To that end, the elements used in existing approaches for polymer risk assessment will be incorporated into the framework and the complexity of polymer compositions and uses will be taken into account.

In addition, it is also desirable to discuss and distinguish chemically-induced effects of polymers and those which are believed to be the result of a physical impact. This discussion is to clarify the issues that can be addressed by chemical risk assessment and management and identify those issues which may not be suitably addressed.

The outcome of this Task Force will be used as a basis for a workshop with stakeholders (e.g. ECHA, National Regulators, Industry Trade Associations etc.).

The Task Force kick-off meeting is planned for April 2018, and it is foreseen that the Task Force will complete its work within 12 months.

# WORKSHOPS AND SYMPOSIA

### 2017 ECETOC AND CEFIC LRI ENVIRONMENT SCOPING AND PROGRESS REVIEW MEETING

02-03 February 2017, Brussels, Belgium

46 participants from industry, academia and regulatory authorities attended this two-day meeting which had 3 major aims:

**1 -** Inform attendees of progress on LRI and ECETOC actions since last year's review.

**2 -** Review activities and progress in 2 focus themes:
- Hazard Assessment/PBTs and UVCBs
- Ecosystem Impact – increasing ecological relevance

**3 -** Share and prioritise ideas for ECETOC action (Task Forces, Expert Teams, Workshops) and/or Cefic LRI research projects received from member companies.

Day 1 provided an update of progress since the last meeting and reviewed the status of activities in the 2 focus themes with the aim to identify research opportunities and to address any identified knowledge gaps. On day 2, breakout groups discussed project proposals received from member companies ahead of the meeting taking into account the research opportunities identified during day 1. These discussions were taken further in a final plenary session, during which projects for prioritisation as potential ECETOC actions and Cefic LRI research projects were identified. Prioritised projects have since been presented to the ECETOC Scientific Committee and CEFIC LRI Issue Team (IT) for evaluation and decisions on further progression.

**ECETOC IS ADAPTING RAPIDLY TO THE NEW RULES OF THE GAME: WITH THE SPECIAL ENDOCRINE TASK FORCE, IT ACHIEVED RAPID, AD-HOC, CROSS-ASSOCIATION COLLABORATION, FUNDING AND IMPACT. THROUGH ITS LONGER TERM PROGRAMME ON 'OMICS TECHNOLOGIES, IT PICKED A POLITICALLY RELEVANT TOPIC EARLY – ENABLING COLLABORATION ACROSS REGULATORS AND ACADEMIA TO ENSURE A SCIENCE-BASED APPROACH.**

**BEN VAN RAVENZWAAY**
ECETOC Scientific Committee Chair

**HOW CAN REGULATORS MAKE SCIENCE BASED DECISIONS WHEN SOCIETY QUESTIONS THE VALUE OF SCIENTIFIC ASSESSMENTS AND TRUST IN PUBLIC AUTHORITIES IS LIMITED? PUBLIC AUTHORITIES ARE ALONE - THE SCIENTIFIC COMMUNITY IS TOO SILENT: THEY PUBLISH ARTICLES AND ATTEND MEETINGS, BUT DO NOT ENTER THE PUBLIC DEBATE: WE NEED TO WORK TOGETHER TO ADDRESS THIS HOSTILITY AND MISTRUST OF SCIENCE.**

**NATHALIE CHAZE**
European Commission

**ECETOC IMPACTS BUSINESS VALUE THROUGH THE DEVELOPMENT OF TOOLS LIKE TRA AND CHESAR; ACTING AS A CHANNEL TO INPUT INTO ECHA GUIDANCE DOCUMENTS; DEVELOPING SCIENCE ON CRITICAL ISSUES LIKE BIOACCUMULATION AND EXPOSURE MODELLING. IT HELPS INFORM OUR GLOBAL APPROACH TO CHEMICALS MANAGEMENT BECAUSE REGIONAL REGULATIONS DIFFER, BUT ISSUES SPREAD RAPIDLY.**

**GRAHAM ELLIS**
Givaudan

**OVER THE PAST THREE YEARS, ECETOC HAS UPGRADED ITS COMMUNICATIONS. THE NEW WEBSITE WITH MORE LANGUAGE TRANSLATIONS WAS LAUNCHED IN 2016, CREATING A 40% INCREASE IN VIEWS AND A GREATER GLOBAL REACH. YOUTUBE CLIPS ON TECHNICAL SUBJECTS "MADE EASY" AND SOCIAL MEDIA ACTIVITIES HAVE STARTED TO GAIN FOLLOWERS.**

**ALAN POOLE**
ECETOC Secretary General

## 2017 ANNUAL TECHNICAL MEETING

08 March 2017, Brussels, Belgium

ECETOC brought together 46 scientists and experts from chemical associations, member companies and the regulatory community to discuss the evolving role of ECETOC in an increasingly risk-adverse and "anti-science" landscape where:

- Regulatory science is held hostage to public scepticism, resulting in hazard-based decisions.
- Trust in public authorities and industry is at an all-time low. Yet efforts to build trust through transparency can backfire because sensationalist media selectively reports and miscommunicates findings to a public who are confused by hazard vs risk.
- Member company decisions to allocate resources to ECETOC are weighted against budget cuts and competing business-critical priorities.

The objectives were to:

- Gain insight from regulators dealing with "anti-science" pressures and companies who have considered leaving ECETOC.
- Discuss responses to a questionnaire sent out to the ECETOC membership on its functionality, visibility and credibility in the current science-policy-business landscape.
- Identify potential new funding opportunities to support ECETOC activities.

Four presentations set the scene for discussions:

**1 -** Functionality: what ECETOC does and how it does it;
**2 -** "Anti-science challenges facing Regulators;
**3 -** A member company perspective on ECETOC;
**4 -** How ECETOC communicates.

Conclusions and recommendations to the ECETOC Board, resulting from the moderated afternoon discussion sessions, were put forward to the next ECETOC Board meeting for consideration.

## WORKSHOP SESSION: DATA STANDARDIZATION ACROSS 'OMIC PLATFORMS IN REGULATORY TOXICOLOGY

15 March 2017, at 56th Annual SOT Meeting and ToxExpo, Baltimore, Maryland, USA

Dr. Alan Poole (ECETOC) presented 'Towards Developing a Framework for Using New Technologies in Next Generation Risk Assessment and Decision Making'. The workshop proposed transparent frameworks and suitable processes to provide a baseline and confidence on the application of 'omics in regulatory decision making, with a specific emphasis on data analysis and interpretation in risk assessment. Challenges and issues in the regulatory application of 'omic data were addressed in the context of status and future direction for developing objective protocols for the analysis, interpretation, and reporting of 'omic results.

## ADVANCES IN HIGH TIER ENVIRONMENTAL EXPOSURE MODELLING: BRIDGING THE GAPS BETWEEN RESEARCH AND PRACTICAL APPLICATION

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

Assessing environmental exposure of chemicals is a challenging but critical part of assessing environmental risk. Approaches to assess exposure can vary between regulatory bodies. For instance, in Europe differences in estimating PECs vary between general chemicals, regulated under REACH, plant protection products (PPP), as defined by the PPP regulation ((EC) No 1107/2009), and pharmaceuticals, regulated by the European Medicines Agency. Nonetheless, a common objective is to ensure the assessment is transparent, robust, and utilises the latest advances in scientific developments, while at the same time providing a reasonable level of conservativism, necessary to account for associated uncertainties and natural variance in the environment that might influence the reliability of the exposure assessment.

During the last three decades, there has been a great deal of resource directed towards activities aimed at advancing the use and application of exposure models. This includes workshops held by SETAC[6], OECD/UNEP[7,8] and ECETOC, key publications[9], and Cefic LRI projects and ECETOC Task Forces. It was felt that the time was ripe to reflect on the use of exposure models used across the industry sectors and regulatory bodies.

