

31st Annual Report

31ST ANNUAL REPORT 2004

ETAD[®]



2004

Ecological and Toxicological Association of
Dyes and Organic Pigments Manufacturers



Mission Statement

MISSION STATEMENT

The purposes of the Association are the following:

To coordinate and unify the efforts of manufacturers of synthetic organic colorants to minimize possible impacts of these products on health and the environment

To achieve these ends by the most economic means without reducing the level of protection of health and the environment

To encourage harmonization of health and environmental regulations in key geographical areas

To represent the positions and interests of the manufacturers of organic colorants towards authorities, public institutions and media

To promote responsible environmental and health risk management during manufacture, transport, use and disposal

To enhance the recognition of the commitment of ETAD members to responsible behaviour with respect to health and the environment

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Introduction

FROM THE PRESIDENT

The 30th General Assembly was held in Genval near Brussels in May 2004 and was followed by a seminar with a number of interesting and challenging presentations from invited guest speakers.

Inevitably the main topic was the proposed new European Chemicals Policy and specifically the REACH proposals. There was an excellent presentation from CEFIC reviewing the history of the proposal and the progress made so far towards a more practicable regulation achieved by successful lobbying by the chemical industry and equally importantly the downstream user industries. Through a number of implementation projects the Commission is now seeking to address industries' concerns about the workability of the current proposals and to understand the complex lines of communication from raw material supplier to end consumer. It is hoped that a Tiered Risk Assessment approach based on volume triggers and existing data will reduce the need for animal testing.

It was with great regret but much appreciation that we bid farewell during the GA in Genval and later in August at the farewell party at the Castle of Bottmingen to Eric Clarke as Executive Director of ETAD, who retired after 13 years in the post and after a total of 26 years in the service of ETAD and its member companies.

During Eric's time as Executive Director the colorants industry has undergone tremendous change not least the major restructuring of the traditional European manufacturers who had played a leading role in the establishment of ETAD in 1974. It has also been a period of increasing legislation particularly within the European Union, which itself has grown from 12 to 25 Member States, placing restriction on the use of many chemicals, including certain azo dyes and their amine precursors.

It is a tribute to Eric's leadership that during this period of dramatic changes, ETAD has successfully adapted and prospered, gaining a worldwide reputation as the authoritative voice of the dye and pigment manufacturing industry, particularly with regard to product safety and environmental protection. It is no coincidence that Eric spent much of his time seeking to demonstrate to the European Commission and the European Chemicals Bureau that industry was prepared to engage with the authorities not only in the development of practical risk-based chemical legislation but also in the monitoring of its enforcement within the EU.

Introduction

FROM THE PRESIDENT

That the membership of ETAD has grown, in particular in the Asian manufacturing countries like Korea and Taiwan and more recently in India, is a testament to Eric's vision that ETAD should be influential in raising standards of responsible manufacturing and hazard communication on a global scale. The fact that he managed to keep the Association together during this difficult time is a reflection of his deep personal commitment to ETAD and his Irish charm.

We wish Eric a long, healthy and happy retirement. His successor Herbert Motschi and his ETAD team will undoubtedly carry on the excellent work.

The colorants manufacturing industry is moving east just as many of its user industries, notably the textile industry, have moved their activities to the lower wage economies of East and South Asia. ETAD has to follow this trend and to consider establishing local Operating Committees in the dyes and organic pigments manufacturing countries of the future. Working initially through the overseas subsidiaries of the traditional member companies, ETAD is endeavouring to attract into membership producers who share ETAD's commitment to

high standards of health, safety and environmental protection in manufacturing operations and are equally committed to effective hazard communication to user industries. In the future it will be these ETAD companies who are best able to satisfy the requirements not only of local legislation on HS&E but also the requirements of the multinational retailers who are seeking to control the use of chemicals in their global product supply chains.

In May 2005 ETAD will hold its 31st General Assembly in Istanbul. Turkey is a key market for dyes and pigments and enjoys a special relationship with the EU as a trading partner. It is a major supply market for retailers in Europe and the programme of invited speakers will reflect the country's unique position at the crossroads between Europe and Asia.

ETAD does not intend to be left behind by the eastward shift of manufacturing. Based on 30 years of expertise in dealing with legislation in a complex and diverse field of chemistry, ETAD is destined to play an even more important role worldwide. Sustainable growth is the vision that lies before us. It will bring many challenges, not least testing our ability to adapt to an ever-changing landscape of member companies and manufacturing locations. It is a unique strength of ETAD that the member companies have co-operated so successfully over the past 30 years despite tremendous competitive pressures in the marketplace. Only by building on this strength will ETAD be able to meet the challenges that lie ahead.

I'm convinced that this is also the major challenge for my successor as ETAD President. I like to take the opportunity to thank the whole ETAD team as well as my colleagues from the Board and all members working in the different Committees for the excellent co-operation during the past two years.



F. - M. Stöhr
President of ETAD

Please take the time to read this Annual Report which gives a brief overview of the main activities within ETAD. I am sure this will convince you and your company that ETAD membership is well worth it!

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PREFACE

The colorants industry has continued its transformation process throughout the world, in which it is increasingly recognized that health and environmental protection are global issues that can only be successfully addressed by worldwide harmonization of requirements.

ETAD's success as a global organization depends not only upon its functioning as a project-oriented knowledge base but also through the involvement of regional operating committees and their cooperation with local chemical associations. Despite the economic constraints in our industry, member companies have allocated significant resources to committee work and task force experts. Their dedicated work and expertise is crucial for ETAD's success. Thank you to all who have contributed to the benefit of ETAD.

