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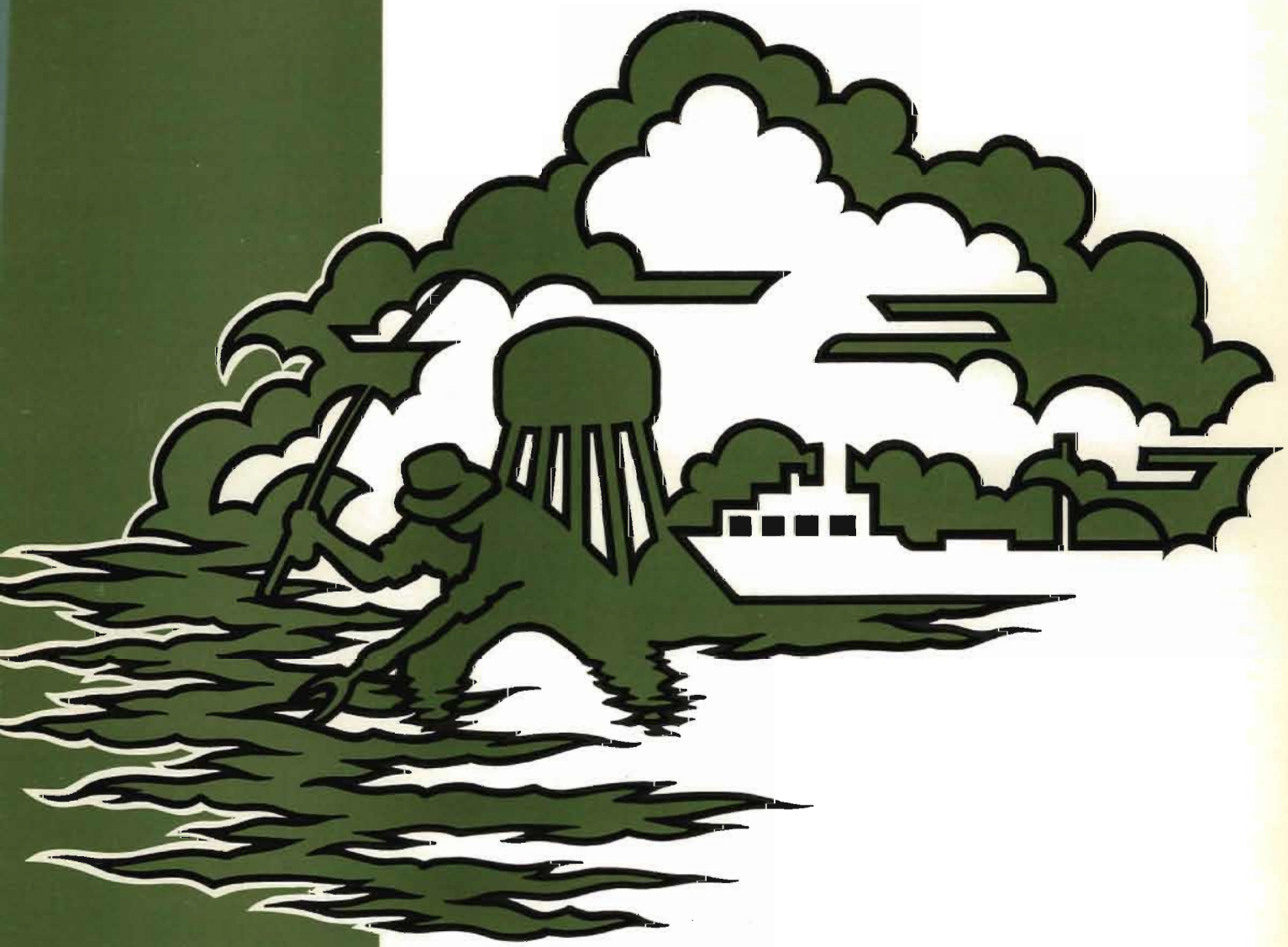
WATER QUALITY BOARD



INTERNATIONAL JOINT COMMISSION

WORKSHOP ON HAZARD ASSESSMENT

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April 9 - 11, 1979
Sponsored by the
GREAT LAKES WATER QUALITY BOARD
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INTERNATIONAL JOINT COMMISSION

WORKSHOP ON HAZARD ASSESSMENT

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NOTICE

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INTRODUCTION

BACKGROUND

WHY WORKSHOPS ON TOXIC AND HAZARDOUS SUBSTANCES?

In response to identified toxic and hazardous chemical problems in both Canada and the United States, and in order to prevent the occurrence of additional future problems, numerous pieces of legislation have been passed in recent years and some are still in the process of being implemented. Given the emergent state of these regulatory programs and a common interest of the Great Lakes jurisdictions in their shared resource, the Great Lakes Water Quality Board of the International Joint Commission agreed to sponsor a series of workshops to address the mutually shared problems and common opportunities associated with development and implementation of regulatory control programs, especially those which necessitate interjurisdictional coordination in the Great Lakes Basin. All media - air, water, and land - were to be considered.

The Water Quality Board approved a series of four workshops. The first three workshops - Hazard Assessment, Early Warning Systems, and Data Acquisition and Management - would address specific aspects of toxic substances control programs at the operational level, including:

1. Criteria for identification of toxic and hazardous substances.
2. Prioritization or ranking of these substances.
3. Early warning systems to prevent crisis situations.
4. Surveillance and monitoring activities in support of control programs.
5. Interjurisdictional movement of materials.

The workshops were conceived as a means to address these and other concerns during the critical stages of control program implementation. The fourth and final workshop would consider an overall strategy for toxic substances in the Great Lakes Basin, based on information and material presented at the first three workshops, and within the context of management and policy considerations.

GOALS

The goals of the workshops were to provide a forum to:

1. Discuss mutual concerns.
2. Develop solutions to the operational problems associated with toxic and hazardous substance regulatory programs.

3. Facilitate the orderly development of compatible control programs for the Great Lakes Basin.

OBJECTIVE

The overall objective was to present tools that participants could use to improve and expand their own control programs and to develop some degree of consistency in those programs.

WORKSHOP 1 - HAZARD ASSESSMENT

The large number of chemicals that are manufactured, processed, used, and disposed of in the Great Lakes Basin underscores the potential for release of toxic and hazardous chemicals to the environment. The need to identify priority substances and to assess their health and environmental impact is clear. Presently, jurisdictions in the Great Lakes Basin select priority substances in different ways and for different reasons, and apparently often without an adequate information base. While such approaches may suffice to meet limited, short-range objectives, a single, mutual priority-setting process based on common, compatible identification criteria is desirable for both short- and long-range investigation and control of toxic and hazardous substances in the Great Lakes Basin.

The first workshop, on hazard assessment, was held April 9-11, 1979 in Ann Arbor, Michigan; 102 people attended.

PURPOSE

The purposes of the Hazard Assessment Workshop were to:

1. Exchange information on existing hazard assessment procedures and related toxic substances control programs.

2. Make recommendations for development and implementation of common hazard assessment procedures and related programs in the Great Lakes Basin.

INTENDED AUDIENCE

The workshop was intended as a forum for federal, provincial, and state personnel working actively in the field of toxic and hazardous substances and also for those in a position to influence policy and decision making. Participants also included representatives from industry, environmental advocacy groups, representatives of elected legislators, and others involved with hazard assessment.

DEFINITION OF HAZARD ASSESSMENT

To provide a common starting point, the following "ideal" definition of hazard assessment was proposed:

> Hazard assessment means the evaluation of existing data and information on chemical substances. Data and information

includes, but is not limited to physical, chemical, and toxicological characteristics; production volume; uses; environmental release and fate; exposure; and economic considerations. The evaluation is usually achieved by means of a formal process or procedure, using specific criteria and rationale within a program framework and with definite goals. The objective is to determine impacts on human health and the environment with a view toward controlling contamination of the ecosystem.

STRUCTURE AND CONTENT

The Hazard Assessment Workshop included formal presentations from invited speakers to describe:

1. Federal environmental programs.

2. Federal health programs.

3. State and provincial environmental and health programs.

4. Non-governmental programs (industry and environmental advocacy).

Each agency, jurisdiction, or program has some basis to determine what aspect(s) of the toxic substance issue will be addressed. After an assessment of the potential hazard is completed, the result is used as the basis for priority setting, standard development, information gathering, and regulatory decision making in areas of human health and/or environmental protection.

Recognizing that each agency, jurisdiction, or program has a specific reason for conducting hazard assessment, and using the proposed definition of hazard assessment above, each invited speaker was requested to address the following areas:

1. How does your agency, jurisdiction, or program make its initial determination of what may constitute a hazard, i.e. what is your starting point? What is the overall function of your agency or program regarding the issue of toxic substances and hazard assessment? The basis could be such points as:
   A. Legal/legislative mandate
   B. Court decision(s)
   C. Product line(s)
   D. Known concerns or inherited issues
   E. Raison d'etre

2. What is your scientific and technical basis for hazard assessment? How and where does your information come from? Speakers were asked to place their emphasis here.

3. What are the unique and innovative characteristics of your programs or activities?

4. After your hazard assessment process is complete to the best extent possible, how, then, do you or can you use it in your activities?

5. What are the limitations encountered or pre-established in your assessment process, priority setting, and decision making? Speakers were asked to integrate, as appropriate, the following points into the four preceding items:
   A. Institutional/historical
   B. Regulatory
   C. Organizational
   D. Budgetary
   E. Personnel (expertise)
   F. Information
   G. Program time constraints

The material and information presented was to be used to:

1. Acquaint participants with existing hazard assessment procedures and methodologies and with how regulatory programs are being implemented.

2. Identify sources of relevant material and information and how they are being utilized by regulatory agencies.

3. Stimulate discussion and continuing scientific and regulatory contacts to facilitate free exchange of information and ideas on hazard assessment.

4. Identify strengths and weaknesses of existing hazard assessment procedures.

5. Identify further research and other programs necessary to support hazard assessment activities.

6. Make recommendations for development of methods to integrate existing hazard assessment procedures and related programs.

7. Develop cooperation and coordination to avoid duplication.

Using the formal presentations as a stimulus, two panel discussions were scheduled to provide speaker/audience interaction and additional input. Facilitators were also asked to take notes on the formal presentations and the panel discussions, and then present a summary of the major points. The key questions related to hazard assessment would then be posted and answers developed by the participants. Specific conclusions and recommendations to improve hazard assessment activities and related programs would also be developed and forwarded for action to the Water Quality Board.

The formal structure of the workshop is given in Table 1.

CONTENT OF PROCEEDINGS

These proceedings contain:

1. Formal presentations by the invited speakers.

2. Summary and conclusions of the discussion sessions.

TABLE 1

PROGRAM OUTLINE FOR HAZARD ASSESSMENT WORKSHOP

MONDAY - APRIL 9

INTRODUCTION

W.G. Turney, Michigan Dept. of Natural Resources

SESSION 1 - FEDERAL ENVIRONMENTAL PROGRAMS

Moderator: D. Kraft, U.S. Environmental Protection Agency
Presentations: Chapters 1-10

PANEL

Moderator: D. Hallett, Canadian Wildlife Service
Discussion and amplification of material presented during Session 1. Additional input from all workshop participants.

TUESDAY - APRIL 10

SESSION 2 - FEDERAL HEALTH PROGRAMS

Moderator: J.R. Hickman, Dept. of National Health and Welfare
Presentations: Chapters 11-16

SESSION 3 - STATE AND PROVINCIAL ENVIRONMENTAL AND HEALTH PROGRAMS

Moderator: G. Rosenblatt, Ontario Ministry of Labour
Presentations: Chapters 17-23

SESSION 4 - NON-GOVERNMENTAL PROGRAMS

Moderator: W. Ward, General Motors Corporation
Presentations: Chapters 24-27

PANEL

Moderator: L. Botts, Great Lakes Basin Commission
Discussion and amplification of material presented during Sessions 2, 3, and 4. Additional input from all workshop participants.

WEDNESDAY - APRIL 11

FACILITATOR PRESENTATIONS

Summary of key points emerging from formal presentations and panel discussions. Development of key questions to be answered.

PANEL OF MODERATORS

Moderator: R. Powers, Michigan Dept. of Natural Resources
Pick out major points answering each question, summarize participants' conclusions, and develop recommendations.

3. Conclusions and recommendations developed by the Workshop Steering Committee subsequent to the workshop and presented to the Water Quality Board.

4. Report of the Water Quality Board to the International Joint Commission.

5. Names and addresses of the participants.

CHAPTER 1

HAZARD ASSESSMENT FOR PURPOSES OF FEDERAL LEGISLATION IN CANADA: THE FISHERIES ACT, THE CLEAN AIR ACT, AND THE ENVIRONMENTAL CONTAMINANTS ACT

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INTRODUCTION

The purpose of my presentation today is to familiarize you with the role of the Canadian federal Department of the Environment in the field of environmental contaminants, and the methods used in the department to priorize and assess the hazards associated with contaminants.

Before getting to that, I would like to say a few words about the role of the department in environmental protection. In Canada, environmental protection is a responsibility shared by both the federal and the ten provincial governments. Although the Canadian constitution does not address environmental control per se, there are institutional trends from which both levels derive authority in this area.

The Environmental Protection Service (EPS) of the Department of the Environment is responsible for development of environmental control regulations. Agreements have been reached between the federal government and some of the provinces, including Ontario, which articulate the responsibilities of each level in the implementation of control programs and enforcement regulations. I want to point out that while there are other pieces of environmental legislation administered by other services in the department, this discussion is confined to those aimed at preventing contamination of the environment.

EPS is comprised of three directorates, each of which administers a particular piece of legislation as shown in Table 1. The Water Pollution Control Directorate (WPCD) administers the Ocean Dumping Control Act and Section 33 of the Fisheries Act, which are designed to prevent the deposit of deleterious substances into waters frequented by fish except as authorized by regulation. The Ocean Dumping Control Act is applied exclusively to marine environments, and other sections of the Fisheries Act are administered by the Department of Fisheries and Oceans, so discussion here will be limited to Section 33 of the Fisheries Act (FA).

The Air Pollution Control Directorate (APCD) administers the Clean Air Act (CAA) whose main purpose is to protect public health by regulating the emission of hazardous pollutants to the atmosphere. The Environmental Impact Control Directorate (EICD) administers the Environmental Contaminants Act (ECA) which controls the release of contaminants by regulating their use.

TABLE 1

LEGISLATION ADMINISTERED BY EPS

DIRECTORATE	LEGISLATIVE MANDATE
Water Pollution Control Directorate	Section 33, Fisheries Act
Air Pollution Control Directorate	Clean Air Act
Environmental Impact Control Directorate	Environmental Contaminants Act

TABLE 2

FISHERIES ACT

Scope - control release of deleterious substances to receiving waters
Approach to control - establish effluent regulations and guidelines for industry sectors.

TABLE 3

PROTOCOL FOR DEVELOPMENT OF CONTROL STRATEGIES - WATER POLLUTION CONTROL DIRECTORATE

1.	Problem identification - selection of industry sectors for review
2.	Detailed review of selected industry sectors
3.	Development of regulations and guidelines

EPS has adopted the preventive philosophy of controlling pollution at the source. The CAA and Section 33 of the FA are used to control releases of harmful substances by establishing emission and effluent guidelines and regulations. The main thrust of the ECA on the other hand is to control the uses of a substance which may result in its release to the environment rather than to regulate quantities which may be released per se. However, ECA may be used to set effluent regulations for a specific contaminant in cases where other legislation will not address the problem. In this sense, ECA is a "catch-all" piece of legislation.

Hazard assessment has been defined, for the purpose of this workshop, as the evaluation of existing data and information on chemical substances using a formal process with specific criteria and rationale within a program framework and with definite goals. The definition of what constitutes a hazardous substance and the criteria used in hazard assessment vary to suit the program objectives and intent of a particular act. The ultimate goal of EPS contaminants programs is to prevent or minimize degradation of the environment through implementation of effective control programs.

I should mention that some of the methods and criteria I will be discussing are under review at this time. The presentation describes the way that assessments are currently carried out for developing strategies. However, we should keep in mind that procedures for hazard assessment will be altered periodically for two reasons:

1. At one time it was a simple matter to priorize problems for regulation since those requiring immediate action were obvious. Having dealt with these, we must now turn our attention to the vast number of substances whose hazardous nature is not so obvious. The task of assessing these hazards and priorizing them for control will be difficult and will require increasingly sophisticated assessment protocols.

2. Environmental protection must compete with other social and economic objectives, and control strategies will have to reflect these considerations. In Canada, all proposed federal regulations are subjected to a socio-economic impact analysis (SEIA) before implementation to weigh the social, economic, and environmental costs and benefits. As a result, while the absolute hazard posed by a substance will remain constant, the degree of acceptable hazard will likely fluctuate as a result of this cost/benefit analysis.

What I would like to do now is consider each of the acts in Table 1 in terms of the methods used to assess hazards for the purpose of development of control strategies.

HAZARD ASSESSMENT: FISHERIES ACT

STARTING POINT AND FUNCTION OF THE WATER POLLUTION CONTROL DIRECTORATE

The legislative mandate of the Abatement and Compliance Branch (ACB), WPCD is Section 33 of the Fisheries Act (Table 2), whose purpose is to protect fish by prohibiting the deposit of deleterious substances into waters frequented by fish. "Deleterious substance" is defined as:

1. Any substance that, if added to any water, would degrade or alter or form part of a process of degradation or alteration of the quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water, or

2. Any water that contains a substance in such quantity or concentration, or that has been so treated, processed, or changed by heat or other means, from a natural state that it would, if added to any other water, degrade or alter or form part of a process of degradation or alteration of the quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water.

Effective control is possible only if the technology is available to prevent the entry of deleterious substances into effluents or to remove them once they enter the effluent. To control pollution at the source, ACB develops effluent standards based on best practicable technology (BPT). This establishes a baseline standard for water pollution control for each major industrial sector. Such baseline standards are applied nationally and prevent the occurrence of "pollution havens", areas that attract polluting industries as a result of inconsistent environmental protection legislation.

The approach to control has been to regulate effluents from industry sectors. At present, regulations are developed to control releases of substances such as BOD, total suspended matter, and organic and inorganic nitrogen from a particular industry sector, rather than to control the release of a particular substance from all industry sectors. In some instances, specific contaminants have been recognized as being deleterious to fish, and controls established, for example, for mercury releases from chlor-alkali plants and for various heavy metals from mining operations.

ACB carries out a sequence of activities as shown in Table 3 in controlling pollution from industrial sectors.

SCIENTIFIC AND TECHNICAL BASIS

Our definition of hazard assessment does not apply in the strict sense insofar as industry sectors are investigated rather than chemical substances. However, for purposes of this discussion, activities one and two will be considered as hazard assessment.

As a first step in problem identification, a discussion paper is prepared which incorporates the following types of information.

1. Current in-house knowledge of the industry sectors, materials used, and effluent problems. A major source of this information is available technical literature, as well as reports prepared by other agencies.

2. Concerns voiced by EPS regional offices and other agencies, e.g. the provincial environment agencies and the U.S. Environmental Protection Agency.

3. National significance of the problem, i.e. does it occur in more than one province.

Although there is no fixed protocol by which industry sectors are prioritized for purposes of investigation, ranking is done using the professional expertise of personnel in ACB and the provincial environment agencies.

The second activity is carried out by a task force made up of representatives from WPCD, provincial agencies, and the industry involved. A technical base is developed which incorporates information on water use, waste effluent sources, and effluent characteristics such as toxicity to fish and recycling and treatment methods.

The task force uses this information to identify best available technology for dealing with the problem. This includes process modifications and recycling and pollutant removal practices which have been demonstrated by current usage within the industry to be environmentally sound and economically viable. The task force makes the recommendations on appropriate effluent levels and the best practicable technology for achieving these.

After considering the recommendations of the task force, ACB develops formal requirements under authority of FA consisting of effluent regulations.

These requirements are implemented by the provinces whenever possible. The EPS regional offices provide technical assistance, and may enforce these requirements where necessary.

A program to address specific chemical contaminants in liquid effluents is currently in its early stages. It is planned to use a combined "contaminant/industry sector" approach whereby problems involving chemical contaminants will be considered in the protocol I have just described. As in the case of industry sectors, the selection and prioritization of chemical contaminants, i.e. what contaminants should be investigated, will include input from other directorates and agencies. Lists of priority chemicals developed by these groups will serve as a starting point and as such ACB will be making indirect use of the prioritization and assessment protocols used to produce these lists. However, it is expected that ACB considerations will not necessarily be limited to chemicals on these lists.

HAZARD ASSESSMENT: CLEAN AIR ACT

STARTING POINT AND FUNCTION OF THE AIR POLLUTION CONTROL DIRECTORATE

The legislative mandate of the Air Pollution Control Directorate (APCD) in controlling the release of air contaminants is the Clean Air Act (CAA) (Table 4). The CAA defines "air contaminant" as a "solid, liquid, gas or odour or a combination of any of them that, if emitted into the ambient air, would create or contribute to the creation of air pollution".

The CAA has three objectives. The first of these is to protect the health of the Canadian public from air pollution. To this end federal regulations are promulgated under Section 7 which limit the emission of hazardous pollutants such as lead, mercury, vinyl chloride monomer, asbestos, and arsenic from specific industry sectors.

TABLE 4

CLEAN AIR ACT

Scope - control release to atmosphere of contaminants and emissions from industry sectors.

Approach to control - establish emission regulations for hazardous contaminants and guidelines for emissions of common contaminants from industry sectors.

TABLE 5

PROTOCOL FOR DEVELOPMENT OF CONTROL STRATEGIES - AIR POLLUTION CONTROL DIRECTORATE

1. Identification and prioritization of air pollution problems (contaminants and industry sectors).

2. Development of work plans.

3. Detailed assessment of contaminants and industry sectors.

4. Development of regulations and guidelines.

The second objective is to promote a uniform approach to the control of other pollutants across Canada. Emission guidelines which reflect best practicable technology for these contaminants are promulgated under Section 8. These are applied nationally and are aimed at preventing "pollution havens".

The third objective is to ensure effective implementation of control strategies, and the CAA enables the federal government to enter into agreements with the provinces to accomplish this. As with the Fisheries Act, control programs initiated by APCD are frequently implemented by the provincial agencies while the CAA provides for direct action by the federal government where this is necessary.

The approach to control is on the basis of both contaminants and industry sectors. As part of the identification of control needs, APCD prepares inventories of sources and emissions of contaminants from all industry sectors. Control strategies may embrace a few or all of the identified sources, including industry sectors, of a particular contaminant.

Historically the control philosophy of APCD has been geared towards correcting a specific problem as it became an issue of concern. In order to permit APCD to prioritize contaminants and industry sectors in an anticipatory, rather than reactionary fashion, the APCD management set up a working group in 1978 to devise a framework or protocol of activities to be used in identifying problems and developing controls. The framework has been accepted by APCD management and is in the process of being implemented. Basically it is comprised of four main activities, as shown in Table 5.

The first activity involves the identification and prioritization of existing and potential air pollution problems in terms of specific contaminants and industry sectors. Work plans are then prepared based on this list of identified concerns. The third activity involves the collection of information on selected contaminants and industry sectors while the fourth activity concerns the development of emisson regulations for hazardous contaminants based on best available technology, and guidelines for emissions of common contaminants from industry sectors based on best practicable technology.

TECHNICAL AND SCIENTIFIC BASIS

Activities one and three involve hazard assessment as defined for purposes of this workshop.

As a starting point, a list of candidate contaminants and industry sectors is prepared, and APCD staff put together brief profiles on each. A ranking committee then prioritizes the candidates into immediate, medium, and long-term concerns based on criteria included in the profile. The prioritization takes into account both objective and subjective criteria (Tables 6 and 7, respectively) although no weighting mechanism has been adopted.

Potential or known health effects are the most important of the objective criteria in ranking a particular concern. It is based on whether or not the contaminant or emission from an industry sector causes or contributes to mortality or serious irreversible or incapacitating reversible illness.

TABLE 6

APCD CRITERIA FOR RANKING OF CANDIDATE CONTAMINANTS AND INDUSTRY SECTORS - OBJECTIVE

1. Health effects
2. Environmental effects
3. Environmental persistence
4. Population exposure
5. Threshold Limit Value (TLV)
6. Ambient air concentrations
7. Gross emissions
8. Formation mechanisms

TABLE 7

APCD CRITERIA FOR RANKING OF CANDIDATE CONTAMINANTS AND INDUSTRY SECTORS - SUBJECTIVE

1. Provincial interest
2. Public and political interest
3. Interest of other organizations
4. Regulatory action of other agencies
5. Concerns of APCD staff

Initial ranking on environmental effects takes into account two factors:

1. Does the contaminant or emission cause or contribute to air pollution which may reasonably be anticipated to result in irreversible or serious reversible damage to the environment, and

2. Is the contaminant or emission a nuisance.

Environmental persistence is significant when adverse health and/or environmental effects may result from an accumulation of the contaminant in the environment.

Population exposure is considered to be an indicator of the extent of a problem in the real world. Accurate estimates of exposure are very difficult to make and should include dispersion models and census tracts. However, information on the number and locations of plants emitting a specific contaminant serves as a useful starting point.

Threshold limit values (TLV's) are considered important as related to health effects. The fact that a TLV exists for a contaminant indicates concern in the area of occupational health.

The ambient air level of a particular contaminant may not be meaningful in itself, but it will be significant when compared to existing TLV's or other standards.

An estimate of gross emissions serves as a crude indicator of the possible magnitude of the problem. Emissions of a specific contaminant from all industrial sectors should be considered, and this will indicate the significance of each sector in terms of the whole.

Finally, formation mechanisms are important when the emission of a specific contaminant results in the formation of other contaminants such as oxidants.

The subjective criteria used by the ranking committee include provincial interest as voiced through the Federal Provincial Committee on Air Pollution, public and political interest and sensitivity as stimulated through the communications media, interest expressed by other organizations such as trade associations and public pressure groups, regulatory decisions of other agencies, and specific concerns of APCD staff. It is obvious that the impact of these criteria on the ranking process can be neither quantified nor ignored.

The second activity in the control strategy protocol involves development of work plans based on the committee's prioritized list of candidates. Candidates are divided into those for which a more elaborate assessment may be carried out and those requiring further basic information gathering.

The third activity includes basic information gathering activities and elaborate assessment of immediate concerns. Basic information gathering is done for medium- and long-term concerns and permits a periodic reassessment of APCD's concern towards these. Some candidates may be judged immediate concerns based on available information in the profile, and it is these that are slated for a more elaborate assessment which is made up of four components as shown in Table 8.

TABLE 8

ELABORATE ASSESSMENT OF CONTAMINANTS AND INDUSTRY SECTORS

1. Health effects risk assessment
2. Environmental effects risk assessment
3. Assessment of available control technology, selection of appropriate control technology
4. Reduced risk assessment

TABLE 9

ENVIRONMENTAL CONTAMINANTS ACT

Scope - control release of contaminants to all receiving media

Approach to control - regulate specific uses involving contaminants. Release regulations may be developed where necessary.

TABLE 10

PROTOCOL FOR DEVELOPMENT OF CONTROL STRATEGIES - ENVIRONMENTAL IMPACT CONTROL DIRECTORATE

1. Development and maintenance of a Priority Chemicals List - DOE/NHW Committee
2. Data acquisition and review
3. Assessment of hazard - DOE/NHW Committee
4. Decision on control strategy - DOE/NHW Committee
5. Regulation development

The health effects risk assessment is based on an in-house review of the literature. This is not meant to be a definitive study for medical purposes, but it does suffice for APCD's initial requirements. The assessment also considers population exposure and the vulnerability of special population groups.

The environmental effects risk assessment takes into account the effects of the contaminant or emission on flora, fauna, visibility, and building materials. Air quality objectives may be used to help quantify the impact of a contaminant, and known synergistic effects are noted.

The in-house determination of best available technology for potentially hazardous contaminants is done by considering existing control technologies in terms of cost, cross-media impact, and potential effectiveness at reducing emissions.

The reduced risk assessment includes a summary of the benefits that are expected to result from the application of the chosen technology to the real world problem. Ideally, these benefits should be quantified in terms of reduction of gross emissions, reduced health risk, reduced social cost, and improvement of ambient air quality.

The last activity in the control strategy protocol involves development of regulations or guidelines that will effectively control the risks to the environment and human health.

HAZARD ASSESSMENT: ENVIRONMENTAL CONTAMINANTS ACT

STARTING POINT AND FUNCTION OF THE ENVIRONMENTAL IMPACT CONTROL DIRECTORATE

The legislative mandate of the Contaminants Control Branch (CCB) of the EICD with regard to controlling dangers posed by chemical substances in the environment is the Environmental Contaminants Act (ECA) (Table 9). The objective of the ECA is to protect human health and the environment from substances that contaminate the environment. The ECA defines "substance" as "any distinguishable kind of inanimate matter a) capable of becoming dispersed in the environment, or b) capable of becoming transformed in the environment into matter described in a)".

This objective is accomplished by carrying out a two-fold task:

1. To identify and deal with existing problems due to chemical substances in the environment, and

2. To anticipate and deal with potential problems which may accrue from the commercial use of a new chemical substance or a new use of an existing one.

The approach to control is in terms of specific contaminants rather than industry sectors. The mandate of the ECA is carried out by regulating the uses of a chemical substance which result in its release to the environment. Regulations under the ECA are developed only where other legislation, regardless of origin, will not adequately deal with the problem.

The Departments of Environment and National Health and Welfare are jointly responsible for the ECA.

In 1975, as part of the preparation for implementation of the ECA, a joint committee known as the Department of Environment/National Health and Welfare Environmental Contaminants Committee was established to direct activities in the assessment and regulation of contaminants. This committee is responsible for the overall direction of activities and key decisions throughout the course of events leading to implementation of control strategies. This protocol of activities is shown in Table 10.

For purposes of our workshop, activities one and three incorporate what we have designated as hazard assessment. While the committee is responsible for the overall direction of the protocol, activities two and five are coordinated by CCB and NHW using input and technical support from EPS regional offices other services within the Department of Environment and other government departments and agencies.

SCIENTIFIC AND TECHNICAL BASIS

The starting point of the protocol is the selection of a priority list of chemicals. The current list is shown in Table 11.

This committee has not adopted a firm set of criteria for selecting and prioritizing chemicals. A number of criteria are currently under review as part of an exercise to revise the current list to reflect new concerns. The current list was developed through consultation with other agencies, universities, and industry and I suspect many of you have undergone similar exercises as a first shot at priority development.

As a prelude to selecting chemicals for the first priority list, the committee circulated a list of some 200 substances which had been designated as hazardous by agencies such as EPA, NIOSH, WHO, and National Research Council, a federal government research group. The criteria used by these agencies included persistence, movement and accumulation in the environment, toxicity to man and biota, and end-use patterns. Recipients were asked to consider these chemicals as a guideline in recommending candidates for the priority list.

It became obvious from the responses that emphasis on each factor varies with expertise and field of concern. For example, people in the area of health protection tended to consider chemicals of established occupational hazard and human toxicity as most important, while environmental and wildlife scientists emphasized those that were environmentally persistent or accumulated in the food chain.

As a beginning, the committee placed particular emphasis on chemicals that were detected in biological indicators, such as fish, in addition to those considered to present hazards to human health. Attempts to consider commercial information met with little success due to a lack of available data. The committee made its final selection using the professional judgement of the members in light of the information available to them.

TABLE 11

PRIORITY CHEMICALS LIST - DEPARTMENT OF ENVIRONMENT/ DEPARTMENT OF NATIONAL HEALTH AND WELFARE ENVIRONMENTAL CONTAMINANTS COMMITTEE

(PUBLISHED IN PART I, CANADA GAZETTE, MAY 20, 1978)

Category I

- Chlorofluoromethanes
- Mirex
- Polybrominated biphenyls (PBB)
- Polychlorinated biphenyls (PCB)
- Polychlorinated terphenyls (PCT)

Category II

- Arsenic
- Asbestos
- Benzene
- Lead
- Mercury

Category III

- Cadmium
- Chlorobenzenes
- Chlorophenols
- Hexachlorocyclopentadiene and its adducts
- Organotins
- Phthalate Esters
- Triaryl Phosphates

The list was published a year ago in the Canada Gazette and a copy of the announcement, containing descriptions of the three categories is included as an appendix to the presentation. Substances in Categories I and II have been designated as hazards based on readily available information. Regulations are under development for Category I substances, while Category II substances are those for which the committee is considering appropriate control strategies.

The second activity of the protocol, data acquisition and review, is directed primarily at Category III substances, i.e. those about which the committee requires further information before it can make an assessment of hazard or risk. The types of information required are listed in Table 12.

The subject of data acquisition will be considered in detail at a future workshop. For the time being I would like to briefly describe the major sources of this information.

Data on the amounts of a chemical in commerce, i.e. production, imports, and exports is obtained from sources such as other government departments including Statistics Canada and Revenue Canada. However, there are obstacles to the free exchange of sensitive data and we are currently exploring ways of removing these.

Much of the qualitative technical information on end-use patterns, i.e. processes and finished products containing the substance is obtained from technical literature and other published sources, but industry must be contacted for quantitative data pertinent to the Canadian scene. I do not need to dwell on the difficulties that exist in transferring information on trade secrets and other sensitive information. Solutions are not easily come by. I will say that attempts are under way to coordinate the information gathering activities of CCB with those of other directorates and the provincial agencies.

Having assembled these data, CCB prepares a review which may include a recommendation for a particular control strategy. However, the Environmental Contaminants Committee is responsible for the final decision in this area.

Detailed information on the human toxicology of a substance is provided to the committee by the Environmental Health Directorate of the Department of National Health and Welfare.

Information on the persistence, environmental levels, and toxicity to biota is obtained from technical literature as well as other services in the Department of Environment. This information, as well as rates and routes of release to the environment from point sources, is assembled under the supervision of the Regional Environmental Contaminants Committees which are made up of personnel from the regional offices of each service. In addition, joint industry surveys with other directorates are under consideration for assembling information on environmental releases.

When detailed information has been assembled on these criteria, the committee makes an assessment of the degree of hazard (risk) to human health or the environment posed by the substance. There is no quantitative mechanism in place for applying the criteria. This is done using the professional expertise of the committee.

If the committee decides on the basis of the assembled data that more information is required to make a proper assessment, the substance remains in Category III until such data become available. If, on the other hand, the committee decides that the substance does present a significant danger, it is placed in Category II and a control strategy is formulated. At this stage, the committee considers whether other legislation, for example, the Hazardous Products Act, will control the hazard and, if so, may make a recommendation to that end. In the case where regulations under ECA are required, the chemical is placed in Category I. CCB is responsible for development of these regulations utilizing technical input from the EPS regional offices.

Control programs are then implemented by the EPS regional offices in cooperation with the provincial agencies. However, unlike control programs developed under the Fisheries Act and Clean Air Act, no formal agreement has yet been reached with the provinces which delineates the responsibilities of each agency.

CONCLUSION

I would like to conclude by summarizing briefly some of the points which I hope have been made clear in this presentation.

The purpose of Section 33 of the Fisheries Act is to protect fish and man's use of fish by regulating the release of deleterious substances to waters frequented by fish. The toxicity to fish of an industrial effluent is the major criterion used to select and prioritize industry sectors for control strategy development.

The Water Pollution Control Directorate develops controls based on the application of best practicable technology for a given industry sector.

A program to consider chemical contaminants, in addition to common substances such as BOD, is in the early stages of development. Assessment of the hazard to fish posed by these substances will become a major part of the directorate's regulation development process.

The main purpose of the Clean Air Act is to protect the health of the Canadian public from emissions of hazardous and common contaminants from industry sectors. Human health effects and related criteria such as ambient air concentrations, TLV's, and population exposure are therefore of utmost importance in the prioritization and assessment procedures used by the Air Pollution Control Directorate. Other criteria include environmental effects such as persistence and the impact of the contaminant or emission on biota, visibility, and building materials.

As in the case of the Fisheries Act, control is based on the application of best practicable technology.

A protocol for the development of control strategies which allows APCD to prioritize and assess problems in an anticipatory rather than reactionary fashion is at the implementation stage.

The purpose of the Environmental Contaminants Act is to protect human health and the environment from substances that contaminate the environment.

Control is based on the regulation of the uses of chemical substances which result in their environmental release.

The approach to control dictates that information on quantities in commerce and end-use patterns, i.e. products, will be important criteria for hazard assessment as will human toxicology and environmental effects. A committee made up of representatives from the Departments of Environment and National Health and Welfare is responsible for assessing the extent of the danger posed by a given substance.

Finally, the methods and criteria for hazard assessment that I have outlined in this presentation are those that are used at this point in time. The approach to pollution control in EPS is currently under review and the outcome is likely to result in alterations in hazard assessment procedures. While obvious criteria such as human health and environmental effects will remain, their impact on the result of the assessment will change somewhat as new factors, such as analysis of the socio-economic impact of proposed regulations, become increasingly prominent in shaping our pollution control philosophy.

TABLE 12

TYPES OF INFORMATION (CRITERIA) USED IN ASSESSMENT OF HAZARD RISK

1. Amounts in commerce
2. End-use patterns
3. Human toxicology
4. Environmental effects - persistence, levels, toxicity to biota
5. Rates and routes of release to the environment

APPENDIX

DEPARTMENT OF FISHERIES AND THE ENVIRONMENT
and
DEPARTMENT OF NATIONAL HEALTH AND WELFARE

ENVIRONMENTAL CONTAMINANTS ACT

The Canada Gazette Part I May 20, 1978

List of Priority Chemicals—3

For the purposes of the Environmental Contaminants Act, in 1976, the two Departments circulated a document (Stage I) on the development of a list of priority chemical substances. Over 100 responses including some integrated responses were received. In addition to these responses a number of qualitative and quantitative factors were taken into account in selecting the List (Stage II) which was made public in March 1977. It is intended that the List should include those substances for which regulations are being developed under the Environmental Contaminants Act and those chemicals upon which efforts to obtain further information should be concentrated to determine whether regulations are necessary. The chemicals on the Stage II List were not ranked but were divided into four Categories that reflected the status of the chemicals with respect to development of regulations or the further investigations needed.

Following circulation of the List and further considerations, the List has been amended. The major change is the elimination of Category IV. The substances from this Category have become the basis of a group of chemicals of interest from which items may be selected for inclusion on the List of Priority Chemicals. Other changes include the moving of mirex, polybrominated biphenyls and polychlorinated terphenyls to Category I, arsenic to Category II and the addition of benzene to Category II. Since this is an "active" listing, it will continue to be reviewed and amended when new information is acquired. The individual amendments may be published in the *Canada Gazette* from time to time, and the complete List of Priority Chemicals will be published once a year in the *Canada Gazette*.

The revised List, including descriptions of the three categories, is as follows:

CATEGORY I: Those substances which the government is satisfied pose a significant danger to the environment or human health and for which regulations are being developed

CHLOROFLUOROMETHANES

The Department of the Environment has published a report recommending the control of chlorofluoromethanes.

MIREX

In its report published in 1977, the Task Force on Mirex has recommended that mirex be prohibited from use in Canada.

POLYBROMINATED BIPHENYLS

A recently published report recommends that the manufacture, importation, commercial use and disposal of polybrominated biphenyls be controlled in Canada. Regulation development is under way.

POLYCHLORINATED BIPHENYLS (PCB)

The Task Force on PCB has published a report. The first regulation is in effect and subsequent ones are being developed.

POLYCHLORINATED TERPHENYLS

A report has been published. Regulation development is under way.

CATEGORY II: Those substances which the government has reason to believe pose a significant danger to the environment or human health and which are being investigated in depth to determine the nature and extent of the danger and the appropriate means to alleviate that danger

ARSENIC

Various government studies have confirmed the presence of arsenic and its compounds in drinking water, ground water, lakes, fish tissue, food and air emissions. The Department of National Health and Welfare has undertaken detailed studies of the human health aspects of arsenic. As a by-product of gold mining, the large quantities of arsenic oxide create a problem of storage, disposal and probable release into the environment (point source). Metallurgical Industries Arsenic Information Regulations under the Clean Air Act requiring the submission of production-related and air emission data have been published in the *Canada Gazette*.

ASBESTOS

Chrysotile and to some extent the other mineral types have been reviewed by the Federal Departments of Consumer and Corporate Affairs (Hazardous Products Act), National Health and Welfare, the Environment and by the International Joint Commission. Problem areas include occupational health, presence in drinking water, residues in the Great Lakes, air emissions, and mining and milling operations. A regulation under the Clean Air Act will be in effect December 31, 1978.

BENZENE

Recent epidemiological surveys have indicated that industrial exposure to benzene substantially increases the risk of leukemia and chromosomal aberrations. While the occupational group unquestionably has the greater risk, leukemogenic potential in the general public following benzene exposure cannot be dismissed. Benzene is a widely used industrial chemical: as a feed stock for plastics (styrene), detergents, pesticides and other chemicals, as a solvent, as a laboratory reagent and as an alternative antiknock additive in gasoline replacing lead tetraalkyls. The amounts used are so substantial that the inadvertent release of benzene (highly volatile) into the atmosphere or waterways cannot be ignored. The current federal position is to limit severely industrial exposure to benzene (1 ppm for a 40-hour workweek) and to curtail its use in consumer products under the purview of the Hazardous Products Act.

LEAD

Lead and its compounds are under review by the National Research Council's Associate Committee on Scientific Criteria for Environmental Quality, and by the Departments of National Health and Welfare, and the Environment. Problem areas include, presence in drinking water, additives in gasoline, discharges from the metal mining industry and from base metal smelting and refining. Lead and its compounds have extensive open-system uses. A regulation under the Clean Air Act is now in effect (August 1, 1976).

MERCURY

Review of the mercury problem in the Canadian environment leading to the development of a national overview is being coordinated by the Department of the Environment. The Department of National Health and Welfare has undertaken detailed studies of the human health aspects of mercury. A regulation under the Fisheries Act is in effect and one under the Clean Air Act will be in effect July 1, 1978.

CATEGORY III: Those substances which the government believes may pose a significant danger to the environment or human health, or about which further detailed information, including toxicology and amounts used, is required

CADMIUM

Cadmium is a highly toxic heavy metal which has widespread losses to the environment. The significance to human health of low levels is being studied by the Department of National Health and Welfare.

CHLOROBENZENES

Many of the chlorinated benzenes have been identified in the tissue of fish or herring gulls from the Great Lakes, indicating their presence in the environment, their persistence and accumulation. The use of mixtures of tri- and tetrachlorobenzene as possible replacements for PCBs could lead to an increase in their already large consumption and thus an increase in environmental exposure. Hexachlorobenzene is the only chlorobenzene classed as an actual serious problem at this time. Residues found in food, human tissue, drinking water, effluents and tissue of fish from the Great Lakes indicate its entry into the environment, its persistence and bioaccumulation. This substance is presently under review.

CHLOROPHENOLS

Pentachlorophenol, in particular, is causing concern because of its toxicity and the presence of various by-product impurities in some batches. These by-products include predioxins, octa-, hepta-, and hexachlorodibenzodioxin. Similar concerns are felt for the mono- to tetrachlorophenols.

HEXACHLOROCYCLOPENTADIENE AND ITS ADDUCTS

This group of substances includes hexachlorocyclopentadiene, Dechlorane Plus, Dechlorane 602, Dechlorane 603, Dechlorane 604, and Citex. The structures of these substances suggest that their behavior in the environment will be similar to mirex and the cyclodiene insecticides (dieldrin, heptachlor). These latter substances are biologically active, accumulate in the food chain, are extremely persistent and are dispersed in the environment. Trace quantities of Dechlorane Plus have been detected in river water. The Department of the Environment is investigating those adducts used as flame retardants to determine specific information on imports, use patterns, losses to the environment and environmental levels.

ORGANOTINS

The number and quantities of these substances currently in use are large and increasing. The number of particular uses, many of which suggest losses to the environment, is also increasing.

PHTHALATE ESTERS

The volume of phthalate esters imported into Canada during 1975 ranked 8th in the top 50 organics. A large number of phthalates is available on the market. Their greatest use is as plasticizers although they have numerous other uses including possible replacement for PCB. Several, including diethyl phthalate, dibutyl phthalate (DBP), and di-(2-ethylhexyl) phthalate (DEHP), have been studied in detail. Residues of DEHP and DBP in air, sediment, water, fish, herring gull eggs have been detected, indicating their presence in the environment. Introduction into the environment is inevitable either during production and processing or as a result of use and disposal of products.

TRIARYL PHOSPHATES

Their increasing use as plasticizers, flame retardants, lubricants, and fuel additives has caused an increase in production and in concern. Tricresyl phosphate has been studied in some detail. It is moderately persistent and highly toxic. Limited evidence of the persistence and stability of triaryl phosphates in the environment indicates that these compounds may be more significant in the environment than has been generally recognized.

Anyone wishing further details or who has comments about the Priority List or its future amendments, or has pertinent information on these chemicals, should contact:

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January 19, 1978

J. E. BRYDON
Chairman
Department of the Environment
National Health and Welfare
Environmental Contaminants Committee

[20-1-o]

CHAPTER 2

FEDERAL HAZARDOUS WASTE ASSESSMENT IN CANADA

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The treatment and disposal of substances that have been designated as hazardous is the receiving end of the regulatory and control system. As you have heard from Mr. Leah, and no doubt will hear from speakers from other jurisdictions, each piece of legislation has the power to regulate specific substances or processes. The need for the regulation of these substances or activities is based upon the raison d'etre of the legislation. The result of all this legislative activity is a varied selection of substances that have become wastes and require environmentally acceptable treatment and/or disposal. To this group are added an even greater number of materials which, although not specifically regulated by substance, are, by their nature, considered hazardous.

Therefore, the hazardous waste agency has to contend with the result of activities by others and has to develop hazard assessment techniques that recognizes everyone's requirements. In addition, since the development of acceptable treatment and disposal techniques requires substantial lead time, the agency must be in a position to anticipate future requirements.

In Canada, the management of hazardous wastes is a shared jurisdiction between the federal and the provincial governments because of the interest of both levels of government in health and environmental matters. Activities which can be perceived to fall under federal jurisdiction include:

1. Direction on the management of substances which become distressed as a result of regulations enacted under federal legislation

2. Transboundary controls on the transportation of hazardous wastes

3. The management of hazardous wastes generated by federal facilities.

In addition, it can be argued that the federal government has a logical role to play in coordinating projects of an interprovincial nature, such as ascertaining the type and the quantity of hazardous wastes being generated throughout the country, and the development of regional treatment and disposal facilities. There is also a federal role in addressing those technical and other activities common to the hazardous waste problem across the country, such as the National Task Force for PCB's.

One piece of federal legislation which has a direct effect on the hazardous waste management program is the Environmental Contaminants Act.

Substances which become distressed by regulations under this act require direction for their management. This direction must cover all aspects of management from collection to final disposal and be produced for the governments and industry who have an operational role.

At present, no federal legislation controls the totality of transboundary movement, either interprovincially or internationally, of dangerous goods. To rectify this situation, a proposed Transport of Dangerous Goods Act was before the last federal Parliament. At the request of Transport Canada, Environment Canada was a member of the secretariat developing this legislation to ensure that the environment would be adequately protected. This act, which in its draft form includes a national code on the transportation of dangerous goods, identifies, at the request of Environment Canada, both hazardous waste and environmental contaminants. For purposes of this code, a general definition of a hazardous waste is proposed. This definition is:

> A hazardous waste means a solid, liquid, or gaseous waste, or combination thereof, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may:
>
> 1. Cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> 2. Pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

You will, undoubtedly, note the distinct similarity of this definition to that of the U.S. Resource Conservation and Recovery Act and to other international definitions at the statutory level. This general definition was proposed in that it covers all of the broad concerns being expressed by interested parties across Canada and because of the substantial flow of wastes between Canada and the U.S. While the development of a regulatory definition of a hazardous waste has only just begun in Canada, it is felt that the free but controlled movement of wastes across borders should be encouraged on a North American basis to take advantage of the best disposal techniques from both an economic and environmental point of view.

Accompanying this definition the code proposes a list of criteria which will define the characteristics of the definition. In the current absence of a refined definition of a hazardous waste, these criteria are adopted from the United Nations Committee of Experts on the Transportation of Dangerous Goods. In other words, they are presently based on transportation and packaging needs. Eventually they will have to be modified to take into account hazardous waste disposal needs.

A one-day workshop was held in Toronto in October 1978 on the definition of a hazardous waste. The consensus of those present was that the federal government, through Environment Canada, should convene a joint industry-provincial-federal government task force to address the matter of defining a hazardous waste. The purpose of the definition is to enable all interested parties to undertake their responsibilities with a consistent and uniform meaning to the term hazardous waste.

This task force has had its first meeting. At that meeting, the following phrase was proposed as a basis for a regulatory definition:

> A hazardous waste is any waste which may constitute a threat to man or the environment by virtue of one or more of the following characteristics: toxicity, flammability, reactivity, corrosiveness, and infectiousness.

In addition to this approach with accompanying criteria, the task force is considering the preparation of lists of processes that generate wastes and a list of specific wastes that are considered hazardous in a manner similar to that adopted by the U.S. Environmental Protection Agency. This activity is in a very early stage in an attempt to develop a definition that is compatible with, but not necessarily identical to those of other jurisdictions.

Another role of Environment Canada is the disposal of hazardous and toxic wastes generated at federal government facilities. Consequently, a code to provide guidelines in the handling and disposal of hazardous and toxic waste was developed before any national guidelines were available. This was consistent with the government's wish to provide a consistent exemplary pollution control program. In order to assist in the effective control of the management of federally generated wastes, wastes were classified by chemical name with recommended disposal methods, handling methods, and hazard levels. The hazards of each substance were identified using the categories of health, flammability, reactivity, and environment. In each category, ratings were assigned from one to four in order of increasing severity. These categories and severity ratings were developed from various sources including the National Fire Protection Association, the Inter-Governmental Maritime Consultative Organization, Canadian legislation, and Environment Canada's personnel.

Until a substitute definition is developed, federal facilities are urged to use this approach to managing their hazardous wastes.

Because more wastes are hazardous than the substances regulated under the Environmental Contaminants Act, the federal government has, and is undertaking cooperative studies with the provinces to ascertain the types, quantities, and sources of hazardous waste in Canada. For lack of established Canadian criteria, the criteria used in the initial studies for assessing hazardous waste were those developed by the State of California. We are currently attempting to cross-reference inventory data developed on this basis.

With this short review, I hope that I have been able to convey some of the non-regulatory hazard assessment work undertaken by Environment Canada in the field of hazardous waste management.

CHAPTER 3

HAZARD ASSESSMENT AND THE NATIONAL RESEARCH COUNCIL'S ROLE IN THE DEVELOPMENT OF METHODOLOGY

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The National Research Council of Canada's Environmental Secretariat was established by an Order in Council of the Cabinet of Canada. The intent was to establish a neutral body outside of the normal government channels which would develop the scientific criteria, or cause-effect relations, which are used by others to define the level of risks associated with the introduction of pollutants into Canadian ecosystems. The Council's role is completely advisory and its mandate does not include regulatory considerations, laws, or the science of risk assessment and criteria development. We have great difficulty in getting this point across, for many people equate scientific criteria with standards and tolerances. In the extreme, we even hear it mistakenly assumed that NRCC is responsible for the administration of the regulations which govern the use of synthetic chemicals in Canada. As you should now understand, after listening to the other speakers from Canada, environmental regulations actually arise from combined federal and provincial responsibilities which are undergoing redefinition at this time.

The approach taken by the NRCC to meet its specific mandate was to establish the Associate Committee on Scientific Criteria for Environmental Quality. Under the umbrella of this organization, subcommittees were established to develop scientific criteria for pollutants in air and water, as well as physical energy phenomena, biological phenomena, heavy metals, pesticides, and related synthetic organic chemicals. The subcommittees have been active and their publications now number over forty. These activities have not been without controversy. They have provided a springboard for what, in my opinion, is a much needed dialogue within the scientific community on the usefulness of available scientific criteria to provide reliable projections within the Canadian context. My own experience as secretary to the Subcommittee on Pesticides and Related Compounds has centered upon the development of criteria for assessing the risk associated with synthetic organic chemicals. I should, therefore, like to spend the remainder of this talk discussing some of the observations which have arisen out of our attempts to develop criteria and frameworks.

Countless frameworks can be envisaged for hazard assessments or criteria evaluation, and we have examined a number of variations in the monographs. In many respects they formalize what should be intuitively obvious, and their real usefulness, it seems, lies in their formalization or structuring of our thinking. They also demand that we ask whether we really do have a concrete, logical sequence of causal relations on which to justify our criteria, standards, or hazard assessments. Our frameworks (e.g. 1-4), like others (e.g. 5,6), are derived from the impingement of the critical path approach (7) upon the requirements of exposure scenarios or models. The aim is to identify

the critical compartment in which an organism is most likely to be exposed to a significant amount of the chemical and to define the nature and length of the exposure, i.e. chronic or short term. Often we find that the data or so-called criteria are insufficient to precisely or reliably delineate exposure patterns. This does not mean that scenarios are not useful. We have found the usefulness of this approach to be twofold:

1. First, one can at times show with some confidence that the exposure expected in a given compartment is relatively low

2. Second, one can often identify the key studies that are likely to improve our predictive capabilities and to suggest which studies are not likely to be helpful.

I shall refer to this use of exposure scenarios as the composite approach, for it involves first the assignment of worst-case estimates to each removal or transfer coefficient and then the analysis of the pollutant flux in each compartment in terms of a given pollutant loading and the complete scenario. In other words, persistence is analyzed through the identification of the intrinsic factors which are rate controlling and through their inclusion in exposure scenarios constructed to mimic a given stiuation or to identify the worst or best case situation. The anticipated exposure as a function of time can be examined quantitatively and can then be compared to the data available for a preliminary screen.

As an example of the composite approach, I would like to discuss a simple description of an aquatic ecosystem (Figure 1). We have found it particularly useful in preliminary evaluations of criteria on a chemical's persistence in aquatic ecosystems. In this system, the ecosystem is described in terms of the relative sizes, e.g. V_S and V_W, and sorptive characteristics of its components. Obviously, persistence is not simply a phenomenon associated with the relative size of each component but is also a function of the sizes of the various transfer coefficients, e.g. k_{WS}, and the removal process, e.g. k_{SO}. Thus, this scheme allows for the fact that persistence is related to the probability that the chemical will be in a given compartment, and the compartment's actual removal capacity. These characteristics are, in turn, controlled by intrinsic properties of the compartment and chemical. For example, the tendency for the chemical to be within the compartment is characterized by factors such as lipid content (e.g. 8), clay content (e.g. 9), and pH. All are reflected in the size of the various transfer coefficients in the scheme. Likewise, the removal capacity depends on factors such as the size and nature of the microbial populations and the pH, and these are reflected in the k_{SO}, etc.

When one thinks of the extremes of ecosystem types and environmental conditions which need evaluation, it becomes clear that other screening frameworks which are inflexible are potentially very misleading. They cannot, by their rigid nature, easily identify the particularly troublesome situations associated with unique combinations of ecosystem properties. Model ecosystems are examples of potentially troublesome screening tools because of the rigidity usually imposed upon them.

In several cases we have had the opportunity to examine a chemical's

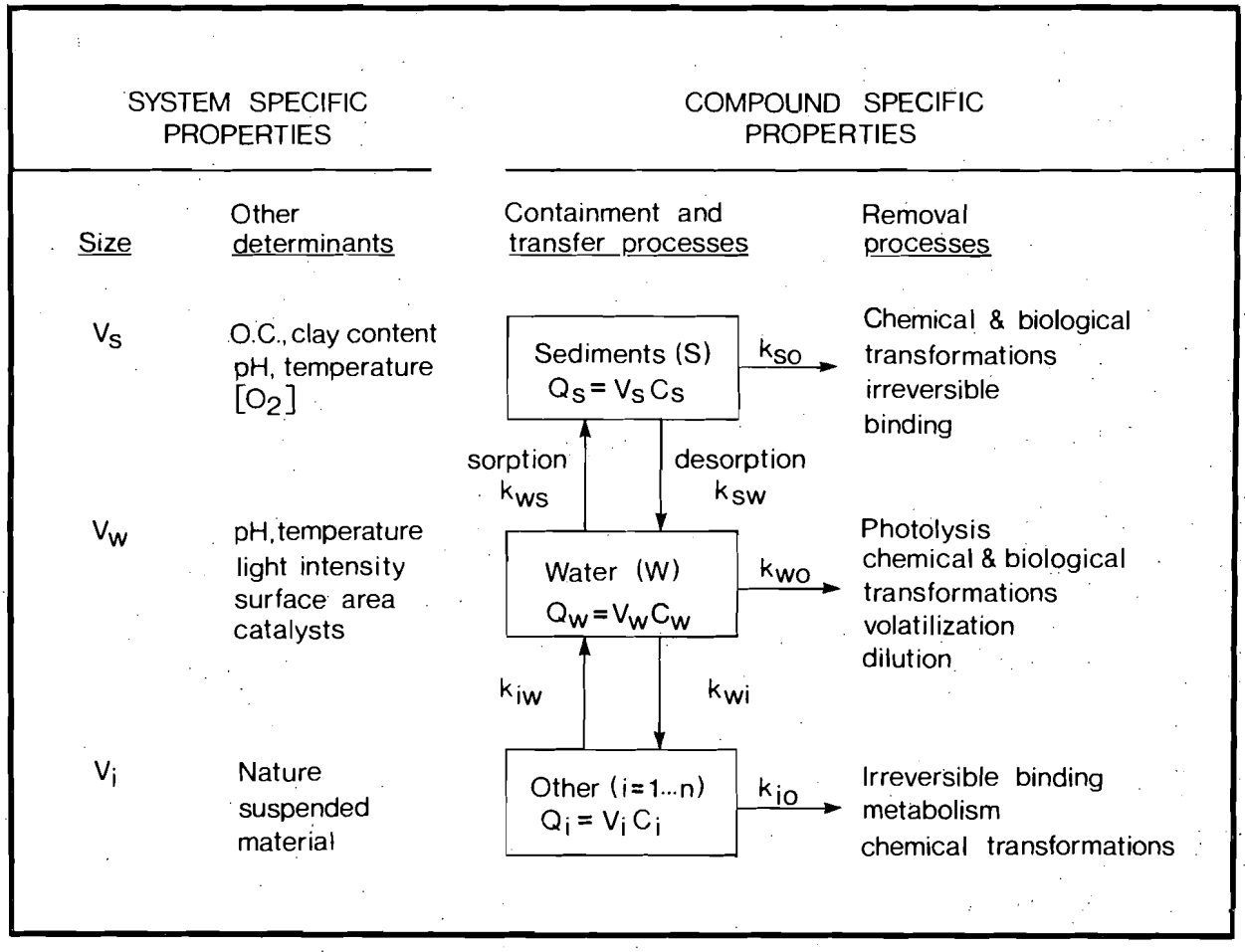

Fig. 1 A SIMPLE CONCEPTUAL MODEL USEFUL IN THE EXAMINATION OF POLLUTANT DYNAMICS IN AQUATIC ECOSYSTEMS

persistence in terms of the results of standard microcosm models and through the more flexible framework of the composite approach. For example, I would like to compare some of the results obtained using data from both microcosm models and the composite approach. This illustration is taken from an analysis we made in a forthcoming publication on a common carbamate insecticide, carbofuran (10).

Two microcosm studies were available. In the standard Metcalf model ecosystem (11), carbofuran was observed to disappear rapidly; it was concluded by the authors of this study that the compound had little propensity to persist (12). They repored that this compound would "not present ecological problems related to persistence". On the other hand, carbofuran was found to undergo little, if any, degradation when introduced into a second model ecosystem. The residues remained virtually unchanged throughout a 37-day period (10). At this point, one can ask "What are assessment personnel to do with these conflicting results?"

Looking only at the results of the second model, they might conclude that carbofuran represents a potential hazard to some organisms due to its persistence. On the other hand, Metcalf's model suggested the opposite. As reported, the studies themselves offer few clues as to the nature of the dichotomy. Obviously, one of the components in the Metcalf model which is missing in the second model can contribute to the ready removal of carbofuran. The assessor is still left with the questions, "Which component is involved?" and "Which is relevant to the ecosystem he is considering?"

Using the composite approach and a careful examination of the available information on the rates of the various potential removal processes, it was possible to conclude that dissipation patterns of carbofuran are relatively well defined as long as simple hydrolysis is the dominant dissipation vector, i.e. in alkaline waters. It was suggested that in such cases preliminary worst-case estimates of the persistence of carbofuran can be based on the calculated half life determined from relatively well developed hydrolysis studies.

Evidence does suggest that microbial and photolytic processes could contribute to the loss of the insecticide in other situations. However, the relative importance of such processes remains unknown because the available studies have not been conducted in a manner that permits one to extrapolate to real-world situations. Thus, the panel cautioned that the persistence of carbofuran in neutral or acidic waters cannot be predicted upon the basis of the available criteria. In other words, evidence could be found to suggest that the compound is not persistent in alkaline waters, but acceptable evidence could not be found to support this claim where neutral or acidic waters are concerned.

Assessment frameworks put a particularly heavy emphasis on our understanding of the basic relations which control transport and degradation phenomena. It is at this point that particular difficulties are encountered. The emphasis in the past has tended to favor the study which provides immediate, functional answers for a specific, often isolated, problem rather than on studies which examine fundamentals. Information derived from such studies may be useful in resolving an immediate problem but it generally

provides a weak base on which to construct defensible scenarios. Fortunately, there has been some shift, and more studies emphasize the basics. However, it will take some time before a good working understanding of the principles is available.

There is a fundamental danger in a situation where we can draw up elegant scenarios and easily generate tables of numbers which do not have well established and reasonably narrow confidence limits. If too much emphasis is placed prematurely on these results, the overall credibility of the approach can conceivably be jeopardized by too many questionable predictions. Given the power of these tools as early indicators of potentially hazardous combinations of chemical and ecosystem properties, it would seem that more emphasis on the principles is justified and required if the situation is to dramatically improve.

