


ece|oc

Annual Report **2003**
Success through Scientific Partnerships





ECETOC, European Centre for the Ecotoxicology and Toxicology of Chemicals was established in 1978 as a scientific, non-commercial association. It is financed by forty-six companies with interests in the manufacture and down-stream use of chemicals.

The main objective of our activities is to identify, evaluate and minimise any potentially adverse effects on health and the environment, which might arise from the manufacture and use of chemicals.

To meet this objective, we facilitate the networking of suitably qualified industry scientists with relevant skills and expertise, complemented, where appropriate, with experts from academia and/or regulatory agencies. The output of our activities includes Workshops, Technical Reports and Monographs, reflecting the current state of the science for the issues under review.

A rigorous internal peer review process has ensured that we have earned recognition and respect by external bodies for scientific integrity. We continue to be a valued partner with many other organisations and regulatory bodies, such as the World Health Organisation and the European Commission, in establishing a scientific foundation for the development of legislation on chemicals.



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Vision and Mission

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
- ✔ 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 the value of the ECETOC offer is 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

Success through Scientific Partnerships

Message from the Chairman

One year ago, ECETOC updated its vision, mission and strategy to more clearly emphasise that ECETOC has a pivotal role to play in fostering scientific excellence and partnerships in the assessment of the health effects and environmental impact of chemicals, pharmaceuticals and biomaterials. In 2003, our 25th Jubilee year, the implementation of this strategy came to fruition.

The Strategy

Promote the use of sound science in both industry and regulatory decision-making and report on the results

ECETOC maintains its strong scientific presence, particularly among regulators at a National, European and International level, through the participation of scientists from its member companies in various task forces and external forums. In 2003, the Jubilee workshops brought together scientific decision-makers from a broad range of stakeholder groups, to discuss key issues relative to the safe use and manufacture of chemicals. In the coming year, ECETOC will continue to foster scientific debate through its networks to address these industry issues.

In close consultation with ECETOC members, define scope, manage progress and interact with research programmes

Our Scientific Committee, together with Task Forces composed of member company scientific experts, provide leadership to continue to address major concerns about the health and environmental impact of chemicals. The visible results are the significant number of technical documents that were produced in 2003. This commitment to the dissemination of peer-reviewed scientific knowledge will continue.

ECETOC has successfully managed the science component of the Long-range Research Initiative (LRI) programme funded by Cefic. This on-going activity continues to provide an effective network between scientists from member companies and their peers in academia, while at the same time incorporating dialogues with regulatory agencies. This is critical to ensure that a scientifically sound basis for risk management and legislation is achieved.



Provide a forum for regulators, academic and industrial scientists for the evaluation of the safe use of chemicals and their associated products

In 2002, ECETOC established the Targeted Risk Assessment (TRA) Task Force. It has in a very short period of time developed a science-based methodology and web based tool that enables risk and exposure screening of chemicals in a very time and cost effective way and transparent fashion. This has resulted in a constructive interaction at national and EU levels with regulators managing the implementation of the EU Chemicals Policy for the Registration, Evaluation and Authorisation of Chemicals (REACH). The TRA methodology is viewed as a very useful tool for the REACH implementation and it is foreseen that this cooperation and partnership will continue as necessary until the regulation is finalised.

Similarly the organisation of stakeholder workshops to exchange views, build scientific consensus and identify research needs, was very effective in 2003 and will continue in the future.

Contribute to understanding of the societal issues associated with health assessment and environmental safety of substances

In response to the new regulatory initiatives such as SCALE, ECETOC has formed a Task Force to address the scientific issues related to Children's Health and the Environment.

We will continue to identify other issues through our outREACH programme, which was initiated in 2003. The goal is to enhance dialogue between member companies at national level and increase the visibility of ECETOC's scientific contributions to a broader constituency of chemical users not currently members of ECETOC. Four outREACH events hosted by ECETOC Board Members are planned for 2004 throughout Europe.

Ensure the value of the ECETOC offer is appreciated by business and regulatory decision makers

The availability of scientific and technical resources from our member companies is critical to the continued success of ECETOC. We need scientists to actively participate in the various task forces and represent ECETOC's position. The openness of regulators to interact and dialogue with industry scientific experts, representing ECETOC's position on methodologies, test methods, TRA, classification and labeling etc. is an important performance measure of their respect for ECETOC's scientific credibility. This will create and have long lasting business value relative to our license to operate, to market and to sell our products.

Identify emerging issues that are of importance to ECETOC member companies

We will continue to identify and understand emerging issues through our various outREACH and networking programmes. This will enable ECETOC to assess and develop scientific positions in a timely and effective manner.

The Challenge

The many demands on our industry will continue as health and environmental issues come more to the forefront. The focus will be on whether our products are fully safe for their intended uses.

It is important, therefore, that sound science is applied when methodologies and tools are being developed to evaluate the hazards and risks of chemicals to humans and to the environment. 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 marketplace.

ECETOC will strive to deliver success based on sound science by building partnerships and alliances and engaging the best scientific experts to deliver high quality credible scientific results.



Acknowledgements

The main achievements of ECETOC during 2003 are described in the following pages of this report. On behalf of the Board of ECETOC, I would like to extend our appreciation to the scientists from member companies and other organisations, who have contributed to the success of ECETOC's programme. Finally, I would also like to thank the Secretariat for their ongoing support, and in particular, the outgoing Secretary General, Dr. Francis Carpanini, for his dedicated service to ECETOC over the past eight years.

A handwritten signature in dark ink, appearing to read 'Peter Peschak', written in a cursive style.

*Peter Peschak
Chairman, ECETOC Board of Directors*

An Overview of 2003

Report from the Secretary General

2003 was a milestone year for ECETOC as it celebrated the 25th Jubilee under the theme of "Scientific Achievement through Partnerships" and implemented the new strategy defined in 2002. The regulatory environment for the chemical users and manufacturers was dominated by the evolution of the new chemical substances policy "REACH" that was adopted by the EU Commission in October. The impact on our industries will be considerable for the foreseeable future and these on-going challenges will nevertheless provide opportunities for ECETOC to demonstrate its unique capabilities to develop sound science that is valued by the regulatory authorities.