The 2-day workshop was attended by 59 experts from industry, academia and regulatory authorities. The workshop provided an opportunity to bring together users and developers of environmental fate models used in assessing exposure, with an emphasis on the following key themes:

**1 -** Review recent advances in exposure models, with a particular emphasis on better quantification of uncertainties.
**2 -** Identify and assess feasibility of models and research representative of harmonised approaches for assessing exposure between the different industry sector groups.
**3 -** Address applicability domain challenges.
**4 -** Discuss and capture advances related to the exposure assessment of chemical mixtures and addressing the exposure of both the parent chemical and transformation products.
**5 -** Identify best practices for addressing the influence of non-chemical stressors on chemical exposure.

A Workshop Report is currently being prepared for publication in Q1 2018 and a number of papers in peer-reviewed journals are anticipated.

Further details on the ECETOC website: **http://www.ecetoc.org/event/workshop-advances-exposure-modelling-bridging-gap-research-application/**

[6] Cowan, C.E., et al., *The Multi-Media Fate Model: A vital tool for predicting the fate of chemicals*. 1995, Pensacola, FL: SETAC Press.

[7] Fenner, K., et al., *Comparing Estimates of Persistence and Long-Range Transport Potential among Multimedia Models*. Environmental Science and Technology, 2005. 39(7): p. 1932-1942.

[8] Wegmann, F., et al., *The OECD software tool for screening chemicals for persistence and long-range transport potential*. Environmental Modelling and Software, 2009. 24(2): p. 228-237.

[9] MacLeod, M., et al., *The State of Multimedia Mass-Balance Modeling in Environmental Science and Decision-Making*. Environmental Science and Technology, 2010. 44(22): p. 8360-8364.

## INDUSTRY ROUNDTABLE DISCUSSION ON THE ROLE OF ECOTOXICOLOGICAL ASSESSMENTS FOR PRODUCT ENVIRONMENTAL EVALUATIONS

16 November 2017, A.I.S.E. offices, Brussels, Belgium

This roundtable discussion was jointly organised by members of the ECETOC Task Force 'Freshwater ecotoxicity as an environmental impact category to guide the selection of chemical-based products' and the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.).

The roundtable discussion was attended by 20 participants. These included members of the ECETOC Task Force, ECETOC's Secretary General Olivier de Matos, A.I.S.E members and industry practitioners who participated in the pilot phase of the EC Product Environmental Footprint (PEF).

The aim of the discussion was to share expert views on the state of the science of ecotoxicological evaluations in Life Cycle Assessment (LCA)/PEF assessment of products, including the USETox tool, and agree ways forward to further develop the science and its application.

## WHEN OMICS MEET REGULATIONS

ECETOC Workshop Session at EUROTOX 2017, 11 September 2017, Bratislava, Slovakia

The robust and reproducible production, storage, analysis and application of omic data in regulatory decision making will require the validation and standardisation of best laboratory practices and use of standardised frameworks. This Workshop sought to begin establishing guidelines and best practices for attaining, analysing and applying omic data in regulatory decision making. The acceptance and establishment of standardised practices and guidelines will provide confidence for regulators and registrants to interpret and apply omic data in regulatory decision making.

Programme of the Session

- **Towards Establishing Criteria in a GLP Like Context for Collecting, Storing and Retrieving Omic Data for Regulatory Decision Making**
  Bennard van Ravenzwaay
  *Experimental Toxicology and Ecology, BASF SE, Ludwigshafen, Germany*

- **Towards Establishing Criteria and Best Practices for Analysing Omic Data for Regulatory Decision Making**
  Weida Tong
  *NCTR/FDA, Jefferson, United States*

- **Towards establishing a consistent set of criteria to assess the use of non-animal methods in regulatory decision making**
  Alan Boobis
  *Centre for Pharmacology and Therapeutics, Imperial College London, London, United Kingdom*

  Stan Parish
  *ILSI Health and Environmental Sciences Institute (HESI), Washington, DC, United States*

  Douglas Wolf
  *Syngenta Crop Protection, LLC, Greensboro, NC, United Kingdom*

For more detailed information, visit the EUROTOX 2017 website: **www.eurotox2017.com/monday/**

# EXPERT WORKING GROUPS


## BIODEGRADATION DEFAULT HALF-LIFE VALUES

Biodegradation is a key process for breaking down and finally removing chemicals from the environment. The biodegradation half-life time is a key input parameter for environmental risk assessment because it helps to predict the effectiveness of biodegradation. It is widely accepted that a chemical which passes the stringent conditions of an OECD Ready biodegradability test system is assumed to be non-persistent in the environment, as it will biodegrade under a broad variety of different environmental conditions. For modelling purposes, a default half-life of 15 days in fresh water has been set for chemicals categorised as 'readily biodegradable'.

ECETOC investigated the appropriateness of the current approach of approximating half-lives on the basis of tests of ready biodegradability. To that end, a biodegradation database generated by ECETOC from published literature was analysed [ECETOC Biodegradation Data Base, Excel file (ECETOC, 2009)].

**ECETOC Technical Report no.129:**
*Biodegradation Default Half-Life Values in the Light of Environmentally Relevant Biodegradation Studies - Analysis of the ECETOC Biodegradation Data Base.*
Published in April 2017, the report is available at:
**https://goo.gl/k7xXpS**

## METABOLOMICS STANDARDS INITIATIVE IN TOXICOLOGY (MERIT): DEVELOPING BEST-PRACTICE GUIDELINES AND MINIMAL REPORTING STANDARDS FOR THE ACQUISITION, PROCESSING AND ANALYSIS OF METABOLOMICS DATA

This initiative will accelerate the use of metabolomics technology to improve safety assessment of chemicals. Metabolomics is the study of the myriad of small molecules which sustain life, by generating energy, or building larger molecules such as DNA. This technology has the potential to transform chemical risk assessment by providing a deeper view of the molecular events underpinning toxicity than is currently possible. However, because it is so new, scientists do not yet have standard procedures for applying metabolomics or reporting its findings, both of which are needed for chemical risk assessment.

The MEtabolomics standaRds Initiative in Toxicology (MERIT) brings together a team of international experts to address this problem by defining best practices and minimum reporting requirements when metabolomics is used in regulatory toxicology. It comprises partners from industry, government agencies, regulators and academia, from across Europe and the USA, including EFSA, US EPA, US FDA, BASF, Syngenta and Unilever.

Dr. Alan Poole, then Secretary General of ECETOC explained that "*Omics has enjoyed a great deal of success in research. Nevertheless, the use of omics data in regulatory assessment has been hindered by the different approaches to the acquisition and processing of the data which can lead to different outcomes, even from identical studies. By focusing on gene expression and metabolic phenotyping, we can gather significant complementary information on regulatory processes and downstream function – both critical to understanding mechanisms of toxicity*".

Mark Viant, co-chair of the new group states "*We need to address all the roadblocks to translating this highly effective technology of metabolomics into mechanism-based safety science. The MERIT project is a critical step towards that goal*".

## EQUIVALENT LEVEL OF CONCERN (ELOC) ACTIVITY

REACH Art. 57f offers the possibility to identify chemicals which raise equivalent level of concern (ELOC) to CMRs and PBTs (so-called SVHC – substance of very high concern). CARACAL and the JRC proposed to compare different health outcomes by the following aspects:

- Type of possible health effects
- Irreversibility
- Delay of health effects
- Quality of life affected
- Societal concern
- Ability to derive a 'safe concentration'

Concept papers discussing potential criteria exist on these aspects, but no scientific discussion has taken place and no clear scientific criteria were established.

To date Endocrine Disrupting, Respiratory and Strong Skin Sensitising chemicals have been identified as possible ELoC requiring further review although eMSCAs and ECHA have indicated that other human health endpoints may be included.

The objective is to identify effects endpoints that are of ELOC to CMRs and PBTs and to propose science-based criteria for the identification of candidate chemicals.

This project has broad benefits to industry and society on the basis that:

- This focusses regulatory and industry resources to substances of real concern; and
- The lack of specificity in applying criteria for ELoC will undermine the credibility of the regulatory programme.

The activity should catalyse

- Expert discussion about how to compare the severity of impact of different diseases; and
- The development of appropriate science-based criteria for identifying substances that are ELoC across different toxicological endpoints.

