



eceloc
WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT
ANNUAL REPORT

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ABOUT ECETOC

A collaborative space for leading scientists from industry, academia and governmental bodies 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.



OUR PURPOSE

ECETOC is the scientific centre for chemical safety assessment.



WHAT WE DO

We provide a collaborative space for leading scientists from industry, academia and governmental bodies 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, governmental bodies 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 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 freely 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

Membership is open to companies engaged in manufacture, processing or use of chemicals or in applied research in the human health and environmental impact of chemicals (see www.ecetoc.org/membership for more details).



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, UN and UNEP.

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 CLP technicalities.

Membership is open to companies engaged in manufacture, processing or use of chemicals or in applied research in the human health and environmental impact of chemicals (see www.ecetoc.org/membership for more details).

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



Telephone: +32 2 675 3600



Email: info@ecetoc.org



Or write to: ECETOC, Rue Belliard 40, 1040 Brussels, Belgium

ECETOC MEMBER COMPANIES

During 2020, the ECETOC Membership comprised the following 30 full Member Companies and 5 Associate Member Companies:

Full members



Associate members



MESSAGE FROM THE CHAIR OF THE BOARD

We are living in unprecedented times, but what gives me hope is our equally unprecedented commitment to the safety of products, as well as our trust in the science that underpins them. Whether it is the safety of disinfectants, hand sanitizers, or vaccines – to name but a few – all of these products have become an integral part of our day-to-day lives.

The global pandemic has also given us an insight into the complexities around the concept of risk, as well as the science that underlies it. Safety and trust have never been more important. Every day, we face questions such as ‘How do I know this vaccine, or product, is safe?’ Or ‘What information can I rely on to guide my decisions and protect my health?’



Dr. **CHANTAL SMULDERS**
Chair of the Board of Administration

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In fact, the scientific information based on evidence is there, but it just isn't reaching enough people. We therefore need to seize the opportunity, even the necessity, to communicate science in a transparent and balanced way. Solid and effective communication about science will help society make informed decisions. And decisions based on trustworthy information will drive better outcomes for society.

Which brings me to ECETOC's mission, which states: 'we work with leading scientists from industry, academia and government bodies to develop and promote trusted and practical scientific solutions which ensure a safe, sustainable and healthy world'.

ECETOC has made enormous progress despite the past year's new and unique challenges and working conditions. I would like to pay tribute to the resilience and perseverance of our ECETOC secretariat and all of our technical contributors in driving through what was a very successful year despite the personal and professional challenges that impacted all of us.

In June 2020, Martin Kayser stepped down from the ECETOC Board, of which he had been a member since 2003 and Chair since 2009. On behalf of the Board, I would like to extend our gratitude and thanks to him for leading ECETOC for the past almost two decades and guiding the organisation to become a strategic and trusted partner in chemical safety science. Martin has always been a strong advocate for science and dialogue and, under his chairmanship, ECETOC strengthened its position as the cross-sectorial scientific organisation with tripartite participation – academia, government and industry. I'd like to wish him all the best in his new role as one of the Executive Committee members of the Alliance to End Plastic Waste, where he can continue to bring a positive contribution, not only to the Alliance but to society at large.

In 2020, ECETOC continued to build on our three broad strategic pillars: visibility, dialogue and impact. The transition from face-to-face workshops and meetings to virtual meetings had the positive consequence that we had more participants than ever, and it is encouraging to see the engagement of so many young scientists from academia, government bodies and industry. The increased visibility with our members and key stakeholders has resulted in a growing membership and a continued constructive dialogue with members and stakeholders, including NGOs, professional organisations, and competent authorities.

I am very grateful to all of our technical experts, who have successfully delivered on our science programme despite the challenging circumstances. More details about the programme are included in this annual report. Major strides

have been made in moving persistence assessments into the 21st century. We have developed new insights and made presentations on persistent, mobile, and toxic chemicals in the context of water resource and environmental protection.

I would also like to highlight our activities on aggregate human exposure data and exposure-based adaptations. Exposure lies at the heart of chemical safety assessments and, by further developing our insight into aggregate human exposures and exposure-based adaptations, we will improve chemical risk assessment while reducing animal testing. The constructive collaboration on these topics between participants representing EU regulatory bodies, national competent authorities, industry, academia and NGOs is very encouraging and demonstrates how we are all committed to achieving science-based solutions.

Through dialogue and collaboration, we learned that, regardless of background and organisation, we all have the common purpose of ensuring the safe use of chemicals and that we share the same challenges in getting there.

In October 2020, the European Commission (EC) published its aspirations for sustainable chemicals in its new 'Chemicals Strategy for Sustainability'. This strategy is part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal. As the expert centre for chemical safety assessment, ECETOC will be actively working on scientific solutions to achieve this transition towards more sustainable chemicals. To that end, we have identified three key themes that will drive our current and future activities. These themes are sustainability, innovation, and education, with science at the centre.

Within the Sustainability theme, we will strengthen our work in areas prioritised by the Chemicals Strategy for Sustainability where we know ECETOC can have a robust contribution, either directly or in partnership with other stakeholders – for example by engaging on the development of a science-based definition of "Sustainability by Design". Sustainable chemistry, risk and exposure will remain of core importance in these activities.

Our Innovation theme will focus on developing integrated approaches to human health safety assessments, including the development and use of improved hazard assessment methods to reduce the need for animal testing. We will further improve and drive progress in chemical safety assessment through targeted activities on innovative methodologies for environmental safety assessment, the digitalisation of data and the use of artificial intelligence.

And our third theme, Education, brings me right back to where I started this message. It is now more important than ever to establish public trust in science. So, not only will ECETOC be offering scientists training in how to communicate their science more effectively, but we will also be focusing on building trust in chemical safety science among society at large.

Chemicals are essential for modern society's high living standards, well-being and comfort. ECETOC, as the centre of expertise for chemical safety science, is here to ensure that society can trust these chemicals, as well as their safe use.

ECETOC will continue to rely on its cross-sectoral collaboration, scientific expertise, and experience to get there. With a dedicated team and the invaluable contributions from many toxicologists, eco-toxicologists, exposure scientists, risk assessors, and communication specialists, we are working harder than ever to continue to develop and promote trusted and practical scientific solutions which ensure a safe, sustainable and healthy world – no matter what disruptions the world may throw at us in future.

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ECETOC 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.

AT THE 2020 ANNUAL GENERAL MEETING:

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

Dr. Melanie Bausen (BASF) was elected to the ECETOC Board.

