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Legislative and Regulatory Considerations for Virtual Elimination of Persistent Toxic Substances. A Report of the Great Lakes Water Quality Board to the Virtual Elimination Task Force of the International Joint Commission

Great Lakes Water Quality Board

Michael Gilbertson

GREAT LAKES WATER QUALITY BOARD
REPORT TO THE VIRTUAL ELIMINATION
TASK FORCE AND TO THE
INTERNATIONAL JOINT COMMISSION

Legislative and Regulatory Considerations for Virtual Elimination of Persistent Toxic Substances

International Joint Commission
Commission mixte internationale

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Disclaimer

This report to the Chairpersons of the Virtual Elimination Task Force and the International Joint Commission was carried out as part of the priority activities of the Great Lakes Water Quality Board.

While the Commission and Task Force supported this work, the specific conclusions and recommendations do not necessarily represent the views of the International Joint Commission or the Virtual Elimination Task Force.

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It is often necessary to make a decision based on information which is sufficient for action but insufficient to satisfy the intellect.

Immanuel Kant, 1786

"Critique of Pure Reason."

1.0 Introduction

Article 2 of the 1978 Great Lakes Water Quality Agreement contains a policy that states that the discharge of any or all persistent toxic substances shall be virtually eliminated. In 1990 the International Joint Commission, which is responsible for assisting the Parties to the Great Lakes Water Quality Agreement in the implementation of the Agreement, set up a Virtual Elimination Task Force to integrate Commission activities concerning this policy. In 1991, the International Joint Commission directed the Great Lakes Water Quality Board to assist the Virtual Elimination Task Force (VETF) in holding a workshop on the legislative and regulatory aspects of virtual elimination drawing on previous work undertaken by the VETF. The Board was asked to address such issues as the institutional, bureaucratic and legal barriers to achieving virtual elimination of persistent toxic substances and the interim measures that can be taken pending statutory law reform.

The workshop was held at the Hilton Hotel, Windsor on June 17 and 18,1992 and included presentations by invited speakers and four breakout sessions to discuss questions on the adequacy of the existing legal framework, barriers to achieving virtual elimination, jurisdictional roles and responsibilities and the concept of reverse onus. The results of the workshop and the subsequent consideration of the topic by the Board are outlined in this report.

The Board recommends as a general working principle that the Parties strengthen pollution prevention programs to reduce or eliminate the creation of pollutants or wastes at the source.

2.0 Criteria for Selecting Existing Chemicals for Virtual Elimination

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The Board recognizes the extensive work that has been done in previous years to prepare lists of existing chemicals for various purposes, including lists of chemicals of concern and of chemicals whose manufacture, use and release should be prohibited. In particular, the Board recognizes work undertaken by the Parties to prepare the three lists pursuant to the Supplement to Annex 1 of the 1987 Protocol to the 1978 Great Lakes Water Quality Agreement. Criteria to include a substance on a list have generally been based on consideration of the physical, chemical and toxicological characteristics of a particular substance based on controlled laboratory experimentation. This practice, however, has resulted in extensive lists of existing chemicals that are impractical for initiating regulatory programs for virtual elimination, not only because of the limited resources available but also because of the inherent usefulness of many of these substances to society.

The Board recommends that a specific list of persistent toxic substances, which will be considered for virtual elimination, needs to be developed and widespread agreement reached and the immediate attention of the regulatory agencies focused on that list.

The Board recommends that priority for the selection of chemicals for virtual elimination be put on those that are persistent, bioaccumulate, are highly toxic and have already exhibited toxicological cause-effect in the Great Lakes ecosystem.

In this way scarce regulatory resources can be focused on achieving the virtual elimination policy through actions that will be of maximum benefit to the organisms (including humans) dependent on the Great Lakes. This does not preclude a secondary set of criteria for selecting substances based on the physico-chemical and toxicological properties to identify existing chemicals for which no toxicological cause-effect has been demonstrated in the Great Lakes ecosystem, but that should be assessed in detail to prevent injury to human health or the environment.

3.0 Adequacy of Existing Legal Authority

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In considering whether the existing legal authority is adequate in relation to the Agreement policy on virtual elimination of persistent toxic substances, the Board has distinguished between legal authority and effective authority. The Board noted that the law is effective only if it is implemented and enforced. Until there is a change in action or behaviour, the ecosystem does not benefit.

Persistent toxic substances pose special problems in terms of legal mandates and authority. Legislation has been implemented in both the United States and Canada to control commercial products used as pesticides, cosmetics, drugs and food additives and in households and the work place. Legislation to control effluents and emissions from industries and municipalities has been in place for several decades. Similarly, laws and regulations to control hazardous wastes have been implemented to protect society and remediate hazardous waste sites. Despite this legislation, persistent toxic substances continue to enter the Great Lakes ecosystem, cause injury to fish and wildlife resources, and affect human perinatal development.

