

eceloc

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# annual report 2002

achievement through partnership

25 years

## vision and mission

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**Vision**

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

**Mission**

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

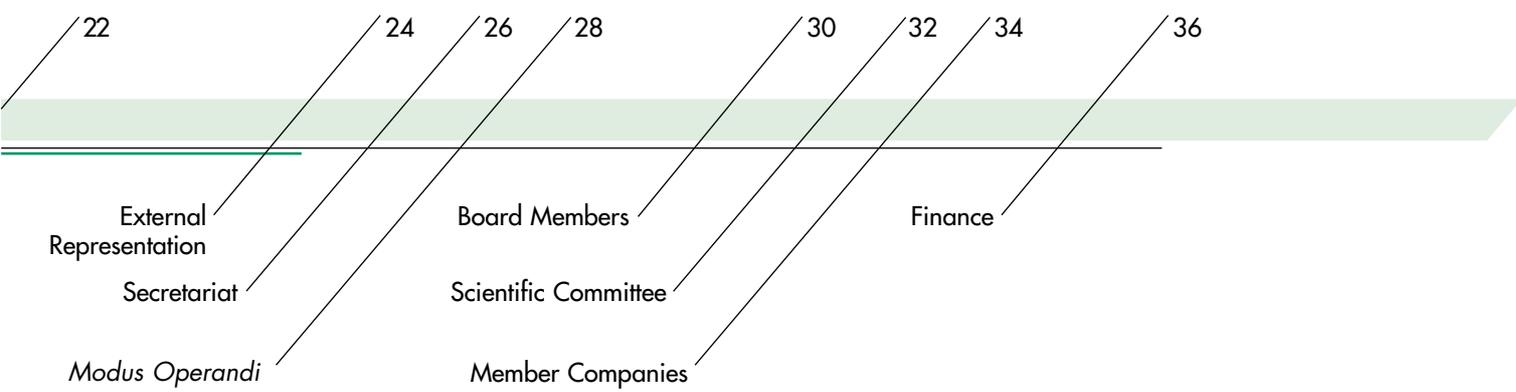
**Strategy**

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

# table of contents



Vision and Mission	2	ECETOC 1978 – 2003. An Evolution	8	Task Forces	12	ECETOC Outputs	18
Introduction	6	Overview – Secretary General	10	Long-range Research Initiative	14		
Achievement Through Partnership		EC White Paper on chemicals policy					



# introduction

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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 downstream 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.



## achievement through partnerships

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### Message from the Chairman

*Peter Peschak*

As we enter the 25th Anniversary of ECETOC, we can reflect with pride on the achievements of our organisation. Thanks to the ongoing contribution of our scientists, ECETOC is widely recognised and respected for its scientific integrity. This has allowed us to work with organisations, both inside and outside our industry, that share our goal of developing scientific consensus towards a better understanding of the impact of chemicals on health and the environment.

The overall theme of our Jubilee Year is "Scientific Achievement Through Partnerships", which highlights the many examples of the alliances and joint efforts that now typify our working practices. These partnerships form the cornerstone for our Jubilee Year programme, which will include a series of science workshops.

In 2002, major progress was made in developing a clear vision and direction to enable ECETOC to continue to support industry and the regulators in achieving their goals; meeting the highest standards of integrity of industrial operations and the manufacture of products safe for their intended use. Reaching scientific understanding and developing appropriate methodologies to achieve these goals, will only be possible if experienced practitioners and specialists from our member companies, academia, regulatory agencies and other industry groups work together. Such goals are consistent with those described in the EC White Paper on chemicals policy.

It is important that ECETOC continues to look ahead and ensures that it provides its members and other stakeholders with the support needed to meet the ongoing demands of our industry. With this in mind, throughout 2002 the Board and Scientific Committee have actively examined all aspects of ECETOC activities, its working practices and the issues that it may have to confront over the next three to five years. One outcome of this process is the new Vision and Mission statement for ECETOC (see page 3). It reaffirms our commitment to science as central to all our activities. It also reflects our aspiration to support the broad constituency of upstream and downstream companies that are represented by our membership.

The participation of ECETOC science teams in Cefic's Long-range Research Initiative programme (LRI) is another major partnership activity, which continues to be of both substantial effort and success. Our ongoing commitment to this programme will ensure that the network between industry scientists and their peers in academia and in regulatory agencies

will continue to be further strengthened. The new Mission also reflects the importance that ECETOC places in contributing to such research initiatives.

### **The Challenge**

The demand for science to develop effective tools to evaluate the hazards and risks of chemicals to humans, and to the environment, will continue to grow. The evolution of new technologies, such as genomics and alternative testing methods, offers opportunities in this respect. In addition, complex political issues, including children's health and the use of animal's in testing, will need to be addressed from a scientific viewpoint.

Against this background, the continued consolidation and re-structuring of our industry will further reduce, and geographically disperse, the industry's pool of scientific expertise. This decline in specialists is not however confined to industry, and as a consequence there must be even stronger emphasis placed on the development of strategic alliances with other stakeholders, in order to achieve our goals. In the long term, this alone is unlikely to be sufficient to satisfy requirements. Consideration must be given to establishing a concerted strategy to attract and develop appropriate scientific experts, so that society can continue to enjoy the many benefits of our industry without unwarranted risk to man or our environment.

### **Acknowledgements**

The main achievements of ECETOC during 2002 are described in the following pages of this report. The Board of ECETOC is grateful to the scientists from our member companies, as well as those from other organisations, who have contributed to the success of ECETOC's programme.

Finally, I wish to express my gratitude to the Secretariat, who have supported and facilitated the teamwork that has led to ECETOC's success over the past 25 years.



