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Risk Assessment, Communication and Management in the Great Lakes Basin. Proceedings of a Workshop, February 1-2, 1993, St. Catharines, Ontario

Great Lakes Water Quality Board

Michael Gilbertson

GREAT LAKES WATER QUALITY BOARD
REPORT TO THE
INTERNATIONAL JOINT COMMISSION

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International Joint Commission
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Compiled and edited by Michael Gilbertson
Secretary, Great Lakes Water Quality Board

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Disclaimer

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Environmental Risk Characterization

Dr. William Farland
Director of the Office of Health and Environmental Assessment of the U.S. Environmental Protection Agency in Washington, D.C.

The purpose of the risk assessment and risk management processes is to compare the risks posed by particular substances or other agents and to identify and deal with the worst and most controllable risks first. Environmental risk characterization is the process of combining various kinds of information from the risk assessment process, including hazard identification, dose-response evaluation and exposure assessment, to describe the likelihood that humans will experience toxicity associated with the substance. This information about the likelihood of toxicity can then be used, together with information on control options, in the risk management process to formulate regulatory decisions.

Since 1986, U.S. EPA has prepared and revised risk assessment guidelines on a variety of issues including mutagenicity, developmental toxicity, chemical mixtures, exposure assessment, and carcinogenicity. More recently, risk assessment guidelines for repro-ductive effects, neurotoxicity and immunotoxicity have been drafted. In 1992 EPA published a framework for ecological risk assessment.

The paradigm used by the U.S. EPA for risk assessment was developed by the National Academy of Sciences and published in 1983. Hazard identification, as a part of the risk assessment process, depends on the collection of all relevant information derived from laboratory experimentation and from epidemiology. It is essential to review data quality and to highlight critical aspects. All of the evidence is evaluated using a weight-of-evidence approach. From this hazard identification process, research can be identified and undertaken that would permit more confident statements to be made about the hazards posed.
The second component of the risk assessment process is the evaluation of the dose-response relationships. The data sets that are found to be valid should be presented together with the plausible models for extrapolation from high to low doses and from tests in laboratory species to evaluation of hazards and risks in humans. The strengths and weaknesses and the degree of scientific consensus concerning the preferred data sets and models should be made explicit.

The range of estimates of the potency of the substance should be included and this should reflect the general uncertainties inherent in the process. The use of alternate data sets,assumptions, and models may result in changes in estimates of the dose-response relationships. The rationale for the use of a default value instead of data from some scientific finding should be made explicit.

The third element of the risk assessment process is exposure assessment which has taken on a very large role in the past few years. The EPA risk assessment guidelines have contained explicit descriptions of the approaches and methods used in the development of exposure scenarios and the range of parameter estimates that are included in an exposure assessment. There is a focus on the populations or subpopulations that the data indicate may be particularly exposed. The potential routes of exposure from particular pathways and sources must be identified and the uncertainties and relative importance of the assumptions, exposure models and confidence in the data must be described. From the review of the exposure information, needed research to increase confidence in the exposure assessment can be identified.

Risk characterization is the process of combining and integrating the information and analyses derived from these first three stages to describe the likelihood that humans will experience any of the forms of toxicity associated with a substance. The major components of the risk are presented, along with the quantitative estimates, where appropriate, to give a combined and integrated view of the evidence. It thus becomes more than the sum of its parts.

In some cases it may be beneficial to use a qualitative assessment of risk in addition to the quantitative assessment. Though a quantitative

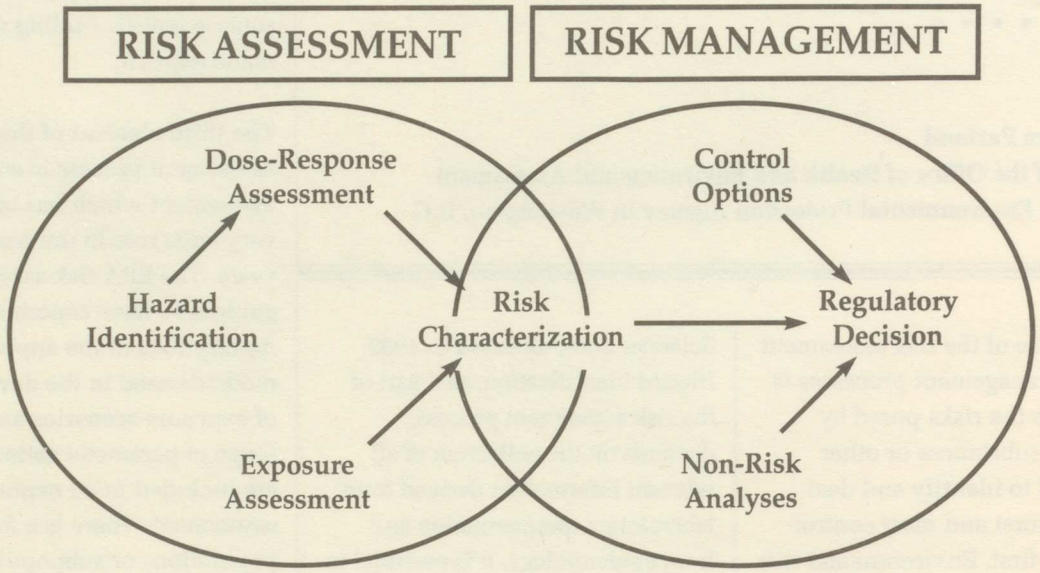

Figure 1 **Environmental Risk Characterization**
—The Relationship Between Risk Assessment and Risk Management

assessment can always be provided, discretion is needed in applying the numerical value in the process of regulatory decision making. Again, it is necessary to identify the key assumptions, their rationale and the extent of scientific consensus, the uncertainties that have been accepted and the effects of reasonable alternative assumptions on the conclusions and estimates. This is a more complex approach than would have been undertaken ten or twenty years ago, but is proving to be more effective for informing decision makers, for instance, in the reassessment of risks posed by dioxins.

There is a series of issues associated with the risk characterization process. Some of the pitfalls in quantitative versus qualitative approaches have been mentioned. A second issue has been termed "the tyranny of the numbers" in which decision makers find themselves driven to take some action without really understanding the basis for a numerical value or the background to a particular approach. A third issue relates to the "bridger" or scientist who must communicate the basis for the risk characterization and the confidence that can be placed in the data, assumptions and inferences. Finally there is the issue of risk communication and effectively transmitting to the public not only the risk characterization but also the complex set of scientific information, inferences and judgement implicit in the process.

The risk management process can be considered as the complex interplay of judgement and analysis that uses the results of the risk assessment, combined with political, economic and social information to produce a decision about whether to undertake certain environmental actions. In addition, risk management includes the determination and accomplishment of those actions that will reduce risk to the greatest degree, given any particular level of resources. While individual risk management decisions may appear to be a process of balancing risk reduction against resources, the system as a whole is designed to balance risk against risk, to aid in the process of deciding which risks should not be addressed so that resources are not used unwisely. Risk management is thus a process designed to identify and deal with the worst and most controllable risks first.

Perhaps the most challenging part of the process, during the next decade, concerns risk communication. It entails the ability to explain risk assessment findings, risk management choices, and the basis for risk management decisions, including the assumptions,

uncertainties, analysis and the process of weighing the validity of the data, facts, values, and judgements that went into the risk management decision. Ideally, risk communication transmits to the public, information from the risk assessment and management processes that is believed to be reliable, together with the values that were applied, and the way the information and values were linked to produce a conclusion.

There is a series of issues for the future of the risk assessment and risk management processes. First there will be a significant challenge in incorporating new and evolving science into EPA's guideline documents on risk assessment for use by EPA scientists and by scientists from other federal, state and regional agencies. A second issue concerns the future of the risk assessment process itself. If the process is too complicated or results are unable to be communicated then other approaches could be tried. There has been a significant effort in trying to understand and characterize sources of uncertainty in the risk assessment process. Another issue is concerned with harmonization of approaches to risk assessment to try to avoid the production of different results which would be confusing to the public. Risk assessment is being harmonized at the international level particularly through EPA activities in the World Health Organization. Finally, the issue of risk communication will continue to be a challenge in the process of making better choices through the use of risk assessment and risk management techniques.

Use of Risk Assessment for Priority Setting Concerning Environmental Issues in the United States

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Dr Robert Huggett
The Virginia Institute of Marine Studies, Gloucester Point, VA

There is a growing consensus in the United States that there is only one kind of environmental risk assessment and that human risk assessment is essentially a subset. In 1987, the U.S. Environmental Protection Agency published the results of a priority setting exercise, undertaken by managers and staff, entitled "Unfinished Business: A Comparative Assessment of Environmental Problems". Thirty-one problems were ranked into four broad categories; a) human cancer risk; b) human non-cancer risk; c) ecological risk; and d) welfare issues. In 1989, the U.S. EPA Administrator, Mr Reilly asked the Science Advisory Board (SAB) to assign priorities to these thirty-one issues. The SAB formed The Ecology and Welfare Subcommittee to;

1) evaluate the procedures and results of the report on "Unfinished Business" in relation to ecological risks and welfare risks; and
2) combine the ecological and welfare rankings, if possible.

The first challenge was to prepare a rigorous methodology for evaluating each risk. In environmental risk assessment, ecologists refer to "stress" rather than "exposure" which tends to be used only in relation to chemical substances; many other factors, such as physical habitat destruction or introduction of exotic species, can affect ecosystems. The three criteria that were used to evaluate risks were; a) scale of the stress (regional, local, or biospheric); b) scale of the transport mechanism (atmospheric, water, or soil); and c) response time for recovery (years, decades, or centuries). In evaluating the original EPA list of problems, there had been a mixture of sources, receptors, media, and specific regulatory obligations. Thus the report tended to reflect the specific program interests of EPA which did not necessarily form a rational basis for evaluating the relative priority of national environmental problems. It was recommended that the Agency should use a matrix of types of ecological stress versus ecosystem types. The basis for defining ecological problems included; a) the spatial extent of the area stressed; b) the importance of the ecosystem affected, within the stressed area; c) the potential of the stress to cause an ecological response; d) the intensity of the stress; and e) the length of time that the effect was likely to occur and the potential for ecological recovery.

Highest ranked ecological problems included habitat alteration, global warming, stratospheric ozone depletion and loss of biological species. Medium

risks included herbicides and pesticides, toxic substances and nutrients in surface waters, acid deposition and airborne toxic substances. The following were ranked as relatively low risks; oil spills, groundwater pollution, radionuclides, acid runoff and thermal pollution. It is noteworthy that many of these rankings were directly opposite to those that would be chosen by the public.

The subcommittee made the following recommendations. First, there should be a formalized process, which should be extramural and continuous, to rank ecological risks from man-made stresses. Second, formal methodologies for ecological risk assessment should be developed. Third, the databases needed for improving future ecological risk assessment should be developed. In this regard, EPA has initiated the $50 million Environmental Monitoring and Assessment Program which will provide a valuable database for this purpose. The fourth recommendation concerned the development of an appropriate methodology for integrating ecological and economic dimensions. More consideration should be given to non-economic aspects of ecological values and welfare risks. For example, before the decline of the oyster in Chesapeake Bay because of overfishing, the waters of that huge estuary were filtered once a week. Now it is filtered only once a year with consequent changes in the chemistry and biology of the Bay. Finally it was recommended that the results from the risk ranking process should be used by the Agency in planning, policy and action.

The subcommittee devised and recommended a new risk paradigm for welfare comprised of the following four components; a) ecological quality which refers to the indirect impacts on humans such as reduced quality or utility of an environmental resource; b) Resource sustainability referring to irreversible losses of ecosystem structure and function, such as loss of critical habitat or species extinctions; c) direct economic effects referring to direct physical changes that cause adverse economic impacts on humans other than health effects; and d) direct non-economic effects such as social nuisances including odours, noise, and reduced visibility.

In summary, the Ecology and Welfare Subcommittee in its report entitled "Reducing Risks", emphasized the importance of the environment, redefined the problems from an ecological viewpoint, identified the importance of time and space in ranking priorities, and identified the need for improved economic analysis. In this regard, there is a new Environmental Economics Committee of the U.S. EPA Science Advisory Board which is comprised of resource economists discussing the findings with the scientists.

Subsequent to the publication of "Reducing Risk", there has been a series of workshops that have been published as three proceedings. They examine the 1983 report of the National Academy of Sciences on human risk assessment to determine how it could be adapted as a framework for ecological risk assessment. Much of the first workshop was concerned with sources of ecological stress such as point and non-point sources, physical habitat alteration, and the introduction of biological stresses. The workshop participants also considered the characteristics of the various stresses such as the intensity, duration, frequency, timing and scale. The general finding was that for a single species and for a single chemical, the NAS risk assessment model is straightforward and useable for ecological risk assessments in either terrestrial or aquatic environments and has been the basis for EPAs work in setting water quality criteria and standards. There are, however, limits to the accuracy of the risk characterization when applied at higher levels of biological organization or when the exposure is to multiple stresses. These limitations in accuracy are caused by limitations in basic understanding of biochemistry, physiology, chemical fate and transport, effects of other stresses and ecological interactions. One promising area to overcome the uncertainties inherent in ecological risk assessment, is the use of biomarkers in which an organism integrates all the man-made stresses and the effects are manifested through biochemical, physiological or histopathological changes such as protein induction, immune system dysfunction, DNA alterations, and bile metabolites.

Application of a Risk Assessment Methodology Used in Canada

Dr. Daniel Krewski
Department of National Health and Welfare
Tunney's Pasture, Ottawa, Ontario

In 1990, the Department of National Health and Welfare published its risk management framework entitled "Health Risk Assessment: The Challenge of Health Protection". The Canadian methodology is similar to that developed by the U.S. National Research Council and envisages risk assessment and risk management as a series of steps. Toxicological and epidemiological data are assembled to identify the presence of human health hazards in the environment. These data are then coupled with quantitative analyses to estimate the magnitude of the risk. A series of management options is identified and evaluated in relation to such other factors as the trade-off between health risks and economic benefits, acceptability of risks, and social, economic and political factors, to make a risk management decision. Resources are required for implementation of the selected risk management strategy selected. Though risk communication is frequently seen as the final part of the risk management process, it should be undertaken throughout. In addition, it is essential to evaluate the effectiveness of the implemented decision through monitoring environmental quality, epidemiological studies and post-market surveillance of new drugs. Awareness of new information on the substance may lead to a reevaluation of the decision and the need for new corrective action.

