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Annual Report

2001



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EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS



Introduction

ECETOC (European Centre for the Ecotoxicology and Toxicology of Chemicals) was established in 1978 as a scientific, non-commercial association. It is financed by around fifty 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 Organization and the European Commission, in establishing a scientific foundation for the development of legislation on chemicals.

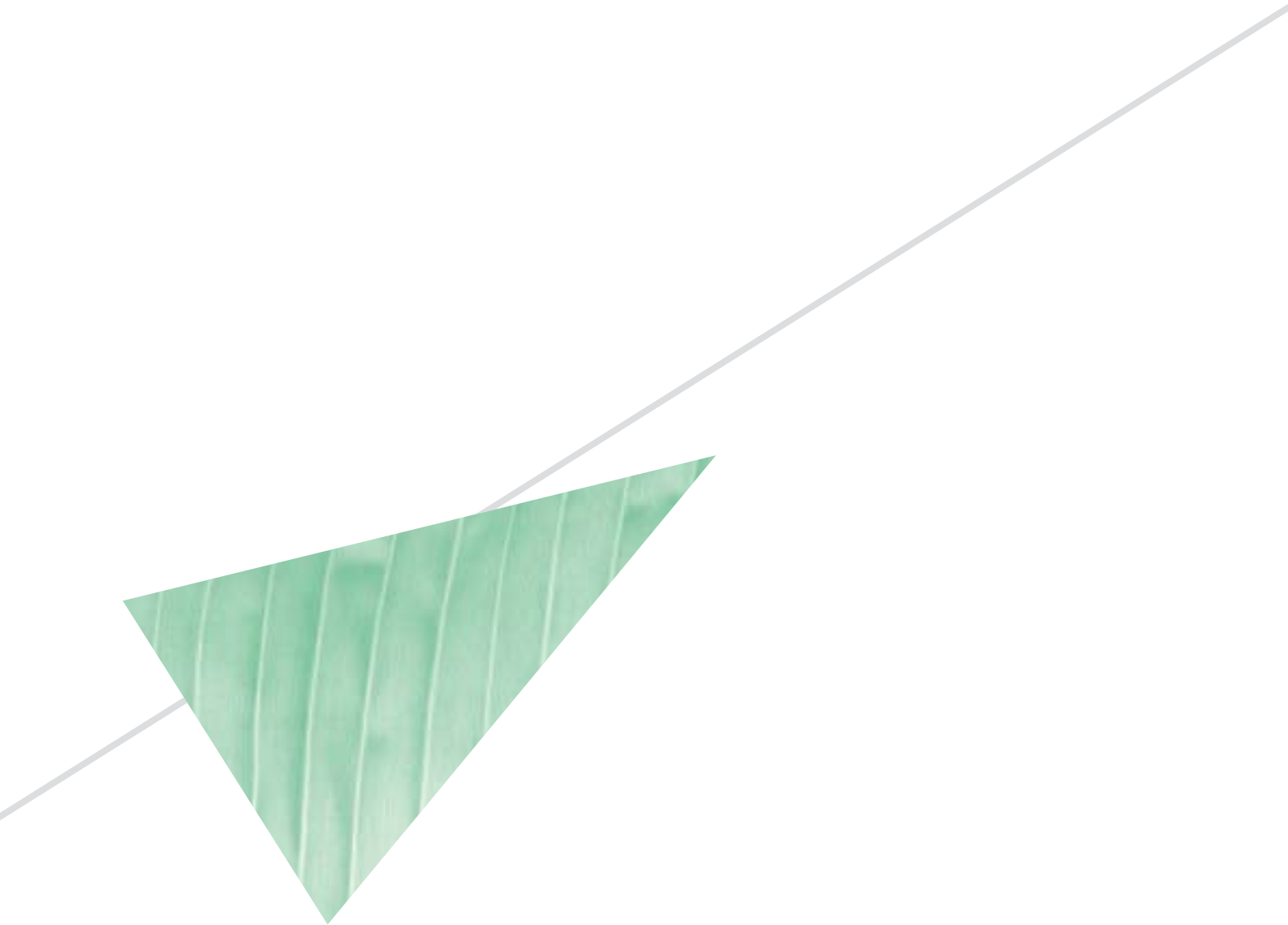


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Challenging Times

Message from the Chairman



Dr. C. Mancel.

Evolving Regulations

Industry is under siege in respect of the proliferation of regulations on chemical safety, ranging from more specific initiatives, such as the 'Biocides' Directive to the all-embracing 'Water Framework' Directive. With the recent launch of the European Commission (EC) White Paper, setting out a strategy for a future Community policy for chemicals, the industry is facing probably the greatest ever challenge in its history to its licence to operate.

The White Paper has been welcomed and acclaimed to a lesser or greater extent by all stakeholders, united in support of its overall goal to ensure a high level of protection for human health and the environment.

At the same time, however, the White Paper has attracted criticism, mainly for its over-ambitious target to complete the registration, evaluation or authorisation of more than 30,000 chemicals over the next decade, as well as concern about ensuring the effective functioning of the internal market and stimulating innovation and competitiveness in the industry.

Of course there has been, and continues to be, much political debate during this crucial formative stage of regulation that will eventually become European Union (EU) law. Ultimately, the burden will fall on science to find the new approaches and methodologies that will be needed to develop and interpret the necessary data to reassure the regulators, and indeed all stakeholders, of the safety of chemicals used and produced by our industry, whilst bringing benefits to all.

A realisation of the magnitude of the demands, as compared with the scarcity of resources and over-ambitious timetable, is already stimulating interest in the development of methods for 'push button' hazard assessment and 'black box' risk assessments. Whilst this may seem like the easy option, the challenge to industry will be to make sure that sound science is not sacrificed in favour of expediency. The alternative will be recourse by the regulators to precautionary principles, a disastrous scenario for the industry.

Partnerships

Faced with such challenges, it is essential that active partnerships are formed to engage the specialist skills in all stakeholder groups, united in a common goal of improved and effective functioning regulations. The involvement of downstream users in the White Paper should be seen as a welcome challenge to include these new constituencies in the partnerships, thus presenting the opportunity to bring additional skills and data to complement the initiatives for developing new methodologies.