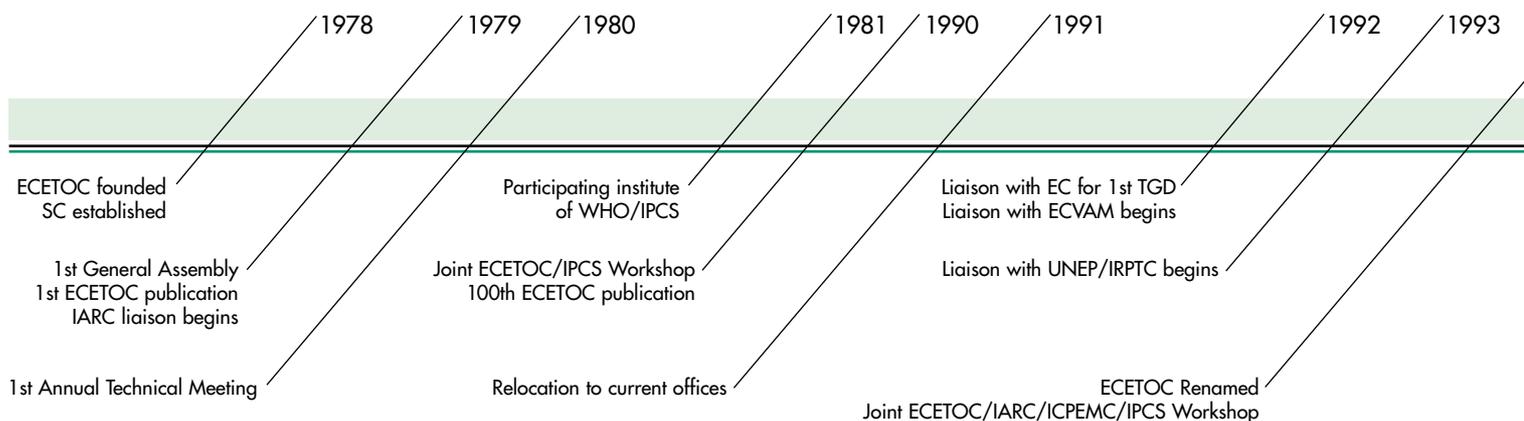
Peter Peschak  
Chairman  
ECETOC Board of Directors

## ecetoc 1978 - 2003, an evolution

ECETOC – originally constituted as the European Chemical Industry Ecology and Toxicology Centre – was founded in 1978 as a scientific, non-commercial organisation.

ECETOC was founded in 1978 as a scientific, non-commercial organisation. Its mandate was to procure, apply and distribute scientific knowledge to help identify, evaluate and minimise potential adverse effects on health and the environment, which might arise from the manufacture and use of chemicals. A Scientific Committee (SC) comprising leading industry scientists in the field of health and environmental sciences was appointed to direct and peer-review the work programme and outputs of the organisation. This pivotal role of the SC continues today.

Acting as a focal point for the considerable specialist expertise that then existed in the member companies, ECETOC began building its scientific credentials with the preparation of critical reviews, guidance documents and issue papers, embracing the fundamental aspects of toxicology and ecotoxicology and their interpretation and extrapolation to effects in humans and the environment. The first Monographs, published in the early 80's, dealt with the complex issue of chemical carcinogens. A steady stream of publications followed covering other aspects such as mutagenicity, reproductive toxicity,



neurotoxicity, skin sensitisation, and respiratory allergy. In parallel, in the environmental sciences, the first report on photo degradation of chemicals in the environment was followed by others dealing with aspects such as atmospheric and aquatic photo transformation, biodegradation and bioaccumulation.

By 1990, ECETOC had published no fewer than 100 reports and was recognised officially by the WHO International Programme on Chemical Safety (IPCS) and the International Agency for Research on Cancer (IARC). Liaison with these and other agencies, such as the European Chemicals Bureau (ECB), and the European Centre for Validation of Alternative Methods (ECVAM) confirmed and developed ECETOC's role as a key contributor to the development of sound scientific approaches to the safety assessment and consequential responsible environmental management of chemicals.

Throughout the 90's, ECETOC continued to keep pace with the evolving science. Various databases were developed, for example on aquatic toxicity, and on eye and skin irritation, and skin and respiratory sensitisers. These are proving particularly valuable to those researching and validating alternatives to animal testing.

ECETOC's relationship with academia was established and reinforced through partnerships in the Task Force activities, collaborative EC sponsored research projects and in successful joint projects, such as the symposia organised with the European Environmental Mutagen Society (EEMS). In 1997,

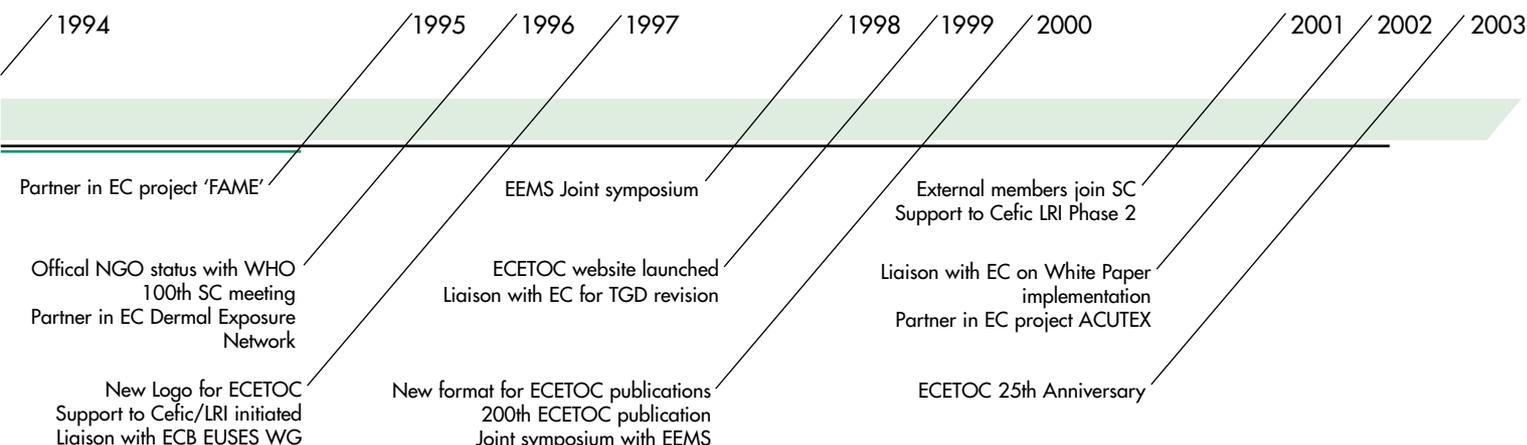
drawing on its networks with leading scientists in academia and regulatory agencies, ECETOC was actively engaged in the founding of the chemical industry's LRI. ECETOC continues to provide the essential scientific input to the development and management of many of the programme areas funded by Cefic.

By the year 2000, more than 200 ECETOC publications had been issued.

In 2001, leading scientists from academia joined the industry scientists in ECETOC's SC and peer-review panel, reinforcing and extending the range of expertise available to guide and test the ECETOC science programme and its outputs.

