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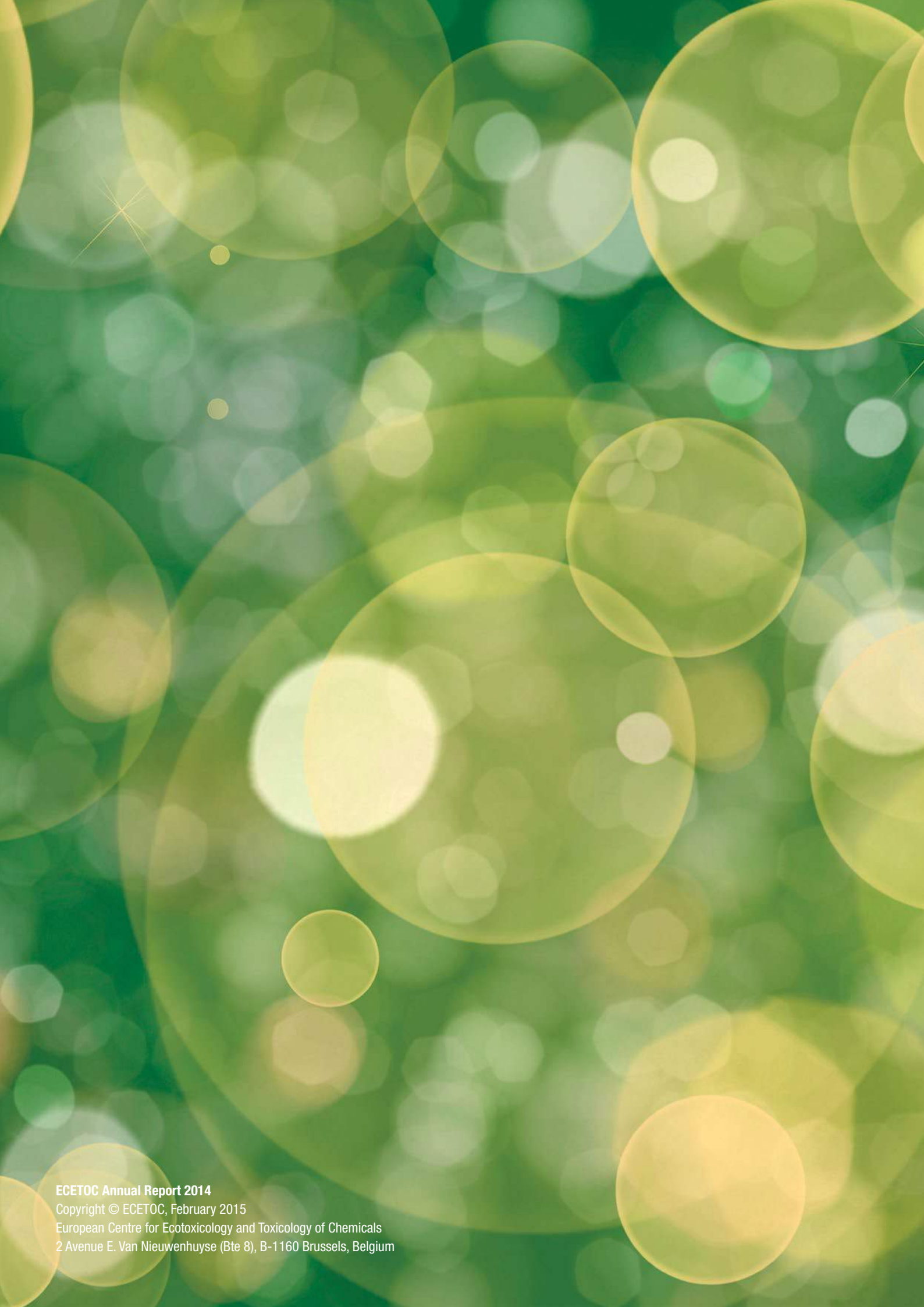
EUROPEAN CENTRE FOR ECOTOXICOLOGY
AND TOXICOLOGY OF CHEMICALS

Annual Report **2014**

www.ecetoc.org



ECETOC Annual Report 2014

European Centre for Ecotoxicology and Toxicology of Chemicals
2 Avenue E. Van Nieuwenhuyse (Bte 8), B-1160 Brussels, Belgium

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ECETOC at a glance

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

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

Purpose

The purpose of ECETOC is to develop concepts, data and positions which underpin the use of scientific principles in the translation of policy into regulation in Europe: to enable the benefits of chemicals to be realised while protecting human health and the environment.

Values

ECETOC has strong values of science and integrity; it works by establishing objective positions and then moving forward, not backwards from a predetermined view.

Vision

ECETOC will be the partner of choice focusing and engaging industry expertise for the European Commission, ECHA, and EFSA in the development of practices and concepts based on science as policy becomes embodied in regulations.

Mission

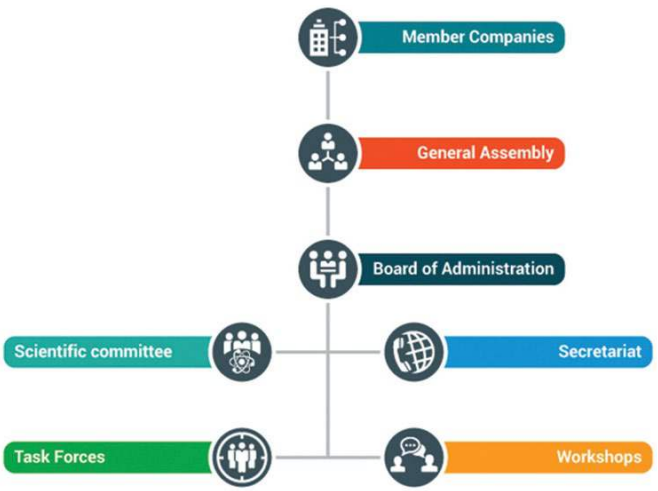
To promote the use of good science in human and environmental risk assessment of chemicals, biomaterials and pharmaceuticals.

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.

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 and appoints the Secretary General, who oversees the day-to-day running of the organisation, and the members of the Scientific Committee which defines, manages and peer reviews the ECETOC work programme.



- As a recognised scientific NGO, ECETOC can be differentiated from industry trade associations and its role is to influence the development of science policy regulation by providing industry with scientific leadership. ECETOC develops and translates science and technical data to enhance and improve risk assessment, for example, the ECETOC-developed TRA (Targeted Risk Assessment Tool) is now in use in more than 85% of all REACH dossiers.
- Ability to shape the European scientific agenda. For example, WHO/ECETOC Workshops on Mode of Action.
- Observer status at ECHA RAC and MSC Meetings.
- Access to ECETOC Expert meetings attended by top academic, industry and regulatory agencies from around the world.
- Membership can influence the scientific agenda of ECETOC through the Scientific Committee, which approves and leads the ECETOC work programme.
- Membership can also influence the scientific agenda of ECETOC by participating in the annual review meetings.

Capacity Building

- Through the use of expert meetings, task forces, workshops and facilitating scientific research, ECETOC provides a platform for training and development of scientists engaged in regulatory risk assessment.
- Engage with and access the expertise of a global network of top quality scientists.

Networking

- Participate in ECETOC task forces, workshops and other meetings.
- Access the ECETOC dedicated members' website, which includes publications, task force and workshop reports and updates/ revisions to ECETOC-developed tools.

By joining ECETOC, you will contribute to the safety of chemicals, pharmaceuticals and biomaterials and the long-term sustainability of the industries involved, as well as demonstrating a commitment to the Responsible Care guidelines created by the International Council of Chemical Associations (ICCA).

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 Secretariat:

Telephone: +32 2 675 3600

Email: info@ecetoc.org

Or write to: ECETOC,

Avenue E. Van Nieuwenhuyse 2, bte.8,

B-1160, Brussels, Belgium

ECETOC Member Companies

During 2014, ECETOC membership comprised the following 40 companies:

Afton Chemical — *Associate member company*

AkzoNobel

Albemarle — *Associate member company*

AstraZeneca

BASF

Bayer

bp

Cepsa — *Associate member company*

Clariant

Colgate-Palmolive

Dow

Dow Corning

DSM

DuPont

eni

Evonik

ExxonMobil

Roche

Firmenich — *Associate member company*

Givaudan

Henkel

Honeywell

Huntsman — Enriching lives through innovation

INEOS ChlorVinyls

IFF International Flavors & Fragrances Inc. — *Associate member company*

Johnson & Johnson

L'Oréal

Lucite International — *Associate member company*

Merck

NiPERA — *Associate member company*

P&G

SC Johnson

Shell Chemicals

Solvay

Statoil

Sumitomo Chemical

Syngenta

Total

Unilever

Wacker

Message from the Chairman of the Board

A cursory review of this Annual Report will demonstrate to the reader that 2014 was productive for ECETOC. During the year, ECETOC issued 3 Technical reports, 4 publications in the scientific literature, (one a special edition of the European Environmental Mutagen Society), made representations at numerous technical and regulatory meetings and organised joint meetings with SETAC, Royal Society of Chemistry, European Environmental Mutagen Society and EUROTOX. I think that we can all agree this is an impressive output against a back drop of continued financial and human resource constraints.

