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ANNUAL REPORT 2004 success through scientific partnerships

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# INTRODUCTION

### An overview of ECETOC

ECETOC, European Centre for Ecotoxicology and Toxicology of Chemicals, was established in 1978 as a scientific, non-profit making, non-commercial association, financed by 48 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 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 Directors 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.

# VISION, MISSION AND STRATEGY

### 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

### Strategy

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



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# SUCCESS THROUGH SCIENTIFIC PARTNERSHIPS

Message from the Chairman



With the only constant being change, ECETOC experienced its share of both of these during 2004. The Association continued implementation of the defined strategy to maintain a pivotal role through partnerships driven by scientific excellence for responsible management of chemicals. Existing strategic liaisons have been strengthened and new ones have been established. At the same time

new activities were undertaken to ensure the future position of ECETOC through growth and broader representation.

In the dynamic environment of the European Union enlargement, significant activity commenced for the implementation of the EU Chemicals Policy 'REACH' with ECETOC's positive engagement fully endorsed by the Board and Scientific Committee. Through this leadership ECETOC will apply sound science when methodologies and tools are being developed to evaluate hazards and risks of chemicals to humans and to the environment. Industry in general and ECETOC members in particular need to be clear that the train has left the station and the journey has already started.

A Consortium under the leadership of Cefic and including ECETOC, successfully bid for the REACH Implementation Projects (RIP) 3.2-1A, 3.2-1B for Chemical Safety Assessment and 3.3-1 for Information Requirements. Introduction of the concepts of 'Risk' versus 'Hazard' involving 'Exposure Scenarios' will be

supported scientifically through the Targeted Risk Assessment (TRA) concepts and methodology in the deliberations of RIP 3.2 and contribute significantly to the core development of an Intelligent Testing Strategy (ITS) within RIP 3.3. These extensive commitments will present a major challenge for ECETOC throughout and beyond 2005.

ECETOC's scientific credibility and integrity, based on recognised experts from member companies and our high quality scientific reports, have further enhanced the relationships with regulatory authorities and academic experts while strengthening the dialogue with the industry associations representing the member company sectors. Several workshops in 2004 have engaged multiple stakeholders including a joint collaboration with WHO - International Programme on Chemical Safety (IPCS), OECD Environment Directorate and the European Commission's Institute of Health and Consumer Protection (IHCP) as well as co-sponsorship from the Cefic LRI programme and the European Centre for the Validation of Alternative Test Methods (ECVAM).

The business strategy and growth opportunities for ECETOC are currently under discussion by the Board. The first aspect is to enable members and potential members to understand the added value of ECETOC for their business in a clear and convincing way and the second is to deliver concrete objectives within the next 5 years to underpin this added value.

Positive progress has been achieved with the addition of five new members for 2005, partly through contacts established at the outREACH events.

Proposals for two new membership categories will be addressed at the 2005 General Assembly. These new categories will attract smaller companies resembling our broad current membership as well as downstream users who are predominantly the customers of the major chemical suppliers, both significantly impacted by the proposed REACH regulations. New scientific approaches are under consideration to provide additional competencies through enhanced skills and networks of influence including the embracing of the ever-increased importance of societal issues.

As the recently appointed Chairman of the Board, it is very satisfying to be able to note the rapid impact that ECETOC outREACH events have delivered and the enthusiasm of our Board Members to host them in the regions, namely Switzerland, UK/Ireland and Benelux. An aggressive outREACH programme is planned for 2005 and, in establishing new frontiers, the latest success has already been achieved in Prague in January 2005, with the new Member States in conjunction with the ChemFed/ChemLeg programme managed by Cefic. Participants from Chemical Industry manufacturers and users, Chemical Federations, and academic experts in toxicology and ecotoxicology contributed to an expanded agenda in record numbers.

### The Challenge of Change

The need for applying sound science to develop effective tools to evaluate the hazards and risks of chemicals to humans and to the environment has never been more critical. Yet the available resources to address the key issues in a timely manner

continue to decline within the industry. Only through a concerted effort of all parties involved in efficiently and effectively resolving these challenges, will our industries be able to compete in the global market-place to bring the many benefits without unwarranted risk to man or the environment. ECETOC will strive to deliver success based on sound science through partnerships, through strategic liaisons and through networking, engaging the best experts from the member companies to deliver high quality scientific results respected by our partners.

### Acknowledgements

The main achievements of ECETOC during 2004 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.

4. Kudoll

**Dr. Jochen Rudolph**Chairman of the ECETOC Board of Directors



### **AN OVERVIEW OF 2004**

### Report from the Secretary General



In a momentous year for the European Union with its expansion from 15 to 25 new Member States, ECETOC has continued through sound science to significantly impact the regulatory environment for the users and manufacturers of chemicals. This has been realised through further emphasis on the 'Success through Scientific Partnerships' as an integral part of the strategic liaison element involving all of the key stakeholders.

Following the October 2003 adoption of the new chemical substances policy 'REACH' by the EU Commission, significant activities in 2004 focused on completing ECETOC's contribution from industry to the science base for development of the eventual regulations. Notably, the Task Force (TF) on Targeted Risk Assessment (TRA) has published Technical Report No.93. The associated web tool (p.21) has been upgraded and has been utilised extensively by member and non-member companies, as well as regulators and academia.

The publishing of technical documents remains a high priority and key deliverable for ECETOC in order to serve the member companies and the broader stakeholder constituencies of regulators and academia. It is a critical measure of the scientific integrity and credibility of ECETOC.

#### Task Forces & Workshops

Emerging issues of note, which resulted in new Task Forces being formed in 2004, were Nanomaterials and Biomonitoring. The former subject, including both natural and social science, were the focus of the Annual

Technical Meeting (ATM) together with a session dedicated to Children's Health and the Environment. In light of the significant activities both in Europe and the United States related to Biomonitoring, the Scientific Committee have been very judicious in defining ECETOC's unique scientific contribution to this extremely visible and complex topic (p.6). The multi-stakeholder workshops flourished in 2004 with five events taking place. Regulators and academics have reaffirmed the value of these consensus-building workshops for the opportunity to have open and transparent science-based discussions on key issues with all stakeholders. Historically, ECETOC has monitored 'Omics' technology in Risk Assessment and in 2004, joined the European Environmental Mutagen Society (EEMS) to co-organise a meeting to discuss the application of 'Omics' in hazard identification, which is to be published as a special issue of Mutation Research in 2005.