The use of the term "risk assessment" in Canada is broader than the meaning used in the U.S. EPA where it refers only to the scientific process of hazard identification and risk characterization. In Canada, it also refers to the process of developing and evaluating different options for risk management. The Society for Risk Analysis has been unable to resolve these differences in the definitions but may be favouring the broader meaning.

Dr Krewski exemplified how the risk assessment methodology is being applied in Canada. During the past eight years, epidemiological data have been collected on 4,000 cases of twenty-one different kinds of cancer among men working in the Montreal area. In addition, exposure profiles to more than 300 industrial agents and to tobacco have been collected. From these data, the relative risks of cancer from exposure to tobacco and specific industrial chemicals have been estimated. The data showed not only the well established ten-fold increase in lung cancer among smokers compared with non smokers, but also increased risk at several other sites including the oesophagus, stomach and urinary bladder. The data have been used to estimate the fraction of the total cancer burden in the population which is attributable to cigarette smoking. About 92% of the incidence of lung cancer and about half of the bladder and oesophageal cancer is due to cigarette smoking. Analysis of the data in relation to the industrial chemicals showed no increased risk in any of the different cancer sites for any of the chemicals including polycyclic aromatic hydrocarbons,and chlorinated solvents of benzene, toluene and xylene. This study firstly showed that there is no epidemic of occupational carcinogenesis associated with these 300 risk factors. Second it shows the difficulty of doing environmental epidemiology when exposures are low enough that any increase in risk is not detectable in conventional studies.

The second study, started in 1984, concerned the presence of radon in Winnipeg, Manitoba where homes have the highest concentrations of this gas in any city in Canada. There were 1,500 people in this study and, through the use of radon dosimeters, integrated exposure profiles were compiled on a retrospective basis for the 750 lung cancer cases and for their 750 matched controls, to construct a cumulative lifetime exposure to radon. The average concentration of radon in homes for the lung cancer cases was 116 becquerels per cubic meter, whereas the exposure of the matched controls was 126 becquerels per cubic meter. After results were adjusted for the effects of smoking, difference in country of origin and for occupation, there was no component of the risk of lung cancer that

was attributable to exposure to radon.

Both of these epidemiological studies which comprised direct measures on populations show the difficulty of attributing an increased incidence of disease at low exposures to the putative factor. An alternative method is to estimate the increased risk to humans indirectly, through extrapolation to low doses from results of laboratory studies on experimental animals, in which high level exposures result in clear increases in the incidence of cancers. The most common assumption concerning the shape of the dose- response curve is that it is linear at low doses. This is generally considered as a default position , in the U.S. and in Canada, in the absence of other evidence to the contrary.

A second major topic in cancer risk assessment is estimation of carcinogenic potency. The most commonly used measure is the TD50 which is the estimated dose that would lead to a 50% increase of tumour risk in exposed animals. There is a very large database concerning carcinogenicity of substances from which there is evidence of a variation in carcinogenic potency ranging over six, seven, or even eight orders of magnitude. Many of these experiments on laboratory animals were undertaken at close to the maximum tolerated dose (MTD) which is defined as the highest lifetime dose at which no significant physiological effect, such as a change in body weight,or reduced survivability, occurs. Surprisingly, there is a strong correlation coefficient of 0.952 between the carcinogenicity potency and the maximum tolerated dose. This relationship might suggest that the carcinogenic potential of a substance could be predicted from a knowledge of the maximum tolerated dose. Similar correlations exist between a) the maximum tolerated dose and the estimates of carcinogenic risk based on extrapolation to low doses, and b) the TD50 and low dose estimates of risk. A correlation of 0.8 exists between the TD50 estimates on an interspecies basis using mice and rat raising questions about the interpretation of these data; specifically, this correlation may be an artifact of the correlation between the MTDs for rats and mice.

One of the recent scientific trends in quantitative risk assessment is towards the use of biologically-based models of carcinogenesis. This approach has had particular applications, for example, in the assessment of risks posed by joint exposures to tobacco and radon among Colorado uranium miners to evaluate whether there are interactive effects. In the two stage carcinogenesis model, normal cells are believed to undergo two mutations in the process of transformation into malignant cells. The cells that have undergone the first mutation are called initiated cells and compounds that cause this are called initiators. Compounds that cause an increase in the rate of proliferation of the initiated cells are called promoters, and compounds that cause the second mutation of the cancer cell are called progressors. For people exposed to low levels of radon alone at about one working level per month, there is a slight increase in relative risk of lung cancer of about 1.3. People who are exposed to tobacco alone at about 10 cigarettes per day have about a five-fold increased risk over background. For people who are exposed to both radon and tobacco together, at low levels, these relative risks can be added together to obtain a joint relative risk. For people exposed to high levels of radon the relative risk is about 12, and for those exposed to large amounts of tobacco the relative risk is about 11. However, the relative risk of contracting lung cancer from high levels of both radon and tobacco is 50 indicating that the joint action at high exposures is synergistic and not additive.

There is also a series of toxicological endpoints, other than cancer, for which risk assessments are undertaken. These are usually based on the determination of the "no observable effect level" or NOEL, and then dividing this level by an uncertainty factor to derive a "reference dose". It is assumed that for these kinds of endpoints, as compared with cancer endpoints, there is a threshold. The approach has not been without criticism since it ignores the slope of the does-response curve, favours smaller studies, and makes no statement about the risks around the NOEL. For these reasons it has been proposed that a "benchmark dose" be instituted which would relate to the increased risk by a certain percentage amount. This approach is analogous to the development of the TD50 for cancer risk assessment. The new benchmark dose needs to be related to the existing NOEL during the transition to this new measure.

Dr Krewski exemplified how quantitative risk assessments are

being undertaken for non-cancer endpoints, using the benchmark dose technique, with reference to data from the U.S. National Toxicology Program on developmental toxicity. To evaluate the risks posed by a potential developmental toxicant,laboratory animals are exposed to the compound and mated. This can result in embryo lethality, resorption, or dead births at term, or malformations among live births. Developmental toxicity data for 2,4,5-T has yielded a benchmark dose of 43 mg/kg based on embryo lethality, and 44.9 mg/kg based on the incidence of malformations in the liveborn animals. This benchmark dose relates to a 5% excess risk level. If the two endpoints were combined, the benchmark dose would be about 36.8 mg/kg. There are examples where the prenatal and postnatal toxicities are very different. The prenatal toxicity of ethylene glycol is about 1,700 mg/kg and the postnatal toxicity is about 450 mg/kg; the benchmark dose based on overall toxicity is slightly lower than this latter value.

Dr Krewski presented the results of a national telephone survey of 1,500 Canadians to study perceptions of risk from a variety of factors. In one part of the survey they were asked to rank about 30 health risk factors of interest to the Department of National Health and Welfare. The top three factors were cigarette smoking, ozone depletion, and breast implants. At the time of the survey there was extensive media coverage on breast implants. The surprising inclusion of breast implants among the top three really reflects the power of the media to influence public opinion. The bottom three were heart pacemakers, bottled water, and contact lenses. It was concluded that generally Canadians have some sense of what the important environmental health risks are in Canada. A second finding was that people generally felt more concerned about the risk to the other person rather than to themselves. Men consistently tend to be less concerned about risks than women. Similarly, younger people are less concerned than older people. Those with more education were less likely to express high concern. The public assigned the greatest responsibility for protecting them against health risks to the medical profession, followed by the Department of National Health and Welfare, Environment Canada and the Department of Agriculture. These results indicated a failure of Canadians to distinguish between the roles of different government departments with respect to health protection programs. The news media was by far the most important source of information on health risks, followed by the medical profession and the Department of Health and Welfare. The Department also fared well in terms of credibility of their information. However the results showed that information from industry was the least credible.

New Priority-setting Initiative in Environment Canada

William Smith
Conservation and Protection, Environment Canada
Ottawa, Canada

The process of environmental protection in Canada is undertaken in a manner quite different from procedures in the U.S. in that it tends to be more consensual and undertaken through close consultation and negotiation to find common cause and approaches. In 1992, a variety of industry associations made a presentation to the Advisory Council on Environmental Protection, advocating the use of risk assessment for priority setting. The basis of this policy presentation was that the federal government is requiring too much, too quickly of industry in relation to environmental protection. Similarly, governments are finding that there are too many issues that are being addressed or concerns that are unaddressed, in addition to serious budget constraints. It has therefore been recognized that there is a need for an integrated framework for priority setting which can use a common basis for comparing different kinds of risks not only for health but also for ecological and economic concerns, to bring about consensus on the urgency for action and to focus scarce resources.

The purpose of the new initiative is to develop a priority-setting system, with advice to guide both the Minister of Environment and his Department in determining the appropriate response to pollution problems resulting from social and economic activity. The system is expected to be comprehensible to different groups with different backgrounds and perspectives. Another important attribute is that it should be understood nationally, regionally and locally as well as internationally.

The first part of the process has been to inventory candidate pollution problems by scanning all the initiatives ongoing in the Department, and through public consultation. For example, many projects are funded through the Green Plan which was a major environmental policy statement announced in 1989. Under the Canadian Environmental Protection Act there is an initiative to develop a second list of priority substances to be assessed. Pollution problems may be identified through the ongoing collection of data from research and monitoring, and through assessment processes.

Candidate pollution problems are then characterized through a screening process to remove from the list those that do not pose a significant risk. Information is collected on the known sources and on the quantities released to the environment, on the fate processes and pathways through to biota, and on the effects. One initiative is to develop, jointly with the Department of National Health and Welfare, a review of scientific protocols used for screening priorities. A second is to undertake a similar review in the field of economic analysis. Consideration is being given to assessing relative risk and the treatment of uncertainty.

The third component of the priority setting system is to score the pollution problems. First consideration is in terms of jurisdictional ownership of the problem and which organization has management responsibility. The second is whether there is an ability to manage or remedy the problem. Other considerations are the level of public concern, the significance of the health consequences and of the ecological changes and the socio-economic impacts.

The final component is concerned with ranking the pollution problems. The term ecological or environmental triage has been coined to refer to the classification of the problems into high, medium and low priority. The high priority group comprise those problems for which there is sufficient information to manage the problems and for which there will be a return. The middle group are those problems that should be monitored and assessed, and the low priority group are those, based on the information available, that are of no significance. This last category is important in that the Minister must be given advice to enable him to decline to take on issues that are of low priority. The process has been valuable in improving communication within the various parts of the Department.

The Department of Environment has prepared an ambitious work plan to implement this priority setting system. A working group of directors and a steering committee have been set up to coordinate the initiative, with representation from other departments directly or indirectly involved in environmental protection. The objective is to involve participation from inside and outside the Department and to consult with partners and stakeholders to develop a consensus about the approach. Project teams are being set up to scope the health, ecological and economic problems and to develop, adapt and integrate the required methods and procedures. There will be a multistakeholder workshop in April 1993 to recommend an approach on a candidate group of problems.

In the short term a framework will be produced that will include criteria for a ranking and weighting procedure. It will have involved other government departments and selected stakeholders, and will have been tested on representative problems. In the medium term, by September, there will be agreement on methods, and in the long term, by November 1993, there will be an initial priority list that can be reviewed by the Minister from which an action plan can be prepared for the Department with the involvement of other government departments.

Comparisons and Contrasts in Risk Assessment in the United States and Canada

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Joel Fisher
Environmental Adviser, International Joint Commission
Washington, D.C.

Risk assessment activities in both countries for human health and environmental purposes have similarities in the techniques used, data bases employed, risk agents studied (chemicals, radiation, life style factors), and motivations. Major differences occur in the goals and purposes as well as the legislative, administrative and culture bases for these activities. In both countries there is also a major shift to risk management rather than risk assessment *per se*, which reflects the strong influence of the 1983 National Academy of Sciences(NAS) study. Though the NAS study was performed by a group based in the United States, it included several scientists from Canada and other countries, and since then, United States and Canadian projects on risk assessment have typically involved experts from both countries.

The federal governments have historically had the largest involvement in risk assessment activities in terms of the number of scientists engaged for policy and regulatory reasons, and evolution of research and analysis, the legislative history, and the funds expended. Even at the international level, it is federal governments which provide the funds for work of such groups as International Agency for Research on Cancer,the World Health Organization, the United Nations Educational, Scientific and Cultural Organisation and others, and many of the specialists achieved their status through mainly federal grants, contracts, employment or similar support.

Both qualitative and quantitative risk assessments are carried out in each country. For quantitative risk assessments, it is necessary to differentiate between risk assessments for systems which have no threshold for risk and those which have a threshold, and by implication, an upper bound safe level or zone of zero risk. These assessments mainly emphasize human health considerations, although environmental risk assessment is a newly emerging and rapidly developing area.

In both countries the approach to quantitative risk assessment for systems with thresholds is basically identical. One seeks a level, the lowest one at which one no longer observes some adverse effect, the no-adverse effect level. One then applies some kind of safety factor to set a threshold level, above which one may be in a zone where an effect may set in, but below which no effect would be expected -- in other words, safety. Procedural controversies and differences arise from setting numerical values for uncertainty

and safety factors. Ecological risk assessment has mainly used the threshold approach, although risk tends to be formulated, not in terms of ecosystems, but rather in terms of the responses of individual sentinel or indicator species for which toxicology data exist.

For those effects which have no threshold, one assumes that even a single contact with the minimum identifiable (usually one molecule for a chemical or some level of energy for a given radiation insult) quantity of an agent carries some risk. All risk is probabilistic, and there is no absolutely safe level. Rather one seeks some societally-acceptable level of toleration of the risk. The controversies associated with societal acceptability motivated the National Academy of Sciences in its 1983 study to move away from this concept to "risk characterization." This new emphasis has resulted in various guidelines, especially the 1986 USEPA guidelines for mutagenicity, carcinogenicity and neurotoxicity, which are undergoing revision. Carcinogenicity and mutagenicity were historically the two main non-threshold risk problems, but the neurotoxicity of lead, which appeared to manifest itself at ever increasingly low levels in children, suggested that this type of problem may also have non-threshold elements.