## INFORMAL EXPERT GROUP – ECHA EUSES UPDATE WORKSHOP PREPARATION

This informal Expert Group was established on short notice at the end of 2017. This came after the announcement from ECHA that they would be holding a EUSES update Workshop in 2018.

Some industry representatives were invited to join ECHA's Workshop Organising Group, and this ECETOC Expert Group is supporting the input of the industry representatives.

The work of this Expert Group will continue beyond the ECHA EUSES update Workshop under the umbrella of the ECETOC TRA Task Force.

# ECETOC TRANSFORMATIONAL PROGRAMMES

**As part of the ECETOC Board decision to spend part of its resources on Thought Leadership, a set of Transformational Programmes addressing topics of longer term scientific relevance have been established aimed at producing transformational change in chemicals management. These are in general horizontal themes to be completed over 3-5 years. 3 programmes were progressed in 2017:**

## USING MOLECULAR DATA WISELY

ECETOC's first Transformational Programme "Applying 'omics technologies in chemicals risk assessment" arose out of the 2014 Human Health Scoping and Review Meeting.

An ECETOC workshop was held in Madrid in October 2016 and the results were presented at the (US) Society of Toxicology (SOT) Annual Meeting, Baltimore MD, USA in March 2017 and at EUROTOX 2017 in Bratislava, Slovakia in September 2017.

Since then, ECETOC has published a series of 5 papers in Regulatory Toxicology and Pharmacology.

Using Molecular Data Wisely responds to a growing need to understand how to get the best value out of the increasing generation of large volumes of 'omics' data. The purpose of the Programme is to enhance the acceptance and establishment of standardised practices (in context of Good Laboratory Practice), processes and guidelines to provide confidence for regulators and registrants to interpret and apply 'omics data in regulatory decision making. Whilst this Programme originated from the 2014 Human Health Scoping and Review Meeting, the direction of some of the current projects under the programme came from the 2016 Review.

Three different Requests for Proposals have been developed and published by Cefic LRI and are intended to build on the output from the 2016 ECETOC Workshop:

- **C4:** Towards the development of an Omics Data Analysis Framework (ODAF) for regulatory application
- **C5:** Integrating Multiple Molecular-level Data Streams to understand (a) range of normal adaptation vs pathology and (b) molecular generated gene expression changes and persistence over time
- **C6:** Omics and Read Across

## ECETOC ACTIVITY: ECOLOGICAL RELEVANCE OF RISK ASSESSMENT

This activity addresses the complexity and variability in Risk Assessment by improving ecological relevance to enable better risk mitigation and risk management.

The programme comprises 3 key elements:

**1 - Assessing the effects of chemicals in ecological communities**

Strategic objectives:

- Drive development of spatially explicit effect assessment approaches for higher tier risk assessment
- Develop effect assessment approaches accounting for temporal variation in population dynamics and community composition
- Develop proposals on how the effects of chemical mixtures on ecological communities could be assessed.

**2 - Exposure science for higher tier risk assessment**

Strategic objectives:

- Assess the state of the science in exposure science and developments needed to refine higher tier risk assessment
- Develop models to generate exposure profiles accounting for spatial and temporal variation.

**3 - Ecosystem service-based approaches for landscape scale risk assessment and risk management**

Strategic objectives:

- Evaluate the use of an ecosystem services approach to setting protection goals to inform chemical risk assessment
- Facilitate engagement of the chemical industry, academia and regulators to advance the practical implementation of the ecosystem service approach in chemical risk assessment and risk management.
- A Task Force, established in 2016, is currently in progress on *Geospatial approaches to increasing the ecological relevance of chemical risk assessments*.

## ECETOC TARGETED RISK ASSESSMENT TOOL

The ECETOC Targeted Risk Assessment (TRA) Tool[10], developed over 15 years ago, is now used in over 90% of dossier submissions to ECHA in order to help effectively and efficiently meet the requirements of REACH Regulation. It is also directly incorporated into ECHA's CHESAR IT exposure platform, enabling direct linkages with IUCLID and efficiencies in CSR development.

There is also growing interest from other geographies to use the ECETOC TRA tool in their developing chemical regulations. ECETOC is aware of at least two regions developing tools based upon the TRA. This offers the opportunity of harmonising regulatory demands across regions. While development of regional tools is beyond ECETOC's commitment, it is important to interact with tool adaptors to facilitate appropriate tool adaptation, so that the technical credibility of the TRA remains intact and harmonisation can be achieved.

Also, like all well used tools the ECETOC TRA requires maintenance and development to meet the demands made upon it. In this respect, it is planned that a new version of the tool will need to be released in the 2019/2020 timeframe. Further, given the tool's presence in CHESAR, ECETOC has the responsibility to work with ECHA as future questions or new science suggest update.

In ECETOC, the TRA activity is currently part of our Transformational Programmes that address topics of longer term scientific relevance and aimed at producing transformational change in chemicals management (cf. **www.ecetoc.org/science-programme/transformational-programmes**).

This Transformational Programme contains work streams addressing:

**1 -** Industry and the European Chemical Authority (ECHA) expectations
**2 -** Internationalisation opportunities
**3 -** Reinforce reputation and brand recognition

Several past, current and future Cefic LRI projects have been developed to address these topics. Generally, such projects are of longer term scientific relevance aimed at producing transformational change in chemicals management. However, there are also other short-term topics that address immediate regulatory scientific needs.

The TRA Steering team is looking at defining, managing and leading how the TRA will be developed into the medium to long term. The purpose of this group is to develop the overall strategy, set priorities, organise the work and liaise and maintain dialogue with ECHA and relevant stakeholders.

Since the last updates of both the TRA user guidance and Technical Report 124 in 2014, new understandings on the performance of the TRA have become available, additional user feedback has been received, and ECHA has issued new user guidance on Use Description (Ch R12) and human and environmental exposure assessment (Ch R14-16). Therefore, in addition to the existing TRA Technical Reports, Technical Report no.131, Targeted Risk Assessment: Further Explanation of the Technical Basis of the TRA v3.1 was published in February 2018[11].

The report addresses topics which users have identified as potentially benefitting from further clarification, as well as areas where REACH practice, whether enshrined in ECHA's most recent guidance or in the structure of its Chesar tool, may differ (or be perceived to differ) from the approach taken in the TRA.


[10] cf. also: http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

[11] available at https://goo.gl/D56cyh

# RISK ASSESSMENT TOOLS


### TARGETED RISK ASSESSMENT (TRA)

See information under 'ECETOC Transformational Programmes' on previous page.

### ECETOC HUMAN EXPOSURE ASSESSMENT TOOLS DATABASE (HEATDB)

The Human Exposure Assessment Tools Database (heatDB) is a resource for risk assessors to use to quickly search and locate human exposure tools and data available in the public domain.

Available sources of exposure data have been gathered, structured and categorised into a harmonised system. Additionally, available tools for exposure assessment were gathered and categorised into the same system. This allows risk assessors to quickly review what data sources and tools are available for given purposes and to have guidance on their appropriate use using a tiering system.

In parallel with this database, ECETOC Technical Report no. 126 provides analysis, discussion and case studies demonstrating different uses of some the different tools and data sources[12]. There are hundreds of identified sources of human exposure data and tools in heatDB.

Thanks to Crème Global for the development and hosting of the database. Users can register for free, login and use the database as required at **https://heatdb.cremeglobal.com/**

### HSSD TOOL: SCENARIO-BASED SPECIES SENSITIVITY DISTRIBUTIONS (SSD)

This software was developed by a consortium of partners to facilitate the uptake of novel approaches to estimate aquatic threshold concentrations (e.g. the concentration at which 5% of the species are exposed above their EC50, $HC_5$). The software improves on existing approaches (Aldenberg and Jaworska, 2000) by allowing for:

Non-exchangeability of species: The standard SSD approach is based on the assumption that the sensitivity of a species for a chemical cannot be predicted a priori. Craig et al. (2012) have demonstrated non-exchangeability by using a large database of tolerances to pesticides for fish species. The model approaches underpinning the SSD Tool account for the fact that some species seem to be more (and less) sensitive to chemicals than others.