### **Strategic Liaisons**

In 2004, there was a focus on strengthening existing relationships and building new strategic liaisons. Increased dialogue and interaction with WHO-IPCS (World Health Organization - International Programme on Chemical Safety) was achieved through collaboration on the 'Workshop on the Use of Human Data in Risk Assessment' in Cardiff, as well as representation at the '7th Meeting of the Steering Committee on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals' in Cincinnati. ECVAM (European Centre for the Validation of Alternative Methods) co-sponsored the 'Workshop on Alternative Testing Approaches in Environmental Risk Assessment' in Crecy la Chapelle, that resulted in improved cooperation. As a result of the work of the 'Whole Effluent Assessment' TF, ECETOC has improved its recognition from the OSPAR

(Oslo-Paris Convention for the protection of the marine environment of the North-East Atlantic) organisation to support future cooperation. New contacts with the EEA (European Environment Agency) have established the possibility that several modelling suites such as GREAT-ER will be hosted by the agency in the future, in order to support a wider acceptance of such technology. ECETOC continued to manage the science programme of the Cefic funded Long-range Research Initiative (LRI) and progress has been achieved in all three supported areas, namely the Health Effects Programme, Human Exposure and Tiered Risk Assessment (HETRA) and the Environmental Programme (p.16).

### Science Awards

In 2003, the ECETOC Science Award was established to recognise the contributions of young scientists in the areas of 'Health Effects', 'Exposure' and the 'Environment'. In follow-up to these three awards, the Scientific Committee invited all three 2003 winners to report on their activities and achievements since receiving their awards; the results were very impressive (p.13). The ECETOC Board endorsed the continuation of this Award for 2004 and the winner was Ms. Mattsson of the Karolinska Institute in Sweden, for her work on the use of Personal Protective Equipment (p.12).

#### outREACH

The planned outREACH events for 2004 for the UK/Ireland and Benelux (p.14) took place as scheduled in London and Arnhem, respectively. ECETOC Board member Mr. D. Hyde hosted the London event on behalf of AstraZeneca with very good representation from UK based member companies and quest companies that use or manufacture chemicals across the various industry sectors participating in ECETOC. In addition, several Contract Research Organisations (CRO) and the Chemical Industry Trade Association, (CIA) were represented. The Benelux event was hosted by ECETOC Board member Prof. J. de Wit on behalf of Akzo Nobel at their global headquarters in Arnhem. Again the presence of member companies based in the Benelux region improved the dialogue between the participants and

ECETOC, the primary goal of these events. Many of the guests were from smaller regional companies and were extremely interested to learn about ECETOC's contribution to improved workability of the proposed REACH regulations through the TRA methodology and web tool. Representatives of the National Chemical Federations of Belgium and the Netherlands and a CRO were also present. The outREACH programme for 2005 will encompass new geographies as well as a re-visit to Switzerland following a bi-annual schedule.

As a result of several initiatives, including the outREACH events, since late in 2003 five new member companies have joined ECETOC either in 2004 or January 1st of 2005. The new members represent a broad spectrum of the industry sectors and will hopefully contribute additional scientific expertise to the activities of ECETOC in order to gain the maximum benefit from their membership through active participation.

The capabilities of the Scientific Committee were expanded and strengthened in 2004, as we welcomed several new members. Dr. A. Sarrif resigned his membership after many years of dedicated service, following his retirement from DuPont. Similar dynamics were also seen at the Board with the retirement of the Chairman, Mr. P. Peschak, ExxonMobil who was succeeded by Dr. J. Rudolph, Degussa. Without the dedicated support and efforts of the industry scientific experts, who contribute to all the activities of ECETOC, the Association would not be able to deliver such a unique and sound scientific approach to the safety assessment and responsible management of chemicals.

The Secretariat have experienced a period of stability in 2004 that it is hoped will continue, to protect the investment in their professionalism. It has been a very strenuous year and I thank them for their outstanding performance.

Mu G Mille

**Dr. Michael Y. Gribble** ECETOC Secretary General



### TASK FORCES

### The following two Task Forces were launched in 2004:

#### **Biomonitoring**

Biomonitoring is an area of increasing interest and concern for chemical companies. Biomonitoring to assess chemical exposure (and related adverse health effects) is not new and has been routinely applied in many workplace settings in the chemical industry for over 40 years. However, the primary issue today is the role that biomonitoring data from the general public have for the evaluation and management of chemical risks. The major difference between biomonitoring data obtained from the workplace and public health settings, is that the former is supported by a developed framework in which the findings can be reliably interpreted. In the latter case, such a framework is absent. The ECETOC Scientific Committee has agreed to initiate a Task Force (TF) with the following provisional Terms of Reference (ToR):

- > Develop criteria for the consistent use of biomonitoring data;
- > develop a risk-based framework and guidance on the interpretation of biomonitoring data for exposure and risk assessment purposes;
- > test the proposed framework using a number of case studies covering a range of environmental exposures;
- > present the conclusions of the TF to external workshops;
- > serve as a network of scientists to track, and input to, ongoing developments in the field of biomonitoring.

The ToR will be accomplished through managing the TF in two phases. The first phase is using an approach which is quite different to the conventional TF and

requires a small group of committed specialists from member companies and academia to achieve a draft report within 4-6 weeks. The second (and in part concurrent) phase is to develop a network of expertise from within ECETOC member companies and to pilot/validate the proposals through the development of a library of supporting case studies.

### Health and Environmental Safety of Nanomaterials

The subject of nanotechnology and nanomaterials has become increasingly visible in the recent past with questions raised whether health and environmental safety have been sufficiently established. Several of our member companies requested that ECETOC should undertake a targeted action plan to address the issue, particularly focused on chemicals and the impacts on the manufacturers and users of chemicals.

A new TF was established in the second half of 2004, with the aim of developing guidance on the health and environmental safety assessment of nanomaterials. The remit of the TF is to develop a White Paper defining nanomaterials and evaluating the available data on their toxicity, biological fate and exposure potential (manufacturing, application and use). This White Paper has been elaborated by a consortium of experts mainly from academia, and is currently being peer-reviewed by TF members. Based on this paper, potential gaps regarding the safety assessment of nanomaterials will be identified and research/testing strategies proposed. The latter is planned to be the subject of an ECETOC workshop to be held in 2005.

#### Children's Health

A TF was started in 2003, charged with reviewing trends in Children's Health and the potential role of chemicals in products and in the environment. Health trends reviewed included respiratory diseases/asthma, allergies, neurodevelopmental and reproductive disorders and cancer. The focus was on low-level, long-term exposures to chemicals. Members of the TF presented preliminary conclusions at the ECETOC Annual Technical Meeting (ATM) in June 2004, and the final conclusions, including identified knowledge gaps and research needs, at the LRI Members' workshop in November 2004 and at the Society for Risk Analysis Meeting in Palm Springs, USA in December 2004. Publication of this review is currently being finalised.

### Specific Substances Programme

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 setting of an occupational exposure limit value. During 2004, new reviews were published on n-Butanol and sec-Butanol, and on the Fluoroalkanes HFC-152a and HFC-245fa, while the existing report on Chlorinated Fluoroalkane HCFC-124 was updated.

### **Whole Effluent Assessment**

Under the leadership of the WEA TF, ECETOC hosted a one-day meeting of the OSPAR Whole Effluent Assessment International Experts Group on

February 24th 2004. The goal of the workshop was to add detail to the OSPAR WEA work programme 2004/2006 for submission to the HSC 2004. Emphasis was placed on the development of flowcharts and guidance on how to address persistence, bioaccumulation and toxicity issues within WEA. An additional goal of the workshop was to distribute tasks between industry and contracting parties.

