



Success through scientific partnerships

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ANNUAL REPORT 2005



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VISION, MISSION AND APPROACH

VISION

Support the safe manufacturing and use of chemicals, pharmaceuticals and biomaterials through sound science

MISSION

Act as an independent, credible, peer-reviewed technical resource to all concerned with the identification of research needs and provision of scientific rationale for the assessment of health effects and environmental impact, and thereby to justify industry's licence and freedom to operate

APPROACH

ECETOC's approach is to:

- ✔ Promote the use of sound science in both industry and regulatory decision-making and report on the results;
- ✔ Contribute to the understanding of societal issues associated with health assessment and environmental safety of substances;
- ✔ In close consultation with ECETOC members, define scope, manage progress and interact with research programmes;
- ✔ Ensure that the value of ECETOC's products and services are appreciated by business and regulatory decision makers;
- ✔ Provide a forum for regulators, academic and industrial scientists for the evaluation of the safe use of chemicals and their associated products;
- ✔ Identify emerging issues that are of importance to ECETOC member companies.

INTRODUCTION



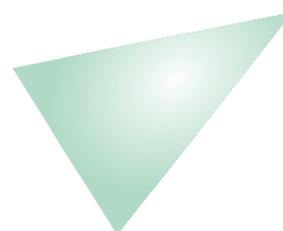
ECETOC, European Centre for Ecotoxicology and Toxicology of Chemicals, was established in 1978 as a scientific, non-profit, non-commercial association, financed by 50 of the leading companies with interests in the manufacture and use of chemicals. A stand-alone organisation, it was established to provide a scientific forum through which the extensive specialist expertise in the European chemical industry could be harnessed to research, review, assess and publish studies on the ecotoxicology and toxicology of chemicals.

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

To achieve this mission, ECETOC facilitates the networking of suitably qualified scientists from its member companies and co-operates in a scientific context with intergovernmental agencies, health authorities and professional institutions.

ECETOC is managed by a Board of Administration comprising up to twelve 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 output of the ECETOC work programme is delivered in published reports and papers, through scientific representation in the activities of international organisations and regulatory groups and through presentations and organisation of specialised workshops and fora.



MESSAGE FROM THE CHAIRMAN

During 2005, ECETOC made great strides in pursuing its vision to support the safe manufacture and use of chemicals, pharmaceuticals and biomaterials through sound science. The organisation continued to deliver the high level of scientific output for which it is noted and respected. It did this through a multitude of activities in order to have a positive influence on chemicals regulation in Europe. While continuing to generate high quality task force output in the form of workshops and peer-reviewed publications, a substantial effort was also invested during 2005 in contributing to the scoping phase of the REACH Implementation Projects (RIP) 3.2-1A & B and 3.3-1. This effort was acknowledged in appreciation received by ECETOC from the European Chemicals Bureau (ECB).

With the new REACH era upon us, the ECETOC Board dedicated much of its time during the past year to the formulation of a business strategy and plan for the coming two to three years. This strategy aims to ensure an enhanced scientific contribution from ECETOC to the regulatory process of safety, health and the environment (SHE), while maintaining its valued profile and broadening its impact. It can be broken down into four key objectives:

to communicate; to broaden the base; to broaden the issues and to reinforce the identity.

Allow me to elaborate...

To communicate

ECETOC will reach out to member companies and to other stakeholders, such as academia, regulators and trade associations, who can benefit from ECETOC's products and services.

This externally focused approach will be pursued via several means including: the ongoing dissemination of complimentary publications to non-profit

stakeholders; the continued organisation of the outREACH programme of events; the involvement of key industry stakeholders, such as academia and the European Commission in our workshops and annual technical meeting and the provision of a quarterly e-newsletter and *ad hoc* e-news to members and non-members.

To broaden the base

ECETOC will expand its stakeholder base both horizontally (regulators, international agencies, non-governmental organisations), and vertically (within industry) through Associate Membership.

ECETOC maintains a policy of openness in cooperating with and providing input to the initiatives of its strategic partners. However, through a variety of activities such as the European Commission's REACH Implementation Projects (RIPs), ECETOC will seek to strengthen and build new *horizontal relationships* with governmental and non-governmental scientific organisations active in the field of chemical regulation.

At the end of 2005, industry, through ECETOC, committed to active participation in Phase 2 of the RIP 3.2-2 and 3.3-2 to deliver the science for the draft EU Technical Guidance Documents. This involvement will ensure a constant interaction with Member State regulators, the European Commission and several national institutes.

ECETOC's *vertical relationships* will be enhanced by means of the creation of a new membership category and the development of a new programme to cater for such members. This programme will focus on educating and informing a broader industry base throughout the value and supply chain. As a result of the forthcoming requirement to register all chemicals, both manufacturers and users of chemicals in the European Union need to



take appropriate action to ensure they have a comprehensive knowledge of the properties and use-patterns of their products that are sold and of the chemicals used in their manufacture. Market segmentation activities are under way and specific targeting of potential members will be implemented during 2006.

To broaden the issues

ECETOC will embrace societal issues in its continued focus on the science, avoiding advocacy or political involvement, and ensuring that its work is relevant and pertinent.

Defined action plans will be led and owned by the Scientific Committee (SC). They will address both specific issues as well as those that affect the cost effectiveness and benefits of regulatory compliance, in a timely manner. The Board supports positive engagement in societal issues which clearly have a scientific safety, health and environment component. Furthermore, it acknowledges that in so doing, ECETOC may require new expertise and visionary approaches within its Scientific Committee.

As new science emerges, ECETOC seeks to establish fora for analysis, debate and cooperation. With its Nanomaterials Workshop in November, ECETOC was able to engage in this emerging technology and provide a fundamental insight into testing strategies and basic risk assessment of this rapidly developing substance type.

The issue of animal welfare in the hazard assessment of chemicals has been very visible during the last year. There has been a high level of commitment to affirmative action from broader industry representation and the European Commission. ECETOC continues to contribute scientific solutions for alternative testing

strategies to support the objective of 'Reduction, Refinement and Replacement' of animal testing. It has committed to carry out risk assessment without the need to generate data in experimental animals wherever possible.

To reinforce the identity

ECETOC must maintain its existing profile that has earned it significant scientific credibility for its unique and differentiated high quality work products. These are developed under the direct peer-review of the SC, which comprises both industry and academic representatives.

All activities and action plans must ensure the clarity of the ECETOC objectives through the separation of science from advocacy or political lobbying.

Acknowledgments

The main achievements of ECETOC during 2005 are described in the following pages of this report. The Board of ECETOC is indebted to the scientists from our member companies, as well as those from other organisations, who have contributed to the success of the ECETOC scientific programme. Finally, I would also like to thank the Secretariat for their ongoing support in this critical role to deliver ECETOC's work product to the membership.

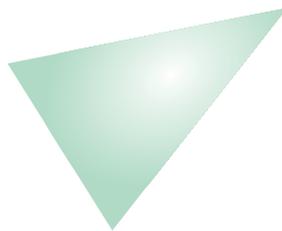
A handwritten signature in black ink that reads "J. Rudolph". The signature is written in a cursive style.

Dr. Jochen Rudolph
Chairman of the ECETOC Board of
Directors

KEY FACTS

During 2005, ECETOC:

- ✔ Concluded eight task forces (see page 13).
- ✔ Launched two task forces (see page 12).
- ✔ Published ten reports (see page 24), including:
 - Three JACC Reports
 - One Technical Document
 - One Monograph
 - One Workshop Report
 - Four Technical Reports.
- ✔ Published six papers as external publications (see page 25).
- ✔ Organised three workshops (see page 14).
- ✔ Welcomed five new member companies (see page 36).
- ✔ Strengthened the financial reserves from €1.25 million to €1.39 million (see page 37).



ECETOC BOARD OF ADMINISTRATION

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

The Board is composed of at least six Members representatives.

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

The following people made up the ECETOC Board of Administration at 31st December 2005:



Dr. Jochen Rudolph, Degussa
Chairman



Dr. Lewis Smith, Syngenta
Vice Chairman



Dr. Martin Kayser, BASF
Treasurer



Mr. David Gartside, AstraZeneca



Dr. Charles Murray,
Procter & Gamble



Prof. Bart Sangster, Unilever



Mr. Thierry Vanlancker,
DuPont de Nemours

On the occasion of the 2005 Annual General Meeting, ECETOC delegates approved the nominations of Mr. D. Gartside (AstraZeneca), Dr. C. Murray (Procter & Gamble) and Mr. T. Vanlancker (DuPont) to the ECETOC Board. Furthermore, the delegates accepted the resignation of Dr. K. Eigenmann of Novartis and thanked him for his contribution. Dr. J. Rudolph (Degussa), ECETOC Chairman and Dr. M. Kayser (BASF), ECETOC Treasurer having both completed their two-year terms were re-elected by the Annual General Meeting. On the same occasion, Dr. L. Smith accepted the role of Vice-Chairman of the ECETOC Board.