As it attains the 25th Anniversary of its founding, ECETOC continues to justify its role in the development of sound science-based regulation of chemicals, participating, for example, in the EC groups engaged in revising the technical guidance document (TGD) for risk assessment of new and existing substances and more recently the major initiative for implementing the chemicals policy as described in the EC White Paper.

The achievements of ECETOC have arisen from the experience and knowledge of the scientists from its member companies, allied with those from the many partnerships that have been built. Continuing success will depend on maintaining and extending these partnerships and above all, on renewing the specialist resources on which they depend.



# an overview of 2002

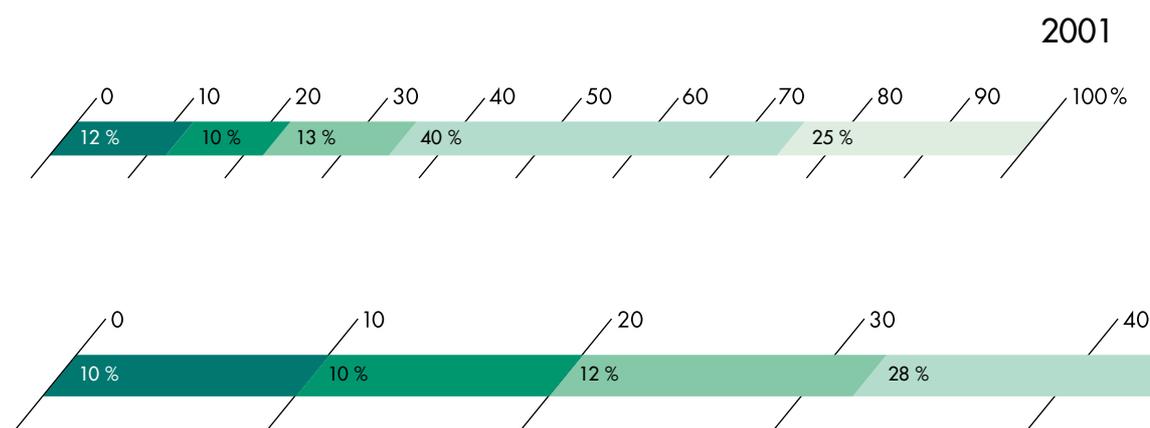
## Report from the Secretary General

In 2002, ECETOC continued to operate and deliver outputs in five main programme areas.

The distribution of total effort expended by the scientific Secretariat across these five areas was changed compared with that of 2001. With the resignation at the end of 2001 of the scientist managing the research programme activities, it was not possible to sustain the level of support to the European Chemical Industry Council (Cefic) for the LRI that was provided in 2001. Notably, the decision was taken to focus support particularly on those areas for which ECETOC had been involved from the onset in 1997, namely the research programme areas of environment, human exposure and tiered risk

assessment and human health effects assessment. Notwithstanding the reduced level of support provided, the contribution made through ECETOC to the LRI programme remains significant (p. 8)

ECETOC has a long and fruitful history of working with the agencies, particularly the European Chemicals Bureau (ECB) responsible for implementing the risk assessment regulations. The Revision by the European Commission (EC) of the Technical Guidance Document (TGD) began in 2000 and is continuing.



With this we proved our ability to act as a focal point for industry in its widest sense, building consensus on contentious scientific issues and delivering the output in a timely fashion to the regulatory groups. The provision of input to the revision for the risk assessment of new and existing substances and biocides continued during 2002, but with a lower level of activity following the completion of 12 of the 14 sections. Work on the remaining two sections of the TGD will continue into 2003.

The proven track record of ECETOC in such collaborative efforts was evident in the productive workshop organised to seek the views of specialists from industry, academia and regulatory agencies on the science needs for chemicals regulation in Europe. With particular emphasis on the EC White Paper on chemicals policy, the workshop identified a number of key challenges for ECETOC scientists to address in its future programme (p. 14). The Task Force on Targeted Risk Assessment has been heavily engaged throughout 2002 in development of a science based pragmatic approach that will enable the ambitious goals of the White Paper to be met. Its preliminary achievements have been welcomed in the regulatory arena and will form the focus for continued collaboration. To complement this work, other Task Forces have begun to address other elements that must feature in the process such as informed testing strategies, appropriate application of human data and alternative methodologies including (Q)SARs.

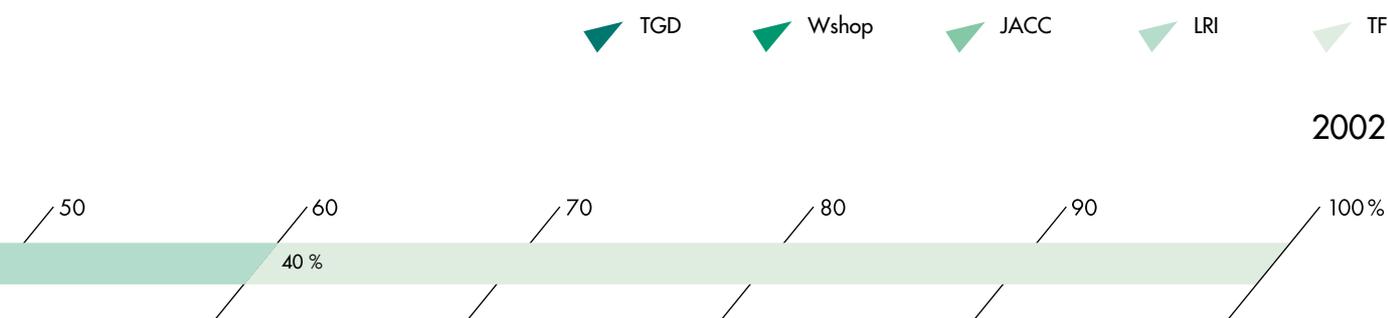
Compared with 2001 the generic Task Force programme accounted for a significantly greater proportion of the effort in 2002. Though a number of Task Forces reached conclusion with the publication

of their reports, these were replaced with new and demanding initiatives driven by existing and emerging regulations that will impact on a broad constituency of industry (p. 16).

The specific substances programme continued to feature in the ECETOC programme reflecting the steady demand from participating companies for ECETOC to host and peer-review their consortia-driven projects.

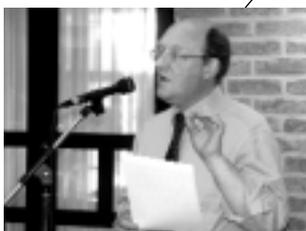
Our outputs and achievements in 2002 remain substantial. There is furthermore a growing interest for our work shown by other organisations, including the regulatory agencies, and for development of strategic alliances to deal with the growing demands that will come from emerging regulations. Still ECETOC is facing a number of challenges. One major pressure on our Industry, and on ECETOC, continues to be the negative effects of mergers, acquisitions and rationalisation, which result in a contraction of the industry and of available resources.