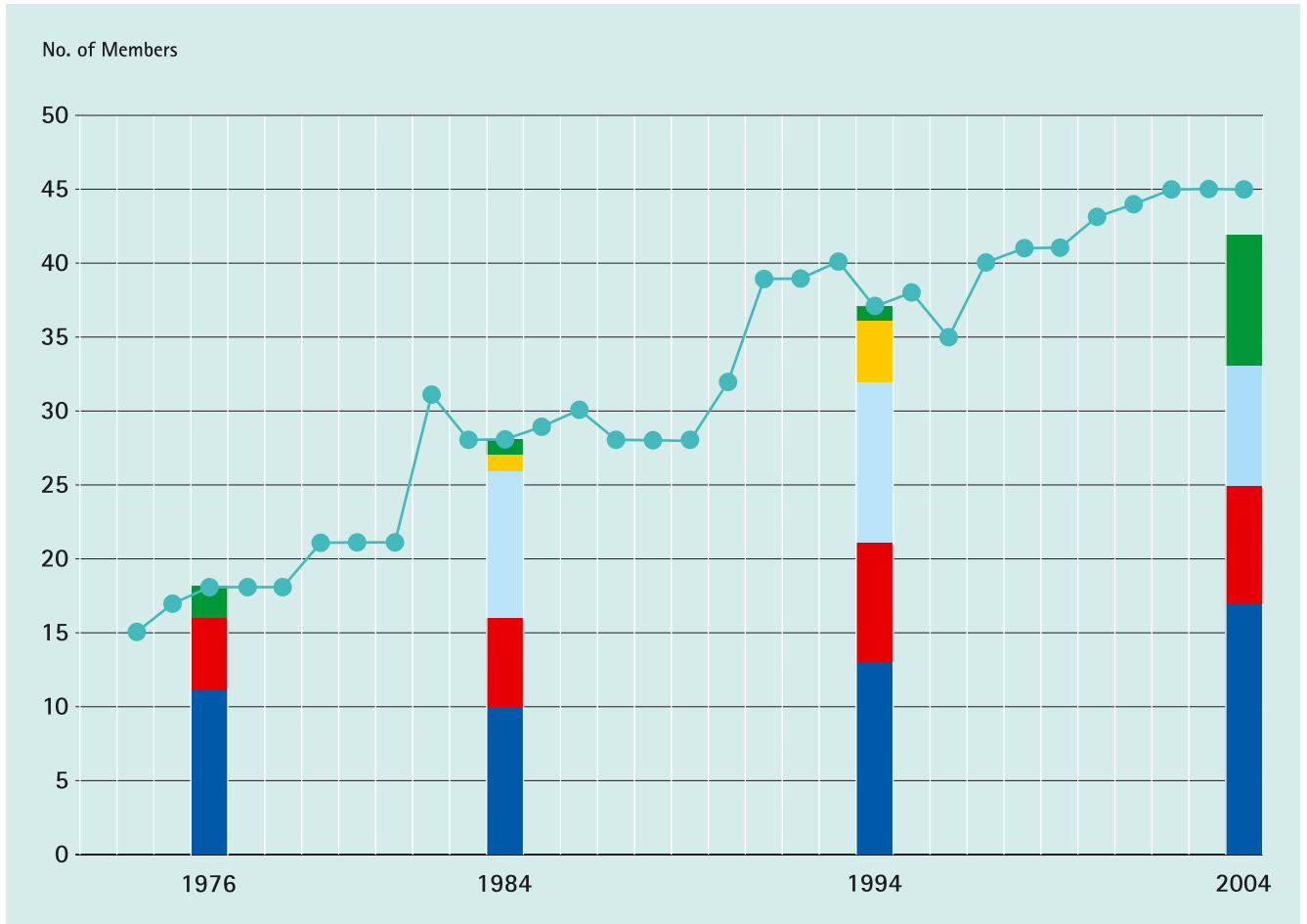
The development of new legislation on organic colorants is still gaining momentum especially in the EU. Whereas the year 2003 marked the onset of REACH legislation, 2004 will enter history with new framework legislation for food contact materials.

The impact of new chemicals control legislation calls for more and more requirements, which in the past were necessary only for cosmetics and consumer care products. In this situation it is important that exposure control is recognised as a key parameter to minimize potential risk and that this should lead to a reduction in hazard testing programs. Testing of increased numbers of performance standards is a growing cost factor in the supply chain for colorants. The recognition that ETAD members perform at high standards generates confidence and mutual trust with retailers and can relieve customers from additional testing costs.

The rapid growth of the dyes and organic pigments manufacturing industry, especially in China, poses increased workplace and environmental problems. Based on its experience and expertise, ETAD has a mandate to assist the development of a colorant industry in these areas that is compatible with a sound environment. ETAD's Board has decided to play an active role in these areas fulfilling the expectations of the leading international association of the colorants industry.

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MEMBERSHIP



■ Europe
 ■ Japan
 ■ USA
 ■ South America
 ■ Asia
 ● No. of members

Yorkshire Chemicals plc. and Yorkshire Amercas Inc. had to leave ETAD due to insolvency in 2004 and BASF Corporation ceased membership of ETAD NA.

The figure illustrates the growth and changing regional composition of the ETAD membership.



The 30th Ordinary General Assembly of ETAD was held in the Hotel Chateau du Lac, Genval on May 13, 2004 commencing at 8.30 hr. The President, Dr. F.-M. Stöhr, opened the proceedings by welcoming the attendees from 11 countries, representing 34 of the 46 member companies, 95 out of the total vote entitlement of 115 votes were present or represented by proxy.

