



Environmental Criteria and Assessment Office (ECAO-Cin)

Annual Report FY92

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SCIENTIFIC LEADERS FOR THE 1990s

Introduction/Purpose

ECAO-Cin was a founding laboratory for risk assessment and science in the early 1980s. The National Academy of Sciences (NAS) paradigm published in the 1983 Red Book became the framework for risk science and decisions. Since early 1980, EPA has been pioneering the risk reduction pathways now in vogue.

ECAO-Cin began a cultural change in mid-1991 to address the complexities of risk science and assessment challenges for the next decade. A cornerstone for this conscious decision to change is an organization committed to continual learning and improvements in leadership theory and practice. For higher productivity and more efficient public health protection, the historical scientific excellence embodied in ECAO-Cin must continue. It can be argued that these ends – scientific individualism versus collaborative leadership – may seem incompatible, but we resolve that they are not. To the contrary, we believe it is essential that they co-exist, build upon each other, and widen to broaden our coalition base.

We have adopted the organizational empowerment techniques of Total Quality Management (TQM) and the model offered by Commonwealth Center for High Performance Organizations, Inc., and are utilizing Dr. John Pickering as our consultant/facilitator.

At this stage, all ECAO-Cin staff members have been oriented to the participative model; our leadership group – System 4 Board – has 1½ years

experience with this model and the general work force has about 6 months of initial steps.

As expected, the rate of adoption, acceptance and application of these value-based approaches to lead more effectively have been widely variable. Changes of this type take time and deal with learned feelings and behaviors. What is clear is that the investment is worthwhile so far; initial improvements seen in attitudes and sharings make ECAO-Cin a more welcome place to work, the power of the model is largely underrated. Productivity gains are expected to improve geometrically as experience and skills with our model increases and accelerates.

Selected Participative Model Improvements to Date

- Customer focus increasing
- Rotating Acting Directorship to include Branch Chiefs
- Internalization of groups within the office
- Genuine reevaluation of priorities and resource availability for ECAO-Cin, OHEA work, IRIS, and Program and Regional support
- Formulation and adherence to a vision
- Model introduced to general work force
- Unity of purpose is a discussed ideal

Time Lines for Scientific Leadership Development

This approach began in June 1991; reached a milestone in June 1992 when the full work force was introduced to the process; and we are looking toward a mid-1993 change in the way we do business with our constituencies internally and externally.

Ways to Measure Continuing Success

We will compare ourselves with other styles of operating in terms of the quality of life at ECAO-Cin, and examine the resource investments needed to achieve success. We will be the providers of choice in what we do.

We will account for our contributions in terms of human lives saved or improved, and ecologic protection and preservation using cost effective tools.

We will measure ourselves in terms of the breadth of the coalitions we build and the results we achieve through collaboration.

Risk Assessment Methods – Guidelines and Research

ECAO-Cin is a primary laboratory that develops risk assessment methods for noncarcinogenic toxicity of single chemical exposures. The main products are research publications and Agency consensus risk assessment guidelines. ECAO-Cin staff chaired two Agency guidelines efforts: the first version of *General Quantitative Guidelines for Risk Assessment of Noncarcinogenicity Toxicity*, and the revision of the *Guidelines for Risk Assessment of Chemical Mixtures*, previously published by EPA in 1986. These guidelines are written by committees representing most major groups in EPA and provide the rationale for official Agency policy for health risk assessments and decisions based on health risk.

Current research on risk assessment methods for single chemicals includes several topics, from statistical approaches (for threshold estimation and refinements to the Reference dose method) to broad assessment techniques (for sludge application and incineration of municipal solid wastes). Mixtures methods have focused on toxicologic interactions between two chemicals and the use of such information in site- or mixture-specific estimation. Current research is on weight-of-evidence methods for nonadditive interactions and on quantitative modifications to the additivity-based Hazard Index. A project with implications for both single chemicals and mixtures focuses on improved methods for using multiple data sets in quantitative estimates. The results of this work has impacted the revision of the Cancer Risk Assessment Guidelines.