Censored data: The SSD Tool will allow < and > data when these are available.

A non-lognormal distribution shape: The SSD Tool model does not assume that species sensitivities can best be described by a lognormal distribution.

The Hierarchical SSD (hSSD) software tool is hosted by Durham University and can be downloaded at **https://goo.gl/xj5tns**

[12] available on the main ECETOC website at http://bit.ly/ecetoc-tr126

# COMMUNICATING THE SCIENCE

**IAN CUMMINGS**
Communications, Media and Web Manager

How best to communicate the output of the ECETOC scientific programme continues to evolve in line with developments in communication technology and the increasing use of tablets and smartphones alongside traditional computers to access information. With these smaller screen sizes, social media channels are often the more practical option over traditional websites to access content, but the right channels need to be chosen for the type of content and for ECETOC this predominantly means Twitter, LinkedIn, ResearchGate and YouTube. ECETOC has been active with social media since 2010 and, without actively publicising these channels, has seen a steady increase in users.

For example, by the end of 2017, the ECETOC Twitter feed[13] had 500 followers and the ECETOC LinkedIn group[14] stood at over 915 members and we should note that many of them are leaders in their fields and industries because who the users are is even more important than just numbers. It is also good to see younger scientists following ECETOC on these channels as they will be the future experts that we will want to work with.

However, the ECETOC website still remains the primary access point for visitors to ECETOC, growing by over 56% year-on-year to over 56,000 visitors during 2017. ECETOC has in recent years moved away from printed publications and a minimal public presence on the internet towards making its publications easily accessible and placing a maximum of content on the public website to be as transparent and open as possible. Consequently, the ECETOC member website has moved away from being the primary access point to publications and information on the Science Programme for ECETOC Members and has evolved into an online working area for work groups such as ECETOC Task Forces. Consequently, early in 2018 ECETOC launched an updated Members area that concentrates on further streamlining the workflow of ECETOC activities.

ECETOC has been active with social media since 2010 and, without actively publicising these channels, has seen a steady increase in users. users are is even more important than just numbers... It is also good to see younger scientists following ECETOC on these channels as they will be the future experts that we will want to work with.

The 2018 communications plan will further develop ECETOC's social media presence and dissemination of its output, starting with a concerted Twitter programme surrounding the 40th Anniversary on the 21st March.

[13] http://www.twitter.com/ecetoc
[14] http://linkd.in/ecetoc-linkedin

# PUBLICATIONS


ECETOC's primary outputs are state-of-the-science reports that are compiled as a result of the scientific partnerships formed in the framework of ad-hoc issues-based task forces. These take the form of both ECETOC's own published reports and articles published in in the open scientific literature.

**Technical Reports** address specific aspects of the science used in evaluating the hazards and risks of chemicals to human health and the environment. (Note: Since 2009, 'Monographs', which were comprehensive reviews of generic topics or issues fundamental to the application of good science in evaluating the hazards and risks of chemicals, and 'Documents', which were scientific briefing papers addressing emerging issues, are also published as Technical Reports.

**Workshop Reports** are summaries of the discussions and conclusions derived from ECETOC sponsored scientific workshops.

**Scientific Articles** are publications in peer-reviewed journals.

**JACC Reports (Joint Assessment of Commodity Chemicals)** are comprehensive reviews of all available toxicological and ecotoxicological data on specific chemical substances, predominantly those having widespread and multiple uses. Each report presents a hazard assessment and identifies gaps in knowledge. The standard format may be extended in support of EU or other international risk assessment, or setting of an occupational exposure limit value.

**Special Reports** are compilations of data targeted to specific regulatory issues/demands.

Please note that, as part of our continuing drive for efficiency and environmental care, all ECETOC publications are now distributed exclusively in electronic format. All reports can be freely downloaded from **www.ecetoc.org/publications**.

## REPORTS PUBLISHED BY ECETOC DURING 2017

**TR129:** Biodegradation Default Half-Life Values in the Light of Environmentally Relevant Biodegradation Studies. Analysis of the ECETOC Biodegradation Data Base

Published April 2017
ISSN-2079-1526-129 (online)
D-2017-3001-250
**https://goo.gl/k7xXpS**

**TR130:** The ECETOC Seven Steps for the Identification of Endocrine Disrupting Properties (ECETOC 7SI-ED)

Published March 2017
ISSN-2079-1526-130 (online)
D-2017-3001-249
**https://goo.gl/75uWn4**

**WR 33:** Chemical respiratory allergy: clinical information and how to use it and improve it October 27-28 October 2016, Madrid

Published March 2017
ISSN-2078-7219-33 (online)
D-2017-3001-248
**https://goo.gl/Ubm6l3**

**WR 34:** Improvement of the OECD 306 screening test. Workshop held at CEFAS laboratories, Lowestoft, UK 17-18 February 2015 and subsequent ring test

Published September 2017
ISSN-2078-7219-34 (online)
D-2017-3001-251
**https://goo.gl/Yk2Zi2**

## ARTICLES PUBLISHED IN THE OPEN SCIENTIFIC LITERATURE DURING 2017

**Baker N, Boobis A, Burgoon L, Carney E†, Currie R, Daston G, Fritsche E, Knudsen T, Laffont M, Piersma AH, Schneider S, Poole A. 2017.**

Building a Developmental Toxicity Ontology
*Birth Defects Research.* 2018;00:1–17
Doi: 10.1002/bdr2.1189

**Tilghman Hall A, Belanger SE, Guiney PD, Galay-Burgos M, Maack G, Stubblefield W, Martin O. 2017.**

New Approach to Weight-of-Evidence Assessment of Ecotoxicological Effects in Regulatory Decision-Making

*Integr Environ Assess Manag* 13(4):573–579 [Open Access]
Doi: 10.1002/ieam.1936

**Basketter D, Poole A, Kimber I. 2017.**

Behaviour of chemical respiratory allergens in novel predictivemethods for skin sensitisation.

*Regul Toxicol Pharmacol 86:101-106* [Open Access]
Doi:10.1016/j.yrtph.2017.03.002

Set of 5 manuscripts in Regulatory Toxicology and Pharmacology produced as an outcome of the 2016 ECETOC Omics workshop:

1 - **Buesen R, Chorley BN, da Silva Lima B, Daston G, Deferme L, Ebbels T, Gant TW, Goetz A, Greally J, Gribaldo L, Hackermüller J, Hubesch B, Jennen D, Johnson K, Kanno J, Kauffmann HM, Laffont M, McMullen P, Meehan R, Pemberton M, Perdichizzi S, Piersma AH, Sauer UG, Schmidt K, Seitz H, Sumida K, Tollefsen KE, Tong W, Tralau T, van Ravenzwaay B, Weber RJM, Worth A, Yauk C, Poole A. 2017.** Applying 'omics technologies in chemicals risk assessment: Report of an ECETOC workshop. *Regul Toxicol Pharmacol* 91(1):S3-S13 [Open Access]
Doi: 10.1016/j.yrtph.2017.09.002

2 - **Sauer UG, Deferme L, Gribaldo L, Hackermüller J, Tralau T, van Ravenzwaay B, Yauk C, Poole A, Tong W, Gant TW. 2017.** The challenge of the application of 'omics technologies in chemicals risk assessment: Background and outlook. *Regul Toxicol Pharmacol* 91(1):S14-S26 [Open Access]
Doi: 10.1016/j.yrtph.2017.09.020

3 - **Kauffmann HM, Kamp H, Fuchs R, Chorley BN, Deferme L, Ebbels T, Hackermüller J, Perdichizzi S, Poole A, Sauer UG, Tollefsen KE, Tralau T, Yauk C, van Ravenzwaay B. 2017.** Framework for the quality assurance of 'omics technologies considering GLP requirements. *Regul Toxicol Pharmacol* 91(1):S27-S35 [Open Access]
Doi: 10.1016/j.yrtph.2017.10.007