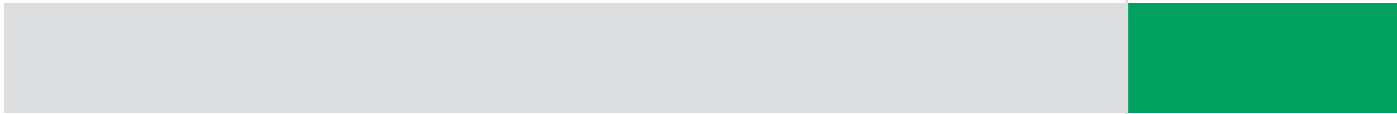
The new strategy and the Jubilee Programme shifted the emphasis of the distribution of efforts by the scientific resources of the Secretariat in the five main programme areas (see charts p.7). The decreased resource targeted against the Technical Guidance Document (TGD) reflects the advanced status of this work.

The increased focus on organising workshops (WS) (p.16) provided forums for partnerships with academia, regulators and industry, successfully informing on the science needs on chemical related topics impacting human health and the environment. Specific emphasis on environmental topics addressed the "Water Framework Directive", "Environmental Monitoring Data" and "Ecological Quality" in 2003 and the premier Workshop Reports from ECETOC have subsequently been published. The workshop programme will continue in 2004 and become an established vehicle to build consensus on contentious scientific issues for industry in its widest sense.

A high level of activity for the specific substances programme saw closure for several Task Forces (TF) in publishing the relevant JACC reports (p.26); the value of this ECETOC programme to our member companies continues to be validated and high expectations are held for completion and publishing of a significant number of reports during 2004.

Compared with 2002 the generic Task Force programme (p.12) maintained its vigorous level of activity throughout 2003. Several Task Forces successfully completed their remits including the publishing of a significant number of scientifically sound reports (p.26). Emerging issues in the regulation of chemicals that impact on a broad constituency of industry resulted in the Scientific Committee forming several new Task Forces (p.12) during 2003 that were well supported by ECETOC member companies through their scientific experts.

Of particular note was the considerable progress achieved by the Task Force on Targeted Risk Assessment (TRA) in developing a science-based methodology to tiered risk assessment of chemical substances (p.8). The longstanding ECETOC partnership with the European Chemicals Bureau (ECB), responsible for the final definition of the REACH regulations, has enhanced alignment of this scientific approach with that of the regulators.



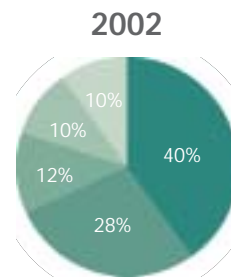
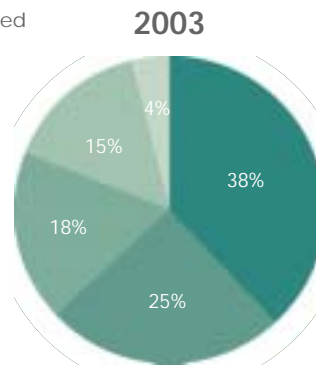
The significant effort against the Long-range Research Initiative (LRI) provided progress in all three supported areas, namely the Health Effects Programme, Human Exposure and Tiered Risk Assessment (HETRA) and the Environmental Programme (p.20). Unfortunately, funding questions delayed the implementation of several research proposals which may negatively impact the Health Effects programme for 2004.

A unique event was the premier of the ECETOC Science Awards (p.22), to celebrate the 25th Anniversary, in the areas of Occupational Health (awarded to Dr. Sean Semple), Health Assessment (awarded to Dr. Vincent Haufroid) and Environmental Fate and Effects (awarded to Dr. Paul Van den Brink). Professor Kees van Leeuwen, Director of the European Commission's Institute of Health and Consumer Protection, presented the prizes during a gala evening organised at the Natural Science Museum in Brussels.

The first outREACH Event occurred in Basel for the Swiss region and was hosted by ECETOC Board Vice-Chairman, Dr. Kaspar Eigenmann, at the Novartis International Headquarters. Primarily designed to enhance the dialogue with local ECETOC member companies, a major deliverable is the definition of the strategic future agenda of the participants. The Events will increase the visibility of ECETOC's scientific contributions through inviting a broader constituency of chemical users that are not currently members of ECETOC. Further Events are planned for 2004 in the United Kingdom, Ireland, Benelux, Accession Countries and Germany.

The ongoing evolution of our industries by acquisition, mergers and divestitures in conjunction with the loss of expertise from member companies dictates that ECETOC seeks to identify and engage all available industry toxicology and ecotoxicology experts to support the science programme. ECETOC with its broad membership base covering a wide range of sectors of the industry and significant experience in partnering with academia and regulatory agencies continues its strong and unique position to act as the industry focal point to develop sound scientific approaches to the safety assessment and responsible environmental management of chemicals.

The year marked the inauguration of a new Secretary General to succeed Dr. Francis Carpanini whose achievements during his 8 years of tenure were very significant and will be missed after his retirement in July.



- ▼ TF
- ▼ LRI
- ▼ JACC
- ▼ WS
- ▼ TGD

Targeted Risk Assessment

The lack of publicly available data on the hazardous properties of chemicals and the slow progress of risk assessment and risk management of industrial chemicals were the driving forces behind the development of a new chemicals policy in the European Union and as a consequence the European Commission recently presented a proposal for the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH). The proposal describes essential features of a new legislative system for implementing the policy set out in the Commission White Paper on a "Strategy for a future Chemicals Policy" (European Commission 2001). The aim of REACH is to ensure that industry obtains adequate information to perform a risk assessment that enables it to adequately manage the risks from the manufacture, use and disposal of substances. The resulting chemical safety report (CSR) should then be registered with the authorities.

One of the key challenges of the proposed European chemicals legislation is that it requires the registration and evaluation of approximately 30,000 chemicals, by producers and importers, over the next 10-15 years. To make the REACH process workable, a scientific and practical approach to prioritise substances for assessment will be required. To address this need, ECETOC has developed a tiered or step-wise concept for identifying and prioritising scenarios where risks to human health and the environment from chemicals might reasonably be expected to be high enough to undertake a more detailed assessment of risk.

The general concept of the ECETOC approach is based on the premise that depending on both the degree of exposure and the hazard, considered together (because a risk can only occur when both of them are present), different information requirements will be needed to demonstrate safe and responsible production and use of a given chemical.

The process also considers existing (and new) risk reduction measures to control exposure, whenever such measures are needed in order to determine a 'no immediate concern' conclusion.