Historically, in the United States, quantitative risk assessments are used by federal agencies to regulate and administer a variety of laws. Because the constitutional basis of United States law gives the federal law primacy, risk assessment is led by the federal government. Several agencies including the USEPA, the Food and Drug Administration, the Consumer Product Safety Commission, and the Occupational Safety and Health Administration, undertake these tasks for various purposes, but most of the work has occurred within the USEPA. The USEPA approach has emphasized quantitative risk assessment as a regulatory tool because of a shortage of other tools which can be used quickly and efficiently.

The International Joint Commission has questioned the dependency on risk assessment at the expense of developing other tools to fill the perceived vacuum. Other groups find the methodologies and analyses sufficiently complicated and ambiguous to question altogether the use of quantitative risk assessments. But despite any qualms, the process has a 20 year history at USEPA. The qualitative uses of risk assessment for such things as priority setting, program analysis, screening of chemicals for experimental purposes has taken a very secondary position to the production of risk assessment models and documents for specific chemicals, mainly as carcinogens.

The comparable risk assessment activities at state and local levels tend to follow the federal example. Where a regulatory requirement for risk assessment occurs, state and local governments often either defer to the federal work or seek extensive federal guidance. On the other hand, where qualitative and discretionary risk assessment activities occur at state and local levels, these are often creative self-generated analyses which demonstrate the increasing expertise in government agencies other than federal. Here the emphasis is on whether or not to regulate as opposed to what should be the regulation. Very often, the local agencies, using qualitative risk assessment, benefit because they have not become hypnotized by numbers and models.

Further, local uses of quantitative risk assessment tend to incorporate local factors and nuances suited to the geographical region and culture. Such influences have caused confusion and controversy, when on numerous occasions, various societal sectors have sought to reconcile differences in risk assessments performed by two groups using the same data but obtaining different results, perhaps as extreme in one case as suggesting great risk and in the other case suggesting no risk. This has led for calls for some commonality of approach in making local adjustments and interpretations because of the clearly contradictory situation described in the two groups performing a common risk analysis.

In Canada, the shared common responsibilities of federal and provincial governments for some activities and the separate responsibilities for certain resources and concerns for health and welfare, produce a picture of shared risk assessment activities. Further, because the regulatory use of risk assessment is not nationally mandated, risk assessments, including qualitative ones, are more commonly used. These include screening purposes, determination of research priorities, and a host of administrative goals which have no regulatory content, at all levels of government.

In the United States, some interesting contradictions have recently arisen in comparing risk assessments for threshold and non-threshold effects for the same chemical. For example, a cancer risk assessment for dioxin would assume no level is safe, and a non-threshold model would yield a level, based on some arbitrary level of societal acceptability of minimum risk. A risk assessment for dioxin based on immunosuppression or immune compromise would suggest a threshold model. However, the no-adverse effect level for immunosuppression is lower than the assumed societally-acceptable limit for the same agent as a carcinogen and thus poses a regulatory dilemma.

A similar example occurred in the late 1970's for arsenic. The levels of adverse effect of arsenic, based on neurofunction, were much lower than the levels based on risk analysis for lung or skin cancer. Arsenic is still regulated as a carcinogen, but regulation as a neurotoxin, at that time presumed to be a threshold based effect, might have been more effective and less controversial. The neurological data appeared to have a greater quality than the carcinogenic data, since the latter contained a variety of assumptions about how individuals were exposed.

In the past ten years, several technological advances have made risk assessment activities possible on a larger scale of public activities. First, the introduction of the personal computer and simple computer networks means that risk assessment analyses need no longer be performed on main frame computers. Small systems with faster computational algorithms permit desk top qualitative and quantitative risk assessments by persons who previously had to negotiate a labyrinth of computer connections and specialized systems. Risk assessment models are now "user friendly," thus removing any skepticism by noncomputer bureaucrats who feared the technical monster.

Data bases are more accessible. Government agencies have made their data bases available to local governments and researchers on customer basis. User fees have helped to support some of these networks. Technology transfer activities have emphasized making the data and methods available to larger audiences.

Quantitative risk assessments no longer inspire the same degree of fear and cynicism as when first proposed for environmental and health work, because there is now a history of their use for twenty year or more. Further, the International Agency for Research on Cancer, through its monograph series on cancer risk of selected agents, has helped to establish risk assessment activities as high quality scientific endeavors and given a basis for government authorities in many countries to regulate carcinogens using some risk assessment process.

The IARC effort, however, cannot render immediate or emergency judgements on carcinogenic risks for selected agents. Revision of existing monographs based on new information, or production of new monographs, must often await the formal publication and availability of data. IARC, for the past twenty years, has assembled monographs and classified carcinogenic risk. Only 25 chemicals have been classified as class 1 carcinogens (those which are established human carcinogens). IARC does not pronounce or classify a given chemical as an established human carcinogen on the request or whim of a petitioner group. Its peer review process rigorously evaluates data and deliberates conclusions, as to carcinogenic risk, according to a set of well-defined and internationally accepted scientific principles.

To make its own regulatory process more efficient, and to speed up the analysis of carcinogenic risk, the USEPA established a carcinogen classification system which parallels the IARC system. Almost 100% comparability between the two classification systems occurs, although chromium compounds present a known example of non-concordant classifications between the two systems. The important aspect of the USEPA classification is that it can respond on the basis of research in progress, in house analyses, reports in draft stages or not yet formally published, and other factors, to produce a tentative classification of a compound as a carcinogen. Further, the classification will reflect the kind of data used for that purpose, and a user knows the basis for the classification in terms of the data used.

Several examples of contrasts and comparisons related to risk assessment do not recognize geopolitical boundaries. Groups in both Canada and the United States fall on each side of the debate, but the debate nonetheless can assist

in understanding the risk assessment environment.

For example, all users of risk assessment carefully note their adherence to the idea of "weight of evidence". But is the word "weight" a noun or a verb? As a noun, one might worry about the number of studies or how much they weigh. Sometimes one need consider only the number of studies which support a given view to develop a judgement. But more often one must worry about the quality of those studies. Here the definition of "weight" as a noun means confidence or quality.

As a verb, one might worry about how to "weight" a given study. Here the definition has a precise statistical meaning, one originating from studies on fuzzy sets and evidence calculations. The meaning relates to the use of an information entropy test which resembles the chi-square distribution. This test combines the statistical probabilities, mainly the significance levels, of certain common parameters from several studies. If all of the studies combined share a common statistical universe, the pooling of probabilities may show that the combination of studies has a stronger basis (significance) than any of the individual studies. This holistic statistical treatment can take a collection of diverse, and individually marginal, statistical studies and convert them to an overall picture of strong statistical significance in favor of a particular conclusion. Very few of the risk assessment studies for health and environmental risks in either the United States or Canada have used this approach. The most recent, and one of the few examples, was the recent paper of Morris et al: "Chlorination by-products, and cancer: a meta-analysis" which appeared in the July 1992 issue of the *American Journal of Public Health*.

Until very recently, scientists could not effectively discern any of the risks associated with chlorine disinfection of drinking water and cancer, because of a combination of factors. These included: lack of a single definitive study designed to quantify cancer risk under patterns of exposure to chlorinated drinking water; generally marginal epidemiological data from existing studies; too few studies with common statistical protocols to permit pooling or aggregating data; lack of exposure models or mechanisms on how the risk would arise; failure to correct for confounding factors (i.e. occupational exposure, patterns of exposure, smoking, and family history); and limited statistical tools. The meta-analysis techniques could accomplish, with several limited studies, what had previously not been accomplished with a single definitive study. Meta-analysis is not metaphysics, and the pejorative overtones in the name of the methodology mask the critical fact that this technique is the purest form of the weight of evidence method, and may explain why it is not being used.

A second issue is the "standard human" for risk assessment. Historically, the risk assessments for carcinogens in both countries were for the North American, 17-year old, white male teenager, weighing 150 pounds, and having a 70-year life span. There was no standard woman, child, nonwhite male, or consideration of any other factor. Yet the epidemiological evidence of certain risks of chemical agents in the Great Lakes region has focused on the exposure of pregnant women, developing fetuses, children between 1 week of age and 7 years, and first-peoples groups (bands, tribes, councils). There was no recognition that the North American white male now lives to 76-78 years, and that the groups at greatest risk have actual life spans which approach 55 years. The interactive effects of such factors as nutrition, growth pattern, multiple insults, and disease history, are ignored. This last factor becomes especially important given the increase, in the general population, in antibiotic and chemotherapeutically-resistant tuberculosis (increasing at 18% a year for the past five years), AIDS-related complex (*pneumocystis carina pneumonia*), and specific increases in hypertension and diabetes in non-Caucasian racial groups.

Furthermore, many of the statistical differences between risk assessments performed by various groups exaggerated the differences between "standard humans." One state jurisdiction adjusted the weight and life span of the person by 10 pounds and 10 years. Several public interest groups in both Canada and the United States attempted to perform the risk assessments for selected chemicals causing cancer on women and developing children, but used the techniques associated with adult males (namely the quantitative risk parameters associated with potency of a carcinogen).

Because the statistical development of quantitative risk

assessment models presents several formidable scientific hurdles, both countries should encourage and move toward more qualitative risk assessments. Because they do not emphasize the mysticism of numbers, they provide screening tools or indicators of possible emerging problems, and can easily be adapted to begin analysis of those situations, presently unstudied, which are essential in developing environmental and health policy.

Interest in risk assessment in the United States has reached the Congress and its auditing arm, the General Accounting Office. The Congress gave the USEPA funds for a study on risk assessment activities with the National Academy of Sciences. The General Accounting Office has just recommended that agencies improve their risk assessment activities through their research programs. In some ways I believe Canada has moved ahead of the United States on this front with its risk assessment approach, and hopefully Canadians will participate in the National Academy of Sciences studies to the mutual improvement of all risk assessment activities.

Use of Risk Assessment and Risk Management in Relation to Fish Advisories

Ed Horn
New York Department of Health
Albany, New York

The development of fish advisories predates the formal risk assessment procedures outlined in other parts of the workshop. Fish advisories are not regulatory, but followed from the discoveries and awareness of contamination of fish, as management decisions.

The first advisory in New York State was published in about 1970 as a result of finding elevated levels of mercury in certain lakes in the state. As mercury contamination was discovered in more lakes, there was a general consensus between the environmental conservation, health, and agriculture and markets' authorities that a state-wide advisory on the consumption of all fish caught inland should be issued.

In addition to the mercury contamination, severe PCB contamination of fish was discovered by about 1976 in the Hudson River. Fish, including gamefish, had levels of PCB as high as 200 parts per million in the reach of river above the Albany-Troy Dam. A tolerance of 5ppm was established for PCB in fish. This level was subsequently lowered to 2ppm in 1985. At the same time it was discovered that striped bass in the lower Hudson River and off Long Island Sound were contaminated with levels up to 20 to 40 ppm. The commercial fishery for striped bass was consequently closed.

A variety of management interventions have been tried. In the upper forty-mile reach of the Hudson River there was a prohibition on the possession of sport fish. A similar prohibition on possession of seven species of fish was instituted in 1976 after the discovery of mirex contamination in Lake Ontario. This prohibition, however, created a firestorm of protest from anglers in the form of civil disobedience and flagrant violation of the regulation. It soon became clear that the ban was unenforceable and the Department of Environmental Conservation rescinded the regulation for virtually all fish from Lake Ontario and instead published advisories not to eat the fish.

In 1985, the Department of Environmental Conservation developed a policy on advisories and on regulations. It was decided that consumption of fish from the recreational fishery would be managed through publication of advisories in consultation, and with the recommendation, of the Department of Health. When an advisory had been issued for a particular species in a particular location, the markets for the commercial fishery would be closed. For example, just this past

year, PCB levels in striped bass warranted the prohibition of commercial harvesting and marketing of selected stocks.

In the past twelve years there have not been many changes in the conceptual basis of, or in the message that has been contained in the advisories. There is now a more formal review of the data, and application of risk assessment techniques to the data. The general improvement in water quality and the availability of new data have led to certain changes in the details of the advisories for certain of the species in particular locations. It has been assumed that the information on contamination of fish would be used to regulate discharges and other sources of contaminants.

The Department of Environmental Conservation is responsible for the monitoring program and for developing the data for the advisories. In annual consultations with the Department of Health, decisions are made on the priority species and locations to be sampled. Methods for preparation of the samples for analyses have been agreed upon and the procedure is to use fillets or fish with the skin on and untrimmed. The data are then reduced to mean values and jointly reviewed to decide on any changes in the advisories. In general, the tolerance levels established by the Food and Drug Administration are used in developing the advisories. There has, however, been some criticism of the advisories by sportfishers who still remember the bans on possession of Great Lakes fish and still perceive the action to have been a political decision rather than one related to health risks. Many sportfishers do not believe the messages contained in the advisory. Part of the disbelief arises from the different conclusions and advice being given by other agencies and jurisdictions on the Great Lakes.

Partly to overcome this disbelief, the Council of Great Lakes Governors created a Fish Advisory Task Force with representation from the responsible agencies from the Great Lakes states. The initial charge was to develop an uniform advisory so that the same advice would be available to anglers independent of the state or jurisdiction in which the fish was caught. There has been considerable progress to develop uniform advisories but it is still uncertain whether the results will be any more acceptable to the public. One of the sources of the differences between jurisdictions is that each may have a slightly different purpose for their advisory. The purpose of the New York State advisory is to redirect anglers from fish that are contaminated to those that are less contaminated.

There are graded levels of advice on the consumption of fish based on the review of the data. For fish with excessive levels of contamination, it has been argued that there should be no consumption. The next level of advice is that there should be only one meal of fish eaten per month. There is a general advisory to the sport fishers that all fish from all bodies of freshwater in the state should only be consumed once a week and that no fish should be consumed by women of childbearing age or by children under the age of 15 years. There is a large number of small bodies of water in the state that have not been monitored because there are few users and only limited resources for sampling and analytical work. In the absence of detailed information it seems prudent that this general advisory should be followed. There are, however, a number of anglers who eat considerably more than one meal of fish per week. There are some who are unaware of the advisory, and the Department is attempting to contact these individuals who are at greater risk than the average, and who would benefit most from following the advice.