REPORT FROM THE SECRETARY GENERAL

As expected, 2005 turned out to be the year in which chemical manufacturers and users were forced to focus on the proposed REACH regulations and, specifically, the REACH Implementation Projects (RIPs). Strongly supported by our member companies, by the Board and the Scientific Committee, ECETOC joined two Consortia led by Cefic. These were for the RIP 3.2-1 A & B and RIP 3.3-1 working group on the Scoping Studies for the Chemical Safety Assessment (CSA)/Chemical Safety Report (CSR) and the Information Requirements respectively. The contributions from the industry experts under the ECETOC umbrella focused critically on the underlying science. They therefore benefited from completed technical documents which had already been published. The ECETOC Targeted Risk Assessment Technical Report (TR) No. 93, with its science-based methodology played a particularly strong role within the work of the former Consortium. The final reports from both Consortia were delivered on time. They were highly appreciated by the relevant European Commission Directorates and have set the scene for the Phase 2 activities of drafting the necessary Technical Guidance Documents for industry. ECETOC will again be a major contributor to this activity during 2006.

Annual Technical Meeting (ATM)

The ATM focused on the ECETOC Science Programme and ECETOC's significant contributions to the RIPs 3.2-1 A & B and 3.3-1. Prof. van Leeuwen, of the Joint Research Centre (JRC), gave us an overview of REACH and how the Commission viewed the implementation programme. This helped to put ECETOC's involvement into the overall context. Prof. van Leeuwen made it very clear that the European Commission was both determined to implement REACH and welcomed the ECETOC engagement. In

particular he stressed that industry must become substantially more committed to the design of the regulations. This is a unique opportunity for industry.

Task Forces and Workshops

In assessing the achievements of our task forces and workshops in 2005, we note that several completed their work and published their reports. A significant milestone was the completion of the revised and updated Technical Report No. 95 on Glycol Ethers. This is a major reference document for industry and regulators. Similarly, the Technical Report dealing with the Trends in Children's Health and the Role of Chemicals (TR No. 96) has been of value in the many discussions on this topic within the European Commission.

The issue of animal welfare and alternative testing methods has been increasing in intensity. The publication of the Technical Report No. 97 titled 'Alternative Testing Approaches in Environmental Safety Assessment' at the end of 2005 was very timely. The Biomonitoring task force completed their work and published a Technical Document in record time. This was achieved using a total immersion approach. Risk assessment of persistent, bioaccumulative and toxic (PBT) chemicals remains a challenge and the publishing of Technical Report No. 98 by the task force on this subject is a significant and timely contribution.

A Workshop was held at the European Mutagen Society Meeting in Kos (see page 14). The proceedings will be published as a special issue of Mutation Research in 2006. In addition, a Workshop that tackled the pertinent subject of the safety of nanomaterials was held in Barcelona. The programme demonstrated a formula that combined natural science with the input of ECETOC, with aspects of social science. It was sponsored by the Cefic LRI programme (see page 18).



Strategic Liaison

As a result of ECETOC's direct involvement in the RIP activities during the first half of 2005, relationships with many of our strategic partners have been significantly enhanced.

A unique opportunity to quantify a special relationship occurred with the request from the World Health Organisation (WHO) to detail our interactions with their organisations as justification for the extension of official relationships with ECETOC with NGO status.

outREACH Events

Three outREACH events were organised during 2005. These continued the programme aimed at increasing interaction between ECETOC and its member companies on a regional basis as well as improving the visibility to non-member companies, national associations and regulators (see page 20). The first, held in January, was hosted by ECETOC's Chairman, Dr. Jochen Rudolph, on behalf of Degussa and ventured into the New Member States using Prague as a regional centre. The one day event was organised in conjunction with the ChemFed/ChemLeg programme managed by Cefic. It was preceded by a networking evening that was appreciated by the participants, who originated from six countries throughout the region. The second event in May was hosted by the ECETOC Treasurer, Dr. Martin Kayser, on behalf of BASF in Ludwigshafen for the German and Austrian region. Finally, in response to the request of participants at the first outREACH event, we returned to Switzerland in December for an event that was hosted by ECETOC delegate Dr. Oliver Straub of F. Hoffmann-La Roche in Basel. These events built on the successful developments ECETOC has made to strengthen its ties with member companies.

New Membership Categories

During 2005, five companies were approved by the Board to become members of ECETOC. In addition, the Board decided, based on substantial feedback gained at outREACH events, to propose the creation of two new Associate Membership categories (see page 22). The proposal was overwhelmingly endorsed by Member Delegates at the Annual General Meeting in April. As a result, the modified Statutes were submitted and approved by the Belgium Ministry of Justice for implementation on January 1, 2006. Associate Membership will extend ECETOC's franchise down the value and supply chain. It will involve medium and small enterprises in bringing together the (eco)toxicological science that industry needs to be able to address the requirements of the REACH regulations.

In September 2005, the Scientific Committee suffered the tragic loss of Dr. Tom Feijtel (see page 32), who had been a pillar of support to ECETOC. Two long-serving members of the Scientific Committee, Dr. Chris Braun and Dr. Christian d'Hondt, resigned at the end of 2005. Dr. Eigenmann resigned from the Board on his retirement from Novartis in February, 2005. The Secretariat lost the valuable services of Mrs. Julieann Humphrey on her mid year return to Australia. She has been succeeded by Ms. Charlotte Amiri as the Web & Media Manager. Finally, a note of gratitude to the industry scientific experts who have contributed to all the ECETOC activities and to the Secretariat for their continued professional support.

A handwritten signature in black ink, reading "M. Gribble". The signature is written in a cursive style and is located below the text of the Secretary General's report.

Dr. Michael Y. Gribble
ECETOC Secretary General

TASK FORCES

The following task forces were launched in 2005:

Assessing mixtures in human health risk assessment

Regulatory and industrial risk assessment of human health has so far been mostly concerned with single chemicals, including technical mixtures. However, humans (consumers, general public) may be exposed daily to 'cocktails of chemicals' at low levels over a long time. Whether this presents a real risk or is just a perception remains a question of debate, as experienced at one of the outREACH meetings (Basel, September 2003). Historically, the combination of effects (hazard) has been taken into account in the 10 x 10 assessment factor normally used for extrapolation from animals to humans (reviewed in ECETOC Technical Report No. 86).

The Scientific Committee considered the merits of establishing a task force to clarify when and/or how mixtures of chemicals should be assessed, i.e. determine when co-exposure is likely to pose a real hazard. Real concern could be triggered by biomonitoring studies, rather than any arbitrary combination of exposure/effect. A realistic assessment of mixtures should prepare the industry for future EU Environment and Health Strategy (SCALE*) and US biomonitoring activities.

Based on an introductory scheme for the risk assessment of mixtures, a task force has been invited to address the following terms of reference:

- Review the pre-work, examine the validity of the proposed concepts, identify limitations and exceptions;
- Advise on how exposure to mixtures might be assessed, including biomonitoring;
- Prepare written pragmatic guidance for a tiered

approach assessing human risk due to combined exposure to chemicals, including examples;

- Identify areas of high priority for future work;
- Communicate the outcome at a suitable symposium or workshop.

Risk assessment of PBT type chemicals

– Case Studies

There are a number of initiatives within the EU aimed at regulation of persistent, bio-accumulating and toxic (PBT) substances, for example the Water Framework Directive, the Existing Substances and Notification of New Substances Regulations and the latest revision of the EU Technical Guidance Document and REACH. Criteria for categorising substances as P, B, and T (and vP and vB) have been proposed by a number of organisations and international bodies such as UNEP and OSPAR.

The Scientific Committee approved for publication the Technical Report No. 98, produced by the task force addressing the risk assessment of PBT type chemicals in September 2005. At the same time it was agreed that the approach needs to be tested and thus a new task force was commissioned to demonstrate the applicability of the proposed approach by applying it to a number of chemicals. This will be done by collating information on selected chemicals, which have been categorised as PBT, for which there is existing information. It will involve the monitoring of experimental work, aimed at producing targeted new information, and using this in the framework. The latter activity is also aimed at demonstrating the importance of producing highly relevant information to fill a major gap so that a risk assessment can be carried out.

* SCALE = Science, Children, Awareness, Legal instruments and Evaluation

The following terms of reference were agreed:

- Select chemicals that can be applied in the framework for both a paper exercise and experimental work;
- Collate existing information required in order to apply the framework to these case-study chemicals;
- Identify additional information requirements to test the application of the framework and commission and monitor the generation of this

information to be carried out under the LRI programme;

- Communicate the findings of the task force via an appropriate peer-reviewed journal and at scientific conferences.

