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ANNUAL
REPORT
2018

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About ECETOC



OUR PURPOSE

ECETOC is the scientific Centre for chemical safety assessment.



WHAT WE DO

We provide a collaborative space for top scientists from industry, academia and governments to develop and promote practical, trusted and sustainable solutions to scientific challenges which are valuable to industry, as well as to the regulatory community and society in general.

We shape scientific knowledge

ECETOC works with leading scientists from academia, governments and industry to answer crucial scientific questions about chemical safety and assessment. We do this by organising workshops, expert meetings and task forces that transform research into practical applications to solve contemporary and future scientific challenges.

We expand scientific knowledge

ECETOC works with Cefic's Long-range Research Initiative (LRI) to develop targeted scientific research and other relevant initiatives. We provide Cefic LRI with scientific advice and support to develop its research programme and coordinate and monitor its projects.

We communicate scientific knowledge

ECETOC provides scientific thought-leadership, creating a practical knowledge base that is shared freely on our website, in our publications and at our meetings and symposia. ECETOC's chemical safety assessment tools are also available on our website.



OUR VALUES

Scientific excellence

We engage top scientists from industry, academia and governments.

Science for the public good

We ensure all of our scientific activities have a primary public purpose and benefit, in particular focusing on protecting human health and safeguarding the environment.

Collaboration

We provide a forum for scientists from industry, government, and academia to exchange ideas and work together to ensure appropriate and valuable scientific outcomes.

Independence

We provide the collaborative space, freedom from commercial pressure and long-term project stability needed to ensure independent scientific research and technical development.

Transparency

We openly address potential conflicts of interest (in publications or internally) and make all our work and the scientific findings resulting from it available to the public.

Diversity

We are dedicated to building a diverse organisation and collaborative environment, with a shared commitment to scientific excellence.



OUR STRUCTURE

ECETOC is governed by a Board of Administration (senior executives from member companies), responsible for the overall policy and finance, which is appointed by the General Assembly.

The Board appoints the Secretary General and 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, managed by the Secretary General.



OUR FINANCING

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

MEMBERSHIP



BENEFITS OF MEMBERSHIP

We create a collaborative environment that brings together the collective scientific expertise of academia, regulatory authorities and industry to contribute to regulatory safety assessments of chemicals.

We share scientific knowledge about current and future regulatory science challenges, as well as what's emerging, what's new, what's affecting industry sectors, regulatory authorities and science in general.

We actively help to shape industry's future science agenda.

Our member companies and the regulatory authorities gain practical scientific understanding and knowledge that they can apply in their organisations. ECETOC helps its members navigate through REACH (Evaluation, Authorisation and Restriction) and CLH technicalities.

Membership is open to companies who manufacture or use chemicals.

See: www.ecetoc.org/ecetoc-membership/benefits-membership/ for more details.

We provide access to ECETOC expert meetings attended by industry, top academic and regulatory scientists.

We train our members' young scientists and enhance their professional networks through participation in Task Forces, Expert Groups and Research Monitoring Teams.

We represent our members in EU and international organisations, such as ECHA, WHO and OECD.

We develop tools to streamline evaluation, registration and management of safe chemistry.



MEMBER COMPANIES

In December 2018, the ECETOC Membership comprised the following 29 full Member Companies and 6 Associate Member Companies:



Associate member company



Associate member company



Associate member company



Associate member company



Associate member company



Your partner in essential chemistry



Message from the CHAIR of the BOARD



Dr. MARTIN KAYSER

Chair of the Board of Administration

2018 was a milestone year for ECETOC as we celebrated our 40th anniversary. Members and VIP guests gathered to celebrate with us at the Bibliothèque Solvay, the historic home of scientific excellence in Brussels, providing a wonderful showcase of ECETOC's past as well as its ambitions for the future.

As I said in my message last year, we can be extremely proud of what we have accomplished over the past four decades for our members and for the furtherance of scientific excellence.

Today, thanks to the dedication, goodwill and personal involvement of the scientists who donate their time to the Science Programme, ECETOC is widely respected for its role in placing science at the heart of decision-making to protect human health and the environment.

The success of the past four decades must not, however, give rise to any complacency about our future. That is why we have invested significant time in 2018 considering our organisation's fundamental purpose, as well as our vision of what we want to achieve in the years to come – and then ensuring that they all dovetail with our long-term strategy.

The new strategy is based on three broad pillars – Visibility, Dialogue and Impact – and the Secretary General and the Secretariat will be actively working to implement them.

In line with our mission of shaping, expanding and communicating scientific knowledge, it is vital that as an organisation we raise our eyes above the day-to-day scientific challenges and consider what is coming down the road; the future trends of science, so to speak.

We need to understand what is emerging, what is new, what is impacting industry sectors, regulatory authorities and science in general.

Only by doing this will we remain at the cutting edge of scientific knowledge and so be able actively to help shape industry's future scientific agenda.

I also believe that ECETOC has a key role to play for the next generation of scientists. We must support and inspire this next generation of scientists and in particular we must encourage more gender diversity in science. We need to find ways to make young people, especially women, passionate and enthusiastic about science.

Science is in real danger of becoming unattractive to the next generation. Unless we can reverse this trend, we run the risk of scientific progress slowing down.

In addition, as the challenges facing the world today become ever more complex, scientists need to find new ways of working together in an open and collaborative environment, with colleagues from both public and private sectors. We must tear down the walls and silos that often limit scientific progress.

That is why ECETOC's mission to gather the very best scientists from academia, government and industry to work together is so important.

We must ensure that in these collaborations there is always a mix of scientific wisdom and experience coupled with youth and fresh thinking. This diversity is the best way to ensure that the frontiers of future science continue to expand.

Finally, I would like to end by expressing my sincere thanks to our Secretary General, Olivier de Matos, and to all of the members of the ECETOC Secretariat, who have so ably and enthusiastically supported and facilitated the Science Programme over the past year.

BOARD of Administration

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 2018 Annual General Meeting:

Proposed new Board Members, Drs. Steve Maund (Syngenta Crop Protection), Chantal Smulders (Shell International) and Volker Soballa (Evonik Industries) were unanimously elected to the ECETOC Board.

The Chair, Martin Kayser, also informed participants that two members had recently stepped down from the Board:

- Dr. Peter Hertl who retired from Syngenta at the end of 2017 and
- Dr. Julia Fentem following Unilever's resignation from ECETOC.



BOARD Members during 2018

MARTIN KAYSER (Chair)
BASF

CHANTAL SMULDERS (Vice-Chair)
Shell International

LORRAINE FRANCOURT (Treasurer)
Dow Europe

PATRICK MASSCHELEYN
Procter & Gamble

STEVE MAUND
Syngenta Crop Protection

CRAIG NESSEL
ExxonMobil Biomedical Sciences Inc.

HEIKO RIECK
Bayer

VOLKER SOBALLA
Evonik Industries

Report from the SECRETARY GENERAL



OLIVIER DE MATOS

Secretary General

It is with great pleasure that I share ECETOC's accomplishments in 2018 with you, as well as take the opportunity to look forward to the new year ahead. In this 40th anniversary year for ECETOC, with the world changing rapidly around us, it was an appropriate moment to spend time thinking beyond our day-to-day activities and reflecting on our purpose, vision and values – and then ensuring that they underpin our strategy for the coming years ahead.

As the scientific Centre for chemical safety assessment, we provide a collaborative space for top scientists from industry, academia and governments to develop and promote practical, trusted and sustainable solutions to scientific challenges which are valuable to industry, as well as to the regulatory community and society in general.

To achieve our aims, our strategy has three broad pillars: increasing our 'Visibility' with ECETOC members and potential members; engaging in a constructive 'Dialogue' with our external stakeholders; and making an 'Impact' on the long-term scientific agenda.

Under the first pillar of 'Visibility', in 2018 we redefined our value proposition for members, something we will be sharing with them over the coming months. We held several face-to-face meetings with members to talk about what was important to them – and these conversations will continue. Additionally, we have been in contact with a number of potential new members and we hope to make new membership announcements in due course. Finally, we are carrying out significantly more work communicating scientific knowledge, both among our membership as well as to external stakeholders.

Under our second pillar, 'Dialogue', ECETOC has been proactively reaching out to our external stakeholders to ensure that our contribution to the scientific conversation is heard. We will continue doing this in 2019 and, whenever appropriate, we will strike partnerships with other organisations to share knowledge and competences.