All anglers who get a license receive the advisory in the guide to the regulations from the Department of Environmental Conservation. It has proved difficult to reach many of the individuals, for instance, who are subsistence fishers on the lower 90 miles of the Hudson River, where a fishing license is not required. From a public health point of view, resources should be directed to getting the message to this group who consume large quantities of fish. There is a difficult balance in giving the advice, between the risks from consumption of the contaminated fish and the benefits of fish from a nutritional point of view, particularly for low income and ethnic groups who may have few alternatives.

Sport Fish Contaminants Monitoring Program in Ontario

Alan Hayton
Ontario Ministry of the Environment and Energy
Toronto, Ontario

The Sport Fish Contaminants Monitoring Program in Ontario was started in 1976 and is undertaken through an agreement between the Ontario Ministry of the Environment, the Ministry of Natural Resources which is charged with the responsibility of issuing fish advisories to the public in Ontario, and the Department of National Health and Welfare.

Three groups within the Ontario Ministry of the Environment and Energy are involved; the Water Resources Branch is responsible for the coordination of the program, data evaluation and preparation of the guide; the Laboratory Services Branch for the chemical analysis of fish tissue; and the Communications Branch for the publication and distribution of the guides. The Ministry of Natural Resources is responsible for the collection of fish through their district offices. Formerly, the Ministry of Labour provided the pertinent medical advice and information on how to issue advisories. There is a reliance on the Department of National Health and Welfare for advice on reevaluation of existing guidelines and on evaluation of the hazards posed by previously unidentified contaminants.

The Guide to Eating Ontario Sport Fish has been published annually since 1977 and currently about 300,000 copies are distributed free per year. The Guide refers to about 1600 locations and generally information is given on two or three species from each location. At some locations, such as the St Clair River where there is a great diversity of species, information on up to twelve different species may be reported. Overall there are over 4,000 location and species records in the 1992 guide. The fish are analyzed for up to 70 substances including mercury and other metals, PCBs, Mirex, various pesticides including toxaphene, PAHs, dioxins and furans. Guidelines have not been prepared for all the 70 substances, but the information is used in other programs to establish trends in levels of contamination. Samples taken from locations remote from the Great Lakes, where contamination by organochlorine compounds is likely to be low, tend only to be analyzed for metals. About 15% of the sites are reanalysed each year, so that inland lakes with the least angling pressure are sampled about every ten years. In contrast, high priority sites such as the Great Lakes are redone much more regularly since, it is expected that concentrations in fish will continue to decline. The advice that is given to sport fish anglers on the consumption of fish is based on the guidelines from the Department of National Health and Welfare. The advice is not directed to specialty groups such as subsistence fishermen or native groups.

In the process of preparing the guidelines, the Department of National Health and Welfare considers the daily intake of each substance from all routes of exposure. The tolerable daily intake is then allocated between the various routes of exposure with a certain allocation to fish.The concentration of each contaminant in the fish is then reviewed to ensure that the tolerable daily intake is not exceeded.

The guideline is also given to the Department of Fisheries and Oceans for the regulation of the commercial fisheries. The method of sampling fish for the commercial fishery is different from that for the sport fishery. For the commercial fishery a composite of all size ranges is sampled and analyzed. the catch is then permitted or restricted on the basis of the results of the analysis of the composite. With the sport fishery, twenty individual fish are sampled and analyzed from throughout the size range. A regression analysis is prepared and consumption advice given for each size class.

Occasionally, analysts will identify a previously undetected substance or find a substance for which there is no formal numerical guideline. For example, fish may contain extremely high levels of an organometallic compound such as organolead. When notified, the Department of National Health and Welfare will give an opinion, on a case-by-case basis, of whether the substance in those

concentrations constitutes a hazard. An advisory may then be issued until the discharge ceases and the contamination is cleaned up.

The other category of contaminants is for those for which there are formal numerical guidelines. For commercial catches of fish, the guideline for acceptance of the catch is 0.5 parts per million. At this level in the sport fishery there are no advisories and the Ministry of the Environment issues information that the fish can be consumed in unrestricted quantities. At concentrations between 0.5 and 1.5 part per million a sliding scale is used so that at higher concentrations there should be lower consumption. At concentrations above 1.5 part per million, the advisory states that no fish should be consumed. Certain more sensitive groups are recognized, including women of childbearing age and children under the age of 15 years. For these groups, there is general advice that no fish should be eaten that are above the unrestricted guideline of 0.5 parts per million. The guidelines for mercury, which was developed in 1978 in consultation with the Department of National Health and Welfare and the Ministry of Labour, is based on the depuration rates to ensure that body burdens are maintained below the no-effect level.

For chlorinated organics a consumption guideline may be set. For example, there is a guideline of 15 parts per trillion for 17 dioxins and furans, expressed as 2,3,7,8-TCDD toxic equivalents. The Department of National Health and Welfare calculated the guideline in the following manner. The guideline dose is 10 picograms/kilogram body weight per day. For a 60 kilogram person, this translates into 600 pg/day. All of the guideline is allocated to fish and consumption of fish is estimated to be 40 g/day. This results in an effective guideline of 15 ppt 2,3,7,8-TCDD in terms of toxic equivalents. In Ontario, there is unrestricted consumption below that guideline. Above that level, an advisory will be issued; restricted consumption is still allowed, except for those groups that are considered sensitive, and provides protection provided that the concentration is not above 36 ppt TEQs.

In addition to giving advice to anglers on consumption of fish for each of the size ranges analyzed, restrictions are placed on consumption of fish with concentrations above the guideline. Where there is a good correlation between contaminant concentration and size of the fish, advice is provided over the size range analyzed, but advice will also be given from an extrapolation to one size class outside of the size range analysed if it exceeds the guideline. In cases where there is a weak regression, the advice tends to be conservative and based on best judgement.

There is a series of issues that may influence the way that advice is formulated and given. The report of the Great Lakes Governors Fish Advisory Task Force is awaited to see whether methods should be changed. Additional guidelines or changes in guidelines, such as the need for congener-specific analyses of PCBs or inclusion of all toxic isomers of dioxins and furans,is dependent upon the provision of advice from the Department of National Health and Welfare. There may be changes in the method of providing advice to the public in 1994. The 1993 Guide will contain a questionnaire to gauge where people are fishing and whether they are adhering to the advice. The advice concerning the chlorinated organics may be modified to give more categories in terms of meals per month for different size ranges of fish. The current advice given to the most sensitive groups advising them to eat less fish than other consumers is being reevaluated based on comments from the Department of National Health and Welfare.

Use of Risk Assessment in Setting Discharge Limits

Dr Milton Clark
Office of Health and Environmental Assessment
U.S. EPA Region V, Chicago, Illinois

The U.S. EPA has implemented a scheme, called the National Pollutant Discharge Elimination System (NPDES), to improve water quality management in the Great Lakes basin. There are two methods that are used; the federal approach is to derive effluent limits based on treatment technology; the other is based on state issued, federally reviewed water quality standards. NPDES permits establish effluent limits based on whichever is the more restrictive of these two methods.

For the derivation of technology-based effluent standards, each specific industry has limits that have been developed for specific pollutants. For instance, in the production of steel, a certain amount of BOD, suspended solids, and ammonia is permitted to be discharged per ton of steel manufactured. If, however, these amounts exceed the water quality standards for that body of water, then this more stringent standard would be imposed.

In the U.S., the water quality approach is undertaken through the development, by EPA, of criteria for ambient water quality. The states are then responsible for implementation of these federal criteria through the establishment of standards for their various water bodies. Effluents are characterized for specific chemicals and for toxicity. Information on critical flow rates and mixing characteristics are modelled for the receiving water, to evaluate exposures and, where there are multiple sources, to calculate the wasteload that may be allocated through individual permits to each industry. Each final permit will contain monitoring requirements, and those industries out of compliance are subject to a compliance process.

These rules were made final on June 2, 1989 and published in the Federal Register. The essential feature is that the power to control water pollution rests at the federal level, with implementation through the states. The limits included by the states, in issuing NPDES permits, must address all pollutants or pollutant parameters which are or may be discharged at a level which will cause, have a reasonable potential to cause, or contribute to an excursion above any state water quality standard, including state narrative criteria for water quality. The U.S. EPA can object to a NPDES permit if the permit does not comply with this policy. This process has resulted in the establishment of two large bureaucracies that many believe should be streamlined for greater efficiency.

In preparing water quality standards, an estimate is made of the final acute value at the end of the pipe. The U.S. EPA requires that this value is not exceeded, whereas some states require that effluents be a half of this value. The derivation of the final acute value is based, ideally, on toxicity data, (acute LC50 or EC50) for at least one species in eight different families. By using statistical procedures, the final acute value is derived such that the value is below the LC50 for 95% of the organisms. In many cases, there is insufficient toxicity data, so the states apply a safety factor between 5 and 10 to the LC50 for the most sensitive of the species tested. When these techniques are applied, for example, to chlorine, the final acute value at the end of the pipe should not be above 38 ppb.

As well as values for chemical-specific toxicity, there is a need to assess the overall toxicity of the whole effluent. For this, the standard is that no more than 50% of the test organisms such as Daphnia, fathead minnows or bluegill sunfish may die in 100% of the sample of effluent. If the effluent fails this test, further testing is required to determine the causative agent. For example, if the toxicity is suspected to be derived from the presence of a metal, then the addition of a chelating agent, such as EDTA would remove the toxicity. The need to investigate the cause of the toxicity of an effluent are incorporated into all permits.

In addition to water quality standards to derive acute values, standards based on a chronic value may be developed to limit the concentration of a substance in an

effluent to ensure compliance outside the mixing zone. Ideally, recommended data are used for at least one species in eight different families. Frequently, there are insufficient chronic studies from which to derive suitable data, and in these cases a safety factor ranging from 10 to 45 is applied to the acute value. The standard is set as an effluent concentration based on a quarter of the seven-day average flow for a ten year low flow situation(25% of the 7Q10). Similarly, a chronic value may be derived for the toxicity of the whole effluent which cannot exceed the no observable effect concentration at the 25% 7Q10. Under these conditions a chronic value for chlorine releases in an effluent would be 11 ppb.

Another kind of discharge limit is for bioaccumulative substances that may cause cancer. The Great Lakes states have issued water quality standards for these specific chemicals set at a one in a hundred thousand risk for a lifetime exposure for 70 years. The standard must be met at the end of the pipe and there is no mixing zone for these substances. A factor is applied based on the bioaccumulation of the compound in fish; for instance, a factor of over 100,000 is applied to PCBs. The states are encouraged to use EPA's potency factors for individual carcinogens. In preparing the risk estimates for discharge limits, it is assumed that the average sportfisher eats 15-20 grams of fish per day; the upper limit for fish consumption by a sportfisher or a subsistence fisher may be 100 grams per day. The cancer risk from the dicharge of an individual chemical cannot exceed one in one-hundred thousand. Where several carcinogens are being discharged, the risks are not added; this issue is currently under discussion.

For compounds that are not carcinogens, discharge limits are calculated on the basis of establishing a reference dose based on a no observable effect level (NOEL) and appropriate safety factors.

Many of the bioaccumulative substances have very large bioaccumulation factors that must be taken into account. In implementation of these standards for control of effluent discharges, compliance monitoring must include detection limits that are extremely low. Typically, detection limits in the part per trillion range are required for compliance monitoring for PCBs, and part per quadrillion range for dioxins.

If an industrial discharger came forward with a request for a permit to continue to discharge 1 ppm of PCB, on the basis that PCB were a non-carcinogen, a discharge limit of 20 ppb would be permitted based on water quality considerations for keeping PCB contamination of fish at an acceptable risk for human consumption. If the PCB were treated as a carcinogen the water quality standard for the ambient environment would be 5ppb. If however the water body was already limited because the load for PCB had already been allocated, then the permit would be zero for the discharge of PCB. If the permittee were to demonstrate that the present discharges do not have any effect on water quality downstream, then some discharge of PCB may be permitted.

The Great Lakes Governors Task Force has been instituted to develop fish consumption advisories based on assessment of risk. The scientists in the Great Lakes basin have been leaders in the development of fish advisories. Levels of contaminants generally, and PCBs specifically, have only declined marginally over the past decade, indicating continued atmospheric loadings and recycling of contaminants from the sediments. Levels of contaminants in fish are still not at levels that are acceptable for unlimited fish consumption.

There is a well-defined process for applying for an NPDES permit. The application is initially reviewed for completeness and accuracy and a public notice published. The public is given an opportunity to comment, and , if there is widespread and significant interest in the permit, public hearings may be held. After the final permit decision has been made there is an opportunity for an evidentiary hearing and the decision from this may be informally or formally appealed to the Administrator. The Administrator may make the final decision on the agency's action.

Process of Setting Effluent Criteria in Ontario

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Dr. Douglas Spry
Ontario Ministry of the Environment and Energy
135 St. Clair Avenue, West
Toronto, Ontario

The Ontario Ministry of the Environment has used risk assessment as a means of developing water quality guidelines and standards for effluent quality requirements, protection of aquatic life, sediment quality management, and for drinking water.

Dr. Spry gave the following two broad definitions of ecological risk assessment:

(a) the process of assigning magnitudes and probabilities to the adverse effects of human activities or natural catastrophes; and
(b) a systematic basis for regulatory decision making.

The Ontario Ministry of the Environment develops Provincial Water Quality Objectives and Guidelines for permissible "safe" exposure by:

a) setting risk as close to zero as possible, with the use of safety factors;
b) evaluating the hazard through examination of published papers of concentration-response data; and
c) complete prohibition of the discharge of some persistent bioaccumulative substances.

The following processes are used by the Ministry in protecting the Ontario environment from the effects of direct discharges;

a) setting goals to define what is to be protected;
b) making regulations to set out legal rights and responsibilities;
c) developing policy to guide the course of action;
d) deriving objectives and guidelines and occasionally legal standards;
e) implementation of those standards to derive effluent requirements;
f) and monitoring for compliance.

