

**THE WALKERTON INQUIRY**

**Commissioned Paper 7**

**MANAGING HEALTH RISKS FROM DRINKING WATER**

By

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and Martha Sinclair

**Toronto**

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## Abstract

The purpose of this review is to assist the Walkerton Inquiry in making recommendations for changes that will prevent or reduce the risks to population health from contaminants present in Ontario drinking water. This report provides a comprehensive review of the scientific basis for drinking water risk assessment and of strategies for managing these risks. While risks associated with the presence of pathogenic micro-organisms in drinking water are emphasized, risks from chemical and radiological contaminants are also considered. Based on a comprehensive review of current practices in drinking water risk assessment, the scientific basis underlying Ontario's drinking water standards appears comparable to that in other jurisdictions, including the United States, Australia, and the World Health Organization. As of August 2000, drinking water safety in Ontario has been governed by Ontario's *Drinking Water Protection Regulation* and the *Ontario Drinking Water Standards*, the latter of which are based in guidelines developed by the Federal-Provincial Subcommittee on Drinking Water of the Federal-Provincial-Territorial Advisory Committee on Environmental and Occupational Health. Opportunities to further strengthen drinking water safety in Ontario include enhancing population health surveillance, developing and applying new scientific methods for characterizing microbiological risks, improving source water protection, and adopting a total quality management approach to drinking water safety. While the ideal goal of zero risk is unattainable in practice, such enhancements can be expected to minimize potential health risks from drinking water in Ontario.

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# 1 Introduction

The importance of a safe and reliable source of drinking water is beyond question. Water is a basic biological necessity without which the human body and life in general cannot be sustained. The average adult normally needs an intake of between 2 L and 4 L of water daily. This requirement is fulfilled when we ingest fluids, water that is present in solid foods, and water resulting from the metabolic breakdown of foods. A study carried out in 1981 by the then Department of National Health and Welfare showed that the average amount of tap water drunk daily is actually 1.34 L per person, only a fraction of the total amount of water used daily by households in Canada.<sup>1</sup>

The composition, or quality, of tap water can influence human health in a number of ways. Some constituents may have a beneficial effect because they play an essential role in human nutrition (e.g., iron) or because they prevent or reduce the incidence of disease (e.g., there is evidence that a small quantity of fluoride in drinking water significantly reduces dental caries). Other constituents can have adverse effects on health.

The potential consequences of a drinking water source becoming contaminated with pathogenic micro-organisms make prevention of such an occurrence critical. Not only may contamination lead to serious and sudden disease outbreaks, but transmission of diseases associated with this form of contamination can easily spread by person-to-person contact, aerosols, and food intake. (Contamination of drinking water with chemical and radiological agents is a secondary, though still important, concern. Health problems associated with these agents usually arise only after prolonged periods of exposure, unless contamination is severe.) Prevention of all these problems thus underscores the need for well-managed drinking water treatment and delivery systems.

While Canada has an abundance of freshwater resources, disease outbreaks have happened in a number of areas in the country as a result of contaminated drinking water supplies. The events in Walkerton, Ontario, have drawn attention to the fact that the potential for such incidents to occur anywhere in the country is high.

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This paper has been prepared for discussion purposes only and does not represent the findings or recommendations of the Commissioner.

<sup>1</sup> Canada, Health and Welfare Canada, Environmental Health Directorate, 1981, *Tap-water Consumption in Canada* (Ottawa: Health and Welfare Canada).

## 1.1 Organization of This Report

This report has been prepared by the Centre for Population Health Risk Assessment at the University of Ottawa. Its purpose is to provide information that will assist the Walkerton Inquiry on matters pertaining to the assessment and management of health risks associated with contamination of drinking water. Emphasis is on microbial contamination. The report has been prepared by experts in microbiology, health risk assessment, chemistry, epidemiology, medicine, health surveillance, and engineering.

In section 2 of the report, we examine frameworks designed to delineate the processes for evaluating risks to human health and for managing those risks. Six of the primary risk management frameworks developed in North America are described and compared. The section includes a detailed description of how frameworks such as these are being used by the Federal-Provincial Subcommittee on Drinking Water in developing and implementing Canada's national drinking water guidelines.<sup>2,3</sup> We also present a list of principles by which good risk management decisions should be made and summarize what is being undertaken in this area by the Federal-Provincial-Territorial Committee on Environmental and Occupational Health. A description of how the public perceives risk and the factors that influence risk perception is also provided.

In section 3, we provide a comprehensive listing of water-borne pathogens, together with descriptions of their characteristics and potential health effects. We also describe potential health threats posed by emerging (new) and re-emerging (reappearing) pathogens. A historical account of disease episodes associated with microbial contamination of drinking water supplies in various jurisdictions is provided, as is an indication of the extent to which pollution episodes have affected human health. Disease outbreaks that have occurred across the United States and Canada – and notably in Ontario and British Columbia – are noted.

In section 4, we examine how the presence of contaminants in drinking water and source water is detected and measured. The focus of this section is on the detection and measurement of microbiological contaminants. Current practices

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<sup>2</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1996b, *Guidelines for Canadian Drinking Water Quality. Supporting Documentation: Tetrachlorethylene* (Ottawa, Health Canada).

<sup>3</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1999a, *Canadian Drinking Water Guidelines Development Process*, Annex 2 (Ottawa: Health Canada).



for monitoring the bacterial quality of water in Saskatchewan are described in detail and those in British Columbia are referenced. A brief description of drinking water monitoring programs for chemical parameters in Ontario as mandated under the *Drinking Water Protection Regulation* and conducted under the Drinking Water Surveillance Program is included. In this section, we also consider the possibility of measuring water quality in Hazard Analysis Critical Control Point and Total Quality Management System frameworks.

In section 5, we describe the approaches used by Canada, Ontario, the United States, Australia, and the World Health Organization for setting standards or guidelines for drinking water quality. Emphasis is given to how risk assessment procedures are used to derive health-based standards or guidelines and how such values may be influenced by socio-economic factors. Approaches for considering chemical, physical, radiological, and microbiological characteristics are included, and the legal standing of the recommendations developed by the various jurisdictions is noted.

We conclude, in section 6, by examining recent developments in microbiological risk assessment and ways in which the practices for managing drinking water can be strengthened. The new approaches to risk assessment are illustrated by reference to four case studies. We also describe in this section the elements and underlying principles of enhanced population health surveillance systems. The limitations of microbiological water quality monitoring and the desirability of a more preventative approach to water quality management are noted; and Australia's efforts to develop a comprehensive water quality management system are described. In conclusion, we point out where there may be opportunities for capitalizing on recent developments in risk assessment as a means of strengthening drinking water safety systems in Ontario.

## **2 Management of Population Health Risks**

Since the 1980s, regulatory authorities have actively developed frameworks with sets of criteria in order to systematically approach risk assessment and make risk management decisions. Managing population health risk is a balancing of science, judgment, perception, and decision- and policy-making criteria. All factors that influence decision makers, stakeholders, and individuals must be considered as the costs and benefits associated with health risks and proposed alternatives are addressed. This section summarizes the evolution of risk management frameworks and the stages that each framework offers to

decision makers, as well as discusses the influence of risk perception and the communication of risks. The section concludes with the application of frameworks to the drinking water standards.

## 2.1 Frameworks for Health Risk Management

The risk posed by a particular agent depends on both the nature of the hazard presented and the probability of its occurrence. Health hazards may be characterized in terms of the health consequences or adverse effects they induce. The seriousness of these effects may vary according to such factors as their nature, severity, and degree of reversibility. The probability of a given effect occurring depends on the agent's potency and the host's susceptibility, and the level of exposure to the agent.

Regulatory authorities have adopted risk management frameworks since the 1980s for two main reasons: (1) to attempt to better balance risks and benefits across society in an acceptable way,<sup>4</sup> and (2) to adopt the trend toward more openness in decision making by using consistent and explicit decision criteria. The need for an orderly and systematic approach to risk assessment and risk management is further supported by the existence of resource constraints, which can compromise the ability of any jurisdiction or agency to implement optimum measures for controlling all risks. Risk management frameworks offer greater objectivity, completeness, and consistency of decisions and greater public accountability.

Several formal models for risk assessment and risk management have been proposed in recent years. They are valuable in clarifying the main elements of risk assessment and risk management, and have served to establish well-defined, functional frameworks within which risks may be logically characterized, evaluated, and controlled. In this section, we review a number of these different frameworks, including those proposed by the U.S. National Research Council (NRC), the U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management, the Canadian Standards Association (CSA), Health (and Welfare) Canada, and the Canadian Public Health Association. After describing each of these models and frameworks in detail, we analyze their similarities and differences.

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<sup>4</sup> S. Hrudey, 1999, "Drinking water and health risks: Balancing risk and reason," in *Balancing Risks and Reasons: Proceedings of the 7th National Conference on Drinking Water*, edited by W. Robertson and G. Somers, conference held in Charlottetown, P.E.I., August 11–13, 1996 (Ottawa: Canadian Water and Wastewater Association).

### 2.1.1 U.S. National Research Council Model

The NRC was established by the U.S. National Academy of Sciences in 1916 to advise the federal government on a broad range of science and technology issues. At the initiative of the U.S. Congress, the NRC conducted a study to find ways of strengthening the reliability and objectivity of the scientific assessment that formed the basis for federal regulatory policies on carcinogens and other public health hazards. The NRC conducted this study under contract to the U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services.

The resulting NRC model, published in 1983, has two stages where research contributes: risk assessment and risk management (Figure 2.1).<sup>5</sup> *Risk assessment* is the process of using a scientific base to define the health effects of the exposure of individuals or populations to hazardous materials or situations. *Risk management* is the process of evaluating regulatory options and selecting from among these options.

#### 2.1.1.1 Risk Assessment

The NRC model divides risk assessment into four components: hazard identification, dose-response assessment, exposure assessment, and risk characterization.

1. *Hazard identification* determines a cause-effect relationship between a particular chemical and a decline in health status, using epidemiological studies of human populations, animal bioassay data, mutagenicity tests, and investigations of molecular structure.
2. *Dose-response assessment* examines the relationship between the magnitude of exposure and the probability of particular health effects occurring.
3. *Exposure assessment* studies the extent of human exposure to a hazard before or after regulatory controls are applied.

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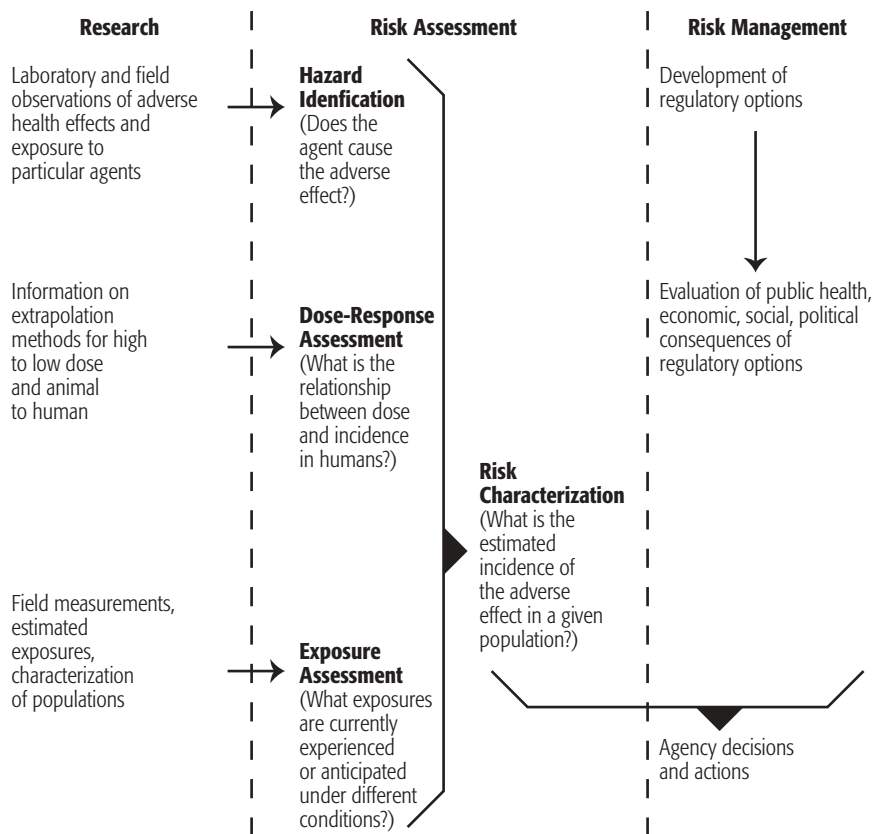
<sup>5</sup> United States, National Research Council, 1983, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press).

4. *Risk characterization* entails hazard identification, dose-response assessment, and exposure assessment, and describes the nature and magnitude of human risk, including attendant uncertainty.

### 2.1.1.2 Risk Management

At the risk management stage, alternative regulatory options are developed and evaluated. Selecting a particular regulatory option involves considering

**Figure 2.1 U.S. National Research Council Framework for Risk Assessment**



**Source:** United States, National Research Council, 1983, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press), p. 21.

the public health, economic, social, and political consequences of implementing that option. Other significant considerations include:

- the technical feasibility of the proposed solution;
- the desired level of control;
- the ability to enforce regulations;
- the uncertainty in scientific data and the corresponding inferences made to fill gaps in knowledge; and
- public perception and extent of public knowledge and information available.

The NRC model states the basis of the decision to implement a specific course of action should be communicated to affected parties.

### **2.1.1.3 *Adoption of the NRC Model***

The U.S. Environmental Protection Agency (EPA) adopted the NRC model in 1984 without making any significant changes to its structure or definitions. The Department of Health and Human Services expanded the model in 1985 to include consideration of non-regulatory options for risk management, such as advisory options and risk reduction through technological means. The Department of Health and Human Services also recommended expanding research activities to reduce the uncertainties associated with scientific knowledge.

### **2.1.2 U.S. Presidential/Congressional Commission Framework**

The U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management was mandated to investigate the policy implications of risk assessment and risk management in regulatory programs under various federal laws.<sup>6</sup> Through a series of hearings and consultation processes, the commission published its recommendations for a risk assessment and risk management framework in the report *Framework for Environmental Health Risk Management*. The framework is designed to guide the private and public sectors in all aspects of risk research, risk assessment, risk characterization, and risk reduction (Figure 2.2). In this way, the framework can be adapted by a variety of agencies for use in a variety of situations.

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<sup>6</sup> United States, Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, *Framework for Environmental Health Risk Management*, Final Report, vols. 1 & 2 (Washington, D.C.).

Three key principles make up the framework: broader contexts, stakeholder participation, and iteration.<sup>7</sup>

*Broader contexts* considers a health and environment problem within its larger technical, political, social, ethical, and perceptual context.

*Stakeholder participation* involves stakeholders at all stages in the framework to ensure the implementation of sound, cost-effective, and informed risk management decisions.

*Iteration* recognizes that important information may emerge during any stage of the risk management process. The framework is flexible and allows for the introduction of new information that may contribute to ‘best fit’ management practices.

#### **2.1.2.1 *Six Stages of the U.S. Framework***

The U.S. framework consists of six stages, which are illustrated in Figure 2.2 as six interlocking circles. This framework differs from pre-existing models that are more linear in approach. It also stresses the collaborative involvement of stakeholders throughout the risk management process. The six stages are outlined below.<sup>8</sup>

1. *Defining problems and putting them in context* involves identifying and characterizing an environmental health problem, or a potential problem, caused by chemicals or other hazardous agents or situations. It places the problem in a public health and ecological context and determines risk management goals. This stage also involves identifying risk managers with the authority or responsibility to take the necessary actions, and implementing a process for engaging stakeholders.
2. *Analyzing risks (risk assessment)* involves describing and estimating the likelihood of adverse health effects from exposure to a harmful substance or agent. Risk assessment is the process of gathering and analyzing the information needed to make such a prediction. Risk assessment comprises four steps: hazard identification, dose-response assessment, exposure

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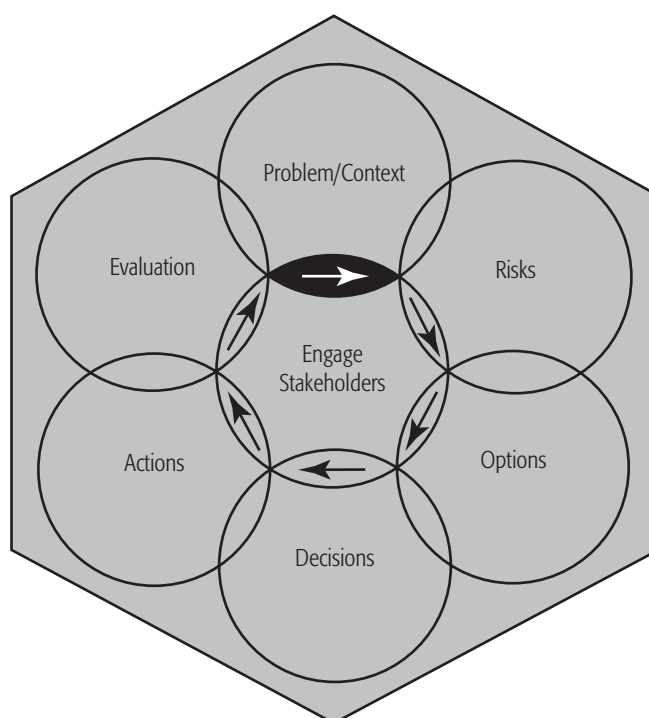
<sup>7</sup> Ibid.

<sup>8</sup> Ibid., p. 8.

assessment, and risk characterization. Risk characterization involves organizing, evaluating, and communicating information about the risk and/or hazard, weight of the evidence, and likelihood of adverse health or ecological effects from particular exposures. Risk characterization includes sufficient information to enable risk managers to make appropriate risk management decisions and disseminate information to stakeholders. Information available to decision makers will include scientific facts, information specific to the situation and region, as well as stakeholders' perceptions of the risk.

3. *Examining options* involves identifying potential options (regulatory and non-regulatory) for managing the risk, and analyzing them for cost-benefit effectiveness and cost distribution and impacts. Potential options are also

**Figure 2.2 The U.S. Presidential/Congressional Commission Risk Assessment and Risk Management Framework**



**Source:** United States, Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997, *Framework for Environmental Health Risk Management*, Final Report, vol. 1. (Washington, D.C.).

analyzed on the basis of their concern for justice and ethics, their feasibility, and any unanticipated risks they may lead to. Through the process of examining risk management options, risk managers and stakeholders may further refine the risk analysis, as well as develop more appropriate options.

4. *Making a decision* involves reviewing the information gathered during the risk analysis, examining options, and determining an appropriate solution. The commission cites seven fundamental criteria for making sound decisions:<sup>9</sup>
  - Base the decision on the best available scientific, economic, and other technical information.
  - Be sure the decision accounts for the problem's multisource, multimedia, multichemical, and multirisk contexts.
  - Choose risk management options that are feasible, with benefits reasonably related to their costs.
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Be sensitive to political, social, legal, and cultural considerations.
  - Include incentives for innovation, evaluation, and research.
5. *Taking action* involves implementing the solutions determined in the previous stages. Although implementation is often regulated by agency requirements, the chance of its success is significantly greater when stakeholders from various perspectives and contexts are included in the process.
6. *Evaluating results* involves reviewing the effectiveness of the implemented risk management actions. The evaluation stage provides information on:
  - whether the actions accomplished were the actions intended;
  - whether cost-benefit predictions were accurate;
  - whether (and, if so, what) information gaps affected the success of implemented actions;
  - whether any new information has emerged that would be beneficial;
  - whether the risk assessment/risk management framework was effective;
  - how stakeholders were involved; and

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<sup>9</sup> United States, Presidential/Congressional Commission on Risk, 1997.



- what lessons were learned that could be applied to future risk management decisions.

### 2.1.3 Health and Welfare Canada Framework (1990 and 1993)

In 1990, Health and Welfare Canada published *Health Risk Determination: The Challenge of Health Protection*, which established a framework to define and address health risks. The publication was revised in 1993, and Figure 2.3 shows the updated risk determination framework. The framework has two major components: risk assessment and risk management.<sup>10</sup>

#### 2.1.3.1 Risk Assessment

In Health and Welfare Canada's framework, risk assessment has four key stages: hazard identification, risk estimation, development of options, and option analysis.

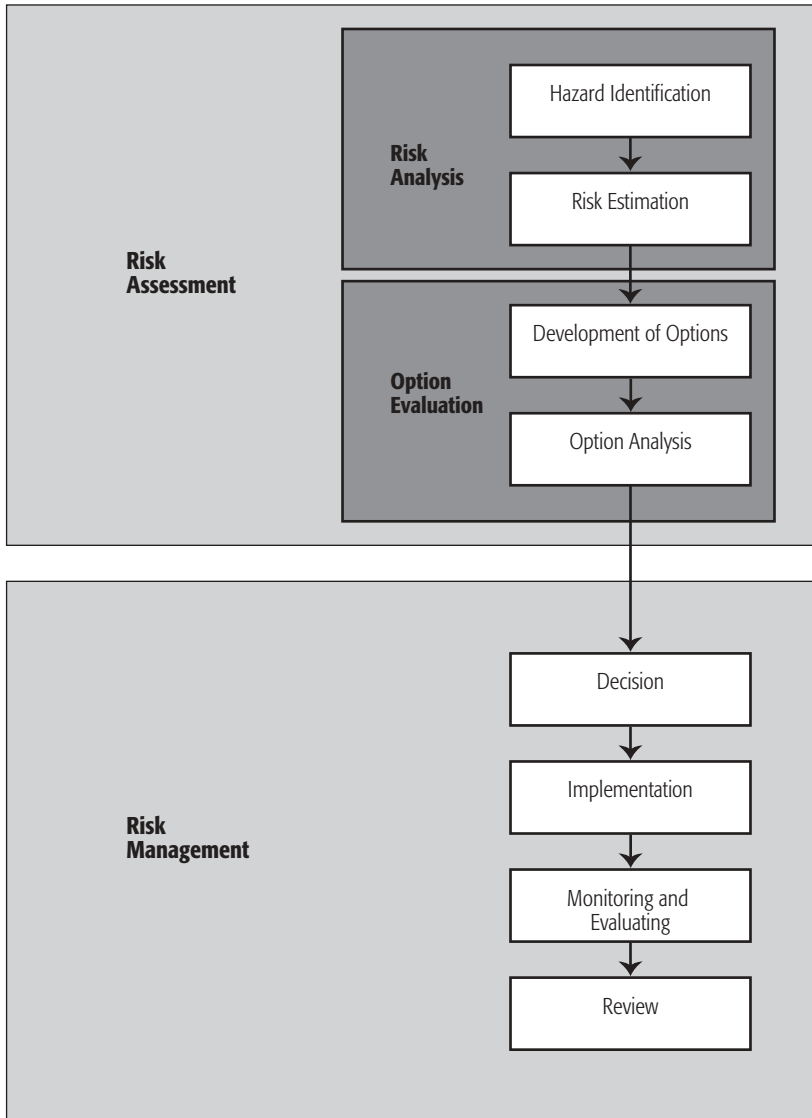
1. *Hazard identification* involves identifying harmful agents and recognizing that specific adverse health outcomes may be associated with exposure to a specific agent.
2. *Risk estimation* involves determining the likelihood that an exposure to an agent would lead to adverse health outcomes.
3. *Development of options* includes developing regulatory options (regulatory and legislative) and non-regulatory options (e.g., advisory options, economic and technological incentives, and current system maintenance options).
4. *Option analysis* involves considering a variety of factors, including legislative authority and agency policies, responsibilities and commitments relating to risk management, urgency of the risk, and option feasibility and its expected effectiveness. Also considered at this stage are possible social, cultural, ethical, political, environmental, economic, and other impacts of each option, and the acceptability of the risk and option to stakeholders is evaluated.

