

EUROPEAN CENTRE FOR
ECOTOXICOLOGY AND
TOXICOLOGY OF CHEMICALS

ANNUAL REPORT 2009

ecetoc

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Cover Photo:

A molecular model of a Ribosome. Ribosomes are present in the cells of all forms of life, from bacteria to humans. DNA is copied to RNA, and Ribosomes read the instructions encoded in RNA to build proteins. Ribosomes were first observed in the 1950s, but the detail of their complex structure wasn't known until the early 2000s.

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INTRODUCING ECETOC

“The strength of ECETOC is not simply its scientific credibility, which is essential, but also its capacity to address real world issues confronting the industry...”

ECETOC was established in 1978 as a scientific, non-profit making, non-commercial association and currently counts as its members 46* of the leading companies with interests in the manufacture and use of chemicals. An independent organisation, ECETOC provides a scientific forum through which the extensive specialist expertise of manufacturers and users can be harnessed to research, evaluate, assess, and publish reviews on the ecotoxicology and toxicology of chemicals, biomaterials and pharmaceuticals.

The Association's main objective is to identify, evaluate, and through such knowledge help the industry to minimise any potentially adverse effects on human health and the environment that may arise from the manufacture and use of chemicals. To achieve

this, ECETOC facilitates the networking of suitably qualified scientists from its member companies and co-operates in a scientific context with international agencies, government authorities and professional societies.

ECETOC is governed by a Board of Administration comprising up to 12 senior executives from member companies. The Board is responsible for the overall policy and finance of the organisation and appoints the members of the Scientific Committee which defines, manages and peer reviews the ECETOC work programme.

The outputs of its work programme are manifested as published reports, papers and specialised workshops. ECETOC also provides scientific representation of manufacturers and users of chemicals via presentations at specialist

forums and takes a scientific role in the activities of international organisations and regulatory groups.

Vision

To be the leading European health and environmental sciences organisation enabling the safe manufacture, handling and use of chemicals, biomaterials and pharmaceuticals.

Mission

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

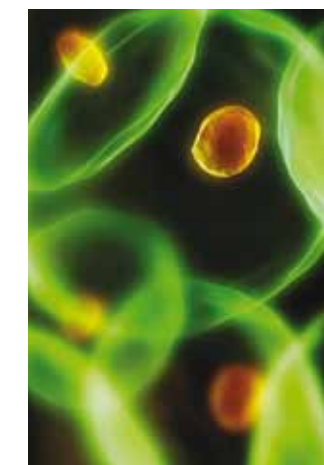
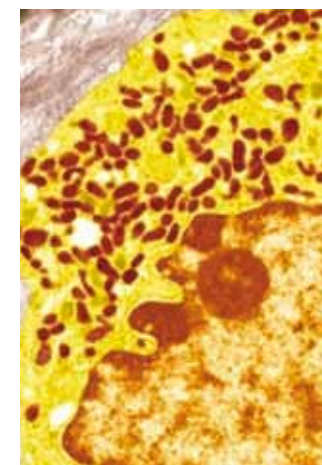
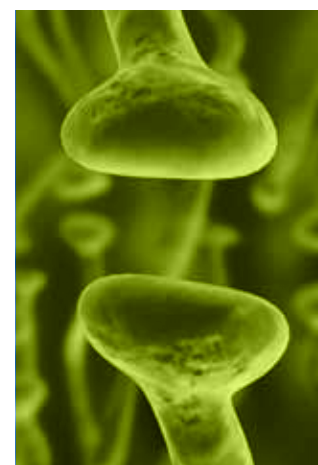
Approach

ECETOC pursues its vision and mission according to an issue-based science strategy that was launched

in 2007. It is broken down into 13 science areas (see section entitled 'Science Programme') that are grouped according to 5 main themes:

- Presence of chemicals in humans
- Presence of chemicals in the environment
- Effects in humans and ecosystems
- Methods
- Science of risk assessment.

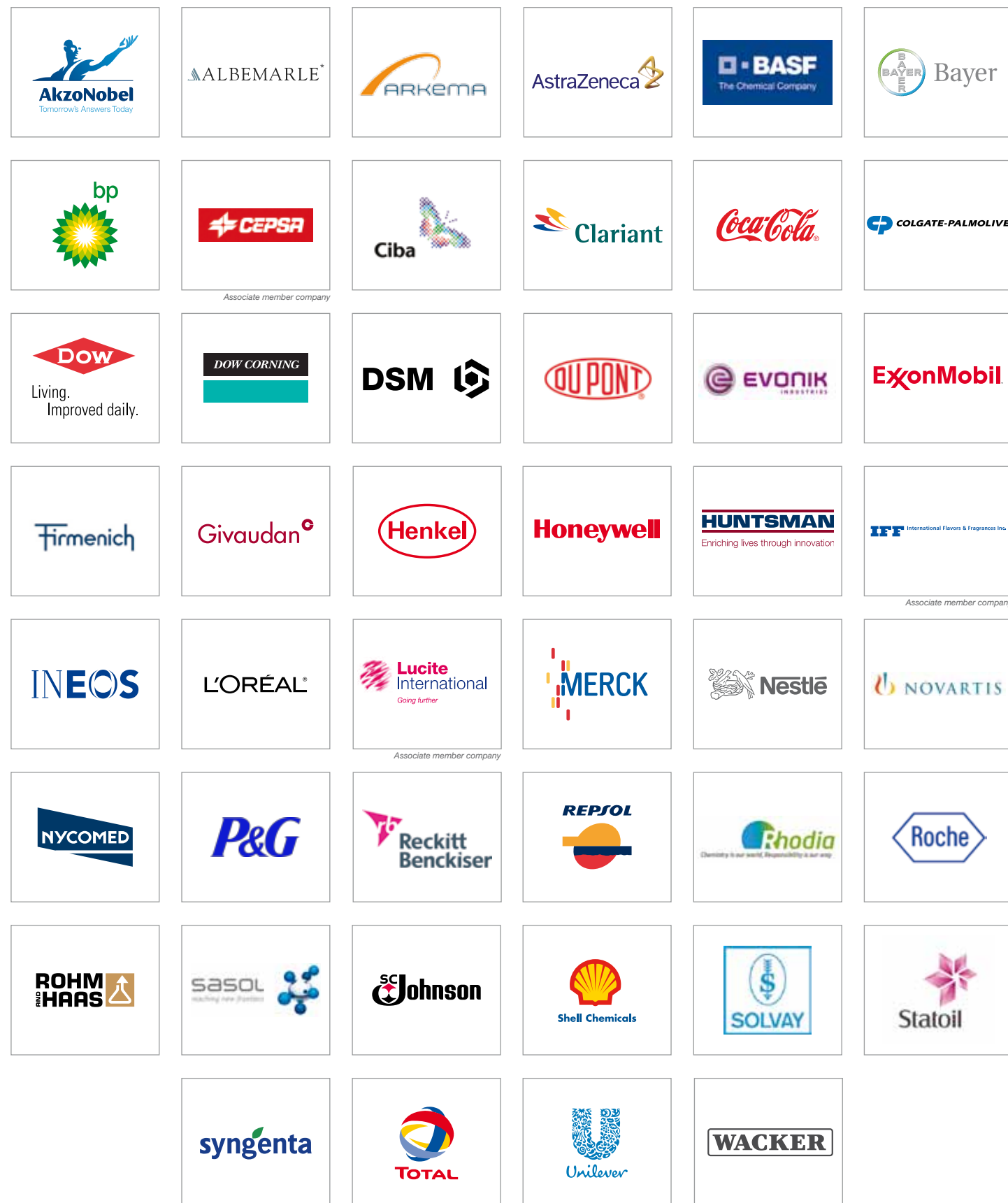
* As of December 2009



MEMBERSHIP

ECETOC Member Companies

At the start of 2010 ECETOC membership comprised the following 46 companies:



Membership benefits



member company employees
benefit from access to a high quality
network of scientific expertise

Manufacturers and users of chemicals (and biomaterials and pharmaceuticals) can become either a Full or Associate Member of ECETOC according to the proportion of their turnover derived from chemicals, (see www.ecetoc.org/membership). Membership of ECETOC demonstrates the practical commitment of a company to the principles of Responsible Care® via their active scientific and technical contribution to initiatives supporting the safe manufacture and use of chemicals, pharmaceuticals, and biomaterials through good science.

The diversity and range of its members' expertise are key ingredients for ECETOC's achievements in the pursuit of this objective. ECETOC's success

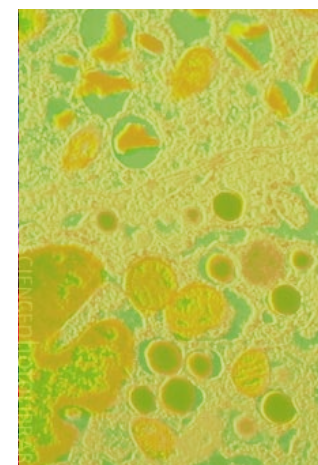
depends on member company employees being able to dedicate their time to furthering projects within the framework of an ECETOC task force.

In so doing, member company employees benefit from access to a high quality network of scientific expertise and ECETOC is able to leverage this pool of knowledge in order to represent and promote the European chemical industry's science in its relationships with European and international institutions.

ECETOC member companies benefit from being in a position to influence its scientific agenda. They can propose subjects to be tackled by its work programme and can have a representative on its Scientific Committee.

Any member company employee can request a login to the ECETOC members' site: <http://members.ecetoc.org> where they can download any ECETOC report, keep track of discussions at Scientific Committee level and check the progress of the work programme.

All member companies receive complimentary printed copies of each new ECETOC report and are entitled to request additional printed versions as and when needed.





MESSAGE FROM THE CHAIRMAN

Times of Change

As many of you will know, I took over as Chairman of the Board of ECETOC at the 2009 Annual General Meeting. It is my great pleasure therefore, to start my first contribution to the annual report by paying tribute to my predecessor Dr Jochen Rudolph. Dr Rudolph was elected to the Board of ECETOC in 1991 and took over the Chair in 2004. After these years of careful stewardship of our association he took a well earned retirement from his company in 2008, but stayed at the helm of ECETOC until the 2009 annual meeting. We will miss his vision and wisdom and wish him all the best for the future.

Testing times for Industry

I take over the chair of ECETOC at a time of great challenge for industry as a whole and the chemical industry in particular. We are faced by a depressed business environment and a transformed regulatory environment at the same time. Meeting these twin challenges will call on all our resourcefulness and adaptability. These constraints mean that, on the one hand company resources are under unprecedented pressure, and yet the need to act together as an industry is greater than ever. My preoccupation will be to work with the Board to ensure that ECETOC is positioned to make the maximum contribution to this joint effort.

2009 was a historic year for our industry with REACH coming into force and other new regulations such as the revised pesticide directive. ECETOC has not been idle during this period, despite the pressures of day to day compliance needs. Eight workshops were organised covering a range of topics from the application of risk assessment tools in the REACH environment to the identification of 'endocrine disruptors'. Likewise, the five technical reports, four workshop reports, and articles published in peer-reviewed open literature during the year reflect a diverse range of topics.

It was a year when ECETOC activities had considerable impact and visibility. The efforts of the targeted risk assessment task force were rewarded by the adoption of large parts of the ECETOC tool into the official European IT

tools for REACH. The task force report and workshop on 'endocrine disruptors' were the first proposals to address the practicalities of identifying which are the chemicals that should be considered under this heading.

Something for everyone

The strength of ECETOC is not simply its scientific credibility, which is essential, but also its capacity to address real world issues confronting the industry as a whole or in part. Some topics may have more immediacy for one sector than another at any point in time. ECETOC task forces and workshops reflect this, as the main burden is normally carried by a small number of companies with the greatest interest. However, as the approach is science driven, we are able to broaden it. To illustrate: we have recently taken several initiatives relating to environmental assessment of pharmaceuticals, but the science input has included experts from agrochemical and consumer product companies.