4 - **Gant TW, Sauer UG, Zhang S-D, Chorley BN, Hackermüller J, Perdichizzi S, Tollefsen KE, Tralau T, van Ravenzwaay B, Yauk C, Tong W, Poole A. 2017.** A generic Transcriptomics Reporting Framework (TRF) for 'omics data processing and analysis. *Regul Toxicol Pharmacol* 91(1):S36-S45 [Open Access]
Doi: 10.1016/j.yrtph.2017.11.001

5 - **Bridges J, Sauer UG, Buesen R, Deferme L, Tollefsen KE, Tralau T, van Ravenzwaay B, Poole A, Pemberton M. 2017.** Framework for the quantitative weight-of-evidence analysis of 'omics data for regulatory purposes. *Regul Toxicol Pharmacol* 91(1):S46-S60 [Open Access]
Doi: 10.1016/j.yrtph.2017.10.010

# CONTRIBUTING TO INTERNATIONAL INITIATIVES

## REPRESENTATION, PRESENTATIONS AND POSTERS AT SPECIFIC MEETINGS

**US Society of Toxicology (SOT) 56th Annual Meeting and ToxExpo**
*12-16 March 2017, Baltimore, MD, USA*
ECETOC represented by Alan Poole
Symposium at SOT: Data Standardization Across 'Omic Platforms in Regulatory Toxicology

**SETAC Europe 27th Annual Meeting: 7–11 May 2017, Brussels " Improving risk assessment and management of chemicals through trans-disciplinary collaboration "**
*07-11 May 2017: Brussels, Belgium*
ECETOC represented by Lucy Wilmot

**Four Posters presented:**

- **Exploring Community-Based Environmental Risk Assessments of Mixtures Using Mode-of-Action Approaches**
  Miriam Leon Paumen (ExxonMobil),
  Frederik De Laender (Namur University),
  Mick Hamer (Syngenta),
  Laurent Lagadic (Bayer CropScience),
  Cecilie Rendal (Unilever),
  Joy Worden (Shell International),
  Andreas Focks (Wageningen Environmental Research [Alterra])

- **Freshwater Ecotoxicity as an Impact Category in Life Cycle Assessment**
  Nikolaj Otte (Henkel),
  Christopher Cooper (International Zinc Association),
  Robert Hoke (DuPont),
  Henry King (Unilever),
  Jacques L'Haridon (L'Oréal),
  Frédéric Palais (Solvay),
  Florian Schmidt (BASF),
  Diederik Schowanek (P&G),
  Thomas Wolf (formerly L'Oréal),
  Michiel Claessens (Chemours),
  Lucy Wilmot (ECETOC)

- **Impact of the revision of the ECHA guidance on PBT assessment of chemicals**
  Bernhard Jene (BASF)
  Sylvia Jacobi (Albemarle)
  Sami Belkhiria (Dow Chemical)
  Marie-Hélène Enrici (Solvay)
  Miriam Leon Paumen (ExxonMobil)
  Kent Woodburn (Dow Chemical)
  Karen Jenner (Givaudan)
  Sylvia Gimeno (Firmenich)
  Björn Hidding (BASF)

- **Industrial SimpleTreat - an updated model for predicting the fate of chemicals which enter industrial wastewater systems; model validation and use in a regulatory context**
  Jaap Struijs (JSscience)
  Dik van de Meent (Radboud University)
  Tom Austin (Shell)
  Diederik Schowanek (P&G)
  Hans Buchholz (L'Oréal)
  Paul Mason (SC Johnson)
  Remi Patoux (Solvay)
  Thomas Wolf (Formerly L'Oréal)
  Johannes Tolls (Henkel)
  C.J. (Kees) van Leeuwen (KWR Watercycle Research Institute)
  Malyka Galay-Burgos (Formerly ECETOC)

**Life Cycle Management 2017**
*06 September 2017, Luxembourg*
Presentation: Freshwater ecotoxicity as an environmental impact category in LCA – Findings of an ECETOC Taskforce. Presented by Nikolaj Otte (Henkel) and Jacques L'Haridon (L'Oréal)

**53rd Congress of the European Societies of Toxicology (Eurotox)**
*10-13 September 2017, Bratislava, Slovak Republic*
ECETOC represented by Alan Poole
ECETOC Workshop Session: When Omics Meet Regulations.

**ECHA Accredited Stakeholder Workshop**
*18 October 2017, Brussels, Belgium*
ECETOC represented by Olivier de Matos

**European Stakeholder Conference on Chemicals Management**
*25 October 2017, Brussels, Belgium*
ECETOC represented by Olivier de Matos

**Cefic General Assembly**
*25-27 October 2017, Vienna, Austria*
ECETOC represented by Olivier de Matos

**19th Annual Cefic LRI Workshop 'Making Sense of Omics'**
*15-16 November 2016, Brussels, Belgium*
Participation by Olivier de Matos

**A.I.S.E. Industry roundtable discussion on the role of ecotoxicological assessments for product environmental evaluations**
*16 November 2017, Brussels, Belgium*
Presentation by members of ECETOC Task Force on Aquatic Ecotoxicity as an Impact Category in LCA

## INPUT TO SPECIFIC PROJECTS AND REPORTS

**ECHA Guidance update related to the 8th ATP to CLP: Guidance on the application of the CLP Criteria [Published July 2017]**
ECETOC representative: Jackie Wennington, ExxonMobil

**ECHA Guidance on Information Requirements and Chemical Safety Assessment (IRandCSA), nanomaterials-related Appendix to Chapter R.6: on QSARs and grouping of chemicals [Published May 2017]**
ECETOC representative: Karin Wiench, BASF

**ECHA Update of the Guidance on Information Requirements and Chemical Safety Assessment (IRandCSA), Chapter R.7a, Section R.7.5 (related to repeated dose toxicity only) [Published July 2017]**
ECETOC representative: Wera Teubner, BASF

**ECHA Updates to existing Appendices to Chapters R.7a, R7.b and R7.c of the Guidance on Information Requirements and Chemical Safety Assessment (IRandCSA (Endpoint specific guidance) on 'recommendations for nanomaterials' covering environmental endpoints [Published July 2017]**
ECETOC representative: Karin Wiench, BASF

**ECHA Updates to existing Appendices to Chapters R.7a and R7.c of the Guidance on Information Requirements and Chemical Safety Assessment (IRandCSA) (Endpoint specific guidance) on 'recommendations for nanomaterials' regarding human health endpoints [Published July 2017]**
ECETOC representative: Karin Wiench, BASF

**ECHA Update of the Guidance on Information Requirements and Chemical Safety Assessment (IRandCSA), Chapter R.11, Part C and specific sections of Chapters R.7b and R.7c (related PBT/vPvB assessment) [published June 2017]**
ECETOC representative: Sylvia Jacobi, Albemarle

**ECHA Guidance on Harmonised Information Relating to Emergency Health Responses, Annex VIII to CLP [Published March 2017]**
Philippe Lemaire, Total

**ECHA Endocrine Disruptor Expert Group**
Participation on behalf of ECETOC by Remi Bars (Bayer)

**ECHA Nanomaterials Working Group**
Participation on behalf of ECETOC by Karin Wiench (BASF)

**ECHA PBT Expert Group**
**The Expert Group advising ECHA on PBT issues has regularly met since May 2013**
Participation on behalf of ECETOC by Sylvia Jacobi (Albemarle)

**ECHA Risk Assessment Committee (RAC)**
Participation as an observer on behalf of ECETOC by Alan Poole [ECETOC] until his retirement in September 2017 then by Olivier de Matos [ECETOC]

**ECVAM Stakeholder Forum (ESTAF)**
Participation on behalf of ECETOC by Remi Bars (Bayer)

**Endocrine Disrupter Expert Advisory Group to the EU Commission (ED EAG)**
Participation on behalf of ECETOC by Remi Bars (Bayer) and James Wheeler (Syngenta, now at Dow)

**OECD Extended Advisory Group on Molecular Screening and Toxicogenomics (EAG MST)**
Participation on behalf of ECETOC by Remi Bars (Bayer)

**OECD Endocrine Disrupters Testing and Assessment (EDTA) Advisory Group**
Participation on behalf of ECETOC by Remi Bars (Bayer)

**WHO/IPCS Chemical Risk Assessment Network**
Participation on behalf of ECETOC by Alan Poole [ECETOC] until his retirement in September 2017 then by Olivier de Matos [ECETOC]

**WHO/IPCS Chemical Risk Assessment Network Combined Exposures Group**
Participation on behalf of ECETOC by Alan Poole (ECETOC)
The Combined Exposures Group is a voluntary informal group. The Group aims to facilitate achievement of the above Network objectives in the field of risk assessment of combined exposures to multiple chemicals.

