







04 ABOUT ECETOC

Our Purpose What We Do Our Values Our Structure Our Financing

MEMBERSHIP 06

8 ECETOC Member Companies

- MESSAGE FROM THE CHAIR OF THE BOARD 10
- **BOARD OF ADMINISTRATION** 14
- **REPORT FROM THE SECRETARY GENERAL** 16

SCIENCE PROGRAMME 20

20 Foreword from the Scientific Committee Chair 24 2020 areas of work 24 ECETOC review meeting 'Towards chemical sustainability - putting the EU Strategy into action'

- 26 Endocrine disruption
- 26 Exposure
- 26 Integrated approach for chemicals assessment
- 28 In vitro to in vivo extrapolation (IVIVE)
- 28 Omics technologies
- 28 qAOP
- 29 Particulate Material
- 29 Persistence and persistent/mobile substances 30 Polymers
- 30 Registration of chemicals under REACH
- 31 Communicating Science
- 32 Science Awards

34 CONTRIBUTION TO CEFIC LONG-RANGE RESEARCH INITIATIVE

36 Human Health and Exposure projects active or initiated during 2020 37 Environmental projects active or initiated during 2020

- MEMBERS OF THE SCIENTIFIC COMMITTEE 40
- **MEMBERS OF THE SECRETARIAT** 42
- FINANCE 44
- 46 **ABBREVIATIONS**

ABOUT ECETOC

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.

OUR PURPOSE

ECETOC is the scientific centre for chemical safety assessment.

WHAT WE DO

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

We shape scientific knowledge

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

We expand scientific knowledge

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

We communicate scientific knowledge

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



OUR VALUES

Scientific excellence

We engage top scientists from industry, academia and governments.

Science for the public good.

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

Collaboration

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

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.







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

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

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.

WHO and OFCD.

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 CLH technicalities.

To apply for membership, contact the ECETOC Secretariat:

Email: info@ecetoc.org \bowtie

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

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

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).

Telephone: +32 2 675 3600

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

ECETOC MEMBER COMPANIES

During 2021, the ECETOC Membership comprised the following 30 full Member Companies and 5 Associate Member Companies:

equinor Henkel Honeywell Lubrizol **MSD** $\mathbf{\Theta}$



TOTAL



















Associate members

syngenta







L'ORÉAL[®]



Enriching lives through innovation

lyondellbasell Merck ohnson wax Roche

SUMITOMO CHEMICAL











MESSAGE FROM THE CHAIR **OF THE** BOARD

ooking back on 2021 it has been the most unusual. challenging yet rewarding year for ECETOC, characterized by collaborative delivery of science, change, and an optimistic outlook for the future.

Dr. CHANTAL SMULDERS Chair of the Board of Administration

COLLABORATIVE DELIVERY **SCIENCE**

The pandemic remained with us throughout 2021, and most All of the activities, whether virtual meetings, workshops, of us therefore spent our time working from home offices. However, the necessity of virtual working turned into an publications, or reports, could not have been delivered without the excellent work of the team in Brussels. I would opportunity for ECETOC, as our virtual meetings attracted like to thank the ECETOC team, as well as the science an unprecedented number of participants, with very diverse consultants for all their efforts and energy in organizing the backgrounds. I am thankful to all of the technical experts meetings and in keeping the organization running smoothly, who have delivered on our science agenda. This report despite not being able to go into the office. Special thanks provides an overview of all our activities, but I would like to goes to our Secretary General Olivier de Matos, who has highlight a few in particular. led the ECETOC organization throughout these challenging The first of these is the ECETOC review meeting 'Towards' times.

chemical sustainability - putting the EU Strategy into action', held on 14 April 2021. This event aimed to identify CHANGE key aspects of putting the EU Chemicals Strategy for Sustainability (CSS) strategy into action and how ECETOC's And this brings me to 'change'. It was with mixed emotions work could support its implementation. The CSS is an that we said farewell to Olivier as Secretary General at the ambitious strategy describing how the EU intends to move end of 2021. On behalf of the entire ECETOC Board, I would to safe and sustainable chemicals and its goals can only be like to thank him for leading ECETOC and establishing the met if all parties work together in collaboration. Successful organization as a credible, scientific organisation, engaging execution of the strategy requires the development of in constructive dialogue with our stakeholders in academia, innovative chemical safety assessment tools, building on industry, regulators and competent authorities. Olivier has the collective scientific knowledge of academia, industry and moved ECETOC forward as a constructive discussion partner, government institutes. The development, implementation, with a clear mission and vision. His leadership has resulted and regulatory acceptance of these New Approach Methods in ECETOC carrying out many more activities, gaining many (NAMs) is needed to enable better safety assessments and more new members, and delivering an incredible number to move away from animal testing. The scientific community of publications and tools. In addition to all this, he has also is making great strides but more is needed, such as the been a caring leader of the team in Brussels and so has development of NAMs for classification and labelling nurtured a fantastic and diverse secretariat. I'd like to wish (building on the success of NAMs for the skin sensitization him all the very best in his new role as Director General at endpoint). My own takeaway from this review meeting was Croplife Europe, where I am certain he will continue to have that not only the scientific community, but regulators too, a positive impact on bringing forward safe products that are keen to collaborate to make the CSS a success for all benefit society. stakeholders.