In the early 1970s, the two countries started to recognize this particular deficiency in their respective legislation and explored ways to develop legislation that deals with the special characteristics of persistent toxic substances. There was a recognition that substances in this class were not only persistent and toxic but also bioaccumulated in food chains and, if released to the environment, were irretrievably dispersed over the globe by hydrologic and atmospheric processes. Thus, these substances not only could not be assimilated by natural degradative or detoxification processes if released to the environment, but release to any medium -- water, air or land -- could result in transfers between media. These substances could not be adequately controlled using traditional product legislation or conventional pollution laws or those governing management of hazardous wastes. To respond to these deficiencies in the laws in the two countries, new legislation was enacted. In the United States, Congress passed the Toxic Substances Control Act to investigate and control these kinds of substances. In Canada, Parliament passed the Environmental Contaminants Act in 1975, which formed the basis of the Toxic Substances Section of the 1988 Canadian Environment Protection Act. Do these pieces of legislation contain the necessary powers to enable the administrations in the two countries to control persistent toxic substances?

Section 6 of the U.S. Toxic Substances Control Act states that if the Administrator of the U.S. Environmental Protection Agency finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk to health or the environment, the Administrator shall prohibit or limit these activities. Section 7 of the former Environmental Contaminants Act enabled the Minister of Environment and the Minister of National Health and Welfare, where they were satisfied that a substance or class of substances was entering or would enter the environment in a quantity or concentration that constituted or would constitute a significant danger in Canada to human health or the environment, to prohibit the import, manufacture, processing, sale, use, or release of the substance. Similar provisions are found in subsection 18(1) of the Canadian Environmental Protection Act which superseded the earlier Environmental Contaminants Act.

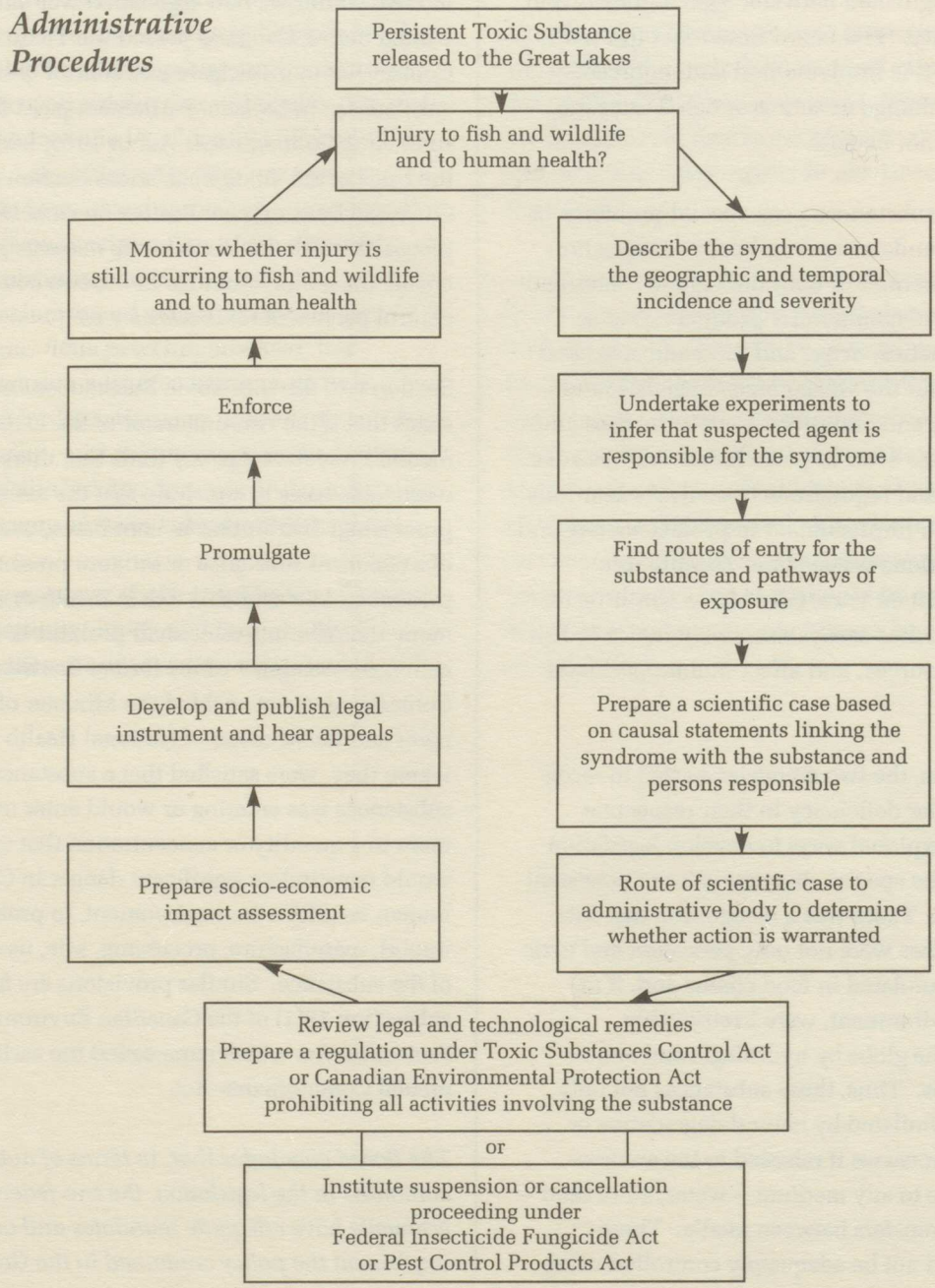
The Board concludes that, in terms of authority contained in the legislation, the two federal governments have adequate mandates and authority to implement the policy contained in the Great Lakes

Water Quality Agreement concerning the virtual elimination of discharges of any or all persistent toxic substances through control of products (see 6.1 below) and control of discharges (see 6.2 below). The Board, however, recognizes that there are significant barriers to effective implementation of this authority.