With its membership spanning a wide range of companies engaged in the manufacture and downstream use of chemicals, ECETOC is uniquely positioned to catalyse this process and to play a central role in developing the scientific strategy to meet this evolving legislation. Indeed, ECETOC is already actively engaged with the Commission in this important work.

Thanks

Once again ECETOC has met its goals, delivering well on its tasks and objectives. The many achievements in 2001 are described in the following pages. We are indebted to the scientists from our members companies, as well as those from other organisations who contributed to the successful outcome of our work programme.

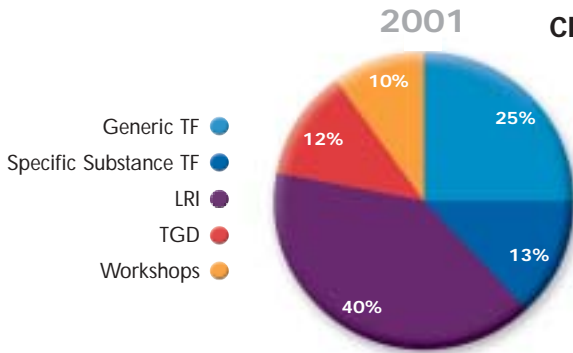
Finally, thanks are expressed to the Secretariat for facilitating the teamwork responsible for ECETOC's successful year.



Dr. C. P. Mancel
Chairman
ECETOC Board of Directors

An Overview of 2001

Message from the Secretary General



Changing Ways

Escalation of regulatory demands and industry's voluntary initiatives concerning health and environmental impacts of chemicals, have placed a growing burden on a steadily diminishing pool of specialist resources in the industry.

This phenomenon became obvious as ECETOC Task Forces struggled to achieve targets as a result of inadequate levels of resources committed by member companies. The ECETOC Board and Scientific Committee responded by developing new *modus operandi* towards achieving improved performance, whilst maintaining or improving further the standards of quality for which ECETOC is respected.

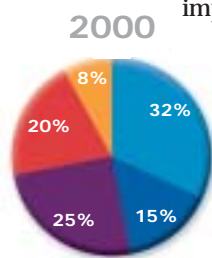
Implementation of these new approaches is well advanced and already delivering benefits in both programme development and in the progress of Task Force initiatives. The Scientific Committee in particular has made

important changes to its composition and its working practices (p.21 and 25). This pivotal committee has been reinforced by the appointment

of a full-time Chairman and three leading academic scientists in the fields of toxicology, human health and environmental sciences.

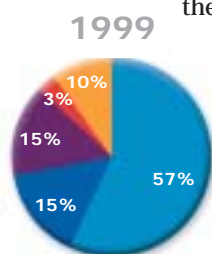
In addition to strengthening the science base of the Scientific Committee in areas of critical importance to the present demands, the external members have added transparency and independence to the strategic science leadership of ECETOC. This benefit will be

further extended with the appointment of an independent external Peer Review Panel, planned for implementation in 2002.



With future programme development by means of multi-stakeholder workshops established as a mainstream activity of the Scientific Committee, ECETOC will be well positioned to continue to play a leading role in

the development of sound science-based approaches to underpin the responsible health and environmental management of chemicals.



2001 Programme Overview

In 2001, ECETOC continued to be active in five main programme areas. There was some change to the distribution of the total effort expended in those areas compared with the figures for 1999 and 2000. However, with one additional scientific programme manager joining the Secretariat for most of 2001, the total effort available was increased by around 30% for the year.

Consequent to the increased Secretariat resources, the effort devoted this year to the support of the European Chemical Industry Council (Cefic) for the Long-range Research Initiative (LRI) was substantially increased (p.10), due largely to provision of support for the endocrine science programme. In all other areas of the ECETOC programme, the total level of effort expended remained more or less constant.



Dr. F. Carpanini in a meeting with Scientific Committee Deputy Chairmen Drs. G. Randall (AstraZeneca) and N. Carmichael (Aventis CropScience) and Chairman Dr. B. Hildebrand.

Participation in the EC revision of the Technical Guidance Document (TGD) for the risk assessment of new and existing substances and biocides (p.12), continued throughout 2001, and indeed further effort will be required in 2002. Through its work in this area, ECETOC has demonstrated its ability to build consensus across a broad range of industry and to deliver its outputs in a timely fashion.

Allied with the recognition by external agencies such as the EC as a trusted partner for the scientific integrity of its outputs, our association is well equipped to play an active role in the evolution of practical approaches and guidance to meet the needs of the EC White Paper on strategy for a future chemicals policy.


The Specific Substances programme (p.8) continued to feature as a significant part of ECETOC activities and outputs. Demand from the participating companies for this work was maintained in 2001, a reflection of the perceived added value of ECETOC for hosting such consortia-driven projects.

Finally, a number of initiatives in the Generic Task Force programme (p.6) reached conclusion in 2001. This key area of work on fundamental issues will continue to feature substantially in the ECETOC programme as the demand escalates for ever more data towards a greater understanding of the impact of chemicals on health and the environment.

Dr. F. M. Carpanini
Secretary General
ECETOC

Task Forces

Generic Issues



This part of the ECETOC programme comprises the Task Force activities addressing issues of concern that are common to a broad constituency of membership. The following initiatives were launched in 2001:

Targeted Risk Assessment

The EC White Paper proposal involves the collection of data on chemicals through the REACH process (Registration, Evaluation and Authorisation of Chemicals). Aspiring to apply the process to more than 30,000 chemicals in the space of a decade, the proposal is ambitious; the ECETOC Task Force was thus commissioned with the challenging objective of developing a structured and pragmatic approach to risk assessment, founded on sound scientific principles, that would facilitate the realisation of the goals of the White Paper. Moreover, the Task Force was charged with delivering the concept to the relevant EC Working Group within a time frame of only a few weeks, whilst securing the broad support of the manufacturers and down-stream users.

A key success factor of the approach will be the ability to channel effort where it is needed, limiting data generation to those essential for sound decision making. The approach should thus effectively reduce costs, particularly in terms of animal testing, without compromising the objectives of the chemical policy.