The Minutes of the 29th Ordinary General Assembly 2003 and the Annual Report 2003 were approved unanimously. The General Assembly also approved unanimously the report of the Treasurer and chartered accountants (PriceWaterhouse-Coopers AG) and the Budget for 2004, as presented by Dr. R. Walsh. Due to the sound financial position of the Association it was possible to avoid any increase in membership costs for the seventh successive year. Dr. T. Helmes presented the accounts for ETAD North America and its Budget for 2004.

Proposals for amendment of the ETAD By-laws, which have been unchanged since May 1997, had been notified to the member companies in accordance with Article 9, together with explana-

tions of the proposed changes. Dr. Clarke reiterated the reasons for the proposed changes and invited questions. Dr. Uebersax's suggestion to vote on the proposals en bloc was accepted and the proposals were adopted unanimously.

The Board proposal for its composition for 2004/2005 was presented. There were no additional nominations and the Board proposal was elected unanimously.

The President made a presentation of the ETAD Vision and Strategy, which was followed by a brief discussion.

Before closing the General Assembly meeting, Dr. Stöhr remarked on the pending retirement of the Executive Director, Eric Clarke, who has



been with ETAD since his secondment from ICI in 1978 for a three-year period.

On behalf of the Assembly, he thanked Eric Clarke for his services to ETAD and wished him well in his retirement.

In succession to Eric Clarke, the President was pleased to announce the appointment of Dr. Herbert Motschi, who joined ETAD from Ciba-Geigy AG in 1991. Dr. Motschi was congratulated on his new appointment and was wished much success, supported by the other ETAD staff, as he takes over his new responsibilities.

The meeting was followed by a Seminar on major regulatory developments at which the following presentations were made:

Mrs. M. Caboara, CEFIC, "CEFIC and ICCA efforts on global harmonisation"



Mrs. U. Jensen-Korte, CEFIC, "REACH, Status of legislation, current and future activities"

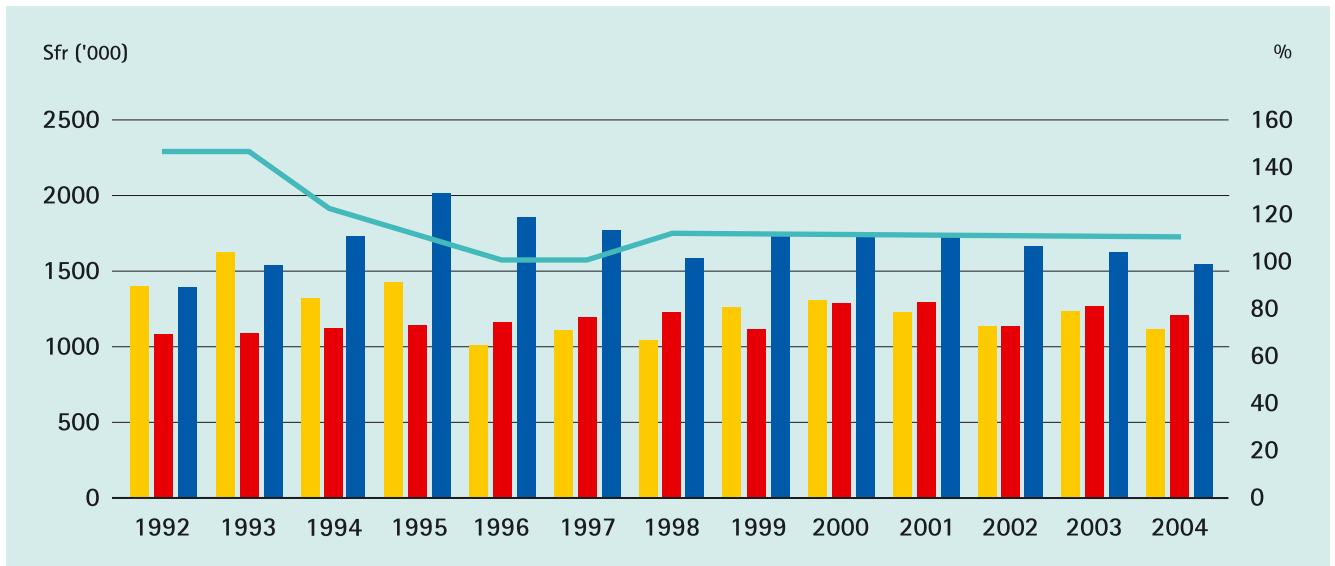
Mr. W. Lakin, GD EURATEX, "Impact of REACH and cooperation with ETAD to minimise costs"

Eurocolour made presentations on its formation and its remit:

Mr. Ph. Féron, CEFIC, "Formation of the Eurocolour cluster"

Dr. R. Fischer, Eurocolour, Brussels, "Key issues and modus operandi of Eurocolour"

FINANCE



ETAD is a non-profit association. The operating expenses are recovered mainly by means of payments by the ETAD member companies. In 2004, total income was SFr. 1.11 million compared with total expenditure of SFr. 1.20 million, resulting in a loss of SFr. 89'260.

Annual income and expenditure has been closely balanced over recent years and the increase in membership has enabled increases in the costs of membership to be avoided since 1998.

The accounts of ETAD North America are kept separately from those of the Basel office to mitigate the effects of exchange rate fluctuations on the financing of

the operations in North America. During 2004, the total income was \$ 217'000 and total expenditure \$ 233'344. The deficit of \$ 14'094 results in closing balance of \$ 20'347. The decline in US dye sales and the resultant loss of membership income led to a reduction of administrative support in 2004.

■ Income (Sfr '000) ■ Expenditure (Sfr '000)
■ Reserves (Sfr '000) — Membership dues

Summary of Income/Expenditure 1992 - 2004 (excluding ETAD North America)

All major projects and topics that were discussed in the EOC in 2004 are ongoing items.