However, whilst high energy output is to be applauded and supported, the ECETOC Membership has challenged the organisation to convert this output into tangible desired outcome. Turning output into outcome is difficult to achieve and quantify and the Board agreed that one path forward to achieving greater outcome was through Partnerships. While working with scientific partners has always been a driving force and desire of ECETOC, in 2014 the Board focused special attention on Partnerships as a pathway to achieve success.

When the Board started exploring Partnership ideas and concepts, a requirement was to ensure that activities undertaken by ECETOC are relevant and important to members. Realistically, it is of course not possible to satisfy everyone completely, but to obtain broad input and agreement the Board instructed the ECETOC Secretariat and Scientific Committee to enhance Membership engagement in selection of the ECETOC scientific portfolio, thereby ensuring its attractiveness to the Membership.

In 2014, ECETOC entered into a consultative process with members that will continue in the form of further Human Health Scoping Meetings, Environmental Progress Reviews and with plans for a State of the Science (STOTS) review in 2016 possibly with LRI. In addition to making sure the scientific content of ECETOC activities meet the desires of the Membership, special focus will be given to ensuring ECETOC activities achieve an agreed desired outcome. A work process with standardised templates has been introduced by the Scientific Committee to ensure all ECETOC activities clearly articulate the strategic purpose and incorporate a pathway to achieve the outcome.

In addition to making sure ECETOC activities are relevant to the Membership, it is also necessary to ensure regulatory relevancy. This can only be achieved by cooperation with the regulatory community and institutions. ECETOC being an accredited stakeholder with various organisations such as ECHA and WHO is in a unique position to bring industry resource and experience to the table, to build risk assessment capacity and provide reliable advice, helping to shape the scientific nature and practice of regulatory risk assessment. Examples of how ECETOC has brought experience and knowledge to increase efficiency and effectiveness of chemical risk assessment are numerous, but action areas include continued enhancement of the TRA Tool to help member companies meet registration needs, participation in Partnership Expert Groups (PEGs) to enable industry science to be included in regulatory debate, and participation at RAC and MSC meetings. ECETOC is now exploring how to become an accredited stakeholder with EFSA.

The third area of Partnership that the Board is looking at is to have ECETOC engaged in high profile scientific activities to ensure ECETOC retains high scientific visibility and is seen as a scientific leader in providing solutions. In 2014 ECETOC worked with various leading societies including SETAC, EUROTOX and Royal Society of Chemistry to address issues concerning risk posed by man-made chemicals. In addition, ECETOC organised expert meetings with scientists from JRC, US EPA and academia to build an ontology of reproductive toxicology AOPs to support the OECD activities. This led to ECETOC being invited to join a scientific consortium in HORIZON 2020 and join the WHO Chemical Risk Assessment Network.

A cross cutting element underpinning the desire for ECETOC to enhance Partnerships is the ability for ECETOC to develop further as an effective learning organisation. This requires ECETOC, on behalf of the industry, to capture information and data not only from ECETOC but also from LRI activities and then structure this information into applicable knowledge, to the benefit of all stakeholders involved in chemical risk assessment. Becoming the “corporate” memory/repository for this knowledge and understanding poses various structural and resource issues, but is a topic that requires attention to ensure that such knowledge is not forgotten or lost to the industry and society as a whole.

In summary, ECETOC is a provider of solutions, and Partnership is one of the key elements identified by the Board to deliver the value ECETOC provides, not only to the industrial Membership, but also to society in general by bringing practical solutions to complex problems. This provides a compelling case for the value of ECETOC and why the support of the Membership is essential, as ECETOC is:

- The industry hub for scientific debate and organised input on chemical regulation and risk assessment
- The industry based scientific organisation to work with regulatory bodies and international institutions
- The organisation to act as the scientific memory/knowledge bank for the industry.

Overall, considering the size of the task and limited human and financial resource, ECETOC does well to generate the quantity and quality of work it is responsible for.

Martin Kayser

Chairman of the Board of Administration

The Board of Administration 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.

The Board is 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.

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 2014 Annual General Meeting:

Dr. Julia Fentem (Unilever), Dr. Petra Hanke-Baier (Procter & Gamble), Dr. Robert Rickard (DuPont SHE & Sustainable Growth Center) & Mr. Steve Rumford (AstraZeneca) were re-elected to the ECETOC Board.

Dr. Adrian Percy (Bayer CropScience) was unanimously elected as a new member to the ECETOC Board.

ECETOC **Board Members (December 2014)**

Martin Kayser
BASF (Chairman)

Steve Rumford[A]
AstraZeneca (Vice-Chairman and Treasurer)

Julia Fentem
Unilever

Petra Hanke-Baier
Procter & Gamble

Peter Hertl
Syngenta

Thomas Jostmann
Evonik Industries

Craig Nessel
ExxonMobil

Karen Niven
Shell

Adrian Percy[B]
Bayer

Robert Rickard
DuPont

Anne Wallin[C]
Dow

[A,B,C] Resigned due to job changes.

Report from the Secretary Ge

"While there probably still is the lone genius scientist sitting under a tree with falling apples or having a Eureka moment, the majority of scientists rely on studying published data and information to reach conclusions and make decisions"

neral

Science Programme

"Let me just say a big THANKS to all of you who have contributed in sweat equity to the output of ECETOC"

Foreword from the Scientific Committee Chairman

I noted in last year's Annual Report that 2013 would be remembered as a year of profound change and also expressed my confidence that ECETOC as a living organisation would navigate well through the "dire straits" of 2014….and we have ! The consequences of the considerable reduction of ECETOC staff have been kept to a minimum by increased efficiency in work and communication processes. I am also very glad to inform you that in Madeleine Laffont, who has joined ECETOC as our new Health Scientist on a part time basis, we have a new and excellent staff member who brings both new ideas and organisational talent on board.

Taking into account the limited resources, setting the right priorities is essential. In 2014, we have seen the development of work processes allowing the Scientific Committee to evaluate proposals for task forces and workshops from our membership in a consistent and transparent way.

Shaping and sharpening the role of ECETOC in science was the objective of the 2014 scoping meetings for human health and environment. In the years to come, ECETOC will devote about 50% of its resources to short-term priority/must do activities, very much in the way that this has been handled in the past. The remainder of our resources will be made available to more strategic areas of work that will take at least 3 – 5 years to accomplish. I was thrilled to see a very high number of proposals being made by our membership and the very active participation in the scoping meetings. These proposals have been discussed with academia and representatives of the regulatory community, indicating that we are moving from a purely industrial organisation in the far past, through a bi-partite situation (presence of academia in the Scientific Committee and task forces) to tri-partite work. In 2014, taking into consideration your input given at the Annual Technical Meeting (ATM), we have seen the development of these strategic projects, one of which will be related to ecotoxicology, one to human health and one to exposure science. The hallmark of these strategic areas should be that these should have a significant impact in terms of advancing and influencing the future regulatory landscape based on scientific principles. For exposure science, it was clear that an improved TRA (Targeted Risk Assessment) Tool would be of greatest value for our membership. This strategic area is now coordinated and advanced by the TRA steering group. For human health, the strategic area is called "using data from developing technologies wisely". This area is in fact an amalgam of a number of proposals presented at the scoping meeting that deal with issues such as: the use of 'omics technologies for regulatory purposes, establishing criteria to enhance the quality and transparency of such technologies, evaluating new "modes of action" such as epigenetics and non-coding RNA, as well as the significance of fetally-induced changes for adult disease. Some of the tasks related to this strategic area will be in the form of classical task forces or workshops. Others will require upfront LRI-funded research to be translated into science-based proposals for regulatory purposes. The strategic area selected for the environment, pending discussion and approval at the next scoping meeting, is "Ecological relevance of toxicity assessment schemes".

ECETOC is a science-based organisation, but our impact should not be measured in terms of number of task forces or workshops held per year. Even the number of peer reviewed publications, although more significant, should not be our key indicator of success. Our success should be determined by the impact that we make on driving science-based regulations, the interpretation thereof and the process of risk assessment. To have impact, it is not only necessary to select those topics of value to both the industry and regulatory community, but also to understand how, where and when the outcome of an ECETOC activity has the greatest effect. The ECETOC Board and Scientific Committee are well aware that ECHA is one of the major players and partners for the chemical industry. Therefore, we realise that working with ECHA in a transparent way on scientific issues that are key for both organisations will be of increasing importance. The presence of ECHA during our Annual Technical Meeting demonstrates this mutual interest.