# SCIENCE AWARDS

**Since 2003, ECETOC recognises talented young scientists by sponsoring annual Science Awards to outstanding works of science. ECETOC sponsored the following awards during 2017:**

## ENVIRONMENTAL SCIENCE RELATED AWARD

SETAC Europe 27th Annual Meeting, 07-11 May 2017, Brussels, Belgium

BRUSSELS 2017
SETAC EUROPE

The ECETOC Best Platform Award honours the early career scientist with the best platform presentation at the SETAC Europe Annual Meeting. At SETAC 2017, the award went to Richard Cross, of the College of Life and Environmental Sciences, United Kingdom, for his presentation on "Routes of uptake and bioaccumulation of cerium oxide and silver nanoparticles depend on their fate in sediments."

Richard Cross accepts the Best Platform Award

More information on the SETAC Nantes meeting can be found at **https://brussels.setac.org/** and **http://globe.setac.org/2017/june/setac-awards.html**

## HUMAN HEALTH SCIENCE RELATED AWARD

EUROTOX 2017, 10-13 September 2017, Bratislava, Slovak Republic

eurotox 2017
CONNECTING FOR A SAFER FUTURE
53rd Congress of the European Societies of Toxicology

This early career award for toxicological research into mechanisms and risk assessment is supported by ECETOC and is presented to young scientists at the EUROTOX Annual Meetings. In 2014, the award was re-named in memory of the late Dr. Christa Hennes, former ECETOC Human Health Sciences Manager, who was instrumental in its organisation. The winner receives a monetary prize and a free invitation to the following year's Eurotox meeting.

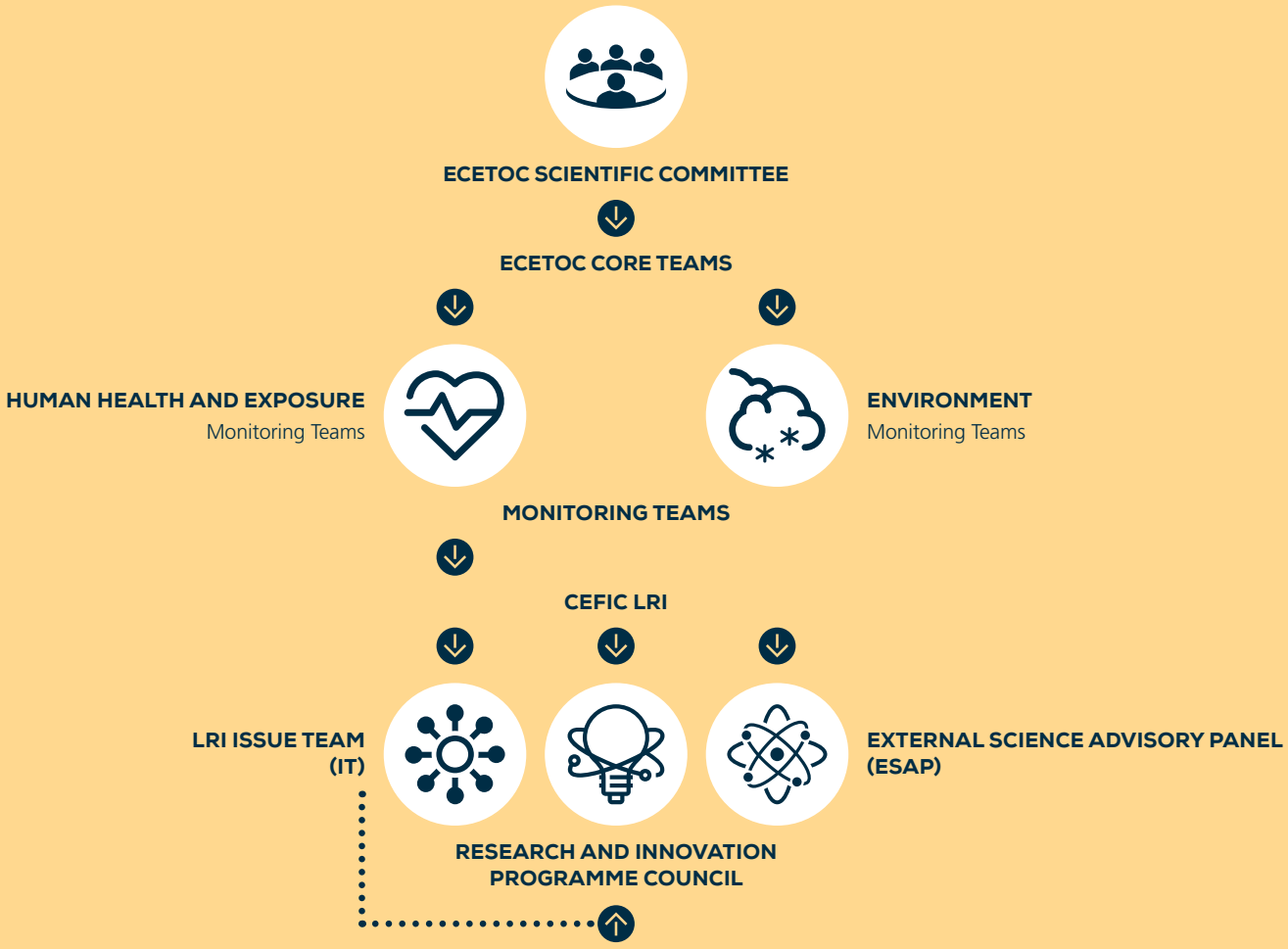
Pavlina Šimečková, the 2017 ECETOC EUROTOX Award winner

The 2017 ECETOC Christa Hennes Early Career Award was presented at EUROTOX, Bratislava, Slovak Republic, to Pavlína Šimečková of the Veterinary Research Institute in the Czech Republic, for "PCB 153 increases degradation of connexin 43 via induction of autophagy in liver progenitor cells."

Eurotox 2017 website:**www.eurotox2017.com**

⑦ ECETOC Contribution to

# Cefic Long-range Research Initiative



Since 1996, the Long-range Research Initiative (LRI) Programme of Cefic, the European Chemical Industry Council, has been providing proactive scientific data on which the entire industry and regulatory bodies can draw to address societal concerns on a reliable basis.

As a fundamental basis for a sustainable chemical industry and a complement to Responsible Care, LRI presents a Research Programme that is forward-looking and ambitious, but also realistic and coherent. LRI invests in long-term research and delivers transparent, quality-assured scientific data, open to the broad public.

As the scientific partner to Cefic LRI, ECETOC provides scientific support to the LRI and input into the Research Programme by managing the scientific evaluation of applications for funding, recommending the best research proposals and monitoring the progress of selected LRI projects. In particular ECETOC is responsible for the:

- Development of topics for research to be considered by the LRI Issue Team (IT).
- Drafting of 'requests for proposals' (RfPs) based on ideas submitted by Cefic and ECETOC members and external experts in the LRI process.
- Setting up selection teams of industry and external experts to choose the best research proposals in response to published RfPs and making recommendations to LRI IT concerning the funding of the proposals.
- Establishment of scientific liaison with the selected institutions and monitoring the scientific quality and progress of the projects.