In addition to these existing legal authorities in the two countries, there may be incentives for product substitution and reformulation by industry, because the prospect of liability for damage caused by releases of persistent toxic substances raises the possibility of litigation. Recent court cases in Canada also point to the possibility of liability of the Crown for injury sustained through non-enforcement of regulations.

Before the barriers to achieving virtual elimination of persistent toxic substances can be identified, the steps in the administrative process must be outlined (Figure 1).

Figure 1
Responsibilities of Regulatory Agency when Injury has been caused by Persistent Toxic Substances.



4.0 Administrative Procedures

The release of certain persistent toxic substances into the Great Lakes has caused injury to fish and wildlife resources and probably caused effects on the development of infants of mothers who ate Lake Michigan fish. Before such causal linkages can be made, extensive research must be undertaken not only to describe the syndrome and its geographic and temporal incidence and severity, but also to demonstrate experimentally that the suspected causal agent is specifically responsible for the syndrome. In addition, plausible routes of entry and pathways of exposure of the affected organisms must be documented.

After these investigations have been undertaken, a scientific case may be prepared on which to base regulatory action. This may include promulgation of a regulation to prohibit activities involving the substance, or litigation to cancel registration of a persistent toxic pesticide. The scientific case may be transmitted to the administrative body that will scrutinize it to determine whether action is warranted.

If the regulatory agency accepts the scientific findings of injury and is satisfied about the causes, it may review the legal remedies and the technological options available to overcome the injury. After legal and technological proposals have been prepared a socio-economic assessment of the proposed action must be developed, from which a decision may be made concerning which legal and technological options to implement.

After the legal instrument has been developed and published and adequate provision made for appeal by interested parties, it may be promulgated. Through enforcement and compliance activities, the government attempts to control environmental exposures to the substance causing the injury. Through environmental monitoring, the long-term trends in the concentrations of the substance and the incidence and severity of the syndrome are documented from which the effectiveness of the legal action can be evaluated. If the regulatory action is successful the injury to fish and wildlife resources and to human health may be eliminated.

5.0 Barriers to Achieving Virtual Elimination

The process itself, because of its complexity and burden of proof, can be a barrier in its own right. Additional specific barriers are identified in the following sections of the report.

Workshop participants felt that one of the most significant barriers to implementing the virtual elimination provisions is the lack of political will. In the absence of centralized authority, success depends on harmonizing programs in many agencies at different levels of government, and on a level of goodwill between individuals and agencies involved. The dynamic tension between science, public policy and economics also contribute as barriers to the successful control of a substance that has caused injury.

The workshop was successful in identifying some of the major impediments to the virtual elimination of persistent toxic substances and restoration of the biological integrity of the waters of the Great Lakes. These include: identification of the injury and the causal agents; preparation and transmission of a valid scientific case; challenges through litigation; failure in the past to use an interagency multimedia approach; the absence of waste destruction technology and of requisite economic resources; and determination of what constitutes acceptable water quality objectives. The Board notes the necessity of lessening the length of time between recognition of effects and the effective response of governments to curtail the injury.

5.1 Identification of the Injury and the Causal Agents

Traditional regulatory approaches to toxic substances have been concerned with potential effects on aquatic resources and their protection through setting water quality objectives and monitoring for violations. While this approach has resulted in significant improvements in water quality, it has not been effective in addressing the actual injury to fish and wildlife resources and human health as a result of exposures to persistent toxic substances such as PCBs and dioxins. Not only is funding generally not available for research on injury, but from a research scientist's career standpoint this kind of science yields less predictable results and may detract from potential for advancement. How research is funded and organized thus presents significant barriers to obtaining evidence and rationale necessary to implement the virtual elimination policy.

One of the first barriers is in the identification of the injury. Much of the damage that has occurred in the Great Lakes over the past forty years, has been so subtle, though biologically significant, that even skilled biologists have had difficulty recognizing injured populations. A second research barrier is that some causal agents, such as specific PCBs and dioxins, have only been analytically identifiable in the past decade. Other agents, such as DDT and dieldrin, were determined up to thirty years ago.

5.2 Preparation and Transmission of a Valid Scientific Case

Historically, government scientists have been rewarded based on productivity which is usually measured by the number of publications in the peer-reviewed scientific literature. Preparation of a scientific case relating injury to a causal chemical agent may take considerable time and warrant only infrequent publication. While criteria have been broadened to include other contributions for promo-

tion, few scientists have the background or skills to carry out this work.