The task force is aiming to submit their findings to a peer-reviewed journal before the end of 2006.

During 2005, in addition to the newly launched task forces, the ECETOC work programme was progressed by the following:

Environment:

- Alternative testing approaches in environmental safety assessment (Technical Report No. 97)*
- Biodegradation Kinetics
- Risk assessment of PBT chemicals (Technical Report No. 98)*

Human Health:

- Acutex (Acute Exposure Threshold Levels - AETLs)
- Derivation of occupational exposure limits from available effects data
- Guidance for the interpretation of biomonitoring data (Technical Document No. 44)*
- Trends in children's health and the role of chemicals (Technical Report No. 96)*
- Health and environmental safety of nanomaterials (Workshop in November 2005)*

Specific Substances:

- Cyanides
- Fluoroalkanes* (3 task forces)
- Synthetic amorphous silica
- Glycol ethers

This part of the ECETOC programme is devoted to the preparation of comprehensive, critical reviews of all available toxicological and ecotoxicological data on specific substances, predominantly those having widespread and multiple uses (Joint Assessment of Commodity Chemicals, JACC). The resulting hazard/risk assessments, including possible gaps in knowledge, are published in the ECETOC series of reports. In some cases, the format is further extended, e.g. in support of EU or other international risk assessment, or the setting of an occupational exposure limit value.

During 2005, new reviews were published on hexafluoropropylene and vinylidene fluoride (fluoroalkanes task force). Existing reports on dichloro-2,2,2-trifluoroethane (HCFC-123) and on the 'Toxicology of glycol ethers and its relevance to man' were updated.

* Task forces concluded in 2005

WORKSHOPS

Chemical Pollution, Respiratory Allergy and Asthma

16-17th June 2005, Leuven, Belgium

Atopic allergy and asthma remain important health issues. It is therefore of significance that in more modernised societies there has, during the last four decades, been a substantial increase in the prevalence of these diseases. The observed changes have been too rapid to be accounted for by modifications to the gene pool and there is a general acknowledgement that alterations in lifestyle, combined with changing environmental factors, are responsible for the increases in prevalence.

Against this background there has been speculation that exposure to some specific chemicals in particular, and chemical pollution in general, may play an important pathogenetic role. Several mechanisms through which this might occur have been proposed. However, there are a number of additional other factors that have been implicated as playing potentially important roles. Among these are diet (both quantity and quality), reduced exposure neonatally and during infancy to infectious micro-organisms, and changes in indoor air quality.

Interest in this subject derived from a survey of Cefic LRI members. A workshop was therefore organised by ECETOC and sponsored by LRI, with the objective of addressing specific questions regarding the possible relationship between chemical pollution, asthma and allergic disease. The workshop was attended by some 40 international scientific and clinical experts from industry, academia and government agencies.

There were wide-ranging and informed discussions about the nature of factors that contribute to the development of asthma and allergy. From these emerged consensus views on the likely contribution of chemicals to changes in the prevalence of these diseases,

and agreement on the key research issues that now need to be addressed. It is clear that further research is required to define the factors that have impacted on the prevalence of asthma and atopic allergy. However, a major conclusion drawn was that, although contributions by some types of chemical exposure have been suggested, in comparison with other acquired and environmental factors the contribution of chemicals is likely to have been modest.

Symposium on Biomarkers and Workshop on Environmental Genotoxins

5th July 2005, Kos, Greece

ECETOC and EEMS (European Environmental Mutagen Society), co-sponsored by LRI (the Cefic Long-range Research Initiative), jointly organised two sessions at this year's annual EEMS conference with the objectives to:

- Review the state of the science in the fast developing area of biomarkers in identifying exposure to environmental stressors and, in the field of molecular epidemiology;
- Address our current understanding of the role of genotoxic environmental agents in childhood disease.

The main Symposium on 'Biomarkers and Molecular Epidemiology - Present state and future trends' attracted close to 200 participants. Following a series of presentations and discussions, it was concluded that the use of biomarkers of exposure in environmental carcinogenesis has been of limited success so far. Proper field validation is required, even for simple DNA adducts in terms of dose-response and background variation. This is especially important in populations with a low level of exposure. Genomics-based biomarkers may present a new data-rich technique, but need proper validation. Another promising possibility



may be the development of epigenetics-based biomarkers. The parallel workshop on 'Environmental genotoxins and children's health' attracted close to 100 participants. It presented a new topic for many members of the audience. Following the presentations and discussions, it was concluded that there is an absence of systematic knowledge on the role of chemical genotoxins in children's diseases. Some child diseases such as asthma and leukaemia are on the increase, while others, like autism and lymphoma are decreasing (see ECETOC Technical Report No. 96 on Children's Health). Children may be more, less or equally sensitive compared to adults and may display 'windows of vulnerability'. The placental perfusion model is promising. Since no causal relation between child cancer and environmental genotoxins has been established as yet, some knowledge gaps need to be filled. These include:

- Discovery of molecular changes in childhood cancer and perinatal animal tumours;
- Ontogeny of metabolism and DNA repair (humans, rodents);
- Analysis of MAL mediated and transgenerational effects (humans, rodents);
- The clarification of nutrition, infection and lifestyle in childhood disease.

Nanomaterials: Testing Strategies to Establish the Safety of Nanomaterials and Societal Aspects of Nanotechnology

7-9th November 2005, Barcelona, Spain

The workshop on nanomaterials brought together about 70 experts from industry, academia, government agencies and non-governmental organisations to discuss questions on safety testing aspects and societal concerns about this emerging technology.

Evaluating the potential hazards of nanotechnology and its products is an emerging area in (eco)toxicology and risk assessment. The development of a safety database and exposure assessments to nanoscale particles is evolving as new particles, materials and exposure methodologies are being developed. Although similar in size, engineered nanoscale materials may have different health impacts when compared to combustion-generated ultrafine particles. The question arises whether nanoparticle toxicity can be extrapolated from existing toxicology databases for macro- and micro-scale particle-types and fibres.

Three major issues were covered at the workshop: nanomaterial characterisation; exposure, both airborne and internal (particle deposition in lungs and skin) and assessment of hazard potential. The participants agreed on elements of a minimum physico-chemical characterisation of nanomaterials for safety testing. Exposure assessment methods and exposure routes were reviewed. Finally, a general tiered testing approach was proposed, involving both *in vitro* and *in vivo* studies.

The second part of the workshop focused on several key societal factors that were likely to affect the future acceptance and commercialisation of nanomaterials. Conditions of opposition to or rejection by society of technological innovations were compared to conditions of acceptance and legitimisation. The outcome of the discussions indicated the relevance of risk perception, risk communication and risk management to the future of nanomaterials.



REACH IMPLEMENTATION PROGRAMME (RIP)

In 2004 the European Commission offered for tender the RIPs pertaining to the 'Chemical Safety Report and Safety Assessment' (RIP 3.2-1A, 3.2-1B) and the 'Testing Information Requirements on Intrinsic Properties of Substances' (RIP 3.3-1A). ECETOC joined in consortia with RIVM, BfR, BAuA, Oekopol, DHI Water & Environmental, TNO, Keml, the Danish EPA, the Environment Agency (UK), and INERIS, led by Cefic to bid for the Scoping Studies for RIP 3.2 and RIP 3.3 and the Preliminary Technical Guidance Document for RIP 3.2-1B. Both bids were successful and the projects started in January 2005.

The basis of ECETOC's contribution in both projects was to provide the science base for the 'Intelligent Testing Strategy' in RIP 3.3 and for the 'Safety Report' in RIP 3.2.

The RIP 3.2 consortium embraced the approach, proposed by the ECETOC Targeted Risk Assessment task force, as a starting point. The limitations and deficiencies of the prototype have been well documented at the end of the Scoping Study, however this approach proved of value. The RIP 3.3 consortium benefited from the work that had been done in the Information Requirements task force. Published Technical Reports from several completed task forces were used to guide the work in the Endpoint Working Groups of RIP 3.3. The broad base of scientific stakeholders in the consortia contributed their science, resulting in very lively debate. In the great majority of cases, consensus was reached, but in the small number of cases where this was not possible, the points of disagreement were clearly defined for work in subsequent phases of the RIP projects.

The Member Companies of ECETOC provided the time of their scientists very generously in what has been a

very resource intensive exercise. ECETOC thanks them for this contribution, especially the individuals who committed much personal time and effort to ensure that the programme time lines were met.

The final reports were submitted in June and were well received by the Commission following a series of Stakeholder Expert Group meetings that were staged at key points during the projects.

The ECETOC participants have since reviewed the value of being part of these consortia and have concluded:

1. ECETOC was able to inject the science of our task forces into the consortia output in a way that would have been impossible without direct participation;
2. The quality of science in industry has again been displayed and found to be a significant contributor to the development of regulation;
3. The resource strain was very high and many of the other programmes that ECETOC has been running with the aid of its members' scientists have had to be delayed;
4. The science network that is the key to ECETOC's forward progress has been reinforced following the interactions in the projects.