## HUMAN HEALTH AND EXPOSURE MONITORING TEAMS

**1 project was completed during 2017 (marked below with #) and 4 new projects secured funding and were initiated with the support of the monitoring teams (marked below with *):**

**AIMT 5:** Building a Prenatal Developmental Toxicity Ontology, integrating existing biological, chemical, *in silico* models and *in vitro* methods and data, aiming at an alternative integrated AOP/MoA framework for mechanistic hazard and risk assessment in developmental toxicology
Principal investigator: Prof. Dr. Aldert Piersma, RIVM, National Institute for Public Health and the Environment, The Netherlands

**AIMT 7:** RVis: Open Access PBPK Modelling Platform
Principal investigator: Dr. George Loizou, Health and Safety Laboratory (HSL), United Kingdom

**AIMT 8:** Prediction of systemic toxicity after repeated exposure by new approach methodologies (NAMs) – is prediction of STOR-RE classification possible?
Principal investigator: Dr. Sylvia Escher, Fraunhofer ITEM, Germany

**B 15.2:** Development of an integrated risk management measure library. [Extension to B15]
Principal investigator: Dr. Wouter Fransman, TNO, The Netherlands

**B 17:** SHINE: Target and non-target Screening of cHemicals in the Indoor enviroNment for human Exposure assessment
Dr. Marja Lamoree, VU University Amsterdam, The Netherlands

**B 18:** Carcinogen Dose-Response Database for Threshold of Toxicological Concern (CDRD-TTC)
Prof. Mark Cronin, Liverpool John Moores University, United Kingdom

**B 19:** Extrapolating the Applicability of Worker Exposure Measurement Data
Principal investigator: Dr. Wouter Fransman, TNO, The Netherlands

**B 20*:** Experimental assessment of inhalation and dermal exposure to chemicals during industrial and professional activities.
Rfp advertised in 2017. Selection Team meeting held 12 October 2017
Principal investigator: Dr. Wouter Fransman, TNO, The Netherlands

**C 3#:** A comprehensive Epigenomic profile of liver tissue from Rat and Mouse [Completed 2017]
Principal investigator: Prof. Richard Meehan, University of Edinburgh, United Kingdom

**C 4*:** Transcriptomics bioinformatics best practices in toxicogenomics for regulatory application
Rfp advertised in 2017. Selection Team meeting held 29 September 2017
Principal investigator: Dr. Florian Caiment, Maastricht University, The Netherlands

**C 5*:** XomeTox - evaluating multi-omics integration for assessing rodent thyroid toxicity
Rfp advertised in 2017. Selection Team meeting held 11 October 2017
Principal investigator: Dr. Jörg Hackermüller, Helmholtz Centre for Environmental Research (UFZ), Germany

**C 6*:** Omics and Read Across.
Rfp advertised in 2017. Selection Team meeting held 13 October 2017 but at time of publishing (February 2018) the final selection is yet to be made

**ECO 36:** Paving the way for QIVIVE: from nominal to free to cellular concentrations in *in vitro* assays
Principal investigator: Prof. Beate Escher, Helmholtz Centre for Environmental Research, UFZ Leipzig, Germany

**N 5:** Histopathology of rats exposed to Barium sulfate nanoparticles by life-time inhalation exposure – Effects and Biokinetics
Principal investigator: Dr. Dirk Schaudien, Fraunhofer Institute for Toxicology and Experimental Medicine, Hannover, Germany

# ENVIRONMENTAL RESEARCH LIAISON TEAMS

**During 2017, 3 projects were completed (marked below with #) and 6 new environmental projects secured funding and were initiated with the support of the monitoring teams (marked below with *):**

**ECO 11.3:** Ring test to revise the OECD 306 biodegradation in seawater test [Extension to ECO 11]
Principal investigator: Dr. Russell Davenport, Newcastle University, United Kingdom

**ECO 20.2:** Development of an alternative testing strategy for the fish early life-stage test for predicting chronic toxicity: assay validation [Extension to ECO 20]
Principal investigator: Prof. Dr. Dries Knapen, University of Antwerp, Belgium

**ECO 23:** Time-Integrative Passive sampling combined with Toxicity Profiling (TIPTOP): an effect-based strategy for cost-effective chemical water quality assessment
Principal investigator: Dr. Timo Hamers Phd, IVM, VU University, Amsterdam, The Netherlands

**ECO 25:** Development of Soup Tests for the Risk assessment of NER in Soil
Principal investigator: Dr. Joop Harmsen, Alterra Wageningen UR, The Netherlands

**ECO 27#:** Chemicals: Assessment of Risks to Ecosystem Services (CARES) [Completed 2017]
Principal investigator: Prof. Lorraine Maltby, University of Sheffield, United Kingdom

**ECO 28:** Modelling approaches for a scenario-based assessment of chemically induced impacts on aquatic macroinvertebrate communities (MACROMOD)
Principal investigator: Dr Monika Hammers-Wirtz, Research Institute for Ecosystem Analysis and Assessment, (gaiac), Germany

**ECO 29:** Application of chemostat systems to include adaptation of microbial communities in persistency testing (CHEMADAPT)
Principal investigator: Dr John Parsons, University of Amsterdam (UvA), The Netherlands

**ECO 30.2#:** Expanding the applicability domain of the chemical activity approach for hazard and risk assessment [Extension to ECO 30, completed July 2017]
Principal investigator: Dr. Jon Arnot and Dr. James M. Armitage, ARC Arnot Research and Consulting Inc., Toronto, Canada

**ECO 31# / 31.2:** Identifying strategies that will provide greater confidence in estimating the degradation rates of organic chemicals in water, soil, and sediment [Completed July 2017, extension 31.2 in progress]
Principal investigator: Prof. Damian Helbling, Cornell University, USA

**ECO 32:** Environmental risk assessment of poorly soluble substances: Improved tools for assessing biodegradation, (de)sorption, and modelling
Principal investigator: Prof. Dr. Andreas Schäffer, Aachen University, Germany

**ECO 33:** Use and Interpretation Of Dietary Bioaccumulation Tests For Hydrophobic Chemicals
Principal investigator: Dr. Frank Gobas, Frank Gobas Environmental Research, Canada

**ECO 34:** A tiered testing strategy for rapid estimation of bioaccumulation by a combined modelling - *in vitro* testing approach
Principal investigator: Prof. Kristin Schirmer, Eawag, Switzerland

**ECO 35:** Interference of hepatotoxicity with endocrine activity in fish
Principal investigator: Prof. Dr. Thomas Braunbeck, University of Heidelberg, Germany

**ECO37:** D-BASS: Developing a Bioaccumulation Assessment Strategy for Surfactants
Principal investigator: Dr. Steven Droge, University of Amsterdam, The Netherlands


**ECO 38:** Cross-validation for improving determinations of water solubility for difficult to test substances
Principal investigator: Prof. Philipp Mayer, Technical University of Denmark, Denmark

**ECO 39:** Review, ring-test and guidance for TKTD modelling
Principal investigator: Dr. Roman Ashauer, York University, United Kingdom

**ECO 40:** Investigations on the bioconcentration of xenobiotics in the freshwater amphipod Hyalella azteca and inter-laboratory comparison of a new BCF test protocol.
Principal investigator: Prof. Dr. Christian Schlechtriem, Fraunhofer IME, Germany

**ECO 41*:** Improved characterization of partitioning and biotransformation for screening organic compounds for the potential to bioaccumulate in airbreathing species.
Rfp advertised in 2017. Selection Team meeting held 06 October 2017
Principal investigator: Prof. Frank Wania, University of Toronto, Canada

**ECO 42*:** UVCB fate-directed toxicity testing and risk assessment (UVCB-FATETOX).
Rfp advertised in 2017. Selection Team meeting held 06 October 2017
Principal investigator: Prof. Dr. Philipp Mayer, Technical University of Denmark (DTU)

**ECO 43*:** Improving sediment toxicity testing design and data interpretation for very hydrophobic substances.
Rfp advertised in 2017. Selection Team meeting held 28 September 2017
Principal investigator: Dr. Michiel Jonker, IRAS, Utrecht University, The Netherlands

**ECO 44*:** Integrating Bioaccumulation Assessment Tools for Mammals (iBAT-Mam).
Rfp advertised in 2017. Selection Team meeting held 02 October 2017
Principal investigator: Dr. Jon Arnot, ARC Arnot Research and Consulting Inc., Canada

**ECO 45*:** Chemicals: Assessment of Risks to Ecosystem Services (CARES) II.
Rfp advertised in 2017. Selection Team meeting held 25 September 2017
Principal investigator: Prof. Lorraine Maltby, University of Sheffield, United Kingdom

**ECO 46*:** Improving the environmental (aquatic) hazard and risk assessment of cationic polymers
Rfp advertised in 2017. Selection Team meeting still to be planned

# ⑧ Members of the Scientific Committee

The Scientific Committee is responsible for the definition, management and peer-review of the ECETOC work programme. Appointed by the Board, the members are selected on the basis of their scientific expertise.