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<sup>10</sup> Canada, Health and Welfare Canada, 1990 and 1993 [update], *Health Risk Determination: The Challenge of Health Protection* (Ottawa: Health Protection Branch), p 3.

In the Health and Welfare framework, risk analysis entails hazard identification and risk estimate (stages 1 and 2). Option evaluation entails development of options and option analysis (stages 3 and 4).

**Figure 2.3 Health and Welfare Canada Risk Determination Framework**



**Source:** Canada, Health Canada, 1993, *Health Risk Determination: The Challenge of Health Protection* (Ottawa: Health Protection Branch), p. 2.

### **2.1.3.2 Risk Management**

Risk management is the second major part of Health and Welfare Canada's framework. It has four main components: decision, implementation, monitoring and evaluating, and review.

1. *Decision* Risk management begins once a decision is made and resources are committed to implement the options.
2. *Implementation* Implementation of options is accompanied by communication with stakeholders.
3. *Monitoring and evaluation* The risk management strategy is monitored and evaluated to determine the effectiveness of implementation and its outcome. Criteria for monitoring and evaluation vary depending on the decisions made at previous levels.
4. *Review* Review of new information may lead to reconsideration and revision of any of the previous components.

### **2.1.4 Canadian Standards Association Framework**

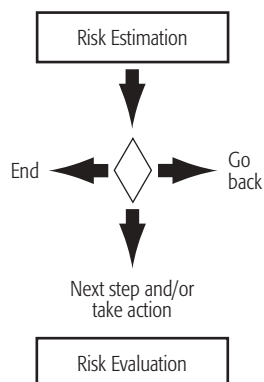
In Canada, the Canadian Standards Association (CSA) provides generic guidance for risk assessment. The CSA is a non-regulatory body made up of government, industry, and academia. Its goal is to provide guidelines on responsible practices that industry can adopt. In 1991, the CSA released *Risk Analysis Requirements and Guidelines*, which provided a general guide to risk management. In 1997, this framework was superseded by the publication of *Risk Management: Guidelines for Decision-Makers*. The 1997 framework is applicable to environmental, ecological, occupational, and other forms of risk. This new framework was unique in that it included risk communication with stakeholders and interested parties throughout the process.

### 2.1.4.1 *Six Steps of the CSA Framework*

The 1997 framework has six steps: initiation, preliminary analysis, risk estimation, risk evaluation, risk control, and action/monitoring.<sup>11</sup> The decisions from each step form a decision diamond wherein potential outcomes can result: end, go back, next step, and/or take action (see Figure 2.4).<sup>12</sup> Documentation at all stages of the risk management process is stressed.

1. *Initiation* involves defining the basic dimensions of the problem. This means outlining the associated risk issues, identifying a risk management team and potential stakeholders, assigning responsibilities, and developing a risk communication scheme.
2. *Preliminary analysis* involves defining the nature of the known risks and evaluating potential risks. Information is gathered and the scope of decision making and possible action is defined. Stakeholder analysis begins. Decisions are made about whether action should be taken immediately, a more detailed analysis should be carried out, or the process should be ended.
3. *Risk estimation* involves estimating the probability, frequency, and impacts of risk situations.

**Figure 2.4 Decision Diamond**



<sup>11</sup> Canada, Canadian Standards Association (CSA), 1997, *Risk Management: Guideline for Decision-Makers*, CAN/CSA-Q850-97 (Etobicoke, Ont.: Canadian Standards Association).

<sup>12</sup> Ibid., p. 8.

4. *Risk evaluation* involves examining the costs, benefits, and acceptability of risk.
5. *Risk control* involves outlining options for addressing the cost, effectiveness, and potential impacts of risk reduction, as well options for dealing with remaining risk. (Option identification may also occur in previous steps of the risk assessment process.)
6. *Action/monitoring* involves implementing risk control. Monitoring activities are established to assess specific control measures and the risk management program, and to detect and follow change (such as change in the regulatory environment, in stakeholder situations or concerns, and in technology).

In the CSA's framework, risk analysis involves conducting preliminary analysis and risk estimation (steps 2 and 3) and identifying the potential for existing hazards to affect individuals, populations, and environments. Risk assessment involves risk analysis and risk evaluation (step 4).

### **2.1.5 Canadian Public Health Association Framework**

In 1989, the Canadian Public Health Association (with funding from Health and Welfare Canada) appointed the National Advisory Panel on Risk/Benefit Management to:

- define and evaluate risk-benefit methodology and address the existence and roles of pharmaceuticals;
- review risk management operational strategies for drugs that include use, development, and distribution;
- develop a risk management framework;
- recommend future research development; and
- initiate and advise on public communication programs.

The panel used Health and Welfare Canada's 1993 risk determination framework as a starting point for the development of its framework. The resulting *Benefit/Risk/Cost Determination Framework* expanded the 1993 framework by including cost and benefits assessments, and used standardized procedures to calculate a net benefit/risk/cost value for the pharmaceuticals under examination.<sup>13</sup>

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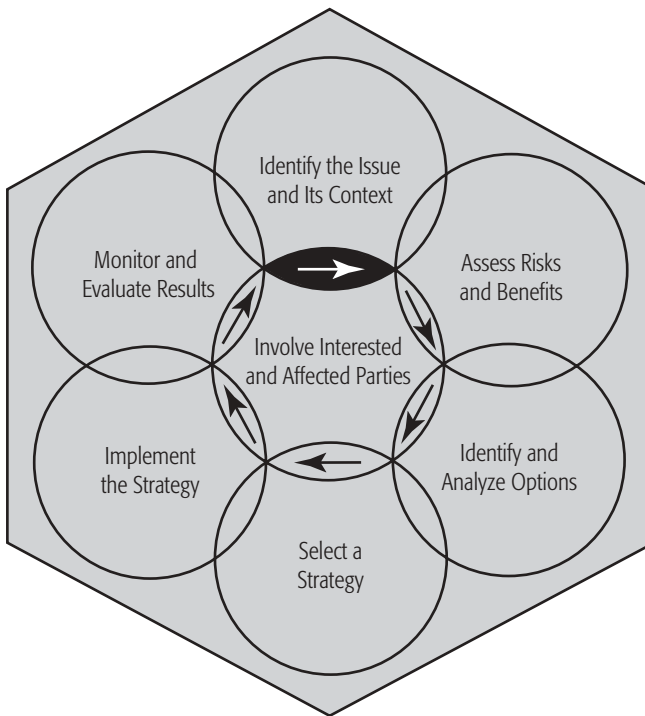
<sup>13</sup> Canada, Canadian Public Health Association, 1993, *Benefit, Risk and Cost Management: Report of the CPHA National Advisory Panel on Risk/Benefit Management of Drugs* (Ottawa: Canadian Public Health Association).

### 2.1.6 Health Canada Framework (2000)

Health Canada is currently revising its approach to managing health risks and has prepared the draft document *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks*. The proposed decision-making framework consists of a series of interconnected steps (see Figure 2.5)<sup>14</sup> that may be grouped into three phases: issue identification (identify the issue and its context); risk assessment (assess risks and benefits); and risk management (identify and analyze options, select a strategy, implement the strategy, and monitor and evaluate the results).

The framework reflects the involvement of interested and affected parties throughout the process, including partners, the public, and other stakeholders.

**Figure 2.5 Health Canada Decision-Making Framework**



**Source:** Canada, Health Canada, 2000a, *Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks* (Ottawa: Health Protection Branch), p. 11.

<sup>14</sup> Canada, Health Canada, 2000a, *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (Ottawa: Health Protection Branch), p. 11.

It is similar in concept to that developed by the U.S. Presidential/Congressional Commission. However, various aspects have been modified in Health Canada's version because of changes in science, society, and technology in the intervening years.

#### **2.1.6.1 Six Steps of Health Canada's 2000 Framework**

1. *Identify the issue and its context* This step is similar to step 1 in the U.S. framework (defining problems and putting them in context) because it too determines the nature of the risk management issue. The Health Canada framework, however, more explicitly describes the tasks involved in establishing the administrative basis and operating procedures needed to proceed through the risk assessment and risk management process.

2. *Assess risks and benefits* This step is similar to step 2 in the U.S. framework (analysing risks), as it also assesses the potential health risks that may result from exposure to a specific agent. However, the Health Canada framework differs in that, where appropriate, it also assesses the potential health benefits related to the agent and examines risks relative to benefits.

Risk assessment is similar to that in the U.S. framework in the traditional (scientific, biophysical) sense. However, there is a difference in the way other types of information (e.g., social, cultural, ethical, economic status, and risk perception) are considered. While the U.S. framework focuses on using this information to provide a context for risk assessment, the Health Canada framework focuses on examining and integrating this information into the risk assessment when there is a demonstrated influence on the level of risk for specific populations. As with biophysical data, an acceptable level of scientific rigour must be applied before such information is incorporated into a risk assessment. This broader approach may be used, for example, when determining different levels of exposure to food contaminants, which may result from different consumption patterns that occur due to social or cultural practices or economic status.

Including benefit assessment as part of the Health Canada framework is not intended to imply that benefits must be assessed in every situation. Rather, it suggests that benefit assessment should be undertaken in a consistent and systematic manner in instances where it is difficult or impossible for consumers to judge the benefits associated with exposure to an agent and to compare them with the associated risks. For example, it is often necessary to evaluate

the benefits of a specific product (e.g., a drug or medical device) when a claim is made that a product improves health, in order to put the risk of that product into the proper context of overall health. At the same time, there are instances when benefit assessment is unnecessary, such as: when the level of risk is deemed to be minimal or *de minimis*, where it is not ethical to consider benefits because it might imply that a product is being endorsed; or where the legislative mandate does not allow benefits to be assessed.

*3. Identify and analyze options* This step is similar to step 3 in the U.S. framework (examining options). As described in the 1993 Health and Welfare Canada framework, a variety of regulatory and non-regulatory options are available for risk management, and a number of factors can be considered in analyzing potential options. The nature and relative importance of the criteria used for option analysis vary depending on the situation.

*4. Select a strategy* This step is similar to step 4 in the U.S. framework (making a decision). A variety of strategies may be used, ranging from a simple approach involving a single risk management option to a multifaceted approach in which several different options are implemented to varying degrees. The selection of a specific strategy frequently depends on considerations such as the scope of the decision, the occurrence of related events or decisions within the same time frame, and the availability of new information. As in step 3 above, the nature and relative importance of these considerations vary depending on the situation.

*5. Implement the strategy* This step, while similar to step 5 in the U.S. framework (taking action), also identifies criteria that can later be used to monitor and evaluate the effectiveness and impacts of the strategy, and to examine how the strategy was carried out.

*6. Monitor and evaluate results* This step is similar to step 6 in the U.S. framework (evaluating results). Evaluation may result in recommending that a previous step in the process be revisited. For example, if a certain risk management option is found to be ineffective, a recommendation could be made to reconsider the alternatives and select an option more likely to be effective.

### **2.1.7 Comparison of Frameworks**

Each of the risk management frameworks described in this section incorporates a similar number of steps or stages (usually six). Conceptually, the frameworks



are also quite similar, but use different terminology to define some of their steps. All frameworks attempt to distinguish between the broad components of risk assessment (scientific considerations) and risk management (socio-economic considerations). All frameworks identify the importance of strong science in risk assessment such that potential health risks can be identified and evaluated in the social context in which they may occur. Thus, the frameworks rely on toxicological and epidemiological data as the primary sources of information for health risk assessment.

The CSA framework considers different types of risks – environmental and workplace – in addition to health risks. Each of the frameworks, except the NRC model, stresses the need for monitoring and follow-up, enabling the modification of a risk management strategy, if necessary. The steps in risk assessment and risk management processes are generally considered to be interconnected rather than sequential. Such an approach allows risk managers to reconsider decisions when new information or analysis is available.

While all frameworks emphasize the importance of distinguishing between the scientific and social aspects of risk assessment and risk management processes, the differentiation between these two stages is not always clear. Hazard identification and risk estimation are clearly in the scientific realm, whereas selecting a control strategy and implementing that strategy fall within the social decision-making domain. However, the NRC model considers that risk assessment includes only hazard identification and risk estimation. Health and Welfare Canada's 1993 framework includes control option analysis (option evaluation) in the assessment phase.

Both science and policy play a role in risk assessment. Some researchers have argued that several of the assumptions and approximations used in scientific risk assessment have political implications and, consequently, it is unrealistic to assume that risk assessment is free of biases that stem from specific interests or viewpoints.<sup>15</sup>

## **2.2 Principles of Risk Management Decision Making**

Comprehensive and sound principles are critical for providing structure and integrity to risk management frameworks. We examined several sets of underlying principles and foundations for risk management while preparing

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<sup>15</sup> V.T. Covello and M.W. Merkhofer, 1994, *Risk Assessment Methods* (New York: Plenum Press).

this report. The breadth and comprehensive nature of these various principles are invaluable for determining those concepts that should be included in an overall set of principles for environmental, human health, and occupational health risk approaches.

### **2.2.1 Health Canada's Ten Principles of Risk Management Decision Making**

The draft document *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* describes ten underlying principles of the risk management decision-making process.<sup>16</sup> The formalization of these principles and their integration into the decision-making steps are the key differences between this approach and the framework developed by Health and Welfare Canada in 1993. The ten principles are described below.

1. *Maintaining and improving health is the primary objective* Health and safety must be given precedence over economic and other considerations in making risk management decisions. Where the interests of protecting the health and safety of Canadians and the right of individuals to make personal choices are at odds, decisions must always favour the former.

2. *Involve interested and affected parties* Opportunities for involving interested and affected parties in the risk management decision-making process must be provided. Individuals and groups must have access to relevant information, and have an opportunity to express their views and influence policy decisions. To be effective, the process for involvement must be clear and explicit, and be carried out systematically.

3. *Communicate in an effective way* Communication must be treated as a two-way process that includes developing an understanding of the needs of interested and affected parties, reacting to concerns, and informing, consulting, and educating. An important aspect of effective communication is providing individuals with enough information to allow them to contribute to the decision-making process in an informed way. The need for effective communication is seen as particularly important where there are large discrepancies between perceptions and scientific assessments of risk.

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<sup>16</sup> Canada, Health Canada, 2000a.

4. *Use a broad perspective* A sufficiently broad understanding of the issue and its context are key factors in focusing risk assessment efforts, identifying risk management goals, selecting efficient and effective strategies, and allocating resources appropriately. Risk assessments should take into account both data from scientific studies and information on health determinants, such as social, cultural, and ethical considerations, and economic status, where such determinants affect the risk level of specific populations. Assessments must also consider interactions between agents rather than focus on agents in isolation. The expected effectiveness of potential risk management options and legislative, international trade, or other requirements are also key considerations. Using a broad perspective also means considering factors such as risks versus benefits, the potential social, cultural, ethical, political, environmental, legal, and economic implications, as well as the perspectives of interested and affected parties.

5. *Use a collaborative and integrated approach* The volume and complexity of information and the cross-cutting nature of many risk issues make it impossible for a single individual or group to maintain the necessary expertise to deal with most health risks. Collaboration can increase efficiency, effectiveness, and consistency of decisions, reduce duplication of effort, and identify gaps in science and policy.

6. *Make effective use of sound science advice* Success in maintaining and improving health requires an evidence-based approach to decision making. The decision-making process must therefore include measures to ensure the quality, integrity, and objectivity of the science base.

7. *Use a precautionary approach* A precautionary approach to decision making emphasizes the need to take timely and appropriately preventive action, even in the absence of a full scientific demonstration of cause and effect. This emphasis in decision making is reflected in the final report of the Krever Commission of Inquiry. The report concluded that a lack of full scientific certainty should not impede preventative measures being taken when reasonable evidence indicates that a situation could cause a significant adverse health effect.<sup>17</sup>

This general concept has been expressed in a variety of contexts, especially in the area of environmental protection. The most widely quoted is one of the

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<sup>17</sup> Canada, Krever Commission, 1997, *Report of the Commission of Inquiry on the Blood System in Canada* (Ottawa: Public Works and Government Services).

principles from the *Declaration of the Rio Conference on Environment and Development*.<sup>18</sup> That principle is embodied in the *Canadian Environmental Protection Act*,<sup>19</sup> which states, “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”<sup>20</sup> There continues to be considerable debate, both nationally and internationally, over the use of the terms ‘precautionary approach’ and ‘precautionary principle,’ and no definitions have yet been universally accepted.

8. *Tailor the process to the issue and its context* Flexibility must be maintained throughout the risk management decision-making process. While recognizing that urgent situations may require quick action, the emphasis on timeliness and flexibility should never be at the cost of thorough and thoughtful – even if rapid – consideration of all the steps identified in the risk assessment and risk management framework. Using a flexible approach may also involve implementing a ‘two-track’ process. Such a process could include both a reactive and timely response involving an interim risk management strategy, and the proactive, systematic development of a longer-term strategy. Using a two-track approach allows the decision-making process to move forward without delaying necessary action until more comprehensive work is done.

9. *Clearly define roles, responsibilities, and accountabilities* The responsibility for improving and maintaining health is shared by individuals, communities, industry, and all levels of government. The roles, responsibilities, and accountabilities of all parties who participate in the risk management decision-making process must be clearly defined. This helps to ensure that participants and other interested and affected parties know what is expected and what commitments have been made. It also helps in the allocation of resources. The respective roles of scientists and policy-makers must be differentiated.

10. *Strive to make the process transparent* All activities, considerations, assumptions, uncertainties, and decisions must be documented to ensure that all aspects of the risk management decision-making process are clear and easily understood. The information must be accessible to interested and affected parties

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<sup>18</sup> United Nations, Environment Programme, 1992, *Rio Declaration on Environment and Development: Principle 15*, Conference on Environment and Development, June 1–14, 1992, Rio de Janeiro, Brazil [online], [cited November 19, 2001], <[www.igc.apc.org/habitat/agenda21/rio-dec.html](http://www.igc.apc.org/habitat/agenda21/rio-dec.html)>.

<sup>19</sup> *Canadian Environmental Protection Act*, RSC 1985, c. 33, as am. by 1999.

<sup>20</sup> *Ibid.*, p. 1.

who may be subject to constraints imposed by requirements for confidentiality. The extent of the documentation needs to be balanced with resources and priorities, especially when the timeliness of the response is critical.

### **2.2.2 Codex Alimentarius Commission's Working Principles for Risk Analysis**

The Codex Alimentarius Commission (CAC) is an international body under the auspices of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO). The CAC is responsible for compiling the standards, codes of practice, guidelines, and recommendations that constitute the *Codex Alimentarius*, or food code. The Codex Committee on General Principles, working with the Joint FAO/WHO Food Standards Programme, has developed draft working principles for risk analysis that focus on the scope and general aspects of risk analysis, as well as on specific principles for risk assessment, risk assessment policy, risk management, and risk communication.<sup>21</sup> Among other considerations, the principles stress the need for transparency and documentation of the process.

### **2.2.3 FAO/WHO's General Principles for Risk Management**

The Joint FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters has also developed a set of general principles for food safety risk management. These principles are listed below.<sup>22</sup>

- Risk management should follow a structured approach.
- Protection of human health should be the primary consideration in risk management decisions.
- Risk management decisions and practices should be transparent.

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<sup>21</sup> United Nations, Food and Agriculture Organization (FAO)/World Health Organization (WHO), Codex Alimentarius Commission, 2001a, *Codex Alimentarius* [online], [cited November 19, 2001], <[www.codexalimentarius.net/](http://www.codexalimentarius.net/)>.

<sup>22</sup> United Nations, Food and Agriculture Organization (FAO)/World Health Organization (WHO), Joint Expert Consultation, 2001b, "Risk management and food safety," *FAO Food Nutrition Papers*, no. 65 (Rome: FAO).

- Determination of risk assessment policy should be included as a specific component of risk management.
- Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.
- Risk management decisions should take into account the uncertainty in the output of the risk assessment.
- Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- Risk management should be a continuing process that considers all newly generated data in the evaluation and review of risk management decisions.

#### **2.2.4 NERAM's Nine Ethical Principles for Risk Management Decision Making**

Comprehensive and sound principles are critical for providing structure and integrity to risk management frameworks. Guiding principles are intended to provide an ethical grounding for considering the many factors involved in risk management decision making. In a draft document prepared for the Committee for Environmental and Occupational Health (CEOH), the Network for Environmental Risk Assessment and Management (NERAM) proposed nine ethical principles to guide risk management decision making.<sup>23</sup> These principles are intended to be aspirational rather than prescriptive. Their application will require flexibility and practical judgment, and each risk management decision will require balancing competing priorities and sometimes making trade-offs between seemingly conflicting principles.<sup>24</sup>

1. *Do more good than harm (beneficence, non-maleficence)* Knowing that zero risk is unattainable, assurance can never be given that 'no harm' will result

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<sup>23</sup> C.G. Jardine et al., 2001, *Review of Risk Management Frameworks for Environmental, Human Health and Occupational Health Risks*, submitted on behalf of Network for Environmental Risk Assessment and Risk Management (NERAM) (Ottawa: Centre for Population Health Risk Assessment and Health Canada).

<sup>24</sup> D. Hattis, 1996, "Drawing the line: Quantitative criteria for risk management," *Environment*, vol. 38, no. 6, pp. 11–15, 35–39.

from a risk management decision. However, decision makers must remember that the ultimate goal of good risk management is to prevent or minimize risk, or to 'do good' as much as possible.

All risk management decisions involve trade-offs; decision makers must seek a balance between the quantity and quality of 'good' and the quantity and quality of potential 'harm.'

2. *Ensure a fair process of decision making (fairness, natural justice)* Risk management must involve a fair process for all parties. It must be just, equitable, impartial, unbiased, dispassionate, and objective as far as possible given the circumstances of each situation. Achieving a fair process necessitates seeking a proper balance among conflicting needs, rights, and demands.

A perceived lack of fairness underlies most, if not all, risk disputes. Ensuring fairness can focus discussion or debate on the quality of evidence, on the inference about risk, and on constructive solutions.