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CHAPTER 4

WATER QUALITY CRITERIA DEVELOPMENT

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In the development of water quality criteria documents, the term "criterion" is a specific numerical value for the concentration of a water constituent that should not be exceeded, a description of a bioassay procedure to arrive at a number, or a narrative description of a condition that should not be exceeded. These criteria represent scientific judgements based upon literature and research about the concentration-effect relationship of a particular water quality constituent to a particular aquatic species within the limits of experimental investigation. The criteria developed and published by the U.S. Environmental Protection Agency (EPA) have no direct regulatory force. They do acquire requlatory force when legally established in state water quality standards where they indicate the quality factors that must be met for the "designated use" or when they are used in the establishment of toxic effluent standards under Section 307. From the base of water quality standards, the criteria also acquire regulatory force in discharge permits and non-point source best management practices. This is the definition under which we operate but you will notice from my discussion of the evolution of water quality criteria that human health effects have become an important factor.

The concept for water quality criteria currently used in the U.S. evolved from the work in the early 1900's by March, who published data in 1917, and the effort by Ellis in 1937 who described the effect of various concentrations of waterborne substances on aquatic life. These early efforts to develop water quality criteria consisted of a listing of the concentration, the test organism, the results of the test within a given time period, and the reference for a cause-effect relationship of a particular water contaminant.

The next major development in water quality criteria came in 1952 when the State of California published McKee and Wolf's book, "Water Quality Criteria". This classic contained over 1,000 references and a summary of the water quality criteria established by state and interstate commissions. A large portion of this document was devoted to cause-and-effect relationships for major water pollutants. In this document the beneficial use concept of directly relating criteria to water use was formulated and has become the major feature of water quality standards. The 1952 version of water quality criteria was revised by McKee and Wolf in 1963. In this revised edition about 4,000 references were cited on water quality criteria. Following the concept

set forth in the earlier edition, criteria were listed according to their effect on water uses.

Later in the 1960's the Department of Interior, recognizing the need for a definitive national approach to the development of water quality criteria, established a National Technical Advisory Committee (NTAC) to develop water quality criteria for five specified uses of water. These were agricultural, industrial, recreational, fish and wildlife, and domestic water supply. The NTAC report or the "Green Book" was designed to provide federal guidance to state water pollution control agencies engaged in water quality studies and water-quality-standard-setting activities. This publication presented a change in the concept of water quality criteria from one that listed a series of concentration-effect levels to a concept that recommended concentrations that would ensure the protection of the quality of the aquatic environment and the designated water use. When a specific aquatic life recommendation for a particular water pollutant could not be made due to lack of information or conflicting data, a recommendation was made to substitute a designated application factor based upon data obtained from a 96-hour bioassay using a sensitive aquatic organism and the receiving water as a diluent for the toxicity test.

Soon after EPA was established, it contracted with the National Academy of Sciences to expand the "Green Book" and develop a water quality criteria document that would include current knowledge. The result was a 1974 publication, "Water Quality Criteria 1972", commonly called the "Blue Book", that presented water quality criteria as of 1972 along the same lines as the "Green Book".

The implementing Federal Water Pollution Control Act, as amended, required EPA to publish water quality criteria. Specifically, Section 304 of the act required the EPA Administrator, after consultation with the appropriate federal and state agencies, to develop and publish and, from time to time, revise criteria for water quality that accurately reflected the latest scientific knowledge on the effects on health and welfare, fish and wildlife, and other effects. Based on the requirements of Section 304, the EPA developed and published "Quality Criteria for Water" (QCW), in 1976. QCW, sometimes called the "Red Book", contained criteria for 54 alphabetically listed parameters.

During the time EPA was developing this document, several environmental groups brought suit against EPA to identify and accelerate activities on criteria development for a number of toxic constituents under Section 307. As a result, under the Consent Decree, in Natural Resource Defense Counsel, et al. vs. Train, EPA was required to publish criteria for 65 specified toxic pollutants. The criteria are to state maximum recommended concentrations consistent with the protection of aquatic life and human health. Because of this action EPA shifted toward the development of criteria associated more with human health and thus its attendant risk-assessment problems.

The work on the 65 toxic pollutants covered under the Consent Decree began at about the time the QCW was published. Since the research of the literature revealed a scarcity of water-quality-related data for some of the 65 pollutants, a parallel research effort was undertaken to develop data on acute

and chronic toxicity to aquatic life in addition to data on bioaccumulation and mutagenicity. By early 1978, draft criteria documents based on these data had been circulated for informal review inside EPA and to other agencies and modified to reflect comments received. It was anticipated that these documents would be published for public comment by mid-1978, the publication date set in the Settlement Agreement.

During the final stages of the document preparation, EPA had begun a re-examination of its water quality criteria program which led to a major recasting of the documents and subsequent revision of their publication schedule. We therefore embarked on an intensive effort to refine and improve the documents. Two major aspects of this effort were:

1. A more formalized approach in deriving criteria from aquatic toxicological data

2. A renewed emphasis on the development of criteria for the protection of human health.

In order to place the EPA action in perspective, it is important to understand the refinements in the definition of criteria. A water quality criterion as we talk about it today is a qualitated or quantitated estimate of the concentration of a water constituent or pollutant in ambient waters which, when not exceeded, would ensure a water quality sufficient to protect a specified water use. A criterion is a scientific entity based solely on data in scientific judgement. It does not reflect considerations of economic or technological feasibility or represent society's judgement of desirability. A criterion based on the protection and propagation of fish, shellfish, and wildlife, for example, is simply the best estimate informed scientists have been able to make of the maximum concentration of a given pollutant that can be tolerated while still maintaining added protection of aquatic life. A criterion intended for the protection of human health, by the same reasoning, is the best estimate of the concentration which may exist and still not pose an undue risk to the humans who drink the water or eat the fish or shellfish from the water.

On March 15, 1979, EPA issued for public comment 27 criteria for the 65 pollutants covered under the Consent Decree. Criteria for the remaining 38 will be issued for public comment in the near future. The final publication is planned for the latter part of 1979. As new information becomes available, indicating that previously established criteria should be revised or that criteria should be established for substances that have not been addressed, it is expected that new or revised criteria will be developed. EPA recognizes that the quality and quantity of the data in the criteria document varies and differences of opinion exist as to what constitutes a sufficient data base for final criteria formulation.

In this regard, EPA is undertaking a program to expand the data base for portions of the aquatic data base dealing with bioconcentration factors and aquatic toxicity. It should be recognized that, when published after public comment, these criteria will not be cast in concrete and will be updated in future years when additional information becomes available indicating such a need.

The Federal Register notice of March 15, 1979 clearly outlines the process of criteria development of EPA. In this process two major factors are considered: concentrations estimated to be protective of aquatic life and concentrations to protect human health. These concentrations were derived separately from essentially different data bases and with methods designed specifically to address the concerns of the two separate areas. One characteristic of the criteria which may require some clarification is the two-fold nature of the aquatic-life criteria. These criteria are comprised of a concentration to be maintained as an average during any 24-hour period and a maximum or ceiling concentration not to be exceeded at any time during the 24-hour period. The average figure represents a concentration level estimated to protect against adverse chronic effects. It is presented as an average because chronic data are usually based on tests lasting from several weeks to more than a year. During these tests the pollutant concentration varies about a mean exposure concentration. Thus some fluctuation is inherent in the a mean no-effect exposure concentration.

The aquatic organisms can be expected to tolerate some excursions over this mean so long as the temporary excursions are not too high or too frequent. These temporary excursions cannot be too high because data show that very high concentrations of chemicals can kill or cause irreversible damage in very short periods. Furthermore, the excursions cannot persist for extended periods since in the case of some chemicals the effect of intermittent high exposure is accumulative. It is necessary therefore to place a limit on how high concentrations go and over what time period they can persist. The derivation of the ceiling value is based on LC_{50} data. In summary, the two-number criterion is intended to describe an ambient water concentration which will produce an average water quality generally suited to the maintenance of aquatic life while restricting the excursions over that average to levels which will not cause harm. In an effort to take specific characteristics into account, criteria for compounds whose toxicity varies markedly with various degrees of hardness have been presented in the form of curves. Although EPA recognizes that other water characteristics such as pH, temperature, and degree of salinity may affect toxicity of some pollutants, the data base at this time is not detailed enough to allow for further specificity.

The objective of the health assessment portion of the criteria documents is to estimate ambient water concentrations which, in the case of non-carcinogens, represent "safe" levels for humans. In the case of suspect or proven carcinogens, the objective is to present various levels of incremental cancer risk. Health assessments follow guidelines developed to assist the scientists in identifying and interpreting all pertinent data on the subject pollutant without impeding the scientific judgement and expertise. The assessments typically contain four elements: exposure, pharmacokinetics, toxicity, and criteria formulation. An exposure section summarizes information on possible exposure routes such as ingestion, inhalation, and dermal contact. The pharmacokinetics section reviews data on absorption, distribution, metabolism, and excretion to assess the biochemical fate of compounds in the human and animal system. The effects section reviews acute, subacute, and chronic toxicity; synergistic and antagonistic properties; and specific information regarding mutagenicity, teratogenicity, and carcinogenicity. In this review the toxic effect to be protected against is

identified. The quality, quantity, and weight of evidence characteristic of the data are taken into account. The last section represents the rationale for criteria development and the mathematical derivation of the criterion. Specific criteria are developed only if the weight of evidence supports the occurence of a toxic effect and if the dose response data exist from which criteria can be estimated. Criteria for suspect or proven carcinogens are given as concentrations in water associated with the range of incremental cancer risks in man based on specific exposure assumptions.

These assumptions include direct exposure through consumption of water or indirect consumption of aquatic organisms which may bioconcentrate pollutants from the water in which they live. In addition to providing a range of concentrations for the consumption of water and edible aquatic organisms, our criteria documents present a range of concentrations based on the consumption of edible aquatic organisms alone. In the latter case we assume that the water consumed by an individual would not contain the pollutant in question. In criteria that reflect both water consumption and aquatic organism routes of exposure, the relative contribution varies with the propensity of a pollutant to bioconcentrate. Consumption of aquatic organisms becomes more important as the bioconcentration factor increases. When the concentration factor is 100, for example, exposure through two routes is equal. At higher concentration factors, such as 1,000 to 100,000, the contribution of the water consumption route becomes relatively minor. For a few pollutants information about exposure from other sources such as air or non-aquatic diet has been used in formulating criteria. As information on total exposure is assembled for pollutants which criteria reflect only two indicated exposure routes, adjustments in water concentration values may be made. It is anticipated that the total exposure considerations will be a primary focus in the next generation of health-based criteria.

Criteria for non-carcinogens have also been developed and represent levels at which exposure to a single chemical is not anticipated to produce adverse effects in man. In these instances similar exposure assumptions were also made. However, while the evidence of adverse effects is clear, data are insufficient to derive a numerical criterion in many cases. In a few cases taste and odor data form the basis for the criterion because chronic toxicity data are lacking or are insufficient, or result in a higher criterion value than that which produces adverse organoleptic effects.

I believe that the procedures and the areas of consideration I have described for the process used by EPA in water quality criteria formulation can have direct application to the workshop goal, to facilitate the gradual and orderly development of compatible toxic substances control programs in the Great Lakes Basin. The guidance outlining the factors to be addressed by those desiring to change the EPA toxic pollutant list is particularly apropos to this goal. These factors as listed in Federal Register, Volume 44, Number 60, March 27, 1979 are:

1. Toxicity of the pollutant:
   a. Acute (96-hour LC_{50}) to freshwater and marine organisms
   b. Maximum acceptable toxicant concentration to freshwater and marine organisms
   c. Embryo-larval and egg-fry tests on freshwater organisms

d. Information on dose-related, lethal, or chronic sub-lethal effects on man, nonhuman mammals, vertebrates including aquatic vertebrates, and other aquatic organisms
e. Information relating to known or suspected carcinogenicity, teratogenicity, and mutagenicity in man or in other animals.

2. Persistence of a pollutant including mobility and degradability in water or the substance.

3. Bioconcentration, bioaccumulation, and biomagnification of a pollutant or of its degradation products or metabolites.

4. Synergistic propensities and effects of the pollutant.

5. Water solubility and octanol-water partition coefficient determinations for the pollutant.

6. Extent of point source discharges into water including qualitative presence and quantitative concentrations of the pollutant in effluents, ambient water, benthic sediments, fish, and other plant and animal aquatic organisms.

7. Potential exposure of persons to the pollutant through drinking water, surface water, fish or shellfish consumption. Potential exposure of aquatic organisms and wildlife to the pollutant.

8. Annual production of the pollutant in the United States.

9. Use patterns.

10. The capability of analytical methods to identify and quantitatively determine the presence of the pollutant in ambient water or wastewater.

CHAPTER 5

INTEGRATED TOXIC SUBSTANCES STRATEGY

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INTRODUCTION

Since World War II there has been a revolution stemming from the manufacture and use of chemicals bringing about increasing economic and social benefits. Our improving standard of living can be measured as a direct proportion to the growth of the chemical industry and its manufacture of new chemicals and products. Unfortunately, it has only been in recent years that we have seen there are risks associated with environmental and human exposure to chemical compounds.

Acute episodes involving toxic substances have tended to bring focus on chemical problems in Region III of the Environmental Protection Agency (EPA). During the past few years numerous events have occurred requiring considerable attention and resources. These include kepone, carbon tetrachloride, asbestos, mercury, PCB's, and nitrosamine problems, several of which are yet to be resolved. The short-term impact of these chemicals is often not difficult to quantify. Chronic effects, on the other hand, are not so easily defined or measured. For example, it has been determined that many chemicals cause chronic or even fatal illnesses which may not be manifested until years following exposure. Recently, there has been the expressed belief that 60-90% of human cancers are environmentally caused. In addition, health statistics indicate the incidence of cancer is increasing.

Evidence accumulated by the medical and scientific communities combined with the numerous documented environmental insults prompted Congress to address control of chemical substances in several statutes administered by EPA and by other federal agencies. The responsibilities of EPA are defined in the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, and the Federal Insecticide, Fungicide, and Rodenticide Act. Other federal legislation includes the Occupational Safety and Health Act, the Food, Drug, and Cosmetic Act, and the Consumer Product Safety Act.

Given the number of laws and the present practice to establish separate organizational entities to administer each statute, it is necessary to establish formal mechanisms to achieve communication and integration to ensure effective address by all appropriate program elements. This document sets forth the framework for accomplishing integration of the toxic substances activities within Region III.

PURPOSE

The purpose of this document is to set forth an intermedia integrated toxics substances strategy for addressing regional toxic substances issues. The fundamental ingredient is communications to facilitate information exchange, to identify and assess problems, to plan and execute corrective actions, and to minimize duplicative efforts, all for the purpose of more effective and efficient utilization of available resources. In order to achieve the objective, the strategy:

1. Describes a management system/organization to achieve the integration of all EPA toxic-substance-related regulatory authorities and to facilitate coordination within the region as well as with headquarters, states, and other federal agencies on toxic substance activities.

2. Identifies organizational elements and their responsibilities, including regional components as well as state and federal agencies having authority to address toxic substance issues.

3. Delineates coordination mechanisms within the Regional Office and with headquarters, states, and other federal agencies to promote communication, eliminate oversights, and reduce duplicative efforts.

4. Identifies procedures for responding to emergency, chronic, and potential toxic substance situations using an integrated approach.

5. Describes types and sources of information for determining existing and potential toxic substance problems within the region including references on chemical toxicity, health and environmental effects, manufacturing processes, and production volume.

6. Outlines a screening procedure for prioritizing potential problem chemicals for purposes of determining type and level of action to be taken with available resources.

ORGANIZATION ELEMENTS AND RESPONSIBILITIES

There are several organizational elements within the Regional Office structure which have functional responsibilities encompassing certain aspects of toxic substances identification, investigation, and control. Actual involvement depends upon the compound, environmental medium, and the situation. The following organizational units have major responsibilities in activities involving toxic substances:

1. Water Division
   a. Water Supply Branch
   b. Water Planning Branch

2. Surveillance and Analysis Division
   a. Water Quality Monitoring Staff
   b. Air Quality Monitoring Branch
   c. Environmental Emergency Branch
   d. Wheeling and Annapolis Field Offices

3. Enforcement Division
   a. Office of Special Programs
   b. Legal Branch
   c. Air Enforcement Branch
   d. Water Enforcement Branch

4. Air and Hazardous Materials Division
   a. Hazardous Materials Branch
   b. Pesticides Branch

5. Office of Toxic Substances

6. Office of Research and Development

7. Office of Chesapeake Bay Program

Presented below are brief functional descriptions of these organizational units emphasizing toxic substances responsibilities.

WATER DIVISION

WATER SUPPLY BRANCH

The Water Supply Branch has the primary responsibility for regional management and implementation of the Safe Drinking Water Act (P.L. 93-523) and the Interstate Quarantine Regulation. More specifically, the branch assures that public water systems are monitored and meet drinking standards through the Public Water System Surveillance Program, regulates underground injection wells in designated states through the Underground Injection Control Program, assesses imminent hazard situations in drinking water systems in conjunction with state and local authorities, and determines actions necessary to protect public health.

WATER PLANNING BRANCH

The branch's toxic-related responsibilities include managing the Water Quality Management Planning Program (Sections 208 and 303 of the Clean Water Act) including water quality standards, funds pretreatment programs in support of the Regional Municipal Construction Grants Program, reviews and approves/disapproves facilities planning aspects of the Construction Grants Program (Section 201 of the Clean Water Act), and reviews states' biennial assessment of water quality (Section 305(b) of the Clean Water Act).

SURVEILLANCE AND ANALYSIS DIVISION

The Surveillance and Analysis Division is responsible for the collection, analysis, and evaluations of environmental quality data in support of regional and national programs. It conducts special studies, investigations, and laboratory analysis to acquire necessary data, and operates the Regional Environmental Emergency Response Center.

WATER QUALITY MONITORING STAFF

The Water Quality Monitoring Staff serves as the divisional focal point for coordination of all requests by program offices for field investigations

and laboratory work, develops and coordinates the field investigation and surveys aspects of the NPDES permit compliance monitoring program, and establishes priorities for field and laboratory investigations.

AIR QUALITY MONITORING BRANCH

This branch provides monitoring capability and technical advice during responses to emergency air incidents and conducts ambient air surveys, facility compliance inspections, and stationary source emission measurements in order to assess compliance with air quality standards and regulations.

ENVIRONMENTAL EMERGENCY BRANCH

This branch has the primary responsibility to develop and implement the Regional Response Plan for Emergency Incidents. As major duties the branch conducts and coordinates cooperating agency and industry responses to oil, toxic, and hazardous material spills, and operates as well as maintains the Regional Response Center providing 24-hour communication to facilitate regional response activities relating to oil and hazardous material spills, hazardous air pollutant incidents, citizen reports, pesticide accidents, and radionuclide incidents.

WHEELING AND ANNAPOLIS FIELD OFFICES

Functional responsibilities are inspection, sampling, and analysis in the areas of toxic and hazardous substances, emergency response, and other facility-type inspections; investigations of water supplies for possible contamination from toxic substances; support of enforcement case development in the toxics area; and surveys of effluents in ambient waters for the priority pollutants. Functional responsibilities include air compliance monitoring, NPDES (National Pollutants Discharge Elimination System) compliance monitoring, the Priority Pollutant Program, ambient monitoring, and state assistance.

ENFORCEMENT DIVISION

The Enforcement Division is responsible for the control, prevention, and eventual abatement of environmental pollution in Region III. This is effected through the maintenance of compliance status with pollution control legislation for the air, water, and categorical, including toxic, programs in EPA. To ensure a compliance status, this division's program includes the issuance or denial of permit applications, review of abatement plans and compliance schedules, and recommendations of enforcement actions, where necessary. The major function of the division office is to ensure the proper administration of these programs and to act as liaison between staff and higher headquarters in program planning and policy matters.

OFFICE OF SPECIAL PROGRAMS

The Office of Special Programs in the Enforcement Division has the primary responsibility for assuring compliance with the various environmental laws covering toxic substances and hazardous wastes. Its role is to coordinate the monitoring of toxic substances and the gathering of evidence when violations of statutes are suspected. The Office of Special Programs prepares the

technical aspects of cases filed for enforcement actions, including administrative penalties and civil or criminal cases, and provides expert witnesses for these cases. Its responsibilities include the development and implementation of a regional strategy for toxics in conjunction with the integrated toxic substances strategy.

LEGAL BRANCH

The Legal Branch provides legal support to the various branches in the Enforcement Division during the development and resolution of enforcement actions under the various environmental statutes. Specifically, the members act as advisors-counselors to technical staff pertaining to evidence gathering and the appropriate enforcement actions to take under which statutes (when more than one applies). This branch prepares legal documents supporting the cases and works with headquarters and the Department of Justice attorneys to assure cases are properly filed and prosecuted.

AIR ENFORCEMENT BRANCH

The Air Enforcement Branch develops and implements the regional air pollution enforcement strategy to ensure the requirements of the Clean Air Act are carried out. The branch coordinates with and provides direction to the enforcement-oriented efforts of the Air and Hazardous Materials Division and the Surveillance and Analysis Division to ensure an effective and unified regional air enforcement program. It develops the technical portion of the enforcement cases against sources in violation of EPA-promulgated emission limitations for referral to the Legal Branch. The Air Enforcement Branch directs the development of the technical portion of the enforcement of National Emission Standards for Hazardous Air Pollutants (NESHAPS) and coordinates the review and evaluation of waiver requests for meeting hazardous emission standards.

WATER ENFORCEMENT BRANCH

The branch has the primary responsibility to implement NPDES (Section 402 of the Clean Water Act), a national permit program to control and regulate point source discharges. The branch receives information on toxic pollutants discharged to navigable waters and issues permits controlling and limiting toxic pollutants. These permits include biomonitoring requirements, best management practices, and pretreatment program requirements.

AIR AND HAZARDOUS MATERIALS DIVISION

HAZARDOUS MATERIALS BRANCH

The branch is responsible for providing and maintaining expertise on environmental issues relating to noise, radiation, and solid waste management and has the primary responsibility to implement the Resource Conservation and Recovery Act of 1976 (RCRA) which involves hazardous waste regulations, control of land disposal practices, comprehensive state solid waste regulations, solid waste research and demonstration, resource conservation and recovery, and enforcement control. The branch provides the technical and financial support mechanism to states to encourage state assumption of the RCRA program responsibilities.

PESTICIDES BRANCH

The branch is responsible for the implementation of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). The branch regulates pesticides by registration, inspection, and the provision of a data base on environmental and health effects of manufacturers and products. They also provide technical and regulatory assistance to states to resume the FIFRA responsibilities.

OFFICE OF TOXIC SUBSTANCES

The Office of Toxic Substances serves as a focal point for coordination and support of toxic-related activities for Region III and as the principal advisor to the region on matters related to toxic substances. In addition to the important advisory/coordination role, the office is responsible for planning and conducting programs required to implement the Toxic Substances Control Act (TSCA) within the region. Major responsibilities include interface with existing regional and other federal/state toxic-related programs; coordinates with regional activities in responding to toxics problems; compile, review, retrieve, analyze, and disseminate pertinent data on toxic substances; keeps both the Regional Office and public well informed about any pertinent information/action taken relative to the regional toxics control program; coordinates in developing and implementing the Regional Integrated Toxics Control Strategy; coordinates EPA's kepone and its related activities with states and other federal agencies to ensure the kepone contamination problem received proper follow up.

OFFICE OF RESEARCH AND DEVELOPMENT

The Office of Research and Development serves the region as a connecting link between EPA's centralized research and development program and each element of the regional program. The primary responsibility of this office is to assure that the Regional Administrator and his staff receive maximum benefit from the broad range of scientific studies in progress under EPA's Office of Research and Development sponsorship, and that studies supported by the national program meet regional technological needs and in a timely manner. Direct technical assistance and support is provided on a case-by-case basis.

OFFICE OF CHESAPEAKE BAY PROGRAM

The Chesapeake Bay Program was created in response to the 1976 Independent Appropriation Bill to assess the principal factors, including toxic substances, having an adverse impact on the environmental quality of the Chesapeake Bay. The program's toxic-related responsibilities include the development and initiation of a comprehensive toxic substance management strategy and the demonstration that the program's management methodology for toxic substance control is transferable to other estuarine environments.

INTEGRATION MECHANISMS

The term "integrated" means by definition to bring together the constituent parts into a composite. Individual elements do not lose their

identity, but are brought together into a coordinated whole devoted to a common goal. It is therefore not the intent of the strategy to diminish or supersede existing organizational responsibilities but to enhance capabilities by integrating efforts and improving communications.

REGIONAL OFFICE

In recognition of the necessity to achieve an integrated program, the Regional Administrator in August 1978 established the Regional Toxic Substances Policy Committee. The membership includes representatives from the Air and Hazardous Materials Division, Enforcement Division, Surveillance and Analysis Division, Water Division, the Chesapeake Bay Program, and Research and Development with Water Supply, Pesticides, Solid Wastes, NPDES permits, and the Environmental Emergencies among the specific organizational units identified. The Toxic Substances Coordinator was designated as the committee chairman.

The principal functions of the committee are to "identify toxic issues and problems, find solutions to them, and work to coordinate all aspects of the regional toxic program." The committee ensures that problems are adequately addressed, programmatic areas covered, schedules established and met, communications maintained, and appropriate reports prepared and disseminated.

STATES AND OTHER FEDERAL AGENCIES

Coordination with other regulatory agencies is essential to avoid duplication and oversight and to maximize utilization of available resources. At the state level, the basic coordinating linkage is between the EPA program offices and their counterparts in the state agencies. This is an established mechanism founded on continuing programmatic interfaces and is considered the most direct and responsive.

In addition, the region is currently initiating the approach of EPA/state agreements designed to formalize programmatic commitments. Objectives of the agreements include integrating efforts for the solution of environmental problems, maximizing returns from federal grants, and providing the states with more flexibility to address high priority problems and needs. This approach provides an avenue to identify areas of coordination.

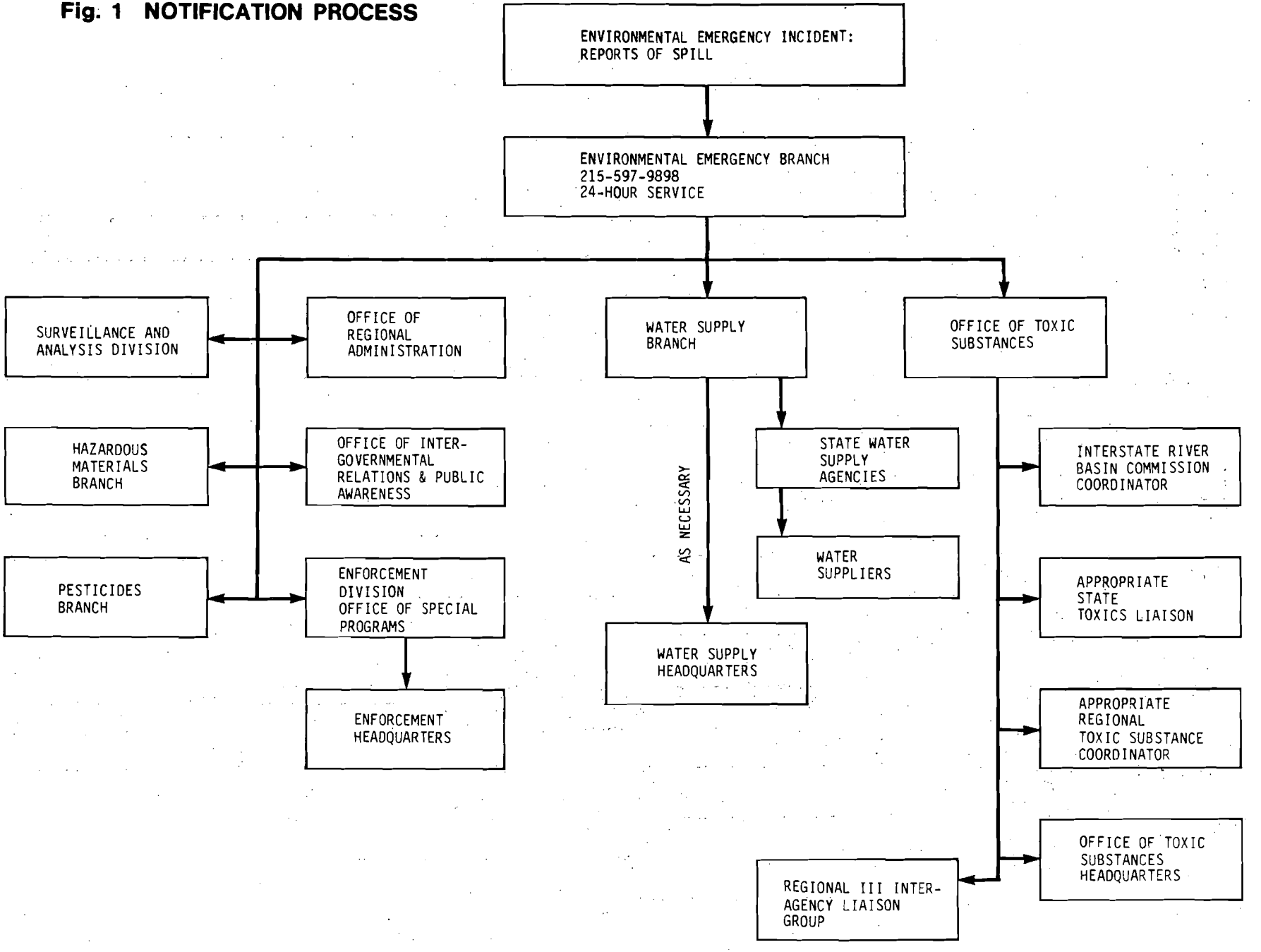
As a further point of coordination, the governors of each state have designated, at our request, persons to serve as liaison with the Regional Office in matters dealing with the Toxic Substances Control Act.

At the federal level regional regulatory coordination efforts are being achieved through an interagency agreement between the Consumer Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, and the Occupational Safety and Health Administration. The purpose of the agreement is to make the regulatory processes more efficient through joint endeavors and the sharing of information and resources.

HEADQUARTERS

Appropriate EPA headquarters elements will be advised by their respective regional counterparts of toxic substances issues and problems. For situations

Fig. 1 NOTIFICATION PROCESS



beyond the capability and expertise of the region, headquarters elements will provide support in terms of advice, technical assistance and interpretation, and, in some instances, manpower and contractor assistance when conditions warrant.

TOXIC PROBLEM CATEGORIES

The region encounters three types of toxic situations that require differing response approaches. For purposes of the strategy the categories of toxic problems are termed as emergency, chronic, and potential. The three categories are addressed below.

EMERGENCY

An emergency event, usually the result of an accident or equipment failure, requires very rapid assessment, response, and actions to protect the public health and the environment. Although a substance may be released to the air, water, or land, the overall response and mitigation efforts will generally necessitate a multi-program approach. Emergencies are usually of short duration; however, the continued presence of a substance in the environment may require activities over an extended time frame.

The regional contingency plan delineates the functional responsibilities of the appropriate program offices and lists the names and telephone numbers of contacts. The Environmental Emergency Branch, Surveillance and Analysis Division, is charged with implementation of the plan once notification is received. Response activities are structured around the Environmental Emergency Branch with other program offices drawn into the assessment and follow-up phases. Figure 1 illustrates the general alerting or notification pattern.

CHRONIC

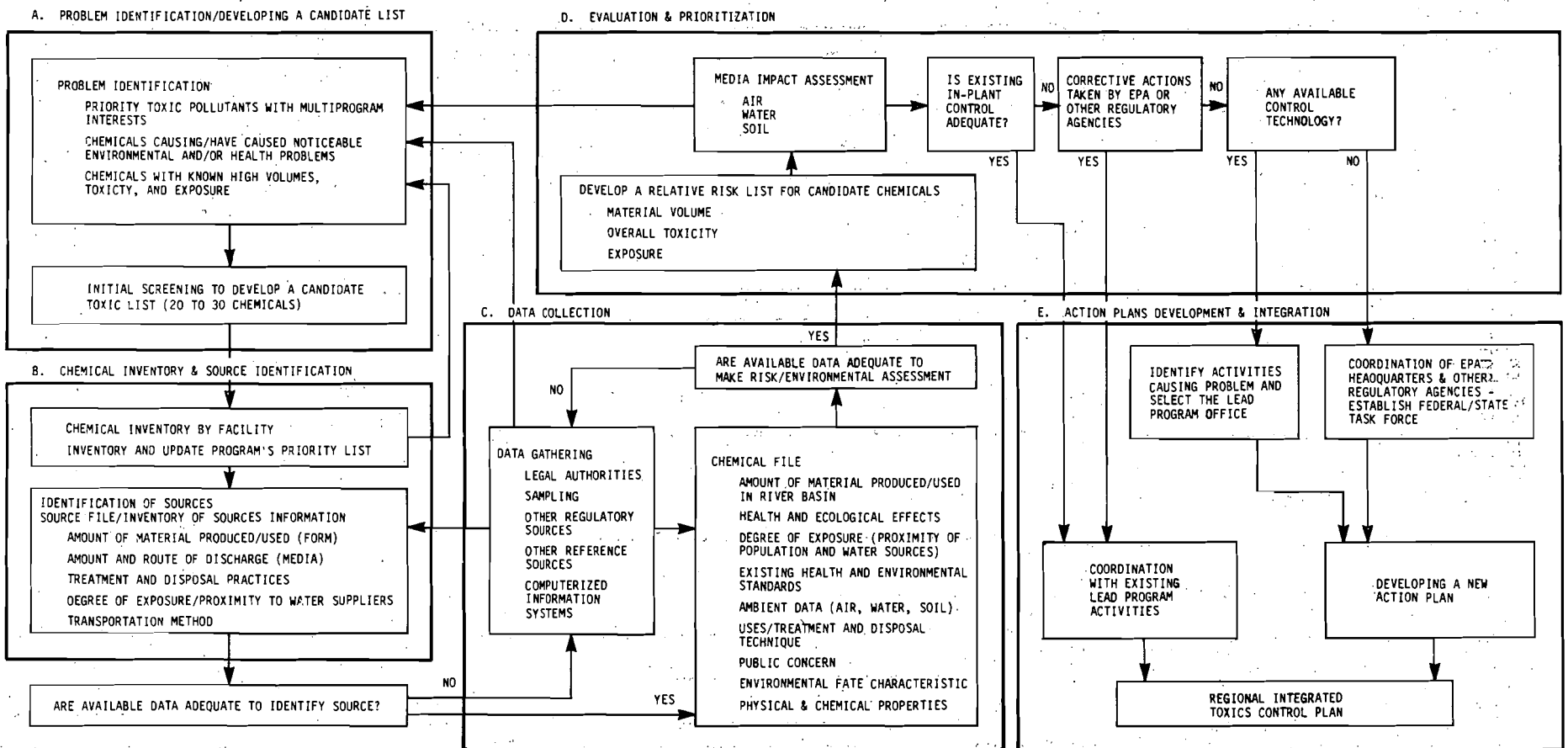
Chronic situations are defined as the discovery of a long-term problem (discharge, emission, in-place pollutant), or the residue remaining following an emergency event. Further defined, the term chronic implies continuing and of a long duration, but not environmental concentration.

The Office of Toxic Substances coordinator is advised of any chronic problem discovery and an evaluation made in conjunction with the program office having apparent responsibility. The purpose of the evaluation is to determine whether or not the problem warrants notification and address of other regional program elements. If deemed to be a multiprogram issue, the coordinator may call a meeting of the Toxic Substances Policy Committee, or only those programs having likely responsibilities. The meeting serves to assess the situation, to determine the lead program office to address the problem, and to decide on a course of action. Additional meetings are held to discuss status and modify actions, as necessary. The coordinator reports progress periodically to the Regional Administrator through the Regional Toxic Substances Incident Report.

POTENTIAL

A potential situation relates to the point of manufacture or use of a chemical compound where, because of the very nature of the substance, release

Fig. 2 PROBLEM IDENTIFICATION AND EVALUATION PROCESS



would be highly detrimental to the public health and the environment. In this situation there may or may not be a problem, but there exists little or no available information to draw a conclusion.

The heart of the activity is to identify chemical manufacture, use, and disposal facilities and then systematically determine whether or not a problem exists using subjective screening and evaluation techniques. Confirmation is accomplished by field investigations within the constraints of resources and priorities. This is explained in more detail in the problem identification section.

Because of the distribution and number of chemical industries within the region and resource constraints, our examination of problem potentials is by geographic areas. Initial efforts are focused on the Ohio-Kanawha River Basin due to the large concentration of chemical facilities and the history of chemical spills affecting, at times, water supplies. Subsequent focus will be on the Delaware River Basin, the Chesapeake Bay area, and then other industrial-specific areas.

Chemical inventories, screening techniques, evaluations, and findings by geographical areas are contained in separate documents.

PROBLEM IDENTIFICATION AND REMEDIAL OPTIONS

A significant portion of the strategy is devoted to procedures for evaluating potential toxic substance problems since by definition emergency and chronic situations are known issues. Obviously, available resources will first be focused on known problems with any remaining time directed to geographic evaluations. The purpose of viewing potentials is essentially a preventive effort where any necessary control can be implemented before conditions reach chronic or crisis proportions. It is expected that evaluations and subsequent ambient investigations will from time to time uncover chronic environmental problems.

The following presents in summary form the steps taken to identify and assess problem potentials of chemical compounds by geographic areas. The procedure presented graphically in Figure 2 is designed to provide a relatively simple and rapid asessment of extremely complex issues. Considering the limited quantity of information available on most compounds, including health and environmental factors, concentration standards or criteria, production volumes, and discharge and ambient data, the process will produce subjective evaluations. Nonetheless, the resulting drawing together of information and subsequent determinations will be considerably better than our current knowledge.

PROBLEM IDENTIFICATION - DEVELOPING A CANDIDATE LIST

Because of limited health and environmental data on chemicals in commerce, it is beyond the ability of the region to identify all compounds having undesirable characteristics that are manufactured, processed, or otherwise used within the region. However, those compounds already designated by research institutions and regulatory agencies as highly toxic and hazardous to human health and the environment provide a starting point.

Listings of chemicals by institution, agency, and program offices have been integrated. Those chemicals having multiprogram interests (chemicals found on more than one list) are shown in the matrix. The matrix is considered dynamic and as more information becomes available it will be modified. Currently, the matrix consists of those chemicals contained in:

1. Clean Water Act, Section 311, Hazardous Substances (271)
2. NRDC Consent Decree Priority Pollutants (129)
3. EPA, Office of Toxic Substances Priority Chemicals (15)
4. EPA, Region III, Safe Drinking Water
5. EPA, Office of Pesticide Programs List of Rebuttable Presumptions
6. Against Registration
7. State Compilations
8. OSHA Priority List
9. NIOSH Engineering Control List
10. Clean Air Act, Section 112, NESHAPS

In addition to the matrix, the presence of chemicals which have caused or are causing noticeable environmental and health problems is identified from the following sources:

1. Spill reports
2. OSHA case file
3. TSCA substantial risk notices
4. EPA and other federal and state agencies inspection and monitoring reports, including the U.S. Geological Survey's Water Quality Alert, the ORSANCO Early Warning System, and bioassay monitoring
5. Industry self-monitoring reports
6. Regional suspected environmental time bombs

The TSCA Inventory Report provides production information on chemicals and can pinpoint chemicals with high production volumes and exposures.

The matrix and the above sources are utilized to develop a candidate list containing 20-30 chemicals that are subjected to further evaluation. Chemicals on the candidate list are determined by considering multiprogram interests, past or present potential health and/or environmental problems, high-volume production/use, toxicity, and exposure potential. Maintenance of a limited candidate list provides ease of handling and address, considering the limited resources that will be available for the effort. The list is subject to continuing update as new information is received.

CHEMICAL INVENTORY - SOURCE IDENTIFICATION

The inventory step is essentially an identification of chemicals by facility within a specific geographical area of the region. Information is compiled using the TSCA Inventory, OSHA case files, Stanford Research Institute directory, Radian Report on Organic Chemical Producers, and other sources. All facilities having chemicals contained on the candidate list are identified and tabulated and a chemical/facility file initiated. Other information added to the file includes amount of chemical produced/used, concentrations and route of discharge, treatment and disposal practices, proximity to population centers, relationship to water intakes (including population served), and means of transportation. This file will facilitate the region's efforts to identify, assess, and respond to potential problem situations.

DATA COLLECTION

The data collection effort has two primary focuses:

1. To accumulate information and/or to identify sources citing health and environmental effects, hazards, and safety precautions relating to each chemical on the candidate list

2. To gather ambient information in the vicinity of appropriate facilities.

Files are being established and reference materials accumulated on each problem chemical. The file will include information on the amount of material produced and used in the river basin, health and ecological effects, the degree of exposure to populations and water suppliers, existing health and environmental standards, ambient data, uses, treatment and disposal practices, and public concern. This information source involves the total presence of the chemical in the river basin and is developed for the purpose of making a problem assessment for each chemical.

Since it is not anticipated there will be sufficient information on discharges and ambient concentrations through existing data sources, other available avenues will be utilized. These avenues include field surveys performed by the region, NEIC, the states, and/or contractors. In addition, there exists the potential for using the formal information request mechanisms to industry provided for in the Clean Air and the Clean Water Acts.

Before embarking on this form of data collection effort and thus the expenditure of limited resources, both the chances of success and the relative information requirements will be carefully screened and prioritized.

EVALUATION AND PRIORITIZATION

With the information contained in the industrial source and individual chemical files, a subjective evaluation will be made to determine the relative problem potential posed by candidate chemicals. Ranking is based upon the levels of production/use, potential population exposure, and hazardous characteristics of the chemical. The three factors will be weighted equally until experience indicates a further refinement is desirable.

Other factors include multimedia impact, inadequate plant controls, multiple sources, age of the facilities, and available control technology. The final ranking establishes the priority of actions to be undertaken to resolve any associated problem.

ACTION PLANS, DEVELOPMENT, AND INTEGRATION

The plan of action is dependent upon the circumstances peculiar to a particular facility. There are many state and federal laws and regulations that will require evaluation and then those that provide the most expedient and complete control mechanisms will be used. Any plan will define responsibilities by individual program activity, specify time schedules, and resource commitments.

The following are some of the most obvious examples of integrated actions to achieve control of toxic substances:

1. Issuance of NPDES permits to assist in the attainment of the primary drinking water standards.

2. Incorporation into the NPDES permits effluent limitations and non-point source control to meet water quality standards, best available technology toxic effluent criteria, and spill prevention plans.

3. Establish enforcement priorities on the basis of environmental and exposure significance, e.g. toxicity, health effects, discharge location versus potable water supply intakes.

4. Inventories of direct and indirect industrial discharges and emissions of toxics, including impact on water and air quality, to establish priorities.

5. Utilization of self-monitoring provisions of water supply, RCRA, and NPDES to obtain data; Sections 114 and 308 letters of the Clean Air and the Clean Water Acts, respectively, for process and discharge information; TSCA's premanufacturing and FIFRA's registration requirements for health and environmental effects data; and the interagency cooperative agreement to develop an integrated, comprehensive information system/file.

6. Utilization of facilities planning (Step 1) grants to include surveys of indirect industrial sources.

7. Integrating monitoring efforts with the states to provide more complete discharge and ambient data.

8. Use the site and production data from the initial TSCA inventory to develop strategies.

9. Develop the mechanism for integrating RCRA and other activities to ensure information transfer and program coordination.

When no apparent solution exists to a problem, all available information will be referred to headquarters for their address.

CHAPTER 6

ENVIRONMENTAL EVALUATION OF SELECTED TOXIC POLLUTANTS

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INTRODUCTION

EPA's current program to control environmentally harmful substances entering U.S. waters results from a 1976 Settlement Agreement between EPA and the Natural Resources Defense Council and other environmental organizations. This agreement establishes schedules for application of best available technology economically achievable (BATEA) by 1983 for controlling discharges of 65 classes of potentially toxic pollutants from 21 industries. It also requires pretreatment and new source performance standards for the same pollutants and industries. The Office of Water Planning and Standards (OWPS) Effluent Guidelines Division (EGD) is responsible for promulgating these technology-based standards. Also, EPA is to establish a program to determine whether more stringent, pollutant-specific effluent limitations, guidelines, and standards will still be needed to prevent interference with attainment and maintenance of water quality after application of the technology-based standards. The OWPS Monitoring and Data Support Division (MDSD) is responsible for this program. The OWPS Criteria and Standards Division is responsible for publishing water quality criteria for the 65 classes of pollutants.

The Settlement Agreement's list of toxic pollutants has become part of Section 307(a)(1) of the Clean Water Act of 1977. Section 307 also gives the EPA Administrator the authority to add pollutants to the list based on each pollutant's toxicity and environmental exposure/impact. These pollutants, subject to BATEA regulations, are also subject to more stringent effluent standards under Section 307(a)(2) if MDSD studies and evaluations determine that BATEA does not adequately control them.

MDSD's implementation of the program required by the Settlement Agreement and Clean Water Act establishes many new approaches to obtain and evaluate pollutant information. This paper describes the strategy and the methods being developed for pollutant prioritizations and risk assessments. It discusses MDSD studies of pollutant production, use, and release to the environment; transport, fate, and distribution in the environment; exposure routes and levels; and the resulting risk to human and other life. It also identifies the objectives of these efforts and their integration into a process leading to regulatory action recommendations.

ACTION ALERT METHODOLOGIES

The MDSD is developing a method to prioritize its work with the Section 307(a)(1) toxic pollutants. Application of this method should result in the systematic identification of pollutant candidates for addition to the Section 307(a)(1) list. It will also be used to identify possible future control actions for toxic pollutants. Therefore, the term "action alert" has been selected for the methodology.

The MDSD and EGD compiled a working list of 129 specific chemical pollutants from the 65 classes of chemicals identified in the Settlement Agreement. The specific pollutants were chosen on the basis of commercial availability, occurrence in waters, and the availability of analytical reference standards. Initial literature reviews and other studies showed that much of the information needed to complete risk assessments for these pollutants, especially for organic chemicals, was not available.

Since the urgency of proceeding with initial studies of risks from a pollutant should not depend on availability of complete data, the action alert methodology is designed to use whatever information is available to rank pollutants on a need-to-act basis. The pollutants with potential for more serious human and aquatic exposure and toxicity are selected for in-depth studies, integrated risk assessments, and action recommendations.

The conceptual frameworks for the action alert systems for chronic risks and acute hazards are shown in Figures 1 and 2, respectively. Data element hierarchies have been derived from these frameworks and are shown in Figure 3. Procedures are being developed and tested to examine specific chemical data at each stage in the hierarchies.

These procedures describe estimates to be made at each stage based on applicable information. For instance, ambient concentrations in water can be estimated using total annual discharge, half life in surface water, and effective surface water volume. Total annual discharge is estimated from known or estimated discharges from various types of point sources (including publicly owned treatment works) and nonpoint sources. There are also ways to estimate contributions from these discharges. These abbreviated methods will be sufficient to signal a problem which requires attention.

The system itself is very detailed. An action alert user's manual is also being prepared to explain the use of the system to others.

A simple example of the application of the system to acute freshwater fish toxicity is explained using Figure 4. A hazard ratio has been defined as exposure divided by toxic dose to allow a user to determine his own significance levels. In the example, water concentrations are plotted vs. LC_{50}'s. Establishing upper and lower hazard ratios of 1/100 and 1/1000 as shown provides three zones on the logarithmic graph. Determination of an LC_{50} level or range establishes the ambient concentrations which will place the pollutant in the lower priority zone 1, the "gray area" of zone 2, or the higher priority zone 3. The system can also be used for a chemical measured in waters, but without applicable LC_{50} data. In this case, the result is less exact than if ranges are available for both concentration and LC_{50}.

FIGURE 1:
CONCEPTUAL FRAMEWORK FOR
ACTION ALERT SYSTEM - CHRONIC RISKS

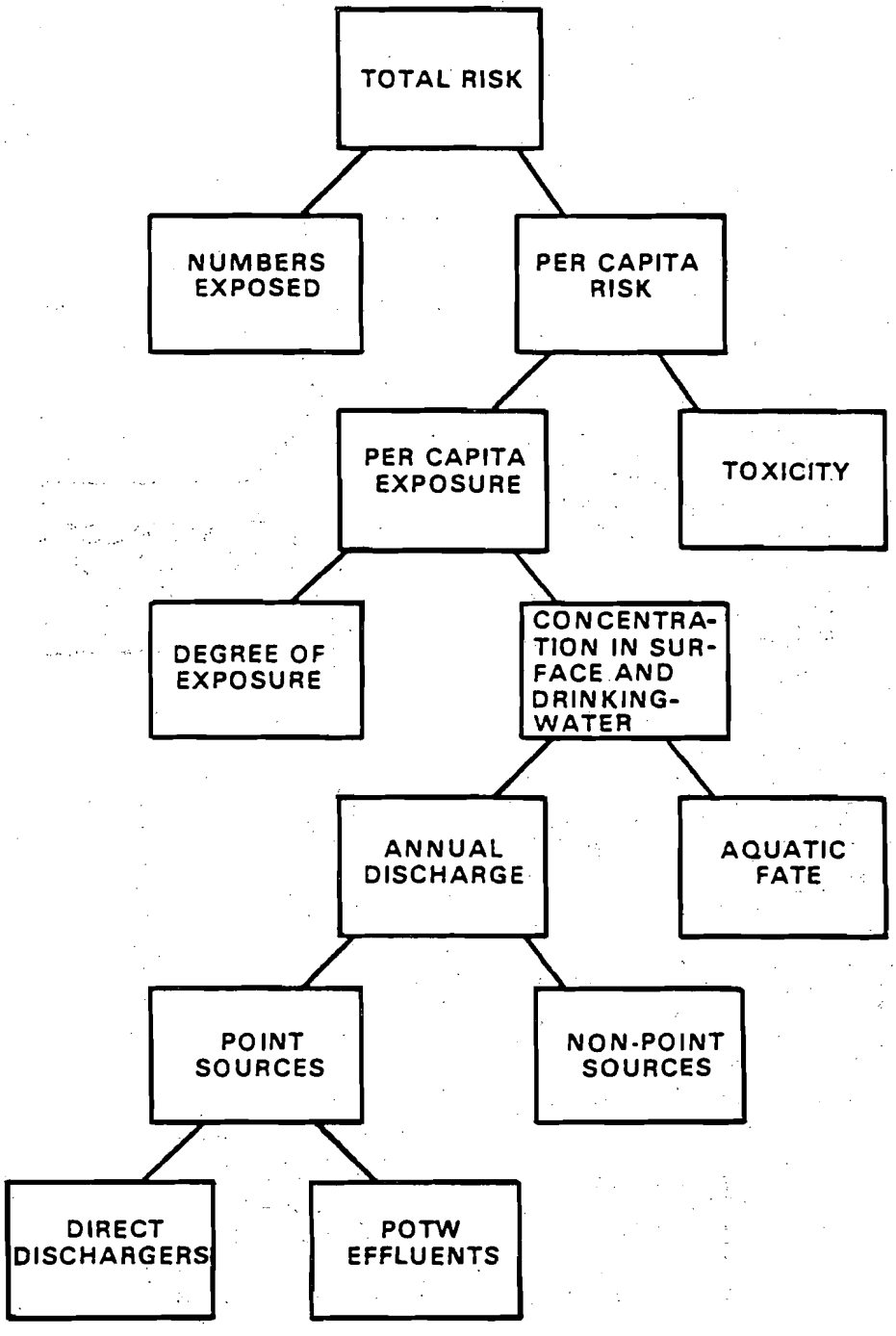
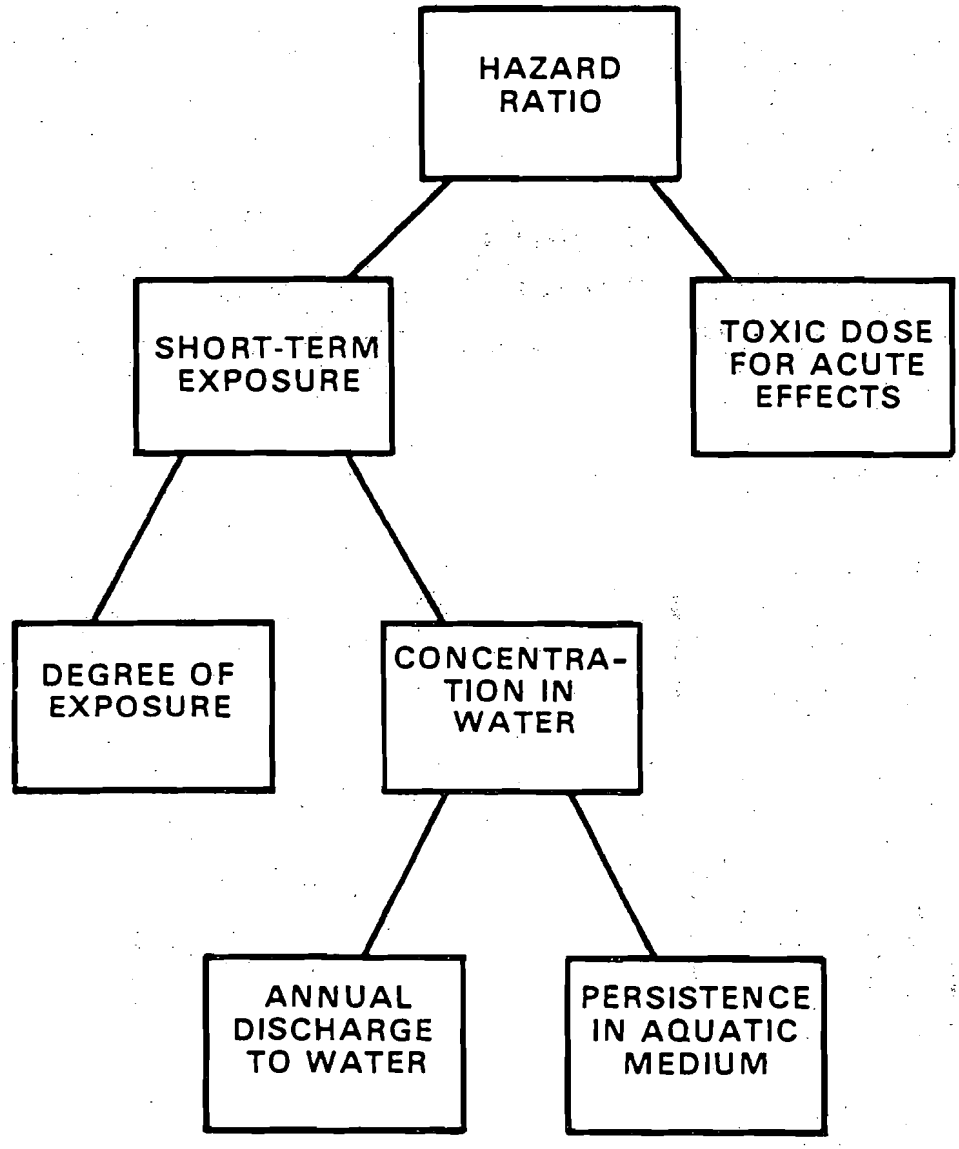


FIGURE 2:
CONCEPTUAL FRAMEWORK FOR ACTION ALERT SYSTEM - ACUTE HAZARDS



The action alert methodology merely screens and ranks pollutants according to their potential risk. It does, however, allow one to make consistent assumptions and comparisons for a number of pollutants. Data sources and reliability must also be identified. Because action alert is a primary screen, the arbitrarily-selected levels can be intentionally set to err on the side of safety. More precise risk analyses follow action alert to apply better criteria for signalling action recommendations.

POLLUTANT STUDIES FOR INTEGRATED RISK ASSESSMENTS

MDSD studies on the 129 pollutants include:

1. Sources and relative contributions to waters, including production quantities, use patterns, and aquatic contributions from industry, publicly owned treatment works, and other sources

2. Presence in waters, fish tissues, and sediments (monitoring)

3. Behavior in the air, water, and terrestrial environment (fate)

4. Health and environmental effects

5. Levels of exposure to humans and other (primarily aquatic) populations based on location, demographics, and habits.

The integrated risk assessments include an evaluation of the overall risk resulting from exposure.

Initial MDSD studies involved literature review, methodology development, and establishing sampling and laboratory procedures. A great deal of useful information was obtained, but many data gaps were identified, especially for organic chemicals. The OWPS Criteria and Standards Division studies involved toxicology, including biological persistence and accumulation potential. Significant results of MDSD studies are being and will be published in other reports and papers.

By using the action alert system and judgements on the amount and quality of the data available, eighteen pollutants have been selected for integrated risk assessments and action recommendations during 1979. These pollutants are shown in Table 1.

THE INTEGRATED RISK ASSESSMENTS

The objectives of the MDSD integrated risk assessments are to integrate information on cultural and environmental flow of pollutants, especially to and through waters, and to estimate exposure and resulting risk.

The generalized flow chart for the risk assessment process is presented in Figure 5. The process begins with analysis of three groups of data: materials balance/fate, ambient monitoring, and toxicology.

The materials balance/fate analysis ascertains pollutant production and use, sources, loss and disposal to the environment, and dispersal through the

FIGURE 3
FAMILY OF HIERARCHIES DERIVED FROM
ORIGINAL CONCEPTUAL FRAMEWORK

NOTE: AMBIENT CONCENTRATION IN WATER
GENERATES A SEPARATE SUBHIERARCHY.