QSARs

While (Quantitative) Structure Activity Relationships, (Q)SARs, have been promoted by some as an alternative to experimental ecotoxicological and toxicological data, hitherto, especially in Europe, there has been a reluctance by many to use such models for regulatory purposes. (Q)SAR technology has been advancing steadily during this time, providing improvements in the statistical and mathematical tools used and the way in which mechanistic information is incorporated into the predictions.

The ECETOC (Q)SAR Task Force has been commissioned to review the current position, building on the outcome of a multi-stakeholder workshop organised by International Council of Chemical Associations (ICCA) LRI, to formulate advice and guidance on the utility and, equally important, limitations of current (Q)SAR methodologies for predicting reliably the health and environmental effects of chemicals, particularly in the context of the EC White Paper. The Task Force is also commissioned with developing proposals for improving the most promising (Q)SARs so that their acceptability can be extended and validation achieved.

Ecological Quality Workshop

Following the Amsterdam Treaty (1997), there was a strengthening of the policy of integrating environmental protection into all Community policies. To integrate policy on water, the Water Framework Directive (WFD) has been introduced, bringing far-reaching changes to environmental protection.

One of the goals of the WFD is to achieve and/or maintain 'good' ecological status. Before it is possible to predict the impact of human activities on the natural environment, it is necessary to understand the forces that drive, and therefore control, the environment. The ECETOC Task Force has been commissioned to organise a multi-stakeholder workshop to debate this concept, and identify the major factors that need to be understood to support the definition and measurement of ecological quality.

Risk Assessment of Carcinogens

In the context of Regulation 793/93/EEC, an approach based on the derivation and use of the T25 dose (dose that produces a 25% incidence of cancer in an appropriately designed experiment) has been proposed by the Norwegian and Dutch Competent Authorities for the risk assessment of non-threshold carcinogens. Many scientists were concerned that this proposal did not take sufficient account of the scientific understanding of the carcinogenic process.

The outputs from an ECETOC workshop on this topic in November 2000, formed the basis for a paper that reviewed critically the proposed T25 method along with alternative methods for risk assessment. An ECETOC Task Force was commissioned to refine this paper in the context of other possible methods for the risk assessment of carcinogens and to make recommendations for a preferred method. This work will be provided to the EC Sub Group engaged in revising the section of the TGD dealing with the risk characterisation of non-threshold carcinogens.

Task Forces Specific Substances

This part of the ECETOC programme includes the preparation of comprehensive critical reviews of the physico-chemical, environmental, (eco)toxicological and human data on specific substances. The following Task Force was launched in 2001:

Glycol ethers

In 2001, the companies producing glycol ethers became aware of increasing concerns on the part of many downstream user industries, local interest groups and the public at large over the potential adverse effects on health of such chemicals. This was evidenced by the inclusion of a number of these substances on the priority lists of OECD and of regulatory agencies. The situation prompted the manufacturers in Europe (Cefic Oxygenated Solvents Producers Association, OSPA) and the USA (American Chemistry Council Glycol Ethers Panels) to plan an international symposium (October 2002) in which such issues could be debated openly.

Since the previous ECETOC review (Technical Report No 64) published in 1995, several new studies sponsored by industry had become available, notably, more extensive studies of chronic toxicity, reproductive toxicity and carcinogenicity. At the request of OSPA, the Scientific Committee agreed to establish a Task Force to produce an up-to-date critical review and hazard assessment of glycol ethers, including a consideration of structure and activity of different groups of compounds. The report is intended to serve as a general source document for the immediate benefit of toxicological and medical staff in producer and user companies, academic scientists and regulatory authorities at national and EU/OECD level, and the WHO IPCS programme.

Specific Substances Programme

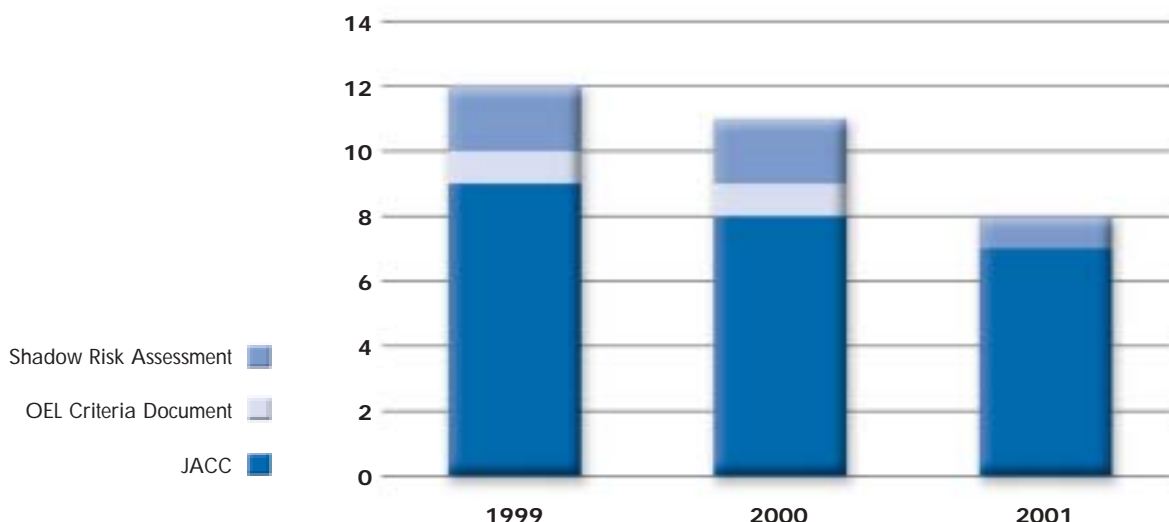
Driven by the demand of member companies, frequently operating in consortia with other producers, the emphasis in this programme is on the preparation of high quality reviews, maintained through a rigorous peer review process. The responsibility for resourcing the Task Force with suitably qualified experts lies with the interested companies.

In addition to preparing comprehensive critical reviews (Joint Assessments of Commodity Chemicals or JACCs) for specific substances, the programme frequently highlights issues of a generic nature. In this way, the programme delivers outputs that are also of value to a broader constituency of the ECETOC membership.

Over the last 3 years, there has been interest in tailoring some reviews towards the EC 'Risk Assessment' Regulation and other targeted end uses e.g. to provide criteria documents for the EU Scientific Committee on Occupational Exposure Limits. Most groups however, continued to report in the traditional JACC format, i.e. an integrated assessment of environmental and human health hazards.