During 2004, in addition to the activity in the new Task Forces, the ECETOC programme was progressed by the following:

#### **Environment**

- > Biodegration Kinetics
- > Alternative Approaches to the Use of Animals for Environmental Risk Assessment
- > Whole Effluent Assessment

### Human Health

- > Acutex (Acute Exposure Threshold Levels-AETLs)
- > Children's Health
- > Derivation of Occupational Exposure Limits from Available Effects Data

### Risk Assessment

- > Information Requirements for Risk Assessment of Chemical Substances
- > Risk Assessment of PBT Type Chemicals
- > Soil and Sediment Risk Assessment
- > Targeted Risk Assessment

### **Specific Substances**

- > Butanols
- > Cyanides
- > Fluoroalkanes
- > Synthetic Amorphous Silica
- > Tetrafluoroethylene, Hexafluoropropylene and Vinylidenefluoride
- $\,>\,$  Toxicology of Glycol Ethers and its Relevance to Man



### **WORKSHOPS**

# The following Workshops were convened during 2004:

ECETOC workshops are convened often in partnership with other interested parties, to develop and communicate understanding and counsel on key issues affecting the environmental and human health aspects of the responsible management of chemicals. The principle aim of an ECETOC organised workshop is to define the State of the Science on a given topic or issue through drawing together the world's leading subject matter experts, who can debate the issue and make conclusions and recommendations.

Workshops have become a major feature of the products and services that ECETOC provides to its member companies. They provide an opportunity to broaden the debate by involving representatives from other organisations, academia and the regulators.

# Use of Human Data in Risk Assessment 23-24 February 2004, Cardiff

Available human data are not always consistently addressed in chemical risk assessment, while questions of data quality often inhibit their interpretation and use. ECETOC, with the aim of initiating a consensus on this topic, organised an international workshop on the 'Use of Human Data in Risk Assessment', in collaboration with the International Programme on Chemical Safety (IPCS), OECD Environment Directorate and European Commission's Institute of Health and Consumer Protection (IHCP). Thirty-one experts from national (7) and international (6) governmental agencies, academia (10) and the chemical industry (8, from ECETOC member companies) participated in the workshop, providing a balance in participation among government, academia and industry.

The workshop proceedings, published as Workshop Report No. 3, include the following main outcome and recommendations:

- > Good quality human data are not readily accessible and their usefulness is frequently constrained by the lack of information on exposures. A clear framework should be developed that enables human data from different sources to be collected and assessed in terms of quality and application in risk assessment.
- > The framework must be built on guidelines for (i) good human data collection practice, (ii) good exposure assessment practice and (iii) good risk assessment practice, and better networking of existing information sources.
- > An action plan is required to improve the recording of existing data, while incentives should encourage the provision of human data of improved quality for risk assessment purposes.

### Influence of Maternal Toxicity in Studies on Developmental Toxicity 2 March 2004, Berlin

Present EU classification of chemicals is based on hazard, and differences of opinion in the interpretation of developmental toxicity study outcomes, when maternal toxicity produced secondary effects on the progeny, have often occurred. Interest in addressing this subject was defined by a Cefic LRI members' survey. A workshop was organised by ECETOC and sponsored by LRI, with the objective to build the grounds for finding consensus on the criteria for an appropriate interpretation of

developmental effects occurring in the presence of maternal toxicity. The aim of the workshop was to define the actions needed to develop a better insight into the genuine incidence of such secondary effects.

Approximately fourty invited participants from academia, governmental regulatory agencies and industry convened in Berlin for a one day workshop.



Participants at the workshop on Maternal Toxicity, Berlin.

Several conclusions and recommendations were made:

- Regulatory classification of chemicals that have caused signs of developmental toxicity relies on a hazard-based approach. It does not take full account of exposure conditions during normal handling and use.
- 2. The currently practiced European classification of chemicals that have shown evidence of developmental toxicity does not provide a clear distinction between developmental effects that occur directly on the embryo/foetus (primary effect) and those that are associated with chemically-induced perturbations of maternal

- homeostasis (secondary effect). The appropriate consideration of such effects has profound ramifications for the classification of chemicals.
- 3. Relevance of route and mode of administration of test chemicals, dose-response data as well as toxicokinetics and toxicodynamics were recognised as important criteria that should be considered in the study design. The existing data are compelling, and one can no longer ignore the scientific evidence that the biological and toxicological effects differ profoundly depending on how the chemical enters into the body.
- 4. The use of expanded end points that are more sensitive to detect chemically induced maternal toxicity than those specified in the OECD 414 test guideline received endorsement from a majority of the participants. However, reservations from representatives of regulatory agencies meant that no true consensus could be reached. An experimental way forward to better define maternal and developmental toxicity in OECD 414 studies received broad support. New data with refined end points to detect the onset of maternal toxicity might improve the interpretation of the results of such studies and might provide a scientific basis for industry and regulators when making decisions leading to classification.
- 5. The majority of participants agreed with the recommendation to make the regulatory process reflect anticipated human exposure. This would mean that risk characterisation, as well as hazard identification, would become an important component in the classification of chemicals.



### ECETOC TRA Web Tool User Workshop 5 March 2004, Brussels

ECETOC has been monitoring the evolution of the EU Chemicals Policy and formed a Task Force on Targeted Risk Assessment (TRA) prior to the proposal of the REACH Regulations. The progression of the proposal through the Commission in 2003 and its presentation to Parliament during 2004, confirms the eventual implementation of the new regulations, requiring broader involvement from ECETOC member companies in the current activities.

The TRA Task Force has been working to propose methods for a tiered and targeted risk assessment process. Many of the concepts and ideas developed by the Task Force have been built into a web-based tool that allows users to enter data and generate a basic risk assessment report. The work of the Task Force entered a critical phase in 2004 and they invited ECETOC member companies and other stakeholders to look at the website, to evaluate chemicals which they have substantive experience of through the system and to provide feedback.

In particular, the purpose of this workshop was to capture User experience with the web tool with the aims of:

- > Identifying areas to further improve the transparency, functionality, security, reliability and user-friendliness of the tool;
- > identifying topics which may require further explanation in the TRA report;
- > establishing a User group which can be used to capture suggestions as experience with the tool develops.

The concepts of the approach have been programmed into a web tool that integrates the core concepts into an easy-to-use format. The web tool is currently being evaluated but has been shown to work across a range of substances and conditions. The web tool can be found at https://www.ecetoc-tra.org. The website is password protected but access can be obtained via the ECETOC Secretariat.

# Alternative Testing Methods in Environmental Hazard Assessment

### 7-9 July 2004, Crecy la Chapelle

Animal welfare and the use of animals for environmental safety assessments is an area of growing public concern and political sensitivity. Concern about animal welfare issues is driving legislative (e.g. REACH and the 6th and 7th Amendment to the Cosmetics Directive) and regulatory changes that impact on the conduct of animal experiments and the requirements for product registration. For example, the European Commission White Paper on the future EU Chemicals Policy, defines, as one of its objectives, the 'promotion of non-animal testing'. As currently envisioned, the proposed legislation would mean that 30,000 chemicals in volume greater than 1 tonne per year would need further assessment. Unless suitable alternatives can be developed and validated, this would mean testing involving 13 million animals, of which 8 million would be fish.