ECETOC BOARD MEMBERS DURING 2020

MARTIN KAYSER BASF (Chair until April 2020, then guest Board member from April until Annual General Meeting in June 2020)

CHANTAL SMULDERS Shell International (Vice-Chair until Annual General Meeting – then elected Chair of the Board)

MELANIE BAUSEN BASF

LORRAINE FRANCOURT Dow Europe (Treasurer, until December 2020)

PATRICK MASSCHELEYN Procter & Gamble

STEVE MAUND Syngenta Crop Protection

CRAIG NESSEL ExxonMobil Biomedical Sciences

HEIKO RIECK Bayer

VOLKER SOBALLA Evonik Industries



REPORT FROM THE SECRETARY GENERAL

We started the year 2020 with high spirits and high hopes after a remarkably successful 2019. Who could possibly have imagined what the following 12 months would bring?

Despite the unprecedentedly turbulent and challenging year, I am delighted to report that our high hopes were fully justified, for which huge and heartfelt thanks are due to our secretariat, our members, our experts, our Scientific Committee and our Board. Throughout this hugely challenging past year, they have all shown astonishing resilience, innovation and flexibility, so enabling ECETOC to continue operating, if not as normal, at least as effectively as

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OLIVIER DE MATOS
Secretary General

we did before Covid struck. And amazingly, 2020 has ended up being ECETOC's most productive year ever. The pandemic barely put a dent in our ambitious plans.

A brief aside to look at the bigger picture. For ECETOC, undoubtedly the most significant development of the past year has been that the whole world's focus was suddenly on science and scientific research as the only means of rescue from the global pandemic. What became clear is that public understanding of science – and its trust in science – is fundamental to the future wellbeing of our planet. The only way out of this global crisis (and, indeed, future crises waiting in the wings) is through trust in science, collaboration between scientists, and complete transparency about scientific advances. Much of this will be down to us, the scientists. So these must be our guiding principles moving forward.

2020 saw two significant changes to our Board of Administration. It has been a huge pleasure to work with our new chair, Chantal Smulders (Shell), following the departure of Martin Kayser early in the year to a new role at BASF. The Board also improved its gender balance with the arrival of Melanie Bausen from BASF onto our governing body, to whom we extend our warmest welcome.

As an organisation, we continued to make excellent 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', despite the turbulent months our membership has remained stable, with the arrival of the multinational pharmaceutical company MSD as a new member in 2020. The year started out with visits to both Givaudan and L'Oréal. However, once the pandemic took hold in March, all further face to face meetings, including a planned trip to the US, had to be cancelled and were replaced by virtual visits and online meetings.

During 2020, we launched a series of webinars for ECETOC members entitled 'The science of communications for the communication of science', which aimed to improve our collective ability to communicate clearly and effectively – more vital now than ever before. We anticipate launching more webinars to support our members during 2021.

Communication was high on our agenda in 2020, which ended up being a bumper year for ECETOC publications. We published more technical reports, manuscripts and workshop reports than ever before – more even than we had originally planned. In total we released three technical reports, two workshop reports and three manuscripts/articles in scientific journals. The scientific subjects covered in these various publications included: analytical tools, test methods and models for polymer risk assessment; the use of aquatic hazard data for environmental risk assessments in sediments and soil; community-based hazard assessment of mixtures; microbiomes; the ingestion and trophic transfer of microplastic particles; a testing strategy to identify maternal thyroid hormone imbalance and neurodevelopmental effects in the progeny; and the ECETOC NanoApp.

Under our 'Dialogue' strategic pillar, in 2020 we further strengthened our relationships with ECETOC's key stakeholders, including a number of new NGOs. We also continued our excellent interactions with scientific regulators. In particular, we were in constant dialogue with the European Chemicals Agency (ECHA), taking part in its annual meeting with leadership and attending almost all of its Committee for Risk Assessment (RAC) meetings, as well as its Committee for Socio-economic Analysis (SEAC) meetings.

We worked closely with ECHA during 2020 on the development of the ECETOC NanoApp. The new tool was discussed several times with ECHA experts, receiving very positive feedback, as well as featuring in an article in ECHA's newsletter in May.

Following its official launch on 30 November, the app gained 100 users within the first month.

ECETOC also took part in the European Commission's REACH Competent Authorities meetings (CARACAL), sharing our scientific perspective on topics such as polymers.

Under the 'Impact' strategic pillar, our major focus in 2020 was engaging on topics of regulatory relevance for our member companies where science was a fundamental element to support decision makers.

Helping us to stay on the front foot with respect to emerging topics of scientific interest, we now have a highly effective process to identify these well in advance. 'Emerging topics' is a permanent item on the agenda of every Scientific Committee meeting. Our organisation is now more plugged into the regulatory reality and we can therefore spend more time analysing and assessing themes that are important for us to engage with.

The adoption of the EU's new Chemical Strategy for Sustainability in October 2020, which is going to have a major impact on most of our membership, will bring more opportunities for science to make a difference. We will continue to have an increasing involvement in this strategy, as well as providing input on how it will be rolled out.

All the stakeholder interaction outlined above has enabled the Board to adapt our strategic plan going forward. From 2021, our strategy for 'making an impact' will focus around three main themes: Sustainability, Innovation and Education. These will be our drivers for the years to come.

To close, I would like to reiterate my sincere thanks and appreciation to everyone – secretariat, members, experts, Scientific Committee and Board – for all of their amazing support in the past challenging year.

None of the achievements above would have been at all possible without it.

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SCIENCE PROGRAMME

FOREWORD FROM THE SCIENTIFIC COMMITTEE CHAIR

I have very little doubt that, when we look back on 2020, we will recall this year as being extraordinary. In addition to the obvious impact on public health and the European economy, the Covid-19 pandemic has had a profound impact on our social contact and well-being.

ECETOC was therefore lucky to have held its annual review and scoping meetings, jointly with Cefic LRI, in the last week of January 2020. I have not seen almost all the participants at those meetings for more than a year now, and I realize that it may still be many months away before we have the opportunity to see each other again.

Nevertheless, we have all shown great skill in adapting and using some of the treasures that science - including chemistry - have brought us. We were able to continue communicating, planning and ensuring forward progress in what seems to be a virtual world.

Similarly, meetings of the ECETOC Scientific Committee (SC) and the Board were all 'virtual' during 2020. Our flexibility in coping with this very unusual situation has shown us how much we can still achieve, even without meeting in person.

The major drawback of virtual meetings, in my opinion, is the difficulty in fostering a creative atmosphere. It is exactly this feeling of thinking and working together towards a common goal of how to advance the science of risk assessment and all its associated fields that I recall with pleasure at our January event.