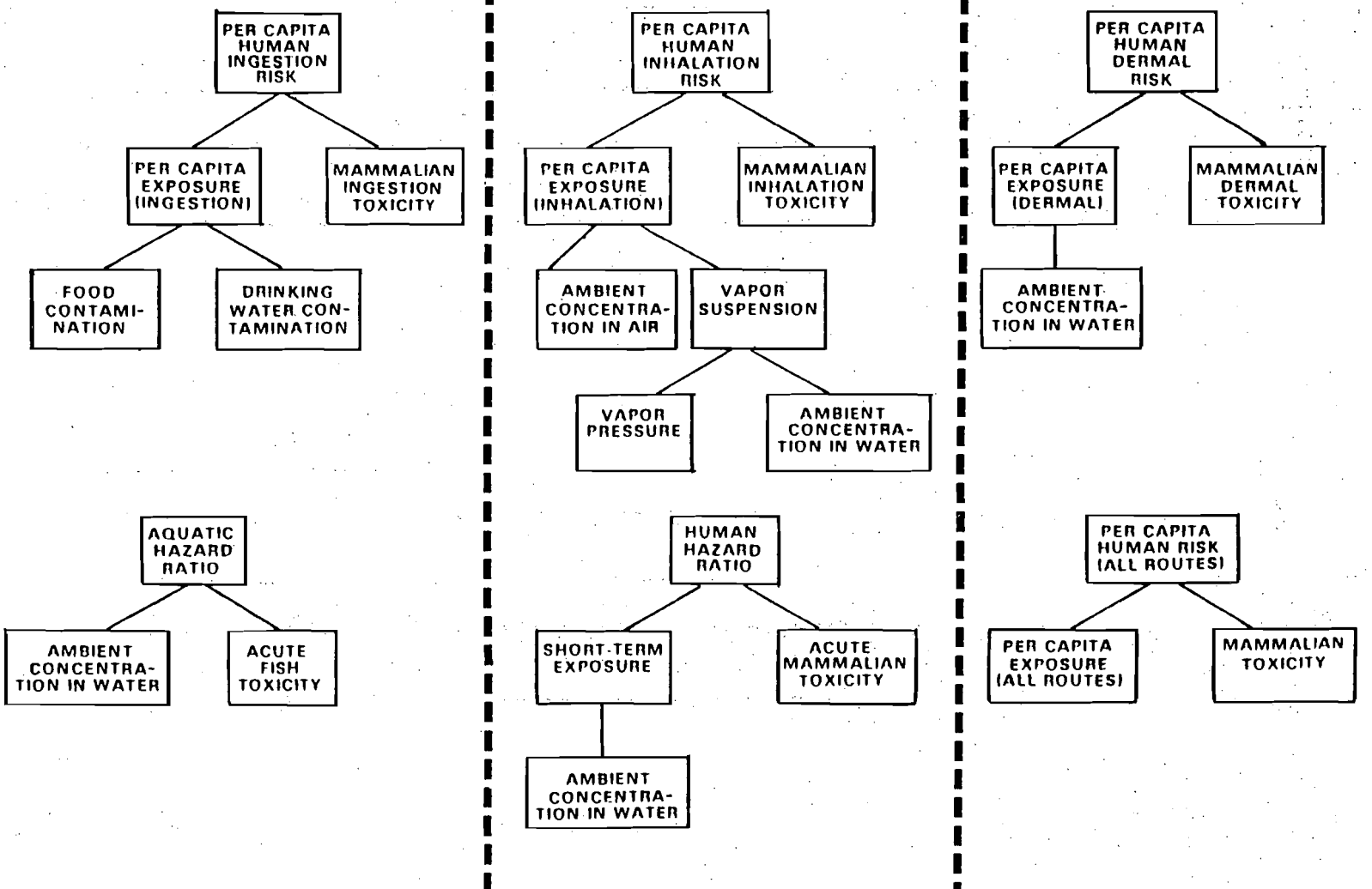


FIGURE 4:

ACTION ALERT APPLIED TO FRESHWATER FISH TOXICITY

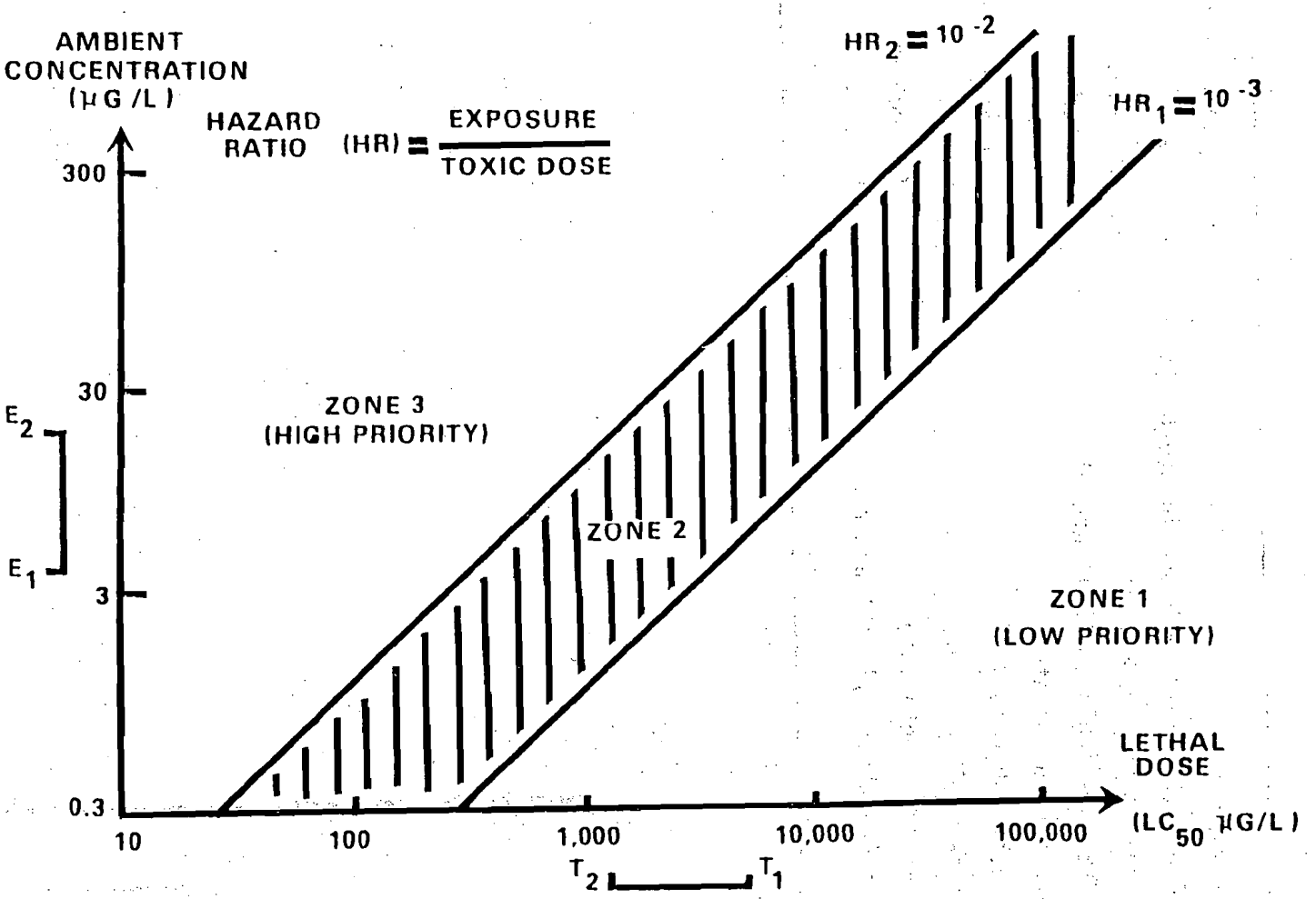


TABLE 1

LIST OF POLLUTANTS SELECTED FOR 1979 ACTION RECOMMENDATIONS

1. Cadmium	10. Butyl benzyl phthalate
2. TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin)	11. Zinc
3. Dichlorodifluoromethane	12. Cyanides
4. BCME (bis (chloromethyl) ether)	13. Copper
5. Dimethyl phthalate	14. Silver
6. Diethyl phthalate	15. Pentachlorophenol
7. Di-n-butyl phthalate	16. Lead
8. Di-n-octyl phthalate	17. Chloroform
9. Bis (2-ethylhexyl) phthalate	18. Mercury

FIGURE 5

GENERALIZED RISK ASSESSMENT PROCESS

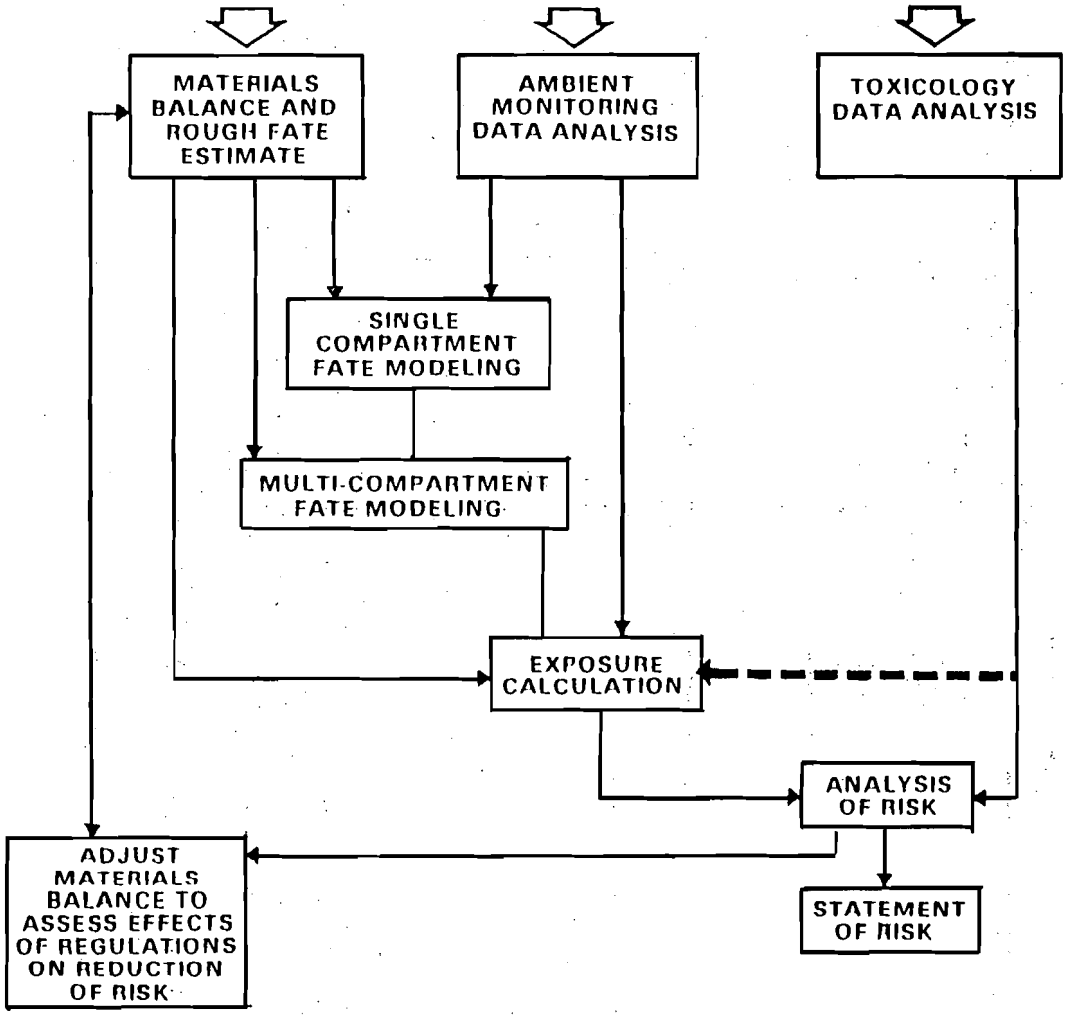
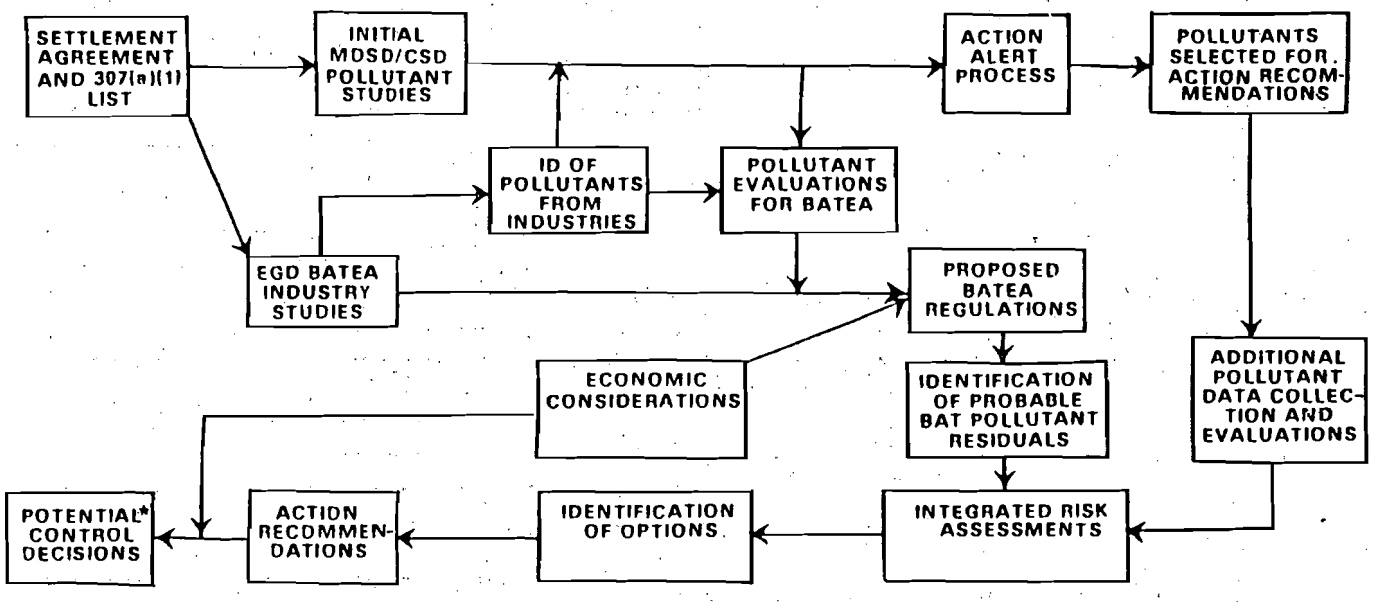


FIGURE 6
FLOW OF ACTIVITIES LEADING TO CONTROL DECISIONS



*DO NOTHING
REMOVE FROM 307(a)(1) LIST
307(a)(2) REGULATION
NATIONAL WQ STANDARDS
REFER TO OTHER AUTHORITIES
- RCRA
- FIFRA
- TSCA
- CAA
- SDWA

environment. The fate modeling procedure may take one of several possible forms depending upon such factors as data availability and chemical properties. Materials balance/fate analysis is performed at the level of detail suggested by available information. If further detail is required and can be achieved, the analyses are taken further. If a single environmental compartment (e.g. air, soil, or water) is responsible for the risks of exposure, only that compartment is investigated. If not, a multi-compartment model is used. The end result of this procedure is a breakdown, by environmental compartment, of the likely equilibrium concentrations of the pollutant following known releases. Fate reaction rates are also investigated to determine how quickly equilibrium can be expected to be reached.

Simultaneously, monitoring data are evaluated for adequacy in calculating exposure to human populations and non-human species. If the monitoring data are utilized in exposure calculations, the fate model is "run" nonetheless and the results are compared with monitoring data. If the model proves inaccurate, it must be adjusted. If the monitoring data prove inadequate, the results of the fate modeling procedure are used to determine exposure levels. Toxicity information provides a basis for risk estimation. MDSD does not calculate exposure where toxicity information shows no concern or risk.

The analysis of human and environmental risk from the pollutant is conducted by comparing exposure levels and toxicity data. Most of the toxicity data are to be provided by the OWPS Criteria and Standards Division.

The risk assessment process may be concluded by rerunning the fate model with new materials balance inputs adjusted to reflect changes resulting from various proposed or suggested regulations. In this manner, the overall risk reductions from different regulatory strategies may be tested for efficacy, efficiency, and cost-effectiveness.

The integrated risk assessment for each selected pollutant will be used by the MDSD as a basis for action recommendations which will identify suitable strategies for reducing the risk. These recommendations could lead to regulatory actions using the Clean Water Act or other regulatory authorities.

THE MDSD ROLE IN THE EPA DECISION PROCESS

The MDSD will use integrated risk assessments to make action recommendations for control of selected pollutants. A flow chart of activities leading to the action recommendations is shown in Figure 6.

The Effluent Guidelines Division BATEA industry studies include sampling and analyses of influents and effluents for the 129 pollutants. MDSD ranks the discharged pollutants by environmental impact, and gives EGD a summary of the environmental fate and effects of each of the most environmentally important pollutants. The MDSD assessments affect considerations of pollutants and industries to be excluded from BATEA regulations due to environmental insignificance. The assessments also provide an environmental basis for regulation, but do not necessarily affect BATEA regulatory decisions because the Clean Water Act specifies that only technology and economics must be considered in a proposed BATEA regulation.

MDSD's major role in the BATEA process is to identify those pollutants which will pose an environmental problem after BATEA is in place. MDSD ranks all of these residual pollutants using the action alert system and selects the most significant for integrated risk assessments and action recommendations.

The initial eighteen pollutants selected for action recommendations in 1979 and the twenty pollutants for 1980 are selected partially on the basis of the frequency and amounts of pollutants found in discharges from the 21 industries.

The 38 selected pollutants are therefore expected to include those found most often in effluents of the 21 industries, and those with the most potential for higher residuals after application of BATEA. The pollutant selections do not include consideration of BATEA pollutant residuals because EGD proposals are ready for few of the 21 industrial categories.

After pollutants are selected, MDSD and its contractors do more work in all of the MDSD study areas, but focus on:

1. The most significant sources to waters
2. The fate characteristics which have the most effect on water movement and behavior
3. The human and aquatic populations most likely to be exposed
4. The risks associated with this exposure.

The data needed for these studies are obtained from the existing literature, developed under new research, or estimated (if more quantitative information is unavailable).

Using the completed integrated risk assessments, MDSD identifies regulatory options for the control of individual pollutants and recommends the preferred option(s) (with their consequences) to the Office of Water Planning and Standards. OWPS is developing a process for employing these recommendations, along with their economic impacts in arriving at a final decision. Possible OWPS decisions include stricter industrial effluent limitations (Clean Water Act, Section 307(a)(2)) or national water quality standards. In other cases, OWPS could recommend that other EPA offices, such as the Office of Toxic Substances or the Office of Solid Waste, take regulatory action on a toxic pollutant to control its entry to waters.

ACKNOWLEDGEMENTS

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CHAPTER 7

IDENTIFICATION, ASSESSMENT , AND REGULATION OF TOXIC POLLUTANTS UNDER THE CLEAN AIR ACT

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INTRODUCTION

The purpose of this paper is to discuss the identification, assessment, and regulation of toxic air pollutants, principally under the Clean Air Act, as administered by the Environmental Protection Agency (EPA). Regulatory authorities under the Clean Air Act are presented, and their potential use for controlling toxic air pollutants is discussed. The evolving process by which EPA's Office of Air Quality Planning and Standards (OAQPS) identifies, assesses, and makes regulatory decisions with respect to toxic air pollutants is outlined.

The term "toxic air pollutant" has developed a somewhat ambiguous meaning. A tendency exists to make a distinction between "toxic" air pollutants such as arsenic or vinyl chloride and the so-called traditional air pollutants such as sulfur oxides or ozone. Although this paper adopts this arbitrary distinction for practical reasons, it is important to remember that the "traditional" air pollutants are indeed toxic in the scientific meaning of the term. The process of assessment and regulatory decision making for these criteria pollutants is among the most rigorous and resource intensive in EPA and, as such, may not be a good model for hazard assessment of large numbers of substances. A discussion of the process as applied to ozone is presented elsewhere (1-3).

The principal focus of the nation's air pollution control program has been to implement programs related to the six major pollutants for which National Ambient Air Quality Standards have been established. As progress is made toward attaining these standards, increasing attention is being directed toward those toxic components of air pollution that may not be adequately controlled by current programs. A significant factor has been the development and utilization of increasingly sophisticated and sensitive techniques for measuring specific chemicals. In particular, applications of gas chromatography, combined with mass spectroscopy, to air sampling in a number of urban and non-urban areas around the country has suggested that populations are being exposed to literally hundreds of airborne chemicals (4-7). Results of source emission testing and surveys of production, use, and handling of high-volume industrial chemicals add to the list of potential air pollutants (8). Examination of these chemicals suggests that a significant number of them are toxic and present some risk to public health. Of particular concern are potential carcinogens, mutagens, and teratogens, substances for which "safe" or threshold levels cannot be conveniently identified.

The special concern for carcinogenic air pollutants has been heightened by the increasing awareness of the importance of environmental factors in the etiology of cancer. Unfortunately, the relative significance of air pollution in causing cancer is not well known. Air pollution is only one of a number of potentially important factors, such as smoking, diet, sunlight, and occupational exposures (9). Because of the magnitude of the cancer problem in the U.S., however, even if only a small percentage is related to air pollution, a large number of people can be affected. Cancer induced by exposures to small amounts of airborne carcinogens may not appear for 10 to 40 years. Thus, in addition to concern over existing cancer rates, it is important to minimize exposures to atmospheric carcinogens in order to prevent future problems before they actually occur.

In addition to concern over the direct effects of toxic air pollutants, a number of indirect adverse consequences can result from atmospheric transformation and removal of air pollutants from the atmosphere to other media. For example, a number of chlorinated organics are transformed by photochemical reactions into phosgene (10). Other halogenated organic chemicals may deplete stratospheric ozone, posing an increased risk of skin cancer (10). Sulfuric acid, when removed in rainfall, may mobilize toxic elements in aquatic systems (11).

REGULATORY AUTHORITIES

A number of regulatory authorities may be used where results such as those outlined above indicate control may be necessary. Although other authorities such as the Toxic Substances Control Act and the Resource Conservation and Recovery Act may be useful, the Clean Air Act, as amended in 1970, 1974, and 1977, is the basic U.S. federal law for controlling the adverse effects of toxic air pollutants. The principal regulatory options provided by the Clean Air Act and their potential applicability to toxic air pollutants are outlined below.

NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS)

Under Sections 108 and 109, primary (health) and secondary (welfare) National Ambient Air Quality Standards can be set for pollutants that are prevalent in ambient air and result from numerous or diverse stationary or mobile sources. States may effect control under State Implementation Plans (SIP's). NAAQS have been established for seven pollutants: carbon monoxide, hydrocarbons, lead, nitrogen oxides, ozone, particulate matter, and sulfur oxides. Under the 1977 Clean Air Act amendments, EPA must update the original six criteria documents and review the NAAQS by the end of 1980. Under Section 108, toxic chemicals might be controlled directly, as in the case of lead, or indirectly, if a toxic substance is a component of an NAAQS pollutant, such as particulate matter.

STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES (OR NEW SOURCE PERFORMANCE STANDARDS - NSPS)

Under Section 111, EPA may set emission standards for new or modified sources that may contribute significantly to air pollution that may reasonably be anticipated to endanger public health or welfare. The standard reflects

the best control (with cost, energy, and other factors taken into consideration) that EPA determines has been adequately demonstrated. When an NSPS for a non-criteria pollutant is set, the states must submit a plan to EPA describing regulations that apply to all their existing sources for this pollutant (Section 111(d)). EPA has promulgated regulations under Section 111 for sources of acid mist (sulfuric acid), carbon monoxide, fluorides, hydrocarbons, nitrogen oxides, particulates, sulfur oxides, and total reduced sulfur.

NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP)

Section 112 of the Clean Air Act provides for control of pollutants that may cause an increase in mortality or an increase in serious irreversible or incapacitating illness. The act requires listing of pollutants that are considered hazardous, establishment of emission limitations and, in some cases, development of technology and work practices that provide an ample margin of safety to protect health. Hazardous pollutant standards have been promulgated for mercury, asbestos, beryllium, and vinyl chloride. Benzene has been listed as a hazardous pollutant, and regulations are being prepared.

NESHAP's have been, and will continue to be, the principal regulatory tool for control of airborne carcinogens. Currently, EPA is developing a formal policy for regulating airborne carcinogens under NESHAP's.

EMISSION STANDARDS FOR MOVING SOURCES

Section 202 of the Clean Air Act provides for the establishment of emission standards for any air pollutant coming from a motor vehicle if the pollutant is harmful to public health and welfare. This section includes the mandated reduction of carbon monoxide, hydrocarbons, and nitrogen oxide emissions. Emission standards have also been set for light-duty trucks, light diesel engines, and heavy-duty gasoline and diesel trucks. EPA is currently evaluating the need for control of potentially toxic emissions from passenger-car diesel engines. After consultation with the Department of Transportation (DOT), EPA issued emission standards under Section 231 for aircraft, which will be enforced by DOT.

REGULATION OF FUELS AND FUEL ADDITIVES

Section 221 provides for the registration of any fuel or fuel additive. The EPA Administrator may require that the manufacturer of any fuel notify him as to the commercial name of any additive, the concentration of the additive in the fuel, the purpose of the additive, and the chemical composition of the additive. EPA may also require that the manufacturer conduct tests to determine the possible health effects of any additive or of the emissions resulting from the use of that additive. If an additive endangers public health or interferes with the action of an emission control device, EPA may prohibit its sale or use.

EMERGENCY POWERS

Section 303 provides EPA with authority to bring suit to stop the emission of air pollutants that are posing an imminent and substantial endangerment to

public health where state officials have not acted. This provision mainly applies to control of criteria pollutants during an air inversion. Applicability to toxic substances has not been tested.

OZONE PROTECTION

Section 157 of the Clean Air Act provides for regulation of any substance, practice, process, or activity that may affect the stratosphere in a way that could endanger public health. The regulations must take into account feasibility and costs of control. This section effectively supplements explicit authorities for stratospheric ozone protection under the Toxic Substances Control Act.

GRANTS FOR SUPPORT OF AIR POLLUTION PLANNING AND CONTROL PROGRAMS

Section 105 provides for grants to state and local agencies for planning, developing, and maintaining air pollution control programs, including implementation of NAAQS. In fiscal year 1979, EPA is distributing approximately $75 million to state and local programs under Section 105. Although the bulk of these resources has been used in implementation of NAAQS and other Clean Air Act requirements, ways of more effectively using these grants to study and control toxics will be investigated.

THE HAZARD ASSESSMENT PROCESS

EPA efforts toward control of toxic air pollutants include the following elements: identification of new pollutants, assessment of potentially significant pollutant threats, and regulatory decision making. Because of the large number of potential and known pollutant problems, setting priorities for each of these elements is vitally important.

IDENTIFICATION AND SCREENING

Potential airborne toxic substances are identified through EPA programs including searches of the scientific literature, monitoring studies, biological assays of substances found in ambient air and source emissions, as well as from information from federal or other public testing or regulatory agencies, private research groups, and other reliable scientific sources. Candidate substances (compounds or mixtures) identified in this manner are screened to determine potential for exposure of the public through ambient air emissions. Readily available information is collected on intentional and inadvertent production, uses, volatility, and other chemical and physical properties. Ambient air measurements and previous scientific assessments are considered where available. Other program offices within EPA and other Interagency Regulatory Liaison Group (IRLG) agencies (17) are often contacted to determine whether any regulatory actions, assessments, or screening activities are underway. On the basis of this screening, a decision is made on whether further assessment is required.

An example of the identification and screening process is the establishment of priorities for 632 organic chemicals that were identified under contract to the OAQPS (8). Summary information on national production volume, volatility, estimated emissions, and toxicity and a numerical rating

scheme were provided by the contractor, and additional data were collected for screening. Highest priority was given to possible carcinogens, mutagens, and teratogens and to compounds likely to be present in the ambient air. As the results of the screening process, priorities for assessment of the 632 organics were assigned as follows:

1. 43 compounds were of priority for (or were already under) assessment.

2. 2 (vinyl chloride and benzene) were already regulated.

3. 63 were low priority for assessment because they are pesticides or are unlikely air pollutants.

4. 482 showed no evidence of carcinogenicity, mutagenicity, or teratogenicity, and most are of low priority for assessment.

ASSESSMENT

The purpose of assessment is to acquire information to support a decision for action by regulatory or other measures and, with input from appropriate offices, to make decisions on each chemical brought through identification and screening. Highest priority is given to air pollutants which may present a significant risk of cancer to the public. In the case of carcinogens, the assessment is conducted in two phases: preliminary (or Type I) risk assessments and detailed (or Type II) risk assessments.

A preliminary risk assessment consists of an evaluation of the likelihood that a substance is a human carcinogen and estimation of the extent of public exposure, and magnitude of risk. Screened substances are submitted to EPA's Carcinogen Assessment Group (CAG) which, following criteria outlined in EPA's Interim Cancer Guidelines (12), evaluate available data to assess the likelihood of human carcinogenicity. Where substantial evidence of carcinogenicity exists from animal and/or epidemiological data, CAG also utilizes available extrapolation techniques to provide a quantitative estimate of the expected cancer incidence rate associated with a given air concentration of the substance. The preliminary analysis of exposure, which is conducted (usually through an OAQPS contractor) simultaneously with the CAG assessment, generally identifies significant source categories, available air measurements and emissions data, and makes use of simplifying assumptions to provide rough estimates of exposures. The combination of the CAG extrapolations and preliminary exposure analysis provides a crude quantitative estimate of expected cancer incidence in the population.

Some controversy exists over the proper role, if any, of quantitative assessments for carcinogens. In our view, although the available quantitative assessment methods must be improved upon to provide for more effective risk management, in their current form, the methods are useful in establishing priorities for regulation and in assessing the need for residual exposure reductions.

Priorities for conducting Type II or detailed assessments are based (4) on the results of the preliminary assessment. The Type II assessment is essentially a refinement of the original assessment and is intended to

directly support regulatory action for specified pollutants of source categories. The Office of Research and Development's (ORD) Environmental Criteria Assessment Office (ECAO) provides detailed documentation of the available scientific information regarding carcinogenicity and other health effects of the pollutant. An OAQPS contractor collects detailed information on the sources of air emissions, production and use, predicted and measured ambient air concentrations, and provides a comprehensive assessment of the duration, extent, and magnitude of national population exposures to the substance. Both population and source category growth statistics are examined to enable projections of future exposures. Detailed air quality models are used to estimate the range of pollutant exposures associated with each major source category. The air quality models used generally permit estimation of exposures of up to 20 kilometres from individual sources. The information collected, together with refined quantitative extrapolations, are used by CAG to provide estimates of the degree of risk and the range of cancer incidence expected from ambient air exposures associated with source categories of the carcinogenic air pollutant. The health effects document, detailed exposure assessment, and quantitative incidence estimates are submitted to EPA's Science Advisory Board for comment.

Currently, OAQPS has a number of potential carcinogens and mutagens in various stages of the assessment process. Table 1 presents a recent summary of the status of these substances. Most of the 43 synthetic organics from the screening process described above are included in this list.

OAQPS also has assessed a number of non-carcinogenic substances, most of them inorganics. For these substances, we have relied heavily on EPA-contracted assessments by the National Academy of Sciences and follow up ORD summaries in determining the need for regulation (e.g. lead, copper, nickel, vanadium). Table 2 lists a number of these additional pollutants which have been assessed or continue to be of interest within or outside of EPA (13).

REGULATORY DECISION MAKING

The purpose of regulatory decision making is to develop documentation and to coordinate an appropriate review process leading to a decision regarding regulation of an air pollutant or source category. The detailed risk assessments can assist in determing the need for some action. Additional analyses encompass identification of alternative technical control options, evaluation of associated health risks, economic and energy impacts, and other environmental impacts. Regulatory options under the Clean Air Act (or other statutory authority) for implementing desirable strategies are evaluated and a decision on the need for regulation is made.

CONCLUSIONS

This paper has outlined regulatory authorities under the Clean Air Act and the process used in identifying and assessing toxic air pollutants to support regulatory decisions. As we move forward in the field of toxic pollutant control, emphasis will be placed on refining concepts and techniques in the following areas:

1. Development and refinement of improved techniques for estimating the health risks to the public of pollutants for which only limited data exist.

2. Establishment of the proper role for consideration of economics and other societal factors when attempting to protect public health through regulation of toxic air pollutants.

3. Development and implementation of exploratory and directed monitoring capability to identify substances prevalent in ambient air and to assess the impact of control strategies. Besides traditional monitoring, the newly developing *in situ* bioassay techniques should be used in exploratory programs (14-16).

4. Encouragement and support for state, local, and industry initiatives to control toxic air pollutants without federal regulation.

5. Improved coordination in the collection and dissemination of information useful in assessment of toxic pollutants.

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TABLE 1

POLLUTANT ASSESSMENT STATUS

CHEMICALS	RISK ASSESSMENT		EXPOSURE ASSESSMENT		HEALTH ASSESSMENT		SAB REVIEW
	TYPE I	TYPE II	TYPE I	TYPE II	ECAO	WATER	
Acetaldehyde	X		X				
Acrolein	X		X				
Acrylonitrile	4-28-78		3-79	9-79	9-79	X	
Allyl Chloride	X		X				
Arsenic		9-79		9-78	9-79	X	1-79
Asbestos					12-79		
Benzene		9-12-78		6-78	9-78	X	1-78
Benzyl Chloride	X		X				
Beryllium	4-79					X	
Bis-Chloromethyl Ether	X		X				
Cadmium		6-79		5-79	5-79	X	8-78
Carbon Tetrachloride	X		X			X	
Chlorobenzene	X		X				
Chloroform	X		X			X	
Chloromethylmethyl Ether	X		X				
Chloroprene	X		X				
Coke Oven Emissions	5-77	4-78		10-78	11-78		5-78
o-,m-,p-Cresol	3-79		X				
o-Dichlorobenzene	X		X			X	
p-Dichlorobenzene	X		X			X	
n,n-Diethyl-nitrosamine	3-79		X			X	
n,n-Dimethyl-nitrosamine	3-79		X			X	
Dioxin	X		X			X	
Epichlorohydrin	X		X				
Ethylene Dibromide	4-21-78		X				

TABLE 1 (CONTINUED)

CHEMICALS	RISK ASSESSMENT		EXPOSURE ASSESSMENT		HEALTH ASSESSMENT		SAB REVIEW
	TYPE I	TYPE II	TYPE I	TYPE II	ECAO	WATER	
Ethylene Dichloride	4-7-78	X		3-79	3-79	X	
Ethylene Oxide	5-79		X				
Formaldehyde	X		X				
Hexachlorocyclo-pentadiene	X		X			X	
Maleic Anhydride	2-16-79						
Manganese	4-79		X				
Mercury						X	
Methyl Chloroform	1-17-79		X				
Methylene Chloride	1-17-79		X				
Methyl Iodide	X		X				
1-Naphthyl Amine	X		X			X	
Nickel	4-79		X				
Nitrobenzene	6-79		X			X	
2-Nitropropane	X		X				
N-Nitroso-N-Ethylurea	3-79		X				
N-Nitroso-N-Methylurea	3-79		X				
Perchloroethylene	4-17-78	X		1-79	1-79		
Phenol	5-79		X				
Polychlorinated Biphenyls	X		X			X	
Polycyclic Organic Matter		5-78		11-10-78		2-79	8-78
Propylene Oxide	X		X				
Toluene	6-79		X			X	
Trichloroethylene	8-21-78		X			X	
Vinyl Chloride							
Vinylidene Chloride	5-30-78		4-79	X	X	X	
o-,m-,p-Xylene	6-79		X				

NOTE: "X" means in process.

All Type I Risk and Type I Exposure Assessments will be completed by January 1980.

TABLE 2

OTHER POLLUTANTS OF CONTINUED INTEREST

POLLUTANT	COMMENTS
Aldehydes	NAS study in progress
Alkylbenzenes	NAS study in progress
Ammonia	Low priority, NAS study
Chlorine, HCl	Low priority, NAS study
Chromium and compounds	Low priority, NAS study
Copper	Low priority, NAS study
Fluorides	111(d) regulation, NAS study
Iron	NAS study
N-Hexane	Neurotoxin, referred by OTS
Lead	NAAQS, NAS study
Manganese	Low priority, gasoline additive, NAS study
Mercury	Existing NESHAP's, NAS study
Nitrates, nitric acid	Possible future problem, NAS study
Reduced sulfur compounds	111(d) refineries, emergencies, NAS study
Platinum group metals	Low priority, NAS study
Selenium	Unlikely atmospheric problem, NAS study
Sulfates	Possible NAAQS
Vanadium	Diminishing with low sulfur oil, NAS study
Zinc	Low priority, NAS study

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CHAPTER 8

HAZARD ASSESSMENT UNDER THE TOXIC SUBSTANCES CONTROL ACT

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From the preceding presentations in this workshop, I have begun to appreciate that many of the problems we are beginning to face in the Office of Toxic Substances have been tackled previously by others in the Environmental Protection Agency (EPA) and in Canada. Since there seem to be an awful lot of similarities in our approaches, either we are all cribbing from the same book or are independently arriving at the same conclusions. In any case, you will probably hear a lot of things in what I say that sound familiar. The Office of Toxic Substances is still in the process of defining the procedures it will use for carrying out risk assessments. This talk will provide a summary of our current thinking on hazard assessment procedures.

IDENTIFYING UNREASONABLE RISKS

Figure 1 shows the several components of carrying out an evaluation of a chemical under the Toxic Substances Control Act (TSCA). I will focus my discussion primarily on the evaluation under TSCA of so-called existing chemicals. As many of you are aware, there is a basic distinction under TSCA between "existing" chemicals, which appear on the TSCA inventory, and "new" chemicals, which are not on that inventory and which are subject to premanufacture notification requirements.

The process of making regulatory decisions under TSCA (Figure 1) is keyed to a finding by the EPA Administrator that some activity with respect to the chemical (e.g. manufacturing, processing, use, or disposal) represents an unreasonable risk. Unreasonable risk is construed here to consist of evaluation of risk, analysis of various engineering control options and economics, and ultimately a combination of those factors into a determination of unreasonable risk. Obviously, the whole process is driven by information gathering, and there is some stage of problem identification. With regard to existing chemicals, the stages within the box in Figure 1 are primarily the responsibility of the Office of Testing and Evaluation. That is the area I will focus on.

THE SEQUENCE OF CHEMICAL ASSESSMENTS UNDER TSCA

Figure 2 presents a further breakdown of the type of operational procedure which we will be using in carrying out the components inside the box in Figure 1. First of all, we view the process of assessment as being a multi-stage process. Several previous speakers have described other multi-stage assessment processes.

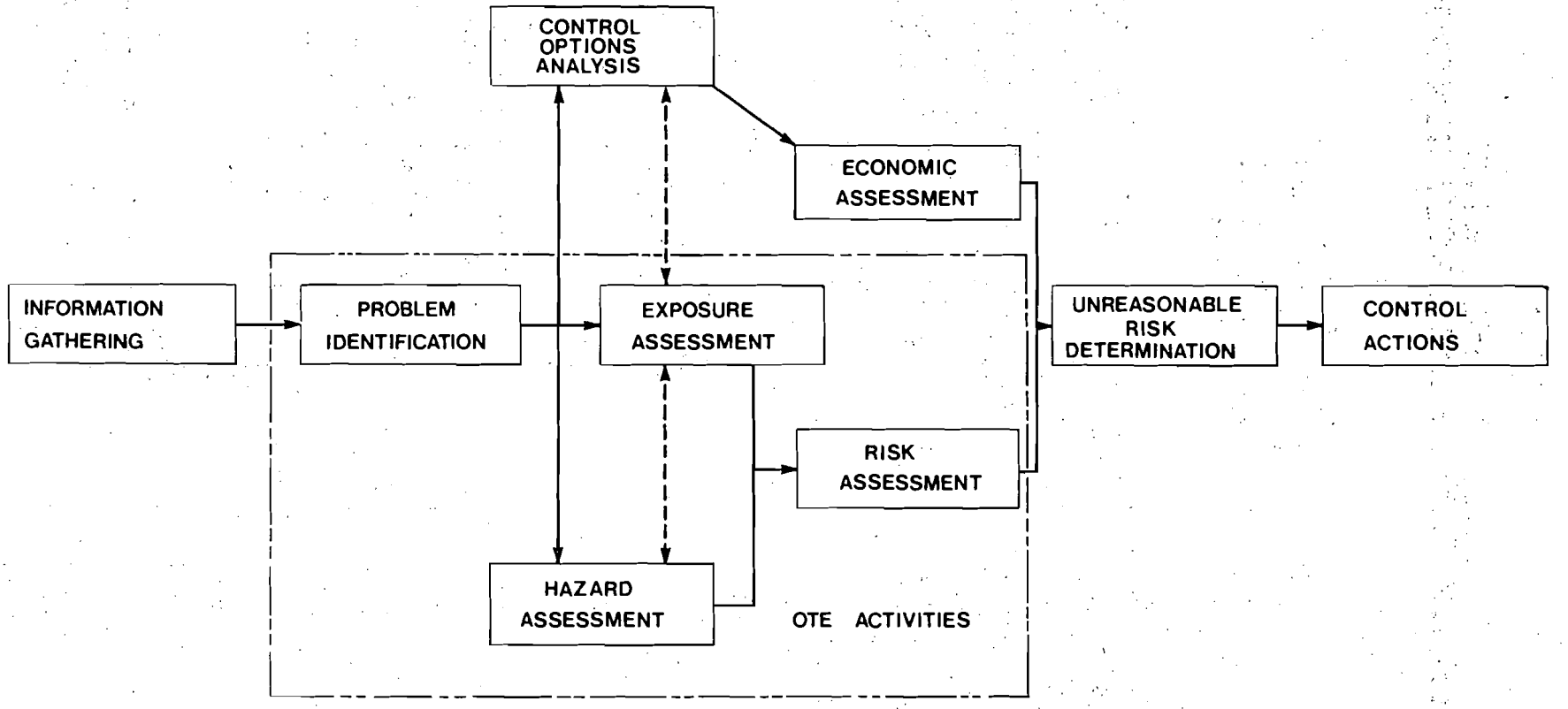

Figure 1. TSCA EXISTING CHEMICALS PROBLEMS ASSESSMENT

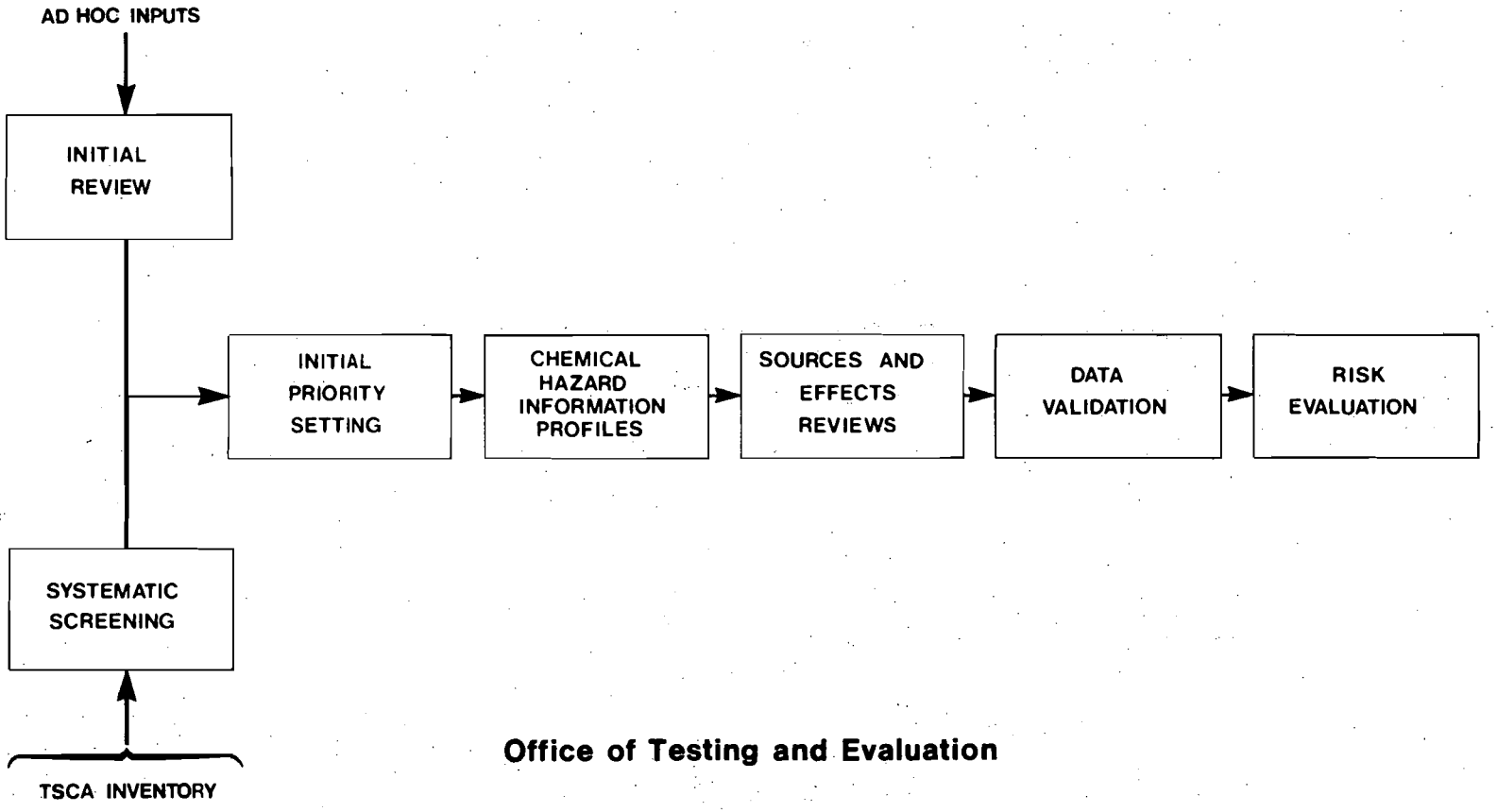

Figure 2. EXISTING CHEMICALS ASSESSMENT PROCESS

There are several stages of either gathering information or filling in the gaps by estimation. One of the differences perhaps in the task which the Office of Toxic Substances has to carry out is that we are, by nature, involved in primarily multi-media assessments. The role of TSCA is similar to that described by a previous speaker describing the Canadian Environmental Contaminants Act. TSCA is a fill-in piece of legislation which is intended to be used for problems where other pieces of legislation cannot adequately deal with specific problems. Our task is to look at the range of possible problems presented by a chemical substance, then to focus in on that subset of problems which may require further action under TSCA.

The basic flow of activities depicted in Figure 2 is initial identification of problems, initial priority setting, and the development of a series of assessment documents. The first document is a chemical hazard information profile, and the second a review of sources and effects of the chemical; those two together represent two stages of, hopefully, a fairly comprehensive look at the chemical in terms of the range of sources and effects of potential concern. The last two stages involve the focusing in on some specific subset of that information and, in the final stage, developing a risk evaluation to support a regulatory decision concerning possible control activities under TSCA.

I might point out that, unlike some of the other programs within EPA and other agencies, the Office of Toxic Substances is organized more along functional lines than along program area lines. That is, the Office of Testing and Evaluation is given the responsibility of carrying out chemical assessment for all types of possible control activities under TSCA. Although I am focusing here on the evaluation of existing chemicals, there will be another process similar to this one, but not exactly the same, that will be used for new chemicals evaluated under Section 5. There are also other components not shown in Figure 2 which deal with the utilization of Section 4 of TSCA. That section allows EPA to promulgate rules requiring industry to test specific chemicals for their effects on health and the environment.

Coming back to Figure 2, there are two types of inputs that we anticipate dealing with. These are identified as ad hoc inputs and the TSCA inventory. There are some ad hoc inputs that result directly from TSCA. For example, Section 8(e) of TSCA requires industry to submit to EPA certain types of information indicative of a substantial risk of injury to health and the environment. To date, we have received over 260 such notices from industry, although they vary substantially in the nature and quality of information they contain. Another sort of ad hoc input is a type to which all chemical assessment programs are subjected - the "pollutant of the month club" as some call it. Here, a specific problem is identified and widely publicized, necessitating an immediate evaluation as to where that problem fits into the overall scheme of assessment and regulatory activities.

There are also the continuing series of investigations of chemicals which are carried out by industry, by other branches of government, and by academic laboratories, any of which may turn up information indicative of a significant risk and trigger further interest and concern on the part of EPA. Each ad hoc submission will undergo an initial review process which will look at the submitted data, provide a quick review of what other ongoing activities are in progress within the Office of Toxic Substances with respect to that chemical,

and attempt to decide whether there is further activity required at that time by our office. If so, the information will be passed on to the priority-setting stage.

The other principal input that we have is our own attempts to systematically look at the "universe" of existing chemicals and identify potential problems. In order to review the many thousands of chemicals which exist on the TSCA inventory, we expect to do such systematic screening through several mechanisms. One will be the use of chemical structure-activity relationships, that is, looking for classes of chemicals which are suspected of having certain types of toxicological effects. Also, we expect to be looking at particular industry areas in an attempt to identify chemicals which may have increasing exposure patterns because of new roles in the chemical industry.

The information from such systematic screening (Figure 2) will also be fed into an initial priority-setting step. There the various possible assessments will have to compete for priority. The type of system which we plan to use is a chemical scoring system for which the prototype is a system used by the TSCA Interagency Testing Committee. This is a system of assigning numerical scores to a number of toxicity- and exposure-related factors and then, primarily through judgement as opposed to explicit mathematical algorithms, making decisions from those scores as to which chemicals should be put higher on the priority list for further evaluation.

Once chemicals are selected through that priority-setting process, we will go into further information gathering and a series of assessment documents; these constitute the rightmost four boxes in Figure 2.

The chemical hazard information profiles are a very rapid turnaround assessment, primarily based on evaluations of the results of literature searches using automated data bases and secondary sources. The questions to be answered at the end of the review of the chemical hazard information profile are:

1. Does this chemical appear to have reported effects and is there a potential for exposure which might warrant regulatory consideration under TSCA?

2. Do any identified problems appear to be solely those which would be dealt with under other legislative authorities within EPA or in other agencies? In this case we would refer the information to those offices for further consideration and probably not proceed under TSCA evaluation.

3. Is the information so inadequate that, although there is some concern, it is not worth going further in assessment? In this case we might branch off and develop testing rules.

4. Is the available information not indicative of high priority? If so, we will simply stop assessment at least for the moment at that stage, file the chemical hazard information profile for future reference, and proceed with looking at other chemicals.

For those chemicals which go forward, a much more in-depth literature review will be performed. The more detailed assessment - the sources and

effects review in Figure 2 - thus created will again try to look at the full range of reported effects and the potential sources of exposure. The goal at this stage is to identify the most important problems (combinations of effects and exposure sources) posed by the chemical and any critical information gaps. We will not at this stage go into a detailed review of the specific studies to ask if this was a fully validated study; rather, we defer that until the very next stage, validation.

When the key studies have been identified, they will receive an in-depth review to determine if there is a sufficient body of data from which a risk evaluation to support regulatory action can be developed. If not, we would again turn to further data gathering, either through more intensive attempts to gather existing data, such as Section 8(d) which allows EPA to require submission of unpublished health and safety studies by industry, or by using Section 4 which allows EPA to require industry to perform further testing.

If the data are judged to be adequate to proceed with risk evaluation, then we will go into a more detailed risk assessment, developing it in cooperation with the control office which will have to utilize this risk assessment to make regulatory decisions.

PRIORITY-SETTING DECISIONS

Priority-setting decisions occur at most of the stages of this process. Certainly, priority setting occurs at both the initial review of ad hoc inputs and in systematic screening. There are some inputs at either stage which we will decide not to proceed on. The initial priority-setting stage is a major effort where we will attempt to order the chemicals which have come to our attention and determine which ones should first be subjected to more intensive assessment. At each of the next two stages, the chemical hazard information profile and review of sources and effects, we will again be doing priority setting, deciding if we have enough information indicative of potential problems that could be dealt with under TSCA to make it worth proceeding beyond this point. Finally, at the end of the whole process there will be yet another stage of priority setting by the regulatory officials in the Office of Toxic Substances as to what priority should be placed on specific sources for control of that chemical's hazards. That decision will be an iterative process between our office and the Office of Chemical Control, which is responsible for developing the regulations. They will have to identify proposed control scenarios which we will then go back and look at in the context of the risk evaluation to determine the relative reduction of risk that might be accomplished through such a control scenario.

I would like to point out that the specific criteria to be used for priority setting at each of these stages are not explicitly defined at this time. We are relying primarily on case-by-case judgements until more specific criteria can be developed. In the case of what constitutes substantial risk data, for example, EPA has published general criteria. We attempt to use those, along with scientific judgement, in evaluating the data which come in. Likewise, at each of the other stages we are primarily making priority decisions by a judgemental process, although we have efforts underway to develop more explicit criteria and see the need for having those as we perform larger numbers of assessments in the future.

CHAPTER 9

PESTICIDE HAZARD ASSESSMENT

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One of the most controversial and difficult jobs of the Environmental Protection Agency (EPA) is the regulation of pesticides. The laws governing pesticide regulation - the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the pesticide provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) - pose particular, even unique challenges in the spectrum of public policy decisions with which EPA is faced every day. Pesticide regulation is an area impacted by rapidly changing technology, imperfect methods of evaluating risk, evolving concepts on the environmental causes of cancer and other chronic health effects, and always differences of opinion over proper balancing of benefits and risks.

Looming above all of these is the knowledge that a significant amount of the nearly 1.5 billion pounds of pesticides which are introduced into the U.S. environment annually is contributed by pesticides whose inherent toxicity and other properties are not well understood, despite half a century of federal pesticide regulation. Our citizens are unable to elect whether or not they will be exposed to many of these compounds, and are unable, therefore, to elect the degree of risk they will accept from pesticides. Exercising that responsibility on their behalf requires EPA to trade off scientific certainty and timeliness. The National Academy of Sciences put this proposition well in observing, "Environmental regulation is not a detached leisurely process of transferring verified results of objective scientific research into clearly indicated environmental decisions."

The authors of the pesticide laws recognized that the public interest could require that action be taken in the face of imperfect knowledge. That, however, is a concept which pesticide producers do not always readily accept, especially in circumstances where it is their product which becomes a candidate for regulatory action. Two general principles of jurisprudence, the presumption of innocence and the requirement for proof of guilt beyond a reasonable doubt, are frequently, and mistakenly, thought to apply in the case of pesticides suspected of causing harm. But because the fundamental rights of people may be placed in jeopardy by pesticides, the "rights" of these chemicals are abridged. FIFRA places the burden of proof that pesticides do not pose unreasonable adverse effects on the proponents of approval. FIFRA authorizes the denial of registration or revocation of approval, "If it appears to the Administrator that a pesticide . . . generally causes unreasonable adverse effects . . ." (emphasis added).

FIFRA and FFDCA are, however, risk-benefit-balancing statutes. Both accord generous appeal rights to persons adversely affected by an initial

decision to deny or withdraw approval of a pesticide. EPA recognizes the tremendous value of pesticides in the production of food, the control of disease vectors, and other benefits to society. We do not seek to ban every pesticide capable of causing harm. We do need to know how much hazard a pesticide may pose, and then decide whether society should accept the risk in return for the benefits. Our goal, then, is to assure that the objective building blocks of what are ultimately subjective regulatory decisions should be evaluated on the best scientific basis attainable, within the constraints of society's resources and with the realization that the pursuit of certainty may come at the expense of continued exposure to harmful substances.

In pesticides regulation, we may be further along in hazard assessment than in some of EPA's more recent programs. The core of the current FIFRA was enacted in 1947, and significantly amended in 1972 to provide for a re-evaluation of the some of 30,000-plus pesticides now on the market in accordance with today's risk assessment tools. We have thus been grappling with the problems of gathering and making regulatory decisions on data in pesticides for some years now, and have some definite procedures which are routinely followed. The pesticides program is also different from some of the other programs which have to deal with hazards in that it is not a pollution abatement program directed toward a "medium" like air and water. That pesticides are not by-products of other manufacturing processes - they are specifically created to be intentionally released into the environment to achieve predesigned benefits - is a distinction of which we are mindful, and of which pesticide users forcefully remind us. Pesticides can be applied in a large variety of locations by persons who have little or highly sophisticated expertise, for diverse purposes, and thus with vastly different potential for hazard based on the innate toxicity and physical characteristics of the product itself, the site of application, the potential routes of exposure to the product, and the capabilities of the applicator. Therefore, EPA must view the application of use of a pesticide from a broad, national perspective. The potential of the chemical for pollution of water is but one consideration in a large array of potential hazards examined.

With that introduction, I would like to get into more specifics on how pesticide hazard assessment actually operates.

Obviously, deciding what is an "unreasonable adverse effect" is no simple task. So to guide our decision-making, we have established by regulation under FIFRA standard indicators of effects which are likely to be "unreasonable". These include criteria for acute toxicity to man, domestic animals, and wildlife; chronic toxicity such as oncogenicity, mutagenicity, and other delayed effects; population reduction in non-target species; and lack of emergency treatments. If a pesticide for which registration is proposed is found to trigger any of these criteria, EPA presumes that the pesticide should not be registered and thus initiates the process known as rebuttable presumption against registration (RPAR).

EPA was given the responsibility in 1972 of reevaluating the risks and benefits of pesticides approved by our predecessors in pesticide regulation. Many pesticides came into wide use at a time when acute effects were the only hazards of concern and when detection methodology was crude. Therefore, pesticides currently in use are subject to reregistration, during which

missing information must be submitted and data will be evaluated against the RPAR criteria.

We also have criteria we consider in setting priorities among those pesticides which do trigger any of the RPAR criteria. These are the nature of the risk involved such as cancer, estimated levels of exposure including production volume, and use on a food or feed crop.

Thus, whenever we suspect a pesticide meets or exceeds any one of these risk criteria, EPA or outside consultant scientists conduct an intensive review of the "trigger studies" to determine their validity. Often we request more than one review of a given study. In the event of an oncogenicity trigger, EPA's Cancer Assessment Group reviews the studies and renders an evaluation of their validity. This is the validation phase.

During this phase we inform the registrants of the pesticide under review of the potential RPAR action and request them to submit any additional information available. We also initiate a world-wide literature search. We attempt to identify all possible triggers in order to prevent insofar as possible, future additional RPAR review of the pesticide in question. If the triggers are found to be valid, we try to gather and assess all available information on the exposure to the pesticide. I should point out that exposure analysis was not a part of the pre-RPAR phase in its infancy, but has been standard policy for the last year. The decision to incorporate exposure analysis into the pre-RPAR phase is, we believe, a key improvement in the process. The problem is that exposure data are often so sketchy and meager that the available information usually does not have a major impact on the initial decision to go forward with a formal announcement of RPAR action. Often there are no available exposure data, and EPA must develop worst-case assumptions to assess potential risk.

The combination of validated hazard information with exposure potential produces the EPA position on the potential risk posed by the use of the pesticide. We summarize this position and supporting data in a document which, after internal EPA review, is published in the Federal Register formally announcing our presumption against registration and initiating the second, rebuttal phase.

During the rebuttal phase we allow a period, ranging from 45 to 105 days, for submission of comments on the validity and regulatory significance of the hazard data EPA has identified. We generally receive most comments during this period, but do not refuse comments arriving after the deadline.

As soon as we know definitely that we will issue an RPAR notice, we also notify the U.S. Department of Agriculture (USDA) and form a Pesticide Impact Assessment Team. This team has the responsibility for collection and evaluation of information on the benefits of and exposure to the pesticide. This is the beginning of the benefits assessment side of the risk/benefit balance.

After the comment period closes, EPA begins its evaluation of the rebuttal comments and completion of the risk analysis. This analysis comprises EPA's position on whether the original risk assessment still stands or has been rebutted.

How are risks rebutted? This can be done in two ways:

1. Prove the study or studies upon which the presumption is based are not scientifically valid

2. Prove that actual exposure to the compound will not cause the effects of concern.

Besides evaluating rebuttal evidence and initiating benefits assessment, during the rebuttal phase we also begin identifying regulatory options or risk reduction measures. The impact of each option on the risks and benefits of each use of the pesticide must be considered. We must also consider the potential risks of alternative pesticides. We reach a final decision only after examining the consequences of each option. Out final decision at the end of the RPAR process will represent EPA's judgement of the best balance of risks and benefits.

In our initial RPAR review we did not identify regulatory options until the risk/benefit analysis of existing uses and restrictions was concluded. However, experience has taught us that we cannot wait until this point in the process for the first consideration of regulatory options. Desirable regulatory options may remain unconsidered because essential supporting information is absent. We have now begun to identify the likely regulatory options as early in the process as possible.

In the event all the triggers have been successfully rebutted the pesticide is returned to the registration process with the costly and time concerning benefits evaluation. The RPAR is terminated by publication of a second document setting our final position on the pesticide.

However, when the rebuttal is not successful, we combine the risk analysis with the benefits analysis and publish a second position document. This document states our proposed regulatory action with regard to the pesticide and invites external review and comment on our proposed decision. Congress has established a seven member Scientific Advisory Panel (SAP) whose members are selected from nominations made by the National Institutes of Health and the National Science Foundation. FIFRA requires that the panel be accorded an opportunity to review any proposed cancellation, from the standpoint of whether EPA's risk assessment is scientifically supported. FIFRA also requires that the USDA have an advance opportunity to comment on the action from the standpoint of the conclusions EPA has drawn about benefits. Our practice has been to solicit comments from USDA and SAP on RPAR's even where we do not propose to cancel uses.

Following receipt of comments by USDA, SAP, and other interested parties, we evaluate these comments and draft a final position document which is our final decision on the appropriate resolution to the RPAR action against the pesticide. Our decision may range from full return to registration, to restriction of registration, through labeling changes, use classification, use pattern changes, to cancellation and suspension. This decision may be appealed, in which case a formal adjudicatory hearing follows.

In sum, RPAR is a process for making initial regulatory decisions on pesticides identified as posing significant hazards with active public

participation outside a formal adjudicatory proceeding. Of course, if at any time during the RPAR process evidence comes to light which heightens our concern, we may take more drastic regulatory action under the law.

In addition to regulating pesticides through product registration under the FIFRA, we also administer complementary sections of the Federal Food, Drug, and Cosmetic Act (FFDCA) which requires the establishment of tolerances, or legal maximum residue levels for pesticides used on food or feed. We establish tolerances both for residues on raw agricultural commodities and for residues on processed foods. This latter type is known as a food additive tolerance and is established whenever the processing of a raw agricultural commodity increases the amount of pesticide present.

As with registration under the FIFRA, the burden of establishing the safety of a tolerance under the FFDCA rests at all times on the petitioner for the tolerance. The petitioner must sustain this burden by providing comprehensive information to EPA on field residues, testing methodology, metabolism and degradation, and toxicology. EPA uses the toxicology data to determine a no-observed-effect level (NOEL) for the pesticide in animals fed the pesticide over their lifetime. These long-term tests are designed to reveal potential adverse effects which may result from continuous low-level ingestion of a chemical, e.g. birth defects, nerve damage, cancer, and gene mutation.

Our Pesticide Program operates on the generally accepted hypothesis that there is no threshold level below which a carcinogen will not have an effect. Therefore, we cannot determine a NOEL for this sort of long-term effect. I will return to the problem of cancer risk assessment later.

Using the NOEL, an acceptable daily intake (ADI) level can in most cases be proposed for man by applying a suitable safety factor. The magnitude of this factor may vary depending on the toxicological data available, but most tolerances on raw agricultural commodities have been established using a 100-fold safety factor on the NOEL of long-term feeding studies.

Because there may be many different commodities for which a tolerance for the same pesticide is sought or has been established, we must take into account the daily intake of all such commodities in deciding whether additional tolerances should be granted. Tolerances for all crops added together should not exceed the ADI. We take into consideration the possibility that residues may be reduced or increased when the food is prepared for consumption. The tolerance is not set at a level higher than may reasonably be expected from the effective use of the pesticide, even though a higher level might still be protective of human health. I might also add that the tolerance is set near the upper boundary level of expected residues and that a high percentage of food samples show residues well below the tolerance level.

On occasion "action levels" are established to permit the marketing of food or feed bearing pesticide residues although a tolerance has not been established within acceptable levels. In circumstances where a pesticide finds its way unexpectedly and inadvertently onto another food for which no tolerance exists, the Food and Drug Administration (FDA) or USDA, in the case of meat and poultry products, may seek a recommendation from EPA on whether to use their prosecutorial discretion to permit the sale of that commodity. Our

recommendation to FDA or USDA is based on a review of toxicity data, estimates of consumption of the contaminated food item, levels at which residues are actually occurring, and the economic and nutritional impact of withholding the contaminated commodity from the market. An action level represents a residue which will not give rise to unreasonable risks. If residues were occurring at a level unsafe for human consumption we would recommend an action level at the limits of reliable detection to protect public health, meaning that the contaminated food commodity cannot be sold in commerce.

I would like to briefly describe the tolerance-setting process when the pesticide involved is a possible carcinogen. If toxicity data indicate that the pesticide is an oncogen, EPA does not use the methods I have just described to establish an ADI. Instead, EPA assumes that no threshold level exists and will use a mathematical model to estimate human response at anticipated levels of exposure. EPA then compares the risks for people consuming the treated food with the benefits likely to result from allowing use of the substance on food. EPA will approve the tolerance for a particular use on food and register the pesticide for such a use, if the benefits outweigh all of the risks associated with such use. On the other hand, if the risks for a particular use exceed the corresponding benefits, EPA will not approve a tolerance or register a pesticide for such a use. EPA would in such cases deny proposed tolerances and revoke existing tolerances. At the same time as EPA revokes existing tolerances, it would establish action levels to permit orderly marketing of food unavoidably contaminated by environmental residues of the pesticide.

Of course, cancer risk assessment is particularly controversial and extremely crucial to health policy development. EPA was, in fact, the first federal regulatory agency to adopt a policy for performing cancer risk assessments as a part of the regulatory process. This policy statement was published as interim guidelines in 1975. Public comment was invited. These interim guidelines provide EPA's approach for the evaluation of carcinogenesis data. This approach, as stated in the preamble, provides for a two-step process. The first step is to decide what, if any, risk is associated with exposure to a potential carcinogen and the impact of this exposure on public health. This is a scientific risk assessment, to be performed independent of social and economic assessments. In the second step, the regulator uses the health risk assessment in conjunction with other considerations of benefits, to the extent mandated by the particular statute, to determine whether or not regulatory action is necessary and if so what level of regulation is appropriate.

The health risk assessment guidelines provide for two determinations, a qualitative statement regarding the likelihood that an agent is a carcinogen and a quantitative statement of the public health burden if the agent goes unregulated. With regards to the first, since only rarely do we know for sure that an agent is a human carcinogen, it is necessary to describe the strength of the certainty - or weight of the evidence - that supports a conclusion that a particular chemical is a carcinogen. Human epidemiology backed up by confirming animal data is the strongest evidence. Most often, this assessment is based on animal bioassay studies alone or supported by short-term tests. The weight of evidence approach acknowledges the differences in data types - that is, human-epidemiology versus animal bioassay data versus short-term in vitro

(test tube) tests - the array of data, and the adequacy of the studies involved. Then, on the assumption that the risk exists, a quantitative risk assessment is made to describe the impact on public health if the agent goes unregulated or is regulated to some prescribed level. Because of uncertainties in the extrapolation from high doses to low doses and in cross-species extrapolation, these are best used as rough indicators of increased risk from the chemical in question to the exposed population.