Our commitment to working in partnership with other organisations wherever practical and possible to some extent counters the continuing trend for consolidation in the industry. However in the longer term there will be a need for a more concerted effort to address the critical shortage in the specialist resources and facilities that are available to the industry, and indeed to the regulators, to meet the demand. ECETOC, with its membership including a wide range of sectors of the industry and a substantial track record for building effective partnerships with academia and regulatory agencies, is well positioned to catalyse the action that must be taken to arrest the decline.



# EC white paper on chemicals policy

ECETOC Annual Meeting, 2002  
Sound Science for Chemicals Regulation in Europe



*David Bove (MEP) launches the event.*



*Secretary General Francis Carpanini discusses a point with ECETOC Board Member David Hyde.*

With its overall theme of the EC White Paper for a chemicals policy and its translation into practical regulations, the 2002 Annual Meeting at the end of May attracted the interest of a broad spectrum of companies and industry organisations as well as representatives from regulatory agencies and academia. The latter two constituencies accounted for over 30% of the 100 participants who attended.

The event was launched with an address from Mr. David Bowe, MEP, who had played a leading role in the Parliamentary discussion of the EC White Paper. His insight into the public interest and political processes that would shape the evolving legislation was a fitting backdrop to the identification of the scientific challenges that would need to be met.

In the presentations that followed from leading regulatory scientists, several key areas in the White Paper were highlighted where science was needed to deliver the goals of the policy. There was particular focus on the registration and evaluation aspects of REACH, a framework to enable and encourage industry to accept the lead in the safe use and disposal of chemical substances.

Syndicate sessions provided the opportunity for all to participate in the process of identifying the key scientific needs for successful implementation of REACH and, indeed current and other emerging chemicals regulation in Europe.

The outputs from the meeting were subsequently collated and further refined by ECETOC Scientific Committee into a series of proposed initiatives; those appropriate for ECETOC's sphere of activity were prioritised for inclusion in the ECETOC work programme. The aim was for all such initiatives to be progressed in partnership with scientists from industry, academia and the regulatory areas, thus ensuring that ECETOC's contribution in this important area was tested and constructive.

Work on a number of these initiatives was commissioned during 2002 and will continue in 2003. Included are the following:

- ▶ Formulation of guidance on scientific criteria to inform testing strategies;
- ▶ establishing a consensus for pragmatic use of alternatives in testing strategies;
- ▶ development of technical recommendations towards refinement of proposed methodology on targeted risk assessment;
- ▶ guidance for evaluation and assimilation of human data in the risk assessment process;
- ▶ further development of broad availability and use of monitoring data.

Progress on each of the proposed projects will be publicised on our Website <http://www.ecetoc.org>



*Jan de Wit (Akzo Nobel), Martin Kuster (Novartis) and Hans-Erik Schiff (Novozymes) at question time.*



*Geoff Randall (Astra Zeneca), Member of ECETOC scientific Committee questions the panel.*

## task forces

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 2002:

### **Whole Effluent Assessment**

Water quality policy and legislation in Europe is directed towards achieving good environmental quality of surface waters and sediments. The current approach is 'substance oriented' in that individual substances are tested for three characteristics, namely persistence, bioaccumulation and toxicity, and the results of these tests are translated into quality targets for surface waters and sediments, as well as emission limits for effluents.

As there are some limitations with this approach, a number of initiatives have been mounted within the EU and OSPAR to develop tools based on the application of bioassays on whole samples (of surface waters, effluents and sediments). ECETOC has commissioned the Whole Effluent Assessment (WEA) Task Force to evaluate the usefulness of this alternative approach in terms of the suitability of the existing tests for effluents, the ability of these tests to determine realistic potential effects to define meaningful endpoints, and to propose a scientifically sound strategy for WEA.

### **ACUTEX**

The aim of Council Directive 96/82/EC ("Seveso II" Directive) is the prevention of major accidents involving dangerous substances and the limitation of their consequences for man and the environment. A three-year research project, ACUTEX, funded within the EC 5th Framework Programme for Research and Technology Development, has been initiated to develop methodology for deriving acute exposure threshold levels (AETLs), related software tools and a technical guidance document. A consortium of eight, comprising government institutes, competent authorities, academia and industry will carry out the project, which is intended to support a harmonised practical application of the directive in the EU member states. .

ECETOC, as one of the consortium partners, was invited to lead the work on "threshold and human health endpoint definitions", a key element of the project. The Task Force commissioned to deliver this element includes participation from the Catholic University of Louvain in Belgium. The group will co-operate with the German Federal Institute for Risk Assessment.

### **Contact Sensitisation: Classification According to Potency**

Developments in Europe suggest that considerations of potency will become an important factor in the EC classification of skin sensitising chemicals. It was thus considered timely to establish what was known of potency and thresholds in the induction of skin sensitisation and elicitation of allergic contact dermatitis, and to identify approaches that might be available for assessment of relative potency for the purposes of categorising chemical allergens.

An ECETOC Task Force was thus commissioned to recommend approaches, initially for the measurement of potency and definition of thresholds for both the induction and elicitation of contact sensitisation.

The basis for this work was an ECETOC report, published in 2000, which considered the conduct of standard skin sensitisation test methods for the purposes of hazard identification and risk assessment. In line with this, recommendations were to be based on standard and accepted methods for which OECD guidelines were available i.e. the local lymph node assay, the guinea pig maximisation test and the occluded patch test of Buehler.

The outputs from the Task Force are to be made available to inform the ECB Experts Group that is considering this issue.

### **Information Requirements for Risk Assessment of Chemical Substances**

Regulators attending ECETOC's Annual Meeting in 2002 expressed an urgent need for guidance on sound scientific criteria to support decisions on deviating from (waiving or triggering) regulatory testing strategies. Such guidance would be applicable to the existing risk assessment activities in the EU, as well as to the future legislation that is proposed in the EC White Paper for a EU chemicals policy.

A Task Force was thus commissioned to undertake a comprehensive review of the toxicological and ecotoxicological endpoints included in regulatory

testing strategies, and their relevance to the evaluation of the hazard and risk of chemical substances under conditions of use.

From this analysis, guidance would be formulated for risk assessment predictions on the scientific principles that should inform decisions for testing and/or risk management, including such factors as extrapolation across groups of substances, physico-chemical properties, bioavailability and exposure considerations.

