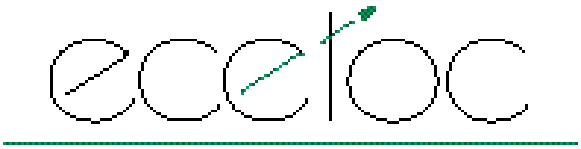


annual report 1997

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

ecetoc
in brief

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), was established in 1978 as a scientific, non-commercial association; it is financed by over fifty companies with interests in the manufacture and 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 scientists from our member companies. The output of our activities is usually in the form of technical reports and monographs reflecting the up-to-date state of the science for the issue under review.

An internal peer-review process has ensured that we have earned recognition and respect by external bodies for scientific integrity. We have become a valued partner with many other organisations and regulatory bodies,such as the WHO (IPCS) and the European Commission,in establishing a scientific foundation for the development of legislation on chemicals.

Message from the Chairman

Achievements

During 1997 ECETOC continued to deliver impressively in all spheres of its activities, including the publication of reports and papers and the organisation of seminars and symposia. In addition the association has not only maintained but has developed further its role in providing representation as a recognised partner with leading international organisations, regulatory groups, academic teams and other industry associations. The further development of such partnerships,which share the common goal of ensuring the responsible management of chemicals, remains a key element of ECETOC's strategy for maximising the effectiveness of scarce specialist resources.

Regulatory activities in the European Union and world-wide moves towards harmonisation continue to amplify the demand for specialised input to ensure that good science underpins developments. Furthermore the demand is not simply for more of the same in respect of expertise. It is also influenced by the increasing complexity of the science stemming from the growth of new "tools" and test systems.In particular scientists face a major challenge in putting into perspective the information which is being generated on mechanistic end-points when there is no definitive evidence of an effect in the target population. This is well illustrated by the issue of endocrine disruption,an area in which ECETOC has again played a key role during 1997.

Two new major activities undertaken in 1997 by ECETOC in conjunction with CEFIC reflect the recognition of ECETOC's scientific leadership for the European industry in the field of health and environmental safety of chemicals.

- ECETOC-CEFIC Joint Seminar on Risk Assessment

This seminar reviewed the experiences of industry with the implementation of the EC Council Regulation on Risk assessment of Existing Substances (793/93). A number of recurring problems were identified for which urgent remedial action was recommended. The Task Force programme was expanded immediately to address these issues.

The European risk assessment process remains a major issue for the industry and will continue to prompt new initiatives for ECETOC.

- CMA-CEFIC Long-range Health and Environmental Research Initiative (LRRI)

Industry is facing ever more searching and challenging questions concerning the potential for chemicals to affect the health of human and wildlife populations and the environment. Acknowledging this the CMA,in alliance with the Chemical Industry Institute of Toxicology (CIIT),initiated a process to define a strategic research programme aimed at reinforcing the relevant areas of health and environmental science.

Joining this initiative in mid-1997,CEFIC commissioned ECETOC to contribute scientific input on behalf of the European sector. Rapidly deploying its network of leading scientists from academia and industry, ECETOC contributed significantly to the successful outcome of the first phase of this initiative, namely the "State of the Science" review. The further implementation of the LRRI within Europe will have a significant impact on ECETOC's future work programme.

Challenges for the future

I have already mentioned two major new activities that will add to the demands on ECETOC to provide scientific leadership for the industry. There will undoubtedly be others. To meet these demands existing partnerships will be strengthened and new ones formed.

Of serious concern is the continuing reduction in specialist resources in the field of health and the environment. Industry faces the challenge of ensuring that this trend does not impair its ability to achieve the responsible environmental management of its activities.

Finally, a key factor in the establishment and retention of ECETOC's reputation for maintaining scientific integrity has been its clear, organisational independence from other more commercially oriented industry associations. It follows that in developing co-operative programmes with such groups,effective and transparent codes of conduct will need to be followed to ensure that ECETOC's organisational integrity is maintained.

Acknowledgements

The main achievements of ECETOC during 1997 are described in more detail in the following pages of this report. We are indebted to the scientists from our member companies, as well as those from other organisations, who contributed to the successful output of our activities.

Thanks are also extended to the Secretariat for its pivotal role in facilitating the teamwork responsible for this success.

J.J. Van de Berg
Chairman,
ECETOC Board of Directors

board of directors

At the Annual General Meeting on 16 April 1997, Mr. J.J. Van de Berg (Solvay), Ir. C. Bronke (DSM), Mr. A. Perroy (Rhône-Poulenc), Dr J. Rudolph (Hüls) and Dr D. Wagnière (Novartis) were re-elected to the Board following expiry of their 2-year mandates.

The Board Composition as of 31 December 1997 was:

CHAIRMAN

Mr. J.J. Van de Berg	Solvay

VICE-CHAIRMAN AND TREASURER

Dr. C.P. Mancel	Procter & Gamble

BOARD MEMBERS

Ir. C. Bronke	DSM
Mr. H. Langballe	Norsk Hydro
Mr. A. Perroy	Rhône-Poulenc
Dr. J. Rudolph	Hüls
Dr. E. Schiff	Novo Nordisk
Dr. D.C. Wagnière	Novartis
Dr. J. Whiston	ICI

Scientific Committee

The Chairman of the Scientific Committee is appointed by the Board for a period of three years, renewable indefinitely, at the discretion of the Board. Ordinary members are appointed by the Board for a period of four years, renewable for a further four years. Appointments to the Scientific Committee are made solely on the basis of scientific contribution.