ECETOC held a workshop, which was co-sponsored by the European Centre for the Validation of Alternative Methods (ECVAM, http://ecvam.jrc.it/) and Cefic Long-range Research Initiative (LRI, http://www.cefic-lri.org), on 7-9th July 2004, to facilitate an active dialogue amongst industry, regulators and academia, on the pragmatic use of alternative (non-animal) approaches. The 37 workshop participants were charged with addressing in vivo, in vitro and in silico approaches, in line with the 3Rs (Replacement, Refinement and Reduction), for the generation of hazard and exposure information within the context of environmental risk assessment.

The primary outcome of the workshop was the development of research networks/programmes to develop alternative methodologies to address the environmental safety of chemicals. The workshop first identified methodology for generating information for environmental risk assessment, in line with the 3Rs. Research to address knowledge gaps in the proposed methodology were identified and research plans including potential funding opportunities, collaborations and timelines were drafted.

# Symposium-Workshop on the Use of 'Omics' in Hazard Identification

### 6 September 2004, Maastricht

A Symposium-Workshop was held during the annual conference of EEMS (European Environmental Mutagen Society). It comprised a Symposium on 'Toxicogenomics in Genetic Toxicology' with over 300 participating scientists, followed by a workshop on 'Hazard Identification by Omics Technologies' with over 150 participants. This significant participation reflects the success of having chosen a topical subject presented by recognised experts with high scientific credibility. The organisation was the

responsibility of an ECETOC Task Force, while Cefic LRI co-sponsored the event.

The audience at the workshop identified the need to provide correlations between genomic data and hazard determination, one approach being to examine carefully the data for indications of toxicity mechanisms, besides just the gene expression signature. Furthermore, there was a lack of standardised methods/systems for data collection, and a need to develop and share databases. The workshop also called for the rigorous application of statistics. With regards to the biological system, care should be taken with experimental variables such as genetic variation, cell growth and differentiation state, changes in vitro of primary cells with time, and cell genetic instability in cells. Finally, it was questioned whether inbred in vivo systems would provide a more stable background than in vitro. Proceedings of the Symposium-Workshop will be published as a special issue of 'Mutation Research' in 2005.



A reception was organised for delegates of the Symposium-Workshop at the Maastricht Town Hall.



# **ECETOC SCIENCE AWARDS**

### Recognising young Scientists

Exposure assessment plays a pivotal role in risk assessment and risk management. Whilst much focus is placed upon the evaluation of hazards, much less effort is invested in research which aims to better understand the nature and extent of exposure. The X2004 Conference held at the University of Utrecht, provided a unique forum that brought together many of the world's leading researchers in the field of exposure assessment. Recognising the need to encourage high quality exposure assessment research, ECETOC worked with the organisers of X2004 to create an award for the best platform or poster presentation by a young scientist at the Conference.

At the closing ceremony of the X2004 Conference, Ms. Mattsson, from the Karolinska Institute, Stockholm, Sweden was presented with this years ECETOC Science Award for her presentation entitled 'Nasal air sampling used to measure inhaled wheat allergen in a bakery with and without using facemasks'.

In identifying the winner, ECETOC Scientific Committee member, Mr. Money (ExxonMobil), commented that 'not only was importance placed on high scientific content and quality of presentation, but particular attention was paid to the originality of the work and its relevance within the broader context of risk management. Ms. Mattsson's research, which involved the application of novel sampling and analytical approaches to better describe the nature of exposure to a widespread occupational allergen, not only helps characterise the magnitude of exposure, but also critically demonstrates the effectiveness of measures taken to control associated risks. As such, it might be anticipated that this research will now lead to the

extension of some of the methodologies into related areas of workplace and consumer exposure.'

In addition to recognising the contribution of the investigator to the scientific content of X2004, the aim of the award was to help promote collaboration between research teams and organisations engaged in workplace exposure-related research.



ECETOC Scientific Committee member, Mr. C. Money (ExxonMobil) together with the 2004 ECETOC Science Award winner Ms. M-L. Mattsson, from the Karolinska Institute Stockholm, Sweden.

### 2003 ECETOC Science Award Winners

Following the successful introduction of the ECETOC Science Award in 2003 as a major innovation for the 25 year Jubilee event, the Scientific Committee invited the three recipients to report on their accomplishments based on the award.



Dr. Haufroid's presentation (Catholic University of Louvain) entitled 'Interest on genotyping and phenotyping of drugmetabolizing enzymes for the interpretation of biological monitoring of exposure to styrene' was a summary of two

papers <sup>a,b</sup> that had been given at the 10th International Congress of Toxicology in Tampere in July 2004 and at the 6th International Symposium on Biological Monitoring in Heidelberg in September 2004. The two publications have been written with support from the ECETOC Science Award and acknowledged therein.

Dr. Semple (University of Aberdeen) talked about his dermal model on exposure to solvents, which was the subject of his award, and about his more recent research on occupational dermal and ingestion exposure. He had also used part of the



award to build academic links whilst teaching in South-East Asia, and as a result was instrumental in his promotion to lecturer at his University.

Dr. den Brink van (University of Wageningen) presented his Perpest expert model that he had developed to predict ecological risks of freshpesticides water ecosystems. presentation to the Scientific Committee



triggered a lively discussion around the validation of the model and on its predictive capability when using laboratory data and for complex effects on ecosystems.

In conclusion, the Scientific Committee acknowledged the value of this new element of the ECETOC science programme and will continue to seek support from the ECETOC Board to present future Science Awards.

- a 'Markers of Individual Susceptibility and DNA Repair Rate in Workers Exposed to Xenobiotics in a Tire Plant' P. Vodicka et al Environmental and Molecular Mutagenesis 44: 283 - 292 (2004).
- b 'Influence of Genetic Polymorphisims on Biomarkers of Exposure and Genotoxic Effects in Styrene-Exposed Workers' L. Godderis et al Environmental and Molecular Mutagenesis 44: 293 - 303 (2004).



### **outREACH**

Following the success of the first outREACH event in 2003, two further events were held in 2004 for the UK/Ireland and Benelux regions. Primary invitees were the Environmental Health and Safety (EH&S) Scientists and senior management including delegates of ECETOC member companies headquartered in these regions. In addition, EH&S representatives were invited from several other companies using or manufacturing chemicals, Contract Research Organisations and Trade Associations.

ECETOC Board member Mr. D. Hyde of AstraZeneca hosted the first event in February at their global headquarters in London. Since many ECETOC member companies are based in the UK, good representation was achieved together with other guests resulting in 45 participants. The event was organised to allow all participants to travel in the morning and, after minimal introductions, immediately address the keynote topic. Following the keynote item, there was an opportunity for all participants to network over a light lunch, before the afternoon session which was a mixture of presentations, working groups and plenary discussion. The event adjourned by mid-afternoon to allow participants to return home the same day. Within 48 hours, participants received a PDF file of all the slides and within a month feedback from their questionnaire responses and the output of the working groups.