3. *Ensure an equitable distribution of risk (equity)* An equitable process of risk management would ensure fair outcomes and equal treatment of all concerned parties through an equal distribution of benefits and burdens. (This includes the concept of distributive justice; that is, equal opportunities for all individuals.)

Including equity in risk management decision making involves considering and balancing who benefits and who is harmed by any risk. It must also consider individual risk versus collective well-being. Equity entails considering particularly vulnerable populations, such as children, minorities, and other sensitive groups, who may have limited abilities in asserting their rights.

4. *Seek optimal use of limited risk management resources (utility)* All agencies recognize that the resources available to them for achieving effective risk management (e.g., intellectual, tangible, and financial resources) are limited. Optimal risk management demands using limited resources where they will achieve the most risk reduction or overall benefit.

However, evaluation of optimal use is more than a narrow cost-benefit analysis. Effective allocation of resources requires a thorough understanding of what is important and what is less important to a particular risk issue. Optimal risk management will always involve balancing the competing uses of resources.

The process of optimizing may also result in trade-offs between individual risks and population risks.

5. *Promise no more risk management than can be delivered (honesty)* Creating expectations for risk management that cannot be met will inevitably generate conflict. Candid public disclosure of available information and what risk assessment and risk management can realistically achieve will help avoid conflict. Failure to admit knowledge limitations impairs the ability to make difficult decisions under uncertainty. Unwarranted confidence in risk assessment (by both risk managers and the public) can be problematic for risk management and risk communication.

Recognizing the practical limitations of risk assessment can ensure honesty in risk management. It is also critical to clearly identify assumptions and uncertainties in the process. Risk cannot be expressed as a single number; rather, it should be reported as a range, fully disclosing all attendant uncertainties and assumptions. Risk estimates must be presented in the complete context of the issue and the assessment process.

6. *Ensure that the risk imposed is no more than the decision maker would tolerate (the Golden Rule)* The Golden Rule is important in risk management because it forces decision makers to remain involved with their decisions and to work to understand the perspectives of affected parties. This is not easily accomplished and requires both effort and commitment on the part of the decision maker.

7. *Be cautious in the face of uncertainty (better safe than sorry)* Uncertainty is inherent in all aspects of determining potential human health, ecological, or occupational risks. Making appropriate decisions in the face of this uncertainty is a major challenge for risk managers.

Dealing with uncertainty depends on many factors, including the potential adverse consequences of the hazard and public concerns about the inherent risk. Risk managers must adopt a cautious approach when faced with a potentially serious risk, even if the evidence is uncertain. Prudent action must be taken even if there is no scientific certainty.

8. *Foster informed risk decision making for all stakeholders (autonomy)* People and communities have the right to be involved in decisions that affect their lives and those of the people they care about. This principle honours both the right for self-determination and informed decision making. Fostering autonomous decision



making means providing people with the opportunity to participate and disclosing of all the information required for informed decisions.

Applying this principle involves moving from the involuntary imposition of risk to the fully informed and voluntary assumption of risk. As such, it will involve some transfer of control of the situation to affected parties. A decision must be negotiable if informed decision making is to be meaningful.

9. *Ensure that risk management processes are flexible and evolutionary to foster new knowledge and understanding (evolution, evaluation, iterative process)* Committing to use the best evidence means that the risk management process must accommodate new evidence and evolve with new understanding of the problem. Incorporating new evidence requires risk management to be a flexible, evolutionary, and iterative process. It also entails using evaluation throughout the risk management process to ensure that understanding of the problem and approach is appropriate, that the process is proceeding successfully, and that risk management measures are effective.

For risk management to be flexible and evolutionary, the process must be iterative and ongoing (i.e., it does not simply deal with immediate or identified risks, but also investigates and prevents potential risks). Good risk management decisions should consider information from a variety of sources and of a variety of natures (e.g., qualitative, quantitative, empirical, and experimental). These decisions should be revised and changed when significant new information becomes available.

### 2.2.5 The Precautionary Principle

A widely used approach in risk management is the precautionary principle. The precautionary principle is a risk management policy tactic introduced in the 1970s to address risk associated with environmental policy and decision making. The precautionary principle is the basis for environmental law as stated in the *Treaty on European Union* in 1992. Since its conception, the definition and practice of the precautionary principle has varied extensively. Consequently, finding consensus is the greatest challenge to the principle's application.<sup>25</sup> Treaty definitions of the precautionary principle have varied from limiting activities where effects are unknown, to writing in cost-benefit analysis or requiring

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<sup>25</sup> K.P. Foster, P. Vecchia, and M.H. Repacholi, 2000, "Science and the precautionary principle," *Science*, vol. 288, pp. 979–981.

scientific evidence of an associated risk. Because of such variation in definition, the Commission of the European Communities issued a communication in 2000 to clarify the use of the principle as a management tool. Foster et al. summarize the key guidelines for the application of the principle as follows:<sup>26</sup>

- Response measures taken to a hazard should be in proportion to the desired and expected level of protection from such a hazard.
- A non-discriminatory process should be applied to all hazards of similar characteristics, whereby similar hazards are addressed using the same criteria and process.
- Where scientific data is available from previous situations, the data should be reconsidered in a consistent manner.
- Cost-benefit analysis should be used only when appropriate.
- Any action planned in regard to a situation should be considered ‘pending,’ so that any encompassing and revealing data that subsequently becomes available may be used.

Because the precautionary principle has political weight in the risk management process, the evolution of its definition will continue, over time, to better address potential risks from both science and non-science perspectives.

### **2.2.6 Making Risk Management Decisions**

The frameworks for risk assessment described in subsection 2.1 provide guidance on risk management. Although the approaches vary, they all maintain the basic elements of a benchmark framework: context, stakeholder relationships, preliminary analysis, risk analysis, evaluation, and monitoring. Any variance in risk management practices is often a result of situational decision making. Decisions rely on value judgments and on the scientific and technical information made available to risk managers. The role of scientific analysis in risk decisions is influenced by several points:<sup>27</sup>

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<sup>26</sup> Ibid.

<sup>27</sup> United States, National Research Council, 1996, *Understanding Risk: Informing Decisions in a Democratic Society* (Washington, D.C.: National Academy Press).

- Risk analysis requires input from a variety of disciplines.
- Scientific knowledge may not always provide objective information.
- Assumptions are made at various stages of assessment.
- Analysis may be influenced by the credibility of the research scientist.

The role of scientific information must also be considered in the context of decision making where risk decisions are public policy choices.<sup>28</sup>

Risk characterization can only be as successful as analytical and public choices allow. Risk decisions are essentially a balancing of criteria, such as protecting public health, ensuring scientific validity, minimizing error, maximizing research opportunities, providing process order, and fostering trustworthiness.<sup>29</sup> Risk assessment is an instrument – not an end in itself – that decision makers use to help them navigate a ‘best course’ through various and situational options.<sup>30</sup>

## 2.3 Perception of Health Risks

As discussed in subsection 2.1, an important characteristic of risk assessment models or frameworks is the objective of providing rational scientific estimates of health risks and identifying sources of uncertainty inherent in the scientific data. However, quantitative estimates of a health risk do not take into account how the public views that risk. In contrast to risk analysis, risk perception is a process in which individuals subjectively or intuitively estimate, evaluate, and comprehend the probabilities and consequences of risks. Since risk analysis does not consider the subjective elements of risk perception, it is important for decision makers to be aware of public concern for health risks in order that risk management decisions receive greater public acceptance. A number of studies have been conducted to gauge the public’s perception of health and environmental risks in Canada, primarily in the form of public opinion surveys that focus on specific issues of concern.

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<sup>28</sup> Ibid.

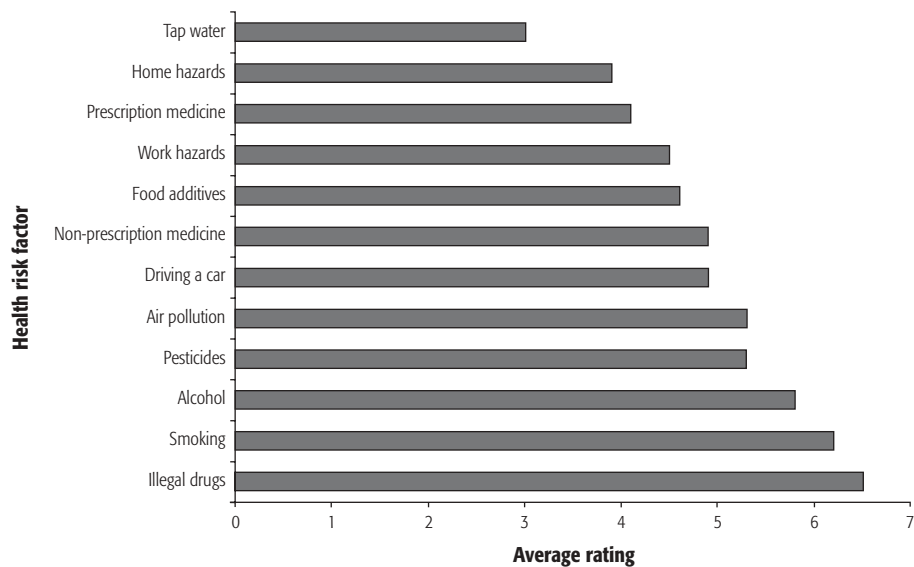
<sup>29</sup> United States, National Research Council, 1994, *Science and Judgment in Risk Assessment* (Washington, D.C.: National Academy Press).

<sup>30</sup> Ibid.

2.3.1 Health and Welfare Canada (1984)

In 1984, Health and Welfare Canada carried out a public opinion survey, conducting personal interviews with individuals from across the country.<sup>31</sup> The objectives of this study were to ascertain the criteria used to evaluate risks, to collect data that Health and Welfare Canada could use to improve communication with the public, and to provide data for internal policy development. According to the survey results, air pollution, pesticides, and food additives were perceived as posing risks of intermediate concern (Figure 2.6).<sup>32</sup> These environmental hazards were considered to affect many, present a risk to future generations, and be known to science. However, these hazards were also considered to induce only limited adverse health effects, which are both delayed and not readily discernible. At the time of the survey, tap water was seen as a lower risk compared with other hazards.

Figure 2.6 Average Ratings Assigned to 12 Health Risk Factors



Source: Canada, Health and Welfare Canada, 1984, *Health Risk Study. Phase II: National Survey* (Ottawa: Health and Welfare Canada).

<sup>31</sup> Canada, Health and Welfare Canada, 1984, *Health Risk Study. Phase II: National Survey* (Ottawa: Health and Welfare Canada).

<sup>32</sup> Ibid.

Respondents were also asked to identify which risk factors they had heard about most often from each of their primary information sources. The results indicated that the three risks assigned the highest perceived risk score (illegal drugs, smoking, and alcohol) were also those the public had heard most about. The two risks assigned the lowest perceived risk ratings (home hazards and tap water) were the ones the public had heard the least about. These observations support the hypothesis that public exposure to risk information is an important determinant of risk perception.

### 2.3.2 Health and Welfare Canada (1995)

A 1995 study commissioned by Health and Welfare Canada covered a wide spectrum of topics related to health risk perception.<sup>33</sup> These topics included ratings of perceived risks, sources of information on health risks, responsibility for risk management, attitudes and opinions about risk, and risk-taking and risk-avoiding behaviours. The perceived risks of 33 environmental hazards affecting Canadians (Figure 2.7a), and of five medical devices and treatments affecting individuals and their families (Figure 2.7b), ranged from high to low levels.<sup>34</sup>

Based on the percentage of responses in the 'high risk' category, cigarette smoking was perceived as the highest risk, while using bottled water and wearing contact lenses were perceived as the lowest risks. Risks that had recently received media coverage, such as ozone depletion, breast implants, crime, violence, and AIDS, all ranked relatively high. Risks related to nuclear power generation, stress, and traffic accidents were perceived as 'considerable.' In contrast, other risks that experts might see as relatively serious, such as bacterial contamination of food and indoor air quality, were rated as lower risks.

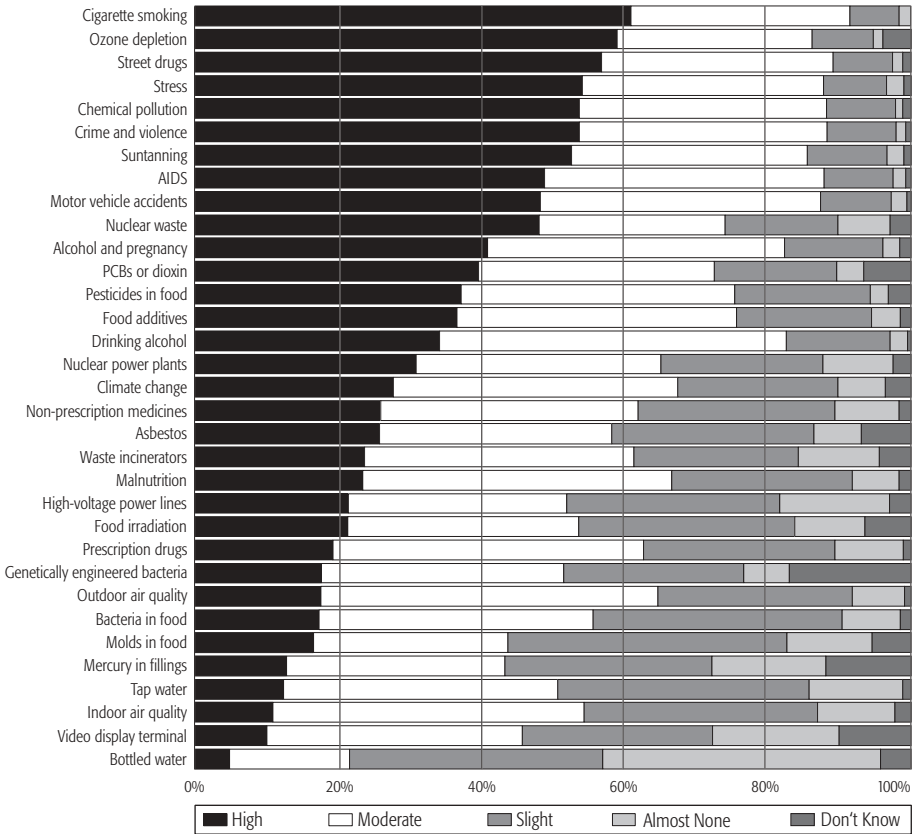
Women generally rated health risks higher than men, particularly for those risks associated with suntanning, breast implants, ozone depletion, and nuclear power plants. In these instances, the differences between women's and men's perceptions were quite large. People with less education generally had higher perceptions of risk than people with more education, and were relatively more

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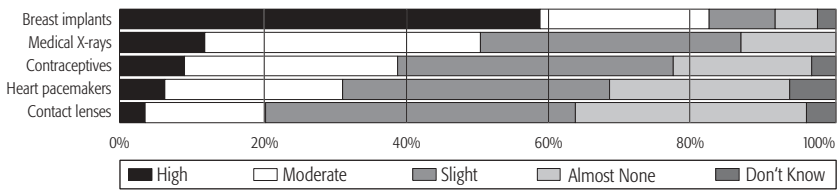
<sup>33</sup> D. Krewski et al., 1995a, "Health risk perception in Canada. I: Rating hazards, sources of information, and responsibility for risk protection," *Human and Ecological Risk Assessment*, vol. 1, no. 2, pp. 117–132.

<sup>34</sup> *Ibid.*, p. 119.

**Figure 2.7a Perceived Risk of 33 Environmental Hazards to the Canadian Public**



**Figure 2.7b Perceived Risk of Five Medical Devices and Treatments to the Canadian Public**



concerned about chemical pollution, street drugs, nuclear waste, AIDS, malnutrition, and high-voltage power lines.

The second component of the 1995 study found that a high degree of concern about health risks was associated with industrial pollution and chemical products (with the exception of medicines).<sup>35</sup> Almost all respondents agreed that land, air, and water were more contaminated than ever. In addition, there was widespread belief that a risk-free environment was an achievable goal, and an unwillingness to accept some health risks to improve the economy. Lifestyle factors such as diet, exercise, and tobacco smoking were perceived to be important modifiers of health risk. However, many respondents agreed that they had little control over risks to their health.

### 2.3.3 Health Canada (2000)

A report prepared by Environics Research Group for Health Canada in 2000 examined public perception of the risks and benefits of seven biotechnology applications:<sup>36</sup>

- bioengineered human prescription drugs;
- bioengineered veterinary drugs;
- pesticides with genetically modified bacteria;
- genetically modified seeds, crops, vegetables, and food;
- transgenic laboratory animals used to gather scientific knowledge (e.g., animals used in the study of human disease and treatment);
- transgenic laboratory animals used in the study of human diseases in which the results are applied to the treatment of human diseases; and
- cloned farm animals

The study was conducted by telephone survey. Interviewing took place between February 25 and March 8, 2000. The number of completed interviews was 1,508, a completion rate of 28%. Those interviewed were all adult Canadians. Data were analyzed with respect to age, gender, income, region, education level, and summary measures (attitudinal groups, leadership and influence,

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<sup>35</sup> D. Krewski et al., 1995b, "Health risk perception in Canada. II: Worldviews, attitudes, and opinions," *Human and Ecological Risk Assessment*, vol. 1, no. 2, pp. 53–70.

<sup>36</sup> Canada, Health Canada, 2000b, *Risk/Benefit Perceptions of Biotechnology Products*, a report prepared for Health Canada by Environics Research Group, July 2000 (Ottawa: Health Protection Branch).

attitudes toward risk, attitudes toward science and technology, and attitudes toward experimentation). Twenty-seven health-related issues were included in the study, 18 of which had been examined previously by Krewski et al.<sup>37</sup>

While the focus of this study was biotechnology, some drinking water-related issues were included. Some general conclusions about risk perceptions were drawn. In terms of microbiological issues, 12% of respondents considered tap water to present a high health risk to Canadians in both the 1995 and 2000 studies. Percentages in the 'moderate,' 'slight,' and 'almost no' risk categories were 38, 35, and 15, respectively. Tap water ranked 14th in the list of 18 health risks common to the 1995 and 2000 studies. Of the total 27 health risks in the 2000 study, tap water placed 19th. Respondents believing that bacteria in food represented a high health risk increased 22 percentage points to 39% between 1995 and 2000. The issue of bacteria in food increased from 14th ranking to 9th (of 18). The percentage of respondents who considered the use of radiation to kill bacteria in food a high health risk also increased 11 percentage points to 32%.<sup>38</sup>

The 2000 study suggested that the level of concern over many health-related issues had increased since 1995. The response in the 'high health risk' category increased for pesticides in food (by 25 percentage points, to 62%) and AIDS (by 26 percentage points, to 75%). Greater than 20 percentage point increases were also found for cigarette smoking, street drugs, and bacteria in food. Risk perception was found to vary with gender, age, education and income level, occupation, and geographic region. In general, women were more likely to express a 'high' level of concern for most health risks. Perception of elevated risk increased with age and decreased with increasing income and level of education. Albertans assigned the lowest proportion of health-related issues to the high risk category, while people in Quebec and the Atlantic provinces were more likely to assess the issues as high risk. Sixty-two percent of Canadians felt that no product is risk free and that therefore a minimum amount of risk was acceptable. Thirty-seven percent preferred that a product be 100% risk free before market release. The 2000 study suggested that the willingness to accept some risk increases with education and income level, and that there are regional differences in 'risk acceptance' levels.<sup>39</sup>

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<sup>37</sup> Krewski et al., 1995a and 1995b.

<sup>38</sup> Canada, Health Canada, 2000b.

<sup>39</sup> Ibid.



The perception that “natural hazards are safer than non-natural hazards,”<sup>40</sup> reported in the 1995 study, was also evident in the perceptions of risks in the 2000(b) study associated with different drug categories. Of the four categories (non-prescription, prescription, bioengineered prescription, and herbal), herbal medicines were considered the least risky, despite being the only drug category that is largely unregulated. Traditional prescription drugs were considered to be more risky than those that were bioengineered.<sup>41</sup>

The data from the 2000 study suggests that 59% of Canadians believe that scientific evidence should be given the most weight when decisions are being made about biotechnology products; 30% thought that people’s concerns and perceptions should be the most important consideration. Only 10% thought that both of these factors should be considered.<sup>42</sup>

### 2.3.4 Perception of Water Quality

Environment Canada sponsored a study of public opinion and attitudes concerning water quality in the Lower Great Lakes Basin in 1978.<sup>43</sup> Information was obtained through telephone interviews with 3,066 individuals selected at random in southern Ontario. The study included an assessment of current public perception of Great Lakes water quality and of public attitudes toward improving water quality.

Over half of the respondents indicated a general dissatisfaction with water quality. Controlling industrial and general pollution was identified as the most important strategy for improving water quality. Over half of the respondents felt that government was not doing enough to improve water quality and indicated a willingness to pay for better water. However, a later study conducted by Environment Canada revealed that, while the majority of Canadians were willing to pay extra taxes (\$10 per year to reduce water and air pollution), only 13% had actually donated funds to an environmental organization.<sup>44</sup> In a study

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<sup>40</sup> P. Slovic et al., 1995, “Intuitive toxicology II. Expert and lay judgments of chemical risks in Canada,” *Risk Analysis*, vol. 15, pp. 661–675.

<sup>41</sup> Canada, Health Canada, 2000b.

<sup>42</sup> Ibid.

<sup>43</sup> Canada, Environment Canada, 1981, *Public Perceptions of Water Quality in the Great Lakes* (Ottawa: Environment Canada).

<sup>44</sup> Canada, Environment Canada, 1983, *Study of Trends in Canadian Environmental and Water Issues Concerning Ontario and the Great Lakes Region* (Ottawa: Environment Canada).

of risk perception and the value of environmental safety, McDaniels et al. found that the willingness to pay for avoiding environmental hazards was dependent on how well the hazards were defined.<sup>45</sup> ‘Well defined,’ in this case, meant that individuals generally had some level of exposure to the hazards.

### 2.3.5 Factors Influencing Risk Perception

Difficulties in understanding probabilistic processes, biased media coverage, misinterpreted personal experiences, and the anxieties generated by life occurrences frequently lead individuals to deny uncertainty, misjudge risks, and maintain unwarranted confidence in judgments of fact.<sup>46</sup> Information processing is hindered by biases and limitations that affect an individual’s subjective evaluations of probabilities. An earlier influential study provided insight into public perception of the frequency of lethal events.<sup>47</sup> That study found that individuals tended to overestimate the frequency of low probability risks, such as floods, and to underestimate the frequency of high probability risks, such as cancer and heart disease. Individuals also tended to exaggerate the frequency of some risks and to underestimate the frequency of others compared to objectively determined frequencies of the same risks.

Knowledge and attitude are related to socio-economic and demographic variables.<sup>48,49</sup> Knowledge about the technical, scientific, and medical aspects of hazards tends to be low, but is generally higher for males, younger adults, and better-educated individuals. Despite their general lack of knowledge, most individuals feel capable of making risk decisions. Attitude, especially concern about risk, is less clearly defined than is knowledge, although older individuals and women, particularly those with young children, generally express the most concern.