A second problem is in deciding what constitutes a valid scientific case relating injury to the causal agent. Workshop participants noted the amount of uncertainty that often surrounds evidence of injury caused by persistent toxic substances and the difficulty in inferring causal relationships and the opposing claims of "good science" versus "bad science." For instance, only one epidemiological study exists of effects on infant development as a result of maternal consumption of Lake Michigan fish prior to pregnancy. Is this study reliable, and is it scientifically valid? *The Board concludes there is enough evidence to suggest that the risks to humans are high and there is a real probability that the effects are important.* There has been significant progress in identifying and applying categories of evidence in making a case based on epidemiological criteria. This methodology and six Great Lakes case studies have been published in the August 1991 issue of the *Journal of Toxicology and Environmental Health.*

Once a valid scientific case has been made it must be transmitted from the scientific community to the regulatory community. These communities have traditionally been two solitudes with unsatisfactory communication between them. The science has, at times, lain dormant in the scientific literature for more than a decade until a non government organization or the media have prepared a polemic story and politicized the issue. As a public constituency is built for the case, the issue may come to the attention of the politicians and regulatory community. Thus science has been used to influence public perception and thereby used to leverage public policy and risk perception.

Based on information from the non-government organizations, the public often perceives that the causal relationships between the effects and the exposures to persistent toxic substances are well understood and accepted. However, public policy makers who hear both the advocates of and detractors from the science tend to remain unconvinced because the data is considered anecdotal and not as rigorous as experimental or chemical analytical results. The crux of the matter for regulatory officials is how to make policy decisions in the face of uncertainty, given the implications of making a decision without a proven cause and effect. The credibility of regulatory decisions is very important to the long-term effectiveness of a regime. In turn, the public questions why the regulatory authorities do not move more quickly. The present system of regulation does not generally make provision for applying the weight of evidence approach. This is a significant impediment.

At the workshop, there was extensive discussion on whether the need to take action should not be proportional to the degree of potential harm or actual injury. On the one hand, some participants questioned whether the level of environmental control should not be related to the confidence in the evidence of injury and the strength of the causal association since costs -- such as product substitution or industrial process change -- associated with prohibiting the use or release of a substance may be very large. On the other hand, others noted the costs to society of the injury caused by these kinds of substances, including the loss of fish and wildlife resources and increased health and educational costs. The policy maker is constantly trying to balance the severity or stringency of the regulations against the costs of losing a valuable natural resource or causing impaired human health or development. With the introduction of legislation concerning damage assessment, the liability for injury caused by persistent toxic substances released from industrial and municipal facilities is accelerating the process of product and process substitution. *The Board concludes that the injury caused by certain persistent toxic substances has been so extensive and the costs to society so high that immediate measures are warranted not only to restore the environment and the affected populations of fish and wildlife, but also to protect human health from continuing exposures and to prevent further releases.*

While the Board endorses the various programs being implemented by the Parties on pollution prevention, it notes the extreme length of time between the past introduction of a substance into commerce, the documentation of socially unacceptable damage, the control of the substance, and the final remediation and restoration of the injured populations.

The Board recommends that the Parties devise more efficient and effective ways to investigate

injury caused by existing chemicals and be prepared to reallocate funds and human resources, where required.

The Board recommends to the Commission that the Research Inventory prepared by the Council of Great Lakes Research Managers be used to evaluate the adequacy of the allocation of funding to investigate actual injury to fish and wildlife resources and to human health caused by exposures to persistent toxic substances.

The Board recommends that the Parties give consideration to the development and provision of incentives for scientists to become involved in cause-effect research, promote broader science assessments in a weight of evidence approach, and make the information widely available to the scientific community and the public.

5.3 Challenges through Litigation and Administrative Process

Once the regulatory community accepts the evidence from the scientific community of the causal relationship between the presence of the persistent toxic substance and the consequent injury and proposes regulatory action to remedy the injury, industry may bring a legal challenge to modify or overturn the proposed action. For instance, the asbestos industry successfully challenged the regulatory action proposed by U.S. EPA under the Toxic Substances Control Act on the grounds that the regulation was not the least burdensome means available.

DDT was introduced for widespread use in 1945 and dieldrin in 1957. In the cancellation proceedings on DDT and dieldrin brought under the Federal Insecticide, Fungicide and Rodenticide Act in the early 1970s, industry sought to retain the registrations of these compounds by unsuccessfully challenging the evidence of damage brought before the U.S. EPA administrative law judge by the Environmental Defense Fund. Similarly, the PCB regulation and the Canadian Environmental Protection Act are being challenged in the Supreme Court of Canada (see below 6.0-Jurisdictional Roles and Responsibilities).

The Board recognizes the beneficial role interventions by industry and environmental advocates can contribute to the assessment of scientific evidence and to discussions of proposed regulatory actions. Regulatory agencies are encouraged to ensure that a balance of views prevails and that mechanisms are in place to encourage the input of all stakeholders. Decisions should be based on an objective assessment of scientific evidence, not the degree of access which certain segments of society have to senior policy officials.