There has been a gradual decline in the number of Task Forces engaged in this programme though many of the current Task Forces are preparing review on more than one substance.

Specific Substances : Active Task Forces



Long-range Research Initiative



ECETOC has played a significant role since 1997 in the Cefic/American Chemistry Council/Japanese Chemical Industry Association funded strategic research programme on human health and the environment

The critical scientific support provided by ECETOC to the Cefic/American Chemistry Council (ACC)/Japanese Chemical Industry Association funded research programme on the effects of industrial chemicals on human health, wildlife populations and the environment, continues to increase. In particular, a major increase in supporting effort was provided during 2001 to integrate the research programme of Cefic's Endocrine Modulation Steering Group into the LRI.

In preparation for a global workshop to review the progress of the research in the different regions and to revisit the needs for the future research programmes, ECETOC completed a review of the State of the Science (STOTS) white papers that formed the backbone of the LRI programme when it was initiated in 1997. ECETOC scientists participated actively in the process for identifying emerging issues to be addressed in the future phases of the programme, and this work is continuing.

ECETOC environmental scientists organised a poster display and 'open' house that was attended by over 100 scientists at the Society for Environmental Toxicology and Chemistry (SETAC) Annual meeting in Madrid in May. The existing programme was later reviewed in a two-day workshop held in November. Research gaps were highlighted and an outline of the programme for 2002-2004 was developed. Similar reviews were undertaken by the endocrine and HETRA teams.

In 2001, new requests for proposals (RfPs) addressing exposure uncertainty and margins of safety, skin protection strategies, biomarkers of exposure, comparison of marine and fresh water ecotoxicity and environmental monitoring were developed and posted on the Cefic LRI website.

Technical Guidance Document



Early in 2000, the European Chemicals Bureau (ECB) launched the revision of its guidance¹ for the risk assessment of new and existing substances and invited ECETOC to participate on behalf of the industry

The bulk of the work of twelve of the fourteen Sub Groups charged with revising the guidance documents for the risk assessment of new and existing chemicals and biocides, was concluded during 2001. The process continued to demand significant input from ECETOC scientists to address the issues and ensure industry's broad consensus was considered in the work of the Commission's Sub Groups.

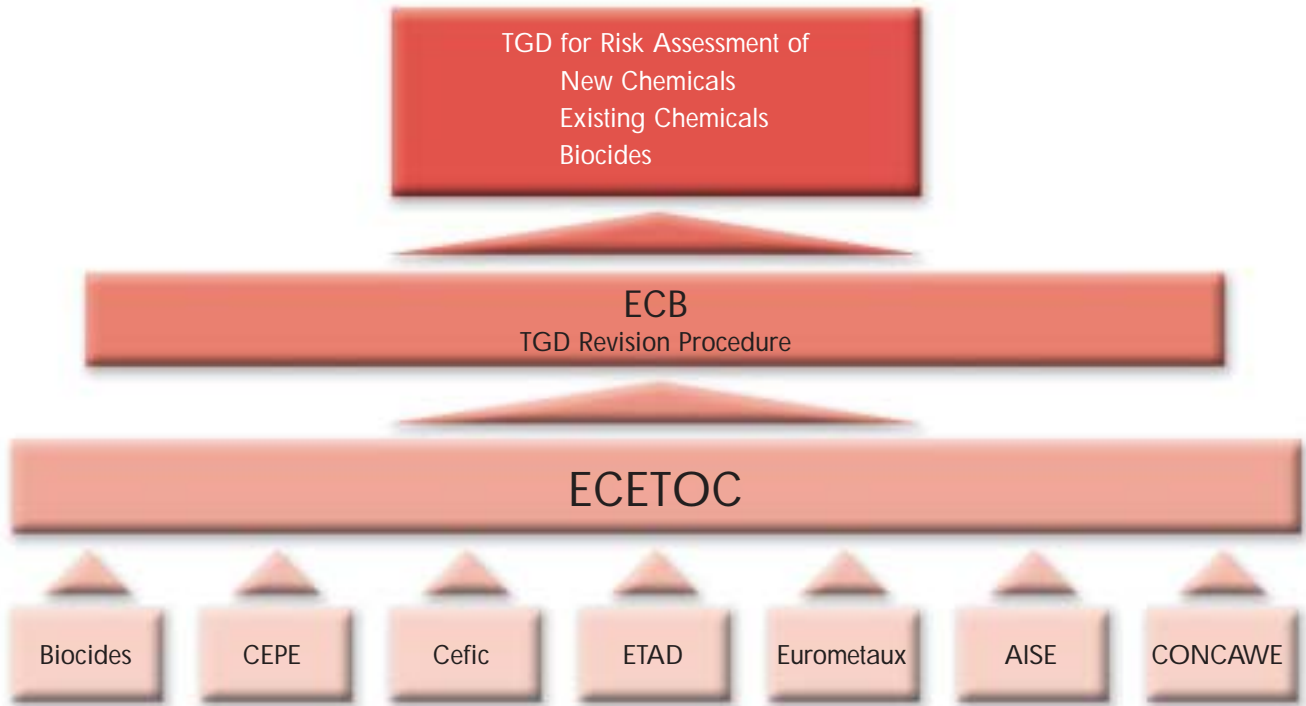
The contributions made through ECETOC were generally well received and often incorporated in the revised sections. The new area of risk assessment in marine environments presented a particular challenge and the outcome is likely to generate further debate amongst scientists engaged in this field.

The work of the two EC Sub Groups assigned to revising guidance on risk characterisation of non-threshold carcinogens and of other endpoints would begin during 2002, once all other sections of the TGD guidance had been finalised.

ECETOC continues to provide input to ECB through its representatives in the final consultative process and in the progression of the outstanding sections.

¹ Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances.

Process employed by ECETOC for TGD Revision



Scientists from ECETOC member companies were appointed to represent the industry on each of the 14 Commission Sub Groups. An infrastructure of support teams, including experts and practitioners from across the industry was established to ensure that the input reflected broad consensus and agreement. Representatives from other industry groups, including the biocides industry, were actively networked to ensure their specific specialist issues were taken into account.