The primary objective of the outREACH event is to improve the dialogue between ECETOC as an organisation and employees of its member companies. This is achieved through an in-depth review of a major topical issue challenging the industry through pending regulatory pressure, whilst highlighting ECETOC's contribution to a solution.



Participants at the outREACH event held in London on February 3, 2004.

So far, this has been the implications of the proposed REACH regulations and ECETOC's contribution to improved workability through the Targeted (or Tiered) Risk Assessment (TRA) methodology and web tool. Subsequently there is a broad overview of all the ongoing activities of ECETOC Task Forces and Workshops focused on the key issues and drivers impacting Safety, Human Health and the Environment for users and manufacturers of chemicals across the broad industrial sectors of ECETOC members. Finally, it provides a forum through Working Groups by industry sector and a Panel Discussion for a debate on future issues which have not surfaced previously. but to which ECETOC could potentially contribute sound science.

A secondary objective is to raise the visibility and profile of ECETOC with selected non-member companies that are users and/or manufacturers of chemicals who can benefit from the work and activities that ECETOC is pursuing.

Through this interaction ECETOC has gained several new members and access to additional toxicology and ecotoxicology experts for populating future Task Forces.

ECETOC Board member Prof. J. de Wit of Akzo Nobel hosted the second event in June at their global headquarters in Arnhem. The participants were equally divided between ECETOC member companies and guests, with active participation from smaller companies who will be significantly impacted by the proposed new REACH regulations. The agenda was identical to the London event and participants appreciated the ECETOC initiative and clearly highlighted the potential to grow the ECETOC membership, if there were additional membership categories catering to small and medium enterprises.

Key points that emerged from the event were:

(i) The support for completing the Targeted Risk Assessment project and the publishing of the Technical Report as a vehicle to influence the Regulators through sound science.



ECETOC Board Member, Prof. J. de Wit (Akzo Nobel).

- (ii) Continue to promote exposure based Risk

  Assessment versus Hazard Assessment within the proposed REACH regulations.
- (iii) Help to build a rational basis for in silico assessment especially (Q)SAR in regulation and Technical Report No. 89 '(Q)SARs: Evaluation of the commercially available software for human health and environmental endpoints with respect to chemical management applications' will be supportive.
- (iv) Build a sound scientific basis for the way in which industry and regulators can use the 'Omic' technologies to promote the safe use of chemical based products.



# LONG-RANGE RESEARCH INITIATIVE (LRI)

Since 1997 ECETOC has played a significant role in developing and overseeing this strategic research programme on human health and the environment

#### **Environmental Programme**

Many of the projects funded under phase I of the environmental programme came to a conclusion during 2004 and although the monitoring team continued its role of monitoring scientific progress in the various projects and identifying emerging areas for research, it was recognised that effort should also be directed towards the further development of the roll-out strategy to inform stakeholders of the progress made during phase I. The objectives of the environmental programme remain:

- > Integration of persistence, mobility, bioavailability, bioaccumulation potential and toxicity into assessing the long-term effects of chemicals on ecosystems and incorporation of these characteristics into approaches to risk assessment.
- > Development and validation of fate and distribution models to improve exposure prediction.

Towards the end of the year, the project 'Identification and sensitivity analysis of the key parameters in the generic estuary model (GEMCO)' was commissioned. The project was funded to develop a QSAR decisions support system to enhance their use in regulatory situations. An Request for Proposal (RfP) to develop biodegradation of poorly soluble substances was posted on the website and three RfPs related to the development of alternatives to animal testing in environmental risk assessment were submitted to the Cefic LRI planning group for approval.

### **Health Effects Programme**

This year, most projects of phase I of the Health Effects science programme were finalised, and the remaining ones are nearly completed. The monitoring team, comprised of ECETOC member company specialists and one academic member from the University of Milano (Dr. Corsini), evaluated the progress made and ensured that the projects were completed with final reporting. The funded research has produced a significant number of publications in scientific journals, as well as papers and poster abstracts presented at international conferences, which have been posted on the LRI website.

Also during 2004, the phase II research projects were ultimately selected and launched after a first evaluation of the expressions of interests addressing the posted RfPs which had been made in the previous year. In the science programme area on Chemical Carcinogenicity, three research projects are being funded to address the RfP titled: 'The biological significance of chemically-induced DNA adducts, the investigation of the possible presence of thresholds, and the use of adducts in genotoxicity hazard and risk assessment'. In the science programme area on Immunotoxicology, Respiratory Toxicology and Allergy, three research projects (one of them being a combination of two proposals) have been awarded to address the RfP titled: 'Hazard identification and characterisation of chemical respiratory allergens', and one research project is addressing the RfP titled: 'The basis for inter-individual differences in susceptibility to

chemical allergy'. The ECETOC - LRI monitoring scientists will maintain an ongoing dialogue with the respective research teams. Another RfP in this programme area: 'Association between chemical pollution and respiratory allergy and asthma' will be the subject of a workshop between the relevant stakeholder groups. ECETOC will hold this workshop during 2005.

### **Human Exposure and Tiered Risk Assessment**

In 2004, the HETRA team oversaw completion of a database of European workplace exposure research activities and the establishment of a framework for a Cefic-supported exposure database. A highlight of the reporting year provided an international workshop on Skin Permeation Methods for Human Risk Assessment (Utrecht, June 2004). This workshop recommended a protocol to generate in vitro skin permeation rate data for representative chemical groups. Furthermore, there were publications on the real and theoretical effectiveness of skin protection strategies (solids) at the workplace. While relevant research on indoor exposure continued to be inventorised in 2004, there were extensive publications in the literature on personal exposure patterns for certain determinants in the European population. The results from all of these projects will enable better characterisation of actual exposures, which is required for sound science-based human risk assessment. In the area of consumer exposure, a sourcebook on exposure factors for Europe was completed.

Further work was aimed at reliable prediction and assessment of exposures of European consumers, such as acquisition of anthropometric data, information on consumer exposures to mixtures, and description of accidental mis-use of chemicals and chemical products.

To improve existing risk assessment methodologies, the ongoing database of chemical structural alerts and substances with low toxicological no-effect levels was enhanced. A paper on the basis for and improvements to the EASE version two models for workplace exposure estimation were in preparation. A study on variability and uncertainty in chemical exposures for regulatory risk assessments was completed. Additional work was initiated concerning risk perceptions, in particular a review of workplace management strategies for chemicals in small enterprises, the potential application of the 'intake fraction' as a tool for targeting risk assessments and development of a workable framework for consistent regulatory decision making.

Finally, with respect to biomarkers of exposure, a review of the role and application of such biomarkers in the management of the occupational health risks was completed, while studies on trends and key developments of such biomarkers in the general population, and on the normal background incidence within the general population, were ongoing. Further work is envisaged to determine the effects of intra- and inter-individual variation.