In February 1997, Dr. P. Gilbert (Unilever) resigned from the Scientific Committee. Dr. J. Solbé (Unilever) was appointed to the Scientific Committee in September 1997

The composition of the Scientific Committee as of 31 December 1997 was:

CHAIRMAN

Dr. W.F. Tordoir	Shell International

VICE-CHAIRMAN

Dr. H. Verschuuren	Dow Europe

MEMBERS

Dr. O.C. Bøckman	Norsk Hydro
Dr. N.G. Carmichael	Rhône-Poulenc
Dr. C. d'Hondt	Novartis
Mr. H.De Henau	Procter & Gamble
Dr. B. Hildebrand	BASF
Dr. J.R. Jackson	Monsanto Europe
Prof. E. Löser	Bayer
Dr. R.J. Millischer	Elf Atochem
Dr. G. Randall	Zeneca
Dr. A.M. Sarrif	Du Pont de Nemours
Dr. J. Solbé	Unilever
Dr. H.J. Wiegand	Hüls

Six meetings of the Scientific Committee were held during the year.

the Secretary General's report

Long-range Health and Environment Research Initiative (LRRI)

CMA and CIIT initiated a process in 1996 to define and mount a strategic research programme on the generic health and environmental issues that could evolve into major concerns or threats to the chemical industry. Under the auspices of CEFIC the European chemical industry joined this major new initiative during 1997.

Several phases of the LRRI process were progressed in 1997. In the first phase agreement was reached on the main topic or issue areas to be included. Those selected were:

- Atmospheric Chemistry
- Chemical Carcinogenesis
- Ecosystem Dynamics*
- Endocrine Disruption
- Environmental and Human Exposure Assessment*
- Immunotoxicity and Allergy*
- Neurotoxicity
- Respiratory Toxicity
- Risk Assessment Methodology

The second phase was the preparation of white papers by leading scientists from industry and academia. In this the "state of the science" was evaluated for each of the nine topic areas and gaps identified that needed to be filled. In the following phase these white papers were subjected to peer review at a US workshop (November 1997) attended by European and US representatives from industry, academia and the regulatory agencies. Following the workshop the white papers were refined,collated as a "State of the Science" report and issued to all involved stakeholders. The report includes more than fifty recommendations for action in the context of long-range health and environmental research.

ECETOC has played a leading role in the process to date, having been commissioned by CEFIC to ensure that the European scientific input was achieved through:

- identification of the three issues to be led by European industry;
- assuming responsibility for the preparation and peer review of the white papers on these three issues;
- identifying appropriate representatives to participate in the US-led white paper teams;
- participation in the critical review of the nine white papers at the November 1997 workshop and in the preparation of the final "State of the Science" report.

The next critical phase of the exercise will be the process to assign priorities to the recommendations for research and to identify a short-list of funding support.

ECETOC, with its established reputation for credibility and scientific integrity, has a unique and important role in the on-going commitment of European industry in advancing the LRRI.

** Issues/topics assigned to ECETOC*

Relationships with Other Organisations

European Commission - DGV

The Occupational Health and Hygiene section of DGV has established an ongoing programme deriving occupational exposure limits (OELs) for a wide range of substances. The process employed for generating these limits involves the review of relevant data by a scientific expert group now termed SCOEL (Scientific Committee for Occupational Exposure Limits to Chemical Agents).

ECETOC has in the past provided input in the form of draft criteria documents on such substances as butoxyethanol,1,3-butadiene, styrene and hydrogen peroxide.

During 1997,ECETOC submitted a report to DGV on 1,3-butadiene (Special Report No. 12) which incorporated the latest data from more-extensive epidemiology and mechanistic studies as a basis for limit setting and a report on hydrocarbon solvents (Special Report No. 13) which proposed a methodology for assigning OELs to such mixtures.

European Commission - Joint Research Centre/European Chemicals Bureau (ECB)

ECETOC's interaction with ECB is mainly in the context of the EC Regulation (793/93/EEC) on the Risk Assessment of Existing Substances. Indeed ECETOC representatives participated in all five of the Technical Meetings convened in 1997 to progress the risk assessment programme. ECETOC's input was confined to generic rather than compound-specific aspects of the process and was underpinned by liaison with the ECETOC Task Forces who are developing further the methodologies of risk assessment.

In addition ECETOC is represented on the ECB EUSES Working Group, which had its first meeting on 22-23 October 1997, and on the ad hoc Working Group on Risk Characterisation for Carcinogenic Substances.

At a meeting held at Ispra (15-21 October 1997) of the Working Group on the Classification and Labelling of Dangerous Substances,ECETOC was represented for discussion of the Swedish proposed "fourth" category of classification.