When completed, all these methods will be incorporated into the Agency risk assessment guidelines.

Scientific Assessments

ECAO-Cin leads the Environmental Protection Agency (EPA) in the development of risk assessments for chemicals that pollute our nation's waters and soils. Our laboratory also develops and reviews risk assessments for chemicals that contaminate our nation's air and food. Our clients include (but are not limited to) all major EPA program offices and all regions, many state agencies, and several international organizations.

Major risk assessment activities in FY92 included the following:

- Review of public comments and re-evaluation of risk assessments for the Phase V chemicals under the Safe Drinking Water Act (SDWA),
- Initiation of noncancer risk assessment for Polychlorinated Biphenyls (PCBs) for the Clean Water Act (CWA),
- Development of many risk assessments in support of the Resource Conservation and Recovery Act (RCRA),
- Development of 15 reportable quantities (RQs) in support of the Superfund Amendments and Reauthorization Act (SARA),
- Completion of a highly visible case study for municipal solid waste combustion (Rutland, Vermont) and the initiation of another incineration case study,

- Completion of a risk assessment methods document for landfilling of sewage sludge,
- Initiation of hazard identification documents for municipal solid wastes recycling and composting, and
- Initiation of Cooperative Agreement with Mississippi State University, the first of its kind – exploring the potential for human and ecologic risk assessment through an aquatic mecososm model.

ECAO-Cin also coordinated EPA's Integrated Risk Information System (IRIS) and co-chairs Agency Work Groups for evaluation of noncancer and cancer effects. We have discussed 42 Reference Doses (RfDs) and 57 Reference Concentrations (RfCs), and handled more than 500 comments to IRIS User Support (IUS). ECAO-Cin's Superfund Health Risk Technical Support Center (SFTSC) also successfully responded to more than 500 requests from 10 regions and 19 states.

Technology Transfer

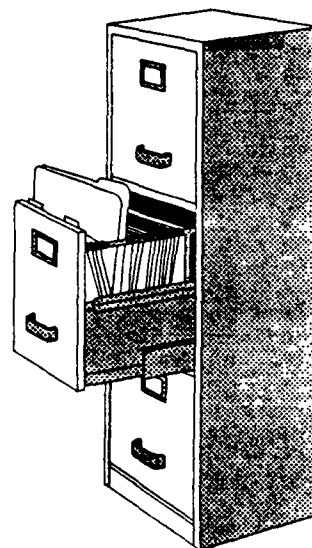
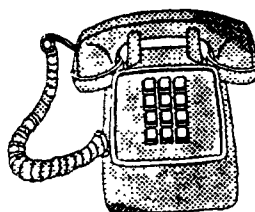
One important aspect of the efforts of ECAO-Cin involves technology transfer and outreach. It is this overall effort that assists in the interpretation and implementation of all our efforts. Increased emphasis is being placed on technology transfer and in the development of technology-driven data bases for internal and external use. ECAO-Cin predicts much growth in its expanded capabilities for site- and chemical-specific assistance at all levels. The technology transfer activities of ECAO-Cin can be grouped into three categories:

- Data base development for public information transfer on risks
- Outreach – national and international
- Consultation/Technical support/assistance on risk assessment science and its application

Since its establishment, ECAO-Cin has been a leader in providing technical evaluations and decisions. Within the past 2 years, this effort has grown and become formalized through the operation of the SFTSC and the IUS, and participation in the efforts of the Air Risk Information Support Center (AirRISC). Each center was established to provide technical evaluations on the important risk assessment activities of ECAO-Cin, the Office of Health and Environmental Assessment (OHEA) and EPA. The SFTSC is one of seven Agency centers established to provide technical support to Superfund regional remedial project managers and on-scene coordinators. Specifically, the ECAO SFTSC was established to assist the Superfund Office in preparing, reviewing, and establishing short- or long-term health-based

cleanup levels (*risk-based*) at Superfund sites and to respond to client requests on a rapid turnaround basis. Over the past year, the SFTSC has completed 514 requests for assistance.