# **ECETOC OUTPUTS**

During 2004 ECETOC generated publications ranging from its traditional reports to external publications in peer-reivewed journals

### **JACC Reports**

- No. 41 *n*-Butanol (CAS No. 71-36-3)
- No. 43 sec-Butanol (CAS No. 78-92-2)
- No. 44 1,1,1,3,3-Pentafluoropropane (HFC 245fa) (CAS No. 460-73-1)
- No. 45 1,1-Difluoroethane (HFC-152a) (CAS No. 75-37-6)
- No. 46 1-Chloro-1,2,2,2-tetrafluoroethane (HCFC 124) CAS No. 2837-89-0 (Second Edition)

### **Technical Reports**

- No. 92 Soil and Sediment Risk Assessment of Organic Chemicals
- No. 93 Targeted Risk Assessment
- No. 94 Whole Effluent Assessment

### **Workshop Reports**

- No. 2 EQS and WFD versus PNEC and REACH are they doing the job? 27-28 November 2003, Budapest
- No. 3 Use of Human Data in Risk Assessment, 23-24 February 2004, Cardiff
- No. 4 Influence of Maternal Toxicity in Studies on Developmental Toxicity, 2 March 2004, Berlin
- No. 5 Alternative Testing Approaches in Environmental Risk Assessment, 7-9 July 2004, Crécy-la-Chapelle

### **Distribution of Reports**

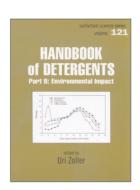
ECETOC publications are distributed to member companies, universities, governmental institutions and many other interested parties such as various regulatory authorities, international organisations and academic groups. During 2004, more than 5,000 publications, varying in scope from Technical Reports (TR), Monographs (Mono), Joint Assessment of Commodity Chemicals Reports (JACC), Workshop Reports (WR), Special Reports (SR) and Documents (Doc), were distributed worldwide.











### **External Publications**

- > Holt, M.S and Fox K.K. Generation and use of data to predict environmental concentrations for use in detergent risk assessments. Surfactant Science Series. In Zoller U, ed, Handbook of Detergents, Part B Environmental Impact, pp147-194. Marcell Dekker Inc, New York, USA, 2004.
- > A structured approach to the evaluation of workplace chemical health risks. Chris Money BSc (Hons) MSc Dip Occ Hyg, ExxonMobil Petroleum & Chemical, Belgium, Christ de Rooij BSc, Solvay, Belgium, François Floc'h MSc PhD, Rhodia, France, Sylvia Jacobi BSc MSc PhD, Degussa, Germany, Patricia Koundakjian BSc (Hons) PhD, Eurofer, Belgium, Sonja Lanz Dip Ing Agr, BASF, Germany, Michael Penman BSc (Hons) MBE, ExxonMobil Petroleum & Chemical, Belgium, Carlos Rodriguez MSc PhD, Procter & Gamble, Belgium, and Gauke Veenstra MSc PhD, Shell Chemicals, UK, 2004.

### **Posters**

- > Suggestions for implementing the 3Rs in acute aquatic toxicity assessment. A Lillicrap (AstraZeneca), C Stevens (Dow Corning), M Comber (ExxonMobil), W de Wolf (Du Pont), S Gimeno (Procter & Gamble), R van Egmond and P Douben (Unilever), G Whale (Shell), M Léonard (L'Oréal), M Holt (ECETOC).
  - Presented at SETAC Europe 14th Annual Meeting in Prague, 18-22 April, 2004.
- > Suggestions for implementing the 3Rs in assessing a chemicals potential to bioconcentrate. M Comber (ExxonMobil), S Gimeno (Procter & Gamble), W de Wolf (Du Pont), A Lillicrap (AstraZeneca), C Stevens (Dow-Corning), R van Egmond and P Douben (Unilever), G Whale (Shell), M Léonard (L'Oréal), M Holt (ECETOC).
  - Presented at SETAC Europe 14th Annual Meeting in Prague, 18-22 April, 2004.



# **ECETOC WEBSITE**

# During 2004 ECETOC launched its newly designed website

On September 1st 2004, ECETOC announced the launch of its newly designed website <a href="www.ecetoc.org">www.ecetoc.org</a>. The original website has undergone an 'extreme makeover', and has been tailored specifically for ECETOC needs, which included the redevelopment of the existing Public and Member Site. This leading edge website technology allows visitors to access extensive information easily via the new navigation model.

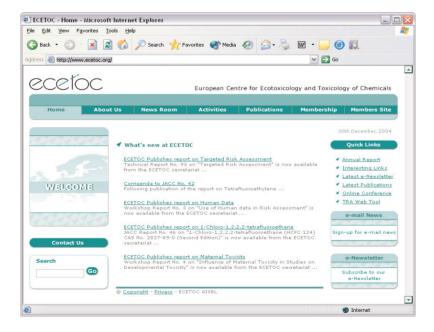
'Through this significant investment we expect to greatly facilitate the ECETOC activities of our members', says Dr. M. Gribble, ECETOC Secretary General.

The website provides information about the Associations' history, work programme, latest news and offers a variety of new online features.

Some of the online features include:

- > A dedicated extranet environment for participating members;
- > email news have the latest news delivered straight to your desk in the area of interest you choose;
- > e-newsletter keeps you up-to-date with the latest developments at ECETOC;
- > an activity section offering online registration to members and the review of activity agendas and other related documents;
- > and a fully-automated easy-to-use audio and web conference system.

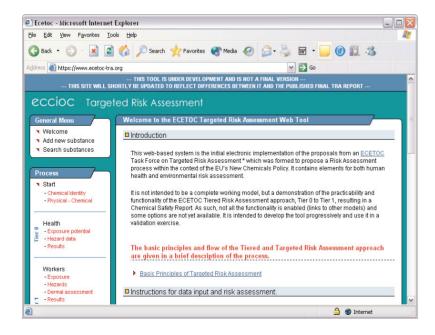
Be sure to visit our website regularly for the most up-to-date information and for a complete list of our publications which can be ordered online.



# ECETOC Targeted Risk Assessment (TRA) web tool

Any new system of risk assessment must be amenable to all stakeholders. In the context of the chemical's supply chain, this extends from chemical suppliers, to formulators, distributors, smaller enterprises and skilled trades. The core operating concepts of any approach must therefore aim to be simple and readily understood without compromising scientific integrity. The TRA Task Force have proposed a tiered and targeted approach to risk assessment. Each tier demands more information in order to improve the confidence in and refine the accuracy of the risk estimate. The outputs from the process are an evaluation and description of the health and environmental risks associated with the manufacture and use of the substance. These can then be used by the chemical supplier (or others with responsibilities within the supply chain) to propose and apply risk management measures.