In addition to our own efforts to develop an internally consistent approach to cancer risk assessment, we have also joined with the Occupational Safety and Health Administration, FDA, and the Consumer Product Safety Commission to develop a coordinated federal government approach to cancer assessment. In February 1979 we issued jointly an interagency document entitled, "Scientific Basis for Identifying Potential Carcinogens and Estimating Their Risks". This is the first time that key U.S. public health regulatory agencies developed or have articulated in one document methods for identifying carcinogens and assessing the dangers they pose to people. It confirms the use of data on animals fed the test substance at a dose rate exceeding expected human exposure as valid indicators of the substance's cancer potential. Also, the report concludes that it is "currently unreliable to predict a threshold below which human population exposure to a carcinogen has no effect on cancer risk". The report, developed by a risk assessment work group of the Interagency Regulatory Liaison Group with assistance from senior scientists at the National Cancer Institute and the National Institute of Environmental Health Sciences, will receive both scientific peer and public review. While the report attempts to describe how these four agencies proceed in making cancer risk assessments, it is not a statement of uniform cancer policy. Each agency will still make regulatory decisions in accordance with the requirements and flexibility of their own individual statutes.

I hope this discussion has provided some insight into how hazard evaluations are made concerning pesticides. The decision-making process is a political one - "political" with a small "p". The answers must be found in the face of uncertainty and constantly expanding scientific knowledge. The better this process and its limitations are understood by the scientific community, state governments, industry, affected users, and the general public, the greater will be the contribution that these diverse elements can bring to our efforts to improve the process and the decisions which emerge from it.

CHAPTER 10

PROPOSED HAZARDOUS WASTE REGULATORY PROGRAM UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT

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INTRODUCTION

The Resource Conservation and Recovery Act (RCRA), which substantially amends the Solid Waste Disposal Act, creates a regulatory framework to control the disposal of those wastes defined as hazardous. Subtitle C of RCRA requires the U.S. Environmental Protection Agency (EPA), in consultation with state governments, to develop national standards for definition of hazardous wastes, generators and transporters of hazardous waste, performance, design, and operating requirements for hazardous waste treatment, storage, and disposal facilities; a permit system for such facilities; and guidelines describing conditions under which state governments will be authorized to carry out the hazardous waste control program.

This cradle-to-grave concept is somewhat unique but necessary to ensure that those wastes which require special management are handled only at facilities with proper permits. All stages of the hazardous waste management cycle are controlled, whether the waste is managed on-site, at the point of generation, or transported to an off-site waste management facility.

The national standards mentioned above have been proposed for public comment and are to be finalized no later than December 31, 1979. RCRA provides that these standards will go into effect six months after final promulgation, or in early summer of 1980.

The proposed regulatory strategy uses a pathways approach wherein the path and destination of any hazardous waste is controlled without particular attention to the source of the waste. This approach is basically different from that used to regulate air and water pollution where specific standards are written for and tailored to each industrial category. The pathways approach was chosen because hazardous wastes are mobile and can be disposed of at locations far from the generating sources, whereas industrial air and water pollution sources are fixed and relatively easy to identify.

I will briefly review the several regulations within the proposed hazardous waste program and then provide additional detail on the proposed definition of hazardous waste.

HAZARDOUS WASTE DEFINITION

RCRA requires hazardous waste to be defined both in terms of inherent characteristics, such as flammability and corrosiveness, and by listing of particular hazardous wastes.

HAZARDOUS WASTE GENERATORS

The proposed standards for hazardous waste generators require them to keep records, make annual reports, ensure proper containerization and labelling of hazardous waste shipped off-site for disposal, and to originate a transport manifest document for each shipment. Retailers, farmers, and generators of small amounts of waste (less than 100 kilograms per month) are excluded from these requirements provided they dispose of waste in state-approved facilities. Generators do not need permits.

HAZARDOUS WASTE TRANSPORTERS

Hazardous waste transporters are required to take the hazardous waste shipments only to the permitted facility designated by the generator, to keep appropriate records, and to report any spills en route. Transporters (as is the case with generators) do not need permits in the federal system, but some states require hazardous waste transporters to be registered.

HAZARDOUS WASTE FACILITY STANDARDS AND PERMITS

National standards for hazardous waste treatment, storage, and disposal facilities not only establish acceptable levels of performance that such facilities must achieve, but also are the criteria against which regulatory officials will measure applications for permits. In setting facility standards, EPA has relied primarily on specific design and operating standards, as opposed to general ambient or source emission standards, because they are more easily understood and enforced than other types of standards.

STATE HAZARDOUS WASTE PROGRAMS

Congress intended that the federal EPA establish national standards for hazardous waste management, but that the individual states implement and enforce this new regulatory program. EPA has developed a guideline which describes the elements a state hazardous waste program must have in order for a state to be authorized to carry out the national program. Among other things, states must have legislation and regulations for hazardous waste management which are no less stringent than in the federal analogs, and must demonstrate that they have adequate resources to administer and enforce the program.

DEVELOPMENT OF THE PROPOSED DEFINITION

I would like to discuss some of the highlights of how the definition of hazardous waste has been developed, leading to our proposed definition which appeared in the Federal Register on December 18, 1978. Before a material can be defined as a hazardous waste, it must first be established that the material is a solid waste. RCRA defines the term "solid waste" to mean:

> Any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities, but does not

include solid or dissolved material in domestic sewage or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under Section 402 of the Federal Water Pollution Control Act, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended.

In defining solid waste, there are three noteworthy aspects of this definition:

1. The term solid waste encompasses not only solids, but also liquids, semisolids, and contained gases

2. Certain materials are explicitly excluded from the definition

3. The term "other discarded material" is included.

EPA has grappled with the meaning of "other discarded material" for over a year since this is one of the more ambiguous yet important parts of the definition. For example, are by-products of manufacturing processes "discarded materials"? Sometimes they are, and sometimes they are not. Are materials sent to recycling or reprocessing centers "discarded materials"?

After substantial discussion and comment inside and outside the Agency, EPA has taken this phrase to mean any material which is:

1. Abandoned or committed to final disposition

2. Reused, if such use constitutes land disposal

3. A waste oil, if it is incinerated or burned as a fuel.

Under this definition, for example, used solvents sent to a reclaiming facility would not be considered a discarded material and, therefore, would not be considered a solid or a hazardous waste. Similarly, materials being transferred between industrial facilities, perhaps via a waste exchange, would not be subject to hazardous waste controls. On the other hand, materials reused in a way involving land application (i.e. soil conditioners, fill materials, dust suppressants) would be considered as discarded materials since reuse of materials in this manner could result in serious adverse impacts due to uncontrolled release and dispersion of contaminants into the environment. Similarly, EPA has singled out waste oil for special control since they are ubiquitous and there are documented health and environmental problems associated with their reuse.

CRITERIA FOR IDENTIFICATION AND LISTING

In defining a hazardous waste as mandated in Section 3001 of RCRA, EPA is required to:

1. Develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste

2. Identify the characteristic of hazardous waste and list particular hazardous wastes.

As a first step in this definition process, EPA has developed a set of criteria in defining the characteristics of a hazardous waste and for listing these wastes. These criteria are identified in Section 250.12 of the proposed rule and are as follows:

1. Criteria for Identifying Characteristics of a Hazardous Waste
   a. Damage cases - Certain wastes are known to have caused substantial public health or environmental damage in documented cases
   b. Availability of economical sampling and analysis procedures for a particular property of the waste

2. Criteria for Listing Hazardous Wates
   a. The waste is known to meet, or strongly suspected of meeting, one of the defined general characteristics
   b. The waste meets the statutory definition of a hazardous waste

Based on these criteria, EPA has elected to define the general characteristics of ignitability, corrosivity, reactivity, and certain aspects of toxicity to identify hazardous wastes. It should be noted that EPA also attempted to define characteristics of infectious and radioactive waste, and other aspects of toxicity such as genetic change potential and bioaccumulation. However, in developing this regulation, difficulties were encountered in describing these properties, and so EPA has elected for now to deal with potentially high-hazard infectious, radioactive, and certain toxic wastes by listing known sources of these wastes or processes likely to produce them. EPA does intend to explore the appropriateness of additional characteristics to further define toxicity and radioactivity and, to this end, has published an Advanced Notice of Proposed Rulemaking seeking additional data related to these concepts. It should also be emphasized that neither the characteristics nor the listing are static. Both may be added to or changed, after opportunity for public comment, as new information develops.

HAZARDOUS WASTE CHARACTERISTICS

In order to provide specific descriptions of wastes meeting these characteristics, each characteristic was defined in terms of specific definable properties. The following is a brief description of each characteristic and its properties.

IGNITABILITY

The objective of the ignitability characteristic is to identify wastes which may present a fire hazard under routine waste disposal and storage conditions. The resulting fires at disposal and storage facilities present not only the immediate danger of heat and smoke, but can initiate explosions, generate toxic vapors and provide a pathway by which toxic particulates can spread to the surrounding area. The term ignitable was chosen to avoid confusion with the Department of Transportation's (DOT) category of "flammable" in its hazardous materials transportation regulations.

There are several methods which can be used to identify ignitable wastes, depending on the physical state. For liquid wastes, flash point was selected

as the property to use since testing methods are available and are the most reproducible. The flash point proposed for identifying ignitable wastes is 140°F (60°C); this value was selected after considering the ambient temperatures to which wastes may be exposed during management.

For solid wastes, a prose definition was selected because test methods are not available for ignitable solids which simulate the field conditions to which a waste is subject during handling and management. For waste gases, EPA proposes to use the DOT identification for flammable compressed gases since the major hazard arising from ignitable gases would be during transport.

CORROSIVITY

A corrosivity characteristic has been included to identify those wastes which:

1. Must be segregated from others because of its ability to extract and solubilize toxic contaminants (especially heavy metals) which might otherwise not migrate

2. To identify those wastes requiring special containers during transportation and storage.

While heavy metal solubilization is an extremely complex phenomenon, pH has been found to be its most important indicator. The pH limits chosen in these proposed regulations were based upon skin corrosion limits and heavy metal solubilization data. The metal corrosion limits were taken from DOT hazardous materials regulations, because EPA's concern about container damage is identical to that of DOT's in this case.

REACTIVITY

The object of the reactive waste characteristic is to identify wastes which under routine management present a hazard because of instability or extreme reactivity. Reactivity includes the tendency to autopolymerize, to create a vigorous reaction with air or water, to exhibit shock and thermal instability, to generate toxic gases, and to explode.

EPA in its proposed regulation included a descriptive definition of a reactive waste, together with test methods for thermal and shock instability, because of the problem in developing general test methods for identifying reactive wastes. While there are many inputs of energy that may cause a waste to react or exhibit hazardous properties, there is no one stress than can cause all reactive waste to do so. To compound the problem, reactivity is not just a function of the composition, temperature, and availability of initiating agents, but is also affected by the mass and geometry of the waste. Thus, the reactivity of a tested waste sample may not necessarily correspond to the reactivity of the waste as a whole.

Since reactive waste is dangerous to the generator's own operations (as well as being hazardous for long-term disposal), generators of reactive waste tend to be aware that their waste has that characteristic. For this reason, EPA feels that the proposed descriptive definition will be an adequate

identification method when used in conjunction with the test methods identifying thermal and shock instability.

TOXICITY

The toxicity characteristic is intended to identify waste which, if improperly disposed of, may release toxicants in sufficient quantity to pose a substantial hazard to human health or the environment. The RCRA definition of hazardous waste requires EPA to make a judgement as to the hazard posed by a waste "when improperly treated, stored, transported, or disposed of, or otherwise managed." For waste containing toxic constituents, the hazard is dependent on two factors:

1. The intrinsic hazard of the constituents of the waste
2. The release of the constituents to the environment under conditions of improper management.

To assess the intrinsic hazard posed by the constituents, a series of toxicity indicators was initially considered:

1. Acute and chronic toxicity to humans, animals, and plants
2. Potential for bioaccumulation in tissue
3. Oncogenicity
4. Mutagencity
5. Teratogenicity

However, the toxicity definition proposed on December 18, 1978 has been limited as noted earlier to include only toxicants for which National Interim Primary Drinking Water Standards (NIPDWS) have been developed.

To determine whether toxic constituents in the waste might migrate in the disposal environment, a procedure has been developed to measure the tendency of the constituents of a waste to leak or leach out and become available to the environment under poor management conditions.

Numerous studies and reports indicate that damage to ground and surface water frequently results from migration of toxic chemicals from a disposal site. Groundwater contamination is a particularly important concern because groundwater is a source of drinking water for almost half of the population. In addition, once contaminated, an aquifer's usefulness as a source of drinking water may be impaired for years. It was thus decided that use of a groundwater contamination scenario to "model" improper disposal would be advisable. By selecting a groundwater contamination scenario, we did not mean to imply that other vectors are not important. However, we do feel that, except in rare cases, control levels set using this model will be sufficient to protect against other routes of contamination.

The model is based on wastes creating a problem through migration of chemicals out of the disposal site and into a drinking water aquifer. I want

to emphasize that the contamination model has been developed for definitional purposes only. It does not address particular disposal methods which might be used by the regulated community.

The test scheme commonly referred to as the extraction procedure has been devised to meet the limited definition of toxic waste. The extraction procedure, coupled with a model scenario of leachate transport, relates the concentrations of certain toxic components found in the extract of the waste to the EPA NIPDWS. Any waste whose extraction procedure extract contains any heavy metals or pesticides controlled by the NIPDWS in a concentration greater than 10 times the drinking water standard is considered to be a hazardous waste.

Any waste which has any of the above characteristics is a hazardous waste by RCRA definition whether or not that waste is listed. Consequently, use of characteristics in the hazardous waste definition implies a responsibility on the part of waste generators to evaluate their wastes for these characteristics (or to declare their wastes hazardous) if there is any doubt about the status of their waste.

HAZARDOUS WASTE LISTINGS

The second way a waste can be brought into the hazardous waste regulatory program is by including that waste on a list. Actually, EPA has developed four separate hazardous waste lists, including:

1. A list of generic hazardous wastes common to many different sources, e.g. electroplating wastes, paint wastes

2. A list of known sources of infectious wastes, e.g. hospital wastes from the laboratories

3. A list of industrial processes known to produce hazardous waste, e.g. heavy ends or distillation residues from carbon tetrachloride fractionation

4. A list of some 275 substances which, if disposed of in pure form or as a result of off-specification production, would be hazardous.

There are approximately 175 specific wastes, waste sources, and wastes from certain processes which EPA has identified as hazardous based on previous studies of industrial wastes, damage cases, testing of wastes, and state hazardous waste program data.

There may be cases, however, where a particular facility within a listed source or process category believes that their waste is non-hazardous because the facility uses different raw materials than normal or has made process modifications or provides on-site treatment prior to disposition. In such cases, the individual facility can petition for exemption from the Subtitle C control program by submitting appropriate waste testing data and requesting a determination of non-coverage of Subtitle C for the facilities' waste.

SUMMARY

In summary, EPA is required to define hazardous wastes using dual approaches of identifying general characteristics and listing specific hazardous wastes. As regulation development evolved, EPA found it necessary to defer proposing certain characteristics considered earlier pending further study. At the same time, EPA has added to and sharpened the focus of the hazardous waste list. The net result of these changes will, we believe, make it much easier for waste handlers to determine whether they are in or out of the Subtitle C regulatory program, and at the same time focus the program on those wastes of most concern.

CHAPTER 11

RECOGNITION, EVALUATION, AND REGULATION OF HEALTH HAZARDS UNDER THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

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The Occupational Safety and Health Act was signed into law in December 1970 and became effective in April 1971. The Occupational Safety and Health Administration (OSHA) was created by this act to carry out five basic functions:

1. To encourage employers and employees to reduce hazards in the workplace and to implement new or improve existing safety and health programs

2. To establish separate but dependent responsibilities and rights for the achievement of better safety and health conditions

3. To establish reporting and recordkeeping procedures to monitor job-related injuries and illnesses

4. To develop mandatory job safety and health standards and to enforce them effectively

5. To encourage states to assume the fullest responsibility for establishing and administering their own occupational safety and health programs which must be at least as effective as the federal program.

This act applies to any employer who affects commerce and has employees.

With only a limited number of compliance officers, OSHA can inspect only a very small fraction of the work places each year. Under the present administration, headed by the Assistant Secretary for OSHA, Eula Bingham, the agency has put into effect several modifications of policy which are based on a common-sense approach. You have probably heard of the agency's elimination of approximately 1,000 regulations that were not directly related to safety or health.

At this time I have to call attention to OSHA's past emphasis on safety. Despite the prevalance of many health hazards throughout industry, OSHA had issued only fifteen specific health standards in the first six years of existence. By specific standards I am not referring to the lists of chemicals that were published in the standards along with their respective PEL's or permissible exposure limits.

I am referring to comprehensive standards which include exposure limits as well as work practice controls, engineering controls, personal hygiene requirements, environmental and personal monitoring, and many other requirements as well.

Think about that: fifteen specific standards in six years. At that rate it would take more than a century to issue standards for substances that are already identified as health hazards. That is why the most important of the new priorities is to speed up the adoption of health standards.

Just how are OSHA's health standards produced?

OSHA begins the procedure either on its own initiative or on petitions from other parties including the Secretary of Health, Education and Welfare (HEW), the National Institute for Occupational Safety and Health (NIOSH), state and local governments, any nationally recognized standards-producing organization, employer or employee representatives, or any other interested person.

I mentioned that recommendations for standards may come from NIOSH. This organization was established by HEW to conduct research on various safety and health problems. They provide technical assistance to OSHA, recommend standards, investigate toxic substances, and develop criteria for the use of such substances in the work place. While conducting this research, NIOSH may make work place inspections, gather testimony, and require employer reporting and measuring of exposure to potentially hazardous materials. They may also require that the employer provide medical examinations and tests to determine the incidence of occupational illness among employees.

Getting back to standards, the remainder of the standards-making procedure includes the publishing of an intent to propose a standard. This is followed by a period for response by interested parties and possibly a public hearing. After that phase OSHA publishes its ruling, with a full text of the standard as well as the effective date.

Under certain conditions, OSHA is authorized to set emergency temporary standards after determination that there are workers in grave danger due to exposure to a toxic substance.

No decision on a permanent standard is ever reached without due consideration of the arguments and data received in written submissions at hearings. However, and I will speak further on this later, any affected party who wishes to appeal the standard because it is too burdensome, inadequate, or not a proper reflection of the record presented, may do so in the U.S. Circuit Court of Appeals.

We now have specific standards for the following:

1. Asbestos

2. Benzene - although in Supreme Court

3. Vinyl chloride

4. Coke oven emissions

5. 14 Carcinogens - of which one has been vacated

6. DBCP - Dibromochloropropane

7. Arsenic

8. Cotton dust (Part stayed by court)

9. Lead (Part stayed by court)

10. Acrylonitrile

In the near future we hope to have standards for hexavalent chrome, pesticides, noise, chlorine, and a comprehensive cancer policy.

I would like to concentrate on carcinogen policy for a moment since the direction taken in this exemplifies best OSHA's position on new standard development and hazard assessment.

Rather than attempting to develop many specific individual standards for all of the various carcinogens, OSHA has proposed a comprehensive cancer policy that will establish procedure for identification, classification, and regulation of potential carcinogens in U.S. work places. The policy would create four classifications for these suspected carcinogens.

There are four categories developed under the Toxic Substances Control Act which we use:

1. Substances whose carcinogenicity has been established in humans or in two mammalian species of test animals or in one species if the test has been replicated

2. Substances whose carcinogenicity has been reported, but the evidence is suggestive or positive in only one species

3. Substances requiring further data development

4. Substances that OSHA believes are not found in U.S. work places, but that would be regulated if they were.

Okay, we have our four lists, now what do we do with them?

Three model standards are to be developed for application more or less across the board.

1. An emergency temporary standard (ETS) to be issued if a substance meets category 1 criteria.

2. A proposed permanent standard for category 1 substances.

3. A proposed permanent standard for substances that meet only the criteria for category 2.

Classification as category 1 would immediately trigger the issuance of the model ETS. This would quickly be followed by rule making using the model for proposed permanent standards.

This process would significantly streamline the rule-making procedure because the basic issues would not have to be re-litigated over and over. Only issues that are unique to a particular chemical, classification, correctness, environmental impact, and so forth might possibly have to be argued.

Hopefully, this generic standard concept can be applied to other groups of chemicals, such as pesticides, to speed the overall standards completion effort.

You will recall earlier that I said I would speak further on the subject of court involvement in the standards making procedure.

It is unfortunate due to the great time delay that the courts must decide between health and the cost of compliance.

One case which exemplifies this concerns the benzene standard. Being a chemical carcinogen, OSHA took the position that it should be regulated to the lowest feasible exposure level, that being one part per million exposure averaged over an employee's eight-hour work day. This position was taken because there is no demonstrated safe level for carcinogenic substances.

The court ruled that OSHA had not considered the cost/benefit analysis mentioned earlier and overturned the standard.

OSHA has won challenges to other specific standards in other appeals courts, so the benzene defeat in the 5th Circuit Court at New Orleans may be attributed to the pro-industry leanings of these judges. At any rate, it has been appealed to the Supreme Court.

What is unfortunate is that the workers go unprotected throughout this entire ordeal.

Other cases involving employee health versus the cost of complying are pending in the field of noise control.

On a more positive note, the courts have upheld the majority of OSHA's lead standard. This standard was developed to control worker exposure to all forms of lead, through all routes of entry. Certain parts of the standard which would have been quite costly to comply with were postponed by the court, but by far the majority of the standard was permitted, including some of the most important sections.

One final topic that I would like to discuss is interagency cooperation with regard to hazard assessment. OSHA, the Consumer Product Safety Commission, the Food and Drug Administration, and the Environmental Protection

Agency are attempting to somewhat coordinate efforts in this area. In September 1977 these four regulatory institutions signed an interagency agreement relating to the regulation of toxic and hazardous substances. Under the agreement the agencies will seek to establish compatible activities in the following areas:

1. Epidemiological practices and procedures

2. Protocol and criteria for testing of hazardous and toxic substances

3. Approaches to the assessment of risk

4. Methods of obtaining, analyzing, storing, and exchanging information

5. Possible sharing of costs and facilities in the field of research and development

6. Compliance and enforcement procedures and policy

7. Public communication and education programs and informational services to industry

8. Regulations and regulatory development activities where hazards can most effectively be controlled by joint participation or by the use of statutory authorities of more than one agency.

One part of this overall joint effort includes referrals to the other cooperating agencies. Lists of possible generic hazard situations of interest to the agencies have been published.

Hopefully, cooperation between these and other agencies will lead to much less duplication of effort, faster standards development, and more efficient overall recognition, evaluation, and regulation of hazards.

CHAPTER 12

U.S. SAFE DRINKING WATER ACT

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In Dr. Hickman's introduction this morning, he was trying to define what it is that a moderator is supposed to do. The Oxford English Dictionary defined it in terms of overseeing an ecclesiastical gathering. This is certainly not an ecclesiastical gathering, and we certainly do not consider hazard and risk assessment a religious matter, but the state of the art sometimes places us in the realm of the metaphysical and occasionally in the mythical. I think it is very important that we try to approach hazard and risk assessment problems in a very pragmatic way, certainly with a philosophical direction, but nevertheless with a very pragmatic approach that recognizes the strengths and weaknesses of the tools at hand.

The Safe Drinking Water Act of course deals with a very necessary commodity and one that is unique in the sense that, on the one hand, it is a natural product, a natural resource and, on the other hand, it is a consumer product and one that is in fact produced by means of technology, by industrial type processes and therefore, it needs to be treated a bit differently than some other materials. There are a couple of myths that we have to dispel. One is that, what is natural is good and what is synthetic is bad, and the other is that the quality of the water in the river or in the lake is necessarily the primary determinant of the quality of the product at the tap. Those are not necessarily true. In the case of drinking water, there are really three main areas where the water is processed where contamination can occur. One is, of course, the source itself and the substances that are present in the source. The second is the treatment process, the chemicals that are removed and the chemicals that are added during the treatment process. The third is the distribution system, the chemicals that are added by extraction from the material through which the water is passed in transport: the pipe and the surface coatings on the pipes.

Assuming the performance of conventional treatment technology, my conclusions more and more are that the source water is not necessarily the most significant in terms of human health risk, and that probably the treatment and distribution processes are very significant contributors. As we look at organic chemicals in source water, we find particularly in surface water that the primary constituents are natural products in the order of milligrams per litre, humus materials, various degradation products of natural life processes. We assume just because of the millennia of human development in association with those kinds of materials that those are innocuous and safe

products. They may or may not be. In many cases they are not even chemically definable but, nevertheless, they are usually there at milligram per litre levels (Table 1).

The synthetic materials that derive from industrial, municipal, and agricultural discharges typically are there in microgram per litre levels or less. Occasionally they go considerably above that because of spills. There certainly are rivers and water sources that are obviously contaminated by these kinds of substances, but when one performs a chemical analysis and tries to identify these chemicals, one finds relatively minute individual quantities.

In the treatment process, one finds the introduction of milligram amounts of additional substances: chlorination byproducts, oxidation products, halogenation products, substances that are added to enhance coagulation. In the distribution system substances such as lead, monomers, vinyl chloride and coal-tar products which are used in some points in pipe coatings, and asbestos which can be used in asbestos cement pipe can be added to the water in various amounts depending upon the aggressiveness of the water's ability to extract substances. So, the question might come to mind, in the name of purification are we not adding many contaminants?

I am going to talk today about two general areas. One is the mandate that the Safe Drinking Water Act gives us in controlling those contaminants and, two, a bit about the methodologies that we use in assessing the risks of substances in drinking water.

The impetus for passage of the Safe Drinking Water Act in 1974 was primarily the public concern about the contamination of drinking water by synthetic or organic chemicals, so one of the questions we have asked ourselves is, is that a major problem. In some places it is, in a lot of places it is not. The primary concern about drinking water quality must be the pathogen concentration in drinking water and the potential for waterborne transmission of disease.

The list of responsibilities under the Safe Drinking Water Act includes standard setting and monitoring frequencies (Table 2). Those that we are really concerned about today are standard setting, monitoring, and analytical procedures because they all enter into the decision process of regulation and standards. At the present time, we have a series of regulations, actually numerical standards, for six organic chemicals (pesticides), ten inorganic chemicals, alpha and beta radiation, microbiology, and turbidity (Table 3).

The way the law was set up, the Environmental Protection Agency (EPA) was supposed to proceed very quickly with the conventional wisdom of 1974 and contract with the National Academy of Sciences (NAS) to produce an additional body of data from which to make decisions on drinking water quality. NAS was to provide recommendations to us; we were supposed to take those recommendations and convert them into what would be called health goals; in other words, these are ideal levels. Then we are to convert these ideal levels into actual standards by incorporating factors such as economics and technology limitations (Table 4).

TABLE 1

ORGANIC CHEMICAL CONTAMINANTS

NATURAL	SYNTHETIC
Humus	Industrial Wastes
Algae	Municipal Wastes
Other Natural Decomposition Products	Runoff
	Chemicals Produced by Chlorination

TABLE 2

SAFE DRINKING WATER ACT

STANDARDS	LABORATORY CERTIFICATION
MONITORING FREQUENCIES	ANALYTICAL PROCEDURES
VARIANCES AND EXEMPTIONS	STATE GRANTS
PUBLIC NOTIFICATION	GROUND WATER PROGRAM
SITING AND OPERATION AND MAINTENANCE	STATE PRIMARY ENFORCEMENT RESPONSIBILITY

TABLE 3

PARAMETERS AND NUMERICAL STANDARDS

SUBSTANCE OR PROPERTY	LIMIT
Arsenic	0.05 mg/L
Barium	1.0 mg/L
Cadmium	0.010 mg/L
Chromium	0.05 mg/L
Lead	0.05 mg/L
Mercury	0.002 mg/L
Nitrate (as Nitrogen)	10 mg/L
Selenium	0.01 mg/L
Silver	0.05 mg/L
Fluoride	1.4 - 2.4 mg/L (ambient temperature)
Endrin	0.0002 mg/L
Lindane	0.004 mg/L
Methoxychlor	0.1 mg/L
Toxaphene	0.005 mg/L
2,4-D	0.1 mg/L
2,4,5-TP (Silvex)	0.01 mg/L
Coliform bacteria	-
^{226}Ra plus ^{228}Ra	5 pCi/L
Gross alpha particle activity	15 pCi/L
Beta particle and photon radioactivity	4 mrem (annual dose equivalent)
Turbidity	1 Tu (up to 5 Tu)

TABLE 4

PROPOSED PROCEDURE TO DEVELOP STANDARDS

I. NATIONAL INTERIM PRIMARY REGULATIONS

- 6 Organics
- 10 Inorganics
- Radionuclides
- Microbiologicals
- Turbidity

II. NATIONAL ACADEMY OF SCIENCES REPORT

1. Recommended MCL Proposals
2. Unquantifiable Contaminants

III. RECOMMENDED MCL'S (HEALTH GOALS) AND LIST OF UNQUANTIFIABLE CONTAMINANTS

IV. REVISED NATIONAL PRIMARY REGULATIONS

NAS did not provide a list of precise recommendations. They certainly surveyed the area and produced a very comprehensive and valuable report which contained much information, but they really did not provide a great amount of guidance on how to proceed to regulation. Thus, it is a difficult task we have because the charge of the Safe Drinking Water Act is as follows: that we are to produce standards that are to protect health to the extent feasible, taking costs and other factors into consideration. The term "protecting health" means that we are to prevent human exposure to substances at levels at which there would be no known or anticipated adverse effect on human health.

Obviously this is a staggering task. Every substance, of course, has some adverse effect at some level. The question is defining the level and determining that there would not be an anticipated adverse effect, thus going far beyond the available information and available data, to assess the hazard for all segments of the human population of risk.

The law itself and the regulations apply to public water systems that serve more than 25 people or 15 service connections. We are talking about 60,000 individual community water systems in the United States ranging from 25 up to 10 million population and perhaps 300,000 non-community supplies, gas stations on interstate highways and the like, so it is a formidible task, obviously, to try to regulate all of those circumstances.

As I was saying before, the sources of contaminants in drinking water are many, and the contribution from the various sources is perhaps surprising. Industrial waste which everybody would pick to be the leading category, in most cases is not the leading category. Municipal sources may be treated or untreated upstream sewage discharge. Urban and rural runoff is very substantial in many cases. Polynuclear aromatics, heavy metals, and many kinds of substances can be washed off agricultural land as well as urban locations. The natural materials, the humic and fulvic materials and so forth are by far the largest quantity. The next largest are those that are produced where chlorination is commonly practiced: the by-products of the disinfectant reacting with the natural products, the chloroform, the trihalomethanes (THM's), the whole host of what are called total halogenated compounds, which are undefined. There is also a host of undefined oxidized compounds which are converted to alcohols, aldehydes, ketones, acids, hydroperoxides, and so forth, a whole host of chemicals that could well be present in treated water.

Ground water contamination represents a different category. Ground waters are typically low in natural organic chemicals. However, when contaminated, such as by improper waste disposal, substantial levels of industrial chemicals have been found.

From the results of one of our surveys of 113 cities two years ago, note that the top four are the THM's: chloroform, bromodichloromethane, dibromochloromethane, and bromoform (Table 5). The high levels found ranged from 470 µg/L of chloroform, and bromoform in one or two locations was as high as 280 µg/L. THM's are present in all drinking waters that are chlorinated. They are introduced by the chlorination step. Analyses of finished water can also detect carbon tetrachloride, benzene, dichloroethane, and trichloroethylene, a pretty decent shopping list of standard industrial high-volume chemicals. The median levels or the range actually was typically in the low parts per billion

TABLE 5

RESULTS OF PHASE II OF SPECIAL MONITORING REGULATION (NOMS) FINISHED DRINKING WATER IN 113 CITIES

COMPOUNDS	CONCENTRATION IN µg/L				
	DETECTION LIMITS	MEDIAN VALUE	NO. CASES FOUND OUT OF 113	AVERAGE LEVEL	RANGE
CHLOROFORM (THM)[a]	.05, .5, 1	59	112	83.5	.002 - 470
BROMODICHLOROMETHANE (THM)[a]	.04	14.0	109	17.5	.02 - 180
DIBROMOCHLOROMETHANE (THM)[a]	.1, .3	3.5	97	11.9	.05 - 290
BROMOFORM (THM)[a]	.3	.15	38	4.2	.15 - 280
CARBON TETRACHLORIDE	.2, .4	.10	13	.313	.1 - 10
1,2-DICHLOROETHANE	.5	.50	2	.346	.02 - 1.8
BENZENE	.1, .2	.08	7	.094	.05 - 1.8
P-DICHLOROBENZENE	.005	.003	20	.026	.002 - 1.6
VINYL CHLORIDE	.1	.05	2	.052	.05 - .18
1,2,4-TRICHLOROBENZENE	.005, .01	.003	2	.008	.002 - .580
BIS(2-CHLOROETHYL) ETHER	.01	.005	13	.016	.005 - .360
1,1,2-TRICHLOROETHYLENE	.03, .06	.02	28	.535	.015 - 49
2,4-DICHLOROPHENOL	.1	-	0[b]	-	- -
POLYCHLORINATED BIPHENYLS	.1, .2	.07	4	.07	.05 - .20
PENTACHLOROPHENOL	.004	.008	5[b]	.008	.007 - .7

a. THM - Trihalomethane, produced in water by disinfection chlorination.

b. Ten city study only.

or fractional parts per billion. In the trichloroethylene case, which was as high as 49 µg/L, seldom do we find that kind of chemical in that large amount in a surface water; however, in some groundwater supplies contamination has been related to leachate from chemical waste disposal practices. There have been cases where, in fact, milligram amounts of some of these substances have been seen in groundwaters.

The Great Lakes typically turn out to be better than the average surface water in the United States, and some of the Great Lakes have very high quality water. However, there are notable exceptions where unacceptable quantities of synthetic organic chemicals have been found in Great Lakes waters.

In the case of the THM's, for whatever the reason, the precursor concentrations in the Great Lakes are considerably lower than most surface waters and in places like Toledo, Chicago, and Detroit, in the finished drinking water we normally would find on the order of 20 to 30 µg/L of THM's, which is quite low relative to most other surface sources.

I would like to now shift gears into how we attempt to make regulatory decisions based on the data bases and the responsibilities that we have under the Safe Drinking Water Act. Standard setting is really a multi-step process. The first step in the case of drinking water is to identify substances that are in the water, so the first priority is analytical chemistry and developing a data base of the chemicals that are there. The second step then is toxicology, after we have prioritized within that list of chemicals based on concentration. I do not mean to say that we only look at concentration first; we look at concentration and toxicology and from there make a determination of human risk potential. Thirdly, the question is technology. Given that a substance is in the water and given that a certain portion of the population is exposed at a certain level, the next question is what can be done about it, how can we prevent contamination of the source, can we institute practices at the treatment plant to reduce the presence of certain chemicals. Then the final question, as always in any regulatory process, is how much does it cost, and it is valid to evaluate the costs and the benefits of any regulatory proposal because, in fact, that must be part of the analysis. The Safe Drinking Water Act directs us to take costs and other factors into consideration.

We make decisions primarily in two areas: standard setting, which is long-term exposure; and emergency situations, which are either situations where there is no standard or where a spill has occurred and where there may be a short-term exposure to a given substance and our advice is requested by state and local authorities. There are two approaches that we use and we divide them as to whether or not there is information as to the substance's carcinogenicity. The one approach is the classical safety-factor approach which is used for non-carcinogens. There is a risk extrapolation approach which we use on carcinogens. That is particularly true when we are talking about long-term exposure risk, but we come up with a particularly complex problem when dealing with the short-term exposure situation, beyond the consideration of acute toxicity.

Risk extrapolations, as you know, are made based on lifetime exposure, assumed seventy-year exposure, assumed certain daily concentrations, certain

average daily exposure. The risk models have not been applied to short-term exposure, so one has to use a different set of criteria in making that judgement. We are always concerned with acute toxicity, acute sub-chronic toxicity and, to some degree chronic toxicity, if there is a situation where the chemical is bioaccumulative, if it is not rapidly cleared from the body.

For the non-carcinogens, for a long-term exposure standard setting and advisory opinions, we use the acceptable daily intake approach. This was spelled out by the NAS in their report of 1977 and it uses the classical three-stage safety factor incorporation. A factor of ten is added to data that are derived from good human epidemiology data and good animal chronic toxicity data, a factor of 100 where we have only good quality data that are animal related, and a factor of 1,000 where the data are not the optimal chronic toxicity data that we would need. This is an arbitrary approach that has been used for many years, and it has been reasonably successful for non-carcinogens. Our assumption is that the ten-kilogram child consuming one litre of water per day is the sensitive population.

In the case of carcinogens, if one makes the philosophical assumption that one cannot determine a threshold, in other words, one cannot determine a "safe" level, one then has to assume that there is a risk at any level of exposure, and then we would use some kind of risk model to apply to the exposure level to try to compute the incremental risk from exposure to that particular substance over the lifetime. However, as you know, there are a large number of different models that are used: linear non-threshold, one hit, multi-stage, population tolerance distribution, and others that we will not describe. They are all of course based on a computation derived from probabilities of the incidents of cancer in a large population exposed to low concentrations of substances as derived from data that are obtained in a small number of animals exposed at very high levels of exposure so, typically, the National Cancer Institute bioassay results are the basis. This may provide one data point, sometimes two, sometimes no response, sometimes the higher dose has a lower incidence than the lower dose. The mechanisms of activity at those high levels are of course not understood but, nevertheless, they are usually the only data we have available. They are fit into one of those models, usually the most conservative one which would be a linear non-threshold model, and one arrives at what is hoped to be the highest limit of risk that one would expect from exposure to that contaminant. Again, it is an incremental risk.

Now, one can do the computation but then the question is, how does one make a decision. When you have computed the risk of 1 µg/L or 2 or 5 µg/L consumed every day, that does not answer the questions, that does not tell you what the standards should be. One then has to make a policy judgement and that is, what is the acceptable level of risk for that substance?

How does one make that judgement, what is the acceptable level? Many factors have to be taken into consideration and they are the ones that I spoke about before: the validity of the model, the availability of technology, the cost of compliance, the population exposed, the potency of the substance, the realities of the situation in terms of the likelihood of that substance contributing to the national health burden.

Just as an example of substances that have been run through the multi-stage model, Table 6 shows some values that would relate to drinking water as one-in-a-million risk levels and one-in-100,000 risk levels using these kinds of assumptions. We assume two litres exposure per day per lifetime, 70 years. In the case of chloroform for a one-in-one-million incremental risk, the number would come to 0.3 µg/L (0.59/2). In the case of vinyl chloride for a one-in-one-million risk, the number comes to 1 µg/L (2.13/2).

These sound like very precise numbers, but they are not. They are really at least plus or minus a factor ten and probably much more because, after one selects the model there are also other factors, the parameters that are fed into the model, the conversion from animal to human, whether one uses the surface area conversion or another kind of conversion, whether one uses female mice, male mice, male rats, and so forth, one gets a different data point, a different response curve, a different slope from that point to the zero-zero point and therefore a different risk level. Most of the models converge at the lower levels of risk. Remember, again, we are dealing with an extrapolation usually over four to six orders of magnitude of exposure. It is a very large jump of course and the uncertainties are very great in making that kind of a move. The uncertainties include interspecies conversion, human-animal interconversion, and also the uncertainties relative to the assumed mechanism of the toxicology that is occuring both in the mouse versus man, and at a very high dose of exposure in the animal versus the very low dose in the human.

There are tremendous gaps of information. We are dealing in a very crude area of pseudoscience here, truly a black art. We have basically no information on several aspects for most chemicals. We have basically no good dose-response for chemical carcinogens nor multiple interactions and certainly not anywhere near the range where we are making decisions in terms of regulations. We generally do not have good body-burden data. We do not know usually what the exposure is in drinking water versus air versus food. We do not usually know what the most sensitive element of the population would be, be it pregnant women or the fetus or the aged or people with prior disease states.

It is really a very difficult situation, one that is worth debating, one that is worth refining, but one that certainly has no absolute conclusion at this time so, there are a couple of things that you might want to look at to perhaps help shed a little more light on these kinds of activities. One of them is the 1977 NAS report, "Drinking Water and Health". It has a large section discussing risk assessment mechanisms. As of yesterday, there was an update on that report entitled, "Problems in Risk Estimation". It has an excellent presentation on the concept of safety factor approaches versus risk assessment approaches, and the concept of using a risk assessment approach or a risk extrapolation approach also for non-carcinogens, not only using the non-threshold hypothesis for carcinogens, but also realizing the fact that we are dealing with distributions of risk in populations exposed to any kind of contaminant, and that any kind of a physiological response may, in many cases at least, be represented by the same sort of risk approach.

The conclusion of the NAS at this point is that we really do not have enough data to use a risk computation for the non-carcinogens, even less than we have for the carcinogens, but nevertheless it is an approach to the directions that we should be thinking about for the future. We must also have

more information on the pharmacokinetics of these chemicals to further refine the risk models, and on synergistic or antagonistic effects.

One could conclude from all of that, that we are all operating in the dark, that we really do not know what the "safe" level is for exposure to any chemical, but we have to make a decision, we have to work within the confines of our regulatory authorities with the best science that we have available, and in light of the realities of human existence. Technology and feasibility are very important realities that must be taken into consideration whenever we make these decisions. We must aim to minimize human risk from exposure to environmental contaminants.

TABLE 6

CONCENTRATION FOR EXCESS LIFETIME CANCER RISK[a,b]

CHEMICAL	10^{-5} µg/L	10^{-6} µg/L
Acrylonitrile	7.7	0.77
Arsenic	-	-
Benzene	-	-
Benzo(a)pyrene	-	-
Beryllium	-	-
Bis(2-chloroethyl) ether	8.3	0.83
Carbon tetrachloride	90.91	9.09
Chlordane	0.56	0.056
Chloroform	5.9	0.59
DDT	0.83	0.083
1,2-Dichloroethane	14	1.4
1,1-Dichloroethylene	-	-
Dieldrin	0.038	0.004
Ethylenedibromide	1.1	0.11
ETU	4.6	0.46
Heptachlor	0.24	0.024
Hexachlorobutadiene	-	-
Hexachlorobenzene	0.34	0.034
N-nitrosodimethylamine	-	-
Kepone	0.23	0.023
Lindane	1.08	0.108
PCB	3.23	0.32
PCNB	71.4	7.14
TCDD	-	-
Tetrachloroethylene	7.1	0.71
Trichloroethylene	90.9	9.09
Vinyl Chloride	21.3	2.13

a. Standardized to 10^{-5} and 10^{-6} risks from National Academy of Sciences report, "Drinking Water and Health", for consumption of one litre of water per day for 70 years.

b. Concentrations causing an excess cancer per 10^{-5} or 10^{-6} for adults would be half the values listed assuming adults drink two litres per day.

CHAPTER 13

CARCINOGENESIS TESTING PROGRAM

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It is not an easy matter to stand before you and adequately relate the efforts of the U.S. Governments's National Cancer Institute (NCI) in the area of hazard assessment. As with most large, mature scientific organizations, we have had our fair share of unique research directions, false hopes, reorganizations, and subsequent reallocations of people and funds. Today, I propose to offer you some explanation of the program for which NCI has received a great deal of notoriety - the Carcinogenesis Testing Program, its accomplishments to date, its basic philosophy and methodology and, perhaps, a guess as to its eventual destination.

The Carcinogenesis Testing Program has or is testing 350 chemical compounds by protocols designed to achieve as an end point an acceptable, definitive and, hopefully, conclusive bioassay. By itself, 350 compounds speaks to NCI's long-standing commitment to the issue of hazard assessment. Much of the work started in the early 1970's and was the single major effort of its kind. It was, however, just the beginning of the program's evolution, and the results of that early, tentative effort have in too many cases been dangerously extrapolated to conclusions unwarranted by the original test objectives.

What were the original objectives? I truly believe that they were merely an attempt to elucidate several basic principles of chemical carcinogenesis. To do that, the program developed a fairly standard protocol that could be used as a relatively simple screening process. We are just now emerging from that earlier naive era and, as the toxicological state of the art advances, the program is eager to stay in the forefront. As I discuss methodology, I ask that you relate my comments to their proper time frame.

Let me start by outlining the chemical selection process that has evolved over the last 4 to 5 years from an initially simple selection, dependent upon the knowledge and scientific interest of a few NCI staff members, to the present, relatively sophisticated system. It may well be one of the significant contributions we have made to this general area. Within the selection process, I think you will see a pattern evolving that by itself leads into or constitutes a form of chemical hazard assessment.

The principal burden of selection presently falls upon the Chemical Selection Working Group (CSWG), which is comprised of NCI staff members and representatives of other government agencies. At any one meeting attendees

might represent the Bureau of Foods and the Bureau of Drugs of the Food and Drug Administration, the Department of Defense, the Consumer Product Safety Commission, the Department of Energy, the National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), the National Aeronautics and Space Administration, and the Occupational Safety and Health Administration.

The CSWG is supported by two organizations, the Washington office of the Stanford Research Institute (SRI), and the Testing Program's prime contractor, Tracor Jitco. After gathering all readily available data and information, SRI prepares a "Summary of Data for Chemical Selection" on each nomination. A small NCI ad hoc contractor support group screens these summaries and presents 10 to 15 to the CSWG at its monthly meeting. A majority vote is required for selection, and each motion normally indicates a low, moderate, or high prioritization recommendation. Ample discussion periods are allowed so that committee members can express opinions as to the weight the various data elements, such as production, use, and chemical structure should be given.

As you might expect, there are a variety of ways to weigh each data element or, in fact, its very absence or presence. For instance, I tend to side with the group that promotes the selection of a compound if the animal test data available are inconclusive or confusing and, certainly, if no test data exist. Others seemingly stress the test data only when they are present and show some positive indication.

Of the data elements, annual production, when available, is one of the most significant since it should best reflect the potential for human exposure on a wide scale. Another major data element is the degree of environmental concern, i.e. the concentration of the compound present in the environment and its persistence. As much significant information as possible is included for our consideration; all pertinent short-term in vivo and in vitro literature references are evaluated. When appropriate, we also seek out and include the areas of metabolism, pharmacokinetics, and structure relationship.

The next step in the selection process is a review conducted by the Chemical Selection Subgroup of the Clearinghouse on Environmental Carcinogens which has been meeting every two months since late 1976. Subgroup members review the selections made by the CSWG and, based on their expertise and experience, a consensus recommendation is formed on each compound, and a numerical priority ranking is assigned.

For those of you who are not familiar with its makeup, the Clearinghouse is chartered by the Department of Health, Education and Welfare and is designed to advise the NCI Carcinogenesis Testing Program. Membership was developed to strike some balance between academia, industry, organized labor, and consumer advocates. This group of approximately thirty experts is variously assigned to one of three groups, the Chemical Selection Subgroup, the Experimental Design Subgroup, and the Data Evaluation/Risk Assessment Subgroup. The Chemical Selection and Data Evaluation Subgroups have been especially active.

Finally, the recommendations of the Clearinghouse subgroup are presented to the Director of the Carcinogenesis Testing Program who, with his senior

staff, makes the final decision as to which chemicals will be tested and in what prioritized sequence. In almost all instances, the advice of the Clearinghouse has not been disregarded; however, there have been occasions when other considerations, such as a direct request for test by a sister regulatory agency, could not be ignored.

To recapitulate, there have been four levels for screening candidates for bioassay: the initial contractor support group, the interagency CSWG, followed by the non-government advisory Chemical Selection Subgroup to the Clearinghouse and, finally, the NCI program group.

By far the most productive development in the chemical selection process has been the evaluation of large groups of chemicals by systematic class reviews. For the purpose of a review, chemicals can be grouped in a variety of ways, for example, by exposure categories, industrial use, or chemical structure. This approach has occasionally resulted in overlap but, in our hands, it has been very productive as measured by the numbers of chemicals selected. Further, there is less likelihood of good candidates being overlooked.

As an example, we have conducted reviews based on industrial and/or commercial use categories such as plasticizers, soaps and detergents, flame retardants, anaesthetics, the GRAS food additives list, hair dyes, and printing inks. To date, we have completed 33 reviews, four are in progress, and another sixteen have been identified.

Once a chemical nomination has survived the tiered evaluation, it is submitted to our in-house Experimental Design Group for their consideration. Although the Testing Program has a standard protocol, it is becoming increasingly apparent that individual chemicals require that some modifications be made as a consequence of a chemical's unique nature or our need for specialized information.

A complete, chronic bioassay cannot be accomplished in much less that 3½ years and 4 years is probably the usual period. The dose setting alone takes approximately 6 to 9 months; there is then a 2-year testing phase, and we must allow at least 6 months for the histopathology wrap-up and report writing.

We start with an LD_{50} determination (Table 1). These initial doses are selected after intelligent guesswork or by clues obtained from the open literature. With increasing frequency, our industrial contacts are helping us with toxicity data they have collected.

Based on the body-count results of the LD_{50} test, we try to estimate the LD_{10} and proceed to test that level and four lower levels in a 14-day, repeated-dose study (Table 2). Hopefully, we arrive at a dose level that in this 2-week period gives no clinical signs of toxicity nor any pathological signs at necropsy. This no-effect dose level is then used as the highest level of a 5-level, 90-day subchronic test (Table 3).

The maximum tolerated dose (MTD) is the end-product of the 90-day subchronic test. It might be wise at this point to discuss what has been the major controversial issue between the NCI Testing Program and the testing of

TABLE 1

ACUTE TOXICITY (LETHALITY)

Purpose	-	To set doses for the repeated-dose study
Groups	-	5 animals of each sex and each strain
Route	-	Gavage
Dose Levels	-	At least 3 levels, separated by a factor of 2
Treatment	-	One day
Observation	-	14 days, no histopathology

TABLE 2

REPEATED-DOSE STUDY

Purpose	-	To set dose for subchronic study
Group	-	5 animals of each sex and each strain, including controls
Route	-	Same as planned for chronic study
Dose Levels	-	Usually 5 dose levels; the upper level should be equal to or less than the LD_{10}
	-	Other 4 doses are fractions thereof, usually 1/2, 1/4, 1/8, and 1/16
Treatment	-	Daily treatment for 14 days in same formulation as planned for chronic study
Observations	-	One day after last treatment
	-	Weekly weights
	-	Gross necropsy - no histopathology

the industrial sector, namely, the matter of dose levels. To understand the NCI position, one must appreciate the mandate given by Congress as we have understood it to date. NCI is to determine, under the most rigorous circumstances that are experimentally feasible, if the individual chemicals to which man is exposed are capable of expressing any degree of carcinogenic potential. For that expression, the Testing Program sets as its high dose level the maximum tolerated dose, anticipating that only relatively massive doses of a subject compound can be expected to show positive effects when groups of 50 animals are used.

The MTD of the early program was determined in a 6- to 8-week subchronic test and was that level which caused no deaths, yet permitted up to a 10% weight loss. The MTD's arrived at by this formula were frequently too high for the long haul of a 2-year chronic study. Often, the MTD had to be adjusted downwards. This led to difficulty in the interpretation of results or, worse, the unproductive early termination of some treatment groups. As a result, the MTD determination has been drastically modified and now is the highest dose of a 5-level, 13-week subchronic study that does not show pathological or toxicological lesions with life-shortening potential in a subsequent 2-year chronic study. We also incorporate a ½-MTD level in all studies. The ½ MTD may, in some instances, provide evidence for a dose response; however, the ½ MTD is actually a back-up in case the MTD is overestimated and the high dose group survival rate is insufficient. The key point concerning the MTD or the dose selection is that we are not concerned with safety evaluation in the usual sense, but only with the expression of any inherent carcinogenicity of the compound. With that in mind, it is possible to appreciate why our dose levels often exceed the occupational or general population exposure by large and sometimes huge proportions, and why our routes of administration do not necessarily reflect the normal human exposure.

Finally, we move into the 2-year chronic test (Table 4). We have a standard protocol for the common routes of administration. When one multiplies 50 animal groups by 2 dose levels, 2 sexes, and then 2 species and finally adds matched controls, the sum total is 600 animals for a dosed-feed or inhalation study.

In gavage studies, in which the compound is suspended in a vehicle and given by stomach tube, it is necessary to add an additional 200 animals for a total of 800. In general, except for modifications such as increased dose levels and the addition or subtraction of interim sacrifices, this will most likely be the model for carcinogenicity tests for the foreseeable future.

Many of you know that in the last six months a new organizational entity has been born, the National Toxicology Program. The NCI testing program components of funds and people have been administratively detailed to it along with varying commitments from the National Center for Toxicological Research at Pine Bluff, Arkansas, as well as from NIOSH and NIEHS. The general theme is to focus the various toxicological efforts of the federal government into one unit, coordinated by Dr. David Rall, Director, NIEHS, and to make an operation more responsive to the needs of the regulatory agencies. Those agencies have set up an oversight committee that will work with Dr. Rall to accomplish these purposes.

TABLE 3

SUBCHRONIC STUDY

Purpose	-	To set dose for chronic study
Groups	-	10 animals of each sex and each strain at each dose level, including controls
Route	-	Same as planned for chronic study
Dose Levels	-	Usually 5 dose levels, the highest being the repeated dose level that showed no clinical signs of toxicity, pathology, or weight loss
	-	Remaining doses are fractions thereof, usually 1/2, 1/4, 1/8, and 1/16
Treatment	-	Daily treatment for 90 days unless increased for special protocol
Observation	-	Weekly weighing and one day after last treatment
	-	Gross necropsy
	-	Histopathology on controls and highest dose level without mortality

It is really much too soon to guess at the impact of this new structure upon the efforts of the NCI. At this time it appears that the NCI will maintain the process I have outlined, up to and through the recommendations of the Clearinghouse subgroup. Those recommendations will stand as the NCI contribution to the selection process of the National Toxicology Program. They must then withstand yet another prioritization in competition with those candidates from all the other components of the national program. This all might seem most cumbersome, but put in the proper perspective of each bioassay's cost and potential impact - $300,000 or more for the simplest protocol, and the possible outright banning of socially significant compounds deemed to be unacceptably dangerous - it seems prudent to put maximum emphasis on the selection process.

There is another major complication looming. With the eventual implementation of the Toxic Substances Control Act, resulting in increased industrial testing activity, the thrust of chemical selection by the hierarchy I have described must necessarily change. Some thought has already been given to compounds that the National Toxicology Program might well confine itself to.

I have tried to give you an explanation of our sometimes exaggerated dose levels and convenient, if not always appropriate, routes of administration. These dose levels and routes often do not readily lend themselves to hazard assessment, we agree. They do, however, normally serve well their intended purpose - to express any inherent possibility of carcinogenicity. But it is not our intention for anyone to blindly accept our results and to extrapolate them to the human situation without thoughtful interpretation. There is a series of potential caveats that must be considered and applied to our tests and their results when applicable.

There are a number of criticisms that are commonly thrown at rodent bioassays, but I would like to draw your attention to certain ones that are of concern to the testing program. There is always the possibility that the test compound can have undetected side effects that would act in an immunosuppressive manner or perhaps even mimic an endogenous hormonal compound with obvious distortion of the compound's real nature. Among the nutritional factors that keep nagging at us are the potential presence of contaminants such as PCB's or the heavy metals. Another possibility is that dosed diets containing a major component of compound (and we do allow up to a 5% level if the particular chemical is essentially non-toxic) could produce an almost mechanical dietary malfunction.

Genetic aspects of concern are the inevitable genetic drift of our nucleus substrains to the point where our historical control animal data might be invalidated and there is always the recurring fear that the specific strain or hybrid we use could be genetically resistant to certain chemical structure categories. Finally, there is the reality that some compounds are lipophilic with a tendency to result in a mounting "body burden" until an eventual but sudden spill over can seriously disrupt a study. Perhaps I have dwelt too long on the problems of extrapolating animal data into human risk assessment, but these are very real dangers that must be faced when the assessment procedure is attempted.

This has been an overview of where the NCI's Carcinogenesis Testing Program has been, its present status, and some of the reasoning behind its present methodology. To look into the future, I can say only that the NCI is considering the best approaches to qualitatively and quantitatively assessing the potential risk to humans from environmental carcinogens. Individuals now serving on the National Cancer Advisory Board are considering this whole problem as a special task and we can anticipate receiving very positive direction from them in the near future.

TABLE 4

CHRONIC STUDY

Purpose	-	To determine carcinogenicity of test agents
Groups	-	50 animals of each sex and each species
	-	Untreated, vehicle, and positive control
	-	No common controls
	-	Age approximately 6 weeks
Route	-	Chosen to get the maximum amount of test agent to the target site
Dose Levels	-	MTD (Maximum Tolerated Dose): that dose level which does not produce toxicologic signs or histopathologic lesions that could be considered potentially life-threatening during the course of a chronic study
	-	1/2 MTD
	-	If not toxic, no more than 5% of test allowed in feed
Treatment	-	103 weeks
	-	Dosed feed-administered 7 days per week
	-	Gavage, I.P. and inhalation-administered 5 days per week
	-	Early animal sacrifice if unusual number of deaths occur
Observation	-	Weekly weighing for first 3 months and then less frequently
	-	Periodic palpation at least monthly
	-	Remove and sacrifice moribund animals
	-	Gross necropsy
	-	Histopathology, extensive

CHAPTER 14

HAZARD ASSESSMENT IN THE U.S. CONSUMER PRODUCT SAFETY COMMISSION

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I would like to introduce you to the Consumer Product Safety Commission. Many of you probably have not had an occasion to deal with us very extensively. We are an independent federal regulatory agency. Contrary to the opinion of many, we are not part of Ralph Nader's organization. We are a regulatory agency with five commissioners; the head of the agency is appointed by the president with the consent of the Senate.

The agency was created by the Consumer Product Safety Act with four purposes in mind:

1. To protect the public against unreasonable risk and injury from consumer products

2. To assist consumers in evaluating imperative safety of consumer products

3. To develop uniform safety standards

4. To promote research and investigation into the causes and prevention of death, illness, and injury.

If you take those in reverse order, it pretty well spells out the mission of our agency, the number one purpose being to protect against unreasonable risk of injury. If you start at the fourth objective and follow backward, hopefully this is what we are going to accomplish.

I heard some comments that we were talking about too many laws and too many acts being involved but, in addition to the Consumer Product Safety Act which created us, we inherited four others which had previously been in existence. These laws were left on the books for various reasons. Some felt that the existing laws were necessary; others, for political reasons or whatever other selfish motivations, felt that the existing laws should remain on the books and not be taken over by the Consumer Product Safety Act.

Just briefly, one is the Flammable Fabrics Act, which formerly had been administered by the Federal Trade Commission; it basically deals with flammability of fabrics, things such as carpets, mattresses, general wearing apparel, and so on.

The Refrigerator Safety Act is probably unique in that as far as I know it is the only law in the books that everyone complies with. In the 1950's there were quite a few problems with children being locked in discarded or old refrigerators and someone slamming the door shut and then leaving them unable to get out and subsequently suffocating. Well, the Refrigerator Safety Act simply says that you will be able to open a refrigerator from the inside without much effort. So everyone went to the magnetic latch on refrigerator doors and consequently, as far as I know we have not found anybody in violation of this law.

One of the other laws that we started was the Poison Prevention Packaging Act which you are probably all somewhat familiar with. This law allows us to set standards to require child-resistant packaging for various chemicals or drugs. Your common aspirin bottle is probably where many of you have been exposed to it. One thing I should point out. We get a lot of complaints about child-resistant packaging. The protocol for child resistant-packaging requires it if they are easily accessible to 90% of the adult population. Therefore, if you are having a problem, you know which segment of the population you fall into.

The other law which more directly affects the topic at hand is the Federal Hazardous Substances Act which is basically a chemical labelling law. It has provisions for banning chemicals and children's articles as well but, basically, it is a labelling law. Common drain cleansers, cigarette lighter fuel, and so on, the precautionary labelling that appears on these packages is required by the Federal Hazardous Substances Act.

Of these five laws, only three really deal with toxic chemicals: the Consumer Product Safety Act itself, the Poison Prevention Packaging Act, and the Federal Hazardous Substances Act. They deal with toxic chemicals, both from the acute and the chronic standpoint.

As an agency, we are small and we are basically a regulatory agency. We are much like the Occupational Safety and Health Administration (OSHA) in our approach to things. We are not a scientific group; we do not generate our own scientific data. We have scientific people on staff and we do quite a bit of contracting, but basically we get our information from the National Cancer Institute (NCI), the National Testing Program, and a number of other agencies or organizations furnish us with the basic data that we use in making our hazard assessments.

Now, in assessing hazards that have to do with consumer products, we approach it basically from three standpoints. First of all, we do the traditional acute hazard assessment which is pretty well in place. I think it is a thing we all pretty well understand. You have a cause-and-effect relationship that is pretty immediately observable.

The other main thrust that we have currently is the chronic hazard assessment which, from what I have heard so far at this workshop, everyone is struggling, trying to really get a handle on this. There are many approaches being used and hopefully sometime off in the future we will have it down to the art that we think we have for assessing the hazard in the acute area.

We have one other approach to hazardous assessment that is a little unique to the Consumer Product Safety Act, and that is kind of an ad hoc hazardous assessment on defects in products. Section 15 of the Consumer Product Safety Act gives us the authority to, first of all, require reporting by a manufacturer of a consumer product. If it presents a substantial product hazard, then not only can we require the reporting to us of this defect or failure to comply with the standards that result in the substantial product hazard, but we can as well require notification of the public or some corrective action, recall, repair, some action to correct the situation. That is something that is kind of set aside from the basic acute and chronic approach that we have to hazard assessment.

Now listening to the discussion last night, I gather that many of you are involved in making your hazard assessment based on hazards to other than people - to fish, wildlife, the environment, and so on. We do not have that difficulty. We only have one group of people or one group that we have to look out for and that is the consumer. We do extend our hazard assessment to the consumer environment pretty much within the household. The general environment, I guess, you would normally regard beyond our scope somewhat. The other thing that we have that is a little different than many of you is that we must base our hazard assessment on consumer products only.