A population’s awareness, and sometimes knowledge, of hazards increases with time. Since knowledge is cumulative, the introduction of new information

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<sup>45</sup> T.L. McDaniels, M.S. Kamlet, and G.W. Fischer, 1992, “Risk perception and the value of safety,” *Risk Analysis*, vol. 12, pp. 495–503.

<sup>46</sup> Slovic et al., 1995.

<sup>47</sup> S. Lichtenstein et al., 1978, “Judged frequency of lethal events,” *Journal of Experimental Psychology: Human Learning and Memory*, vol. 4, pp. 551–581.

<sup>48</sup> A. Whyte and I. Burton, 1980, *Environmental Risk Assessment* (Chichester: John Wiley & Sons).

<sup>49</sup> D.A. Stapel and W. Koomen, 1997, “Social categorization and perceptual judgment of size: When perception is social,” *Journal of Personality and Social Psychology*, vol. 73, pp. 1177–1190.

over time helps people define risk problems and priorities. Given the increasing scientific and technical complexity of many current risks, individuals must accept much of the information and interpretations of information by experts on faith. The perceived credibility of presented information is often related to the perceived credibility of the information source. Doctors and government agencies appear to have the highest credibility; the media has the lowest credibility.<sup>50</sup>

Since the public does not perceive all risks in the same light, it is important to understand the specific characteristics of risks that influence the perception of them. Many risk characteristics are highly correlated with one another. Analyses of their interrelationships indicate that, in general, three main factors influence risk perception: the degree to which a risk is understood, the degree to which a risk invokes feelings of dread, and the number of people exposed to the hazard.<sup>51</sup>

A detailed review of factors known to influence risk perception was conducted by Whyte and Burton.<sup>52</sup> Their findings, which are summarized in Table 2.1, indicate that a risk is perceived to be more serious if its consequences are immediate and it directly impacts the individual, rather than if it causes only an indirect effect through a complex chain of events. Dreaded hazards that create fear or anxiety are of greater concern, as are those involving a large number of simultaneous fatalities, particularly if the fatalities are grouped in space or time, as generally occurs in a major accident.

Concern increases if the process or mechanism leading to a given risk is not understood, or if the individual has little or no control over the risk. Similarly, involuntary risks are less readily accepted than voluntary risks, and unfamiliar risks are of greater concern than familiar ones. Situations in which children are at risk are viewed with even greater concern, as are situations in which the victims are identifiable and not just numbers or statistics.

Concern is also heightened when individuals have little knowledge about the risk. This issue is complex. Initial awareness may cause alarm, which decreases once understanding is gained. However, when more knowledge is obtained, the uncertainty associated with scientific knowledge becomes more significant than the gain in reassurance. Siegrist and Cvetkovich state that when people

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<sup>50</sup> Canada, Health and Welfare Canada, 1984.

<sup>51</sup> Slovic et al., 1995.

<sup>52</sup> Whyte and Burton, 1980.

are not knowledgeable about a hazard they rely on social trust for risk judgments, whereas people who are knowledgeable rely less on authorities and social trust.<sup>53</sup> Thus, an individual’s knowledge level is indicative of his or her perceived control in a situation, and control influences the individual’s perceived severity of the risk.

Risks for which the information source is not perceived as credible tend to be viewed with greater concern than those for which the information source is reliable. In his study of radiation risk, Hendee suggested that risk is best communicated by a knowledgeable individual (e.g., a physician), who is perceived as being concerned with the best interests of the community, because risk response is emotionally rather than intellectually formulated.<sup>54,55</sup> Concern may also increase when a hazard receives much media attention, although the net effect on public perception depends on the kind and content of the coverage.

**Table 2.1    Factors Influencing Risk Perception**

| <b>Factors Tending to Increase<br/>the Perception of Risk<br/>(examples in parentheses)</b>  | <b>Factors Tending to Decrease<br/>the Perception of Risk<br/>(examples in parentheses)</b>  |
|--|--|
| <ul style="list-style-type: none"><li>• Immediate events (tornado)</li><li>• Direct experiences (bridge failure)</li><li>• Dread hazards (bioterrorism)</li><li>• Many fatalities per event (air crash)</li><li>• Fatalities grouped in space and time (plague)</li><li>• Mechanisms or a process not understood (some types of cancer)</li><li>• Uncontrollable (cosmic radiation)</li><li>• Involuntary (air pollution)</li><li>• Children at risk (lead)</li><li>• Identifiable victims (auto crash)</li><li>• Lack of knowledge (mad cow disease)</li><li>• Lack of confidence in source (industry)</li><li>• Extensive media attention (environment)</li><li>• Unfamiliar (electromagnetic fields)</li><li>• Major accident (Chernobyl)</li></ul> | <ul style="list-style-type: none"><li>• Latent or delayed events (asbestos poisoning)</li><li>• Indirect experiences (drought)</li><li>• Common hazards (asthma)</li><li>• Few fatalities per event (avalanche)</li><li>• Fatalities scattered in space and time (lightning strikes)</li><li>• Mechanisms or a process understood (influenza)</li><li>• Controllable (smoking)</li><li>• Voluntary (skydiving)</li><li>• Children not at risk (Alzheimer’s disease)</li><li>• Statistical victims (deaths projected from risk models)</li><li>• Knowledge (household injuries)</li><li>• Confidence in source (academic)</li><li>• Little media attention (genetic disorders)</li><li>• Familiar (house fire)</li><li>• Minor accident (Three Mile Island)</li></ul> |

**Source:** After A. Whyte and I. Burton, 1980, *Environmental Risk Assessment* (Chichester, England: John Wiley & Sons).

<sup>53</sup> M. Siegrist and G. Cvetkovich, 2000, “Perception of hazards: the role of social trust and knowledge,” *Risk Analysis*, vol. 20, pp. 713–719.

<sup>54</sup> W.R. Hendee, 1991, “Personal and public perceptions of radiation risks,” *Radiographics*, vol. 11, pp. 1109–1119.

<sup>55</sup> L. Sjöberg, 1998, “Worry and risk perception,” *Risk Analysis*, vol. 18, pp. 85–93.

## 2.4 Communication of Health Risks

Often, the aim of risk communication is to effect some change in behaviour that will result in decreased exposure to a hazard and, thus, a reduced probability of adverse consequences. Reducing fear and promoting confidence and involvement in the risk management process are other possible communication aims. The following scenario seems like a logical and likely progression: An individual is informed of the risk associated with a particular exposure. The individual's perception of the magnitude of the risk alters depending on the new information communicated about it. This leads to either precautionary behaviour or risk acceptance, depending on how the individual has adjusted his or her perception. There are two assumptions inherent in this scenario: (1) it is assumed that risk perception will be altered by receiving new risk information; and (2) a behavioural change will result.

That public risk perception is altered by communicating health risk information would seem to be a logical supposition; however, there is limited evidence from recent research that this is, in fact, the case.<sup>56,57</sup> Risk perception is a complex concept for which there is, at present, only limited understanding.<sup>58</sup> It is intuitive and therefore subjective, depending on an array of different factors that may be classified into two broad groups: characteristics of the hazard and characteristics of the individual.<sup>59</sup> Perceived risks are higher for hazards that people dread or feel of a lack of control over. Involuntary risks, such as risks with potentially fatal consequences or those for which there is a lack of knowledge or the potential for widespread exposure, are also associated with high levels of perceived risk.<sup>60</sup> The potential for catastrophe and the likelihood of identifiable victims also heighten risk perception, as does repetitive media

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<sup>56</sup> L.G. Aspinwall, 1999, "Persuasion for the purpose of cancer risk reduction: Understanding responses to risk communication," *Journal of the National Cancer Institute Monograph*, vol. 25, pp. 88–93.

<sup>57</sup> M. Gerrard, F.X. Gibbons, and M. Reis-Bergan, 1999, "The effect of risk communication on risk perceptions: The significance of individual differences," *Journal of the National Cancer Institute Monograph*, vol. 25, pp. 94–100.

<sup>58</sup> A.J. Rothman and M.T. Kiviniemi, 1999, "Treating people with information: An analysis and review of approaches to communicating health risk information," *Journal of the National Cancer Institute Monograph*, vol. 25, pp. 44–51.

<sup>59</sup> I.B. Vertinsky and D.A. Wehrung, 1990, *Risk Perception and Drug Safety Evaluation*, Health Canada, catalogue no. H42-2/10-1990 [online], [cited November 14, 2001], <[www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/publicat/risk-per\\_e.html](http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/publicat/risk-per_e.html)>.

<sup>60</sup> P. Slovic, 1987, "Perception of risk," *Science*, vol. 236, pp. 280–285.

coverage and lack of trust in a regulatory body. (Mass media remains the main source of information on health-related issues for the majority of Canadians.<sup>61</sup>)

Worldview and societal and cultural contexts also affect an individual's perception of risk. There is a tendency to cling to existing ideas concerning the level of perceived risk and to avoid accepting and integrating new information about that risk. Defensive responses and an overly optimistic view of an individual's own risk level ('optimistic bias') can diminish the impact of a risk message. An individual's receptivity to change his or her level of risk perception has also been found to depend on self-esteem. Those with higher self-esteem were more resistant to change.<sup>62</sup>

As discussed above, it is assumed that risk behaviour will change following an adjustment of risk perception. There is even less evidence that providing health risk information can produce a change in behaviour directly.<sup>63</sup> Predicting health-behaviour change following a particular risk communication is a challenge to risk managers. Theoretical models of changes in health behaviour traditionally describe behavioural change as a series of discrete stages.<sup>64</sup> Interventions that are effective in bringing about change at one stage may be ineffective at another. Moreover, much of the risk communication research has focused on particular diseases or behaviours. Knowledge that is applicable across different situations is very limited.

As pointed out by Vertinsky and Wehrung, the attempt to provide accurate, often quantitative, information in an open and objective manner does not often assuage public concerns.<sup>65</sup> The differences in risk perception between laypersons, technical experts, and decision makers can lead to ineffective communication (see, for example, Sly [2000] and references therein, and Slovic et al. [1995]).<sup>66,67</sup> It is necessary for those involved in the promotion and regulation of public health and safety to be aware of and sensitive to the risk

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<sup>61</sup> Canada, Health Canada, 2000b.

<sup>62</sup> Gerrard, Gibbons, and Reis-Bergan, 1999.

<sup>63</sup> P.M. Sandman and N.D. Weinstein, 1993, "Predictors of home radon testing and implications for testing promotion programs," *Health Education Quarterly*, vol. 20, pp. 471–478.

<sup>64</sup> Gerrard, Gibbons, and Reis-Bergan, 1999.

<sup>65</sup> Vertinsky and Wehrung, 1990.

<sup>66</sup> T. Sly, 2000, "The perceptions and communications of risk: A guide for the local health agency," *Canadian Journal of Public Health*, vol. 91, no. 2, pp. 153–156.

<sup>67</sup> Slovic et al., 1995.

perceptions of the public. These perceptions represent legitimate concerns that should be addressed in the communication of risk.

Several factors that contribute to the effectiveness of a risk communication strategy have been identified. Empathy and two-way communication are crucial. Any communications should be delivered clearly, avoiding jargon and overuse of quantitative information. The risk should be placed in context and levels of uncertainty addressed. Active involvement in the issue should be encouraged by prompting audience participation and providing information on actions individuals can take to reduce personal risk. Contact persons and information sources should be clearly identified and easily accessible.

In summary, recent research suggests that there is no simple relationship between solely providing health risk information and changing public risk perception. Risk perception results from a complex interaction of individual characteristics and hazard factors. An effective risk message must contain both information and empathy, conveyed in a manner that promotes stakeholder involvement. The aim is to produce an atmosphere of mutual respect to facilitate an interactive exchange of information and concerns.

## **2.5 Application of the Proposed Health Canada Framework to Canadian Drinking Water Guidelines**

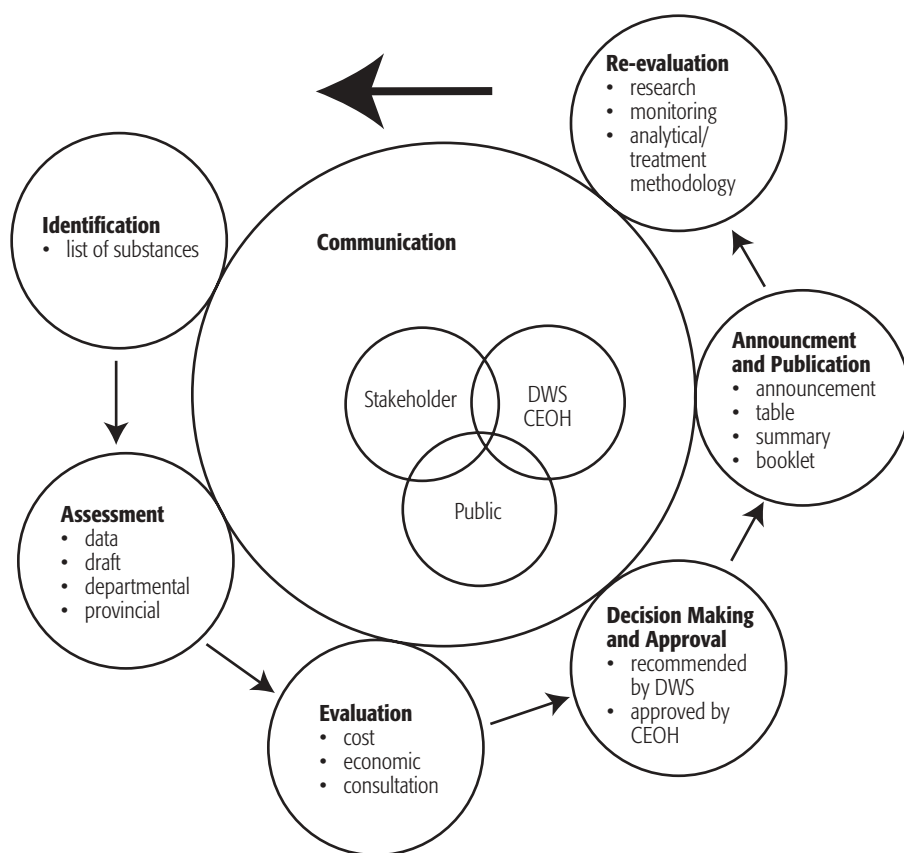
Development of the *Guidelines for Canadian Drinking Water Quality* is a responsibility of the Federal-Provincial Subcommittee on Drinking Water, which is part of the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH). The subcommittee, which meets biannually, is made up of expert representatives from the federal, provincial, and territorial governments. Health Canada provides the secretariat for the drinking water subcommittee.

The subcommittee studies microbiological, chemical, physical, and radiological parameters relevant to drinking water issues in Canada, and develops guidelines for some of these parameters. These guidelines are described in the document *Canadian Drinking Water Guidelines Development Process*.

The framework used to develop the guidelines (see Figure 2.8) is made up of a set of interlocking circles. It is based on the proposed Health Canada decision-making framework described in subsection 2.1. This approach is intended, in

part, to delineate the science-based assessment of health risks and other factors that determine the final guidelines, and hence drinking water management. The secretariat assesses the human health risks of the drinking water parameters and develops the health-based guidelines for the subcommittee's consideration. Subcommittee members are responsible for assessing other aspects that can affect the management of identified risks, such as the practicality, cost, and potential benefits of a proposed guideline in light of other health protection priorities in their jurisdictions. Provisions for public consultation, expert review, and communication activities are included at critical stages in the development of the guidelines.

**Figure 2.8 Framework for Developing the Canadian Drinking Water Guidelines**



**Note:** DWS – Drinking Water Subcommittee; CEOH – Committee for Environmental and Occupational Health.

**Source:** Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water Quality, 1999a, *Guidelines for Canadian Drinking Water Quality*, 6th ed. (Ottawa: Health Canada), p. 3.



The subcommittee is also guided by criteria outlined in the publication *Strategies for Population Health – Investing in the Health of Canadians*. In this report, the Federal, Provincial, and Territorial Committee on Population Health recommended three broad strategic directions for national action one of which was to “develop comprehensive intersectoral population health initiatives for a few key priorities that have the potential to significantly impact population health.”<sup>68</sup> The advisory committee further suggested that the following criteria could be used to select one or more priority areas:<sup>69</sup>

*National significance:* will be seen by the public as, or would be explainable as, an area that is truly of national importance.

*Impact:* has clear potential, based on sound research evidence, to significantly improve population health and reduce health disparities.

*Common directions:* is consistent with the population health directions and priorities of provincial/territorial and federal governments.

*Capacity:* the capacity exists to take effective action on the strategy, at reasonable cost, e.g. sufficient knowledge to proceed, likelihood of sustained support, capacity to measure progress, good opportunities for intersectoral action.

*Return on investment:* could be accomplished with an affordable expenditure of resources, and offers the potential for a good return (in terms of improved health and related health outcomes) on the investment.

*Flexibility:* provides flexibility for each jurisdiction and stakeholder to implement the strategy in their own way.

Development of the national guidelines “relies on a flexible process that must accommodate the diverse needs of various jurisdictions.”<sup>70</sup> Thus, certain steps in the framework “may be modified or circumvented in order to address the needs of the jurisdictions involved.”<sup>71</sup>

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<sup>68</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1996a, *Guidelines for Canadian Drinking Water Quality*, 6th ed. (Ottawa: Health Canada), pp. 37–38.

<sup>69</sup> Ibid.

<sup>70</sup> Canada, Health Canada, 1999a, p. 3.

<sup>71</sup> Ibid.

### 2.5.1 Six Steps of the Framework for Developing Drinking Water Guidelines

1. *Identification and selection of parameters for review* Three criteria are used to determine whether a substance should be considered further by the subcommittee for guideline development. To be considered, a substance should:<sup>72</sup>

- be detected at a level which is of possible health significance;
- be frequently detected at elevated concentrations; and
- have the potential to cause adverse health effects.

Parameters of interest across the country or to multiple jurisdictions receive particular attention. Before developing a guideline, the subcommittee establishes whether controlling the substance in drinking water has a “clear potential, based on sound research evidence, to significantly improve population health and reduce disparities.”<sup>73</sup> Approval by the CEOH is also required.

The subcommittee studies data on the potential health effects of a substance and its presence in water supplies, which enables it to determine whether a guideline for the substance is needed. Provincial and territorial subcommittee members identify available field monitoring data and existing, current, or future sampling programs in their jurisdictions. They also identify economic, cost, and other information that may be relevant to future guideline development. The secretariat generally keeps track of the availability of national monitoring data and published health-related literature on the substance.

The subcommittee uses a multiple-rating system based on the above criteria to establish a priority list of substances for which guidelines should be developed. Subcommittee members rate each substance according to its frequency and concentration detected in drinking water supplies. The secretariat rates health effects based on assessments conducted elsewhere in Health Canada, in the U.S. Environmental Protection Agency (EPA), or in the World Health Organization (WHO). Using the exposure and health effects ratings, the subcommittee establishes the priority list by consensus.

The subcommittee re-examines the list of nominated substances once a year. It submits the list and schedules for conducting detailed reviews of each substance

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<sup>72</sup> Canada, Health Canada, 1999a, p. 4.

<sup>73</sup> Ibid.

to the CEOH for approval. If the CEOH disagrees with any of the subcommittee's recommendations, a substance is either dropped from the list or more information is requested to justify the initial recommendation. The list is currently limited to six entries and may include substances already under review, substances that will be assigned to a Health Canada reviewer, and/or substances that will be reviewed at a later date.

In determining whether or when to proceed with developing a guideline, the secretariat may consult with other jurisdictions. In making use of similar work being undertaken elsewhere in Health Canada, the EPA, and the WHO, the secretariat avoids duplication.

*2. Assessment of the health risks* This stage entails preparing a criteria summary: a secretariat member conducts a science-based assessment of the potential health risks of a substance and derives a health-based guideline. Information considered in step 1 is augmented by a detailed review of the scientific literature. In addition, provincial and territorial jurisdictions particularly concerned about a substance may initiate monitoring programs. The secretariat considers any additional monitoring data when assessing exposure of the population to the substance. The criteria summary also includes information on methods for analyzing the substance in drinking water and on technologies for water treatment.

Internal evaluators and external experts review the criteria summary. The document is amended after each review stage, if necessary. The first review is carried out within Health Canada. The proposed classification of a substance in terms of its potential health effects and its proposed guideline value are scrutinized by senior scientific evaluators within Health Canada's Drinking Water Program. The criteria summary is then submitted to three external reviewers who have expert knowledge of the substance. Reviewers are drawn from Canadian or American universities, the EPA's Drinking Water Program, or a member state of the WHO. These peer reviewers evaluate the criteria summary for concordance with Health Canada's *Approach to the Derivation of Drinking Water Guidelines*. The reviewers also respond to questions set out in the *Guide for Peer Reviewers*.<sup>74</sup>

The criteria summary is then sent to a Health Canada committee composed of senior staff. The committee ensures that the summary conforms to departmental

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<sup>74</sup> David Green, Secretary of the Secretariat to the Federal-Provincial Subcommittee on Drinking Water, Health Canada [personal communication with the authors, October 23, 2000].

policies on health risk assessment and is scientifically sound. Finally, the criteria summary is submitted to the drinking water subcommittee and the CEOH for review by the provinces and territories. These reviews can range from cursory internal examinations by a specific ministry to detailed evaluations by external agencies or non-governmental organizations on behalf of a ministry. All comments from the provinces and territories are addressed and documented, and the criteria summary is amended as necessary. A final draft of the criteria summary, including the proposed health-based guideline, is returned to the subcommittee.

*3. Evaluation (cost-benefit analysis)* After the subcommittee examines the health risks associated with the presence of a substance in drinking water, it studies the feasibility of implementing the recommended guideline. It considers the costs of changes or improvements in water treatment technology required to meet the proposed guideline and identify any socio-economic factors; and it assesses other control strategies that may be more cost effective in reducing exposure to the substance. The subcommittee weighs the costs of water treatment against the benefits of exposure reduction. For example, a savings in health care costs might be realized from the treatment of a health problem associated with exposure if the exposure is reduced. Possible socio-economic benefits from reducing exposure include less work-related sick leave and more productivity. The subcommittee may consider any side benefits resulting from improved drinking water treatment, such as removing other contaminants or extending the life of the water distribution system. These cost-related and socio-economic evaluations are primarily the responsibility of provincial and territorial members of the subcommittee.

At this stage, the subcommittee may also amend a health-based guideline recommended for the substance.

Providing stakeholders and public interest groups with an opportunity to review and comment on the proposals is important at this time. Maximizing the public's understanding of the risk management and decision-making process – and thus increasing the likelihood of acceptance of the final decision for controlling a substance – is a key objective. However, the subcommittee determines the extent and nature of public involvement (see subsection 2.5.2). Following the consultations, the secretariat incorporates any comments into a national summary report, which may be amended following review by the subcommittee. The final report is then distributed to the subcommittee and the CEOH, and to any parties that participated in the consultations.