Workshops

ECETOC workshops provide an opportunity to broaden debate on key issues by involving representatives from other organisations, academia and the regulators

Chemicals and the Environment A Waste of Resources?

Annual Meeting, Brussels, 22 May 2001

Organised as part of the ECETOC Annual Meeting, the event also served as the first programme development workshop and was designed by the Scientific Committee to consider the key messages that were emerging in relation to chemicals and the environment. The meeting was successful, attended by some fifty participants from member companies, academia and from external organisations.

A provocative keynote address by Professor David Bellamy on causes of environmental concern, was followed by presentations from other leading experts on the dynamics and threats of ecosystems, and the causes and effects of environmental contamination of fresh and marine water and soil. A lively panel discussion brought the morning's proceedings to a close.

The afternoon was devoted to four syndicate sessions on fresh water, marine, terrestrial and ecological interactions, the objective of which was to consider the key messages emerging from the morning's lectures. Suggestions were made on how ECETOC could contribute, through its Task Forces and Workshops, to addressing the identified issues. These proposals took note of external pressures on, and internal drivers of, ECETOC member companies, including legislative pressures and corporate social responsibility.

Workshop on PBPK Modelling, Munich, 11-12 October 2001

Sponsored by several industry groups including Cefic and ACC, the workshop was organised by ECETOC to discuss the current status of physiological-toxicokinetic modelling (PTM) and its utility in health risk assessment of chemical substances. The workshop presented an overview of PTM approaches and applications in toxicology and, the limitations and strengths in hazard identification and risk assessment were illustrated using examples of models. Designed to appeal to regulatory scientists and others interested in health risk assessment of chemicals, the workshop was attended by 65 participants from industry, academia, regulatory agencies and consulting organisations.



In the foreground speakers Prof. Løkke (Danish Environmental Research Institute) and Paasivirta (University of Jyväskylä) at the Annual Meeting.



Prof. D. Bellamy who gave the keynote address at the event.



Panellists (from left) Dr. G. Csanády (GSF), Dr. P. Kreuzer (STTV), Prof. H. Greim (Technical University Munich) at the PBPK Modelling Workshop.

The presentations, which ranged from an overview of PTM presented by Dr. M. Andersen to specific presentations of the application of PTM to certain chemical-specific issues, stimulated much discussion during question/answer sessions.

The computer model demonstrations were particularly effective, giving participants a more tangible appreciation of PTM. They attracted great interest and generated considerable informal debate. The final panel discussion led by Professor E. Dybing was animated, reflecting the importance of this analytical approach in the extrapolation of toxicological data to humans.

The workshop proceedings, including the panel discussion and abstracts of the demonstrations, are to be published during 2002.

Degradation of Chemicals in the Environment Paris, 16 - 17 October 2001

ECETOC organised this two-day workshop on degradation of chemicals in the environment on behalf of Cefic. Participation was by invitation only and attracted 42 representatives from academia, the regulatory agencies and industry of Europe, the USA and Canada.



Prof. D. Calamari (University of Insubria) speaking on fresh water contamination issues at the Annual Meeting.

The workshop consisted of a morning of presentations, followed by a series of parallel syndicate sessions held over the remaining day and a half. The topics addressed included extrapolation from freshwater to marine and terrestrial environments, development of a testing strategy, minimum data requirements, QSBRs and the use of modelling to predict persistence.



Prof. P. Calow (University of Sheffield) emphasises a point during discussions on ecosystems at the Annual Meeting.

The workshop concluded that research is urgently required to develop a better understanding of the factors affecting biodegradation in the environment. In particular, current test methodologies were considered unsuitable for use in predicting whether or not a chemical would meet the proposed criteria for persistence; new laboratory tests needed to be developed for providing realistic data on the rate and extent of biodegradation in the various environmental compartments.

Conclusions from the workshop will be published in 2002, and should be considered, alongside the forthcoming report from the ECETOC Persistence Task Force, in the development of further Cefic LRI research initiatives in this important area.

Other External Representation

In addition to major collaborative exercises such as the ECB led TGD revision, ECETOC provides representation by experts from its member companies to the work of a number of external organisations. In 2001 these included:

- **International Programme on Chemical Safety (IPCS) Eighth Final Review Board Meeting for Concise International Chemical Assessment Documents (CICADs)**
Geneva, 8-12 January
ECETOC represented by Dr. W. ten Berge (DSM).
- **OECD Ad Hoc Group for Reporting Exposure Information**
ECETOC represented by Dr. C. Money (ExxonMobil) and Dr. C. Lally (Procter & Gamble).
- **Rijksinstituut voor Volksgezondheid en Milieuhygiëne (RIVM) Symposium on New Developments in Risk Assessment**
Bilthoven, 2 May
ECETOC represented by Dr. C. Lally (Procter & Gamble) and Dr. W. ten Berge (DSM).
- **Society of Toxicologic Pathology (STP) 20th Symposium**
Orlando, 24-28 June
ECETOC Task Force Adverse vs Non-adverse Effects represented by Dr. R. Lewis (Syngenta).

- **European Consensus Platform for Alternatives (ECOPA) Workshop**
Brussels, 27-28 October
ECETOC represented by Dr. P. Botham (Syngenta).
- **European Centre for the Validation of Alternative Methods (ECVAM)**
During 2001, ECETOC continued to be represented by Dr. P. Botham (Syngenta) on the ECVAM Scientific Advisory Committee.
- **ECVAM Workshop on the Use of Fish Cells in Ecotoxicology**
Ispra, 23-24 October
ECETOC represented by Dr. H. Ruffli (Syngenta).
- **European Cosmetic Toiletry and Perfumery Association (Colipa)**
Dr. I. Kimber (Syngenta) continued to represent ECETOC on the Skin Tolerance Task Force.
- **Colipa**
Dr. P. Botham (Syngenta) continued to represent ECETOC at the on-going Colipa meetings to discuss alternatives to animals.
- **ILSI Europe**
ECETOC continued its active membership of the Environment and Health Task Force. ECETOC represented by Mr. M. Holt.
- **SETAC**
ECETOC is represented on SETAC Europe Council through the membership of Mr. M. Holt.