The problem that we have with data which originate out of NCI or other sources is that they are normally based on a straight chemical and very few consumer products are a straight chemical. The modern industry insists on mixing all these things together and trying to confuse us, and they are very successful. Therefore, we have to take the data that are generated from outside of the agency and try within the agency to apply it to the products which are subject to our jurisdiction.

Now, in the acute hazard assessment area we have a definition of hazardous assessment within the Hazard Assessment Act itself. First of all, it defines the term "hazardous substance" and lists a number of hazards that would subject a product to the statute - gross toxic flammable and so on - and then it continues on. If that substance or mixture of substances may cause substantial personal injury or substantial illness during or as a partial result of any customary or reasonably foreseeable handling or use including reasonable foreseeable ingestion by children. So, therefore, you know it is very easy to do an LD_{50} on a product and find that it has an LD_{50} which is lower than 5 g/kg of body weight, then you have something that is within the toxic definition of the statute. However, this only gets you to first base. We have to somehow bridge that gap to reasonably foreseeable use of the product. Is it going to result in injury or illness?

Now, one example that I think of offhand is moth crystals, which our friends from the Environmental Protection Agency normally regulate, but we come across it often and, in testing, normally we have found it within the toxic range. However, the physical form that we find it in has to be considered as well. The male portion of the audience is probably familiar with the paradichlorobenzene block that is in the men's room in the urinal. How, paradichlorobenzene is toxic. However, trying to ingest this, other than the distastefulness of where you are going to have to get it, you are probably going to break your teeth to chew it. It is as hard as a brick, practically

insoluble in water and, therefore, you can impose labelling requirements on this because it is toxic. You know, is it reasonably foreseeable that anyone is going to eat it and get ill. Now, in the crystal form or moth balls or something like this, it is much more readily ingested, but the form that we normally run across it, I think if we took someone to court to impose labelling requirements or any other requirement on it, they would probably have a pretty good chance that no reasonable foreseeable injury is going to result, so this is the type of thing we have to consider when we get into consumer products.

The data sources that we rely on include any number of things. In addition to the test data that we get from other agencies, in the acute area, there is a wealth of literature available on various toxic materials.

We look to the national clearinghouse and poison control centers which accumulate data on injuries that result across the country from various products. We have our own system, the NEIS system, National Electronic Injury Surveillance System which is, I believe, in 119 emergency rooms located throughout the country that we collect data on product injuries from. We have a program of reviewing death certificates to see which consumer products are causing death.

We get many consumer complaints. We have a couple of 800 numbers set up to facilitate getting consumer complaints and then as a result of consumer complaints we do in-depth investigations to see how the product was being used, was it being misused, was it being used as you would normally foresee it, and was it an accident or an injury that resulted because of the inherent characteristics of this product or was it misused, or was it intentional misuse even, going one step beyond.

The other thing that we have to plug in here is common sense. I do not know how you quantify common sense, but it is something that whenever you are making any hazard assessment, I think that until we get our hazard assessment technique down to a fine art, you have to use a certain degree of common sense. I think this goes across board, not only the acute, but the chronic area as well.

Now, in the chronic area last June 13, we published the Consumer Product Safety Commission carcinogen policy. It set up procedures for us to screen, classify, evaluate, and take regulatory action on consumer products in the carcinogen area. The screening process is not simple, but I will try to state it simply. It is simply a procedure of accumulating all of the data that exist on any number of chemicals and screening them out, which ones look suspicious, which ones do not, which ones appear to be in consumer products and have a problem with it.

The second step is classification, we had set up a procedure classifying a little differently than the OSHA scheme in that our policy was not going to result in automatic regulatory actions, but rather in setting the basis for regulatory actions which have been done on an ad hoc basis. Well, the first time we set out to classify a chemical it was perchloroethylene. The court in Louisiana stepped in and we are now enjoined from using our interim carcinogen policy. However, really all the court did was stop us from this classification process. I do not sympathize with the arguments that were submitted by

the local companies, but I can see their argument that this classification process certainly is going to have an impact on the marketability of the product. Since it was a preliminary step and nothing was definite at that point, I can see their argument even though I disagree with it.

The next step beyond this is to evaluate these chemicals and in evaluating them we have to ask a number of questions in our assessment. Does it contain a chemical that can cause injury to people or is the chemical in question able to do this? Is it going to harm humans? Certainly the answer to date indicates that it could cause problems in certain animal species. Can we make the transition - then, is the chemical in consumer contact. There is no use of us carrying on our investigation if it does not exist in consumer products. Say, it is only a feed stock chemical used in the petrochemical industry and never exists in consumer products; we can pretty well drop our investigation at that point. If it is in consumer products, is it going to get out in such a way that it is going to expose people to the chemical and, if this is true, is there going to be any uptake of the chemical once it has gotten out of the product. Of course, the ultimate step is that if you get an affirmative answer to all of these questions, is there anything we can do about it? The alternatives we have essentially are to label the product and warn people, ban the product from use in consumer products, rely on some voluntary actions by the affected industry or perhaps do nothing more than embark on an information and education program to try to educate people in dealing with it.

We do not have the luxury that OSHA has in that you can make the safe handling of a product a condition of employment. Consumers just have never been brought into line yet. You can tell them how to use it safely and maybe go with an educational campaign, but you are not always successful in getting them all to cooperate with you. So many times the only alternative we have is to allow people to be exposed to it or ban it so that they cannot expose themselves to it. Currently, we have banned asbestos in a couple of consumer products, e.g. patching compounds used on walls. We are currently working on benzene. It looks right now like we are going to probably do some more developmental work on benzene and await the Supreme Court decision on OSHA's case before we go ahead.

CHAPTER 15

HEALTH HAZARD ASSESSMENT IN THE BUREAU OF CHEMICAL HAZARDS

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INTRODUCTION

This paper attempts to describe briefly the type and scope of activities of the Bureau of Chemical Hazards and more specifically the work of the Monitoring and Criteria Division. The bureau is that part of the Canadian Department of National Health and Welfare concerned with assessing the health effects of chemical and microbiological agents in the environment and recommending actions to control those which are harmful. We are not concerned with foods, drugs, or cosmetic products which are looked after by other parts of the department.

LEGISLATIVE BASE

The acts with which the Bureau of Chemical Hazards is principally concerned are:

1. The Hazardous Products Act regulates or prohibits the sale, importation, or advertising of a wide range of dangerous products.

2. The Food and Drugs Act and the Department of National Health and Welfare Act provide authority for a wide range of activities within the department. Of particular relevance to the Bureau of Chemical Hazards, they allow for the control of drinking water quality both as a public health measure and more specifically since drinking water is defined as a food.

3. The Pest Control Products Act requires that pesticide chemicals are registered for use in Canada, and ensures that they are labelled with directions that will permit their safe use.

4. The Canada Labour Code Safety Act (Part IV) gives wide powers to control health hazards in work places under federal jurisdiction.

5. The Clean Air Act gives the federal government authority to set national air quality objectives. The act also has provisions for setting national emission standards where there is a significant danger to health. The Clean Air Act also regulates fuel additives such as the maximum amount of lead in gasoline.

6. The Environmental Contaminants Act provides authority to control hazards to human health and the environment resulting from the release of substances to the environment.

PROJECT AREAS

Many of these acts are either the responsibility of other federal departments or are administered jointly with other departments. The efforts of the Bureau of Chemical Hazards are therefore concentrated on the conducting of research into and assessment of the health effects of problem chemicals, and the provision of health advice to other departments. To do this, the Bureau carries out work in five broad project areas:

1. Product Safety - The identification of potential health hazards which may result from exposure to chemical substances in consumer products, and the assessment of probable risk to man.

2. Drinking Water - The generation of guidelines for drinking water quality. Research is conducted to determine the nature and quantities of trace contaminants and their potential health effects. Ways to remove toxic materials are investigated.

3. Environmental Contaminants Evaluation - The objectives of this project are to:
   a. Identify and evaluate environmental contaminants
   b. Assess the risks to health
   c. Reduce man's exposure to harmful contaminants.

   Priorities are to some extent determined by the Environmental Contaminants List of Priority Substances.

4. Occupational Health - The identification of hazardous chemicals in the workplace. Recommendations are made to other government departments, both federal and provincial.

5. Pesticides - The objectives are to assess the potential hazards of new and existing pesticide products to pesticide applicators, formulators, agricultural workers, and bystanders, and to prevent unwarranted exposure to these compounds.

PRIORITIES

The decision as to which specific chemicals are investigated within these broad project areas is determined in a number of ways. Since we are an advisory agency, our work is determined to some extent by the problems referred to us by other departments, e.g. pesticide submissions are sent for evaluation by the Department of Agriculture. Since we are a part of government, we must also respond to public concerns. We also carry out research to identify hitherto unforeseen hazards. In addition, we do make some attempt to prioritize the environmental chemicals for investigation by evaluating the potential that a chemical has for hazard based on the following factors:

1. The severity and frequency of effects on human health

2. The ubiquity or abundance of the substance in the environment

3. Its persistence in the environment

4. The possibilities for environmental transformation into more toxic substances

5. The size of the target population.

It was by using these and other considerations that the list of the priority substances was developed in collaboration with Environment Canada (Table 1).

ORGANIZATION OF THE BUREAU OF CHEMICAL HAZARDS

To carry out its activities, the bureau is organized into two divisions: the Monitoring and Criteria Division and the Environmental and Occupational Toxicology Division. The Monitoring and Criteria Division is essentially concerned with determining or predicting the dose of a particular chemical to which man is exposed by reason of the environment in which he lives or the place where he works. The Environmental and Occupational Toxicology Division, on the other hand, investigates the toxicological properties of chemicals with a view to predicting the potential effects on man. Consideration of these two aspects together permits a health hazard assessment to be performed leading to recommendations and regular control if necessary. The remainder of the paper will attempt to indicate how we in the Monitoring and Criteria Division attempt to estimate dose or exposure of man to specific chemicals.

ESTIMATION OF EXPOSURE

Man is exposed to chemicals principally through three routes - the food he eats, the water he drinks, and the air he breathes. In some cases certain chemical substances can also be absorbed through the skin. When considering the dose of a chemical received by the general population, we therefore need to know the concentration of the substance in food, air, and water, and the amounts of these media which man takes in. In developing exposure information we would ideally like to have data on the topics listed in Table 2. We would probably never be able to gather this complete range of data for any one chemical, but these are the fields that we would search:

1. Physico-Chemical Properties - For a new substance this could lead to an appreciation of the likely behaviour in the environment: where might it be found and its potential for persistence.

2. Sources of Environmental Pollution - Does it occur naturally? What is the relative contribution from man-made activities? What are the trends?

3. Environmental Transport and Distribution - Consideration is given to the formation of degradation products and commonly formed impurities, e.g. DDE formed from DDT, and dioxins in chlorophenols.

TABLE 1

ENVIRONMENTAL CONTAMINANTS-PRIORITY SUBSTANCES

CATEGORY I

Those substances which the government is satisfied pose a significant danger to the environment or human health and for which regulations are being developed:

1. Chlorofluoromethanes
2. Mirex
3. Polybrominated biphenyls
4. Polychlorinated Biphenyls
5. Polychlorinated Terphenyls

CATEGORY II

Those substances which the government has reason to believe pose a significant danger to the environment or human health and which are being investigated in depth to determine the nature and extent of the danger and the appropriate means to alleviate that danger:

1. Arsenic
2. Asbestos
3. Benzene
4. Lead
5. Mercury

CATEGORY III

Those substances which the government believes may pose a significant danger to the environment or human health, or about which further detailed information, including toxicology and amounts used, is required:

1. Cadmium
2. Chlorobenzenes
3. Chlorophenols
4. Hexachlorocyclopentadiene and its Adducts
5. Organotins
6. Phthalate Esters
7. Triaryl Phosphates

TABLE 2

INFORMATION REQUIRED FOR ASSESSMENT OF HUMAN EXPOSURE

IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES

1. Nomenclature and structural formula
2. Melting point, boiling point, solubility, partition coefficients, vapour pressure
3. Photostability, thermal stability, chelating ability, adsorptivity, pH stability

SOURCES OF ENVIRONMENTAL POLLUTION

1. Natural occurrence
2. Industrial production data and projections
3. Utilization patterns - by industry and the general public, extent of use
4. Industrial release to air and water
5. Effect of waste-disposal methods, effectiveness of control technologies

ENVIRONMENTAL TRANSPORT AND TRANSFORMATION

1. Transportation and distribution between media (water, air, soil)
2. Environmental transformations and degradation processes
3. Interaction with physical, chemical, and biological factors
4. Bioconcentration and persistence
5. Consideration of degradation products or impurities

ENVIRONMENTAL LEVELS AND HUMAN EXPOSURE

1. Levels in food, air, and water
2. Occupational and other situations of exposure (e.g. hobbies, smoking)
3. Estimate of effective human exposure from all sources
4. Biological indicators of exposure

4. Exposure Levels - The aim to develop an estimate of human exposure from all sources. The information discussed previously provides an account of the factors which contribute to exposure and can point the way to control strategy.

Food is often the largest single contributor. In many cases good data on levels are available from monitoring activities, and this can be coupled with consumption habits.

Air is often a minor source but considerable variation can be encountered with occupation and other situations such as hobbies and smoking.

The amounts of drinking water consumed vary from person to person and depend on factors such as age and air temperature. Until recently we have assumed that an adult consumes, on average, two litres per day. We have recently conducted a survey to investigate drinking water consumption patterns in Canada. The results are shown in Table 3. Approximately 1,000 persons were surveyed by questionnaire in both winter and summer. Tap water consumption was investigated in the various forms listed. The average was 1.34 litres per day with little difference between summer and winter.

EXAMPLES

I would now like to conclude with a few examples from our own laboratories where we have attempted to gather information on particular substances to which Canadians are exposed via their drinking water. In 1976/77 we carried out a survey of trihalomethanes in the drinking water supplies of 70 cities. Thirty-eight percent of the population were covered by the survey. Samples were taken of the raw water, treated water, and at two points in the distribution system. Since chloroform is formed by the action of chlorine added at the treatment plant and free chlorine is present throughout, as expected, higher levels of chloroform are found at the consumer's tap. Such a survey, of course, presents the situation at only one instance in time. It may not represent the picture at other times of the year and may lead to errors if used to calculate potential dose to man. So we did some further work in the Ottawa/Hull region. We measured chloroform levels in the water at three treatment plants every two weeks for a year. These data, when coupled with consumption data, allow a much more accurate estimate of chloroform intake from drinking water.

At the same time as the trihalomethane survey was carried out, samples of drinking water were also taken for a survey of NTA. NTA has been used extensively in household detergent products in Canada since about 1970 when a limit was imposed on their phosphate content. Most cities had levels less than 10 µg/L. One of the points of concern to us was to determine whether NTA levels are increasing in our water supplies. The results of a similar survey conducted in 1975 show that the tendency is towards lower rather than higher levels of NTA, even though the more recent data were acquired from a mid-winter survey when the levels would be expected to be at their highest values.

Other studies on substances in tap water include polynuclear aromatic hydrocarbons in Ottawa tap water (Table 4). This is only a partial list

TABLE 3

DRINKING WATER CONSUMPTION STUDY

Average consumption (litres/day) for various forms and for both seasons

FORM OF WATER	AGE				
	0 - 5	6 - 17	18 - 54	55 and over	Total
Tea	.01	.04	.26	.42	.21
Coffee	.01	.06	.44	.42	.30
Milk	.09	.12	.05	.08	.08
Other Beverage	.28	.34	.17	.11	.21
Home Made Beer/Wine	-	.02	.06	.03	.04
Water	.24	.42	.39	.37	.38
Added Water (Ice)	.01	.02	.03	.02	.03
Soup	.06	.07	.07	.11	.08
Popsicles	.03	.03	-	-	.01
Baby Beverage	.04	-	-	-	.01
All Forms	.76	1.14	1.47	1.57	1.34

TABLE 4

PARTIAL LIST OF

POLYNUCLEAR AROMATIC HYDROCARBONS

DETERMINED IN OTTAWA TAP WATER, 1977

COMPOUND	CONCENTRATION, ng/L	
	Jan.	Feb.
Naphthalene	4.8	6.8
2-Methylnaphthalene	4.6	2.4
1-Methylnaphthalene	2.0	1.0
1,3-Dimethylnaphthalene	1.1	1.9
2,3,5-Trimethylnaphthalene	5.2	0.65
Biphenyl	1.1	0.70
3,3'-Dimethylbiphenyl	5.2	0.31
4,4'-Dimethylbiphenyl	7.0	0.57
Fluorene	2.2	0.15
Phenanthrene	2.2	0.52
Anthracene	2.2	0.52
Fluoranthene	1.9	0.55
Pyrene	1.7	0.53
Triphenylene	8.1	3.3
Benz(a)anthracene	8.1	3.3
Chrysene	8.1	3.3

Benoit, et al., Intern. J. Environ. Anal. Chem., 1979, in press.

TABLE 5

CHLORINATED PESTICIDE RESIDUE LEVELS IN OTTAWA TAP WATER, 1976

PESTICIDE	CONCENTRATION, ng/L	
	Range	Mean
α-BHC	0.1 - 15	6 ± 4
γ-BHC	0.4 - 11	3 ± 3
Heptachlor	0.1 - 1	0.6±0.3
Aldrin	0.1 - 6	0.9± 1
Heptachlor Epoxide	0.2 - 9	3 ± 3
o,p'-DDE	0.1 - 0.5	0.2±0.2
Dieldrin	0.1 - 4	1 ± 1
o,p'-DDE	0.1 - 3	1 ± 1
Endrin	1 - 7	4 ± 4
o,p'-DDT	0.2 - 8	3 ± 3

Williams, et al., Pest. Monit. J., 12, 163(1978).

TABLE 6

N-NITROSODIETHANOLAMINE IN CUTTING FLUIDS

SAMPLE	N-NITROSODIETHANOLAMINE (mg/g)		PERCENT NITRITE
	THIN LAYER CHROMATOGRAPHY	GAS CHROMATOGRAPHY-MASS SPECTROMETRY	
A	0.55	0.36	8.0
B	0.41	0.23	7.2
C	4.15	5.53	8.2
D	0.69	0.40	3.4
E	0.83	0.99	9.8
F	trace	-	0.2
G	0.83	0.62	8.6
H	0.42	0.35	3.8
I	-	-	1.7

showing those detected at highest concentration. The variation in levels within one month is shown.

Table 5 shows the results of monitoring selected pesticides monthly from January to December 1976, in Ottawa tap water. No obvious trends were noted.

Finally, I would like to show an example of some work in the consumer product field. Synthetic cutting fluids, used to reduce friction during metal grinding or drilling, usually contain ethanolamines as emulsifiers and nitrite to minimize corrosion. These components can react to give high concentrations of carcinogenic nitrosamines. We analyzed 24 different brands of cutting oils, as shown in Table 6. Concentrations up to 5,000 mg/kg were found in eight products. This resulted in a ban under the Hazardous Product Act of the sale of cutting oils which contain the two components which can give rise to nitrosamine formation.

CHAPTER 16

HAZARD ASSESSMENT IN THE TOXICOLOGICAL EVALUATION DIVISION

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I have attempted to develop a short talk using the guidelines that were sent to the speakers. Firstly, I would like to identify the group to which I belong by saying, I am a member of the Pesticide Section, Toxicological Evaluation Division, Bureau of Chemical Safety, Foods Directorate, Health Protection Branch, Department of National Health and Welfare.

The legal jurisdiction behind what we do is the Food and Drug Act and Regulations. For the most part, the part of the act which applies to us is Part 1, Article 4, which states, "No person shall sell an article of food that:

(a) has in or upon it any poisonous or harmful substance;
(b) is unfit for human consumption;
(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
(d) is adulterated; or
(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

The next point which I will address is what is our scientific and technical base for hazard assessment, or, how and where does our information come from. Well, the latter part is the simpler to answer, as far as pesticides go. The majority of our information comes from what we call a submission or petition from the manufacturing company that wants to put the pesticide on the market. In the evaluation procedure, the submission is sent to Canada Agriculture which controls the registration of pesticides in Canada under the Pest Control Products Act. In turn, Canada Agriculture has a number of agencies evaluate the parts of the submission which are of interest to them.

In the Foods Directorate, we review all pesticides which have a food use. This includes reviewing the chemistry of the active ingredient and formulations, field trial residue data, and results of toxicity studies with laboratory animals.

As our name - Bureau of Chemical Safety - indicates, the majority of evaluations are "safety in use" of chemicals. The burden of proving the safety is on the company producing the chemical. Our requirement for toxicity studies is open-ended, that is, although we have some specific requirements, any number of studies may be requested until we are satisfied that the "safety in use" of the product has been established.

Although we are mainly interested in assessing the toxicity of repeated exposure to the pesticide, we require that the acute toxicity be studied in males and females of two species. One of the species should be non-rodent. Dermal and inhalation acute toxicities and eye and skin irritation studies are of interest and reviewed but are of greater importance to those in occupational health.

Investigations of the toxicity from short-term exposure to the pesticide are carried out by having the test animal consume a diet containing various levels of the pesticide. The length of the study may vary from 90 days for rats to 1 year for dogs. The studies are begun with males and females of weanling age. Often, in this study of short-term toxicity, 21-day dermal and inhalation studies are carried out, but again these are of more interest to those in evaluating hazards to pesticide manufacturers and applicators.

Then, we have the studies required for the evaluation of chronic exposure to the pesticide. This study if designed properly may also be used for assessing the carcinogenic potential of the pesticide. Males and females, of weanling age, are exposed to the pesticide for their entire life or a minimum of 18 and 24 months for mice and rats, respectively. This pesticide is incorporated into the diet at 4 to 5 levels and includes a zero level (control diet).

A variety of parameters, including body weight, food and water consumption, appearance, behaviour, clinical chemistry, urinalysis, hematology, gross- and histopathology, and organ weights are examined or measured and recorderd for evaluation in the 90-day and 2-year studies.

The effect of the pesticide on reproduction is investigated by carrying out 2- or 3-generation studies with 2 litters per generation. The test animal is frequently the rat, and dietary exposure to the test chemical begins when the F_0 generation are weanlings and continues until the F_{2b} or F_{3b} are autopsied. A number of parameters including number of pregnancies, weight of dam, size of litter, weight of litter at birth and at weaning, and survival of litter are recorded. All animals are autopsied and examined grossly. Histopathological examinations are carried out on animals in the final autopsy.

The teratogenicity potential of the chemical is measured by dosing pregnant rats or rabbits at specified times and examining the offspring for abnormalities.

The study of the metabolism of the pesticide in at least one species is a requirement. If the short- or long-term studies indicate a significant species difference in the toxicity of the pesticide, then metabolic studies with both species should be carried out. The differences in toxicity may be explained by difference in metabolism.

The protocol for the study of delayed neurotoxicity is under review. Presently, the adult hen is the test animal of choice and a single dose is administered usually along with atropine. The hens are observed for 21 days, autopsied, and examined histopathologically. Only organophosphorus pesticides are required to be tested for delayed neurotoxicity.

Mutagenicity testing methods designed as short-term cancer tests are undergoing very active review and, although we encourage companies to submit results of these tests, no regulatory action will be taken on these results at this time.

The toxicity studies are designed to establish the no-observed-toxic-effect level (NOEL), which is expressed on a mg/kg body weight per day basis. To calculate the acceptable daily intake (ADI), a safety factor is applied to the NOEL obtained with the most sensitive species.

The use of the term ADI is unique to the safety evaluation of food additives and pesticides, and I am sure that people in those areas would like to keep it that way. However, the ADI has been adopted by people in other areas. We prefer the term "tolerable daily intake" for contaminants such as PCB's. The World Health Organisation Expert Committee on Pesticide Residues defined ADI as "the daily dosage of a chemical that, during an entire lifetime, appears to be without appreciable risk on the basis of all the facts known at the time".

After we have calculated the ADI for the pesticide under review, the maximum exposure from residue in food is estimated by multiplying the tolerance(s) requested for the pesticide by the quantity consumed of the food(s) for which a tolerance(s) has been requested. The food consumption figures are actually food disappearance figures, and may be an over-estimate of the actual consumption. Also, we over-estimate exposure by assuming that all the food(s) has been treated with the pesticide and the residue is at the tolerance level. If the ADI is larger than the "maximum estimated exposure", then we would normally recommend that the requested tolerance(s) be granted.

The great majority of the information used for establishing an ADI for a pesticide is included in the manufacturer's submission. However, in the case of chemical contaminants in foods, the information used to calculate a "tolerable daily intake" may come mainly from the scientific literature. A strength of our pesticide safety evaluation program is that the toxicity studies must be carried out and evaluated prior to the compound being offered for sale. Also, field trials must be carried out and the residue data generated can be used to estimate maximum exposure.

The major weaknesses of our evaluation are that:

1. We are using data generated with laboratory animals to assess safety in humans

2. Chemicals are tested individually, whereas man is exposed to a variety of chemicals

3. Residue and toxicity data of contaminants may be insufficient

4. Maximum estimated exposure does not include exposure from the presence of the chemical in air and water.

CHAPTER 17

HAZARD ASSESSMENT BY THE ONTARIO MINISTRY OF THE ENVIRONMENT

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INTRODUCTION

The legislation under which the Ontario Ministry of the Environment (MOE) operates is contained in the Ontario Water Resources Act (Revised 1970), the Environmental Protection Act (1971), the Pesticides Act (1973), and the Environmental Assessment Act (1975). Only the Pesticides Act defines a special mechanism for the control of toxic substances, but all four authorize MOE to protect human health and the environment from the effects of emissions or discharges of contaminants. Contaminant is defined as "any solid, liquid, gas, odour, heat, sound, vibration, radiation or combination of any of them resulting directly or indirectly from the activities of man" which may cause any of a number of specified effects. For the purposes of this workshop, we are concerned especially with the control of chemical contaminants, both those which create a localized hazard in the vicinity of a point source and those which may be hazardous to human health or the environment through chronic low-level exposure. The following describes how the assessment of such hazards is currently carried out in the Province of Ontario, and how hazard assessment priorities are determined.

In Ontario, a chemical contaminant need not be declared hazardous before being subject to regulation. The need to carry out hazard assessments is not prescribed legislatively or judicially, and the need to determine priorities is based only on resource limitations. The regulation of a hazardous contaminant, then, proceeds in exactly the same way as for any other contaminant.

DEFINITION OF "HAZARDOUS"

As an operational definition, a hazardous contaminant is a toxic substance which, by itself, in combination with other substances, or by an environmental transformation product or metabolite:

1. Causes a severe, irreversible effect on human health or other critical biological or ecological effect

2. May cause its effects through low-level, chronic exposure

3. Is discharged in sufficient quantity and resides in the environment in such a form and for sufficient time as to create an opportunity for exposure.

DEVELOPMENT OF REGULATIONS

Emissions to the atmosphere are regulated on the basis of standards or guidelines for exposure of critical (i.e. most sensitive) receptors as prescribed by permissible point of impingement concentrations. Critical receptors may be humans (health, odour, aesthetics), animals, plants, aquatic life, or economic materials. These regulations are developed on a case-by-case basis with regard to individual chemicals, but the numerical concentrations apply to all sources across the province. Variances in source emission rates are allowed, as long as a worst-case atmospheric dispersion calculation indicates that the permissible concentration will not be exceeded at any point of impingement or critical receptor over any 30-minute period. Certain chemicals may also be regulated by so-called air quality criteria, which are longer-term (e.g. 24 hours, 1 month, 1 year) benchmarks for community air quality, without reference to a particular source. Sampling and analytical methods are now specified routinely with a regulation. The kinds of information and opinion which go into air standard or guideline development are summarized in Tables 1 and 2.

Discharges to receiving waters in Ontario are controlled by the imposition of effluent requirements. These are derived by comparing the results of a site-specific receiving water study with any relevant federal or provincial effluent regulations or guidelines, and imposing the more stringent requirement.

All sources in the province - new and existing - must be in compliance with air and water requirements or be put under a supervised control program leading to compliance.

A new or modified source of any air or water discharge must obtain a certificate of approval of pollution control equipment before operation may proceed.

The Ontario environmental legislation which has been described may not be used to prohibit the use of any substance, only to regulate its discharge to the ambient environment. In this context, however, it is possible to prescribe "zero" discharge. Nor does the legislation make provision for pre-manufacture or pre-market toxicity testing or routine inventory reporting of designated chemicals.

SOURCES OF INFORMATION

The regulatory procedures for air and water (or any other part of the natural environment) contaminants depend upon knowing what contaminants are in or expected to be in a discharge from a specific source. At present, MOE obtains this information from the following sources:

1. Lists of chemicals and process details submitted in an application for a certificate of approval or in response to a ministry request for this information in the case of an existing plant.

2. Lists of chemicals generated by industrial sector surveys.
   a. General - other agencies
   b. Specific to Ontario - in-house or consulting engineers

Table 1. DERIVATION OF THE LIMITING AMBIENT AIR CRITERION FOR A CONTAMINANT

	Effect on Humans	Effect on Vegetation / Effect on Animals	Effect on Property and Materials
Investigated by	Special Studies and Services Branch, Ministry of Labour	(1) Phytotoxicology Section Air Resources Branch	Technology Development and Appraisal Section Air Resources Branch
Usual Sources of Information	1. Published epidemiological studies 2. Studies on human exposure (1) Acute toxicity (2) Chronic toxicity 3. Studies on animal exposure (2) Acute toxicity (2) Chronic toxicity 4. Published Threshold Limit Values for Occupational Exposure (American Conference of Governmental Industrial Hygienists)	1. Published articles on effects on specific plant species 2. Greenhouse experiments on sensitive species under controlled conditions 3. Field experience with actual case histories (2) Toxicity Unit Water Resources Branch 1. Published toxicity studies on fish and aquatic plants. 2. Toxicity tests carried out on fish species. 3. Communication with other agencies engaged in similar studies.	1. Published articles on observed effects on animals 2. Contact with the Veterinary Branch of the Ministry of Agriculture and Food 3. Personal communication with experts in the field	1. Literature search with respect to — Corrosion Soiling Odour Threshold Synergistic Effects using standard sources such as: (1) Kirk-Othmer Encyclopedia (2) Dangerous Properties of Industrial Materials (Sax) (3) Compilation of Odor and Taste Threshold Data (Stahl) 2. Actual experience in the field involving ambient air studies

Table 2. FACTORS INVOLVED IN THE DETERMINATION OF ½ hr. AVERAGE STANDARD

1. Average sampling time differential
2. Background concentration of the contaminant
3. Practical consideration of emission control
4. A variety of unique factors such as synergistic effects, air reactions, and special health considerations.

3. Systematic inventories - consultants or in-house
   a. Individual plant sites
   b. Industrial sectors/chemical families
   c. Trade associations
   d. Data from federal or other provincial agencies.

4. Monitoring of existing sources and the general environment.

ASSESSMENT CRITERIA AND PRIORITY SETTING

It is impossible to develop regulations for all toxic chemicals so identified - for all of the reasons well known to workshop participants. The critical question then becomes not just "Which toxic chemicals are potentially hazardous?" but "Which potentially hazardous chemicals or source discharges are the most hazardous?" That is, the most difficult task is to determine hazard assessment priorities among the many chemical and point source candidates. This problem is not new to workshop participants, nor is the problem of having these priorities decided by the communications media.

In order to facilitate the development of a rational priority selection and early warning scheme, MOE established the Hazardous Contaminants Program and a Hazardous Contaminants Technical Committee which, in addition to MOE scientific and technical staff, has members from the Ontario Ministries of Labour, Industry and Tourism, Agriculture and Food, and an observer from Environment Canada. The members of this committee are working level scientists and engineers who, for the most part, are actively involved in research and development, monitoring, abatement, health effects assessment, and related fields.

In early 1977, the committee undertook a hazard rating exercise based on the checklist in Figure 1, in order to determine a short priority list of potentially hazardous chemicals. The candidates were to be selected from:

1. The Hazardous Substances List (1976), a list of about 150 chemicals ranked and selected on the basis of an index, which was the ratio of the estimated Ontario use rate (tonnes per year) to the Ontario occupational health guideline (TLV) for that substance, and on a subjective estimate of potential for release in Ontario. The Hazardous Substances List had been selected from a tabulation of about 3,500 candidate chemicals (and their properties) which were determined to be used in Canada in significant quantities.

2. A joint priority chemicals list developed by the Ontario Ministries of Environment, Health, Labour, and Natural Resources for a priority-setting exercise undertaken by Environment Canada.

3. Any other candidate chemicals which had been flagged by the individual evaluator from experience or reading in his own area of interest or specialty.

The nominated chemicals were ranked according to their total scores in this exercise, but the entire list of nominated chemicals was reviewed by the entire committee and a revised ranking determined. The chemicals so selected were placed in three categories:

Figure 1. HAZARD RATING CHECKLIST
MOE HAZARDOUS SUBSTANCES PROGRAMME

INSTRUCTIONS:

Rate each substance on a separate form. On the basis of your current knowledge of the various aspects of each substance described by the criteria (descriptors) in the checklist below, assign a rating value between the limits indicated. Tick (✓) those descriptors which influenced your rating in each category. Please circle the letter (A,B,C,D) or letters preceding the categories of descriptors about which you have the greatest knowledge.

Name of Substance(s) Rated:

Score	Category
	A. Human Health Effects (0 - 40 Points)
☐	General Environmental Exposure Effects
☐	Long-Term (Chronic) Effects
☐	Carcinogenesis
☐	Mutagenesis
☐	Teratogenesis
☐	Neuropathy/Behavioural effects
☐	Acute Effects
☐	Occupational Exposure Effects (Known Episodes, etc.)
	B. Environmental Impact (0 - 25 Points)
	Non-Human Biological Effects (Experimental or Known Episodes)
☐	Phytotoxicity
☐	Toxicity to Aquatic Life
☐	Toxicity to Other Animal Life
☐	Ecological Systemic Effects/Synergisms
☐	Effects on Inanimate Materials (Corrosion, etc.)
	Chemical Dynamics
☐	Persistence
☐	Environmental Chemistry/Transformations
☐	Water
☐	Air
☐	Soil
☐	Baseline Concentrations/Natural or Existing Background
	C. Discharges to the Environment (0 - 20 Points)
	Industrial/Municipal
☐	Quantities Present
☐	Concentrations in Discharges (measured or estimated)
☐	End Use or Disposal (including transporation, storage, etc.)
☐	Accident Potential for Release to the Environment
☐	Diffuse Sources (landfills, consumer product use, etc.)
	D. Social and Economic Impact (0 - 15 Points)
☐	Exposed Population (size, sensitivity)
☐	Effected Geographic Area (size, sensitivity)
☐	Social Costs (health care, etc.)
☐	Abatement and Control Costs
	TOTAL SCORE

1. Those requiring immediate attention and action by MOE - action meaning information gathering, problem identification, monitoring, regulation development, and so on as each case required

2. Those about which the committee expressed concern but which would not require immediate action, or for which programs were already underway

3. Those which were cited by at least one evaluator but which were not thought to require specific action in the near future.

The first two categories from this list are shown in Table 3. It looks much like everybody else's priority list. During the intervening two years, however, very few new potentially hazardous situations have been identified in the field which have involved chemicals not on this relatively short list. It is currently being revised by the Hazardous Contaminants Technical Committee.

The description of our priority-setting procedure indicates that additions or deletions are not made according to a formalized prescription. Priorities are determined, basically, by consensus of ministry scientific and technical staff achieved through the application of common sense to information and experience. The number of priority chemicals is limited to that which the committee believes can be properly addressed with available resources. It is an action list rather than a comprehensive hazard inventory and serves as the basis for allocating limited resources.

WATERBORNE HAZARDS

The original Hazardous Substances List and the committee's priority list reflected concerns for airborne contaminants more so than waterborne contaminants, for various reasons. Recently (November 1978) MOE published a hazardous substances policy respecting waterborne contaminants, which was accompanied by a list of specific chemical substances whose release "shall be evaluated on a case-by-case basis". This list, which is entitled "Substances with Undefined Tolerance Limits", is essentially the ministry's water quality trace contaminants priority list for future action. The intent is that all effluents to receiving waters in which these contaminants could be hazardous will be evaluated for the listed parameters, as shown in Table 4.

Principal among the sources used to develop the water quality priority list were:

1. Proposed annexes to the Canada-U.S. Great Lakes Water Quality Agreement, 1976.

2. Environment Canada/Health and Welfare Canada, "List of Priority Chemicals, 1977".

3. U.S. Interagency Testing Committee, "Chemical Substances for Further Evaluation", 1977.

4. U.S. Environmental Protection Agency, "Preliminary Assessment of Suspected Carcinogens in Drinking Water", 1975.

along with considerable in-house toxicity test data and collected reference material on substances toxic to aquatic organisms.

TABLE 3

MINISTRY OF THE ENVIRONMENT PRIORITY CHEMICAL SUBSTANCES

CATEGORY A HIGHER PRIORITY	CATEGORY B LOWER PRIORITY
Arsenic (antimony, selenium, tellurium)	Polyhalogenated biphenyls
Polycyclic aromatic hydrocarbons	Asbestos
Halogenated aromatic hydrocarbons	Lead
Mercury	Phenols
Radionuclides	Phthalic esters
Nickel (zinc, chromium, cadmium)	Acrylamide, acrylonitrile
Vinyl chloride	Ammonia
Halogenated aliphatic hydrocarbons	Nitrosamines
Aromatic hydrocarbons	Bromine
Aromatic amines	Nitrogen oxides and nitrates
Chlorine and chlorine dioxide	Hydrazine (and related compounds)
	Ozone

TABLE 4

WATER MANAGEMENT IN ONTARIO

SUBSTANCES WITH UNDEFINED TOLERANCE LIMITS

METALS

- Aluminum
- Antimony
- Barium
- Boron
- Cesium
- Cobalt
- Manganese
- Molybdenum
- Strontium
- Thallium
- Tin
- Vanadium

ORGANICS

- Acrylonitrile
- Alkyl Amines
  - Diethylamine
  - Dimethylamine
- Aryl Amines
  - Benzidine
  - Napthylamine
- Aryl Chlorides
  - Dichlorobenzene
  - Hexachlorobenzene
  - Trichlorobenzene
  - Trichlorobenzene
  - Tetrachlorobenzene
- Aryl Sulfonic Acids
  - Dodecylbenzene
- Azo and Diazo Compounds
- Benzene and Aliphatic Derivatives
  - Toluene
  - Xylene
  - Diethylbenzene
  - Dimethylbenzene
- Carbon Tetrachloride
- Chlorinated Ethylenes
  - Trichloroethylene
  - Tetrachloroethylene
- Chlorophenols
  - Pentachlorophenol
- Furfural
- Haloforms
  - Chloroform
  - Chloro-Bromomethanes
- Mercaptans
  - Methylmercaptan
- Nitrosamines
  - Dimethylnitrosamine
- Nitro Aromatics
- Phenols and Derivatives
  - Cresols
- Polycyclic Aromatic Hydrocarbons
  - Naphthalene
  - Benzo(a)pyrene
- Quinoline
- Styrene
- Sulphonates
  - Dimethylsulphonate
  - Diethylsulphonate

PESTICIDES

- Bayer '73
- Benomyl (Benilate)
- Dichlorobenil
- Disulfoton (Disyston)
- Kelthane (Dicofol)
- Methyl Parathion (Metaphos)
- Naled (Dibrom)
- Rotenone
- PMA
- TFM
- Herbicides actively used in Ontario (9 listed)
- Insecticides actively used in Ontario (4 listed)
- Fungicides actively used in Ontario (3 listed)

SUMMARY AND CONCLUSIONS

These priority lists, hopefully, identify those chemicals which have the highest potential to cause hazards to human health or the natural environment. The lists do highlight those substances about which much more information needs to be gathered before thorough and reliable hazard or risk assessments can be carried out.

At present, most hazard assessments are carried out on a case-by-case basis, as the need arises, with respect to point source discharges. Various branches of MOE carry out day-to-day hazard assessments on the above cases: Water Resources Branch, Air Resources Branch, Pollution Control Branch (sewage treatment, water treatment, pesticides), and Waste Management Branch. The Water Resources Branch generates many of the toxicity test data required for their assessments and those of the Pollution Control Branch by in-house experiments and effluent testing on aquatic organisms.

Both air and water assessment programs make use of monitoring data from extensive air and water quality networks and from numerous special surveys.

In summary, MOE has no formal protocol for carrying out hazard assessment or priority selection for either airborne or waterborne contaminants. These activities occur as parts of the day-to-day program. The Hazardous Contaminants Program and the Hazardous Contaminants Technical Committee provide a forum for coordination and joint planning of the air and water assessment programs, but the strength of the ministry's approach to hazard assessment is that it is integrated with the regular activities of the operating branches and is not isolated in a separate branch or office.

At the initiative of MOE, risk assessments regarding human health and other biological effects of priority contaminants and other substances for which regulations are required are carried out by medical consultants in the Special Studies and Services Branch, Ontario Ministry of Labour. In the following presentation, Dr. Joan McEwan of that branch will describe in more detail the sources of data and assessment methods which are used.

Below are some observations:

1. Priority lists of environmental contaminants will differ depending upon the scale of an agency's jurisdiction. Local and state or provincial priorities will be different from regional, national, or global priorities. That is, it may not be possible to agree on a common list.

2. It is not necessary, in fact, it may not be desirable to aim for a common priority list for all Great Lakes area agencies. It is more important that agencies responsible for carrying out hazard assessment:

    a. Know what each others' priority substances are
    b. Have an established means of communicating about specific actions being undertaken with regard to hazardous contaminants
    c. Have access to a common information clearinghouse for chemical data and status of regulatory activities.

3. It is such a clearinghouse or data-gathering centre which should have a master priority list which encompasses the participating (sponsoring) agencies' lists.

4. Priorities will differ depending upon whether the agency's focus is on control of local impact of point sources or on global trace contamination by highly persistent substances. The hazard assessment methodologies and the required input data may very well differ for these cases.

5. Different hazard assessment strategies may be required for evaluating new or existing sources.

6. Priorities must be related to the available human and fiscal resources. It makes little sense to develop an elaborate, formal hazard assessment scheme or inventory data-reporting system if an agency does not have or will not have the resources to address or follow up the output.

7. In Ontario, risk assessment is normally carried out separately from risk-benefit or socio-economic impact analysis. This process appears to allow for a more-or-less objective (scientific) evaluation of risk before the mitigating economic factors are considered.

CHAPTER 18

ONTARIO MINISTRY OF LABOUR PROGRAMS

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The role of the Occupational Health and Safety Division of the Ontario Ministry of Labour reflects in its evolution the response of regulating agencies to the changing needs of the times.

A Division of Industrial Hygiene within the Ontario Department of Health was created in 1921. There was an urgent need, in particular, for control of the health of miners at a period when tuberculosis was a significant cause of death among them. A comprehensive program of annual chest x-rays and certification for miners was established in 1926. Through the next two decades, with the establishment of much new industry in the province, other industrial medical programs were developed, but this early initiative, established under the Silicosis Act, remained one of the utmost importance in the field of preventive health.

Gradually, the scourge of tuberculosis lessened, as did the morbidity and mortality associated with other infectious diseases, and attention was focused on other aspects of preventive medicine such as cancer, heart disease, and accidents, major killers to the present day.

The Industrial Hygiene Division flourished until the mid-1960's. Growing awareness of the importance of clean air and water with respect to toxic chemical and physical agents led to the realization that separate and more extensive legislation was required in this area.

In 1971, a Provincial Ministry of the Environment (MOE) was created and services of the Industrial Health Division relating to water quality, air pollution, waste disposal, and pesticides were transferred to its jurisdiction from the Ministry of Health. Many members of staff from this division moved to MOE but there remained within the Ministry of Health the medical and much other technical support, particularly in the field of radiation. At that time, the Industrial Hygiene Division became part of a Community Health Division with the appropriately timely title of Environmental Health Services Branch.

In 1976, based on a recommendation made by Professor Ham in the Royal Commission Report on the Health and Safety of Workers in Mines, the branch moved to the Ontario Ministry of Labour, and later split into two branches, one concerned mainly with day-to-day problems and surveillance of the work force, and the other of which I am a member, representing its Director, Dr. Max Fitch, named the Special Studies and Services Branch. In our branch, there are four Services: Safety Studies, Radiation Protection, the Radiation Laboratory, and Health Studies.

The branch continues to act as the medical advisor to MOE and provides support in radioactivity matters to that ministry as well as to the Ministries of Health, Housing, and Natural Resources.

Approximately one third of our activities are related to matters other than strict occupational health and safety.

The Health Studies Service has as its major activities:

1. The carrying out of epidemiological studies on groups of workers likely to be at risk from exposure to chemical or physical agents in the work place.

2. The provision of consulting services to government agencies as above and to other agencies on request, not excluding advice to the general public. There is also close consultation with research groups, and liaison with the Workmen's Compensation Board and the Atomic Energy Control Board.

3. A very important and rather overwhelming part of our work consists of the preparation of criteria documents for our own ministry and for MOE. Thus it is apparent that there are several roles to be developed concurrently and our approach to this problem may be of interest.

The group consists of seven physicians, including the Chief of the Service, a biostatistician, a research scientist, and support staff. We have the special advantage of very close proximity to the excellent library within the ministry and the library facilities of the University of Toronto.

The dual role we have in respect of the preparation of criteria documents for hazardous substances has its own strengths and weaknesses. To illustrate, once a decision is made on a priority, data acquisition can proceed on all aspects related to health, and the documents produced can be adapted to reflect either workplace or environmental (community) exposure.

On the other hand, there is the possibility of requests for evaluation of different toxic substances from each ministry which could lead to a dilution in the quality of work and depth of the research and to neglect of areas of original study and day-to-day consulting services, both of which provide the staff with particular interest and contact with real world situations.

Dr. Caton has given you the method of determination of a hazard rating and development of a priority chemicals list for MOE. For the sake of completeness, I will describe very briefly the method by which the Ontario Ministry of Labour determined its priority list of chemicals.

A representative from each of five branches of the Occupational Health and Safety Division (Occupational Health, Special Studies and Services, Mines Engineering, Industrial Safety, and Construction Safety) under the chairmanship of a member of the Standards and Programs Branch, met in 1977. Input from a variety of professions was assured. Fourteen hazards which had received much attention in recent years were listed and reviewed for the

reasons for which they were considered highly hazardous. These reasons included knowledge or suspicion of carcinogenicity, known or suspected mutagenic/teratogenic effects, long-term effects, preventability, specificity in diagnosis, numbers of workers exposed, toxicity, claims to the Workmen's Compensation Board, problems in testing, gaps in research, any knowledge of dose/effect, and existence of a good threshold limit value. Safety hazards were considered separately.

All available data from Ontario records were assembled and reviewed, and these included statistics from the Workmen's Compensation Board, chest disease records, epidemiological studies, and data collected for the Royal Commission on the Health and Safety of Workers in Mines. The priority lists of both Environment Canada and MOE, already mentioned, were included in this review process.

A priority list was then assembled in a process whereby each representative prepared a rating and a consensus was reached for 17 hazards. These are listed in Table 1.

The list was prepared at the end of 1977 and is, as most other similar lists, constantly under review for changes in content and priority.

Despite the existence of such a list it must be conceded that work patterns are frequently disrupted by priorities of another kind which I know you have all experienced. I am referring, of course, to public, press, or political pressure, any of which can override our priority system.

In the Health Studies Service, when evaluating a toxic substance for its effect on human health, certain general principles are observed:

1. Our concern is for the medical aspects of the problem and the safety of the material for the target population, be this the worker, his family, or the community at large.

2. Evaluation tends to be towards a conservative approach, thus allowing for:
   a. Overlapping of risks - occupational/environmental
   b. The possible potentiation of action between pollutants
   c. Individual susceptibility

3. We must be prepared to review conclusions in the light of new evidence.

As a corollary to the above principles, I would add that we must also be aware of possible risks of substances used as alternatives, and of the extent of use of the product, potential for increase in use, and the adequacy of methods of measurement. If the current methods are inadequate, this should be stated. It is our experience that good data on exposure are vital to the determination of any accurate estimation of risk.

In an individual assessment of risk, the starting point is an extensive review of the literature. The Ministry of Labour library has a comprehensive

TABLE 1

MINISTRY OF LABOUR PRIORITY CHEMICAL SUBSTANCES

1. Asbestos	10. Silica
2. Benzene	11. Nickel
3. Chlorinated hydrocarbons (including PCB)	12. Arsenic
4. Carcinogens	13. Mercury
5. Diesel emissions	14. Isocyanates
6. Vinyl chloride	15. Lead
7. Noise	16. Vibration
8. Radiation	17. Wood Dust
9. Coke oven emissions	

index catalog to the journal literature as well as collections of monographs and research reports covering all areas of toxicology and occupational health and safety. Supplementary to this in-house material, the library has access to a wide range of data bases which provide very thorough and up-to-date coverage of world-wide literature and usually include abstracts of the articles. The most frequently used data bases for our purposes are those provided by the U.S. National Library of Medicine. These include Chemline, Toxline, Medline, Cancerline, and RTECS (Registry of Toxic Effects of Chemical Substances). In addition to these data bases, searches can be made on chemical and biological abstracts, NTIS (U.S. National Technical Information Services), and many others.

Any references not obtainable in the ministry library can usually be quickly obtained at the nearby Science and Medicine Library at the University of Toronto or through our own interlibrary loan services.

The quality of the published material is of vital importance. It is frequently found that early careful work, even with less sophisticated methods of measurement but compensated for by scrupulous observation, is of value.

Human and animal toxicology is reviewed, with the inclusion of as much information on metabolism as can be determined from both. In vivo and in vitro experiments are studied.

Concern is, as a general rule, on chronic toxicity from chronic doses at typically low-level concentrations and the end point is very often cancer. Acute exposures are unpredictable and need to be considered on an individual basis, but nevertheless may give clues directing attention to target organs or specific metabolic pathways.

In animal experiments, study is made of the test species and its suitability, the route of exposure and its suitability, level or levels or exposure, duration of exposure, and type and frequency of effects.

Epidemiological studies alone are sometimes of less value than would appear at first sight, and often lack accompanying environmental measurements or, more important, measurements relating to the time when first exposure took place. This is particularly true of many studies relating to cancer-causing agents and is quite understandable, given that some a priori judgement has to be made in order to collect the data in the first place.

In review of human metabolism, all routes of entry to the body are evaluated. For instance, air levels of the pollutant may predominate but contribution from food and water and skin contact may also be important. Information on environmental degradation or persistence forms part of our evaluation. Specific compounds must be separately assessed. Particle size and shape are obviously of great significance in calculations involving the dynamics of uptake and retention in the lung. Persistence in the body and the potential for mobilization of persistent forms of the chemical may be important in specific situations.

However, the potential for carcinogenicity remains the single most important factor for consideration, and this and the suspicion of mutagenicity

or teratogenicity greatly influence our recommendations. We hope to be able in this branch to increase our capability for applied research into the methods of study for identification of pre-malignant changes or host factors predisposing to cancer. Plans are under way for a joint facility with the University of Toronto.

There are problems facing us in important areas, pertinent to this workshop. One is the uncertainty of the relationship, in many instances, between exposure and human biological changes which themselves cannot at present be linked in any clear-cut way to an adverse health effect.

Another relates to the difficulties of finding, in epidemiological studies, a population large enough to demonstrate excess morbidity or mortality for the less common diseases, particularly certain forms of cancer. This leads us to search for different ways of assessing risk, such as by calculating the potential detriment to a given population by exposure to a given level of pollutant, and we are giving this aspect of our work much attention.

A third is the difficulty in translating effects on laboratory animals to man.

Additionally, we are constantly searching for ways to organize our work to produce an optimum balance between the priorities of the agencies we serve.

CHAPTER 19

MICHIGAN'S CRITICAL MATERIALS REGISTER AND HAZARD ASSESSMENT PROGRAM : PAST, PRESENT, AND FUTURE

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My presentation this afternoon is on Michigan's Critical Materials Register and Hazard Assessment Program. This presentation is designed to illustrate how the Critical Materials Register has evolved from a subjective list of chemical substances, selected by using a simple set of criteria, to an objective list of critical materials, selected on the basis of a comprehensive hazard assessment system.

The Critical Materials Register (CMR) was created in 1971 pursuant to Act 245, Public Acts of 1929 (Michigan Water Resources Commission Act), as amended by Acts 200 and 293, Public Acts of 1970 and 1972, respectively. These acts require annual reporting of wastewater discharge, and use and discharge of materials appearing on a Register of Critical Materials. Reports are required from every person doing business in Michigan who discharges wastewater to the waters of the state or any sewer system, if the wastewater contains process wastes in addition to sanitary sewage. The act provides for creation of an advisory committee of environmental specialists to assist in the compilation of the Register. Historically, the act delegated authority to the Water Resources Commission to implement this program. This authority has since been transferred, by executive order, to the director of the Department of Natural Resources.

The original CMR was developed by a committee of university, industrial, and state representatives under the guidance of the Water Resources Commission staff. This Register contained 73 specific compounds and classes of compounds which were selected because of their toxicity to organisms or aesthetic problems at concentrations of five parts per million or less (Table 1). The advisory committee selected these compounds based on data presented in the publication "The Control of Spillage of Hazardous Polluting Substances", prepared by Battelle Institute in 1970 for the Federal Water Quality Administration.

The advisory committee recognized numerous shortcomings inherent in the Register due to the limited data base. Because of this, provisions were made for periodic review and revision of the CMR as more information became available.

The advisory committee reconvened in 1972 and the Register was revised and reduced to 62 compounds and classes (Table 2). No changes were made in the Register between 1972 and 1976.

Numerous problems resulting from the release of toxic substances to the environment were discovered in the late 1960's and early 1970's. In response to these problems, the advisory committee was once again assembled in 1977 to

TABLE 1

MICHIGAN CRITICAL MATERIALS REGISTER - 1971

I. INORGANIC MATERIALS (BUT INCLUDING ORGANIC DERIVATIVES)

Classes of inorganic compounds:

A. Cations			B. Anions
Antimony	Lead	Silver	Azides
Arsenic	Mercury	Thallium	Cyanides
Cadmium	Nickel	Tin	Sulfides
Chromium	Selenium	Zinc	
Copper			

II. ORGANIC MATERIALS

A. Toxic to humans and/or fish at 5 ppm or less:

1. Organic compounds:

Abietic Acid	Dimethyl dioxane	Peracetic Acid
Acridine	Dioxane	Phenanthrene
Acrolein	Hydroquinone	Quinoline
Beta propriolactone	Lactonitrile	Quinone
Benzene	Mesityl Oxide	Turpentine
Benzaldehyde	Naptholic Acid	Polychlorinated Biphenyls
Benzyl Bromide	Napthol	Hexachlorobenzene
Dichloropropane	Napthenic Acid	Hexachlorobutadiene
Diethylbenzene	Oleic Acid	

2. Classes of organic compounds:

Amines	Nitrobenzenes
Anilines	Phenolic compounds
Butyraldehydes	Phthalates
Chlorinated Benzene Compounds	Pyridines
Ether containing compounds	Silanes

B. Cause aesthetic problems at 5 ppm or less (i.e. taste and odor)

Compounds		Classes of Compounds
Amyl Acetate	Ethyl Acrylate	Picramates
Butyl Alcohol	Isoprene	Xylenes
Butyric Acid	Mesitylene	
Carbon Disulfide	Styrene	
Crotonaldehyde	Vinyl Toluene	
Cumene		

III. PESTICIDES, HERBICIDES AND FUNGICIDES

Herbicides	Pesticides	
Tordon	Aldrin	Endrin
2,4,5-T (and its formulations)	DDT	Heptachlor
	Dieldrin	Toxaphene

Table 2. MICHIGAN CRITICAL MATERIALS REGISTER - 1972

I. INORGANIC MATERIALS	Parameter Number		Parameter Number
Antimony	95000	Mercury	95006
Arsenic	95001	Nickel	95007
Cadmium	95002	Selenium	95008
Chromium	95003	Silver	95009
Copper	95004	Sulfides	95015
Cyanides	95014	Thollium	95010
Lead	95005	Zinc	95012

II. ORGANIC MATERIALS	Parameter Number		
Acridine	95017	Hexachlorobenzene (HCB)	95040
Acrolein	95018	Hexachlorobutadiene (HCBD)	95041
Aldrin	95067	Hydroquinone	95027
*Ammonia	95089	Isoprene	95059
Amyl Acetate	95052	Lactonitrile	95028
Anilines (incl. Benzidines)	95043	Mesitylene	95060
Benzaldehyde	95021	Mesityl Oxide	95029
Benzene (Solvent)	95020	Napthol	95031
Benzyl Bromide	95022	Naphthenic Acid (Napthalene)	95032
Beta propriolactone	95019	Nitrobenzenes	95047
Butyl Alcohol	95053	Phenolic compounds	95048
Butyraldehydes	95044	Phrenanthrene	95035
Butyric Acid	95054	Phthalates	95049
Carbon Disulfide	95055	Picramates (nitro-phenols)	95063
Chlorinated Benzene Compounds	95045	Polychlorinated biphenyls (PCB's)	95039
Crotonaldehyde	95056	Pyridines	95050
Cumene	95057	Quinoline	95036
DDT	95068	Quinone	95037
Dichloropropane	95023	Styrene	95061
Dieldrin	95069	Tordon	95065
Diethylbenzene	95024	Toxaphene	95072
Endrin	95070	Vinyl Toluene	95062
Ethyl Acrylate	95058	Xylenes	95064
Heptachlor	95071	2-4-5 T (and its formulations)	95066

*New entry—initial reporting on this material not required until report due January 1974 (covering 1973 calendar year).

review and revise the CMR and chemical selection process. A decision was made to move toward development of an objective system for selection, and a model was developed to evaluate chemicals for possible inclusion on the CMR (Figure 1).

The criteria for selection of critical materials were developed so chemicals with known carcinogenicity and those exhibiting very high acute toxicity to mammals (i.e. LD_{50} less than 5 mg/kg) or aquatic life (i.e. LC_{50} less than 1 mg/L) were automatically placed on the CMR. Known carcinogens were defined as those chemicals appearing on the National Institute for Occupational Safety and Health (NIOSH) carcinogen list, those shown through epidemiological studies to be carcinogenic in man, or those shown to be carcinogenic at low doses in at least two species of laboratory animals. Chemicals exhibiting moderate acute toxicity, as defined by an LD_{50} range of 5 to 500 mg/kg for mammals or LC_{50} range of 1 to 10 mg/L for aquatic organisms, had to possess additional properties, implicating them as environmental hazards, before they were included on the Register. These properties included suspect carcinogenicity, mutagenicity, teratogenicity, bioaccumulation, environmental persistence, or affect the taste and odor of fish. Compounds exhibiting low acute toxicity (i.e. LD_{50} greater than 500 mg/kg or LC_{50} greater than 10 mg/L) were not included on the CMR.

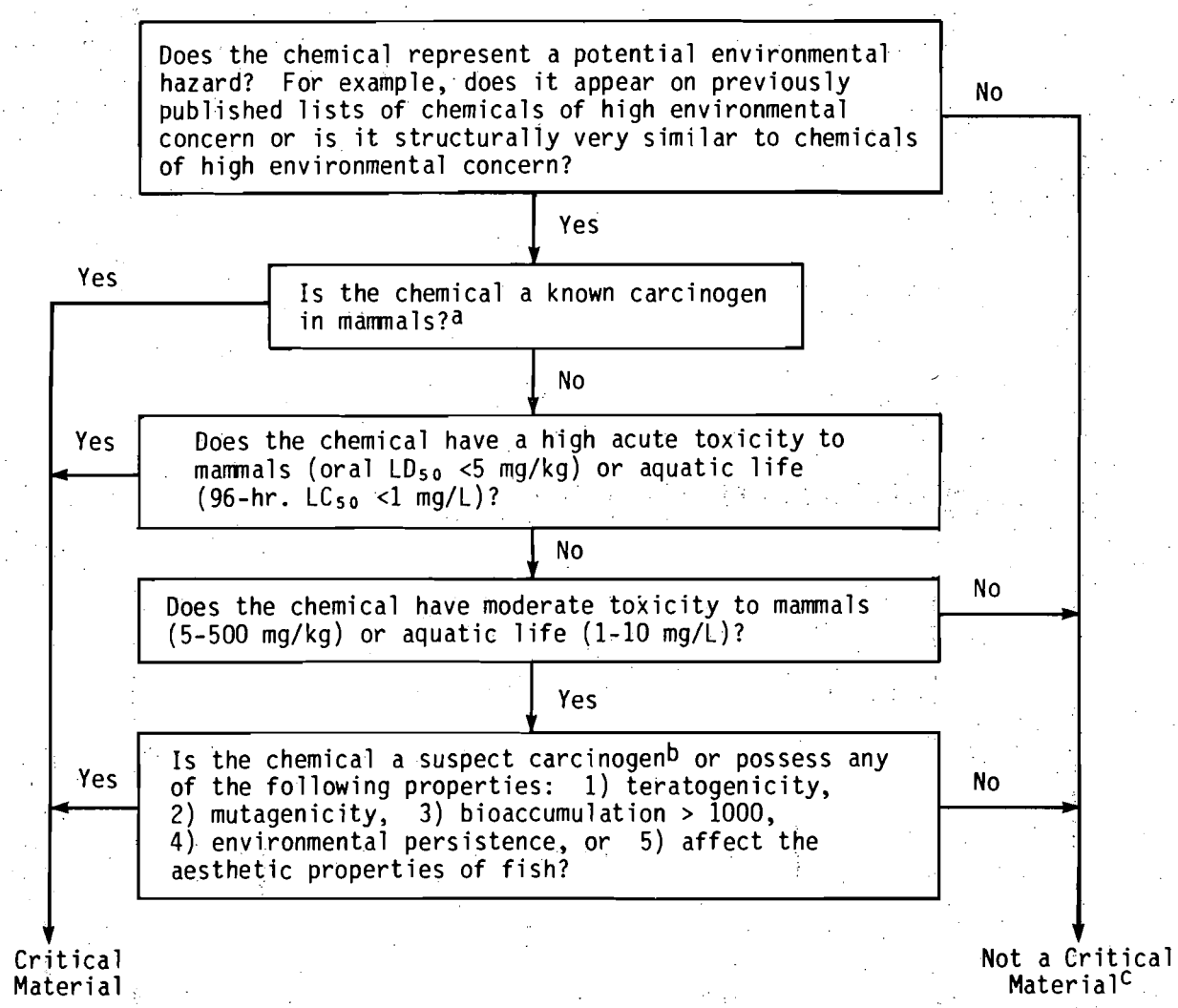
An enormous number of industrial compounds were being manufactured at this time. The advisory committee decided to limit screening to those chemicals recognized in the past by various authorities as representing potential environmental hazards. This was accomplished primarily by using previously published lists of toxic substances, including:

1. Michigan's 1976 CMR
2. The Federal Spill Regulations List
3. The List of Priority Pollutants compiled by the Environmental Protection Agency
4. The International Joint Commission Lake Ontario Persistent Toxic Pollutants List, 1977
5. The Environmental Protection Agency's Tentative List of Restricted-Use Pesticides, 1976.