Then, with great pleasure and on behalf of the Board, I would Another highlight of 2021 was the publication of the third also like to welcome Blanca Serrano Ramón as our new report by the Task Force 'Assessing the human health and ECETOC Secretary General, starting in April 2022. Blanca environmental safety of polymers', Technical Report 133is a chemist by background with extensive experience in 3, in September. This third report in a series sets out seven chemical safety regulations and we are proud and delighted case studies that assess the usefulness of the Conceptual to have her on board! Framework for Polymer Risk Assessment (CF4Polymers) There have also been changes on the ECETOC Board. At that had been outlined in the first report. The case studies the Annual General Meeting we said farewell to Lorraine evaluate the applicability of tools, test methods and models Francourt and Heiko Rieck and we welcomed Jihane Ball and for polymer risk assessment that were considered in the Arndt Wellmann. I'd like to thank Lorraine and Heiko for their Task Force's second report. The trilogy of publications valuable insights, expertise and contributions to the Board, showcases the pro-active scientific work done to support the and am looking forward to working with Jihane and Arndt. future registration requirements of polymers by providing a

science-based framework and tools, exactly aligned with the ECETOC mission of "working with leading scientists from academia, governments and industry to develop and promote trusted and practical scientific solutions which ensure a safe, sustainable and healthy world".

With our new Board Members, as well as a new Secretary General, I have an optimistic outlook that ECETOC has a strong future ahead. The pace of regulatory change is picking up, offering ECETOC the opportunity to introduce the scientific solutions developed through our organization. To meet the high demand of scientific solutions, we have reviewed and updated our strategy, which focuses on the themes of Sustainability, Innovation, and Education, with Science at the centre. The EU's ambitions for a Green and Sustainable Europe can only be met if there is a paradigm shift in how we carry out chemical safety assessments: sophisticated exposure assessment combined with human (or eco-system)-relevant hazard assessment, making use of all data and advanced data analytics. We have progressed enormously in the past year. This puts the challenge back on regulators to keep up with the pace of the progression in science to ensure society will benefit.

ECETOC will continue to rely on its cross-sectoral collaboration, scientific expertise, and experience to develop and promote trusted and practical scientific solutions. We all have a role to play to ensure these solutions are implemented and trusted so they can achieve the outcome we are striving for: a safe, sustainable and healthy world.

With great pleasure and on behalf of the Board, I would like to welcome Blanca Serrano Ramón as our new ECETOC Secretary General, starting in April 2022.



RE-ELECTION OF BOARDOFF BOARDOFF ADDININGSTRATION

he 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.

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

RE-ELECTION OF BOARD MEMBERS AT THE 2021 ANNUAL GENERAL MEETING:

Drs. Patrick Masscheleyn (Procter & Gamble) and Craig Nessel (ExxonMobil Biomedical Sciences) were re-elected to the ECETOC Board.

ELECTION OF BOARD MEMBERS AT THE 2021 ANNUAL GENERAL MEETING:

Drs. Jihane Ball (Dow Europe) and Arndt Wellmann (Bayer) were elected to the ECETOC Board.

ECETOC BOARD MEMBERS DURING 2021

CHANTAL SMULDERS Shell International (Chair) CRAIG NESSEL ExxonMobil Biomedical Sciences (Vice-Chair) JIHANE BALL Dow Europe (from June 2021) MELANIE BAUSEN BASF PATRICK MASSCHELEYN Procter & Gamble STEVE MAUND Syngenta Crop Protection (Acting Treasurer) HEIKO RIECK Bayer (until June 2021) VOLKER SOBALLA Evonik Industries ARNDT WELLMANN Bayer (from June 2021)

14



REPORT FROM THE SECRETARY GENERAL

he convention when writing your farewells as part of a report on the past year is usually to leave all of the warm words and valedictions to the end of the piece.

OLIVIER DE MATOS Secretary General

But it is precisely these warm words normally in the final paragraphs that illustrate just how remarkable this past year has been for ECETOC, while at the same time explaining why it is such a wrench for me to leave this amazing organisation.

At the start of 2021, we had rather optimistically hoped to leave the Covid pandemic behind us as the year progressed. As we now know, that was not to be – and so we started a second full year of working under the most adverse of circumstances.

Many other small organisations might have opted for a succer "let's just get through this year" approach. Instead, everyone look a committed fully – and we continued to deliver outstanding 2021. science under the most testing of conditions.

In 2021, every meeting of the Scientific Committee was a full house. I need hardly say that these are all eminent scientists, with enormously busy agendas in addition to their work with ECETOC. But they all showed up for entire days of virtual meetings. It is simply priceless for an organisation to have that level of commitment.

To me, this highlights exactly how close-knit the ECETOC scientific network is. This team spirit between academia, government and industry scientists has been created and forged over many years – and without these trusted and close ties, it would have been impossible to achieve what was achieved during 2021.

I was also blessed with a wonderful team in the ECETOC secretariat – and they continued to prove their enormous worth in 2021, delivering both for me and for the organisation as a whole. The team is also expected to grow soon with the arrival of Virginie van der Steeg's baby boy.

When I became Secretary General in September 2017, although ECETOC was doing outstanding scientific work, it was comparatively unknown. It was also not communicating about the great science it was doing, with the result that it was not making much impact on the development of legislation in Europe.

My mandate was to put science at the heart of decision making in the European Union. And underpinning this mission was to foster a much better understanding of science on the part of regulators and other stakeholders.

We therefore identified three interlinked strategic priorities: creating more visibility with ECETOC's members and potential members; establishing a dialogue with external stakeholders; and making an impact on the long-term scientific agenda.

Looking back, I am grateful that we had the opportunity to make excellent advances in the first two pillars before Covid transformed everyone's working environment and holding face-to-face meetings and discussions became impossible.

Having set the first two pillars solidly in place, over the past year we have been entirely focused on the third: ensuring that our scientific excellence makes a regulatory impact. This involves ensuring that we are (virtually) sitting at the table in all relevant discussions and that our science is recognised as the basis for decision-making. Here I believe we have also succeeded. As just one of many examples, you need only look at the regulatory impact of our work on polymers in 2021.

With these three strategic pillars now firmly in place, I believe ECETOC has an excellent foundation for the future. The organisation is in great shape – and its cross-sectorial position gives it authority with the EU institutions, as well as enormous expertise within the scientific community.