The goal of the Ministry in management of the water resource of the province is to preserve and protect the water resources of the Province of Ontario for the benefit of the environment including human, aquatic and terrestrial communities. For the management of the quality of surface waters, the goal is to ensure that the surface waters of the province are of a quality which is satisfactory for aquatic life and recreation.

Although there are nearly 20 acts dealing with water quality, the most important pieces of legislation for the regulation of discharges and spills are the Ontario Environmental Protection Act, the Ontario Water Resources Act, the Pesticides Act and the Federal Fisheries Act. Regulations have been promulgated for ambient air standards under the Ontario Environmental Protection Act. Similarly, under this act, regulations for the Municipal/Industrial Strategy for Abatement are being promulgated for best available technology. The goal of the MISA program is the virtual elimination of persistent toxic contaminants from all discharges into Ontario waters. Under the Ontario Water Resources Act, certificates of approval are issued for industries and municipalities directly discharging to Ontario waters.

Five policies for management of water quality of surface waters have been discussed in the 1984 Blue Book entitled "Water Management; Goals, Policies, Objectives and Implementation Procedures of the Ministry of the Environment." First, for areas with water quality better than the objectives, water quality shall be maintained at or above the objectives, though some lowering of the water quality is permissible. Second, for those areas with water quality that do not meet the objectives, the policy is that there shall be no further degradation and all practical measures taken to upgrade the water quality to the objectives. The policy on effluent requirements is established on a case-by-case basis dependent on the assimilative capacity of the receiving water and on the provincial water quality objectives. The established Ministry procedure on hazardous substances is to develop appropriate water quality criteria and to prevent the release of certain persistent, bioaccumulative substances. Finally, the policy on mixing zones restricts their use in several ways. They should not: contain aesthetically objectionable materials; threaten species survival outside the mixing zone; cause delayed or irreversible effects; impinge on water supply and recreational use; hinder migration of or cause shock to aquatic life; violate

acceptable loadings from all point-source dischargers to a water course.

Legal standards are the numerical or narrative limits that are enforceable through environmental control laws or regulations such as those contained in the air regulations or the MISA regulations. Objectives, such as those contained in the table of provincial water quality objectives in the Blue Book, are the numerical or narrative limits to protect a designated water use and for which sufficient data exist to sustain an objective. Similarly, guidelines are the numerical or narrative limits to protect a designated water use, but for which there is an insufficient database to support development of an objective. Criteria are the concentrations of a substance, derived from the scientific literature, at which effects occur and on which recommended limits such as guidelines and objectives, can be based.

In the development of water quality standards (not legal) using hazard assessment, different approaches are used in the two countries. In the approach used by the U.S. EPA, the final water quality criteria protect about 95% of the genera tested. All species and genera must be protected in Canada and Ontario. Many of the standards developed in Ontario are for single media such as for water, air or sediments, but there are some multimedia standards under development based primarily on protection of humans as the receptor.

Water quality objectives represent the desirable level of water quality that the Ministry strives to maintain in surface waters of the Province. The methodology for derivation of Ontario's water quality objectives was published in 1992 and a list of over 300 compounds has been compiled for which objectives or guidelines are being drafted. The process of development of objectives or guidelines considers evidence related to toxicity, bioaccumulation, mutagenicity, taste and odour, and assumes a threshold for effects. The data that are used in the preparation of an objective should have been published and include measurements of the test concentrations. The dataset should also be of such a quality that the addition of other test results would likely have little effect on the final number for the objective. A safety factor of 10 is applied to the lowest concentration at which an effect is observed, to protect aquatic life, and a factor of two is applied for the protection of aesthetic uses.

Provincial water quality guidelines are similar to objectives but based on a less complete data set. For these calculations, whatever acceptable data are available on toxicity, bioaccumulation, mutagenicity, taste and odour are considered. To the lowest effect endpoint, a safety or uncertainty factor is applied, ranging from 13 where there was a database almost good enough for an objective, to 9000 where very few data were available.

Provincial sediment quality guidelines are listed for three levels of effects based on organisms that are actually found over a range of clean and contaminated sediments. No effect, lowest effect and severe effect levels are calculated. The no effect level is calculated for organic contaminants from the provincial water quality objectives using a partition coefficient between sediment and water that has been normalized for organic carbon content. The lowest effect and severe effect would protect 95% and 5% of naturally occurring species respectively.

These various objectives and guidelines are used as guidance to the six regional offices of the Ministry of the Environment in deriving effluent requirements for direct discharges to the Ontario environment. The long term goal is that all waters in the province will meet the water quality objectives. The process for achieving this is through the writing and implementation of certificates of approval, control orders, and development of technology-based regulations under the MISA program. A mass balance approach is used for assessment of the quality of receiving waters. For those waters that do not meet the provincial objectives, there is a special process for dealing with those deviations.

A certificate of approval is a legally-binding agreement under the Ontario Water Resources Act and may include specifications concerning: any construction; concentrations of specific chemicals in an effluent;definition of a violation; permitted flows; monitoring programs for chemical analyses, toxicity and effluent flows; assessment of environmental impact; contingency and rehabilitation plans; and whether financial responsibility is required.

In summary, Ontario primarily uses a hazard assessment approach to meet the goal of protecting all aquatic life, by establishing safe concentrations, and incorporating these into permits, and monitoring effluents and discharges for compliance.

Wildlife Criteria Development Under the Great Lakes Water Quality Initiative

John Sullivan
Bureau of Water Resources Management
Wisconsin Department of Natural Resources
Madison, Wisconsin

In the past few years, several individual states have developed water quality criteria for protection of wildlife; New York state developed criteria for piscivorous wildlife based on concentrations of persistent toxic substances in the flesh of fish; Michigan developed estimates of safe concentrations in relation to terrestrial life cycles; and Wisconsin developed criteria for protection of wild and domestic animals.

In the 1970s and 1980s, in the process of implementing the Wisconsin program for secondary wastewater treatment, particularly for industrial wastes, a large proportion of the persistent toxic substances was removed from effluents. With the improvement in water quality, several species of fish-eating birds returned to reestablish colonies or territories. Observations by biologists of the reproductive success of these birds indicated the presence of embryotoxic and teratogenic chemicals. Up to that time traditional water quality guidelines had been developed by the U.S. Environmental Protection Agency only for protection of aquatic life and human health. The lack of wildlife criteria has been a significant obstacle for the U.S. EPA with respect to its overall mission of protection of the environment. Wisconsin therefore set up an advisory committee, comprised of scientists from academia and the state bureaucracies, to develop water quality criteria for wildlife. It has proven difficult, because the numbers derived for wildlife are so much more stringent than those for aquatic life and human health, to get acceptance and implementation of the wildlife criteria.

In 1989, Wisconsin was assigned the lead role for the development of wildlife criteria under the Great Lakes Water Quality Initiative. The purpose of the Initiative was to bring consistency between jurisdictions in terms of water quality standards, and thus environmental controls of industry, throughout the Great Lakes Basin. In addition to the criteria development for wildlife, criteria are being developed for protection of aquatic life and human health. The Initiative was mandated under The Great Lakes Critical Programs Act in 1990, at the same time as an advisory committee of wildlife biologists and toxicologists was being set up to develop the criteria. Final drafts of the criteria documents were prepared in 1991 and the wildlife document was reviewed by the U.S. EPA Science Advisory Board in 1992 and released for public review.

The approach that has been used for calculation of the wildlife criteria is similar to that used for determination of criteria for non-cancer endpoints for protection of human health. The criteria for wildlife were calculated using a reference dose and an estimate of the oral intake of the substance. The values derived were then expressed as concentrations of the substance in water to protect wildlife. Species representative of the Great Lakes basin were chosen based on a range of body weights and foraging behaviour. The mink and river otter were identified as representative species of mammals, and the bald eagle, osprey, and belted kingfisher as representative avian species. Wildlife values were calculated for each of the identified species, based on the available toxicity data for each of the specific classes of wildlife. The geometric mean of the wildlife values that were thereby derived, was then calculated for each class. The wildlife criterion for the Great Lakes Water Quality Initiative was taken to be the lower of the avian and mammalian values. The risk assessment methodology for derivation of wildlife criteria is based on the same methodology used for protection of human health. In contrast to human health protection, for wildlife protection the objective is to protect the population and the species rather than the individual. In addition, the methodology only relates to exposures of wildlife to persistent toxic substances and does not consider other natural or man-made stresses on the species.

A two-tiered approach was used to evaluate data for the hazard assessment. Tier one, which was for the establishment of a wildlife criterion, should include information on the following:

Risk Communication - Principles and Approaches

Dr. William Leiss and Ms. Lori Walker
Department of Communication
Simon Fraser University, British Columbia

Risk communication is an essential part of risk assessment and risk management because it represents the interface, or zone of encounter, between the science of risk, on the one hand, and the public's perception of risk on the other. Increasingly, decision makers are faced with responding to public concerns, involving public stakeholders in establishing management strategies, and persuading the public of the appropriateness of the eventual outcomes. Given the important and growing role of the public in risk management, understanding the communication process is as important as understanding the risk itself.

Risk communication is any purposeful exchange of views between interested parties about health and environmental risks and activities that are perceived to give rise to those risks. It takes place between and among stakeholders, including interested parties, government agencies, unions, business and industrial associations, media, researchers, professional organizations, public interest groups, environmental groups, and individuals. In addition to being a natural outcome of attempts of various groups to understand a risk, a risk communication campaign, or risk communication messages may be undertaken by stakeholders to persuade other stakeholders that their decisions involving risk are the right ones. In other words, stakeholders are interested groups in society who seek to persuade others that their interpretation of health or environmental risk is correct, and that others should adopt policies and practices that reflect their interpretation of risk. For example, an agency may wish to defend it's decision to accept a certain level of a chemical in a body of water. The agency may state the chemical level represents an acceptable risk, a minimal risk or a reasonable tradeoff between risk and benefit. Another agency or an individual may call for zero risk.

Very often those stakeholders arguing about what constitutes an acceptable risk, present very different evidence to make their case. The result is often that non-expert stakeholders, trying to make sense of a risk, become hopelessly confused, frustrated and skeptical. In order to overcome some of the confusion, risk communication suggests that institutions wishing to present their position in the best light, use knowledge of persuasive communication. Well known forms of persuasive communication include advertising, social marketing, government advertising, and religious programming. Risk communication, as a form of persuasive communication, as compared with propaganda, is not manipulation, which is an attempt to get someone to do or think something that they would not otherwise do or think, in the absence of their intervention. Persuasive communication presupposes a detailed understanding of the authentic needs of the target audience and of their ways of thinking about things. It works on an appropriate message and uses the audience's understanding of things as input for designing the best possible presentation of the case that the proponent wants to make. Persuasive communication is an iterative process and uses the analysis of feedback from the target audience to fine tune the message design and delivery over time. But most importantly risk communication guarantees its status as a democratic form of persuasive communication, versus a manipulative one, because it proposes that stakeholder groups be equipped with the resources and expertise to conduct their own persuasive communication campaigns if they wish.

Risk communication can also take place after a decision is made. However, how that decision is made, specifically, if public stakeholders were involved in the decision, is very important. This is because without public involvement on a decision, risk communication is simply another form of public relations - one way communication - "We talk and we know best, and you listen." The days that the public peacefully accepted the recommendations of government, industry and science are gone, and involving the public is an effective way of opening up the decision-making process to non-

experts and it is essential to rebuilding their trust in expert decisions.

What risk communication aims to do then, as a form of persuasive communication, is to inform or initiate behaviour within the framework of democracy. The audience, which is some part of the citizenry, has the final say as to whether or not it finds the message to be sufficiently persuasive to affect its attitudes or its behaviours. Thus, persuasive communication is always inherently a two-way or reciprocal communication and carries the possibility that the sender may not persuade the audience, and that the feedback from the audience may require the sender to accept a response that is at odds with the sender's own firm beliefs and policy decisions.

The central premise that communication is a two-way process means that risk perception becomes an important part of discussions in public participation. Traditionally, information coming from experts was central in decision-making. Risk communication proposes to open up that process by recognizing that the point of view of the lay person is legitimate. Risks may be perceived to be threatening quality of life or privacy, which are issues that may not come up in traditional risk assessment processes. Or the rights of private citizens may be perceived to have been forfeited in favour of industry, leading to feelings of mistrust and outrage. Experts must decide how to express the technical evaluation in a way that is meaningful to the intended audience, by using appropriate analogies to describe the selected risk assessment process and by also being very sensitive about how the technical terminology is being understood or misunderstood. Experts must also seek to anticipate potential misunderstandings and be ready to counteract them sympathetically which means that individuals or groups who oppose a particular strategy are not treated like the enemy but rather as those who have a right to question a decision that directly affects them.

These are not easy goals to accomplish. Information about risk involves using terms that are difficult to understand, such as, reference doses, uncertainty factors, no-observed-adverse-effect levels. Messages also involve uncertainty in the form of error ranges, impressions, extrapolations, and limited generalizability. Understanding the risk fully means dealing with an enormous amount of information. The public is inundated with facts and opinions and only a certain amount can be processed and what is processed is often highly oversimplified.

The obstacles to the process of effective risk communication have been systematized with the use of a theoretical construct comprised of:

i) an information source;
ii) a channel;
iii) a receiver; and
iv) a message.