This inspiring event set in motion several ECETOC activities



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

which I would briefly like to mention here. Based on the presentations and subsequent discussions during the meeting, as well as the subsequent SC meetings, three activities in the area of human health sciences are currently under preparation.

Remarkably, the initial proposals were made by regulators and non-industry research institutes. This demonstrates two things to me: first, ECETOC is fast becoming a competent and trusted organization for advancing the science of non-members; and second as an organization, we are willing and able to take a good proposal and/or advice and then turn this into concrete action.

The three works streams that were initiated are related to the best use of 'IVIVE (in vitro to in vivo extrapolation) models', the quantitative use of 'omics data for risk assessment and providing guidance for the development of quantitative adverse outcome pathways (qAOP). And what all three have in common is that they are future orientated activities.

Good IVIVE models are necessary for risk assessment using data from in vitro studies. 'Omics data are currently produced mainly to identify hazards, but they are not really used for (quantitative) risk assessment. Finally, although

AOPs are being developed at a good pace, without taking into account quantitative aspects, they are not applicable to risk assessment. So, if we are successful in providing good guidance on these issues, ECETOC will have contributed significantly towards a world where the concept of 'risk in the 21st century' is truly effective.

In a very similar vein, the Task Force on 'exposure-based adaptations' focused on answering the question of how, using exposure-based adaptation, unnecessary animal testing could be reduced while still meeting regulatory requirements. The Task Force workshop was attended by 76 participants, including representatives of EU regulatory bodies, national competent authorities, industry, academia and NGOs. Here is yet another example of how ECETOC provides a tripartite platform for cooperation on scientific issues, with the objective of exploring how to make better use of new technologies and alternative approaches.

In 2020, the 'Transformational Programme' on 'Introducing Environmental Relevance into Environmental Risk Assessment' drew to a close. Two Task Forces working under the auspices of this programme have completed their work, with the publication of two Technical Reports: TR 134 - Sufficiency of aquatic hazard data for environmental risk assessment in sediment and soil, published in April 2020 (ISSN-2079-1526-134); and TR 135 - Exploring community-based environmental hazard assessment of mixtures using mode-of-action based approaches, published in May 2020 (ISSN-2079-1526-135).

The Task Force on 'Geospatial approaches to increasing the ecological relevance of chemical risk assessments' is also in the process of finalising its Technical Report. The common denominator of these task forces is that they all provide an approach into how environmental risk assessments can be carried out with more granularity, taking into account both the complexity of the ecosystems, their resilience and the importance of considering the current status of a particular environmental habitat.

There are increasing public and regulatory concerns over the potential health risks posed by aggregate exposure, i.e. exposure to (the same) substance from multiple sources via multiple routes. The key questions are whether there is truly any basis to consider aggregate exposure and whether the source-by-source approach can identify, or miss, significant risks. The Task Force on 'Mid-tier approach to aggregated exposure assessment', formed in 2020, is building on previous ECETOC work and is exploring suitable

methodologies/tools for a mid-tier aggregate exposure assessment that would determine the key exposure sources for a given substance, or whether a more detailed aggregate assessment would be useful.

The complexity of aggregate exposure to the same substance offers a flavour of the challenges ahead of us, when risk assessment needs to be based on multiple chemicals leading to the same adverse outcome. The qAOP approaches mentioned above would need to be evaluated in the context of multiple pathways affecting a common key

event and combined with the work on aggregate exposure for each chemical in question.

For some people, this may sound far-fetched. However, the EU's Green Deal and its Chemical Strategy for Sustainability are highly likely to go down this path. To avoid overly simplistic solutions, I believe that ECETOC should take on these challenges, bringing together the best scientists from academia, regulatory bodies and industry to ensure that any future legislation takes into account best current practices, as well as stimulating research to improve these.

So far, Europe and a good proportion of the rest of the developed world have been in the comfortable position of focusing on risks, or perceived risks, of chemicals without taking into account their benefits. The insufficient availability of disinfectants at the beginning of the Covid-19 pandemic demonstrated how quickly even chemicals with an unfavorable hazard profile (disinfectants are reactive after all) can become an essential need for society.

In 2020, Secretary General Olivier de Matos and I had another opportunity to present ECETOC's work to a meeting of the leadership of ECHA. Needless to say, our most used and valued tool within the context of REACH - the TRA - was a key subject of our presentations. The Worker TRA Task Force focused its efforts on reviewing the literature and external validation studies of exposure estimations using TRA tool version 3, with the aim of developing a curated database. The Consumer TRA Task Force worked on developing manuscripts relating to infrequent EA, as well as a review of the conservativeness of the TRA consumers' model. The TRA tool was also presented in a webinar to the Chinese risk assessment community. The Environment TRA Task Force continued to provide input to ECHA's EUSES update project.

Of perhaps similar importance to industry and ECHA was the launch of ECETOC's second web application, the NanoApp. This tool has been designed to help industry register nanomaterials under the EU's REACH legislation. The App defines the boundaries of sets of similar nanoforms and then generates a justification for the REACH registration. It uses established criteria and rules that systematically evaluate the similarity between nanoforms and, on that basis, concludes whether a set of nanoforms can be justified or not. Its decision logic follows the ECHA guidance in a transparent and evidence-based manner. It may serve to provide more uniformly structured dossiers to ECHA while also reducing the need for animal tests. Therefore, this activity, too, follows the common denominator of ECETOC's mission of providing solid science while reducing unnecessary burdens and, in particular, unnecessary animal testing.

In 2019, ECETOC's Polymer Task Force published the Conceptual Framework for Polymer Risk Assessment (TR 133-1). At the heart of this framework, you will find a concept and methodology which is quite similar to that of the NanoApp: (1) problem formulation (RA scope and protection goal definition); (2) identification/characterization of the test substance; (3) grouping approach evaluation; (4) hazard identification; (5) determination of exposure scenarios; and (6) risk assessment and characterization.

The Polymer Task Force continued its work during 2020,

publishing TR 133-2 - Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment. And later this year, it anticipates publishing a third report (TR 133-3), in the form of a series of case studies putting the framework into practice.

Although providing good scientific content should remain our core activity, getting things done at the right time is nearly as important - and in this respect we also got it right. The opportunity arose for ECETOC to contribute to the recently established CARACAL sub-group on Polymers. Here we could discuss the outcomes of the report prepared for the European Commission on The proposed activities presented at the meetings have since been further considered by the ECETOC Scientific Committee and the Cefic LRI Issue Team in terms of progression as ECETOC activities and/or Cefic LRI research projects. and review the criteria for identifying Polymers Requiring Registration.