Finally, under the 'Impact' pillar, our Progress Review and Scoping meetings have continued to shape the science programme, ensuring that it focuses both on topics of immediate concern, as well as on anticipating future scientific trends. We received more than 50 proposals for projects following a call for proposals, a recognition of ECETOC's value to its members.

Not having unlimited resources, however, we needed to prioritise and as a result not every project was taken forward. Those that were not prioritised in 2018 will be considered once again for the 2019 scientific programme. Nonetheless, we have established six new Task Forces and initiated a new Transformational Programme.

In 2019, we are planning to launch our next biennial call for proposals ahead of the 2020 Progress Review and Scoping meetings. ECETOC needs to strike the right balance between working on short-term topics that demonstrate immediate value to our Membership and longer-term topics that have a much higher strategic value, so that we can engage with and contribute to scientific debates much earlier in the process. We must make it a priority to track societal trends, focusing on activities that promote scientific excellence. 2018 was not just a year of future gazing and strategising – it was also a busy year on the ground.

In February, we published Technical Report 131, addressing technical questions that ECETOC and ECHA have received for which further clarification was thought necessary. And in December, we published Technical Report 132, evaluating the challenges and limitations associated with toxicity testing of microparticles and poorly soluble liquids in water. In May, as part of our mission to nurture young scientists, ECETOC sponsored the Best Platform Award at SETAC Rome 2018, an award honouring early-career scientists and one that we will continue to support in 2019. In July, we unveiled significant updates of data, as well as new tools, to ECETOC's Human Exposure Assessment Tools Database (heatDB). And in September, the ECETOC Christa Hennes Early Career Award (ECA) recognised young scientists at EUROTOX Brussels 2018.

Overall, it has been a busy and successful year for ECETOC, none of which would have been possible without the active contributions of all our members, for which we offer our sincere thanks and appreciation.

Finally, over the new year's holidays, ECETOC moved into its new offices in the centre of Brussels, where we very much look forward to welcoming you in the years to come.

SCIENCE PROGRAMME



Dr. BENNARD VAN RAVENZWAAY

Chair of the Scientific Committee

The final week of January is when ECETOC organises its review and scoping meetings to discuss the Environmental, Human Health and Exposure Programme.

Last year, something almost magical happened: there were more than 50 proposals submitted dealing with human and exposure sciences. A great many of these represented incremental steps to improve the quality and particularly the efficiency of developing and using data for risk assessment. Combining a number of these proposals was the starting point to launch our new Transformational Program for human health and exposure, which even I must admit is pretty ambitious.

To give you a flavour of the goals and challenges involved, here are the major points: ECETOC wants to increase the efficiency of the risk-identification and risk-assessment process for chemicals, allowing more chemicals and their uses to be assessed, as well as allowing aggregate and cumulative assessments to be made in a scientifically-sound way.

Our proposals to improve the system are:

- ▶ develop an Overall Framework for Chemical Safety in the 21st Century;
- ▶ develop a revised hazard categorisation scheme based on predicted human safe doses within each adverse outcome category;
- ▶ develop a use categorisation scheme which could be used in conjunction with a revised hazard categorisation for rapid safety decisions;
- ▶ develop Threshold of Toxicological Concern(s) for the full range of adverse outcomes/study types;
- ▶ develop a tiered hazard identification/characterisation framework, populated with existing and developing New Approach methodology (NAM);

- ▶ start a programme to develop a tiered system of 'smart studies' for repeat-dose toxicity and developmental toxicity; and

- ▶ develop an adequately-tiered risk assessment process.

I can already imagine many of you smiling or shaking your heads, thinking this will be impossible.

It is certainly challenging! However, given the enthusiastic support from all participants in the meeting I believe we can achieve this goal in a stepwise process.

Many of the points above are already being addressed. The 'Toxicology in the 21st century' initiative, as laid out 10 years ago by the US national academy of sciences, is a starting point. The HESI work based on these principles provides a good scheme for tiered data development and risk assessment based on exposure.

We need to map current ECETOC and Cefic LRI programmes, as well as other initiatives, to connect these activities with the goals of the Transformational Programme. There are opportunities in the use of information technologies and in silico approaches. With the increasing amount of hazard identification data obtained in the REACH process, the opportunities for read-across are also enhanced.

The challenges ahead will most likely be related to the inclusion of classification and labeling concepts in a new testing paradigm. Moreover, ways to enable aggregate and cumulative risk assessments to be carried out more effectively and efficiently will need to be developed.

The environment, human health and exposure scoping meetings in 2019 switched focus somewhat, towards reviewing our current activities.

I am aware that this represented a change, particularly for the environmental scientists, who are used to discussing new projects in these meetings. I can assure you that ECETOC and Cefic LRI still remain open to receiving proposals for new activities.

It is, however, also necessary to take stock and inform members of the progress made in activities launched out of the 2018 scoping meetings. I am pleased to report that good progress has indeed been made, as you will see in the overview provided in this Annual Report. The discussions that took place relating to our current activities have convinced me that this type of regular review is essential for a healthy organisation. New ideas and a more focussed approach to our ongoing activities have emerged based on these reviews.

I am confident that in 2020 we will have another successful scoping session, this time with more emphasis on future activities – so reserve a slot in your diaries for the event, in late January or early February. I believe that alternating between scoping and review meetings will give us a process that allows the initiation of creative and future-orientated new activities, as well as feedback on progress and direction.

In human health, the discussion is still underway to maintain scientific positions in the regulation of endocrine disruptors (ED). A fast-track ECETOC Task Force provided comments and a framework for the classification of ED compounds. On top of that, thyroid hormone changes have now become the new frontier for future ED regulation. Just nine months after its launch, our new Special T4 Task Force delivered a state-of-the-art paper relating to modes of action of thyroid hormones, with particular emphasis on developmental neurotoxicity. Of particular interest here is the first combined involvement of classical toxicology and epidemiology. This Task Force will continue its work and present its results in a workshop later this year.

In exposure sciences, the Targeted Risk Assessment (TRA) tool is being expanded. For ECHA and our industries, the TRA is a driving force towards efficient exposure assessment. The desire to make the TRA ever more usable for even more types of exposure – and with even more detail – demonstrates the strength of this approach: start at a simple level and then expand whenever possible.

I am convinced that the TRA will very soon tap into more and more databases to provide the granularity needed for more sophisticated risk assessment. Because there is occasionally a need to “dive deep” to demonstrate safety of use of chemicals, this need will be the driving force for building better exposure databases all over the world.

If we think about exposure-based testing as an essential part of toxicology in the 21st century (our TP for human health), then improved exposure databases will be critical for success.

In 2018, the Technical Report 132 ‘An evaluation of the challenges and limitations associated with aquatic toxicity and bioaccumulation studies for sparingly soluble and manufactured particulate substances’ was published. This report provides a comprehensive overview of the state of science.

Together with the revision of the OECD 23 document (Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures), which was supported by the ECETOC Task Force, experimental ecotoxicologists now have two documents which will serve as an important guide when it comes to difficult aquatic tests.

In the environmental fate sector, ECETOC agreed to follow up the 2018 Cefic LRI and CONCAWE Workshop on “Recent developments in science supportive to the persistence and biodegradation assessment” by forming a Task Force. This Task Force will compile the feedback and findings from the Workshop and ensure they are scientifically underpinned to strengthen the regulatory applicability of the approaches discussed.

In October 2018, Olivier de Matos and I had a day-long meeting with representatives of ECHA, including Björn Hansen and his directors.

We were warmly received and the overall feeling of the meeting was “what took you so long to come and visit us”. This demonstrates for me, above all, ECETOC’s credibility and the applicability of our work to risk assessment.

The different points under discussion included: exposure assessment (EUSES and the TRA); ECETOCs approach for the read-across for nano materials; classification and labelling issues; grouping and read-across for chemicals, polymers, microplastics, etc... basically everything that is on ECHA’s plate at this moment in time.

Although this sort of meeting seldom has an immediate effect, it is an excellent sounding board to determine whether our current activities are in line with the current regulatory issues. I can assure you that they are. It is our intention to schedule annual meetings with ECHA to maintain this open form of communication and discussion.