ECETOC is involved with ECB in the Fate and Activity Modelling of Environmental Pollutants Using Structure-Activity Relationships (FAME), an EU project aimed at the development and validation of QSARs to be used in connection with priority setting and,to a lesser extent, for risk assessment of substances in the context of EU legislation. It is co-ordinated by the Research Institute of Toxicology of Utrecht University (RITOX). ECETOC is a sub-partner of the co-ordinator of the project in which other partners are the German Fraunhofer Institute for Environmental Chemistry and Ecotoxicology, the Dutch National Institute of Public Health and Environmental Protection,the Swedish Research Group for Chemometrics of the University of Umea,and ECB.

The prime role of ECETOC in FAME is that of advisor particularly concerning application and

validation of QSARs. During 1997,ECETOC has worked towards facilitating access to high-quality data sets which can support the development of QSARs.

European Commission - ECVAM

ECETOC continues to be represented by Dr. P. Botham (Zeneca) on the Advisory Scientific Committee (ESAC) of the European Centre for the Validation of Alternative Methods (ECVAM). ECVAM was established in 1992 in response to Article 23 of Directive 86/609/EEC with the goal of promoting the scientific and regulatory acceptance of alternative methods which were of importance to the biosciences and which reduced, refined or replaced the use of laboratory animals. The aims of ECVAM are wide-ranging and not solely related to toxicity testing although to date activity has focused on that area.

OECD

ECETOC has continued to maintain close, co-operative links with OECD and its programme of activity in relation to test-method development (toxicology and ecotoxicology) and risk assessment. Input from ECETOC is made through the consultation process established by OECD in respect of the Test Guidelines programme both in terms of submission of written comment and in nomination of suitably qualified experts to serve on the working groups.

During 1997,ECETOC member companies were invited to comment on a wide range of topics and test-guideline proposals including the following:

- Guideline 211 (update): *Daphnia magna* Reproduction Test
- Guideline: Fish, Toxicity on Egg and Sac-fry
- Guidelines: Terrestrial Plant Testing (including Guideline 208 update)
- Draft Detailed Review Paper: Appraisal of Test Methods for Sex-hormone Disrupting Chemicals
- Guideline: Dermal Irritation in Human Volunteers
- Working Group on Avian Reproductive Toxicity
- Guideline:Fish, Juvenile Growth Test
- Guideline:Aerobic and Anaerobic Transformation in Soil

In addition, nominated representatives from ECETOC participated in co-ordination groups such as the Risk Assessment Advisory Board (RAAB) and as observers in various workshops including the following:

- Technical Working Group on Hazard Classification and Labelling for the Aquatic Environment,10-11 March 1997.

World Health Organization

In 1996 ECETOC was admitted into official relations with the World Health Organization (WHO) as a Nongovernmental Organization (NGO).

This public acknowledgement of the fact that both organisations share the goal of protecting health and the environment from the adverse effects of chemicals was earned as a result of many years of close collaboration between ECETOC and various WHO bodies, notably IPCS.

International Programme on Chemical Safety (IPCS)

ECETOC continues to work closely with the IPCS in its various programme areas. As with all ECETOC representation in external meetings, selection of suitably-qualified and experienced scientists is through a procedure which involves the Scientific Committee. Where possible such representation is undertaken by the Chairman or member of an ECETOC Task Force that has been dealing with the topic in question. In all cases the importance of maintaining ECETOC's scientific integrity through such participation is emphasised in briefings before the event.

IPCS Environmental Health Criteria (EHC) Document Programme

During the development of the IPCS EHC documents, ECETOC provides comment and data through the consultation process and, in most cases,a specialist representative to participate as an observer in the IPCS Task Group meeting to finalise the EHC.

During 1997, ECETOC participation in the EHC programme included:

Methyl tertiary butyl ether (MTBE):IPCS Task Force meeting,Ottawa,Canada, on 17-21 March 1997. Dr. A.Mallett (Arco) representing ECETOC.

Scientific Principles and Methods for Assessing Allergic Hypersensitisation Associated with Exposure to Chemicals: IPCS Task Group meeting,Bilthoven,The Netherlands on 8-12 September 1997. Dr. D. Basketter (Unilever) representing ECETOC.

Scientific Principles and Methods for Assessing Respiratory Tract Injury Caused by Inhaled Substances: IPCS Task Group meeting,Bilthoven,The Netherlands on 13-17 October 1997. Dr. A. Gamer (BASF) representing ECETOC.

Acetone: IPCS Task Group meeting, Carshalton, United Kingdom on 1-5 December 1997. Dr. D. Owen (Shell) representing ECETOC.

IPCS Concise International Chemical Assessment Documents (CICADs) programme

IPCS launched this new series of chemical assessments in 1996. The purpose of these new documents is to accelerate the progress of the review of chemicals within the IPCS programme through a process designed to minimise the effort required compared with the EHC programme. To do this is a new format has been proposed in which the review is more focused on the defined lead effects of the chemicals.

A further saving of resource comes from the practice of utilising already existing reviews taken from reliable sources such as those produced by regulatory authorities. ECETOC is involved in the initial consultation and review of draft CICADs and participates in the final review board meetings and in the Steering Group with experts from academia and national authorities.

During1997, ECETOC participation in the CICAD programme included:

Steering Group for CICADs,London, United Kingdom on 15-17 September 1997. Dr. F. Carpanini represented ECETOC.

Final Review Board on CICADs, Berlin, Germany on 26-28 November 1997. Dr. R. Ebert (Hüls) represented ECETOC.