ECETOC has limited resources, and these are unlikely to increase in the future, so selecting the issues that matter most will remain essential for our future (effectiveness). Providing high quality work at the precise time it is needed is the next level of magic (efficiency). With both the NanoApp and the Polymer Risk Assessment framework, we have shown that we are not only able and willing, but indeed capable of doing that!

I have been incredibly impressed at how ECETOC's activities have continued unabated during these times when it has been impossible to meet in person. It demonstrates our strength and our belief in our work as a science organization improving the quality of risk assessment. Taking into account the challenges that lie ahead of us, I very much hope we will be able to meet in person once again in the relatively near future, because we will need a lot of creativity to ensure that, in helping to shape the future of chemical regulations under the umbrella of sustainability, practicable science-based solutions prevail.

2020 AREAS OF WORK

GETTING STARTED: ECETOC AND CEFIC LRI 2020 SCOPING MEETINGS FOR ENVIRONMENTAL SCIENCES AND HUMAN HEALTH AND EXPOSURE SCIENCES

28-29 January 2020 (Environment) and 30-31 January 2020 (Human Health and Exposure), Brussels

The ECETOC and Cefic LRI 2020 Scoping Meetings enable ECETOC and Cefic LRI to prioritise their activities and scientific research for the coming years. They were each attended by approximately 60 invited participants from Europe and North America, representing ECETOC and Cefic member companies, academia, regulators, and consultancies.

The scoping meetings consisted of a series of five-minute 'elevator pitches' for new projects or research, which were then discussed and refined in separate sessions and finally voted on by participants.

The proposed activities presented at the meetings have since been further considered by the ECETOC Scientific Committee and the Cefic LRI Issue Team in terms of progression as ECETOC activities and/or Cefic LRI research projects.

The meeting reports and all presentation slides can be seen at the following links:

- Environmental Sciences Scoping meeting ([link here](#))
- Human Health and Exposure Sciences Scoping meeting ([link here](#))



LEGENDA / ICON SET

Please find below a few icons that will mark a few key topics in this article.



▶ Meeting



▶ Webinar



▶ Task Force



▶ Report / Publication



▶ Transformational Programme



▶ Tool

ENVIRONMENTAL RELEVANCE IN RISK ASSESSMENT

As the Transformational Programme on 'Introducing Environmental Relevance into Environmental Risk Assessment' draws to a close, two Task Forces working under this programme have completed their work with the publication of the following two Technical Reports:

TR 134: Sufficiency of aquatic hazard data for environmental risk assessment in sediment and soil was published online in April 2020 (ISSN-2079-1526-134)

TR 135: Exploring community-based environmental hazard assessment of mixtures using mode-of-action based approaches was published online in May 2020 (ISSN-2079-1526-135)

A third Task Force on 'Geospatial approaches to increasing the ecological relevance of chemical risk assessments' is in the process of finalising its Technical Report.

EXPOSURE

The Task Force on 'Exposure-based adaptations' focused its 2020 activities on the preparation of a joint online workshop to explore the scientific feasibility of exposure-based adaptations in the regulatory setting. The workshop, on 14 October 2020, was organized with the European petroleum refineries association, Concawe, and the European Partnership for Alternative Approaches to Animal Testing (EPAA). It was attended by 76 participants including representatives of EU regulatory bodies, national competent authorities, industry, academia and NGOs.

The event discussed how using exposure-based adaptation could reduce unnecessary animal testing to meet regulatory requirements. It also assessed the potential barriers and pitfalls to this approach, as well as how to devise acceptance criteria for exposure and toxicity data expected in exposure-based adaptation.

The workshop was split into three main sessions:

- Setting the scene for the regulatory basis for and experience with exposure-based adaptations
- Providing the analysis of the existing provisions for exposure-based adaptations
- Providing a proposal for modifying the 'risk-based' exposure-based adaptation and breakout groups to discuss the proposal

The outcome of the workshop will be part of a consolidated ECETOC technical report which will form the basis for future scientific and advocacy work around the use of exposure-based adaptations to meet regulatory requirements. The report is expected to be published in the first quarter of 2021.

The Task Force objectives are relevant in the context of the wider ECETOC Human Health Transformational Programme.

The Task Force on 'Mid-tier approach to aggregated exposure assessment', formed in 2020, intends to build on previous ECETOC work and explore suitable methodologies/tools for a mid-tier aggregate exposure assessment (AEA) that would determine the key exposure sources for a given substance, or whether a more detailed aggregate assessment would be useful.



There are increasing public and regulatory concerns regarding potential health risks posed by aggregate exposure, i.e. exposure to (the same) substance from multiple sources via multiple routes. The key questions are whether there is indeed any basis for consideration for aggregate exposure, whether the source-by-source approach can identify or miss significant risks to the environment and human health, and if so, when and by how much. Additional concerns relate to the fact that a substance and its diverse uses can be regulated under different legislations; the question is then how potentially identified risks from aggregate exposure could be best managed when the key exposure sources fall under different regulatory regimes.

Currently, these questions are addressed by following a tiered approach to aggregate exposure assessment (AEA). However, work undertaken in 2016 by the ECETOC TF on Effective Use of Human Exposure Data revealed that meaningful aggregate (consumer) exposure assessment is only possible with high tier approaches that rely on detailed (distributional) exposure factors data.

The new Task Force therefore identified the following objectives:

- Explore suitable methodologies/tools for a mid-tier AEA
 - Estimate reasonable worst-case or realistic AE
 - Criteria for the need and scope of a more detailed assessment
- Address the complexities/uncertainties stemming from combination of different exposure assessment methods/tools, multiple lines of evidence and independent sources of information
- Widen scope to products beyond cosmetics and food (e.g. household and DIY products, articles), investigate methodologies applicable to both consumers and workers

The Task Force will aim to deliver the following:

- A systematic evaluation of AEA methods, including comparative assessment of advanced mid-tier techniques vs the first-choice low-tier additive and high tier (probabilistic person-oriented) approaches
- A framework for advanced/refined aggregate exposure assessment and practical recommendations for its application in the regulatory context
- A peer-reviewed manuscript explaining the framework and demonstrating its utility and efficiency
- A dedicated workshop for results dissemination and technical advocacy

The new Task Force's work is expected to last between 24-30 months, finishing by the end of 2022.

INTEGRATED APPROACH FOR CHEMICALS ASSESSMENT

The ECETOC Transformational Programme to develop an Integrated Approach for Chemicals Assessment aims to increase the efficiency of the EU's current system for assessing hazard and exposure, as well as the current rules for classification and risk characterisation.



The evolution of the EU's chemical assessment process aims to allow more chemicals and more uses to be evaluated with confidence within the current total resource from regulators and registrants. The new processes will operate within the existing frameworks, including current classification and labelling, as well as allowing the assessment of concurrent and sequential exposure. Lastly, this will allow advances in scientific knowledge and methodology to be used.