Since 2017, we have had a new and inspiring ECETOC team. In January 2019, ECETOC moved offices to the centre of Brussels. We are on the move, being proactive and helping to translate data into knowledge and knowledge into a better way to assess the safety of our products and uses for humans and the environment.

I encourage you to be part of that team, to help ECETOC help our membership and, ultimately, the entire regulatory community.

COMPLETED ACTIVITIES

MEtabolomics standaRds Initiative in Toxicology (MERIT):

Developing best-practice guidelines and minimal reporting standards for applications of Metabolomics in Regulatory Toxicology.



Background

During the past two decades, metabolomics has become a mature and widely-used technology in academic research, resulting in thousands of publications, yet to date its application to regulatory science, including regulatory toxicology, has been limited. While several factors contribute to this slow uptake, the most commonly cited roadblock is the lack of standardisation, validation and reporting formats for metabolomics.



Objective

The MEtabolomics standaRds Initiative in Toxicology (MERIT) project brought together a team of international experts from industry, government agencies, regulators and academia to address this need with the aim of developing best practice guidelines, method performance standards and minimal reporting standards for the acquisition, processing and statistical analysis of untargeted metabolomics and targeted metabolite data in the context of regulatory toxicology.

The MERIT Expert Group has prepared a manuscript – currently under peer review – intended to provide stakeholders with practical guidelines for designing, undertaking, reporting and assessing the quality of a metabolomics study.

Furthermore, it is intended to be a living document with revisions anticipated in response to evolving technologies and approaches.

Aquatic toxicity and bioaccumulation of sparingly soluble manufactured particulate substances (TASK FORCE):

ECETOC established this Task Force in 2016 in response to increasing concerns among the scientific community, policy makers, and the general public about the impact of particles and poorly soluble liquids in the water environment.

The Task Force has now completed its work and has identified an urgent need to strengthen the quantitative and mechanistic understanding of how particle intrinsic and extrinsic properties,

as well as test system extrinsic properties, influence Observed Adverse Effects in aquatic toxicity testing for NMs, MPs and poorly soluble liquids.

To advance the scientific understanding of the potential impacts of particles and poorly soluble liquids, the Task Force recommends that there be multi-stakeholder discussions to identify and prioritise key research needs and to develop a consensus on how best to assess the risks associated with the exposure to particles originating from commercial activities. The considerations and recommendations set out in the Task Force report can be used as a basis for these discussions. The Task Force report was published in December 2018.

Assessing the human health and environmental safety of polymers (TASK FORCE):

The Task Force ‘Assessing the human health and environmental safety of polymers’ met in Brussels in April 2018 for its kick-off meeting.

The Task Force has been working to develop a conceptual framework for the human health and environmental safety assessment of polymers, taking into consideration the elements used in existing approaches applied internationally for polymer safety assessment, as well as the complexity of polymer compositions and life cycles.

The Task Force mandate is extensive. The first deliverable from the work will be published in April 2019. The Task Force also intends to share the outcome of its work in a workshop with stakeholders. Since the Task Force began, DG Environment initiated a project on ‘Scientific and technical support for the development of criteria to identify and group polymers of concern for Registration / Evaluation under REACH and their impact assessment’.

The Task Force has met with DG Environment representatives and the contracted consultants for the project, to discuss synergies between this project and the work of the Task Force.

Though the scope of the Task Force work is broader than that of the EC project, some key technical areas of overlap were identified. ECETOC was invited to be a member of the project.

Advisory Group and it was also agreed to continue the dialogue via ad-hoc interactions, on certain topics, outside of the Advisory Group. The option of holding a combined Stakeholder workshop is also under discussion.

TASK FORCES ESTABLISHED

Special T4 TASK FORCE



Background

A potential connection between reduction of thyroid hormones, in particular thyroxine (T4), and impaired neuronal (mental) development in children is under discussion. This debate has caused uncertainty in the EU plant protection product (PPP), biocide (BP) and REACH regulatory environments.

For chemicals regulated under REACH, this uncertainty has resulted in ever-increasing requests to conduct animal studies, using large numbers of rodents, to address developmental neurotoxicity. Similarly, the European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA) Guidance for the identification of endocrine disruptors in the context of the PPP and BP Regulations, that was published on 7 June 2018, implies the need to generate large quantities of animal studies to address concerns related to thyroid disruption.

Together with its member companies, ECETOC is firmly committed to the obligation to protect humans and the environment from detrimental effects of chemicals. ECETOC is equally committed to the 3Rs principle to replace, reduce and refine animal testing. As a result, ECETOC is concerned that the EFSA and ECHA Guidance does not provide any concrete direction on how the outcomes of the requested animal studies should be used to reliably distinguish between chemicals that do, or do not, disrupt the thyroid hormone system. This lack of useful guidance risks unnecessary animal studies being carried out that do not serve to protect either humans or the environment.

Specifically, ECETOC is concerned that the EFSA and ECHA Guidance singles out individual parameters for the assessment of thyroid disruption.

Instead, a comprehensive assessment of a spectrum of parameters (including both thyroid histopathology and serum hormone levels) is necessary to identify if a chemical has the potential to disrupt the thyroid hormone system in humans. ECETOC is also concerned that the EFSA and ECHA Guidance does not appropriately address important biological differences between the rat and human thyroid hormone system or neurological development.

Together with Cefic and the European Crop Protection Association (ECPA), ECETOC commented on all stages of the development of the EFSA and ECHA Guidance on the identification of endocrine disruptors.

Shortly after the publication of the final Guidance, ECETOC, Cefic and ECPA jointly addressed the European Commission, welcoming the fact that the final Guidance was considerably improved on earlier draft versions, while highlighting a number of major concerns that remained, including those above relating to thyroid disruption.

Of the final Guidance, ECETOC, Cefic and ECPA jointly addressed the European Commission, welcoming the fact that the final Guidance was considerably improved on earlier draft versions, while highlighting a number of major concerns that remained, including those above relating to thyroid disruption.



Objective

Against this background, in Summer 2018, ECETOC convened a 'Special T4 Task Force'. The main objective of this Task Force is to overcome the scientific uncertainty triggered by the EFSA and ECHA Guidance with regard to the assessment of thyroid disruption.

The ECETOC Special Task Force T4 is engaged in the following activities:

1. Collate epidemiological evidence for how serum thyroid hormone changes lead to neurodevelopmental impairment in humans;
2. Establish how (a) rat thyroid histopathological findings and thyroid hormone changes; and (b) rat thyroid hormone changes and neurodevelopmental changes are correlated;
3. Identify and compare the specific steps of the pathways that lead to thyroid disruption in humans and rodents.

For each of these topics, the ECETOC Special T4 Task Force is considering the current understanding of endocrine biology and ongoing related research work.

The outcome of the Task Force's work, which will be published as an ECETOC Report, will contribute to the establishment of specific guidance that will reliably predict whether a chemical has the potential to disrupt the thyroid hormone system in humans.

Persistent chemicals and water resources protection: Improving knowledge on environmental and intrinsic factors which may influence transport to and contamination of groundwater



Background

There have been several recent initiatives to identify substances of concern to drinking water, for example the recent proposals on identifying Persistent/very Persistent, Mobile/very Mobile and Toxic (PMT/vPvM) substances. ECETOC established that it had a role in supporting the development of a science-based framework to assess potential concerns for drinking water resources.



Objective

The objective of the Task Force is to improve exposure assessment methods through a greater understanding of the factors influencing the transport of substances to groundwater, such as the mobility in soil.

The Task Force will critically evaluate the EU's currently proposed PMT/vPvM criteria and assess the appropriateness of the proposed PMT hazard-based approach versus a risk assessment and suitable risk management to guarantee long-term sustainable protection of water sources. The Task Force is anticipated to complete its work in 12 months and the outcome will be published as an ECETOC Report and/or published article.

Human Exposure Task Force



Background

In 2014 the ECETOC Human Exposure data Task Force was initiated with an initial focus on aggregate consumer exposure. The main outputs from this Task Force were the Human Exposure Assessment Tools Database (ECETOC heatDB – see under Risk Assessment tools) and the Guidance for Effective Use of Human Exposure Data in Risk Assessment of Chemicals (ECETOC TR 126).

Delegates at the 2018 Human Health Scoping meeting gave broad support to the development of a strategic visionary programme for exposure science. They welcomed the 'Innovation in fit for purpose human exposure assessment' proposal and recommended that the ECETOC Scientific Committee asked the Human Exposure data TF to map out this proposal and prioritise the work that was needed.