The Core Objectives behind the approach are:

- > To focus assessment resources on those production and use scenarios of chemicals that constitute a possible concern for man or the environment.
- > To ensure that all decisions are based upon RISK and account for all relevant information required to reach any soundly-based judgement.

- > To simplify but maintain the scientific integrity of the risk assessment process.
- > To be consistent with the requirements of the existing European health and environmental legislation.

ECETOC's Targeted Risk Assessment methodology applies a tiered, iterative approach to risk assessment, and consists of three phases i.e. Tiers 0, 1 and 2. By applying this approach, the level of refinement and detail of the information required for a risk evaluation is proportional to the potential risks of a chemical, based on consideration of both hazards and exposures together, rather than in isolation. Both hazard and exposure must be taken into account, - the risk of a given chemical depends on how and where it is used (exposure) and not just on its intrinsic properties (hazard).

Tier 0 - The aim of the Tier 0 is to "screen" substances and conditions of no-immediate concern out of the process, because their general exposure and hazard potential are low, and identify those other chemicals and conditions where further targeting risk assessment is required. The process used is simple and transparent, well-defined and validated, and sufficiently conservative to avoid missing any situations where a major risk may be present.

Tier 1 - Substances and conditions that are not deselected in the Tier 0 are evaluated in Tier 1. The aim of the Tier 1 is to provide specific information on use and exposure scenarios to carry out a more refined risk assessment to separate the production and uses of "no immediate concern" from those that require a more detailed investigation.

Tier 2 - Scenarios identified as being of potential concern at Tier 1 proceed to a detailed risk assessment. This assessment is consistent with the established EU risk assessment principles, and enables final risk assessment conclusions to be reached for those scenarios.

This three phase approach is shown schematically on page 11.

It should be noted that in each Tier (but especially in the Tiers 1 and 2), the existing risk reduction measures already in place to control exposures are considered. If unacceptable risks are identified during the process, the manufacturers or importers will need to consider additional controls, as necessary, to support the ultimate goal of ensuring that all uses of a given substance are of "no concern."

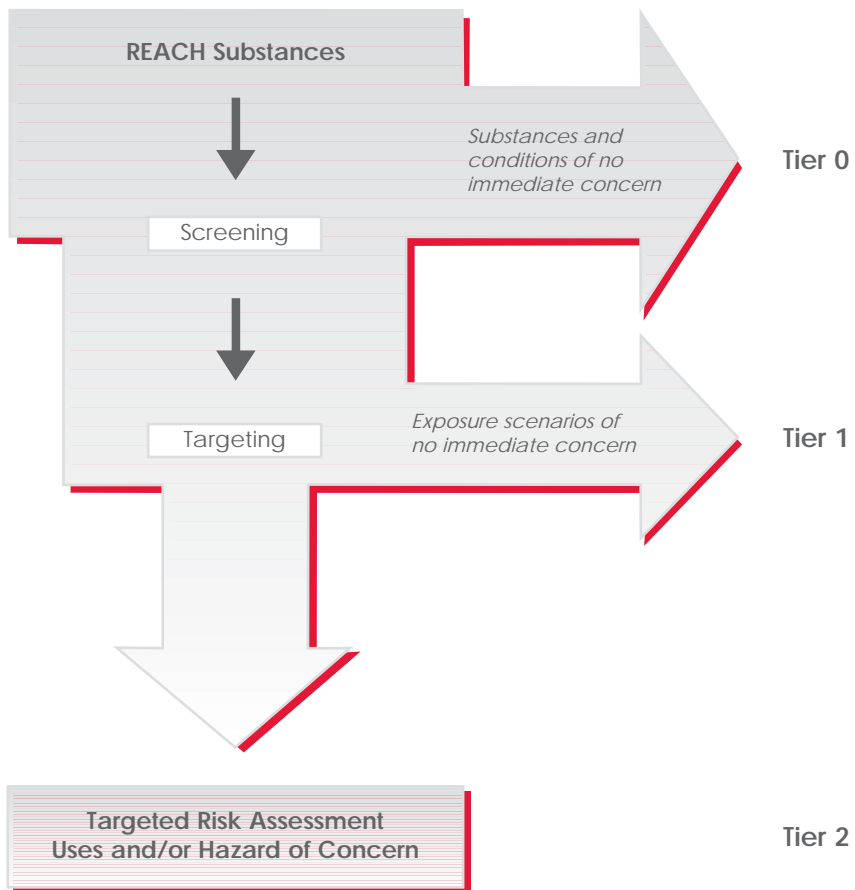
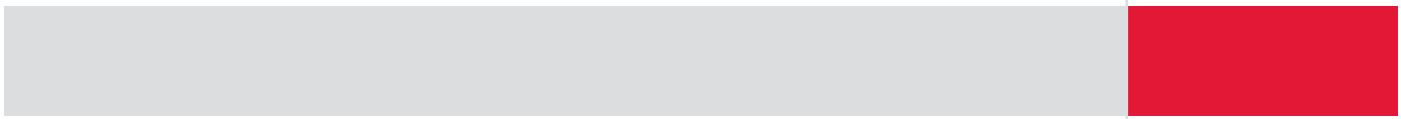


The advantages of the approach may be summarised as:

- > All substances and their uses are systematically screened for their possible risks, considering hazards and potential exposures together;
- > TRA provides a CSR for those substances/uses that are not identified as being a concern at the Tier 0 and Tier 1 levels, prioritises the relative risks of different substances and their conditions of use and identifies substances and uses that require a more detailed evaluation;
- > The tiered approach uses an increasing level of refinement and detail of the information (both on exposure and hazard) and allows for iteration to account for available risk management measures;
- > It helps identify the further work and information necessary to complete the Chemical Safety Assessment (CSA) for other chemicals and TRA;
- > The data and resource demands will consequently be proportionate to the likely risks of the substance, and target the available resources to scenarios of possible concern;
- > Using risk assessment as the basis for defining additional information needs through targeting and exposure driven testing encourages the appropriate use of resources and respects animal welfare;
- > The approach enables manufacturers and the authorities to make a choice between generation of further information or implementation of more stringent risk reduction measures. As it is simple to use and understandable by all stakeholders, it will generate clear and consistent decisions.

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 web site is password protected, however, access can be obtained via the ECETOC Secretariat.



