ANNUAL REPORT '19

ecetoc

We are the Centre for chemical safety assessment

CONTENTS

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.

We ensure all 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), which is appointed by the General Assembly and responsible for ECETOC's overall policy and finance.

The Board appoints the Secretary General, as well as 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.

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.

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 Harmonised Classification and Labelling (CLH) technicalities.

Membership is open to companies who manufacture or use chemicals
See: www.ecetoc.org/membership for more details.

To apply for membership, contact Olivier de Matos,
ECETOC Secretary General

Telephone: +32 2 675 3600
Email: info@ecetoc.org

ECETOC MEMBER COMPANIES

During 2019, the ECETOC membership comprised the following 29 full member companies and five associate member companies:

29 full member companies

ARKEMA · BASF The Chemical Company · BAYER · CLARIANT · CORTEVA agriscience Agriculture Division of DowDuPont · DOW · DSM · DUPONT · EVONIK POWER TO CREATE · ExxonMobil Chemical · equinor · Givaudan · Henkel · Honeywell · HUNTSMAN Enriching lives through innovation · L'ORÉAL · Lubrizol · lyondellbasell · MERCK · Nouryon Your partner in essential chemistry · P&G · Roche · Shell · SC Johnson A FAMILY COMPANY · SOLVAY asking more from chemistry® · SUMITOMO CHEMICAL · syngenta · TOTAL · WACKER

5 associate member companies

Afton CHEMICAL · ALBEMARLE · CEPSA · Firmenich · NiPERA NICKEL HEALTH AND ENVIRONMENTAL SCIENCES

ECETOC MEMBERS

MESSAGE FROM THE

Dr. MARTIN KAYSER
Chair of the Board of Administration

ACTIVELY AND SUCCESSFULLY DELIVERING ON OUR NEW VISION AND STRATEGY

If 2018 was a milestone year for ECETOC, in particular celebrating our 40th anniversary, then 2019 has been a year in which we accelerated onwards from this milestone and actively and very successfully started to deliver on our new vision and strategy.

As you all know, ECETOC's new strategy is based on three broad pillars: visibility, dialogue and impact. In 2019, ECETOC's visibility has risen significantly, especially among our members and key stakeholders. As a result, our membership is growing. We have also had an active dialogue with both new and existing members, as well as with a great many of our stakeholders including NGOs.

And, perhaps most important of all, our scientific activities are having impact across Europe and even beyond, reaching all regions.

EVEN BUSIER YEAR AHEAD

ECETOC has strengthened its position as the cross-sectorial scientific organisation whose activities all have tripartite interactions – academia, government and industry – and I am convinced that, over the coming years, we will consolidate our position even further.

This is in no small amount due to the dedication, goodwill and personal involvement of all of the scientists who have freely donated their time and energy to our Science Programme, for which we are extremely grateful.

Looking ahead, it is clear that 2020 will be an even busier year than this past one – and we will continue to demonstrate that ECETOC is fundamental when it comes to putting science at the heart of decision-making.

Among all this activity, it is very encouraging to see the ever-increasing engagement of young scientists in our meetings, activities and research projects.

They are the future. Without them we cannot succeed in the long term. And so ECETOC's efforts to encourage, support and nurture this next generation of scientists must continue unabated.

BRIGHT FUTURE SECURED

In all, I believe ECETOC is in a very good place today. We are most definitely bringing enormous benefit and value to our members as well as to our stakeholders and society at large and, I am sure, we have a bright future ahead of us.

So now, with our future fairly well secured, it is a good moment for me, after almost 17 years as a member of the ECETOC Board, to step down as Chairman and as a Board member. Knowing that the organisation that I care about so deeply is in excellent hands, this is a good time to hand over the reins and let the next person take ECETOC forward into the future.

I have been a member of the ECETOC Board since 2003 and Chairman since June 2009. It has always been both a pleasure and a privilege to serve on the Board. My ongoing commitment to ECETOC has always felt fundamental to me as a scientist, as well as being my positive contribution to society at large.

"... it is very encouraging to see the ever-increasing engagement of young scientists in our meetings, activities and research projects. "

TIME FOR A CHANGE

However, the turn of a new decade is a special moment, one that is a good opportunity for a change, and so starting this year I will take on a new role in my company, BASF.

About one year ago, our industry launched an initiative called Alliance to End Plastic Waste and I will be supporting my CEO, Martin Brudemüller, as one of the Executive Committee members of the Alliance. I will also be active in my role as Co-Chair of the ICCA CP&H Leadership Group as well as continuing to be a member of the Cefic PCPS supporting the chair and BASF board member Saori Dubourg.

But let me come back to the Alliance to End Plastic Waste. The issue of plastic in the environment, including microplastics, has, with incredible speed, become one of the most visible and publicised environmental issues of our times. Not only is waste management critical for our industry's future success, it is also a cornerstone of a circular economy and an issue that we must solve in the context of carbon management and climate change.

ECETOC is actively involved in addressing microplastics and I want to stress again what I have said many times: to identify and implement sustainable solutions for chemicals and waste, we need a solid scientific base. It needs institutions like ECETOC, with its high reputation within the science community, partnering with academia and authorities, to develop and provide this foundation.

EXCITED TO FOLLOW THE NEXT CHAPTERS

I wish my successor as Chairperson every success for the years to come. You can be 100% certain that I will continue to take a very active and positive interest in all ECETOC's activities going forward. I am excited to follow the next chapters in ECETOC's story and watch it go from strength to strength.

Finally, I would like to conclude by expressing my sincere thanks to ECETOC's Secretary General, Olivier de Matos, and to all the members of the Secretariat. They are the secure foundation that has allowed and enabled our organisation to develop so successfully.

I am extremely grateful for their continuing enthusiasm, energy and efficiency – and I know they will be the bedrock of ECETOC's continuing success in the years ahead.

"My ongoing commitment to ECETOC has always felt fundamental to me as a scientist, as well as being my positive contribution to society at large."

CHAIR OF THE BOARD

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 2019 ANNUAL GENERAL MEETING:

Mrs. Lorraine Francourt (Dow Europe) & Drs. Martin Kayser (BASF), Patrick Masscheleyn (Procter & Gamble), Craig Nessel (ExxonMobil Biomedical Sciences) and Heiko Rieck (Bayer) were re-elected to the ECETOC Board.

ECETOC BOARD MEMBERS DURING 2019:

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

HEIKO RIECK
Bayer

VOLKER SOBALLA
Evonik Industries

ECETOC BOARD OF ADMINISTRATION

REPORT FROM THE

OLIVIER DE MATOS
Secretary General

A YEAR FULL OF POSITIVE MOMENTUM AND PROGRESS ON ALL FRONTS

Once again, it is with great pleasure that I share ECETOC's accomplishments in 2019 with you, as well as take the opportunity to look ahead to the new year.

I am delighted to report that the past 12 months have been full of positive momentum – not least enjoying our first year in new offices in rue Belliard 40.

We made good progress in all three of our strategic pillars: increasing 'Visibility' with members and potential members; engaging in constructive 'Dialogue' with external stakeholders; and making an 'Impact' on the long-term scientific agenda.

Under 'Visibility', membership numbers are on the rise and we now have 34 members. I was very happy to welcome both DuPont and Huntsman Corporation as new members in 2019.

Our membership represents the sustainability of our organisation and we will make ECETOC even more sustainable in 2020, as several companies are considering joining us in 2020.

MAXIMISING OUR POTENTIAL

I spent the past year visiting member companies, aiming to understand the strategic directions of each of our members, as well as receiving their feedback and their expectations of us. I also discussed ECETOC's work and the added value we can bring to them through their membership.

I will continue visiting members through 2020, my aim being to maximise the fantastic potential of our organisation.