EU-White Paper and the new expanded EU

Because of the expansion of the EU – 10 Central and Eastern European Countries joined the EU at the same date 01. 05. 2004 – the EU authorities had other priorities on their agenda. The published timeframe for the legislative process is getting more and more delayed.

This situation is an opportunity for us to get the whole REACH moving in a better and more practical direction. Projects like SPORT (Strategic Partnership on REACH Testing) or PRODUCE (Piloting REACH On Downstream Use and Communication in Europe) to train all parties involved in the practical application of REACH are now the main focus of the authorities. These projects can only help to avoid regulations that are not workable, like the idea of Chemical Safety Reports for preparations that would have to be supplied by the industry for every single chemical used in the preparation!

Seven RIPS (REACH Implementation Projects) have been defined to evaluate the different aspects of the REACH process and the communication of information on chemical hazards along the supply chain.

ETAD is still working on the very important item of regulation of PBTs (persistent bioaccumulative and toxic) or vPvBs (very persistent and very bioaccumulative), which will be subject to authorisation. These chemicals are not only in the focus of REACH, but are also of special interest for the Canadian Authorities.

Skin-sensitisation risk from dyes

The contract to extending the research project with Profs. Hatch and Maibach as mentioned in the AR 2003 has been signed. But the situation is still the same as in the past: only very few cases of consumer sensitisation have been reported by the dermatologists, most of them obviously due to the poor fastness properties of the dyed articles.

As the number of cases reported from the dermatologist network is still very low, this project helps the industry to draw a realistic picture of consumer risk.

Consumer risks due to dyed textiles

As articles are not subject to REACH the risk assessment for finished goods, especially textiles, is in the focus of the EU and several Member States.

The minutes of the 11th meeting of the working group textiles (task force "Gesundheitliche Bewertung"), December 16th, 2003, at the German Federal Institute for Risk Assessment (BfR) in Berlin have been published. The joint VCI/ETAD test program was officially accepted by the BfR. Prof. Platzeck gave a presentation explaining this approach as a pragmatic one at the ETAD GA 2004 in Genval.

The theoretical assessment of consumer exposure is the main purpose of the EIS Task Force in Ispra. Dr. Papameletiou reported in Genval about his progress to build up a data base to allow a more scientific and specific assessment for the individual risk of consumers.

REACH and consumer risks will remain the major issues for the foreseeable future!

Whereas perhaps some ten years or so ago the pigments industry in comparison to the dyestuffs industry seemed to have less regulatory issues and to be impacted less by developing legislation, this situation has now significantly changed and the organic pigment manufacturers find their products under scrutiny by the authorities world-wide with the PBT/vPvB issue continuing to dominate our industry.

Aliachem (Czech Republic) joined ETAD in January 2004, bringing the number of companies represented on the POC to eleven. This gives us now a broad coverage of the pigments industry across the world and enables the development of legislation to be followed (in conjunction with the RAC) and allows an industry-based response to the authorities.

PBT/vPvB

It is recognised that many organic pigments will meet the EU screening criteria for PBT substances and many pigments and solvent dyes are included on the Canadian „Yellow“ List. While pigments from their end application are persistent and there is no indication of any acute human or environmental toxicity, there is little robust evidence to confirm a lack of bioaccumulation. The situation is made more complex by the current lack of an agreed protocol for a fish feeding study and the experimental difficulties associated with carrying out such a test for substances that are essentially insoluble in water and in fat. Additionally, the large number of chemically different organic pigments placed on the market would necessitate the need for many animal studies.

In 2003 ETAD agreed with the UK Environmental authority to co-sponsor a study with a consulting firm W.S. Atkins to group organic pigments for the purpose of a targeted test programme to determine their bioaccumulation potential. In 2004 ETAD continued to be active in all stages of the preparation of this report and contributed significantly to its final form and to the design of a decision tree, whereby, on the basis of physico-chemical data, pigments could be excluded as potentially bioaccumulative. This report will now be presented to the EU experts group for consideration.

Parallel to this study individual ETAD members have, together with their own analytical experts, separately attempted to determine the solubility of a number of organic pigments in water and n-octanol and from this to get robust log Pow values. The currently available experimental methods do not function well for really insoluble products and current QSAR methods look at the structure of the molecule and take little account of inter-molecular interactions. It has been shown to be experimentally difficult to determine solubility values in the ppb range and to ensure that it is a genuine solution that is being analysed. A working group of analytical experts has now been formed to bring together the expertise from the companies and to propose a robust test procedure. This work is now being progressed with urgency as the authorities are pressurising the industry to demonstrate clearly that pigments are not PBTs.

Other Activities undertaken in 2004

- The PCB analytical method for organic pigments has been finalised and will be discussed with DIN as a possible standard method.
- ETAD contacted the EU authorities to express concern regarding the proposed new French Positive List. Our concerns as well as those expressed by EUROCOLOUR were not accepted on mainly formal grounds as the new framework directive (not published at the time of our submission) sees the possibility of positive lists for specific end applications.
- The POC continues to monitor the development of Food Contact Legislation within the EU; indeed Dr Rossi gave a presentation at the 2004 GA in Brussels. The publication now of the new Framework regulation and the draft of the so-called super regulation for plastics will impact our downstream users and consequently organic pigment manufacturers. We are developing a strategy to ensure our concerns are made clear to the EU working group.

- The study being carried out by PIRA (Pira Paper, Printing & Packaging), looking at the migration of pigments and contaminants into food simulants, is being followed. There are concerns that specific data results from the study will be reported out-of-context and steps will be taken to avoid this. However, changes within PIRA have made this more difficult to follow.