Task Forces

Alternative Testing Methods in Environmental Hazard Assessment

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 and regulatory changes that impact on the conduct of animal experiments and the requirements for product registration. The principle of the 3Rs (reduce, refine, replace) when designing and conducting tests for establishing the safe use of chemicals is well established and it is stated in the EC White Paper on Chemicals Policy that the use of animals should be kept to a minimum. The European Commission is also committed to the promotion of alternative non-animal test methods, through maximising the use of existing alternatives, and encouraging development of new non-animal alternative test methods. The 7th Amendment to the Cosmetics Directive is another major step in the direction of replacement of animals in tests.

Whilst work to develop alternative test methods in the human safety field is well advanced, the development of alternative test methods for environmental purposes needs to be addressed. The Scientific Committee concluded that there was a need to review and evaluate the currently available alternative testing methods in the context of their applicability as part of a strategy to deal with the assessment of the impact of chemicals in the environment.

Children's Health

Numerous reviews and research initiatives have been undertaken by government, industry, research organisations and academia that are aimed at understanding better how chemicals, man-made or naturally occurring, might adversely affect children's health. This interest has grown substantially over the last 2-3 years, e.g. in the EU, the Commission launched an initiative called SCALE (science, children, awareness, legislation, evaluation) which will soon evolve into an EU action plan.

As part of the chemical industry's activities in this area, the support of ECETOC has been sought in developing a State of the Science Paper that will identify the gaps in understanding and knowledge regarding the role and impact of chemicals in products and in the environment (collectively called environmental chemicals) on children's health. This will help to identify areas of appropriate research that might be funded within the LRI programme to contribute to the understanding of the issue. An ECETOC Task Force has been initiated to undertake this gap analysis and to recommend needs and priorities for a research programme addressing children's health.



Biodegradation Kinetics

Criteria for persistence have been proposed by a number of organisations, and international bodies such as OECD, ECETOC, US-EPA, ISO and national bodies (e.g. BSI, DIN, ASTM, AFNOR, NEN, etc.) have all developed 'Standard' methods for measuring a chemical's degradability. The Existing Substances and Notification of New Substances Regulations and the latest revision of the Technical Guidance Document (TGD; EC, 2002) also address persistence and there are a number of other initiatives within the EU aimed at regulation of persistent, bioaccumulating and toxic (PBT) substances, for example the Water Framework Directive (EC, 2000) and the PBT Management Strategy.

A previous ECETOC Task Force on Persistence proposed a strategy for allocating substances into one of four categories based on all available degradation data. They also concluded that evaluation of persistence in the marine environment should be given priority and research should be carried out with the aim either to reduce the uncertainty in extrapolating from standard freshwater/marine biodegradation studies to the marine environment, or to demonstrate the need for marine studies to be conducted for determining persistence.

A Task Force has been commissioned to undertake a review of existing biodegradation data to establish the validity or otherwise of using data generated for the freshwater environments to predict biodegradation in the marine environment.

Risk Assessment of Substances with PBT Characteristics

There are a number of initiatives within the EU aimed at the regulation of persistent, bioaccumulating 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 Technical Guidance Document. Criteria for categorising substances as P, B and T have been proposed by a number of organisations, and international bodies including for example, UNEP and OSPAR.

The Scientific Committee has established a Task Force to undertake a review of the approaches used to identify PBT substances and, the uncertainty associated with the methodologies and to propose a scientifically sound risk based approach to the assessment of PBT substances.

Derivation of Occupational Exposure Limits from Available Effects Data

It is possible that the REACH proposals will require chemical suppliers to develop Occupational Exposure Limits (OELs) in support of registered substances. Whilst much guidance has previously been developed on how OELs should be derived (for example the ECETOC reports No's. 59 and 86, together with various in-company schemes and published articles), these invariably address substances that are supported by extensive effects data. One characteristic of REACH will be that such extensive data are likely to be lacking for the majority of materials. Therefore, it is desirable that if there is to be consistency in the derivation of OELs, then guidance should be developed which accounts for the nature of available information and the associated uncertainties. Moreover, in the context that there is a possibility that any Technical Guidance in support of REACH may also address such an activity, it is clearly beneficial for a position to be developed in advance of such discussions.

An ECETOC Task Force was thus commissioned to review the available guidance (regulatory, company and other sources) on the derivation of OELs from available effects data with the aim of developing a science based approach that will enable health-protective workplace exposure limits to be consistently developed by chemical suppliers. In addition, the Task Force was charged to clearly specify the uncertainty factors that should be considered in the development of OEL's, accounting for the availability and quality of available data, and to identify the boundary conditions within which the guidance is applicable. The final aim is to apply and validate the approach using representative case studies for a range of typical industrial chemicals.



During 2003, in addition to the activity in the new Task Forces, the ECETOC programme was progressed by the following:

Environment

- > Aquatic Hazard Assessment II
- > Persistence of Chemicals in the Environment
- > Whole Effluent Assessment

Human Health

- > Acutex (Acute Exposure Threshold Levels-AETLs)
- > Adverse Versus Non-adverse Effects (Toxicological End-points)
- > Contact Sensitisation: Classification According to Potency
- > Toxicological Mechanisms

Risk Assessment

- > Environmental Risk Assessment of Difficult Substances
- > Information Requirements for Risk Assessment of Chemical Substances
- > PBPK Modelling Workshop
- > (Q)SARs
- > Risk Assessment Factors
- > Soil and Sediment Risk Assessment
- > Targeted Risk Assessment

Specific Substances

- > Butanols
- > Cyanides
- > Fluoroalkanes
- > Methyl tert-Butyl Ether (MTBE) Risk Assessment
- > Synthetic Amorphous Silica
- > Tetrafluoroethylene, Hexafluoropropylene and Vinylidene fluoride
- > Toxicology of Glycol Ethers and its Relevance to Man

Workshops

ECETOC scientific workshops and seminars come in various guises. They can be multi-stakeholder or industry only, vary in duration from 1 to 3 days and may be open to all or be by invitation only. Whatever the format, the workshops and seminars 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 leading subject matter experts who debate the issue and make conclusions and recommendations. Capturing the outcome of the workshop in a summary document, white paper or report provides a vehicle to more broadly communicate the defined science gaps related to the issue and helps to catalyse active research programmes which address safety, human health and environmental concerns that have been raised.

The use of workshops has been a major feature of ECETOC's Silver Jubilee year and has extended the products and services that ECETOC provides to its member companies. During 2003 one industry only workshop and three multi-stakeholder workshops were convened. They provided an opportunity to broaden the debate, by involving representatives from other organisations, academia and regulators.