5.4 Interagency Multimedia Approach

Substances such as PCB, DDT and dieldrin pose special problems for regulatory authorities. Not only do they enter the different media of the environment through different routes, but they also move between media when released. Regulatory control of release into the environment through one route of entry may result in releases into other media, thereby continuing the injury. Most agencies are organized on a media-specific basis reflecting the media-specific legislation they administer, and thus regulatory control of a persistent toxic substance within a facility tends to be uncoordinated. Similarly, most regulatory controls are developed on an industry-specific basis, while these substances have been used in many industrial sectors. Thus, industry-specific controls are only partially effective.

Although the U.S. Toxic Substances Control Act and the former Environmental Contaminants Act of Canada were explicitly drafted on a multi-media basis, traditional media-specific agencies have been slow to reorganize and reallocate funding to implement multi-media controls based on these acts. Agencies have preferred to implement separate controls on these substances through the existing media-specific organizations. Efforts to implement multi-media controls through coordination of single media permits are complex and have met with only limited success. A new strategy is needed on how to deal with multi-media exposures and releases.

The Board recommends that the Parties examine the administrative arrangements within existing regulatory authorities to ensure that multi-media control strategies and mechanisms become the norm.

5.5 Lack of Acceptance of Waste Destruction Technology and Absence of Economic Resources

In the mid 1970s, it became clear in both countries that use of PCBs must be controlled and eventually prohibited. It also became clear that if there was insufficient destruction technology available to destroy the waste PCBs, complete prohibition at that time would have created a larger toxicological hazard than allowing continued use in closed systems such as transformers and capacitors. As an example, high-temperature destruction of PCBs in modified cement kilns was an early proven technique but was not implemented because of public concern. Large stores of PCB wastes must be monitored until acceptable waste technology becomes available. Incineration of wastes has, however, been prohibited in some jurisdictions and this is a serious impediment to achieving virtual elimination of persistent toxics. A life cycle approach must be taken in dealing with persistent toxic substances because of the direct relationship between, for example, a policy decision to destroy waste PCBs or to prohibit the use of PCB.

Several participants at the work sessions considered the economic and technological costs of achieving virtual elimination of persistent toxic substances since these are directly implied as a result of legislative and regulatory actions. Some suggested that special economic instruments such as surcharges, tax abatements, grants and loans or accelerated depreciation of capital investments were required to finance change. The liability inherent in managing wastes of persistent toxic substances has recently encouraged their destruction rather than storage or release to the environment. Some suitable technology for destruction of persistent toxic substances is available but the existing capacity across the two countries is insufficient. New technology is being developed and, after trials, may be approved for service. Technology is also available for cleanup of contaminated sediments and poorly constructed chemical landfill sites.

The Board recommends that the Parties develop strategies and policies that encourage the destruction of persistent toxic substances rather than storage or release to the environment. More specifically for waste PCBs, the Board supports the use of approved and encouragement of emerging technology, since the risks associated with continued use and storage far outweigh the risk of environmental damage from destruction of the wastes.

5.6 Water Quality Objectives

The release of any substance to the environment as a result of human activities has the potential to cause harm to resources and human health. Thus governments must define what quantity or concentration of a substance is acceptable in the environment and what releases are "assimilable." Under Article IV of the Boundary Waters Treaty a brief paragraph contains a prohibition of pollution. It states that "it is further agreed that ... boundary waters and waters flowing across the boundary shall not be polluted on either side to the injury of health or property on the other." This short prohibition of pollution has been the international law governing international freshwater resources between Canada and the United States since 1909. There is no definition in the Treaty of what constitutes injury, but the Parties have generally been able to agree on the meaning on a site specific basis. The Great Lakes Water Quality Agreement provides a definition of pollution by prescribing specific water quality objectives, thereby identifying lawful and unlawful pollution in the waters of the Great Lakes drainage basin, and thereby giving an interpretation of Article IV.

This approach has been remarkably successful in relation to reductions of loadings of conventional and assimilable pollutants that cause eutrophication and local toxicity, and conforms with Great Lakes Water Quality Agreement policy that discharges of toxic substances in toxic amounts be prohibited. In essence it has allowed for the release of assimilable pollutants to the environment. This results in an ambiguity in relation to the policy on persistent toxic substances, which states that the "discharge of any or all persistent toxic substances be virtually eliminated." Scientists who developed the water quality objectives do not seem to have differentiated between persistent toxic substances and toxic

substances and have not considered, in the policy sense, the advisability of legitimizing what can be regarded as a discharge that causes harm. By incorporating values for PCB, dieldrin, DDT, and other persistent toxic substances in Annex 1 of the Agreement, the representatives of the Parties involved in developing water quality objectives and the drafters of the Agreement defined what appears to be acceptable ambient concentrations for persistent toxic substances.

The objectives that were derived at the time were several orders of magnitude too high to restore the damaged fish and wildlife resources and to protect human health because: 1) the bioconcentration factors in the field are much larger than those estimated from classical aquatic toxicology experiments; and 2) subtle but ecologically significant toxicological phenomena occur at much lower exposures than previously thought, particularly for embryonic developmental processes controlled by endocrine systems. Field data from the Great Lakes suggest that the water quality criteria for PCB may have to be revised downward by a factor of 10^5. This will have a profound effect on calculations of the quantities in effluents, emissions and other potential sources such as landfill sites that must be brought into the ambit of the regulatory community.