There are two areas for further development where I have absolutely no doubt that my successor will pick up the baton:

first, creating more diversity in our scientific community, in particular promoting more women scientists; and second, encouraging more young scientists to get involved in ECETOC's work. ECETOC is a fantastic organisation for young scientists to learn, to develop their networks and to do what they like best: cutting-edge science.

It has been a wonderful four years working at ECETOC. From my very first job interview for the position of ECETOC Secretary General, I felt a warm connection – let's call it great chemistry perhaps! And ever since then, it has been a real privilege and a pleasure to have played a small part in ECETOC's more than 40-year history, working alongside such eminent and committed scientists on issues of great importance. The ECETOC Board has also been endlessly supportive, as well as a source of sound advice and friendship for me.

There are just too many for me to thank everyone individually, but I would like to single out for a special thank-you Chantal Smulders and Ben van Ravenzwaay, chairs of the Board of Administration and Scientific Committee respectively, for their unstinting support and friendship over the past years. It is not an exaggeration to say I could not have done it without them.

I leave ECETOC having learnt an enormous amount – and not just about science. ECETOC has given me the opportunity to try out new ideas, to test things and to be a leader. I sincerely hope my contribution over the past four years will help the long-term sustainability of ECETOC.

I have made great friends from throughout the organisation and I will always follow ECETOC's future story with a fond eye.

I wish you all well.

This team spirit between academia, government and industry scientists has been created and forged over many years – and without these trusted and close ties, it would have been impossible to achieve what was achieved during 2021.

77

SCIENCE PROGRAMME **FOREWORD FROM** THE SCIENTIFIC **COMMITTEE CHAIR**

n my 2020 report, I remarked that we would almost certainly remember 2020 as an extraordinary year. No doubt the same will apply to 2021. Our ability to adapt to applies to the whole of our society, as well as (and maybe in particular) to ECETOC.

Although many of us have experienced hardship and loneliness – and some even the loss of friends and family – I have very seldom encountered bitterness or desperation. In fact, I have heard more people expressing their emotions, sympathy and demonstrating empathy than I have in all the years before the Covid crisis.

20

This is remarkable, and even more so when you consider that we have had to become very efficient in dealing with totally new methods of communication. As they were in new situations is as remarkable as our resilience. This 2020, all of the ECETOC Scientific Committee (SC) meetings, as well as Board meetings, were held virtually in 2021. Moreover, all of the meetings throughout the entire year had a full attendance. As SC meetings involve the participation of approximately 20 eminent scientists, all of whom have very busy agendas, I would like to thank each and every one of them for this remarkable display of commitment to ECETOC.

> Nor was it just the SC that demonstrated their commitment and engagement: in 2021 we also saw an extremely high level of activity in all of our task forces, expert groups, workshops and in our Transformational Programmes (TP). Once again, a big thank-you goes out to all the scientists from academia, the regulatory agencies and industry who made this happen.

DR BENNARD VAN RAVENZWAAY Chair of the Scientific Committee

promoting the EU's resilience of supply and sustainability of At the beginning of October 2020, the European Commission published its Chemicals Strategy for critical chemicals: Sustainability (CSS). It is part of the EU's zero pollution establishing a simpler "one substance one assessment" ambition, a key commitment of the European Green Deal. process for risk and hazard assessment of chemicals: The strategy aims to protect citizens and the environment better and to boost innovation for safe and sustainable playing a leading role globally by championing and promoting chemicals. Both of these aims are clear, and I am certain high standards and not exporting chemicals that are banned that ECETOC's membership will fully support these goals. in the EU. So how can we jointly evaluate the best way forward to achieve these laudable goals? As usual, the devil lies in the details, and as the expression goes "the road to hell is paved with good intentions". The proposed actions by the EU are achieve this, in April last year, ECETOC organised a virtual summarised below:

Given that ECETOC activities are limited to guestions relating to science, rather than policy, it was essential to consider how we could best contribute to the EU action plan. To meeting to discuss chemical sustainability. The event aimed banning the most harmful chemicals in consumer products to identify key aspects of putting the EU CSS into action and - allowing their use only where essential; how ECETOC's work could support its implementation. There were more than 100 attendees from the ECETOC membership, account for the cocktail effect of chemicals when assessing regulatory bodies and from academia. In a series of breakrisks from chemicals: out groups, participants identified areas of interest where phasing out the use of per- and polyfluoroalkyl substances ECETOC could support the CSS implementation. The outcome (PFAS) in the EU, unless their use is essential: of these breakout discussions will be used as a strategic guide for the SC when it considers ECETOC's future scientific boosting the investment and innovative capacity for activities. Its importance should not be underestimated, production and use of chemicals that are safe and sustainable because we have only limited resources and therefore

by design, and throughout their life-cycle;



need to focus on activities that will contribute most to the advancement of the sciences that relate to risk assessment and, as such, contribute to the EU goals.

How to communicate complexity is a scientific issue that we have to live with and grapple with. Our TP for the environment is very much related to the goal of making studies and assessment for the environment more relevant and reducing complexity. Over the past few years, several task forces and expert groups have worked hard to make progress in this area. In 2021, ECETOC's work was very much focused on the issue of persistence, resulting in several peer-reviewed publications, a technical report and a contribution to a review of OECD test guidelines. Beyond providing a proposal for a tiered approach for the assessment of drinking water safety, ECETOC also established a dissemination platform for persistence assessment. This is an excellent example of ECETOC using new approaches to increase its visibility and to highlight the scientific work it does.