The Programme is developing and promoting a framework based on integrating different sources of information in an objective way to provide sufficient weight of evidence to make assessments with confidence. This will benefit society by protecting human health through understanding the impact of more chemicals, singly or together; by using fewer animals in testing; by harvesting the dividends of society's investment in new methods; and by building on heritage data.

The work is scientifically based, finding objective ways to weigh the evidence so allowing new scientific insights to be used. It is also legally based, working within the current legal framework. And it works with stakeholders to develop and implement the framework in a cooperative and stepwise manner.

The **'Special T4' Task Force** continued to work in 2020 towards a science-based testing strategy to identify maternal thyroid hormone imbalances and neurodevelopmental effects in the progeny. Its work is split into four streams, each having their associated manuscripts.

The manuscript for the first workstream, **Part I: Which parameters from human studies are most relevant for toxicological assessments?** was published in December in the journal Critical Reviews in Toxicology.

A second manuscript, entitled Part II: How can key events of relevant adverse outcome pathways be addressed in toxicological assessments? was also submitted to Critical Reviews in Toxicology at the end of the year.

Two further manuscripts, Part III: Finding evidence from rodent studies on (1) (mechanisms of) effects caused by different substances; and (2) specific adverse outcomes? and Part IV: A tiered testing strategy are both still under development, with expected publication dates in the first half of 2021.

IN VITRO TO IN VIVO EXTRAPOLATION (IVIVE)

Following up on the proposal for Generic models for quantitative in vitro to in vivo extrapolation (QIVIVE), presented during the 2020 Scoping Meeting, the ECETOC Scientific Committee has given its support to organising a workshop in 2021.

The objective of this workshop will be to address the following:

- Review existing (prototype) QIVIVE strategies that provide structures and elements useful as building blocks for kinetic models;
- Provide a QIVIVE guidance paper by defining essential and sensitive components of existing kinetic models and for combining them into preferred models; and
- Define a guidance for incorporation of QIVIVE into IATA and regulatory hazard and risk assessment.

The workshop's main target audience is the scientific community (both public and private), that needs to review existing QIVIVE work and define essential elements of an approach

that could be agreed as a standard for regulatory chemical safety assessment. A secondary audience is regulators, as the goal is that these innovative approaches are accepted and implemented into the regulations. Industrial stakeholders are of interest as well.

The workshop deliverables are:

- Developing guidance for the incorporation of QIVIVE into Integrated Approaches to Testing and Assessment (IATA) and regulatory hazard and risk assessment of chemicals, including:
 - Guidance on the use of Physiologically based toxicokinetics (PBTK) models for estimating internal dose in target tissues; and
 - Guidance on translating nominal concentration (assumed to be the internal dose in the target tissue) into effective concentration in the in vitro model.
- Producing a workshop report describing its proceedings including agenda, presentations, discussions and conclusions, as well as the identification of possible research needs.

The guidance and workshop report should be ready for submission in the open scientific literature within six months of the workshop.

The organising committee held a kick-off discussion in October 2020.



MICROPLASTICS

The ECETOC Microplastics Scientific Platform, whose members include representatives from ECETOC, Cefic LRI, Cefic Microplastics Issue Team and PlasticsEurope, continued to meet and liaise on current and planned activities during 2019 and into 2020.

The following open access critical review paper was prepared for and reviewed by the Scientific Platform, and was published in March 2020: Gouin T (2020) ‘Toward an Improved Understanding of the Ingestion and Trophic Transfer of Microplastic Particles: Critical Review and Implications for Future Research’.

Environmental Toxicology and Chemistry 3(6): 1119–1137 <https://doi.org/10.1002/etc.4718>



OMICS TECHNOLOGY

The Data from omics technologies - point of departure for adverse and non-adverse effects workshop proposal presented during the 2020 Scoping Meeting was endorsed by the ECETOC Scientific Committee.

Omics methods allow a wide and comprehensive characterisation of cellular, tissue or organism responses to external stimuli. These methods contribute to a better understanding of cellular or organ responses to toxicants.

The amount of ‘omics data’ being produced is increasing fast. There are currently no criteria to establish adverseness of omics response data. Therefore, it is difficult to integrate omics data into a quantitative risk assessment.

An ECETOC workshop therefore aims to determine the best method(s) to identify ‘point of departure’, taking into account random noise, and to find criteria / methods to distinguish between adverse and non-adverse responses. To do so, a mix of regulators, industry and academia attendees will be invited to share their experience.

The workshop will increase understanding of what constitutes toxicologically relevant marker sets, as well as increase the acceptance and use of omics data for risk assessment purposes in a quantitative way.

The kick-off discussion of the workshop’s organising committee took place in November 2020.



PARTICULATE MATERIAL

An Expert Group on ‘Strategies to overcome challenges in aquatic testing of particulate material’ has been established to develop a white paper which describes the current status of particulate material testing approaches; identifies challenges when following these approaches; and develops a testing strategy to overcome these challenges.

The Expert Group held a preliminary meeting in September and plans to hold a full kick-off meeting before the end of 2020.



PERSISTENCE AND PERSISTENT/MOBILE SUBSTANCES

The Task Force **'Moving persistence (P) assessments into the 21st Century'** started work in July 2019 and continued to work throughout 2020.

Two manuscripts have been drafted for submission in January 2021: 'Conceptual framework for moving persistence (P) assessments into the 21st Century' and 'Scientific concepts and methods for moving persistence (P) assessments into the 21st Century'.

The ECHA PBT Expert Group was invited to review the two manuscripts in October and November 2020 and to provide feedback to the Task Force.

The Task Force also organised a **webinar** on 29 September 2020 to share their work and gather feedback from key stakeholders. The participants at the webinar included 25 academics, 37 consultants, 156 industry representatives, 35 regulators and 11 others.

Earlier in the year, the Task Force also presented their interim findings at **SETAC Europe 30th Annual Meeting** (SETAC SciCon) 'Open Science for Enhanced Global Environmental Protection' in May 2020. This included:

- a platform presentation by Aaron Redman (ExxonMobil) on 'Moving persistence (P) assessments into the 21st Century: Developing a new paradigm to assess degradation potential of chemicals'
- a poster presentation 'Scientific concepts and methods for moving persistence (P) assessments into the 21st Century'
- a poster presentation 'Conceptual framework for moving persistence (P) assessments into the 21st Century'

Discussions amongst stakeholders on how to manage persistent and mobile substances to ensure protection of drinking water has continued throughout 2020. The 'Persistent chemicals and water resources protection' Task Force was launched in 2019 and has continued its work throughout 2020.

