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Committee on the Assessment of Human Health Effects of Great Lakes Water Quality. Annual Report 1983

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Great Lakes Water Quality Board / Great Lakes Science Advisory Board
Report to the International Joint Commission

1983 Annual Report

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Preface

The 1983 Annual Report of the International Joint Commission's Committee on the Assessment of Human Health Effects of Great Lakes Water Quality was prepared for both the Water Quality Board and for the Science Advisory Board.

Highlights from the activities of the Committee from its previous reporting date in November 1982, to the present, are reported here.

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Committee has proceeded to determine whether, for some of the compounds named, Acceptable Daily Intake (ADI) values have been determined by various agencies. Where ADI values are not available, the Committee is determining whether available toxicity data are sufficient to determine the amount likely to be hazardous to health. The Committee is also aware of the discovery in the Great Lakes ecosystem of many additional compounds and is considering a review of this list using the methodologies described in earlier reports.

In several chapters of this Report, the Committee calls for additional data, knowledge and research. The Great Lakes Basin is fortunate to have good research institutions, excellent laboratory capabilities, responsive governments, the coordinating functions of the (1978) Water Quality Agreement institutions and above all, educated and enlightened citizens. If these institutions are properly funded and are able to continue their work and if we continue to act on a basis of knowledge, we shall be able to assert with even greater confidence than is now possible that the Great Lakes Basin is a healthy place in which to live.

1. Drinking Water: Additional Concerns

1.1 Epidemiology: Drinking Water and Health

1.1.1 Introduction

Most of the scientific evidence which is used for determining whether a water contaminant is hazardous to humans is based on animal experimentation. The great advantage of animal toxicity studies as compared with studies among humans is the ability to experimentally control and ascertain the environmental exposures under study, the other factors which may influence disease (genetics, diet, environment, age, sex) and the disease outcomes. Nevertheless, since there may be considerable differences between various species in their biological reactions to chemicals and since the nature of exposure differs in a free-living population from experimental conditions, the setting of standards for humans based on animal evidence is fraught with uncertainty. It would therefore be convenient if we could obtain direct scientific evidence concerning human response to chemicals.

1.1.2 Applications of Epidemiology

Epidemiology is the science concerned with addressing the determinants of disease in human populations. Unfortunately, there has been very little epidemiological investigation of the possible impact of water contaminants on human health and this is the reason for our virtually complete dependence on animal toxicity information. There are two reasons for this lamentable gap in knowledge: lack of interest on the part of funding bodies; and methodological difficulties of carrying out epidemiological studies in this field. The difficulties of such studies are: a) the ascertainment of exposure of humans to particular contaminants; and b) the ability to tease out specific factors among the myriad exposures and characteristics of people which may be responsible for their diseases. Such methodological problems are inherent in all types of epidemiology, but they may be more acute and impervious to solutions in some areas of investigation than others. For instance, one can cite: the demonstration of harmful effects of cigarette smoking and alcohol; the demonstrated relationship between blood pressure, cholesterol, exercise and heart disease; and the occupational disease caused by asbestos exposure. These are only a few of the important and useful findings which epidemiology has produced by overcoming the methodological difficulties.

The impact on health of water contaminants is more difficult to study because it is much more difficult to estimate how much PAH, for instance, a person has been exposed to through water than it is to estimate how much tobacco has been smoked, or how much asbestos exposure was received at work, or the blood pressure history. As stated above, an additional obstacle to the conduct of epidemiological research in this field has been the lack of funding as compared with that available for research on occupational, lifestyle and

other factors in disease. With adequate funding, there is every reason to believe that epidemiological methods can be applied to estimate the impact of environmental chemicals on some segments of the population.

1.1.3 Design of Epidemiological Studies

Epidemiologists deal with human populations whose patterns of exposure to various factors is not controllable. Hence, they must be imaginative and thorough in their comparisons of the "exposed" with the "unexposed". Research designs are therefore idiosyncratic and must be adapted to the availability of data sources. It is thus impossible to present an all-encompassing prescription for the ideal epidemiological study. It may, for example, be possible to study the cancer effects of trihalomethanes with one methodology, the neurologic effects of dioxin with another methodology, the teratogenic effects of dioxin with a third, etc. For a whole range of possible exposure-disease associations, it may be virtually impossible to generate useful epidemiological evidence. This must be assessed on a case-by-case basis.

1.1.4 Methodology

Although the methodology must be tailored to the problem, it is possible to enumerate and briefly describe some of the main types of epidemiological study. Two basic types of study are those based on the comparison of geographic units and the comparison of individual people.

1.1.4.1 Ecological Studies

The first approach typically consists of establishing the correlation between death or disease rates in geographic areas on a state or county or province or national basis, with some index of exposure to the putative risk factor in the same areas. This so-called "ecological correlation" is the cheapest and quickest type of epidemiological study and it is the most common type that has been carried out in the study of the effects of water constituents. Unfortunately, it is the least sensitive type of study for identifying real effects and it is very vulnerable to biases and misinterpretation.

The best investigated water quality parameter using such methods has been fluoridation. Whereas one analysis of the ecological correlations carried out by non-epidemiologists purported to show that cities with fluoridated water experienced high cancer rates, a more careful and correct analysis has shown there to be no such effect.

Other waters studied by such methods have included both surface and groundwaters and those containing chlorine and asbestos. For these factors, the evidence has been too meagre and/or equivocal to draw reliable conclusions. There certainly has been no overwhelming evidence of harmful effects, although the limitations of the methodology precludes an assurance of absolute safety.

1.1.4.2 Studies on Individuals

Studies based on individuals tend to be more sensitive, more conducive to adjusting for possible confounding factors and more expensive. There are three basic (and several subtypes) of studies based on individuals to elucidate the association between an exposure factor and a disease:

a) a cohort study is one in which a group of individuals can be identified who were or are exposed to the product under study. An appropriate comparison group of non-exposed persons can be identified and the disease outcomes in the two groups compared;

b) a case-control study is one in which a disease or a group of diseases is defined, persons falling ill or dying of these diseases identified and an appropriate comparison group of non-diseased people is identified. The occurrence of exposure to the factor under study is determined and compared among the affected and un-affected;

c) a cross-sectional study is one in which a respresentative sample of some community is identified. The study consists of determining for each person whether they have experienced the exposure under study and whether they have the disease under study.