Pooling resources

Since its founding in 1978, the secret of success for ECETOC has been based on a few fundamental ideas:

- Sharing knowledge and expertise for the common good
- Promotion of data driven processes in risk assessment
- Scientific dialogue with non-industry experts
- Use of best available science

These principles remain as important today as they were then. The industry is challenged to meet all its needs with limited resources and ECETOC is there to help them achieve this objective. Companies are forced to prioritise and day to day pressures compete with longer term goals. In this environment, which is unlikely to change, ECETOC's role seems even more important to maintaining industry's image as a partner in the scientific debate.


Martin Kayser
Chairman of the Board of Administration

ECETOC BOARD OF ADMINISTRATION

The Board of Administration is empowered by the Annual General Meeting with the management and administration of ECETOC and delegates these tasks on a daily basis to its Secretary General.

The Board is composed of at least six Members representatives. Two Members are entitled to represent the Associate members A category and the Associate members B category respectively.

Members may propose candidates for the Board; these candidates must have managerial duties within their company and possess scientific and technical experience.

ECETOC Board Members as of end December 2009



Martin Kayser
BASF
Chairman



Steve Rumford
AstraZeneca
Treasurer



Hans-Juergen Bender
Procter & Gamble
International
Operations SA



Julia Fentem
Unilever



Mireille Quirina
DuPont de Nemours
International SA



Richard Phillips
ExxonMobil
Petroleum
& Chemical



Thomas Jostmann
Evonik Industries
GmbH



*Jochen Rudolph hands over
the Chairmanship of the Board
to Martin Kayser*

On the occasion of the 2009 Annual General Meeting, having served two years since their last election, the following members' re-election to the Board was unanimously approved: Dr. **Martin Kayser** of BASF and Mrs. **Mireille Quirina** of DuPont de Nemours.

Proposed new Board Members: Dr. **Thomas Jostmann** of Evonik Industries and Dr. **Richard Phillips** of ExxonMobil were endorsed.

Dr. **Jochen Rudolph**, a Board member since 1991 and Chairman of the Board since 2004, resigned his Chairmanship and Membership of the Board, following his retirement from Evonik Industries.

The Chairmanship is now in the capable hands of his successor, Dr. Martin Kayser, who thanked him for his excellent Chairmanship of the Board, his dedication and support. Dr. Kayser has been a member of the Board since 2003 and Treasurer since 2004.

Dr. Kayser was replaced as Treasurer by Mr. **Steve Rumford**



REPORT

FROM THE SECRETARY GENERAL



Joseph Louis Gay-Lussac



Humphry Davy



Charles Darwin

It is often thought that good science is produced by elderly professors on the back of a lifetime of study and experiment. This notion may be based on the way careers are structured, but should not be assumed to be an immutable law.

When modern science was getting into its stride in the 18th century, the stars of science were often very young by today's standards. When Joseph Louis Gay-Lussac formulated his law describing how gases expand when heated, he was 24 years old, working as a researcher at the Polytechnique in Paris; he became professor of chemistry there at age 31. His contemporary, Humphry Davy, was 22 when he began publishing the properties of Nitrous Oxide in the Journal of the Royal Society; he was made a fellow of that prestigious institution at the age of 25.

In the last few years many companies have been recruiting younger scientists to cope with the demands they face. This is partly due to a shortage of experienced experts and partly in order to bring in new blood. Many of these young professionals are on a steep learning curve in their companies and will become a vital resource for ECETOC as well.

For several years ECETOC has been recognising and supporting the development of young scientists by giving awards at scientific conferences, such as EUROTOX, SETAC EUROPE and EPICOH.

In 2009 however, we went one step further and organised an event specifically for younger scientists. The annual technical meeting featured posters, presentations and debates from scientists in the early years of their careers. In fact, many were still completing their PhDs or were postdoctoral students.

In order to enrich the interactive possibilities and the variety of subjects presented, we invited young colleagues from Academic departments with whom ECETOC has had contacts over the past years. Many members of the Scientific Committee were present along with other "friends of ECETOC" and the event had a pleasantly relaxed and convivial atmosphere.

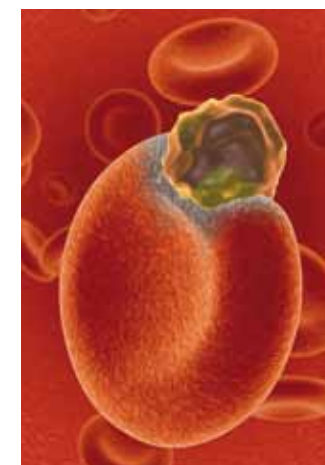
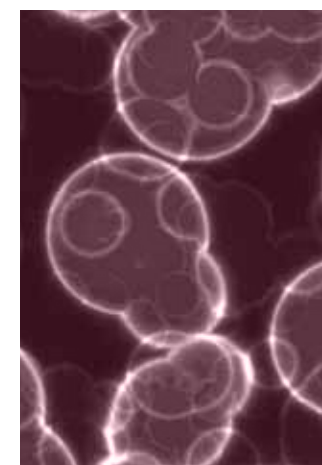
The overwhelming impression was of youthful enthusiasm combined with a high level of intellectual maturity. The quality of the posters was highly professional and the presentations were clearly and confidently delivered. Likewise in the breakout groups, the debate was fresh and lively, but no lack of understanding or naivety was in evidence.

The poster session was organised as a competition, with all participants being involved in the judging. The quality being uniformly high, the result was not obvious until all the votes were counted. The competition was won by Jillian Ross from the University of Dundee in Scotland, working on transgenic rodent models of liver carcinogenicity. The chairman of the Scientific Committee had the pleasure to present her with a commemorative copy of Charles Darwin's "The Origin of Species". This was considered symbolic as not only was 2009 the second centenary of Darwin's birth, but also he was a conspicuously young scientist. He was only 22 when he left on the famous voyage of "The Beagle".

At ECETOC, we are actively encouraging member companies to propose less experienced staff to participate in our activities. Of course, there is no substitute for experience and our task forces will continue to rely on a core of senior experts. However, the younger scientists have much to gain and much to contribute. They will gain in exposure to the more experienced members and contribute fresh approaches and new insights. I hope before long we will be seeing more of these young persons on our task forces and at workshops.

Neil Carmichael

Neil Carmichael
Secretary General



SCIENCE PROGRAMME

Foreword from the **Scientific Committee Chairman**



Many people in our member companies have been busy during the past year finding their way through the implementation of REACH. Some parts of the new legislation have turned out to be more difficult than we expected, and some have been more straightforward. It is tempting to wonder about the return on investment in terms of improved human and environmental health that will result from the increased activity and expenditure in both industry and government. Many people have commented to me that without the impact of ECETOC's sensible scientific inputs, many more areas would have been more difficult to manage. Of course, when one says ECETOC, one really means all the experts from our member companies and experts from academia and consultancies who have worked with them.



The original premise of ECETOC was to harness the expertise which resides in the industry and use it to apply good science to the safety of the manufacture and use of chemicals. There have been major changes in society, in science and in our industry in the 30 years since ECETOC was founded, but the basic concept of working together to bring good science to bear is still valid. However, the balance appears to have moved from jointly evaluating chemicals to jointly assessing particular areas of science. We have also seen tremendous consolidation in the industry, the number of industry experts has reduced and even fewer of them come from institutes doing hands on experimental work.

In addition, the science has become more complex and the level of transparency expected by the public has also increased, so the need for an organisation such as ECETOC is as great as it ever was. The Board and the Scientific Committee have decided that it is time to take stock of how ECETOC takes its place in the "Teenies" as the new decade seems to be labelled. Reviewing our strategy and developing new ideas will be the theme of the Annual General Meeting and the Annual Technical Meeting this year.

I will be handing over the Chairmanship of the Scientific Committee this year after the Annual General and Technical Meetings as I will by then have retired from Syngenta after working in the chemical industry for over 30 years. I was fortunate to be a member of several ECETOC task forces early in my career and I have valued the insight, scientific rigour and camaraderie gained from that involvement. I am pleased to see that ECETOC still provides an excellent grounding for young scientists in our member companies, and that in recent years we have been able to help young scientists in academia as well with our awards and with our young scientist event at last year's Annual Technical Meeting.

It has been a privilege to serve as the Chairman of the Scientific Committee and to work with many colleagues that I have known for many years. It has also been rewarding to make new friendships and develop new partnerships. I am confident that the next few years will see ECETOC thrive as it builds on its past achievements, even though it may strike out in new directions.




John Doe,
Syngenta
Chairman of the Scientific Committee


The 2009 Science Programme (Strategy)

ECETOC pursues its vision and mission according to an issue-based science strategy that was launched in 2007. It is broken down into 13 science areas that are grouped according to 5 main themes:


- Presence of chemicals in humans
- Presence of chemicals in the environment
- Effects in humans and ecosystems
- Methods
- Science of risk assessment

The reader may wish to note that some activities are relevant to and mentioned in more than one science area.



Presence of chemicals in humans	
SCIENCE AREA	2009 ACTIVITY
 Chemicals in human tissue The main objective of this strategic science area is to ensure that the results of biomonitoring studies are placed into appropriate context within risk assessment to human health.	<ul style="list-style-type: none">• Publication of Technical Report No. 104 on a framework for the integration of human and animal data in chemical risk assessment• Publication of Workshop Report No. 14 concerning the use of markers for improved retrospective exposure assessment in epidemiology studies• Monitoring of 4 LRI projects concerning biological guidance values• Monitoring of 3 LRI projects concerning key biomarkers
 Chemicals in indoor air The overall goal of this strategic science area is to address approaches to assess the impact of chemicals found in indoor air on human health.	<ul style="list-style-type: none">• Commissioning of a review into childhood asthma and contributing factors• Selection of an LRI project on indoor environment and risk assessment
 Mixtures The overall aim of this strategic science area is to contribute to the development of a pragmatic, realistic, and science-based framework for the risk assessment of chemical mixtures.	<ul style="list-style-type: none">• Establishment of a task force to develop guidance for assessing the impact of mixtures of chemicals in the aquatic environment• Selection of an LRI project on indoor environment and risk assessment


Presence of chemicals in the environment	
SCIENCE AREA	2009 ACTIVITY
 Exposure issues The overall aim of the strategic science area is to achieve recognition by regulators and non-governmental organisations that decisions on the acceptability of the presence of chemicals in the environment require a risk assessment involving both their hazardous concentrations and exposure concentrations.	<ul style="list-style-type: none">• Publication of Technical Report No. 108, a collation of existing marine biodegradation data and its use in environmental risk assessment• Establishment of a task force to develop guidance for assessing the impact of mixtures of chemicals in the aquatic environment• Establishment of a task force on risk assessment approaches for PBT/vPvB or POPs

	<ul style="list-style-type: none">• Establishment of a task force on the application of critical body burden (CBB) in risk assessment of substances of very high concern (SVHC)• Establishment of a task force on the ERA of ionisable compounds• Organisation of a workshop on the significance of bound residues in environmental risk assessment (Published as Workshop Report No. 17 in February 2010)• Organisation of a scoping meeting on pharmaceuticals and the environment in March• Involvement in the EU 6th Framework Programme: NORMAN Project Advisory Committee• Involvement in the EU 6th Framework Programme: RISKBASE Project Advisory Committee• Selection of an LRI project on the generation of a validated CBB database and to validate a CBB chronic toxicity range for narcotics• Selection of an LRI project on the rapid estimation of trophic magnification factor (TMF) using laboratory, field and computer modelling methods in aquatic organisms• Monitoring of an LRI project on the integrated environmental fate and human food chain bioaccumulation model for polar and non-polar organic substances• Monitoring of 2 LRI projects concerning cross taxonomic biotransformation potential• Monitoring of an LRI project on relationships of biotransformation across organisms• Monitoring of an LRI project on the environmental relevance of laboratory bioconcentration test• Monitoring of an LRI project on applying and verifying PBT/POP models through comprehensive screening of chemicals• Monitoring of an LRI project on the influence of microbial biomass and diversity on biotransformation
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Effects in humans and ecosystems	
SCIENCE AREA	2009 ACTIVITY
 Sensitive sub-populations Certain sub-populations, notably children, may be assumed to be more sensitive than healthy adults. The overall aim of this strategic science area is to provide a focused scientific opinion for regulatory decision making that is targeted at or affects sensitive sub-populations. Currently, this area comprises mainly children's health outcomes. In the future, it may also address the sub-population of the elderly.	<ul style="list-style-type: none">• Commissioning of a review into childhood asthma and contributing factors• Involvement in the EU Consultative Forum on the Health and Environmental Action Plan (observer seat)• Monitoring of an LRI project on the reprogramming of DNA methylation during mammalian development and environmental impact of endocrine disruptors• Monitoring of an LRI project on the review of neurodevelopmental function tests in children