The follow-on to the RIP scoping projects is now being considered by the Commission. The ECETOC membership has made it clear that they see ECETOC participating in the next phase. The means of their participation needs to be managed carefully in terms of resource commitment and in ensuring the maximum impact of ECETOC's scientific expertise is achieved.

ECETOC SCIENCE AWARD

ECETOC has been running an annual Science Award since 2003. This programme is continuing to achieve its objective of recognising excellent scientists in the early stage of their research careers.

The 2005 ECETOC Science Award was presented to Ms. Carolina Wijnheden of the Institute of Environmental Medicine at the Karolinska Institutet, Stockholm, Sweden, for her and her co-authors' poster: 'Effects of TCDD on the Osteoblastic Cell Line UMR-106.' The scientific relevance of the results of this project is that this cell line may be a suitable *in vitro* model system for studies on mechanisms behind the effects of dioxin and dioxin-like compounds on bone tissue.

The poster was presented at the annual congress of EUROTOX held in Krakow, Poland, 11-14th September 2005, under the theme: 'Persistent Organic Pollutants – Integrated Exposure and Risk Assessment'. The criteria applied for the evaluation of the posters were originality and potential impact of the research project, adequacy of the methodological approach adopted, scientific value of the results, as well as care, quality and clarity of the presentation.

This award was presented by Dr. Michael Gribble, ECETOC Secretary General, and Prof. Corrado Galli, University of Milano, at the congress dinner.



Dr. Michael Gribble, ECETOC Secretary General presents the award to Ms. Carolina Wijnheden of the Institute of Environmental Medicine at the Karolinska Institutet, Stockholm, Sweden

LONG-RANGE RESEARCH INITIATIVE (LRI)

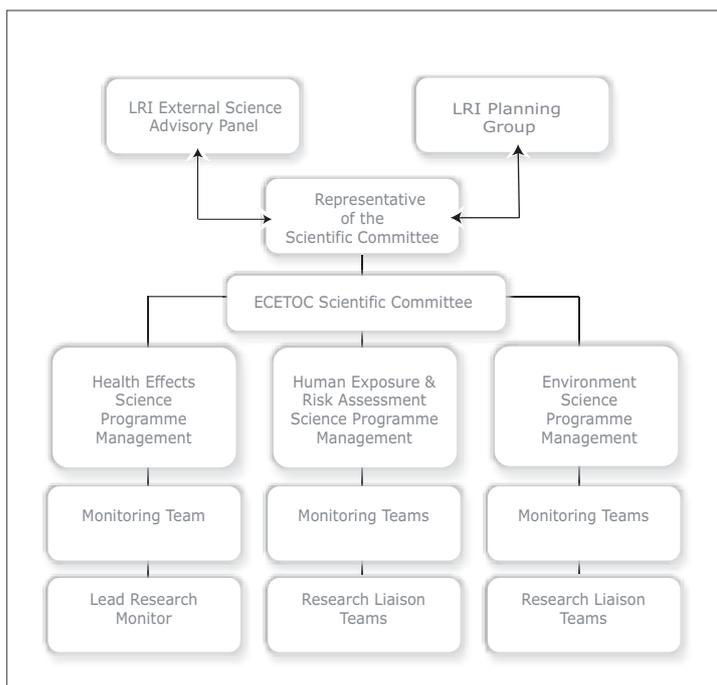
The American Chemistry Council (ACC) and the Chemical Industry Institute of Toxicology (CIIT) initiated a process in 1996 to define and mount a strategic research programme on the generic health and environmental issues that could evolve into major concerns or threats to the chemical industry. This initiative soon grew to incorporate participation of both the European and Japanese chemical industries under the respective auspices of the European Chemical Industry Council (Cefic) and the Japanese Chemical Industry Association (JCIA). At this time Cefic commissioned ECETOC to ensure appropriate and effective input to the programme by industry and academic scientists.

ECETOC is responsible for the scientific management of the programme on behalf of Cefic.

ECETOC organises, under the guidance of the Scientific Committee and the Secretariat, the Selection and Monitoring Teams composed of recognised scientific experts from member companies and academia. These teams (as shown in the diagram) are responsible for identifying new research to support needs impacting human health and environment issues related to chemicals. They also prepare appropriate Requests for Proposals (RfPs) for consideration by Cefic.

Following the publication of selected RfPs by Cefic, the ECETOC teams review the scientific merit of the proposals submitted by contract research groups (including universities, institutes etc.). They then recommend to Cefic which projects to fund.

After contractual closure, the ECETOC teams monitor the scientific progress achieved by the independent researchers up to and including publication of the peer-reviewed results in the open scientific literature.



LRI project management structure within ECETOC

ECETOC continues to play a significant role in the management of the Cefic LRI. By the end of 2005, 120 projects had been completed since the inauguration of the programme.

Human Health Effects Programme

In 2005, the two science areas Immunotoxicology, Respiratory Toxicology and Allergy, and Chemical Carcinogenicity remained the primary focus of the LRI Health Effects Research Programme. The HEMT (Health Effects Monitoring Team) oversaw the progress on the final reporting of the phase I projects. They have also evaluated the first results of the phase II projects launched during the previous year. The RfP on the 'Association between chemical pollution and respiratory allergy and asthma' was addressed by a workshop held by ECETOC in June 2005. The HEMT also defined three new research projects that are concerned with the development of alternative methods for toxicity testing. This is a new area of responsibility for the HEMT and reflects the creation by Cefic of an Alternatives Issue Management Team (AIMT). An RfP on 'Reduction and refinement of *in vivo* mutagenicity/genotoxicity tests' is planned to be addressed in a workshop. 'Signal transduction pathways and the development of alternative approaches to reproductive testing' was published to invite suitable research proposals, and the RfP on 'Use of a human skin irritation model to assess skin corrosion' will be addressed at a later date in collaboration with ECVAM.

Human Exposure & Tiered Risk Assessment (HETRA)

Various projects were reported in 2005, while the HETRA team made several new proposals.

To better characterise actual human exposure to chemicals at the workplace, an evaluation was made of the effectiveness of equipment to protect workers from skin exposure to solid substances. A start was made with the generation of data on *in vitro* skin permeation of representative chemicals. This should allow for more reliable quantitative structure-activity relationship (QSAR) development. The role of biomarkers in monitoring possible exposure to chemicals at the workplace was evaluated and

reported.

Furthermore, the ongoing inventory of relevant research on the indoor environment was completed. In the area of consumer exposure, a project was begun to describe the nature of accidental misuse of chemicals and chemical products. Further to the assessment of trends in biomarkers of chemical exposure in the general population, the background incidence of such biomarkers continued to be evaluated. A new study commenced on intra- and inter-individual variations of key biomarkers of chemical exposure within the general population. Finally, to enable tiered approaches to human risk assessment in situations where very limited data are available, the current database on SARs and low toxicological effect levels of chemicals was progressed. It will be extended with a module on reproductive toxicity. The HETRA team initiated a project to evaluate the potential application of the intake fraction as a tool for targeting human risk assessments.

Environment Programme

A 1-day workshop organised in conjunction with Delft Hydraulics on the use of the generic estuary model (GEMCO) was held in May and a paper for submission to a peer-reviewed journal is in preparation. The recommendations for research projects made by the TF working on 'Alternative testing approaches in environmental safety assessment' were developed into three RfPs namely:

1. Identifying trans-generic biotransformation potential;
2. Establishing a BCF gold standard database;
3. Evaluation of fish embryo and fish cell line tests for their potential use as alternatives to fish acute studies.

Databases being prepared in projects 1 and 2 will be compatible with the relational database management system (RDBMS). This is currently being developed in the data management and (Q)SAR applications decision support tool project.

outREACH EVENTS

outREACH events were established in 2003 with the primary aim of improving the dialogue between ECETOC as an organisation and employees of its member companies on a regional basis. Each outREACH meeting achieves this through the in-depth review of a topical issue challenging the industry in the form of pending regulatory pressure. How ECETOC can contribute to solutions is highlighted in these meetings.

During 2005, 3 such events were held in association with local member company hosts in the Czech Republic, Germany and Switzerland. Participants comprised environmental health and safety scientists and senior management of both member and potential member companies in respective regions.



Dr. Jochen Rudolph, ECETOC Chairman and Dr. Mike Gribble, ECETOC Secretary General at the Prague outREACH event

Prague, Czech Republic, 27th January 2005

The clear message communicated by the New Member State participants was that REACH, the Environment and Health Plan, the Water Framework Directive and IPPC remained the key issues driving their agendas in 2005.