- The documentation for C.I. Pigment Green 7, which is on the OECD HPV (High Production Volume) list has been completed and submitted with BASF as the lead company.

- The labelling of Rosin and Rosin derivatives still gives cause for uncertainties. HARRPA (Hydrocarbon Resins, Rosins Resins and Pine Chemicals Producers Association) has presented the results obtained from the evaluation of a selection of representative derivatives and their potential to cause skin sensitisation. The method selected for this was the Local Lymph Node Assay (LLNA), which was to become the preferred EC method for classification and labelling as well as for new substance notification purposes. These results were provided on a

confidential basis and will be published as soon as the regulators fix the criteria for classification based on the mouse local lymph node assay. In the interim period, HARRPA recommends self-classification for substances agreed by the ECB and CEFIC to be sensitizers. The ETAD POC will follow-up with HARRPA.

- We continue to co-operate with other associations within the EU to ensure as far as possible a common understanding of legislation and its effect on organic colorants and downstream users.
- In response to the need for a global approach and to avoid unnecessary duplication of efforts, the POC saw a need to cooperate even more closely with related associations. CPMA was invited to participate at our GA in Brussels. However, differences in legislation and requirements to generate data have as yet not delivered the desired goals.

REGULATORY AFFAIRS COMMITTEE (RAC)

The Regulatory Affairs Committee (RAC) is composed of professionals who are responsible within their companies for world-wide regulatory compliance. Presently, standing RAC members represent eight ETAD member companies.

RAC's main remits are:

- Actively monitoring the development of chemical control regulations world-wide and assessing potential impact on the colorants industry.
- Ensuring awareness among member companies of new regulatory requirements.
- Providing advice on the interpretation of the regulatory requirements.
- Providing links with other European Industry Associations which are also involved in regulatory affairs.

Individual RAC members are allocated the responsibility to report on particular countries. This useful specialisation and sharing of workload increases efficiency.

Two predominant issues required special attention of RAC in 2004:

The classification of Disperse and solvent dyes under the EU preparations directive 1999/45/EEC (DPD) and the problem of PBT categorisation:

Sparingly soluble Disperse dyestuffs (as well as solvent dyes and organic pigments) could be suspected to meet the requirements for classification as PBT and R53 substances. RAC supplemented experimental evidence to further assess this category of dyestuffs/pigments.

Existing model equations for the calculation of BCF values need in particular precise solubility data. RAC therefore launched an experimental program for the determination of such input parameters, which then could be used for the validation of the model equations. BCF data calculated using the experimental input data showed good correlation with experimental BCF values. As the next step authorities have to be informed about such calculated BCF values for the exemption from R53 and/or PBT classification, if experimental data are lacking.

Revision of the ETAD Code of Ethics and the Guidance Document

- a) A draft revision of the outdated Annex A to the Code of Ethics was worked out. It includes a general manufacturing and marketing ban of azo dyes capable of releasing a carcinogenic amine by the cleavage of azo bonds.
- b) The ETAD Guidance Document was partly revised in order to adjust it to new developments and give it a more binding character:
 - Labelling of certain allergenic dyes
 - Information on reductively cleavable Cat 3 amines in the Safety Data Sheets
 - Guidance on the environmental classification of sparingly water-soluble colorants
 - Proposals for the description of personnel protection in the SDS.

Both initiatives can only become fully successful, if Member Companies are willing to extend the ETAD obligations beyond the legal minimum.

Other main activities of RAC undertaken throughout 2004 were:

- Monitoring the implementation of the Chinese legislation on the Notification of New Chemical Substances.
- Monitoring the development of the new EU Chemicals Legislation (REACH).

2004 for the JOC describes two major existing issues, which are continuing from previous years.

Amended chemical legislation (The Kashin-bo)

The new law scheme has become effective in April and the main points are as follows:

New Chemicals

Low volume exemption chemicals are assessed by both biodegradability and bioaccumulation. They can be imported up to 10 tons per year if they are not highly accumulative and are not suspected to cause adverse health effects. In addition to this, exemptions for intermediates and chemicals for export have been revised.

For chemicals with a partition coefficient below 3.5 (log Pow) a fish accumulation study is not required for notification.

As a result, three stages are described for notifications of new chemical substances and the necessary data are increasing with the quantity marketed. Up to 1 ton, minor quantity exemption allows submission with no data, up to 10 tons limited data (degradation and accumulation) are required.

In contrast, the ecotoxicological information - toxicity to fish, algae and daphnia - is necessary for a full notification.

Existing chemicals

The authorities proposed an idea for the data collection scheme of existing chemicals. The background is the fact that over the past 20 years the number of chemicals with available degradation and accumulation information is about 1,400, those with health effect information is about 300 under the scheme of the law.

The necessary information for existing chemicals in compliance with the law scheme is primarily biodegradation. If chemicals show ready degradable properties no further information is required. If they are not readily degradable, full screening toxicity and ecotoxicity information is required which are expensive to perform.

Currently those chemicals are considered under the scheme, which are manufactured and/or imported in total annual quantity of higher than 1000 tons.

Contact dermatitis caused by textile products

The ECO-Mark standards for clothing made from the recycled PET fabrics and its blends are published and include a list of some dyestuffs.

During this discussion, another working project was completed by a study report and proposed a draft of the JIS standards for analytical procedure of dyestuffs and testing method of the skin sensitization.

These standards will become effective in 2005.