Under 'Dialogue', in 2019 we strengthened our existing relationships with key stakeholders, as well as beginning a dialogue with new ones. In particular, I am happy to have started constructive discussions with two NGOs: the European Environmental Bureau (EEB) and the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

We have also created and facilitated targeted partnerships, building on existing relationships and reinforcing ECETOC's position as a collaborative scientific space. One example is the joint workshop on exposure-based waving with the scientific division of the European petroleum refiners association, Concawe, in April 2020.

RECONNECTED WITH MAJOR SCIENTIFIC FORA

We have also reconnected with the major scientific fora and EU bodies that influence scientific decision-making.

We now have an ongoing dialogue with ECHA, keeping them updated on our work and activities – and in 2019 we gained 'observer' status at the UN's Stockholm Convention on POPs. In 2020, we will expand this dialogue to include the OECD, WHO, and JRC, as well as relevant European Commission Directorate Generals such as DG Research.

Under 'Impact', we have now put in place a systematic process to identify emerging topics of scientific interest. This will enable us to be on the front foot with respect to emerging topics and, I hope, spend less time 'defending science' reactively.

"We have also reconnected with the major scientific fora and EU bodies that influence scientific decision-making."

During 2019, we had 16 task forces in operation (seven on environment and nine on human health and exposure). In addition, we launched a new transformational programme looking into an Integrated Approach for Precision based Risk Assessment in the 21st Century.

And then on top of all that, we still found the time to organise three workshops (on carcinogenicity and on thyroid T4).

MORE THAN 100 EXPERTS INVOLVED

All in all, we had more than 100 experts involved with ECETOC activities – and we are extremely grateful to them for all of their time and wisdom. It is a sign of trust, as well as an endorsement of the relevance of our work.

Other activities during 2019 included establishing the dose-setting taskforce, which is already planning a report this coming year.

We have also reorganised the TRA group to update the existing tool and we now have a steering committee, with three sub-groups – for consumers, for workers and for the environment.

Since our Annual Technical Meeting in March, which discussed 'Communicating Science Across the Divide', we have launched a webinar series entitled 'Applying the science of communication to the communication of science'. Its aim is to build knowledge among our members – particularly scientific experts – of how to communicate their science and their science stories better, making them compelling and memorable while still ensuring the content remains accurate and rigorous.

The webinar series will continue in 2020 and our intention is to become THE reference point for science communications in Europe.

REFRESHED ECETOC WEBSITE

We have also started to ensure that every single ECETOC output is properly disseminated and promoted, starting in 2019 with the Technical Report of the Polymer Taskforce (Part 1) and announcements about the update of our HeatDB tool.

Finally, we have refreshed the ECETOC website to make it more accessible, as well as increased our visibility on social media.

The result is more followers, more promotion of ECETOC and more awareness of our values and our work.

If anything, 2020 looks even busier, with a wealth of workshops and technical reports lined up.

We are planning to publish nine technical reports, at least four manuscripts and two workshop reports – that means at least one publication every 6-8 weeks throughout the year.

These include Parts 2 and 3 of the Polymers Taskforce Technical Report; a report from the Persistent Mobile and Toxic (PMT) taskforce; updates on the TRA; a number of joint workshops; and many scientific manuscripts.

We are also planning two or more contributions to SETAC in Dublin.

HEARTFELT THANKS TO MARTIN KAYSER

I would like to conclude by paying tribute and offering heartfelt thanks to our Chairman, Martin Kayser, who is standing down in 2020. Martin being chair of ECETOC was instrumental in my deciding to join the organisation back in 2017.

Together with the entire Board and Scientific Committee, Martin has been 100% supportive, engaged and proactive, always ready to contribute and share thoughts or feedback.

Under Martin's excellent leadership, ECETOC has become an important association in Europe. We will certainly miss him, but I am assured he will continue to keep a benevolent and supportive eye on all our activities in the future.

I very much look forward to working with our future Chair, whoever that may be, and to continuing the work we have done together up to now, strengthening and reinforcing the foundations to ensure the sustainability of the organisation and the promotion of ECETOC as the Centre for Chemical Safety Assessment.

Lastly, none of the above would have been possible without the active contributions of all our members, for which we at ECETOC offer our sincere thanks and appreciation.

"Under Martin's excellent leadership, ECETOC has become an important association in Europe. We will certainly miss him, but I am assured he will continue to keep a benevolent and supportive eye on all our activities in the future."

SECRETARY GENERAL

Dr. BENNARD VAN RAVENZWAAY
Chair of the Scientific Committee

FOREWORD FROM THE SCIENTIFIC COMMITTEE CHAIR

TACKLING THE CHALLENGE OF COMMUNICATING SCIENCE EFFECTIVELY

The principal topic at last year's Annual Technical Meeting (ATM) was communications. Some of the quotes relating to the communication of science sound simple and straight forward: "If you can't explain something simply, you don't understand it well", or "You don't really understand something unless you can explain it to your grandmother".

So why is it so difficult to communicate science to a broader audience?

The world is transforming rapidly and we face new scientific challenges on many fronts. The way society views science and the way the political world uses it has also dramatically changed. Today, there is great public scepticism about science.

Scientific expertise remains absolutely essential, in particular to solve some of the world's greatest challenges. But because of this public scepticism, scientists are becoming less trusted.

FINDING THE BALANCE

We need to simplify how we communicate science because we are no longer speaking only to other scientists. We are speaking to a much wider audience – and this audience does not always understand what we are saying, or the implications arising out of it.

Finding the balance between communicating complex issues, such as the results of a complicated assessment of multiple lines of scientific evidence, or crafting a simple elevator speech, are not things scientist are used to doing, or necessarily trained to do. In addition, emotional elements, both positive and negative, also need to be included to communicate science effectively. This is something that scientists tend to (or prefer to) forget.

In her presentation to the ATM, Prof. Dr. AJ (Tinka) Murk, University of Wageningen, Netherlands, gave a number of excellent examples of how simple and straightforward communication, based on common sense, can be used in situations such as the deadly toxic pangasius' issue.

COMMUNICATION TRAINING WEBINARS

Good science communication is going to become ever more important for ECETOC, as well as for any scientist confronted with this task. As science communication training is still fairly rare, ECETOC has launched a mini-series of webinars to build knowledge among ECETOC membership – particularly scientific experts – of how to communicate their science and their science stories better, with passion and eloquence, making them both compelling and memorable, while still ensuring the content remains accurate and rigorous.

A topic which needs both excellent science and skilful communication relates to plastics and microplastics. ECETOC is now fully engaged in the Microplastics Scientific Platform.

Its first output is called "Towards improved understanding of the ingestion and trophic transfer of microplastic particles – Critical review and implications for future research". The Scientific Platform participants undertook a critical review of the literature related to the biological uptake and bioaccumulation of MPs reported over the past 50 years, both in aquatic and terrestrial species at all levels of biological organisation.

GROUND-BREAKING WORK

Not entirely unrelated to the issue of plastics/MPs is the ground-breaking work of the Polymers Task Force. Technical Report 133-1, published in May 2019, presents the Conceptual Framework for Polymer Risk Assessment (CF4Polymers) which is based upon a review of the state-of-the-art polymer grouping and risk assessment (RA). The CF4Polymers provides guiding principles to be considered in assessing potential ecological and human health hazards and risks posed by polymer products to facilitate consistency.

"Emotional elements, both positive and negative, also need to be included to communicate science effectively."