The final report will include illustration and testing of the principles using case studies.

During 2002, 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)
- Risk Assessment Core Group
- Risk Assessment Factors
- Soil and Sediment Risk Assessment
- Toxicological Mechanisms
- Environmental Risk Assessment of Difficult Substances
- PBPK Modelling Workshop
- Targeted Risk Assessment
- (Q)SARS

#### **Environment**

- Aquatic Hazard Assessment II
- Ecotoxicity of Borates
- Persistence of Chemicals in the Environment

#### **Specific Substances**

- Butanols
- Fluoroalkanes
- Methyl tert-Butyl Ether (MTBE) Risk Assessment
- Glycol Ethers
- Synthetic Amorphous Silica
- Tetrafluoroethylene, Hexafluoropropylene and Vinylidene fluoride
- Cyanides



## long-range research initiative

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In providing scientific support to Cefic, ECETOC has played a significant role since 1997 in developing and overseeing this strategic research programme on human health and environment.

*Participants at  
the (Q)SAR Workshop  
organised by ECETOC  
for ICCA LRI in  
Setubal, Portugal.*

The specialist support provided by ECETOC to the Cefic/American Chemistry Council (ACC) Japanese Chemical Industry Association funded research programme on the potential impact of the chemicals industry on human health, wildlife populations and the environment is a critical success factor in many programme areas.

During 2002, a number of the projects sponsored in the first phase of the Cefic LRI programme and monitored by the ECETOC teams, reached their concluding stages. Following their participation in the review of the State of the Science (STOTS) gap analysis in 2001, the ECETOC monitoring teams, complemented by experts from academia, continued the process of identifying emerging issues and topics for research. A number of new requests for proposals (RfPs) for research in the health effects, human exposure and environment areas, were developed and provided to Cefic to include in its funded programme.

### **Health Effects Programme**

ECETOC scientists on the Health Effects Monitoring Team continued to be actively engaged in the overview of a programme comprising studies in chemical carcinogenesis, chemical allergy with respect to sensitisation of the respiratory tract and occupational asthma and investigation of the influence of irritancy on respiratory hypersensitivity.

The research on chemical carcinogenesis, which includes work using emerging technologies to study gene expression, has already provided important information and molecular mechanisms of carcinogenesis and knowledge that can contribute to improved approaches for identification and characterisation of non-genotoxic carcinogenic hazards and more reliable risk assessments.

In view of the importance of this area in the context of occupational health, the studies in the field of chemical allergy and respiratory toxicity have focused on the challenge of developing reliable methods for identification and characterisation of chemical respiratory allergens. The progress made in the first phase studies will inform future work that will be undertaken.

With the assistance of external experts, proposals were made to Cefic with six RfPs developed for further research in the field of chemical carcinogenesis and contact and respiratory allergy as well as new areas including reproductive and development toxicity and neurotoxicity.

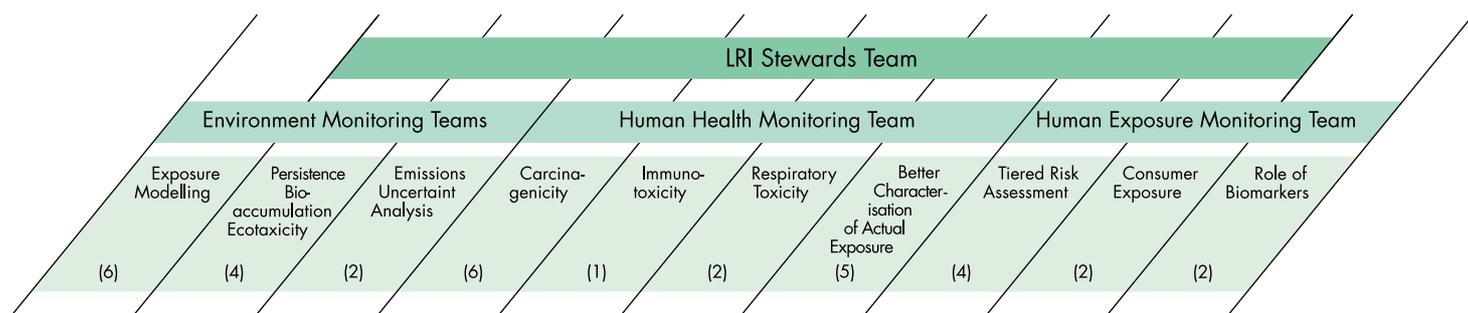
### **Human Exposure and Tiered Risk Assessment**

The Human Exposure and Tiered Risk Assessment (HETRA) Monitoring Team has continued its support to Cefic through oversight and development of the programme in a targeted and strategic manner, identifying critical opportunities for partnership with various organisations to extend the utility and impact of the research.

During 2002, the HETRA monitoring team progressed a programme comprising four main themes, better characterisation of actual exposures, tiered approaches to risk assessment, nature of determinants of human exposure and the role of biomarkers in exposure monitoring.

In conjunction with external experts, the Team developed proposals for a variety of projects and 14 RfPs have been identified for Cefic to extend the programme in its second phase, emphasising the importance of achievement through multi-centre projects involving key stakeholders.

The diagram shows how the research projects are distributed in the sub-divisions of these three areas.



### Environmental Programme

The Environmental monitoring team within ECETOC continued to oversee and develop the programme that is directed towards filling gaps in the understanding of exposure and potential chemical effects on organisms in the environment.

Although several ecological concepts in need of research were considered, the first phase was particularly concerned with matters related to persistence, bioavailability, bioaccumulation fate and the extrapolation of fresh water aquatic ecotoxicity data to other environmental compartments (i.e. soil and sediment organisms and seawater taxa). For the modelling component of the programme, the priority was to assess and reduce uncertainty, and to improve the validity and predictive power of the models, and the understanding of processes and accuracy of model input data. The outcomes from this programme will greatly increase industry's ability to direct resources towards an intelligent testing approach to environmental risk assessment.

The monitoring team, in conjunction with external experts has reviewed its programme area and formulated proposals to Cefic to extend the research activities in the second phase in which the programme will be increasingly characterised by both an ecological/field component and an in-silico/*in-vitro* component.