A small number of additional compounds not appearing on these lists but identified as potential environmental hazards by the advisory committee were also screened.

The literature search and collection of data on these CMR candidates were performed by student assistants carefully selected from Michigan State University. Chemical evaluations began with a review of a variety of in-house references primarily used to define physical characteristics and develop an overview of toxicity and other adverse effects. The evaluations continued by using the resources of various sections of the State of Michigan, Michigan State University, and University of Michigan libraries. Physical, chemical, and toxicological data were compiled on a chemical evaluation form, which

Figure 1. MODEL FOR SCREENING AND SELECTING CRITICAL MATERIALS, 1977



a. A known carcinogen is defined as a chemical meeting one of the following criteria: 1) Appears on the NIOSH carcingoen list 2) has been demonstrated through epidemiological studies to be a human carcinogen 3) has been shown at low doses (1% of LD_{50}) to increase tumor production by oral administration in at least two species of animals.

b. A suspect carcinogen is defined as a chemical meeting the following criteria: has been shown to increase tumor production only at high doses (>1% of LD_{50}) or by a route other than oral or in only one species.

c. A chemical not meeting these criteria may still be designated a critical material if the CMR advisory committee determines the compound represents an unreasonable environmental risk due to other factors.

was then utilized by the advisory committee for screening the CMR candidates through the selection model. The end result was the 1977 CMR which contained 218 compounds and classes (Table 3).

The advisory committee reconvened early in 1978 to evaluate the existing program. With the rapidly expanding data base, the advisory committee decided to develop a more objective screening process which could better balance the degree of emphasis put on each factor. A hazard assessment process was developed using a priority ranking-point assignment system. Factors of environmental concern for potentially deleterious substances were separated into eight specific areas:

1. Acute toxicity
2. Carcinogenicity
3. Hereditary mutagenicity
4. Teratogenicity
5. Persistence
6. Bioaccumulation
7. Aesthetics
8. Chronic adverse effects

Criteria and rationales for each factor were developed. Each category within the eight individual factors was assigned a point value commensurate with its level of environmental concern in keeping with the overall objectives of the program. A chemical which received a score of seven points in one factor, or a cumulative score of seven points or more in several factors, was included on the 1978 CMR. The factors which have the most severe impacts on the environment and human health (i.e. acute toxicity, carcinogenicity, mutagenicity, teratogenicity, and bioaccumulation) received a maximum score of seven points. These factors represent a very high level of concern and were restrictively defined.

The acute toxicity criterion was divided into five scoring categories and a category for insufficient information (Table 4). This factor was scored according to the route of exposure and concentration of the chemical which elicited the effect. The critical concentrations defining the category classifications were based upon generally accepted critical levels found in the available literature on acute toxicity. A compound which is extremely toxic to mammals, as defined by an oral or dermal LD_{50} of less than 5 mg/kg, received a score of seven, while a compound which was moderately toxic to mammals received three points. Data available for each type of exposure were evaluated independently; however, the overall score assigned to the acute toxicity factor was the highest score given to any individual category. For example, a chemical substance which has an oral LD_{50} of 5 to 50 mg/kg, a dermal LD_{50} of 200 to 500 mg/kg, and an aquatic 96-hour LC_{50} of less than

1 mg/L was assigned a score of seven points based on the extreme aquatic toxicity.

The carcinogenicity criterion was also divided into five scoring categories and a category for insufficient information (Table 5). Seven points were given to a chemical which has been demonstrated to be a human positive, human suspect, or animal positive carcinogen by the oral or dermal route of exposure. Human positive carcinogens were defined as chemicals which had been demonstrated by epidemiological and/or clinical studies to cause cancer in man. Human suspect carcinogens were defined as chemicals which were animal positive carcinogens and had been suggested to cause cancer in man but adequate epidemiological and/or clinical data were not available at that time to unequivocally substantiate their carcinogenic effect in man. A chemical was classified as an animal positive carcinogen if it was shown to cause cancer in at least one animal species in replicate studies or demonstrated to cause cancer in more than one animal species. Chemicals were classified as human positive, human suspect, and animal positive carcinogens according to data reported by the International Agency for Research on Cancer, National Cancer Institute, or NIOSH.

An animal suspect carcinogen was defined as a chemical that caused cancer by the oral or dermal route of exposure in one animal species in a non-replicated study. This category received three points. Two points were given to chemicals which had been demonstrated to be an animal positive or animal suspect carcinogen by a route other than oral or dermal. A potential carcinogen received one point. Potential carcinogens were defined as chemicals which had been shown to cause mutations or cell transformations using tests designed to demonstrate carcinogenic potential.

The hereditary mutagenicity criterion was divided into four scoring categories and an insufficient information category (Table 6). A confirmed hereditary mutagen received a score of seven points. To be a confirmed mutagen, a chemical must produce both a statistically significant dose-related mutagenic effect in test microorganisms, without the use of metabolic activators, and an inheritable mutation in a complex multicellular animal. A chemical which produces only an inheritable mutation in a complex multicellular organism received a score of four points. Two points were assigned to chemicals which caused statistically significant dose-related mutations in exposed test microorganisms.

The teratogenicity criterion was divided into three scoring categories due to the limited data base (Table 7). A confirmed teratogen, as shown by epidemiological evidence or positive teratogenicity studies using two animal species, was scored seven points. Three points was assigned to a suspect teratogen.

The bioaccumulation criterion was divided into five scoring categories and a category for insufficient information (Table 8). This factor was assigned points according to data on bioaccumulation in fish or by using the n-octanol/water partition coefficient (log P) as an indicator of bioaccumulation. Priority was given to actual bioaccumulation information over partition coefficient data. A chemical which had a log P of 5.0 and was shown to bioaccumulate 800 times in fish received a score of two points.

Table 3. MICHIGAN CRITICAL MATERIALS REGISTER, 1977

I. Inorganic Materials

A. The following inorganic materials and all their compounds are to be reported

	Parameter Number
Antimony	Class-01-0
Arsenic	Class-01-1
*Beryllium	Class-01-2
Cadmium	Class-01-3
Chromium	Class-01-5
*Cobalt	Class-01-6
Copper	Class-01-7
Cyanides	Class-01-8
*Hypochlorite	Class-01-4
Lead (organic forms only)	Class-01-9
*Lithium	Class-02-0
Mercury	Class-02-1
Nickel	Class-02-2
Selenium	Class-02-3
Silver	Class-02-4
Thallium	Class-02-5
*Tin (organic forms only)	Class-02-6
Zinc	Class-02-7

B. The following specific inorganic materials are to be reported (do not report compounds)

	Parameter Number
Ammonia	07664-41-7
*Asbestos	01332-20-4
*Chlorine	07782-50-5
*Phosphorus (elemental)	07723-14-0
*Phosphorus oxychloride	10025-87-3
Hydrogen sulfide	07783-06-4
Potassium sulfide	01312-73-8
Sodium sulfide	01313-82-2

II. Organic Materials

	Parameter Number
*acetone cyanohydrin	00075-86-5
acridine	00260-94-6
acrolein	00107-02-8
*acrylonitrile	00107-13-1
*allyl chloride	00107-05-1
*aminoazobenzene	00060-09-3
*2-aminobiphenyl and 4-aminobiphenyl	Class-05-1
*amitrole	00061-82-5
aniline	00062-53-3
aziridines, including	
*ethyleneimine	00151-56-4
*N-(2-hydroxyethyl) ethyleneimine	01072-52-2
*propyleneimine	00075-55-8
*other aziridines (specify)	Class-05-2
benzene	00071-43-2
benzidine	00092-87-5
*benzo(a)pyrene	00050-32-8
*benzyl chloride	00100-44-7
*brucine	00357-57-3
butyric acid	00107-92-6
carbon disulfide	00075-15-0
*carbon tetrachloride	00056-23-5
*chlorinated dibenzofurans	Class-05-3
*chlorinated dioxins	Class-05-4
chloroalkyl ethers, including	
*bis (2-chloroethyl) ether	00111-44-4
*bis (2-chloromethyl) ether	00542-88-1
*methyl (chloromethyl) ether	00107-30-2
*other chloroalkyl ethers (specify)	Class-05-5
2-chloroaniline	00095-51-2
*2-chloroethanol	00107-07-3
*chloroprene	00126-99-8
crotonaldehyde	04170-30-3
di-n-butyl phthalate	00084-74-2
dichlorobenzenes	Class-05-6
3,3'-dichlorobenzidine	00091-94-1
*1,4-dichloro-2-butene	00764-41-0
dichloropropanes	Class-05-7
*dimethylamine	00124-40-3
*dimethylaminoacetyl -2,4,6-trimethylaniline	Class-05-8
*4-dimethylaminoazobenzene	00060-11-7
*dimethylbenzyl hydroperoxide	00080-15-9
*dimethyl sulfate	00077-78-1
epoxides, including	
*1-chloro-2,3-epoxypropane	00106-89-8
*ethylene oxide	00075-21-8
*2,3-epoxy-1-propanal	00765-34-4
*2,3-epoxy-1-propanol	00556-52-5
*other epoxides (specify)	Class-05-9
ethyl acrylate	00140-88-5
*ethylamine	00075-04-7
*ethylenediamine	00107-15-3

*indicates new critical material

Table 3. CONT'D.

Organic Materials (continued)

*ethylenediamine-tetraacetic acid (EDTA)	00060-00-4
*ethylene dibromide	00106-93-4
*formaldehyde	00050-00-0
*furfural	00098-01-1
hexachlorobenzene (HCB)	00118-74-1
hexachlorobutadiene (HCBD)	00087-68-3
*hexachlorocyclohexane (lindane)	00608-73-1
*hexachlorocyclopentadiene	00077-47-7
*hexamethylenetetramine	00100-97-0
hydrazines, including	
*diethylhydrazines	Class-06-1
*dimethylhydrazines	Class-06-2
*hydrazine	00302-01-2
*hydrazobenzene	00122-66-7
*semicarbazide	00057-56-7
*other hydrazines (specify)	Class-06-3
hydroquinone	00123-31-9
hydroxylamines, including	
*hydroxylamine	07803-49-8
*methyl hydroxylamine	00067-62-9
*other hydroxylamines (specify)	Class-06-4
lactonitrile	00078-97-7
*methylene(bis)-2-chloroaniline	00101-14-4
*methyl iodide	00074-88-4
naphthalenes, including	
*naphthalene	00091-20-3
naphthenic acid	01338-24-5
naphthol	01321-67-1
*1-naphthylamine and 2-naphthylamine	Class-06-5
*other naphthalenes (specify)	Class-06-6
nitrosoamines, including	
*N-nitroso-diethylamine	00055-18-5
*N-nitroso-dimethylamine	00062-75-9
*N-nitroso-dimethylaniline	00138-89-6
*other nitrosoamines (specify)	Class-06-6
*pentachloroethane	00076-01-7
*peroxyacetic acid	00079-21-0
phenolics, including	
2,3 and 4-chlorophenol	Class-07-1
cresols	
dichlorophenols	Class-07-3
2,3 and 4-nitrophenol	Class-07-4
pentachlorophenol (PCP)	00087-86-5
phenol	00108-95-2
resorcinol	00108-46-3
tetrachlorophenols	Class-07-5
trichlorophenols	Class-07-6
xylenols	Class-07-7
other phenolics (specify)	Class-07-0
*polybrominated biphenyls (PBB)	Class-07-8
polychlorinated biphenyls (PCB)	Class-07-9
*β-propiolactone	00057-57-8
quinoline	00091-22-5
quinone	00106-51-4
*sodium azide	26628-22-8
styrene	00100-42-5
sultones, including	
*1,4-butane sultone	01633-83-6
*1,3-propane sultone	01120-71-4
*other sultones (specify)	Class-08-1
*tetrachloroethanes	Class-08-2
*thiourea	00062-56-5
*triaryl phosphate esters	Class-08-4
triazenes, including	
*1-(4-chlorophenyl) -3,3-dimethyl triazene	20241-05-8
*3,3-dimethyl-1-phenyl triazene	07227-91-0
*other triazenes (specify)	Class-08-3
*tris (dibromopropyl) phosphate	00126-72-7
*vinyl chloride	00075-01-4

III Pesticides (To be reported only by manufacturers and formulators)

	Parameter Number
*aldicarb	00116-06-3
aldrin	00309-00-2
*4-aminopyridine	00504-24-5
*antimycin	00642-15-9
*atrazine	01912-24-9
*azinphos-methyl	00086-50-0
*barban	00101-27-9
*captan	00133-06-2
*carbaryl	00063-25-2
*carbofuran	01563-66-2
*carbophenothion	00786-19-6
*chlordane	00057-74-9
*chlordecone	00143-50-0
*chlorfenvinphos	00470-90-6
*chlorpyrifos	02921-88-2
*clonitralid	01420-04-8
*coumaphos	00056-72-4
*crotoxyphos	07700-17-6
*cycloheximide	00066-81-9
DDT	00050-29-3
*demeton	08065-48-3
*diallate	02303-16-4
*diazinon	00333-41-5
*dibromochloro-propane (DBCP)	00096-12-8
*dicamba	01918-00-9
*dichlone	00117-80-6
*dichlorophenoxyacetic acid (2,4-D)	00094-75-7
*dichlorvos	00062-73-7
*dicrotophos	00141-66-2
dieldrin	00060-57-1
*dimethoate	00060-51-5
*dinocap	39300-45-3
*dinoseb	00088-85-7
*dioxathion	00078-34-2
*diquat	00085-00-7
*disulfoton	00298-04-4
*diuron	00330-54-1
*endosulfan	00115-29-7
endrin	00072-20-8
*EPN	02104-64-5
*ethion	00563-12-2
*fensulfothion	00115-90-2
*fenthion	00055-38-9
*ferbam	14484-64-1
*fonofos	00944-22-9
heptachlor	00076-44-8
*leptophos	21609-90-5
*linuron	00330-55-2
*malathion	00121-75-5
*methomyl	16752-77-5
*methoxychlor	00072-43-5
*methyl mercaptan	00074-93-1
*methyl parathion	00298-00-0
*mevinphos	07786-34-7
*mexacarbate	00315-18-4
*mirex	02385-85-5
*monocrotophos	06923-22-4
*naled	00300-76-5
*nicotine	00054-11-5
*oxydemeton-methyl	00301-12-2
*paraquat dichloride	01910-42-5
*parathion	00056-38-2
*phorate	00298-02-2
*phosazetim	04104-14-7
*phosmet	00732-11-6
*phosphamidon	13171-21-6
*rotenone	00083-79-4
*silvex	00093-72-1
*simazine	00122-34-9
*sodium fluoroacetate	00062-74-8
*strychnine	00057-24-9
*sulfotepp	03689-24-5
*TDE	00072-54-8
*TEPP	00107-49-3
*terbufos	13071-79-9
*thiram	00137-26-8
toxaphene	08001-35-2
trichlorophenoxyacetic acid (2,4,5-T)	00093-76-5
*trichlorfon	00052-68-6
*trifluralin	01582-09-8
*triphenyltin hydroxide	00076-87-9
*ziram	00137-30-4

TABLE 4

HAZARD ASSESSMENT CRITERION, ACUTE TOXICITY

SCORE AND CATEGORY	ORAL LD_{50}	DERMAL LD_{50}	AQUATIC 96-HR LC_{50}
7 Extremely Toxic	<5 mg/kg	<5 mg/kg	<1 mg/L
3 Highly Toxic	5-50 mg/kg	5-200 mg/kg	1-10 mg/L
2 Moderately Toxic	>50-500 mg/kg	>200-500 mg/kg	>10-100 mg/L
1 Slightly Toxic	>0.5-5 g/kg	>0.5-5 g/kg	>100-1000 mg/L
0 Relatively Nontoxic	>5 g/kg	>5 g/kg	>1000 mg/L
* Insufficient Information			

TABLE 5

HAZARD ASSESSMENT CRITERION, CARCINOGENICITY

SCORE	CATEGORY
7	The chemical has been demonstrated to be a human positive, human suspect, or animal positive carcinogen by the oral or dermal route of exposure based on data reported by the International Agency for Research on Cancer (IARC), National Cancer Institute (NCI), or National Institute for Occupational Safety and Health (NIOSH).
3	The chemical has been demonstrated to be an animal suspect carcinogen by the oral or dermal route of exposure.
2	The chemical has been demonstrated to be an animal positive or animal suspect carcinogen by any route other than oral or dermal; or has been demonstrated by accepted mutagenicity screening tests or accepted cell transformation studies to be strongly potential carcinogen.
1	The chemical has been demonstrated by accepted mutagenicity tests or accepted cell transformation studies to be a potential carcinogen.
0	The chemical has been tested by the above systems and has not been demonstrated to cause cancer or to be a potential carcinogen.
*	Insufficient information

TABLE 6

HAZARD ASSESSMENT CRITERION, HEREDITARY MUTAGENICITY

SCORE	CATEGORY
7	Confirmed hereditary mutagen
4	Suspect hereditary mutagen in multicellular organisms
2	Suspect hereditary mutagen in micro-organisms
0	Not demonstrated to be a hereditary mutagen
*	Insufficient information

TABLE 7

HAZARD ASSESSMENT CRITERION, TERATOGENICITY

SCORE	CATEGORY
7	Confirmed Teratogen
3	Suspect Teratogen
0	Not Teratogenic
*	Insufficient Information

TABLE 8

HAZARD ASSESSMENT CRITERION, BIOACCUMULATION

	CATEGORY	
SCORE	BIOACCUMULATION	LOG P
7	$\geq$4000	$\geq$6.00
3	1000 - 3999	5.00 - 5.99
2	700 - 999	4.50 - 4.99
1	300 - 699	4.00 - 4.49
0	<300	<4.00
*	Insufficient Information	

The chronic effects, persistence, and aesthetics criteria were less restrictively defined because of limited data. These factors received, correspondingly, lower point values. Persistence of a chemical substance in the environment was of high concern since, through longer exposure, it may increase the impact of the other factors. However, four points was the maximum score for this factor due to the lack of standardization among test methods. The persistence criterion was divided into five scoring categories and one category for insufficient information (Table 9). Data in the form of half-life ($t_{0.5}$) of the chemicals in soil or water were used to allow comparisons between chemicals. The range of time defining the category classification was selected by the advisory committee based primarily on pesticide persistence information.

Aesthetic effects may have adverse impacts on the value and usefulness of aquatic systems. However, aesthetics was scored at a lower level since these effects are of less concern than the more critical biological effects. This criterion was divided into three scoring categories with a score of three being the highest point value (Table 10). The aesthetics factor was scored according to data on tainting of fish and/or taste and odor of water, or other properties of nuisance such as foaming, film formation, and coloring of water.

The final criterion, chronic adverse effects, was divided into four scoring categories, and it had a maximum score of four points (Table 11). This factor received a lesser rating primarily because test methods were not standardized or well defined, the test results were hard to interpret, and many of the more severe chronic effects were incorporated in other factors.

The data collection process was also revised during the development of the hazard assessment system. Existing data on critical materials and CMR candidates had to be updated and additional information had to be obtained before the advisory committee could accurately assess these materials using the eight-factor scoring system.

In order to accommodate the necessary data, the chemical evaluation form was redesigned. The form was enlarged and partitioned into five sections:

1. Chemical identification
2. Physical and chemical characteristics
3. Acute toxicity
4. Chronic toxicity
5. Environmental disposition

The chemical identification section included common chemical name, Chemical Abstract Service name and number, "Registry of Toxic Effects of Chemical Substances" identification number, and synonyms. The physical and chemical characteristics section included formula and structure; physical properties such as state, melting and boiling points, and solubility; n-octanol/water partition coefficient; and finally, uses, hazards, and production volume and location. Acute toxicity was divided into sections for data on terrestrial life, aquatic life, and humans. The chronic toxicity section included carcinogenicity, mutagenicity, teratogenicity, and other adverse chronic effects

TABLE 9

HAZARD ASSESSMENT CRITERION, PERSISTENCE

SCORE	CATEGORY	HALF LIFE IN WEEKS (SOIL OR WATER)
4	Very persistent	>52
3	Persistent	40 - 52
2	Slowly degradable	27 - 39
1	Moderately degradable	14 - 26
0	Readily degradable	0 - 13
*	Insufficient Information	

TABLE 10

HAZARD ASSESSMENT CRITERION, AESTHETICS

SCORE	ESTIMATED THRESHOLD LEVEL IN WATER (mg/L) PRODUCING TAINTING OF FISH AND/OR TASTE AND ODOR	FOAMING PROPERTIES AND/OR PRODUCES FLOATING FILM AND/OR IMPARTS MAJOR COLOR CHANGE TO WATER
3	0.0001 - 0.001	
2	>0.001 - 0.01	
1	>0.01 - 0.1	Yes
0	>0.1	No

TABLE 11

HAZARD ASSESSMENT CRITERION, CHRONIC ADVERSE EFFECTS

SCORE	CATEGORY
4	Irreversible effects
2	Reversible effects
1	Adverse effects by routes other than oral, dermal or aquatic
0	No detectable adverse effects
*	Insufficient information

to terrestrial life, aquatic life, and humans. The environmental disposition section included data on bioaccumulation, persistence, degradation products, and metabolism. It should also be noted that all information on the evaluation form was referenced.

Data were collected on a total of 418 chemical substances for the 1978 Critical Materials Register and Hazard Assessment Program. These included the 218 compounds or classes of compounds on the 1977 CMR and 200 additional compounds which were selected primarily from the "Preliminary List of 300 Chemical Substances" compiled by TSCA's Interagency Testing Committee.

The actual process of scoring the chemicals was carefully and accurately conducted to insure the integrity of the program. Each factor in the hazard assessment process was scored with either a point value or an asterisk for all chemical substances which were evaluated. A hazard assessment sheet was used to tally the scores (Table 12). All available data were fully evaluated to determine proper criterion and category placement. It was often necessary to obtain the original research publications before a decision could be made. A total of 190 compounds or classes received a cumulative score of seven or more points and these constituted the 1978 CMR (Table 13).

The advisory committee has met twice this year to discuss potential revisions of the existing Register and Hazard Assessment Program. A decision has been made to incorporate air pollution and inhalation toxicity data into the hazard assessment system. Criteria and rationales are being developed to implement this change. The chronic adverse effects factor, discussed earlier, has been rewritten to accommodate the rapidly increasing data base and to place increased emphasis on this factor. At the present time, student assistants are collecting data on approximately 500 compounds for hazard assessment and possible inclusion on the current Register. Many of these compounds were evaluated during previous years, but their data base was either incomplete or out of date. Computer searches are being used to facilitate information acquisition in addition to the data sources identified earlier.

Critical materials information reported by Michigan business is used principally in programs designed to identify and prevent toxic substances problems before they develop into crises. The major use of the data is to identify businesses using or discharging amounts of toxic substances which could cause environmental damage. Critical materials data from each reporting facility are compiled into a data acquisition system for review and analysis by Department of Natural Resources staff. Judgements on whether a quantity of a critical material being discharged is potentially detrimental are based on the characteristics of the facility, its receiving water, and the toxicity and other properties of the critical material itself. Use data and facility description information are analyzed to determine if cumulative loadings of critical materials are likely to be discharged from the facility and whether these discharges are likely to result in environmental degradation. Follow-up action may entail direct contact with the business for further information or clarification and/or a detailed inspection visit to the facility. If a facility inspection identifies a problem, a follow-up environmental assessment is conducted to determine the degree and extent of environmental contamination. Administrative procedures or formal legal action would be initiated to achieve abatement should such action be necessary.

The reported information is also used in the calculation of surveillance

Table 12. CRITICAL MATERIALS REGISTER HAZARD ASSESSMENT SHEET

Common Chemical Name _____
Chemical Abstract Name _____

Chemical Abstract No. |_|_|_|_|_|_|_| - |_|_|_| - |_|

I. Acute Toxicity

Score _____

Score	ORAL LD_{50} mg/kg	DERMAL LD_{50} mg/kg	AQUATIC 96 HOUR LD_{50} mg/L
7	<5	<5	<1
3	5-50	5-200	1-10
2	>50-500	>200-500	>10-100
1	>500-5000	>500-5000	>100-1000
0	>5000	>5000	>1000
*	Insufficient Information		

II. Carcinogenicity

_____

Score	Category
7	Human positive human suspect Animal positive
3	Animal suspect
2	Carcinogenic by a route other than oral or dermal Strongly potential carcinogen by accepted mutagenicity screening tests or accepted cell transformation studies
1	Potential carcinogen by accepted mutagencity screening tests or accepted cell transformation studies
0	Not carcinogenic
*	Insufficient Information

III. Hereditary Mutagenicity

_____

Score	Category
7	Confirmed
4	Suspect - multicellular organisms
2	Suspect - micro-organisms
0	Not a hereditary mutagen
*	Insufficient Information

IV. Teratogenicity

_____

Score	Category
7	Confirmed
3	Suspect
0	Not teratogenic
*	Insufficient Information

V. Persistence

_____

Score	Category
4	Very persistent
3	Persistent
2	Slowly degradable
1	Moderately degradable
0	Readily degradable
*	Insufficient Information

VI. Bioaccumulation

_____

Score	Bioaccumulation	Log P
7	>4000	>6.00
3	1000-3999	5.00-5.99
2	700-999	4.50-4.99
1	300-699	4.00-4.49
0	<300	<4.00
*	Insufficient Information	

VII. Aesthetics

_____

Score	Category: Fish Tainting/Taste and Odor (Threshold level in water - mg/l)	Category: Foaming, floating film, and/or major color change
3	0.0001-0.001	
2	>0.001-0.01	
1	>0.01-0.1	Yes
0	>0.1	No

VIII. Chronic Adverse Effects

_____

Score	Category
4	Irreversible effects
2	Reversible effects
1	Adverse effects by route other than oral, dermal, or aquatic
0	No detectable adverse effects
*	Insufficient Information

Table 13. MICHIGAN CRITICAL MATERIALS REGISTER, 1978

I. Inorganic Materials

A. The following inorganic materials and *all their compounds* are to be reported

	Parameter Number
antimony	Class-01-0
arsenic	Class-01-1
beryllium	Class-01-2
cadmium	Class-01-3
chromium	Class-01-5
cobalt	Class-01-6
copper	Class-01-7
cyanides	Class-01-8
hypochlorite	Class-01-4
lead	Class-01-9
lithium	Class-02-0
mercury	Class-02-1
nickel	Class-02-2
selenium	Class-02-3
silver	Class-02-4
thallium	Class-02-5
zinc	Class-02-7

B. The following specific inorganic materials are to be reported (do not report compounds)

	Parameter Number
chlorine	07782-50-5
hydrogen sulfide	07783-06-4

II. Organic Materials

	Parameter Number
acetone cyanohydrin	00075-86-5
*2-acetylaminofluorene	00053-96-3
acrolein	00107-02-8
*acrylamide	00079-06-1
*acrylic acid	00079-10-7
acrylonitrile	00107-13-1
aminoazobenzene	00060-09-3
4-aminobiphenyl	00092-67-1
amitrole	00061-82-5
aniline	00062-53-3
benzene	00071-43-2
benzidene	00092-87-5
benzo(a)pyrene	00050-32-8
brucine	00357-57-3
1,4 butane sultone	01633-83-6
carbon disulfide	00075-15-0
carbon tetrachloride	00056-23-5
*chloramines	Class-08-6
chlorinated dibenzofurans	Class-05-3
chlorinated dioxins	Class-05-4
1-chloro-2,3-epoxypropane	00106-89-8
2-chloroethanol	00107-07-3
*chloroform	00067-66-3
bis(2-chloroethyl)ether	00111-44-4
bis(2-chloromethyl)ether	00542-88-1
2,3 and 4-chlorophenol	Class-07-1
1-(4-chlorophenyl) -3,3-dimethyl triazene	07203-90-9
chloroprene	00126-99-8
di-n-butyl phthalate	00084-74-2
cresols	Class-08-5
dichlorobenzenes	Class-05-6
3,3'-dichlorobenzidine	00091-94-1
dichlorophenols	Class-07-3
dichloropropanes	Class-05-7
1,2,3,4 diepoxybutane	00298-18-0
4-dimethylaminoazobenzene	00060-11-7
dimethylhydrazines	Class-06-2
3,3-dimethyl-1-phenyl triazene	07227-91-0
dimethyl sulfate	00077-78-1
2,3-epoxy-1-propanal	00765-34-4
ethylene dibromide	00106-93-4
ethyleneimine	00151-56-4
ethylene oxide	00075-21-8
formaldehyde	00050-00-0
hexachlorobenzene (HCB)	00118-74-1
hexachlorobutadiene (HCBD)	00087-68-3
hexachlorocyclohexane (lindane)	00608-73-1

*indicates new critical material

Table 13. CONT'D

Organic Materials (continued)	
hexachlorocyclopentadiene	00077-47-4
hydrazine	00302-01-2
hydrazobenzene	00122-66-7
hydroquinone	00123-31-9
n-(2-hydroxyethyl)ethyleneimine	01072-52-2
lactonitrile	00078-97-7
methyl(chloromethyl)ether	00107-30-2
methylene(bis)-2-chloroaniline	00101-14-4
*1,2(methylenedioxy)-4-propenyl benzene	00120-58-1
*methyl hydrazine	00060-34-4
naphthalene	00091-20-3
1-naphthylamine	00134-32-7
2-naphthylamine	00091-59-8
*4-nitrobiphenyl	00092-93-3
2,3 and 4-nitrophenol	Class-07-4
n-nitroso-diethylamine	00055-18-5
n-nitroso-dimethylamine	00062-75-9
n-nitroso-dimethylaniline	00138-89-6
pentachloroethane	00076-01-7
*pentachloronitrobenzene	00082-68-8
pentachlorophenol	00087-86-5
peroxyacetic acid	00079-21-0
phenol	00108-95-2
polybrominated biphenyls (PBB)	Class-07-8
polychlorinated biphenyls (PCB)	Class-07-9
1,3-propane sultone	01120-71-4
β-propiolactone	00057-57-8
propyleneimine	00075-55-8
semicarbazide	00057-56-7
styrene	00100-42-5
tetrachloroethanes	Class-08-2
*tetrachloroethylene	00127-18-4
thiourea	00062-56-6
triaryl phosphate esters	Class-08-4
*trichloroethylene	00079-01-6
trichlorophenols	Class-07-6
tris(dibromopropyl)phosphate	00126-72-7
vinyl chloride	00075-01-4
xylenols	Class-07-7

III Pesticides (To be reported only by manufacturers and formulators)

	Parameter Number
aldicarb	00116-06-3
aldrin	00309-00-2
4-aminopyridine	00504-24-5
antimycin A	01397-94-0
*azinphos-ethyl	02642-71-9
azinphos-methyl	00086-50-0
barban	00101-27-9
*bendiocarb	22781-23-3
*benomyl	17804-35-2
captan	00133-06-2
carbaryl	00063-25-2
carbofuran	01563-66-2
carbophenothion	00786-19-6
chlordane	00057-74-9
chlordecone	00143-50-0
chlorfenvinphos	00470-90-6
chlorpyrifos	02921-88-2
clonitralid	01420-04-8
coumaphos	00056-72-4
crotoxyphos	07700-17-6
cycloheximide	00066-81-9
DDT	00050-29-3
demeton	08065-48-3
diallate	02303-16-4
diazinon	00333-41-5
dibromochloropropane (DBCP)	00096-12-8
dichlone	00117-80-6
dichlorophenoxyacetic acid (2,4-D)	00094-75-7
dichlorvos	00062-73-7
dichrotophos	00141-66-2
dieldrin	00060-57-1
dimethoate	00060-51-5
dinocap	39300-45-3
dinoseb	00088-85-7
dioxathion	00078-34-2
diquat	00085-00-7
disulfoton	00298-04-4
endosulfan	00115-29-7
endrin	00072-20-8
EPN	02104-64-5
ethion	00563-12-2
fensulfothion	00115-90-2
fenthion	00055-38-9
fonofos	00944-22-9
*fluchloralin	33245-39-5
heptachlor	00076-44-8
leptophos	21609-90-5
malathion	00121-75-5
*maleic hydrazide	00123-33-1
methomyl	16752-77-5
methoxychlor	00072-43-5
methyl mercaptan	00074-93-1
methyl parathion	00298-00-0
mevinphos	07786-34-7
mexacarbate	00315-18-4
mirex	02385-85-5
monocrotophos	06923-22-4
naled	00300-76-5
nicotine	00054-11-5
oxydemeton-methyl	00301-12-2
paraquat	01910-42-5
parathion	00056-38-2
phorate	00298-02-2
phosazetim	04104-14-7
phosmet	00732-11-6
phosphamidon	13171-21-6
rotenone	00083-79-4
silvex, propylene glycolbutyl ether ester	02317-24-0
simazine	00122-34-9
sodium fluoroacetate	00062-74-8
strychnine	00057-24-9
sulfotepp	03689-24-5
TDE	00072-54-8
TEPP	00107-49-3
terbufos	13071-79-9
thiram	00137-26-8
*torak	10311-84-9
toxaphene	08001-35-2
trichlorfon	00052-68-6
*trichloronate	00327-98-0
trichlorophenoxyacetic acid (2,4,5-T)	00093-76-5
trifluralin	01582-09-8
triphenyltin hydroxide	00076-87-9
ziram	00137-30-4

fees required from industry. These fees are used for monitoring for critical materials and other water pollution concerns. Critical Materials Register data are used in the development and revision of National Pollutant Discharge Elimination System (NPDES) permits. All chemicals included on the CMR must be considered in a Pollution Incident Prevention Plan developed by each facility using or storing these materials, as required by the Part 5 rules of Act 245, as amended. Critical materials data are also made available to other governmental agencies. The Michigan Department of Public Health utilizes the data to identify potential impacts on human health via exposure to water contaminated by critical materials. The Air Quality Division of the Department of Natural Resources can make use of these data to investigate possible fugitive emissions of critical materials.

Funding for an expanded Critical Materials Register data analysis, follow-up, and compliance monitoring program is being sought from the Environmental Protection Agency via a Toxic Substances Control Act Cooperative Agreement. The objectives of this agreement will be to develop:

1. A more efficient, effective, and comprehensive system for analyzing and sorting CMR data

2. An expanded program to investigate potential problems identified by CMR data analysis

3. A program to monitor and increase compliance with the CMR program

4. Procedures to integrate the CMR program more closely with existing pollution control programs.

Additionally, the handling and storage of chemical evaluation data and hazard assessment scores would be computerized.

In conclusion, Michigan's Critical Materials Register has evolved from a subjective list of chemical substances, selected by using a rather limited data base and a simple set of criteria, to an objective list of critical materials, selected on the basis of a comprehensive hazard assessment system using a more complete data base. The major limitation in our program, as with any other hazard assessment procedure, is the data base. The degree of objectivity in a hazard assessment system is controlled by the availability and accessibility of pertinent information. Academia, industry, and government must work together to increase the quantity and quality of information on environmental chemicals. Major emphasis must be placed on standardizing environmental testing protocols. Additionally, cooperative international data acquisition systems must be further developed to increase the accessibility of this information.

In closing, I must emphasize that members of the CMR advisory committee, past and present, deserve the entire credit for this work. I trust that I have accurately conveyed their product to you. I would like to take this opportunity to thank all the people who have served on the advisory committee, with special recognition to representatives from academia and industry.

Additional information on the Michigan Critical Materials Register and Hazard Assessment Program is available from the Michigan Department of Natural Resources, Office of Toxic Materials Control, P.O. Box 30028, Lansing, Michigan 48909.

CHAPTER 20

HAZARD ASSESSMENT IN WISCONSIN

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In Wisconsin, the state Department of Natural Resources is responsible for the environmental protection program. These responsibilities include the protection of water supplies, the abatement of air and water pollution, and the regulation of the disposal of solid wastes. The state Department of Health and Social Services has the responsibility for public health and radiation protection; the state Department of Agriculture, Trade and Consumer Protection is responsible for pesticide regulation; and the state Division of Emergency Government coordinates the state's response to floods, tornados, and other disasters. My remarks will be limited to the programs and activities of the Department of Natural Resources.

The department has a staff of about 360 engineers, biologists, chemists, other technical personnel, attorneys and administrators to carry out the environmental program. Structurally the program is divided into three major segments: air management, water management, and waste disposal. Geographically, the department has a central office in Madison and six district offices with satellite area offices which administer the program.

Under a new Wisconsin law passed in 1978,

> Hazardous substance means any substance or combination of substances, including wastes, of a solid, liquid, gaseous or semisolid form which, because of its quantity, concentration or physical, chemical or infectious characteristics, may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness, or pose a substantial present or potential hazard to human health or the environment. Such substances may include, but are not limited to, those which are, to the degree determined by the Department, toxic, corrosive, flammable, irritants, strong sensitizers or explosive.

Hazardous substances problems surface as a result of department surveillance programs, monitoring and reporting by industry, and tips provided by an environmentally conscious public.

Fish kills, vegetation die offs, irritating air, unsightly conditions, and contaminated water supplies are all reported to us by the public very soon after the event occurs. We also experience about one chemical or oil spill per day which is reported to the department. In addition we periodically uncover problems resulting from the improper disposal of hazardous wastes. All of these events trigger the initiation of our hazards assessment process.

Each problem is handled differently, but typically we use the following reference sources when assessing hazards:

1. For contaminants in fish and wildlife - the U.S. Food and Drug Administration (FDA) tolerance levels for foods sold in interstate commerce.

2. For substances in water - the interim primary drinking water regulations established by the U.S. Environmental Protection Agency (EPA), "Water Quality Criteria" (EPA Red Book), the lists of hazardous substances and the list of toxic pollutants published by EPA pursuant to the Federal Water Pollution Control Act.

3. For responding to spills of hazardous substances - Volumes I and II of the chemical "Hazard Response Information System" published by the U.S. Coast Guard.

4. For substances in the air - "Documentation of the Threshold Limit Values for Substances in Workroom Air", published by the American Conference of Government Industrial Hygienists.

In addition, we use many other reference texts and refer to the biological and the chemical literature. When the literature does not provide the answers, we telephone other state agencies, EPA, FDA, the Chemical Transportation Emergency Center (CHEMTREC), or other sources to see if we can get the answers. In many instances, however, there are no answers available.

A case in point is our investigation of chlorinated and nonchlorinated compounds in the lower Fox River. The lower Fox River is 39 miles long and receives the treated discharge from 15 pulp and/or paper mills, one electric power plant, and 11 municipal wastewater treatment plants serving a population of over 250,000 people.

In this investigation we studied wastewater, surface waters, sediments, snow, and biological samples and were able to identify 105 compounds by gas chromatography/mass spectometry. Twenty of these compounds including PCB's appear on EPA's list of toxic pollutants. Other compounds identified, including chloroguaiacols, chlorophenols, resin acids, and chlororesin acids have been reported to be toxic to fish by other investigators of pulp and paper mill wastewaters. Also identified were other wood-extractive and lignin-related compounds such as acetovanillone, fatty acids, guaiacol, syringaldehyde, and vanillin. Several identified compounds commonly used in industry are benzothiazole, bisphenol A, and nonyl phenol. Several compounds apparently not previously reported in wastewater are chloroindole, chlorosyringaldehyde and, tentatively, chlorobisphenol A's.

Concentrations of the various compounds ranged from 0.5 to 100 µg/L. An exception was dehydroabietic acid (DHA), a toxic resin acid not found on the Priority Pollutant List. It was frequently found in pulp and paper mill effluents in concentrations ranging from 100 to 8,500 µg/L.

The Fox River investigation provided more questions than answers. For instance:

1. Little or nothing is known about the toxicities of many of the compounds identified.

2. Where toxicity data are available, there is often a lack of threshold toxicity values for aquatic life.

3. For those substances found which appear in EPA's toxic pollutant list, there are no applicable effluent standards at the present time.

4. There is no information on most of the substances identified with respect to their potential for bioaccumulation and, except for PCB's and DDT, there are no FDA standards for levels of these substances in foods.

To answer all of the questions raised by this study would take several years of work utilizing the combined effects of many laboratories.

A second example of the problems with hazard assessment is provided by the train derailment which occurred near East Troy on July 16, 1974 and resulted in the spillage of 75,000 pounds of phenol. In spite of a prompt clean-up effort, private wells in the vicinity were soon contaminated with phenol. Persons up to 5 miles away were insisting that their wells were also contaminated. Our testing of private wells showed that wells close to the spill site contained up to 300 mg/L of phenol while those further out and upgradient from the direction of groundwater flow from the spill site contained up to 0.018 mg/L phenol.

A decision had to be made to define the level of phenol in drinking water which would indicate contamination. Residents with contaminated water supplies would then be supplied with drinking water. In our search for standards for phenol in drinking water we found the U.S.S.R. standard of 1 mg/L which appeared to be too high and EPA's recommended standard of 0.001 mg/L for chlorinated water supplies (based on taste and odor considerations) which appeared to be far too low. Finally we elected to use a standard of 0.1 mg/L recommended by our state health officer.

About 20 homes having wells exceeding this level were supplied with water until a deep municipal well could be constructed to supply the area. Had we gone to the 0.001 mg/L standard, an unworkable number of residents would have had to have been supplied with drinking water because our testing showed that groundwaters normally exceeded 0.001 mg/L phenol in many locations.

The Fox River study and the phenol spill illustrate the fact that in hazard assessment we are frequently at the frontiers of knowledge. At such times the answers can only be obtained through investigation and research. Funding is always needed for staff and laboratory capability to adequately assess the hazards which are brought to our attention.

CHAPTER 21

HAZARD ASSESSMENT IN NEW YORK STATE - INTRODUCTION

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A broad range of toxic-substances-related programs in New York State require an assessment to be made to determine possible public health and environmental impacts. On the one hand, there are programs in which ambient or emission levels must be set for specific chemical substances. These levels include water quality standards for classified bodies of water, permissible air emission levels for specific sources, the development of action levels in relation to spills and other emergencies, and the development of action levels to determine when advisories on consumption of fish and wildlife should be issued. On the other hand, there are case-specific problems where an individual site, such as a dump or a contaminated sediment, must be evaluated for its specific public health and environmental hazards.

To obtain a meaningful hazard assessment, the questions asked must be phrased carefully. We are still grappling with that problem but in general the appropriate questions for our purposes take the following forms:

1. Does an imminent threat to public health or the environment exist that requires immediate state action?

2. Does a potential hazard to public health or the environment exist that requires state action?

3. What numerical value (concentration or total amount) should be established in a particular medium or resource to protect public health and the environment?

In New York, the Department of Environmental Conservation has the regulatory authority to control emissions to the environment, and it also has a major natural resource management responsibility. It has the expertise to assess hazards to the environment, but it must rely on the Department of Health to advise it on matters related to public health hazards. This bureaucratic structure has led New York to develop a two-pronged approach using the Department of Health's Toxicology Center for the public health assessment and the Department of Environmental Conservation's Bureau of Environmental Protection for the environmental assessment. A working relation between the two departments on hazard assessment has been in effect for about two years, and it is constantly being refined as our experience grows.

Dr. Nancy Kim of the New York State Department of Health will explain how assessments of public health hazards are made, and Dr. Edward Horn of the New York State Department of Environmental Conservation will explain how assessments of environmental hazards are made.

CHAPTER 22

ENVIRONMENTAL HAZARD ASSESSMENT IN NEW YORK STATE

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As Bob Collin noted in his introduction, there are at least two different types of hazards that require different approaches to their evaluation. The first is a recognized hazard that can be addressed by the establishment of proper effluent or ambient standards. We know, for example, the concentration at which many chemical substances are toxic or produce other deleterious effects. In practice, we can, therefore, establish water quality or air quality standards which will insure both human health and the maintenance of a balanced indigenous population of living organisms. Many human activities can be regulated in this fashion because we have a reasonably good idea of what substances are involved, how they are reaching the environment and, in a gross way, what the effects will be. Another type of hazard exists, however, which cannot be regulated via standards. Abandoned dumps and landfills may constitute an environmental hazard which must be evaluated by field investigation. Our preference is to use test animals in a bioassay to evaluate this type of hazard.

For both types of hazard, however, a need exists to precisely define what constitutes an imminent or potential environmental hazard. Table 1 presents a list of criteria for identifying an environmental hazard. Standards should be set to prevent these criteria from being met, and these criteria should be used in evaluating dumps and landfills for the existence of a hazard.

This presentation will describe the basic framework of standard setting and environmental hazard evaluation in New York.

WATER QUALITY STANDARDS

New York has recently begun to revise its water quality standards. This is the first attempt to draft standards for a variety of toxic substances, particularly metals, pesticides, and miscellaneous toxic organic compounds. This effort has received a great deal of criticism from industrial representatives who fear a significant economic impact. I will not address economic analysis of these standards except to recognize the need to have one performed, preferably by a neutral third party.

The first step in establishing water quality standards involves the selection of chemical compounds which require regulation. In New York, this choice required weighing the toxicity, amount of use, and present occurrence

TABLE 1

ENVIRONMENTAL HAZARD CRITERIA[a]

1. Morbidity and/or mortality of any individual of an endangered species of plant or animal.
2. Morbidity and/or mortality of large numbers of non-endangered plants or animals.
3. Reproductive failure of any species of plant or animal.
4. Contamination of fish or wildlife edible flesh to an extent that its consumption by humans is considered a health risk.
5. Substantial disruption of a large or unique ecosystem.
6. Damage to unique natural or man-made structures.

a. Modified from Reference (37).

of the substance in New York biota. Compounds in widespread, large usage and those with demonstrated toxicity, particularly those known to be detected in aquatic biota, received attention first. A Statewide Industrial Survey conducted by the Department of Environmental Conservation in 1977 has provided us information about a wide variety of organic compounds. We plan to gather similar information on the use of agricultural pesticides. A Statewide Toxic Substances Monitoring Program has provided information regarding contamination of fish populations. Both types of surveys identify areas in the state that deserve more monitoring attention and/or some form of management action.

Once the priority compounds have been identified, a maximum acceptable toxicant concentration (MATC) must be determined. We have adopted the principle that the MATC ("safe concentration") should reflect a no-observable-effect concentration for the most sensitive fish species.

Several methods have been developed to derive the MATC. Some of these rely on field observation, but most rely on extrapolation or interpretation of laboratory studies. The most direct method involves determining by field exposure that fish survive for some predetermined time and measuring the concentrations of the variety of toxicants present (15, 17). Problems with this approach for standard setting include the inability to control fluctuations of toxicants, to isolate interactions of toxicants, and to detect the very low concentrations of the toxicant.

Most of these problems can be alleviated by exposing fish in laboratory culture to a variety of toxicant concentrations. Two types of exposure are commonly used, static and flow-through, with the latter preferred for a number of reasons. In either type of study, however, the "safe concentration"depends on the type of effect that one observes and how long one looks for an effect. Ideally, a whole life cycle should be completed under exposure, thus assuring that all stages in the life cycle have been tested for sensitivity to the toxicant. Short-term (24-hour) exposure of adults with observation of effect limited to lethality provides much less assurance that a MATC has been identified than chronic studies.

To accommodate the varying types of information available regarding the toxicity of various compounds, we have adopted a modification of the method described by Mount and Stephan (31) and by Henderson (16). This method employs an application factor (AF) to median tolerance limits (TL_m) to determine the MATC. Thus,

$$MATC = AF \times TL_m$$

If extensive long-term chronic bioassay information is available, there is no need to adjust the TL_m downward and the application factor is one. On the other hand, if only short-term acute studies have been done, the MATC is undoubtedly lower than the measured TL_m. It is not unusual for the application factor to be as low as 0.01 or 0.001. Table 2 contains application factors experimentally derived (i.e. using both chronic and acute data for the same fish and toxicant). Summarized in Table 3, one can see that very low application factors (0.001) are needed for persistent pesticides while a MATC can be safely estimated from acute studies for non-metals and non-persistent pesticides using application factors as high as 0.1. Reliance on application

Table 2. CALCULATED EXPERIMENTALLY DERIVED APPLICATION FACTORS FOR CERTAIN CHEMICALS AFFECTING FISH OR SAFE FOR FISH AS REPORTED IN SCIENTIFIC LITERATURE.[a]

Chemical	Fish Species	Application Factor		Reference
		Safe	Unsafe	
Metals				
Cadmium	Flagfish	0.0016	0.0032	Spehar, 1976
Cadmium	Fathead minnow	0.005	0.008	Pickering and Gast, 1972
Cadmium	Bluegill	0.0015	0.0039	Eaton, 1974
Copper	Fathead minnow	0.03	0.07	Mount, 1968
Copper	Fathead minnow		0.07	Pickering et al., 1977
Copper	Fathead minnow	0.14	0.24	Mount and Stephan, 1969
Copper	Fathead minnow	0.04	0.07	Brungs et al., 1976
Copper	Brook trout	0.10	0.17	McKim and Benoit, 1971
Copper	Bluegill	0.02	0.04	Benoit, 1975
Chromium (hexavalent)	Brook trout	0.003	0.006	Benoit, 1976
Chromium (hexavalent)	Rainbow trout	0.003	0.006	Benoit, 1976
Lead	Rainbow trout	0.0035	0.0064	Davies et al., 1976
Lead	Brook trout	0.012	0.029	Holcombe at al., 1976
Methylmercury	Brook trout	0.004	0.013	McKim et al., 1976
Silver	Rainbow trout	0.006-0.014	0.013-0.026	Davies et al., 1978
Zinc	Fathead minnow	0.003	0.02	Brungs, 1969
Zinc	Flagfish	0.017	0.034	Spehar, 1976
Non-metallics				
Chlorine (total residual)	Fathead minnow	0.12-0.17		Arthur et al., 1975
Chloramines	Fathead minnow	between 0.1 and 0.2		Arthur and Eaton, 1971
Chloramines	Coho salmon	0.20	0.38	Larson et al., 1977
Cyanide	Fathead minnow	0.11	0.16	Lind et al., 1977
Cyanide	Brook trout	0.06	0.12	Koenst et al., 1977
Other non-pesticide/non-metallics				
Linear alkylate sulfonate	Fathead minnow	0.15	0.32	McKim et al., 1975
Pesticides (persistent)				
Atrazine	Brook trout	0.01	0.02	Macek et al., 1976
Atrazine	Bluegill	0.01	0.07	Macek et al., 1976
Atrazine	Fathead minnow	0.01	0.03	Macek et al., 1976
Chlordane	Brook trout		<0.007	Cardwell et al., 1977
Chlordane	Bluegill		0.021	Cardwell et al., 1977
Diazinon	Fathead minnow		<0.0004	Allison and Hermanutz, 1977
Diazinon	Brook trout		<0.0007	Allison and Hermanutz, 1977
Guthion®	Fathead minnow	0.0017	0.0027	Adelman and Smith, 1976
Heptachlor	Fathead minnow	0.12	0.26	Macek et al., 1976
Lindane	Bluegill	0.30	0.42	Macek et al., 1976
Lindane	Brook trout	0.34	0.64	Macek et al., 1976
Lindane	Fathead minnow	0.13	0.34	Macek et al., 1976
Trifluralin	Fathead minnow	0.017	0.044	Macek et al., 1976
Pesticides (non-persistent)				
Acrolein	Fathead minnow	0.14	0.50	Macek et al., 1976
Carbaryl	Fathead minnow	0.023	0.075	Carlson, 1971
Captan	Fathead minnow	0.26	0.62	Hermanutz et al., 1973
Captan	Bluegill	0.26	0.62	Hermanutz et al., 1973
Endosulfan	Fathead minnow	0.23	0.47	Macek et al., 1976
Malathion	Bluegill	0.043	0.090	Eaton, 1970
Malathion	Fathead minnow	0.019	0.053	Mount and Stephan, 1967

a. From Reference (35).

factors to set standards may result in establishing an unnecessarily stringent water quality standard or may provide inadequate protection to the biota. It is clearly less satisfying than having long-term chronic exposure data. Setting the value of the application factor will always require a great deal of judgement, and thus the uniformity of approach undergirding the set of standards will probably be violated. Some standards will be less stringent and less protective than others. In the absence of a better methodology, however, New York has used this method in establishing its revised set of standards.

SITE-SPECIFIC HAZARDS

Many sources of toxicants cannot be regulated or assessed by setting standards. Indeed, the identification of some hazards may not be efficiently addressed by the available types of chemical analysis for a variety of known toxicants. Abandoned dumps and landfills are prime examples, particularly when the owners, operators, or manufacturers of the discarded material cannot be located or did not keep adequate records. Some form of field bioassay makes the most sense under these circumstances, although simple field inspection by qualified biologists can often be equally effective. Hazards to aquatic biota are more easily identified but, in principle, the effect of volatilized toxicants could also be demonstrated.

Three different types of bioassay have been utilized in New York, two utilizing fish and the third, macroinvertebrates (immature insects). The simplest (logistically) entails capturing small fish (usually dace or other minnows) from an upstream or nearby stream location and placing the caged fish at a defined effluent or just downstream. A control group of fish is placed in an appropriate comparable habitat. Such bioassays can often be extended over several days and have in some cases extended over several weeks. Thus, they are only sensitive to highly toxic conditions or rapidly bioaccumulated materials such as PCB. In the Hudson River, four native species of fish accumulated 2.6 µg/g Aroclor 1016 in their edible flesh over 14 days (39).

This same approach can be modified by using laboratory-cultured fish such as fathead minnows *(Pimephales promelas)* or presumably any organism that is easily reared. We have chosen fathead minnows because they are reasonably sensitive to a wide variety of toxicants, rather ubiquitous in New York waters, and can acclimate to a wide array of natural waters. As a model organism, few other fish possess their attributes. The major shortcoming to using a laboratory-reared fish is the time and inconvenience needed to acclimate the fish to natural physical conditions (temperature in particular) at the site.

New York has begun to experiment with a third approach in order to find a more sensitive and rapid bioassay. Insects with aquatic stages in their life cycle are ubiquitous in aquatic ecosystems. Enough individuals can usually be collected in the field, placed in wire (stainless steel) or plastic cages, and exposed to an effluent or to a presumed contaminated body of water. Observations can often be carried out over several days under ideal conditions. Organisms must, of course, be selected to survive in the physical conditions of the site and should also be kept under control conditions to evaluate the method of handling and other spurious sources of mortality.

TABLE 3

SUMMARY OF "SAFE" APPLICATION FACTORS FOR VARIOUS TYPES OF TOXICANTS DETERMINED FROM LABORATORY EXPERIMENTATION [a]

CHEMICAL GROUP[b]	APPLICATION FACTOR			
	> 0.1	< 0.1	< 0.01	< 0.001
Non-metals	80	20	0	0
Metals	6	94	50	0
Non-persistent pesticides	57	43	0	0
Persistent pesticides	31	69	38	15

a. Values represent the percentage of results which fall in the range noted.

b. Specific compounds or substances can be found in Table 2.

All bioassays suffer by not providing much information about the specific cause of mortality or morbidity. A pathologist can sometimes narrow down the cause of death, and extensive work with macroinvertebrates may eventually provide similar or better resolution. Some chemical analysis is almost always required. Although the source of mortality is not necessary to prove that a hazard exists, remedial action becomes almost impossible until the causative agent has been identified. At present and for the foreseeable future, good judgement, intuition, and luck will be required to pinpoint the primary source of a problem.

SUMMARY

In New York, assessing and managing environmental hazards relies on two different approaches. Where specific toxicants are known to be discharged into the environment, "safe" standards are set primarily from laboratory experiments. These maximum acceptable toxicant concentrations (MATC) reflect no observable effect on the most sensitive fish species. Mortality from 96-hour exposures or reproductive failure generally constitute the observed effect.

If the specific toxicants are unknown but a discharge or other site is a possible hazard, in situ bioassays yield the quickest and least controversial evaluation. No one questions an environmental hazard if fish cannot survive in the water or accumulate enough of a toxicant to be considered unsafe to eat.

Surely, any less stringent testing or standard setting will fail to protect the native biota. It is conceivable, however, that these measures may not adequately protect our fish and wildlife resources. Substances which bioaccumulate must be treated with extreme caution, as their effects are often not observed from direct exposure to the toxicant. Bioaccumulation appears to correlate well with the octanol/water partition coefficient (29), but undoubtedly exceptions exist. We may not be able to prevent all environmental hazards, but the approach which is presented here should go a long way toward controlling the most flagrant.

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CHAPTER 23

NEW YORK STATE DEPARTMENT OF HEALTH'S HAZARD ASSESSMENT PROCEDURE

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The initial involvement in risk and health assessment carried out by the New York State Department of Health centered on determining acceptable levels of organic chemicals in drinking water. In addition, we have been concerned with arriving at guidelines for contaminants in food products such as fish. We have served as an advisor for the state's Department of Environmental Conservation by providing information regarding the possible human health effects of organic chemicals and stating the levels which may present an unacceptable risk to public health. More recently, we have been involved in recommending guidelines for ambient levels of compounds in air and water. These guidelines are used by the Department of Environmental Conservation to calculate air and water emissions which should not endanger public health through subsequent chronic ingestion or inhalation.

The first methods used by the Health Department to arrive at acceptable ambient concentrations were those suggested by the National Academy of Sciences, by the Food and Drug Administration (FDA), and by the World Health Organization (WHO). For the most part, these groups use similar methods and make use of the same types of toxicological procedures. The National Academy of Sciences' publication, "Drinking Water and Health", provides a basic review of toxicological problems and methodology. Their protocols were recommended to the Environmental Protection Agency as methods for regulating contaminants in drinking water and can provide a quick reference for many of the concepts that will be touched on only lightly in the following discussion.

There are four basic approaches which the department has used in setting an acceptable intake level for a compound. Which method is ultimately chosen for a particular compound depends, to a great extent, on the quantity and quality of available toxicological data. The four methods are:

1. Calculating dose-risk relationships from carcinogenic experiments
2. Establishing no-observed-adverse-effect levels
3. Analyzing for chemical similarities
4. Categorizing organic chemicals by functional groups.

The first method can only be used if the compound under consideration has been shown to be a carcinogen and has animal or human dose-response data. The

second method, involving a no-observed-adverse-effect level, is not restricted to carcinogenic compounds but does require that a substantial amount of toxicological data be available for that compound. The last two methods are used when very little toxicological information exists for the compound under consideration. The third method is used if the compound is chemically very similar to another substance which has been studied extensively. The fourth method is used if the compound has not been studied but resembles a group of compounds that has some toxicological data. This last approach is most useful if the compound contains only one functional group.

From the above description, obviously the first two methods are the methods of choice; however, they require a substantial amount of toxicological data. For many questions, particularly those arising from industrial discharges into water, adequate toxicological data cannot be found. Even the most common measurement of toxicity, the oral-rat LD_{50}, has not been determined in these instances. The last two methods have been developed to answer those questions and, because of the very nature of their derivation, involve a number of assumptions; in addition, many doubts can be expressed about the appropriateness of their use. If these methods were not used, the only other choice would be to give no answer and either completely eliminate discharges of these chemicals or allow unlimited discharges. These last alternatives seem equally undesirable and less acceptable than using a reasonable, although questionable, method to arrive at some decision.

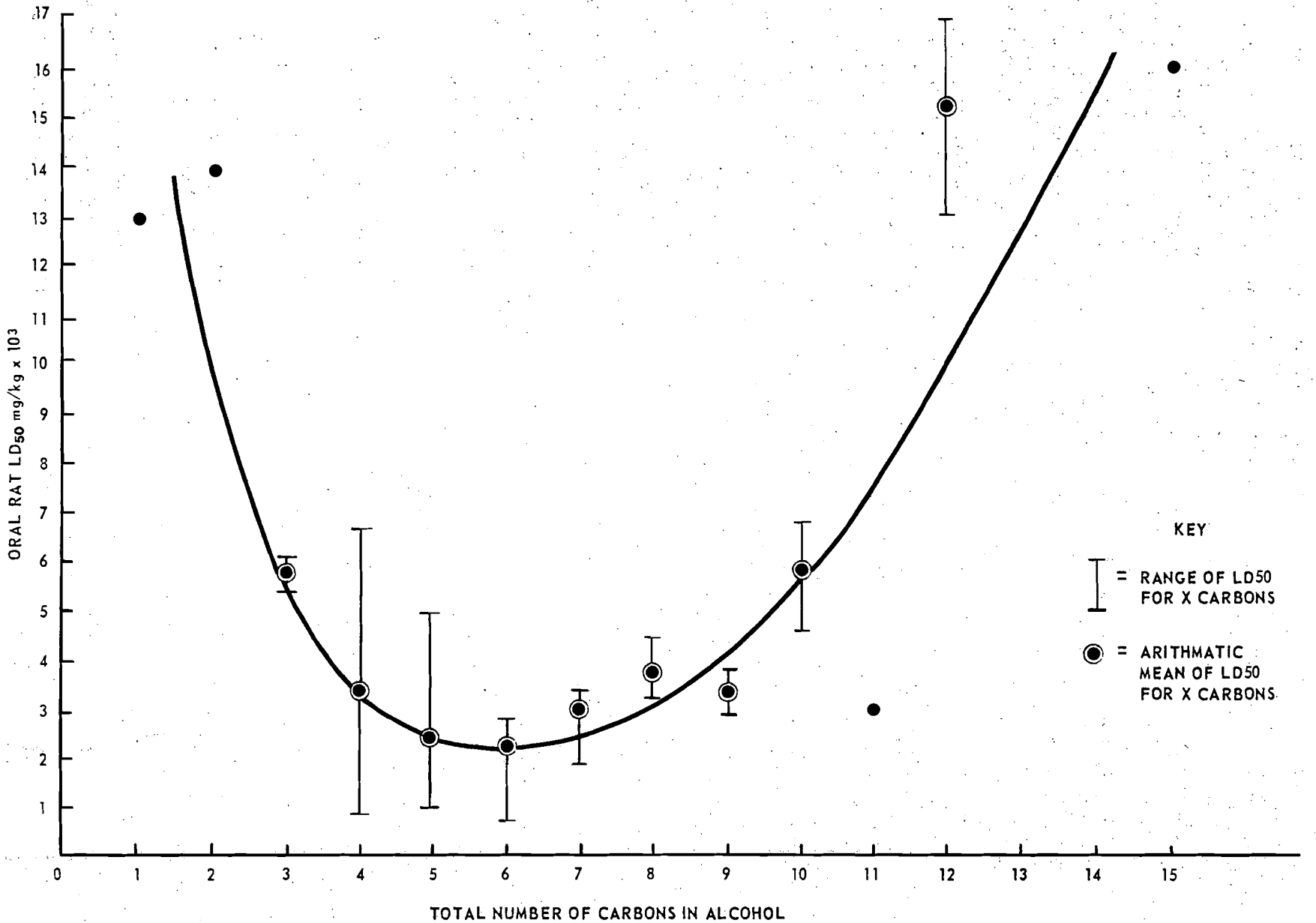
A cancer-risk calculation usually uses dose-response data from animal studies. Although human data would be preferable, quantitative, epidemiological data are almost impossible to obtain for use in these calculations. The Department of Health uses two statistical methods, the log-probit method of Mantel-Bryan and a version of the Armitage-Doll theory computerized by Guess, Crump, and Deal. These programs fit the usual animal dose-response data to a curve and extrapolate to lower dose levels. The dose for a given risk from the animal data is then converted to a human dose using an interspecies conversion based on differences in surface area. Therefore, a particular dose can be associated with a particular risk; the decision as to what is an acceptable risk cannot be based solely on scientific information but must consider other factors. Currently, the department is tentatively using as an acceptable lifetime risk 1×10^{-6} at a statistical assurance level of 95%, which is approximately the same acceptance level used by FDA for determining allowable residues of carcinogenic compounds in food.