The 2009 Science Programme (Strategy)


 <div>Reproductive health<p>In the public debate, the topic ‘reproductive health’ is often associated with exposure to chemicals. The overall aim of this strategic science area is to ensure that the methods and the testing strategy to identify and characterise developmental and reproductive toxicants are appropriate and optimised.</p></div>	<ul style="list-style-type: none">• Organisation of a workshop to develop guidance on interpreting endocrine disrupting effects within the constraint of REACH and the revised 91/414 Pesticide Directive and publication of the related Technical Report No. 106 and Workshop Report No. 16• Acceptance of an article submitted for publication in ATLA on the modular approach to the extended one-generation reproduction toxicity study• Monitoring of an LRI project on the evaluation of signal transduction pathways in model organisms as critical indicators of developmental toxicity• Monitoring of an LRI project on the characterisation of testicular toxicity using traditional and omic tools• Monitoring of an LRI project on the reprogramming of DNA methylation during mammalian development and environmental impact of endocrine disruptors
 <div>Biodiversity and ecosystems<p>The objective of this strategic science area is to identify the key science issues relevant to risk assessment of chemicals in the environment in a way that is relevant to the potential impact on biodiversity of aquatic and terrestrial ecosystems.</p></div>	<ul style="list-style-type: none">• Establishment of a task force to develop guidance for assessing the impact of mixtures of chemicals in the aquatic environment• Establishment of a task force on exploring novel ways of using SSD to establish PNECs for industrial chemicals• Organisation of a workshop to develop guidance on interpreting endocrine disrupting effects within the constraint of REACH and the revised 91/414 Pesticide Directive and publication of the related Technical Report No. 106 and Workshop Report No. 16• Monitoring of an LRI project about population dynamics modelling for ecotoxicology



Methods	
SCIENCE AREA	2009 ACTIVITY
 <div>Intelligent / integrated testing strategies (ITS)<p>The overall aim of this strategic science area is to contribute to a more effective approach to hazard and risk assessment. This should also support the further development and application of alternative approaches to hazard assessment, and thereby improve the workability of REACH. Good ITS approaches can reduce cost and use of animals while providing best quality data for the risk assessment process.</p></div>	<ul style="list-style-type: none">• Publication of Technical Report No. 104 on a framework for the integration of human and animal data in chemical risk assessment• Publication of Technical Report No. 107, an addendum to ECETOC’s approach to targeted risk assessment and the organisation of a range of workshops to launch the approach and associated assessment tools• Establishment of a task force on risk assessment approaches for PBT/vPvB or POPs• Establishment of a task force on the application of critical body burden in risk assessment of SVHC

<ul style="list-style-type: none">• Organisation of a joint workshop in association with ILSI-HESI concerning the use of mode of action information to improve regulatory decision making• Organisation of symposium at World Congress on Animal Alternatives: Animal use / Chemicals and pesticides• Progression of a task force on the assessment and management of dermal risks from industrial chemicals• Preparation of an overview of established TTC values and those under development• Acceptance of an article submitted for publication in ATLA on the modular approach to the extended one-generation reproduction toxicity study• Involvement in the EU 6th Framework Programme: OSIRIS Project Advisory Committee• Involvement in the ECHA Partner Expert Groups• Involvement in the ECVAM Scientific Advisory Committee• Development of the request for proposals for an LRI project on approaches for read-across in chemical risk assessment• Development of the request for proposals for an LRI project on read-across/QSAR and environmental mode of action assessment for pharmaceuticals• Selection of an LRI project on cross-taxonomic biotransformation potential• Selection of an LRI project on the relationship of biotransformation across organisms• Selection of an LRI project on a toxicogenomic approach to enhance the specificity and predictive value of the murine local lymph node assay• Monitoring of an LRI project on the evaluation of signal transduction pathways in model organisms as critical indicators of developmental toxicity• Monitoring of an LRI project on overcoming current limitations in metabolism prediction of industrial chemicals• Monitoring of an LRI project on tools for probabilistic uncertainty analysis in environmental risk assessment• Monitoring of an LRI project concerning the reference/ validation chemical set for persistence benchmarking• Monitoring of an LRI project on the development and validation of abbreviated <i>in vivo</i> fish concentration test• Monitoring of LRI projects concerning a RepDose database, extended RepDose for reprotox and use of RepDose for TTC• Monitoring of an LRI project concerning a BCF database• Monitoring of an LRI project on fish cell line & embryo assays• Monitoring of an LRI project about the environmental relevance of laboratory bioconcentration test• Monitoring of an LRI project about identification and sensitivity of key parameters of GEMCO. This project was finalised in 2009 and the results were published in the open literature
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The 2009 Science Programme (Strategy)

 'Omics' and related technologies <p>The emerging technologies of genomics, proteomics and metabonomics are already available for hazard if not risk evaluation. This area requires industry involvement to ensure that these technologies are used in an appropriate manner and exploited to their full potential.</p>	<ul style="list-style-type: none">• Monitoring of an LRI project on the characterisation of testicular toxicity using traditional and omic tools
 Risk assessment of innovation <p>The purpose of this strategic science area is to evaluate and develop approaches for addressing the health and environmental risk assessment for innovative products. At present, activities are focussed on potential health impacts and environmental effects of nanomaterials.</p>	<ul style="list-style-type: none">• Publication of a special issue on the toxicity of engineered nanomaterials in 'Toxicology Letters'• Organisation of a symposium at EEMS/ICEM 2009 on the (geno)toxicity of engineered nanomaterials• Selection of an LRI project towards standardised testing guidelines (reproductive toxicity) relevant to nanomaterials• Monitoring of an LRI project looking at the tiered approach to testing and assessment of nanomaterial safety to human health• Monitoring of an LRI project on the assessment of nanoparticles specific effects in environmental toxicity testing

Science of risk assessment	
SCIENCE AREA	2009 ACTIVITY
 Role of chemicals in the causality of disease <p>This strategic science area aims to put the presumed associations between chemicals in the environment and disease into their proper scientific perspective. The focus is particularly directed towards rigorous methodology in observational epidemiology.</p>	<ul style="list-style-type: none">• Publication of Technical Report No. 104 on a framework for the integration of human and animal data in chemical risk assessment• Publication of Technical Report No. 105 on the evaluation of cardiac sensitisation test methods• Organisation of a workshop concerning the enhancement of the scientific process and transparency of observational epidemiology studies and publication of the associated Workshop Report No. 18• Progression of a task force to critically review the data on the carcinogenicity of formaldehyde• Commissioning of a review into childhood asthma and contributing factors• Selection of an LRI project on the assessment of risk factors influencing trends in incidence of female breast carcinoma

	<ul style="list-style-type: none">• Monitoring of an LRI project on the reprogramming of DNA methylation during mammalian development and environmental impact of endocrine disruptors
<div></div> <div><h3>Risk, hazard and precaution</h3><p>The precautionary principle can lead to unrealistic worst case assumptions based on an evaluation of hazard. The aim is to take into account all available scientific tools to adequately characterise risk not only based on hazard characteristics but also on exposure data and dose-response considerations.</p></div>	<ul style="list-style-type: none">• Publication of Technical Report No. 107, an addendum to ECETOC's approach to targeted risk assessment and the organisation of a range of workshops to launch the approach and associated assessment tools• Establishment of a task force on risk assessment approaches for PBT/vPvB or POPs• Establishment of a task force on guidance for assessment factors to derive DNELs• Establishment of a task force on the ERA of ionisable compounds• Establishment of a task force on exploring novel ways of using SSD to establish PNECs for industrial chemicals• Establishment of a task force on the application of critical body burden (CBB) in risk assessment of substances of very high concern (SVHC)• Organisation of a symposium at the European Toxicology Forum in October on the classification of carcinogens• Organisation of a joint workshop in association with ILSI-HESI concerning the use of mode of action information to improve regulatory decision making• Organisation of a workshop to develop guidance on interpreting endocrine disrupting effects within the constraint of REACH and the revised 91/414 Pesticide Directive and publication of the related Technical Report No. 106 and Workshop Report No. 16• Acceptance of an article submitted for publication in <i>Crit Rev Toxicol</i> on guidance for carcinogen classification guidelines under GHS• Acceptance of an article submitted for publication in <i>Regul Toxicol Pharmacol</i> on potency values from the local lymph node assay: application to classification, labelling and risk assessment• Progression of a task force to critically review the data on the carcinogenicity of formaldehyde• Progression of a task force to review the available human and clinically relevant data on the use of cyanide antidotes• Progression of a task force to critically review all data on linear polydimethylsiloxanes (PDMS) and update JACC report No. 26
<div></div> <div><h3>Science in society</h3><p>The overall aim of the strategic science area is to better promote the use of science in EU decision making, to improve the image of industry science with EU policymakers and other scientists, and to enhance the acceptance of science by the general public.</p></div>	<ul style="list-style-type: none">• Establishment of a task force on the environmental impact assessment within the socio-economic analysis of chemicals.

Highlights of 2009

Task forces completed



Cardiac sensitisation methods

At its April meeting, the Scientific Committee reviewed a report prepared by the task force on 'cardiac sensitisation' test methods and the report was consequently approved for publication (Technical Report No. 105).

Cardiac sensitisation means that the normal heart rhythm becomes perturbed, for example when halogenated or unsubstantiated hydrocarbon vapours are inhaled for a short time in combination with high internal adrenaline levels (stress). The resulting cardiac arrhythmias may be fatal. Therefore the cardiac sensitisation potential (and other toxicological properties) of fluorocarbon products needs to be known before those products can be safely used, especially in air-conditioning and fire-fighting applications. Although not a standard regulatory endpoint, the cardiac sensitisation test is a key element in the toxicological assessment of alternative halogenated hydrocarbon products.

The report reviews how cardiac sensitisation studies have been conducted on halogenated hydrocarbons (using the adrenaline-treated dog) and the way in which those test results are used in the prediction of human risk from acute exposure to high concentrations. Critical aspects of the test protocol are the selection of the dose of adrenaline used to 'challenge' the heart, and the definition of a positive response (i.e.

cardiac arrhythmia). For risk assessment, i.e. extrapolation of the animal data to humans, no additional safety factors need to be applied. For improved risk assessment, human blood levels of the inhaled compounds can be estimated using biokinetic modelling. While the report discusses various possible alternatives to replace or refine the current dog model, the task force concludes that there is no clear alternative test system at present.

Little is known about the underlying biological mechanism of the cardiac sensitisation effect; cardiac sensitisation following exposure to halogenated hydrocarbons seems to be a complex event that is not fully understood at present. The report includes a summary of a separate paper drafted by one task force member entitled "Mechanisms involved in cardiac sensitization by volatile anesthetics" (published in the journal *Critical Reviews in Toxicology*).