The significance of issue selection and timing can be exemplified by one 2014 ECETOC task force: "Grouping of nano-materials". This topic is very important to our member companies as well as to ECHA and no specific guidance was available until now. The task force managed to review literature, provide initial proposals and to publish their first paper. More significantly, they were invited to present their grouping and read-across strategy to ECHA. Although we do not yet know how much of our work will be taken up by ECHA, this example does demonstrate the relevance of issue selection, communication of our work and cooperation with regulatory bodies to achieve success in the way defined earlier.

It is not my intention, and also beyond the scope of this foreword, to present all of the contributions, reports and publications of the scientists of our membership who have worked under the ECETOC umbrella in 2014. Let me just say a big THANKS to all of you who have contributed in sweat equity to the output of ECETOC. I know personally only too well how difficult it sometimes is to balance this volunteer work against increasing internal company demands. Also I would like to acknowledge the member companies who allow their staff to work in ECETOC groups. From my own experience, I know that this nearly always is a win-win situation. The work done by members of your staff in ECETOC projects serves a direct goal, established in the terms of reference for each activity. In addition, and possibly equally significant, these activities allow your staff to increase their experience and establish personal relationships with scientists experienced in the field. This dual system of giving and taking is one of the assets of ECETOC; let's continue to make this happen for the benefit of our companies, their staff and our society.

Bennard van Ravenzwaay

Chairman of the Scientific Committee

Highlights of 2014

ECETOC Targeted Risk Assessment Tool Update to TRAv3.1 and Publication of related Addendum to Technical Report No. 114 on the Technical Basis for version 3 of the TRA

ECETOC's Targeted Risk Assessment (TRA) tool calculates the risk of exposure from chemicals to workers, consumers and the environment. It 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 (ECHA, 2010a,b).

In response to feedback received from users of the TRA, ECETOC has further improved the consumer portion of the model by the inclusion of the ability to account for infrequent uses of consumer products. The changes which have been developed in cooperation with ECHA are now found as version 3.1 of the TRA and are also to be found within version 2.3 of Chesar (https://chesar.echa.europa.eu).

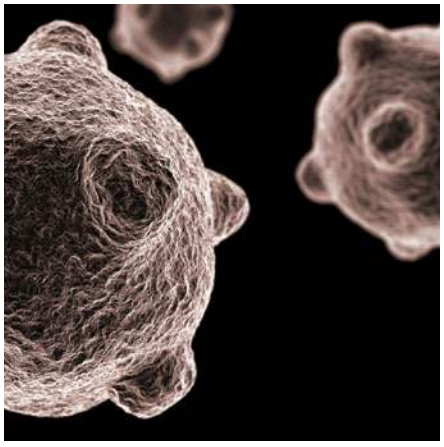
A detailed explanation of the rationale for the changes is contained in an Addendum to ECETOC Technical Report 114 (just published as ECETOC Technical Report No. 124) which provides further clarification of how ECETOC has applied 'transfer factors' in the TRA's prediction of oral, dermal and inhalation exposures. These improvements now enable the information contained within developments such as the DUCC Specific Consumer Exposure Determinants (http://www.ducc.eu/Activities.aspx%20) to be suitably processed.

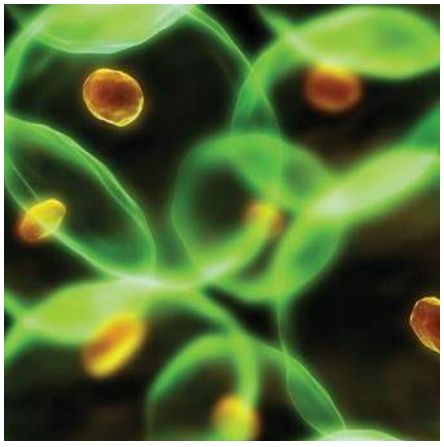
The update to version 3.1 was used as an occasion to include an updated specific environmental release class (SpERC) list and improvements of the functionalities by offering the export and import of single substance datasets. Version 3.1 is available both as an integrated model and a standalone version for the consumer part, and can be found at the ECETOC TRA website http://www.ecetoc.org/tra together with updated user guides for these tools and ECETOC TRA Technical Reports.

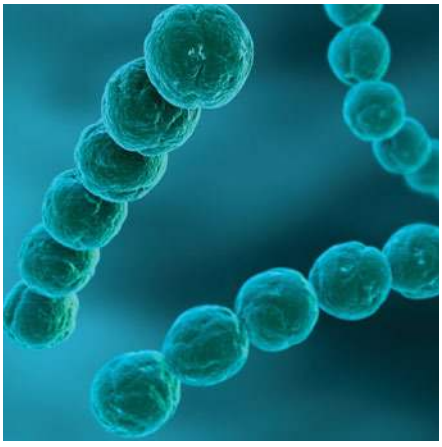
The Addendum to ECETOC Technical Report 114 has been published as ECETOC Technical Report 124: Addendum to TR114: Technical Basis for the TRA v3.1. The Summary and free PDF of the report are available at http://bit.ly/ecetoc-tr124

ECHA. 2010a. REACH Technical Guidance on information requirements and chemical safety assessment, Chapter R14: Occupational Exposure Estimation. European Chemicals Agency, Helsinki, Finland.

ECHA. 2010b. Guidance on information requirements and chemical safety assessment, Chapter R15: Consumer Exposure Estimation (Version 2, April 2010). European Chemicals Agency, Helsinki, Finland. Addendum to TR114 : Technical Basis for the TRA v3.1 (June 2014)







Completed Task Forces

New Information and Weight-of-Evidence in PBT/vPvB Assessment of Chemicals

An ECETOC task force reviewed the new information and 'weight-of-evidence' approach set out in Annex XIII of REACh as amended in 2011, to better assess whether a chemical substance is persistent, bioaccumulative and toxic (PBT), or very persistent /very bioaccumulative (vP/vB). An integrated evaluation strategy is proposed with focus on P and B assessment (on T sufficient guidance exists). In principle, if the available screening information indicates the absence of PBT or vPvB properties, there is no need or obligation for higher-tier assessment and/or further testing. Weight-of-evidence analysis depends on the available information and may include several hypotheses and lines of evidence. Further research is recommended on several topics (endpoints), to fill gaps in knowledge before developing new criteria and specific guidance that allow regulatory conclusions to be drawn, in particular for terrestrial B assessment.

The document is published as ECETOC Special Report 18: Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH).

The Summary and free PDF of the report are available at http://bit.ly/ecetoc-sr18

Contribution of New Technologies to Characterization and Prediction of Adverse Effects

A taskforce was set up to investigate how newly developed methods in toxicity testing contribute to hazard and risk assessment of chemicals. The taskforce aimed at identifying the opportunities and current limitations of these new methods in comparison with traditional studies in laboratory animals.

Identification of the potential hazards of chemicals has traditionally relied on studies in laboratory animals where changes in clinical pathology and histopathology compared to untreated controls defined an adverse effect. More recently, a paradigm shift in toxicity testing has been proposed, mainly driven by concerns over animal welfare but also thanks to the development of new methods.

Currently, technologies based on computer modelling, isolated cell systems and genetics, are available to provide detailed insight in toxicological Mode of Action (MOA) of adverse effects observed in laboratory animals.

The vision described as Toxicity Testing in the 21st century (Tox21c) aims at predicting toxic effects in animals, based on these above-mentioned new technologies.

At present, a practical application of the Tox21c vision is still far away. While moving towards toxicity prediction based on these new technologies, a stepwise reduction of animal testing is foreseen by combining animal tests with new technologies. Furthermore, newly developed methods will also be increasingly applied, in conjunction with established methods in order to gain trust in these new methods. This confidence is based on a critical scientific prerequisite: the establishment of a causal link between data obtained with new technologies and adverse effects manifested in animal studies. It is proposed to apply the principles described in the WHO/IPCS framework of MOA to obtain this link. Finally, an international database of known MOAs obtained in laboratory animals using data-rich chemicals will facilitate regulatory acceptance and could further help in the validation of the adverse outcome pathway concepts.

Rouquié D, Heneweer M, Botham J, Ketelslegers H, Markell L, Pfister T, Steiling W, Strauss V, Hennes C. 2014.

Contribution of New Technologies to Characterization and Prediction of Adverse Effects.

Accepted for publication in Critical Reviews in Toxicology

A Critical Appraisal of Existing Concepts for the Grouping of Nanomaterials

It is well-accepted that nanomaterials need to be safe. However, conducting a full testing scheme for each and every variant of each nanomaterial will lead to an enormous amount of data that may not be necessary for risk assessment. This would be a waste of time, money, and even worse, laboratory animals. A solution to this dilemma is the so-called 'grouping of chemicals'. Science-based grouping approaches allow the prediction of a substance's toxicity by comparing it to other similar substances. For conventional non-nanosized substances, grouping is already allowed, for example by European Chemicals Regulation. However, grouping nanomaterials is more complex as it requires the consideration of physical, chemical and biological properties and, although various agencies and consortia have made proposals, there is currently no unified global grouping concept.