Electronic implementation of the TRA approach has been achieved through the development of a webbased tool that allows users to enter chemical specific data and generate a basic risk assessment report. The tool demonstrates that, although the (eco)toxicology and exposure science behind the approach is complex, it can be automated to show the practicability of the concepts in a working model and that it need not be a resource-intensive activity. The design ensures that the results are well documented and understandable, and that consistent answers are achieved from the set of 'rules' that have been written out in a logical pattern. The design of the tool is novel and it is believed that it will have applications (after suitable amendment) outside the scope of REACH, e.g. general product stewardship. Access to the password protected website (https://www.ecetoc-tra.org) can be obtained from the ECETOC secretariat.





# **EXTERNAL REPRESENTATION**

ECETOC, in addition to major collaborative exercises, provided expert representation to the work of a number of other external organisations in 2004. These included:

- Risk of Derm Workshop
   Brussels, 21-22 January
   ECETOC represented by Dr. C. Hennes (ECETOC).
- > Global Chemicals Regulations Conference Arlington, 9-11 March ECETOC represented by Dr. T. Feijtel (Procter & Gamble), Mr. C. Money (ExxonMobil) and Mr. M. Penman (ExxonMobil).
- > SETAC Europe 14th Annual Meeting
  Prague, 18-22 April

  ECETOC represented by Dr. D. van Wijk
  (EuroChlor) who gave a platform presentation
  on behalf of the ECETOC Whole Effluent
  Assessment Task Force entitled: 'Suggestions
  for implementing whole effluent assessment'.
  Dr. D van Wijk (Euro Chlor), Dr. S Belanger
  (Procter & Gamble), Dr. P Chown (Concawe),
  Dr. M Comber (ExxonMobil), Dr. V Coombe
  (AstraZeneca), Dr. M Geurts (Akzo Nobel),
  Dr. W Guhl (Henkel), Dr. H Johnsen (Statoil),
  Dr. P Lemaire (Atofina), Dr. N Swinnen
  (Solvay), Dr. W ten Berge (DSM), Dr. R Toy
  (Shell), Mr. G Whale (Shell), Mr. M Holt (ECETOC).
- > Belgian Platform for Alternative Methods to animal testing
   Brussels, 21 April
   ECETOC represented by Ir. H. Vrijhof (ECETOC).

- > IARC Monograph Working Group 'Expert Working Group for the Carcinogenicity Classification of Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxy-2-propanol'. Lyon, 2-9 June ECETOC represented by Prof. P. Gelbke (BASF).
- > X2004 Conference Utrecht, 14 June ECETOC represented by Mr. C. Money (ExxonMobil) who gave presentations, entitled: 'One Option for a Future Improved EASE Model' and 'The ECETOC Approach to the Targeted Risk Assessment of Chemicals at Work'.
- OECD Workshop on Data Interpretation Procedures
   Berlin, 1-2 July
   ECETOC represented by Dr. R. Phillips (ExxonMobil).
- 10th International Congress of Toxicology
   Tampere, 11-15 July
   ECETOC represented by Dr. C. Hennes (ECETOC).
- > 'Simulation Testing for Environmental Persistence
  (STEP)' Workshop
  Rotterdam, 4-5 October
  ECETOC represented by Dr. J. Snape (AstraZeneca)
  who gave a presentation entitled: 'The
  Recommendations of the ECETOC TF on
  Persistence of Chemicals in the Environment'.

- > 1st International Symposium on Occupational Health Implications of Nanomaterials Buxton, 12-14 October ECETOC represented by Dr. C. Hennes (ECETOC).
- > WHO IPCS 7th Meeting of the Steering
  Committee on the Harmonization of Approaches
  to the Assessment of Risk from Exposure to
  Chemicals
  Cincinnati, 25-26 October
  ECETOC represented by Dr. M. Gribble (ECETOC).
- > Technical Committee NES (New and Existing Substances) subgroup
  Ispra, 9-10 November
  ECETOC represented by Dr. J. Snape (AstraZeneca) who gave a presentation on the identification of PBT and vPvB substances working group.
- > CONCAWE Annual Meeting
  Brussels, 24 November
  ECETOC represented by Mr. M. Holt
  (ECETOC) who gave a presentation entitled
  'Whole Effluent Assessment Where does the
  data lead us?'
- > ETH (The Swiss Federal Institute of Technology)

  Zurich, 26 November

  ECETOC represented by Dr. D. van Wijk (EuroChlor)

  who gave a presentation entitled: 'Whole Effluent

Assessment (WEA): Results of the ECETOC Task Force and OSPAR WEA Activities' in their programme 'Sicherheit und Umweltschutz in der Chemie Seminarreihe Wintersemester'.

- > UK HSE/EC Workshop on the Future of the EASE Model
  Edinburgh, November
  ECETOC represented by Mr. C. Money (ExxonMobil)
  Paper presented on 'One Option for a Future
  Improved EASE Model'.
- > Würzburger Forum Toxikologie on Thresholds and Non-monotonic Dose-relationships Würzburg, 3 December ECETOC represented by Ir. H. Vrijhof (ECETOC).
- > Society for Risk Assessment Annual Meeting Palm Springs, 6 December ECETOC represented by Dr. G. Charnley (Health Risk Strategies) Dr. D. Goldstein (Monsanto) and Dr. R. J. Lewis (ExxonMobil).



# STRATEGIC LIAISONS

- > European Centre for the Validation of Alternative > OSPAR Whole Effluent Assessment programme for Methods (ECVAM) Ispra, ECVAM Scientific Advisory Committee ECETOC represented by Dr. J. Fentem (Unilever).
- > ECB, Health Working Group ECETOC represented by Dr. C. Hennes (ECETOC).
- > ILSI Europe, Environment and Health Task Force ECETOC represented by Mr. M. Holt (ECETOC).
- > SETAC Europe Council ECETOC represented by Mr. M. Holt (ECETOC).
- > European Environment Agency (EEA) Copenhagen, Denmark ECETOC represented by Dr. T. Feijtel (P&G), Mr. C. Money (ExxonMobil), Prof. P. Calow (Danish Environmetal Assessment Institute), Dr. M. Gribble (ECETOC) and Mr. M. Holt (ECETOC).
- > International Life Sciences Institute (ILSI) Health and Environmental Science Institute (HESI) ECETOC represented by Dr. M. Gribble (ECETOC).
- > World Health Organisation (WHO) International Programme on Chemical Safety (IPCS) ECETOC represented by Mr. C. Money (ExxonMobil), Ir. H. Vrijhof (ECETOC) and Dr. M. Gribble (ECETOC).

- 2004-2006, hosted by ECETOC on 24th February ECETOC represented by Dr. D. van Wijk (Eurochlor) and Mr. M. Holt (ECETOC).
- > Institute for Consumer Health Protection (IHCP) ECETOC represented by Dr. T. Feijtel (P&G), Mr. C. Money (ExxonMobil) and Dr. P. Douben (Unilever).
- > EU Commission's Initiative SCALE Consultative Forum ECETOC represented by Dr. D. Owen (Shell).

# **SECRETARIAT**

# ECETOC's continued success relies greatly on its Secretariat

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.