### (Q)SAR Workshop

While (Quantitative) Structure Activity Relationships (Q)SARs have been promoted as an alternative to experimental work for several years, there has been much resistance to their application in the regulatory arena in Europe. (Q)SAR science has been advancing steadily by providing better ways of predicting mechanistic information and by improved statistical and mathematical tools. Consequently (Q)SARs are now being increasingly viewed as potentially one of

the most cost-effective ways to estimate the physico-chemical properties and certain ecological and human health effects of industrial chemicals.

ECETOC organised an invitation only workshop in Setubal, Portugal, on behalf of the International Council of Chemical Associations (ICCA) LRI. Over 60 scientists with mammalian/human health and environmental backgrounds from the USA, Canada, Europe and Japan and representing academia, the regulatory community and industry met for three days to:

- Summarise how (Q)SARs were being applied in regulatory programmes around the world and identify further needs for their use of (Q)SARs;
- review the possible uncertainty, reliability and applicability of QSARs in the context of current scientific improvements;
- develop proposals for guidance on reporting (Q)SAR results, (Q)SARs uncertainty, validity assessments and applicability criteria and scope for regulatory use of (Q)SARs;
- develop a vision for a global (Q)SAR decision support framework for risk assessment and classification.

The workshop urged industry to take the lead to develop further the acceptability criteria and to test existing (Q)SARs against the proposed criteria for use in priority setting, risk assessment and classification. This exercise was considered essential to build confidence in the use of (Q)SARs.

The ECETOC (Q)SAR Task Force was engaged in the planning of the workshop and in reviewing its output. A report was prepared on the current status and was used to develop the input to the OECD Special Session on (Q)SARs held 22nd November. The final version of the ECETOC TF report will be available in 2003.

## ecetoc outputs

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During 2002 ECETOC generated publications ranging from its traditional reports to external publications in peer-reviewed journals

### **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.

### **Technical Reports**

No. 83 *The use of T25 estimates and alternative methods in the regulatory risk assessment of non-threshold carcinogens in the European Union*

No. 84 *Scientific principles for soil hazard assessment of substances*

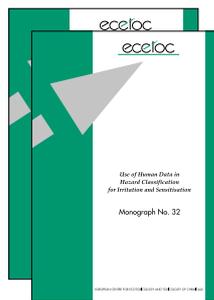
No. 85 *Recognition of, and differentiation between, adverse and non-adverse effects in toxicology studies*



**Monographs**

No. 31 *Guidance on evaluation of reproductive toxicity data*

No. 32 *Use of human data in hazard classification for irritation and sensitisation*



**External Publication**

Lewis RW, Billington R, Debryune E, Gamer A, Lang B, Carpanini F. 2002. *Recognition of adverse and non-adverse effects in toxicity studies. Toxicol Pathol 30:66-74*



## external representation

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ECETOC, in addition to major collaborative exercises, provided expert representation to the work of a number of other external organisations in 2002. These included:

- ▼ Research Institute for Fragrance Materials (RIFM)  
 New Jersey, 15 January  
 Presentation by Secretary General on ECETOC and the promotion of sound science for responsible chemical regulation.
  
- ▼ International Agency for Research on Cancer (IARC) Monographs Working Group Meeting on Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene  
 Lyon, 12-19 February  
 ECETOC represented by Dr. T. Green (Syngenta).
  
- ▼ International Programme on Chemical Safety (IPCS) Tenth Final Review Board Meeting for Concise International Chemical Assessment Documents (CICADs): Hydrogen Cyanide and Cyanides  
 Monkwood UK, 19 September  
 ECETOC represented by Dr. M. Pemberton (Lucite).
  
- ▼ OECD 33rd Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology  
 Paris, 5-8 February  
 ECETOC Document (No. 42) on genomics, transcript profiling, proteomics and metabolomics (GTPM) submitted as a background papers for session on 'omics'.
  
- ▼ OECD 34th Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology  
 Paris, 5-6 November  
 Presentation by the Secretary General on behalf of the ECETOC (Q)SAR Task Force.
  
- ▼ European Centre for the Validation of Alternative Methods (ECVAM)  
 Dr. J. Fentem (Unilever) represented ECETOC on the ECVAM Scientific Advisory Committee, in place of Dr. P. Botham (Syngenta), whose term of office expired in the course of the year.
  
- ▼ European Cosmetic toiletry and Perfumery Association (Colipa)  
 Dr. I. Kimber (Syngenta) continued to represent ECETOC on the Skin Tolerance Task Force.
  
- ▼ ILSI Europe  
 ECETOC, represented by Mr. M. Holt, continued its active membership of the Environment and Health Task Force.
  
- ▼ SETAC  
 ECETOC is represented on SETAC Europe Council through membership of Mr. M. Holt.
  
- ▼ International scientific symposium on the health effects of glycol ethers, organised by the European Oxygenated Solvents Producers Association (OSPA) and the Ethylene and Propylene Glycol Ethers Panel (EGEP) of the American Chemistry Council (ACC)  
 Paris, 17-18 October.  
 ECETOC Represented by Dr. Owen (Shell Chemicals) TF Chairman.



Dr. F. Carpanini  
 Ms. M. Butler  
 Dr. C. Hennes  
 Mr. M. Holt

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Secretary General  
 Health Sciences Manager  
 Health Sciences Manager  
 Environmental Sciences Manager

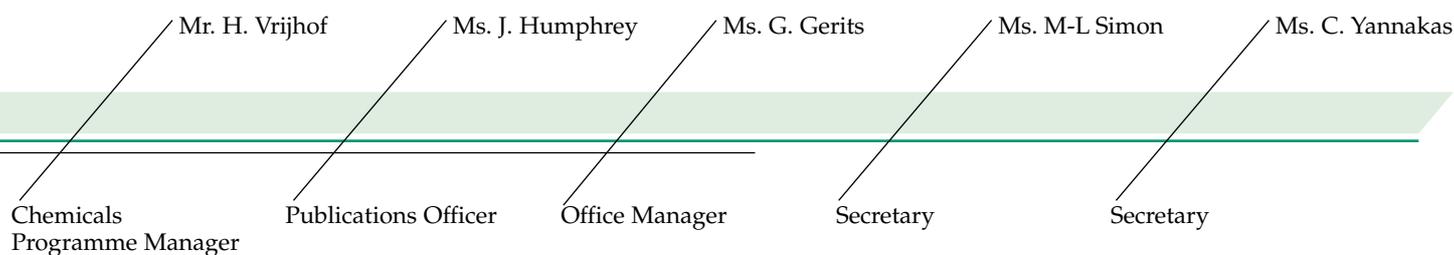
Front row from left:  
 Geneviève Gerits, Francis Carpanini,  
 Christa Hennes, Julieann Humphrey.  
 Back row from left:  
 Henk Vrijhof, Christine Yannakas, Margaret Butler,  
 Marie-Laurence Simon, Martin Holt.