"Water Framework Directive - Awareness Workshop" London > January

The WFD is one of the largest and most impressive pieces of environmental legislation to have been generated by the European Community and is a major step forward in the coherence and integration of water policy across existing and future member states. This awareness workshop was attended by 34 scientists and HSE managers from 20 member companies. There were presentations from the UK Environment Agency, the European Commission and the European Crop Protection Association and it provided an opportunity to discuss the implications for the chemical industry of the Water Framework Directive (WFD) and its revised, upcoming EU chemicals legislation.

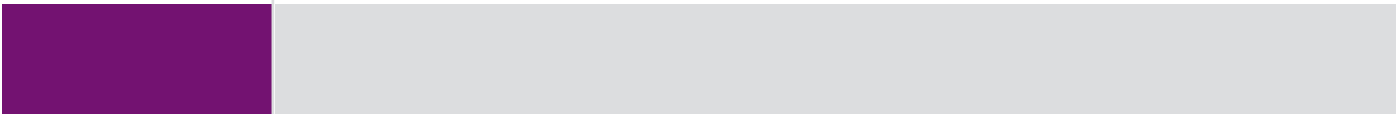
There are major, and largely unrecognised implications for industry within the community, and particularly for manufacturers and users of synthetic chemicals. Some of these are positive benefits but some have potentially profound negative implications for the future of chemical innovation.

The areas identified where industry involvement could be important were:

1. Pilot river basin implementation phase and management plans be involved, try to apply guidance to gain experience with the application of guidance documents and identify problems. Whilst it is too late to contribute to the guidance documents, the testing phase could benefit from industry input. The decision on whether or not the guidance documents need to be amended will be based on the outcome of the pilot studies. These pilot studies will begin soon. Individual companies discharging into the pilot basins are advised to consider whether or not they could become part of the team;
2. Industry in general could benefit by sharing their experiences from the different national river basin pilot studies - in particular how implementation of the WFD affects a particular company; ECETOC could consider whether it has a role to play or collaborate with Cefic to provide a forum to share these experiences;
3. The key managerial measure will be the river basin management plan and industry was advised to participate;
4. Once the classification of a given stretch has been agreed as 'less than good' then there will be an action plan to identify which chemicals, if any, are responsible for the quality classification. The spotlight of cause will probably fall initially on point discharges. There could be a role here for the ECETOC Task Force on whole effluent assessment (perhaps broaden terms of reference to include toxicity assessment of river waters);
5. Biological classification in marine environment (indices and tools for coastal areas, industry data sets for coastal waters) are still under debate. UK has the lead. ECETOC could consider setting up a Task Force to monitor developments and be involved in this activity.

"Availability, Interpretation and Use of Environmental Monitoring Data" Brussels > March

In recent years, there has been a growing emphasis on monitoring chemical substances in the environment, and the need for measured data will continue to increase. The WFD, High Production Volume Chemicals (HPVC) programme and POP/PBT activities, as well as the revised, upcoming EU chemicals legislation will depend more and more on monitoring data. In risk assessments, exposure is of critical importance and only measured data can ultimately represent a realistic situation.



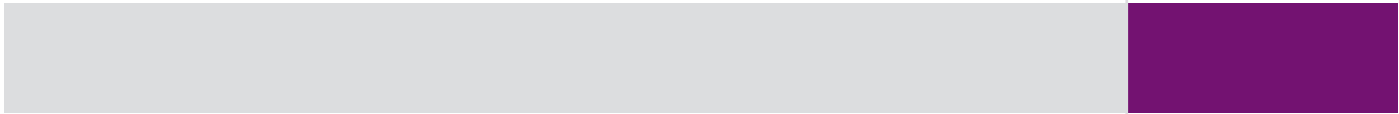
Over 40 participants with backgrounds in chemical and/or biological monitoring representing governments, academia and industry met for a 1½ day workshop, held in Brussels in March. The workshop was organised in conjunction with Euro Chlor (representing the European chloro alkali industry) and was designed to build upon recommendations, made during the 1998 OECD Berlin Workshop, on ways to improve the use of monitoring data in exposure assessment of industrial chemicals. The major areas addressed were application (model validation, probabilistic approach in exposure assessment, trend analyses, policy compliance checks, etc), reliability and representativeness (sampling strategies, site selection, analytical quality control, treatment of 'below detection limit' data, etc.), and availability and accessibility of monitoring data (data sources, broad access, development of a future European monitoring network, etc). Whilst historically, monitoring has concentrated on chemical analysis, many of the issues still to be resolved will apply equally to biological monitoring, an area which will become increasingly important as the WFD is implemented across the European Union. Each topic was introduced by a presentation and followed by syndicate sessions. The current status of environmental measurements databases was reviewed and methods to improve the understanding of applications were identified.

"ECETOC Approach to Targeted Risk Assessment" Brussels > May

There were more than 100 participants from over 60 companies, associations and federations at this one day workshop held to present the ECETOC Targeted Risk Assessment approach, to identify areas for its refinement, to endorse the approach and to discuss the status of the implementation of the revised, upcoming EU chemicals legislation.

"Ecological Quality" Budapest > November

Over 40 participants with backgrounds in ecotoxicology and epidemiology representing governments, academia, consultancies and industry met for a 2-day workshop held in Budapest on 27 and 28 November 2003. Additional sponsorship was arranged with the Environment Agency of England and Wales and the Cefic Long-range Research Initiative (LRI). In ecological risk assessment the tendency has been to measure what we can and what we have been measuring for the past 50 or so years. However, as the regulatory focus shifts to assessing and managing the quality of real ecological systems, as it is for example in the Water Framework Directive (WFD), then increasingly there will be a need to reconsider the relevance of what is being done. This is quite apart from raising the most fundamental question of all - what is meant by ecological quality? - and this raises a number of other questions that are not just of theoretical importance.



Therefore the broad aim was to refine understanding of the concept of ecological quality status that is made explicit in the EU Water Framework Directive but which ought to be implicit in all aspects of ecological risk assessment and management. The more specific aim was to identify challenges, opportunities and research needs arising from the more explicit use of ecological quality status in environmental protection. The recommendations from the workshop are intended for the community of stakeholders in general; but they will be considered particularly by the ECETOC Scientific Committee and prioritised for further action by ECETOC.

Further Workshops are planned for 2004 and this will remain a regular feature of the ECETOC programme in the future.