To develop a consistent approach for grouping nanomaterials, the ECETOC Nano Task Force first reviewed the available schemes but concluded that none cover all aspects relevant to nanomaterial safety assessment. In a second step, the Task Force will identify the best available concepts to combine into a comprehensive unified framework that can be applied internationally for the grouping of nanomaterials. As described above, if the scheme is accepted, it will save time, money and animal experimentation.

The Task Force review of available proposed schemes is published as an Open Access article in Regulatory Toxicology and Pharmacology and a proposed unified framework is expected in 2015.

Landsiedel R, Arts J, Hadi M, Keene A, Kreiling R, Lyon D, Maier M, Michel K, Petry T, Warheit D, Wiench K, Sauer U. 2014.

A Critical Appraisal of Existing Concepts for the Grouping of Nanomaterials.

Regulatory Toxicology and Pharmacology (In press – uncorrected proof)

Doi: 10.1016/j.yrtph.2014.07.025 (Open Access)

The following shortcut can be used to download the article from the publisher's website: http://bit.ly/ecetoc-art2014-arts-et-al

ECETOC Task Force Paper on Incorporating Potency Into Classification for Carcinogenicity and Reproductive Toxicity

Classification should give guidance on the potential hazards of chemicals. Once the nature of the hazard is known, potency is the most important indicator of the degree of the hazard. Classification for carcinogenicity and reproductive toxicity does not distinguish between chemicals with up to 7 orders of magnitude difference in potency. This can cause problems in communication and has downstream consequences for the use of chemicals which may be inappropriate. There is methodology in the EU guidelines for assessing potency which is scientifically valid and should be used more widely. Classification schemes which incorporate potency have been developed. These would promote clarity of communication and more relevant downstream risk management for chemicals. It is hoped this work will start a discussion on changing the GHS criteria.

Hennes C, Batke M, Bomann W, DuHayon S, Kosemund K, Politano V, Stinchcombe S, Doe J. 2014. Incorporating potency into EU classification for carcinogenicity and reproductive toxicity.

Open Access article accepted for publication in Regulatory Toxicology & Pharmacology

Doi: 10.1016/j.yrtph.2014.07.022 [Epub ahead of print]

This Open Access article is available via http://bit.ly/ecetoc-art2014-Hennes-et-al

Task Forces Established

Adapting Simple Treat for Simulating Behaviour of Chemical Substances

In the EU the fate of chemicals in wastewater treatment is currently simulated with SimpleTreat 3.1. RIVM is currently revising SimpleTreat 3.1 for simulating municipal wastewater treatment plants. A recent ECETOC workshop provided major insights for advancing the modelling assessments of industrial wastewaters based on the revised SimpleTreat model.

Hence it is proposed to establish an advanced simulation approach for industrial wastewater treatment. An advanced SimpleTreat module is developed which can be customized for individual industrial wastewater treatment plants. The development of this tool is to be performed by the Radboud University as contractor. An ECETOC task force will supervise the tool development, complement the tool framework and guidance for the use of this tool and to develop regulatory support for the advanced simulation approach for chemicals in industrial wastewater treatment.

Workshops

2014 Environment Progress Review

29-30 January 2014, Brussels, Belgium

The 2014 environment progress review took place with a large turn-out of 41 scientists from member companies, academia, Paul Whitehouse from the (English) Environment Agency, Ioanna Katsiadaki representing Cefas (UK) and Professor Marco Vighi of the EU Scientific Committee on Health and Environmental Risks (SCHER), author of the EU Report Addressing the New Challenges for Risk Assessment.

This annual meeting sets out to inform and review the spectrum of ECETOC environmental activities: task forces, workshops and LRI projects. The first day consisted of a review of existing ECETOC and LRI projects. The second day focussed on identifying new ideas for ECETOC and LRI activities.

The following activities were identified after the discussions:

- Workshops:

Fate and exposure models. *Currently under discussion within the strategic science direction*

Use and assessment of Human biomonitoring data. *This was discussed within the Human Health Scoping Meeting*

Defining the Applicability Domain of Chemical Activity in Risk Assessment. *Currently in preparation for Q4 2015*

- Task Forces:

Anaerobic biodegradation. *Currently under discussion within the strategic science direction*

Application of MoA knowledge to assess impacts of chemical mixtures at a community level. *This task force is currently being established*

Linking chemical thresholds and biological status: are EQSs set appropriately. *It has been decided that this activity would be better addressed in the hands of regulatory agencies*

- RfPs for LRI: After being awarded funding and following the selection process these RfPs have been established as the following research projects:

Targeted risk assessment based on ecosystem services: ECO 27

Community level assessment using ecological scenarios based on functional diversity: ECO 28

Biodegradation rates: ECO 29

Mining of Databases to correlate chemical activity to MOA: ECO 30

- Other:

Workshop on Eco 11 to assess value of increased biomass on biodegradation in OECD 306 (organised by ECETOC for Feb 2015 with OSPAR and CEFAS).

***In vivo* fish bioconcentration testing for validation of *in vitro* (S9) data from Eco 8.2.** Robin ring test organised by ECETOC with NC3Rs

2014 Science Scoping Meeting on Human Health & Human Exposure in Risk Assessment

05-06 February 2014, Brussels, Belgium

ECETOC brought together 38 scientists from its member companies, academia, the European Chemicals Agency (ECHA), the Joint Research Centre (JRC) and Cefic LRI to brainstorm Breakthrough Questions that if answered, will improve risk assessment.

The objective of the meeting was to help establish the mid to long-term ECETOC and strategic science direction in the area of Human Health & Exposure and to provide suggestions for future Cefic LRI programmes.

The outcome was a list of 12 topics to be scoped out for possible action by ECETOC and LRI funding. Bringing together member company scientists and external experts in this way helped generate relevant proposals with clear regulatory and policy impact, indeed some of the priority topics selected were suggested during the science panel debate. It was agreed that efforts should be made to improve communication of ECETOC and Cefic LRI output to a broader audience including those involved in decision-making and regulatory risk assessment.

The next meeting of this kind will be held in 2016, when it will join forces with the Environment Progress Review. Thereafter, it will become a yearly ECETOC Health Progress Review event. The full meeting report, including the list of key elements and objectives for action, can be downloaded from the following link: http://bit.ly/ecetoc-2014hhsm

ECETOC Workshop Addresses Aquatic Toxicity Using Species Sensitivity Distribution

11-13 February 2014, Amsterdam, The Netherlands

Group photo of the workshop participants

Predicting the toxicity of chemicals to aquatic communities is an integral element in environmental risk assessment. It is therefore a major component in environmental protection strategies and in the process of managing the safe use and disposal of chemicals. Hazard (toxicity) is most frequently predicted using concentration–effect data from single species toxicity tests which measure effects on individuals. However, the protection goals are generally wider i.e. populations, communities and ecosystems. Species sensitivity distributions (SSDs), describe the statistical distribution of species sensitivity to a toxicant and so can predict hazardous concentrations (HCps) affecting a certain percentage (p) of all the species in a community. Estimated HCps for environmental protection are usually the 5th percentile of the distribution and are used to derive a protective threshold concentration for an ecosystem.

ECETOC and the Environment Agency for England organised a three day workshop to discuss and review current statistical SSD models, when and how they should be used in regulatory applications and their ecological significance. A number of recommendations were made on how SSD methods could be further developed to improve the quality of decisions needed from both the prospective risk and retrospective impact assessment of chemicals.

The document is published as ECETOC Workshop Report No.28: Estimating toxicity thresholds for aquatic ecological communities from sensitivity distributions. 11-13 February 2014. The report can be freely downloaded via http://bit.ly/ecetoc-wr28

Symposia and Other Meetings

2014 Annual Technical Meeting on Addressing Company Needs and Regulatory Aspirations at European and Global Level

12 June 2014, Brussels, Belgium

On 12th June 2014, ECETOC brought together 46 scientists from its Member Companies, academia, journalism and the European Chemicals Agency (ECHA) for its Annual Technical Meeting (ATM), with the objective to assess how well it fulfils member company needs and regulatory aspirations at European and Global Levels, and to brainstorm how improvements can be made.

The Chairs of the Scientific Committee and Board set the context in terms of scientific, regulatory and global business needs. Then, participants heard about ECETOC's achievements in its Environment, Human Health and Exposure science programme. Finally, guests from ECHA and Chemical Watch gave their analysis of ECETOC from the outside, before participants broke out into groups to discuss the question: Have We Got It Right?