## 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.

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. C. Hennes, Ms. J. Humphrey and Ms. C. Yannakas joined our team.

At the end of 2002, staff employed were:



## *modus operandi*

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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.

The content of the ECETOC work programme is derived from both internal (member company) needs and external drivers (e.g. initiatives taken by particularly by regulatory authorities, especially the European Union).

Multi-stakeholder science workshops are convened regularly under the direction of the Scientific Committee, towards identifying potential issues and formulating initiatives for addressing them in the ECETOC programme.

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 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 from the Peer-review Panel.

ECETOC publications are provided to all members companies and to other interested parties, such as the various regulatory authorities, international organisations and academic groups, for use as required.

## board members

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Mr. P. Chaigneau (DuPont de Nemours), Mr. C. Holmes (Procter & Gamble) and Prof. L. Smith (Syngenta) were elected to the Board at the Annual General Meeting (AGM) on 28th May 2002.

In addition, Dr. K. Eigenmann, Mr. D. Hyde, Mr. H. Schiff and Mr. P. Peschak were re-elected for a further term of two years following expiry of their mandates.

Dr. C. Mancel (Procter & Gamble) resigned his Chairmanship and membership of the Board following his retirement from Procter & Gamble. The Board elected Mr. P. Peschak (ExxonMobil Chemical) as Chairman, Dr. K. Eigenmann (Novartis) as Vice-chairman and Dr. J. Rudolph as Treasurer.

The composition of the ECETOC Board following the 2002 Annual General Meeting was:

<b>Name</b>	<b>Company</b>	<b>Function</b>
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	
Mr. H. Schiff	Novozymes	
Prof. L. Smith	Syngenta	

## scientific committee

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The Scientific Committee held 7 meetings during the year.

Drs. N. Carmichael, C. d'Hondt, and H-J. Wiegand and Prof. G. Randall were re-appointed by the Board for a further four years, following expiration of their mandates in 2002.

The Board appointed Mr. C. Money (ExxonMobil) as a member of the Scientific Committee in 2002.

Dr. J. Jackson resigned from the Scientific Committee in December 2002.

The composition of the ECETOC Scientific Committee as at December 2002 was:

<b>Name</b>	<b>Affiliation</b>	<b>Function</b>
Dr. B. Hildebrand	Consultant	Chairman
Dr. N. Carmichael	Bayer 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	Novartis	
Dr. P. Douben	Unilever	
Dr. T. Feijtel	Procter & Gamble	
Prof. H. Greim	Munich Technical University	
Dr. J. Jackson	Monsanto	
Mr. C. Money	ExxonMobil	
Dr. A. Sarrif	DuPont deNemours	
Dr. G. Swaen	Maastricht University	
Dr. B. van Ravenzwaay	BASF	
Dr. H-J. Wiegand	Degussa	

\*Formerly Aventis CropScience

## member companies

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ECETOC Membership at December 2002:



3M  
 Akzo Nobel  
 AstraZeneca  
 Atofina  
 Ausimont  
 Aventis CropScience  
 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'Oréal  
 Lyondell Chemical  
 Merck  
 Monsanto  
 Norsk Hydro  
 Novartis  
 Novozymes  
 Petresa  
 Polimeri Europa  
 Procter & Gamble  
 Reckitt Benckiser  
 Repsol Quimica  
 Rhodia  
 Rohm & Haas  
 Shell Chemicals  
 Solvay  
 Statoil  
 Syngenta  
 Unilever  
 Wacker Chemie