Guidance for the classification of carcinogens under the globally harmonised system of classification and labelling of chemicals (GHS)

The criteria for classification and labelling under the GHS (globally harmonised system) developed by the United Nations Conference on Environment and Development (UNCED) have been introduced in the EU as a new regulation alongside REACH. They are replacing classification and labelling guidelines

under Directive 67/548/EEC. As regulatory authorities worldwide are beginning to use these GHS criteria, it has been noticed that their interpretation varies in different parts of the world.

A task force was established in 2007 to develop guidance for the application of the GHS criteria, in particular with respect to the endpoint carcinogenicity, and thereby to include considerations of mode of action, potency, exposure and other elements of risk assessment. The task force has finished its remit early last year. The approach developed is in the form of a series of questions to be applied during the evaluation of data from experiments with rodents. Answers to each question can lead either to a classification decision or to the next question. The scheme is illustrated with five case studies, i.e. thiamethoxam, melamine, dichlorvos, formaldehyde, and Sudan I. The extensive paper has appeared in the March 2010 issue of *Critical Reviews in Toxicology*.

Reference to the ECETOC scheme has been made in the report of the REACH Implementation Project - RIP 3.6 (on the introduction of the GHS guidelines into the new EU chemicals legislation). The task force had already presented first concepts for wider input at EUROTOX 2007 at the ECETOC-organised session 'Carcinogen Classification - Moving from a hazard to a risk-based system', and the final scheme was shared at last year's European meeting of the Toxicology Forum.



TTC – Threshold of toxicological concern

The task force, which had been established to evaluate the concept of the 'threshold of toxicological concern (TTC) regarding its general applicability for industrial chemicals', defined and monitored an LRI-funded project 'Use of RepDose for evaluation / refinement of the TTC-concept'. Phase I of the project evaluated the RepDose database (of repeated dose studies) with respect to the influence of study parameters (duration, species, and route) on LOEL/NOEL values, which underlie the TTC for non-carcinogenic endpoints. The second part of the project derived (OECD-) guideline-specific TTC values for sub-acute, sub-chronic and chronic non-carcinogenic endpoints, both for the oral and the inhalation application route. This project was carried out by the Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM) and was presented at several conferences.

Finally, an overview of established TTC values and those under development has been prepared. It can be downloaded from ECETOC's website.



Collation of existing marine biodegradation data and its use in environmental risk assessment

In 2003, risk assessment in the EU was extended to include the marine environment. This acknowledged that there are additional concerns for the risk

assessment of the marine environment which may not be adequately addressed in the methodologies used for freshwater environments. In recognising this increased focus on protecting the marine environment, this task force was established as part of ECETOC's ongoing activities to improve understanding of the persistence of chemicals in the environment. The task force compared the available marine, estuarine and freshwater biodegradation data to determine if a scientific basis for extrapolation between the environmental compartments existed.

Quality control and assurance criteria were established for the identification of suitable non-standard biodegradation test data and the ECETOC Marine Biodegradation Kinetics database (EMBK), which consists of >800 data, was prepared. These data have been used to review the scientific basis of the REACH default values and the task force has concluded that the default rate constants for readily biodegradable chemicals should be reconsidered when the next revision of the REACH technical guidance documents are conducted. The findings have been published as Technical Report No. 108 which includes a copy of the database on a cd.



Framework for the integration of human and animal data in chemical risk assessment

Human data form the most direct evidence for an association between health effects and exposure to chemicals. The availability and quality of human data vary greatly from one chemical to another; this may be strongly related

to the prevalence of exposure and to concern about potential health effects. Guidance is currently available on the evaluation and use of animal toxicological data and human exposure data in the risk assessment process. However, such specific guidance is not available for human health effects, despite the fact that most international authorities recognise that the incorporation of human data would improve the utility and robustness of the risk assessment process.

Consequently, ECETOC identified the need to review and evaluate the different types of human data that are available, and to provide guidance on how such data could be used best in the risk assessment process. A multidisciplinary task force was thus assembled to address the problem, and to consider in particular when and where human data could be used to support risk assessment and risk management decisions, and how human and animal findings could be integrated and used in tandem.

Quality aspects play an important role in the choice of data sources regarding the leading health effect that will be crucial in the risk assessment process. Thus, quality aspects of human data, as well as of animal data, have been extensively addressed in this report.

Following the description of the quality aspects of the human and animal data, a framework for the integration of these data and their use in the risk assessment process is proposed. The framework takes into account human as well as animal data; it is strongly encouraged to use both sources in a combined approach. Ideally, human data and animal data will be complementary and should confirm each other (i.e. both indicate excess risk, or both indicate the absence of risk).

Highlights of 2009

In cases where they are in apparent contradiction, efforts should be made to develop a better understanding of the biological basis for the contradiction. This will often be informative and result in a more reliable basis for risk assessment.

With this report (Technical Report No. 104), ECETOC provides guidance on how human data can be used and integrated into chemical risk assessment and management processes. The proposed framework is illustrated by a number of examples, and a journal publication is planned.



Guidance for the interpretation of endocrine disrupting effects

Recent revision of the European directive on plant protection products and new regulations concerning chemicals will allow the authorisation of a chemical product on the basis that they do not have endocrine disrupting properties. However there is no presently agreed guidance on how to identify endocrine disrupting properties. Consequently, an ECETOC task force was formed in 2008 to provide scientific based criteria that may be used within the context of the plant protection products directive and REACH.

The report that was created by the task force reviews and summarises existing definitions of an endocrine disrupter, as well as the test methods currently available to identify endocrine activity and/or toxicity (Technical Report No. 106). Specific scientific criteria for the determination of endocrine disrupting properties that integrate information from both regulatory (eco)toxicity studies

and mechanistic/screening studies are proposed. These scientific criteria rely upon the nature of the adverse effects detected in regulatory (eco)toxicity studies that give concern for endocrine toxicity and the description / understanding of the mode of action of toxicity which scientifically support and explain the adverse effects. The criteria developed are presented in the form of flow charts for assessing relevant effects for both human and environmental species. These charts are illustrated using example substances. In addition, since all chemicals having endocrine disrupting properties may not represent the same hazard, an element or assessment of potency is also proposed to discriminate chemicals of higher concern from those of lower concern.

The task force organised a workshop in June to introduce and discuss this guidance. See under Workshops.



Targeted risk assessment

The original ECETOC targeted risk assessment (TRA) task force reported in 2004 (Technical Report No. 93) and launched the supporting web-based tool shortly after. Since 2004 almost 2000 users have registered with ECETOC to gain an access to the tool and benefit from its abilities. As part of the process for maintaining the integrity and relevance of the TRA approach, ECETOC has also held a series of meetings and events with experts from member companies and regulatory authorities with the aim of identifying what further modifications may be either necessary or beneficial.

The TRA task force was re-convened in 2006 with the aim of reviewing the

current basis for the approach and making recommendations for further improvements. The task force's initial recommendations were delivered to ECETOC's Scientific Committee in 2007 and were subsequently scoped in terms of the work effort required to integrate them into an updated version of the TRA tool. At the same time, the value of the TRA was recognised under the Commission's REACH activity on the developing Technical Guidance on Information Requirements and Chemical Safety Assessments (CSAs). Specifically, the TRA has been seen as a preferred approach for evaluating worker and consumer health exposure (at the Tier 1 level). At the same time, the need to develop a more workable and pragmatic approach to environmental risk assessment using the principles laid down within the EUSES model was accepted.

Since the summer of 2007, ECETOC has developed the ideas and science underpinning the TRA and continued its dialogue with the Commission/ECHA. The TRA task force has therefore worked during 2007-2009 to develop improved exposure estimation models for workers, consumers and the environment that carry forward the principles that were pioneered in the original TRA web tool whilst accommodating many helpful suggestions from the stakeholder processes. The new tool was launched during Q2 2009 at www.ecetoc.org/tra.

In December 2009, Technical Report No. 107 was published which describes the current structure of the revised TRA approach (for workers, consumers and the environment), details the nature of the changes from the original TRA, and describes the process of justification/verification where such changes are substantive.

Subsequent to the release of the TRAv2 in July 2009, ECETOC has held a series of meetings and events with experts from member companies and regulatory authorities with the aim of identifying what further modifications may be either necessary or beneficial.

While the science underlying the ECETOC Targeted Risk Assessment remains unchanged,

ECETOC has revised certain aspects of the Targeted Risk Assessment tool in order to: - take into account the latest development of the REACH Guidance Chapters R12, R14, R15, and R16 - respond to the users' feedback and to implement the full functionality of the tools.

There has been huge interest in the tools worldwide, with the TRA tool guide even

being translated into Japanese, and users registering from as far afield as South America, China, and Japan. This increased International visibility will be of great benefit to ECETOC and its members in the coming years.

Workshops completed



Enhancement of the scientific process and transparency of observational studies

On September 24-25 2009, ECETOC organised a workshop in London aimed at strengthening the scientific process of observational epidemiology studies. The workshop was attended by invited epidemiologists from industry and academia. The main outcome of the workshop was the endorsement of an Observational Epidemiologic Studies Register (OSR) which will greatly strengthen the transparency and reliability of this type of research and will also increase the scientific

rigor applied in this area. The idea of setting up an OSR came from clinical trials research on the effectiveness of pharmaceuticals in treating diseases, where such a register has been established several years ago. There was near unanimous agreement that the advantages of an OSR far outweigh the disadvantages and the participants agreed to further disseminate the initiative. The report of the workshop is available at the ECETOC website (Workshop Report No. 18). Several interesting spin-offs of the workshop can be mentioned. The Lancet and the British Medical Journal have both published commentaries on the workshop which were supportive of the ECETOC initiative proposing

the establishment of an OSR and emphasising the advantages expected. Lancet recommends researchers to register their observational studies at a WHO-compliant registry and to provide a link to the original protocol in the publication. Editors of several other epidemiology journals have expressed an interest in the workshop and are considering to further address the initiative in their journals.



Guidance on identifying endocrine disrupting effects

To debate and test an approach for identifying endocrine disrupting effects,

a workshop was organised in June 2009.

This approach, developed by the associated task force (see above) provides guidance in the form of flowcharts that could be used as a decision tree for the identification of endocrine disrupting effects in human health (toxicology) and environmental assessments (ecotoxicology). The aim of the workshop was to assess the suitability of such an approach and the outcome was summarised in Workshop Report No.16.

Highlights of 2009



Nano(geno)toxicity of nanoparticles symposium in association with EEMS at ICEM 2009 meeting

ECETOC and EEMS (European Environmental Mutagen Society) repeated their successful collaboration this year to organise a symposium and forum on the first day of the 10th International Conference on Environmental Mutagens (ICEM) which took place 21-25 August in Florence, Italy. The aim of the symposium and forum discussion on the "Genotoxicity of engineered nanomaterials" (ENM) was to review the biological significance of the available information on ENM and discuss approaches to identify and evaluate possible genotoxic effects. Knowledge of the mechanism of genotoxicity should support the rationale of genotoxicity testing of ENM.

Speakers at the symposium explained that the major target organs of ENM exposure are the lung, the central nervous system, and the cardiovascular system. An important point is the physico-chemical characterisation of the test material according to the endpoint studied (e.g. inflammatory response, DNA damages).

Genotoxicity can be the result of a direct interaction with the DNA or indirectly as a consequence of interaction with a non-DNA target such as the spindle apparatus or DNA repair enzymes. Furthermore, it is essential to clarify whether ENM induce primary genotoxicity (elicited by the particles themselves) or cause secondary effects (elicited by the recruited inflammation). For example, although not equivalent measurements, both DNA damage assessed by the Comet assay and micronucleus production are indicators for genotoxicity but as endpoints incapable of differentiating between a primary or secondary mechanism.

The forum expanded on the problems associated with genotoxicity testing of nanomaterials, and elucidated possible genotoxic mechanisms to support improved test strategies. In the ensuing discussion the audience addressed four questions; whether:

- (i) current OECD tests are appropriate and sufficient
- (ii) ENM found systemically are biologically relevant
- (iii) there is a minimal set of parameters to be reported in a study
- (iv) which ENM material can be used as a reference?