"Regulatory toxicology is less about Science and more about box-ticking – but it is here to stay and it is increasingly important because it's our license to operate"

The TRA tool aligns industry work processes with regulatory needs – leading to significant savings and a reliable Chemical Safety Assessment. Without the TRA, CSA's couldn't have been done in time for REACH"

"ECHA wants to be the hub of good regulatory science. We recognise there is a need to communicate regulatory needs to scientists to guide R&D and get concerted action"

"You will make headway with good arguments, supported by robust science – as long as the interests behind those arguments are openly stated. Be open about who's involved and what you want to achieve"

As a result of the brainstorm breakout groups, participants arrived at a number of Key Elements and Objectives for Action which were considered by the ECETOC Scientific Committee in October 2014 for incorporation into the overarching ECETOC strategy. The resulting decisions and developments will be presented at the 2015 ATM. The full meeting report, including the list of Key Elements and Objectives for Action, can be downloaded from the following link: http://bit.ly/ecetoc-2014ATMreport

Genotoxicity of Nanomaterials

Symposium at the European Environmental Mutagen Society (EEMS) Meeting at the University of Lancaster, 06-10 July 2014, Lancaster, UK

This ECETOC-sponsored Symposium, that included speakers from UK, Switzerland, Finland and Germany, reviewed the current state of the science regarding genotoxicity testing of nanomaterials. In summary, the results of genotoxicity testing of nanomaterials in different *in vitro* cell systems have produced mixed results requiring the introduction of clear guidelines and harmonisation of testing conditions including consideration of exposure conditions, cell harvesting and analysis. *In vivo* investigations have also provided mixed results. For example, following intratracheal instillation of high doses of selected nanomaterials, cells in the bronchiolar lavage fluid exhibited signs of DNA damaging effects, suggesting an inflammatory mode of action.

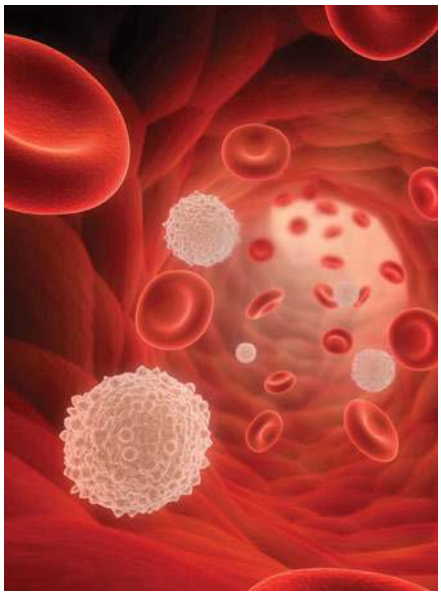
Long-term health effects of nanomaterials is still an ongoing research area, in particular the mode of action by which nanomaterials might induce lung tumours after inhalation. For risk assessment and regulation, consideration must be given to the relevance of high dose effects to humans as well as potential thresholds of effects.

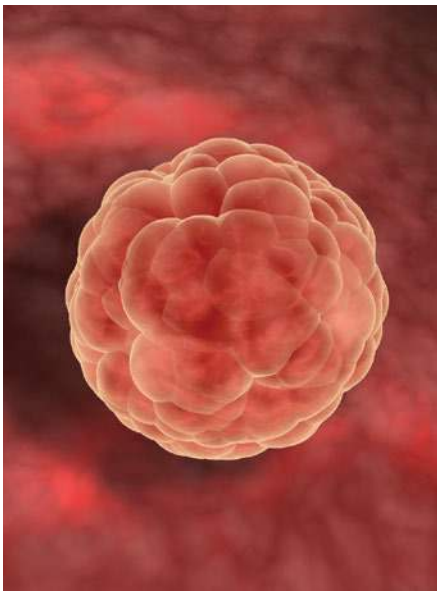
It was agreed that the output of the Symposium will include a state of the art scientific review of current genotoxicity methodology and suggestions for further research.

Application of AOP/MOA-Based Approaches in Chemical Risk Assessment

Session organised by ECETOC at EUROTOX 2014, 09 September 2014, Edinburgh, Scotland

This symposium provided a state-of-the art discussion on how development of new technologies at the molecular level contributes to Modes of Action (MoA) investigations and to the definition Adverse Outcome Pathways (AOP). The impact of these new developments on chemical risk assessment for humans was also discussed. Starting with a historical perspective of the main activities in these areas, specific presentations discussed the AOP programme within OECD and the applicability of these new types of approaches for high volume chemicals (e.g. REACH legislation). A discussion on the implementation of MoA and AOP in risk assessment concluded the symposium in the light of Tox 21c principles.





Communicating the Science

Publications

ECETOC's primary outputs are state-of-the-science reviews 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.

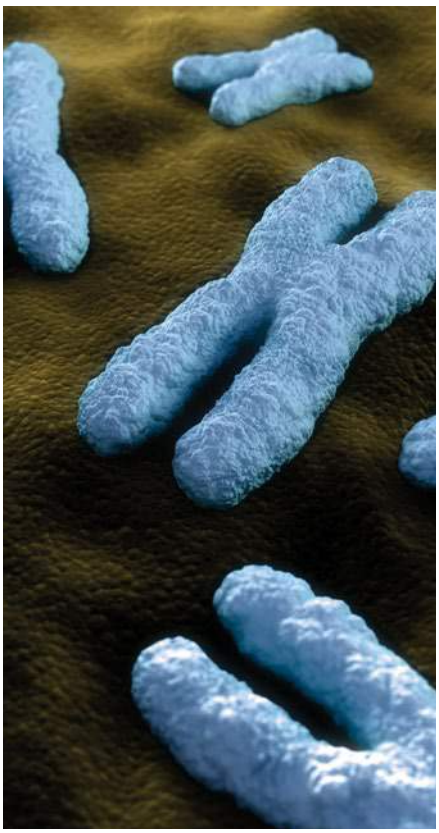
Scientific Articles are publications in peer-reviewed journals.

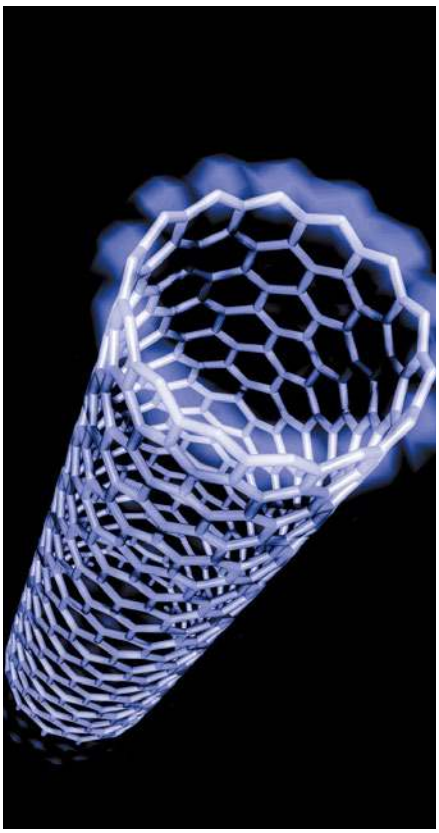
JACC Reports (Joint Assessment of Commodity Chemicals) are comprehensive reviews of all available toxicological and ecotoxicological data on specific chemical substances, predominantly those having widespread and multiple uses.

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 http://www.ecetoc.org/publications





Reports Published by ECETOC during 2014

Technical Report

No. 124 Addendum to TR114 : Technical Basis for the TRA v3.1 (June 2014)

Special Report

No. 18 Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH) (July 2014)

Workshop Report

No. 28 Estimating toxicity thresholds for aquatic ecological communities from sensitivity distributions. 11-13 February 2014, Amsterdam (November 2014)

Articles Published in the Open Scientific Literature during 2014

Hennes C+, Batke M, Bomann W, DuHayon S, Kosemund K, Politano V, Stinchcombe S, Doe J. 2014. Incorporating potency into EU classification for carcinogenicity and reproductive toxicity.

Regulatory Toxicology & Pharmacology. 70(2):457-467. Doi: 10.1016/j.yrtph.2014.07.022 (Open Access) [† Deceased]

Arts J, Hadi M, Keene A, Kreiling R, Lyon D, Maier M, Michel K, Petry T, Sauer U, Warheit D, Wiench K, Landsiedel R. 2014.

A Critical Appraisal of Existing Concepts for the Grouping of Nanomaterials.