Objective

The Task Force was reinstated in May 2018, with the aim of agreeing priority needs for exposure science to address, to define the activities needed to meet those needs (project proposals, workshops) and to identify opportunities from other programs (exposome, human biomonitoring) as well as for collaboration (i.e. with ISES Europe).

Exposure-based waiving Task Force



Background

Within the REACH legal text there are two ways to adapt the standard testing requirements: column 2 of annexes VII to X, and Annex XI. Annex XI contains three potential options – testing not possible or justified due to the properties of the substance or existing weight of evidence; use of read across; exposure-based waiving. Of these, the exposure-based waiving is the least used and successful (based on analysis of compliance check decisions). Of all the possible adaptations, the use of exposure-based waiving is the only option that allows researchers to waive all higher tier mammalian toxicity studies (Annex IX and X) (all other adaptations require some form of higher tier experimental data on the substance or an analogue). However, the wording of annex XI, part 3 makes it almost impossible to meet successfully the criteria for using exposure-based waiving. This essentially removes the possibility to make use of it to reduce animal testing for potentially low exposure substances such as non-SCC intermediates, monomers, and other low exposure potential substances that are >100 or >1000t per annum. This is in stark contrast to environmental endpoints under REACH, and human health testing requirements e.g. for food contact materials and cosmetic ingredients, where testing is triggered based on exposure considerations.



Objective

The objective of the Task Force, expected to last 18 months, is to develop a science-based decision and documentation framework for exposure-based waiving of human health endpoints for chemicals. This can demonstrate proactively what would constitute science-based decision-making, valuing animal lives and efficient regulation:

1. Identify what is already in place regarding exposure-based testing/waiving (primary focus EU, other regions for comparison) in REACH and other regulation, e.g. food contact. Leverage the various ECETOC and CEFIC LRI projects that study human and environmental exposure and exposure modelling tools to determine how best to build the exposure side of an argument for supporting exposure-based waiving.
2. Assess the current barriers to acceptance of the exposure-based waiving approach for human health aspects of chemicals.
3. Assess the exposure capabilities required to support exposure-based testing/waiving
4. Develop a consensus of how 'fit-for-purpose' health-based guidance values (e.g. DNELs) can be derived for respective use types and exposure levels (what hazard data are crucial, what assessment factors would apply in which cases – e.g. is a 28d study sufficient for safety assessment).
5. Develop a consensus on what is needed from the risk assessment – e.g. RCR <1 or RCR <<<1? (e.g. current REACH text states 'exposures are well below the DNEL').
6. Discuss uncertainties and requirements for documentation
7. Derive a framework with case examples for publication and a workshop

EXPERT WORKING GROUPS ESTABLISHED



ECETOC Coordination of Industry Contribution to the ECHA EUSES Update Project

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

Johannes Tolls (Henkel) and then Diederik Schowanek (Procter & Gamble) were the ECETOC representatives on ECHA's Workshop Organising Group and interacted with the ECETOC Expert Group to support the input of the industry representatives.

The ECHA Workshop on EUSES update needs took place in Brussels in June 2018 and featured a presentation from Diederik Schowanek: 'ECETOC Modelling Workshop 2017: Outcome & Reflections on EUSES'.

The ECETOC Expert Group remained active after the June 2018 workshop, under the umbrella of the ECETOC TRA Task Force, to discuss with the ECHA Workshop Organising Group the workshop outcomes and next steps.

Since the workshop, ECHA has established 'Topic Expert Groups (TEGs)', comprising small groups of experts from ECHA, industry, academics and Member State Competent Authorities.

Initially, the TEGs will exchange views and agree on requirements to be shared with IT consultants during the feasibility pre-study being carried out by ECHA until May 2019.

Further input may be required in the next phase of the project, e.g. EUSES v3 and the update of the related guidance.

ECETOC's current role is to coordinate the industry contribution to the EUSES update project. This is being done by industry delegates to the Topic Expert Groups, who are in coordination with a wider industry stakeholder group.

WORKSHOPS AND SYMPOSIA

Expert Meeting on Advancing the Science of Bioaccumulation Assessment

29 January 2018, Brussels

ECETOC organised this Expert Meeting just prior to the annual Environment Scoping and Progress Review meeting.

The Expert Meeting had two main objectives:

1. Discuss and review the ongoing initiatives, research projects and regulatory activities relating to the science of bioaccumulation assessment of chemicals;
2. Identify gaps in this area of science and potential key topics that still need further development.

20 experts from industry, academia and regulatory stakeholders participated in the meeting. The morning session of the meeting comprised the following presentations:

- ▶ **Mark Bonnell** (ECC): Application of Bioaccumulation Data and Needs for Prioritization and Assessment Under CEPA;
- ▶ **Todd Gouin** (TG Environmental Research): Recent and current Cefic LRI/ECETOC projects;
- ▶ **Tim Springer** (EAG): OECD Test guideline 305: Advances in calculation of BCF estimates, complications, and unresolved issues;
- ▶ **Hank Krueger** (EAG): In vivo BCF and BMF testing;
- ▶ **Leon Van Der Wal** (OECD): Relevant OECD activities;
- ▶ **Kent Woodburn** (Dow Corning) & Nathalie Vallotton (Dow): Development ECHA guidance on Bioaccumulation assessment ECETOC's 2016 R.11 guidance update working group;
- ▶ **James Franklin** (Independent Scientist): A more holistic approach to mobility – Taking into account its relationship to B and P.

In the afternoon, there was a brainstorm session to identify gaps in the science/knowledge and possible areas of research and opportunities to develop the science. The following topics were considered:

Developments in ecotoxicity and bioaccumulation test methods /metrics; How to take advantage of toxicology knowledge, e.g. toxicokinetics; Bioaccumulation modelling; Risk assessment approaches in relation to bioaccumulation potential; and Benefits of latest techniques such as genomics.

Ideas from the brainstorming session were taken forward as proposals to the Environment Scoping and Progress Review meeting.

2018 ECETOC and Cefic LRI Environment Scoping and Progress Review Meeting

30-31 January 2018, Brussels

ECETOC and Cefic LRI convened the Environment Progress Review and Scoping Meeting 2018 in Brussels, attended by approximately 50 invited participants from Europe and North America representing ECETOC and Cefic member companies, consultancies, academia, regulators and authorities.

The meeting had three aims:

1. To inform attendees of the progress on relevant ECETOC and Cefic LRI actions since the 2017 Environment Progress Review and Scoping Meeting;
2. To review specific activities and progress in two focus themes: Hazard assessment of persistent, bioaccumulative and toxic (PBT) substances; Microplastics in the environment.
3. To share and prioritise proposals for ECETOC action (e.g. task forces (TFs) or workshops) and/or Cefic LRI research projects that would contribute to improving the environmental hazard and risk assessment of chemicals and chemical products.

After a summary of ECETOC and Cefic LRI environmental activities over the past year, two presentation sessions reviewed the status of activities in the two focus themes and identified knowledge gaps and the need for action.

Session I:

Hazard assessment of PBT substances featured the following presentations:

- ▶ **Björn Hidding** (BASF SE, DE): PBT context and introduction to Session I - Current status in a nutshell;
- ▶ **Johanna Peltola-Thies** (European Chemicals Agency (ECHA), FI; dial-in presentation): Update and perspectives from the ECHA;

- ▶ **Michelle Embry** (Health and Environmental Sciences Institute (HESI), USA): Toxicokinetics and new developments for in vitro bioaccumulation;
- ▶ **Björn Hidding**: Introduction to the Persistent, Mobile, Toxic (PMT) concept;
- ▶ **Andreas Schäffer** (RWTH Aachen University, DE): Characterisation of non-extractable residues (NERs) of chemicals in the environment.

These presentations were followed by a PBT brainstorming session resulting in the proposal of new topics for further consideration by ECETOC and / or Cefic LRI.

Key issues that were highlighted during the discussions included the need to establish benchmark substances to improve PBT hazard and risk assessment – and to design and conduct case studies to show how such benchmark substances could be used in practice.

Session 2:

Microplastics in the environment encompassed the following presentations:

- ▶ **Gordon Sanders** (Givaudan, CH): Introduction to Session 2 – Summary of ECETOC/LRI activity to date;
- ▶ **Valentina Bertato** (EU Commission, General Directorate Environment): Regulatory perspectives on microplastics in the environment;
- ▶ **Albert Koelmans** (Wageningen University, NL): Towards risk assessment of plastic debris.