The product of this effort is a report on site- and chemical-specific technical support/assistance in health/risk assessment by providing the most current or scientifically defensible risk characterization for single compound or mixtures at Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) sites. ECAO-Cin's SFTSC also has the responsibility for coordinating with regions, other SFTSCs and the various superfund offices (such as the Office of Solid Waste [OSW]) to ensure that the response provided is justified in terms of science or program policy, and that the same techniques are applied to all National Priority List (NPL) sites.



International Activities

ECAO-Cin has always been involved with global environmental activities and issues. The primary conduit of such involvement has been with the International Programme on Chemical Safety, World Health Organization (IPCS/WHO). ECAO-Cin serves as a focal point for the Office of Research Development (ORD) and OHEA scientific interactions with IPCS/WHO. Efforts have included the development of health assessments and documentation for IPCS, which are distributed worldwide; participation on expert task forces; and participation in symposia and training sessions on health risk assessment. Other international activities include participation in the Binational Committee to develop water quality objectives for the Great Lakes as part of the International Joint Commission (IJC) for the Great Lakes and the Great Lakes Water Quality Initiative (GLWQI). Over the next several years we will focus upon followups in the Agenda 21 agreement at Rio as applied to global risk assessments.

During FY-92, through our involvement with IPCS, we have successfully hosted an international task force meeting to develop health risk assessments for the pesticides *benomyl* and *carbendazim*. Experts from nine countries representing 11 organizations/universities met in Cincinnati to develop environmental and health risk assessments for these two pesticides. The guidance documents developed will be distributed and used worldwide, particularly in low economic countries. We have also served as the lead organization in developing environmental health criteria documents for *malathion* and *cresols*.

Our participation in international meetings and committees included the following:

Dr. Debdas Mukerjee taught a week-long seminar on effects of cancer risk assessment at Kiel, Germany, where he is Adjunct Professor at the University of Kiel.

Dr. Michael Dourson was invited to Geneva to assist the IPCS. Discussions focused on consideration of methods for deriving *guidance values* for human exposure to chemical substances in the environment. Dr. Dourson chaired the subgroup on Uncertainty Factors (UF).

Dr. Terry Harvey visited Copenhagen, Denmark, to evaluate and support two WHO topics for IPCS. These included *Hypersensitivity to Chemicals – An Updating to the 1992 WHO Report* and *Use of Quantitative Risk Assessments by IPCS/Agenda 21 in Rio*.

Dr. Rita Schoeny presented a paper at the *First International Meeting on Environmental Mutagens in Human Populations at Risk* in Cairo, Egypt. This meeting was unusual in its outreach to African and Middle Eastern nations.

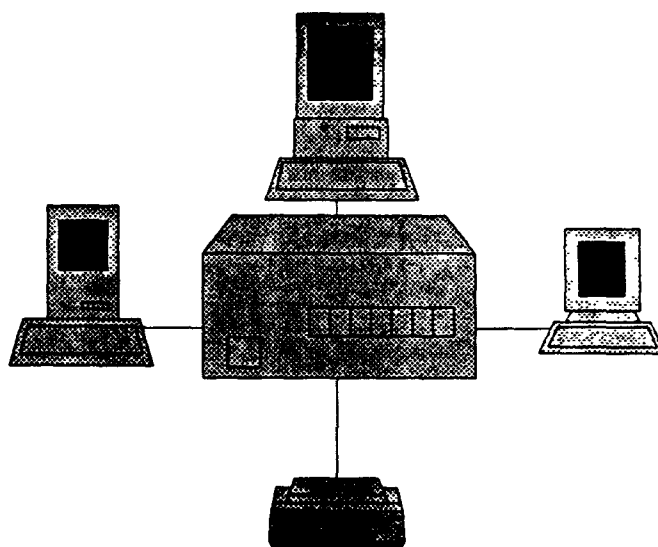
Information Management

High quality, reliable human health risk assessment information, which has been put into a meaningful and useful context and communicated to decision makers, is a significant product for ECAO-Cin. This information represents use of the best available science data and assessment techniques, which serves as the primary Agency resource for risk management and regulatory decisions. Data bases are developed and used by ECAO-Cin as well as by other federal agencies, state and local governments, and several international organizations and countries. Several systems are available from ECAO-Cin for the creation, collection, use, processing and transmission of this quality information. IRIS, MIXTOX and Lead Biokinetic models are all examples of this Risk Assessment Communication Network developed by ECAO-Cin.