The International Law Association, in preparing the Helsinki Rules, has differentiated between the equitable use of waters for removal of wastes and a prohibition on the discharge of substances generally considered to be highly dangerous into the waters of an international drainage basin. It would seem that substances such as PCB, dieldrin, DDT and dioxin should be generally regarded as ultrahazardous, and thus their release to the international waters of the Great Lakes basin should not be legitimized by promulgating water quality objectives for these substances.

The Board concludes that there is no acceptable assimilative capacity for persistent, bioaccumulative toxic substances in the Great Lakes Basin Ecosystem and thus the only appropriate water quality objective that should be included in the Great Lakes Water Quality Agreement for these substances is zero.

The Board concludes that for persistent toxic substances it is not appropriate to attempt to set ambient water quality objectives in the environment, except when such objectives are recognized as interim steps as they are in the Great Lakes Water Quality Agreement. For such substances it is necessary that the policy of virtual elimination be directly implemented through elimination from use, the deployment of best available treatment technology and destruction from all other sources.

The Board recommends that the Parties apply water quality objectives for persistent, bioaccumulative toxic substances only for the purpose of establishing benchmarks or interim guidelines or regulations. The Board recommends that the Parties recognize, both directly and implicitly, that persistent substances which are both highly toxic and bioaccumulative cannot be tolerated by the Great Lakes Basin Ecosystem and should be virtually eliminated. Before the end of the next biennial period, the Parties should prepare plans and schedule dates for implementation of the virtual elimination policy.

6.0 Jurisdictional Roles and Responsibilities

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Because the Great Lakes resource is shared by two nations, there is agreement that the federal governments must ensure a consistent approach to product, processing and pollution control and to water quality. This consistent approach is essential to implement a fair economic basis for industry within and between the two countries. While the more effective action is binational, it may be more feasible to obtain unilateral action on one side of the border or the other.

In addition to the role of national and local governments, because persistent toxic substances move between countries and continents through atmospheric, aquatic and biological processes, it is essential that prohibitions on activities involving specific persistent toxic substances be undertaken on a global level. For example, there is no prohibition on the manufacture of DDT in the United States for export to other countries. Use in the recipient country may lead to atmospheric translocation back to the United States and to the Great Lakes basin. Thus, the virtual elimination policy cannot be attained without an international treaty for compounds such as DDT. The Montreal Protocol, which includes a scheduled reduction in manufacturing of chlorofluorocarbons is an example of the kind of international action needed.

The Board recommends that the United States and Canada become advocates for an international convention to achieve global action to prohibit the manufacture, export, sale, distribution, use and release of DDT, dieldrin, PCB and chlordane.

In both countries there are two major areas of responsibilities for protecting human health and the environment from substances that enter the environment. These are: 1) control of the commercial aspects such as manufacture, import, export, distribution and sale of the substances; and ii) control of the disposal or of the release of the substances to the environment.

6.1 Product Control

UNITED STATES

In the United States, the control of products in interstate commerce is the jurisdictional responsibility of the federal government, under the Commerce Power of the Constitution. Thus the U.S. Federal Government is involved in regulation of the quality, for instance, of food, drugs, cosmetics and pesticides. In 1976, when the damage caused by certain persistent toxic substances -- particularly PCBs -- became intolerable, Congress found that:

1) Human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

2) Among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

3) The effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

Congress then set out the policy of the United States and the intent that:

1) Adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

2) Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

3) Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of the Toxic Substances Control Act (TSCA) to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

Intent of Congress: - It is the intent of Congress that the Administrator shall carry out this Act (TSCA) in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

Thus in terms of control of substances that are likely to present an unreasonable risk of injury to health or the environment, Congress enacted legislation that clearly showed that it believed it had a mandate in this area and intended to assess and control these kinds of risks though it tempered this authority with economic considerations. Though TSCA has been used to prevent the entry into U.S. commerce of many new substances, the act has not been used to control any existing substance other than PCB which was mandated under Section 6(e). Proposed regulatory controls of existing substances have been successfully litigated by industry on the grounds that the proposed regulation was not the least burdensome means available. *The Board concludes that the requirement in the Toxic Substances Control Act, that the Administrator use the least burdensome means available for proposed regulatory controls of substances that present an unreasonable risk of injury to health or the environment, has rendered the act ineffective for timely control of existing chemicals.* Since TSCA is the only piece of U.S. legislation designed to investigate and control new substances and existing substances on a multi-media basis, the requirement that the Administrator use "the least burdensome requirements" to protect human health or the environment against unreasonable risk of injury has become unworkable.

CANADA

The situation in Canada is more complex because no constitutional head of power similar to the U.S. Commerce Power exists, either under the British North America Act of 1867 or the Constitution Act of 1982. These limitations were explored in detail in 1972 by the Legal Subcommittee of the Cross Mission Task Force on Environmental Contaminants Legislation in their deliberations on a constitutional basis for a proposed Environmental Contaminants Bill. The Legal Subcommittee noted the existence of provincial legislation to control products for consumption and use, to protect humans. It also noted the existence of provincial laws and regulations to control the release of substances to all three environmental media.