Miscommunication can be analyzed with reference to these components.

i) Source problems include, disagreements among experts, uncertainties in risk estimations, lack of pertinent data, limited understanding of public perception of risk, and use of bureaucratic, legal or technical jargon. Source problems include doubts about the accuracy, truthfulness or completeness of a message which arise from doubts about the impartiality, competence or thoroughness of experts who are assessing risks.

ii) Channel problems include selective, biased, or sensationalist reporting, misleading photographs or television visuals, premature disclosure of incomplete findings, oversimplification in reporting technical information and failure to followup on subsequent findings or events. Many channel problems are directly related to the human propensity to assess as most dangerous what makes the greatest impact on us visually, despite any statistical efforts. This practice is logically exploited by the media, and as a result car crashes and weeping relatives at funerals often end up weighing heavily in our assessments of what constitutes risk.

iii) The receiver of the messages may also complicate the communication process. Receiver problems include, poor understanding of the concept of risk, poor understanding of relative risks, difference in attitudes between familiar and unfamiliar risks, overemphasis on low probability-high consequence risks, and unrealistic demands for certainty and regulatory action.

iv) Message problems, most often result from inadequacies in the established scientific data bases relevant to proposed developments, so that key information is not available when decisions are made. They also result from the irreducible uncertainties that are necessarily a part of the statements of risk in scientific terms (expressed as probabilities) and from the inherent complexities in the concept of risk itself. Message problems include, inherent complexity of risk assessment methods, inherent complexity of probability extrapolation, inadequate data on a particular hazard or exposure, changes in risk assessment over time, and lack of trust in disinterested experts.

A better understanding of the many factors that can go wrong begins with an understanding of how information about risk flows, and where miscommunication occurs. Figure 2 shows the different players in the risk communication process and divides them into experts within the technical sphere and the public, placed within the domain of perceived risk. Risk communication flows back and forth between experts and the public and each use a very different language of discourse. In any one particular risk situation, the role of these players can grow or diminish and that line that divides the experts' sphere and the publics' sphere can move around as well. Experts use the language of mathematics, probability, science and engineering to describe what they consider objective, rational evidence in support of a decision. Non-experts, on the other hand, use the language of the ordinary citizen to describe, not necessarily objective facts, but subjective, sometimes, irrational perceptions. They talk about life styles and fears.

Given the power of these perceptions, however subjective and irrational, to affect the quality of decisions about risk, the single most important lesson is this, both domains and both languages are legitimate and are entitled to receive full respect. Violation of this lesson is guaranteed to produce mistrust, acrimony and ultimately a lack of acceptance of responsible risk management in society.

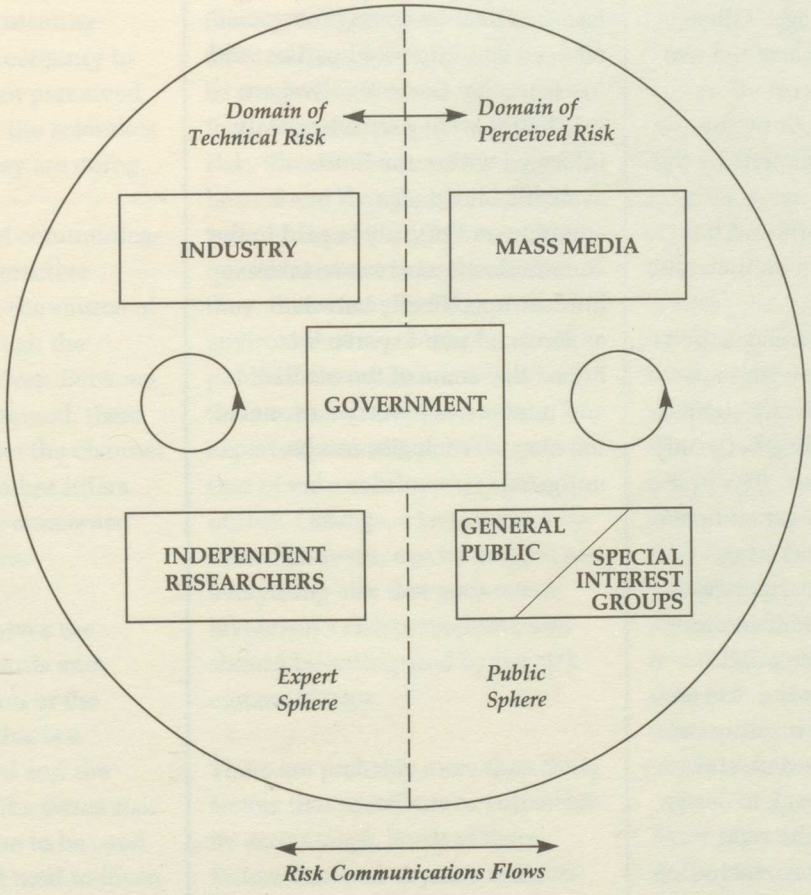

Figure 2 **The Communications Processes Model of Risk Assessment**

Within the expert sphere, major types of risk communication include submissions from industry to government regulators and associated negotiations, technical conferences by industry associations, industrial and university research, expert committees set up by government, setting of standards, and technical publications. Within the domain of perceived risk, communication often takes the form of media reporting, public meetings, public hearings conducted by agencies, citizen contact with government, social marketing, and interest group activities. Between the domain of the expert and of the public, communication takes the form of interpretations by independent scientists to the public, government interpretations of technical data, industry programs directed at public attitudes and the corporate image. Other communications between the two domains include "revealed" attitudes and behaviour by the public, the hiring of experts by the public or interest groups, media interviews with experts and the clash of experts in the public view.

Risk communication offers experts and non-experts who wish to use it, five golden rules to any communication strategy dealing between and within the spheres. The first rule is to know the target audience through use of the marketing techniques of surveys, interviews and focus group sessions in order to fully understand the public reception of risk. Second, use an iterative process and incorporate a series of exchanges and careful attention to the feedback to design the message. Third, the right presentation techniques, including graphical formats for presenting complex technical information should be used and pretested wherever possible. Fourth, unpleasant facts should not be hidden because sooner or later the negative side is bound to come out. Credibility will be enhanced if the information is volunteered rather than producing it under duress. Finally, never appear indifferent to public perceptions of risk, since no matter how absurd the statement appears, it should be taken at face value, as a legitimate concern and addressed as such to the best of your ability.

Risk communication cannot quell every conflict that arises in the face of decisions involving risk. Clearly some conflict is a legitimate part of the democratic process. The aim of risk communication is, instead, to; 1) raise the levels of understanding of relevant issues or actions among the affected and interested parties; and 2) assure that those involved are satisfied that they are adequately informed within the limits of available knowledge. If more attention and priority is paid to the communication between stakeholders, specifically between experts and non-experts, it is hoped that some of the conflict and unnecessary worry surrounding new technologies can be mitigated.

Technical Versus Personal Risk Assessment

Dr June Fessenden MacDonald
The Institute for Comparative and Environmental Toxicology
Cornell University, Ithaca, New York

In the process of communicating with the public about risk, there is more than the technical data involved. Effective risk communication must be a dialogue between the expert and the public, and must include the involvement of the public from the beginning. If the jargon is removed from a presentation to the public, members of a lay audience are quite capable of understanding technical data. Similarly, it is essential to be careful when communicating information about uncertainty to make sure that it is not perceived, by the audience, that the scientists do not know what they are doing.

Ideally, the process of communication should be an interactive relationship between the source of the information, through the channel and the receiver. Between the source and the channel, there are filters and between the channel and the receiver are other filters. This talk is primarily concerned with these latter filters.

Risk assessment involves the determination of hazards and toxicity and estimation of the potential for harm. Risk is a function of the hazard and the exposure. However, the terms risk and hazard have come to be used interchangeably, and tend to mean the same thing to the public. Experts tend to present technical information on hazard or risk in the form of a certain proportion of people, plants, fish, or animals that are likely to die if a certain course of action is followed. For instance, information on the hazard of the use of a carcinogenic compound might be expressed as a one in a million chance of death. The public, however, is not just interested in the probability of death, but is also interested in any kind of damage including aesthetic damage to the environment. Being alive and not feeling too well can be a significant source of worry. In fact, when the public considers risk, they are interested not just in hazard and exposure but add the term "vulnerability". They ask the questions about how vulnerable they, their community, and their environment are. Thus risk for the public is the technical risk times their vulnerability. It is when experts ignore the public's perception of vulnerability that outrage occurs. Outrage, a term coined by Peter Sandman, can be defined as everything else that goes into a layperson's risk perception, and should be anticipated by the risk communicator.

There are probably more than thirty factors that contribute to vulnerability and outrage. Some of these factors that lead to more concern include; involuntary exposures to risks; hazards caused by human actions or failures as compared to natural causes; risks that are unfamiliar; or are uncontrollable by self and those that are controlled by others. Other factors contributing to outrage are; a lack of trust in the responsible institutions; effects that are dreaded; or that are irreversible. When there is a high degree of uncertainty, in that the risk is not understood or is not detectable, there tends to be greater concern. Similarly, when there is an inequitable distribution of the risks and benefits, or where children, the elderly or the sick are specially at risk, there is the potential for greater outrage. Finally there is greater concern in situations that have relevance to a violation of accepted moral standards.

Dr Fessenden MacDonald related some of her findings from a survey of the sources of information in a community that had an environmental problem. The radio was an important source of information for people in the community. Neighbours and friends were also significant sources of information; but not physicians, since problems caused by chemicals in the environment were not thought to be of a medical concern. Trusted information came from radio talk shows, and people from the community identified with the person taking the phone calls and with those phoning in. Environmental groups have used radio phone-in shows to great advantage in defending an issue in, what is seen to be, a credible, caring and trustworthy way without the jargon and uncertainties.

There are several factors related to the process of risk management that are known to affect the response of communities. If the

process is poorly organized and surrounded by secrecy, or there is a denial or ignoring of past problems because of liability or political implications, there will tend to be more outrage within the community. Similarly, if the risk communicator is perceived to be untrustworthy, defensive or arrogant, or uses incomprehensible jargon, or is perceived to be very different or have different values from the people in the community, there will be more outrage. Thus, ideally, the messenger should engender trust, respect and credibility and should share similar values to those of the community and the message should be clear, comprehensive and compatible.

Dr Fessenden MacDonald ended her presentation with reference to the cultural values of the U.S. population that tend to act as filters for the message. These include values related to "The American Dream" which include the family and children, a home, wilderness and the ability to go to a park to swim, fish and hike. There is an "American Style" which calls for a fast response to a threat, rather than another study, and requires some involvement and even control of the process as part of the personal response. A third cultural value relates to the "American Character". While there is an attitude of self reliance and a wish for the government not to tell the person what to do, people do expect the government not to allow them to be injured.

Discussion

One of the central topics that was discussed by the workshop participants was the way in which risk assessment and risk management should be used in environmental decision-making. Can specific recommendations be made at this time on the application of these techniques to the determination of human health risks, risks to the aquatic environment, and to wildlife? Can the risk assessment methodology be applied to a broad range of issues so that topics that are apparently dissimilar can be compared to evaluate their relative priority? In Canada, is the technique sufficiently well advanced that it could be used for development of the next priority substances list under the Canadian Environmental Protection Act?

In the past, the Commission has accepted risk assessment as a quantitative tool, but has also reflected some of the public scepticism about its application. There needs to be more than the application of data to computer programs in environmental decision-making. Information from other sources must be taken into account, and the apparent authority that the discipline has attracted should be tempered with an appreciation of the inherent uncertainties in the techniques. The Commission has tended to endorse the use of risk assessment for priority setting and in deciding what problems are worth pursuing and which are not. The Commission has also urged the use of risk assessment in relation to carcinogenesis from inhalation of pollutants, as well as the more familiar application in relation to the ingestion of pollutants.

There is a question concerning the definition of risk assessment. The narrow definition relates to quantitative risk assessment which is the use of modelling techniques to make statements about the risks associated with the presence of a particular agent in the environment. There is, however, a broader definition which relates to the comparison of unlike factors and to the options for risk management. The general trend seems to be towards this broader use of the term.

One of the future applications of risk assessment techniques is in the area of the development of indices of potency so that comparisons can be made between the risks posed by carcinogens and non-carcinogens.

There was a wide ranging discussion about risk acceptability as an aspect of risk management and risk communication. It was noted that there are social and cultural aspects to this topic as well as a variation in the acceptability of risks in different localities. This may pose difficulties for the Commission which is supposed to put forward advice and recommendations for the entire Great Lakes basin. As a corollary of this, there may be merit in putting forward a more flexible approach to the implementation of decisions based on risk assessment. However, that more flexible approach may be subject to public distrust since more judgement and discretion would be required. In addition, there are the questions of who should decide on what risks are acceptable to whom, and how should the uncertainties implicit in the assumptions in the risk calculations be incorporated into a flexible approach?

The workshop was made aware of the extraordinarily stringent criteria that have been developed for the protection of wildlife. The implementation of these criteria will have social and economic repercussions that need to be determined. One suggestion that was made to overcome this situation was that there might be several levels of standards including; an idealized goal that would be worked towards in the long run; and something that could be met more easily in the shorter term. This is an approach that has been used in preparing the National Ambient Air Quality Objectives.

The two countries that share the Great Lakes have the luxury of making the environment an issue of moral relevance. In many developing countries, environment is not treated as morally relevant. But in much of North America, the environment has become a moral

issue in the same way that our children, the elderly, and the sick are treated as moral concerns.

The Commission might give some thought to the issue of environmental indicators. It may be some time before significant improvements will occur in the quality of the waters of the Great Lakes, but there must be a comprehensive set of indicators in place to track the progress over time. This is needed not only for the administrators responsible for the improvements, but also for the public in terms of how it perceives the problems and progress in restoring the Great Lakes basin.

Conclusions and Recommendations

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Based on the presentations and on the discussion that followed, the Board made the following conclusions and recommendations:

The Water Quality Board concludes that both Canada and the United States have developed formal frameworks for health risk assessment and risk management. These frameworks are generally similar and take into account hazard identification and risk estimation, as well as strategies for risk management.

The Water Quality Board concludes that the term "risk assessment" is used in different ways. The U.S. National Research Council used the term to describe the scientific use of toxicological and epidemiological data for hazard identification and risk estimation, whereas Health and Welfare Canada considers the development of risk management options as part of risk assessment. Although risk assessment is sometimes interpreted more narrowly in terms of quantitative risk assessment, current trends are towards broader use of this term.

The Water Quality Board concludes that risks to human health are generally considered separately from risks to the environment. Although methodologies for human health risk assessment tend to be more developed than those for environmental risk assessment, there are a number of commonalities between them.

The Board recommends that, because information on health and environmental risks may be available from many different sources, a weight of evidence approach is needed in order to prepare a comprehensive evaluation of the available data and assessment of the risks.