The Task Force is in the process of finalising a Technical Report which is expected to be published in Q1/Q2 2021. The report includes an assessment of the currently proposed Persistent, Mobile, Toxic (PMT) criteria and a review of exposure and risk assessment tools currently applied. The report proposes a tiered approach to assess drinking water safety.

The interim work of the Task Force was shared at the following events:

- Norman/UFZ workshop 'Persistent, Mobile and Toxic Substances: A challenge for analytical chemistry and water quality control', in January 2020, which included:
 - a platform presentation by Sascha Pawlowski (BASF) on 'Persistent chemicals and water resources protection: Conclusions from the ECETOC Task Force'
 - a poster presentation 'Review of predictive risk assessment approaches for the transport of chemicals to groundwater'
- SETAC Europe 30th Annual Meeting (SETAC SciCon) 'Open Science for Enhanced Global Environmental Protection', in May 2020, which included:



- a platform presentation by Sascha Pawlowski (BASF) on 'Persistent chemicals and water resources protection: Conclusions from the ECETOC Task Force'
- a poster presentation 'Necessity of Joint Consideration of Persistence and Mobility for Determining the Leaching Potential of Chemicals'
- a poster presentation 'Review of monitoring data and critical evaluation of proposed P/vP and M/vM criteria'
- a poster presentation 'Consideration of Relevant Metabolites in the Context of the PMT Concept and Protection of Water Resources'
- a poster presentation 'Review of predictive risk assessment approaches for the transport of chemicals to groundwater'

POLYMERS

The Task Force 'Assessing the human health and environmental safety of polymers' continued its momentous work on this broad-scope topic during 2020, publishing a Technical Report in March 2020 which followed up the Conceptual Framework for Polymer Risk Assessment (CF4Polymers; ECETOC TR No. 133-1) that it had published last year.

TR 133-2: Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment was published online in March 2020 (ISSN-2079-1526-133-2).

The Task Force then continued its work on the third report of the trilogy (TR 133-3) which will provide a series of case studies putting the TR 133-1 CF4Polymers and TR 133-2 into practice. TR 133-3 is anticipated for publication in September 2021.

The Task Force's work remains highly relevant, in particular in relation to the European Commission's continued activity to assess the need to register certain types of polymers under REACH. In this context, the opportunity also arose for ECETOC to contribute to the recently established CARACAL sub-group on Polymers (CASG-Polymers).

Olivier de Matos, accompanied by Task Force Stewards Mark Pemberton (Systox) and Gordon Sanders (Givaudan), participated in the first and second meetings of this sub-group on 11 September and 16 December 2020.

The main objectives of these meetings were to discuss the outcomes of the report prepared for the Commission on 'Scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment', as well as review the criteria for identifying Polymers Requiring Registration (PRR).

Prior to the September meeting, the Polymers Task Force had prepared and submitted to CARACAL a spreadsheet of detailed comments on the Commission's report, accompanied by an executive summary containing general comments on key issues.



REGISTRATION OF CHEMICALS UNDER REACH

NanoApp

ECETOC formally launched its keenly-awaited new NanoApp on 30 November this year. The web-based tool has been designed to help industry register nanomaterials under the EU's REACH legislation. The app was developed by a team consisting of BASF in Germany, Leitat in Spain and ThinkWorks in the Netherlands.

The Commission Regulation ((EU) 2018/1881), of 3 December 2018, introduced the obligation for manufacturers to register nanoforms of a substance under REACH from 1 January 2020.

The App defines the boundaries of sets of similar nanoforms and then generates a justification for the REACH registration. It uses established criteria and rules that systematically evaluate similarity between nanoforms and, on that basis, concludes whether a set of nanoforms can be justified or not. Its decision logic follows the ECHA guidance in a transparent and evidence-based manner. The App covers primarily the ['Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification'](#).

The NanoApp was developed by a core team comprising BASF in Germany, Leitat in Spain and ThinkWorks in The Netherlands. The decision logic, the methods and cut-offs used by the tool were all discussed with industry, in particular members of the former ECETOC Nano task force, the academic and regulatory partners of the EU-funded research project GRACIOUS and the Nanotechnology Industries Association (NIA).

Following the development of a beta-version, the App was provided to ECHA in February for testing and to review the rationales for the methods and cut-offs used by the tool. Details on the rationale and decision rules used by the ECETOC NanoApp can be found at Janer et al, Nanotoxicology (2020) [DOI:10.1080/17435390.2020.1842933](#).

Within the first 2 weeks of the launch, over 80 people requested to use the tool and over 30 of them participated in the first users training webinar organised on 10 December.

Targeted Risk Assessment

Three parallel Task Forces (Workers, Consumers and Environment) continued their work throughout 2020 to bring the TRA tool in line with the current regulatory requirements.

The Worker Targeted Risk Assessment Task Force focused its efforts in 2020 on the review of literature and external validation studies on exposure estimations using TRA tool version 3 with the aim of developing a curated database. A technical report to summarise its findings and propose improvements to the tool is expected to be published in the first quarter of 2021.

A summary of the current developments of the Task Force was published in the International Journal of Environmental Research and Public Health ([Int. J. Environ. Res. Public Health 2020, 17\(22\), 8443](#)).

The Consumer Targeted Risk Assessment Task Force's work in 2020 focused on the developments of two manuscripts: Publication on infrequent EA and Review of conservativeness of TRA consumers' model. Both publications are expected to be released in the first half of 2021.

In parallel, the Task Force was asked to present the TRA tool to the SOT Chinese community

via a webinar organised in June 2020. The Chinese SOT expressed interest in adapting the TRA tool to Chinese parameters, following a similar exercise by the Japanese and Korean local teams.

The Environment Targeted Risk Assessment Task Force continued to provide input to ECHA's EUSES update project. In parallel, the Task Force is also exploring a potential need to update the models for assessment of humans exposed via the environment.



COMMUNICATING SCIENCE

Communicating and disseminating scientific knowledge, both to its members as well as to external audiences, is at the core of ECETOC's raison d'être. Writing and publishing scientific papers, organising webinars and workshops, and creating useful tools for industry and regulators are an integral part of ECETOC's work every year.

HeatDB

ECETOC's Human Exposure Assessment Tools Database (heatDB), was enhanced with new data and tools during 2020 as part of its annual update. The latest update covers the period from June 2018, where the previous heatDB update stopped, until the end of 2019. It added 19 new data sources and six new tools, bringing the database totals to 252 data sources and 52 tools. Future updates will aim to be synchronised with the calendar year.

heatDB is a resource for risk assessors to use to search and locate human exposure tools and data available in the public domain. Available sources of exposure data have been gathered, structured and categorised into a harmonised system.