During the subsequent plenary discussion on microplastics and the environment, the need to define ‘microplastics’, also as compared to ‘nanomaterials’, was highlighted as fundamental for all science and policy actions.

The EU Commission had taken the lead in initiating action related to microplastics, expecting that international activities, e.g., by the World Health Organisation, would follow. ECETOC, Cefic LRI, and individual member companies should seek opportunities for dialogue with, e.g., the ECHA.

On Day 2, four breakout groups discussed 40 actionable topics that had been suggested by ECETOC / Cefic member companies and other interested parties ahead of the meeting. The Organising Committee of the meeting had assigned these actionable topics to one of four main topics:

1. Ecotoxicology: 12 proposals;
2. Environmental Fate and Behaviour: 9 proposals;
3. Exposure and Risk Assessment: 11 proposals;
4. Risk Management / Man via Environment: 8 proposals.

Each breakout group addressed one of these main topics and discussed, refined and sometimes combined the proposals, also taking into account the knowledge gaps and research opportunities identified during the Day 1 discussions.

The breakout group discussions were summarised by the rapporteurs in a final plenary session and a vote took place to prioritise actionable topics for recommendation as potential ECETOC activities and/or Cefic LRI research projects.

2018 ECETOC and Cefic LRI Human Health Progress Review and Scoping Meeting

1-2 February 2018, Brussels

The ECETOC and Cefic LRI Human Health Progress Review and Scoping Meeting was attended by approximately 50 invited participants from Europe and North America representing ECETOC member companies, consultancies, academia, regulators or authorities.

The meeting had three aims:

1. Inform attendees of the regulatory community perspectives on knowledge gaps, policy priorities and research needs in the human health science area and on potentially relevant industry input;
2. Inform attendees of progress on relevant ECETOC and Cefic LRI actions that resulted from the prior Human Health Progress Review and Scoping Meeting 2016;
3. Share and prioritise proposals for ECETOC action (e.g., task forces (TFs) and workshops) and/or Cefic LRI research projects that would contribute to improving the human health hazard and risk assessment of chemicals and chemical products. The attendees were also invited to engage in visionary thinking to draw up a new ECETOC Transformational Programme (TP).

Whereas ECETOC TFs and Cefic LRI research projects involve targeted cross-sectoral and multi-disciplinary expert action and generally extend across 12 to 18 months, ECETOC TPs address horizontal themes of longer-term scientific relevance and aim at producing transformational change in chemicals management.

They are to be completed over 3-5 years and can be supported by Cefic LRI research projects.

During a Panel Discussion on Regulatory Perspectives, three panellists presented their views on gaps, priorities and needs in the human health science area and potentially relevant industry activities:

- ▶ **Tewes Tralau** (German Federal Institute for Risk Assessment (BfR), DE);
- ▶ **Jacqueline Van Engelen** (National Institute for Public Health and the Environment (RIVM), NL);
- ▶ **Maurice Whelan** (EU Commission, General Directorate Joint Research Centre (JRC), IT).

The panellists highlighted exposure assessment as a key challenge to streamline regulatory testing needs.

New Approach Methodologies (NAMs; e.g., in vitro methods, in silico modelling and omics technologies) provided opportunities to improve human health hazard assessment and reduce animal testing needs. However, it was pivotal to build trust in these new methodologies.

Next, a Review Session comprised the following presentations:

- ▶ **John Doe** (Parker Doe LLP, UK): ECETOC Endocrine Disruption TF: How the European Commission framework can work in practice;
- ▶ **Ben Van Ravenzwaay** (BASF SE, DE): Cefic LRI project: EMSG 56 Combined low-dose exposures to anti-androgenic substances;
- ▶ **Mark Pemberton** (Systox Ltd., UK): ECETOC TP: Applying 'omics technologies in chemicals risk assessment; work stream 1: Quantitative weight-of-evidence;
- ▶ **Hans-Martin Kauffmann** (BASF SE, DE): ECETOC TP: Applying 'omics technologies in chemicals risk assessment; work stream 2: Good Laboratory Practice (GLP);
- ▶ **Timothy Gant** (Public Health England, UK): ECETOC TP: Applying 'omics technologies in chemicals risk assessment; work stream 3: Making sense of the data;
- ▶ **Ursula G. Sauer** (Scientific Consultancy – Animal Welfare, DE): ECETOC TP: Applying 'omics technologies in chemicals risk assessment: Wrap up;
- ▶ **Rosemary Zaleski** (Exxonmobil, USA): ECETOC's Targeted Risk Assessment (TRA) Tool: An update;
- ▶ **Robert Landsiedel** (BASF SE, DE): Concepts for grouping nanomaterials in Europe;
- ▶ **John O'brien** (Crème Global, IE): Human Health Exposure Data TF: Online Exposure Tool.

The overall discussions on current key issues showed how closely science was interlinked with policy initiatives, and that good policy should be based on sound science. Therefore, it was pivotal to involve all relevant stakeholders at all stages of the ECETOC or Cefic LRI actions.

On Day 2, three breakout groups were formed to discuss the 51 actionable topics that had been suggested by ECETOC member companies and other interested parties ahead of the meeting.

The Organising Committee of the meeting had assigned each actionable topic to one of three main topics and had further grouped them by common overarching theme, if applicable:

1. Adversity: 15 proposals;
2. Exposure: 18 proposals;
3. Innovative Chemical Testing: 18 proposals.

The breakout group discussions further took into account the knowledge gaps and research opportunities identified during the Day 1 discussions to propose further actionable topics, if considered relevant.

Thus, a proposal for a new TP was drawn up, two new proposals related to Exposure, and one each related to Adversity and Innovative Chemicals Testing.

The breakout group discussions were rounded up in a final plenary session where voting took place to prioritise actionable topics for recommendation as potential ECETOC actions and/or Cefic LRI research projects.

40TH ANNIVERSARY EVENT

21 March 2018, Brussels

Almost 80 guests attended an event at the Bibliothèque Solvay in Brussels celebrating the 40th Anniversary of the founding of the ECETOC. For the past four decades, ECETOC has been a champion of scientific excellence and science-based decision-making in Europe and has provided a forum for top scientists from academia, government and industry to work together to develop and promote practical and realistic science-based solutions.

In the opening address, ECETOC Secretary General Olivier de Matos welcomed the guests and then outlined ECETOC's new strategy to guide the organisation in the years ahead.

The first keynote speaker of the day was Geert Dancet, former Executive Director of ECHA, who praised ECETOC's contribution to chemicals legislation over the past four decades, in particular its scientific contributions relevant to the development and implementation of REACH.

After lunch, there were two lively panel discussions, moderated by Madeleine Laffont (Business4Good, BE). The first consisted of Jim Bridges (University of Surrey, UK), ECETOC Scientific Committee Chair Ben van Ravenzwaay (BASF) and former ECETOC Secretary Generals Neil Carmichael and Mike Gribble, who debated whether "we can draw lessons from the past, but we can't live in it" (a quote from Lyndon B. Johnson).



from left to right:
Ben van Ravenzwaay (BASF), Mike Gribble (former ECETOC), Neil Carmichael (former ECETOC)
and Jim Bridges (UNIVERSITY OF SURREY, UK)

This was followed by a second debate on whether “if you don’t know where you are going, any road will get you there” (from Lewis Carroll). This second panel featured Melanie Bausen (BASF), Rabea Graepel (Leiden University), Thomas Hartung (John Hopkins University) and Tina Mehta (Dow AgroSciences).

Ben van Ravenzwaay, Scientific Committee Chair, then drew together the main conclusions of the day. He said that both evolving technology and big data are contributing to “opening

the black boxes that we had” in terms of understanding scientific processes and biological mechanisms, which will in turn enable better and safer new chemicals to be developed.

He added that, it was clear from the discussions during the day, that ECETOC has a bright future ahead, but the big challenge would be to ensure that ECETOC maintains the trust of all its stakeholders and continues to demonstrate that it is unbiased by being completely transparent.



from left to right:

Tina Mehta (DOW AGROSCIENCES), Thomas Hartung (JOHN HOPKINS UNIVERSITY), Rabea Graepel (LEIDEN UNIVERSITY) and Melanie Bausen (BASF)



The final keynote speech was delivered by the renowned scientist and broadcaster Dr. Maggie Aderin-Pocock, often referred to as the BBC’s ‘face of space’, who told delegates that the key to expanding the frontiers of future science is ‘gender diversity’ and inspiring the young-generation.