SCIENCE PROGRAMME

Due to the versatility and complexity of polymers, consisting not only of the polymeric substance (polymeric macromolecules), but also of intentionally added substances (e.g. stabilisers) and non-intentionally added substances (e.g. impurities) and the possibility that polymer products can change their form during different life cycle stages, conventional risk assessment approaches used for chemicals need to be modified for polymers. Once again, and similar to the novel approach taken for grouping of nano-materials, ECETOC shows that it is a driver for innovation in the science of risk assessment.

TRA TOOL IS A DRIVING FORCE

In exposure sciences, the Targeted Risk Assessment (TRA) tool continues to be a driving force to efficient exposure assessment, whether for ECHA or for our industries. The desire to make the TRA ever more usable for more types of exposure and a more detailed approach, demonstrates the strength of this approach. Start at a simple level and 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 to build better exposure databases all over the world.

In discussions about our transformational program for human health, we have seen that a high-quality exposure assessment provides opportunities for reduced animal testing. Consumer product companies are already using the combination of exposure assessment databases with toxicology in the 21st century concepts.

The use of *in silico* and *in vitro* methods to predict a range of potential hazards, and the transformation of concentrations used in *in vitro* methods to a dose in mg/kg bw (as used in conventional risk assessment) can be done using *in vitro – in vivo* extrapolation (IVIVE). The quality of these methods has improved significantly over the last few years, and reasonable prediction concerning the dose range of safe uses can be made. However, in the end it is the correct exposure estimate that matters most. I am convinced that the best way forward to achieve reduced (animal) testing is to invest more in exposure assessment sciences.

TWO KEY ENVIRONMENT TASK FORCES

Late 2018 and early 2019, ECETOC established two environmental Task Forces. The Task Force on "Persistent chemicals and water resources protection" has been considering a proposed approach to managing persistent, mobile and toxic substances which was developed by the German competent authorities, Umwelt Bundes Amt (UBA). As this new approach introduces new triggers (e.g. for toxicity or mobility in soil), it is very important to validate and, if necessary, challenge the approach scientifically to achieve a meaningful and reasonable framework for ground- and drinking water protection. Faithful to our goal to work as a tripartite organisation, this Task Force has attracted the attention of scientist from academia, the regulatory community and industry.

The second important environmental Task Force is "Moving Persistence (P) Assessment into the 21st Century", which aims to wrap up the existing state-of-the-art knowledge on biodegradation. Science has moved on in the past two decades, but most of the existing test guidelines and assessment schemes still rely on data from last century! The aim of this Task Force is to translate that knowledge in a way that regulators can use today.

Both Task Forces have attracted significant attention and are working in a tri-partite environment, with representatives from regulatory and academic communities as well as industry scientists.

"ECETOC's ability to respond rapidly is complimented by our ability to look ahead and to dive into areas of science which may have an influence on the risk assessment of chemicals in the future."

KEEPING ECHA UPDATED

As we did in 2018, Olivier de Matos and I had a full-day meeting in September 2019 with several representatives of ECHA, including Björn Hansen and his directors. Unlike 2018, we did not need to introduce ECETOC as an organisation. This time, it was all about our activities and ECHA's expectations.

We were able to provide ECHA with updates on our work developing an online application for read-across cases for nano-materials, the work of the polymer grouping and risk assessment Task Force, our activities on thyroid hormone issues, as well as on the Worker & Consumer TRA and exposure-based triggering for information requirements (called "exposure based waiving"). Finally, we also updated ECHA on the dose selection Task Force.

EXAMPLE OF ECETOC AGILITY

The issue of potential intentional underdosing was brought to the attention of ECHA in 2018. It is important for the reputation of our industries to avoid such a perception. It is equally important for regulators to understand that dose selection not only involves data interpretation, extrapolation between species and in time, but also essential aspects of animal welfare. The fact that we were able to initiate this Task Force, within months after this issue was brought to our intention, is an excellent example of the agility of ECETOC.

The best opportunities to work with ECHA can be found in emerging issues, where the gathering of scientific evidence, knowledge-gap analysis and recommendation for future research are discussed. I believe we already have a template for such joint activities: our workshops! Indeed, the sessions we have had on 'omics sciences, epigenetics, and last year's workshop about the metabolic capacity of the microbiome all had significant regulator participation.

RAPID RESPONSE

ECETOC's ability to respond rapidly is complimented by our ability to look ahead and to dive into areas of science which may have an influence on the risk assessment of chemicals in the future. Within the context of an LRI project, ECETOC organised a 1.5-day workshop on the 'Gut microbiome associated metabolic capacity and host-microbiome co metabolism', attended by experts from academia, regulatory agencies and industry, and featuring 10 scientific presentations.

After the presentations, participants discussed and identified knowledge gaps, such as defining what a good microbiome is, how to define functional end-point to understand microbiome-associated metabolic processes, and questions related to interindividual variability.

REVIEW AND SCOPING MEETINGS

The last week in January, when ECETOC's review and scoping meetings take place, should by now be a fixed point in the agenda of any scientist involved in ecotoxicology, human health and exposure sciences.

For members of ECETOC's Scientific Committee, the discussion at our review and scoping meetings provide an excellent sounding board for topics that have emerged.

I would like to emphasise that any ECETOC member has a right to propose ideas for workshops or Task Forces to the Scientific Committee at any point in the year. There is no need to wait for the annual review and scoping meetings to make a proposal, particularly if there is an ad hoc urgent need for action.

The spread sheet for workshop / Task Forces proposals has been streamlined and provides good guidance on how best to prepare for a presentation to the scientific committee. Please use the opportunity as often as you feel necessary – it is far better to discuss a few additional proposals than to forget an essential issue.

HIGHLIGHTS OF 2019

TASK FORCES ESTABLISHED

DOSE LEVEL SELECTION IN TOXICITY STUDIES

BACKGROUND:

While regulators and policymakers need to promote chemical safety, they should take all aspects of the process of safety assessment of chemicals into account.

These include risk assessment, C&L requirements, as well as animal welfare. The Task Force is an opportunity to provide the best information to achieve such a balance, as well as to help support the appropriate design and interpretation of toxicity studies.

OBJECTIVES:

The Task Force is currently developing a peer review guidance which:

- Reflects the current state of scientific knowledge;
- Provides appropriate options for different industry sectors;
- Recognises, addresses and reconciles the different uses to which data are put – risk assessment and hazard identification relevant to human safety; and
- Ensures a responsible approach to animal welfare.

TIMELINE:

Duration ~ 8 months
Expected end: end of Q2 2020

MOVING PERSISTENCE (P) ASSESSMENTS INTO THE 21ST CENTURY: DEVELOPING A NEW PARADIGM TO ASSESS DEGRADATION POTENTIAL OF CHEMICALS

BACKGROUND:

Recent progress in scientific understanding of the underlying processes of persistence and degradation has provided an opportunity to develop an improved framework, as well as best practices, for persistence and degradation assessments.

OBJECTIVES:

The Task Force will revisit the principles for P assignments of organic chemicals in the context of new research. The Task Force intends to develop two publications:

- A perspectives paper, considering persistence as a context-specific concept; and
- A methods paper, focusing on key aspects to improve and expand experimental design and strategies.

The Task Force intends to hold a Stakeholder workshop during 2020.

TIMELINE:

The Task Force held its kick-off meeting in July 2019 and aims to complete its work by the end of 2020.

The Task Force is co-chairing the joint session "Persistent (P) and PMT/vPvM Substances in the Environment: Improving Experimental and Weight of Evidence Assessment Methods, Providing Solutions, and Informing Regulations" at SETAC Dublin 2020.

WORKSHOPS

ECETOC AND CEFIC LRI ENVIRONMENT PROGRESS REVIEW AND SCOPING MEETING 2019

28-29 January 2019, Brussels

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

The meeting had the following objectives:

- Present the progress and/or outcome of selected current ECETOC activities;
- Review the Cefic LRI work programme;
- Share and consider perspectives on emerging topics of scientific interest;
- Gain consensus on the future priorities for ECETOC and Cefic LRI activities to close the identified knowledge gaps and address the emerging topics.