There have been only a few drinking water studies based on individuals and these have been primarily case-control studies.

1.1.5 Conclusions

There is some suggestive evidence of excess risk of rectal cancer among persons who had consumed chlorinated water. No other remarkable associations, however, have become apparent. It is important to note that, even more than in animal experimentation, a finding from an epidemiological study needs replication by other researchers under different conditions before it should be accepted as a fact.

1.1.6 Recommendations

1. That the Human Health Effects Committee utilize up to $20,000 to procure consulting services in epidemiology to develop a strategy for epidemiologic studies on the human health effects of Great Lakes water contaminants.

2. Based on the outcome of the above consultation, the IJC would be provided with advice regarding recommended studies and their funding.

1.2 Health Related Surveillance and Monitoring Programs

1.2.1 Introduction

The Committee held a Roundtable in March 1982, to examine the surveillance and monitoring requirements specifically for assessing human health hazards posed by contaminants in the Great Lakes Basin Ecosystem, to delineate human exposure. Information on existing fish surveillance and monitoring programs,

as defined in the Proceedings of the Roundtable, was available and published. No information on similar programs on water quality, however, was obtainable at that time.

1.2.2 Approach

A water quality monitoring questionnaire was developed to obtain the first comprehensive picture of existing drinking water quality sampling in the Great Lakes Basin.

The questionnaire comprised the following five sections with several subsections under each as shown below.

Section I. Ambient Water - a) Monitoring Agency; b) Specific Chemical Substances or Microorganisms Monitored: 1) On EPA Priority Pollutant List? Those on EPA List Not Monitored; 2) Inorganic or Organic Chemicals Not on EPA List; 3) Microorganisms; c) Monitoring Location; d) Frequency of Monitoring.

Section II. Raw Water and Finished Drinking Water - a) Monitoring Agency; b) Specific Chemicals, Physical Properties or Microorganisms Monitored: 1) on EPA Priority Pollutant List? Those on EPA List Not Monitored; 2) Inorganic or Organic Chemicals Not on EPA List; 3) Microorganisms; 4) Physical Parameters; c) Monitoring Site; d) Monitoring Frequency.

Section III. Industrial Effluent - a) Monitoring Agency and Guidelines; b) Chemicals Monitored; 2) Microorganisms Monitored; 3) Other; c) Location and Frequency of Monitoring: 1) Monitoring of Ambient Water Receiving Discharge; 2) Monitoring of Sewage Treatment Effluent Prior to Discharge.

Section IV. Contact for Additional Information - Details

1.2.3 Results

Responses to date have been obtained from all but two of the Great Lakes States and the Province of Ontario. Evaluation of the responses is underway and will be reported by the Committee at a later date.

1.3 Water Treatment

The objective of water treatment is to provide to consumers a drinking water which is safe and aesthetically pleasing. The primary function of water treatment plants is and has always been to prevent the spread of waterborne disease; this function, i.e., the elimination of microorganisms responsible for human disease (as pointed out in last year's report from this Committee) must remain paramount. Concern is emerging, however, regarding the presence in drinking water of chemical contaminants which may have detrimental effects on the long-term health of consumers; this concern is particularly acute in the area of surface waters used as drinking water sources. There is insufficient information on the effects of many of these contaminants to enable the setting of maximum acceptable concentrations (MAC's) for them in finished drinking water, although prudence suggests that levels should be as low as practicable. Attention should be focused on the following areas.

1.3.1 Conventional Water Treatment

There exists a need to characterize fully the efficiency of each stage of conventional water treatment*, in the removal of as wide a variety of contaminants or contaminant classes as possible. Whilst there have been processes, such as activated carbon, suggested as additional auxiliary steps for treatment of waters containing specific contaminants, it appears that the possibilities of conventional treatment have not been fully exploited.

In recent years, increased emphasis has been placed on the removal of suspended matter with removal measured as a decrease in turbidity. The justification for this was mainly the interference of particulate matter with measurements of bacterial contamination. Many contaminants of concern, primarily organic, are associated with particulate matter; they are either adsorbed to mineral and organic particles or may be enriched in plankton organisms. It is, however, possible that optimum treatment for turbidity removal may not produce maximum removal of certain classes of organic compounds or conversely if treatment is optimized for contaminant removal, turbidity removal may not be optimal.

Results from research on the capabilities of the conventional treatment would permit value judgements to be made as to whether "better" quality water would result by optimizing for either contaminant removal or turbidity control. Whereas this issue could be addressed in appropriately amended objectives, guidelines or regulations for water treatment, it is clear that these would be different for each treatment system because of differences in water quality. Here, as in other areas of environmental management, regulations that are both overly detailed and uniform would probably be counter-productive. It would be more appropriate to set objectives for each treatment system within a broad regulatory framework, once the evaluation of conventional treatment has been accomplished.

A similar approach should be applied to wastewater to minimize the discharge of contaminants of concern. In last year's annual report, the Committee recommended a study of the association with particulate matter of pathogenic microorganisms in wastewater effluent, implying that improved removal of particulate matter would minimize the need for chemical disinfection with its acknowledged disadvantages.

1.3.2 Treatment Philosophy

The drinking water objectives, guidelines or standards of the various Great Lakes Basin jurisdictions set maximum acceptable concentrations (MAC's) for many contaminants in drinking water, based primarily on public health considerations. These MAC's are intended to be <u>minimum</u> standards of drinking water quality. With few exceptions, modern water treatment technology without auxiliary treatments is capable of producing water exceeding these standards, e.g., the production of a finished water with 0.1 FTU (turbidity units) is possible, the MAC being 1 FTU (in the U.S., 5 FTU, if turbidity does not interfere with bacteriological examination and maintenance of a chlorine

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* i.e. chemically assisted filtration and disinfection

residual). Some suppliers of water have tended, however, to view MAC's as a target level and have made little effort to apply conventional treatment practice more efficiently to produce further quality improvement.

Similar developments have occurred in wastewater treatment. The IJC has laboriously developed a phosphate discharge limit of 1.0 mg P L^{-1} based on the knowledge and consideration that 0.2 to 0.3 mg P L^{-1} can be customarily achieved in several treatment schemes. Similarly, discharge limits of 30 mg L^{-1} for 5-day BOD or suspended solids are well within the capabilities of conventional water treatment plants. Although the higher values were set to accommodate those plant malfunctions which occur periodically, are of short duration and are probably unavoidable, operators may be content to allow plant efficiency and effluent quality to decline to the mandated levels. In both water and wastewater treatment, this can result in savings in the use of chemicals and therefore even the omission of treatment steps may be condoned and even encouraged by plant management.