Plenary Session at the Ecological Quality Workshop, Budapest November. Seated in the foreground is ECETOC Scientific Committee Member Dr. P. Douben (Unilever) left and Mr. M. Holt ECETOC's Environmental Sciences Manager right.



Long-range Research Initiative

Environmental Programme

This year saw four of the modelling projects established in phase I of the environmental programme being brought to a conclusion. By the end of 2003 there were 6 active projects, five of which will finish within the next twelve months. Plans are being developed for an effective roll-out of results from the phase I programme. Two new Requests for Proposals (RfPs) were prepared, the preferred bidder for one which addresses the development of a decision support tool for QSARs has been approved and the project will start early in 2004.

Health Effects Programme

The Health Effects monitoring team within ECETOC continued to support the LRI programme through evaluation of scientific progress and achievement of funded projects. These projects addressed issues relating to respiratory toxicity, chemical allergy and chemical carcinogenicity. Most projects were finalised during 2003 and the remaining ones are scheduled for completion in 2004. Collectively, the research teams supported through LRI produced a significant number of high quality publications and presented their work at international meetings.

For the next phase of the LRI programme, research proposals were evaluated by the Monitoring Team, together with scientific experts from outside industry. These proposals focused on chemical carcinogenicity (biological significance of chemically-induced DNA adducts) and on immunotoxicology, respiratory toxicology and allergy (hazard identification and characterisation of chemical respiratory allergens; bases for inter-individual differences in susceptibility to chemical allergy; the influence of chemical pollution on the development of allergy and asthma). Detailed recommendations were made to LRI on the projects to be selected, and, where appropriate, on potential collaborations between research teams. These projects are expected to be launched during 2004.

In addition to its remit to monitor current research projects and to advise on the selection of new projects, the monitoring team also engaged in defining future research needs for the chemical industry. A strategy meeting was held in 2003 to which selected experts from academic and government laboratories were also invited. Current issue clusters for the chemical industry were reviewed, including children's health and alternative approaches to safety assessment, as well as emerging issues on health effects. A number of important research priorities have been identified as a result of this process and are presently being considered in greater detail.

Human Exposure and Tiered Risk Assessment

Better characterisation of actual exposures is required in order to provide the fundamental input data for sound science-based human risk assessment. In 2003, the HETRA monitoring team oversaw further development of a database of European workplace exposure research activities and establishment of a framework for a Cefic-supported exposure database. Following a new RfP, an international workshop was planned on methods to determine dermal exposure modelling permeation for human risk assessment, while another project was to evaluate the real and theoretical effectiveness of skin protection strategies (solids) at the workplace. Following the establishment and management of an inventory of relevant research on indoor exposure, such exposure patterns were studied for certain determinants in the European EXPOLIS population. By December 2003, 6 projects were ongoing (1 newly selected) and 4 RfPs drafted in this area.

In the area of consumer exposure, the HETRA team oversaw development of an integrated approach to reliably predict European consumer exposure to pollutants, and an exposure factors sourcebook for Europe. Several additional RfPs were drafted, for example to obtain further information on consumer exposures to mixtures. By December 2003, 2 projects were ongoing and 2 RfPs drafted in the consumer area.

To support tiered approaches to human health risk assessment, the HETRA team organised an industry workshop on the identification of chemical structure activity relationship (SAR) alerts (combinations of functional groups) for substances with low toxicological no-effect levels (NOELs); the project was continued. In addition, the HETRA team was involved in a review of the basis for and improvements to the EASE version 2 models for workplace exposure estimation, and oversaw a study on variability and uncertainty in chemical exposures for regulatory risk assessments. Further RfPs were drafted in this area, for example to review the workplace management strategies for chemicals in small enterprises. By December 2003, 5 projects were ongoing and 2 RfPs drafted on tiered risk assessment methodology.

With respect to the role of biomarkers of exposure, research was monitored on the role and application of such biomarkers in the management of the occupational health risks, and on trends and key developments of such biomarkers in the general population. Two further RfPs were drafted, to obtain further information on the normal background incidence, and to determine the effects of intra- and inter-individual variation, of key biomarkers of chemical exposure within the general population. By December 2003, 2 projects were ongoing and 2 RfPs drafted on the role of biomarkers of exposure.

Science Awards

Recognising Young Scientists

To celebrate its 25th Anniversary, ECETOC, launched a Science Award for young European Scientists. The purpose of the Award is to recognise the Science of health and the environment that allows us to protect ourselves, and our surroundings, whilst developing the economic future and quality of life in our community.



ECETOC Board of Directors, Treasurer, Dr. J. Rudolph (Degussa) launches the 25th Jubilee Science Awards

"We are recognising young scientists who have published their research in world-renowned journals and whose work will significantly contribute to a more sustainable future via new initiatives like the 'EU Chemicals Policy' and the 'Water Framework Directive'", said Professor Geoff Randall, Chairman of ECETOC's Scientific Committee. "The awards will fund the young scientists to network with other centres of excellence to extend their work and to build an effective research community."

In recognition of the importance of the Award, Prof. Kees van Leeuwen, Director of the European Commission's Institute of Health and Consumer Protection (EC IHCP), presented the prizes to the winners in a prestigious event at the splendid Natural History Museum in Brussels.

Competition for the prizes was strong both in numbers and in the quality of the applications received. A panel of leading independent scientists selected the successful candidates. The Award winners for 2003, each received a prize of €10,000 and will be invited to a meeting with senior European scientists in 2004 to present an account of how the award assisted them in their work. For 2003, ECETOC's Jubilee Year, the awards and their winners were:

Occupational Health

Awarded to Dr Sean Semple, University of Aberdeen, United Kingdom

He was awarded the prize for the development of an original approach for modelling dermal and inhalation exposure to solvents by spray painters: Semple, S, *et al.* 2001. A dermal model for spray painters. Part II: Estimating the deposition and uptake of solvents. *Ann Occup Hyg* 45: 25-33.



The event was held at the Natural History Museum in Brussels

Health Assessment

Awarded to Dr Vincent Haufroid, Catholic University of Louvain, Belgium

He was awarded the prize for his work to develop an approach using the genotyping and phenotyping of metabolising enzymes to identify the most reliable biomarkers for chemicals exposure: Haufroid, V, *et al.* 2002. Interest of genotyping and phenotyping of drug-metabolizing enzymes for the interpretation of biological monitoring of exposure to styrene. *Pharmacogenetics* 12: 691-702.