With the second method, a no-observed-adverse-effect level (a dose which does not produce a toxic effect) is determined. The highest level in a multi-dose animal experiment which did not produce a toxic effect is used to set the guideline. The dose from the experiment is expressed in milligrams per kilogram, modified by a safety or uncertainty factor, and converted to milligrams for man. This value is known as an acceptable daily intake (ADI). Assumptions are made as to the amount of air taken into the lungs or the amount of water that is drunk in a day by a person. After a fraction of the total ADI for each route of entry is established, an ambient guideline for air or water can be calculated.

One example of using chemical similarity involves the phosphonate type of compound that is widely used in some industrial formulations. HEDP,

FIGURE 1

LD_{50} OF ALIPHATIC ALCOHOLS BASED ON NUMBER OF CARBONS



(1-hydroxyethylidene)bisphosphonic acid, is an organic phosphonate compound that is used in the treatment of Paget's disease and in bone-scanning techniques. Because it has been prescribed for the treatment of a disease, some human, chronic, toxicological data are available that can be used to set a guideline. A guideline for another, similar compound, TePMEDA (N,N-tetraphosphonomethylethylenediamine), was needed. This compound has been tested for use in bone-scanning techniques but has not been administered to humans in a chronic manner. Therefore, a limited amount of biochemical information is available, including sites of deposition in the body and organ distribution. Since these processes are similar for both compounds, the same guideline was suggested for each. This technique is only useful for two chemically very similar compounds, one of which has been studied extensively or at least to the extent that some level of acceptable chronic exposure can be established.

The Department of Heath has begun to establish a system for regulating compounds using chemical properties. The compounds that had been found in drinking water prior to the summer of 1977 were examined for available toxicological data and were arranged into classes depending on the functional groups present in the molecules. All the data that could be found in secondary sources for any compound in one of these classes were assembled. The data included were oral-rat LD_{50} values, drinking water standards developed by WHO or any other country, and threshold limit values proposed by the Occupational Safety and Health Administration or the American Conference of Governmental and Industrial Hygienists. Other general ideas such as metabolism and the possible bioaccumulation in man of a class of compounds were also considered. A guideline for drinking water was based on the more toxic members of each class. Compounds shown to be more toxic than the majority of the class were given separate guidelines. This approach is very useful in obtaining a first approximation of the toxicity of a particular compound and seems reasonable when very little or no toxicological information is available for a particular compound.

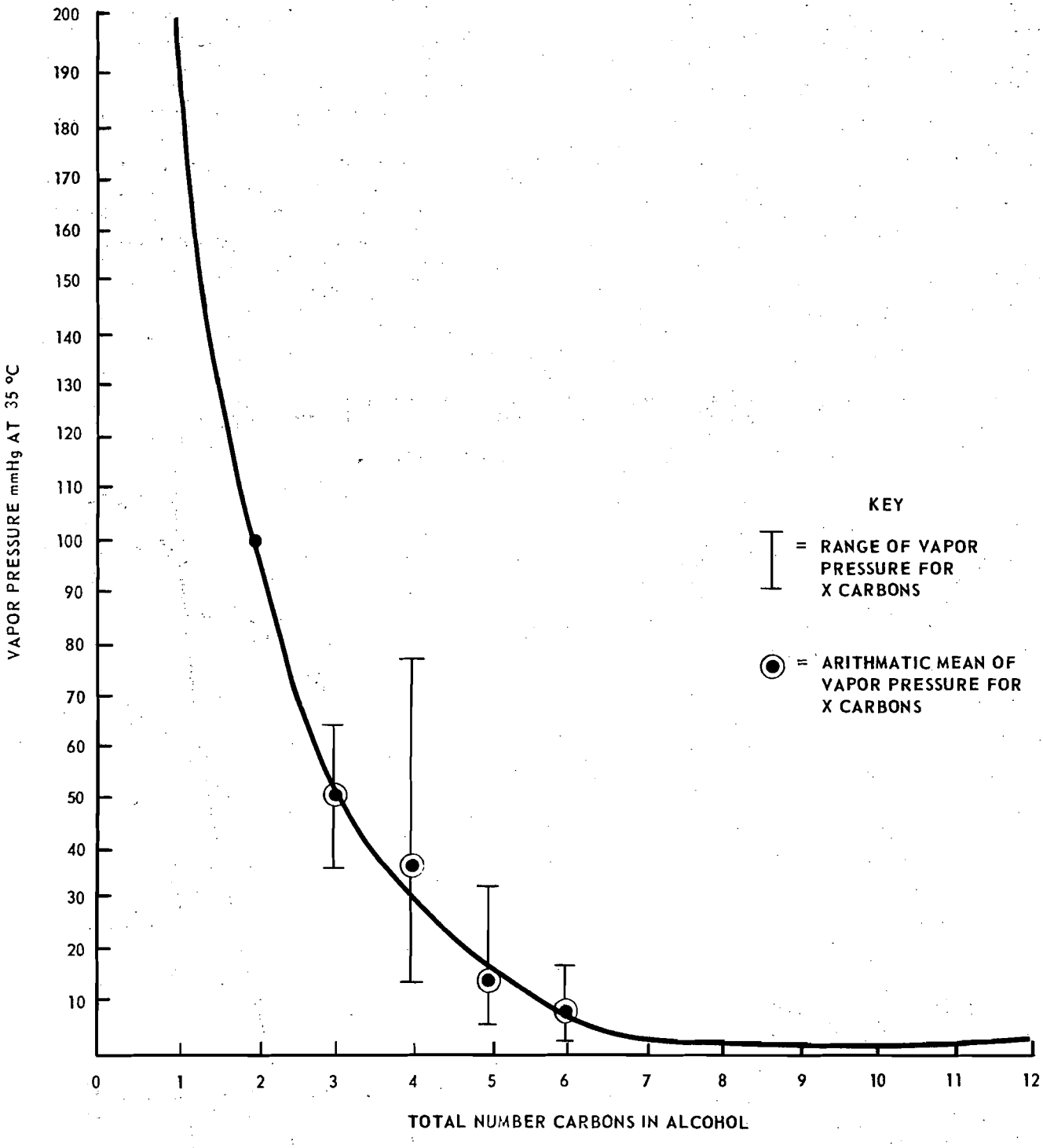
The derivation and a possible scientific validation of the class value for aliphatic alcohols will be given as an example. In Figure 1, the oral-rat LD_{50} values for aliphatic alcohols are plotted versus total carbons in the molecule. The observed trend may be related to the physical-chemical properties of the compounds.

The explanation for the variaton may involve the absorption and excretion characteristics of these compounds. For example, the percentage absorbed by the gastrointestinal tract may decrease as the total carbons in the alcohol increase. Also exhalation by the lungs is a possible route of excretion; the compounds with high vapor pressures, corresponding to those alcohols with fewer carbons, may be exhaled rapidly without being metabolized. The combination of these two processes may explain the observed trend in oral-rat LD_{50} values. Graphs of vapor pressure and log (octanol/water) partition coefficients, which may measure absorption and excretion properties, are also presented (Figures 2 and 3).

A second example of the fourth procedure involves four compounds which are derivatives of hexachlorocyclopentadiene. None of the compounds under consideration had enough toxicological information to set a guideline on the basis of cancer-risk calculations or no-observed-adverse-effect levels. One

FIGURE 2

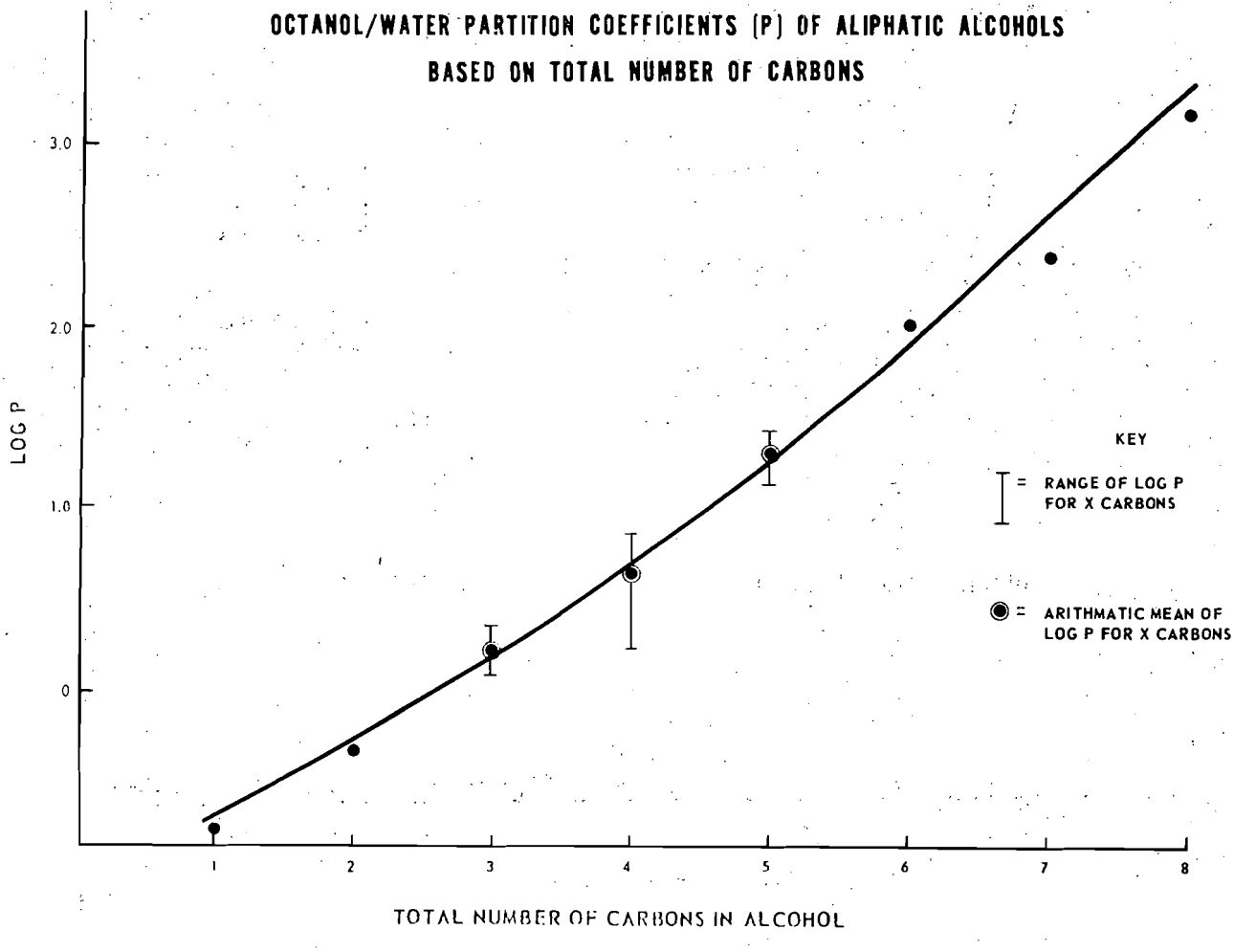
VAPOR PRESSURE OF ALIPHATIC ALCOHOLS BASED ON TOTAL NUMBER OF CARBONS



had been implicated as a metabolite of heptachlor or dilor (two pesticides which are hexachlorocyclopentadiene derivatives). Another had some information from acute toxicity studies and from a few limited chronic toxicity studies. The other two compounds were chemically similar to hexachlorocyclopentadiene and other diene pesticides which have been studied extensively. A guideline was set for the compounds under consideration by examining the standards that had been set for other halogenated diene pesticides and using the standards of the more toxic dienes in the group. Most of the diene pesticides considered have been shown to be carcinogenic in at least one animal species and, as such, have dose-response data on which to base a cancer-risk calculation. However, these data were not used; the diene pesticide standards considered were based on no-observed-adverse-effect levels.

This has been a brief summary of the department's approach to setting guidelines for chemicals in air, water, and food. As is true with most toxicological decisions, many assumptions are made and at times the question of arbitrariness can be raised. However, the methodologies chosen are the best available at this moment and hopefully protect the public health and welfare under conditions that may not allow a well-defined, completely defensible, scientific procedure.

FIGURE 3



CHAPTER 24

THE COSTS OF NOT TESTING NEW CHEMICALS, OR WHAT YOU DON'T KNOW CAN HURT YOU

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As a point of departure for my discussion today, I would like to share with you an incident that happened last August. The event concerns an explosion at a chemical facility and release of a pesticide to the surrounding community. It is representative of the exposure of humans and the general environment to any chemical substance and mixture covered by the Toxic Substances Control Act (TSCA). One should keep in mind, while listening to this tale, whether the exposures of humans and the environment, to this or any other chemical substance, was preventable.

Just before 8 A.M. on Friday, August 18, 1978, there was an explosion at the Stauffer Chemical Company facility located in Chicago Heights, Illinois. Three miles away, the force of the explosion knocked Ray Bakke out of bed and his sleeping parakeet off its perch.

The force of the blast set off burgler alarms all over the communities south of Chicago: Calumet City, Whiting, Highland, Gary, and Hammond. A block away, the explosion uprooted a telephone pole and threw it across two cars.

Carol Bond, who lives about two miles away from the Stauffer plant, said, "There was a big, red ball and smokey fire in the sky after the explosion. Thick, black smoke just billowed out all over." In addition, a black mushroom cloud lifted off the site and travelled south.

The blast took place on the second floor of a three-story building owned by Stauffer Chemical. The interior of the building was destroyed. Two men were killed, buried under the rubble as they sat in a company lunchroom located next to the room in which the blast took place. The explosion took place because of an apparent mishap in handling a highly toxic pesticide called EPN. Stauffer spokesmen were stunned. "EPN is not classified as a volatile material", a Stauffer representative told the press. "It will burn, but it doesn't catch fire easily. It's certainly not thought of as being explosive."

Chicago Heights is home to at least a dozen industries that store material known to be volatile and, as a result, the Chicago Heights police and fire departments try to be prepared to handle chemical disasters. Unfortunately, almost no one knew that Stauffer was manufacturing EPN at Chicago Heights, and even fewer people were aware that EPN was capable of causing permanent central nervous system damage. Among the federal agencies, only the U.S.

Environmental Protection Agency (EPA) - not the Occupational Safety and Health Administration and not the National Institute of Occupational Safety and Health - knew that EPN was being manufactured in Chicago Heights. Furthermore, the EPA was forbidden to divulge that information to the public, under the provisions of Title 10 of the FIFRA, which protects a manufacturer's trade secrets. More on this later.

There were 18,000 pounds of EPN in Stauffer's Building 81, and almost all of it escaped. A reporter later described it as gathering in yellow puddles around the site. Liquids from the site also ran into Thorn Creek, a tributary of the Little Calumet River. When this material was tested it was found to contain not only EPN, but also p-nitrophenol (a degradation product of EPN), formaldehyde, hydrochloric acid (the combination of these two chemicals leads to the formation of BCME), sulfuric acid, phosphoric acid, and other solvents. Some of the chemicals probably escaped in the smoke that billowed off the site.

It is now difficult to assess the levels of EPN to which people may have been exposed. The few tests taken that Friday found relatively low levels: Levels of EPN in run-off from the site were less than 1.0 ppm, while airborne levels half a mile away from the plant were less than 1.0 ppb. It should, however, be pointed out that the air sampling was performed in the wrong direction to the prevailing wind pattern at the time the sampling was done.

Chicago Heights Fire Chief Giulio Narcisi arrived at the Stauffer plant about three minutes after the alarm sounded. He was immediately told that EPN was involved in the explosion and that it was dangerous. He told reporters, however, that the Stauffer officials also said that there would be little real danger from EPN because the chemical decomposes quickly on contact with water. In fact, although EPN does decompose more quickly than do other pesticides, it requires about 40 hours to degrade, even under optimum conditions. Apparently, however, both fire and police personnel were told that gloves were the only protective clothing they required, even though Chicago Heights fire trucks were equipped with protective clothing and masks.

According to fire department officials, Stauffer Chemical representatives also told them that there was no need to evacuate the area unless smoke from the plant touched the ground. (It should be mentioned that at the time of the explosion the Chicago area had a typical August temperature inversion; as a result any airborne EPN was held in the immediate area for approximately 36 hours). At a food processing plant near the Stauffer site, plant managers ran onto the lawn of their building when the explosion took place and also observed the rescue operations from the building's roof. Several of the men breathed smoke from the site for periods of from 15 minutes to half an hour. When they called the Chicago Heights fire department, a switchboard operator told them they were in no danger.

Aside from the police and fire department, members of the public received no information from Stauffer. John G. Gliottoni, Chicago Heights Commissioner of Public Health and Safety, was on the scene three minutes after the alarm, but he was not told about EPN. He walked through the chemicals in his street clothes.

Personnel from the Metropolitan Sanitary District (MSD) of Greater Chicago also became involved in the blast site when it was discovered that chemicals flowing into Thorn Creek might reach the Chicago River. Fifteen MSD workmen, in addition to supervisors, spent from two to ten hours each at the site, some of them becoming soaked to the skin in chemicals while constructing a dam to keep the chemicals from spreading. According to internal MSD memoranda, MSD personnel began arriving at the site around noon; they were not informed that the chemicals might be dangerous until after 8 P.M.

By about 1 P.M. Stauffer employees, rescue workers, and others had begun arriving at St. James Hospital in Chicago Heights complaining of chest irritation, breathing difficulties, nausea, and dizziness. 57 people went to St. James, and 35 were kept overnight.

Citizens for a Better Environment (CBE) became involved in this when it became apparent that Stauffer Chemical and the EPA were not going to inform the public about the long-term health hazards of exposure to EPN. I had been studying the toxicity data base on EPN and was in possession of EPN-related documents obtained under the Freedom of Information Act.

The data base on EPN is quite substantial and most of it points to the conclusion that EPN is capable of causing delayed, progressive deterioration of the central nervous system. Further, the Office of Pesticide Programs is now entering its third year of reviewing the risks associated with the continued use of EPN. The EPN working group has concluded that all pesticides containing EPN which are registered ". . . exceed the chronic risk criterion relating to delayed neurotoxicity." Furthermore, based upon exposure estimates, they have concluded that the anticipated amount of EPN to which field workers and scouts may be exposed by inhalation may not provide an ample margin of safety. Moreover, unprotected persons located adjacent to sites of application may inhale doses of EPN which may not provide an ample margin of safety and, finally, that the estimated exposure of the general population to EPN resulting from the consumption of residues on food may not provide an ample margin of safety.

The acronym EPN stands for o-ethyl-o,p-nitrophenyl phenyl phosphonthioate. It is structurally related to leptophos. The majority of the toxicity testing on EPN has been conducted in chickens, and the lowest effective concetration of EPN which will cause ataxia in the hen is 10 ppb. Applying a safety factor of 100 would make the safe exposure concentration for humans 100 ppt.

The first patent on EPN was taken out by the E.I. DuPont de Nemours Company in 1950. The only other patent is held by Nissan Chemical Company Ltd., of Japan, dating from 1967. There are only two manufacturers of EPN in this country: Velsicol Chemical Company, in Bayport, Texas, and Stauffer Chemical Company, at Chicago Heights, Illinois and Mount Pleasant, Tennessee. Stauffer manufactures EPN exclusively for DuPont Chemical Company, in an arrangement similar to the one which Life Sciences had with Allied Chemical in Hopewell, Virginia.

You may well be wondering what this all has to do with TSCA. The preceeding example came about not through lack of information but through a

failure to disclose that information to the public. With the type of testing that is being suggested for a new chemical substance, one wonders whether EPA will be provided with sufficient information with which to make a determination of safety, and whether this information will be shared with the public.

The House Committee Report giving the legislative history of TSCA stated specifically that:

> . . . Because of the lack of testing by manufacturers and processors of chemicals to determine their health and environmental effects, the general population and the environment now serve as the laboratory for discovering adverse health and environmental effects. Aside from the glaring inequities in relying on human experience to indicate when a chemical is harmful, such a method is also a grossly inefficient way to identify problems. For example, vinyl chloride and asbestos were relatively easy hazards to identify because exposure to these agents could be correlated to incidences of otherwise rare cancers in a uniquely defined group of workers. Other kinds of hazards, and other substances, cannot be expected to present such easily traceable cause and effect relationships. As a result exposure to an extremely harmful chemical may continue unabated because the harm it causes will never be linked to the chemical.

It seems reasonable to conclude that Congress, when it passed the TSCA wished to protect human health and the environment from unreasonable risks from exposures to new chemical substances as well as existing chemical substances. Section 4(b)(2)(A) of the act states that:

> The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and other characteristics which may present such a risk. . . .

As it presently stands, the EPA Office of Toxic Substances is concerned with obtaining human health effects information, primarily information dealing with a substance's propensity to cause cancer, mutations (somatic cell), and birth defects. CBE has some problems with this approach. If the new chemical substance were a phosphonate, it would go through the testing screen with flying colors, since it is non-persistent, does not biomagnify to an appreciable degree, and does not cause the big three diseases. However, the phosphonates do indeed have some human toxicity problems as we have seen.

When one carefully analyses the complete testing guidelines packages, one is left with the conclusion that many chronic effects of concern (such as neurotoxicity) to a wide range of organisms are either briefly touched upon or omitted entirely. EPA appears to be operating under the assumption that it is better to publish a small number of "defensible" testing guidelines than it is

to publish a large number of less defensible ones. Yet, there is a fallacy to this argument, and that is, the less information one has about a given chemical (or the greater the degree of uncertainty one has about the total impact of that chemical), the more likely one will make an incorrect evaluation of the hazard or safety of that chemical substance.

The distinction between the failure to find an effect and conclusion that there is no effect is not trivial. The distinction is so important, especially in the area of environmental risk management, that its blurring can be given the name of the fallacy of the false negative. The fallacy is to believe that a decision procedure designed to limit false positives necessarily yields any conclusion about the non-existence of an effect when there is a negative finding.

A simple illustration is helpful. A pail contains tennis balls except for the possibility of a single yellow ball. The problem is to determine whether the pail contains the yellow ball. In the decision procedure, the observer is allowed to look only at the top layer. Under the procedure the test scores positive if the observer see a yellow ball in the top layer; the test scores negative if the observer does not see a yellow ball in the top layer. The probability of a false positive is limited to zero. If there is no yellow ball in the pail, the observer will not see one in the top layer; there is no way for the test erroneously to find an effect when it does not exist. However, the probability of a false negative, a conclusion that the ball is not present when it acutally is, can vary all the way from zero to one, from never to always, depending on the number of layers of balls.

If the pail is only one layer deep, the probability of a false negative is zero. However, if the pail is several layers deep the distinction becomes more important. There exists the possibility of not seeing the yellow ball even though it is present. Thus, as the depth of the pail is varied from a single to an infinite number of layers, the probability of a false negative varies from zero to one, even though the chance of a false positive is always held to the same limit, zero.

The less uncertain the structure, (i.e. the more information available), the more likely it is that a negative finding will lead to a valid conclusion. In the illustration, the important structure is the depth of the pail or the ratio of balls that can be seen to those that cannot. If the observer is allowed to see nine-tenths of the balls and still does not see the yellow ball, he can conclude with only a 10% chance of a false negative, that the yellow ball is not present.

However, in environmental risk, with long latencies and diffusion of effects, effects are well hidden. For these risks the pail is deep, and careful investigation is required to support a negative conclusion drawn from a negative finding. In one model of carcinogens in drinking water, where the chance of a false positive was held to 5%, the chance of a substantial effect going undetected was still 40%.

Therefore, it would be advisable for EPA to acquire as much information as it can on the biohazardous effects of a new chemical substance before that new chemical substance is introduced into the environment. While we concede that

such testing may, in the immediate future, be costly, in the long run such testing may prove to be biohazard insurance for a manufacturer. If a corporatist were really creative, he could see that toxicity testing could prove to be a plus on his accountant's input/output sheets. For example, if a manufacturer discovered a substitute chemical for one which has been shown to be more risky to life forms than the benefits accrued to the user (and the manufacturer), he could publicize his discovery by showing, through the results of his toxicity testing, that his new chemical does the same job as the old one without the harmful side effects which the old one has. This idea is not novel; it has been applied in the pharmaceutical industry for years, such as aspirin substitutes and penicillin substitutes.

Further, if a corporatist has a truly creative public relations department, he would see that if he told the truth about a chemical the public may in fact turn out to be less chemophobic than he realizes. However, the corporatist, in his misguided sense of corporate ethics, still persists in trying to gull the public into believing that 2 + 2 = 3 or, stated another way, that while a chemical that he manufactures is hazardous, it is not as hazardous as say, crossing the street or driving a car. This is patent nonsense, and I do not believe that the same public who bought and then rejected that argument for nuclear power will be as willing to buy it second hand with the risks associated with their ubiquitous and often involuntary exposure to chemical substances.

Claire Nader pointed out at the N.Y. Academy of Sciences meeting last year that:

> The promoters of a technology have a significant time jump on anyone who wants to consider harmful or potentially harmful effects. It is very hard for an assessor to catch up; corporatists have massive resources on their side and assessors are usually excluded at the time significant decisions and investments, both monetary and professional, are being made.

At many of the meetings I have attended over the past two years dealing with the implementation of TSCA, I have heard over and over again that full-scale biohazard testing will cripple the chemical industry, that it will stifle innovation and is an infringement of corporate business practices; besides, most of the chemical horror stories were created by slip-shod small chemical industries not representing "normal" business activities in the industry as a whole. In light of the Stauffer incident I can only conclude that corporations will continue to make choices for the quality of life unless and until they are held responsible and fully accountable for their actions. Corporations have carved out a universe of power which, for the most part, is not disciplined by public law. Only slightly, and in recent times, have modest enforcement of new environmental laws restrained this lifeshaping power. Nonetheless, to the extent that the Love Canals, Stauffer Chemicals, and Hemlock, Michigans, are still happening, such power is a form of social control that is outside the law. Corporate behavior of this kind makes the case bluntly that there are other forms of coercion besides government regulations, a kind above the law (here I refer to the use of undue influence in informal processes, both legislative and executive wherein, for example, the regulators are co-opted by the regulated) and beyond the law (here I refer

to harmful effects that do not show up until years after the insult when the statute of limitations has run its course).

We have not yet scratched the surface of assessing the total impact of the plethora of chemicals in the environment and what their cumulative effects will be on this immediate generation or many generations to come. How can one assess on a monetary basis the destruction of an ecosystem, the human tragedy of an individual crippled as a result of his exposure to a delayed neurotoxin, the deterioration of the gene pool whose effects may not be felt for many generations hence? What it all comes down to is this: we need to have information more on the overt and subtle signs of toxicity of any given chemical substance or combination of substances. Furthermore, this information must be shared with the public by corporations and the regulatory agencies whose job it is to protect the quality of human and environmental life. The access to this information by the public must be more expeditious than the present system, where one has to submit a Freedom of Information Act and then wait anywhere from 3 to 8 months to get a response. When you have to fight to obtain information which affects your health and safety, information often defined as proprietary, you can tend to question your own right to it.

The events that followed the explosion at the Stauffer Chemical Company in Chicago Heights illustrate many of the problems that beset attempts to regulate toxic chemicals. Chemical manufacturers are unwilling to accept data based on experiments in animals; Dr. Herbert Northrop, Stauffer's Director of Occupational Medicine stated at a press conference that, "Just because we've got evidence for chickens doesn't mean the same thing for humans. And there were no chickens at the blast site." Unfortunately, the "there were no chickens at that blast site" mentality is typical of the industry as a whole. As a result, however, they may expose workers, the public, and the environment to unnecessary risks by refusing to admit that their products might be dangerous. In addition, they scoff at and even hinder attempts to develop information on human health effects. Thus they perpetuate a vicious circle; they will not institute safeguards without human health data, but human health data are difficult to obtain unless some precautions are taken.

Public officials, who are often unwilling to antagonize industry and who do not want to frighten their constituents, may be eager to accept industry's appraisal of the safety of its own products. Doctors may not be trained in medical school on the effects of environmental poisons and thus may wittingly or unwittingly support the industry analysis.

Unless and until the toxicity information generated by industry is accessible to the public and that the industry is held accountable and fully responsible for its actions, we will continue to have the sort of vandalism which the Stauffer incident epitomizes not only today, or tomorrow, but for many decades to come.

CHAPTER 25

ASTM HAZARD ASSESSMENT PROCEDURE

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BACKGROUND

This paper grows out of my involvement with the ASTM Hazard Evaluation Scheme (1). This scheme is being developed within the ASTM Committee on Pesticides and its Subcommittee on Safety to Man and the Environment. For those of you who are not aware of the American Society for Testing and Materials, it is a private non-profit organization founded in 1898. It has its headquarters in Philadelphia in a modern, attractive building which houses a permanent staff of about 160 persons. The official statement of the ASTM scope says that the purpose is "the development of standards on characteristics and performance of materials, products, systems, and services, and the promotion of related knowledge". The primary purpose, that is the developing of standards, is accomplished through committees, subcommittees, and task groups made up of volunteer members (approximately 26,000 from industry, government, and the private sector). The process is voluntary and the final standards are arrived at by an involved process to assure a consensus.

While initially ASTM standards were primarily of a physical testing nature, currently the activities of many ASTM subcommittees and task groups relate to biological aspects of materials. The task group which I have chaired has focused on a practice which would provide guidance for doing the aquatic testing on pesticides or other substances to determine their potential impact on aquatic life. This Hazard Evaluation Task Group was formed in 1974 when a need was recognized to develop a priority for the aquatic tests that were needed and then to provide overall guidance for the application of these tests in a systematic way. This group was initially made up predominantly of aquatic biologists, but the recognition of the more holistic approach to hazard evaluation has since enlisted the support of chemists, microbiologists, and environmental engineers. The practice that I will be speaking about today does not have official authorization by ASTM but is based on the current draft status and represents the consensus of those involved, representing government, academia, and industry. There are two published papers based on earlier drafts (2,3).

Two excerpts from the scope of the latest draft procedure are key to understanding the objective of this scheme:

> This practice describes a stepwise scheme to develop data to evaluate

> the hazard to aquatic organisms resulting from intended and unintended release of substances to the environment. . . . This practice is designed to quantify the hazard to aquatic species, but does not attempt to judge the acceptability of the hazard. Judgments about the acceptability of a hazard are social, rather than scientific, and depend upon the potential benefits likely to accrue from use of the substance.

These excerpts emphasize two salient points: first, the scope pertains to evaluation of hazard only to aquatic organisms and, secondly, it does not attempt to make judgements about the risk-benefit or acceptability of the hazard.

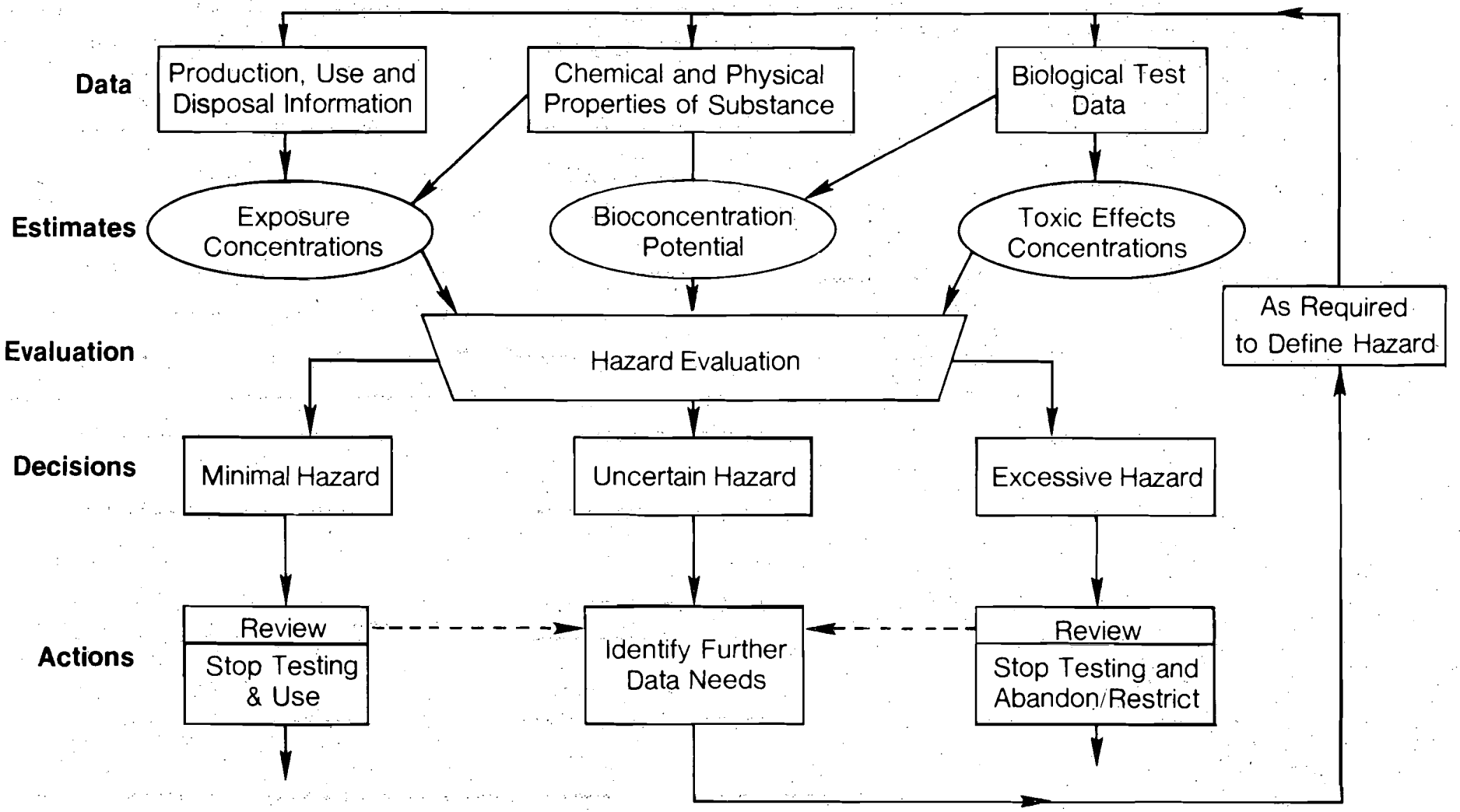
SUMMARY OF THE SCHEME

The total ASTM scheme at its present point of development runs some sixty or more typewritten pages and therefore is too complicated to present fully here. The description or recommendations of specific tests is not included. This paper will emphasize only some of the principles and concepts developed for hazard evaluation to aquatic organisms. A direct quote from the summary of the scheme may be useful:

> This practice describes an iterative process to evaluate the hazard of a substance to aquatic organisms. This is done by considering the relationship between a substance's estimated exposure concentration(s) and the potential for adverse effects resulting from its toxicity and propensity to bioaccumulate.
>
> Data to estimate exposure and effects are collected using a phased series of tests. These tests progress from simple, inexpensive ones with a relatively high degree of uncertainty for evaluating hazard, to complex, expensive tests which decrease the uncertainty. Each iteration consists of reviewing the collected data, considering other relevant information, making the appropriate comparison between the estimated exposure concentration(s) and effect concentration(s), and finally making a decision regarding the adequacy of the data base for evaluating hazard.
>
> The available data may be adequate to conclude either that the hazard associated with the substance is excessive, or that it is minimal. Alternatively, the available data may be inadequate to characterize the hazard associated with the substance. When the available data are inadequate, additional information requirements are identified, the data are collected, and the hazard is reevaluated. The process is repeated until the hazard of the substance to aquatic organisms is characterized to the extent necessary to meet the objectives of a particular hazard evaluation.

Figure 1 and the sections that follow will provide a more complete picture of how the process is applied.

Figure 1. CONCEPTUAL DIAGRAM OF THE ASTM PROCEDURE FOR EVALUATING HAZARD OF A SUBSTANCE TO AQUATIC ORGANISMS



ELEMENTS OF HAZARD EVALUATION

The first key element in evaluating hazard of a substance to aquatic organisms is a determination or an estimation of the concentration, form, and location of that substance in the environment. Production quantities of a substance do not by themselves provide any clear signal of hazard. The aquatic estimated exposure concentrations are calculated from the production, use, and disposal patterns for the substance; utilize its chemical, biochemical, and photochemical degradation; and consider its expected chemical and physical reactions and interactions which affect its partitioning and transport. In the aquatic environment, a substance may be dissolved in water, bound to sediments, or incorporated in a food source. Form, location, and concentration considerations aid in deciding whether aquatic species need to be tested, the kinds of tests to be conducted, and the test concentrations to which the organism should be exposed.

The second key element essential to evaluating the hazard of a substance is quantitation of its toxicity to aquatic organisms. Adverse effects on survival, growth, reproduction, or behavior of organisms resulting from either acute or chronic exposure to a toxicologically active substance can, of course, cause degradation in aquatic ecosystems only if concentrations are significant.

Thirdly, since many aquatic organisms are components of the diet of aquatic and terrestrial organisms, including man, another key element in evaluating the hazard of a substance is a determination of its propensity to bioaccumulate in aquatic food chains.

HAZARD EVALUATION AND DECISION ALTERNATIVES

By comparing the estimated environmental concentrations with those causing toxicity effects and with knowledge about the bioaccumulation potential, evaluation can be made of the hazard to the aquatic community and the possibility of hazard to consumers of aquatic organisms. After such an evaluation, one of three decisions may be reached:

1. Hazard is minimal and no further testing is required.
2. Hazard is excessive and no additional testing is needed.
3. More information is needed to make an appropriate evaluation.

MINIMAL HAZARD

Hazard can be judged minimal only if the hazard due to both toxicity and bioaccumulation is judged minimal. Before a final decision to consider usage without further testing is implemented, the following factors should be ascertained:

1. Exposure situations and concentrations were realistically estimated.
2. Test species selection was reasonable in type and scope.

3. Test conditions were proper for the substance and the environmental exposure situations likely to occur.

4. Effects concentrations data are reliable and the safety factors utilized adequately considered any uncertainty.

EXCESSIVE HAZARD

Hazard may be judged excessive due to concerns about either toxicity or bioaccumulation. Before a final determination that leads to abandonment, careful consideration should be given to the specific cause of such determination and any factors which might mitigate the findings, such as:

1. The estimated exposure concentration(s) calculated may be too conservative if degradation or partitioning factors were not considered or were unknown.

2. Toxic effect may be caused by an impurity in the substance that could be removed or would not persist in the environment.

3. The form or availability of the substance in the environment may be different from those tested and the substance therefore may be less hazardous.

4. The limiting adverse effect observed in the toxicity test will be unimportant in the environment.

5. The bioconcentration factor calculated from physical-chemical properties may be higher than a determined value.

6. The toxic effect concentration was conservatively extrapolated from acute toxicity data and the estimate may be lower than actual chronic response testing would produce.

Consequently, there are certain specific actions which might mitigate the finding of excessive hazard and avoid abandonment of a substance, including:

1. Restrict the quantities to be produced or used.

2. Provide better or alternate containment in manufacturing, distribution, use, or disposal.

3. Restrict geographic or temporal range of manufacture, use, or disposal to avoid exposure of sensitive species.

4. Modify physical properties or purify substance to reduce exposure potential or toxicity.

5. Consider more definitive fate-type testing which might support lower environmental concentration estimates.

6. Consider longer-term or special toxicity tests which can be utilized with less conservative safety factors.

7. Consider determining bioconcentration factor experimentally, which may yield a lower factor than that calculated.

If such actions are not productive or cannot be justified, the hazard evaluation should be considered completed.

UNCERTAIN HAZARD

More information or testing is needed when hazard cannot be defined as minimal or excessive, or where modification of an earlier tentative decision may be sought. The decision for added testing should be selective to answer the most critical question with minimal resources. An appropriate balance should be maintained on tests to define fate of the substance and the effect of the substance.

THE PHASED APPROACH

As an iterative and continuing process, it is theoretically possible to terminate testing or to identify further test requirements at any or all times. For efficient use of resources, it is important to make decisions at the earliest possible point. This scheme, somewhat arbitrarily divided into three phases, insures review and a considered decision before committing to the escalating costs and time requirements involved in moving to a later phase. More frequent, at least partial review is recommended because each new test result provides potential feedback to the evaluation process.

APPLICATION OF THE PHASED APPROACH

While the ASTM procedure was designed initially to assess new or proposed substances, it can be applied to substances already in distribution and known to be present in the aquatic environment. Recall in each phase, estimates on three elements are necessary for input to the hazard evaluation: exposure concentrations, toxic effects concentration, and bioconcentration potential. Types of data which could be needed in each phase are outlined in Figure 2 and discussed below.

PHASE I

This phase uses available information to attempt to define the scope and type of any needed testing or the priority of attention that should be focused on any particular substance.

Even with limited information, it is possible to decide that aquatic hazard is minimal when exposure is low or when the structure and properties of the compound strongly indicate that toxicological activity is unlikely and that the potential for bioaccumulation is remote.

When a substance is already in use, there will normally be more information available about its properties and probably acute aquatic toxicity

Figure 2. CONDENSED LIST OF DATA CONSIDERATIONS FOR PHASES I, II, AND III

PHASE I Gather Existing Information on Substance or Similar Materials	**PHASE II** Additional Data from Existing Sources or from Shorter Laboratory Tests	**PHASE III** Additional Data from Special and Longer Term Tests
USAGE AND DISPOSAL PATTERNS	IMPROVED INFORMATION ON USAGE AND DISPOSAL PATTERNS	RESCRUTINY OF USAGE AND DISPOSAL PATTERNS
LITERATURE/STRUCTURE • Properties of Substance or Related Compounds	MORE COMPLETE CHEMICAL AND PHYSICAL DATA	STUDY OF CHEMICAL AND PHYSICAL PROPERTIES/EFFECTS • Stability/Fate • Possible Residues • Potential for Concentration
BASIC CHEMICAL AND PHYSICAL DATA • Reactivity • Solubility • Vapor Pressure, etc.	STABILITY TEST RESULTS • Chemical • Biological • Photo	DATA FROM HUMAN SAFETY TESTS • Chronic Levels • Developmental Effects • Metabolism
KNOWN BIOLOGICAL EFFECTS •Target Organism and Human Safety Data, etc.	PARTITIONING/DISTRIBUTION • Water/Solids • Water/Air • Water/Solvent	ACUTE AQUATIC DATA ANALYSIS • Acute Effect Concentration • Time Effects • Species Differences • Other Materials • Concentration Response Curve
AQUATIC TOXICITY •Structure Related Materials	ACUTE AQUATIC TOXICITY SCREENING TESTS	LIFE CYCLE AQUATIC TESTS • Species Considerations • Full Cycle • Partial • Critical Stage
AQUATIC TOXICITY •Test Material if Available	EXPANDED ACUTE TOXICITY TESTS • Other Conditions • Other Organisms • Other Methods	BIOCONCENTRATION TESTING • Direct Concentration • Biomagnification

data. More importantly, past monitoring or measurement in the aquatic environment may provide a very solid basis for estimated exposure concentrations.

In Phase I, it is very important to identify those substances which can be used with minimal hazard and to set aside or consider restriction of those which could create excessive hazard. This allows us to focus the majority of testing on those where hazard is uncertain. When further test needs are identified, the process proceeds to Phase II.

PHASE II

In the ASTM scheme, Phase II involves gathering additional information or new test data to address the unresolved concerns identified in Phase I. Requirements in this phase may include acute toxicity tests and/or the chemical, physical, and biological testing necessary to refine predictions of environmental concentration or to estimate bioaccumulation potential. Test requirements will differ widely, depending on the structure and the biological activity of the substance, upon its chemical and physical properties, and upon potential exposure concentrations.

Some measure of the stability of the compound is usually desirable, and its structure and disposal pattern should suggest whether chemical, biological, or photo processes are likely to be most important.

The partitioning of a substance, again, can be estimated from structure and solubility considerations, but some simple sorption or partition coefficient tests to confirm the distribution can be desirable to secure better estimates of aquatic concentrations and potential for bioaccumulation.

If no reliable data or estimate of the aquatic toxicity of the substance is available, at least one acute screening test will be needed. The structure, toxicological activity, and potential for significant exposure should dictate need for expanding acute toxicity tests to other species, trophic levels, or water conditions. Some comprehensive guidelines for customizing an acute toxicity testing program appropriate for each material are included in Figure 3. The kind and scope of aquatic toxicity testing needed will obviously be different for evaluating a pesticide or other known biologically active substance than for the great majority of chemicals.

An especially careful review of data and the estimates made from them is in order at the conclusion of Phase II, since the testing required in the following phase escalate steeply in time and cost. Attention should be focused on the ratio of the acute LC_{50} values and estimated long-term exposure concentrations. For most materials, the acute LC_{50} will exceed the maximum acceptable toxicant concentration (MATC) determined in full-life exposure by less than 100X.

Bioconcentration factors calculated from partition coefficient tests when less than 100 are generally a clear signal that actual exposure of test organisms is not required. In all judgements the total chemical and biological data available should be utilized. Some general guidelines for making a hazard decision at the end of Phase II are included in Figure 4.

Figure 3. FACTORS AFFECTING DESIGN OF ACUTE TOXICITY TESTING PROGRAM

PROPERTIES AND RESPONSES	IMPLICATION FOR TESTING
A) Stability or Reactivity would Reduce Test Concentrations Volatility, sorption, solubility losses may be significant; material may exert significant oxygen depletion; degradation may reduce test concentration.	Flow-through testing needed on same species used in static tests.
B) Static and Flow-Through results Differ Significantly	
1) If flow through test gives lower LC50	1) Use flow-through for other species. Chemically monitor test concentration. Determine if factor causing less toxicity in static has environmental significance (e.g. degradation, sorption)
2) If static test gives lower LC50	2) Determine if factor making more toxic is compound related (e.g. more toxic degradation product) or test related (e.g. low D.O.)
C) Relationship of LC50 to Expected Environmental Concentration	
1) LC50 is >100X expected acute exposure level	1) Further acute testing probably not required.
2) LC50 is ≤100X expected acute exposure level	2) Further acute testing on species of other genera or trophic levels should be considered.
D. Variations in Response between Species	
1) Minor and reasonable differences between genera or trophic levels	1) No further extension in particular genera.
2) Order of magnitude or unexpected differences	2) Extend testing to other species in sensitive genera or trophic level
E. Physical/Chemical Properties of Test Material	
1) Material nonionic and water soluble	1) No special test conditions.
2) Material ionic and cation exchange likely to affect solubility.	2) Test in harder test water.
3) Material has limited solubility under "standard" test conditions	3) Test at higher test temperature; check effect of solubulizing.
4) Material exerts excessive pH change at test conc.	4) Test in buffered test water.
5) Degradation appears likely to alter toxicity substantially.	5) Test effect of delaying introduction of test species and monitor/control/renew toxicicant concentration.
6) Solubility or sorption indicates association with solids or sediments.	6) Test with benthic species.
F. Location Considerations	
1) Unusual species or ones of unknown sensitivity may be exposed to significant concentrations	1) Test on this special species if important and available.
2) Valuable fishery or shell fishery may be exposed to significant concentrations	2) Test on important species or best models for them.
G. Special Toxicological Information	
1) Material is effective pesticide.	1) Test on appropriate and related non-target species.
2) Material is effective herbicide	2) Test on algae and aquatic macrophyte species.

Figure 4 DECISION ALTERNATIVES ON HAZARD

I. MINIMAL HAZARD - NO FURTHER AQUATIC TESTING NEEDED TO SUPPORT USE

A. Chemical structure, components, and similar compounds are generally accepted as biologically innocuous at anticipated environmental concentrations.

B. Animal toxicological data obtained for human safety are reassuring.

C. Acute aquatic toxic response concentrations greatly exceed expected environmental concentrations and the substance shows no indication of cumulative action.

D. Substance in environmental systems is short-lived so that concentrations projected in surface waters will be well below any reasonably predicted chronic response level for parent material and its transformation products.

E. Chemical/physical data relating to stability and partitioning give no cause to suspect bioconcentration at biologically significant level.

Note - A reasonable and strong positive combination of the above factors is required to substantiate a "Minimal Hazard" conclusion and to warrant wide scale use without further aquatic safety testing.

II. EXCESSIVE HAZARD - RESTRICTION OR OTHER ACTION NEEDED TO JUSTIFY USE

A. Acute toxic response of important, sensitive, or appropriate species lies within estimated environmental exposure concentrations.

B. Acute toxic response provides only marginal safety factor and time/toxic response curve makes adverse chronic/life stage or reproductive effect likely at environmental concentrations.

C. Partitioning data make bioconcentration likely to a degree likely to be detrimental.

Note - A strong negative signal on one or more of the above could indicate excessive hazard and a high probability that registration or clearance would require substantial testing with low probability of positive answer.

III. TEST FURTHER - USAGE MAY BE PROPER BUT MORE DATA NEEDED TO DEFINE HAZARD

A. Experience with similar chemical structures is sparse or mixed so that definitive input from this source is lacking.

B. Mammalian toxicity data for human or other safety evaluations show developmental or unusual biological activity.

C. Projected environmental concentrations are not significantly below toxic response concentrations in acute aquatic tests.

D. Stability of material indicates continuing aquatic concentrations representing significant chronic exposure.

E. Partitioning data indicate bioconcentration could be substantial and possibly could provide dosage in toxic range for aquatic food chain or predator species.

PHASE III

When factors reviewed and evaluated using the general criteria outlined in Figure 4 identify further test needs, they could include:

1. Studies that allow more accurate or more comprehensive determination of the environmental fate and concentration of the substance, or

2. Toxicity tests involving extended exposures or which assess effects on reproduction or on critical life stages of aquatic organisms, or

3. Bioconcentration studies on aquatic organisms to assess more directly the propensity of a substance to be bioaccumulated to a degree posing hazard to consumer aquatic species or man.

Programs in this final phase are always substance-specific and even procedures frequently used cannot be considered routine or standard. All tests should be selected after very careful planning and need to be supported by substantial chemical effort.

At completion of a properly designed laboratory testing and assessment program, the hazard of most materials to aquatic organisms can be adequately quantified. The use or continued use of a substance should be supported by knowledge that makes the following statements appropriate:

1. The substance, its impurities, and any environmental reaction products are well enough understood that "ecological surprises" are unlikely.

2. The substance, from its expected use and disposal, will not reach concentrations that are acutely toxic to species which will be unintentionally exposed to it.

3. Any episodic non-planned exposure of aquatic organisms to toxic concentrations resulting from spills or other accidents would be limited in geographical scope and temporary in nature.

4. Any expected continuing concentrations of the substance in surface waters would appear unlikely to exceed the maximum acceptable toxicant concentration (MATC) determined or estimated for appropriate and sensitive species.

5. The properties of the substance, or tests on it, do not indicate a degree of biological concentration which would be adverse to directly exposed organisms or to those who use them for food.

6. There do not appear to be any long-term environmental sinks where the substance might be concentrated that are capable of developing a delayed and perhaps difficult-to-reverse problem.

CONCLUSIONS

The ASTM procedure for hazard evaluation to aquatic organisms has been developed with a flexibility that allows its application not only to assessment of new chemicals, but the scheme can be entered and applied for substances already in use. The procedure emphasizes the parallel development of chemical, physical, and biological data to allow early and sequential estimates of exposure concentrations against which toxicological effect can be compared to reach judgements about hazard or further testing needs.

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2. Maki, A.W. and J.R. Duthie, "Summary of Proposed Procedures for the Evaluation of Aquatic Hazard", in "Estimating the Hazard of Chemical Substances to Aquatic Life", Cairns, et al., Eds., American Society for Testing and Materials, STP 657, pp. 153-163, 202-237, Philadelphia, August 1978.

3. Duthie, J.R. "The Importance of Sequential Assessment in Test Programs for Estimating Hazard to Aquatic Life", in "Aquatic Toxicology and Hazard Evaluation", Mayer and Hamelink, Eds., American Society for Testing and Materials, STP 634, pp. 17-35, Philadelphia, October 1977.

CHAPTER 26

AQUATIC HAZARD ASSESSMENT - CONCEPTS AND APPLICATION

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INTRODUCTION

The need has existed for a number of years to have at our disposal some concepts and techniques on how to assess the hazards of chemicals to aquatic organisms and their ecosystems. This is important not only for new chemicals but also to review certain existing chemicals. In recent years this need has been partially met as a result of a cooperative effort on the part of scientists from government, industries, and universities. The purposes of this presentation are:

1. To review progress that has been made to date on some of the concepts of aquatic hazard assessment.

2. To indicate some of the needs which must still be met.

3. To show how the concepts can be applied to some of today's problems.

About five years ago the Detergent and Phosphate Division of Monsanto began to develop a system to study the aquatic safety of a new high-volume chemical to partially replace phosphate in detergents. In presenting that aquatic safety program in meetings and through publication (1), it became obvious that the subject of performing aquatic hazard assessments was an important new topic. A subsequent publication by Monsanto presented more details on aquatic hazard evaluation (2).

HAZARD ASSESSMENT CONCEPTS

Numerous approaches and procedures now exist to evaluate aquatic safety/hazard of chemicals. From these a few consistent concepts or facts of hazard evaluation have emerged, and these are:

1. Hazard assessment of a chemical is performed by comparison of toxicity to organisms with its exposure concentration, the safety factor concept.

2. Laboratory methodologies do exist to perform a number of tests from simple acute lethality through chronic tests on growth, reproduction, physiology, and behavior using both freshwater and marine organisms.

Field tests on effects are not yet developed to the same degree as clean-water laboratory studies.

3. Methodologies also exist to estimate and/or measure the exposure concentrations of chemicals in various compartments of the aquatic environment. Much research is currently under way to improve this area of environmental science.

4. Data on toxic effects and environmental fate are most appropriately obtained in a step-wise sequential tier manner. This principle recognizes that not all chemicals require, or should be expected to undergo, the same amount of testing. It is also valuable from an industrial viewpoint to develop data in a sequential manner to facilitate necessary business decisions to stop or continue toward commercializing a new product.

5. Three decision criteria are built into the testing program to give guidance for when:
   a. The hazard is acceptable and no more data are needed.
   b. The hazard is unacceptable and commercialization should be stopped or risk management practices must be developed.
   c. The hazard is marginally acceptable and can only be resolved with additional data.

6. The closer the assessment is made to real-world conditions the more confidence we tend to have in our estimate of hazard. A chemical that only receives simple laboratory testing must demonstrate a much greater margin of safety between the effect and exposure concentration than a chemical with a narrow margin of safety. This means that marginally acceptable assessments of hazard may have to be ultimately resolved with actual field studies under use conditions.

7. No subjective system of hazard assessment should be expected to replace good scientific judgement weighing the risks with the societal benefits of a chemical.

HAZARD ASSESSMENT PROCESS

Aquatic hazard assessment of a chemical can be performed using the currently available array of toxicity and environmental fate tests presented in "Estimating the Hazard of Chemical Substances to Aquatic Life"(2). Because of the limited resources and time available, and the fact that there are so many chemicals which need testing under the new vigorous testing schemes, decisions must be made to test chemicals only to the point that a confident decision can be reached on the hazard of the material. At Monsanto we have found that use of the tier approach facilitates this decision process. Four tiers have been used:

1. Screening tests of short duration and minimum expense which help eliminate obvious potential problem materials.

2. Predictive tests of greater utility for estimating hazard but with a greater investment of time and resources.

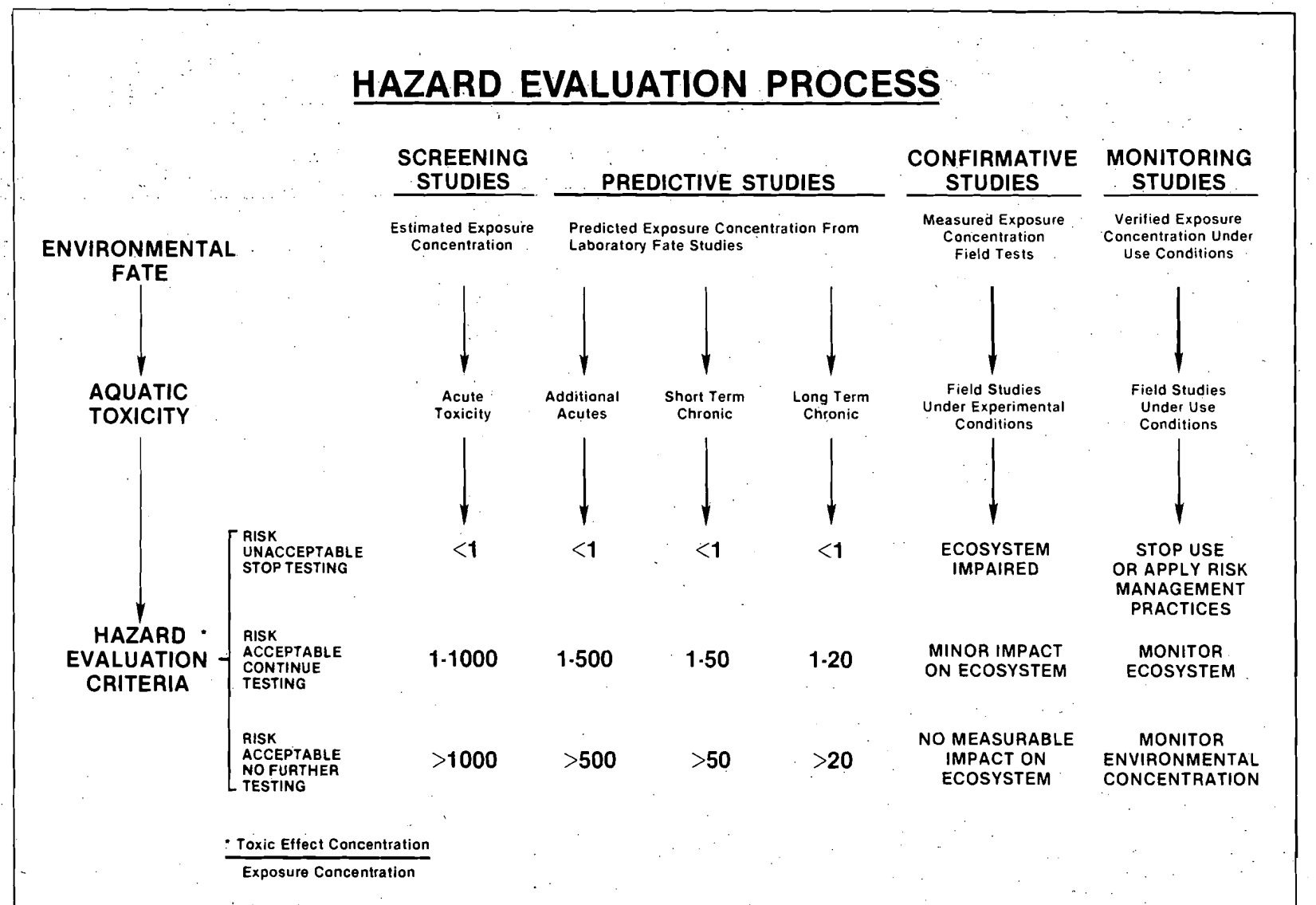

Figure 1. INCORPORATION OF AQUATIC TOXICITY AND ENVIRONMENTAL FATE DATA INTO THE AQUATIC HAZARD EVALUATION PROCESS.

3. Confirmative tests which take us into the field to confirm some of the earlier laboratory data.

4. Monitoring studies which are conducted after commercialization to validate the safety of a material under actual use conditions.

Figure 1 summarizes the concepts and details of an aquatic hazard assessment procedure which is in the process of being developed at Monsanto. It incorporates most of the principles of other procedures. Data are acquired sequentially in the tiers of screening, predictive, confirmative, and monitoring. Hazard is assessed by comparison of exposure concentration in environmental fate studies to toxic effects. Three types of decisions emerge as a result of this comparison:

1. Hazard is unacceptable - stop testing and development of the chemical or develop risk management practices. This happens when there is no safety margin because the exposure concentration (either estimated, predicted, measured, or validated) exceeds the toxic effect concentration.

2. Hazard is acceptable - no further testing is needed because the margin of safety is judged more than adequate.

3. Hazard is acceptable but the margin of safety is not as large as would be desired - acquire additional data in order to increase the confidence in the hazard assessment. This third case frequently means performing real-world studies of the confirmative type and/or monitoring the impact of the chemical on aquatic ecosystems under actual use conditions.