Fluorescent Brightening Agents (FBAs) in recycled papers for food contact packaging

Local health government sections raised objections in some cases checked for compliance with food safety regulations of paper packages and trays used in shops for direct food contact. They detected fluorescent whitening agents in imported papers, but also in those made from recovered fibres and recycled papers.

FBAs are only allowed for use in food packaging if they are not extractable. If papers show fluo-

rescence, a migration test has to be performed by extraction in hot water and absorption onto cotton based material. If the test is positive for FBAs, then such products are illegally placed on the market and have to be removed and disposed together with the food that was in contact.

A working group has been established by MHLW (Ministry of Health, Labour and Welfare), National Food and Pharmaceuticals Institute, including paper industry associations, to set up certain safety standards for papers intended to come into contact with food. Currently no qualified standard is available for paper products. The law refers to other countries' regulations for such products including the EU resolutions or the EPA in the U.S.A. Considering the present situation, the working group will discuss not only fluorescent brightening agents, but also other chemicals used in manufacturing processes of papers and residuals in the recycled fibres as well.

Introduction

ETAD North America concentrated on its core activities in 2004 by focusing on regulatory developments in the U.S., Canada, and Mexico, advocating the industry's position with respect to the proposed RCRA (Resource Conservation and Recovery Act) hazardous waste ruling, coordinating testing program efforts, addressing product stewardship needs, and exploring customer outreach opportunities.

Regulatory Developments in the United States

Through the ETAD North America legal counsel, the members stayed abreast of regulatory and legislative issues. With the exception of the proposed hazardous waste listing rule, none of the other developments in 2004 had a major impact on the dyes industry.

- The Environmental Protection Agency (EPA) is considering proposals for reducing the reporting burden for the Toxic Release Inventory (TRI), which will benefit dye manufacturers who have reporting obligations.
- EPA's amendments to the TSCA Inventory Update Rule (IUR)

will require manufacturers and importers to furnish exposure information and some site-specific information on downstream uses. Some higher volume dyes will be impacted by this change in reporting requirements. Further revisions to the reporting requirements are anticipated during 2005.

- The Occupational Safety and Health Administration (OSHA) proposed a new standard of 1 $\mu\text{g}/\text{m}^3$ for Cr (VI) in the workplace. ETAD North America members do not anticipate that the new standard will significantly impact their dye manufacturing operations.
- The EU REACH proposal has relevance to ETAD North America members because of the direct impact on suppliers outside the EU and potential to influence legislation in the U.S. and other countries.

ETAD North America continues to follow these issues and will keep the members informed of further developments.

Hazardous Waste Listing Rule

ETAD North America submitted extensive comments in February objecting to EPA's new proposal for a hazardous waste listing rule for dyes RCRA.

If promulgated as proposed, the rule would impose burdens (e.g., fees, reporting/record-keeping, modification of waste treatment/disposal systems) on facilities whose solid wastes contain any of a list of target constituents at or above risk-based annual mass loading levels. Following EPA's issuance of the final rule in February 2005, ETAD North America will assess its impacts on U.S. dye manufacturers and determine whether further action is appropriate.

Chemical Testing

The Executive Director's office continues to monitor developments in the High Production Volume (HPV) Challenge Program by participating in chemical industry trade association meetings and maintaining contact with EPA's program staff. EPA is developing the HPV Information System (HPVIS), a public access database for all gathered data (i.e., robust summaries, test plans, test results) under the HPV Program. The American Chemistry Council, perhaps joined by other industry associations, plans to introduce a voluntary extended HPV program to cover chemicals newly identified as U.S. HPV's based on 2002 manufacture and import data. Elements of the new program, which will include hazard assessment and exposure assessment, were developed during 2004. Also during 2004, ETAD North America submitted comments to EPA seeking exclusion of Direct Black 22 from the proposed HPV test rule under Section 4 of the Toxic Substances Control Act (TSCA).

ETAD North America followed developments in various biomonitoring programs even though no dyes appear yet on any of the study priority lists. At

issue is how to evaluate and use the results of biomonitoring studies and the implications of those results for the chemical industry in general. Industry wants to ensure that validated screening methods and a meaningful list of subject chemicals are used.

The members also followed progress in development of an endocrine disruptors test program. A priority-setting process, which was implemented during 2004, will yield a candidate test list. Validation of test methods is ongoing, but validation testing of chemicals is not expected to begin until 2006.

Stilbene Brighteners

The Stilbene Whitening Agents Task Force (SWATF) continued its work on the HPV category study of stilbene brighteners with a targeted submission to EPA of a test plan and robust summaries during the first half of 2005.

Exposure

An ETAD North America task force is developing trigger points and general guidance for conducting exposure assessments. These tools will benefit members in many different ways such as by strengthening PMN applications, complying with IUR reporting requirements, responding to customer inquiries, dialogue with the authorities, coordinating responses to various testing initiatives, and fulfilling product stewardship obligations. This effort should have potential benefit to European members as well because of the need to provide exposure information under REACH.

Customer Outreach

ETAD North America met with EPA's Design for the Environment (DfE) program staff to explore possible collaborative efforts that would improve the visibility of ETAD to customers and create value for ETAD members. Both parties agreed to keep an open dialogue based on DyeCare® emphasizing how dyes are used and promoting safe handling and guidance materials. It was envisioned that a joint ETAD/DfE program would

emphasize product stewardship and pollution prevention as a proactive approach to product selection.

In separate action, ETAD North America established contact with the National Coalition of Textile Organizations. Both organizations agreed to cooperate and share information.

Canada

Representatives from Canadian member companies assisted the Executive Director's office in monitoring developments in Environment Canada's categorization and screening of the Domestic Substances List (DSL) based on predicted persistence (P), bioaccumulation (B), or inherent toxicity (iT). Following a meeting in August with the Canadian authorities, ETAD North America is preparing comments and a proposal for a scientifically based approach to categorizing the PBI potential of dyes on the DSL.