Professional pride on the part of a plant operator and fiscal responsiblity on the part of the City fathers are both laudable, but subversion of legislative or regulatory intent can have unanticipated consequences for water quality and public health. In the case of drinking water, delivery of a safe product to the consumer depends as much on the selection of treatment processes that are appropriate for the source of supply, taking into account the type of pollution to which it may be subject, as on the monitoring of the finished water to ensure that objectives or regulations are achieved.

Jurisdictions should, as well as requiring that the various current quality objectives are met in finished waters, define the treatment steps which must be implemented at the plants as a minimum requirement and determine exactly how plant performance is to be measured. Results from the investigations recommended above should assist jurisdictions in this activity. In the treatment of wastewater only now are there several studies underway in the Basin and elsewhere to assess wastewater treatment plant performance using statistical methods and correlating effluent quality to seasonal and other factors. We are certain that other IJC Committees monitor progress in this field and that their findings will be applied from time to time as is appropriate.

1.3.3 Sampling and Analysis

Enormous advances have been made in our ability to detect trace levels of chemical species in water samples. Measurements in the parts-per-billion range or even lower are common. When a contaminant is detected for the first time, it is not unusual that the method of detection is non-standard and is not accompanied by an adequate quality control protocol. Jursidictions must be cautious in the reporting and interpretation of such results.

For contaminant monitoring, only accepted sampling and analytical protocols should be used with adequate quality control. A great deal of credibility has been lost by agencies from the release of results which later proved to be inaccurate due to errors in the analytical method or through faulty sampling.

We must also point out that the normal environmental variability for most chemical contaminants is greater than the laboratory error. With adequate quality control, any single measurement is significant, but it is also hardly, if ever, a truly representative measurement of the environmental or human exposure. Many measurements in space and time are required to establish human exposure from a single source. In addition, background measurements (i.e., measurements in areas unaffected by the source) and measurements of exposure from all sources (i.e., water, food and air) are necessary to evaluate the relative significance of any single source.

There have been opinions voiced to the effect that the high sensitivity of modern analytical techniques is to be deplored. On the contrary, we feel that sensitive analytical methods provide margins of safety in the protection of public health and in decision-making. They also provide information on background levels, sources, pathways and fates of contaminants before they become a hazard.

The awareness of the presence of toxic contaminants can create public fear. There are public officials who prefer to see a negative laboratory result suggesting the absence of a contaminant, because the indication of the presence of a contaminant forces them to make a decision while the apparently negative result does not. Furthermore the public, not being familiar with standard or objective-setting methodology and suspicious of risk assessment procedures, is generally not prepared to accept that there is a "safe" level for contaminants which potentially cause health effects in humans. There may be public and political pressure demanding the complete removal of such contaminants during water treatment. The current water quality objectives or standards represent levels of contaminating substances which can be regarded as safe. Regulatory agencies should be prepared energetically to defend these levels and resist pressure to modify and/or to add advanced treatment steps to the conventional process train if it produces drinking water which meets all objectives and standards.

1.3.4 Recommendations

1. The Commission should request that the jurisdictions encourage and enforce as may be necessary, the operation of each water and wastewater treatment plant in the Great Lakes Basin in accordance with both the stated and approved design criteria for that plant and best operating practices. Drinking water and effluent standards, when less stringent, should not become a justification, an excuse, or an incentive to operate such plants at a lower level of performance.

2. Additional research should be undertaken to investigate the removal of unconventional contaminants by conventional water and wastewater treatment systems, with emphasis on the potential benefits to be derived from the high-grade removal of particulate matter in combination with consistently reliable operation.

3. Once these factors are considered, jurisdictions should be prepared to defend water quality objectives, guidelines and standards (i.e., safe levels established from toxicological studies, with appropriate safety margins) and to resist pressures to add advanced treatment steps to the

conventional process train as long as such a conventional process produces water or effluent meeting all applicable objectives, guidelines and standards.

4. Caution is to be used in the interpretation of single and scanty measurements of environmental contaminants, except if they indicate a potential for imminent danger to the public health. Even if the methods of sampling and analysis are standardized and subject to rigid quality control - as they always should be - environmental variability tends to exceed the normal laboratory margin of error, so that obtaining conclusive exposure information for environmental contaminants always requires a certain minimum program of sampling and analysis.

1.4 Groundwater and Sampling Protocols

In its (1982) Annual Report, the Committee raised the issue of groundwater reserves in the Great Lakes Basin as present and alternate sources of potable water. It was pointed out that enacting and enforcing appropriate watershed regulations to protect these resources from encroachment and contamination would be an appropriate course for the regional and local authorities to follow.

The Committee is aware of the interest of the Science Advisory Board in the issue of groundwater contributions to the Great Lakes and the potential for contamination of the Great Lakes from contaminated groundwater. Whereas this concern is valid and appropriate under a narrow interpretation of the Great Lakes Water Quality Agreement, the Health Effects Committee feels that the Ecosystem Concept embraced by the Commission warrants the Commission's interest in the broader issue of protecting all drinking water sources for the residents of the basin. The two issues are closely related, because stringent controls on the discharge of wastes directly into the lakes or their tributaries directly creates an incentive to dump wastes on land, resulting in the contamination of groundwater aquifers which are current or potential sources of drinking water.

1.4.1 Recommendations

1. The Committee requests that the Science Advisory Board in its review of groundwater contamination affecting the Great Lakes ecosystem, include those groundwater resources serving or potentially serving the residents of the basin as sources of potable water.

2. Toxicological Evaluation

2.1 Preface

The Great Lakes Water Quality Agreement of 1978 permits the Commission to recommend to the Jurisdictions possible new or revised water quality objectives for chemicals which may be found in compartments of the Great Lakes Basin ecosystem. New or revised objectives reflect a new understanding of specific effects produced in organisms (including humans) by chemicals as well as their modes of action. A major portion of the new knowledge of chemicals and their effects on exposed organisms relates to particular types of effects -- notably carcinogenicity -- which can be broadly considered here as: "the induction or production of cancerous lesions either directly or in the presence of other specific chemicals as promoters, adjuncts or potentiators".