In the past, important contributions by ECETOC may have not been sufficiently taken into consideration due to a lack of communication. This is changing. In September 2021, a webinar on 'Assessing the safety of polymers: Examples of grouping approach' was organised to communicate the results of ECETOC's third report on the topic of "Assessing the human health and environmental safety of polymers". Importantly, the webinar was well attended by scientists from the regulatory community (European Commission, ECHA, Competent Authorities) and a recording of the webinar has been made available on ECETOC's YouTube channel. In addition, ECETOC has launched a series of webinars in which general science principles are presented. A better understanding and appreciation of science, including its limitations, is a key element for our society. The Covid crisis has demonstrated graphically just how important this is, and how the lack of transparent communication of science can lead to ignorance and unnecessary suffering.

The TP for Human Health and Exposure also proposes a tiered approach to information requirements. Its conceptual framework has been developed over the past few years and was published in a high impact peer reviewed journal in Q1 of 2022. It was also presented to high-level ECHA representatives in the autumn of 2021. There are several important learnings from the concept and from the initial feedback received. Tiered approaches have again been demonstrated to be the most efficient way of gathering the right amount of information for a situation with "enough precision to make a decision".

Exposure and hazard information are equally important and need to be developed concomitantly. In this context, ECETOCs engagement with exposure science, from the TRA to more sophisticated models, is paying dividends. However, to reduce uncertainty in exposure assessment, a lot more work – including more profound collaborations between producers, processing and formulating industry and companies responsible for product sales - needs to be carried out. Finally, although the members of the TP working group considered that REACH Annex XI would provide sufficient leeway for the initial implementation of the tiered approach, this opinion was clearly not shared by ECHA representatives. It is therefore essential for us to keep the communication channels open and to receive feedback and adjust when necessary. In the future, it will be key to convince the EU Commission and its member states that there are ways to effectively reduce the need for animal testing by new approach methods (NAMs).

Two workshops, held in November 2021 and January 2022, were very much related to this topic. Current in vitro approaches, as part of the NAM repertoire, deliver important information concerning hazard properties. Many of these assays are developed and performed to provide a "yes" or "no" answer. For risk assessment purposes, however, this will not be enough. Quantitative in vitro data need to be transformed in a process called "in vitro to in vivo extrapolation" (IVIVE) to obtain the equivalent in vivo information to carry out a risk assessment. In the first workshop, the key component of IVIVE, the physiologybased pharmacokinetic models (PBK) were presented and participants discussed their suitability to perform this task. In addition, the most relevant input parameters for the PBK model were identified. In the second workshop, data from 'omics technologies were evaluated, asking the question how one would best determine the "point of departure", i.e. the lowest concentration at which a biological response is seen that is different from control variation. In addition, participants discussed how to distinguish between an adaptive response and an adverse one. Both workshops contributed to the advancement of the use of NAMs in a regulatory context and the reduction of animal testing. Both workshops also contributed in the long term to achieving the goals of our TP. Once again, both workshops had a high level of participation by representatives of regulatory bodies.

As I have mentioned in the past, ECETOC is at its very best when we deal with scientific approaches and methods that are future-orientated. Finally, and very much related to the tiered approach in the TP is the availability and sharing of data, and in particular those from in vivo studies. REACH has led to an unprecedented amount of animal testing and will continue to do so over the coming years. Those data can and should be used in a better way than just to inform the risk assessment of the substance in question. Structure activity relationship methods are now more advanced than they were in the past and should be able to identify chemicals which are sufficiently similar to new or less investigated chemicals to allow for a read across component as part of an overall evaluation strategy of available information. This would require companies submitting in vivo studies under REACH to allow others to make use of these data for regulatory purposes. I am fully aware that this is a controversial topic and that data sharing and compensation is not trivial, but I personally believe that this is would contribute profoundly to the reduction of animal testing, provided that regulatory agencies are sufficiently confident about using such an approach.

As you may have noticed, I am very proud of all that ECETOC has achieved in the past, and in particular, during such a with some words in your language. difficult year as 2021. So, yes, I believe we are doing well, but Caro Olivier, muito obrigado por tudo o que could we be even better? I believe we could! Here, I want to mention two specific points. The most limiting factor that we fez pelo ECETOC. É incrível como uma única experience is the lack of resources. This is both in terms of pessoa pode fazer uma enorme diferença our financial possibilities, as well as in the experts available para uma organização; você certamente for our activities. Over the last two decades, we have seen a shift in terms of capabilities to perform (eco)toxicological fez. Vou sentir falta das nossas conversas, studies from industry to contract research organisations dos bons conselhos e simplesmente da sua (CROs). Currently most of those studies are done by CROs, companhia. Vamos todos sentir muito a sua but they are not yet members of ECETOC. I am convinced that CROs could contribute a great deal to our work, that falta no ECETOC. Desejo-lhe tudo de bom they share our interest in good science and that they would para o seu novo trabalho e os seus novos therefore be willing to contribute to improving both the desafios, mas tenho certeza que irá domináprocess and guality of risk assessments for humans and the environment. So, one of my hopes for this coming year los com excelência. is that at least one CRO joins ECETOC in 2022. My second point relates to having a broader representation of societal Abraços. organisations involved in the work that ECETOC is carrying out. There are now several NGOs who are using excellent scientists to demonstrate that their issues are properly backed up by science, or can be resolved by good scientific practises. Would it not be more effective to include those NGO scientists in our task forces, expert groups and workshops to work jointly on issues, rather than trying to convince them - after the fact - about our conclusions and proposals?

Finally, the end of 2021 brought about two great changes. The first is that I retired from BASF in Ludwigshafen, Germany after 34 years of working in various areas of toxicology (from the laboratory, to regulatory affairs, to leadership). I am very thankful to the members of the SC and the Board

that they have enough trust in me to allow me to continue to serve ECETOC as chairman of the SC. Thank you all for your confidence!