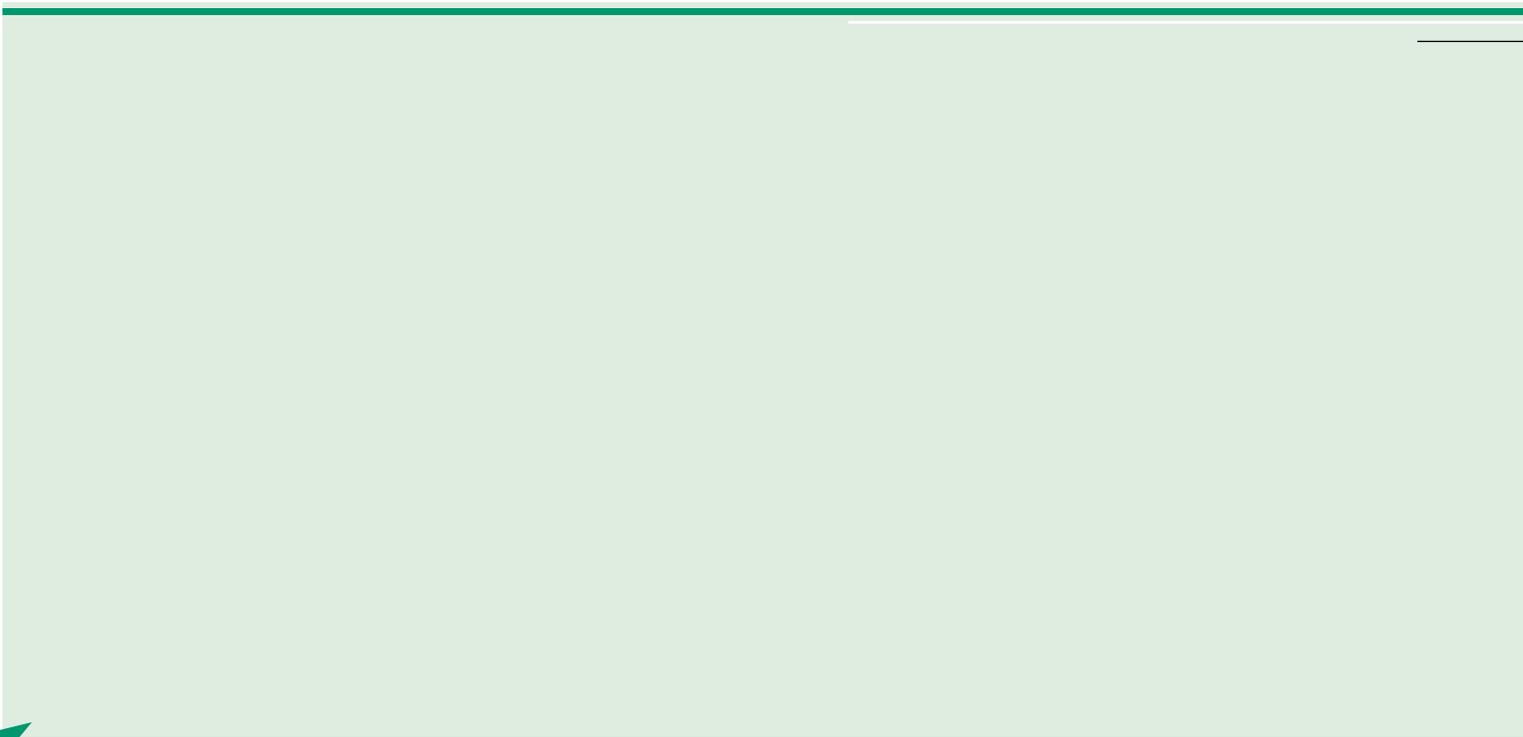
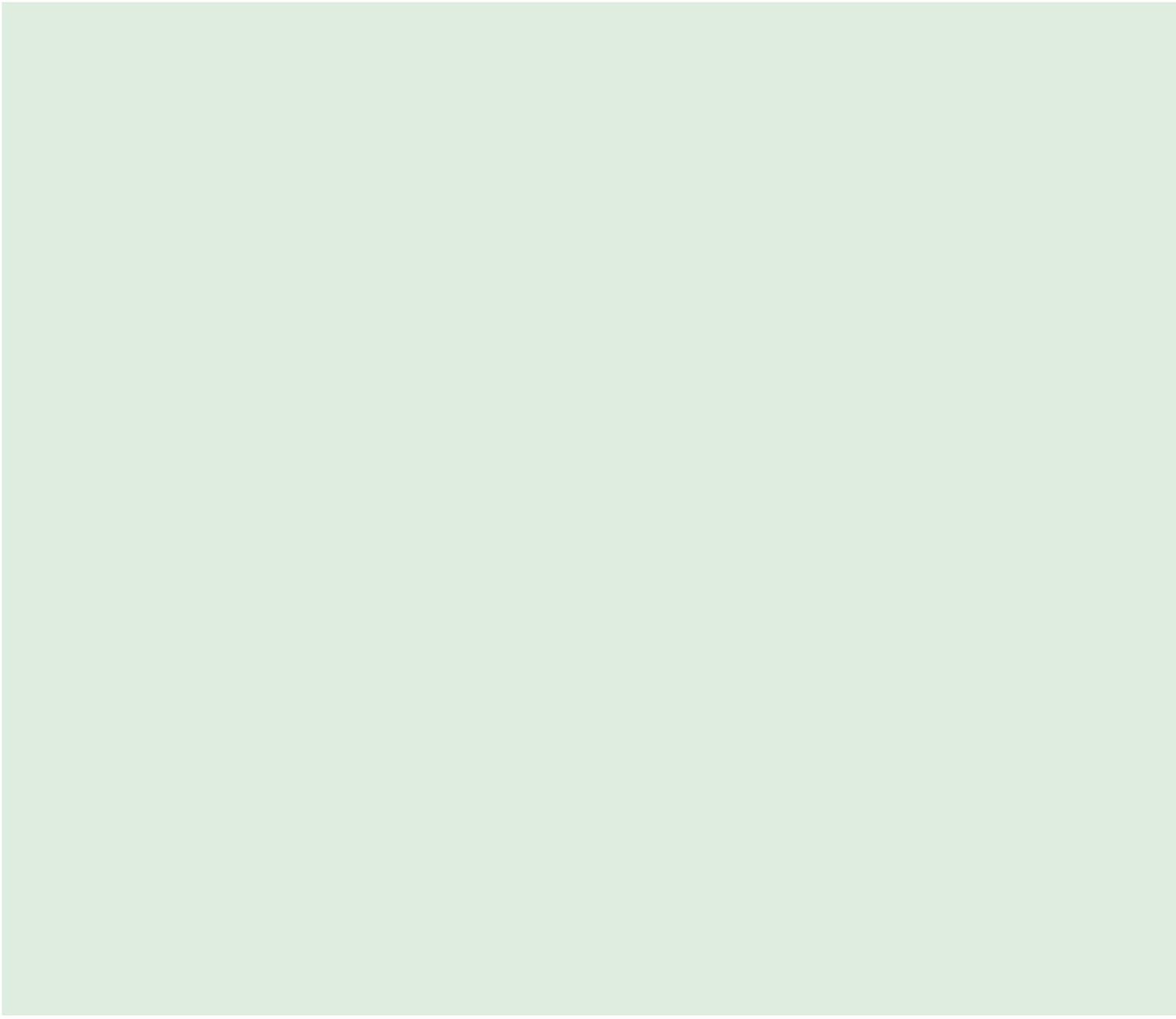
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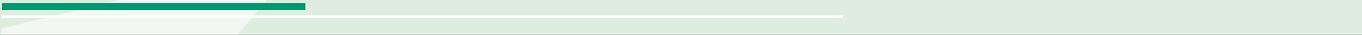
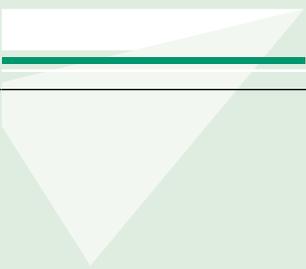
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<b>Income</b>	<b>Actual 2002 in Euro</b>
<b>Subscription</b>	
Full Members	1,290,000
'New' Members	40,000
<b>Total Subscription Income</b>	<b>1,330,000</b>
<b>Bank Interest</b>	<b>66,154</b>
Document Sales	10,002
Project-related	156,582
<b>Total</b>	<b>1,562,738</b>

<b>Balance sheet and reserves</b>	<b>Actual 2002 in Euro</b>
<b>Balance Sheet</b>	
Income	1,562,738
Expenditure	1,687,428
Operating Margin	-124,689
<b>Reserves</b>	
Opening	1,337,532
Operating Margin	-124,689
Closing Reserve	1,212,842
<b>Estimated Reserve Required</b>	<b>450,000</b>

<b>Expenditure</b>	<b>Actual 2002 in Euro</b>
Salaries (and related expenses)	1,042,861
Office Running Expenses	258,087
Travel Expenses on Mission	15,363
Meetings and Consultants	284,200
Professional Services	9,741
Bank Charges	3,663
Capital Expenditure	3,895
Publications	49,952
Miscellaneous	19,667
<b>Total</b>	<b>1,687,428</b>





**Published by:**

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