SESSION I: Progress and/or outcome of current selected key ECETOC activities

This session featured the following presentations:

- **TODD GOUIN** (TG Environmental Research, United Kingdom): ECETOC Task Force (TF): Aquatic toxicity and bioaccumulation of sparingly soluble manufactured particulate substances;
- **VÉRONIQUE POULSEN** (L'Oréal R&D, France): ECETOC TF: Towards a framework for assessing the human health and environmental safety of polymers;
- **KEES VAN GINKEL** (Nouryon, the Netherlands): Potential new ECETOC TF: Moving persistency (P) assessment into the 21st century – Developing a new paradigm to assess the biodegradation potential of chemicals; and
- **MICK HAMER** (Syngenta, United Kingdom): ECETOC TF: Exploring community-based environmental hazard assessments of mixtures based on mode-of-action (MoA) approaches

SESSION II: Review Cefic LRI work programme

BRUNO HUBESCH (Cefic LRI, Belgium) presented the new Cefic LRI projects originating from the 2018 Review and Scoping meeting (ECO 47, ECO 48, ECO 49, ECO 50, ARC.5; http://cefic-lri.org/projects/) and ongoing LRI projects that relate to the key ECETOC activities (Session I), or the emerging topics (Session III). The following two LRI project ideas originating from the 2018 Review and Scoping meeting, which have not yet been taken forward, were also presented: Analytical methods to assess human exposure to plastic particulates in food and the indoor environment; and Fish Embryo Toxicity (FET) test – improved regulatory acceptability.

Sessions I & II moderated Q&A and panel discussion

The objective of this session was to gain consensus on future priorities for ECETOC and Cefic LRI activity to close knowledge gaps identified in the above sessions.

The panel members were the presenters from the previous sessions and the moderator was Dennis Landsbert-Noon (Panda Communications, Belgium).

Overall, meeting participants agreed that the ongoing ECETOC and Cefic LRI activities were of high scientific relevance, addressing current scientific challenges for ecological hazard assessment and risk assessment (RA) as well as related societal hot topics.

Specific comments and discussions referred to the following topics:

It was noted that there was increasing political pressure placed on environmental risk assessment of particulates, whilst the available test methods and risk assessment tools were not necessarily relevant. Environmental risk assessment should be adapted to enable the assessment of particulates, including improvement of exposure considerations and mode of action.

Regarding risk assessment of polymers, it was noted that this should prioritise the steps of the life cycle that are potentially most hazardous. Drivers for toxicity are mainly bioavailability, the presence of specific functional groups, and charge density. It was agreed that consideration of natural polymers as benchmarks in the risk assessment of polymers could offer insights.

Participants agreed that addressing the environmental risk assessment of mixtures required long-term commitment. Furthermore, there was consensus around the need to identify priority chemical mixtures that are of utmost environmental concern, as well as relevant MoAs for these priority mixtures.

SESSION III: Emerging Topics

This session featured the following presentations:

- **MARLIES HALDER** (European Commission, DG Joint Research Centre, Italy): Alternative methods for ecotoxicology/bioaccumulation: Route to validation and regulatory application. Dr Gordon Sanders (Givaudan, Switzerland; member of the ECETOC SC) made the presentation on Dr Halder's behalf as she was unavailable for health reasons;
- **BEATE ESCHER** (Helmholtz Centre for Environmental Research (UFZ), Germany): Identification of priority mixtures in the environment: Tools available and their limitations; and
- **TATIANA SANTOS** (European Environmental Bureau (EEB), Belgium): The non-governmental organisation (NGO) perspective on emerging scientific topics and associated knowledge gaps.

Sessions II moderated Q&A and panel discussion

The objective of this session was to gain consensus on the opportunities and priorities for future ECETOC and Cefic LRI activities that addressed the emerging topics which had been presented.

All participants at the meeting confirmed the timeliness and urgency of activities (i) to accelerate the validation and regulatory application of alternative methods for ecotoxicology and bioaccumulation testing and (ii) to assess the environmental impact of mixtures. Further, all participants welcomed the opportunity to engage in an exchange of views with an NGO regarding the knowledge gaps associated with emerging scientific topics. Thoughts on what industry could do to support the 'safer-by-design' initiative were shared.

URSULA G. SAUER (Scientific Consultancy – Animal Welfare, Germany) summarised the presentations and discussions and presented five actionable topics identified as an outcome of the discussions:

1. Persistency particulates/polymers (LRI or ECETOC): Persistency in relation to particulates, and perhaps polymers in general;

2. Mixtures/communities follow-up (ECETOC): Follow-up activities relating to the Task Force on community-based and mixtures assessment;

3. Analytical – plastic particulates (LRI): Analytical methods to assess human exposure to plastic particulates in food and the indoor environment (NB: will also include environmental matrices);

4. Regulatory acceptability FET (LRI): Improved regulatory acceptability of the Fish Embryo Test (FET);

5. EEB suggested activity (ECETOC): Support safer-by-design research and development; translate academic research into applications/business needs; consider jointly developing ecolabelling.

The meeting participants were invited to take part in an indicative vote to prioritise the five topics with the aim that they be considered by the LRI and ECETOC decision-making bodies (LRI Issue Team or ECETOC Scientific Committee, as appropriate) in March.

All of the presentation slides from the meeting are accessible via the link: http://www.ecetoc.org/science-programme/scoping-meeting/

2019 ECETOC & CEFIC LRI HUMAN HEALTH & EXPOSURE SCIENCE PROGRESS REVIEW AND SCOPING MEETING

30-31 January 2019

ECETOC and Cefic LRI convened the Human Health & Exposure Science Progress Review and Scoping Meeting 2019 on 30-31 January in Brussels, Belgium. Approximately 40 invited participants from Europe and North America attended the meeting, representing ECETOC and Cefic member companies, academia, regulators, and consultancies.

OLIVIER DE MATOS (Secretary General, ECETOC) opened the meeting by outlining its objectives:

- presenting progress and/or outcome of current selected key ECETOC activities, including consideration of potential ECETOC and/or Cefic LRI follow-up;
- reviewing the Cefic LRI work programme;
- sharing and considering participants' perspectives on emerging topics; and
- gaining consensus on the priorities for future ECETOC and Cefic LRI activities to close the identified knowledge gaps and address the emerging topics.

SESSION I: Progress and/or outcome of current selected key ECETOC activities

This session featured the following presentations:

- **PHIL BOTHAM** (Syngenta, United Kingdom) presented the outline for a new transformational programme as voted for during the 2018 scoping meeting and subsequently agreed by the ECETOC Scientific Committee: Human health and exposure 2018: An integrated approach for precision-based risk assessment in the 21st century
- **ALAN BOOBIS** (Imperial College of London, United Kingdom) presented the rationale for and scope of the planned ECETOC-sponsored workshop Hazard identification, classification and risk assessment of carcinogens: too much or too little? taking place as a satellite workshop to Eurotox 2019 on 8 September 2019 in Helsinki, Finland (see report below).
- **NINA HALLMARK** (Bayer, Germany) presented the completed and planned activities of the ongoing Special Thyroxine (T4) Task Force that took up its work in July 2018.
- **TIM MEIJSTER** (Shell, the Netherlands) presented the priorities and work topics scoped out by the Human Health Exposure TF as either ECETOC or Cefic LRI activities.