Dr Aderin-Pocock said: “We need to find ways to inspire the next generation to be passionate about science, especially young girls, through positive role models and by communicating the ‘worlds of wonder’ that science reveals. ‘Using her life experience as an example of how to encourage more girls to get involved in science, she said.’ The biggest thing that we have working in our favour is that sense of wonder.”

A full report on the 40th anniversary event is available as a special issue ECETOC e-newsletter at:

www.ecetoc.org/wp-content/uploads/2018/07/ECETOC_e-newsletter_34_Summer_2018.pdf

Dr. Aderin-Pocock

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. Three Transformational Programmes are ongoing and one new programme has been developed.

Using Molecular Data Wisely

ECETOC's first Transformational Programme "Applying omics technologies in chemicals risk assessment" was initiated by the 2014 Human Health Scoping & Review Meeting. It 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.

Introducing Environmental Relevance into Environmental Risk Assessment

This Transformation Programme was developed in 2015 to address the complexity and variability in Risk Assessment by improving ecological relevance to enable better risk mitigation and risk management.

The programme comprises three key elements:

1. Assessing the effects of chemicals in ecological communities
2. Exposure science for higher tier risk assessment
3. Ecosystem service-based approaches for landscape scale risk assessment and risk management

ECETOC Targeted Risk Assessment Tool

Since the introduction of the TRA in 2004, many thousands of users have downloaded the tool and its supporting technical guidance from the ECETOC website. In addition to the guidance contained in the tool's User Guide, ECETOC has supported the TRA via a help facility and has described its technical basis in ECETOC Technical Reports TR93 (2004), TR107 (2009), TR114 (2012) and TR124 (2014).

Since 2010, the worker and consumer modules of the TRA have been used as the basis for estimating human exposures to chemicals within ECHA's Chemical Safety Assessment (CSA) tool.

ECETOC Technical Report no.131: Targeted Risk Assessment: Further Explanation of the Technical Basis of the TRA v3.1 was published in February 2018 and can be downloaded from <https://goo.gl/D56cyh>

It addresses many of the technical questions that either ECETOC or ECHA have received since 2014 and for which further clarification was thought to be needed or useful.

Human Health and Exposure Transformational Programme



Background

This new Transformational Programme emerged during the Human Health Scoping meeting which took place in February 2018. Concerns were raised regarding the limitations and constraints of the current regulatory framework.

Chemicals have many uses which benefit society. A regulatory system has evolved over the last 50 years to allow the use of chemicals to benefit society without causing harm to people. The regulatory system does not currently allow new approach methodology to be used in the assessment of toxicity. ECETOC believes that much of the technology which is required to provide a 21st century regulatory system for chemicals (including pesticides and biocides) already exists, but it requires a revised framework to be developed.



Objective

A small team from the ECETOC Scientific Committee has been set up to work on drafting a concept that will first present and analyse our current system for assessing hazard, exposure and the current rules for classification and risk characterisation.

It will then develop a series of proposals (or actions that could be addressed) to increase the efficiency of the process, allowing more chemicals and uses to be assessed and allowing aggregate and cumulative exposure assessments to be made.

RISK ASSESSMENT TOOLS

Significant updates to ECETOC's Human Exposure Assessment Tools Database

Significant new data and tools have been added to ECETOC's Human Exposure Assessment Tools Database (heatDB) following a recent update.

heatDB gathers together all publicly available sources of human exposure data, as well as assessment tools, then structures and categorises them into a harmonised system.

Available on the ECETOC website, it enables risk assessors to review quickly what data sources and tools are available for any given purpose and then provides guidance on their appropriate use using a tiering system.

heatDB covers biomonitoring, cosmetics and personal care, foods, generic human exposure factors, household products and other consumer products.

As part of the latest update, a comprehensive web search – using the search engine PubMed, provided by the National Center for Biotechnology Information (NCBI) – looked at all existing literature, databases and projects on human exposure.

Multiple expert teams then collectively reviewed each new data source and tool in each of the product categories for content, relevance and overall quality.

The review found 63 new data sources and seven new tools which have now been added to heatDB. In addition, 10 existing data sources and 1 tool were delisted from heatDB, either because of outdated hyperlinks, duplication, or if an updated version of the data source was available.

Overall, heatDB was increased from 182 to 235 data sources and from 41 to 47 tools.

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, HC5). The software improves on existing approaches (Aldenberg & Jaworska, 2000).

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

The Hierarchical SSD (hSSD) software tool is hosted by Durham University and can be downloaded at:

www.maths.dur.ac.uk/~dma0psc/ecorisk/PDxGrwJMBc6AacPv34huMQr5rZ8/



COMMUNICATING THE SCIENCE



Publication

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 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. (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.

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

As part of ECETOC's drive for efficiency and environmental care, all our publications are now distributed exclusively in electronic format and can be freely downloaded from www.ecetoc.org/publications



Reports Published by ECETOC during 2018

TRI31: Targeted Risk Assessment: Further Explanation of the Technical Basis of the TRA v3.1

Published February 2018

ISSN-2079-1526-131 (online)

D-2018-3001-252

WR 35 Advances in (environmental) exposure modelling: Bridging the gap between research and application. 4-5 May 2017, Brussels

4-5 May 2017, Brussels

Published March 2018

ISSN-2078-7219-35 (online)

D-2018-3001-253

TRI32: An evaluation of the challenges and limitations associated with aquatic toxicity and bioaccumulation studies for sparingly soluble and manufactured particulate substances

Published December 2018

ISSN-2079-1526-132 (online)

D-2018-3001-254

Articles Published in the Open Scientific Literature during 2018

Skin and respiratory chemical allergy: confluence and divergence in a hybrid adverse outcome pathway

Kimber I, Poole A, Basketter D. 2018

Toxicol Res 7:586-605

Doi 10.1039/C7TX00272F

CONTRIBUTING TO INTERNATIONAL INITIATIVES

Representation, Presentations and Posters at Specific Meetings in 2018

10 January

European Risk Forum Lunchtime Discussion with Jim Romine, Head, Research Institute for Fragrance Materials (RIFM) and with Laure Alexandre, Director, SpiritsEUROPE, on Is there a role for self-regulation in regulatory risk management; Brussels (Olivier de Matos)

20 February

UNEP Meeting; Paris (Olivier de Matos)

7 March

ECHA Biocidal Products Committee; Helsinki (Olivier de Matos)

10 April

Nanotechnology Industries Association (NIA) Symposium; Brussels (Olivier de Matos)

5 June

ESAP Meeting (Olivier de Matos)

27 September

Cefic-LRI and Concawe Workshop on Recent Developments in Science Supportive to the Persistence and Biodegradation Assessment; Helsinki (Lucy Wilmot)

12 October

Meeting with ECHA; Helsinki (Olivier de Matos and Bennard van Ravenzwaay)

14-15 November

20th Annual Cefic-LRI Workshop: "20 Years of LRI Advancing Risk Assessment"; Brussels (Olivier de Matos, Alice Brousse and Lucy Wilmot)

5 December

A.I.S.E. Cleaning & Hygiene Forum; Brussels (Olivier de Matos)

1 February

RAC Meeting; Helsinki (Olivier de Matos)

21 February

The use of toxicokinetic data for assessing bioaccumulation; Leipzig (Lucy Wilmot)

9 March

ECHA EUON Conference; Brussels (Olivier de Matos)

3-17 May

SETAC Europe 28th Annual Meeting 'Responsible and Innovative Research for Environmental Quality'; Rome (Lucy Wilmot)

2-5 September

54th Congress of the European Societies of Toxicology (Eurotox) and Christa Hennes Award; Brussels (Olivier de Matos and Alice Brousse)

28 September

Human Biomonitoring in Europe - science and policy for health citizens; Vienna (Alice Brousse)