4. *Decision making and approval* Both the subcommittee and the CEOH must approve the decision to establish a new or revised guideline. Before meeting to discuss the guideline, subcommittee members review a package containing all the consultation materials, including the consultation summary. If the subcommittee decides a guideline is warranted, its recommended value, a consultation summary, economic, and other relevant information is forwarded to CEOH for endorsement. If the CEOH approves the guideline, it is reported to the Conference of Deputy Ministers of Health. If the CEOH rejects the guideline, the subcommittee is directed as to what additional information is required.<sup>75</sup>

5. *Announcement and publication* After obtaining the CEOH's approval for a new guideline, the secretariat prepares a public announcement for the media. This statement is made available to all subcommittee members, who are responsible for its release within their own jurisdictions. The guideline is then published in two main formats: as a criteria summary in the *Guidelines for Canadian Drinking Water Quality – Supporting Documentation* binder (within one year of CEOH approval), and in the booklet *Guidelines for Canadian Drinking Water Quality*. The booklet is updated every two or three years. The supporting documentation and a summary table of the guideline values are also posted on Health Canada's Web site at <[www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)>.

6. *Re-evaluation* The secretariat usually identifies the need to update a guideline. However, each year, when the subcommittee develops its work plan, it considers whether to update existing guidelines, especially when new health-related data is available or changes in analytical methods or treatment have occurred. Any member of the subcommittee or interested party may request the re-examination of an existing guideline.

## 2.5.2 Communication

Communication is a key component in the drinking water guideline framework. Public announcements and consultations are the main communication vehicles.

Following each subcommittee meeting, a public announcement is made available to subcommittee members to distribute to interested parties and is

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<sup>75</sup> Section 5 details how a science base is used to develop drinking water standards and guidelines (step 2) and how socio-economic and practical considerations are taken into account in the decision-making process (steps 3 and 4).

also posted on Health Canada's Web site. Although the announcements include summaries of the subcommittee's activities, they do not provide values for draft guidelines at an early stage of development.

Public consultations begin when the subcommittee first identifies a substance for consideration. Public participation is particularly important in risk management (i.e., at the evaluation stage), and consultations become more structured once the criteria summary for a substance has been submitted to the subcommittee for evaluation. At this time, the subcommittee identifies the level of consultation required and informs the CEOH. National consultation on the proposed guideline is held<sup>76</sup>; regional or provincial/territorial consultations may also be recommended, depending on regional or provincial/territorial concerns. Each provincial and territorial subcommittee member is responsible for soliciting public input and determining the appropriate consultation procedures for his or her jurisdiction. The Health Canada member of the subcommittee is responsible for organizing and conducting national focus groups involving other federal departments and agencies, industries and manufacturers, and national organizations and associations.

The secretariat confers with the subcommittee to prepare consultation packages. Each consultation package contains the criteria summary, the proposed guideline (including both the health-based and final number, if amended for socio-economic reasons), a treatment technology document describing commonly used or available methods, available cost and economic analysis synopses, and any other relevant information. The secretariat sends the packages to all parties who have participated in consultations.

The Canadian consultation process is less formal than that followed in the United States, where public consultations must comply with legislation (see subsection 5.3.1). How extensive public consultation and public involvement are in Canada is not clear, and probably varies between federal and provincial levels of government and between provinces.

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<sup>76</sup> National consultations are held where a new revised guideline is being prepared; consultations are not normally held for a guideline that is re-affirmed or for which a numerical limit is not set (D. Green, Secretary of the Secretariat to the Federal-Provincial Subcommittee on Drinking Water, Health Canada [personal communication with the authors, November 12, 2001]).

## 2.6 Summary

Authorities have adopted risk management frameworks to balance societal risks and benefits, to move toward systematic and open decision-making processes, and to increase objectivity and public accountability. The models and frameworks discussed in this section are conceptually alike, incorporating a similar number of steps or stages (e.g., risk identification, risk analysis, option consideration, consultation, and evaluation). All frameworks distinguish between risk assessment and risk management, and stress the importance of examining health risks from a strong scientific base and understanding their socio-economic context. Except for the U.S. National Research Council (NRC) model, the frameworks emphasize the need for monitoring and follow-up. They stress flexibility, incorporating pertinent information as it becomes available. Although the frameworks distinguish between science and policy, both areas play important roles in the risk management process. Stakeholder involvement becomes increasingly more important as the frameworks evolve and the risk management process becomes more defined.

This section also examined risk management decision-making principles. Health Canada has outlined ten main principles aimed at identifying affected individuals or groups, initiating communication, adopting precautionary principles, practising sound science, and ensuring a contextual and transparent process. The working principles for risk analysis currently being developed by the Codex Alimentarius Commission (CAC), the Food and Agriculture Organization (FAO), and the World Health Organization (WHO) were also described, as were the nine ethical principles laid out by the Network for Environmental Risk Assessment and Risk Management (NERAM). The application of these nine principles requires flexibility and practical judgment to ensure that decision making is a balance of priorities, benefits, and costs.

To develop its guidelines, the Federal-Provincial Subcommittee on Drinking Water Subcommittee selects microbiological, chemical, physical, and radiological parameters relevant to drinking water issues. The framework used for guideline development is flexible, accommodating the needs of various jurisdictions, and stresses the importance of communication with stakeholders and the public.

Some understanding of public risk perception must inform risk assessment frameworks. In a series of public surveys and reports, Health Canada identified areas of high health risks. Overall, individuals rated health risks associated with

tap water as relatively low and health risks related to smoking as high. Public perception is believed to be influenced by several factors, such as media coverage, heightened awareness during a hazard event, scientific knowledge, and situational knowledge.

### **3 History of Drinking Water-Related Disease Outbreaks in Canada and the United States**

The importance of safe drinking water to public health has been recognized for over a century. Microbiological parameters that can affect drinking water quality include protozoa (e.g., *Giardia*, *Cryptosporidium*), bacteria (e.g., *Escherichia coli* O157:H7, *Salmonella*, *Shigella*, *Campylobacter*, *Yersinia*, *Aeromonas*, *Legionella*), and enteric (intestinal) viruses (e.g., Norwalk virus, rotaviruses, hepatitis A and E viruses). Fungi have not been implicated in water-borne human disease.

Gastrointestinal illness (diarrhea) is the health effect most commonly caused by water-borne pathogens. Although not generally considered to be life-threatening in normal, healthy adults, these illnesses can affect sensitive subpopulations, such as infants and the elderly, more severely. Water-borne pathogens, such as the hepatitis A virus, may cause more serious effects (e.g., jaundice and liver damage). They may also cause death.

This section describes the micro-organisms important in the water-borne transmission of disease and provides a history of outbreaks in Canada and the United States.

#### **3.1 Acute and Chronic Infections: Past and Present**

Acute water-borne diarrheal illness was common in many communities in the Western world until the first modern forms of water treatment (sand filtration, chlorination) were developed in the late 19th century. Water-borne disease analysis, particularly from a population-health perspective evolved significantly as a result of the investigations of Dr. John Snow. Dr. Snow hypothesized a relationship between cholera and household water supply during the London cholera outbreaks in the mid-19th century. Dr. Snow had observed that the



highest mortality rate (an estimated 500 per day) occurred within 229 m (250 yards) of Broad Street. Further investigation, including individual household examination, isolated the Broad Street pump as the main source of contaminated water. With this insight, Dr. Snow approached local city officials to have the handle removed from the pump.

Since then, widespread use of chemical disinfecting agents, such as chlorine, has decreased the number of outbreaks due to bacterial pathogens. However, some outbreaks caused by *Campylobacter jejuni* (*C. jejuni*), *Campylobacter coli* (*C. coli*), *Escherichia coli* O157:H7 (*E. coli* O157:H7), and *Yersinia enterocolitica* (*Y. enterocolitica*) continue to occur. Protozoan parasites can also cause acute diarrheal illnesses, and epidemic transmissions of cryptosporidiosis and giardiasis are well recognized. Many water-borne parasitic outbreaks have only recently been recognized.

Chronic diseases caused by water-borne agents are very poorly understood. It is known, however, that some water-borne microbial agents cause systemic disease. For example, infection with the water-borne parasite *Toxoplasma gondii* (*T. gondii*) may result in retinal eye disease and impaired vision. A proportion of infections due to the Vero or Shiga toxin-producing *E. coli* (the serotype O157:H7 is only one serotype) may have serious effects on kidney function. Infections caused by *Cryptosporidium parvum* (*C. parvum*) or due to the Shiga toxin-producing *E. coli*, such as O157:H7, are managed only by supportive treatment, as there are no effective antibiotics for these organisms.

While some emerging pathogens, such as *C. parvum* and *E. coli* O157:H7, are now recognized as causing water-borne disease, evidence for the water-borne nature of others remains tentative. For example, *Helicobacter pylori* (*H. pylori*) causes both acute and chronic health effects, including intestinal cancers.

### 3.2 Emerging Threats and a New Paradigm: Looking Ahead

Significant advances since the 1950s in the development and treatment of water supplies and in the protection of both surface and groundwater sources have generally improved the quality of drinking water delivered to the consumer. However, drinking water continues to be threatened as a result of increases in population, concentrated land use, and the aging infrastructure used to collect,

treat, and deliver the water. Moreover, the phenomena of emerging and re-emerging pathogens have only recently been described,<sup>77</sup> and the former is now recognized as causing significant water-borne disease outbreaks.

Infectious diseases caused by emerging pathogens represent an important 'new microbial paradigm,' which has implications for drinking water suppliers and for the public. For example, the parasite *C. parvum*, well known by veterinarians for decades, has recently caused very large epidemics of water-borne human disease in many parts of the world.<sup>78</sup> Another parasite, *T. gondii*, known to be food-borne or to spread to the fetus during pregnancy, has recently been described as the cause of a large water-borne disease outbreak in a Canadian municipality.<sup>79</sup> Some bacteria, such as the Shiga toxin-producing *E. coli* O157:H7, have only recently acquired new virulence factors through DNA transfer. This genetic exchange (a lateral gene transfer between related species) also occurs in other enteric pathogens, such as *Vibrio cholerae* (*V. cholerae*), *Yersinia*, and *C. jejuni*.<sup>80,81</sup>

It is noteworthy that the U.S. Institute of Medicine's 1992 report, *Emerging Infections: Microbial Threats to Health in the United States*, emphasizes the potential for new diseases to spread to human populations from animals. Two recent examples of this phenomenon are the spread to human populations of the HIV virus from non-human primates and of the Nipah virus from pigs. It is also noteworthy that, at present, the disease-causing agent is not determined in many cases or in many outbreaks.

### 3.3 Micro-organisms Important in Water-borne Transmission

Viruses, bacteria, and parasites are micro-organisms that are widespread in the environment. Only a few members of each group are capable of causing disease in humans. Those that do are called pathogens. In most instances, micro-organisms

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<sup>77</sup> United States, Institute of Medicine (IOM), 1992, *Emerging Infections: Microbial Threats to Health in the United States* (Washington, D.C.: National Academy Press).

<sup>78</sup> W.R. MacKenzie et al., 1994, "A massive outbreak in Milwaukee of *Cryptosporidium* infection transmitted through the public water supply," *New England Journal of Medicine*, vol. 331, pp. 161–167.

<sup>79</sup> W.B. Bowie et al., 1997, "Outbreak of toxoplasmosis associated with municipal drinking water," *Lancet*, vol. 350, pp. 173–177.

<sup>80</sup> R. Lan and P.R. Reeves, 1996, "Gene transfer is a major factor in bacterial evolution," *Molecular Biology and Evolution*, vol. 13, pp. 47–55.

<sup>81</sup> H. Ochman, J.G. Lawrence, and E.A. Groisman, 2000, "Lateral gene transfer and the nature of bacteria innovation," *Nature*, vol. 405, pp. 299–304.

are considered to be only potential pathogens in that they infect a host, but disease does not always follow. It is also known that people with various types of immunodeficiencies (immune systems that are unable to provide optimal protection) are at risk of infection from a wider range of potential microbial pathogens than the normal population. Risk from any one pathogen depends on the immune deficiency of a specific host, as well as on the biological characteristics of the micro-organism. The complexities of the interactions between host and micro-organism must be considered at the population level in this context.

Micro-organisms that are transmitted through drinking water share common features. Most of the viruses, bacteria, and parasites causing water-borne outbreaks have animal hosts. Therefore, they may be spread either directly or indirectly from animals to humans. Most of these micro-organisms are capable of surviving well in the environment. This characteristic increases their potential for causing water-borne infections. All three groups may cause either gastrointestinal disease (diarrhea, nausea, vomiting, and abdominal cramps) or systemic illness, including kidney failure associated with *E. coli* O157:H7 infections, hepatitis caused by some viruses, and eye disease caused by some parasites, such as *T. gondii*. The majority of outbreaks are characterized by gastrointestinal disease.

Each group of micro-organisms also behaves differently. Understanding the biological characteristics of each group of microbial pathogens is necessary before one can assess their importance to community health and appraise the rationale behind drinking water-testing methods and their limitations.

### 3.3.1 Viral Micro-organisms

Viral micro-organisms are the smallest of the micro-organisms (0.02–0.3  $\mu\text{m}$  [micrometres] in size). Viruses depend entirely on other living cells for reproduction. Many genera of viruses (the majority lacking a lipid coating and therefore more stable in the environment than those with a coating) have been identified as the cause of water-borne outbreaks. These include the enteroviruses (polio, coxsackie), caliciviruses, rotaviruses, hepatitis viruses (A and E), and adenoviruses.<sup>82</sup> Most pathogenic water-borne viruses cause enteric disease and come from the feces of infected humans or animals.

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<sup>82</sup> M.D. Sobsey, 1999, "Methods to identify and detect microbial contaminants in drinking water," in *Identifying Future Drinking Water Contaminants, Quantitative Risk Assessment for Water-Borne Pathogens* (Ottawa: National Research Council).

Viruses capable of causing water-borne disease are described below.

*Caliciviruses* are non-enveloped (no lipid coat) RNA-type viruses that have been named after the places where outbreaks occurred. The Norwalk virus is a member of this group. Caliciviruses commonly cause mild gastrointestinal illness worldwide. They can spread orally from person to person or through a common source, such as water contaminated with fecal matter. Outbreaks are common in extended care facilities as a result of person-to-person spread.

*Enteroviruses* include polioviruses, coxsackieviruses, and echoviruses. They are a diverse group of micro-organisms that can cause many different manifestations of disease (such as aseptic meningitis or myocarditis). The role played by water in the transmission of these viruses remains unclear.

*Hepatitis viruses* differ from each other, but all of them infect the liver. Hepatitis A is an enterovirus; hepatitis E is a calicivirus. These two viruses are found in the intestinal tract and may be water-borne. Both cause liver disease. Other hepatitis viruses such as hepatitis B, C, and D are transmitted only through exposure to blood and body fluid.

*Rotaviruses* are RNA viruses belonging to the Reoviridae family. They cause diarrhea, and can spread orally from person to person or through a common source, such as water contaminated with fecal matter. They can also spread through sneezing and coughing. Rotaviruses are a common cause of diarrhea in children.

### 3.3.2 Bacteria

Bacteria are larger than viruses (0.5–1.0  $\mu\text{m}$  in size). These single-celled organisms multiply independently of other living cells. They are classified on the basis of their reaction (Gram-positive or Gram-negative) to the Gram stain (a crystal violet dye). They are also well-known causes of water-borne infections and include numerous genera, species, and strains that differ in their ability to cause disease. Some of the genera that have traditionally been associated with water-borne disease include

*Salmonella* (including *S. typhi*), *Shigella*, *Vibrio*, *Yersinia*, and *Campylobacter*. In some genera, such as *Campylobacter*, only some of the species are virulent (cause disease in humans). In other genera, not all strains within a species are virulent, but some strains cause disease. The best example of this is the genus

*Escherichia*. The pathogenic species is *E. coli*, but not all strains of this species cause disease. In fact, the majority of *E. coli* are harmless residents of human and animal gastrointestinal tracts. Thus, they can act as markers of fecal contamination. Only when an *E. coli* strain acquires a virulence factor will it cause disease. New virulence factors may be acquired through DNA exchange (such as the Shiga toxin-producing *E. coli* O157:H7). As mentioned above, this genetic exchange also occurs in other enteric pathogens, such as *V. cholerae*, *Yersinia*, and *C. jejuni*. Bacteria with newly acquired virulence factors are examples of emerging pathogens.

Bacteria capable of causing water-borne infections are described below.

*C. jejuni* are Gram-negative, comma-shaped bacteria. They can infect humans and a variety of animals. They are found in the intestinal tracts of many warm-blooded animals and are a common cause of gastrointestinal illness. Disease may be severe, with bloody diarrhea that sometimes requires hospitalization.

*Aeromonas* spp. are Gram-negative rods found in the environment worldwide. Most human infections are thought to originate from food sources and the role of water-borne sources is not clear. Evidence linking *Aeromonas* to diarrhea is still not definitive, but when isolated by diagnostic laboratories from extra-intestinal sites, these bacteria are considered to be pathogens. Infection of wounds, for example, follows a breach of human skin or mucosal surface then contact with contaminated water or soil.

*Legionella* are Gram-negative bacteria that require special nutrients to reproduce in vitro. Over 25 species of *Legionella* have been identified, many of which can cause a type of pneumonia called legionnaires' disease. (*L. pneumophila* accounts for most cases of legionnaires' disease.) The disease is most probably the result of inhaling aerosols of water containing the micro-organism. Legionnaires' disease may be severe. *Legionella* can also cause a milder, non-pneumonic illness called Pontiac fever.

*Pathogenic E. coli* are rod-shaped, Gram-negative bacteria. Only 11 of the more than 140 existing serotypes of *E. coli* cause gastrointestinal disease in humans. The others are normal resident flora of human and animal intestinal tracts. Thus, as one of the fecal coliform group, *E. coli* is used in the laboratory as a marker of fecal contamination. Some strains carry additional genes that result in virulence. As previously discussed, one of these serotypes, *E. coli* O157:H7, is a major cause of bloody diarrhea. It may also cause systemic illness, such as

renal (kidney) or hematological (blood) disease. Other serotypes may also produce the same Shiga toxin.

*Salmonella* are rod-shaped, Gram-negative bacteria. They are a common cause of human disease. Over 2,200 known serotypes of *Salmonella* exist; all are pathogenic to humans. Most cause gastrointestinal illness with diarrhea. A few, however, can cause other more serious types of disease, such as typhoid (*S. typhi*) and paratyphoid fevers (*S. paratyphi*).

*Shigella* are rod-shaped, Gram-negative bacteria with four main species (*S. sonnei*, *S. flexneri*, *S. boydii*, and *S. dysenteriae*). They infect only humans and primates, and diarrhea may be severe. Bacillary dysentery (bloody diarrhea with abdominal cramps and fever) occurs in some people.

*V. cholerae* are comma-shaped, Gram-negative bacteria. They are found in humans and are passed in their feces. *V. cholerae* bacteria cause cholera and severe intestinal disease, with massive watery diarrhea, vomiting, dehydration, and other symptoms. Death may occur in several hours. Epidemics occur in developing countries.

*Y. enterocolitica* are Gram-negative bacteria that cause acute gastrointestinal illness with relatively mild diarrhea. They are found in humans, pigs, and other animals. *Yersinia* are unusual bacteria in that they can grow at temperatures as low as 4°C (39°F).

In the emerging-disease paradigm, entirely new genera and species of bacteria are now recognized as having the potential for water-borne spread. Two examples of this are *H. pylori*, known for its ubiquitous infections and associations with intestinal cancers, and *Mycobacterium avium-intracellulare* (*M. avium* and *M. intracellulare*), which cause respiratory and systemic disease primarily in immunocompromised hosts.

*H. pylori* was, until recently, considered part of the *Campylobacter* group. This micro-organism has been closely associated with peptic ulcers, gastric carcinoma, and gastritis. *H. pylori* probably infects only humans and a few animals, but little is understood about the epidemiology of *H. pylori*'s transmission. Infections are prevalent worldwide.

*M. avium* and *M. intracellulare* are not well characterized by the Gram stain (they take it up unreliably because they have a high lipid content in their coat). Being closely related to *M. tuberculosis*, they are stained using another chemical.

Because they retain the dye after exposure to acid, they are called acid-fast bacteria. *M. avium* and *M. intracellulare* are opportunistic in that they cause disease (systemic illness or respiratory illness) almost always in persons with underlying immunodeficiencies (either AIDS or chronic respiratory disease). These micro-organisms are relatively slow growing and therefore may be easily overgrown by other bacteria in laboratory cultures.

### 3.3.3 Parasites

Parasites are the largest micro-organisms, apart from the Microsporidia group (more than 3  $\mu\text{m}$  in size). They are classified as eukaryotes because of their complex cellular structure. However, relatively little research has been carried out on this challenging group of micro-organisms. There are two types of parasites that have a major impact on human health: the helminths, or worms, and the protozoans. Protozoans are unicellular and divide by binary fission. Helminths are more complex, multi-organ worms. Protozoans and helminths are the major types of water-borne parasites. In general, the transmission of helminths by water has not been studied.

Parasites are characteristically resistant to the standard levels of disinfecting chemicals used for bacteria. They persist for long periods of time in water and have a rich zoonotic niche (zoonoses are infections in animals that can also cause infections in humans). Another important characteristic of protozoan parasites is that, unlike most of the other groups of micro-organisms, they do not reproduce outside the host (i.e., in the environment or in the laboratory). This and the lack of surrogate tests make laboratory detection of parasites in water samples more difficult than detecting bacterial or viral pathogens.

The parasites most frequently associated with water-borne disease outbreaks are described below.

*Giardia lamblia* (syn. *intestinalis*) is a protozoan that has a two-stage life cycle. The active growing form (trophozoite) is found in the gut of infected humans and animals, while the resting stage (cyst) is found in the environment.<sup>83</sup> *G. lamblia* cysts (8–10  $\mu\text{m}$ ) are oval-shaped and are excreted in the feces of humans, numerous animals, and birds. Infection (giardiasis, commonly called ‘beaver fever’) may result in gastrointestinal symptoms, such as diarrhea,

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<sup>83</sup> Cysts (*Giardia*) are formed by asexual reproduction in the gut of the host animal.

abdominal cramps, and malaise. Individual *Giardia* strains differ in virulence and infectivity.

*C. parvum*, and most recently other species of *Cryptosporidium*, such as *C. felis* and *C. megalidis*, may cause infections in humans. This protozoan was only recently recognized as causing illness in humans, although it was well-known to cause disease in young domestic animals. The oval oocysts (3–5 µm) are excreted in feces.<sup>84</sup> It is at this stage that *C. parvum* is found in the environment. Ingesting the oocysts results in infection of intestinal tract cells. In immunocompromised hosts, particularly those with AIDS, severe watery diarrhea may result. As yet, there is no medical treatment to shorten the course of this illness. Like *Giardia*, *Cryptosporidium* strains may differ in terms of virulence and infectivity, but further research is required.