The second is the farewell we had to say to our Secretary General, Olivier de Matos. Olivier has changed the organisation more than anyone else before him. We have all become more agile; he has stopped the decline in our membership; he has enhanced the relationships with our members, as well as with the regulatory agencies. He has also revived the ECETOC secretariat, which is now a very lean (but not mean) fighting machine. There are so many more points that I could mention here, but I would like to finish on a more personal note. Dear Olivier, working with you over the past four years has been one of the great privileges and pleasures in my professional career. In addition to the sciences, communication ideas and strategies we have discussed, I will always remember our more personal conversations in Portuguese about food, wine, Portugal and many other things. So, I would like to end with some words in your language.

2021 AREAS OF WORK

ECETOC REVIEW MEETING 'TOWARDS CHEMICAL SUSTAINABILITY - PUTTING THE EU STRATEGY INTO ACTION'

On 14th April 2021, ECETOC organised a virtual <u>Review Meeting</u>, framed around the theme of chemicals sustainability. The event aimed to identify key aspects of putting the EU Chemicals Strategy for Sustainability (CSS) into action and how ECETOC work could support the implementation. There were over 100 attendees to the event, from ECETOC membership, regulatory bodies and academia.

Prof. Annemarie van Wezel (Environmental ecologist at the University of Amsterdam) opened the day with a speech on the science toward a free-toxic environment, highlighting among many aspects the importance of a less fragmented EU legislation framework (e.g. one substance - one assessment) as well as chemical design and making best use of available technology.

The keynote was followed by a panel discussion between Prof. van Wezel, ECHA's Director of Hazard Assessment Christel Musset, JRC's Head of Chemical Safety and Alternative Methods Unit Maurice Whelan and ECETOC's Chair of the Board Chantal Smulders. The discussion focused on responding to a series of questions around the recent Chemicals Strategy for Sustainability, its successful implementation, obstacles and the role ECETOC could play to address these challenges.

In the next session, updates were provided on the following relevant ECETOC activities: Persistent chemicals and water resource protection (Task Force – presented by Nathalie Vallotton (Dow)); Assessing the human health and environmental safety of polymers (Task Force – presented by Mark Pemberton (Systox Ltd)); and exposure science developments (Task Forces – presented by Tanya Dudzina (ExxonMobil)).

Towards the end of meeting a series of break-out group discussions took place. These aimed to identify areas of interest for ECETOC to support the CSS implementation. The outcome of these breakout discussions was presented in a plenary session, for further review by the Scientific Committee.



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

ENDOCRINE DISRUPTION

ECETOC has initiated work on the topic of whether sufficient knowledge is available on the endocrine system of invertebrates to include them in regulatory evaluation of endocrine disruptors. This proposed activity originated at the 2020 ECETOC/Cefic LRI Scoping meeting.

This activity has started with a literature review.

An ECETOC steering committee has been working with a consultant to develop the manuscript: 'Assessing the endocrine disrupting effects of chemicals on invertebrates in the European Union', which has been submitted to Critical Reviews in Environmental Science & Technology.

EXPOSURE

The Task Force on 'Mid-tier approach to aggregate exposure assessment', formed in 2020, focused in 2021 on exploring various aggregate exposure assessment methods that could fall under the mid-tier assessment definition, i.e. those that can offer reasonable worst-case estimate of aggregate human exposure without the need to generate additional input data. Range of approaches evaluated include the Maximum Aggregate Ratio approach, use specific tonnage-based method, surface area in use for articles scenarios, along with traditional low-tier additive approaches widely used in regulatory safety assessments.

These different methods are now being tested in several case studies aimed to identify gaps, limitations, and exposure data requirements for mid-tier assessments. Learnings from these case studies will form the basis for practical recommendations to exposure and risk assessors as to what may constitute mid-tier approaches, what methods can work best for which scenarios, to what extent refinement of aggregate exposure can be achieved compared to low-tier assessments, and where the development of higher-tier (probabilistic) approaches is warranted. The Task Force looks forward to sharing its findings in a comprehensive technical report in Q3 2022.

The 'Special T4' Task Force work in 2021 focused on progressing with the third manuscript on : 'Finding evidence from rodent studies on (1) (mechanisms of) effects caused by different substances; and (2) specific adverse outcomes?', to continue the series of manuscripts published in 2020 i.e.

- Part I: Which parameters from human studies are most relevant for toxicological assessments? was published in December in the journal Critical Reviews in Toxicology.
- Part II: How can key events of relevant adverse outcome pathways be addressed 0 in toxicological assessments? was also submitted to Critical Reviews in Toxicology at the end of the year.

A fourth manuscript is planned for publication in 2022.

INTEGRATED **CHEMICALS** APPROACH FOR 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.



In 2021, the team produced a paper published inArchives of Toxicology called A Framework for Chemical Safety Assessment Incorporating New Approach Methodologies Within REACH . The paper proposes a framework for chemicals assessment based on use of new approach methodologies (NAMs) which takes into account in silico, in vitro and in vivo methods designed to meet the requirements of REACH in which both hazard and exposure can be assessed using a tiered approach.

The application of the framework as described in the paper would allow a measured and phased introduction of new methodology in chemical safety assessment initially with more developed methods of hazard assessment, or with low tonnage chemicals or with low exposure situations.

The regulatory acceptability of such a framework in EU still remains to be confirmed, although there is a general agreement between various stakeholders (industry, academia, regulators) that that the way chemical safety assessment is done needs to change.

The 'Special T4' Task Force work in 2021 focused on progressing with the third manuscript on : 'Finding evidence from rodent studies on (1) (mechanisms of) effects caused by different substances; and (2) specific adverse outcomes?', to continue the series of manuscripts published in 2020 i.e.

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

at the end of the year.

A fourth manuscript is planned for publication in 2022.





Part II: How can key events of relevant adverse outcome pathways be addressed in toxicological assessments? was also submitted to Critical Reviews in Toxicology

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 hybrid workshop was held on 9 and 10 October 2021, with an audience of approximatively 40 participants representing industry, academia and regulatory bodies, out of which six met face-to-face at the ECETOC office in Brussels.