Mexico

No new regulatory developments or membership opportunities were noted in Mexico during 2004.

ETAD NA Business Plan

After completing a business plan development effort and discussing the results with the CEOs, ETAD North America decided to focus on its core activities of regulatory advocacy, product stewardship, testing, exposure assessment, and information which provide the most value to the member companies.

Pigments

The pigments market in 2004 increased by 4% compared to the year 2003. The prices continue to be affected by strong pressure of imports from Asia. Regarding the year 2005, we have a good outlook for Brazil. The sector which achieved the greatest increase in 2004 was the Coating Sector followed by Specialities, Plastics and Printing. Brazil achieved a record production in the automobile industry in 2004 surpassing 2.200.000 units from which 30% were consigned to export. Fortunately colour is again a marketing argument in the automobile industry which is extremely fruitful for the high performance pigments. The customers require more and more the environmental responsibilities of their suppliers.

Textile

Increasing exports of textile and leather articles to the EU lead to a higher concern that the products utilized in the process are in line with EC-Directive 2004/21/CE.

The performance of the textile industry was similar to previous year with a total turnover of 25 Billion US\$. The export share reached nearly 10% with increasing trend.

Also environmental issues are handled with higher priority in all regions.

Position Papers

ETAD: Setting a risk based detection limit of sensitizing disperse dyes on textiles, September 2004

ETAD: Diarylide pigments and the PBT/vPvB issue, October 2004

ETAD Position on two French Notifications 2004/327/F and 2004/328/F, October 2004

ETAD North America: Comments on EPA's Proposed Rule on Identification and Listing on Hazardous Wastes: Dyes and/or Pigments Production Wastes. Submitted to U.S. Environmental Protection Agency, February 23, 2004.

ETAD North America: Comments on C. I. Direct Black 22 (CAS 6473-13-8). Submitted to EPA, Docket No. OPPTS-42213A, Proposed HPV Test Rule, April 1, 2004.

Publications

Hatch, K.L.; Motschi, H., Maibach, H.I.: Textile-dye and colored-textile allergic contact dermatitis. *Exog. Dermatol.* 2003, 2, 206 – 209



Brochure

ETAD's mission for a sustainable growth in a colourful world, December 2004 (Versions: English UK & US, Chinese)

Lectures

Clarke, E.A.: Evaluation of Skin sensitization risks from dyed textiles. Presented at the Congress of European Textile Finishers' Organisation (CRIET), Ghent, Belgium, May 28-30, 2004

Motschi, H.: Evaluation of Skin Sensitization Risk from Consumer Textiles. Presented at the 4th International Conference "Health & Textiles", Biella, Italy, March 25-26, 2004



General Information

ORGANIZATION

General Assembly

Board

Executive Committee

Secretariat

EOC

ENA

IOC

JOC

BROC

POC

RAC

European
Operating
Committee

ETAD
North
America

Indian
Operating
Committee

Japanese
Operating
Committee

Brazilian
Operating
Committee

Pigments
Operating
Committee

Regulatory
Affairs
Committee

BOARD OF DIRECTORS 2004/2005¹⁾ COMMITTEE MEMBERS AND OFFICERS

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	Mr. Daniel Gronier	Francolor Pigments SA
	Dr. Meinhard Rolf	Lanxess
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	Mr. Yoshimi Yamada [°]	Ciba Specialty Chemicals KK
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	Mr. Mark L.H. Meesters	Stahl International bv
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	Dr. Detlev Wormsbächer	Clariant GmbH

General Information

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Mr. R. Y. Mani	Clariant
Dr. G. G. Patkar	Colour-Chem

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Vacant	Senior Scientist
Ms. Diana Colombo	Administrative Assistant

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Mr. W. Richard Bidstrup	Legal Counsel of ETAD North America Cleary, Gottlieb, Steen & Hamilton
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* Representative of U.S. Operating Committee of ETAD

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¹⁾ The Board of Directors 2005/2006 will be elected at the General Assembly Meeting on May 19, 2005.

²⁾ These lists give current membership (i.e. January 2005).

General Information

BACKGROUND HISTORY OF ETAD

In the 1960s a number of people prominent in the dyestuffs industry came to realize that the large, but nevertheless limited, scientific and technical resources within the individual companies could be used more effectively on a coordinated basis to solve any ecotoxicological problems ahead.

The rapid growth in environmental legislative activity at both national and international levels called for a collaborative approach by the industry, and the establishment of a much closer cooperation with the regulatory authorities. After thorough legal and administrative preparatory work, an international association, ETAD was formed in 1974. In 1976, ETAD's interests were extended to include synthetic organic pigments.

In the U.S.A., the American Dye Manufacturers' Institute (ADMI) had established an Ecology Steering Committee in 1971. In 1977, because ADMI was not solely a technical organization and because of uncertainties over the question whether ETAD membership could pose difficulties for American companies, the Dyes Environmental and Toxicology Organization (DETO) was formed. In early 1982 most DETO members decided to join ETAD, and the activities of the two organizations were merged. Whereas on an international basis ETAD representation includes organic pigments and dyestuffs, within the U.S. it represents only the dyestuffs interests of the U.S. members, as pigment manufacturers are

already represented in the U.S. by the Color Pigments Manufacturers Association, Inc. (CPMA).

Over the last ten years, ETAD has become more business-oriented in its selection of projects. It has formed closer contacts with the customer industries and major retailers of consumer goods, and collaborates closely with other sector groups, notably within CEFIC. Issues specifically affecting the industry and regulatory developments are the association's main focus. By taking an ethical stance, ETAD membership has gained recognition as a commitment to high standards of health and environmental protection.