Regulatory Toxicology and Pharmacology 70(2):492-506. Doi: 10.1016/j.yrtph.2014.07.025 (Open Access)

van Ravenzwaay B, Kleinjans J, Vrijhof H. 2014. Editorial - Epigenetics and chemical safety *Mutation Research/Genetic Toxicology and Environmental Mutagenesis* 764–765:1-2. Doi: 10.1016/j.mrgentox.2014.01.008

Thomson J P, Moggs J G, Wolf C R, Meehan R R. 2014. Epigenetic profiles as defined signatures of xenobiotic exposure. *Mutation research. Genetic toxicology and environmental mutagenesis* 764-765:3-9. Doi: 10.1016/j.mrgentox.2013.08.007

Mirbahai L, Chipman J K. 2014. Epigenetic memory of environmental organisms: A reflection of lifetime stressor exposures *Mutation Research/Genetic Toxicology and Environmental Mutagenesis* 764:10-17. Doi: 10.1016/j.mrgentox.2013.10.003

Cadet J. Wagner J R. 2014. TET enzymatic oxidation of 5-methylcytosine, 5-hydroxymethylcytosine and 5-formylcytosine. *Mutation research. Genetic toxicology and environmental mutagenesis* 764-765:18-35 Doi: 10.1016/j.mrgentox.2013.09.001

Vandegehuchte M B, Janssen C R. 2014. Epigenetics in an ecotoxicological context *Mutation Research/Genetic Toxicology and Environmental Mutagenesis* 764:36-45 Doi: 10.1016/j.mrgentox.2013.08.008

Siddeek B, Inoubli L, Lakhdari N, Rachel P B, Fussell K C, Schneiderg S, Mauduita C, Benahmed M. 2014.

MicroRNAs as potential biomarkers in diseases and toxicology.

Mutation Research/Genetic Toxicology and Environmental Mutagenesis 764:46-57 Doi: 10.1016/j.mrgentox.2014.01.010

Zarakowska E, Gackowski D, Foksinski M, Olinski R. 2014.

Are 8-oxoguanine (8-oxoGua) and 5-hydroxymethyluracil (5-hmUra) oxidatively damaged DNA bases or transcription (epigenetic) marks? *Mutation Research/Genetic Toxicology and Environmental Mutagenesis* 764:58-63 Doi: 10.1016/j.mrgentox.2013.09.002

Jaksik R, Lalik A, Skonieczna M, Cieslar-Pobuda A, Student S, Rzeszowska-Wolny J. 2014.

MicroRNAs and reactive oxygen species: Are they in the same regulatory circuit?

Mutation Research/Genetic Toxicology and Environmental Mutagenesis 764:64-71 Doi: 10.1016/j.mrgentox.2013.09.003

Kleinjans J, van Ravenzwaay B. 2014 Epigenetics and chemical safety – Concluding remarks

Mutation Research/Genetic Toxicology and Environmental Mutagenesis 764:72-73 Doi: 10.1016/j.mrgentox.2014.03.003

Rouquié D, Heneweer M, Botham J, Ketelslegers H, Markell L, Pfister T, Steiling W, Strauss V, Hennes C. 2014.

Contribution of New Technologies to Characterization and Prediction of Adverse Effects.

Accepted for publication in Critical Reviews in Toxicology

Contributing to International Initatives

Representation at specific meetings

→ 25-26 March 2014:

Federal Institute for Occupational Safety and Health (BAuA), Dortmund, Germany. The ETEAM Conference - Challenges and Perspectives of Tier 1 Exposure Assessment. Participation on behalf of ECETOC by Chris Money (ExxonMobil)

→ 11-15 May 2014:

Basel, Switzerland. SETAC Europe 24th Annual Meeting. Session on endocrine disruptors: exposure, hazard and risk assessment. Participation by Malyka Galay Burgos (ECETOC) on the Organising Committee

→ 04 June 2014:

Royal Society of Chemistry, London, UK. RSC Expert Panel on Endocrine Disrupter Low Dose Effects. Participation on behalf of ECETOC by Malyka Galay Burgos on the Organising Committee

→ 24-28 August 2014:

Prague, Czech Republic. 9th World Congress on Alternatives and Animal Use in the Life Sciences. Participation on behalf of ECETOC by Malyka Galay Burgos (ECETOC)

→ 23-24 September 2014:

Helsinki, Finland. LRI-ECHA Bioaccumulation Workshop. Participation on behalf of ECETOC by Malyka Galay Burgos (ECETOC)

→ 14-15 October 2014:

Brussels, Belgium. 10th SETAC Europe Special Science Symposium (SESSS10) focused on "Bioavailability of organic chemicals: linking science to risk assessment and regulation". Participation on behalf of ECETOC by Malyka Galay Burgos on the Organising Committee

→ October 2014:

Paris, France. OECD Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA) of the Test Guidelines Programme - Advisory group meeting. Remi Bars (Bayer) presented Endocrine « low dose » activities initiated by ECETOC and now pursued by the U.K. Royal Society of Chemistry

→ 18 November 2014:

London, UK. International Expert Workshop on Systematic Review of Evidence for Chemical Risk. Participation on behalf of ECETOC by Malyka Galay Burgos (ECETOC)

Input to Specific Projects and Reports

→ 6th Framework Programme Co-ordination Action Project "Norman"

Participation in Advisory Board on behalf of ECETOC by Stuart Marshall (Unilever)

→ 7th Framework Programme Co-ordination Action Project "EUROECOTOX"

The EUROECOTOX project EU-FP7 funding finished at the end of 2012 but the feasibility and strategic importance of continuing the EUROECOTOX network was discussed at the final project meeting in Brno (Czech Republic). It was decided that from December 2012 the network would be managed by Dr Malyka Galay Burgos of ECETOC, one of the EUROECOTOX partners, since ECETOC has a proven track record in supporting the use of alternatives to animals for environmental assessments.

→ ECHA Biocidal Products Committee

Participation on behalf of ECETOC by Mandy Osterloh-Quiroz (Dow)

→ ECHA Endocrine Disruptor Expert Group

Participation on behalf of ECETOC by Remi Bars (Bayer)

→ ECHA Guidance on IR&CSA, Chapter R.7a, Section R.7.2 (irritation/corrosion)

Participation on behalf of ECETOC by Pauline McNamee (P&G)

→ ECHA Guidance on IR&CSA, Chapter R.7a, Section R.7.6 (reproductive toxicity)

Participation on behalf of ECETOC by Christine Palermo (ExxonMobil)

→ ECHA Guidance on IR&CSA, Chapter R.12 (use descriptor system)

Participation on behalf of ECETOC by Manon Loos (Albemarle)

→ ECHA Member State Committee (MSC)

Participation as an observer on behalf of ECETOC by Alan Poole (ECETOC)

→ ECHA Nanomaterials Working Group

Participation on behalf of ECETOC by Karin Wiench (BASF)

→ ECHA PBT Partner Expert Group

Participation on behalf of ECETOC by Michiel Claessens (DuPont)

→ 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

→ 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)

→ ILSI Europe Environment and Health Task Force

Participation on behalf of ECETOC by Malyka Galay Burgos (ECETOC)

→ Klimisch Update for Environmental Risk Assessment

The ring test has been evaluated and commented with input from scientists in the ECETOC membership. The outcome of this exercise was presented at a special workshop at SETAC Glasgow 2013. Several publications, including a peer reviewed paper, a book and several reports are expected to be

Science Awards

published in 2015. For more information contact Malyka Galay Burgos at ECETOC.

→ 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)

→ STFC / NERC Bioinformatics and Environmental 'Omics Network

The overarching objective of the network is to build bridges between scientific communities in bioinformatics and environmental 'omics. The network will be co-aligned with the establishment of the new UK National Environmental Research Council (NERC) Environmental 'Omics Synthesis Centre (EOS), which has the remit of exploring emerging areas of bioinformatics and environmental 'omics and their application to environmental problems. ECETOC is represented by Malyka Galay Burgos.

→ WHO/IPCS Chemical Risk Assessment Network

Participation on behalf of ECETOC by Alan Poole (ECETOC)

With the objective of recognising talented young scientists, ECETOC has been active in the provision of an annual Science Award to outstanding works of science since 2003. In 2014, ECETOC sponsored the following awards for young scientists and is proud to announce the winners:

Environmental Science Related Award

SETAC Europe 2014
15 May 2014 Basel, Switzerland

The ECETOC Best Platform Award honours the early career scientist with the best platform presentation at the SETAC Europe Annual Meeting. The award winner receives a monetary prize and free registration to the next SETAC Europe Annual meeting.
Steffi Böhme of the Helmholtz Centre for Environmental Research (Department of Bioanalytical Ecotoxicology) won this year's award for her presentation 'Visualisation of silver nanoparticle uptake by Laser Ablation - Inductively Coupled Plasma Mass Spectrometry'.

Event website: http://basel.setac.eu/awards_programme/young_scientist_award

Christa Hennes Young Scientist Award

Eurotox 2014
7-10 September 2014, Edinburgh, Scotland

In 2014, the human health science related award was been renamed in memory of Dr Christa Hennes who sadly passed away in December 2013 and who was instrumental in organising this award. This is a Best Poster Award for toxicological research into mechanisms and risk assessment, selected by a panel in which ECETOC participates. The winner receives a monetary prize and a free invitation to the following year's EUROTOX meeting. The 2014 winner was Dr Laura Pastor Castro of the University of Navarra, Spain, for her abstract "Sex-dependent gene expression of kidney transporters after ochratoxin A exposure in F344 rats".