The International Joint Commission has very limited experience in receiving and applying this new toxicological information to the formulation of advice to the Governments. Furthermore, the Commission is confronted with widely differing philosophies and regulatory approaches among various jurisdictions in applying this new toxicological information to programs of environmental and public health protection and improvement. There is a basic need for a reference or source document on this subject within the Commission that can be used by the Commissioners when approaching the formulation of advice to Governments. This document would provide the Commissioners with the necessary guidance for understanding and applying complex scientific information to policy with respect to exposure to toxic contaminants.

The Chapter that follows introduces the Commission to the nature of toxicological information. It describes some of the special problems that must be considered when the toxicology of environmental contaminants is addressed, as contrasted by the approaches that are used in the conventional toxicology of food additives, drugs and products of convenience. It also marks the commitment of the Health Effects Committee to undertake a long-range assessment of the problems and policy needs of various components of the life sciences associated with the expert toxicological evaluation of levels of chemicals found in the Great Lakes Basin ecosystem.

2.2 Introduction

The waters of the Great Lakes Basin may be contaminated by chemicals from a variety of sources. These include: industrial wastes; runoff from agricultural land (herbicides, pesticides, etc.); air and sewage discharges, discharges or spills from ships; etc. Concentrations of most pollutants in the water are small. Yet, if the activity of a specific chemical is sufficiently great, there is a possibility that a low concentration could have an adverse (i.e. toxic) effect on human health.

Human exposure to water pollutants can occur in a number of ways. Many communities draw upon the Great Lakes for their water supply. People drink the water and consume foods prepared in it. If a pollutant can be absorbed through the skin or mucous membranes, swimming in the Great Lakes or in private or public pools could result in minor exposure. For some individuals, consuming Great Lakes fish could be an important exposure route. The potential human health hazard from chemicals may be increased, since fish can concentrate some chemicals in their tissues; hence consumption by man may lead to significantly greater exposures than obtained through water alone. Although concentrations of pollutants could be reduced or eliminated by control at the source of the pollutant if a realistic evaluation of the potential hazard (1) justified such action, a zero level of most pollutants is impractical and impossible.

If studied under appropriate experimental conditions, almost any agent can be shown to be toxic in some way for animals. This includes physical agents and chemicals which are essential for life support such as oxygen and water, many natural components of food (2) and essential metals such as cobalt and selenium. Thus, any chemical may be presumed to present a potential hazard if tolerated exposure levels for that agent are exceeded. The evaluation of the potential hazard is based upon the type of adverse effect(s) that may be produced and by the amounts of that agent required to produce the adverse effect(s) compared with the projected exposure level(s) for the human.

2.3 Toxicology

Toxicology is the study of the adverse (or unwanted) effects produced in living organisms by various agents (chemical, physical). The level below which adverse effects are not observed is the threshold level. Threshold levels of different agents can vary greatly depending on species and mode of exposure and therefore should be determined for each agent under the appropriate exposure conditions. This has been a common practice when the safety of drugs or food additives is determined and is being used for industrial and environmental chemicals (3,4). The duration of toxicology studies in animals varies from single dose exposure (acute toxicity) to continuous or intermittent exposure for a few days to near lifetime (subchronic and chronic toxicity). The exposure may be by oral administration, inhalation, injection or other routes as may be needed, usually depending upon the projected human exposure. These studies include various types of diagnostic procedures such as general observation, hematology, biochemistry and pathology to detect abnormalities and to provide an overview of the activity of the agent. Studies of the effects on both male and female reproductive capacities and on the progeny are a part of the overall evaluation of the potential hazard. Adjunctive studies may be done to aid in the interpretation of the results (4).

Pharmacokinetics (blood level, distribution of agents through the body and subsequent excretion) and metabolism studies (action of the body on the agent as well as of the agent on the body's biochemistry) are often useful in the interpretation of toxicological findings. Recently, they have been used more frequently because adequate analytical methodology has been developed to facilitate these studies.

In contrast to studies in whole animals (i.e. in-vivo tests), in-vitro tests are often used. However, because of the complicated chemical interactions within the whole animal, in-vitro tests should be considered as screening tests to detect certain types of activity. They are also useful as adjunctive tests to the whole animal studies to aid in elucidating the mechanism of action leading to the toxicity observed in the whole animal (5). Perhaps as our knowledge of the interactions in the intact animal increases, the in-vitro methods will become more useful for predicting toxicity in the whole animal.

The methodologies for immunological toxicity and behavioural toxicity are being developed but are not yet accepted by all toxicologists as suitable for routine use. More work is needed in this area.

The type of toxicity that might be produced by the various agents is quite varied and can be reversible or irreversible. The toxicity of a single agent may be different for different species of animals or it may be similar for several species. One species may be more sensitive than another to the toxic effects of one chemical. Since the nature of human exposure to environmental factors is much more complicated than any experiment can simulate and since there are inter-species physiological variations, the prediction of hazard for man based on the results of animal tests requires caution and scientific judgement.

2.4 Evaluation of Potential Hazard

Some chemicals can produce adverse effects in an organism after acute exposure. It is unlikely that this would occur through exposure to the water of the Great Lakes unless the concentration of the chemical were very high, such as in local spills or where the substance was extremely active. Some of these chemicals, found in the Great Lakes, have been listed by the Committee in its (1981) and (1982) Annual Reports (Tables 1 and 7.1, respectively). On the other hand, some chemicals are relatively non-toxic acutely, but they could exert their toxic effects even at low concentrations if exposure were more or less continuous over extended periods of time, especially if the chemical is accumulated in living tissues. Carcinogenic effects can be of this type. An evaluation of potential hazard should then include consideration of the type of adverse effect that might be produced and the possibility that toxic concentrations might be reached.

Non-carcinogens generally have a certain exposure level below which observable adverse effects are not produced (threshold level). Thus, exposure levels are set using conventional safety factors such as 1/100 of the threshold level. Chemicals which are carcinogens (or mutagens) pose a more complex problem. It has been stated that, for this type of chemical, there is no threshold level and that one molecule of a carcinogenic chemical may initiate the process of cancer. This would mean then that for absolute safety, there should be no exposure (zero exposure). Since there is a dose response for carcinogens, the lower the dose the less the chance there is of developing cancer by an exposed individual. Statistical methods developed to calculate a "socially acceptable" risk are based in part on the dose response.