SESSION II. Review of Cefic LRI work programme

BRUNO HUBESCH (Cefic LRI, Belgium) presented new LRI projects to begin in 2019 (C7, B21, EMSG59; cf. http://cefic-lri.org/request-for-proposals/) and ongoing LRI projects (EMSG58, ECO36, ECO48, ECO49; http://cefic-lri.org/projects/) of relevance for the emerging topics to be presented on Day 2.

Dr. Hubesch also referred to the research proposal *Analytical methods to assess human exposure to plastic particulates in food and the indoor environment* presented at the 2018 scoping meeting, that LRI had not yet taken up since it ranked 6th in the 2018 vote. This proposal was again voted on during the 2019 Environmental Scoping Meeting.

The subsequent moderated Q&A and panel discussion (moderator: Dennis Landsbert-Noon, Panda Communications, Belgium) served to gain consensus on future priorities for ECETOC and Cefic LRI activities to close the knowledge gaps identified in the presentations.

All meeting participants agreed that the ongoing ECETOC and Cefic LRI activities were of high scientific relevance. Conceptual thinking was required to improve substance risk assessment, and new concepts for human health hazard and exposure characterisation should consider the biological mechanisms underlying observed effects. In this regard, knowledge on adverse-outcome-pathways (AOPs) or substance-specific modes-of-action (MoAs) was pivotal to making progress in all ongoing activities. Such knowledge would also serve to identify species-differences in key events of AOPs or MoAs and hence to determine the human health relevance of effects observed in research animals.

Discussions relating to exposure assessment addressed the need to make better use of available exposure data during risk assessment. Moreover, exposure assessment reliability should be increased by the development of innovative tools for the collection of exposure data. With regard to aggregate exposure assessment, participants recommended that this should only be done if it could be shown that it was necessary for the RA of the substance under investigation.

Participants highlighted how valuable it was that ECETOC and Cefic LRI engaged in multi-stakeholder dialogue, networking, and collaboration, noting that this was indispensable to achieving scientific progress in an efficient and effective manner, as well as facilitating consideration of new scientific evidence in relevant political activities. The multi-stakeholder dialogue should consider stakeholders both from the EU and from non-EU countries and also include the regulatory community, academia, and non-governmental consumer, environmental, and animal protection organisations.

The need to disseminate the scientific outcome of activities to the public was also discussed. Often, ECETOC and Cefic LRI activities relating to societal hot topics, as well as any new scientific evidence, could be used to objectify, for example, public perception of potential risks. For this reason, scientific issues had to be presented in a language understandable to lay-people. Some participants cautioned that communicating to the public required careful consideration of the role of science in public opinion. The overarching role of both ECETOC and Cefic LRI was to advance scientific understanding of relevant topics and to establish a scientific position based on that understanding. The best ways to communicate scientific positions to the public would need to be established on a case-by-case basis.

SESSION III: Emerging topics

- **GERARD SWAEN** (Maastricht University, the Netherlands) delivered a presentation on Endocrine disruption and epidemiology.

- **JON ARNOT** (Arnot Research & Consulting, Canada) presented Exposure and cell testing (*in vitro to in vivo extrapolation (IVIVE)*)

- **STEPHANIE L. WRIGHT** (King's College London, United Kingdom) presented Microplastics and toxicology of particles

The subsequent moderated Q&A and panel discussion (moderator: Dennis Landsbert-Noon) served to gain consensus on the opportunities and priorities for future ECETOC and Cefic LRI activities to address the presented emerging topics. All participants confirmed the timeliness and urgency of the emerging topics that were presented, noting that a number of ECETOC and Cefic LRI activities already addressed endocrine disruption, IVIVE and microplastics. Based on this, the meeting agreed that further activities could be initiated, taking into consideration activities under way by other science organisations and research funding programmes.

SESSION IV: Gain consensus on priorities for future ECETOC and LRI activities to close knowledge gaps identified during the meeting

URSULA G. SAUER (Scientific Consultancy - Animal Welfare, Germany) summarised the presentations and discussions from the meeting and presented the 11 actionable topics identified as an outcome of these discussions:

The actionable topics relating to the Transformational Programme (TP) An integrated approach for precision-based risk assessment in the 21st century included:

- **TP-1:** Revised hazard categorisation scheme taking into account thresholds of toxicological concern and adverse outcome categories (ECETOC activity)

- **TP-2:** Tiered hazard identification and characterisation framework using new approach methodologies (ECETOC activity)

- **TP-3:** "Smart studies" for repeated-dose and developmental toxicity testing (Cefic LRI)

An actionable topic relating to the work of the ECETOC T4 TF that would be initiated after the ECETOC Thyroid Disruption Workshop planned for end 2019 was:

- **T4-1:** In vivo testing strategy for thyroid disruption and developmental neurotoxicity testing (Cefic LRI)

Actionable topics relating to the work of the ECETOC Human Health Exposure (HHE) TF included:

- **HHE-1:** Optimise benefits of REACH worker exposure models (Cefic LRI)

- **HHE-2:** Aggregate human exposure assessment (actionable topic for the ECETOC HHE TF)

- **HHE-3:** Human exposure assessment of substances of unknown and variable composition and biological materials (UVCB's) and mixtures (Cefic LRI)

Actionable topics relating to the emerging topic Endocrine disruption and epidemiology (Epi) were:

- **Epi-1:** Improve and standardise epidemiological studies (ECETOC workshop; followed by Cefic LRI action)

- **Epi-2:** Review one particular endocrine disease to identify the relative contribution of different risk factors (Cefic LRI)

An actionable topic relating to the emerging topic Exposure & cell testing (IVIVE) was:

- **IVIVE-1:** Develop approaches to identify chemical transformation rates and pathways in in vitro and in vivo systems (Cefic LRI)

An actionable topic related to the emerging topic Microplastics (MP) and toxicology of particles was:

- **MP-1:** International Council of Chemical Associations (ICCA) Microplastics Task Force to select one of the actionable topics identified by Dr. Wright (cf. Slide no. 15) to be taken up by Cefic LRI

Participants took part in an indicative vote to prioritise these actionable topics, so that they could be recommended for further consideration by the LRI and ECETOC decision-making bodies (LRI Issue Team or ECETOC Scientific Committee, as appropriate) in March.

All of the presentation slides from the meeting are accessible via the link http://www.ecetoc.org/2019-ecetoc-and-cefic-lri-human-health-progress-review-and-scoping-meeting/.

HAZARD IDENTIFICATION, CLASSIFICATION AND RISK ASSESSMENT OF CARCINOGENS: TOO MUCH OR TOO LITTLE? A ONE-DAY SATELLITE WORKSHOP TO EUROTOX 2019

8 September 2019 in Helsinki

Approximately 150 participants attended the ECETOC-organised workshop 'Hazard Identification, Classification and Risk Assessment of Carcinogens: Too Much or Too Little?', a satellite workshop to the EUROTOX 2019 Conference.

The workshop focused on non-genotoxic carcinogens, exploring two themes:

- The basis for hazard identification and classification of non-genotoxic carcinogens: are substances that are not carcinogenic to humans being classified as carcinogens? Or vice versa, are substances that are carcinogenic to humans being missed due to insufficiencies of the available data or methods?

- Current methodologies for the quantitative risk assessment of non-genotoxic carcinogens: Are current methods overly conservative, or insufficient to provide adequate protection?

The workshop included perspectives from stakeholders, as well as a panel discussion and concluding thoughts. The lively discussions and presentations highlighted the relevance of the topic, as well as emphasising the importance of engaging in science-based communication to re-design hazard and risk assessment, as well as C&L of non-genotoxic carcinogens.

A report of the workshop is being prepared by the ECETOC Organising Committee and will be submitted as an open-access manuscript for publication in 2020.