ECETOC Outputs

During 2001 ECETOC generated several publications ranging from its traditional reports to external publications in peer-reviewed journals

Technical Reports

- **No. 79** Exposure Factors Sourcebook for European Populations (with focus on UK data)
- **No. 80** Aquatic Toxicity of Mixtures
- **No. 81** Human Acute Intoxication from Monochloroacetic Acid: Proposals for Therapy
- **No. 82** Risk Assessment in Marine Environments

Monographs

- **No. 30** Genetic Susceptibility to Environmental Toxicants
Mutation Research Special Issue 482: 1-117

JACC Reports

- **No. 40** Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions

ECETOC Documents

- **No. 42** Genomics, Transcript Profiling, Proteomics and Metabonomics (GTPM). An Introduction





External Publications

- Kimber I, Basketter DA, Berthold K, Butler M, Garrigue J-L, Lea L, Newsome C, Roggeband R, Steiling W, Stropp G, Waterman S, Wiemann C. 2001. Skin sensitization testing in potency and risk assessment. *Tox Sci* 59: 198-208.
- Steiling W, Basketter D, Berthold K, Butler M, Garrigue JL, Kimber I, Lea L, Newsome C, Roggeband R, Stropp G, Waterman S, Wiemann C. 2001. Skin sensitisation testing – new perspectives and recommendations. *Fd Chem Toxic* 39:293-301.
- Schowanek *et al.* 2001. GREAT-ER: a new tool for management and risk assessment in river basins. *Wat Sci Technol* 48: 179-185.
- Ahlberg R, Gennart J-P, Mitchell R, Schulte-Koerne E, Thomas ME, Vahervuori H, Vrijhof H, Watts CD. 2001. *An environmental risk assessment of MTBE use in Europe*. The Association for Environmental Health and Sciences, First International Congress on Petroleum Contaminated Soils, Sediments and Water. London. 19pp.
- Roberts RA, Crump KS, Lutz WK, Wiegand H-J, Williams GM, Harrison PTC, Purchase IFH. 2001. Scientific analysis of the proposed use of the T25 dose descriptor in chemical carcinogen regulation. An ECETOC workshop review. *Arch Toxicol* 75: 507-512.

Posters

- SETAC Meeting, Madrid, May 2001
 - Lemaire *et al.* EAT 3: ECETOC compilation of a high quality aquatic ecotoxicology database;
 - Eadsforth *et al.* Comparison of the sensitivity of freshwater and seawater organisms to chemicals using the ECETOC EAT 3 database;
 - Tencalla *et al.* Comparison of acute chronic ratios for chemicals using the ECETOC EAT 3 database;
 - Koch *et al.* Environmental risk assessment of substances with 'unique' properties.

ECETOC 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.

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 to the Task Forces are accomplished in a timely fashion



Dr. F. Carpanini.

At 31 December 2001, staff employed were:

Dr. F. Carpanini	Secretary General
Ms. M. Butler	Health Sciences
Ms. E. Eysenbach	Research Programme
Mr. M. Holt	Environmental Sciences
Mr. H. Vrijhof	Chemicals Programme
Ms. L. Starks	Publications Officer
Ms. G. Gerits	Office Manager
Ms. M-L Simon	Secretary
Ms. J. Durkin	Secretary

ECETOC's continued success relies greatly on its Secretariat. This team of dedicated professionals assists the scientists of our member companies to fulfil their tasks in respect of ECETOC. During the year, Ms. L. Starks and Ms. J. Durkin joined our team. Ms. S. Henssler left ECETOC in June.



Front row from left: Margaret Butler, Francis Carpanini, Jeanette Durkin.

Back row from left: Lisa Starks, Martin Holt, Marie-Laurence Simon, Henk Vrijhof, Geneviève Gerits.

Modus Operandi

New operating practices are being introduced within ECETOC to meet the need for change crucial to sustaining the effectiveness, authority and reputation built by the association since its foundation in 1978.

Board

ECETOC continues to operate under the general direction of a Board comprised of up to twelve senior executives from member companies. The Board is responsible for the overall policy and organisational strategy of the association.

Scientific Committee

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

Before 2001, membership of the Scientific Committee was open only to senior scientists from ECETOC member companies. In mid-2001, three leading external experts in the fields of toxicology, environmental science and occupational epidemiology were appointed to complement the competencies of the twelve industry members. Through these appointments, the range of expertise necessary to direct effectively the ECETOC work programme will be greatly reinforced whilst the transparency and independence of the committee's processes will be increased.

Task Forces

Up till now, ECETOC outputs have been generated mostly through Task Forces comprised of appropriate experts drawn from member companies, the final composition being subject to endorsement by the Scientific Committee, taking into account the range of skills required to address the selected topic.

Under the new procedures, more-detailed project planning will be instituted in an initial 'scoping' meeting to define clearly the overall objectives, resources needed, deliverables and time plan. These project proposals form the basis for the Scientific Committee's decision on how the initiative is to be progressed, choosing between the conventional 'sweat equity' approach or the use of contractors.

The process and range of options for resourcing and progressing ECETOC Task Force projects to a final output is shown on page 23.

Programme Development

The content of the programme is derived from both internal (member company) needs and external drivers (for example, initiatives taken by regulatory authorities, especially the EC). According to our new procedures, a more-structured approach will be adopted under the direction of the Scientific Committee. Once or twice each year, multi-stakeholder science workshops will be convened towards identifying potential issues and formulating initiatives for addressing them in the ECETOC programme.