Although the "no threshold" level concept indicates that one molecule can cause cancer, it is likely that many molecules would be required to assure that a single molecule would pass through a complicated cell complex and reach the proper site on a deoxyribonucleic acid (DNA) molecule (6). There would be many reactive sites for interaction, in addition to those of DNA, which would not result in cancer formation. However, other mechanisms may increase the carcinogenic effect of a chemical agent. In addition, any natural defense mechanisms of the body would further reduce the probability of a carcinogenic effect. Also, at sufficiently low exposures, it is possible that the latency period for the development of a cancer could be increased beyond the natural lifetime of the exposed individual.

Statistical methods have been developed to evaluate exposure levels associated with any level of risk so that, for example, only 1 in 1,000,000 individuals exposed to a certain level of a carcinogen may develop cancer. It is then up to society to select risk levels it considers acceptable. For the most part, these methods were developed with the express desire to be deliberately conservative, i.e. to be overprotective (see references 7, 8, 9).

In dealing with the potential hazard of carcinogens, there has been a tendency to consider all carcinogens as equal, ignoring potency and mechanisms of action. A better understanding of some of the mechanisms of carcinogenesis might permit the establishment of threshold levels which could then be used as a means of developing safe exposure levels. This would improve the precision of risk variables.

Whereas nearly all chemicals known to produce cancer in humans do produce cancers in one or more species of experimental animals, there has been some concern for the predictability of the results of the animal studies for man. Some of the animals used in these tests have a relatively high and variable incidence of spontaneous tumors which can create problems in interpreting the results. In addition, the doses used in some of the studies are so high that the metabolic processes of the animal may be altered, so that the chemical would not be handled in the same manner as when lower doses are used. It is easy to use statistical results blindly for making decisions. The judgement of the toxicologists and pathologists in collaboration with statisticians in concluding that a chemical is or is not a carcinogen should be given full consideration throughout the decision-making process. Similar concerns were expressed in a paper by a Task Force of Past Presidents of the Society of Toxicology (10).

Any plans to regulate exposure to carcinogens must be sufficiently flexible to regulate: 1. those chemicals which are known to be highly toxic or carcinogenic to man; 2. those which are weakly toxic; or 3. those presumed to be potentially carcinogenic hazards, based on non-human data which may include controversial work or be of questionable statistical significance.

2.5 Environmental Contaminants - Special Considerations

Unlike the toxicological evaluation of drugs, food additives, etc., there are special problems associated with the evaluation of environmental chemicals. First of all, environmental chemicals may already occur in air,

water, biota and often humans themselves. Thus, the evaluation of these chemicals must take into account their immediate presence, their past and future levels and their interactions with a wide range of other chemicals to which humans may be exposed on a daily basis. Exposure may be highly variable and difficult to quantify because of limited information on the frequency of occurrence and level of the contaminant in the environment. The issues are not how much of a particular agent can be safely added to a food-stuff or administered as a drug to obtain a suitable prophylactic effect, but rather how much low-level contamination of our life support media (food and/or water and/or air) can be accepted without undue hazard to health. Although zero-exposure is ideal, it is neither realistic nor probable. Hazard evaluations of environmental chemicals must take into account these realities.

A second special aspect of evaluation of environmental chemicals is the frequent lack of epidemiological data. This results both from the lack of support for these studies and the difficulty of detecting low incidence, adverse health effects or reproductive outcomes specific to any one chemical or to a wide range of chemicals found at very low levels. These data deficiencies have significant impacts on our ability to assess hazard and risk. Hence, we are frequently forced to set arbitrary and conservative safety factors for environmental chemicals using limited toxicity data derived from studies with experimental animals. These are intended to account for the possibility of interactive effects between the various contaminants and the implications of exposure of ultra-sensitive individuals.

2.6 Release of Information - Public Perception

Humans fear the unknown and tend to react strongly to unexpected events perceived as a threat to their well being. Media interest in and high visibility of toxic contaminant issues fuels this concern in the population. Members of the lay public are not scientists and do not understand the technical terms which are second nature to professionals. The news media, in interviewing such scientists, incorporate unfamiliar but dangerous sounding terminology in their stories which are then passed on verbatim to the public which, in turn, becomes alarmed.

Not infrequently, the public are informed via the news media that a pollutant has been found that is potentially toxic or is an animal carcinogen. Seldom is there reference to its potency, potential exposure levels, characteristics that may affect its activity or to the experimental data which led to its being labelled as a potential hazard. When it is reported that a carcinogen has been found in drinking water but with no statement regarding its concentration in the water, there is often an emotional impact because the natural perception is that exposed individuals may develop cancer. This is clearly unacceptable. There must be responsible commentary on the relative potency of the carcinogen, the exposure level and if known, the levels which have been shown to produce the adverse effects in animals or in man. Better explanations of definitions and terms are also vital for improved communication of scientific results.

The news media and the scientific community share the responsibility for informing the public in a fair and factual manner. The discovery of an environmental contaminant with the potential to affect human health

constitutes news. Considering the competition for time and space in the news media and the brevity that is required to convey a multitude of facts in a complex world, there is the temptation to add to the poignancy of such news by referring only to the proven or suspected carcinogenicity of a compound or to deal summarily with scientific uncertainty by inserting just one more word, i.e., the adjective "potential".

Another aspect affecting the public's perception of hazard is the manner in which exposure information - often scanty - is reported and how it is related to effect levels. Stating that "minute traces" of a compound were found does not help, because "traces" of some compounds are indeed toxic. Furthermore, publication of precise concentration data obtained with the most modern technology available is far more alarming to the public than announcing that the chemical was "not detectable", using far less sensitive equipment. The only acceptable way of dealing with this situation is to indicate how measured exposure levels compare with measured effect levels for the compound or compounds in question.

It is unfortunate that public debate often focuses on the credibility of environmental measurements and toxicological data. These data should be reliable and peer-reviewed. Scientists have a moral responsibility to provide assurances of the quality of their work and not to "leak" data until they have been rigorously confirmed. Recently, this moral responsibility has not been met and the credibility of scientific data has, on occasion, been seriously questioned by both the public and by other scientists. In the field of environmental health, the jurisdictions conscientiously attempt to set intervention levels well below adverse health effects levels. Safety factors of at least 100 are applied, often in addition to extrapolations to a very low predicted incidence of illness. Whereas these assumptions are quite well-intended, they are also quite arbitrary. The differences in intervention levels set by Great Lakes Basin jurisdictions reflect only small differences in the estimates of potential exposure and the perception of the uncertainties of the hazard. Thus, the public should not be surprised to learn that action levels differ between jurisdictions. Actually, it is surprising that they do not differ by much.