The Legal Subcommittee, in making the case for new federal legislation, stated that, "The release or escape to the environment of certain substances, which are known or potential contaminants, poses a national, rather than a purely local, problem. It is, therefore, a federal responsibility to identify these substances and to ensure that appropriate controls are imposed in the national interest. It is also clear that existing federal legislation, no matter how well armed, is not designed to deal with the problem in the comprehensive/substance oriented manner which scientific considerations dictate ought to be adopted."

The Legal Subcommittee then reviewed the following heads of power that might potentially be considered as the basis for the proposed legislation: Regulation of Trade and Commerce; Taxation;

Statistics; Navigation and Shipping; Fisheries; Criminal Law; Federal Works and Undertakings; Agriculture; Peace, Order and Good Government; and Federal Activities. Of these the Criminal Law and Peace, Order and Good Government were considered the heads of power with the greatest likelihood of support to develop a comprehensive and realistic policy on controlling environmental contaminants. Thus the resulting Environmental Contaminants Act was oriented to providing authority to the federal government to collect information to assess the dangers posed by particular substances and to control all activities involving those that were a significant danger to human health or the environment.

The Legal Subcommittee, however, noted that: "protection of man's (sic) environment is not the exclusive domain of Parliament. Under such heads of power as provincial trade and commerce, provincial and municipal institutions, local works and undertakings, property and civil rights, matters of a local and private nature, agriculture and natural resources, the provincial legislatures can legitimately claim a substantial interest in and responsibility for controlling and regulating the release of contaminants into the provincial environment."

In the 1980s, there was considerable criticism of the Environmental Contaminants Act, particularly by nongovernment organizations, because "only" five substances had been regulated. An Environmental Contaminants Act Amendments Consultative Committee was set up to advise the Minister of Environment and Minister of National Health and Welfare. The ministers drafted omnibus legislation entitled The Canadian Environmental Protection Bill which included authority to formulate national environmental quality objectives, expanded the powers to investigate and regulate "toxic substances", including substances new to Canada, and included authority to regulate fuels and nutrients. Other provisions included formulation of environmental quality guidelines for federal works and undertakings and the authorities contained in the Clean Air Act and Canada Water Act. The regulation-making power was generally consolidated and expanded. After consultation with the provinces the bill was presented to Parliament and became law in 1988.

There were no court cases involving the Environmental Contaminants Act which could have tested the constitutionality of the legislation. There has, however, recently been a challenge to the provisions contained in the Canadian Environmental Protection Act. This case is still before the Quebec Court of Appeal. The case is important because it may clarify the role of the Canadian Federal Government in the assessment and control of persistent toxic substances. It is thus briefly reviewed below.

Between December 27, 1989 and January 3, 1990, PCB-contaminated oil was released from Hydro-Quebec transformers into the St. Maurice River at Shawinigan. In June 1990, Environment Canada charged Hydro-Quebec with: a) releasing the PCBs in contravention of the Chlorobiphenyls Interim Order; and b) failing to report the release of a toxic substance in accordance with paragraph 3b(1)(a) of the Canadian Environmental Protection Act. Between March 4 and 6, 1991 a court case was held and Hydro-Quebec argued that the Chlorobiphenyls Interim Order was *ultra vires* the authority of the federal government. On August 12, 1991, Judge Michel Babin rendered his written judgement for the case. He concluded that paragraph 6(a) of the Interim Order could not be authorized under either the peace, order and good government powers (i.e. the national interest) or the power of Parliament to legislate on areas of criminal law. Regarding the national interest, Judge Babin believed that the definitions of "toxic substances" and "environment" in the Canadian Environmental Protection Act are too broad to justify the power of Parliament to regulate these substances under its constitutional residual powers. The judge also believed that use of the criminal law power could not be justified because of the broadness of those same definitions. On September 11, 1991, the Crown launched an appeal of Judge Babin's decision. On August 6, 1992 the Quebec Court of Appeal upheld the trial judge's decision.

The Board notes that the constitutional basis for the involvement of the Parliament of Canada in management of toxic substances is being challenged and that there is a potential for parts of the Canadian Environmental Protection Act to become ineffective in the control of persistent toxic substances.

The Board recommends that the Parties should improve the effectiveness of the United States' Toxic Substances Control Act and the Canadian Environmental Protection Act respectively to

control and virtually eliminate existing persistent toxic substances to advance the general objectives contained in the Great Lakes Water Quality Agreement.

6.2 Alternatives to the Regulatory Approach

Workshop participants considered alternatives to the regulatory approach, since this method of administration results in serious delays in protecting the environment and in implementing remediation. Alternatives include a negotiated phase-out of manufacture and use of certain substances such as has been proposed through the Canadian multi stakeholder process called Accelerated Reduction and Elimination of Toxic Substances (ARETS). The negotiation should set a timetable for implementation and should include all persons with interest in the project. A negotiated agreement would be a voluntary approach that could be codified through a memorandum of understanding. It is uncertain at this time as to the legal status or enforceability of these alternative measures in the two countries.