23-24 October

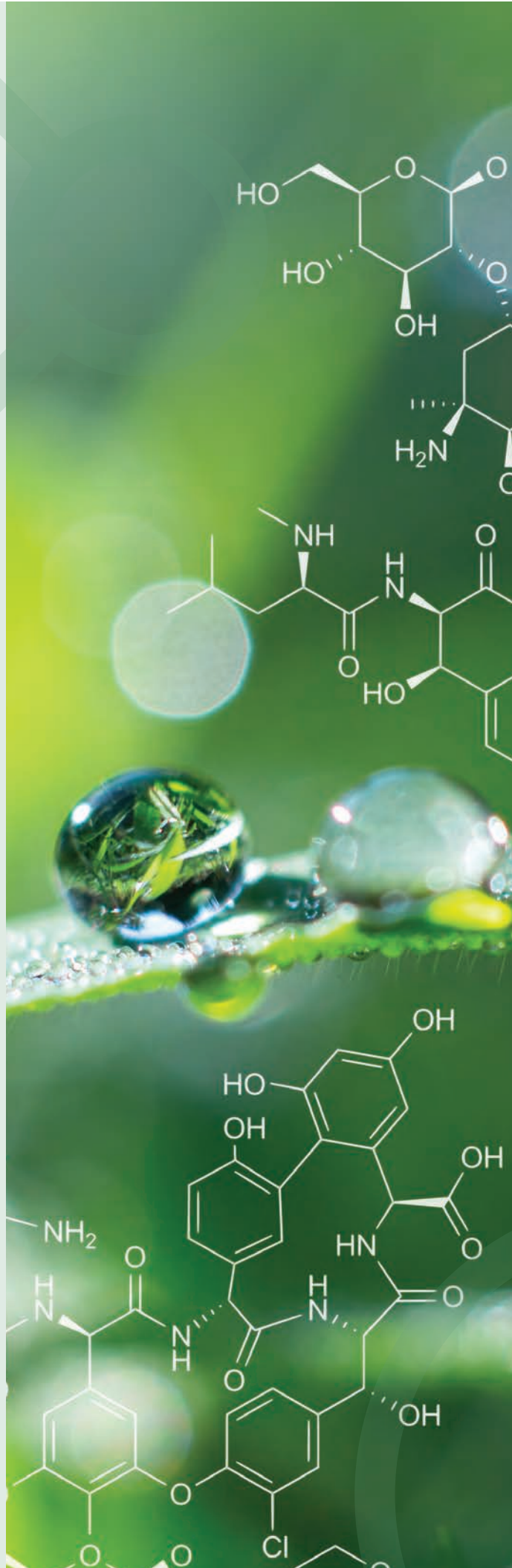
SETAC Europe 13th Special Science Symposium: Extrapolation of Effects Across Biological Levels: Challenges to Implement Scientific Approaches in Regulation; Brussels (Lucy Wilmot)

20-21 November

9th International Fresenius Conference Endocrine Disruptors; Cologne (Alice Brousse)

10-14 December

ECHA MSC Meeting (Olivier de Matos)



Input to specific projects and reports

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

Participation on behalf of ECETOC by Sylvia Jacobi (Albemarle)

ECHA Risk Assessment Committee (RAC)

Participation as an observer on behalf of ECETOC by Olivier de Matos (ECETOC)

ECVAM Stakeholder Forum (ESTAF)

Participation on behalf of ECETOC by Remi Bars (Bayer)

Endocrine Disruptor 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 Disruptors Testing and Assessment (EDTA) Advisory Group

Participation on behalf of ECETOC by Remi Bars (Bayer)

SCIENCE AWARDS

Since 2003, ECETOC has been recognising talented young scientists by sponsoring annual Science Awards to outstanding works of science. ECETOC sponsored the following awards during 2018:

Environmental science related award 13-17 May 2018, Rome

The ECETOC Best Platform Award honours the early career scientist with the best platform presentation at the SETAC Europe Annual Meeting.



At SETAC 2018 in Rome, the award went to **Michael Bertram** of Monash University, Australia, for his presentation on ‘**Exposure to the widespread androgenic steroid 17 β -trenbolone alters behaviour in fish**’.

More information on the SETAC meeting can be found at <https://rome.setac.org/>

Human health science related award Eurotox 2018: ECETOC Christa Hennes Young Scientist Award 2-5 September 2018, Brussels

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.



The 2018 ECETOC Christa Hennes Early Career Award was presented at EUROTOX in Brussels to **Dr. Wael Naboulsi**, from Signatope GmbH in Reutlingen, Germany, for “**Abstract P23-19: A classical and an immunoaffinity-proteomic study to identify and validate drug-induced kidney injury biomarker in canine**”.

More information on the Eurotox 2018 meeting can be found at www.eurotox-congress.com/2018/

CONTRIBUTION to CEFIC

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

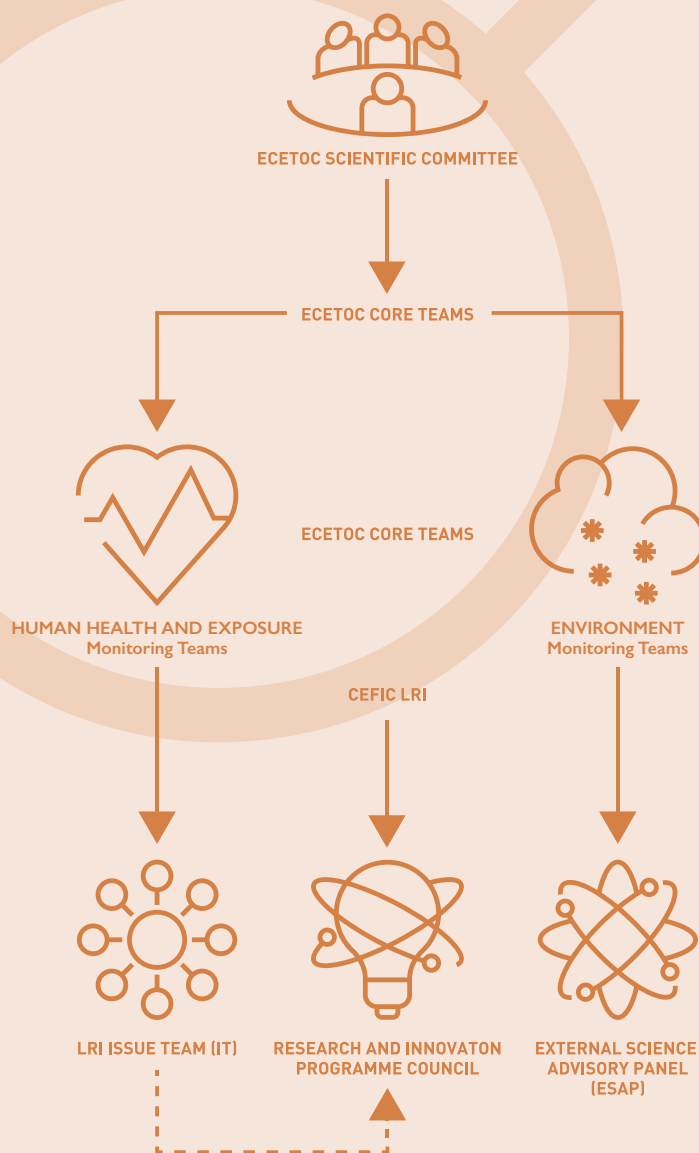
As a fundamental basis for a sustainable chemical industry and a complement to Responsible Care, LRI presents a Research Programme that is forward-looking and ambitious, but also realistic and coherent.

LRI invests in long-term research and delivers transparent, quality-assured scientific data, open to Cefic members.

As the scientific partner to Cefic LRI, ECETOC provides scientific support to the LRI programme by managing the evaluation of applications for funding, recommending the best research proposals and monitoring the progress of selected LRI projects.

In particular ECETOC is responsible for:

- ▶ Development of topics for research, either based on recommendations from completed Task Forces/Expert Groups or ideas originating from the annual ECETOC/Cefic LRI scoping meetings, 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.
- ▶ Establishment and coordination of Selection Teams comprising industry and external experts, to identify the best research proposals in response to published RfPs and making recommendations to LRI IT concerning the funding of the proposals.
- ▶ Establishment and coordination of Monitoring Teams, comprising industry and external experts, that monitor the progress of the project against the agreed objectives, and act as a discussion partner throughout the project.



ECETOC

Review & Scoping meetings

RfP drafting

Selection pannels

Monitoring

JCIA
LRI

ACC
LRI

CEFI LRI

Project definition

Funding

Dissemination

Cefic LRI
External
Scientific
Advisory
Panel

Human Health and Exposure Monitoring and Selection activities 2018

The following Cefic LRI projects were active or initiated during 2018, with the support of the Monitoring Teams and Selection Teams.