CICADs were reviewed for the following chemicals:1,1,1,2-tetrafluoroethane, 2-butoxyethanol, manganese, triglycidylisocyanurate, N-phenyl-1-naphthylamine.

WHO Working Group Meeting on Chemical Substances in Drinking Water

Dr. M.Richold (Unilever) represented ECETOC at this working group meeting held at WHO Headquarters,Geneva on 22-26 April 1997. The meeting was convened by the unit of Urban Environmental Health (UEH) in co-operation with the International Programme on Chemical Safety (IPCS) to finalise a set of health criteria documents for the chemicals selected at the Co-ordinating Committee meeting for the Updating of WHO Guidelines for Drinking-water Quality, Geneva, December 1995.

International Agency for Research on Cancer (IARC)

ECETOC has established a long-standing relationship with IARC, receiving an invitation to nominate an observer at each of the meetings of experts convened from time to time to evaluate specified chemicals in respect of their carcinogenicity to man.

In 1997,Dr. L. Bloemen (Dow) was appointed as the ECETOC observer for the IARC Working Group Meeting for the Evaluation of Carcinogenic Risks to Humans of Dibenzo-p-dioxins and Polychlorinated Dibenzofurans, Lyon,France, on 4-11 February.

PRESENTATIONS

ECETOC Annual Technical Meeting, Brussels, Belgium

The Annual Technical Meeting was held at Le Meridien Hotel, Brussels on 25 November 1997.

Entitled "Demands of today – Challenges of Tomorrow" the programme was divided into two parts, the first devoted to the work underway in ECETOC Task Forces addressing aspects driven by the regulatory demands of classification and risk assessment of chemicals. The benefits of establishing scientific consistency for both classification and risk assessment were illustrated and led to a call for the establishment of a network of qualified specialists in industry to support these activities.

In the second part, the origins and goals of the Long-range Health and Environmental Research Initiative (see page 6) were outlined and the possible implications for ECETOC and the industry debated.

ECETOC-CEFIC Joint Seminar and Workshop on Risk Assessment "Experiences and Challenges"

The main objective of the joint seminar, which took place on 17 April, was to provide a forum for the chemical industry to exchange experiences on "successes and failures" arising from its contribution to the implementation of the EC Council Regulation on Risk Assessment of Existing Substances (793/93).

The main messages and conclusions of the seminar were reviewed on the following day (18 April) in a joint workshop, the aim of which was to identify opportunities for improvement of the process both in terms of its speed of progress and quality of output. Of the five syndicates formed to progress the workshop, two were led by ECETOC and were dedicated to the scientific aspects of the human and environmental risk assessment components. These syndicates examined the opportunities for industry to be more proactive while at the same time maintaining a sound scientific foundation, thus improving the outcome and speed of the process. Many of the problems were identified as arising from inexperienced assessors and their uncertainties in interpretation and extrapolation of data. This often resulted in requirements for unnecessary additional testing and excessively low exposure limits. However, the lack of scientific/technical resources in industry to challenge these demands was also clearly signalled and the need for this to be urgently addressed was highlighted.

To address the needs specified, ECETOC was requested to commission several new Task Forces. Those initiated in 1997 on generic issues included Toxicological Mechanisms, Envirionmental Monitoring and Terrestrial Risk Assessment (see pages 16 and 17 for further details). It is anticipated that further Task Forces related to the risk assessment process will be initiated during 1998.

ECETOC Workshop on Genetic Polymorphism

It has long been recognised that human beings are all different and that similar differences are to be found in non-human populations. For

many years there has been debate as to the extent to which such differences result from "nature/genetic constitution" or from "nurture" (i.e. social upbringing and education). Recent advances in genetics,particularly molecular genetics,biochemistry and cell biology, allow detailed study of the specific contributions of genetic variants (genotype) and their corresponding expressions in the intact individual (phenotype) and of the structure and function of individuals and their susceptibility to disease. As a result,human variability is beginning to be described in terms of genetic polymorphism. In view of these advances it seemed timely for ECETOC to hold the above exploratory workshop on 16 January 1997.

The workshop reviewed the impact that genetic polymorphism was likely to have on experimental design in toxicology and on chemicals risk assessment and management. Questions posed included to what extent these factors could be taken into account at present and whether there might be a requirement to include in the future this branch of science in the management of risk from exposure to industrial chemicals.The main issues were presented at an open meeting on 16 January. An ECETOC members' discussion the following day resulted in a recommendation to set up an ECETOC Ad Hoc Group to look into the topic. (See page 16 for further details)

Conference Target 2000

The target referred to is the reduction of animal experimentation by 50% by the year 2000.On behalf of ECETOC, Dr. P. Botham (Zeneca) attended a meeting in Brussels on 14/15 April 1997 which was organised on behalf of EC DGXI to discuss progress.

Significant progress had been made in some countries,such as the UK and Germany, taking as reference points 1986 or 1989. A major contribution to these reductions has come from the pharmacuetical and efficacy testing areas where high-throughput screening and the development of transgenic animal models, for example, are leading to significant downward trends. From the regulatory point of view, the harmonisation and rationalisation of toxicity testing is expected to have some beneficial effect in reducing the numbers of animals used in safety assessment. Significant progress has also been made in the refinement of experimental procedures to reduce pain and suffering, for example in developing tiered testing schemes for irritation and corrosion.