EXPERT

GUT MICROBIOME ASSOCIATED METABOLIC CAPACITY AND HOST-MICROBIOME CO METABOLISM

8-9 July 2019 in Porto

The ECETOC'19 – microbiome experts meeting was organised to assess progress on research findings regarding the 'Gut microbiome associated metabolic capacity and host-microbiome co metabolism'.

The workshop included scientists and professors working on Gut Microbiome research in the fields of host health and disease. Ten scientific presentations were made by participants from prestigious research institutes, universities and companies. The second day of the workshop featured discussion about knowledge gaps in the field of gut microbiome associated metabolism.

A key driving factor behind the ECETOC'19 Workshop was to bridge knowledge gaps and produce research ideas for the CEFIC-LRI ELUMICA project, whose aim is to explain gut microbial metabolic capacity as well as understand metabolism-related gut microbial functionality.

The workshop was divided into two sessions. The first was to introduce and provide insights into the research currently being conducted into gut microbiome associated metabolism.

Presentations were made on the following topics: gut microbiota and host co-metabolism of xenobiotics; the influence of intestinal microbiota on phytochemicals present in natural products; *in-vitro* based analysis of gut-host co-metabolism; characterisation of human gut microbiome; the use of fecal metabolomics to understand the gut microbiome; *in-silico* based xenobiotic concentration predictions of gut microbial metabolism; and standardization of tools for detailed microbiome-associated metabolism analysis.

The second session involved discussion of potentially unaddressed, as well as other already-known research findings, with the aim of bridging any knowledge gaps and addressing the unknowns.

Knowledge gaps that were discussed included: defining what a good microbiome is; which matrix could be regarded as a functional end-point to understand microbiome-associated metabolic processes; interindividual variability; and the necessity of biomarkers for disease identification.

In a break-out session, participants also discussed specific research questions, such as direct microbiome-specific drug reactions, gut microbiome-specific enzyme activity, host-factors determining microbiome-drug interactions, predicting microbial functionality using metagenome-level information, understanding more about microbe-microbe interactions and its role on the metabolism.

WORKING GROUPS

ECETOC

As part of the ECETOC Board's decision to devote part of its resources to thought leadership, ECETOC has established a set of Transformational Programmes (TP), with 3-5 year timespans, addressing topics of longer-term scientific relevance which have the potential to transform chemicals management.

Four Transformational Programmes are underway:

PROGRAMME 1: 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. The TP 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 Programme aims to enhance the acceptance and establishment of standardised practices (in the context of Good Laboratory Practice), as well as to create processes and guidelines that provide confidence for regulators and registrants to interpret and apply 'omics data in regulatory decision-making.

Cefic LRI projects currently underway as part of this TP are:

- **LRI C4:** Transcriptomics bioinformatics best practices in Toxicogenomics for regulatory application;
- **LRI C5:** XOMETOX – Evaluating multi-omics integration for assessing rodent thyroid toxicity;
- **LRI C6:** Toxicogenomic approaches to support read-across; and
- **LRI C7:** ELUMICA – Elucidating Microbial Metabolic Capacity.

PROGRAMME 2: INTRODUCING ENVIRONMENTAL RELEVANCE INTO ENVIRONMENTAL RISK ASSESSMENT

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

The programme comprises 3 key elements:

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

PROGRAMME 3: TARGETED RISK ASSESSMENT

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 Chesar 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

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

Subgroup: Worker Targeted Risk Assessment

The Task Force is currently reviewing a series of external validation studies on worker exposure estimations using the ECETOC TRA tool, version 3.

Publications such as the BAuA-sponsored E-team work are included in this review phase.
The objectives are to

- Assess where some elements in the TRA are inaccurate;
- Provide input and ensure alignment with the ENES Action 3.2 group (led by ECHA);
- Harvest new insights from current LRI projects [LRI B15.3; B19.2; B20].

The group is also in contact with a number of academics and regulators to engage them as external advisors.

Subgroup: Consumer Targeted Risk Assessment

The Task Force is currently working to

- Provide a peer-review manuscript on infrequent and/or short-duration exposure estimates to bring clarity and align risk assessors on a science-based approach;
- Develop a manuscript evaluating the conservativeness of the TRA-consumer module.

Subgroup: Environment Targeted Risk Assessment

In the first half of 2019, ECETOC coordinated industry's contribution to the first stage (IT feasibility study) of the ECHA EUSES update process. This was done via a series of ECHA-organised Technical Expert Groups (TEGs) with industry delegates and industry stakeholder groups.

Towards the end of 2019, ECHA confirmed it intended to develop a common chemical risk assessment tool for REACH and biocides (combining EUSES and Chesar) in early 2020.

ECHA expects to continue to consult with the TEGs on relevant technical aspects, though has also recently circulated a market survey for scientific services to support the update of EUSES.

The Environment branch of the TRA Task Force will continue to liaise with ECHA and the TEGs. Diederik Schowanek (P&G), Paul Mason (SC Johnson), as well as Lucy Wilmot (ECETOC), continue as members of ECHA's EUSES update Steering Committee.

PROGRAMME 4: DEVELOPMENT OF AN INTEGRATED APPROACH FOR CHEMICALS ASSESSMENT

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

Chemicals have many uses which are of great benefit to society. A regulatory system has evolved over the past 50 years that enables the use of chemicals 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 that it requires a new framework.

Objectives

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.

The team has recently been in dialogue with external stakeholders to seek interest and exchange thoughts (for example, recent discussions with the EC Joint Research Centre, as well as the European Crop Protection Association were very positive).

The next step is to test the concept with examples, looking at one sector first, to explain and show regulators how it would work in practice.

PUBLICATIONS

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

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 2019

TR 133-1: The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers)
Published May 2019
ISSN-2079-1526-133-1 (online)

ARTICLES PUBLISHED IN OPEN SCENTIFIC LITERATURE DURING 2019

Use cases, best practice and reporting standards for metabolomics in regulatory toxicology
Published July 2019, Viant et al., in Nature Communications (https://doi.org/10.1038/s41467-019-10900-y)

COMMUNICATING
THE SCIENCE

REPRESENTATION, PRESENTATIONS AND POSTERS AT SPECIFIC MEETINGS

SETAC EUROPE 29TH ANNUAL MEETING
26–30 May – Helsinki, Finland

PLASTIC HEALTH SUMMIT
3 October 2019 – Amsterdam, The Netherlands
LUCY WILMOT

EC SCIENCE ADVICE MECHANISM STAKEHOLDER MEETING 'ENVIRONMENTAL AND HEALTH RISKS OF MICROPLASTIC POLLUTION'
25 April 2019 – Brussels, Belgium
LUCY WILMOT

WOOD PFA WORKSHOP ON THE DEVELOPMENT OF CRITERIA TO IDENTIFY AND GROUP POLYMERS FOR REGISTRATION/EVALUATION UNDER REACH
21-22 May 2019 - European Commission (DG ENV), Belgium
OLIVIER DE MATOS

21ST ANNUAL CEFIC-LRI WORKSHOP
20-21 November – Brussels, Belgium
Participation by OLIVIER DE MATOS, ALICE BROUSSE, LUCY WILMOT

VCI PROJEKTGRUPPE POLYMERE
12 September – Frankfurt am Main, Germany.
JEN C. OTTE, BASF, presented 'ECETOC Polymers Task Force: Assessing the human health and environmental safety of polymers'

PERSONAL CARE PRODUCT COUNCIL AND COSMETIC EUROPE JOINT MEETING
15 June – Brussels, Belgium.
NATHALIE VALLOTTON, Dow, presented 'ECETOC Polymers Task Force: Assessing the human health and environmental safety of polymers'

SETAC NORTH AMERICA 40TH ANNUAL MEETING
3-7 November – Toronto, CA.
CHRISTOPHER HOLMES (Applied Analysis Solutions), a member of the ECETOC Task Force on Geospatial approaches to increasing the ecological relevance of chemical risk assessments, presented a poster 'Geospatial approaches to increasing the ecological relevance of Environmental Risk Assessment' summarising the work of the Task Force so far.