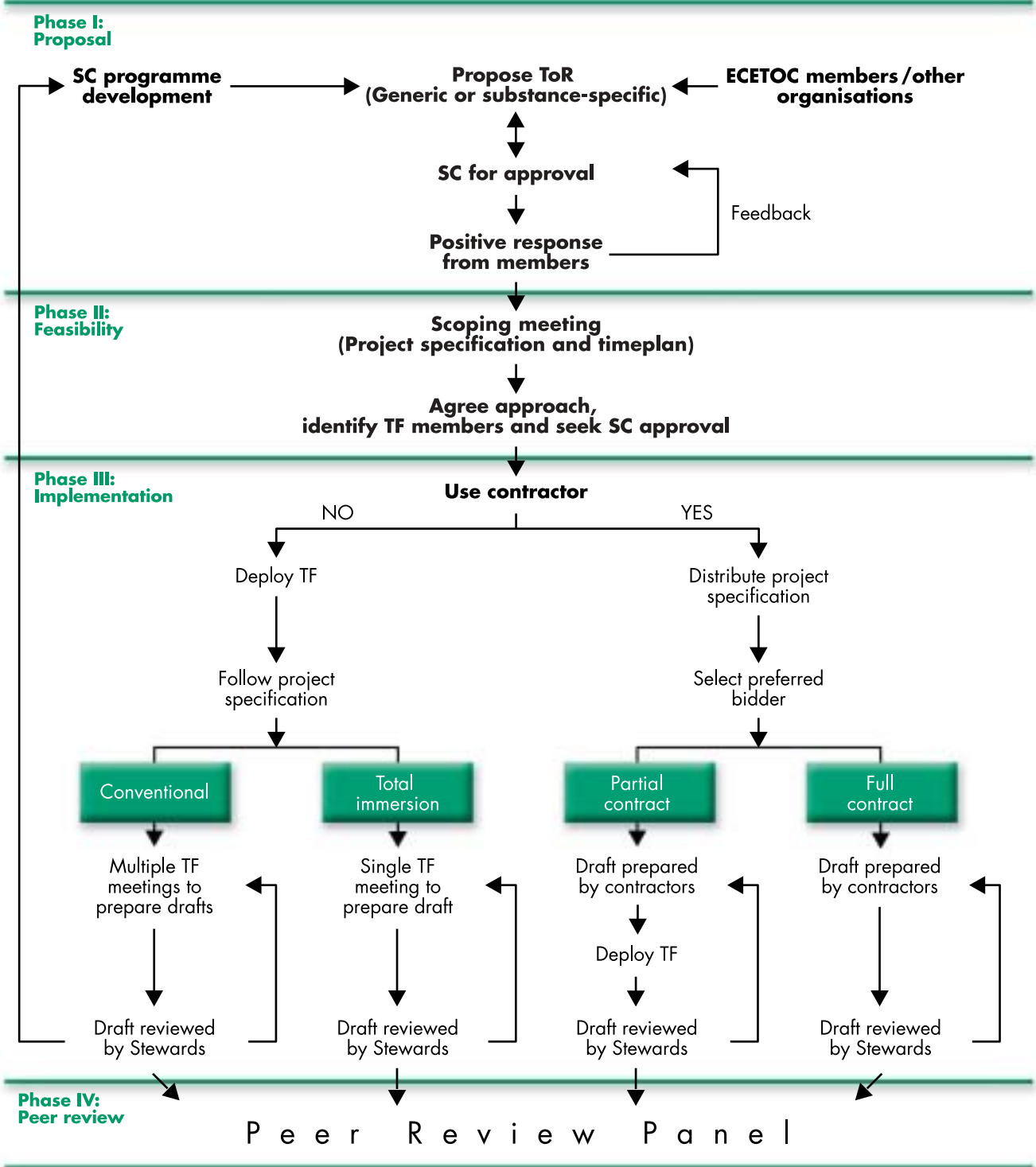
In parallel with this, suggestions for the programme will continue to be invited from all members of ECETOC, and from outside organisations, including academia and regulatory authorities. For a proposal to be progressed, it must be supported by at least two member companies and judged to meet the scientific standards required by the Scientific Committee. Provided these criteria are met, the projects will be progressed following the new Task Force procedures (p.23).

Publications

The main output of ECETOC's work programme is the publication of 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 will continue to be published following peer review by the Scientific Committee. However, plans are well advanced to appoint a panel of independent experts to undertake reviews of ECETOC publications prior to their final approval and release. Under the new procedures, once this Peer Review Panel is established in 2002, all ECETOC reports will be required to undergo this extension of the peer review process.

Copies of all ECETOC 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.

ECETOC Task Force Process Map



Board Members

The composition of the ECETOC Board following the 2001 Annual General Meeting was:

Name	Company	Function
Dr. C. Mancel	Procter & Gamble	Chairman
Mr. P. Peschak	ExxonMobil Chemical	Vice-chairman & Treasurer
Dr. J. De Wit	Akzo Nobel	
Dr. K. Eigenmann	Novartis	
Mr. D. Hyde	AstraZeneca	
Dr. J. Rudolph	Degussa	
Mr. H. Schiff	Novozymes	

Following the Annual General Meeting (AGM) on 21 May 2001, Mr. J-J Van de Berg (Solvay) resigned his Chairmanship and membership of the Board following his resignation from Solvay. The Board elected Dr. C. Mancel (Procter & Gamble) to succeed Mr. Van de Berg as Chairman and Mr. P. Peschak to succeed Dr. Mancel as Vice-chairman and Treasurer, both with effect from the AGM. Following his retirement from his company, Mr. C. Bronke (DSM) also resigned his seat on the Board.

Dr. J. De Wit (Akzo Nobel) was elected to the Board at the Annual General Meeting on 21 May 2001.

In addition, Dr. J. Rudolph was re-elected for a further term of two years following the expiry of his mandate.

Scientific Committee

The composition of the ECETOC Scientific Committee as at December 2001 was:

Name	Affiliation	Function
Dr. B. Hildebrand	Consultant	Chairman
Dr. N. Carmichael	Aventis CropScience	Vice-chairman
Prof. G. Randall	AstraZeneca	Vice-chairman
Dr. E. Bomhard	Bayer	
Dr. C. Braun	Akzo Nobel	
Prof. P. Calow	Sheffield University	
Dr. C. d'Hondt	Syngenta	
Dr. P. Douben	Unilever	
Dr. T. Feijtel	Procter & Gamble	
Prof. H. Greim	Munich Technical University	
Dr. J. Jackson	Monsanto	
Dr. R. Millischer	Atofina	
Dr. A. Sarrif	DuPont de Nemours	
Prof. L. Smith	Syngenta	
Prof. J. Solbé	Unilever	
Dr. G. Swaen	Maastricht University	
Dr. B. van Ravenzwaay	BASF	
Dr. H-J. Wiegand	Degussa	



Prof. H Greim (Munich Technical University) and Dr. C. Braun (Akzo Nobel)



Dr. B. van Ravenzwaay (BASF) and Dr. A. Sarrif (Du Pont de Nemours) at a meeting of the Scientific Committee.