From left: Award winners, Dr. P. Van den Brink, Dr. V. Haufroid, and Dr. S. Semple with Prof K. van Leeuwen (EC IHCP), Dr. J. Rudolph and ECETOC SC Chairman Prof. G. Randall.

Environmental Fate and Effects

Awarded to Dr Paul Van den Brink, Wageningen University and Research Centre The Netherlands

He was awarded the prize for development of an application employing highly original use of case-based reasoning in the risk assessment of pesticides, solving new problems by using past experience and learning: Van den Brink, PJ, *et al.* 2002. Perpest model, a case-based reasoning approach to predict ecological risks of pesticides. *Environ Toxicol Chem* 21: 2500-2506.



outREACH

The realisation of an outREACH programme was achieved in 2003 in the format that the ECETOC Board had envisaged during 2002. The prototype event was hosted by Board Vice-Chairman, Dr. Kaspar Eigenmann of Novartis International AG, at their Basel facility in Switzerland. Primary invitees were the EH&S Scientists and Senior Management including Delegates of ECETOC Member Companies headquartered in Switzerland. In addition EH&S Representatives from several other companies using or manufacturing chemicals, Contract Research Organisations and Trade Associations were invited.



Participants at ECETOC's first outREACH event, Basel September 1st 2003



ECETOC Scientific Committee Chairman Prof. G. Randall launches 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, highlighting ECETOC's contribution to a solution. Subsequently there is a broad overview of all the on-going activities of Task Forces and Workshops focused on the key issues 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 could benefit from the work and activities that ECETOC is pursuing. Through this exposure ECETOC may gain new Members and access to additional toxicology and ecotoxicology experts for populating Task Forces in the future.

In addition, the outREACH Event provides a forum for feedback through a pre-Event questionnaire, to establish and define issues which ECETOC does not currently address, but which participants perceive as future challenges that should be added to the active agenda at the Scientific Committee level. This input will be very valuable in continuing to refine the Value Proposition that ECETOC offers to the various industry sectors represented by existing and enlarged Membership in the future.



Former ECETOC Secretary General Dr. F. Carpanini (centre), outlines the importance of the programme



Dr. M. Richards, Ciba Specialty Chemicals Inc. (left) and Mr. M. Candolfi, RCC Ltd (right) at question time



outREACH Discussion Panel
From left:
Dr. F. Carpanini
Dr. T. Fejtl, Procter & Gamble
Dr. K. Eigenmann, ECETOC Board Member
Prof. G. Randall, ECETOC SC Chairman
Dr. M. Gribble, ECETOC Secretary General



ECETOC Outputs

During 2003 ECETOC generated the following publications:

Technical Reports

- No. 86 Derivation of Assessment Factors for Human Health Risk Assessment
- No. 87 Contact Sensitisation: Classification According to Potency
- No. 88 Environmental Risk Assessment of Difficult Substances
- No. 89 (Q)SARs: Evaluation of the commercially available software for human health and environmental endpoints with respect to chemical management applications
- No. 90 Persistence of Chemicals in the Environment
- No. 91 Aquatic Hazard Assessment II

JACC Reports

- No. 41 *n*-Butanol (CAS No. 71-36-3)
- No. 42 Tetrafluoroethylene (CAS No. 116-14-3)
- No. 43 *sec*-Butanol (CAS No. 78-92-2)

Monograph

- No. 33 Application of Physiological - Toxicokinetic Modelling to Health Hazard Assessment of Chemical Substances (Toxicology Letters, Special Issue)

Special Report

- No. 17 Risk Assessment Report for Existing Substances Methyl tertiary-Butyl Ether



Workshop Report

No. 1 Availability, Interpretation and Use of Environmental Monitoring Data

Document

No. 43 Contact Sensitisation: Classification According to Potency, A Commentary

External Publication

M. Holt, K. Fox, M. Daniel, H. Buckland. Linear alkylbenzene sulfonate and boron monitoring in four catchments in the UK contribution to GREAT-ER # 11. The Science of the Total Environment 314-316 (2003) 271-288.

Posters

- > The ECETOC Approach for the Assessment of Workplace Health Risks Under the EU Chemicals Policy
- > Acutex Task Force - An Assignment to ECETOC in a Multi-Partner Project



Website

Visit our Website <http://www.ecetoc.org> for the most recent information on our activities, workshops and seminars and a list of publications that can be ordered through the site.

External Representation



ECETOC, in addition to major collaborative exercises, provided expert representation to the work of a number of other external organisations in 2003. These included:

- > EU Commission's Initiative SCALE Consultative Forum
ECETOC represented by Dr. D. Owen (Shell Chemicals).
- > European Centre for the Validation of Alternative Methods (ECVAM)
Ispra, 27-28 February and 15-16 December
Dr. J. Fentem (Unilever) continued to represent ECETOC on the ECVAM Scientific Advisory Committee.
- > OECD Expert Group on Multimedia modelling
The Netherlands, 16-17 June
ECETOC represented by Dr. A. Riddle (AstraZeneca Brixham).
- > ILSI-Europe Workshop 'Structure-based thresholds of toxicological concern: Guidance for application to substances present at low levels in the diet, for chemical substances'
Vienna, 20-21 March
ECETOC represented by Dr. E. Schrader (Henkel).
- > EU Commission's Initiative SCALE Stakeholders Information and Consultation
Meeting on 11 July
Dr. A. Sarrif (DuPont) attended on behalf of ECETOC.
- > Tripartite Meeting of the European Commission (EC), Global Industry (ICCA) and the OECD Secretariat on the (Q)SAR Project
Paris, 8 September
ECETOC represented by Dr. M.Y. Gribble (ECETOC) and Dr. J. Jaworska (Procter & Gamble).

- > WHO/IPCS 11th Final Review Board on CICADs (Varna, Bulgaria, 8-9 September)
Dr. W ten Berge (DSM, Netherlands) participated in the final review of Concise International Chemical Assessment Document (CICAD) on the human health aspects of hydrogen cyanides and cyanides, where he represented the views of the ongoing ECETOC Task Force.
- > ECVAM Workshop 'Strategies to replace in vivo acute systemic toxicity testing'
Ispra, 15-18 September
ECETOC represented by Dr. A. Colombo (Polimeri Europa).
- > Whole Effluent Assessment TF at the OSPAR workshop to discuss the whole effluent assessment demonstration programme held in Utrecht on 24-25 September.
ECETOC represented by Dr. D. van Wijk (Euro Chlor).
- > ECB, Health Working Group (formerly CMR working group)
ECETOC represented by Dr. C. Hennes (ECETOC).
- > ILSI Europe
ECETOC represented by Mr. M. Holt (ECETOC), continued its membership of the Environment and Health Task Force.
- > SETAC
ECETOC represented on SETAC Europe Council through membership of Mr. M. Holt (ECETOC).