In 2020, the ECETOC secretariat also started to analyse the tool's use by members and to identify potential improvements that can be made.

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>

Communications webinar series

During 2020, a series of three webinars on 'Applying the science of communication to the communication of science' were developed and delivered to ECETOC members. The webinars, in February, March and June 2020, were delivered by Dennis Landsbert-Noon (Panda Communications, Brussels) and aimed to give members – particularly scientific experts – the tools and know-how to communicate their science and science stories better.



They explained how to inject passion and eloquence into scientific communication, bringing it to life by making it both compelling and memorable, all the while still ensuring the science remains accurate and rigorous.



Environmental science awards

During the SETAC Europe 30th Annual Meeting (SETAC SciCon), held virtually from 3–7 May 2020, young scientists competed for the Young Scientist Awards, sponsored by ECETOC and SETAC Europe, which recognises the best poster and the best platform presentation of the year.

The Best Platform Award was presented to Eldbjørg B. Veia, from the Technical University of Denmark, for her presentation "Framework to Define Environmental Sustainability Boundaries" (full report available [here](#)).



I am proud and happy to be awarded the YSA for my platform presentation. As a young scientist, I sometimes doubt my abilities to contribute to my research field, so it meant a lot to me to be recognized with this award



ELDBJØRG B. VEA
Winner of the "Best Platform Award"
at SETAC SciCon 2020



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.

ECETOC provides scientific support to the Cefic LRI as follows:

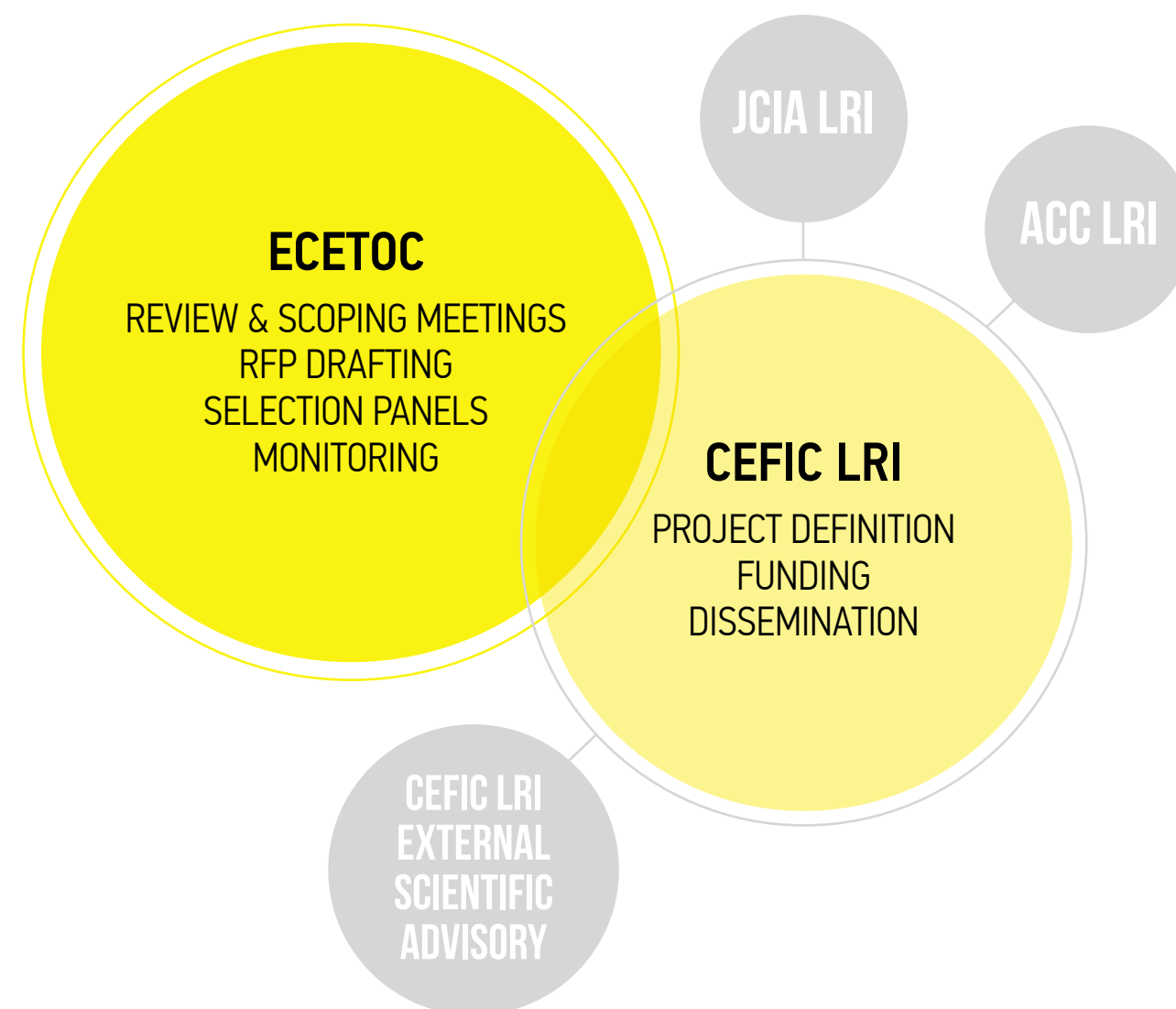
Organisation of joint ECETOC/Cefic LRI biennial scoping meetings to scope topics for further consideration as new projects by the Cefic LRI Issue Team (IT);

Drafting of 'requests for proposals' (RfPs) for new projects prioritised by the Cefic LRI IT;

Establishment and coordination of selection panels to review the research proposals submitted in response to published RfPs and make recommendations to the Cefic LRI IT concerning the funding of the proposals;

Establishment of monitoring teams to act as a discussion partner with the research teams and support Cefic LRI in the monitoring of project progress.

Information on the Cefic LRI projects active or initiated during 2020 is set out below.



HUMAN HEALTH AND EXPOSURE PROJECTS ACTIVE OR INITIATED DURING 2020

The following Cefic LRI projects were active or initiated during 2020, with the support of the ECETOC Monitoring Teams and Selection Teams.

Projects completed during 2020 are marked below with ►. Projects for which funding was secured and that will start in 2021 are marked as ●.

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.

AIMT11 ●

Expansion of a regulatory accepted in vitro testing battery for developmental neurotoxicity evaluation. Principal investigator: Dr Ellen Fritsche, IUF Leibniz Research Institute, Dusseldorf, DE.

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.