Day one of the workshop focused learning about existing models and tools while the second day was dedicated to break-out group sessions, which addressed the following questions:

- How can we make existing models/applicability domains reliable and accepted by regulators?
- What are the critical input parameters to existing and new models?
- What are the commonalities and differences in the models?

After the break-out discussion, the participants discussed main findings and discussed initial conclusions. The outputs of the workshop will be presented in a peer-reviewed paper, to be

OMICS TECHNOLOGIES

The Data from omics technologies - point of departure for adverse and non-adverse effects workshop proposal endorsed by the ECETOC Scientific Committee will be organised on 20 and 21 January 2022.

This workshop will explore current developments and challenges and seek to understand where more progress needs to be made, evidence gaps filled and importantly how to translate the research into application to advance the application of 'omic' methods in regulatory toxicology.

The workshop main learning points, recommendation and conclusion will be summarised in a workshop report, to be circulated to the participants and available on the ECETOC website

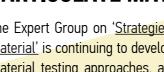
qAOP

The quantitative Adverse Outcome Pathways (AOPs) proposal for a workshop, endorsed by the Scientific Committee in 2020, aims to bring together the research, academia, industry and regulatory community, to discuss identify main aspects which need to be addressed with respect to the design, interpretation and application of Quantitative Response-Response Relationships starting from qualitative/descriptive AOPs, by creating a dialogue among these different stakeholders.

The Organizing Committee, formed of ECETOC Scientific Committee members, with support from regulators, has worked on identifying the main questions to be addressed in the October 2022 workshop and will continue in early 2022 with the practical aspects related to the organisation of the workshop.







This is an ever-changing landscape, but the group is staying informed of the developments and integrating these into their work. They hope to publish the white paper Q2/Q3 next year.

PERSISTENCE AND PERSISTENT/MOBILE SUBSTANCES

Two manuscripts of the Task Force 'Moving persistence (P) assessments into the 21st Century' were submitted to Integrated Environmental Assessment and Management (IEAM) for publication :

'Moving persistence assessments into the 21st Century: A role for weight-of-evidence (WoE) and overall persistence (Pov)' (published in December 2021)

and

(to be published in early 2022)

The work of this Task Force is being continued by the ECETOC dissemination platform: 'Moving persistence (P) assessments into the 21stcentury'. The Platform, which brings together ECETOC members as well as representatives from CEFIC LRI, CONCAWE and Cosmetics Europe is planning a series of podcasts, online discussions and face-to-face/hybrid events. These activities aim at further communicating the framework originally developed by the Task Force as well as engaging with stakeholders to advance the development of persistence assessment methodologies.

The members of the Task Force and Dissemination Platform have contributed to the questionnaires of the UBA/Fraunhofer/Ramboll project 'Reviewing OECD Test Guidelines relevant to environmental assessment with regard to the state of the art in science and technology'.

The 'Persistent chemicals and water resources protection' Task Force published Technical Report 139 in May this year. The report evaluates the scientific basis of the UBA propertybased PMT/vPvM criteria and sets out a tiered approach for assessment of drinking water safety, which includes a tier 0 screening, followed by exposure and risk assessment approaches in tiers 1-3. The report also identifies research needs to further progress the science.

The Task Force is currently working on a manuscript to highlight the key aspects of the Technical Report. They hope to publish this in Q2 2022.

Sascha Pawlowski (Chair of the Task Force) and Gordon Sanders (Task Force Steward) have participated during 2021 on behalf of ECETOC to the PBT Expert Group ad-hoc group calls with the Commission on the proposed new CLP hazard classes for PBT/PMT and PBT/vPvB.



PARTICULATE MATERIAL

The Expert Group on 'Strategies to overcome challenges in aquatic testing of particulate material' is continuing to develop a white paper describing the current status of particulate material testing approaches, and the challenges when following these approaches, and putting forward a testing strategy.

'Scientific concepts and methods for moving persistence assessments into the 21st Century'

POLYMERS

The Task Force 'Assessing the human health and environmental safety of polymers' published the keenly awaited third report of the trilogy, <u>Technical Report 133-3</u>, in September this year. This third report sets out a series of seven case studies assessing the usefulness of the Conceptual Framework for Polymer Risk Assessment (CF4Polymers) outlined in the first report. The case studies also evaluate the applicability of tools, test methods and models for polymer risk assessment considered in the second report.

ECETOC is continuing to contribute to the CARACAL sub-group on Polymers (CASG-Polymers), and some members of the Task Force have maintained their involvement and are very active in this context, currently working on a proposal for a testing scheme for polymers..

The Task Force presented the following poster at SETAC Europe 2021: 'The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) and Considerations on applicability of standard tools, test methods and models'. The Task Force has submitted three abstracts for SETAC Europe 2022, focussing on the case studies and the ECETOC grouping approach.

The Task Force held a webinar on 7 September on <u>'Assessing the safety of polymers:</u> <u>Examples of grouping approach</u>' a few weeks prior to the release of Technical Report 133-3. The webinar was well attended, with 20 of the approximately 70 participants being from the European Commission, ECHA, and Competent Authorities. A <u>recording of the webinar</u> was made available on ECETOC's YouTube channel; in less than 4 months, the video was viewed over 330 times, making it ECETOC's 6th most popular video of all times.

REGISTRATION OF CHEMICALS UNDER REACH

NanoApp

Following the successful launch of the NanoApp and a first users training webinar in late 2020, a second training webinar was organised on 14 January, which attracted over 30 participants.

The team behind the NanoApp also published a second article, <u>Creating sets of similar</u> nanoforms with the ECETOC NanoApp: real-life case studies, in Nanotechnology in April. This paper brings concrete examples of how the tool can successfully be used to justify similar sets of nanoforms for REACH registration.