A set of articles based on the symposium and forum presentations will be published in the journal *Nanotoxicology*.



Pharmaceuticals and the environment scoping meeting

Since its establishment in 1978, ECETOC's membership has included pharmaceutical companies, chemical companies with significant consumer and personal care portfolios and food companies as well as chemicals, petrochemicals and agrochemicals. However, it came to its attention recently that there were options for sector specific activities, such as for example, in the pharmaceutical sector that were not yet fully explored. Accordingly, a meeting was organised in Brussels to discuss ways in which ECETOC could address the underlying science issues relevant to human and environmental risk assessment of pharmaceuticals.

15 different companies (23 attendees in all) were invited to participate. During the discussions, seven priority topics were highlighted, of which 3, were prioritised and specific activities have now been initiated. They are:

- Bound residues: a workshop was organised in Brussels in October and a further task force is due to start in 2010
- ERA of ionisable compounds: a task force was established in summer 2009



Significance of bound residues in environmental risk assessment

Bound residues, including non-extractable residues, are an important factor in PBT assessment and the risk assessment of chemicals. Precautionary risk assessments usually assume 100% bioavailability, i.e. all of the chemical present is available, for degradation or to have potential toxic effects on the biota. This precautionary approach generally overestimates the exposure concentration by the amount that is not available and therefore overestimates the level of risk to biota in the environment. Although it is a position that has been recognised and referenced by REACH (2008) and OECD test guidance (2002), there is no agreed guidance on how to determine what is available and what is not, and how information on bound residues should be interpreted in the risk assessment. As a result, it continues to be debated from a scientific and regulatory point of view. ECETOC held a 2-day workshop attended by 38 stakeholders representative

- Read across/MoA/QSAR: A pharma-specific task force is due to start in 2010.

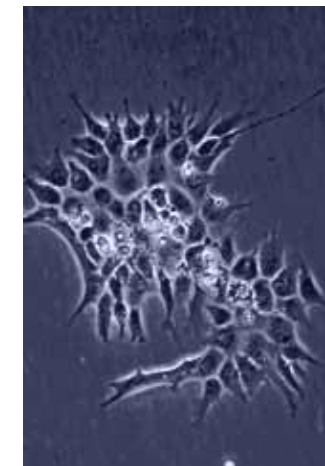
of industry, academia and regulatory authorities from the USA, Canada, Europe and Asia in Brussels on 21-22 October to further this debate and to develop guidance on how to account for bound residues and bioavailability in environmental risk assessment. The conclusions, future regulatory and research needs, and a framework outlining a possible approach for advancing and improving the risk assessment of bound residues, are presented in Workshop Report No. 17.



Targeted risk assessment launch workshops for members and non-members



The TRA task force held a members' workshop in February 2009 to beta-test the revised versions of the three exposure estimation models (environment, consumers and workers). Comments and feedback



have been incorporated and the final versions have been presented at a fully-subscribed non-member workshop in May 2009. At this event, ECETOC shared the new tools together with supporting user guides. This non-member workshop presented these key REACH tools that function to support the work of CSA and Exposure Scenario development within Consortia and Substance Information Exchange Forums (SIEFs), and explained the rationale and key changes from 2004.



Using mode of action information to improve regulatory decision making

A workshop entitled 'Using mode of action information to improve regulatory decision making' was held



2-3 November at the City Presentation Centre in London. This event was organised in co-operation with HESI, and was sponsored by Cefic LRI.

The main goal of the meeting was to examine to what extent toxicological mode of action information can be used to modify human risk assessment. This approach evaluates the known key steps in the toxicological mode of action in animals with the available information on the relevance of this pathway in man. The discussion centred on the 'mode of action framework' which is promoted by the WHO International Programme on Chemical Safety (IPCS) and is similar to the approach proposed by ECETOC in Technical Report No. 99 – 'Toxicological modes of action: relevance for human risk assessment' which was published in 2006. Presentations were made by a distinguished



group of speakers from academia and industry, which used case studies to illustrate the practical use of the framework.

There was a high level of agreement on using this approach where sufficient information is available to characterise a 'mode of action'. There was of course some debate as to how much data would be needed to establish a 'known mode of action', which could then be extrapolated from one example to less thoroughly investigated chemicals. One of the main recommendations of this meeting was the establishment of a register of those modes of action which are sufficiently well described as to be useful in employing this approach in risk assessment within a regulatory context.

Highlights of 2009

Task forces established



Approaches for read-across in chemical risk assessment

Recent advances in bioinformatics, rapid assay technologies and computational toxicology have raised the prospect of predicting the functioning of cellular pathways in humans in a mechanistic way. Biologically significant alterations of key pathways may result in adverse health effects. With this in mind and acting upon a request from Cefic-LRI, the Scientific Committee established a task force to review, and illustrate with practical examples, how to employ data from high-throughput screening techniques (e.g. 'omics, cytogenetics) in the application of existing *in silico* methods (e.g. enzyme kinetics modelling, systems biology) used for performing read across in chemical hazard identification. The task force should also indicate how to evaluate the relative robustness of the results and adequacy of the read-across approach. Identified gaps in knowledge and priorities for research could then be the subject of a request for proposal under the LRI.



Development of guidance for assessing the impact of mixtures of chemicals in the aquatic environment

The theory of mixture toxicity has become more sophisticated over recent years but the long held principles of concentration addition still seem to provide a generally reliable, rough and conservative, estimate of toxicity. This means we can usually predict the toxicity of mixtures for risk assessment purposes when we know roughly the properties (e.g. via summary parameters) or chemical components of a mixture. However, we do not tend to consider interaction of specific chemicals or chemical mixtures with other unknown chemicals present in the environment, i.e. we do not ask; what is the potential impact of all chemicals present in the environment? This leaves industry vulnerable to criticism, in particular for not determining whether chemicals present in the environment, including those at concentrations below their respective PNECs, act additively to cause an overall effect.

Taking into account that it is not possible to consider, or even predict, all the potential combinations of chemicals in the environment, prospective risk assessment of mixtures, as currently used in regulation of individual chemicals is not possible. However, a retrospective approach comparing actual with expected (or desired) biological quality, e.g. diversity and/or function can provide integrated assessments of whether environmental mixtures really cause impacts. A key advantage of retrospective assessment is that actual ecosystems are assessed rather than extrapolates to them. A retrospective approach can also provide a reality check on the identification of priority concerns identified by the EU Water Framework Directive (WFD). However, this is not a simple activity and requires development of methods to discriminate impacts of chemicals (or other stressors) from natural environmental variation.

Retrospective assessments can also inform the debate over the apparent loss of biodiversity – is chemicals management inadequate and therefore unsustainable? Since both the chemical

industry and the water industry have stakes in ensuring good water quality, this approach may facilitate future co-operation, i.e. a wider multi-sector involvement in understanding the true impact of chemicals and the effectiveness of treatment infrastructure.

The task force will review field based comparative approaches for assessing impacts on the aquatic environment and develop guidance on suitable methods. Using case studies, it will identify research needs, including how methods can be implemented and what diagnostic tools are required. Finally, it will consider the value of retrospective assessment in assessing the capacity of aquatic communities for tolerating man made discharges.



Environmental impact assessment in socio-economic analysis of chemicals: practical guidance based on case studies

Following the successful workshop in 2008 on the role of risk assessment in socio-economic analysis (published as Workshop Report No. 13), a task force on the topic has been established. Its remit is to establish a user-friendly framework for the assessment of environmental impacts to be used in socio-economic analysis (SEA) e.g. in REACH, and demonstrate the principles with a number of case studies. For perspective, under REACH an SEA may be the only route for countering proposals for no authorisation and for moderating proposals for restrictions. For this, it will be crucial to express risks

in ways that can be valued, i.e. in terms of units of life or ecology saved by the banning or the restrictions. The same was the case under the Existing Substances Regulation but limitations in risk assessments, especially those involving thresholds of effects (PEC/PNEC ratios), meant that few quantitative SEAs were carried out. Similar limitations have been encountered under the US Toxic Substance Control Act (TSCA).

The task force has a mixed industry and academic membership, both environmental scientists and economists. The case studies will be developed in the first instance with the requirements of REACH in mind while recognising that the Water Framework Directive and the EU 'biodiversity' legislation also have important SEA needs.



Exploring novel ways of using SSD to establish PNECs for industrial chemicals

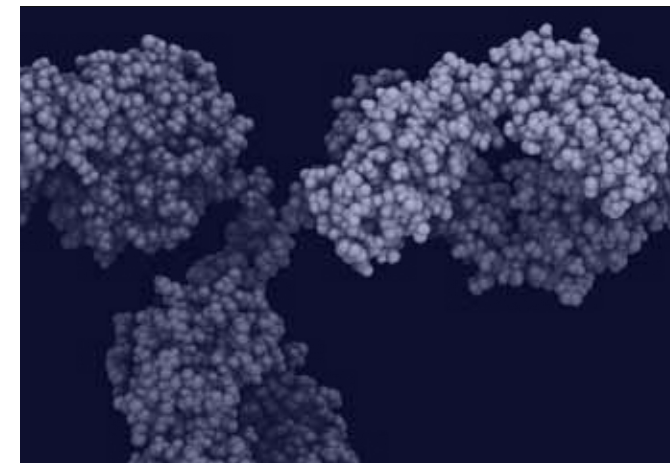
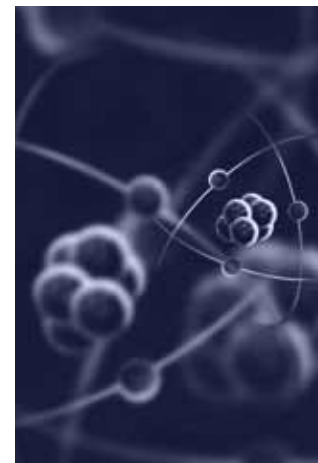
One of the recommendations to come out of the 2008 ECETOC workshop on 'probabilistic approaches for marine hazard assessment' was the need for statistical guidance and communication as well as a recommendation to evaluate a number of approaches that may have the potential to improve the estimation of SSDs (species sensitivity distributions).

An ECETOC task force began to address some of these considerations. In parallel, Unilever initiated an initial exploration of the Interspecies Correlation Estimation (ICE) method in collaboration with Andy Hart of FERA and Peter Craig of Durham University. As a result, a meeting was

held in London on 20 August to discuss combining the two projects. The outcome of the London meeting was that the Unilever post-doc project was adopted as an ECETOC task force in collaboration with the Environment Agency of England and Wales and possibly the US Environmental Protection Agency (EPA).

The task force will look at methodology for estimating HC5 including confidence limits, based on moderate number of tested species, which is scientifically supported and also comprehensible and acceptable to regulators. It is conceivable that more than one methodology may be required depending on circumstances, depending for example, on the number of species for which relevant test data are available. It will make clearly-defined and practical calculations for HC5 estimates and PNECs.

An underlying principle of this proposal is to deliver methods which will be usable and useful in practical regulation. This does not preclude the investigation of wider scientific and statistical issues in so far as they may have implications for practice.



Highlights of 2009



Environmental risk assessment (ERA) of ionisable compounds

The release of 'ionisable compounds' (where behaviour depends on pH, ionic strength, etc.) into the environment presents the risk assessor with particular problems. The Scientific Committee therefore, acting upon a recommendation from the meeting on pharmaceuticals in the environment, established a task force to review the current understanding and available literature on partitioning property data of ionisable compounds at environmental relevant pHs, including estimation methods for these properties in case measured data are lacking. This should improve our ability to better predict the environmental concentration of ionisable compounds in aquatic environments.

The work of this task force may also help to define a generic model environment with appropriate soil and water properties, and other parameters required for effective environmental risk assessment of ionisable

compounds. This should include identification of the key parameters needed to better predict the bioconcentration factor (BCF) of ionisable compounds.