Although the meeting succeeded in giving clear and realistic messages to those members of the EC and European Parliament that their expectations for significant further reduction of animal use were now being better managed,it was considered unlikely that it would have diminished the political pressure for further targets in animal reduction.

Sixth Meeting of the International Neuro-toxicology Association, Szeged, Hungary

Two presentations,under the titles of "Organophosphorus Pesticides and Long-term Health Effects" and "A Critical Review of the Hazard Identification of Organophosphorus Pesticides", were made by Dr. W. Classen (Novartis),at the above international meeting, held in Hungary (29 June-4 July 1997). As a member of the ECETOC Task Force on Organophosphorus Pesticides and Long-term Health Effects,Dr. Classen highlighted the views and interim conclusions of the Task Force, particularly in respect to the lack of evidence supporting the so-called "chronic syndrome".

The presentations stimulated lively debate and the views put forward received support from the audience. The feed-back will be incorporated into the final output of the TF in its report planned for publication in 1998.

Japan Chemical Industry Ecology-Toxicology & Information Center (JETOC) Tokyo and Osaka, Japan

At the invitation of JETOC, Dr. F. Carpanini (ECETOC) delivered presentations under the title of 'ECETOC-Sound Science for Responsible Management of Chemical Safety' to seminars held in Tokyo (22 July 1997) and Osaka (24 July 1997) and attended by representatives from JETOC and its member companies.

In addition to giving an account of the ECETOC organisation and its operating practices, Dr Carpanini outlined the history of the chemical safety regulations in Europe and their continuing evolution within the framework of EEC Regulation 793/93.The presentations concluded with a review of the priority health and environmental issues facing the chemical industry in Europe and ECETOC's plans to address them.

Follow-up meetings with Japanese industry and Government officials enabled an in-depth discussion of specific topics of mutual interest including the EC risk assessment process, endocrine disrupters and the emerging LRRI.

Japan Bioassay Research Center, Hirasawa, Japan

Dr. F. Carpanini (ECETOC) visited the Japan Bioassay Research Center on 30 July 1997. In an exchange of information with the Director, Dr. Matsushima,and his team,Dr Carpanini presented an overview of ECETOC and its work programme. The presentations were followed by a review of the laboratory facilities which were originally founded by the Japan Ministry of Labour.

Conference. The Challenges of Responsible Risk Manage-ment, Brussels, Belgium

Mr. A. Moses,Chairman of a previous ECETOC Task Force on Assessment Factors in Human Health Risk and Assessment, represented ECETOC at the above conference held on 6/7 October 1997. In the conference session on "Toxicology and Risk Analysis" he delivered a presentation on inter- and intra-species variation and the application of considerations thereof in risk analysis.

PUBLICATIONS

The following ECETOC reports were published in 1997

NO.	MONOGRAPHS
27	Aneuploidy

NO.	TECHNICAL REPORTS
55	Pulmonary Toxicity of Polyalkylene Glycols
72	Methyl tert-Butyl Ether (MTBE). Health Risk Characterisation
73	The Value of Aquatic Model Ecosystem Studies in Ecotoxicology

NO.	SPECIAL REPORTS
11	Ecotoxicology of Some Inorganic Borates (Interim Report)
12	1,3-Butadiene OEL Criteria Document (2nd Edition)
13	Occupational Exposure Limits for Hydrocarbon Solvents

NO.	DOCUMENTS
34	The Challenge Posed by Endocrine-disrupting Chemicals
35	Exposure Assessment in the Context of the EU Technical Guidance Documents on Risk Assessment of Substances
36	Comments on OECD Draft Detailed Review Paper: Appraisal of Test Methods for Sex-hormone Disrupting Chemicals
37	EC Classification of Eye Irritancy

EXTERNAL PUBLICATIONS

Development of a Geographically-referenced Regional Assessment Tool for European Rivers - GREAT-ER. Contribution to GREAT-ER 1. Feijtel T.C.J. et al.(1997) Chemosphere, 34, 2351-2374

The Challenge posed by Endocrine-disrupting Chemicals. Ashby J.et al. (1997) Environmental Health Perspective, 105, 164-169

TASK FORCES

Ongoing Task Forces

During the course of the year, work was progressed by the following Task Forces:

- Acrylates and Methacrylates:Methacrylates OEL Criteria Document;Methyl Acrylate; Polyfunctional Acrylates and Methacrylates
- Aneuploidy
- Aquatic Hazard Assessment II
- Aquatic Model Ecosystem Studies in Ecotoxicology
- Aquatic Toxicity of Mixtures
- 1,3-Butadiene - OEL Criteria Document
- 1,3-Butadiene Risk Assessment
- Dermal Exposure Liaison Group
- ECIMOS (ECETOC Integrated MOdelling System)
- Ecotoxicity of Borates
- Environmental Oestrogens
- EU Classification of Eye Irritancy
- EU Working Group Uses 2.0
- Exposure Modelling
- GREAT-ER (Geography-referenced Regional Exposure Assessment Tool for European Rivers)
- Human Data for Classification Purposes
- Methyl Tertiary-Butyl Ether (MTBE)
- Mutagenesis :Threshold-mediated Mechanisms
- OELs for Hydrocarbon Solvents
- Organophosphorus Pesticides and Long-term Health Effects
- Perchloroethylene
- Polyalkylene Glycols (PAG)
- Reproductive Toxicity
- Quantitative Structure Activity Relationships (QSAR) in Ecotoxicology
- Skin and Respiratory Sensitisers: Reference Chemicals Data Bank
- Skin Notification. Verification
- Terrestrial (Soil) Hazard Classification
- Toxic Effects of Dusts

New Task Forces

During the year new Task Forces were established in relation to the following issues:

- Butanols

Since the last comprehensive review of these substances by IPCS in 1987, new data have become available, in particular on iso-butanol. Driven by forthcoming EU/OECD risk assessment activities,interested member companies are supporting a comprehensive review of the available data towards the preparation of one or more JACC report(s).