In parallel with the regulatory approach, the Board recommends that the Parties pursue a voluntary approach, involving all interested parties, to the phase-out of the manufacture and use of certain persistent toxic chemicals, as a viable alternative. The Canadian multi-stakeholder process called the Accelerated Reduction and Elimination of Toxic Substances (ARETS) can be considered as a model.

6.3 Control of Releases

UNITED STATES

Authority for control of releases rests primarily with the federal government in the United States, with state delivery of the programs for protecting the environment from toxic substances. The U.S. Clean Air Act and Clean Water Act are intended to protect single media based on best available technology. The Resource Conservation and Recovery Act and Comprehensive Environmental Response Compensation and Liability Act (Superfund) are to manage solid waste and cleanup of past inappropriate disposal of toxic wastes. The Federal Insecticide Fungicide and Rodenticide Act is for registration and labelling of pesticides and control of how they are used and released. The Toxic Substances Control Act is the federal law that was designed to prohibit releases of specific toxic substances from all sources to all media.

CANADA

Under the Canadian constitution the provincial governments have responsibility for matters of a local nature which includes most aspects of management and control of releases of wastes and toxic substances. The Ontario Water Resources Act and the Environmental Protection Act both contain provisions to issue orders and certificates of approval controlling operation of facilities and discharges. The goal of the Municipal-Industrial Strategy for Abatement (MISA) program is the virtual elimination of persistent toxic contaminants from all discharges to Ontario's waters.

The Canadian federal government has a series of legislative authorities governing the release of pollutants. Section 36(3) of the Fisheries Act generally prohibits discharge of substances deleterious to fish or human use of fish. Regulations are based on best available technology on an industry sector basis. Provisions under the Canadian Environmental Protection Act are also concerned with the release of pollutants. The section on toxic substances, which incorporates the authorities from the former Environmental Contaminants Act, contains legislative provisions to control releases of specific toxic substances from all sources to all media.

Because the Canadian Environmental Protection Act is based on the Criminal Law and on Peace, Order and Good Government, it can likely be used for those substances that are: i) so noxious that involvement with them would constitute a criminal activity and ii) so pervasive that they have become a matter of national concern. Persistent toxic substances such as PCBs and some other organochlorine compounds would seem to fit this category.

7.0 Reverse Onus

Considerable ambiguity still exists as to what the concept of reverse onus refers. In the Commission's 5th Biennial Report, it was considered related to prevention of harm from new chemicals entering the market place and to discharges of persistent toxic substances.

At the workshop, there was agreement that where new substances are introduced into commerce or new uses of existing substances are intended, the proponent should develop adequate information to enable governments to assess the hazards posed. This system of reverse onus is now well established in both countries for new pesticides and drugs that are designed to be biologically active. The two countries have extensive bureaucracies to evaluate information on the safety of new chemicals. Because chemicals are articles of international commerce, the Organization for Economic Cooperation and Development has developed an agreed list of tests that must be undertaken and evaluated before marketing a new substance in OECD countries. Canada is in the process of promulgating regulations to require this premarket testing of chemicals under the Canadian Environmental Protection Act (CEPA). In the U.S., a regulation would have to be developed under the Toxic Substances Control Act (TSCA) to implement the OECD decision. The Water Quality Board concludes that the institutional mechanisms and data requirements for evaluating new chemicals are well developed in the two countries and internationally.

Is there a role for reverse onus in relation to persistent toxic substances already in commerce? When certain persistent toxic substances have been released to the Great Lakes, they have caused injury to fish and wildlife resources, to the use of the resources, and probably caused effects on human reproduction and development. When injury of this kind occurs, particularly from transboundary pollution, the system of justice in both countries places specific types of responsibilities on governments and on those governed (see Figure 1). Part of the purpose of the workshop was to investigate how these responsibilities are placed relative to the injury caused by persistent toxic substances because this determines the ability of the societies to manage those materials appropriately. *The Board concludes that when injury from persistent toxic substances occurs, the role of government is to secure enough documentation to support conclusions: i) that injury has or is likely to have occurred; ii) that a particular persistent toxic substance(s) is or is likely to have been the cause; and iii) that a particular party is or is likely to have been culpable.* It seems that when unlawful damage has occurred, there is a series of duties for the government to fulfil, but none of this implies a reverse onus on industry.

At the international level the roles of governments in relation to injury caused by substances have been identified by the International Law Association in the Helsinki Rules as elaborated at the Montreal Conference in 1982 dealing with water pollution. Here there are considerable reverse onus duties. First, there is the general rule of international law that a state must not permit the use of its territory for purposes injurious to the interest of other states in a manner contrary to international law. Second, where substantial injury has occurred there is a duty on the state, in whose territory the water pollution originated, to abate the pollution and compensate the injured cobasin state as well as give notice of the change of circumstances that caused the injury. The Parties should examine the Helsinki Rules to see whether the reverse onus principles and rules laid down by the International Law Association on pollution of international drainage basins should be included in the Great Lakes Water Quality Agreement.