Demand for access and availability of these risk assessment tools has increased greatly in the past several years. This especially applies to the IRIS and MIXTOX data bases. Current activities for the data bases are highlighted below.

- Upgrade/expansion of IRIS information to include 50 new chemical-specific substances, Drinking Water Health Advisory data, and other information
- Upgrade of MIXTOX, software, expansion of references, and distribution of MIXTOX Version 1.5
- Incorporation of interaction data on carcinogens into MIXTOX

ECAO-Cin plans to broaden these activities in the future. For IRIS, future activities include the development of a collateral federal system, or initiation of FTTA agreements for marketing and distributing IRIS 2. We envision this system serving as a worldwide model for the implementation of Agenda 21.



ECAO-CIN RESOURCES
(Dollars in \$K)

	<u>FY91</u>	<u>FY92</u>	<u>FY93</u>
Full-Time Equivalent (FTE)	40.1	37.6	37.7
 R&D – Extramural by Media			
AIR QUALITY	12.8	108.9	0.0
WATER QUALITY	255.8	231.4	145.8
DRINKING WATER	190.3	168.6	681.7
HAZARDOUS WASTE	623.2	582.1	172.7
MULTIMEDIA	113.7	113.0	387.0
RIHRA	155.0	135.0	0.0
SUPERFUND	1,208.9	789.5	703.1
SERDP		800.0	
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TOTALS	2,559.7	2,928.5	2,090.3

ECAO-CIN PUBLICATIONS – FY92

Abstracts

Brady-Roberts, E. 1992. Municipal and Solid Waste Management.

Choudhury, H., S. Griffin and M. Mumtaz. 1991. Risk Assessment of Acetone, Ethyl Acetate, Ethyl Ether as a Chemical Mixture.

Cleverly, D., C. Travis and G. Rice. 1992. Demonstration of the U.S. EPA's Indirect Exposure Chamber Methodology for Combustors.

Dourson, M.L., J.L. Cicmanec and K.A. Poirier. 1991. Testing a Novel Approach to Estimate Health Risk Above the Reference Dose (RfD/Reference Concentration (RfC)).

Hertzberg, R.C. and L.A. Knauf. 1992. Severity Modeling Instead of a NOAEL for Noncancer Risk Assessment. Tri-Service Conference on Applications of Advances in Toxicology to Risk Assessment, Wright-Patterson Air Force Base, Dayton, OH. May 1992.

Hertzberg, R.C., P. Durkin and M. Mumtaz. 1992. A Generalized Model for Defining Additivity for Chemical Mixtures. Tri-Service Conference on Applications of Advances in Toxicology to Risk Assessment, Wright-Patterson Air Force Base, Dayton, OH. May 1992.

Mather, F.J., S.A. Blakley, L.E. White, A.J. Englande, M.S. Arata, C.N. Correa and P.A. Murphy. 1992. Sample Size Estimation in Environmental Epidemiological Studies with Continuous Exposure Measurements. Presented at International Society for Environmental Epidemiology 4th Annual Meeting, Cuernacava, Mexico. August 1992. (To be published in Arch. Env. Health, 1993)

Mumtaz, M., R. Schoeny and T. Harvey. 1991. The Risk Assessment Process at the U.S. EPA: Current Guidelines and Reference Numbers. Tri-Service Conference on Applications of Advances in Toxicology to Risk Assessment, Wright-Patterson Air Force Base, Dayton, OH. May 1992.