The standard JACC format is to be adapted and expanded to be directly applicable to the risk assessment processes.The report(s) will also address the setting of appropriate occupational exposure limits.

- Environmental Monitoring

One of the major concerns of risk assessors is the generation of acceptable and realistic environmental exposure data. Although much work has been done to develop generic models to predict environmental concentrations,the use of measured data to support both risk assessments and model validation suffers from the lack of agreement over what are good quality monitoring data.This issue has been recognised by OECD, which is organising a workshop in 1998. A Task Force was initiated to address what constitute quality data,how many data (spatial and temporal) are required and what are representative data,in time to make a constructive contribution to the workshop.

- Genetic Polymorphism

A need was identified at the follow-up meeting to the ECETOC Workshop on Genetic Polymorphism (16 January 1997) for an objective review of the available evidence that genetic polymorphism (GP) might be an important determinant of the sensitivity of humans to the effects of chemicals.

As a first step, the Scientific Committee appointed an ad hoc Group to review the available evidence and formulate recommendations on what further steps should be taken by ECETOC in this field. Aspects to be considered by the ad hoc Group include evaluation of existing experimental measurement and testing techniques in providing reliable information on GP of relevance in risk assessment and the utility at present of building GP into risk assessment and risk management.

- Methyl *tert*-Butyl Ether (MTBE)

MTBE is included on the third priority list for risk assessment under Council Regulation EEC/793/93 and a EC risk assessment document is to be prepared by the Finnish Environment Institute.

In response to requests from interested member companies and the CEFIC European Fuel Oxygenates Association (EFOA), a Task Force was appointed with a remit to interact positively with the EC risk assessment Rapporteur providing support wherever possible.

Drawing initially on the recently published ECETOC Technical Report No 72 (MTBE Health Risk Characterisation),the Task Force will

endeavour to identify relevant critical health and environmental data, and prepare a written summary risk assessment as a foundation for its interaction with the authorities

- Monochloroacetic acid and its Sodium Salt

Monochloroacetic acid (MCAA) is included on the third priority list in relation to Council Regulation 793/93 on the risk assessment of existing chemicals. An EC risk assessment will thus be undertaken soon.

In the absence of a comprehensive up-to-date review of the health and environmental effects of MCCA, interested member companies requested the appointment of a Task Force to prepare an expanded JACC report which could form the basis of industry input to the EC risk assessment process.

The agreed objectives of the Task Force also include the preparation of a paper (for publication in a scientific journal) on the dangers of serious delayed intoxication following absorption of MCAA through the skin.

- Peracetic Acid

A risk assessment for peracetic acid will be required under the (proposed) EC Biocidal Products Directive 97/C/69/03.

In the absence of a comprehensive up-to-date review of the health and environmental effects of peracetic acid, interested member companies in conjunction with of the CEFIC Peroxygens Sector Group requested the appointment of a Task Force to prepare an expanded JACC report. It is planned that the final report will provide the basis for scientific input to the risk assessment and will embody the setting of an appropriate occupational exposure limit.

- Terrestrial Risk Assessment

The EU approach to risk assessment of chemicals is detailed in the Technical Guidance Documents,which were published in 1996. The scientific basis for this and other risk assessment schemes for the soil and sediment compartments requires much closer consideration.

In establishing this Task Force, the Scientific Committee reflected on the experiences reported by scientists involved in the EC risk assessment activity. In preparing its review and formulating guidance on the assessment of risk to the soil and sediment compartments the Task Force will address,in particular, the key issues of bioavailability, sorption and desorption, persistence, routes of exposure and suitable test methods.

- Toxicological Mechanisms*

By and large, toxicological data derived from experimental animals provide a reliable indication of potential effects in humans. There are, nevertheless,a significant number of examples where comprehensive data on the mechanisms of toxicity in animals allow us to conclude that some of these effects have little or no relevance to humans.