It should be noted that these "safety margins" have been presented at this time only as a point of discussion. Adoption of any rigid guidelines at this time in the emerging science of aquatic hazard assessment would be inappropriate. However, there is a definite need to establish an understanding of what the acceptable and unacceptable criteria are for the protection of aquatic ecosystems. It is precisely because we do not understand all there is to know about assessing real aquatic hazard that we must bring the subject up front and discuss it.

Figures 2 and 3 graphically demonstrate in a simple way the concept of acceptable and unacceptable hazards. As data are collected in the tiers of screening, predictive, and confirmative, the biological effect concentration is greater than the expected and measured exposure concentration (Figure 2), then the hazard is not as great as when the exposure concentration exceeds the biological effect concentration (Figure 3). Obviously in this latter case the chemical in question probably would not have been developed beyond the early tiers. Both these cases are an over-simplification of a very complicated matter which needs to be brought to the attention of the scientific community and resolved.

HAZARD EVALUATION NEEDS

As a result of this newly emerged understanding of aquatic hazard

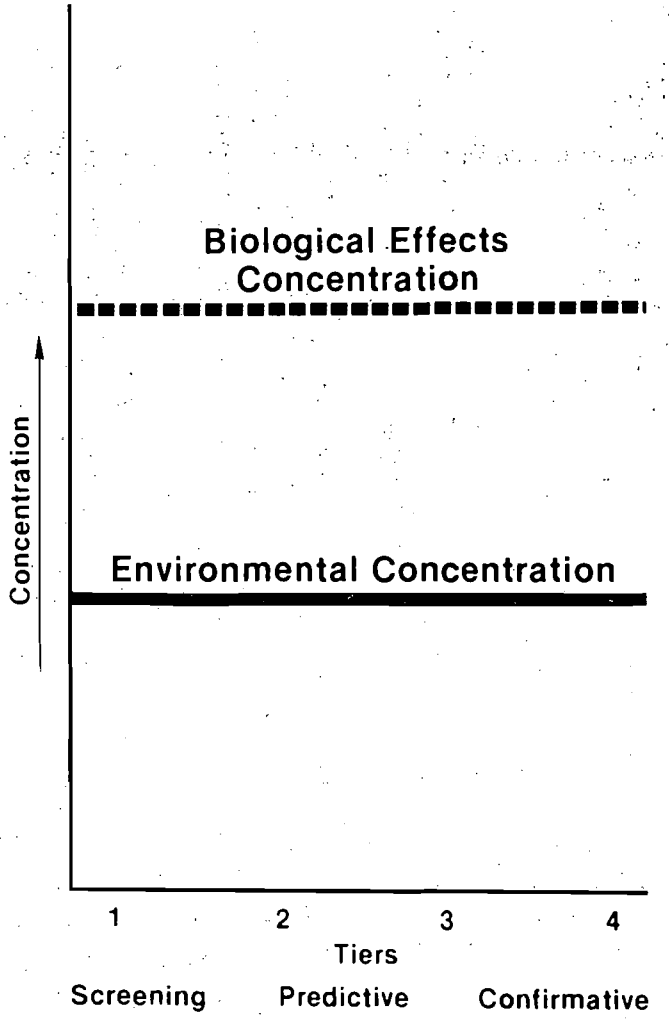

Figure 2. COMPARISON OF BIOLOGICAL EFFECTS CONCENTRATION TO ENVIRONMENTAL CONCENTRATION WHEN THERE IS A LARGE MARGIN OF SAFETY.

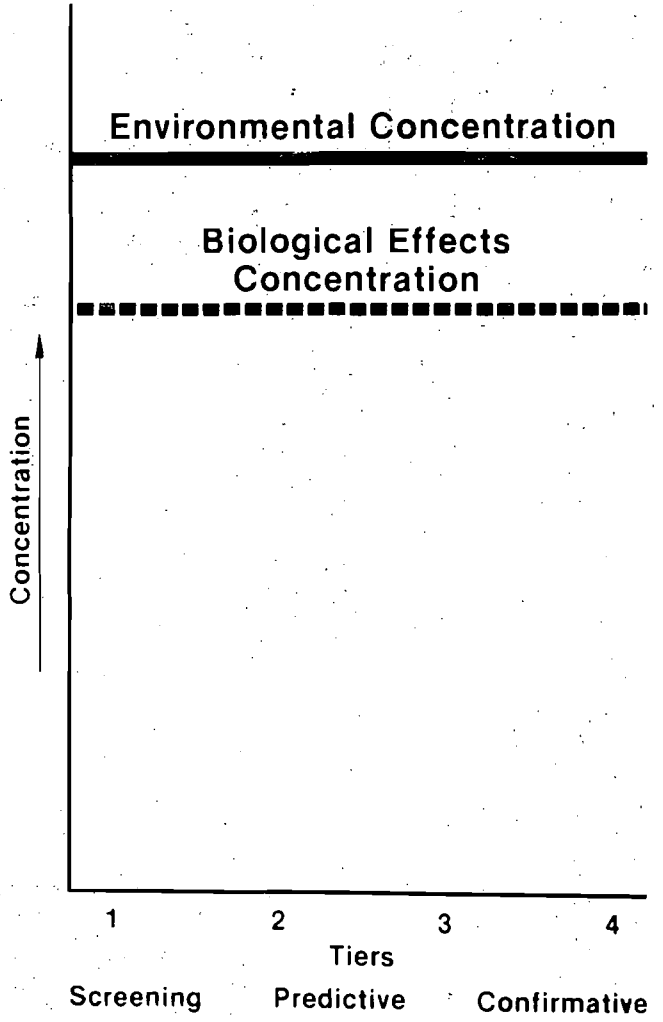

Figure 3. COMPARISON OF BIOLOGICAL EFFECTS CONCENTRATION TO ENVIRONMENTAL CONCENTRATION WHEN THERE IS NO MARGIN OF SAFETY.

assessment a dilemma has arisen. Simply stated, we, as aquatic toxicologists, have failed to demonstrate what the relationship really is between our clean water laboratory toxicity data and the toxicity of the same chemical under real-world conditions. For those chemicals which fall in the marginal range of acceptability it may be crucial to know the effect of the real world on toxicity. It could either reduce toxicity through mitigating effects to an acceptable level or synergistically enhance toxicity to an unacceptable level.

Figures 4 and 5 present these two scenarios. Figure 4 demonstrates a hypothetical case where the heavily-depended-on clean-water laboratory studies of the screening and predictive tiers result in a fairly close estimate of biological effect and exposure concentration. However, when the confirmatory studies are conducted in natural waters of the real world, a different understanding of hazard results. Although the total concentration of a chemical may be confirmed as predicted, factors such as suspended solids, colloidal material, and dissolved matter make only a fraction of the total chemical available to the aquatic organisms. The effect of these factors "mitigate" the toxicity so that it really takes much more total exposure to obtain the same significant biological effect. The effect of this is that the margin of safety is really much greater than was perceived from the clean water laboratory data.

On the other hand, Figure 5 demonstrates the reverse case where the perceived wide margin of safety is significantly reduced because of some synergistic effect present in the natural water.

Although both these cases are hypothetical, it is important for us to get a better understanding of how the factors of the real world can influence our estimates of hazard. It seems quite likely to me that we have overlooked the role of mitigating effects while emphasizing the difficult-to-document cases of significant synergistic effects. Both no doubt operate. The challenge is to conduct more quality field studies and find out what the real utility is of our clean-water laboratory studies. Perhaps after the data have been obtained we will have much more confidence in our laboratory data, or we may realize that field studies must play a larger role in aquatic hazard assessment.

HAZARD ASSESSMENT APPLICATIONS

As a result of the cooperative effort of many scientists which has led us to preliminary state-of-the-art concepts of aquatic hazard assessment, aquatic toxicolgists now have a better understanding of how to use their data to solve current problems. Numerous industries now utilize the published methods in new product safety development programs. In addition the United States Environmental Protection Agency's Interagency Testing Committee (ITC) recognized the need to develop a scoring system to identify chemicals which need additional safety data (3). Figures 6 - 8 depict in a general way how the concepts of aquatic hazard assessment could be built into a chemical scoring system.

Aquatic toxicologists have come to rely most heavily upon certain types of tests using representative organisms from each of the trophic levels (4). These are presented in Figure 6 in the form of a matrix. If toxicity and exposure data on a particular chemical were available to completely fill in

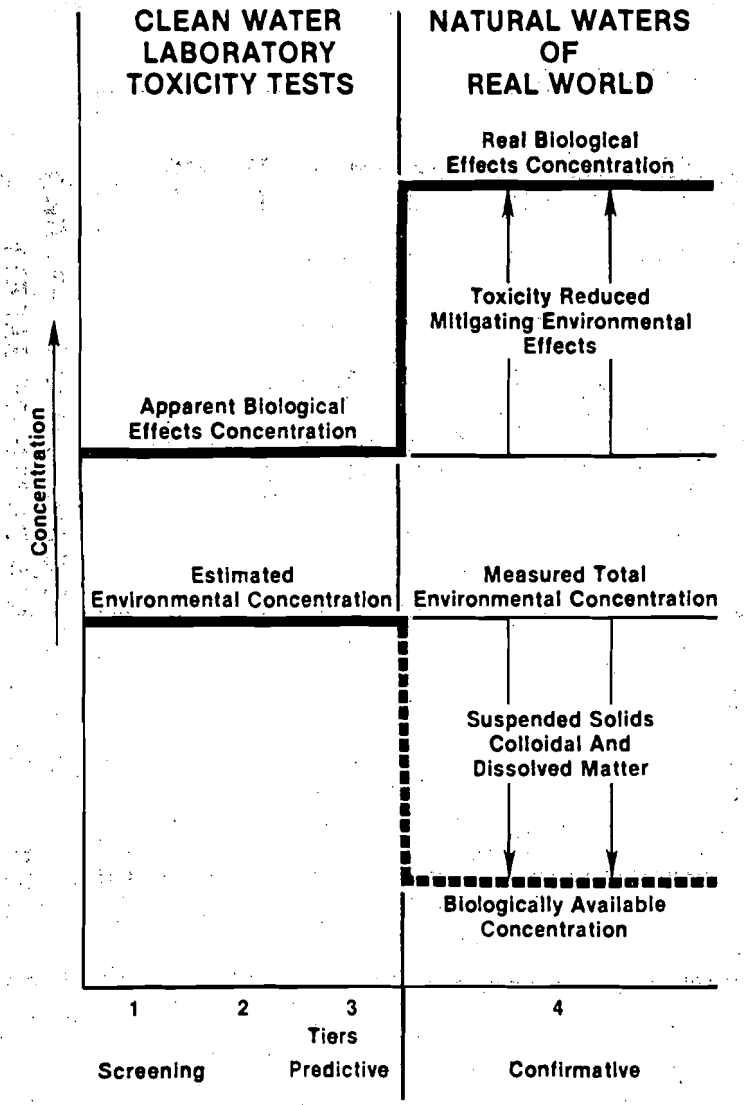

Figure 4. HYPOTHETICAL SITUATION OF AN APPARENT SMALL MARGIN OF SAFETY FROM CLEAN WATER LABORATORY TOXICITY DATA ACTUALLY BEING MUCH GREATER BECAUSE OF MITIGATING EFFECTS OF NATURAL WATERS.

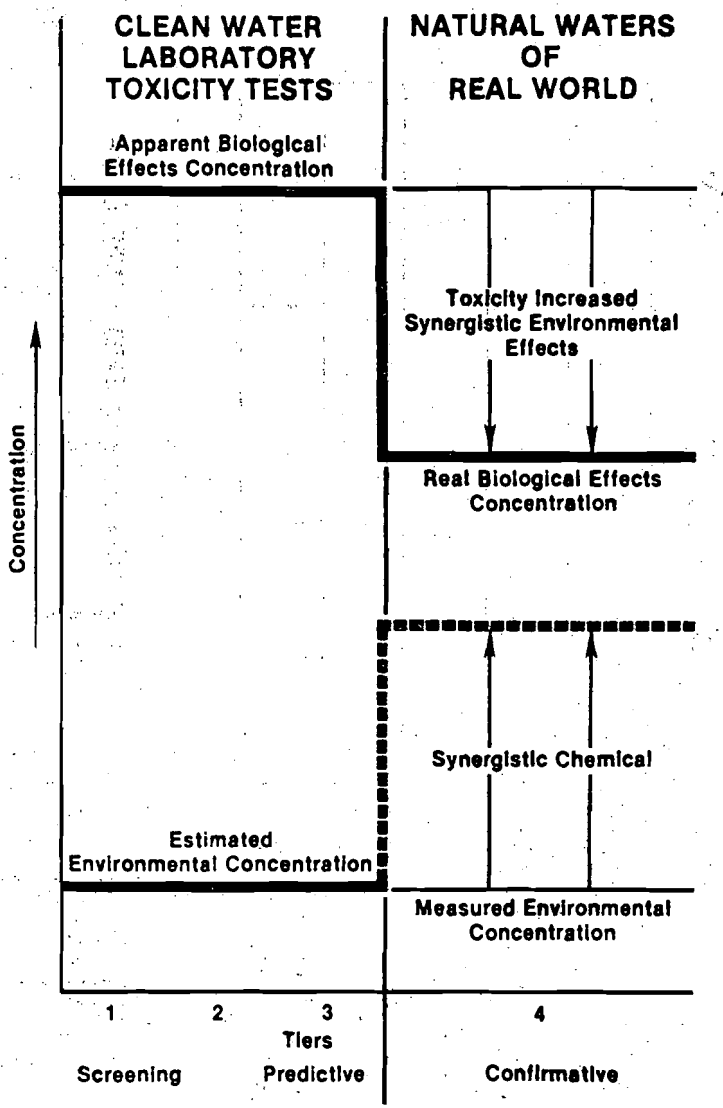

Figure 5. HYPOTHETICAL SITUATION OF AN APPARENT LARGE MARGIN OF SAFETY FROM CLEAN WATER LABORATORY TOXICITY DATA ACTUALLY BEING MUCH SMALLER BECAUSE OF SYNERGISTIC EFFECTS OF NATURAL WATERS.

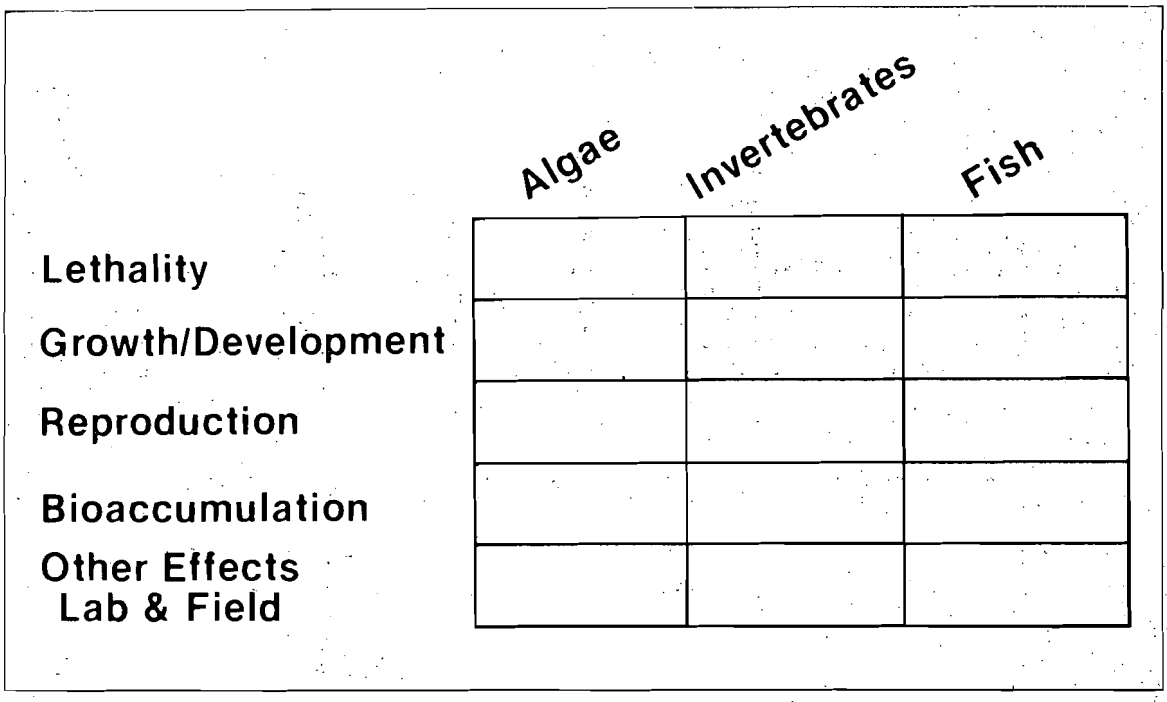

Figure 6. MATRIX OF AQUATIC ORGANISMS AND END POINTS OF AQUATIC TOXICITY TESTS.

Data Base	Toxicity Safety Factor	Bioconcentration Factor	Score
Measured	0	$>10^4$	+3
	<10	10^3-10^4	+2
	10-100	10^2-10^3	+1
	>100	$<10^2$	0
Estimated	10-100	10^2-10^3	−1
	<10	10^3-10^4	−2
	0	$>10^4$	−3

Figure 7. SCORES ASSIGNED FROM MEASURED (0 to +3) AND ESTIMATED (−1 to −3) DATA BASES OF SAFETY FACTORS AND BIOCONCENTRATION FACTORS.

the matrix with safety factors, it would be a relatively easy matter to judge the hazard of that chemical to aquatic life. Furthermore, if meaningful scores could be assigned to the safety factor data for the matrix, then it might be possible to summarize the aquatic hazard of a chemical in a numerical manner. Such a system has been considered by the ITC.

Figure 7 shows how scores from -3 to +3 could be assigned to safety factors (effect concentration divided by exposure concentration) and bioconcentration factors (tissue concentration divided by exposure concentration). Zero to +3 would be used only when measured toxicity and bioconcentration factors (BCF) data were available, and -1 to -3 would be used when the data had to be estimated, such as an octanol/water partition coefficient instead of a measured BCF. Upon review of the biological effects, toxicity, bioconcentration, and exposure concentration data of a chemical, the compartments of the matrix would be filled in. A numerical evaluation would be conducted by adding all positive numbers and all negative numbers separately to arrive at a final two-number summary. A +45 would mean all 15 compartments received a score of +3 because no toxicity safety margins existed and the BCF was >10,000, a possible hazardous situation. A score of 0 would indicate a chemical of no concern because of very large safety margins. Very few chemicals would be expected to fall in these two extreme categories; most would likely receive a plus and minus score.

Figure 8 shows how the numerical scores of numerous chemicals could be plotted to give a visual impression of relative hazard. Chemicals in the positive "higher hazard" area would be more likely to need risk management consideration than those in the low hazard area. Similarly, chemicals which received high negative scores would fall in the "higher hazard" area. They would qualify for needing additional study.

If this approach to scoring chemicals for aquatic hazard assessment was applied to some of today's chemicals, it might be useful in helping to set some priorities on which chemicals were environmentally most important.

CONCLUSIONS

It was my purpose to present some of the more-or-less accepted concepts of aquatic hazard evaluation, indicate areas that need additional work, and show how the concepts of aquatic hazard assessment can provide a basis of a chemical scoring system.

With the current level of interest in this subject of hazard assessment, the cooperation that exists among scientists, and the inevitable fact of more regulation of chemicals in the environment, it is quite likely we can expect significant improvement in our understanding of hazard assessment in the near future.

ACKNOWLEDGEMENTS

Figures 1 - 5 were reproduced with permission granted to the author by Ann Arbor Science Publications from the book on "Dynamics, Exposure, and Hazard Assessment of Toxic Chemicals in the Environment", American Chemical Society Symposium, Miami, Florida, September 11-13, 1978, Edited by R. Hague.

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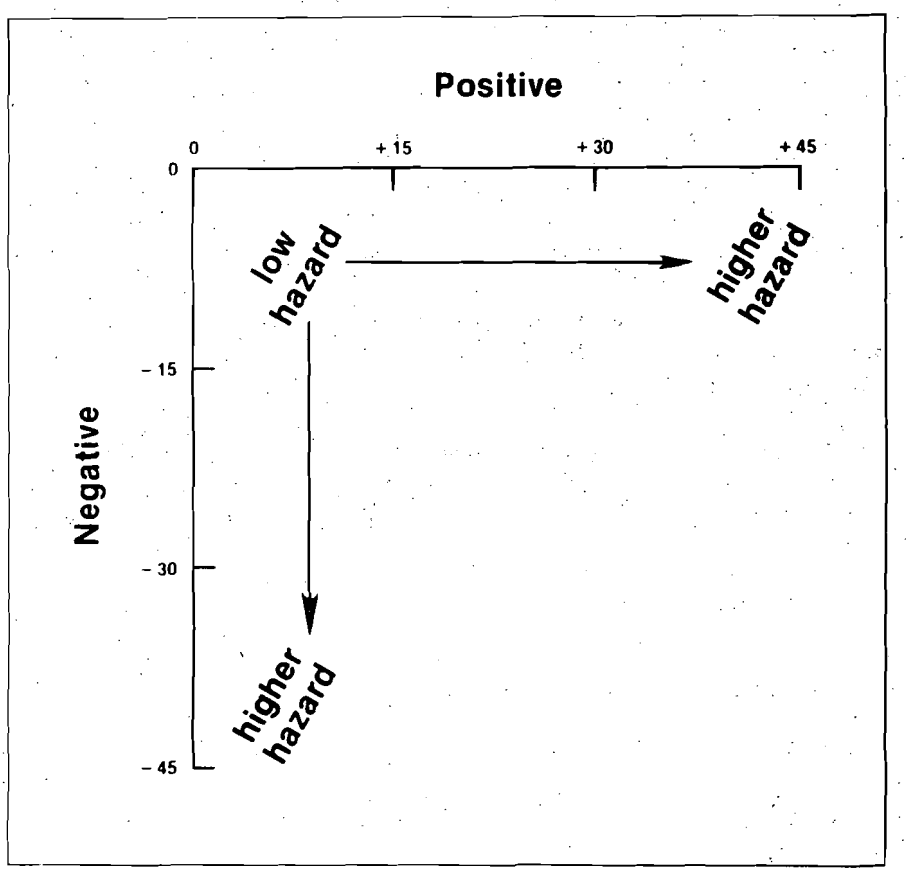

Figure 8. SUM OF POSITIVE AND NEGATIVE SCORES ON A PARTICULAR CHEMICAL RESULTS IN PLACEMENT IN CATEGORIES OF LOW HAZARD OR HIGHER HAZARD.

CHAPTER 27

A METHOD FOR SELECTING THE MOST APPROPRIATE ENVIRONMENTAL EXPERIMENTS ON A NEW CHEMICAL

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INTRODUCTION

The chemical industry has long been concerned with the health and environmental properties of the products that they manufacture and distribute. The effort that is expended in this area has grown exponentially in the past few years due to our growing understanding of the environment. This increased awareness of potential problems is requiring better predictive techniques for making early decisions on what tests are needed (see, for example, (1)). Of necessity, such predictions must be based on laboratory findings, since it is not feasible to use the environment as a testing ground and, in addition, the newly enacted Toxic Substances Control Act (TSCA) requires a company to submit information to the U.S. Environmental Protection Agency (EPA) prior to manufacture and distribution.

Section 5 of TSCA, dealing with premanufacture notification, has generated interest in defining the tests that predict the environmental impact of a chemical. One of the concepts that is emerging is based on tier testing (2). The objective of this approach is to enable the studies to proceed in a logical manner and to optimize the amount of information in a cost-effective manner.

The basic process in any hazard evaluation involving the environmental effects of chemicals is to make predictions of the expected environmental concentration (EEC) and to match this with the experimentally determined no effect level for appropriate environmental organisms. Once the data demonstrate that the EEC is below the no effect level, the product should be considered acceptable from an environmental point of view. Estimating environmental exposure is difficult. It may be accomplished for a localized situation where the source inputs and the ecosystem such as a river or lake can be identified. Atmospheric exposures can also be estimated for volatile compounds. However, in most other systems reliance is made on the benchmark approach (3). In such an approach the properties of a new chemical are matched with similar chemicals of known environmental distribution, e.g. "DDT-like materials" will behave like DDT.

This paper will present a technique that estimates the distribution of the chemical in the air, water, and soil. By comparing this profile with the intended use pattern, decisions can be made on what further action is required. It should be pointed out that this model is designed for assessing environmental as opposed to human health hazard. A different approach will be required for this latter decision.

The discussion will conclude with the presentation of several case studies using existing products.

THE ENVIRONMENTAL PROFILE

The proposed technique is the extension of several previous studies on compartmental analysis (4-6). The output from this analysis is a ranking of the environmental distribution to be expected in the three main compartments: air, water, and soil. While the results are given in percent, the numbers are not meant to be absolute but are designed to yield a relative rank of importance. By matching this profile against the use pattern of the chemical it becomes easier to decide on what future tests may be required.

A scenario is used for generating the profile where the chemical is added to a water compartment (Figure 1) at a fixed rate of 0.15 g/h for a 30-day period, followed by a 30-day clearance phase (6). The half-life for clearance from the fish biomass is estimated and the percent of the total material found at 30 days in the air, water, and soil compartments are calculated.

The estimated half-life ($t_{\frac{1}{2}}$) for clearance from fish is that which would be observed in this ecosystem, which depends on the system parameters (e.g. water depth) and is not to be confused with the clearance rate of a chemical from fish in pure water.

Using a series of common chemicals ranging from toluene to DDT exhibiting a wide range of solubilities and vapor pressures, four regression equations were found to describe the results in a statistically significant manner. These equations are shown below:

$$\% \text{ of chemical in air} = -0.247\,(1/H) + 7.9 \log S + 100.6$$

$$\% \text{ of chemical in water} = 0.054\,(1/H) + 1.32$$

$$\% \text{ of chemical in soil} = 0.194\,(1/H) - 7.65 \log S - 1.93$$

$$\log (t_{\frac{1}{2}}) = 0.0027\,(1/H) - 0.282 \log S + 1.08$$

where $H = \dfrac{\text{vapor pressure x molecular weight}}{\text{solubility (ppm)}}$ (mm Hg m^3/mole)

$S = \dfrac{\text{solubility (ppm)}}{\text{molecular weight}}$ (mM/litre)

$t_{\frac{1}{2}}$ = half-life for clearance from fish in this ecosystem (h)

The chemicals along with the relevant data are shown in Table 1. Table 2 shows the results of the computer simulation and the prediction by means of these regression equations.

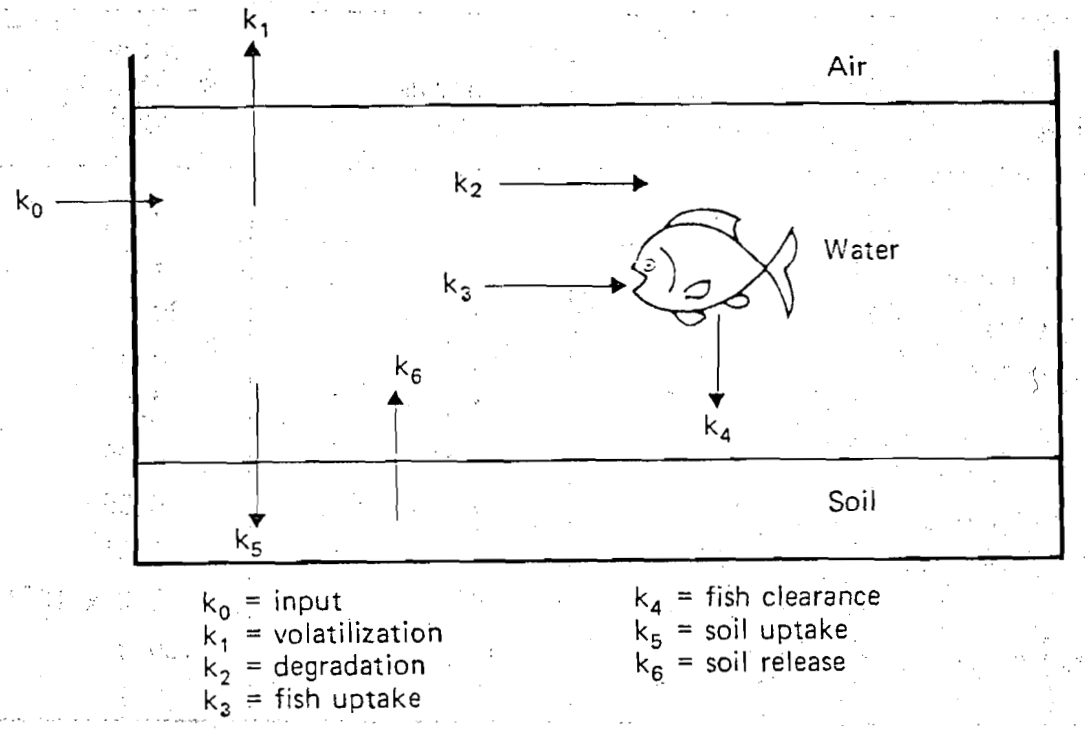

Figure 1. COMPARTMENTAL MODEL SHOWING THE MOVEMENT AND DISTRIBUTION OF A CHEMICAL IN AN AQUATIC ECOSYSTEM

TABLE 1

PROPERTIES OF A SERIES OF CHEMICALS

TESTED IN THE SIMULATED AQUATIC ECOSYSTEM

CHEMICAL	MOLECULAR WEIGHT	VAPOR PRESSURE (mm Hg)	WATER SOLUBILITY (ppm)
Toluene	92	30	470
p-Dichlorobenzene	147	1	79
Trichlorobenzene	180	0.5	30
Hexachlorobenzene	285	10^{-5}	0.035
Diphenyl	154	9.7×10^{-3}	7.5
Trichlorobiphenyl	256	1.5×10^{-3}	0.05
Tetrachlorobiphenyl	291	4.9×10^{-4}	0.05
Pentachlorobiphenyl	325	7.7×10^{-5}	0.01
DDT	350	10^{-7}	1.2×10^{-3}
Perchloroethylene	166	14	150

TABLE 2

DISTRIBUTION OF THE CHEMICALS SHOWN IN TABLE 1 IN THE VARIOUS COMPARTMENTS OF THE SIMULATED ECOSYSTEM

CHEMICAL	WATER, %	SOIL, %	AIR, %	$t_{1/2}$ FROM FISH[a], h
Toluene	0.9 (1.33[b])	0.4 (~0)	98.6(~100)	10(7.6)
p-Dichlorobenzene	1.24 (1.31)	1.28 (0.24)	97.5 (98)	15 (14)
Trichlorobenzene	1.33 (1.34)	2.06 (4.09)	96 (94)	17 (20)
Hexachlorobenzene	3.57 (1.98)	39.4 (31)	56 (68)	162(164)
Diphenyl	2.27 (1.59)	5.4 (9)	92.2 (89)	27 (29)
Trichlorobiphenyl	1.38 (1.33)	15.2 (26)	83 (71)	96(134)
Tetrachlorobiphenyl	1.5 (1.34)	17 (27)	81 (71)	104(139)
Pentachlorobiphenyl	1.5 (1.34)	21 (33)	77 (65)	229(226)
DDT	1.26 (3.17)	67.5 (46.5)	28 (49)	915(517)
Perchloroethylene	1 (1.32)	1. (~0)	98 (100)	14 (12)

a. This is the time for clearance from the fish in the simulated aquatic ecosystem once addition of chemical was terminated.

b. The numbers in parenthesis were estimated from the regression equations.

FISH CLEARANCE

If $t_{\frac{1}{2}}$ is greater than 100, a potential problem of bioconcentration is indicated. This is an arbitrary decision and is based on the results of Table 2. Using the benchmark concept (3), the chemicals in Table 2 with a $t_{\frac{1}{2}}$ greater than 100 are known to have bioconcentration problems; consequently, if the chemical screened has this high a number, it should be examined experimentally for degradability and possibly bioconcentration in aqueous systems.

SOIL

Again, using the benchmark approach the chemicals in Table 2 suggest that 4% is a reasonable cut-off point. In other words if the amount of chemical in the soil compartment is greater than 4%, degradation in soil needs to be investigated.

WATER

In a similar manner if the amount of chemical in the water compartment is greater than 2%, degradation studies are required.

This first cut is designed to give some direction to where further testing is needed. Every case will be slightly different, and attempting to formulate a decision tree to steer through the many possibilities would be a wasted exercise. The only firm conclusion is that testing should be continued until enough is known about degradation, distribution, and toxicity of the compound to insure that the expected environmental concentration resulting from the use is below the no effect level. Once this is demonstrated, manufacture and distribution should be allowed.

If in a particular application the concentration reflecting no adverse biological effect is close to the expected environmental level, then more refined measurements on the ecosystem will be required. For example, the actual receiving body of water will need characterization. Some typical properties are shown in Table 3. Simultaneously, an improved estimate of the input function will be needed. Such a function should describe the rate and amount at which the product is anticipated to enter the particular ecosystem.

CASE STUDIES

KEPONE

This is a chemical that has received a great deal of attention (see, for example, (7) and (8)). Produced primarily for use as a pesticide, it was accidentally discharged into the James River from the manufacturing site at Hopewell, Virginia. The physical properties are listed in Table 4. Performing the profile analysis, the results in Table 5 are generated. This profile immediately suggests the types of problems that can be associated with the distribution of such a chemical in an aquatic system. These may be listed as follows:

TABLE 3

TYPICAL PROPERTIES OF THE AQUATIC ENVIRONMENT NEEDED TO PREDICT THE CONCENTRATION OF A CHEMICAL IN THAT ENVIRONMENT

PROPERTY
Surface Area
Depth
pH
Flow/Turbulence
% Carbon in Sediment
Temperature
Salinity
Suspended Sediment Concentration
Trophic Status

TABLE 4

PROPERTIES OF CHEMICALS EXAMINED FOR POTENTIAL ENVIRONMENTAL HAZARD

CHEMICAL	MOLECULAR WEIGHT	VAPOR PRESSURE (mm Hg)	WATER SOLUBILITY mg/L
Kepone[a]	491	2.5×10^{-5}	3 at pH 7.0
Mirex[a]	546	6×10^{-6}	0.005
Chlorpyrifos	350	1.9×10^{-5}	2

a. Values obtained from G. Dawson, Battelle Pacific Northwest Laboratories, Richmond, Washington.

TABLE 5

THE PARTITIONING PATTERN GENERATED FROM THE REGRESSION EQUATION [a,b]

CHEMICAL	% OF CHEMICAL IN			$t_{1/2}$ FOR CLEARANCE FROM FISH, h
	SOIL	AIR	WATER	
Kepone	62	23	14	231
Mirex	37	60	1.4	320
Chlorpyrifos	74	8.5	18	335

a. From Reference (2).

b. This partitioning is based on physical properties and it does not include any type of degradation mechanism.

1. The potential for bioconcentration is evident by the half-life for clearance (greater than 100 h from the simulated ecosystem).

2. The great affinity for the soil and water suggests a major problem in these compartments with the continued release of kepone into an aquatic environment.

This analysis indicates the need for further testing on possible degradative mechanisms. Such tests have been performed and indicated the following: kepone is persistent in the environment, i.e. it resists photo and biological degradation and it does in fact bioconcentrate (8). These results confirm the conclusions from the preliminary analysis.

Furthermore, these conclusions reflect the type of problems that were created by the discharge of the chemical from the manufacturing plant at Hopewell, Virginia (8). Levels ranging up to 10 ppm were found in the James River sediment and high concentrations were found in the Chesapeake Bay (7). Even the ambient air near the plant contained detectable levels of kepone (7), affirming the predicted release to the atmosphere from the results in Table 2. Dawson, *et al.* (8) estimated that up to 200,000 pounds of kepone were released from the Virginia site; furthermore, it is estimated that up to one quarter of this amount currently resides in the sediments of the river. Thus, it is seen that the actual field observations agree with the profile generated by the equations and shown in Table 5.

The examination of the kepone incident indicates that the proposed regression equations do have the capability of quickly focusing on the key areas for further testing. It also serves as an alert system of what precautions are necessary in both the manufacture and distribution of the product.

MIREX

In 1969 a large scale, federally coordinated program was implemented to eradicate the imported fire ant in the southeastern United States. The agent chosen for this work was an insecticide known as mirex. While some early warnings over the widespread use of this close relative to kepone were registered, it was not until mirex was found in fishes from Lake Ontario and in seals from Europe (9) that the concern over the environmental impact became important. More intensive investigations soon demonstrated that the Lake Ontario ecosystem was badly contaminated. By sampling the bottom sediments of the lake, two distinct sources were apparent: one off the mouth of the Niagara River and the other in the area of Oswego, New York. Since a chemical company on the Niagara River produced mirex, the manufacturing plant was implicated as one of the major sources. The Oswego source was traced back to a plant in Volney, New York.

As the second case study, it is interesting to evaluate mirex by generating the environmental profile. Using the physical properties of mirex listed in Table 4, the profile of this chlorinated hydrocarbon was determined and is shown in Table 5. The potential problems associated with mirex become quite evident. The tendency to bioconcentrate in fish is indicated by the long half-life for clearance, while the association with the soil compartment is high. Such a high affinity for sediment suggests that once an aquatic

ecosystem becomes contaminated, the mirex in the sediment will act as a source for further contamination of the food chain long after the direct source has been terminated. A similar situation has been postulated for the PCB (polychlorinated biphenyl) contamination of Lake Michigan (10). While there are many similarities between mirex and kepone, there is one important difference (Table 5). In the case of mirex there is a greater tendency for the chemical to escape into the atmosphere. In many ways mirex more closely resembles DDT. Due to the relatively high volatility rate both are capable of being circulated around the globe. Fortunately, the production of mirex was much smaller than DDT (50 million pounds of DDT annually at the peak as compared to 50 thousand pounds for mirex) so that detectable levels in species far removed from the source such as penguins have not been observed.

However, there is no question that Lake Ontario has become contaminated with mirex. What is important in this discussion is that the simple profile presented in Table 5 combined with further testing showing persistence (9) has the ability to predict what actually occurred. If such a profile had been generated on a new chemical, the next steps would be to confirm the magnitude of the bioconcentration effect, determine the biodegradation rate in water and soil, and determine the acute and chronic effects on various target organisms. Armed with such information the producer would be alerted to the dangers of excessive discharges from the manufacturing site. This would allow time to build proper safeguards into the process in order to prevent such an incident from occurring. However, given a proper plant design and trained pesticide operators there appears to be no environmental reason why such a material cannot be used for the intended purpose of controlling the imported fire ant. In the case of mirex the human health problems may preclude the safe use of the pesticide (9).

CHLORPYRIFOS

The third case study involves chlorpyrifos (0,0-diethyl-3,5,6-trichloro-2-pyridyl phosphorothioate). The key properties are shown in Table 4 and the profile resulting from the application of the equations is given in Table 5. Without any further data, the profile suggests similar problems to kepone. Obviously, before such an insecticide can be widely distributed degradation studies are needed. Such experiments were performed and indicated a rapid hydrolysis in water (11), a significant rate of metabolism by fish (12), and a rapid destruction by photodegradation in both air and water (13). When all of these rate constants were included in the computer simulation (5), a much faster fish clearance time (less than 100 h) was observed. In addition, the major portion of the added insecticide ended up as hydrolysis products (5). Prior experimentation on the fate of the pyridinol entity led to the conclusion that the aquatic plants and microbial population converted this intermediate to CO_2, NH_3, and H_2O (14). Such a situation implies that there is no persistence of chlorpyrifos in an aquatic ecosystem. The only precaution that must be observed is that when the pesticide is distributed into water for insect control, the application rate must be adjusted in order that the initial level is below the acute toxicity level for the fish species that might be present. By knowing the physical characteristics of the receiving body of water (see Table 3), the application rate can be adjusted via a computer simulation to achieve this safe level (5).

CONCLUSION

These three case studies indicate that it is possible to quickly focus in on the key environmental questions that might be associated with a new product. Using the chemical and physical properties, it is possible to visualize where in the environment the chemical will reside. Based on this information the relevant biological testing can be performed. Incorporating the additional data into the model a more refined estimate of exposure can be made. Such cycling needs to be performed until the investigator is satisfied that the expected concentration is below the no effect level. When this is reached no further testing is required.

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SUMMARY OF PRESENTATIONS AND DISCUSSION SESSIONS

INVITED PRESENTATIONS

The major intention of the invited presentations was to provide an opportunity for speakers to describe the scientific and technical basis for their hazard assessment programs and their information sources. This was to have led into a discussion by all participants of operational problems and how they are dealt with. The workshop was to have ultimately developed solutions to these problems so that existing control programs could be expanded or improved.

Most of the invited presentations reviewed agency mandates, authorities, programs, and the philosophy used to determine the hazard of a compound. Consequently, most of the presentations were very general. Further, because hazard assessment techniques are based on available technology and can be traced to common origins, the presentations were, not surprisingly, very similar.

DEFINITIONS AND TERMINOLOGY

The major stumbling block to consideration of the issue of hazard assessment was the definition of the terms "hazard" and "assessment". The workshop organizers had assumed that participants had a common understanding of the meaning of these terms. This was not so and, although participants became more fully aware of the various possible interpretations of these words, no agreement was reached on an explicit definition of hazard assessment.

Understanding the different connotations which can be conveyed by the terms "hazard" and "assessment" provides perspective for the subsequent material presented below.

The term "assessment" can be modified by several words: priority, exposure, toxicity, hazard, risk, benefits, regulatory alternatives, and alternative technologies. Each modifier results in a different meaning for the term "assessment". Some lead to decisions whether to control, others to how to control, and still others to who should control. Assessment of priorities leads to whether to investigate.

Some participants equated "risk assessment" with "hazard assessment", and others frequently equated "risk assessment" with "determining an acceptable level of risk". There is a need to differentiate between the technical evaluation of the nature and extent of a chemical problem and the judgement that a given level of risk is acceptable from a regulatory standpoint. To determine an "acceptable level" of risk, one must weigh the actual risk posed by a chemical against the social and economic consequences of control.

Some participants focused on hazard assessment as simply a mechanism for

targeting substances or prioritizing them as the primary objective; these persons did not stress the in-depth evaluation of any given substance to determine whether or not that substance poses a hazard that should be controlled in some way. Other participants viewed this in-depth evaluation as the "hazard assessment" (the assessment of the hazard posed by the chemical) as the guts of the process, with preliminary screening of potential candidates and prioritization only as first steps and not the end product.

FRAMEWORK FOR DISCUSSION

Because of these different interpretations of what is meant by the term hazard assessment, as well as the diversity of backgrounds of the participants and the nature of the invited presentations, eight points were developed for consideration during the general discussions:

1. Define hazard assessment, risk assessment, and safety.
2. What are the main points to be considered in a general hazard assessment process?
3. How are these points to be defined in criteria?
4. What cutoffs or levels of concern can be established for each point?
5. How do these points relate to each other in the overall hazard assessment process?
6. How adequate and available are current information, data, and assessment systems?
7. How is priority setting carried out in relation to the hazard assessment process?
8. Give examples.

Using these points, the participants identified the issues and concerns discussed below.

FRAMEWORK AND PROCEDURES FOR ADDRESSING TOXIC SUBSTANCES

Workshop participants developed a conceptual framework for dealing with toxic substances (Table 1). There was considerable discussion of the considerations that enter into hazard assessment. However, since a definition of hazard assessment could not be agreed upon, there was therefore also no agreement on which items in the framework constituted hazard assessment. Most participants agreed that the first three items in Table 1 should constitute part of the hazard assessment process, but not whether the fourth item (risk) should also. Difficulty was also expressed on how to relate hazard assessment with the remaining items in Table 1.

There was also a question whether or not early warning systems, regulation development, and enforcement comprise some part of the hazard assessment process. Participants had different perceptions of what constitutes a hazard, the magnitude of that hazard, and the appropriate response to limit exposure to that hazard.

TABLE 1

CONCEPTUAL FRAMEWORK FOR TOXIC SUBSTANCES

1. Identify Candidate Substances
2. Set Priorities for Assessment
3. Assess Compounds: Effects
   Exposure
4. Identify Risk

} HAZARD ASSESSMENT?

5. Assess Risk and Make Decision on Controls
6. Set Priority for Controls
7. Regulation and Periodic Review and Follow-up

TABLE 2

FACTORS TO BE CONSIDERED FOR A HAZARD ASSESSMENT

1. Acute Toxicity
2. Carcinogenicity
3. Mutagenicity
4. Teratogenicity
5. Persistence
6. Bioaccumulation
7. Aesthetics
8. Chronic adverse effects
9. Production and use information on a geographic-specific basis
10. Degradation products
11. Presence in environment: where and under what circumstances
12. Estimated releases
13. Physical and chemical properties

What segment of the environment or the ecosystem should be considered for an assessment? The impression was given that the basis for hazard assessment, regulation, and toxic substances control is human health. However, since man is not necessarily the most sensitive biological species, consideration should be given to changing the basis to the environment or, better, the ecosystem.

The specific procedures for dealing with hazardous substances reflect the specific agency, program, or jurisdictional approaches and philosophies. Protocols are well established, recognized, and data are being generated. In general, the most appropriate route appears to be to gather literature information, generate laboratory data as required, and establish maximum allowable concentrations for the various environmental media or components of the ecosystem, based on available data. Criteria would be subjected to periodic review, as additional data become available, and allowable levels adjusted accordingly.

The general approach appears to be long-term preventive planning and program implementation rather than developing effective and coherent assessment and amelioration mechanisms to deal with episodes or emergencies. Because the implementation of laws has been slow, many participants felt that there is insensitivity and a lack of help to respond to immediate concerns not only for assessing a hazard but also for addressing the whole issue of toxic substances.

FACTORS FOR HAZARD ASSESSMENT

Factors which should comprise a hazard assessment were agreed upon (Table 2). For a given substance, both exposure and effects should be considered and, for each, both laboratory and field data are desirable. The field data should include both environmental and human health information. Of course, for new materials or compounds, projections of effects or environmental concentrations to real-world situations will necessarily and desirably be done from laboratory data alone.

Standard testing protocols should be developed and followed for acquiring the requisite data and information for each criterion in Table 2. The criteria can then be used to conduct an assessment, such as for the purpose of determining candidate substances, ranking a list already in hand, or reaching a decision on controls, depending on one's meaning of the term assessment.

No agreement was reached on how to score, rank, and use the criteria listed in Table 2, especially when the data and information base is minimal. This lack of agreement reflects in part the many various reasons for conducting an assessment and how each system is used. The significantly different approaches, scopes, or viewpoints to hazard assessment are representatively summarized in Table 3, which contrasts national and local perspectives, aims, and objectives (e.g. long-term preventive planning versus short-term contingency). The need for both short- and long-term hazard assessment must be recognized and acknowledged. Additional evaluation techniques may be necessary to address specific local needs.

DATA AND INFORMATION AVAILABILITY

A number of government and non-government groups possess toxicity, public

TABLE 3

NATIONAL VERSUS LOCAL APPROACHES TO HAZARD ASSESSMENT

	NATIONAL PERSPECTIVE	LOCAL PERSPECTIVE
1. Regulation and Control	By chemical	By source
2. Coverage	Few chemicals	Many chemicals
3. National production	High volume	High or low volume
4. Distribution	Ubiquitous	Localized
5. National economic impact	Large	Usually small
6. Hazard assessment	Full and comprehensive	Quick and dirty (refined later as required)
7. Lead group	National headquarters with monitoring input from local groups	Local with assistance from national staff
8. Time frame	Lengthy process	Quick turn-around required

health, industrial storage, and other relevant data on compounds. There was a goodly amount of data and information at the workshop which had been compiled and could be reviewed and, indeed, a great deal of information exchange took place. One apparently jurisdictional problem, however, was that some of this material could not be released, i.e. could not be shared freely such as for proprietary reasons. In other cases, a good deal of information was available for distribution but, for a number of reasons, was not well publicized. In still other cases, the information was no longer up to date.

Twenty or more U.S. federal agencies, with mandates drawn from more than a score of laws, are involved in research and regulation of toxic chemicals. This exemplifies the logistics of communication. Furthermore, in the U.S., at least 200 separate and differently organized chemical data systems are presently in use. One consequence is extensive and costly duplication of effort; another is that needed chemical data and assessment information has not been conveniently available to, or on file with emergency personnel as, for example, in the case described by Ms. Choffnes. However, efforts are under way by such multi-agency groups as the Interagency Liaison Regulatory Group, the Regulatory Council, and the National Toxicology Program, to coordinate relevant agency activities. Similarly, a committee is working on integration of U.S. federal data banks into a single system.

USE OF DATA AND INFORMATION

Availability of data and information does not guarantee solution to hazard assessment problems. Although it initially appeared that some agencies had good programs for identifying and handling hazardous substances, as discussions became more specific, it was apparent that, although they had more information on compounds, they were certainly in no better control of the situation.

There is no perfect hazard assessment procedure and the data base is incomplete; nonetheless, hazard assessment must be conducted and decisions reached. Even if all the requisite tests and information (Table 2) have been completed and compiled for a given compound, scientific value judgement must still be exercised to determine allowable levels. However, there was a definite unwillingness to accept or decide at the working level that a single particular hazard assessment method must be used, despite its imperfections or, if an assessment had been completed, there was no consensus on the level at which the hazard should trigger an action, i.e. once a potential hazard is identified, what does one do?

Again, much of this disagreement arose out of differences in definition of the terms hazard, risk, and assessment. One participant stated there was more interest in ranking substances rather than hazards; another stated that knowledge is not necessarily the problem but rather the use of that knowledge. Others noted that interactions of one compound with another can produce antagonistic, synergistic, additive, or potentiated effects and that, therefore, rating systems can be misleading.

HAZARD ASSESSMENT FOR THE GREAT LAKES BASIN

Even with different program and agency goals and objectives, participants agreed there are several areas for cooperation regarding hazard assessment.

Further, any activities undertaken specifically for the Great Lakes Basin should complement other ongoing activities in each country and worldwide.

BASIS

A number of the participants felt that the Michigan Critical Materials Register could be utilized as a starting point for developing a hazard assessment scheme for the Great Lakes Basin. Participants emphasized, however, that it is only a starting point. The material being developed by the Health Effects Committee, a joint committee of the Great Lakes Water Quality Board and the Science Advisory Board, and the industrial protocols described in the workshop presentations would also contribute to practical assessment methods. All this material together could be developed into a system specific for the Great Lakes Basin, perhaps under the auspices of the International Joint Commission (IJC).

Two IJC-related reports, "Status Report on the Persistent Toxic Pollutants in the Lake Ontario Basin" (Appendix E to the Water Quality Board's 1976 annual report) and "Status Report on Organic and Heavy Metal Contaminants in the Lakes Erie, Michigan, Huron, and Superior Basins" (1977 Appendix E), list those substances detected in the Great Lakes System. These reports, plus production and use data, should comprise the list of candidate substances specific for the Great Lakes Basin for which a hazard assessment should be conducted. Nonetheless, local priorities and risk will also have to be considered.

COORDINATION

A group to develop and coordinate a hazard assessment scheme specifically oriented to the Great Lakes ecosystem could be established by either the IJC or by the regulatory agencies, but the group's responsibility (e.g. support, administrative, or contributory in technical matters) and the qualifications of its members would have to be clearly defined.

Coordination would be a key activity of this group, especially considering the plethora of programs in existence and their varying degree of compatibility.

A qualified scientific or technical staff would be imperative in order to ensure that all the diverse physical, chemical, biological, and toxicological information could be properly and consistently compiled in order to reach a conclusion regarding hazard. Such a qualified staff is also imperative in order to deal with any misleading, controversial, or even wrong data which can sometimes be associated with various chemicals. One pundit noted that without these data, we would have fewer environmental contaminants today.

The extent to which a coordinating group for the Great Lakes Basin would become involved with subjective assessment because of social, economic, and political considerations was also raised.

The success of any IJC effort to address hazard assessment would require the commitment of agencies to participate in the program, to consider the resulting assessments in their individual programs, and to be willing to compromise. Success would also depend on the resources and the authority

granted to the group. It was further recognized that the task of pulling everybody together and keeping the program on course would be formidable.

CLEARINGHOUSE

One step leading to better and more consistent hazard assessment and, ultimately, regulation of toxic substances would be to establish and maintain a central information clearinghouse for the Great Lakes Basin, preferably under the auspices of the IJC. Such a clearinghouse would ensure wider sharing of information on chemicals among the many federal, state, and provincial government agencies and programs, industry, and others who require that information in order to perform their jobs (e.g. emergency response). A similar approach has long been in clinical use, as represented by "The Clinical Toxicology of Commercial Products", where information has been assembled in one place for emergency reference. Other examples include CHEMLINE and TOXLINE.

Some components of such a clearinghouse were described by participants. Information for each criterion in Table 2 should be compiled. For a Great Lakes information base, a cross-referencing system would be necessary to identify trade names, chemical constituents, biological activity, handling precautions, and similar such information.

Computers would enlarge and increase the flexibility of the system and help to keep it "absolutely current". The clearinghouse could also take the form of a registry of accessible data bases and programs. Other sources of information should also be identified.

A computer system should be operational and accessible 24 hours a day for international emergency reference. Other systems or aspects of the system could be identified as being available for more detailed reference on a more routine or less frequent basis. A clearinghouse approach applied to the computer information system and coordinated, for example, through the IJC, would avoid the obvious potential for duplication.

Data and information needs should be identified and laboratory research should be conducted to develop and validate data on effects, routes, fate, persistence, and degradation products of identified substances.

FUTURE WORKSHOPS

The consensus was that the subsequent workshops - Early Warning Systems, Data Acquisition and Management, and Summary - should be postponed. Holding these workshops without first resolving the issues raised at this first workshop would only result in further proliferation of confusion. In addition, many of the same questions would probably reappear, still unanswered, at the following workshops. On the other hand, beneficial information exchange which could have been achieved through the workshop mechanism has been delayed.

REPORT OF THE STEERING COMMITTEE TO THE WATER QUALITY BOARD

Based upon the presentations and the discussions at the Hazard Assessment Workshop, the Steering Committee prepared a summary report to the Water Quality Board. The Board accepted the report and included it in its 1978 Annual Report, which was presented to the International Joint Commission (IJC) on July 11, 1979. The report of the Steering Committee follows.

CONCLUSIONS

1. The state of the art of hazard assessment is in an early stage of development, and is not as advanced as first assumed.

2. Virtually all the resources available for toxic substances control programs have been devoted to the early states of hazard assessment (specifically, list development) and to regulation.

3. There is a lack of coordination between the hazard assessment and control phases of toxic substances programs.

4. There are fundamental differences between the program orientations at the national level and at the local level (state, provincial, and national). The time frame for action at the local level is much shorter than that at the national level. Thus, hazard assessment needs of the two levels are different.

5. Hazard assessment signifies different things to different people (agencies), is implemented in different ways, and is frequently confused with risk assessment and also with determination of an acceptable level of risk.

6. There is a lack of communication - both within and among hazard assessment programs - which has resulted in fragmentation and duplication of efforts.

7. There is a lack of understanding of Annex 12 of the 1978 Great Lakes Water Quality Agreement and, consequently, of a commitment to implement it.

8. There is a serious lack of toxicological information and of information on the physical and chemical properties of chemical substances; information now available is not currently available in a central storage location.

9. Priority setting by hazard assessment is an essential part of toxics programs but should consume only a small part of the resources committed to the program.

10. Some viable (operable) hazard assessment procedures are underway and there is a definite need to build on these.

THE BASIC PROBLEM

Based on the above conclusions and on the discussion at the workshop, the Committee arrived at the following statement of the general hazard assessment problem in the Great Lakes Basin.

There is a very large number of chemicals which are potentially toxic, either singly or in combination, present in the Great Lakes Basin. We need to:

1. Continually identify chemicals of concern

2. Focus scarce resources on a small number of chemicals of higher concern in order to control these at the source

3. Develop systems to provide early warnings and assessment

4. Conduct research on these substances to provide necessary decision information.

As a first step in improving hazard assessment in the Great Lakes Basin, the Committee suggests the following as a general operational definition:

> Hazard assessment is an orderly process using available data and information in a concerted, logical manner to screen chemical substances and to identify those substances on which scarce resources should be focused.

Hazard assessment consists of a series of progressively more detailed screens that are used for different purposes. It is a dynamic, evolutionary process that involves transfer of information between levels in the program, and improvement in methods as more information becomes available, as well as a reassessment of chemical substances on a regular basis.

A general scheme of the role of hazard assessment in overall toxic substances control programs is suggested in Table 1. The starting point for the scheme is the chemicals in use. For example, the inventory compiled under the auspices of the Toxic Substances Control Act lists more than 43,000 chemicals.

RECOMMENDATIONS

1. The Steering Committee recognizes an immediate need for a hazard assessment scheme to screen the candidate substances found in the Great Lakes Basin so that a needed toxic substances program can be planned and carried out in a critical manner. The following measures should be carried out:

   A. The existing Michigan hazard assessment process should be used as the process for initially screening the candidate chemical substances.

TABLE 1

OVERALL TOXIC SUBSTANCES CONTROL SCHEME

SCREEN	FOCUS OF EFFORT	DEGREE OF DETAIL	NUMBER OF SUBSTANCES
Level 1	Priority lists, chemicals found through monitoring, preliminary inventories, use-pattern surveys	General	Large
Level 2	Hazard assessment of the chemicals through examination of physical, chemical and toxicological properties. No effort is made to rank the chemicals passing through the screen. An example of this screening process is the Michigan Critical Materials Hazard Assessment.		
Level 3	Production, use, location, special studies, exposure levels, human and ecological effects monitoring - equal effort given to all substances.		
	Hazard Assessment Stops Here		
Level 4	Risk assessment, social, economic, political factors		
Level 5	Decision on control		
Level 6	Regulation, enforcement, and surveillance	Specific	Small

B. A list of candidate chemicals should be submitted from various Great Lakes Basin sources for the initial screen.

C. The data base derived from this process should be made available for the Great Lakes Basin agencies. The whole screening process should be as open as possible to enable information to be made available at every step. The data base should be made compatible with the United States federal chemical information base and ISHOW, the data base developed under the Science Advisory Board's sponsorship.

D. A clearinghouse pertaining to activities on hazard assessment of toxic substances should be established. The information inventory should be updated on a regular and frequent basis.

E. Similar, well planned and coordinated efforts should be instituted for the other parts of the toxic substances program to establish:
   i) An additional screening process using inventory data, use patterns surveys, and early warning monitoring systems to further refine the candidate list.
   ii) A risk assessment process.

2. A new working group chosen from regulatory agency staff actively engaged in hazard assessment should be established to develop and implement the hazard assessment process. Full time staff should be dedicated solely to this activity to assist the work group. Contract resources should be made available to the work group.

3. Other workshops planned (Early Warning Systems and Data Management and Acquisition) should be deferred until the activities of the hazard assessment working group are defined.

REPORT OF THE WATER QUALITY BOARD TO THE INTERNATIONAL JOINT COMMISSION

The Water Quality Board outlined in its 1978 Annual Report to the International Joint Commission (IJC) a course of action to be taken for hazard assessment in the Great Lakes Basin. The Board's report is presented below.

> The Water Quality Board, in reviewing the contaminants problem in the Great Lakes Basin, has found that the national programs of both countries and the individual programs of the jurisdictions are addressing the problem in varying degrees and from a number of viewpoints. There already exists a large number of programs directed toward the control of toxic substances in various parts of the ecosystem. These individual programs to control contaminants released to air, water, and land; in food; from industrial and agricultural practices; and other sources result in a diversified and segmented approach to the whole problem. . . .
>
> The Board recognizes the importance and enormity of the task confronting agencies involved in implementing laws to control toxic and hazardous substances. Accordingly, the Board has placed greater emphasis on toxic substances by directing its committees to focus on these substances in the Great Lakes Basin. In keeping with this new focus, the Board is sponsoring a series of workshops as part of a comprehensive review of the contaminants problem and programs to control the discharge of toxic and hazardous substances in the Basin. A steering committee was appointed to organize and conduct the workshops under the supervision of the Water Quality Board.
>
> The first of the series of workshops was held April 9-11, 1979 to review the procedures used by agencies in hazard assessment because of its importance in regulatory decision-making for toxic substances control.
>
> The workshop demonstrated that the fragmented approach to hazard assessment by the different agencies makes appraisal of the effectiveness of programs directed at the Great Lakes problems difficult. . . .
>
> The Board concludes there is a need for a hazard assessment program to integrate the efforts of all agencies and evaluate the hazard of toxic substances found in the Great Lakes Basin. Such a program would not be a substitute for other assessment operations. There is a need to maintain and expand existing programs and ensure they are compatible with the requirements in the 1978 Agreement. Accordingly, the Board recommends that a small work group be formed to conduct a hazard assessment program specifically oriented to the Great Lakes ecosystem to complement existing agency efforts. The success of this

effort requires the commitment of agencies to participate in the program and to consider the assessment in their individual programs.

Other workshops will be deferred until the hazard assessment component of the program is more fully developed. . . .

The Water Quality Board presented to the IJC the following recommendation regarding hazard assessment. The Board urged the Commission to consider and adopt this recommendation, and to forward it to Governments:

To support toxic substance control programs of each jurisdiction and in the interest of coordinating the toxic substance control programs, the Commission should sponsor the establishment of a work group to undertake hazard assessment of substances found in the Great Lakes ecosystem. The success of this effort requires the commitment of agencies to participate and to consider the assessments in their individual programs.

POSTSCRIPT

COMMENTS ABOUT THE WORKSHOP

The format and the organization of the Hazard Assessment Workshop, in part, contributed to not fully achieving the objectives of the workshop. Major comments and suggestions of the participants were:

1. An introductory keynote speaker or a panel, clearly stating the objectives and the goals of the workshop, would have provided more direction and cohesiveness. A large part of the problems encountered resulted from the fact that many participants had different pre-conceptions about the purpose of the workshop and/or were not fully open to other perspectives. Some also wanted to expand the scope of the workshop from just hazard assessment to encompass the entire toxics question.

2. Fewer speakers would have permitted more discussion and questions after each presentation.

3. The format allowed presentation of methods, mandates, authorities, and programs, but the large attendance prevented participants from really coming to grips with the problems associated with hazard assessment and beginning to develop solutions.

4. Round-table, small group discussions on selected topics would have been useful.

5. Objectives of the workshop and definitions of terms should have been specifically stated and agreed upon at or even before the start.

6. Presentations should have been distributed beforehand. Written presentations had originally been requested by the Steering Committee, but few speakers met the deadline.

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