Mumtaz, M. and J. Coleman. 1992. The Risk Assessment of Chemical Mixtures: Fine Tuning the Hazard Index. Tri-Service Conference on Applications of Advances in Toxicology to Risk Assessment, Wright-Patterson Air Force Base, Dayton, OH. May 1992.

Mumtaz, M. and P. Durkin. 1992. A Weight-of-Evidence Scheme for Assessing Interactions in Chemical Mixtures. Tox. Ind. Health. (In press)

Mumtaz, M., D.J. Reisman, B. Peirano, L. Knauf, C. DeRosa, K. Enslein, V. Gombar and V.M.S. Ramanujam. 1992. Computer-Assisted Estimation of Chronic LOAEL Based Upon Quantitative Structure Activity Relationships. Toxicologist. 12(1): 94. Abstract #289.

Mumtaz, M., D.L. McKean, K. Garrahan, B. Means and D. Davoli. 1992. Hazardous Waste Site Risk Assessment: An Illustrative Case Study. Tri-Service Conference on Applications of Advances in Toxicology to Risk Assessment, Wright-Patterson Air Force Base, Dayton, OH. May 1992.

Mumtaz, M., K. Poirier and R. Hertzberg. 1993. Feasibility of Developing Target Organ Toxicity Doses for Estimation of Toxicity of Chemical Mixtures. Submitted for Society of Toxicology, March 1993 meeting in New Orleans.

Murphy, P.A. 1992. Quantifying Chemical Risk from Epidemiologic Studies: Application to the Disinfectant By-Product Issue. Presented at The First International Conference on the Safety of Water Disinfection: Balancing Chemical and Microbial Risks, J.W. Marriott Hotel, Washington, DC, August 31-Sept. 3.

Patterson, J. and L. Tuxen. 1992. The Integrated Risk Information System: Opportunities for Public Input.

Poirier, K.A. and G.L. Foureman. 1992. Development of an Oral Reference Dose (RfD) for Selenium: Essentiality and Toxicity Considerations. Toxicologist. 12(1): 248. Abstract #940.

Riley, T.J., J.A. Cauley, P. Murphy and D. Black. 1992. The Relation of Water Chlorination to Serum Lipids in Elderly White Women. Am. J. Epidemiol. 136: 969.

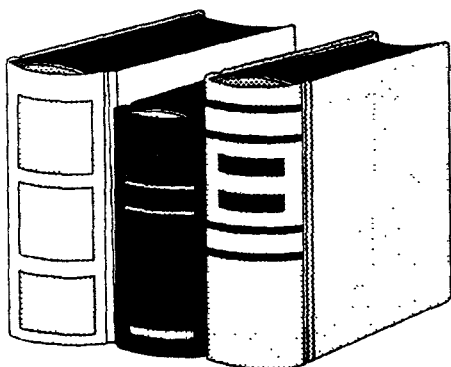
Schoeny, R. 1992. Utilization of Mutation Assays for Assessment of Potential Human Health Risk From Environmental Mixtures. Presented at IVth European ISSX Meeting – Toxicological Interactions: Relevance of Social, Environmental and Occupational Factors, Bologna, Italy, July 3-6, 1992.

Schoeny, R. 1992. Risk Assessment of Products of Incomplete Combustion. Presented at 1st International Conference on Environmental Mutagenesis in Human Populations at Risk, Cairo, Egypt, January 19-24, 1992.

Smallwood, C.L., K.M. Schenck and B.W. Lykins, Jr. 1992. Health Effects Associated with Disinfectant By-Products Formed from Chlorine, Chloramine, or Ozone. Presented at The First International Conference on the Safety of Water Disinfection: Balancing Chemical and Microbial Risks, J.W. Marriott Hotel, Washington, DC, August 31-Sept. 3.

Stiteler, S., W. Melan, L.A. Knauf, R. Schoeny and S. Velazquez. 1992. A Computer Program for Testing the Statistical Compatibility of Data Sets with a Common Multistage Model.

Velazquez Tutt, S. and J.T. Du. 1991. Derivation of the RfD for Manganese. To be published with Proceedings from the Workshop on Risk Assessment of Essential Elements, Herndon, VA, March 10-12, 1992.