Two projects were completed (marked below with #). Three new projects and three extensions secured funding and were initiated with the support of the monitoring teams (marked below with *).

AIMT 5.2*:

A computational model for neural tube closure, based on the dedicated developmental ontology constructed in the LRI AIMT-5 project, for in silico predictive toxicology of neural tube defects [Extension to AIMT 5]. 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 12.3*:

Extension for CEFIC Project B12-ETHZ DustEx – Assessing the relevance of the dust contribution in consumer exposure to substances from consumer products and articles (DustEx) Principal investigator: Dr. Natalie Von Götz, ETH Zurich, Switzerland

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 18.2*:

Carcinogen Dose-Response Database for Threshold of Toxicological Concern (CDRD-TTC) [Extension to B 18]. Prof. Mark Cronin, Liverpool John Moores University, UK

B 19#:

Extrapolating the Applicability of Worker Exposure Measurement Data (Completed June 2018). Principal investigator: Dr. Wouter Fransman, TNO, The Netherlands

B 20:

Experimental assessment of inhalation and dermal exposure to chemicals during industrial and professional activities. Principal investigator: Dr. Wouter Fransman, TNO, The Netherlands

B 21*:

In Vitro Data to Parameterise PBPK Models for Inhalation Exposure. Rfp advertised in 2018. Selection Team meeting held 16 October 2018. Principal investigator: Dr. Katarina Schwartz, Fraunhofer ITEM, Germany

C 4:

Transcriptomics bioinformatics best practices in toxicogenomics for regulatory application. Principal investigator: Dr. Florian Caiment, Maastricht University, The Netherlands

C 5:

XomeTox - evaluating multi-omics integration for assessing rodent thyroid toxicity. Principal investigator: Dr. Jörg Hackermüller, Helmholtz Centre for Environmental Research (UFZ), Germany

C 6:

Toxicogenomic Approaches to Support Read-Across. Principal investigator: Dr. George Daston, P&G, OH, USA

C 7*:

The metabolic capacity of the intestinal microbiome. Rfp advertised in 2018. Selection Team meeting held 17 October 2018. Principal investigator: Dr. Saskia Sperber, BASF, Germany

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

EMSG 59*:

Species comparison in liver-mediated thyroid and thyroid-related toxicities Part I: Characterization of liver-mediated thyroid toxicity in the rat. Rfp advertised in 2018. Selection Team meeting held 15 October 2018. Principal investigator: Aldert Piersma, RIVM, Netherlands

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 Monitoring and Selection activities 2018

The following Cefic LRI projects were active or initiated during 2018, with the support of the Monitoring Teams and Selection Teams.

Nine projects were completed (marked below with #), and four new projects and one project extension secured funding (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] (Completed December 2018). 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 (Completed April 2018). 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 (Completed November 2018). Principal investigator: Dr. Joop Harmsen, Alterra Wageningen UR, The Netherlands

ECO 28#:

Modelling approaches for a scenario-based assessment of chemically induced impacts on aquatic macroinvertebrate communities (MACROMOD) (Completed December 2018). 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 31.2:

Identifying strategies that will provide greater confidence in estimating the degradation rates of organic chemicals in water, soil, and sediment [Extension to ECO 31]. 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 (Completed October 2018). 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 (Completed October 2018)

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 (Completed November 2018). 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 (Completed February 2018). Principal investigator: Dr. Roman Ashauer, York University, United Kingdom

ECO 39.2*:

Development of user-friendly, robust GUTS software [Extension to ECO 39]. Principal investigator: Dr. Roman Ashauer (Syngenta from January 2019), 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 (Completed December 2018). 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. Principal investigator: Prof. Frank Wania, University of Toronto, Canada

ECO 42:

UVCB fate-directed toxicity testing and risk assessment (UVCB-FATETOX). 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. Principal investigator: Dr. Michiel Jonker, IRAS, Utrecht University, The Netherlands

ECO 44:

Integrating Bioaccumulation Assessment Tools for Mammals (iBAT-Mam). Principal investigator: Dr. Jon Arnot, ARC Arnot Research & Consulting Inc., Canada

ECO 45:

Chemicals: Assessment of Risks to Ecosystem Services (CARES) II. Principal investigator: Prof. Lorraine Maltby, University of Sheffield, United Kingdom

ECO 46:

Improved aquatic Testing and Assessment of cationic Polymers (iTAP). Principal investigator: Dr. Hans Sanderson, Aarhus University, Denmark

ECO 47*:

Improving IVIVE extrapolation models to predict bioconcentration using in vitro biotransformation rates for bioaccumulation assessment in fish. RfP advertised in 2018. First Selection Team Meeting held 26 October 2018; Second Selection Team Meeting taking place 27 February 2019. Principal investigator: To be confirmed

ECO 48*:

Develop Fate and Transport Model for Microplastics in the Aquatic Environment RfP advertised in 2018. Selection Team Meeting held 17 October 2018. Principal investigator: Prof. Matthew MacLeod, Stockholm University, Sweden

ECO 49*:

Evaluate factors that determine the environmental hazards of microplastics RfP advertised in 2018. Selection Team Meeting held 19 October 2018. Principal investigator: Prof. Albert Koelmans, Wageningen University, The Netherlands

ECO 50*:

Getting Real: Assessing spatial and temporal variability in species assemblages and potential implications for chemical risk assessments. RfP advertised in 2018. Selection Team Meeting held 15 October 2018. Principal investigator: Prof. Ralf Schäfer, University of Koblenz-Landau, Germany



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 2018, the Scientific Committee consisted of the following members:

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RÉMI BARS
Bayer CropScience

PETER BOOGAARD
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ExxonMobil Biomedical Sciences Inc.

External Expert

MEMBERS of the SECRETARIAT

THE ECETOC SECRETARIAT is responsible for co-ordinating and managing the scientific work programme.

The team supports the scientists working on the ECETOC programme in meeting the objectives set by the Scientific Committee.

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Communications, Web and Media Manager

FRANCESCA UGUCCIONI

Administrative Assistant

LISA WINGATE

Administrative Assistant

FINANCE

INCOME ACTUAL 2018 IN EURO

Subscription	
Full Members	1.000.500
Associate Members	60.000
Total Subscription Income	1.060.500
Bank Interest	738
Investment income	0
Project-related	266.749
Exceptional income	0
Total	1.327.987

EXPENDITURE ACTUAL 2018 IN EURO

Salaries and Associated Costs	583.971
Office Running Expenses	197.272
Travel Expenses	4.129
External Contractors	220.744
Board, Committees and Annual General Meeting	58.186
Task Forces	91.781
Workshops	90.150
Sponsorships and Awards	4.500
Publications, Communications and Website	50.221
Professional Services	50.292
Bank Charges	2.478
Capital Expenditure	10.137
Miscellaneous and Contingency	29.437
Total	1.393.298

BALANCE SHEET AND RESERVES ACTUAL 2018 IN EURO

Balance Sheet	
Income	1.327.987
Expenditure	1.393.298
Operating Margin	-65.311
Reserves*	
Opening	1.968.147
Operating Margin	-65.311
Closing Reserves	1.902.836

*Estimated Reserve Required: 234.000

ABBREVIATIONS

ACC – American Chemistry Council

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

ED EAG – Endocrine Disrupter Expert Advisory Group to the EU Commission

EDTA – (OECD) Endocrine Disrupters Testing and Assessment Advisory Group

EFSA – European Food Safety Authority

ESAP – External Science Advisory Panel

ESTAF – ECVAM Stakeholder Forum

EU – European Union

EUROTOX – Association of European Toxicologists and European Societies of Toxicology

FDA – (US) Food and Drug Administration

GLP – Good Laboratory Practice

heatDB – ECETOC Human Exposure Assessment Tools Database

IPCS – International Programme on Chemical Safety

IR&CSA – (ECHA Guidance on) Information Requirements and Chemical Safety Assessment)

JACC – Joint assessment of commodity chemicals

JCIA – Japan Chemical Industry Association

JRC – (EC) Joint Research Centre

LRI – Cefic's 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

SIG – (Cefic Long-range Research Initiative) Strategy Implementation Group

SOT – Society of Toxicology (US)

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



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