In some instances, environmental contaminants are detected at or near the health effects level. At this point, very painful decisions must be made at short notice both by government and by the individuals affected. Thus, the entire decision-making process is suddenly under test. Is Society already fully equipped to deal with these situations? Is a jurisdiction with a high level of concern for environmental contamination indeed able to convince citizens that all will be done to protect them adequately? Or does the use of strong measures or the use of emergency powers by a concerned government, which are often necessary to affect improvement, unduly alarm citizens and create unnecessary public fear? Rather, it is extremely important that public debate focus more fully on the question of intervention levels not in absolute terms but relative to acceptable risk and background levels. We live in a world where environmental measurements no longer have results of "zero". At best they are in the form of "less than" some specified detection limit.

It is informative to remember that Society appears to be in general agreement that coliform bacteria (which in their typical form are <u>not</u>

pathogenic) should not be found in drinking water. This provides a margin of safety against exposure to other bacteria which are pathogenic. The level of coliforms permitted by regulation, however, is not zero but one coliform bacterium in 100 ml, on the average. Here, a standard with a safety margin has become accepted and more importantly, is considered affordable. In the area of chemical contamination of the environment, a consensus of this kind has yet to be reached.

2.7 Recommendation

Scientific information, without adequate definition and explanation, can be alarming and dangerous. Environmental researchers, politicians and members of the press must work much harder to provide responsible public information on environmental contaminants.

2.8 References

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3. Further Evaluation of Chemicals Recommended by the Committee for Monitoring and Surveillance

3.1 Introduction

The Committee on the Assessment of Human Health Effects of Great Lakes Water Quality has carefully reviewed toxicology and exposure data available for those chemicals reported in the Great Lakes Basin and has communicated its evaluation in its 1981 and 1982 Annual Reports. It provided a list of chemicals in Table 7.3 of its 1982 Annual Report and recommended additional monitoring and surveillance of the levels of these chemicals in the basin.

This year, the Committee has decided to initiate the process of prioritizing these chemicals by estimating the amounts of these chemicals that could lead to an adverse health effect. This activity of the Committee will be staged over an 18-month period, and Part One of its assessment is reported here.

3.2 Evaluation

Table 1 lists those chemicals identified by the Committee in Table 7.3 of its 1982 Annual Report that have Acceptable Daily Intakes (ADIs) or estimated cancer risks established by the jurisdictions and other international agencies. Those chemicals for which ADIs have not been developed but were reported in Table 7.3 (1982) are under review by the Committee.

After estimating the amounts that might be hazardous to health and after receiving adequate monitoring and surveillance data (see the Proceedings of the Roundtable on the Surveillance and Monitoring Requirements for Assessing Human Health Hazards Posed by Contaminants in the Great Lakes Basin Ecosystem, IJC, Windsor, November 1982), the Committee expects to be able to set action priorities for these chemicals. This evaluation will take into account the contribution of contaminant levels in water, air and foods (especially fish) toward this level of concern in the general population and critical subpopulations within the basin that may be at above average risk from such exposure.

For those chemicals that have an inadequate data base to permit the estimation of a level of concern, the Committee will identify the studies required to complete the evaluation.

3.3 Additional Contaminants in the Ecosystem

In the preceding years, the Committee compiled toxicity profiles for a number of chemicals listed in the "Status Report on the Persistent Toxic Pollutants in the Lake Ontario Basin", Appendix E, 1976 Annual Report of the Great Lakes Water Quality Board, December 13, 1976 and in the "Status Report on Organic and Heavy Metal Contaminants in the Lakes Erie, Michigan, Huron and Superior Basins", Appendix E to the 1977 Annual Report of the Great Lakes

TABLE 1

CHEMICALS IN TABLE 7.3 OF THE COMMITTEE'S (1982) ANNUAL REPORT, FOR WHICH THE JURISDICTIONS OR OTHER INTERNATIONAL AGENCIES HAVE ESTABLISHED ADIs VALUES OR THE RISK OF CANCER

Chemical Name and CAS Number	ADI[1]	Cancer Risk[2]	Reference[9]
Pesticides			
Endosulfan	0.0075 mg/kg (FAO)[3]	--	
115-29-7	0.28 mg/per/d (EPA)	--	EPA PB81-117574
Hexachlorobenzene[4]	--	0.72 ng/L (WHO)	EPA PB81-117392
118-74-1			
Oxychlordane[5]	--	0.46 ng/L (EPA)	EPA PB81-117384
26-880-48-8			
Pentachlorophenol[4]	0.003 mg/kg/d (NAS)	--	
87-86-5	0.03 mg/kg/d (EPA)	--	EPA PB81-117764
2,4,5-Trichlorophenoxy acetic acid	0.1 mg/kg/d (NAS)	--	EPA PB81-103111
93-76-5	0.3 mg/kg/d (WHO)	--	EPA PB80-212665
Halogenated Hydrocarbons			
Carbon tetrachloride[4]	--	0.4 µg/L (EPA)	EPA PB81-117376
56-23-5		6.94 µg/L	EPA PB81-121782
			DWH, Vol. 1
1,2-dichloroethane[4]	--	0.94 µg/L (EPA)	EPA PB81-117400
107-06-2		2.31 µg/L	DWH, Vol. 3
1,2-dibromoethane	--	--	--
106-93-4			
Hexachloroethane	--	1.9 µg/L (EPA)	EPA PB81-117400
67-72-1		8.74 µg/L	
1,2-dichloroethylene	--	--	--
540-59-0			
Trichloroethylene[4]	--	45 µg/L (EPA)	DWH, Vol. 3
79-01-6		28 µg/L	DWH, Vol. 1
Tetrachloroethylene[4]	--	--	--
127-18-4			