Event website: http://www.eurotox2014.com

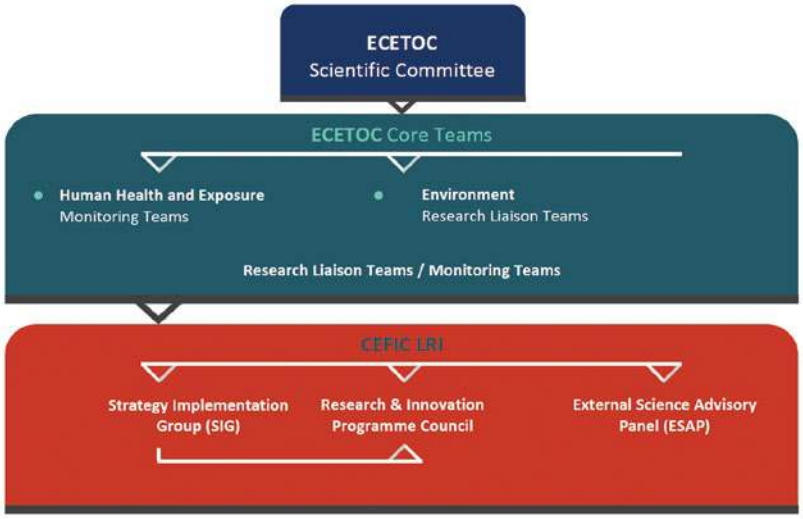
ECETOC Contribution to Cefic Long-range Research Initiative

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 Strategy Implementation Group (SIG). (A core team may organise a workshop with academic, government and industry scientists for this purpose.)
- Drafting of 'requests for proposals' (RfPs) based on ideas submitted by Cefic and ECETOC stakeholders 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 SIG 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 & Exposure Monitoring Teams

The current research portfolio under the health and exposure programme looks as follows with projects starting in 2014 marked below with *:

AIMT2: Mechanism-based characterisation of systemic toxicity for RepDose database substances employing *in vitro* toxicogenomics
Principal investigator: Dr. Rob H Stierum, TNO, AJ Zeist, The Netherlands

AIMT3: Data-integration for endpoints, cheminformatics and omics
Principal investigator: Dr. Joost van Delft, Maastricht University, The Netherlands

AIMT4*: Moving from DECO towards OECD
Principal investigator: Dr. Danyel Jennen, Maastricht University (UM), Maastricht, The Netherlands

AIMT5*: AOP/MOA of Developmental Ontology
Request for Proposals (RfP) advertised in 2014. *Selection Team meeting held in February 2015*

AIMT6*: CON4EI: CONsortium for *in vitro* Eye Irritation testing strategy
Principal investigator: Dr. An Van Rompay, Flemish Institute for Technological Research (VITO), Belgium

B6: A toxicogenomic approach to enhance the specificity and predictive value of the murine local lymph node assay
Principal investigator: Dr. Darrell Boverhof, Dow, Midland, MI, USA

B7: Determining the nature of chemical substance additively from household consumer products
Principal investigator: Dr. Natalie von Götz, ETH, Safety and Environmental Technology Group, Zürich, Switzerland *(Final report delivered in January 2014)*

B9: Characterising the nature of dermal exposure from consumer products and articles
Principal investigator: Ir. Rudi Torfs, VITO (Flemish Institute for Technological Research), Mol, Belgium

B10: Animal and human NOAELs: cross-species comparison, inference and synthesis
Principal investigator: Dr. Lesley Rushton, Imperial College London, UK
(Final report delivered in April 2014)

B11: Integrated external and internal exposure modelling platform
Principal investigator: Assoc. Prof. Dimosthenis Sarigiannis, Centre for Research and Technology Hellas, Thessaloniki, Greece

B12*: Assessing the relevance of the dust contribution to substances from consumer products and articles
Principal investigator: Dr. Natalie von Götz, ETH, Safety and Environmental Technology Group, Zürich, Switzerland

B13: Development of a mechanistic *in silico* multi-scale framework to assess dermal absorption of chemicals
Principal investigator: Prof. Gerald Kasting – University of Cincinnati, OH, USA

B14*: Skin Sensitisation – Chemical Applicability Domain of the Local Lymph Node Assay (LLNA)
Principal investigator: Dr. Anne Marie Api – RIFM, NJ, USA

B15: Developing a robust method of allocating efficiency measures to regulatory instruments in the chemicals industry
Principal investigator: Prof. Len Levy – Cranfield University, UK

B16*: External validation of Tier-1 workers dermal exposure estimates in ECETOC TRA.
Request for Proposals (RfP) advertised in 2014.
Selection Team meeting held in February 2015

C3*: A comprehensive Epigenomic profile of liver tissue from Rat and Mouse
Principal investigator: Prof. Richard Meehan, University of Edinburgh, UK

EMSG57: Endocrine disruptors and obesity, diabetes and heart disease: State of the science and biological plausibility
Principal investigator: Dr. Judy LaKind, LaKind Associates, Catonsville, MD, USA

EMSG58*: Human adverse health effects of endocrine active substances: assessment of the quality of individual epidemiological studies and of the overall mechanistic and epidemiologic evidence
Principal investigator: Prof. Carlo La Vecchia, IRCCS - Istituto di Ricerche Farmacologiche Mario Negri (IRFMN), Milan, Italy

HBM4: Understanding inter- and intra-individual variability in HBM spot samples
Principal investigator: Dr. Ir. Roel Smolders, VITO (Flemish Institute for Technological Research), Mol, Belgium.
(Final report delivered in 2014)

N1: Tiered approach to testing and assessment of nanomaterial safety to human health
Principal investigator: Dr. Otto Creutzenberg, Fraunhofer Institute of Toxicology and Experimental Medicine, Hannover, Germany

N3: Towards standardized testing guidelines (reproductive toxicity) relevant to nanomaterials
Principal investigator: Dr. J.J.M (Han) Van de Sandt, TNO, AJ Zeist, The Netherlands

N4*: Science-based grouping of nanoparticles for industrial application of safe-by-design
Principal investigator: Dr. ir. Hans Bouwmeester, RIKILT- Wageningen University and Research Center, Wageningen, The Netherlands

N5*: Biokinetics and long-term effects of inhaled nanoparticles
Request for Proposals (RfP) advertised in 2014.
Selection Team meeting held in February 2015

Environmental Research Liaison Teams

4 new environmental projects secured funding and were initiated in 2014 with the support of the research liaison teams (marked below with *). The current research projects are:

ECO 8.3: Fish cell line & embryo assays: follow up to the CEllSens ECO8/8.2 project (completed). A Round-Robin test of the RTgill-W1 cell line assay has now been established

Principal investigator: Prof. Kristin Schirmer, Eawag, Switzerland

Currently, in collaboration with the NC3Rs a RTgill-W1 round robin is taken place with the plan to have a first draft of a publication ready for distribution to the partners by end of February 2015

ECO 9: Investigating the environmental relevance of laboratory bioconcentration test

Principal investigator: Dr. Heather A. Leslie, VU University, The Netherlands *[Finalised]*

ECO 11: Influence of microbial biomass and diversity on biotransformation

Principal investigator: Dr. Russell Davenport, University of Newcastle, UK (Eco 11 workshop on the improvement of the OECD 306 screening test held 17-18 February 2015 at CEFAS Laboratories, Lowestoft UK)

ECO 13: Applying and verifying PBT/POP models through comprehensive screening of chemicals (completed)

Principal investigator: Prof. Michael McLachlan, Stockholm University, Sweden *[Finalised]*

ECO 14b: Development and validation of an abbreviated *in vivo* fish bioconcentration test

Principal investigator: Dr. Duane Huggett, University of North Texas, USA *[Finalised]*

ECO 15: Rapid estimation of TMF using laboratory, field and computer modelling methods in aquatic organisms *[Finalised]*

Principal investigator: Prof. Michael McLachlan, Stockholm University, Sweden *[Finalised]*

ECO 16: Critical body residue validation for aquatic organisms exposed to chemicals causing toxicity by baseline narcosis

Principal investigator: Dr. Joop Hermens, University of Utrecht, The Netherlands *[Finalised]*

ECO 17: Evaluation of test methods for measuring toxicity to sediment organisms

Principal investigator: Prof. Albert Koelmans, Wageningen University, The Netherlands (Eco 17 workshop prospective sediment risk assessment, held on 24-02-14 in Wageningen), The Netherlands *[Finalised]*

ECO 18: Identifying limitations of the OCED water-sediment test (OECD 308) and developing suitable alternatives to assess persistence

Principal investigator: Dr. Kathrin Fenner, EAWAG, Department of Environmental Chemistry, Switzerland

ECO 19: Towards more ecologically realistic assessment of chemicals in the environment

Principal investigator: Dr. Frederik De Laender, Ghent University, Belgium

ECO 20: Development of an alternative testing strategy for the fish early life-stage (FELS) test (OECD 210)