General Information

CODE OF ETHICS

Preamble

The aim of ETAD is to minimize possible negative effects on health and the environment arising from manufacture and use of synthetic organic colorants and to ensure information on the best practicable protection is provided to the purchasers of these products.

To achieve this goal and to promote the image of a responsible and safety minded manufacturing industry, it is necessary that in all aspects related to human and environmental safety, members be encouraged to adhere worldwide to a high ethical standard.

Therefore, at the proposal of the Board, the General Assembly of ETAD approves this Code of Ethics as a key policy of the Association. All ETAD member companies are obliged to comply with this Code of Ethics.

1. Principles of responsible care

ETAD members are committed to support a continuing effort to improve the industry's responsible management of synthetic organic colorants. Members shall develop, produce and distribute products in a responsible manner which protects human health and the environment from unacceptable risks during manufacture, transport, use and disposal. Specifically, members shall implement a responsible care program in which the member undertakes to manage its business in accordance with the following principles:

- To recognize and respond to any community concerns about synthetic organic colorants and its manufacturing operations;
- To produce only synthetic organic colorants that can be manufactured, transported, used and disposed of safely;
- To make health, safety, employee training, quality assurance and environmental considerations a priority in planning for all products and processes;
- To provide employees, distributors and customers information on the health or environmental effects of synthetic organic colorants and recommend appropriate protective measures to ensure their safe use, transportation and disposal;
- To operate all facilities in a manner that protects the environment and the health and safety of employees and the public;
- To promote research on the health, safety and environmental effects of its products, processes and waste materials;
- To cooperate with public authorities in establishing well-founded environmental, safety and health regulations; and
- To promote these principles of responsible care to others who produce, handle, use, transport or dispose of synthetic organic colorants.

The responsible care program shall fulfil, but not be limited to, the specific obligations described under paragraphs 2 – 5 below.

2. Product Safety Policy

It is the policy of ETAD members to take all reasonably practicable steps in order to ensure human and environmental safety in the use of the dyestuffs and organic pigments (synthetic organic colorants), manufactured or distributed by them. Members shall comply worldwide with all applicable laws and regulatory requirements dealing with the safety and the environmental impact of synthetic organic colorants.

ETAD recognizes that the legal requirements for hazard communication differ considerably in various regions where organic colorants are marketed. A primary objective of this Code of Ethics is to ensure

that such differences do not deprive customers in countries with less stringent requirements of hazard information which is made available to their counterparts in countries with more comprehensive regulations. To achieve a common high standard of hazard communication ETAD members shall

- fully inform all customers about all known significant hazards;
- adopt policies to assure an equivalent level of hazard communication worldwide concerning their product.

3. Products Safety Information

3.1. Safety Data Sheets

Member companies shall ensure that for each of the synthetic organic colorants on their selling range, there is a safety data sheet with an appropriate information content and that it is supplied to all customers.

3.2. Labelling

The EU regulations provide an appropriate basis for classification and labelling of organic colorants.

Where the laws of the country the products are sold to, require more stringent or mandate different labelling, the members shall adhere to such required or mandated labelling. In countries with less stringent requirements the labelling shall be in accordance with the EU system or an equivalent consistent with the policy of achieving a uniformly high standard of hazard communication.

3.3. Education and Awareness Programs

ETAD members shall endeavour to inform customers of the safe handling procedures best suited to the products involved.

4. Cessation of manufacture and sale of certain hazardous colorants

The manufacture and sale of certain hazardous colorants by ETAD members is inconsistent with the high ethical standards expected of ETAD members, and the cessation of sale is a requirement of the Code of Ethics. These colorants are listed in Annex A to the Code of Ethics. Additions to Annex A may be made by the Board, but such additions will become binding only if they are approved by the next meeting of the General Assembly.

In view of the commitment to exposure controls in United States workplaces, as well as legal issues, the Board of Director's policy respecting dyes listed in Annex A shall not apply to ETAD members' sale or distribution of any such dyes in the United States for use in workplaces in the United States. In any such cases, the ETAD member shall obtain written assurance that appropriate exposure controls are in use prior to sale or distribution of dyes listed in Annex A.

5. Compliance

Member companies shall comply with the Code of Ethics and shall make every effort to ensure that their subsidiaries do so.

Annex A

benzidine-based dyes

General Information

BENEFITS OF ETAD MEMBERSHIP

Recognition

Recognised by regulatory authorities, customers, and the public as the authoritative source of information on health, safety, and environmental issues relating to organic colorants.

Representation

Represents interests of members and customers to government authorities, the media, other industries, public interest groups, organised labour, academia, and research/testing/consulting organisations.

Harmonisation

Advocates, where regulations are necessary, a harmonisation of the requirements, so that compliance costs are reduced.

Code of Ethics

Encourages members to adhere worldwide to a high ethical standard and promotes image of a responsible and safety-minded manufacturing industry.

Guidance

Provides guidance to ETAD member companies on interpretation of new regulatory requirements and recommends specific measures to implement the ETAD Code of Ethics.

Education and training

Develops and publishes education and training materials pertaining to organic colorants, e.g. for safe handling practices, product stewardship, and pollution prevention.

Research and testing

Cost-sharing of research and testing programs aimed at a better understanding of the health and environmental aspects of dyes and organic pigments.

Information

Responds to inquiries about the colorants' industry, provides information on topical issues and disseminates comments and position papers.

Database

Maintains and makes available to members a computerised database of literature pertaining to the health and environmental aspects of dyes.

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