Guidance on assessment factors to derive DNELs

The European Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) requires detailed registration dossiers including chemical safety assessments (CSA) for all chemicals produced or imported in amounts of > 10 tons/year that are to be prepared by chemical manufacturers and importers. The CSA includes Exposure Scenarios (ES) and assessments of exposure for all supported uses and requires these to be justified against Derived No-Effect Levels (DNELs) which are in turn based upon hazard assessments. The DNELs developed must address acute or repeated exposure, different exposure routes (such as inhalation or skin contact), differentiate between

systemic and local effects, and between workplace and general population exposure as appropriate for the intended use pattern.

Soon after the publication of Chapter R.8 of the 'Guidance on information requirements and chemical safety assessment' (REACH TGD) a discussion started within the scientific community of the chemical industry as to whether the default Assessment Factors (AFs) contained within Chapter R.8 should predominantly be used in circumstances where only limited information is available on a substance. This is opposed to situations where the knowledge base is much broader and it can be scientifically justified to use more suitable data-derived AFs for the safe use of chemicals with adequate risk management measures.

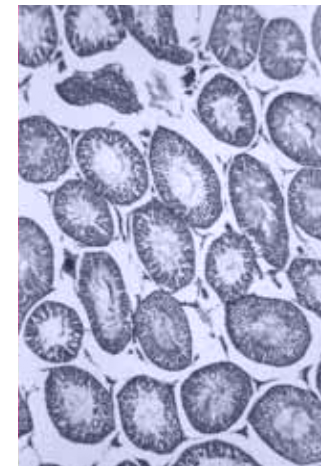
An ECETOC task force was established to lay out a practical basis by which industry will be able to refer to a science-based approach for the consistent and reliable identification of suitable AFs. Based upon a critical comparison of AFs contained in the REACH TGD with those identified in ECETOC Technical Report

No. 86, criteria will be described which should be applied where industry (in registrations under REACH) is able to justify the application of alternative AFs from those contained in the REACH TGD, Chapter R.8. The concepts which were developed have been shared for wider input at a workshop in early 2010 with participants from industry, academia and regulatory agencies.



Risk assessment approaches for PBT/vPvB or POPs

Due to the argued inadequacies of current risk assessment methodologies, several regulations (e.g. POPs, REACH authorisation) either do not allow or limit possibilities to conduct risk assessments as a basis for risk management decisions. Instead, decisions are based on a strict interpretation of the precautionary principle leading to hazard (rather than risk) based restrictions. A scoping meeting was convened by ECETOC in April 2008 that identified this subject as one where an



ECETOC task force could explore opportunities to progress the science.

This task force was established in 2009 with the mandate to collate published risk approaches; to address ongoing research, issues of data availability, and data quality e.g. with regard to reliable data on total emissions. If possible, the task force will recommend a scheme of approaches for risk assessments of PBT/vPvB or POP substances (see ECETOC Technical Report No. 98 'Risk Assessment of PBT Chemicals') and identify possibilities for further research in this area. The task force will present a poster at SETAC 2010 and the overall outcome of this activity is planned for the beginning of summer 2010

in the form of an ECETOC Technical Report followed shortly by a peer-reviewed paper.



The application of critical body burden in risk assessment of SVHC

Two ECETOC task forces on the risk assessment of PBTs have produced recommendations to enable the risk assessment of materials of high concern under REACH and other regulatory programs. In the first task force, one key approach for the development of a more robust 'PNEC' was

identified as the application of critical body burden (CBB) in higher tier risk assessment and food chain assessment. The second task force was convened to provide a case study using the CBB approach. The final output for this group was a weight of evidence approach to identifying mode of action for organic chemicals, a critical piece necessary for the use of the CBB approach. In 2008, a PBT workshop was held to identify priority programs for ECETOC to further advance PBT risk assessment methodology. This task force is one of the proposed outputs of that workshop.

The main objective of the task force is to report on the use of CBB in risk assessment and identify opportunities for

its application for SVHCs. It is intended that this would result in recommendations for developing relevant data for ERA as well as further research needed in this area. Furthermore, either a peer-reviewed publication or an ECETOC report in addition to a targeted LRI project is anticipated.



SCIENCE AWARDS

With the objective to recognise young scientists, ECETOC has been active in the provision of an annual Science Award to outstanding works of science since 2003.

The 1st Science Award was accorded on the occasion of ECETOC's 25th Anniversary to recognise the achievements of three promising European investigators in the fields of science relevant to its mission of supporting the safe manufacturing and use of chemicals, pharmaceuticals and biomaterials through good science.

Since then the format of the Award may have varied, however the objectives have remained the same.

In 2009 ECETOC sponsored the following awards for young scientists and is proud to announce this year's winners:



Participants of 2009 annual meeting with prize-winner Jillian Ross

Environmental science related award

This year's environmental science award for a young scientist was presented to Lucia Vergauwen of the University of Antwerp for her platform paper "An integrated study to the effects of temperature acclimation in zebrafish" which she gave at the annual meeting of SETAC Europe.

Occupational health and exposure award

The young scientist award on research on occupational health and exposure was given to Craig Moore of Newcastle University for his platform presentation "The influence of everyday clothing on percutaneous absorption and distribution of model penetrants *in vitro*" at the OEESC (Occupational and Environmental Exposure of Skin to Chemicals) 2009 conference.

Human health related science award

The third of this year's young scientist awards was presented at the EUROTOX 2009 meeting. It went to Katherina Sewald of the Fraunhofer Institute for Toxicology and Experimental Medicine for her poster presentation: "Respiratory toxicology and immunotoxicology in human precision cut lung slices (PCLS)".

Next generation of scientists award

Additionally in 2009 and with the objective to encourage the involvement of young scientists in the work of ECETOC, a poster competition was held on the occasion of the 2009 annual meetings. Participants at the annual meetings voted for the winner: Jillian Ross of CXR Biosciences in Dundee, who presented her poster entitled: "Human constitutive androstane receptor (CAR) supports the hypertrophic but not the hyperplastic response to the murine non-genotoxic carcinogen phenobarbital *in vivo*".

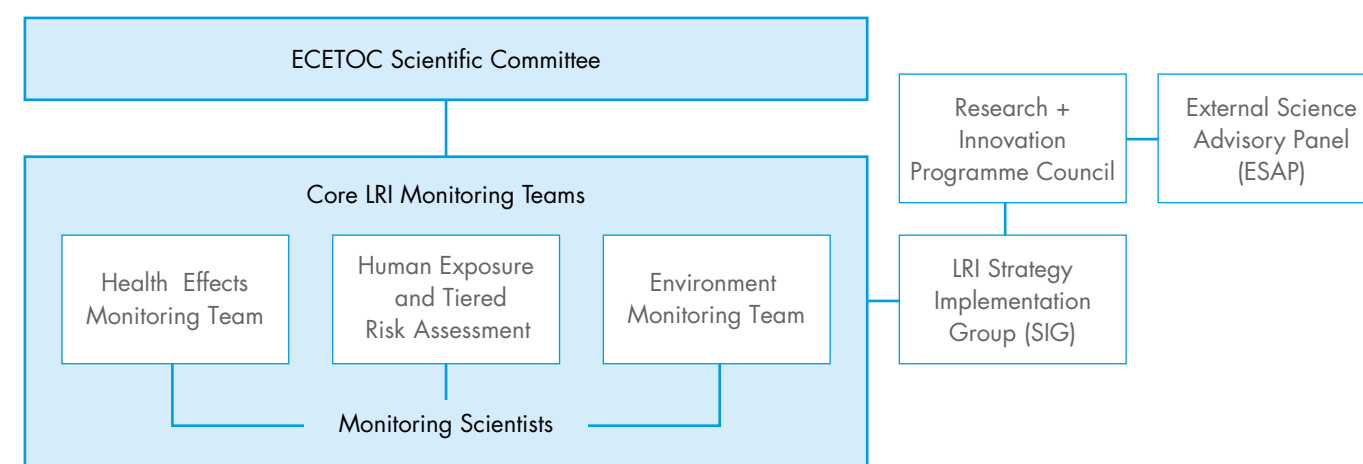
LONG-RANGE RESEARCH INITIATIVE

The idea for LRI began in the USA in 1996, with the goal of responding to public and stakeholder concerns through scientific investigation. The focus is on gaps in industry's knowledge and understanding that are critical for risk assessment. The broad aim is a validated infrastructure of scientific advice on which the entire industry and regulatory bodies will draw to respond more quickly and accurately to the public's questions. Today's LRI is jointly managed by the American Chemical Council, Japanese Chemical Industry Association, and European Chemical Council (CEPIC). The LRI sponsors research to help address some of the priorities of the European public health strategy: improving risk assessment of chemicals; and more specifically monitoring effects of chemicals on health; understanding the environmental factors in human health; establishing endocrine disruption references; and co-ordinating research, data and activities at a European level. LRI also addresses many of the environmental objectives of the European Union, including: linking environmental factors to health effects; understanding and reducing chemical risks to environment; and improving animal testing in risk assessment.

ECETOC has been a key partner to CEPIC from the earliest stage of the LRI process. It provides scientific support into the LRI, and input into the Research Programme.

Within the LRI, ECETOC has the responsibility of maintaining three 'core teams' consisting of industry scientists, who manage the scientific evaluation of applications for funding, recommend the best research proposals and monitor of the progress of selected LRI projects. In particular they are responsible for the:

- Development of topics for research to be considered by the LRI Strategy Implementation Group (SIG). (A core team may organise a workshop with academic, government and industry scientists for this purpose)
- Drafting of 'requests for proposals' (RFPs) based on ideas submitted by CEPIC and ECETOC stakeholders in the LRI process
- Setting up selection teams of industry and external experts to choose the best research proposals in response to published RFPs and making recommendations to LRI SIG concerning the funding of the proposals
- Establishment of scientific liaison with the selected institutions and 'monitoring' the scientific quality and progress of the projects.



Health Effects **Monitoring Team (HEMT)**

Three new projects were initiated in 2009 with the support of specially recruited selection teams (below marked with *). One project was successfully finalised: ‘Review of neurodevelopmental function tests in children’, and has been published in the open literature. The current research portfolio under the health effects programme looks as follows:

Theme: Methods

Intelligent / integrated testing strategies (ITS)

- Evaluation of signal transduction pathways in model organisms as critical mediators of developmental toxicity**
- Overcoming current limitations in metabolism prediction of industrial chemicals
- A toxicogenomic approach to enhance the specificity and predictive value of the murine local lymph node assay*

** Also addresses the Strategic Science Area: Reproductive health

‘Omics’ and related technologies

- Characterisation of testicular toxicity using traditional and omic tools**

Risk assessment of innovation

- Tiered approach to testing and assessment of nanomaterial safety to human health
- Towards standardised testing guidelines (reproductive toxicity) relevant to nanomaterials*

Theme: Science of risk assessment

Role of chemicals in the causality of disease

- Reprogramming of DNA methylation during mammalian development and environmental impact of endocrine disruptors**
- Assessment of risk factors influencing trends in incidence of female breast carcinoma*

Human Exposure and Tiered Risk Assessment **Monitoring Team (HETRA)**

In recent years, there has been growing recognition that unintentional injuries (including accidental poisonings) resulting from random and ‘unavoidable’ accidents are largely preventable. Developing and implementing effective injury prevention policies has become a firm public health concern. A prerequisite to action, however, is to develop a good understanding of the nature and cause of injury by accidental poisoning. It is also important to have a means for evaluating the effectiveness of preventative measures. To address this gap in knowledge, a consortium led by the UK Health and Protection Agency completed a two-and-a-half-year HETRA project entitled “Description of the nature of the accidental misuse of chemicals and chemical products” (DeNaMiC). The project provides an overview of the nature and extent of injury from chemicals and chemical products in the European region and details the circumstances of how these exposures occur.