Secretariat

The ECETOC Secretariat is responsible for the co-ordination and management of the 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. During the year, Dr. M. Gribble joined our team.

At the end of 2003, staff employed were:

Dr. Michael Gribble	Secretary General
Dr. Christa Hennes	Health Sciences Manager
Mr. Martin Holt	Environmental Sciences Manager
Ir. Henk Vrijhof	Chemicals Programme Manager
Ms. Genevieve Gerits	Office Manager
Ms. Julieann Humphrey	Publications Officer
Ms. Marie-Laurence Simon	Secretary
Ms. Christine Yannakas	Secretary

Acknowledgement:

ECETOC would like to express their gratitude to Dr. Francis Carpanini for 8 years of dedicated service as Secretary General. He supported and facilitated the teamwork that led to ECETOC's success during the 25th Jubilee year. Ms. Margaret Butler, Health Sciences Manager, retired in May after 7 years of dedicated service to ECETOC.



*Front row from left:
Ms. M-L Simon, Ms. G. Gerits, Dr. C. Hennes, Ms. J. Humphrey*

*Back row from left:
Ir. H. Vrijhof, Mr. M. Holt, Ms. C. Yannakas, Dr. M. Gribble*



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 the twelve senior scientists from member companies on this pivotal ECETOC committee have been complemented by three 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. These project proposals form the basis for the 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 ECETOC's work programme is published in a range of reports, varying in scope from the 'JACC' reports on specific chemicals, to 'Monographs' dealing with the fundamental principles underlying the various branches of science in toxicology and ecotoxicology. Reports continue to be published following peer review by the Scientific Committee and external experts. ECETOC's publications are provided to all member companies and to other interested parties, such as the various regulatory authorities, international organisations and academic groups, for use as required.

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.

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 with the 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 or manufacturing chemicals.

Board Members

The composition of the ECETOC Board as at December 2003 was:

Name	Company	Function
Mr. P. Peschak	ExxonMobil Chemical	Chairman
Dr. K. Eigenmann	Novartis	Vice-chairman
Dr. J. Rudolph	Degussa	Treasurer
Mr. P. Chaigneau	DuPont de Nemours	
Prof. J. De Wit	Akzo Nobel	
Mr. C. Holmes	Procter & Gamble	
Mr. D. Hyde	AstraZeneca	
Dr. med. M. Kayser	Bayer	
Mr. H. Schiff	Novozymes	
Prof. L. Smith	Syngenta	

Dr. med. M. Kayser (Bayer) was elected to the Board.

In addition, Dr. J. Rudolph (Degussa) Treasurer and Prof. J de Wit (Akzo Nobel) were re-elected for a further term of two years following expiry of their mandates. Mr. H. Schiff (Novozymes) resigned from the ECETOC Board at the end of 2003 after 11 years of dedicated service to ECETOC.

Scientific Committee

The composition of the ECETOC Scientific Committee as at December 2003 was:

Name	Affiliation	Function
Prof. G. Randall	AstraZeneca	Chairman
Dr. N. Carmichael	Bayer CropScience	Vice-chairman
Dr. C. Braun	Akzo Nobel	
Prof. P. Calow	Sheffield University	
Dr. C. d'Hondt	Novartis	
Dr. P. Douben	Unilever	
Dr. T. Feijtel	Procter & Gamble	
Prof. H. Greim	Munich Technical University	
Mr. C. Money	ExxonMobil	
Dr. A. Sarrif	DuPont de Nemours	
Dr. G. Swaen	Maastricht University	
Dr. B. van Ravenzwaay	BASF	
Dr. H-J. Wiegand	Degussa	

The Scientific Committee held 7 meetings during the year.

Prof. G. Randall (AstraZeneca) was elected by the Board to the position of Chairman.

Both Dr. B. Hildebrand (Consultant) and Dr. E. Bomhard (Bayer) retired from the Scientific Committee during 2003. Dr. N. Carmichael (Bayer CropScience) retired at the end of 2003.

Member Companies

ECETOC Membership as at December 2003:



3M
AKZO NOBEL
ASTRAZENECA
ATOFINA
BASF
BAYER
BORAX
BOREALIS
BP CHEMICALS
CIBA SPECIALTY CHEMICALS
CLARIANT
COCA-COLA
COGNIS
COLGATE-PALMOLIVE
DEGUSSA
DOW CORNING
DOW CHEMICAL
DSM
DUPONT DE NEMOURS
EXXONMOBIL CHEMICAL
F. HOFFMANN LA ROCHE
HENKEL
ICI
IFF
JANSSEN PHARMACEUTICA
L'OREAL
LYONDELL CHEMICAL
MERCK
MONSANTO
NORSK HYDRO
NOVARTIS
NOVOZYMES
PETRESA
POLIMERI EUROPA
PROCTER & GAMBLE
RECKITT BENCKISER
REPSOL QUIMICA
RHODIA
ROHM & HAAS
SASOL
SHELL CHEMICALS
SOLVAY
STATOIL
SYNGENTA
UNILEVER
WACKER-CHEMIE

Finance

Income	Actual 2003 in Euro
Subscription	
Full Members	1,354,500
'New' Members	31,500
Total Subscription Income	1,386,000
Bank Interest	31,065
Document Sales	8,850
Project-related	259,178
Total	1,685,093

Balance Sheet and Reserves	Actual 2003 in Euro
Balance Sheet	
Income	1,685,093
Expenditure	1,736,626
Operating Margin	-51,532
Reserves	
Opening	1,212,850
Operating Margin	-51,532
Closing Reserve	1,161,317
Estimated Reserve Required	450,000

Expenditure	Actual 2003 in Euro
Salaries (and related expenses)	1,000,190
Office Running Expenses	252,694
Travel Expenses on Missions	14,393
Meetings and Consultants	370,363
Professional Services	11,365
Bank Charges	4,176
Capital Expenditure	3,000
Publications	57,171
Miscellaneous	23,271
Total	1,736,626



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