B12.4

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

B15.3Ext ●

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.

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.

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. Jorg Hackermuller, 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.

C9 ●

Mining the developmental toxicity biomarker genome in the zebrafish embryo test. Principal investigator: Dr Sylvia Escher, Institute ITEM, Hannover, DE.

EMSG 59

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

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.

EC036 ►

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 PROJECTS ACTIVE OR INITIATED DURING 2020

The following Cefic LRI projects were active or initiated during 2020, with the support of the ECETOC Monitoring Teams and Selection Teams.

Projects completed during 2020 are marked below with ►. Projects for which funding was secured and that will start in 2021 are marked as ●.

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 3 I]. 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.

ECO 37 ►

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, DK

ECO 39.2 ►

Development of user-friendly, robust GUT S 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 *Hyaella azteca* and inter-laboratory comparison of a new BCF test protocol (Phase 11). [Extension to ECO 40]. Principal investigator: Prof. Dr. Christian Schlechtriem, Fraunhofer IME, Germany.

ECO 41

Improved characterisation of partitioning and biotransformation for screening organic compounds for the potential to bioaccumulate in air-breathing 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 44.2

Integrating Bioaccumulation Assessment Tools for Mammals (iBAT-Mam) –Principal Investigator; Jon Arnot, ARC Arnot Research and Consulting, CA

ECO 45 ►

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

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: Dr. Andreas Schaffer; 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 (GET REAL). Principal investigator: Prof. Ralf Schafer, University of Koblenz-Landau, Germany.

ECO 51

Strengthening Weight of evidence for FET data to replace acute Fish Toxicity (SWIFT). Principal investigator: Dr 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 LRT P Assessment (CC-ALT). Principal investigator: Prof. Knut Breivik, Norwegian Institute for Air Research (NILU)

ECO 54 ●

Next generation risk assessment methods for substances associated with mobility concerns. Principal investigator: Dr Li Li, University of Nevada, NV, US

ECO 55 ●

Impact of Sample Collection on Microbial Population and Validity Criteria in the OECD 309 Surface Water Mineralisation Test. Principal investigator: Dr Odd Gunnar Brakstad, SINTEF Ocean AS, Oslo, NO.

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 2020, the Scientific Committee consisted of the following members:

Ben van Ravenzwaay - *Chair*

Rémi Bars

Phil Botham

Timothy Gant*

BASF

Bayer CropScience

Syngenta

King's College London

Helmut Greim*

Andreas Häner

Joop Hermens*

Heli Hollnagel

Philippe Lemaire

Lorraine Maltby*

Lo Meisters

Mark Pemberton*

Aaron Redman

Carlos Rodriguez

Gordon Sanders

Gerard Swaen*

Johannes Tolls

Jan Urbanus

Kees van Leeuwen*

Erik van Miert

Technical University Munich

F. Hoffmann-La Roche

University of Utrecht (until November 2020)

Dow Europe

Total Fluides

University of Sheffield

Corteva Agrisciences

Systox Limited

ExxonMobil Petroleum and Chemical

Procter & Gamble

Givaudan International

Maastricht University (until July 2020)

Henkel

Shell Health

KWR Water Research Institute

Solvay

**external experts*



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.

OLIVIER DE MATOS — Secretary General

ALICE BROUSSE — Human Health Sciences Manager

ANDREEA CUCIUREANU — Human Health Sciences Manager

GENEVIÈVE GÉRITS — Office Manager

ANDREA SALVADORI — External Relations Manager (from September 2020)

FRANCESCA UGUCCIONI — Administrative Assistant

VIRGINIE VAN DER STEEG — Administrative Assistant (from June 2020)

LUCY WILMOT — Environmental Sciences Manager

LISA WINGATE — Administrative Assistant (until July 2020)



FINANCE

INCOME ACTUAL 2020 IN EURO

Subscription	
Full members	1.035.000
Associate members	50.000
Total subscription income	1.085.000
Bank Interest	-4.636
Investment income	0
Project related income	299.887
Exceptional income	63.249
Total	1.443.500

EXPENDITURE ACTUAL 2020 IN EURO

Salaries and Associated Costs	640.396
Office Running Expenses	148.686
Travel Expenses	5.228
External contractors	291.783
Board, Committees & Annual General Meeting	33.668
Task Forces	182.850
Workshops	48.003
Sponsorships & Awards	10.020
Publications/communication/website	68.071
Professional Services	44.711
Bank Charges	2.732
Capital expenditure	13.754
Miscellaneous & contingency	16.407
Total	1.506.309

BALANCE SHEET AND RESERVES ACTUAL 2020 IN EURO

Balance Sheet	1.443.500
Income	1.506.309
Expenditure	-62.809
Operating Margin	

Reserves	Reserves
Opening Reserve	1.758.755
Operating Margin	-62.809
Closing Reserve	1.695.946
Reserve required for Closure	251.324



ABBREVIATIONS

AEA

Aggregated Exposure Assessment

AGM

Annual general meeting

AOP

Adverse Outcome Pathways

CARACAL

(EC) Competent Authorities for REACH and CLP

Cefic

European Chemical Industry Council

Chesar

(ECHA) Chemical Safety Assessment and Reporting tool.

CLP

Classification, Labelling and Packaging

CSA

Chemicals Safety Assessment

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

EPAA

European Partnership for Alternative Approaches to Animal Testing

EU

European Union

EUROTOX

Association of European Toxicologists and European Societies of Toxicology

EUSES

European Union System for the Evaluation of Substances

FDA

(US) Food and Drug Administration

GLP

Good Laboratory Practice

heatDB

ECETOC Human Exposure Assessment Tools Database

IATA

Integrated Approaches to Testing and Assessment

IPCS

International Programme on Chemical Safety

IR&CSA

(ECHA Guidance on) Information Requirements and Chemical Safety Assessment)

IVIVE

In vitro to in vivo extrapolation

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

NGO

Non-Governmental Organisation

OECD
Organisation for Economic Co-operation and Development

PBT
Persistent, Bioaccumulative Toxic

PBTK
Physiologically based toxicokinetics

PEG
(ECHA) Partner Expert Group

PMT
Persistent, Mobile, Toxic

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

qAOP
quantitative Adverse Outcome Pathways

QIVIVE
Quantitative in vitro to in vivo extrapolation

SC
(ECETOC) Scientific Committee

SEAC
(ECHA) Committee for Socio-Economic Analysis

SETAC
Society of Environmental Toxicology and Chemistry

SIG
(Cefic Long-range Research Initiative) strategy implementation group

SOT
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

RIVM
The Dutch National Institute for Public Health and the Environment

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THANK YOU FOR READING!

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