Currently, NanoApp counts over 160 registered users.

Targeted Risk Assessment (TRA)

Three parallel Task Forces (Workers, Consumers and Environment) continued their work throughout 2021 to bring the TRA tool in line with the current regulatory requirements.

The *Worker Targeted Risk Assessment Task Force* focused its efforts in 2021 to finalize the review of literature and external validation studies on exposure estimations using TRA tool version 3 and developed a curated database. The findings and proposed improvements to the tool will be available in a technical report, expected to be published in the second quarter of 2022.

The *Consumer Targeted Risk Assessment Task Force*'s work in 2020 focused on the development of the manuscript: 'Publication on infrequent EA'.











The *Environment Targeted Risk Assessment Task Force* will shortly be launching a Request for Proposals for a literature review on state of the science of modelling humans exposed indirectly via the environment. The Task Force is also liaising with Environment and Climate Change Canada (ECCC) on their work on validating SimpleTreat and development of a novel model.

The work of the three branches of the TRA Task Force is overseen by the *TRA Steering Team*, which includes the Chairs from each of the three branches. The TRA Steering Team also holds bi-monthly coordination calls with ECHA to share updates and developments. In addition, the Chairs of each of the three branches participate to ECHA's Chesar Platform Stakeholder Community. The Chesar Platform, a chemical risk assessment tool combining Chesar and EUSES, is being developed by ECHA, and will serve both REACH and Biocides regulations. The Stakeholder Community will play a key role in collecting and discussing a wide range of scientific proposals, from assessment methodologies and approaches to the usability of the tool.

COMMUNICATING THE 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

During the first half of the 2021, ECETOC's Human Exposure Assessment Tools Database (heatDB) went through an extensive review period which culminated in the release of a new and improved version launched at the end of May.

The new version, besides featuring a fresh new look, allows to obtain a full overview of tools and databases at-a-glance and no longer requires users to search separately for them. An additional tiering system curated by experts provides users with additional guidance for more accurate results among the over 340 entries of the database.

The launch of the tool was accompanied by a curated communications strategy, which included a short <u>promotional video</u> highlighting the tool's features.

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.

SCIENCE AWARDS

Environmental science related awards

At SETAC's Europe 31st Annual Meeting (SETAC SciCon), held onine from 3–6 May 2021, Tim Boogaerts from the University of Antwerp, Belgium, was awarded with ECETOC's award for Best Presentation for his work entitled "Development and Application of a High-Throughput Bioanalytical Method for Sewage Surveillance for SARS-CoV-2".

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 for the 2021 ECETOC Christa Hennes Award was Dr. Johanna Nyffeler, from ORISE post-doctoral grantee at US EPA for the abstract entitled: "High-throughput phenotypic profiling within the NAMs-based, tiered hazard evaluation strategy at the United States Environmental Protection Agency".



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;

published RfPs and make recommendations to the Cefic LRI IT concerning the funding of the proposals; and

the monitoring of project progress.

Information on the Cefic LRI projects active or initiated during 2021 is set out below.

ECETOC

REVIEW & SCOPING MEETINGS RFP DRAFTING SELECTION PANELS MONITORING

CEFIC LRI

EXTERNAL

SCIENTIFIC **ADVISOR**

- Establishment and coordination of selection panels to review the research proposals submitted in response to
- Establishment of monitoring teams to act as a discussion partner with the research teams and support Cefic LRI in

ACC LR

JCIA LRI

CEFIC LRI

PROJECT DEFINITION FUNDING DISSEMINATION

HUMAN HEALTH AND EXPOSURE PROJECTS ACTIVE **OR INITIATED DURING 2021**

The following Cefic LRI projects were active or initiated during 2021, with the support of the ECETOC Monitoring Teams and Selection Teams.

1 project was completed (marked below with). 3 new projects secured funding and will be initiated in 2022 with the support of the monitoring teams (marked below with •):

AIMT 11

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

B12.5Ext

Determining chemical emission parameters for dust exposure for specific material characteristics, so that human exposure can be predicted. Principal investigator: Dr.John Little, Virginia TECH, US.

B21

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

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.

B24

Modeling exposure and biodistribution of microplastic particles in the human body - Principal Investigator: Bart Koelmans, Wageningen 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

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.

C10

A tiered strategy of modelled doses, analogy concepts, and testing to approach the human hazard of microplastic particles via inhalation pathway (Stage 1). Principal investigator Dr Tanja Hansen, Fraunhofer ITEM, Germany

EMSG 59.2 Ext

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, Universita degli Studi di Milano, Italy.

DURING 2021

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

4 projects were completed (marked below with). 4 new projects an 1 project extension secured funding (marked below with •):

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 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.

ELUMICA - Elucidating Microbial Metabolic Capacity. Principal investigator: Saskia Sperber,

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,

ENVIRONMENTAL PROJECTS ACTIVE OR INITIATED

ECO 42

UVCB fate-directed toxicity testing and risk assessment (UVCB-FATETOX). Principal investigator: Prof. Dr. Philipp Mayer, Technical University of Denmark (DT U).

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 44.2

Integrating Bioaccumulation Assessment Tools for Mammals (iBAT-Mam). [Extension to ECO 44]. 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: 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).

EC0 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.

EC0 53

A Chemical Categorisation Approach for LRT P Assessment (CC-ALT). Principal investigator: Prof. Knut Breivik, Norwegian Institute for Air Research (NILU)

EC0 54

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

EC0 55

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

EC0 56

UTOPIA: Development of a mUltimedia uniT world OPen-source model for microplastic. Principal investigator: Prof. Matthew MacLeod, Stockholm University, SE

ECO 57

µPLANET – microPlastic Long-range transport Assessment aNd Estimation Tools. Principal investigator: Dr Antonia Praetorius, University of Amsterdam.