*Cyclospora cayetanensis* (*C. cayetanensis*) is a newly identified protozoan parasite that is similar in shape to *Cryptosporidium*. It has caused several known water-borne disease outbreaks in the world and was originally thought to be a blue-green alga. Its oocysts are round or ovoid, and are 8–10 µm in size, larger than those of *Cryptosporidium*. *C. cayetanensis* oocysts are similar in form to *Cryptosporidium*'s oocysts. Symptoms of infection include watery diarrhea and abdominal cramping. *C. cayetanensis* has also caused large food-borne outbreaks worldwide.

*Entamoeba histolytica/dispar* is an amoebic parasite that causes amoebiasis. Cysts are excreted in human feces. When cysts are ingested, they infect the large bowel. Some strains (*histolytica*) are virulent and may be invasive. There are, however, no routine ways of distinguishing *histolytica* species from the non-virulent *dispar* species. Like the other protozoan parasites, culture is not routinely done. Most infections are acquired in developing countries.

*T. gondii* commonly infects mammals and birds, but its complete life cycle only occurs in wild and domestic cats. Infections are prevalent, but illness is rare. Symptoms include fever, swelling of the lymph glands in the neck, blindness and mental retardation in fetuses, and encephalitis in AIDS patients. An outbreak of toxoplasmosis in British Columbia (1995), which infected up to 3,000 residents, has been linked to municipal drinking water.<sup>85</sup>

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<sup>84</sup> Oocysts (*Cryptosporidium*) are formed by a more complicated process involving both sexual and asexual stages (the “oo” in oocyst signifies sexual reproduction).

<sup>85</sup> Bowie et al., 1997.



*Microspora* is a large group of protozoan parasites that are common in the environment, though there is little information about them. These parasites infect many animals, including insects, fish, amphibians, reptiles, birds, and mammals. Only two species are known to significantly affect humans: *Enterocytozoon bieneusi* and *Encephalitozoon intestinalis*. Both of these parasites can infect people who have AIDS.

### **3.4 Reported Water-borne Disease Outbreaks in Ontario and British Columbia**

Although water-borne diseases are regularly reported, such reports do not reflect all disease occurrences. Few people who experience gastrointestinal upsets seek medical attention, and few jurisdictions have active disease outbreak surveillance programs. Outbreaks are often not recognized, or, if they are, drinking water is not recognized as the source of infection. In addition, it is likely that a proportion of water-borne disease is endemic (always present) and consequently difficult to recognize. Therefore, the number of water-borne disease outbreaks and illnesses could be much greater than what is reported.

This is not unique to water-borne illnesses. Some outbreaks of disease from other sources likely also go unreported or unrecognized. In a review of the annual number of enteric disease outbreaks in Ontario from 1994 to 1998,<sup>86</sup> and in other reviews, the cause of a significant proportion of epidemics was unidentified agents. For outbreak data to be compared fairly, surveillance programs must be similar in design for each disease type being reported and in the scope of data gathering.

The following subsections discuss the reporting programs being used to document water-borne disease outbreaks in Ontario and British Columbia.

#### **3.4.1 Outbreaks in Ontario**

The Ontario Ministry of the Environment has been keeping a record of adverse microbiological water quality data since July 2000. To track specific disease

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<sup>86</sup> Ontario, Ministry of Health and Long-Term Care, 1999a, "Reported enteric disease outbreaks in Ontario, 1994 to 1998," *Public Health and Epidemiology Report Ontario (PHERO)*, vol. 10, no. 8 [online], [cited August 27, 1999], <[www.gov.on.ca/health/english/program/pubhealth/phero\\_199908.html](http://www.gov.on.ca/health/english/program/pubhealth/phero_199908.html)>.

outbreak history, the Ontario Ministry of Health and Long-Term Care maintains a database on disease outbreaks that are reported through the outbreak module of the Reportable Diseases Information System (RDIS). The system was started in 1990 and functioning as designed in 1993. *Public Health and Epidemiology Report Ontario (PHERO)* summarizes articles on outbreaks. Most of the articles before 1996 focused on food-borne diseases. In 1996, Health Canada organized national notifiable diseases (diseases that must be reported in Canada) into five categories, one of which is called Enteric, Food and Water-borne Diseases. As mentioned earlier, enteric diseases affect the gastrointestinal tract and include many food- and water-borne diseases. Water-borne diseases include diseases that result from drinking contaminated water.

In August 1999, *PHERO* published an article that presented data based on the RDIS.<sup>87</sup> In the five-year period from 1994 to 1998, there were 1,628 enteric outbreaks. Of these, an average of 54% had a laboratory-confirmed cause. The findings showed that viruses caused an overwhelming number of the outbreaks, and that the viruses were transmitted from person to person. The article concluded that a reporting bias was likely because outbreaks are better detected in institutional settings than in the community at large. Of the 1,628 enteric outbreaks, 1% (or 16 outbreaks) were the result of water-borne transmission. However, these outbreaks were never definitively determined to be associated with drinking water.

For comparative purposes, we looked at the two most recent reports from the U.S. Centers for Disease Control's (CDC's) *Morbidity and Mortality Weekly Report (MMWR)*.<sup>88,89</sup> According to these reports, drinking water accounted for an average of 36% of the outbreaks associated with both drinking water and recreational water. Applying this proportion to the Ontario example, we can estimate that approximately 6 of the above 16 water-borne disease outbreaks reported in Ontario between 1994 and 1998 would be associated with drinking water.

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<sup>87</sup> Ibid.

<sup>88</sup> United States, Centers for Disease Control, 1998, "Surveillance for water-borne disease outbreaks, 1995–96," *Morbidity and Mortality Weekly Report*, vol. 47 (SS-5), pp. 1–34.

<sup>89</sup> United States, Centers for Disease Control, 2000, "Water-borne disease outbreaks, 1997–98," *Morbidity and Mortality Weekly Report*, vol. 47 (SS-4), pp. 1–35.

### 3.4.2 Boil Water Advisories in Ontario

Since January 2000, the Ontario Ministry of Health and Long-Term Care has been keeping records of boil water advisories in a new database. Our efforts to obtain any information or records in the database for this report have been unsuccessful. In our view, such records should be made available to the public, since non-disclosure can lead to further mistrust of government's efforts to protect public health by controlling drinking water risks. Prior to January 2000, records would likely have resided only in the 42 local public health units throughout the province. The Ontario Ministry of Health and Long-Term Care does not know the status of their records for boil water advisories.

A fact sheet from the Ontario Ministry of Health and Long-Term Care states that a boil water advisory can be issued for a number of reasons. It may be based on a bacteriological (microbial) examination that finds bacteria or parasites. It may also follow a disease outbreak that is linked to drinking water. A 'precautionary' boil water advisory is based on information other than a bacteriological examination indicating that the water is not safe to drink.

The extent of the restriction on water use depends on the situation and on the reason for issuing the boil water advisory. Some major boil water advisories that have occurred in Ontario are described below.

#### 3.4.2.1 *Waterloo (1993)*

A cryptosporidiosis outbreak in the late spring of 1993 resulted in a boil water advisory for the Kitchener-Waterloo area. The area is served by the Mannheim Water Treatment Plant, which began operation earlier in 1993. The Grand River is its water source. The plant is a conventional surface water treatment plant and, at the time of the outbreak, used chemical coagulation, filtration, and chlorine disinfection. Treatment also included ozonation for taste and odour control.

Until this treated surface water supply was put on line, the Kitchener-Waterloo area had been served solely by groundwater. At the time of the outbreak, the plant was taken off line, but Grand River water continued to be treated and then sampled for *Cryptosporidium* oocysts. Once three successive samples were shown to be free of the oocysts, the plant went back on line. Ozonation continued to assist in the disinfection process. A later report on long-term

water quality planning for the Mannheim Treatment Plant suggested a 6-log (or 99.9999%) removal of *Cryptosporidium* oocysts, considering the water quality of the Grand River.<sup>90</sup> This degree of removal follows guidelines from the U.S. Environmental Protection Agency (EPA) for removals needed for raw waters of varying quality.

Another result of the outbreak was the suggestion that the population had developed some kind of immunity through exposure to *Cryptosporidium* oocysts. Other water supply systems downstream on the Grand River showed no increased disease level. People in Kitchener-Waterloo, however, who had normally been supplied by groundwater, showed an increased disease level when the new plant went on line.

### 3.4.2.2 *Temagami (1994)*

The town of Temagami draws its water supply from two separate water sources. Net Lake supplies Temagami North and Lake Temagami supplies Temagami South. Temagami experienced an outbreak of water-borne giardiasis from February to May 1994. Beavers were not implicated as the main source of contamination at Temagami South. Rather, contamination was traced to leakage from the sanitary sewer system into the lake, and was further aggravated by surface runoff following a winter thaw. The water treatment systems at both Temagami North and Temagami South used coagulation, filtration, and disinfection. However, in both systems there was inadequate contact time for disinfection to inactivate *Giardia*. At Temagami South, the situation was made worse because of operational problems; treated water from the plant was allowed to flow directly into the distribution system without any contact time for disinfection.

A giardiasis attack rate of 30% was reported based on symptoms noted in an extensive epidemiological survey.<sup>91</sup> A nearby control community had only a

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<sup>90</sup> Regional Municipality of Waterloo, 2000, Engineering Report, E03-20/4876-01:C06-60/EC/WSD.00, E-00-81, August 23, 2000 (Waterloo, Ont.) [online], [cited November 19, 2001], <clerkweb.region.waterloo.on.ca/scripts/Ipsiis.dll/CWAgendas/e-00-081.pdf>.

<sup>91</sup> P.M. Wallis, B. Primrose, and W. Robertson, 1998, "Outbreak of waterborne *Giardia* caused by sewage contamination of drinking water," *Environmental Health Reviews*, vol. 42, no. 2, pp. 44–51.

1.5% occurrence rate. A boil water advisory was issued on March 5, 1994. The advisory was lifted on May 18, 1994, after filtration efficiency was optimized and a free chlorine residual (the chlorine remaining, after reaction, to act as the disinfectant) was maintained in the distribution system for one and a half weeks. To avoid further outbreaks at the two plants, increased contact time to inactivate *Giardia* with chlorine and optimized coagulation and filtration were required.

#### **3.4.2.3 Collingwood (1996)**

Collingwood's water supply is obtained from Lake Huron (Georgian Bay). In 1996, its treatment consisted of chlorination with no coagulation, flocculation, or filtration processes. As a result of a cryptosporidiosis outbreak affecting 125 people in Collingwood, a boil water advisory was issued that lasted for almost a year until filtration facilities were established.

#### **3.4.2.4 Thunder Bay (1998)**

A boil water advisory for Thunder Bay, South Ward, was issued in mid-September 1997. The advisory was a response to the detection of *Giardia* cysts in the distribution system of the unfiltered Loch Lomond supply. While there was no evidence of an outbreak, there was an endemic level of giardiasis similar to that in other communities, including those with source water filtration. The local medical officer required a demonstration of measures and programs to reduce disease risk in the drinking water supply. Investigations into alternative disinfection practices included the use of chlorine dioxide followed by chlorine. A meeting was held with representatives of the Ontario Ministry of Health, the local medical health officer, and the Ontario Ministry of Environment to discuss options. Ultimately, the chlorine dioxide/chlorine application option was dropped in response to complications of a supply take-off to a First Nations community prior to the proposed chemical oxidant treatment and the desire not to add additional chemicals to the supply. The final outcome was a treatment system for the Loch Lomond supply that incorporated membrane filtration. A long-term consideration was the expansion of the Bare Point filtration plant, using Lake Superior as a raw water source. The boil water advisory was lifted early in the spring of 1998, once a temporary membrane filtration system was in place.

### 3.4.3 Outbreaks in British Columbia

British Columbia obtains most of its drinking water supplies from surface water sources, which are treated by chemical disinfection only. Outbreaks of acute water-borne infectious diseases have been well documented in British Columbia municipalities. Table 3.1 summarizes these outbreaks.<sup>92</sup>

The majority of outbreaks documented in the last two decades were caused by protozoan parasites, such as:

- *C. parvum*: 4 outbreaks
- *G. lamblia* (syn. *intestinalis*): 13 outbreaks
- *T. gondii*: 1 outbreak

Studies have shown that these parasites are widely distributed in wild and domestic animals.<sup>93,94,95,96</sup>

Bacterial pathogens, also recognized to be widespread in animals, caused numerous cases of infection in humans:

- *Campylobacter*: 6 outbreaks
- *Salmonella*: 2 outbreaks
- unidentified, infectious diarrheal agent: 4 outbreaks

In British Columbia, records of boil water advisories are available from 1986 to 1999. As Figure 3.1 shows, there has been an exponential increase in the number of advisories, peaking in the mid-1990s when several British Columbia communities experienced significant water-borne outbreaks, despite chemical disinfection.

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<sup>92</sup> Barry Boettger, Water Quality Consultant, B.C. Ministry of Health, Public and Preventive Health Division, Victoria, B.C. [personal communication with the authors, 2000].

<sup>93</sup> R. Fayer et al., 1996, "Spontaneous cryptosporidiosis in captive white-tailed deer (*Odocoileus virginianus*)," *Journal of Wildlife Diseases*, vol. 32, pp. 619–622.

<sup>94</sup> C.S.L. Ong et al., 1997, "An outbreak of cryptosporidiosis in Southeastern, B.C.," in *Proceedings of the 1997 International Symposium on Water-borne Cryptosporidium*, edited by C.R. Fricker, J.L. Clancy, and P.A. Rochelle (Denver, Col.: American Water Works Association), pp. 355–366.

<sup>95</sup> M.E. Olson, 1997a, "*Giardia* and *Cryptosporidium* in dairy calves in British Columbia," *Canadian Veterinary Journal*, vol. 38, no. 11, pp. 703–705.

<sup>96</sup> M.E. Olson et al., 1997b, "*Giardia* and *Cryptosporidium* in Canadian farm animals," *Veterinary Parasitology*, vol. 68, no. 4, pp. 375–383.

Table 3.1 Water-borne Disease Outbreaks in British Columbia, 1980–2000

| Year | Location                 | Local Health Authority | Organism   | Laboratory Cases | Clinical Cases | Epidemiological Estimate | Suspected Source |
|------|--------------------------|------------------------|--|------------------|----------------|--------------------------|------------------|
| 1980 | Nakusp                   | East Kootenay          | <i>Campylobacter</i>   | 12               |                | 800                      | Wildlife         |
| 1981 | 100 Mile House           | Cariboo                | <i>Giardia</i>   | 69               |                |                          | Beaver           |
| 1982 | Kimberley                | East Kootenay          | <i>Giardia</i>   |                  |                |                          | Wildlife         |
| 1984 | Chilliwack               | Upper Fraser           | <i>Salmonella</i>  | 82               |                |                          | Broken Watermain |
| 1985 | Greston                  | East Kootenay          | <i>Giardia</i>   | 72               |                |                          | Beaver           |
| 1986 | Penitcton                | Okanagan-Similkameen   | <i>Giardia</i>   | 362              | 497            | 3,125                    | Beaver           |
| 1986 | Penitcton                | Okanagan-Similkameen   | <i>Giardia</i>   | 109              |                |                          | Beaver           |
| 1987 | Black Mountain (Kelowna) | Okanagan-Similkameen   | <i>Giardia</i>   | 60               |                |                          | Wildlife/Cattle  |
| 1987 | Kamloops                 | Thompson               | <i>Campylobacter</i>   |                  |                |                          | Wildlife         |
| 1988 | Near Lytton              | Thompson               | <i>Salmonella</i>  |                  |                |                          | Wildlife         |
| 1990 | Klimate                  | Terrace                | <i>Giardia</i>   | 28               |                |                          | Beaver           |
| 1990 | Greston                  | East Kootenay          | <i>Giardia</i>   | 130              |                |                          | Wildlife         |
| 1990 | Fernie                   | East Kootenay          | <i>Giardia</i>   | 50               |                |                          | Wildlife         |
| 1990 | West Trail/Rossland      | Kootenay Boundary      | <i>Giardia</i>   | >40              |                |                          | Wildlife         |
| 1990 | Matsqui                  | Upper Fraser           | Unidentified   |                  |                |                          |                  |
| 1991 | Barriere                 | Thompson               | <i>Giardia</i>   | 25               |                |                          | Wildlife         |
| 1991 | Granisle                 |                        | Unidentified   |                  |                |                          |                  |
| 1991 | Fort Fraser              | Northern Interior      | Unidentified   |                  |                |                          |                  |
| 1992 | Kaslo                    | East Kootenay          | <i>Campylobacter</i>   | 10               |                |                          | Wildlife         |
| 1993 | Fernie                   | East Kootenay          | <i>Campylobacter</i>   | 35               |                |                          | Cattle           |
| 1995 | Victoria                 | Capital Health         | <i>Toxoplasma gondii</i>   | 110              |                | 3,000                    | Cats/Cougar      |
| 1995 | Revelstoke               | North Okanagan         | <i>Giardia</i> , <i>Campylobacter</i> , <i>Yersinia</i> , <i>Cryptosporidium</i> | 62; 71; 9; 4     |                |                          | Beaver/Wildlife  |
| 1996 | Cranbrook                | East Kootenay          | <i>Cryptosporidium</i>   | 29               | 107            | 2,097                    | Calves           |
| 1996 | Kelowna                  | Okanagan-Similkameen   | <i>Cryptosporidium</i>   | 177              |                | 10,000                   | Human            |
| 1996 | Valemount                | Northern Interior      | <i>Giardia</i>   | 10               |                |                          | Wildlife         |
| 1997 | Princeton                | Okanagan-Similkameen   | Unidentified viral   | 146              |                |                          | Sewage Break     |
| 1998 | Chilliwack               | Upper Fraser           | <i>Cryptosporidium</i>   | 19               |                |                          | Cattle           |
| 1998 | Camp Malibu              | Coast Garibaldi        | <i>Campylobacter</i>   | 26               |                |                          |                  |

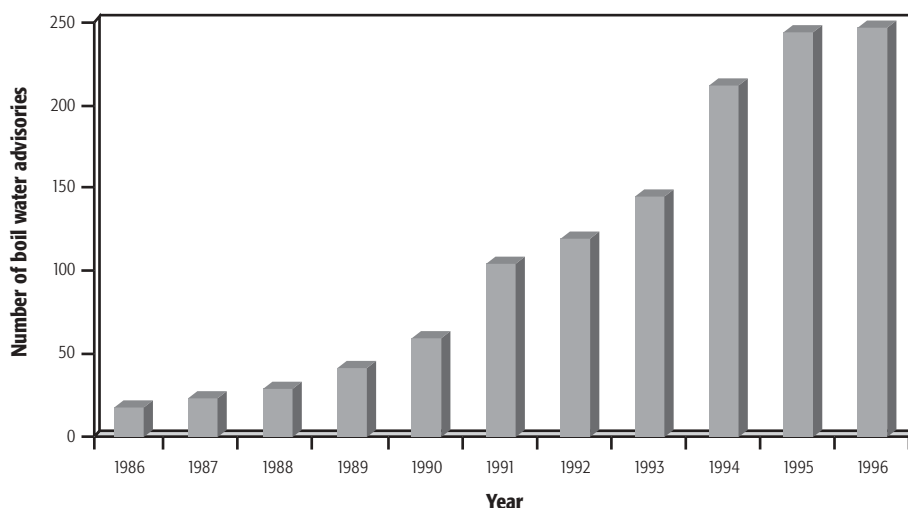
**Source:** B.C. Centre for Disease Control (BCCDC) Outbreak Co-ordination, Vancouver, B.C. [authors' files, updated November 22, 2000, BCCDC Laboratory Services]; and B.C. Ministry of Health and Ministry Responsible for Seniors, Public Health Protection Branch, Vancouver, B.C.

**Note:** In 1996, a cryptosporidiosis outbreak occurred in Penitcton, B.C. The provincial medical health officer decided that the burden of evidence did not support the conclusion that the outbreak was water-borne.

### 3.5 Outbreaks Across Canada

The (former) Health Protection Branch of Health Canada prepared annual summaries of food-borne and water-borne disease occurrence across the country. Its last published report presented water-borne disease data from 1992 to 1993.<sup>97</sup> Unpublished data for 1994 to 1995 are also available. (Data for the Canadian outbreaks described below are taken from these sources; more recent data have not been compiled.) The 1993 report summarizes the etiologic agents (causes), date of onset, source of the suspect water, the specific vehicle that carried the disease (e.g., river, lake, home well, or community supply), and clinical data. The etiology is broken down into specific agents: microbiological (bacterial and parasitic), chemical, probably microbiological, and unknown agents.

**Figure 3.1 Boil Water Advisories in British Columbia, 1986–1996**



**Source:** Barry Boettger, Water Quality Consultant, B.C. Ministry of Health, Public and Preventive Health Division, Victoria, B.C. [personal communication with authors, 2000.]

<sup>97</sup> Canada, Health Canada, 1993, *Food-borne and Water-borne Disease in Canada – Annual Summaries: 1992 and 1993* (Ottawa: Polyscience Publications Inc., in cooperation with the Health Protection Branch of Health Canada and the Canada Communication Group Publishing Services, Public Works and Government Services).



### 3.5.1 Outbreaks from 1992 to 1993

In 1992, there were 48 outbreaks and 1,402 cases of water-borne disease: 37 outbreaks occurred in Quebec, 7 in Saskatchewan, 3 in Ontario, and 1 in British Columbia. It is important to note that for the Ontario cases where giardiasis was identified, two cases were traced to individual home wells and the third to lake water.

Across Canada, outbreaks of water-borne disease in 1992 occurred as follows:

- *G. lamblia* (syn. *intestinalis*): 10 outbreaks
- *Campylobacter*: 4 outbreaks
- *Streptococcus*: 3 outbreaks
- Norwalk-like viruses: 3 outbreaks
- *Salmonella*: 2 outbreaks
- heavy metal: 2 outbreaks
- hepatitis A: 1 outbreak
- *Shigella*: 1 outbreak
- *Schistosoma*: 1 outbreak
- probable bacterial origin: 6 outbreaks
- unknown etiology: 15 outbreaks

The largest outbreak, which arose from wells contaminated with fecal coliforms from spring runoff, resulted in 500 cases of disease. Those who were ill had Norwalk virus in their stools.

Ten cases nationwide involved community systems, and five occurred at camps. Wells were specifically implicated in nine incidents, and seven outbreaks were associated with contaminated surface water. In two small outbreaks, contaminated shower water caused skin and eye irritation. Two other outbreaks were associated with contaminated swimming-pool water. In 1992, outbreaks were noted in every month, with more occurring in March, April, June, and July.

In 1993, there were 24 outbreaks and 521 cases of water-borne disease across Canada: 13 outbreaks occurred in Quebec, 6 in Ontario, 3 in Saskatchewan, and 1 each in British Columbia and New Brunswick. Of the Ontario outbreaks, one was caused by a rotavirus in an institutional well. The other outbreaks in Ontario were caused by *G. lamblia*: two associated with river or lake contamination, one traced to an individual home well, one linked to drinking

water in Venezuela (following an individual's travels there), and one for which the water source was not determined.