The Water Quality Board recommends that the Parties should continue to develop an integrated framework to ensure that assessments of risk to human health and environment are compatible.

The Water Quality Board recognizes the need for close collaboration among organizations involved in Great Lakes water quality management. Such collaboration is essential in order to achieve uniformity in health and environmental standards pertaining to the Great Lakes.

The Water Quality Board recommends that the International Joint Commission encourage state and provincial authorities to work together to develop joint fish advisories to ensure uniformity of the information conveyed to the public.

The Board concludes that, though the systems for setting discharge limits are located at different levels of government in the two countries, the methods for setting discharge limits are broadly comparable.

The Board notes that the numbers derived for protection of wildlife are much more stringent than those for aquatic life and human health.

The Water Quality Board concludes that effective risk communication is essential for the management of risk, particularly communication to the public of risk related information prepared by technical specialists. In this context, it is important that the underlying assumptions and scientific uncertainties employed in quantitative estimates of risk be clearly stated.

The Board recommends that ways of strengthening risk communication practices in areas of interest to the International Joint Commission be explored in collaboration with specialists in communication.

Annex 1
Risk Assessment and Risk Management in Canada and the United States: A Comparative Analysis

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Dr. Daniel Krewski
Health Protection Branch
Health and Welfare Canada
Tunney's Pasture, Ottawa, Ontario

Dr. William Farland
Dr. Herman Gibb
Office of Health and Environmental Assessment
U.S. Environmental Protection Agency
Washington, D.C.

1. INTRODUCTION

Regulatory bodies worldwide have long been concerned about the deleterious effects of pollutants on our environment, and the potential impact of environmental contaminants on human health. The state of the environment and its relationship with human health have recently been subjected to systematic study both in Canada (Environment Canada 1992, Health and Welfare Canada 1992) and the United States (U.S. EPA 1990a,b,c, Council on Environmental Quality 1989).

Environmental issues have been high on the Canadian public's list of concerns, with a recent poll indicating that 97% of respondents were either somewhat or very concerned about the effects of environmental pollution on human health and safety (Environmental Monitor 1990). In response to those concerns, the Government of Canada (1990) announced a major new environmental program known as the "Green Plan." The Green Plan establishes specific goals and objectives designed to promote both environmental quality and environmental health in Canada.

Methodologies for evaluating risks to both the environment and human health have undergone considerable refinement within the last two decades. New scientific methods for identifying toxic chemicals present in the environment have been developed, such as short-term laboratory screens for substances with carcinogenic potential. Sensitive biomarkers of human exposure, susceptibility, and response to environmental toxicants have also been developed (Hulka and Margolin, 1992).

To reduce uncertainties in health risk assessment, the U.S. Environmental Protection Agency's Office of Research and Development (ORD) established a systematic and integrated program on Research to Improve Health Risk Assessments (RIHRA). This research program is designed to provide critical data on the relationship between exposure, dose to target tissue (delivered dose), and associated health effects. The program emphasizes laboratory and field research to improve understanding of basic biological mechanisms, especially as they relate to our ability to extrapolate from one set of circumstances (e.g. humans exposed to long-term concentrations). In implementing an integrated and systematic research effort, the RIHRA program will enhance the ability to quantify the human risks associated with environmental exposures.

In addition to these technical scientific advances, systematic approaches to risk assessment and risk management have been proposed. Although risk assessment and risk management have received much attention in recent years, the United Nations Scientific Committee on Problems of the Environment pioneered this field nearly 15 years ago (Kates 1978, Whyte and Burton, 1980).

The International Joint Commission sponsored a bilateral workshop on current methods for risk assessment and risk management in February 1-2, 1993. The purpose of this paper is to provide an overview of risk assessment and risk management practices in Canada and the United States, particularly in relation to Great Lakes water quality. General principles of risk management as practised in the two countries are summarized in Section 2. Current scientific issues in health risk assessment are described in Section 3. Different strategies for risk assessment are outlined in Section 4. The role of risk perception, risk communica-

tion, and risk acceptability in risk management is discussed in Section 5. A comparative analysis of risk assessment and risk management in Canada and the United States is presented in Section 6. Applications to Great Lakes water quality are noted in Section 7. Conclusions are provided in Section 8.

2. PRINCIPLES OF RISK ASSESSMENT AND RISK MANAGEMENT

Guidelines for health risk management have been developed by regulatory authorities in Canada, the United States, and elsewhere (Krewski and Birkwood, 1987). The first comprehensive analysis of the process of health risk management was conducted by the Committee on the Institutional Means for the Assessment of Risks to Public Health within the U.S. National Academy of Sciences (National Research Council 1983). The committee identified the main elements of risk assessment and risk management, and proposed a formal framework to describe the process. This model for risk assessment and risk management was subsequently adopted by both the U.S. Environmental Protection Agency (1984) and the U.S. Department of Health and Human Services (1985), and has received widespread acceptance within the United States.

The NRC model makes a clear distinction between *risk assessment* and *risk management* (Ruckleshaus 1983). In effect, risk assessment refers to the use of scientific data and methods to identify health hazards present in the human environment, and to characterize the level of risk associated with such hazards. Risk management refers to the development, evaluation and implementation of strategies for controlling health risk. In reality, the separation between risk assessment and risk management is conceptual rather than physical, since risk management decision making is a dynamic interactive process rather than an isolated component of the entire process.

In Canada, the Health Protection Branch of the Department of National Health and Welfare has developed a general framework for risk assessment and risk management (Health and Welfare Canada 1990). This framework represents the most recent form of a model that has evolved over the last decade or so within the Health Protection Branch. Despite the somewhat different format of presentation, most of the individual elements of this model are represented within the framework developed by the U.S. National Research Council.

The main difference between the two models is perhaps one of nomenclature. In the United States, the term *risk assessment* is confined to the scientific enterprises leading to risk characterization. In Canada, however, the term risk assessment has broader connotations, including the development and evaluation of regulatory and other options for risk management. The ambiguity of the term *risk assessment* has been noted previously by the U.S. National Research Council (1993, p. 18), who observed that "broader uses of the term [risk assessment] than ours also embrace analysis of perceived risks, comparisons of risk associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decision -- functions that we assign to risk management."

The Society for Risk Analysis established a working group to establish a definition for this and related terms, but failed to reach consensus on the meaning of risk assessment (Gratt 1987).

Analysis of the process of risk assessment and risk management have been done in other countries such as the United Kingdom (Royal Society 1983) and by international agencies such as the World Health Organization (1985). Although somewhat different in format, these other models focus on essentially the same elements identified in the United States and Canadian models (Krewski and Birkwood, 1987). Recently, the Canadian Standards Association (1991) proposed a broad framework for risk assessment designed to encompass health, engineering, and other risks (Figure 1). This framework is based on the broad view of the term risk assessment, including risk evaluation (which includes consideration of risk acceptability and options for risk management), in addition to risk analysis (comprised of hazard identification and risk estimation).

Risk assessment in engineering was addressed in a recent report by the Ad Hoc Working Group on Risk Assessment of the Federal Coordinating Council on Science, Engineering, and Technology (1992) of the U.S. Government. The stated objectives of the report were to summarize some of the

general characteristics of risk assessments of engineered systems and provide some example applications, to describe methods used in risk assessments of engineered systems, and compare it with health risk assessment.

3. SCIENTIFIC ISSUES IN RISK ASSESSMENT

Environmental health hazards are identified using toxicological experiments conducted in the laboratory or epidemiological studies of human populations. The characterization of human health risks is, however, generally not a straightforward matter. The use of toxicological data as the basis for inferences about human risk requires extrapolation of laboratory data to humans and possibly from high doses used in laboratory studies to lower doses corresponding to human exposure levels. Epidemiological studies of environmental hazards are difficult to conduct because of the limited sensitivity of such studies when human exposure is low, and the multiple exposures to which humans are subjected.

The U.S. Environmental Protection Agency has developed risk assessment guidelines in a number of areas. Guidelines have been published for key health effects, including carcinogenicity (U.S. EPA 1986a), mutagenicity (U.S. EPA 1986b), and developmental toxicity (U.S. EPA 1991b). Risk assessment guidelines for chemical mixtures (U.S. EPA 1986c), exposure assessment (U.S. EPA 1992a) and ecological hazards (U.S. EPA 1992b) have also been issued. Revisions to the guidelines for carcinogenicity and chemical mixtures are currently underway, and new guidelines on reproductive effects, neurotoxicity, and immunotoxicity are in preparation. In the absence of epidemiological data, laboratory studies of the carcinogenicity of environmental chemicals may be used to obtain quantitative estimates of potential cancer risk. Extrapolation of laboratory test results to low levels of exposure is often done under the assumption that the dose-response curve is linear in the low dose region (OSTP 1985, Health and Welfare Canada 1992). The U.S. Environmental Protection Agency (1986a) uses the linearized multi-stage model as developed by Crump (1984) for low dose cancer risk estimation. Other approaches to linear extrapolation are also possible, including the model-free extrapolation method developed by Krewski *et al.* (1991). Although low dose linearity represents a reasonable default assumption for carcinogenic risk assessment, this assumption may be obviated in the presence of biological data suggesting the existence of a threshold.

The high doses used in laboratory studies present particular problems in testing chemicals for carcinogenic potential. The use of the maximum tolerated dose

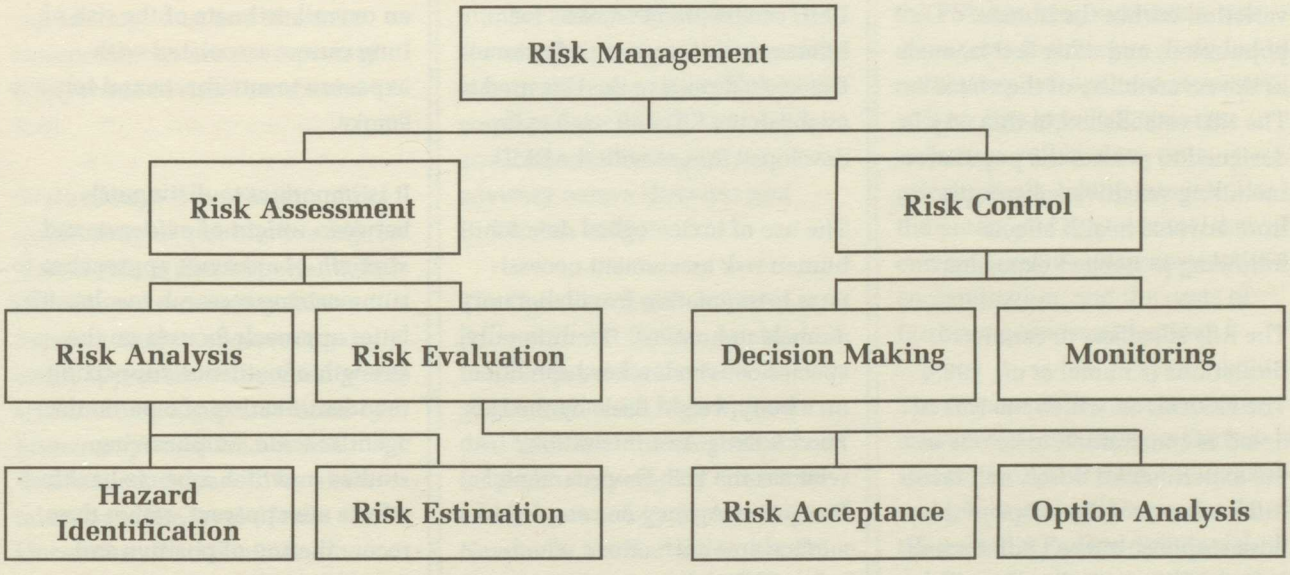

Figure 3 **The Canadian Standards Association Framework for Risk Assessment**

(MTD) can lead to effects at high doses that might not be expected to occur at lower doses. Krewski *et al.* (1993) observed that quantitative estimates of carcinogenic potency are highly correlated with the MTD. Gaylor (1989) exploited this association to develop preliminary estimates of low dose cancer risks based on the MTD. This correlation has raised further questions about the interpretation of estimates of cancer risk based on laboratory studies in rodents (National Research Council 1993).

Toxicological studies are also used to investigate adverse health effects other than cancer (Arnold *et al.*, 1990). Such studies are used to identify a no-observed-adverse-effects level (NOAEL), or the dose that does not lead to a significant increase in the rate of occurrence of adverse health effects. A reference dose (RfD = NOAEL/UF) is then established by dividing the NOAEL by an uncertainty factor (UF) (Barnes and Dourson, 1988). The UF provides for possible differences in sensitivity between animals and humans, variation within the human population, and other factors such as the reversibility of the effect. The RfD established in this way is designed to protect the population, including sensitive subgroups, from adverse health effects following prolonged exposure.

The RfD is subject to certain limitations (Kimmel *et al.*, 1993). The NOAEL on which the RfD is based is constrained to be one of the experimental doses, and takes little account of the shape of the dose response curve. Since small less sensitive experiments will lead to larger NOAELs, a higher RfD may be established with an inferior study. Whereas the NOAEL is often assumed to be essentially risk-free, Gaylor (1992) noted that the average excess risk of a teratogenic effect was in excess of 1% in 45 developmental toxicity studies reported in the literature.

Crump (1984b) proposed the use of a benchmark dose (BMD) as an alternative to the RfD. The BMD is formally defined as the dose leading to a specified, and experimentally measurable increase in risk such as 5%. The BMD avoids many of the disadvantages of the NOAEL, including the ambiguity about the level of risk associated with the NOAEL. Krewski and Zhu (1993) have recently developed methods for estimating BMDs associated with embryo lethality, teratogenicity, or overall toxicity based on laboratory studies of developmental toxicity. In its most recent risk assessment guidelines for developmental toxicants, the U.S. Environmental Protection Agency (1991) suggests the use of this methodology with actual data. However, before the BMD can be used as a basis for human risk assessment, adjustment factors analogous to the UFs used to establish the RfD will need to be developed for use with the BMD.