New regulations for chemicals, biocides and cosmetics require thorough and careful data mining for SAR approaches and further prioritisation for integrated testing. With this in mind, after several years of development, the Fraunhofer ITEM has completed a database named ‘RepDose’ on experimental NOEL/LOEL values for various repeated dose toxicity endpoints. Originally conceived by the HETRA group, RepDose

currently contains data on 655 substances and can be accessed on the internet using Ambit structure descriptors, while an additional tool allows for a number of standard queries (www.repdose.de). A companion database ‘FeDTeX’ on fertility and developmental endpoints is under construction. FeDTeX will enable the evaluation of reproductive toxicity data, in particular NOELs/LOELs on fertility and developmental effects, of presently 100 chemicals.

Four other HETRA projects were further progressed to enable the development of guidance values for use in the interpretation of human biological monitoring data.

Finally, the HETRA group assisted by external experts evaluated new proposals for research on ‘Indoor environments & risk assessments’, and ‘Realistic estimation of exposure to substances from multiple sources’. (The RFPs had resulted from a workshop on consumer exposure.⁽¹⁾) In all, four projects were selected and these were recommended to CEFIC-LRI for funding.

⁽¹⁾ Workshop on “Exposure and risk assessment of chemical mixtures in consumer products”. IHCP (Institute for Health and Consumer Protection) and ECETOC, JRC, Ispra, Italy: 29-30th January 2009

Environment **Monitoring Team (EMT)**

Three new projects secured funding and were initiated in 2009 with the support of the liaison research teams. These were: Generate a validated CBB database and validate a CBB chronic toxicity range for narcotics, Rapid estimation of TMF using laboratory, field and computer modelling methods in aquatic organisms, and Development and validation of abbreviated *in vivo* fish concentration test.

The current research projects under the Environment Monitoring Teams look as follows:

Theme: Presence of chemicals in the environment

Exposure issues

- Integrated environmental fate and human food chain bioaccumulation model for polar and non-polar organic substances. This project was finalised in 2009 and the results were published in open literature
- Cross taxonomic biotransformation potential (2 projects)
- Relationships of biotransformation across organisms
- Environmental relevance of laboratory bioconcentration test
- Applying and verifying PBT/POP models through comprehensive screening of chemicals
- Influence of microbial biomass and diversity on biotransformation
- Generate a validated CBB database and validate a CBB chronic toxicity range for narcotics
- Rapid estimation of TMF using laboratory, field and computer modelling methods in aquatic organisms.

Theme: Effects in humans and ecosystems

Biodiversity and ecosystems

- Population dynamics modelling for ecotoxicology. This project was finalised in 2009 and the results were published in open literature.

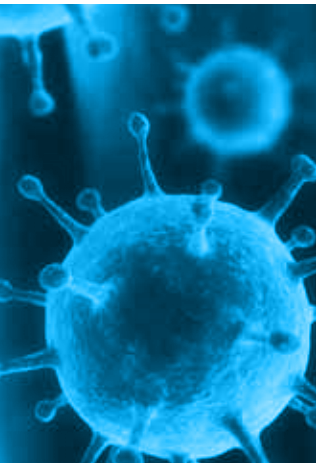
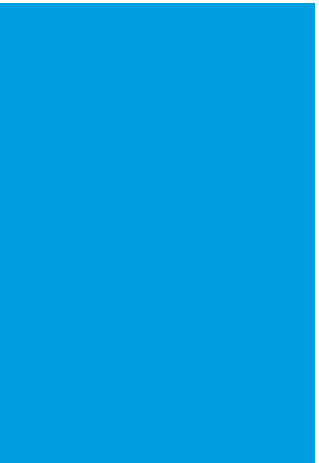
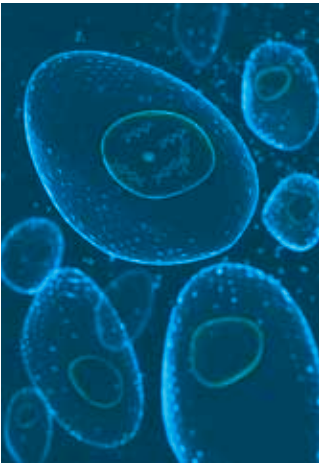
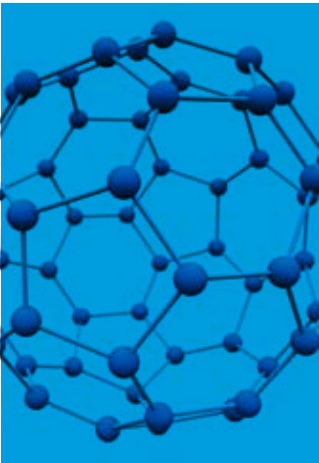
Theme: Methods

Intelligent / integrated testing strategies (ITS)

- BCF database / extension. This project was finalised in 2009 and the database is available
- Fish cell line & embryo assays
- Environmental relevance of laboratory bioconcentration test
- Tools for probabilistic uncertainty analysis in environmental risk assessment
- Cross taxonomic biotransformation potential
- Relationship of biotransformation across organisms
- Reference / validation chemical set for persistence benchmarking
- Development and validation of abbreviated *in vivo* fish concentration test
- Identification and sensitivity of key parameters of GEMCO. This project was finalised in 2009 and the results were published in open literature

Risk assessment of innovation

- Assessment of nanoparticles specific effects in environmental toxicity testing.



COMMUNICATION

PUBLICATIONS

ECETOC's primary outputs are its published 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 publications and the publication of its reports in peer-reviewed journals.

In 2009 ECETOC ceased producing reports designated as a 'Monograph' or a 'Document'.

Instead, '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 all to be published as Technical Reports.

- **JACC Reports** (Joint Assessment of Commodity Chemicals) are comprehensive reviews of toxicological and ecotoxicological data on individual chemical substances.
- **Special Reports** are compilations of data targeted to specific regulatory issues/demands.
- **Technical Reports** address specific applications of the science in evaluating the hazards and risks of chemicals to human health and the environment.
- **Workshop Reports** are summaries of the discussions and conclusions derived from ECETOC sponsored scientific workshops.

REPORTS PUBLISHED BY ECETOC

TECHNICAL REPORTS

- No. 104 Framework for the integration of human and animal data in chemical risk assessment. (January 2009)
- No. 105 Evaluation of cardiac sensitisation test methods. (September 2009)
- No. 106 Guidance on identifying endocrine disrupting effects (June 2009)
- No. 107 Addendum to ECETOC targeted risk assessment technical report No. 93 (December 2009)
- No. 108 Collation of existing marine biodegradation data and its use in environmental risk assessment (December 2009)

WORKSHOP REPORTS

- No. 14 Use of markers for improved retrospective exposure assessment in epidemiology studies (February 2009)
- No. 15 The probabilistic approaches for marine hazard assessment (June 2009)
- No. 16 Guidance on interpreting endocrine disrupting effects (October 2009)
- No. 18 Enhancement of the scientific process and transparency of observational epidemiology studies (November 2009)

Complementary copies of ECETOC reports are provided to member companies, the academia, government authorities and international agencies, and some non-governmental organisations. All reports can be freely downloaded from www.ecetoc.org.

ARTICLES PUBLISHED IN THE OPEN SCIENTIFIC LITERATURE

McGregor D, Boobis A, Binaglia M, Botham P, Hoffstadt L, Hubbard S, Petry T, Riley A, Schwartz D, Hennes E C.

Guidance for the classification of carcinogens under the globally harmonised system of classification and labelling of chemicals (GHS).

Critical Reviews in Toxicology 40, 3, 245-285 (2010, submitted August 2009)

...

Loveless SE, Api A-M, Crevel RWR, Debruyne E, Gamer A, Jowsey IR, Kern P, Kimber I, Lea L, Lloyd P, Mehmood Z, Steiling W, Veenstra G, Woolhiser M, Hennes E C.

Potency values from the local lymph node assay: application to classification, labelling and risk assessment.

Regulatory Toxicology and Pharmacology 56, 54-66 (2010 Submitted July 2009)

...

Norppa H, Greim H, eds. **Toxicity of engineered nanomaterials.**

Special Issue Toxicology Letters 186, 147-176 (8 May 2009)

...

Wiegand H-J, Krüger N, Norppa H, Carmichael N, Greim H and Vrijhof H.

Toxicology of engineered nanomaterials – Introduction.

Toxicology Letters 186, 147 (2009)

...

Carmichael P, Kirsch-Volders M, Vrijhof H.

Thresholds for genotoxins and their application in risk assessment - Editorial.

Mutation Research 678, 71 (2009)

...

Carmichael P, Kirsch-Volders M, eds.

Thresholds for genotoxins and their application in risk assessment.

Mutation Research/ Genetic Toxicology and Environmental

Mutagenesis 678, 71-158 (August 2009)

...

Pottenger L H, Carmichael N, Banton M I, Boogaard P J, Kim J, Kirkland D, Phillips R D, van Benthem J, Williams G M, Castrovinci A.

ECETOC Workshop on the biological significance of DNA adducts: Summary of follow-up from an Expert Panel Meeting.

Mutation Research 678, 152-157 (2009)

...

Moore N, Bremer S, Carmichael N, Daston G, Dent M, Gaoua-Chapelle W, Hallmark N, Hartung T, Holzum B, Hübel U, Meisters L, Schneider S, van Ravenzwaay B, Hennes E C.

A modular approach to the extended one-generation reproduction toxicity study. The outcome of an ECETOC task force and international ECETOC/ECVAM workshop.

Alternatives to Laboratory Animals (ATLA) 37, 219-225 (2009)

...

ONLINE COMMUNICATION

ECETOC completed an overhaul of its internal information management, resulting in a new extranet for members, database and document management system.

The new members' site is a platform for greater transparency of ECETOC's work and aims to improve the ability with which task forces and workshop organising committees co-operate.

EXTERNAL REPRESENTATION

REPRESENTATION AT SPECIFIC MEETINGS OR INPUT TO SPECIFIC PROJECTS:

Workshop on 'Exposure and risk assessment of chemical mixtures in consumer products'

IHCP (Institute for Health and Consumer Protection) and ECETOC

Ispira, Italy
29-30 January 2009

ECETOC was represented by Chris Money of ExxonMobil, Peter Boogaard of Shell, Carlos Rodriguez of Procter & Gamble, and Henk Vrijhof of ECETOC

ECNIS – NewGeneris Stakeholder Workshop: 'Food and Environmental Cancer Risks for Adults and Children'

Brussels, Belgium
16 March 2009

ECETOC was represented by Christa Hennes of ECETOC

10th International Conference on Environmental Mutagens

Florence, Italy
21-25 August 2009

ECETOC was represented by Maria Donner of DuPont Haskell, Julie Muller of Solvay, and Henk Vrijhof of ECETOC

Nanotechnology – OEH Conference

Helsinki, Finland
26-29 August 2009

ECETOC was represented by Christa Hennes of ECETOC

Genomics in cancer risk assessment workshop

Venice, Italy
27-28 August 2009
ECETOC was represented by John Doe of Syngenta and Chairman of the ECETOC Scientific Committee

World Congress on Animal Alternatives

Rome, Italy
30 August - 3 September 2009

Neil Carmichael of ECETOC chaired the session 'Areas of animal use/Chemicals and pesticides'

David Owen of Shell presented ECETOC's activities in support of alternatives to animal testing

DG SANCO Scientific Committee's Scientific Hearing on the Opinions 'Risk assessment of products of nanotechnologies' and 'Safety of nanomaterials in cosmetic products'

Brussels, Belgium
10 September 2009

ECETOC was represented by Christa Hennes of ECETOC

OECD countries activities regarding testing, assessment and management of endocrine disruptors workshop

Copenhagen, Denmark
22-24 September 2009

ECETOC was represented by Remi Bars of Bayer CropScience, Nina Hallmark of ExxonMobil, and James Wheeler of Syngenta from the task force on 'Guidance on interpreting endocrine disrupting effects within the regulatory context'