During 2017, the Scientific Committee consisted of the following members:

**Bennard van Ravenzwaay** (Chair)
**BASF**

**Rémi Bars**
**Bayer CropScience**

**Peter Boogaard**
**Shell International**

**Phil Botham***
**Syngenta**

**Claire Davies****
**Unilever Safety and Environmental Assurance Centre**

**Andreas Flückiger**
**F. Hoffmann-La Roche**

**Helmut Greim#**
**Technical University Munich**

**Joop Hermens#***
**University of Utrecht**

**Heli Hollnagel**
**Dow Europe**

**Philippe Lemaire***
**Total Fluides**

**Fraser Lewis*****
**Syngenta**

**Guiseppe Malinverno******
**Solvay**

**Lorraine Maltby#**
**University of Sheffield**

**Marie-Louise (Lo) Meisters**
**DuPont de Nemours**

**Sandeep Mukhi***
**Honeywell Performance Materials and Technologies**

**Mark Pemberton**
**Systox Ltd. (Representing Lucite)**

**Carlos Rodriguez**
**Procter & Gamble**

**Gordon Sanders***
**Givaudan Suisse**

**Gerard Swaen#***
**Maastricht University**

**Johannes Tolls**
**Henkel**

**Saskia van der Vies#*******
**VU University Medical Center**

**Kees van Leeuwen#**
**KWR Watercycle Research Institute**

**Erik Van Miert***
**Solvay**

**Rosemary Zaleski**
**ExxonMobil Biomedical Sciences**

#External expert
*From September 2017
**Replaced Stuart Marshall, January - September 2017
***Until September 2017
****Until January 2017
*****Until March 2017

# ⑨ Members of the Secretariat

**The ECETOC Secretariat is responsible for the co-ordination and management of the scientific work programme, ensuring that the tasks assigned by the Scientific Committee are accomplished in a timely fashion. ECETOC's continued success relies greatly on its Secretariat. This team of dedicated professionals supports the scientists engaged in the work of the ECETOC programme in meeting the objectives set by the Scientific Committee.**

**Alan Poole**
**Secretary General**
[Retired August 2017]

**Olivier de Matos**
**Secretary General**
[From September 2017]

**Lucy Wilmot**
**Environmental Sciences Manager**
(Contracted to ECETOC by PFA-Brussels)

**Alice Brousse**
**Human Health Sciences Manager**
(Contracted to ECETOC by PFA-Brussels)

**Geneviève Gérits**
**Office Manager**

**Ian Cummings**
**Communications, Web and Media Manager**

**Christine Yannakas**
**Administrative Assistant**
[Retired end 2017]

**Francesca Uguccioni**
**Administrative Assistant**

**Lisa Wingate**
**Administrative Assistant**
[From January 2018]

# ⑩ Finance

## INCOME ACTUAL 2017 IN EURO

| | |
|---|---|
| **Subscription** | |
| Full Members | 1.058.000 |
| Associate Members | 70.000 |
| **Total Subscription Income** | **1.128.000** |
| | |
| Bank Interest | 1.382 |
| Investment income | 0 |
| Project-related | 363.648 |
| Exceptional income | 1.250 |
| **Total** | **1.494.281** |

## EXPENDITURE ACTUAL 2017 IN EURO

| | |
|---|---|
| Salaries and Associated Costs | 582.672 |
| Office Running Expenses | 185.137 |
| Travel Expenses | 3.105 |
| External Contractors | 258.880 |
| Board, Committees and Annual General Meeting | 44.715 |
| Task Forces | 58.775 |
| Workshops | 287.567 |
| Sponsorships and Awards | 7.500 |
| Publications, Communications and Website | 49.056 |
| Professional Services | 20.753 |
| Bank Charges | 5.592 |
| Capital Expenditure | 7.488 |
| Miscellaneous and Contingency | 66.084 |
| **Total** | **1.577.325** |

## BALANCE SHEET AND RESERVES ACTUAL 2017 IN EURO

| | |
|---|---|
| **Balance Sheet** | |
| Income | 1.494.281 |
| Expenditure | 1.577.325 |
| Operating Margin | -83.045 |
| | |
| **Reserves*** | |
| Opening | 2.051.192 |
| Operating Margin | -83.045 |
| **Closing Reserves** | **1.968.147** |

*Estimated Reserve Required: 196.786

# ⑪ Abbreviations

| | |
|---|---|
| **AGM** | Annual general meeting |
| **AOP** | Adverse outcome pathways |
| **Cefic** | European Chemical Industry Council |
| **Chesar** | (ECHA) CHEmical Safety Assessment and Reporting tool |
| **CLP** | Classification, labelling and packaging |
| **CSA** | Chemicals safety assessment |
| **DNA** | Deoxyribonucleic acid |
| **EAG MST** | (OECD) Extended Advisory Group on Molecular Screening and Toxicogenomics |
| **EC** | European Commission |
| **ECETOC** | European Centre for Ecotoxicology and Toxicology of Chemicals |
| **ECHA** | European Chemicals Agency |
| **ECVAM** | European Centre for the Validation of Alternative Methods |
| **ED EAG** | Endocrine Disrupter Expert Advisory Group to the EU Commission |
| **EDTA** | (OECD) Endocrine Disrupters Testing and Assessment Advisory Group |
| **EMFF** | European Maritime and Fisheries Fund |
| **ESTAF** | ECVAM Stakeholder Forum |
| **EU** | European Union |
| **EUROTOX** | Association of European Toxicologists and European Societies of Toxicology |
| **FAME** | Fisheries and Aquaculture Monitoring and Evaluation |
| **FDA** | (US) Food and Drug Administration |
| **GLP** | Good laboratory practice |
| **heatDB** | ECETOC Human exposure assessment tools database |
| **IARC** | International Agency for Research on Cancer |
| **IPCS** | International Programme on Chemical Safety |
| **IRandCSA** | (ECHA Guidance on) Information Requirements and Chemical Safety Assessment) |
| **IRPTC** | International Register of Potentially Toxic Chemicals |
| **JACC** | Joint assessment of commodity chemicals |
| **JRC** | (EC) Joint Research Centre |
| **LRI** | (Cefic) Long-range Research Initiative |
| **MoA** | Mode of action |
| **NER** | Non-extractable residue |
| **OECD** | Organisation for Economic Co-operation and Development |
| **PBT** | Persistent, bioaccumulative toxic |
| **PEG** | (ECHA) Partner Expert Group |
| **RAC** | (ECHA) Risk Assessment Committee |
| **REACH** | EU regulatory framework for the registration, evaluation and authorisation of chemicals |
| **RfP** | Request for proposal |
| **RIVM** | The Dutch National Institute for Public Health and the Environment |
| **SC** | (ECETOC) Scientific Committee |
| **SETAC** | Society of Environmental Toxicology and Chemistry |
| **SOT** | (US) Society of Toxicology |
| **SVHC** | Substance of very high concern |
| **TRA** | Targeted risk assessment |
| **UNEP** | United Nations Environment Programme |
| **US EPA** | Environmental Protection Agency |
| **UVCB** | Substances of unknown or variable composition, complex reaction products or biological materials |
| **WHO** | World Health Organisation |
| **WoE** | Weight-of-evidence |

ECETOC Annual Report 2017



Since 1978 ECETOC, an Industry-funded, scientific, not-for-profit think tank, strives to enhance the quality and reliability of science-based chemical risk assessment. Learn more at **www.ecetoc.org**

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EUROPEAN CENTRE FOR ECOTOXICOLOGY
AND TOXICOLOGY OF CHEMICALS

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