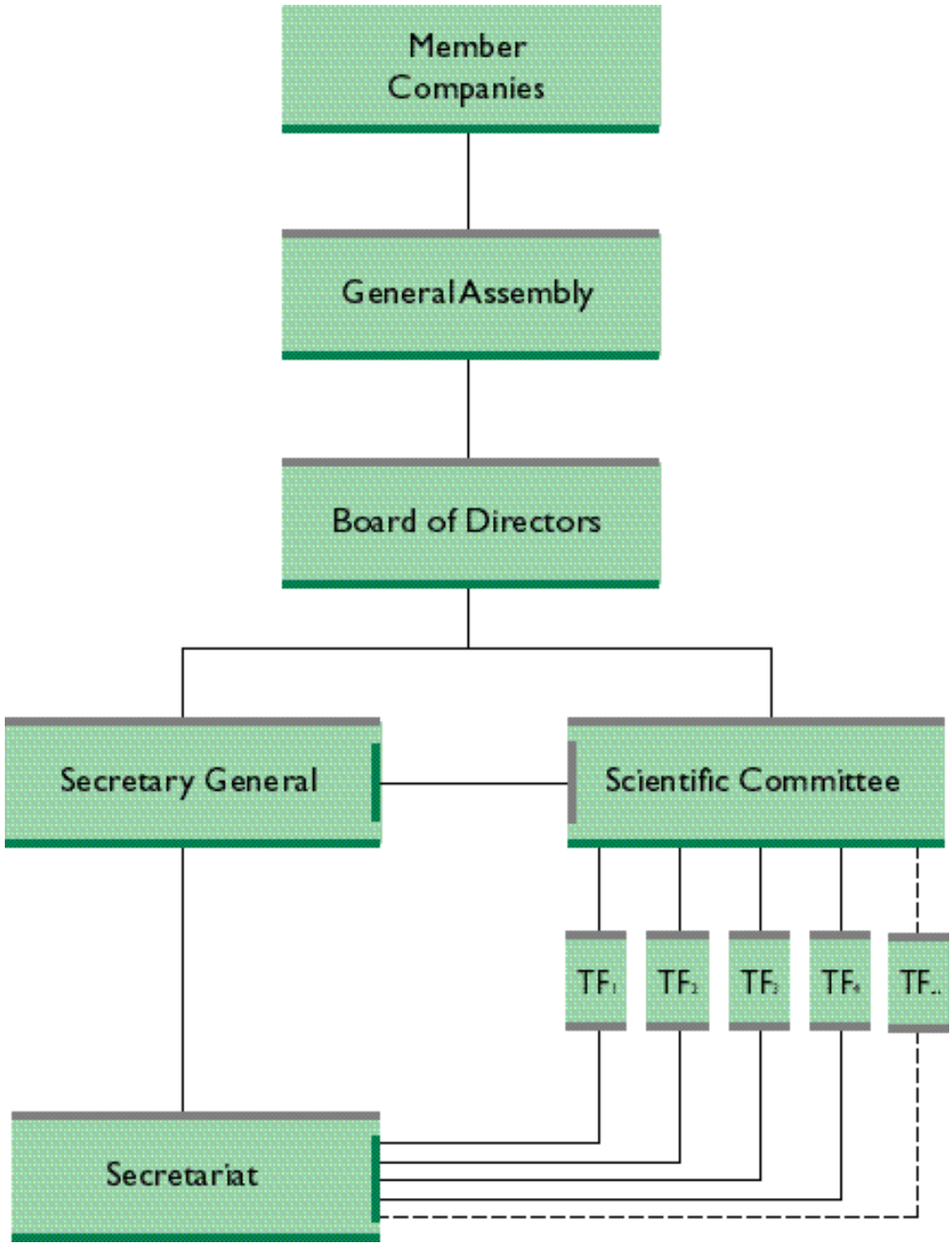
If these examples are not taken into account, the outcome of risk assessments based on the data taken at face value are likely to be highly conservative and misleading,a situation of particular concern for those involved in the EC Risk assessment activities.

** Full title:Criteria for Evaluating the Relevance of Toxicological Mechanisms in Rodent Models to Predict Human Risk*

The Scientific Committee, recognising the pressing need for guidance on this fundamental aspect of hazard characterisation (a critical component of any risk assessment process), appointed a Task Force to develop such guidance, illustrated with suitable examples. The report would be aimed at providing assistance to those scientists faced with evaluating experimental animal data in the context of risk assessment.

Organisation and Membership

ECETOC Organisation



ECETOC Modus Operandi

Board

ECETOC operates 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 finance of the association.

Scientific Committee

Crucial to the success of ECETOC in establishing and maintaining its authority and reputation as a source of sound scientific information and judgement, is its Scientific Committee. Composed of fifteen top industry scientists (mainly toxicologists, ecotoxicologists and physicians) the Committee is appointed by the ECETOC Board. Members are selected on the basis of their proven scientific expertise, thereby underpinning their role of assuring sound scientific standards and quality.

The Scientific Committee is responsible for the definition,management and peer review of the ECETOC work programme. A major part of this work programme is the production of ECETOC publications by Task Forces appointed by the Scientific Committee.

Task Forces

ECETOC publications are produced by Task Forces composed of appropriate experts drawn from member companies and other organisations as required. Although all member companies have the opportunity to nominate members to the Task Forces, their final composition is subject to endorsement by the Scientific Committee, taking into account the range of skills required to address the selected topic. The work of the Task Force follows the Terms of Reference established by the Scientific Committee and is directed by a Chairman who is appointed to the task by the Scientific Committee. Most but not all Task Force activities result in one or more ECETOC publications. The specific objectives of the other projects undertaken by Task Forces vary, and frequently involve activities with other organisations.

Secretariat

The Board, Scientific Committee and Task Forces are supported and assisted in their activities by a small team of scientists with administrative support,led by the Secretary General. Further details of ECETOC staff members are given on page 22.