DG SANCO Scientific Committee's Scientific Hearing on the Draft Opinion 'Use of the threshold of toxicological concern (TTC) approach for the safety assessment of chemical substances'

Brussels, Belgium
24 September 2009

ECETOC was represented by Detlef Keller of Henkel and Bob Safford of Unilever

IARC Meeting on Monograph 100

Lyon, France
20 – 27 October 2009

ECETOC was represented by Gerard Swaen of Dow Chemicals

ECHA workshop: 'Guidance of DNEL/DMEL from Human Data'

Helsinki, Finland
30 October 2009

ECETOC was represented by Gerard Swaen of Dow Chemicals

DG SANCO Scientific Committee's Stakeholder Dialogue on Risk Assessment

Brussels, Belgium
20 November 2009

ECETOC was represented by Neil Carmichael of ECETOC, Mary Spurgeon of Unilever, Matthias Vey of IFRA and Frederike Wiebel of Henkel

SAFE Consortium Workshop: 'Dietary Exposure to Endocrine-Active Pesticides'

Brussels, Belgium
26–27 November 2009

The workshop was chaired by Neil Carmichael of ECETOC

REPRESENTATION IN ON-GOING EXPERT GROUPS:

6th Framework Programme Co-ordination Action Project 'RiskBase'

ECETOC was represented in the Advisory Panel by Andrew Riddle of AstraZeneca

6th Framework Programme Co-ordination Action Project 'NORMAN'

ECETOC was represented in the Advisory Panel by Watze de Wolf of DuPont

6th Framework Programme Integrated Project 'OSIRIS'

ECETOC was represented in the Advisory Panel by Watze de Wolf of DuPont

OECD Working Party on Manufactured Nanomaterials

ECETOC was represented (via BIAC) in the project on alternative methods in nanotoxicology by Monika Maier of Evonik, David Warheit and Mike Kaplan, both of DuPont

WHO/IPCS Harmonisation Project Core Group

ECETOC was represented by John Doe of Syngenta and Chairman of the ECETOC Scientific Committee

Consultative Forum on Environment and Health organised by EU Commission

ECETOC was represented by David Owen of Shell

ECHA Risk Assessment Committee (RAC)

ECETOC was represented by Marie-Louise Meisters of DuPont and Chris Money of ExxonMobil

ECHA Member States Committee (MSC)

ECETOC was represented by David Owen of Shell and Neil Carmichael of ECETOC

ECHA Partner Experts Groups (PEGs)

ECETOC was represented by 17 industry experts on current PEGs, recruited from 40 experts in the stakeholder expert group nominated by ECETOC

ECVAM Scientific Advisory Committee (ESAC)

ECETOC was represented by David Owen of Shell; later in the year replaced by Neil Carmichael of ECETOC

PRESENTATIONS AND POSTERS:

International Commission on Occupational Health (ICOH) meeting

Cape Town, South Africa
24 March 2009

Andreas Flückiger of Hoffmann-La Roche presented the key conclusions from the task force on 'Guidance for the interpretation of biomonitoring data'

NC3Rs – 'The 3Rs today' poster event

London, United Kingdom
25 March 2009

Kim Travis of Syngenta presented a poster based on the work of the ECETOC task force on a framework for human data

<http://www.nc3rs.org.uk/page.asp?id=973>

Occupational and Environmental Exposure of Skin to Chemicals Conference (OEESC)

Edinburgh, United Kingdom
14-17 June 2009

John Perkins of Dow AgroSciences presented the concepts developed by the task force on the 'assessment and evaluation of risks resulting from dermal exposure to chemicals'

European Societies of Toxicology Congress (EUROTOX)

Dresden, Germany
13–16 September 2009

Winfried Steiling of Henkel presented the key conclusions from the task force 'Potency values from the local lymph node assay: Application to classification, labelling and risk assessment'

Toxicology Forum – European Meeting

Brussels, Belgium
20-22 October 2009

Douglas McGregor, consultant, presented the outcome of the task force 'Guidance for the classification of carcinogens under the globally harmonised system of classification and labelling of chemicals (GHS)'

Kim Travis of Syngenta presented the 'ECETOC framework for the integration of human and animal data in chemical risk assessment' Neil Carmichael of ECETOC gave a paper entitled 'Pesticides, poisonings and the 'real risk' assessment'

MEMBERS OF THE SCIENTIFIC COMMITTEE

John Doe <i>(Chairman)</i>	Syngenta
David Owen <i>(Vice Chairman)</i>	Shell Chemicals
Remi Bars	Bayer CropScience
Peter Calow	Roskilde University
Watze De Wolf	DuPont de Nemours
David Farrar	Ineos Chlor
Andreas Flückiger	F. Hoffmann-La Roche
Helmut Greim	Technical University Munich
Fraser Lewis	Syngenta
Guiseppe Malinverno	Solvay
Stuart Marshall	Unilever
Chris Money	ExxonMobil Chemical
Mark Pemberton	Lucite
Carlos Rodriguez	Procter & Gamble
Dan Salvito	RIFM
Gerard Swaen	Dow Chemical
Johannes Tolls	Henkel
Saskia van der Vies	Amsterdam Free University
Ben van Ravenzwaay	BASF
Eckhard von Keutz	Bayer HealthCare
Hans-Jürgen Wiegand	Evonik Industries

MEMBERS OF THE SECRETARIAT



Neil Carmichael
Secretary General



Christa Hennes
Health Sciences Manager



Henk Vrijhof
Chemicals Programme Manager



Malyka Galay-Burgos
Environmental Sciences Manager



Ian Cummings
Communication, Web & Media Manager



Geneviève Gérits
Office Manager



Christine Yannakas
Secretary



Anita Jennings
Secretary

The ECETOC Secretariat is responsible for the co-ordination and management of the scientific work programme ensuring that the tasks allocated by the Scientific Committee are accomplished in a timely fashion.

ECETOC's continued success relies greatly on its Secretariat. This team of dedicated professionals supports the scientists engaged in the work of the

ECETOC programme in meeting the objectives set by the Scientific Committee.

By the end of 2009, Charlotte Amiri (Communication, Web & Media manager) decided to leave ECETOC to be able to spend more time with her family. She was replaced at the start of 2010 by Ian Cummings.

FINANCE

INCOME ACTUAL 2009 IN EURO

Subscription

44 Full Members

5 Associate A Members

1 Associate B Members

Total Subscription Income

1.434.000

Bank interest

10.479

Document sales

315

Project-related

301.446

Total

1.746.239

EXPENDITURE ACTUAL 2009 IN EURO

Salaries (and related expenses)

959.654

Office running expenses

218.049

Travel expenses on mission

12.379

Meetings and consultants

458.923

Professional services

12.890

Bank charges

4.397

Capital expenditure

3.902

Publications

33.200

Miscellaneous

17.961

Website

23.336

Total

1.744.691

BALANCE SHEET AND RESERVES ACTUAL 2009 IN EURO

Balance Sheet

Income

1.746.239

Expenditure

1.744.691

Operating margin

1.548

Reserves¹

Opening

1.850.064

Operating margin

1.548

Closing reserves

1.851.612

¹ Estimated Reserve Required: 480.000

GLOSSARY OF ABBREVIATIONS

(Q)SAR

(Quantitative) Structure Activity Relationship

3Rs

Replacement, Refinement and Reduction of Animals in Research

AF

Assessment Factors

ATLA

Alternatives to Laboratory Animals

BCF

Bio-Concentration Factor

BIAC

Business and Industry Advisory Committee to the OECD

C&L

Classification and Labelling

CAR

Constitutive Androstane Receptor

CBB

Critical Body Burden

CEFIC

European Chemical Industry Council

CSA

Chemical Safety Assessments

DeNaMiC

Description of the nature of the accidental misuse of chemicals and chemical products

DG SANCO

European Commission Directorate General for Health and Consumer Affairs

DMEL

Derived Minimum Effect Level

DNA

Deoxyribonucleic acid

DNEL

Derived No Effect Level

ECB

European Chemicals Bureau

ECHA

European Chemicals Agency

ECVAM

European Centre for the Validation of Alternative Methods

EEMS

European Environmental Mutagen Society

EMBK

ECETOC Marine Biodegradation Kinetics database

EMT

Environment Monitoring Team

ENM

Engineered Nanomaterials

EPA

(US) Environmental Protection Agency

ERA

Environmental Risk Assessment

ES

Exposure Scenarios

ESAC

ECVAM Scientific Advisory Committee

EU

European Union

EUROTOX

Association of European Toxicologists and European Societies of Toxicology

EUSES

European Union System for the Evaluation of Substances

FeDTeX

The database for fertility and developmental endpoints

FERA

Food and Environment Research Agency

GEMCO

Generic Estuary Model for Contaminants

GHS

Globally Harmonized System of Classification and Labelling of Chemicals

HC5

Hazardous Concentration for 5% of species

HEMT

Health Effects Monitoring Team

HESI

Health and Environmental Sciences Institute

HETRA

Human Exposure and Tiered Risk Assessment

IARC

International Agency for Research on Cancer

ICE

Interspecies Correlation Estimation

ICEM

International Conference on Environmental Mutagens

ICOH

International Commission on Occupational Health

IFRA

International Fragrance Association

IHCP

Institute for Health and Consumer Protection

ILSI-HESI

International Life Sciences Institute – Health and Environmental Science Institute

IPCS

International Programme on Chemical Safety

ITEM

Institute of Toxicology and Experimental Medicine

ITS

Intelligent/Integrated Testing Strategies

JACC
Joint Assessment of Commodity Chemicals

JRC
Joint Research Centre; The European Union’s scientific and technical research laboratory and an integral part of the European Commission

LOEL
Lowest Observed Effect Level

LRI
Cefic’s Long-range Research Initiative

MoA
Mode of Action

MSC
Member State Committee

NC3Rs
National Centre (UK) for the Replacement, Refinement and Reduction of Animals in Research

NOEL
No Observed Effect Level

OECD
Organisation for Economic Cooperation and Development

OEESC
Occupational and Environmental Exposure of Skin to Chemicals

OEH
Occupational and Environmental Health

OSR
Observational Epidemiologic Studies Register

PBT
Persistent Bioaccumulative Toxic

PCLS
Precision Cut Lung Slices

PDMS
Polydimethylsiloxanes

PEC
Predicted Environmental Concentration

PEG
Partner Experts Groups

PNEC
Predicted No Effect Concentration

POP
Persistent Organic Pollutant

RAC
Risk Assessment Committee

REACH
EU regulatory framework for the Registration, Evaluation and Authorisation of Chemicals

REACH TGD
REACH Technical Guidance Document

RepDose
The database of NOELs/LOELs in repeated dose studies.

RfP
Request for Proposal

SAR
Structure-Activity Relationship

SEA
Socio-Economic Assessments

SETAC
Society of Environmental Toxicology and Chemistry

SIEF
Substance Information Exchange Forum

SIG
LRI Strategy Implementation Group

SSD
Species Sensitivity Distributions

STOTS
State of the Science Reviews

SVHC
Substances of Very High Concern

TMF
Trophic Magnification Factor

TRA
Targeted Risk Assessment

TSCA
Toxic Substance Control Act

TTC
Threshold of Toxicological Concern

UNCED
United Nations Conference on Environment and Development

vPvB
very Persistent very Bioaccumulative

WFD
EU Water Framework Directive

WHO
World Health Organization



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ECETOC, European Centre for Ecotoxicology and Toxicology of Chemicals, was established in 1978 as a scientific, non-profit making, non-commercial association, currently financed by 47 of the leading companies with interests in the manufacture and use of chemicals. A stand-alone organisation, it was established to provide a scientific forum through which the extensive specialist expertise in the European chemical industry could be harnessed to research, evaluate, assess and publish reviews on the ecotoxicology and toxicology of chemicals, biomaterials and pharmaceuticals

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