Participants indicated appreciation of the ECETOC work programme giving particular emphasis to the significance of:

1. Mixtures and risk assessment;
2. Application of genomics and related technologies;
3. The use of *in silico* methods;
4. Biomonitoring and its application;
5. One substance consortia for data collection under REACH;
6. Societal issues and cost benefit analysis;
7. Specific substance issues on phthalates in consumer goods, occupational exposure for butadiene and mercury regulations.

The above issues will be addressed within the scientific programme. In addition, market forces (which are beyond ECETOC's remit) such as competition from the Far East and the cost of raw materials were also highlighted by participants as issues of concern.

Ludwigshafen, Germany, 11th May 2005

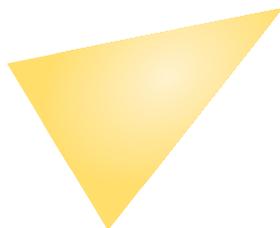
German outREACH participants affirmed the relevance of dedicating ECETOC resources to the EU REACH Implementation Project (RIP) by strongly endorsing ECETOC's active participation in RIP within the framework 'using sound science to influence regulation.'

What's more, they underlined the following further issues, highlighting the possibility that they be addressed within ECETOC's work programme:

1. Alternatives to animal testing;
2. Endocrine disruption;
3. Food regulation (Novel, Functional, GMO and Indirect Food);
4. SCALE*;
5. Interaction with NGOs in the early stages of policy development.

The last of these, the interaction with NGOs, was

* SCALE = Science, Children, Awareness, Legal instruments and Evaluation



highlighted to be of particular relevance to participants. This was because of its potential to influence the development of regulation in a powerful way. The thinking of participants also touched on types of activity that could be addressed within ECETOC's work programme, which they listed as:

1. Preparation of safety data sheets (SDSs) for widely used materials;
2. Acting as a clearing house for R50 and R51 classified substances;
3. Preparation of exposure scenarios;
4. Preparation of chemical safety reports.

Basel, Switzerland, 15th December 2005

The third outREACH event was kindly hosted by Dr. Oliver Straub, the ECETOC delegate for and on behalf of F. Hoffmann-La Roche in Basel, Switzerland. It marked the 6th such happening and the first return-visit within the outREACH programme.



Dr. Oliver Straub of F. Hoffmann-La Roche, host of the Basel outREACH

It brought more than twenty people in contact with the daily activities of ECETOC. The event allowed them to debate and to give direct input into the ECETOC work programme. In the first instance, delegates expressed their endorsement of ECETOC's active

participation in the REACH Implementation Projects (RIPs), specifically in order to seek every reasonable opportunity to point out and rectify the logic flaws in REACH. In addition, feedback highlighted the following priority issues:

1. Exposure assessment and modelling;
2. Mixtures and multiple stressors;
3. Nanomaterials;
4. Pharmaceuticals in the environment;
5. Effects on sub-populations;
6. Probabilistic risk assessment;
7. Use of human data in risk assessment;
8. Thresholds for sensitisers.

In terms of operations, delegates suggested that ECETOC consider:

1. Establishment of expert panels to help members with specific problems;
2. Pursuing an integrating role bringing trade associations together; and
3. Co-operating with non-governmental organisations (NGOs).

The feedback provided from all the outREACH events will guide ECETOC in shaping its future work plan. Events for 2006 will be targeted at France and a possible return to the UK and Ireland to maintain the local contact with the member companies located in these countries.

ECETOC'S NEW MEMBERSHIP CATEGORIES

During 2005, ECETOC has been working to allow small and medium-sized companies to have improved access to the ECETOC network as Associate Members. This will enable them to benefit from products and services to help fulfil their health, safety and environment obligations.

A role in the changing industry

The market for the manufacture and use of chemicals is made up of large, medium and small companies. However, currently it is mainly the large entities which are involved in ECETOC. The market is changing and individual organisations are seeing the benefits of co-operating to share scientific resources focused on the impact of their products on safety, health and environment issues. Furthermore, small and medium-sized companies are becoming more and more concerned with issues of ecotoxicology and toxicology due to regulatory and consumer pressures.

Therefore, in pursuing its mission to act as an 'independent, credible, peer-reviewed technical resource to all concerned', ECETOC will be playing a greater role in bringing together scientists and providing ecotoxicology and toxicology related scientific services to both manufacturers and users of chemicals in all sectors.

Increased diversity and sharper focus

Associate Membership was approved by ECETOC delegates of our member companies at the 2005 General Assembly. This decision resulted from a consideration as to how the organisation can best serve the manufacturers and users of chemicals in a new REACH era.

What is the expected impact for our current membership?

It is expected that existing and potential full member companies will continue to steer and guide ECETOC's scientific programme. They will maintain access to the same high quality services, but will also benefit from a broader perspective of the supply chain with the potential for a wider network of scientists and a more diverse work programme.

There is no doubt that associate member companies will influence the general direction of ECETOC through Board and Scientific Committee positions. What's more, they will benefit from a range of advantages at a reduced annual membership fee, including:

- Scientific expert involvement in the ECETOC work programme;
- Ability to put forward programme topics;
- Networking opportunities and the exchange of ecotoxicology and toxicology information;
- Receipt of free or reduced price services.

ECETOC has been reaching out to a broad range of smaller chemicals users and manufacturers at its series of successful outREACH events over the past two years. It looks forward to continuing to offer its broader membership further such networking opportunities as well as training, workshops, information services and, of course, its core publishing services.

CRITERIA & BENEFITS

Type	Full Membership	Associate Membership A	Associate Membership B
Criteria	Companies manufacturing or using chemicals with a global turnover* greater than €2.0 billion.	Companies manufacturing or using chemicals with a global turnover* greater than €0.5 billion but less than €2.0 billion.	Companies manufacturing or using chemicals with a global turnover* greater than €0.1 billion but less than €0.5 billion.
Fee	€31.500 per annum	€9.000 per annum	€3.000 per annum
Eligibility	<ul style="list-style-type: none"> ● Block voting rights at Annual General Meeting (10 votes per Member company) ● Participation at Annual Technical Meeting ● Topic proposal ● Board membership ● Scientific committee membership ● Task force chairmanship (based on expertise) ● Task force membership 	As per Full Membership, with the following differences: <ul style="list-style-type: none"> ● Voting rights at Annual General Meeting (3 block votes per Member company) ● 1 Associate Membership A board seat 	As per Full Membership, with the following differences: <ul style="list-style-type: none"> ● Voting rights at Annual General Meeting (1 vote per Member Co.) ● 1 Associate Membership B board seat
Services	<ul style="list-style-type: none"> ● Free publications ● Access to members' website (unlimited logins per company) ● Invitations to workshops (based on expertise) ● New services when introduced 	As per Full Membership	As per Full Membership
Benefits	Full Membership allows the member company to: <ul style="list-style-type: none"> ● Contribute to the chemical industry's state of the science; ● Influence the long-term thinking of international agencies; ● Propose topics for scientific review; ● Propose candidates for task force chairs; ● Nominate task force members; ● Network and share scientific information with other chemical organisations; ● Receive ECETOC publications free of charge; ● Get access to specific members' pages of the website. 	As per Full Membership	As per Full Membership with the following exception: <ul style="list-style-type: none"> ● Associate Members do not receive complimentary ECETOC publications. Instead they are required to pay a reduced fee (€100 instead of full cost);

* 'Turnover' refers to turnover for sales of chemicals or products made *inter alia* of chemicals in the previous year.

COMMUNICATING THE SCIENCE

The results of the scientific cooperation undertaken by ECETOC's working groups are manifested in a range of ways that include published reports, posters and presentations. Furthermore, representation of ECETOC in public scientific fora acts to further disseminate the scientific work.

Publications

Its published state of the science reports form the primary output and take the form of both ECETOC's own publications and the publication of its reports in peer-reviewed journals.

Complimentary ECETOC publications are provided on publication and by request to member companies, academia, national and supra-national organisations. They are also distributed to a wide range of industry observers such as non-governmental organisations. In addition, ECETOC publications are requested by a range of commercial non-member organisations, who value their contents.

During 2005, ten publications (see below) were published and disseminated each time to approximately 500 contacts.