The use of toxicological data for human risk assessment necessitates extrapolation from laboratory animals to humans. Traditionally, species conversion has been done on a body weight basis by the U.S. Food & Drug Administration, whereas the U.S. Environmental Protection Agency has employed surface area corrections when extrapolating between species. Following empirical results reported by Travis and White (1988), these two agencies have recently adopted an intermediate approach based on scaling in accordance with body weight to the three-fourths power. Both body weight and surface area corrections continue to be used by the Canadian Health Protection Branch. When available, physiologic pharmacokinetic models offer a more biologically based approach to species conversion, since the physiological, biochemical and metabolic parameters characterizing the model may be known for different species (Andersen *et al.*, 1987).

When information on a particular risk factor is available from a number of sources, a weight-of-evidence approach may be used to arrive at a summary statement on risk, taking into account the strengths and weaknesses of individual studies. This may be done in an informal fashion, or using statistical methods for meta-analysis of a series of studies on a particular environmental hazard (McNight 1992). Wald (1986) used meta-analytic methods to arrive at an overall estimate of the risk of lung cancer associated with exposure to environmental tobacco smoke.

It is important to distinguish between *weight-of-evidence* and *strength-of-evidence* approaches to summarizing research results. The latter approach focuses on the strength of evidence supporting the identification of a particular agent as toxic, emphasizing studies in which adverse health effects are apparent, rather than reconciliation of positive and negative studies. Carcinogen classification schemes, such as that used by the International

Agency for Research on Cancer (Vainio *et al.*, 1992), tend to be based on the strength of the toxicological and epidemiological evidence that an agent may pose a carcinogenic risk to humans.

The final stage of risk assessment in the framework used by the U.S. Environmental Protection Agency is *risk characterization.* In the risk characterization, conclusions about hazard and dose response are integrated with those from the exposure assessment. In addition, confidence about these conclusions, including information about the uncertainties associated with the final risk summary, is highlighted. The characterization integrates all of the preceding information to communicate the overall meaning of, and confidence in, the hazard, exposure, and risk conclusions (Habicht 1992). In our view, it is insufficient to summarize risk assessment results in terms of a single numeric value such as the RfD or BMD. Qualitative information on data quality, risk estimation methodologies, working assumptions, and alternate interpretations are an important component of risk characterization.

Evaluation and expression of the uncertainty of quantitative expression of risk is also important. In addition to uncertainty due to experimental or observational error, appreciable uncertainty can arise from data gaps. If levels of human exposure are not well determined, there will be uncertainty as to the level of risk. Uncertainty in the values of parameters in physiologically-based pharmacokinetic models used to describe the distribution and metabolism of toxic chemicals impacts uncertainty on the dose of reactive metabolites reaching target tissues in the body (Portier and Kaplan, 1989).

Such uncertainty can be expressed in terms of a distribution of possible risks, rather than a single estimate, allowing for both measurement error and data gaps. This approach to risk characterization has recently been used by McKone and Bogen (1992) in evaluating the health risks of groundwater contaminants, and by the National Research Council (1993) in evaluating the risks of dietary residues of pesticides. However, it has not yet been formally adopted by federal regulatory authorities in either Canada or the United States.

4. RISK MANAGEMENT STRATEGIES

In Canada, regulations governing health and environmental risks may be established under a number of federal statutes. Nonregulatory approaches to risk management are also widely employed, including those of an economic, technological, or advisory nature (Krewski and Birkwood, 1988).

The Canadian Environmental Protection Act (CEPA) established in 1988 provides the federal government with broad powers to deal with health and environmental problems posed by chemicals and biotechnology (Armstrong and Newhook, 1992). Under this Act, a Priority Substances List (PSL) of 44 substances will be evaluated over a five year period. A substance is identified as toxic if "...it is entering or may enter the environment in a quantity or under conditions

(a)having or that may have an immediate or long-term harmful effect on the environment;
(b)constituting or that may constitute a danger to the environment on which human life depends; or
(c)constituting or that may constitute a danger in Canada to human life or health."

This legal definition of toxic embodies the notion that harm to human health or the environment is a function of both the potency of the substance and the level of exposure to the substance. Note that an environmental contaminant to which humans are exposed may thus not be considered as legally toxic if the level of exposure is so low that no adverse health effects would be expected. Since carcinogenic substances may pose some risk even at low levels of exposure, all carcinogens are defined as toxic under CEPA. Once the toxicity of substances on the PSL has been evaluated, risk management strategies designed to reduce exposure where necessary will be developed. Exposure reduction will be done on a priority basis, taking into account the potency of the toxicant, the current level of environmental contamination, and the costs of further exposure mitigation.

The responsibility for risk management decision making in Canada is shared jointly between the federal and provincial governments. In the past, the Federal-Provincial Advisory Committee on Environmental and Occupational Health has been largely responsible for

recommending national exposure guidelines, which can be adopted or modified by provincial governments to meet their specific needs. In establishing national guidelines, the FPACEOH takes into account both health and environmental risks, as well as the costs associated with exposure mitigation.

The U.S. Environmental Protection Agency established national environmental standards to protect both human health and the environment. Individual states may adopt the EPA standard or choose a more stringent standard for a particular environmental contaminant. State agencies may also establish their own standards for contaminants for which EPA has not developed a standard.

Paull *et al.* (1993) recently conducted a survey of state methodologies for deriving drinking water guidelines for chemical contaminants. It was found that 27 of the 50 states relied on EPA guidelines, the remaining 23 developed at least some of their own guidelines. States which developed their own guidelines tended to use EPA risk assessment methodologies, although differences in the application of these techniques can lead to guidelines different from those developed by EPA.

5. RISK PERCEPTION, RISK COMMUNICATION, AND RISK ACCEPTABILITY

Risk perception, risk communication, and risk acceptability represent three distinct, although often confused, considerations in risk management that warrant particular discussion. In addition to scientific estimates of risk, public perception of health and environmental risks requires consideration in risk management. In order to obtain information on the public's perception of health risks in Canada, the Department of National Health and Welfare recently conducted telephone interviews with 1,500 Canadians to determine their views on a range of risk related issues.

A detailed analysis of the results of this study was conducted by Decision Research (1993). Women, the elderly and people without post-secondary education consistently reported greater concerns about these risk factors than did men, younger people, and people with post-secondary education, respectively. People also expressed consistently greater concern for risk to other members of society than to themselves and their families. Questions relating to the psychology of risk revealed a lack of appreciation of the fact that the level of risk decreases with decreasing exposure: many people felt that even low exposures to cancer causing substances would be likely to result in the development of this disease.

As described in *Reducing Risks: Setting Priorities and Strategies for Environmental Protection* (U.S. EPA 1990d), the dichotomy between public perceptions and professional understanding of environmental risk presents an enormous challenge to a pluralistic, democratic country. Government agencies must be sensitive to public concerns about environmental problems since those concerns tend to drive national legislation, thus making environmental laws more reflective of public perceptions of risk than of scientific understanding of risk. Consequently, governmental budget and staff resources tend to be directed at those environmental problems perceived to be most serious by the general public. The obvious way to bridge the dichotomy is to improve the public's understanding of the scientific and technical aspects of environmental risk while improving scientists' understanding of the basis of public concern. Public perceptions of environmental risk tend to incorporate deeply held subjective values, like justice and equity, that, although difficult to quantify, reflect important elements of the quality of life that government is bound to protect. Moreover, since the scientific understanding of any environmental problem is likely to evolve as the science improves, and since environmental policy necessarily embodies subjective values, scientific understanding should not be the sole determinant of environmental policy.

Risk communication occupies a central role in risk management (Leiss and Krewski, 1989). Covello *et al.* (1987) have defined risk communication as "any purposeful exchange of information about (health and environmental) risks between interested parties." This broad definition encompasses exchange of technical information between experts, discussion of perceived risk among non-experts, and dissemination of technical information from technical experts to the media and the public. Although gaps between actual and perceived risk are not easily altered by providing technical information on risk to the public,

effective risk communication can serve to clarify misunderstanding and increase confidence in risk assessment (National Research Council 1989). Although, most of the public's information on health and environmental risks is provided by the news media, health professionals such as physicians enjoy the greatest credibility as sources of information on risk (Decision Research 1993). The importance of risk communication is now widely recognized, with guidelines on effective risk communication published by Covello *et al.* (1991), Hance *et al.* (1991), and others.

The evaluation of health and environmental risk management issues raises questions about the acceptability of risk. Life is inherently risky, with even common everyday activities posing some level of risk. Given that a zero-risk environment is an unattainable goal, criteria are required to determine how aggressively exposure mitigation activities should be pursued. In the United States, *de minimus* risk standards have been established for carcinogens present in the environment. Risks in excess of 1 in 10,000 usually lead to mitigation action, risks of 1 in 1,000,000 or less are generally viewed as tolerable. With intermediate risks in the range of 10^{-6} - 10^{-4}, the introduction of controls may be based on a balancing of risks, costs and benefits. Cancer risk estimation is also done in Canada, although such explicit criteria for risk acceptability tend to be avoided.

6. COMPARISON OF RISK MANAGEMENT IN CANADA AND THE UNITED STATES

Risk assessment is now widely used by federal, provincial and state agencies in Canada and the United States in developing standards for environmental health and quality. In the past, federal agencies have tended to play a leading role, in part because of the resource commitment, required for professional communication and collaboration between Canadian and American scientists, is common.

Based on the preceding review, it is possible to identify a number of similarities and differences in risk assessment and risk management practices between Canada and the United States. Both countries have developed formal frameworks for risk management. Although both frameworks contain essentially the same elements, small differences exist, in much the same way as do rules for Canadian and American football. There is, however, a significant difference in the use of the term *risk assessment* between the two countries, with the Canadian definition being considerably broader in scope.

Risk management practices in the United States appear to place somewhat greater emphasis on quantitative estimates of risk than is the case in Canada, particularly when carcinogenic effects are at issue. This may reflect fundamental structural differences in the legislative statutes underlying risk management actions in the two countries. This difference is consistent with the apparently greater opportunity to employ non-regulatory options for risk management in Canada.

Examples of non-regulatory options for risk management in the United States include the Toxic Release Inventory published by the U.S. EPA (U.S. Environmental Protection Agency 1993). The Toxics Release Inventory (TRI) was established by the Emergency Planning and Community Right-to-Know Act of 1986 which Congress passed to promote planning for chemical emergencies and to provide information to the public about the presence and release of toxic and hazardous chemicals in their communities. Following passage of the Pollution Prevention Act of 1990, the TRI was expanded to include mandatory reporting of additional waste management and pollution prevention activities. The TRI program gives the public unprecedented direct access to toxic chemical release and transfer data at the local, regional, and national level. The public can see this information to identify potential concerns, gain a better understanding of potential risks, and work with industry and government to reduce toxic chemical releases and the risks associated with them.

Another example of a non-regulatory option in the United States is the Green Lights program (U.S. EPA 1992c), a voluntary program that encourages United States businesses and governments to install energy-efficient lighting by providing extensive information and technical support. Among the many benefits from participation in this program are considerable cost savings, improved lighting

quality, and the public recognition associated with a proactive environmental strategy.

Both Canada and the United States support the use of weight-of-evidence approach to the evaluation of data on health and environmental hazards. With this approach, all of the available data is given full consideration, and an overall assessment of potential risk made.

The responsibility for risk management decision making in Canada is shared jointly between the federal and provincial governments. In the United States, federal regulatory agencies tend to predominate.

7. GREAT LAKES WATER QUALITY

The Governments of Canada and the United States, as Parties to the Great Lakes Water Quality Agreement are responsible for water quality in the Great Lakes basin. The goal of human health criteria for the Great Lakes and their tributaries is the protection of humans from unacceptable exposure to toxicants due to consumption of contaminated fish or drinking water from the Great Lakes. Dermal absorption of toxic chemicals as a consequence of water oriented recreational activities is also of concern.

The Environmental Protection Agency (1991a) has established procedures for deriving human health criteria for Great Lakes water, based on the principles described in Section 3 of this background paper. In general terms, uncertainty factors are used to establish exposure guidelines for non-carcinogens. Exceptions to this practice may be made for genotoxic teratogens or germline mutagens thought to produce reproductive or developmental effects. Exposure guidelines for carcinogens are established on the basis of the lifetime average exposure leading to an incremental risk of 1 in 100,000. Exposure guidelines are set as the basis of the total exposure from both drinking water and fish consumption, allowing for bioaccumulation in fish. For bioaccumulative compounds, exposure from other sources is also considered.

8. CONCLUSIONS

Both Canada and the United States have developed general frameworks for risk assessment and risk management at the federal level. The term *risk assessment* is used somewhat differently in the two countries. In the United States, risk assessment consists of the application of scientific methods for hazard identification and risk estimation. In Canada, risk assessment goes beyond these scientific activities to include the development and evaluation of regulatory and non-regulatory options for risk management.

Despite this apparent difference in terminology, the principles and approaches to risk assessment and risk management in Canada and the United States are generally similar. Although scientific analysis of risk transcends national boundaries, inferences about health and environmental risks may require assumptions that are difficult to verify in practice. For example, in the absence of information to the contrary, it is often assumed that the dose-response curve for DNA reactive carcinogens will be linear in the low dose region. Differences in assumptions made about the risks posed by low levels of exposure to dioxin have lead to exposure guidelines that range from 0.006 (U.S. EPA) to 10 (Canadian HPB) pg/kg body weight/day (cf. Lucier 1992). Differences in legislative statutes governing risk management practices in different countries can also lead to differences in environmental standards in different countries. The Toxic Substances Control Act (TSCA) makes explicit provision for consideration of the costs associated with environmental regulations in the United States, thereby permitting a balancing of economic benefit against health risk.

Risk assessment is a rapidly developing interdisciplinary field in which new methodologies continue to emerge. Weight-of-evidence approaches to the global evaluation of all of the available scientific data on a particular environmental hazard are being developed to arrive at a summary statement about risk. Expression of the uncertainty associated with risk estimates is becoming an important component of risk characterization.

In the past, risk assessment guidelines have been developed primarily by national government agencies in North America and Europe. International bodies such as the International Programme on Chemical Safety and the International Agency for Research on Cancer, both part of the World Health Organization, are currently developing recommendations on the scientific principles to be applied in health risk assessment.

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