At the end of 2004, staff employed were:

### Name

Dr. Michael Y. Gribble

Dr. Christa Hennes

Mr. Martin Holt

Ir. Henk Vrijhof

Ms. Geneviève Gérits

Ms. Julieann Humphrey
Ms. Marie-Laurence Simon

Ms. Christine Yannakas

### **Function**

Secretary General

Health Sciences Manager

Environmental Sciences Manager

Chemicals Programme Manager

Office Manager

Publications Officer

Secretary

Secretary



Front row from left: C. Hennes, M. Gribble, J. Humphrey

Back row from left: H. Vrijhof, M-L. Simon, G. Gerits, C. Yannakas, M. Holt



## **MODUS OPERANDI**

Since ECETOC's inception in 1978, the original modus operandi has undergone considerable refinement, crucial to sustaining the centre's effectiveness and reputation for scientific integrity in a changing world

#### **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 judgment.

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 / Contractors**

When the Scientific Committee has agreed in principle a project, an initial 'scoping' meeting defines clearly the overall objectives, resources needed, deliverables and timeplan. project proposals form the basis for Scientific Committee's decision on how the initiative is progressed, the choice being essentially between the sweat equity approach (conventional Task Force) or, to a lesser or greater extent, through the use of a contractor. ECETOC's outputs mostly 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.

### **Publications**

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

- > Technical Reports addressing specific applications of the science in evaluating the hazards and risks of chemicals to human health and the environment;
- > JACC Reports on specific chemicals;
- > Monographs dealing with the fundamental principles underlying the various branches of toxicology and ecotoxicology;
- > Special Reports compilations of data targeted to specific regulatory issues and demands;
- > Workshop Reports summaries of the discussions and conclusions derived from ECETOC sponsored scientific workshops;
- > Documents scientific briefing papers, addressing emerging issues.

Reports continue to be published following peer review by the Scientific Committee and external experts, with the exception of Worskhop Reports. 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 to improve 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 using and/or manufacturing chemicals.

### Workshops

The principle aim of an ECETOC organised workshop is to define the State of the Science on a given topic or issue through drawing together the world's leading subject matter experts who can debate the issue and make conclusions and 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.



# **BOARD MEMBERS**

# ECETOC Board as at December 2004:

Name	Company	Function
Dr. J. Rudolph	Degussa	Chairman
Dr. K. Eigenmann	Novartis	Vice-chairman
Dr. med. M. Kayser	Bayer	Treasurer
Prof. J. De Wit	Akzo Nobel	
Mr. D. Gartside	AstraZeneca	
Mr. D. Hyde	AstraZeneca	
Dr. C. Murray	Procter & Gamble	
Prof. B. Sangster	Unilever	
Prof. L. Smith	Syngenta	
Mr. T. Vanlancker	DuPont	

At the Annual General Meeting (AGM) on June 2nd 2004, the ECETOC delegates elected Prof. B. Sangster (Unilever) to the Board. Mr. R. Chaigneau (DuPont), Dr. K. Eigenmann (Novartis), Mr. D. Hyde (AstraZeneca) and Prof. L. Smith (Syngenta) were re-elected to the Board.

Mr. P. Peschak resigned his Chairmanship and membership of the Board effective May 31st 2004, following his retirement from ExxonMobil. Mr. P. Chaigneau (DuPont), Mr. D. Hyde (AstraZeneca) and Mr. C. Holmes (Procter & Gamble) also resigned from their membership of the Board during 2004.

# **SCIENTIFIC COMMITTEE MEMBERS**

# ECETOC Scientific Committee as at December 2004:

Name	Company	Function
Prof. G. Randall	SNIK-C	Chairman
Dr. R. Bars	Bayer CropScience	
Dr. C. Braun	Akzo Nobel	
Prof. P. Calow	Danish Environmental Assessment Institute	External
Dr. C. d'Hondt	Syngenta	
Dr. W. De Wolf	DuPont	
Dr. J. Doe	Syngenta	
Dr. P. Douben	Unilever	
Dr. T. Feijtel	Procter & Gamble	
Dr. Med. A. Fluckiger	F. Hoffmann-La Roche	
Prof. Dr. Med. H. Greim	Technical University Munich	External
Dr. T. Hutchinson	AstraZeneca	
Mr. C. Money	ExxonMobil	
Dr. D. Owen	Shell Chemicals	
Dr. A. Sarrif	DuPont	
Dr. G. Swaen	Dow Europe	
Dr. B. van Ravenzwaay	BASF	
Dr. H-J. Wiegand	Degussa	

The Scientific Committee held 6 meetings during the year.

The Board appointed Dr. R. Bars (Bayer CropScience), Dr. W. De Wolf (DuPont), Dr. J. Doe (Syngenta) Dr. med. A. Fluckiger (F. Hoffmann-La Roche), Dr. T. Hutchinson (AstraZeneca) and Dr. D. Owen (Shell Chemicals) as members of the Scientific Committee in 2004.

Dr. A. Sarrif resigned his membership of the Scientific Committe effective December 31st 2004, following his retirement from DuPont.



# **MEMBER COMPANIES**

ECETOC membership as at January 2005:

3M Worldwide Imperical Chemical Industries

Akzo Nobel International Flavors & Fragrances

AstraZeneca Janssen Pharmaceutica Products

ATOFINA L'Oréal

BASF Aktiengesellschaft Lucite International

Bayer AG Merck

Borax Monsanto

Borealis Nestlé

BP Novartis AG

Ciba Specialty Chemicals PETRESA

Clariant International Polimeri Europa

Coca-Cola Procter & Gamble

Cognis Corporation Reckitt Benckiser

Colgate-Palmolive Company Repsol YPF

Degussa AG Rhodia

Dow Europe GmbH Rohm and Haas

Dow Corning SASOL

DSM S.C. Johnson

DuPont Shell Chemicals

ExxonMobil Solvay S.A.

F. Hoffmann-La Roche Statoil

Henkel KGaA Syngenta

Honeywell Unilever

Huntsman (Europe) BVBA Wacker-Chemie GmbH

< Member Companies & Finance >

# **FINANCE**

Income		Actual 2004 in Euro
	Subscription	
	Full Members	1,386,000
	New Members	21,000
	Total Subscription Income	1,407,000
	Bank Interest	22,853
	Document Sales	9,425
	Project-related	337,661
	Total	1,776,940
D	Sheet and Reserves	Actual 2004 in Euro
palance		Actual 2004 in Euro
	Balance Sheet	1 776 040
	Income	1,776,940
	Expenditure	1,690,456
	Operating Margin	86,484
	Reserves	1 101 210
	Opening	1,161,318
	Operating Margin	86,484
	Closing Reserve	1,247,802
	Estimated Reserve Required	750,000
Expenditure		Actual 2004 in Euro
	Salaries (and related expenses)	871,031
	Office Running Expenses	241,837
	Travel Expenses on Missions	19,593
	Meetings and Consultants	419,298
	Professional Services	11,038
	Bank Charges	6,830
	Capital Expenditure	19,631
	Publications	52,547
	Miscellaneous	13,607
	Website	35,045
	Total	1,690,456



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### ECETOC

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