Across Canada, water-borne gastroenteritis outbreaks in 1993 occurred as follows:

- *Giardia*: 8 outbreaks
- *Campylobacter*: 2 outbreaks
- rotavirus: 1 outbreak
- probable microbiological origin: 5 outbreaks
- unknown etiology: 3 outbreaks

One death occurred as a result of *E. coli* O157:H7, which could have had non-potable water as its source. Surface water was implicated in six outbreaks, and wells were specified in two. No outbreaks of dermatitis from recreational activities occurred.

In 1993, incidents occurred throughout the year, with only slightly more noted in April and September.

### **3.5.2 Outbreaks from 1994 to 1995**

In 1994, there were 23 outbreaks and 617 cases of water-borne disease: 13 incidents occurred in Quebec, 7 in Saskatchewan, and 3 in Ontario. Two of the three Ontario outbreaks involved *Giardia*. The major giardiasis outbreak, which caused approximately 150 cases of illness, occurred as a result of contaminated drinking water. The municipality in which the outbreak took place was treating lake water that was heavily contaminated with sewage. A second giardiasis outbreak originated in a private home and a third in a church well; the latter was categorized as probably microbiological (*E. coli*).

Across Canada, outbreaks of water-borne disease in 1994 occurred as follows:

- hepatitis A: 4 outbreaks
- *Giardia*: 3 outbreaks
- *Campylobacter*: 1 outbreak
- *Cryptosporidium*: 1 outbreak
- *Shigella*: 1 outbreak
- probable bacterial origin: 10 outbreaks
- unknown etiology: 4 outbreaks

The largest outbreak involved 74 shigellosis cases associated with drinking water at a restaurant. Water was contaminated at several locations in the community. Those who were ill had *Shigella* in their stool samples. In 1994, outbreaks occurred in every month except September and December.

In 1995, there were 23 outbreaks and 314 cases of water-borne disease across Canada: 10 outbreaks occurred in Quebec, 6 in Ontario, 5 in Saskatchewan, and 2 in British Columbia. In Ontario, *Campylobacter* caused one outbreak associated with water from an individual home. No source for the water was given in that outbreak. *Giardia* caused three outbreaks associated with a community water supply, a camp, and an unknown situation. The causes of two other outbreaks were listed as unknown: one was traced to an individual home and the other to a health care facility.

Across Canada, outbreaks of water-borne disease in 1995 occurred as follows:

- *Giardia*: 6 outbreaks
- *Campylobacter*: 3 outbreaks
- hepatitis A: 2 outbreaks
- *Aeromonas*: 1 outbreak
- *Salmonella*: 1 outbreak
- probable bacterial origin: 6 outbreaks
- unknown etiology: 2 outbreaks

The largest outbreak, with 100 cases, occurred at a camp where non-potable water was consumed. Five to ten illnesses occurred each day over a two-week period. In 1995, outbreaks occurred every month except May, September, October, and December. The months in which three outbreaks occurred in 1995 was not reported.

### 3.5.3 The Reliability of Canadian Outbreak Data

As emphasized in subsection 3.4, it is critical that public health surveillance programs be thorough, report the same diseases, and have similar data-gathering systems. Since the information reported from 1992 to 1995 is incomplete, only qualitative comparative assessments can be made.

The number of acute cases of infection occurring at an endemic level (not associated with an outbreak or epidemic) is not known. It is probable that

endemic transmission is greatly underestimated for many reasons. First, an outbreak in the community is more dramatic and recognizable than the occurrence of individual cases. Second, many individual cases are not captured by public health surveillance systems. For example, cases are not reported when an individual does not visit a doctor. (Many people do not see their doctor for mild diarrheal illness.) If an individual *does* see a doctor, the case may not be sent for laboratory diagnosis because laboratory use may be tied to the physician's salary cap. Thus, laboratory identification and subsequent reporting are lost. Third, even when the law requires communicable diseases to be reported, case data are not always submitted. Thus, the public health reporting system breaks down.

The present public health surveillance system is inadequate in its scope and ponderous in its ability to effect a response. There is interest at both national and provincial levels to address surveillance issues. Recent studies using new tools to track infection at a population level have identified many cases that are *not* identified by current public health surveillance systems.<sup>98</sup> Applying these new tools may result in more active surveillance systems.

### 3.6 Outbreaks in the United States

In the United States, national statistics on outbreaks associated with drinking water have been available since 1971. The CDC, the EPA, and the Council of State and Territorial Epidemiologists have maintained a collaborative surveillance system of the occurrences and causes of water-borne disease outbreaks both in drinking and recreational water.

#### 3.6.1 Outbreaks from 1980 to 1996

The handbook *Water Quality and Treatment*, prepared by the American Water Works Association (AWWA), summarizes water-borne disease outbreak data from 1980 to 1996.<sup>99</sup> It notes that, despite many improvements related to

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<sup>98</sup> J. Isaac-Renton et al., 1999, "Epidemic and endemic seroprevalence of antibodies to *Cryptosporidium* and *Giardia* in residents of three communities with different drinking water supplies," *American Journal of Tropical Medicine and Hygiene*, vol. 60, pp. 578–583.

<sup>99</sup> American Water Works Association (AWWA), 1999, *Water Quality and Treatment*, 5th ed. (New York: McGraw-Hill).

wastewater disposal practices, surface water and groundwater protection, and the development, protection, and treatment of water supplies, increasing population and aging infrastructure still pose many threats to the delivery of safe drinking water.

From 1980 to 1996, there were 402 outbreaks with 500,000 associated cases of water-borne disease. The majority of these cases arose from a cryptosporidiosis episode in Milwaukee in 1993. As with many reporting systems, however, it is likely that a majority of water-borne outbreaks in the United States are not reported, since few states have an active disease outbreak surveillance program.<sup>100</sup> Consequently, disease outbreaks are often not recognized in a community or, if they are, are not traced to a drinking water source. A high of 52 outbreaks was reported in 1980, with a steady decline until 1992, when a slight increase to 28 outbreaks was reported. Outbreaks then continued to decline. Six outbreaks were reported in 1996.

The discrepancy between disease occurrences and disease reports may be lessening.<sup>101</sup> Greater public awareness of water-borne disease and greater media attention to drinking water problems may be factors in this change. Identifying new agents of water-borne disease and actively testing for them in drinking water supplies may also be factors. As well, improvements in sampling and analytical techniques have resulted in a better definition of water-borne disease etiology.

According to the AWWA's handbook, a number of micro-organisms were implicated in water-borne disease outbreaks from 1980 to 1996. Chemical contamination accounted for about 11.5% of disease outbreaks. The most prevalent diseases caused by micro-organisms for this time period were:

- undefined gastroenteritis
- giardiasis
- shigellosis
- gastroenteritis
- Norwalk virus
- campylobacteriosis
- hepatitis A
- cryptosporidiosis

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<sup>100</sup> Ibid.

<sup>101</sup> Ibid.

These diseases, along with those caused by chemical contamination, accounted for about 96% of all reported outbreaks. Gastroenteritis accounted for over 45% of reported outbreaks. The causative agent was not identified in about one-half of all reported outbreaks.<sup>102</sup>

Craun observed that most outbreaks are caused by the use of contaminated, untreated water or are due to inadequacies in treatment.<sup>103</sup> Craun notes that majority of outbreaks tend to occur in small systems.

### 3.6.2 Outbreaks from 1995 to 1998

The two most recent reports from the CDC's *Morbidity and Mortality Weekly Report (MMWR)* state that the number of water-borne disease outbreaks in 1995 was comparable to the reported number of outbreaks from 1987 to 1994, except for an increase in 1992.<sup>104</sup> The number peaked between 1979 and 1982. However, in 1996, the number of reports (six) was much lower than in previous years. The data for 1997 to 1998 follow this lower trend. Reasons for the 1979 to 1982 peak, the increase in 1992, and the recent decreasing trend may be due to changes in surveillance activities or in reporting. The lower number of reports could also be the result of new water treatment regulations being implemented, such as the EPA's *Surface Water Treatment Rule*<sup>105</sup> first announced in 1989.

More stringent EPA standards for acceptable turbidity values have been implemented in all states since the outbreak of cryptosporidiosis in Milwaukee in 1993. Many water utilities have increased efforts to produce drinking water of a higher quality than that required by regulations. As well, initiatives by public health officials have helped maintain consistently high-quality drinking water. Many of the larger drinking water utilities in the United States have joined the Partnership for Safe Water (an AWWA/EPA cooperative effort). The partnership helps treatment plants achieve low turbidity values in treated water, thereby lowering the risk of parasitic protozoan disease outbreaks, such as cryptosporidiosis and giardiasis.

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<sup>102</sup> Ibid.

<sup>103</sup> G.F. Craun, 1986, "Statistics of water-borne disease outbreaks in the U.S. (1920–1980)," in G.F. Craun, ed., *Waterborne Diseases in the United States* (Boca Raton, Fla.: CRC Press), pp. 73–159.

<sup>104</sup> United States, Centers for Disease Control, 1998 and 2000.

<sup>105</sup> 54 Federal Register 27486-27541 (June 29, 1989).

The 1997–1998 *MMWR* report states that drinking water outbreaks associated with surface water decreased from 31.1% during 1995 and 1996 to 11.8% during 1997 and 1998.<sup>106</sup> The report suggests that this reduction could have resulted from efforts by the water industry and more stringent regulation implementation. In contrast to the situation for surface water, the proportion of outbreaks in systems supplied by a groundwater source increased from 59.1% (13 outbreaks) during 1995 and 1996 to 88.2% (15 outbreaks) in 1997 and 1998. The report does not suggest a reason for this increase. (Many ‘groundwater’ supplies need to be defined either as ‘true groundwater’ or as ‘groundwater under direct influence of surface water.’ A set of rules to specify this definition is still under debate.)

In their conclusions, both *MMWR* reports state that ways to improve the surveillance system for water-borne disease outbreaks should be explored.<sup>107</sup> For example, reviewing information gathered through other mechanisms and programs (e.g., tracking boil water advisories and compiling computerized data about source and drinking water) could help detect such outbreaks when they occur. The reports also mention the need for special epidemiological studies to supplement the findings of the existing surveillance system. These studies would address such issues as the significance of newly identified agents of water-borne disease to public health, the effectiveness of prevention strategies in non-outbreak settings, and the timeliness with which state and local health departments act in response to these pathogens.

### 3.7 Current Issues and Future Directions

The reporting of water-borne disease and the determination of disease etiology are critical aspects of controlling health risks from drinking water. Both Ontario and Canada have programs for compiling data on food-borne and water-borne disease outbreaks. However, the reporting of water-borne diseases within Canada and Ontario has been somewhat sporadic and sometimes unclear as to source. Moreover, the information is often kept in different locations. This lack of sustained, coordinated reporting has not always promoted the use of disease outbreak information as a way to help control health risks from drinking water. Ontario and Canada need to obtain more specific information and to implement more timely reporting. By using the data, both jurisdictions could develop effective programs to reduce the risks associated with drinking water.

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<sup>106</sup> United States, Centers for Disease Control, 1998.

<sup>107</sup> United States, Centers for Disease Control, 1998 and 2000.

The United States maintains a more comprehensive reporting program than do either Ontario or Canada. It defines drinking water-related, water-borne disease outbreaks more specifically in terms of etiology, seasonal/geographic information, and other associated data. As mentioned in subsection 3.6.1, it is likely that a majority of water-borne outbreaks are not reported, since few states have an active disease-outbreak surveillance program. However, as the AWWA notes, this discrepancy between disease occurrences and disease reports may be lessening.<sup>108</sup>

### **3.7.1 Effective Public Health Surveillance Systems**

Comprehensive public health surveillance systems are important programs that can help jurisdictions responsible for the delivery of drinking water effectively allocate their resources to minimize risks. Opportunities exist in Canada and elsewhere to employ emerging public health surveillance systems in the detection and prevention of disease outbreaks. Such surveillance systems would be significantly more useful if they could be expanded to include other readily available information, such as the following.

- Geographical information: the type of drinking water source (e.g., lake, river, groundwater)
- Land use information: the activities on and uses of land adjacent to the water source or recharge area
- Drinking water program information: the types of broad-based programs that are in place, including information on approvals, treatment requirements, sampling, reporting and surveillance, and water supply facility inspections (supply risk analysis)
- Facility information: the size of a facility (outbreaks often seem to occur in smaller communities, so facility size may be related to the vulnerability of water supplies); the true cost of supplying drinking water supply
- Operational information: operator training and licensing status
- Pathogen information: the organism types causing the outbreaks and diseases reported (e.g., bacteria, protozoa, toxic algae)

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<sup>108</sup> Isaac-Renton et al., 1999.



Having access to such information in a database would enable jurisdictions to analyze the reasons for and the patterns of an outbreak. Thus, they could identify critical areas within their drinking water production systems and develop appropriate risk management policies (see also subsection 4.3.3, which discusses Hazard Analysis Critical Control Point). Capturing water quality reports in the same database, especially those reports that exceed standards, could indicate changes of, and impacts on, source or treated water. This information could also be used to identify critical areas that require policy or program development related to outbreak prediction and prevention.

The Cooperative Research Centre for Water Quality and Treatment in Australia (CRCWQT) is using a geographic information system (GIS) to capture promising data in terms of scope and accuracy, and to determine priority rank. Such technology might be explored further in Canada.

### **3.7.2 Sustainable Program Funding and Policy Development**

Ongoing funding of programs that directly affect drinking water is essential. These programs involve such critical areas as water supply and facility design approvals, treatment requirements, direct and indirect additives (e.g., treatment chemicals and materials used to store and transport drinking water), sampling, reporting and surveillance, and water supply facility inspections (e.g., supply risk analysis, Hazard Analysis Critical Control Point). Sustainable program funding can maintain the robustness of existing programs and ensure that needed policies and programs are developed. Sustainable funding can also ensure that policies are developed to regulate activities that affect drinking water indirectly, such as the use of land for urban, agricultural, and industrial development.

In the broader public health context, decision makers should evaluate health risk reduction and the related cost-effectiveness of various public health protection priorities. Such an evaluation will help them make appropriate decisions about policy development and program funding. The development of regulations based on water treatment and/or contaminant levels, together with management to ensure consistency, should always consider the costs associated with health risk reduction.

## 4 Measurement of Microbiological Water Quality

When discussing water quality measurement, it is important to distinguish routine monitoring from investigative testing. *Routine monitoring* involves a series of tests that are conducted frequently at various points in a water supply system.

*Investigative testing* involves special purpose testing programs that are designed to improve knowledge of the water supply system and to assist in longer-term management improvements.

Routine monitoring tests are designed to check that a water supply system is operating effectively, and that water of the desired quality is being produced. Routine monitoring includes those parameters that are specified under regulatory criteria (compliance monitoring). Test results outside normal background levels of variation for a given parameter suggest that a problem may exist. Such results should initiate further investigation, usually beginning with inspecting the affected part of the water supply system for faults or damage, then retesting and examining other relevant parameters. Given the function and frequency of routine monitoring, it is necessary that tests can be performed in large numbers, are reliable and not too technically complex, and are inexpensive.

Investigative testing may include baseline monitoring and event-based monitoring to identify and characterize hazards, develop effective controls, and improve performance. Investigative testing programs are carried out for defined time periods and may include more complex and expensive test methods.

Contamination of drinking water may arise because of the presence of potentially harmful microbiological, chemical, physical, and radiological agents. This section emphasizes detection and measurement of microbiological agents, and reviews current practices and some recent developments. A brief description of drinking water monitoring programs for chemical and physical parameters in Ontario and Saskatchewan is also included.

Additional information on methods used for the examination of water and wastewater can be found in the publication issued jointly by the American Public Health Association, American Water Works Association (AWWA), and the Water Environment Federation.<sup>109</sup>

<sup>109</sup> American Public Health Association, 1998, *Standard Methods for the Examination of Water and Wastewater*, 20th ed. (Washington, D.C.: American Public Health Association, American Water Works Association, and Water Environment Federation).

## 4.1 Pathogens and Indicator Organisms

Drinking water that is contaminated with human or animal fecal material may contain a wide range of pathogenic micro-organisms. As detailed in subsection 3.1, pathogens can be broadly divided into viruses (e.g., hepatitis A), bacteria (e.g., *E. coli* O157:H7), and protozoa (e.g., *Giardia*). Section 3 also outlines the effects that different types of pathogens can have on human health. Understanding the biological characteristics of each group of microbial pathogens is necessary for appraising the rationale behind drinking water testing methods and their limitations.

Based on current clinical knowledge and documented water-borne outbreaks, it appears that human enteric viruses in water supplies most probably result from human fecal contamination. Pathogenic bacteria that infect humans originate in both mammals and birds, while pathogenic protozoa appear to originate in humans and other mammals. Viruses and the major protozoal pathogens (*Giardia* and *Cryptosporidium*) are unable to replicate outside a suitable host. Common bacterial enteric pathogens can grow outside the host under suitable laboratory conditions, but are unlikely to grow to any significant degree in contaminated water.

### 4.1.1 Use of Indicator Organisms to Detect Contamination

When drinking water treatment was developed in the late 19th century, fecal contamination from humans and animals posed the greatest threat to water supplies. Thus, there was a need to test untreated water to determine whether such contamination had occurred, and to check treated water to ensure that contaminants had been successfully removed.

However, it soon became obvious that testing water for harmful micro-organisms was not a practical option. Little was known about organisms responsible for disease, and the methods for detecting them were complex and time consuming. Instead, public health microbiologists decided to search for micro-organisms that were always associated with fecal pollution but did not cause illness. They came up with the following desirable properties of such micro-organisms:

- They are always present in the feces of humans and animals.
- They are present in high numbers.

- They are easy to detect by simple and inexpensive methods.
- They are unable to multiply after they had left the body and entered the water supply.

Thus, the presence of ‘indicator’ micro-organisms could indicate that fecal contamination had occurred, and that fecal pathogens might also be present in the water supply. A series of indicator organisms was identified, and these became the basis of microbiological water quality monitoring around the world.

#### **4.1.1.1 *Escherichia coli***

*Escherichia coli* (*E. coli*) bacteria are found in the intestines of warm-blooded animals. *E. coli* does not come from environmental sources. For this reason, *E. coli* is a highly specific indicator of fecal contamination in drinking water. The vast majority of *E. coli* bacteria are harmless, and only a few relatively rare types are capable of causing disease in humans (see subsection 3.2).

#### **4.1.1.2 *Fecal coliforms***

Fecal coliforms make up a group of bacteria that includes *E. coli* and other intestinal bacteria. Fecal coliforms also include some bacteria that live in decaying vegetation and in agricultural or industrial waste. In some laboratories, a slightly different testing method is used; the bacteria detected are called thermotolerant (heat-tolerant) coliforms. Fecal coliforms and thermotolerant coliforms are essentially the same.

Fecal coliforms are less specific indicators of fecal contamination than *E. coli*, because they may arise from non-fecal and fecal sources.

#### **4.1.1.3 *Total coliforms***

Total coliforms make up a larger group of bacteria that includes *E. coli* and fecal coliforms. Total coliforms also include many non-fecal organisms that can grow in the environment. Total coliforms occur in much greater numbers in water sources than either fecal coliforms or *E. coli*, and for this reason changes in their numbers (e.g., die-off as a result of chlorination) are easier to detect.

However, total coliforms are not good indicators of fecal contamination, because they may originate from many sources other than feces.

#### **4.1.2 Development of Test Methods to Detect Indicator Organisms**

The methods used to detect indicator organisms have changed considerably since 1900. Microbiologists have long recognized that, among indicator organisms, *E. coli* provides the most specific indication of fecal contamination, since it originates only from feces.<sup>110</sup> However, in the early 1900s, no simple test was available to distinguish *E. coli* from other coliform bacteria. Observations that *E. coli* formed the majority of coliform bacteria in human feces, and that total coliforms were readily isolated from contaminated waters, led to the assumption that the presence of total coliforms reflected the presence of *E. coli*. Therefore, total coliforms were adopted as the standard indicator organism. At the time, sanitation standards were low, and gross fecal contamination of water supplies was not uncommon. Therefore, total coliforms were a reasonable surrogate for *E. coli*.

In 1948, a somewhat more specific test for fecal-thermotolerant coliforms was developed, and was soon adopted for general use in water quality monitoring. Testing for total coliforms was retained, however, because it had already gained wide acceptance.

##### **4.1.2.1 Test Methods Since 1990**

Changes in test methods since 1990 have led to a broader definition of coliforms, covering a wider range of bacterial species and including some that are primarily environmental in origin. Tests for total and fecal-thermotolerant bacteria were originally based on growth of the micro-organisms in the laboratory, and on their ability to produce both acid and gas from lactose fermentation. In 1994, microbiologists adopted a modified definition that stated only acid production from lactose fermentation was required for identification of coliforms. This change made the test technically simpler, but meant that additional species of bacteria were now included in the coliform group.

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<sup>110</sup> S.C. Edberg et al., 2000, "*Escherichia coli*: The best biological drinking water indicator for public health protection," *Journal of Applied Microbiology*, vol. 88, pp. 106S–116S.

Further developments in test methods were based on detecting the beta-galactosidase enzyme system that is responsible for the fermentation of lactose, rather than on detecting the acid produced from fermentation. These defined substrate technology (DST) methods used a colour change generated by the action of the beta-galactosidase enzyme system on various chemical analogues of lactose to detect bacteria. This methodology detects several additional species of bacteria that are not found using the methods described above. Thus, over time, the changing definition of coliforms has led to both the total coliform and fecal coliform groups becoming considerably broader and less specific as indicators of fecal pollution than they initially were.

As sanitation and water management practices in developed nations improved over the 20th century, the degree of fecal contamination of water supplies decreased and the proportion of total coliforms and fecal coliforms of fecal origin declined. Currently, the majority of total coliform micro-organisms detected in water supplies are of environmental rather than fecal origin.<sup>111</sup>

Since the development of these techniques in the late 1980s continuing refinements in DST methods have resulted in the development of a number of test kits that quickly and specifically identify *E. coli*.<sup>112</sup> These tests may be used in the field to indicate the presence or absence of *E. coli* or in the laboratory to provide a quantitative measure. Because of the availability of this method, a number of countries, including EU countries<sup>113</sup> and New Zealand,<sup>114</sup> have already moved to adopt *E. coli* testing and to discontinue fecal coliform testing.

Retaining total coliforms as an indicator organism is being questioned in many quarters, as it is clear that the presence of these micro-organisms no longer has a direct relationship with fecal contamination or with risks from fecal pathogens.<sup>115</sup> In 1998, the EU removed total coliforms as a mandatory, primary

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<sup>111</sup> M.J. Allen et al., 2000, "The plain, hard truth about pathogen monitoring," *Journal – American Water Works Association*, vol. 92, no. 9, pp. 64–76.