ECO 58

University, US.

ECO 59

Hydrology, UK.

ECETOC is also providing selection and monitoring support to Concawe and Cosmetics Europe Long Range Science Strategy (LRSS) on their project with RfP title 'Developing a Persistence Assessment Tool (PAT) for P assessment under REACH', which will kick-off in Q1 2022.

Comprehensive additive release and bioaccessibility model for risk assessment of microand nano-plastics in the environment. Principal investigator: Prof. P Lee Ferguson, Duke

FRAGMENT-MNP: Developing a mechanistic model of Micro and NanoPlastic FRAGMentation in the ENvironmenT. Principal investigator: Dr Claus Svendsen, UK Centre for Ecology &

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 2021, the Scientific Committee consisted of the following members:

Ben van Ravenzwaay Rémi Bars Phil Botham **Timothy Gant*** Helmut Greim* Andreas Häner Heli Hollnagel **Philippe Lemaire** Lorraine Maltby* Lo Meisters **Miriam Leon Paumen**

Mark Pemberton* **Aaron Redman Carlos Rodriguez** Gordon Sanders Johannes Tolls Jan Urbanus Kees van Leeuwen* Erik van Miert

*external experts

40

BASE Bayer CropScience Syngenta King's College London **Technical University Munich** F. Hoffmann-La Roche Dow Europe **Total Fluides** University of Sheffield Corteva Agrisciences ExxonMobil Petroleum and Chemical (from September 2021) Systox Limited ExxonMobil Petroleum and Chemical Procter & Gamble Givaudan International Henkel Shell Health KWR Water Research Institute Solvay

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 ANDREEA CUCIUREANU — Human Health Sciences Manager GENEVIÈVE GÉRITS — Office Manager EMMA JACK — CEFIC LRI Human Health Sciences Manager ANDREA SALVADORI — External Relations Manager FRANCESCA UGUCCIONI — Administrative Assistant VIRGINIE VAN DER STEEG — Administrative Assistant LUCY WILMOT — Environmental Sciences Manager



FINANCE

INCOME ACTUAL 2021 IN EURO

Subscription

Full members	1.035.000
Associate members	50.000
Total subscription income	1.085.000

Bank Interest Investment income Project related income Exceptional income

Total

EXPENDITURE ACTUAL 2021 IN EURO

Salaries and Associated Costs	571.162
Office Running Expenses	140.762
Travel Expenses	2.083
External contractors	214.308
Board, Committees & Annual General Meeting	16.206
Task Forces	220.301
Workshops	60.952
Sponsorships & Awards	8.299
Publications/communication/website	40.130
Professional Services	21.956
Bank Charges	-771
Capital expenditure	10.942
Miscellaneous & contingency	46.125
Total	1.352.45

BALANCE SHEET AND RESERVES ACTUAL 2021 IN EURO

Balance Sheet Income Expenditure Operating Margin

Reserves

Opening Reserve Operating Margin Closing Reserve Reserve required for Closure 1.695.946 -68.066 1.627.880 196.962

1.284.389

1.352.455

-68.066

-12.769

191.243

1.284.389

20.915

anu sumu siziro padoly non zizir zani nortod rom to noillin c

90.9



ABBREVIATIONS

AGM Annual general meeting

AOP Adverse outcome pathways

CARACAL Competent Authorities for REACH and CLP

CASG Compentent authorities sub-group

Cefic European Chemical Industry Council

CF4Polymers Conceptual Framework for Polymers

Chesar (ECHA) CHEmical Safety Assessment and Reporting tool.

CLP Classification, Labelling and Packaging

CONCAWE European Petroleum Refiners Association

CRO Contract research organisation

CSS Chemical Strategy for Sustainability

CSA Chemicals Safety Assessment

<u> 16</u>

DNA Deoxyribonucleic acid

EA Exposure Assessment

EC European Commission

ECCC Environment and climate change Canada

ECETOC

ECHA European Chemicals Agency

EU European Union

EUROTOX

EUSES European Union System for the Evaluation of Substances

heatDB ECETOC Human Exposure Assessment Tools Database

IEAM Integrated Environmental Assessment and Management

IRAS Institute for Risk Assessment Sciences

IVIVE In vitro to in vivo extrapolation

JRC (EC) Joint Research Centre

LRI Cefic's Long-range Research Initiative

LRSS Cosmetics Europe Long Range Science Strategy

NAMs New Approach Methods/Methodologies

NGO Non-governmental organisation

European Centre for Ecotoxicology and Toxicology of Chemicals

Association of European Toxicologists and European Societies of Toxicology

NIVA

Norwegian Institute for Water Research

NILU Norwegian Institute for Air Research

OECD Organisation for Economic Co-operation and Development

ORISE Oak Ridge Institute for Science and Education

Ρ

Persistence

PAT Persistence assessment tool

PBK Physiology-based pharmacokinetic

PMT Persistent, mobile and toxic

PBT Persistent, Bioaccumulative Toxic

qAOP Quantitative adverse outcome pathways

qIVIVE Quantitative in vitro to in vivo extrapolation

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

TMEx Tiered Methods for Quantifying Exposure

TΡ (ECETOC) Transformational Programme

TRA Targeted risk assessment

UBA

UFZ Helmholtz Centre for Environmental Research

US EPA Environmental Protection Agency

UVCB materials

vPvB Very persistent, very bioaccumulative

vPvM Very persistent, very mobile

WHO World Health Organisation

WoE Weight-of-evidence

Umweltbundesamt (German Environment Agency)

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



THANK YOU FOR READING!

Copyright © ECETOC, April 2021

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.

Learn more at ecetoc.org.

This report is only distributed in electronic format under the ECETOC paperless policy.

ECETOC AISBL

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