INPUT TO SPECIFIC PROJECTS AND REPORTS

POLYMERS CONSULTATION
In April 2019 the ECETOC Polymers Task Force developed and submitted responses to the WOOD-PFA online survey relating to the DG Environment study 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'.

EXCHANGE NETWORK ON EXPOSURE SCENARIO ENES
Action 3.2: Consolidate the different worker exposure tools into a common framework
Jan Urbanus (Shell) as Chair of the ECETOC Worker TRA Task Force is representing ECETOC in this ENES initiative led by ECHA, which started in 2018.

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 2019:

ENVIRONMENTAL SCIENCE RELATED AWARDS

During SETAC Europe 29th Annual Meeting in Helsinki, 156 young scientists competed for the Young Scientist Awards, sponsored by ECETOC and SETAC Europe, which recognizes the best poster and the best platform presentation.

The Best Poster Award was presented to Maxime Gauthier of Irstea, France, for his poster on
'Developmental and Vitamin A-Based Biomarkers for Pesticide Contamination in Two Potential Arthropod Sentinels, the Honey Bee Apis mellifera and the Gammarid Gammarus fossarum'.

The Best Platform Award was received by Simone Rizzuto, Lancaster University, UK, for his presentation titled
'Freshwater Phytoplankton Community Response Across Different Historical Contamination Backgrounds'.

HUMAN HEALTH SCIENCE RELATED AWARDS

The 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 recipient of the **2019 ECETOC CHRISTA HENNES Early Career Award** is **DR. JULIA KUHNLENZ** from TissUse GmbH, Berlin, Germany for the following abstract **'Establishment of a Multi-Organ-Chip based identification platform for endocrine disruptors.'**

In the same category, a highly commended recognition has also been given to **DR. GOVIND SHARAN GUPTA** from Karolinska Institutet, Institute of Environmental Medicine, Division of Molecular Toxicology, Stockholm, Sweden for the following abstract **'Cobalt-impregnated tungsten nanoparticles and cobalt ions trigger toxicity in differentiating neuronal cells: potential link to parkinsonian neurodegeneration.'**

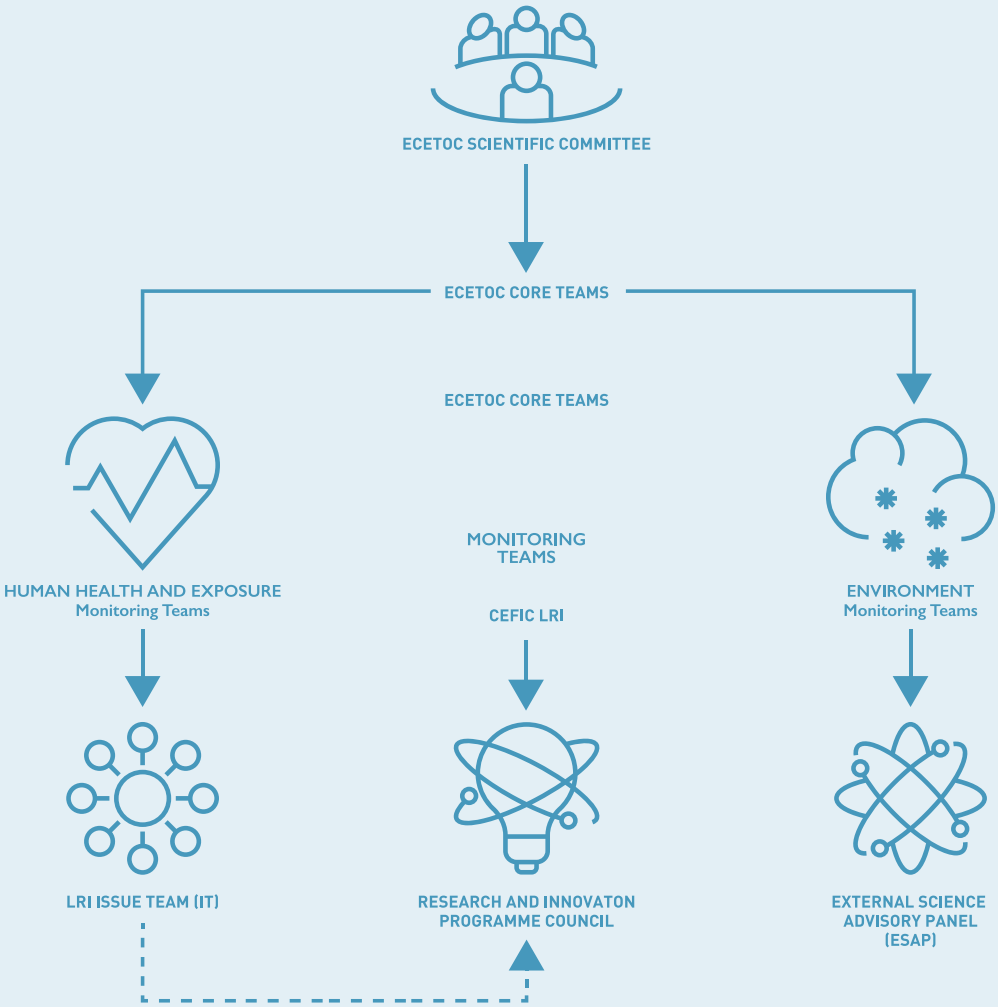
ECETOC CONTRIBUTION TO CEFIC LONG-RANGE RESEARCH INITIATIVE

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

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

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

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



HUMAN HEALTH AND EXPOSURE MONITORING TEAMS

3 projects were completed during 2019 (marked below with #). 4 new projects secured funding and will be initiated in 2020 with the support of the monitoring teams (marked below with *):

AIMT7#:
Open Access physiologically-based pharmacokinetic modelling platform. Principal investigator: Dr. George Loizou, Health and Safety Laboratory (HSL), United Kingdom

AIMT 5.2:
A developmental ontology based computational model for mammalian neural tube closure for in silico prediction of compound induced neural tube defects. Principal investigator: Prof. Dr. Aldert Piersma, RIVM, National Institute for Public Health and the Environment, The Netherlands

B12.3Ext:
Assessing the relevance of the dust contribution in consumer exposure to substances from consumer products and articles (DustEx). Principal investigator: Dr. John Little, Virginia TECH, US

B15.3:
Ext: ECEL v3.0: Technical improvements and population of the integrated risk management measure (RMM) library. Principal investigator: Dr. Wouter Fransman, Netherlands Organisation for Applied Scientific Research (TNO), The Netherlands

B17#:
SHINE - Target and non-target Screening of cHemicals in the Indoor environment for human Exposure assessment Dr. Marja Lamoree, VU University Amsterdam, The Netherlands

B18.2:
Incorporation of repeated dose study information for non-DNA-reactive carcinogens into the CPDB database and analysis of threshold values. Principal Investigator: Sylvia Escher, Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Germany

B19.2:
Refinement of a framework for extrapolating of worker exposure measurement data. Principal Investigator: Dr. Wouter Fransman, Netherlands Organisation for Applied Scientific Research (TNO), The Netherlands

B20#:
Experimental assessment of inhalation and dermal exposure to chemicals during industrial and professional activities. Principal Investigator: Dr. Wouter Fransman, Netherlands Organisation for Applied Scientific Research (TNO), The Netherlands

B21:
In Vitro Data to Parameterise PBPK Models for Inhalation Exposure. Principal investigator: Dr. Katharina Schwarz, Fraunhofer ITEM, Germany