ECETOC publications

JACC Reports

- No. 47 1,1-Dichloro-2,2,2-trifluoroethane (HCFC-123)
CAS No. 306-83-2 (Third Edition)
(Published May 2005)
- No. 48 Hexafluoropropylene (HFP) CAS No. 116-15-4
(Published September 2005)
- No. 49 Vinylidene Fluoride CAS No. 75-38-7
(Published November 2005)

Technical Documents

- No. 44 Guidance for the Interpretation of Biomonitoring Data
(Published November 2005)

Monographs

- No. 34 Toxicogenomics in Genetic Toxicology and Hazard Determination
(Published in Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 575 (2005) 1-117. J.H.M. van Delft and T.W. Gant, editors, July 2005)

Workshop Reports

- No. 6 Workshop on Chemical Pollution, Respiratory Allergy and Asthma
(Published December 2005)

Technical Reports

- No. 95 The Toxicology of Glycol Ethers and its Relevance to Man (Fourth Edition) Vol. I and Vol. II Substance Profiles
(Published February 2005)
- No. 96 Trends in Children's Health and the Role of Chemicals (Published June 2005)
- No. 97 Alternative Testing Approaches in Environmental Safety Assessment
(Published December 2005)
- No. 98 Risk Assessment of PBT Chemicals
(Published December 2005)



Externally published publications

- A rule-based screening environmental risk-assessment tool derived from EUSES.
G. Boeije, M. Comber, T. Feijtel, M. Holt, V. Koch, A. Lecloux, A. Siebel-Sauer, V. Vandenberghe, P. Vanrolleghem, F. Verdonck, W. De Wolf.
Chemosphere 58 (2005) 1169-1176
- The ECETOC approach to targeted environmental risk assessment.
G. Boeije, M. Comber, T. Feijtel, M. Holt, V. Koch, A. Lecloux, A. Siebel-Sauer, W. de Wolf.
Environmental Toxicology and Chemistry, Vol. 24 No 2. pp 251-252, 2005
- Mode of action and aquatic exposure thresholds of no concern.
G. Boeije, M. Comber, T. Feijtel, M. Holt, V. Koch, A. Lecloux, A. Siebel-Sauer, W. De Wolf.
Environmental Toxicology and Chemistry, Vol. 24 No 2. pp 479-485, 2005
- Influence of maternal toxicity in studies on developmental toxicity.
C. Hennes, B. van Ravenzwaay, F. Welsch, H.J. Wiegand.
Regulatory Toxicology and Pharmacology 43 (2005) 114-115
- Toxicogenomics in Genetic Toxicology and Hazard Determination – Introduction and Overview.
B. Elliott, T.W. Gant, A. Sarrif, J.H.M. van Delft, B. van Ravenzwaay, F.J. van Schooten, H. van Steeg, H. Vrijhof.
Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 575 (2005) 1-3.
- Toxicogenomics in genetic toxicology and hazard determination – Concluding remarks.
T.W. Gant, A. Sarrif, J.H.M. van Delft, and E. van Vliet.
Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 575 (2005) 116-117.

COMMUNICATING THE SCIENCE (cont'd)

▼ Posters and Presentations

● Society of Toxicology Annual Meeting

6-10th March 2005 New Orleans, USA

- Dan Goldstein of Monsanto gave a *presentation* entitled 'Trends in children's health' based on the related task force.
- Frank Welsch of Orbitox and Christa Hennes of ECETOC presented a *poster* entitled 'The influence of maternal toxicity in studies on developmental toxicity'.

● British Society of Toxicology Annual Congress

20-23rd March 2005, Warwick, United Kingdom

- David Owen of Shell Chemicals gave a platform *presentation* of the ECETOC task force summary of important areas of concern in children's health.

● SETAC Europe Annual Meeting

23-26th May, Lille, France

- Ian Malcomber of Unilever, gave a platform *presentation* entitled 'A risk based strategy for the assessment of PBT and vPvB chemicals' in his role as chairman of the ECETOC task force on risk assessment of PBT chemicals.
- A *poster* entitled 'Addressing the 3 Rs when assessing a chemical's potential to bioconcentrate' was displayed on behalf of the Risk Assessment of PBT Chemicals task force, that comprised: Mike Comber of ExxonMobil, Watze de Wolf of DuPont, Sylvia Gimeno of Procter & Gamble, Marc Léonard of L'Oréal, Christine Stevens of Dow-Corning, Roger van Egmond of Unilever, Graham Whale of Shell and Martin Holt of ECETOC.
- Adam Lillicrap of AstraZeneca gave a platform *presentation* entitled 'Proposals for the implementation of the 3Rs in the assessment of acute aquatic toxicity'.

● EEMS Annual Meeting

3-7th July 2005, Kos, Greece.

- Dirk Pallapies of BASF gave a *presentation* on 'Trends in childhood disease' based on the related task force.

● Eurotox Annual Meeting

11-14th September 2005, Krakow, Poland

- Ian Kimber of Syngenta, gave a platform *presentation* entitled 'Chemical pollution, asthma and allergy: an ECETOC perspective' based on findings of a related ECETOC workshop.
- Herman Autrup of University of Aarhus gave a *presentation* entitled 'Children at risk: Report from an ECETOC task force'.

● SETAC US Annual Meeting

11-15th November 2005, Baltimore, USA

- Dan Salvito of RIFM gave a platform *presentation* entitled 'A scheme for using internal exposure in environmental risk assessment' on behalf of the ECETOC task force on risk assessment of PBT chemicals.
- A *poster* entitled 'Alternative testing approaches in environmental safety assessment' was presented on behalf of the like-named task force, that comprised: Adam Lillicrap of AstraZeneca, Christine Stevens of Dow-Corning, Mike Comber of ExxonMobil, Watze de Wolf of DuPont, Sylvia Gimeno of Procter & Gamble, Roger van Egmond of Unilever, Peter Douben of Unilever, Graham Whale of Shell, Marc Léonard of L'Oréal and Martin Holt of ECETOC.

● University Paris V Life Sciences and Health Masters Studies

28th November 2005, Paris France

- Mike Gribble, ECETOC Secretary General gave a guest *presentation* on behalf of ECETOC entitled 'Our role and contributions and our impact on European regulation'



Representation

ECETOC expert representation was provided to a number of organisations and initiatives during 2005. The following lists them chronologically:

- **EEA funded expert workshops on modelling of environmental concentrations from emission data.**
2nd March, Harwell, United Kingdom
 - ECETOC, represented by Martin Holt of ECETOC, took part in the workshops.
- **Workshop on poison centres and the use of human data in consumer product risk assessment.**
May 2005, Berlin, Germany.
 - ECETOC, represented by Chris Money of ExxonMobil, participated in the workshop to provide occupational health and exposure expertise.
- **BIAC/OECD Chemicals Meetings**
8-9th June 2005, Paris, France
 - ECETOC, represented by Chris Money of ExxonMobil participated in the Policy Dialogue on Exposure Assessment.
- **European Commission DG Enterprise**
16th June 2005, Brussels, Belgium
 - ECETOC, represented by Chris Money of ExxonMobil participated at a REACH information meeting in order to present the ECETOC Targeted Risk Assessment Model.
- **WHO/IPCS re-evaluation of human and mammalian toxic equivalency factors (TEFs) of dioxins and dioxin-like compounds.**
27th June 2005, Geneva, Switzerland.
 - ECETOC, represented by Jan Wilmer of Dow Europe, provided an industry observer at a public session for interested parties to present their views and specific questions about this project.
- **EEMS Annual Meeting.**
3-7th July 2005, Kos, Greece.
 - ECETOC was represented Barry Elliot of Syngenta, who co-chaired a session on 'Biomarkers and molecular epidemiology: Present state and future trends', as well as by Hendrick Vrijhof of ECETOC.
 - ECETOC, represented by Hans-Jürgen Wiegand of Degussa co-chaired a workshop entitled 'Environmental genotoxins and children's health' (Note: Hendrick Vrijhof replaced Hans-Jürgen Wiegand due to unforeseen circumstances).
- **EU 6th Framework for RTD (2002-2006)**
8th July 2005
 - ECETOC, represented by Watze de Wolf of DuPont contributed to the 'Fourth call for proposals in sub priority 1.1.6.3 Global change and ecosystems' information day entitled 'Intelligent testing strategies for chemicals.'
- **WHO/IPCS environmental health criteria documents**
August 2005
 - Ian Kimber of Syngenta peer-reviewed the document 'Principles and methods for assessing autoimmunity associated with exposure to chemicals' on behalf of ECETOC.
- **EEA funded expert workshops on modelling of environmental concentrations from emission data.**
16th August, Copenhagen, Denmark.
 - ECETOC, represented by Martin Holt of ECETOC, took part in the workshops.