Programme Selection

A topic for consideration by ECETOC may be proposed by any member company or any other organisation whether trade association, academia or regulatory authority. For the proposal to be progressed it must be supported by at least two member companies; in addition it must be judged to meet the scientific standards required by the Scientific Committee. Provided these criteria are met,specific Terms of Reference are drawn up and endorsed by the Scientific Committee prior to selection of Task Force members.

Publications

The main output of ECETOC's Task Force activities is the publication of a range of reports varying in scope from the 'JACC (Joint

Assessment of Commodity Chemicals)' reports on specific chemicals to 'Monographs',dealing with the fundamental principles underlying the various branches of science in toxicology and ecotoxicology.

All reports are published following peer review by the Scientific Committee and copies are sent to all member companies and to other interested parties, such as the various regulatory authorities, international organisations and academic groups, for use as required.

Representation

ECETOC regularly receives invitations to send representatives and observers to a variety of fora,such as the IPCS,OECD, IARC and the EU Commission groups,where the health and environmental effects of chemicals are discussed and evaluated.

Workshops and Seminars

Workshops and seminars are convened, often in partnership with other interested parties and groups,in order to develop and communicate understanding and counsel on the key issues affecting the responsible environmental management of chemicals.

Dr. F.M.Carpanini

ECETOC SECRETARIAT

As of December 1997 staff employed were:

Dr. F.M.Carpanini	Secretary General
Mrs.M. Butler	Scientific Officer
Mr. M.Holt	Scientific Officer
Ir. H.Vrijhof	Scientific Officer
Dr. H.J.Niessen	Scientific Officer (part time)
Mrs.M. De Mesmaeker	Office Manager
Miss N.Devos	Secretary
Miss A.Ngoy	Secretary
Mrs.A. Siroux	Publications Officer

ECETOC MEMBERSHIP

During 1997, Ciba Speciality Chemicals and Janssen Pharmaceutica joined ECETOC as new members;Novartis joined as a full member.

Veba Oel resigned its membership with effect from 31 December 1997.

Member Companies at December 31st 1997 :

MEMBERS	YEAR OF JOINING
3M	1993
AKZO NOBEL	1978
ALBRIGHT & WILSON	1978
ARCO CHEMICAL	1985
AUSIMONT (MONTECATINI)	1996
BASF	1978
BAYER	1978
BENCKISER (MIRA LANZA)	1996
BOEHRINGER INGELHEIM	1980
BORAX	1995
BOREALIS	1994
BP CHEMICALS	1978
CIBA SPECIALITY CHEMICALS	1997
COCA-COLA	1996
COLGATE-PALMOLIVE	1979
DEGUSSA	1978
DOW CORNING	1990
DOW	1978
DSM	1978
DU PONT DE NEMOURS	1990
ELF ATOCHEM	1978
ENICHEM	1978
EXXON CHEMICAL	1978
FINA	1987
FMC	1996
HENKEL	1978
HOECHST	1978
HOFFMANN LA ROCHE	1978
HÜLS	1978
ICI	1978
JANSSEN PHARMACEUTICA	1997
L'OREAL	1987
LONZA	1987
MERCK	1978
MONSANTO	1978
NESTE OY	1987
NORSK HYDRO	1978
NOVARTIS (CIBA-GEIGY, SANDOZ)	1978
NOVO NORDISK	1991
PERSTORP REGENO	1996
PETRESA	1987
PROCTER & GAMBLE	1978
RHÔNE-POULENC	1978
ROHM & HAAS	1980
SHELL CHEMICALS	1978
SOLVAY	1978
STATOIL	1990
TH.GOLDSCHMIDT	1988
UNILEVER	1978
UNION CARBIDE	1995
VEBA OEL	1978
WACKER CHEMIE	1978
ZENECA	1993

finance

INCOME	ACTUAL 1997 BF
Subscriptions	
Full Members	54,000,000
New Members	1,875,000
Total Subscriptions	55,875,000
Bank interest	1,084,664
Document sales	563,672
Project-related	739,157
GRAND TOTAL	58,262,493

EXPENDITURE*	ACTUAL 1997 BF
Salaries	33,227,999
Office	10,252,261
Travel	858,540
Meetings and consultants	2,916,227
Publications	1,947,460
Professional services	404,611
Bank charges	133,284
Capital expenditure	726,910
Miscellaneous	1,154,287
TOTAL	51,621,579

** The expenditure figures shown cover the administrative costs of the ECETOC offices, Secretariat and meeting arrangements. They do not take into account the costs of resources provided by Member Companies in terms of project related expenditure or the in-put of Task Force members and external representation.*

BALANCE SHEET AND RESERVES	ACTUAL 1997 BF
Balance sheet	
Income	58,262,493
Expenditure	51,621,579
Operating Margin	6,640,914
Reserves	
Opening	24,570,261
Operating Margin	6,640,914
Staff Commitments	(675,580)
Closing Reserve	30,535,595
Reserve Required	18,500,000

Published by:
European Centre for Ecotoxicology and Toxicology of Chemicals
Av E Van Nieuwenhuyse 4,1160 Brussels
Tel +32 2 675 36 00 Fax +32 2 675 36 25
E-mail:info@ecetoc.org