Chemical Name and CAS Number	ADI[1]	Cancer Risk[2]	Reference[9]
Vinyl chloride 75-01-4		0.22-2.8 µg/d (EPA)[6]	EPA PB81-117889
Vinyl bromide 593-60-2	--	--	--
3-chloro-1-propene 107-05-1	--	--	--
2,3-Dichlorobutadiene 1653-19-6	--	--	--
Hexachlorobutadiene 87-68-3	--	0.45 µg/L (EPA)	EPA PB81-117640
Dichlorobenzene(1,2) 95-50-1	--	--	
541-73-1 (1,3)	--	--	
106-46-7 (1,4)	0.0134 mg/kg/d (NAS)	--	DWH, Vol.1
γ-Hexachlorocyclohexane 319-84-6	--	9.2-62.5 ng/L[7]	EPA PB81-117657 PB80-21386
Chlorinated naphthalenes	--	--	
Brominated biphenyls	--	--	
Chlorinated terphenyls	--	--	
Aromatic Hydrocarbons			
Ethyl benzene 100-41-4	--	--	
Styrene 100-42-5	0.133 mg/kg/d (NAS)	--	DWH, Vol. 1
Benzo(a)pyrene[4] 50-32-8	--	2.8 ng/L (EPA)[8] 31.1 ng/l	EPA PB81-117806 PB81-117608
Chrysene 218-01-9	--	--	
Dibenz(a,h)anthracene[4] 53-70-30	--	--	

Chemical Name and CAS Number	ADI[1]	Cancer Risk[2]	Reference[9]
Benzo(b)fluoranthene[4] 205-99-2	--	--	
Benzo(j)fluoranthene[4] 205-82-3	--		
Phenols			
Cresol (o,m,p) 1319-773	--	--	
2,4,5-trichlorophenol 95-95-4	7 mg/per/d (EPA)	--	EPA PB81-117434
2,4,6-trichlorophenol 88-06-2	--	1.2 µg/L (EPA) 3.6 µg/L	EPA PB81-117434 DWH, Vol. 4
Ethers			
Dioxane 123-91-1	--	--	
Acids and Esters			
Phthalic acid, diisobutylester 84-695	0.11 mg/kg/d (NAS)	--	EPA PB81-117780 DWH, Vol. 1
Phthalic acid di(2-ethylhexyl)ester 117-817	0.6 mg/kg/d (NAS)	--	EPA PB81-117780 DWH, Vol. 1
Miscellaneous			
Aniline 62-53-3	--	--	
Azobenzene 103-33-3	--	--	
3,3-dichlorobenzidine 91-94-1	--	0.01 µg/L (EPA) 0.02 µg/L	EPA PB81-117517
Elements			
Nickel 7440-02-0	0.031 mg/per/d	--	EPA PB81-117715 DWH, Vol. 1

FOOTNOTES

1. Acceptable Daily Intake.

2. Cancer risk (expressed as a virtually safe dose) is based on a risk assessment model for one cancer per million (10^{-6}) of population exposed. When two values are given, they have been derived using different models. Values expressed as µg/L are based on 2L consumption of water per adult per day.

3. Agencies referred to are: U. S. Environmental Protection Agency (EPA); U.S. National Academy of Science (NAS); Food and Agriculture Organization (FAO); and World Health Organization (WHO).

4. The WHO has set drinking water guidelines or suggested tentative (t) guidelines:

hexachlorobenzene	0.01 µg/L
pentachlorophenol	10 µg/L
carbon tetrachloride(t)	3 µg/L
1,2-dichloroethane	10 µg/L
trichloroethylene(t)	30 µg/L
tetrachloroethylene(t)	10 µg/L
benzo(a)pyrene	0.01 µg/L
PAH(total)	0.2 µg/L

5. Data given are for chlordane.

6. Range in values for males and females and for hepatocellular carcinoma and angiosarcoma.

7. Range in values for γ and β isomers and technical grade material.

8. All PAH considered together as a single class.

9. References refer to EPA publications (numbers given):
   PB (number) refers to the NTIS locator number for an EPA Water Quality Criteria Document;
   DWH reference refers to National Academy of Science reports on Drinking Water and Health.

Water Quality Board, July 1978. These chemicals were grouped according to the particular concerns - and levels of concern. The Committee requested additional information on the occurrence and abundance of these chemicals to enable it to produce estimates of health risk. For a great number of Appendix E chemicals, toxicity information is incomplete and the Committee suggested that the environmental data base (including inventory and use data) be reviewed by the several jurisdictions to develop a sense of priority for toxicological studies of those compounds to which the population in the basin is exposed in a significant way. This approach is warranted not only because this list of chemicals is quite large, but primarily because some Appendix E data are too anecdotal or otherwise unverified.

To this date, the Committee has not received exposure information for either the named contaminants of concern (Table 3, 1981 Annual Report; Table 7.3, 1982 Annual Report) nor for the much greater number of substances for which toxicity data are insufficient to enable evaluation. The Committee reiterates the need for this information, which can only be provided by those agencies which are concerned with inventories of toxic substances.

Even before the completion of this task, we learned of the discovery (see A Document of Chemical Substances Present in the Great Lakes Basin Ecosystem, to be presented by the Great Lakes Water Quality Board to the IJC, November (1983)) of over 600 additional chemical compounds in the Great Lakes, many of them in fish and in this instance and with the insistence by the Committee, unverified data were excluded. On the other hand, this entry may still be incomplete since a review of the formal literature for pertinent data has not as yet been completed. The Committee will undertake the task of reviewing this information from a toxicological perspective. Again, obtaining more complete exposure information will be essential for both human health risk estimates and the setting of priorities for chemicals for further toxicological study.

In order to obtain the most current data on environmental contaminants, the Commmittee has called on the Great Lakes research community to bring newly discovered contaminants to its attention.

The Committee also notes that over 200 chemicals which were listed in Appendix E do not appear in the updated listing. Since the data bases for the two listings do not overlap, the Committee requests a determination as to whether these chemicals are still present in the Great Lakes Basin Ecosystem, whether they have decayed or otherwise disappeared, or whether their original discovery was likely to be in error.

3.4 Recommendation

The Committee renews its recommendation to the jurisdictions to determine population exposure to the chemicals of concern listed in the Committee's previous reports. This includes pinpointing the source or sources of the chemicals, the verification of Appendix E information and data and additional measurements as appropriate.