B22*:
Tiered Methods for Quantifying Exposure to Complex Substances ("TMEx-Complex"). Principal investigator: Prof. J. Mark Parnis, Trent University, Canada

B23*:
Optimizing the benefit of REACH worker exposure assessments: ensuring meaningful health risk communication. Principal investigator: Dr Wouter Fransman, Netherlands Organisation for Applied Scientific Research (TNO), The Netherlands

C4:
Transcriptomics bioinformatics best practices in toxicogenomics for regulatory application. Principal investigator: Dr. Florian Caiment, Maastricht University, The Netherlands

C5:
XOMETOX -Evaluating multi-omics integration for assessing rodent thyroid toxicity. Principal investigator: Dr. Jörg Hackermüller, Helmholtz Centre for Environmental Research (UFZ), Germany

C6:
Toxicogenomic Approaches to Support Read-Across. Principal investigator: George Daston, Procter & Gamble, United States

C7:
ELUMICA -Elucidating Microbial Metabolic Capacity. Principal investigator: Saskia Sperber, BASF SE, Germany

C8*:
MetAbolomics ring-Trial for CHemical groupING (MATCHING). Principal investigator: Prof. Mark Viant, University of Birmingham, United Kingdom

EMSG 59:
Developing a quantitative AOP for liver-mediated thyroid modulation after prenatal exposure to a xenobiotic compound in the rat. Principal investigator: Aldert Piersma, RIVM, Nederlands

EMSG 60*:
Incidence trends of selected endocrine-related diseases and conditions in Europe and North America, and the contribution of changes in human reproduction. Principal investigator: Dr. Eva Negri, Università degli Studi di Milano, Italy

ECO36:
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

ENVIRONMENTAL MONITORING AND SELECTION ACTIVITIES 2019

The following Cefic LRI projects were active or initiated during 2019, with the support of the Monitoring Teams and Selection Teams. One project was completed (marked below with #), and three 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 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 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

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 39.2:
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 40.2*:
Investigations on the bioconcentration of xenobiotics in the freshwater amphipod Hyalella azteca and inter-laboratory comparison of a new BCF test protocol (Phase II). [Extension to ECO 40]. 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 46:
Improved aquatic Testing and Assessment of cationic Polymers (iTAP). Principal investigator: Dr. Hans Sanderson, Aarhus University, Denmark

ECO 47:
SNAPFISH "Searching for refiNed in vitro Approaches to Predict bioconcentration in FISH. Principal investigator: Andreas Schäffer, Institute for Environmental Research, RWTH Aachen University.

ECO 48:
Nano2Plast – Extending nanoparticle models to open source models of the fate and transport of microplastic in aquatic systems. Principal investigator: Prof. Matthew MacLeod, Stockholm University, Sweden

ECO 49:
Microplastic Effect Thresholds for Aquatic Species (METAS).. Principal investigator: Prof. Albert Koelmans, Wageningen University, The Netherlands

ECO 50:
Incorporating spatial and seasonal variability in community sensitivity into chemical risk assessment (GETREAL). Principal investigator: Prof. Ralf Schäfer, University of Koblenz-Landau, Germany

ECO 51*:
Strengthening Weight of evidence for FET data to replace acute Fish Toxicity (SWiFT). Principal investigator: Adam Lillicrap, Norwegian Institute for Water Research (NIVA)

ECO 52*:
Bioavailability, complex substances and overall persistence (BCOP): three themes to deliver a step-change in persistence assessments. Principal investigator: Christopher Hughes, Ricardo Energy and Environment

ECO 53*:
A Chemical Categorisation Approach for LRTP Assessment (CC-ALT). Principal investigator: Knut Breivik, Norwegian Institute for Air Research (NILU)

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 2019, the Scientific Committee consisted of the following members:

BENNARD VAN RAVENZWAAY (Chair)
BASF SE

RÉMI BARS
Bayer CropScience

PETER BOOGAARD replaced by **JAN URBANUS**
since November 2019
Shell International

PHIL BOTHAM
Syngenta

TIMOTHY GANT #
University of Surrey

HELMUT GREIM #
Technical University Munich

ANDREAS HÄNER
F. Hoffmann-La Roche

JOOP HERMENS #
University of Utrecht

HELI HOLLNAGEL
Dow Europe GmbH

PHILIPPE LEMAIRE
Total Fluides

LORRAINE MALTBY #
University of Sheffield

MARIE-LOUISE MEISTERS
Corteva

MARK PEMBERTON
Systox Ltd

CARLOS RODRIGUEZ
Procter & Gamble

GORDON SANDERS
Givaudan

GERARD SWAEN #
Maastricht University

KEES VAN LEEUWEN #
KWR Watercycle Research Institute

ERIK VAN MIERT
Solvay SA

JOHANNES TOLLS
Henkel

ROSEMARY ZALESKI replaced by **AARON REDMAN**
since November 2019
ExxonMobil Biomedical Sciences Inc.

.....
External Expert

MEMBERS OF THE SCIENTIFIC COMMITTEE

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.

OLIVIER DE MATOS
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Office Manager

IAN CUMMINGS
Communications, Web and Media Manager

FRANCESCA UGUCCIONI
Administrative Assistant

LISA WINGATE
Administrative Assistant

MEMBERS OF THE SECRETARIAT

FINANCE

INCOME ACTUAL 2019 IN EURO

Subscription	
Full members	1.000.750
Associate members	50.000
Total subscription income	1.050.750
Bank Interest	1
Investment income	0
Project related income	277.821
Exceptional income	0
Total	1.328.572

EXPENDITURE

Salaries and Associated Costs	569.642
Office Running Expenses	181.591
Travel Expenses	14.145
External contractors	226.480
Board, Committees & Annual General Meeting	63.560
Task Forces	177.071
Workshops	116.078
Sponsorships & Awards	7.000
Publications/communication/website	54.949
Professional Services	38.228
Bank Charges	1.850
Capital expenditure	14.590
Miscellaneous & contingency	7.469
Total	1.472.653

BALANCE SHEET AND RESERVES ACTUAL 2018 IN EURO

Balance Sheet	
Income	1.328.572
Expenditure	1.472.653
Operating Margin	-144.081
Reserves	
Opening Reserve	1.902.836
Operating Margin	-144.081
Closing Reserve	1.758.755
Reserve required for Closure	215.000

ABBREVIATIONS

AGM
Annual general meeting

AOP
Adverse outcome pathways

Cefic
European Chemical Industry Council

Chesar
(ECHA) CHEmical Safety Assessment and Reporting tool.

CLP
Classification, Labelling and Packaging

CSA
Chemicals Safety Assessment

DNA
Deoxyribonucleic acid

EAG MST
(OECD) Extended Advisory Group on Molecular Screening and Toxicogenomics

EC
European Commission

ECETOC
European Centre for Ecotoxicology and Toxicology of Chemicals

ECHA
European Chemicals Agency

ED EAG
Endocrine Disrupter Expert Advisory Group to the EU Commission

EDTA
(OECD) Endocrine Disrupters Testing and Assessment Advisory Group

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

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
(US) Society of Toxicology

SVHC
Substance of very high concern

TRA
Targeted risk assessment

UNEP
United Nations Environment Programme

US EPA
Environmental Protection Agency

UVCB
Substances of unknown or variable composition, complex reaction products or biological materials

WHO
World Health Organisation

WoE
Weight-of-evidence

Since 1978 ECETOC has provided 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.

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ECETOC AISBL

Rue Belliard 40
B-1040 Brussels, Belgium
Tel: (32) 2 675 3600
Email: info@ecetoc.org
Website: www.ecetoc.org
VAT: BE 0418344469