Book Chapters

DeRosa, C., M. Mumtaz, H. Choudhury and D. McKean. 1992. An Integrated Approach to Risk Characterization of Multiple Pathway Chemical Exposures. Chapter 12. In: Comparative Environmental Risk Assessment, R. Cothorn, Ed. Lewis Publ., Inc., Boca Raton, FL.

Mumtaz, M. and R. Hertzberg. 1992. The Status of Interaction Data in Risk Assessment of Chemical Mixtures. In: Hazard Assessment of Chemicals, Vol. 8, J.P. Saxena, Ed. Hemisphere Publ. Corp., Washington, DC. p. 47-49.

Velazquez, S. and K. Poirier. 1991. Problematic Risk Assessments for Drinking Water Contaminants: Selenium, Aldicarb and Nickel. In: Drinking Water Contamination and Health: Integration of Exposure Assessment, Toxicology and Risk Assessment, 1st ed., R. Wang, Ed. Marcel-Dekker, Inc., New York, NY. (In press)

ECAO-CIN Assessments Cleared in FY92

Reportable Quantity Documents (RQs) for the following:

Aldrin/Dieldrin
m-Cresol
o-Cresol
p-Cresol
N,N-Dimethylformamide
Pentachlorobenzene
Propoxur
Quinoline
Sodium Azide
Thioacetamide
Toxaphene
m-Xylene
o-Xylene
p-Xylene

Health and Environmental Effects Documents (HEEDs) for the following:

Alachlor
Aniline
1,2-Dichloroethylene (Mixed Isomers)
Phthalic Anhydride

GLOBALIZATION OF RISK ASSESSMENT – THE FUTURE

Situation/Future

As a follow-up to the UNCED meeting in Rio in mid-1992 and the signing of Agenda 21, ECAO-Cin looks forward to facilitating equilibrated and regional, international risk assessment endeavors in risk science for methods and specific assessments for chemicals, mixtures, and biota. Included in this multimedia, global forum will be the World Health Organization (WHO), OECD, ICPTS, and the like. Also the NAFTA environmental activities will be supported through these and related efforts.

Future Liaisons with Other Agencies

ECAO-Cin has embarked on a liaison project with scientists and engineers for the Federal Highway Association (FHWA) of the Department of Transportation (DOT). This is in response to a statutory mandate, which specifies that the EPA and DOT will jointly prepare a report to Congress on the potential health and environmental impacts of use of crumb rubber modifier in asphalt pavement. A good working relationship with various sections of the FHWA has been established and the briefing paper is being prepared with input from EPA and DOT. As requested, a preliminary report to Congress delineating risk assessment issues and research needs will be submitted in June of 1993.

Connections with the Department of Defense (DOD) are being expanded in FY93. For the past 2 years, ECAO-Cin scientists have participated in scientific conferences on human health risk assessment sponsored by DOD and held

at the Wright-Patterson Air Force Base in Dayton, Ohio. The conference this year will be jointly sponsored by EPA and DOD with ECAO-Cin. Joint research plans are being discussed with DOD and DOT scientists looking towards managing cleanup of environmentally impaired federal facilities on a greatest risk basis.

Future Academic Consortium

A recent thrust of ECAO-Cin is the establishment of an academic consortium in the area of human health and environmental comparative risk assessment. The objectives of the consortium are several.

- A major objective is to open dialogue with both bench researchers and risk translators to establish areas of mutual interest in academia, government, and industry.
- A second objective is to provide direction to mathematical and laboratory research such that it is useful to risk assessment; this can be done by fostering research congruent with our aims and by involving EPA personnel in the planning of research programs.
- A third objective is to further educational opportunities in risk assessment by aiding in the design and teaching of courses in risk assessment.

The relationship with Universities will provide entrees to EPA staff for career growth, i.e., finishing a degree, taking a postdoctoral traineeship, or doing a sabbatical or some other kind of laboratory residence project and thus keep risk assessors in tune with other research activities.