The Scientific Committee held 6 meetings during the year.

Dr. B. Hildebrand (ex BASF) re-joined the Scientific Committee in May 2001, following his appointment as Chairman.

For the first time, in September 2001, three non-company members namely Prof. P. Calow (Sheffield University), Prof. H. Greim (Munich Technical University) and Dr. G. Swaen (Maastricht University), joined the Scientific Committee.

Following retirement from their companies, Prof. J. Solbé (Unilever) and Dr. R. Millischer (Atofina) resigned from the Scientific Committee in December 2001, as did Prof. L. Smith (Syngenta).

Dr. P. Douben (Unilever) joined the Scientific Committee in December 2001.

ECETOC Scientific Committee – Independent Members

Professor Peter Calow, OBE

University of Sheffield, United Kingdom



Scientific Committee Chairman Dr. B. Hildebrand with independent members Prof. H. Greim, Prof. P. Calow, Dr. G. Swaen.

Since 1984 Professor Calow has been Professor of Zoology at the University of Sheffield. He currently holds various senior advisory posts, including Chairman of the UK Government Advisory Committee on Hazardous Substances, member of the Board of Trustees from the Health and Environmental Scientists Institute, council member of the Freshwater Biology Association and member of the Academic Advisory Committee of the University of Buckingham. He is also a member of the EC Scientific Committee on Toxicology, Ecotoxicology and the Environment (SCTEE).

Professor Calow is a member of the External Science Advisory Panel to the Cefic Long-range Research Initiative Task Force (now the Cefic Research and Science Board) and has participated actively in the ECETOC groups that have developed the foundations for the LRI environmental research programme.

Professor Dr. med. Helmut Greim, M.D.

Technical University Munich, Germany

Professor Dr. med. Helmut Greim, M.D. is currently Chairman of Toxicology and Director of the Institute of Toxicology and Environmental Hygiene at the Technical University in Munich.

He has served on a number of professional committees, including the German Society of Pharmacology and Toxicology, and the Board of Experts on the Environment for the Federal Ministry of the Environment. Currently he is Chairman of the German Advisory Committee on Existing Chemicals (BUA) of Gesellschaft Deutscher Chemiker (GDCh), and Chairman of the Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK).

Professor Greim serves as a member of two Scientific Committees of the EC, namely, the SCTEE and the Scientific Committee on Occupational Exposure Limits (SCOEL). He has participated actively in the ECETOC groups that developed the foundations for the LRI chemical carcinogenicity research programme.

**Dr. Gerard Swaen,
University of Maastricht, The Netherlands**

Since 1982 Dr. Swaen has been employed at Maastricht University. He is currently Head of the Occupational Epidemiology Unit of the Department of Epidemiology. Having served as a member since 1986, Dr. Swaen is now Chairman of the Dutch Health Council Committee on the Evaluation of Carcinogenic Substances in Outdoor Air. He is also a member of the Dutch Expert Group on Occupational Standards and of the Permanent Committee on Electromagnetic Fields.

Dr. Swaen regularly serves as an expert in the field of occupational diseases in legal cases.

Member Companies

ECETOC Membership at December 2001:

3M	Henkel
Akzo Nobel	ICI
AstraZeneca	Janssen Pharmaceutica
Atofina	L'Oréal
Ausimont	Lyondell Chemical
Aventis CropScience	Merck
BASF	Monsanto
Bayer	Norsk Hydro
Borax	Novartis
Borealis	Novozymes
BP Chemicals	Perstorp
Ciba Specialty Chemicals	Petresa
Clariant	Procter & Gamble
Coca-Cola	Reckitt Benckiser
Colgate Palmolive	Repsol Quimica
Degussa	Rhodia
Dow Corning	Rohm & Haas
Dow Chemical	Shell Chemicals
DSM	Solvay
DuPont de Nemours	Syngenta
EniChem	Th. Goldschmidt
ExxonMobil Chemical	Unilever
F. Hoffmann-La Roche	Union Carbide
FMC	Wacker Chemie
Fortum	

Task Forces

During 2001, in addition to the activity in the new Task Forces, the ECETOC programme was progressed by the following:

Risk Assessment

- Adverse Versus Non-adverse Effects (Toxicological End-points)
- Marine Risk Assessment
- Risk Assessment Core Group
- Risk Assessment Factors
- Terrestrial Risk Assessment
- Toxicological Mechanisms
- Use of Observational Data
- Exposure Factors Sourcebook
- Environmental Risk Assessment of Difficult Substances
- PBPK Modelling Workshop

Health Effects

- Reproductive Toxicity
- Skin Sensitisation Testing
- Toxicogenomics and Proteomics

Environment

- Aquatic Hazard Assessment II
- Aquatic Toxicity of Mixtures
- Ecotoxicity of Borates
- Persistent Organic Pollutants
- Terrestrial (Soil) Hazard Classification
- Persistence

Specific Substances

- Butanols
- Fluoroalkanes
- Methyl Tert-Butyl Ether (MTBE) Risk Assessment
- Monochloroacetic Acid and its Sodium Salt
- Peracetic Acid
- Synthetic Amorphous Silica
- Tetrafluoroethylene and Hexafluoropropylene
- Cyanides

Finance

Income	Actual 2001 in Euro
Subscription	
Full Members	1,316,000
'New' Members	14,000
Total Subscription Income	1,330,000
Bank Interest	68,956
Document Sales	12,000
Project-related	308,735
Grand Total	1,719,691

Balance sheet and reserves	Actual 2001 in Euro
Balance Sheet	
Income	1,719,691
Expenditure	1,670,269
Operating Margin	49,422
Reserves	
Opening	1,288,111
Operating Margin	49,422
Closing Reserve	1,337,533
Estimated Reserve Required	446,208

Expenditure	Actual 2001 in Euro
Salaries (and related expenses)	1,107,252
Office Running Expenses	204,688
Travel Expenses on Mission	30,045
Meetings and Consultants	230,244
Professional Services	10,669
Bank Charges	3,985
Capital Expenditure	13,140
Publications	46,593
Miscellaneous	23,653
Total	1,670,269

Published by:

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