COMMUNICATING THE SCIENCE (cont'd)

- **Human risk characterisation chapters of the revised EU technical guidance document (TGD).**
August 2005.
 - ECETOC, together with CONCAWE commented on the draft document.
- **EU project NORMAN (Network of reference laboratories and related organisations for monitoring and biomonitoring of emerging environmental pollutants - Priority 6.3 - Global Change and Ecosystems - Proposal N° 018486).**
Launched in September 2005 for a duration of 3 years.
 - ECETOC was represented by Martin Holt, member of the Secretariat on the advisory group to the project.
- **Eurotox Annual Meeting.**
11-14th September 2005, Krakow, Poland.
 - ECETOC, represented by Christa Hennes, member of the Secretariat co-chaired a workshop on children's health.
 - ECETOC, represented by Mike Gribble, member of the Secretariat, chaired a workshop on chemical pollution and development of asthma.
- **International Agency for the Research on Cancer (IARC) Monograph on the evaluation of carcinogenic risks to humans.**
October 2005.
 - ECETOC provided peer-reviewed comments on the draft preamble.
- **OSPAR Whole effluent assessment workshop.**
28-29th November 2005, London, UK.
 - ECETOC, represented by Martin Holt, member of the Secretariat, took part in the workshop.
- **Sixth European workshop of national platforms on alternative methods.**
17-18th December 2005, Brussels, Belgium.
 - ECETOC was represented by Christa Hennes, member of the Secretariat.
- **The application of the threshold (step-down) approach to the testing of chemicals, plant protection products and pharmaceuticals by ECVAM and the European Chemicals Bureau.**
Ongoing.
 - ECETOC, represented by Mike Comber of ExxonMobil and Scott Bellanger of Procter & Gamble is supporting ECVAM in the peer-review of this work.
- **ILSI Europe Environment and Health Task Force.**
Ongoing.
 - ECETOC was represented by Martin Holt, member of the Secretariat within the task force.
- **European Commission DG SANCO public consultation December 2005**
 - ECETOC's Nanomaterials task force commented on the SCENIHR opinion on 'The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies'.

STRATEGIC LIAISON

Based on our continued emphasis on success through scientific partnerships, ECETOC has continued to focus on nurturing and expanding the relationships which reinforce our vision, mission and strategy.

As will be clear from many entries in this Annual Report, the industry's involvement through our member company scientists in the scoping phases of the REACH Implementation Projects (RIP) has consumed considerable resources. However, it has also significantly increased the interaction with many of our strategic partners. These partners were members of the two consortia in which ECETOC participated. They included the competent authorities from several Member States, trade associations and several pan-European institutes. Important interactions with the EU Commission through the leadership of DG Joint Research Centre (JRC), specifically with the European Chemicals Bureau (ECB), were achieved at the RIP Stakeholder Expert Group meetings throughout the projects. These meetings also allowed for very useful contacts with other interested parties such as NGOs. As Phase 2 of the programme crystallised later in the year, contact increased further and broadened to include the European Centre for the Validation of Alternative Methods (ECVAM). Furthermore, the relationship has been well supported by Julia Fentem of Unilever, ECETOC's official representative to ECVAM Scientific Advisory Committee (ESAC). Our on-going relationship included an ECETOC/ECVAM project on the provision of information relating to relationships between fish, daphnid and algal toxicity to which twelve member companies submitted data.

ECETOC has had an official relationship in the capacity of a recognised NGO with the World Health Organisation (WHO) since 1996. In April 2005 we

were requested to provide a dossier on the activities of ECETOC during the period since the last review in early 2003 at which our extension of NGO status had been confirmed. A substantial dossier documenting the collaborative interaction between the two organisations was compiled by Hendrick Vrijhof and Mike Gribble from the Secretariat with much assistance from Chris Money of ExxonMobil. ECETOC is also grateful to the many other industry scientists who were involved during the year. The dossier detailed particular collaboration with the International Programme on Chemical Safety (IPCS) and the International Agency for Cancer Research (IARC).

A unique initiative entailed a project with the European Diisocyanate & Polyol Polymers Producers Association (ISOPA) to control the quality of an international polymers database.

Ongoing dialogue within the realm of ECETOC's strategic liaisons are noted in detail within the chapter 'Communicating the Science' (pages 24-28). These served to further strengthen ECETOC's valued relationships with SETAC, OSPAR, ILSI Europe, ILSI-HESI, European Environment Agency (EEA), EUROTOX and the European Environmental Mutagen Society (EEMS), among others.

MODUS OPERANDI

Board

ECETOC operates under the general direction of a Board comprising up to twelve senior executives from member companies. The Board is responsible for the overall policy and finance of the association.

Scientific Committee

Appointed by the Board, the Scientific Committee provides strategic leadership for the ECETOC science programme. The committee is crucial to the success of ECETOC, in establishing and maintaining its authority and reputation as a source of sound scientific information and judgement.

Since mid-2001, the competencies of senior scientists from member companies on this pivotal ECETOC committee, have been complemented by leading external experts in the fields of toxicology, environmental science and occupational epidemiology.

Through these appointments, the Board has reinforced the range of expertise available to direct effectively, the ECETOC science programme, while increasing the transparency and independence of the committee's processes.

Programme Selection

Fundamental generic issues continue to feature substantially in the ECETOC programme as the demand escalates for a greater understanding of the impact of chemicals on health and the environment. In parallel with the workshops, suggestions for the ECETOC work programme continue to be invited directly from all members of ECETOC and from outside organisations, including academia and

regulatory authorities.

For a proposal to be progressed, it must be supported by at least two member companies and judged to meet the scientific standards required by the Scientific Committee. Provided the above criteria are met, specific Terms of Reference are drawn up and endorsed by the Scientific Committee.

Task Forces

When the Scientific Committee has agreed in principle a project, an initial 'scoping' meeting defines clearly the overall objectives, resources needed, deliverables and time plan. These project proposals form the basis for the Scientific Committee's decision on how the initiative is progressed, the choice being essentially between the approach of task force members undertaking the work (conventional task force) or, to a lesser or greater extent, through the use of a contractor. Most of ECETOC's outputs continue to be generated and underpinned by task forces. A task force comprises appropriate experts, drawn from member companies. The final composition is subject to the endorsement of the Scientific Committee, taking into account the range of skills required to address the selected topic.



▼ Workshops

The principal aim of an ECETOC organised workshop is to define the State of the Science on a given topic or issue. This is done by drawing together the world's leading experts on the subject. They debate the issue, draw conclusions and make recommendations. The outcome of the workshop is a summary document, white paper or report that defines the science gaps related to the issue. The recommendations catalyse active research programmes which address safety, human health and environmental concerns that have been raised.

▼ Publications

The main output of the ECETOC work programme is published in a range of reports:

- Technical Reports address specific applications of the science in evaluating the hazards and risks of chemicals to human health and the environment;
- JACC Reports (Joint Assessment of Commodity Chemicals) are comprehensive reviews of toxicological and ecotoxicological data on individual chemical substances;
- Monographs are comprehensive reviews of generic topics or issues fundamental to the application of sound science in evaluating the hazards and risks of chemicals to human health and the environment;
- Special Reports are compilations of data targeted to specific regulatory issues/demands;

- Workshop Reports are summaries of the discussions and conclusions derived from ECETOC sponsored workshops;

- Technical Documents - scientific briefing papers, addressing emerging issues.

Reports (with the exception of Workshop Reports) continue to be published following peer-review by the Scientific Committee and external experts.

ECETOC publications are provided to all member companies and to other interested parties, such as various regulatory authorities, international organisations and academic groups.

▼ outREACH Events

outREACH events are organised by geographic regions throughout Europe with the primary objective of improving the dialogue between ECETOC as an organisation and employees of its member companies. The current scientific programme is reviewed with emphasis on a specific critical issue. A secondary objective is to raise the visibility of ECETOC with selected non-member companies which use and/or manufacture chemicals.



A TRIBUTE TO DR. TOM FEIJTEL

It is with great sadness and a feeling of immense loss that all those, including industry scientists associated with ECETOC, learnt of the tragic death of Dr. Tom Feijtel on 19th September after an unfortunate bicycling accident.

All our thoughts and condolences have been extended to his immediate family who will feel and know the greatest loss of such an outstanding individual; a person who was giving of himself, his knowledge and his expertise without boundaries.

Within the ECETOC organisation Tom has been contributing for more years than most people can remember, as a task force member and, additionally, as a very active member of the Scientific Committee since 1998. Together with his ecotoxicology colleagues he has driven the Environmental programme of ECETOC on behalf of the member companies to achieve a level of scientific recognition of which they can all be justifiably proud. At the same time he brought tireless enthusiasm to the broader activities of the Scientific Committee to help ensure that the credibility of industry scientists involved with the manufacture and use of chemicals was beyond reproach. His scientific talents were respected and appreciated within his company, Procter & Gamble, by regulators and academia on a global basis and by his myriad of industry friends and colleagues everywhere.

All those who have worked with, known and been associated with Dr. Tom Feijtel over the years, will remember him with great fondness as a person who aspired to great things in everything he did, including his dedication to ECETOC. He will be sorely missed.

SCIENTIFIC COMMITTEE

2005 has been a very demanding year for the Scientific Committee. We were deeply saddened by the tragic loss of Tom Feijtel. Our loss was trivial compared to that of his family but none the less, was keenly felt. Tom was a very active contributor to the Scientific Committee and he has left a legacy of initiatives that we are proud to continue.