Principal investigator: Prof. Dr. Dries Knapen, University of Antwerp, Belgium

ECO21: Mechanistic Bioaccumulation Model(s) for Ionogenic Organic Substances in Fish

Principal investigator: Dr. Jon Arnot, ARC Arnot Research & Consulting Inc, Canada

ECO22: Advancing the use of passive sampling in risk assessment and management of contaminated sediments: an inter-laboratory comparison study on measurements of freely dissolved (bioavailable) concentrations using different passive sampling formats

Principal investigator: Dr. Michiel Jonker, University of Utrecht, The Netherlands

ECO23: 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

ECO24: Computer based prediction of the formation of Non-Extractable Residues (NER) of xenobiotics and their metabolites in soils and sediments with regard to their environmental hazard

Principal investigator: Dr. Gerrit Schüürmann, Helmholtz Centre for Environmental Research (UFZ), Leipzig, Germany

ECO 25: Development of Soup Tests for the Risk assessment of NER in Soil

Principal investigator: Dr. Joop Harmsen, Alterra Wageningen UR, The Netherlands

ECO26*: Adapt SimpleTreat for simulating behaviour of chemical substances during industrial sewage treatment

Principal investigator: Prof. Dik van de Meent, Radboud Universiteit, The Netherlands

ECO27*: Chemicals Assessment of Risks to Ecosystem Services (CARES).

Principal investigator: Dr. Lorraine Maltby, University of Sheffield, UK. *1st meeting planned February 2015*

ECO28*: Aquatic Community level assessment of chemical toxicity using ecological scenarios

Request for Proposals (RfP) advertised in 2014. *Selection Team meeting held in February 2015*

ECO29*: Application of chemostat systems to include adaptation of microbial communities in persistency testing

Principal investigator: Dr. John Parsons, University of Amsterdam (UvA), The Netherlands. *1st meeting planned February 2015*

ECO30: Expanding the applicability domain of the chemical activity approach for hazard and risk assessment

Principal investigator: Dr. Jon Arnot and James M. Armitage, ARC Arnot Research & Consulting Inc., Toronto, Canada

EEM 9.3: Linking IUCLID & AMBIT

Principal investigator: Dr. Nina Jeliazkova Institute of Parallel Processing, Bulgarian Academy of Sciences, Sofia, Bulgaria

EMSG 55: Critical evaluation of individual and combined natural and synthetic endocrine active compounds in fish: an *in vitro* and *in vivo* approach

Principal investigator: Prof. Tom Hutchinson, CEFAS, UK *[Finalised]*

N2: Assessment of nanoparticle specific effects in environmental toxicity testing (Complete but now leading to a Workshop)

Principal investigator: Dr. Alistair Boxall, University of York, UK

Members of the Scientific Committee

The Scientific Committee is responsible for the definition, management and peer review of the ECETOC work programme. The Board appoints the Chair and members of the Scientific Committee based on their scientific expertise.

Ben van Ravenzwaay (Chairman)	BASF
Remi Bars	Bayer CropScience
Peter Boogaard	Shell
Andreas Flückiger	F. Hoffmann-La Roche
Helmut Greim	Technical University Munich
René Hunziker	Dow Europe
Fraser Lewis	Syngenta
Guiseppe Malinverno	Solvay
Lorraine Maltby	University of Sheffield
Stuart Marshall	Unilever
Marie-Louise Meisters	DuPont
Mark Pemberton	Systox Ltd. (formerly of Lucite)
Carlos Rodriguez	Procter & Gamble
Lesley Rushton	Imperial College London
Dan Salvito	RIFM on behalf of IFF
Jason Snape	AstraZeneca
Johannes Tolls	Henkel
Saskia van der Vies	Amsterdam Free University
Kees van Leeuwen	KWR Watercycle Research Institute
Rosemary Zaleski	ExxonMobil Biomedical Services

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.

During 2014, the Secretariat comprised the following members:

Alan Poole	Secretary General
Malyka Galay-Burgos	Environmental Sciences Manager
Madeleine Laffont	Human Health Scientist
Ian Cummings	Communication, Web & Media Manager
Geneviève Gérits	Office Manager
Christine Yannakas	Administrative Assistant
Sonia Pulinckx*	Administrative Assistant

* Retired end July 2014. It was a pleasure working with Sonia and we wish her well in her retirement.

Finance

INCOME ACTUAL 2014 IN EURO

Subscription	
33 Full Members	1.138.500
7 Associate Members	70.000
Total Subscription Income	**1.208.500**
Bank Interest	0
Investment income	7.537
Project-related	251.479
Total	**1.467.516**

EXPENDITURE ACTUAL 2014 IN EURO

Salaries (and related expenses)	743.698
Office Running Expenses	196.338
Travel Expenses on Missions	10.558
Meetings and Consultants	283.524
Professional Services	31.776
Bank Charges	2.804
Capital Expenditure	14.877
Publications	46.941
Miscellaneous	28.849
Website	21.500
Total	**1.380.865**

BALANCE SHEET AND RESERVES ACTUAL 2014 IN EURO

Balance Sheet	
Income	1.467.516
Expenditure	1.380.865
Operating Margin	86.651
Reserves*	
Opening	1.990.866
Operating Margin	86.651
Closing Reserves	**2.077.517**

* Estimated Reserve Required: 275.364

Abbreviations

AOP
Adverse outcome pathways

ATM
Annual technical meeting

BIAC
Business and Industry Advisory Committee to the OECD

BAuA
(German) Federal Institute for Occupational Safety and Health

Cefic
European Chemical Industry Council

Chesar
ECHAs CHEmical Safety Assessment and Reporting tool

CSA
Chemicals Safety Assessment

DECO
Data-integration for Endpoints, chemoinformatics and omics

DNA
Deoxyribonucleic acid

DUCC
Downstream Users of Chemicals Co-ordination Group

ECETOC
European Centre for Ecotoxicology and Toxicology of Chemicals

ECHA
European Chemicals Agency

ED EAG
Endocrine Disrupter Expert Advisory Group to the EU Commission

EEMS
European Environmental Mutagen Society

EFSA
European Food Safety Authority

EOS
NERC Environmental 'Omics Synthesis Centre

EPA
(US) Environmental Protection Agency

ESTAF
ECVAM Stakeholder Forum

EU
European Union

EUROECOTOX
European Network for Alternative Testing Strategies in Ecotoxicology

EUROTOX
Association of European Toxicologists and European Societies of Toxicology

FELS
Fish early life-stage

GHS
Globally harmonised system of classification

HBM
Human biomonitoring

HCp
Hazardous Concentration for p% of species

ICCA
International Council of Chemical Associations

ILSI
International Life Sciences Institute

IOC
Ionogenic organic compound

IPCS
International Programme on Chemical Safety

JACC
Joint assessment of commodity chemicals

JRC
Joint Research Centre

LRI
Cefic's Long-range Research Initiative

MoA
Mode of action

MSC
(ECHA) Member State Committee

NER
Non-extractable residue

NERC
(UK) National Environmental Research Council

NOAEL
No observed adverse effect level

NORMAN
Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances

OECD
Organisation for Economic Co-operation and Development

PBT
Persistent, bioaccumulative toxic

PEG
(ECHA) Partner Expert Group

POP
Persistent organic pollutant

RAC
(ECHA) Risk Assessment Committee

REACH
EU regulatory framework for the registration, evaluation and authorisation of chemicals

RepDose
Database for the analysis of relationship between chemical function groups/ categories and target organs in repeated dose studies

RfP
Request for proposal

RNA
Ribonucleic acid

SC
Scientific Committee

SCHER
EU Scientific Committee on Health and Environmental Risks

SETAC
Society of Environmental Toxicology and Chemistry

SIG
LRI strategy implementation group

SpERCs
Specific environmental release classes

STFC
Science and Technology Facilities Council, UK

STOT
State of the science

TMF
Trophic magnification factor

Tox21
(US) Toxicology in the 21st century program

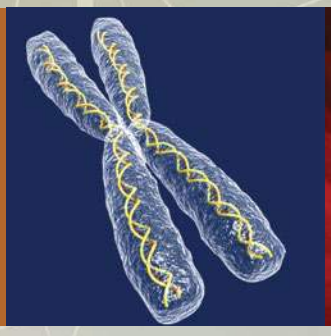
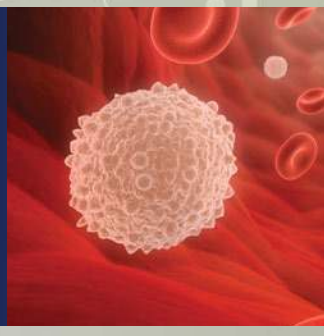
TR
ECETOC technical report

TRA
Targeted risk assessment

vPvB
Very persistent and very bioaccumulative

WHO
World Health Organisation

WR
ECETOC workshop report

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

ECETOC AISBL

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