4. Research Needs

4.1 Peer Review of Unsolicited Applications for Research Support - International Issues

4.1.1 Background

Agreements between the jurisdictions call for the appropriation of funds for research projects on the Great Lakes. Administration of the Canadian funds is by an interagency group which acts as a peer review panel upon applications for research support submitted by Canadian researchers. Administration of any U.S. appropriation is by the U.S. Environmental Protection Agency by two different mechanisms. According to information received from the U.S. EPA Office of Research Grants and Contracts in Washington, D.C., the funds are not administered through the peer review mechanism for extramural competitive grants established at EPA headquarters. That Office operates several peer review panels for the review of unsolicited grant applications. None has Great Lakes research specifically included in its mandate. It appears that the Great Lakes research funds are administered by the EPA Duluth Laboratory which maintains a Great Lakes focus, but is not involved in the competitive grant program. Like the other EPA laboratories, it distributes research funds, but relies on outside reviewers on a case-by-case basis.

Neither government appears to have addressed the question of coordination or compatibility of the research review and grant administration processes to make possible joint research programs by researchers from the U.S. and Canada or programs that are specifically designed to be compatible and that are coordinated across the international border. We are aware, at least in one instance, of a plan by two eminent specialists to secure samples from the Great Lakes and process them in their respective specialized laboratory facilities located in the U.S. and Canada. The purpose of the research was to address a single issue by using two different techniques with the results complementing each other. The individuals were unable to introduce their applications to their respective national agencies to be reviewed in a timely fashion and in the proper context. It would appear that it is the intent of the agreement between the jurisdictions to encourage and to facilitate research of this kind.

4.1.2 Recommendation

Upon recommendation by the Science Advisory Board, the Commission may request that the jurisdictions develop or improve, as the case may be, administrative mechanisms for the review and funding of research projects directed at Great Lakes issues, with particular emphasis on a coordinated peer review mechanism for unsolicited applications for such projects as researchers from the two countries may wish to undertake jointly.

5. Future Directions

5.1 The summary of water monitoring activities relevant to estimates of population exposure from Great Lakes water quality will be completed and the results presented in the next Annual Report of the Committee. A similar survey of toxicology testing activities will be undertaken.

5.2 Estimates of amounts of chemicals likely to pose a human health hazard will be made of additional Appendix E chemicals of concern, where sufficient toxicity data are available.

5.3 The Committee will consider the need to prepare toxicity profiles for newly-identified contaminants detected in the Great Lakes Basin Ecosystem and the categorization and prioritization of these chemicals according to previously established procedures.

5.4 Conferences and workshops on structure-activity relationships and the toxicity of complex mixtures are being monitored and their outcomes may be discussed in a future Annual Report of the Committee.

5.5 The Committee plans to develop an issue paper on the public perception of the dioxin issue and related matters. The discussion of other current and topical issues in toxicology and in the areas of microbiological hazards in the Committee's Annual Reports will be continued.

5.6 The role of epidemiology in determining the effects on human health of environmental factors in the Great Lakes Basin will be further investigated. An invited study is being considered. Developments in this area at the WHO and the International Agency for Research of Cancer and a major U.S. cancer study are being followed and position papers on them will be presented as new material becomes available.

6. Recommendations

6.1. Drinking Water: Additional Concerns

6.1.1 Epidemiology

6.1.1.1 That the Human Health Effects Committee utilize up to $20,000 to procure consulting services in epidemiology to develop a strategy for epidemiological studies on the human health effects of Great Lakes water contaminants.

6.1.1.2 Based in part on the outcome of the above consultation, the IJC would be provided with advice regarding recommended studies and their findings.

6.1.2 Water Treatment

6.1.2.1 The Commission should request that the jurisdictions encourage, and enforce as may be necessary, the operation of each water and wastewater treatment plant in the Great Lakes Basin in accordance with both the stated and approved design criteria for that plant and best operating practices. Drinking water and effluent standards, when less stringent, should not become a justification, an excuse, or an incentive to operate such plants at a lower level of performance.

6.1.2.2 Additional research should be undertaken to investigate the removal of unconventional contaminants by conventional water and wastewater treatment systems, with emphasis on the potential benefits to be derived from the high-efficiency removal of particulate matter in combination with consistently reliable operation.

6.1.2.3 Once these factors are considered, jurisdictions should be prepared to defend water quality objectives, guidelines and standards (i.e. safe levels established from toxicological studies, with appropriate safety margins) and to resist pressures to add advanced treatment steps to the conventional process train as long as such conventional process produces water or effluent meeting all applicable objectives, guidelines and standards.

6.1.2.4 Caution is to be used in the interpretation of single and scanty measurements of environmental contaminants, except if they indicate a potential for imminent danger to the public health. Even if the methods of sampling and analysis are standardized and subject to rigid quality control - as they always should be - environmental variability tends to exceed the normal laboratory

margin of error so that obtaining conclusive exposure information for environmental contaminants always requires a certain minimum program of sampling and analysis.

6.1.3 Groundwater and Sampling Protocols

6.1.3.1 The Committee suggests that the Science Advisory Board in its review of groundwater contamination affecting the Great Lakes Basin Ecosystem include those groundwater resources serving or potentially serving the residents of the basin as sources of potable water.

6.2 Toxicological Evaluation

Scientific information, without adequate definition and explanation, can be alarming and dangerous. Environmental researchers, politicians and members of the press must work much harder to provide responsible public information on environmental contaminants.

6.3 Further Evaluation of Chemicals Recommended by the Committee for Monitoring and Surveillance

6.3.1 The Committee renews its recommendation to the jurisdictions to determine population exposure to the chemicals of concern listed in the Committee's previous reports. This includes pinpointing the source or sources of the chemical, the verification of information and data and additional measurements as is appropriate.

6.4. Research Needs

6.4.1 Peer Review of Unsolicited Applications for Research Support - International Issues

6.4.1.1 Upon recommendation by the Science Advisory Board, the Commission may request that the jurisdictions develop or improve, as the case may be, administrative mechanisms for the review and funding of research projects directed at Great Lakes issues, with particular emphasis on a coordinated peer review mechanism for unsolicited applications for such projects as researchers from the two countries may wish to undertake jointly.

Appendix

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Terms of Reference

The Committee will take the following under its purview:

1. assess the risk to health posed by contaminants in the Great Lakes ecosystem;

2. review action levels and guidelines for selected substances;

3. provide to the International Joint Commission through its Boards, interpretation and consultation on health matters; and

4. maintain awareness of current advances and knowledge as they relate to human health aspects of the Great Lakes ecosystem.

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