The core work of the Committee this year has been characterised by innovative approaches. We joined forces with Regulators and Institutes across Europe to successfully bid, with Cefic as project leader, for a Commission project to provide the first stage of REACH Implementation Project (RIP) 3.2 and 3.3. ECETOC undertook to lead the process that put into place the underpinning science for these RIPs. There was a tremendous effort by the scientists from member companies to put all this work together over a really tight timescale. As a result, in addition to making a major contribution to a very successful project, we have built up good relationships with regulatory scientists. They have said that they valued the excellent scientific contribution that ECETOC has made and the European Commission has welcomed ECETOC into the second phase, which will run through 2006.

The RIP projects put tremendous demands on the resources of our Member Companies. As a result we had to manage the existing programme very carefully to ensure that critical deadlines were met and that resources were not overstretched. One way in which we did this was by developing the 'Rapid Action Task Force.' This is a process whereby we devote intensive effort over a short time period to produce a report to a critical deadline. The pilot for this was the Biomonitoring task force which delivered in record time. The concentrated effort helped in terms of

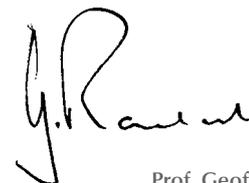
resource planning in member companies and in the Secretariat.

The other innovation in 2005 was the introduction of societal issues into a Nanomaterials Workshop which was sponsored by LRI. We devoted a whole day to presentations and discussions with social scientists. The participants were surprised by how much they learnt from each other. As a result of this exercise, there are now the foundations of a professional network that will help the Scientific Committee to guide its future work in this challenging area.

The scientific work plan has been reviewed and updated during the year. In so doing, we identified that we were not as clear as we wanted about our longer term direction and the five year horizon. To help to us meet this need, we have arranged to use the Annual Technical Meeting in 2006 as a Futures Workshop that will guide this thinking.

Both Christian d'Hondt and Chris Braun retired from the committee in this period. We thank them for their contribution over the years and wish them well.

The Scientific Committee monitors developments in the external world and within our member companies and will ensure that our work remains relevant and topical to their needs. In so doing, it welcomes input from scientists in companies who may not be part of the Scientific Committee or task forces.



Prof. Geoff Randall
Chairman of the Scientific Committee



SCIENTIFIC COMMITTEE

At the end of 2005, the Scientific Committee comprised the following members:

Geoff Randall	Consultant* (Scientific Committee Chairman)
Remi Bars	Bayer CropScience
Chris Braun	Akzo Nobel
Peter Calow	Danish Environmental Assessment Institute*
Watze de Wolf	DuPont
Christian d'Hondt	Syngenta
John Doe	Syngenta
Peter Douben	Unilever
Andreas Flückiger	F. Hoffmann-La Roche
Helmut Greim	Technical University Munich*
Tom Hutchinson	AstraZeneca
Chris Money	ExxonMobil
David Owen	Shell Chemicals
Gerard Swaen	Dow
Ben van Ravenzwaay	BASF
Hans-Jürgen Wiegand	Degussa

The Scientific Committee met six times in 2005 and benefited from the dedicated contribution of the aforementioned members, including Christian d'Hondt and Chris Braun who both resigned during the year.

* External

SECRETARIAT

At the end of 2005, ECETOC employed the following members of staff in order to assure the smooth management of daily activities:

Michael Y. Gribble	Secretary General
Christa Hennes	Health Sciences Manager
Martin Holt	Environmental Sciences Manager
Hendrick Vrijhof	Chemicals Programme Manager
Charlotte Amiri	Web & Media Manager
Geneviève Gériets	Office Manager
Marie-Laurence Simon	Secretary
Christine Yannakas	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. During 2005, Charlotte Amiri succeeded Julieann Humphrey as Web & Media Manager.



Back row from left:
Geneviève Gériets, Marie-Laurence Simon, Martin Holt and Hendrick Vrijhof
Front row from left:
Christa Hennes, Charlotte Amiri, Michael Gribble and Christine Yannakas

MEMBER COMPANIES

At the end of 2005, ECETOC membership comprised the following 50 companies:

3M Worldwide	Imperial Chemical Industries
Akzo Nobel	INEOS Group*
Altana*	International Flavors & Fragrances (IFF)
Arkema	Janssen Pharmaceutica Products
AstraZeneca	L'Oréal
BASF	Lucite International
Bayer	Merck
Borax	Monsanto
Borealis	Nestlé*
BP	Novartis
Ciba Specialty Chemicals	Petresa
Clariant	Polimeri Europa
Coca-Cola	Procter & Gamble
Cognis	Reckitt Benckiser
Colgate-Palmolive	Repsol YPF
Degussa	Rhodia
Dow Corning	Rohm and Haas
Dow Europe	Sasol
DSM	S.C. Johnson*
DuPont	Shell Chemicals
ExxonMobil	Solvay
F. Hoffmann-La Roche	Statoil
Henkel	Syngenta
Honeywell	Unilever
Huntsman (Europe)*	Wacker-Chemie

* New in 2005

FINANCE 

Income	Actual 2005 in euro
Subscription	
Full Members	1,386,000
New Members	26,250
Total subscription income	1,412,250
Bank interest	22,645
Document sales	13,415
Project-related	378,197
Total	1,826,507
Balance sheet and reserves	Actual 2005 in euro
Balance sheet	
Income	1,826,507
Expenditure	1,686,028
Operating margin	140,479
Reserves	
Opening	1,247,802
Operating margin	140,479
Closing reserve	1,388,281
Estimated reserve required	750,000
Expenditure	Actual 2005 in euro
Salaries (and related expenses)	877,080
Office running expenses	245,767
Travel expenses on missions	21,110
Meetings and consultants	453,646
Professional services	11,045
Bank charges	5,756
Capital expenditure	14,275
Publications	32,764
Miscellaneous	19,285
Website	5,300
Total	1,686,028

GLOSSARY OF ABBREVIATIONS

ACC	American Chemistry Council
AIMT	LRI Alternative Issue Management Team
BAuA	Federal Institute for Occupational Safety and Health, Germany
BCF	Bioconcentration Factor
BfR	Federal Institute for Risk Assessment, Germany
Cefic	European Chemicals Industry Council
CIIT	Chemical Industry Institute of Toxicology, USA
CONCAWE	The oil companies' association for environment, health and safety in refining and distribution
CSA	Chemicals Safety Assessment
CSR	Chemicals Safety Report
DG	EU Directorate General
DG SANCO	EU Directorate General Health and Consumer Protection
ECB	European Chemicals Bureau
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECVAM	European Centre for the Validation of Alternative Methods
EEA	European Environment Agency
EEMS	European Environment Mutagen Society
GEMCO	Generic Estuary Model for Contaminants
GMO	Genetically Modified Organisms
HEMT	Health Effects Monitoring Team
HETRA	Human Exposure & Tiered Risk Assessment
IARC	International Agency for the Research on Cancer
ILSI	International Life Sciences Institute
ILSI-HESI	ILSI Health and Environmental Institute
INERIS	National Institute for the Environment and Risk, France
IPCS	WHO International Programme on Chemical Safety
ISOPA	European Diisocyanate & Polyol Polymers Producers Association
JACC	ECETOC's Joint Assessment of Commodity Chemical programme
JCIA	Japanese Chemical Industry Association
Keml	Environmental Protection Agency, Denmark
LRI	Cefic's Long-range Research Initiative
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OSPAR	Commission for the Protection of the Marine Environment of the North-East Atlantic
PBT	Persistent, Bio-accumulative and Toxic
QSAR	Quantitative Structure Activity Relationship
RDBMS	Relational Database Management System
REACH	Registration, Evaluation and Authorisation of Chemicals
RfP	Request for Proposal
RIFM	Research Institute for Fragrance Materials
RIP	EU REACH Implementation Programme



RIVM	National Institute for Public Health and the Environment, The Netherlands
RTD	Research and Technical Development
SAR	Structure Activity Relationship
SC	ECETOC Scientific Committee
SCALE	Science, Children, Awareness, Legal instruments and Evaluation
SCENIHR	EU Scientific Committee on Emerging and Newly Identified Health Risk
SETAC	Society of Environmental Toxicology and Chemistry
TCDD	Tetrachlorodibenzodioxin
TEF	Toxic Equivalency Factor
TF	Task Force
TGD	EU Technical Guidance Document
TR	ECETOC Technical Report
UNEP	United Nations Environment Programme
vB	Very bio-accumulative
vP	Very persistent
WHO	World Health Organisation
WR	ECETOC Workshop Report

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ECETOC, European Centre for Ecotoxicology and Toxicology of Chemicals, was established in 1978 as a scientific, non-profit, non-commercial association. It is financed by 50 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, review, assess and publish studies on the ecotoxicology and toxicology of chemicals.

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