<sup>112</sup> S.C. Edberg et al., 1988, "National field evaluation of a defined substrate method for the simultaneous enumeration of total coliforms and *Escherichia coli* from drinking water: Comparison with the standard multiple tube fermentation method," *Applied Environmental Microbiology*, vol. 54, pp. 1595–1601. [Published erratum appears in *Applied Environmental Microbiology*, vol. 54, p. 3197.]

<sup>113</sup> European Union, 1998, *Drinking Water Directive*. Council Directive 98/83/EC on quality of water intended for human consumption. Adopted on November 3, 1998 [online], [cited November 19, 2001], <europa.eu.int/eur-lex/en/lif/dat/1998/en\_398L0083.html>.

<sup>114</sup> New Zealand, Ministry of Health, 2000, *Drinking Water Standards for New Zealand* [online], [cited September, 25, 2000], <www.moh.govt.nz/moh.nsf>.

<sup>115</sup> Allen et al., 2000.

indicator organism for drinking water monitoring.<sup>116</sup> Monitoring for total coliforms is no longer required in New Zealand,<sup>117</sup> and Australia is also reassessing of the role of this indicator organism.<sup>118</sup>

## **4.2 Measurement of Source and Finished Drinking Water Quality**

Currently, routine monitoring of water quality is based on the detection of indicator organisms that are surrogate markers of contamination. However, our knowledge of micro-organisms is incomplete, and our approaches to investigating microbiological contamination are imperfect. This section discusses both traditional and alternative approaches to routine monitoring.

Considerable advances in methods to detect pathogens have been made since the initial indicator organisms (discussed in subsection 4.1) were identified. Direct testing for pathogens, however, has not been adopted for routine monitoring purposes. The reasons for this are described below.

### **4.2.1 Traditional Approaches to Routine Water Monitoring**

#### **4.2.1.1 *Traditional Indicator Organisms***

Microbiologists consider that the traditional indicator organisms (fecal coliforms and *E. coli*) provide a good measure of potential health risks from bacterial pathogens. However, they correlate less well with viral risks and rather poorly with risks from protozoa.<sup>119</sup> The reasons for this relate to the biological and physicochemical properties of the different groups of pathogens. The bacterial pathogens are very similar to the fecal indicator bacteria in terms of their ability to survive in the environment and their response to water treatment methods. Therefore, contamination events or water treatment failures that lead to the appearance of these indicators in finished water supplies may also result in the appearance of bacterial pathogens. In contrast, both viruses and protozoa

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<sup>116</sup> European Union, 1998.

<sup>117</sup> New Zealand, Ministry of Health, 2000.

<sup>118</sup> P. Callan, Assistant Director, National Health and Medical Research Council/Agriculture and Resource Management Council of Australia and New Zealand, Health Advisory Section, Canberra, Australia [personal communication with the authors, 2000–01].

<sup>119</sup> G.F. Craun et al., 1997, "Coliform bacteria and waterborne disease outbreaks," *Journal—American Water Works Association*, vol. 89, no. 3, pp. 96–104.

tend to survive longer in the environment and have a higher degree of resistance to disinfection than do fecal bacteria. Thus, they may be present when bacterial indicators are absent.

#### 4.2.1.2 *Alternative Indicator Organisms*

Researchers have studied various alternative indicators in an attempt to provide better markers of viral and protozoal risks, and work continues in this area. For example, *Clostridium perfringens* is an anaerobic bacterium that can be grown in the laboratory, but, unlike coliforms, it produces environmentally robust spores. The properties of such spores are thought to more closely mimic the resistance of protozoan parasites to chemical disinfection and physical removal by water treatment processes, and for these reasons have been studied.<sup>120</sup>

Many other alternative indicators to total coliforms have been proposed, including enterococci, *Bacteroides fragilis*, Bifidobacteria, bacteriophages, and non-microbiological indicators such as fecal sterols. Of these alternative indicators, enterococci seems to have gained the most support.<sup>121,122</sup> However, some researchers have voiced similar concerns over low specificity for fecal contamination associated with the use of enterococci, as with total coliforms.<sup>123,124</sup> Despite the investment of considerable resources in the investigation of these potential new indicators, none has yet been accepted as being practical and broadly applicable for routine monitoring purposes.

#### 4.2.1.3 *Limitations of Routine Monitoring*

It is important to realize that routine monitoring of treated water quality (i.e., after water has left the treatment plant) can trigger a corrective response only after a problem has occurred and affected the finished product. Microbiological

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<sup>120</sup> D.L. Sorenson, S.G. Eberl, and R.A. Diska, 1989, "Clostridium perfringens as a point source indicator in non-point polluted streams," *Water Research*, vol. 23, pp. 191–197.

<sup>121</sup> L.W. Sinton, A.M. Donnison, and C.M. Hastie, 1993, "Faecal streptococci as faecal pollution indicators – A review. 2: Sanitary significance, survival and use," *New Zealand Journal of Marine and Freshwater Research*, vol. 27, pp. 191–197.

<sup>122</sup> United Nations, World Health Organization (WHO), 1996, *Guidelines for Drinking Water Quality*, 2nd ed., vol. 2: *Health Criteria and Other Supporting Documentation* (Geneva: WHO).

<sup>123</sup> Edberg et al., 2000.

<sup>124</sup> B. Pinto et al., 1999, "Characterization of faecal streptococci as indicators of faecal pollution and distribution in the environment," *Letters in Applied Microbiology*, vol. 29, pp. 258–263.



tests generally require incubation times of several to 48 hours, and if adverse test results are obtained, preliminary investigations to verify the problem are likely to take at least several hours more. Thus, by the time a public health response can be triggered (e.g., a boil water advisory), it is likely that people will have already consumed the affected water.

Routine monitoring is an essential component of water supply management, but it is not enough to protect public health. In this section, we have already stated that the role of routine monitoring is to verify that the components of the water supply system are operating correctly and that water of the desired quality is being delivered to consumers. Monitoring of this nature cannot be a preventive management tool because of the time delay between sampling and obtaining the result. For this reason, implementing intensive microbiological monitoring schemes that emphasize more frequent sampling of finished water may not be a cost-effective way to improve microbiological safety. More intensive microbiological sampling of finished water can improve future water quality only if it provides information that helps better system management.

#### **4.2.2 Other Approaches to Routine Water Monitoring**

Some jurisdictions are taking a new approach to finished water monitoring, linking monitoring frequency to evidence of water treatment plant performance. New Zealand's recently revised drinking water standards permit a 75% decrease in monitoring frequency for *E. coli* in a distribution system, provided that specified levels of free active chlorine (chlorine that has not yet reacted with any micro-organisms or other organic material) are continuously maintained in water leaving the water treatment plant.<sup>125</sup> Such levels must be demonstrated by daily chlorine measurements.

Ensuring the microbiological safety of drinking water necessitates balancing water source protection and water treatment techniques for a water supply with management of the distribution system to prevent recontamination of treated water. Due to the intermittent and often unpredictable nature of pathogen contamination, water system managers must emphasize a 'best practice' approach to produce water of consistent microbiological quality. Subsection 6.4.3 discusses the Australian framework for this preventive management approach.

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<sup>125</sup> New Zealand, Ministry of Health, 2000.

#### 4.2.2.1 *Limitations of Pathogen Testing*

The emergence of protozoal pathogens as major causes of water-borne disease has prompted renewed interest in the direct detection of pathogens in water rather than in monitoring for indicators. Microbiologists have developed a number of methods to detect protozoa and viruses. For protozoa, testing is most often based on microscopic identification of defined organisms, sometimes using immunological enhancements to identify the parasite. A number of molecular-based tests have also been developed to detect segments of protozoal genetic material. For some viruses, immunological and molecular techniques are also available for detection and identification.

All of these tests have deficiencies that limit their use for routine monitoring of drinking water supplies.<sup>126</sup>

- Pathogens are present only intermittently in source water supplies. While a large number of pathogens may be present in animal and human feces, the number of people infected with a specific pathogen in a particular population will vary over time as a consequence of changes in exposure, population immunity, and, perhaps, seasonal factors. The potential for pathogens to enter water supplies will also be influenced by catchment management practices and precipitation patterns. Therefore, it is not possible to know which pathogens will be present at any given time, nor how abundant they will be.
- When present, pathogens are usually in low numbers. Although an infected individual may excrete very large numbers of a pathogen, most individuals in a population will not be simultaneously infected. Thus, the infected material is likely to be 'diluted' by large quantities of non-pathogenic fecal micro-organisms and environmental micro-organisms. In contrast, fecal indicator organisms will always be present in much higher numbers in water contaminated by human or animal feces.
- Pathogen numbers in treated water are even lower. The degree of pathogen removal accomplished by water treatment depends on the specific system and the specific pathogen in question; however, reductions of several orders of magnitude are possible. Thus, reliable detection of pathogens in treated water requires water samples of much larger volume than that required

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<sup>126</sup> Allen et al., 2000.

for pathogen detection in source water. This is technically more difficult and expensive.

- Tests are subject to false positive and false negative results. All test methods have some limitations on their sensitivity and specificity, and thus may sometimes produce incorrect results. This is a particular problem when newly developed tests move from the research laboratory, with its high levels of expertise and quality control, to routine and more widespread monitoring situations, where lower levels of skill and quality control often prevail. This is not a straightforward process, and generally requires several years of development and troubleshooting to achieve an acceptable and reproducible standard of performance. Test methods for environmental samples pose a particular challenge as the composition of samples is extremely variable, with many contaminants that may potentially affect the test result. The difficulties experienced with methods for protozoa testing illustrate these problems.<sup>127,128</sup> There have been a number of incidents where public health alerts have been issued after the apparent detection of *Cryptosporidium* in water supplies, but investigations have thrown doubt on the test results, and no evidence of water-borne disease has been found.<sup>129</sup>
- Small numbers of samples result in significant statistical limitations on the interpretation of the result. Micro-organisms are not uniformly distributed in water, but follow a random statistical distribution. They may also exist as clumps rather than as single cells. One cannot measure a single sample and assume that the concentration detected is the average concentration of cells in the water source. Taking more samples can improve statistical accuracy. However, increasing the number of samples to detect pathogens is generally limited by cost and logistical considerations (e.g., laboratory capacity).
- The test result does not necessarily indicate whether the organism is able to infect humans (i.e., viability and infectivity may be uncertain). For bacterial pathogens, detection methods generally require growth, or at

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<sup>127</sup> J.L. Clancy et al., 1994, "Commercial labs: how accurate are they?," *Journal – American Water Works Association*, vol. 89 (May), pp. 89–97.

<sup>128</sup> F.W. Pontius and J.L. Clancy, 1999, "ICR Crypto data: worthwhile or worthless?" *Journal – American Water Works Association*, vol. 91, no. 9, pp. 14–22.

<sup>129</sup> J.L. Clancy, 2000, "Sydney's 1998 water quality crisis," *Journal – American Water Works Association*, vol. 92, pp. 55–66.

least some metabolic activity, so there is a reasonable assumption that the cells are viable and able to cause infection. However, for viruses and protozoa, tests are based on detecting physical components of the cell (e.g., genetic material or cellular structures) and do not necessarily indicate viability. For these organisms, viability and infectivity can only be reliably assessed by more complex techniques, such as tissue culture and animal infection, which are beyond the scope of routine testing.

- Test methods are generally quite technically demanding and therefore expensive. To illustrate cost differences, the costs of routine microbiological monitoring for indicator organisms (less than \$20 per sample for both fecal coliforms and total coliforms) may be compared with those for *Cryptosporidium* oocysts (several hundred dollars per sample).
- The delay between sampling and obtaining the result may be too long for timely public health action. Routine microbiological tests for indicators generally require a period of at least several hours, and more commonly one to two days to produce a result. Some specialized pathogen tests may take even longer. Notifying health authorities, conducting preliminary investigations, and deciding on appropriate public health action are likely to take several more hours. This means that in the event that pathogens are found in treated water, the affected water will probably reach customers and be consumed by many of them before a jurisdiction can initiate an action, such as a boil water advisory.

The limitations of pathogen testing have resulted in regulatory authorities in most countries not recommending routine testing for these organisms. A notable exception has been the UK. There the Drinking Water Inspectorate has imposed mandatory daily monitoring for *Cryptosporidium* on water supplies considered to be at risk of contamination. Where water supplies exceed the specified average concentration of oocysts (1 oocyst/10 L), water authorities may be subject to prosecution and an unlimited fine.<sup>130</sup> This legislation was developed primarily as a legal and political response to the failure of a court case against a water utility. However, the cost-effectiveness of such monitoring as a public health measure has been questioned.<sup>131</sup>

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<sup>130</sup> United Kingdom, Her Majesty's Stationery Office (HMSO), 1991, *The Water Supply (Water Quality) Regulations 1989* (Statutory Instrument 1989 No. 1147, as amended by Statutory Instrument 1989 No. 1384 and Statutory Instrument 1991 No. 1837) (London: Queen's Printer).

<sup>131</sup> C.K. Fairley et al., 1999, "Monitoring not the answer to *Cryptosporidium* in water," *Lancet*, vol. 354, pp. 967–969.

In the United States, the EPA mandated large water authorities to test source water for *Cryptosporidium* over an 18-month period. Such testing allowed the gathering of *Cryptosporidium* occurrence data, a component of the *Information Collection Rule*.<sup>132</sup> However, the specified test method was significantly flawed, and doubts have been expressed on whether the results have provided useful information for water quality management.<sup>133,134</sup> A further round of source water testing, using an improved method, will be required under the proposed *Long Term 2 Enhanced Surface Water Treatment Rule*. The results of this testing program will be used to assign water sources to risk categories, and a graded range of treatment requirements will then be required depending on the source water category. *Cryptosporidium* testing will not be required after the initial sampling program.<sup>135</sup>

While pathogen testing is generally considered to be of doubtful value for routine monitoring and day-to-day system management, it can form an important part of investigative monitoring programs. Such programs should be aimed at assessing the relative importance of pathogen sources in catchments and characterizing the conditions (e.g., extreme weather events) that may lead to elevated numbers of pathogens in source water. Investigative programs should also assess the impact of mitigation strategies, such as watershed protection, and should optimize water treatment processes.

### 4.2.3 Testing for Other Parameters

In addition to tests for indicator organisms, routine water monitoring generally tests for a range of other parameters that are relevant to assessing microbiological risks or provide information for day-to-day system management. These parameters are described below.

#### 4.2.3.1 Turbidity

Turbidity is a measure of the fine suspended or colloidal material in water, and is detected by the measurement of how much light is scattered when directed

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<sup>132</sup> 61 Federal Register (May 14, 1996).

<sup>133</sup> Pontius and Clancy, 1999.

<sup>134</sup> Allen et al., 2000.

<sup>135</sup> United States, Environmental Protection Agency (EPA), 2000, *Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee Agreement in Principle* [online], [cited December 29, 2000], <[www.epa.gov/EPA-WATER/2000/December/Day-29/w33306.htm](http://www.epa.gov/EPA-WATER/2000/December/Day-29/w33306.htm)>.

through a water sample in a standard measuring cell. Turbidity is dependent on the size, shape, and translucency of suspended particles in the sample. Such material tends to protect micro-organisms in water from the disinfecting action of chlorine, but there is no direct and reproducible relationship between turbidity and microbiological water quality. Elevated turbidity is evaluated in conjunction with more direct measures of microbiological water quality, such as indicator organisms.

Turbidity is measured in nephelometric turbidity units (NTU), and an aesthetic objective of 5 NTU has been set for water at consumer taps. The *Ontario Drinking Water Standards* (2000) set a maximum acceptable turbidity value of 1.0 NTU or less for water entering the distribution system. This value has traditionally been accepted as being sufficiently low to ensure that adequate disinfection can be achieved. However, well-operated modern filtration plants are able to produce water with very low turbidity in the range of 0.1 to 0.3 NTU.

Waterborne disease outbreaks have sometimes been associated with rises in turbidity, either due to highly contaminated source water overwhelming treatment capability, or failures in treatment processes that result in suboptimal removal of pathogens. Even short periods of suboptimal filter performance may be associated with health risks; therefore, emphasis on the need to maintain continuous filter performance has been increasing.

Frequent or continuous measurement of turbidity from individual filters in water treatment plants is now widely used to monitor the effectiveness of filtration and to maintain optimum operating conditions. In this context, increases in turbidity may be a sign of impending filter 'breakthrough,' which may allow pathogens retained in the filter medium to enter the filtered water supply.

In the United States, the *Interim Enhanced Surface Water Treatment Rule* specifies turbidity requirements for different types of filtration systems. For conventional and direct filtration systems, the turbidity level of representative samples of a system's combined filter effluent water must be less than or equal to 0.3 NTU in at least 95% of the measurements taken each month. The turbidity level of representative samples of a system's filtered water must never exceed 1 NTU.

For slow sand and diatomaceous earth filtration, the turbidity level of representative samples of a system's filtered water must be less than or equal to 1 NTU in at least 95% of the measurements taken each month, and the turbidity

level of representative samples of a system's filtered water must never exceed 5 NTU (unchanged from the combined filter effluent turbidity requirements in the 1989 *SWTR*). For both the maximum and 95th percentile requirements, compliance is determined based on measurements of the combined filter effluent at four-hour intervals. The EPA will require further improvements in filter performance including monitoring and turbidity limits for individual filters within treatment plants when the *Long Term 1 Enhanced Surface Water Treatment Rule* takes effect.

Filtration is presently the primary barrier against disinfectant-resistant pathogens such as *Cryptosporidium*, and filter performance in compliance with the *Interim Enhanced Surface Treatment Rule* is considered to provide a 2-log removal of such organisms. Filtration plants that consistently maintain even lower levels of turbidity (e.g., 0.1 NTU) would be expected to achieve a higher degree of removal.

#### **4.2.3.2 Particle Counting**

Particle counting is not currently used on a routine basis in most water supplies. However, it has been increasingly recognized as a way to monitor the performance of water treatment plants, and – like turbidity monitoring – provides an early indication of problems with filtration processes.

#### **4.2.3.3 pH**

The pH of water is a measure of its acidity or alkalinity. While a fairly wide pH range is acceptable in terms of the palatability of drinking water, pH influences the dose needed for disinfection and the timing of that dose. It is routinely monitored for this reason.

#### **4.2.3.4 Temperature**

Temperature also affects the disinfection process and is monitored for the same reason as pH is.

#### **4.2.3.5 *Free and Total Chlorine***

In chlorinated water supplies, routine measurements are made of free (available) and total chlorine<sup>136</sup> to check that adequate disinfection has been achieved, and that the desired disinfectant residual level is maintained.

### **4.3 Design of Routine Monitoring Programs**

#### **4.3.1 Current Design of Monitoring Programs**

Currently, water quality monitoring programs are designed to incorporate the following.

- Frequency of samples: Sampling is generally conducted on a weekly basis, with the number of samples taken based on the size of the population served by the water supply.
- Location of samples: For compliance purposes, most regulatory bodies require that samples represent the quality of water supplied to the consumer. Therefore, samples must be taken at a number of points in the distribution system where consumers are located.
- Selection of test methods: In order to ensure comparability of results between water supplies and laboratories, standard test methods are specified.
- Quality control of all stages of sampling, transport, testing, and reporting: Good laboratory practice requires that testing be carried out in a uniform manner with adequate documentation and quality control. Again, this ensures accuracy and comparability of results.
- Laboratory or method certification/accreditation: Regulatory authorities may require or recommend that tests be carried out only by laboratories

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<sup>136</sup> When chlorine is added to drinking water, it reacts or combines with substances, including living cells, already present in water. Some of these chlorinated compounds (e.g., chloramines) are effective in destroying micro-organisms; chlorine that is bound but still effective is called 'combined chlorine.' The disinfectant remaining, once the 'chlorine demand' has been satisfied, is called the 'chlorine residual' or 'free available chlorine.' 'Total chlorine' is the sum of the free available chlorine and combined chlorine.



with specific certification to ensure an externally verified level of proficiency.

- Costs and availability of resources: Monitoring programs are considered in the context of available resources, and are designed to provide necessary and useful information in a cost-effective manner.

Water quality standards and guidelines generally include requirements or recommendations on sample locations and frequencies, and on the manner in which compliance is assessed (e.g., running averages). In addition to carrying out the sampling program required for assessing regulatory compliance, water authorities may also choose to do additional monitoring of the same parameters or additional parameters for their own operational purposes.

#### **4.3.2 Monitoring Within a Total Quality Management System Framework**

Water quality monitoring may be considered within a Total Quality Management System (TQMS) framework. Industry has effectively used TQMS as a quality driver, and the framework has international scope. Clinical and environmental laboratories throughout North America are using various forms of TQMS. The National Committee for Clinical Laboratory Standards (NCCLS) has recently published guidelines for use of TQMS in diagnostic laboratories. Use of the ISO system of the International Organization for Standardization is becoming a measure of the overall quality of an environmental testing laboratory.

Ten elements are considered in a TQMS framework: (1) Organization, (2) Personnel, (3) Equipment, (4) Purchasing and Inventory, (5) Process Control, (6) Documents and Records, (7) Occurrence Management, (8) Internal Assessment, (9) Process Improvement, and (10) Service and Satisfaction. Within this framework, each laboratory test method may be considered in the following phases or stages:

- pre-analytical phase (sampling, transporting samples, ordering test);
- analytical phase (laboratory testing or testing); and
- post-analytical phase (reporting, communicating).

#### 4.3.2.1 *Pre-analytical Phase of Testing*

Standardization of sampling, transport, and storage conditions is important in any analytical context, but it is particularly critical for microbiological testing. Some micro-organisms are able to grow in water samples, thus producing a spuriously high result, or false positive. Conversely, some micro-organisms may die or deteriorate in samples, producing a spuriously low result, or false negative. The aim is to ensure that the sample reaches the analytical phase with as little alteration as possible in microbiological content from the time it was taken from the water supply. Generally, samples should be stored and transported at 4°C and tested within 24 hours of collection. In larger urban centres, samples are normally delivered to the testing laboratory within six hours of collection.

*Sampling and transport for turbidity testing* Turbidity is a relatively stable parameter. Therefore, the time between sampling and testing, and the conditions of transport, are less critical than for microbiological tests.

*Sampling and transport for bacterial indicators* Time considerations are important as some bacteria will multiply over time and produce falsely elevated concentrations (above acceptable standards) if they are delayed in transport to the laboratory. In some jurisdictions, sampling frequency may be connected to turbidity levels; high turbidity counts precipitate more bacterial sampling. Separate sampling is required for microbiological samples (another sample is needed for chemical testing).

For bacterial indicator testing, small volumes (usually 100 mL) are sampled. Aseptic collection techniques and sterilized collection bottles are required, and any disinfectant residual in the water must be neutralized (otherwise the disinfectant would continue to kill micro-organisms during transport and storage).

*Sampling and transport for specific pathogens* Specific pathogen sampling has the same constraints as bacterial indicator sampling and transport. Samples are time sensitive. Delays in transport may result in the overgrowth of non-pathogenic bacteria and produce a false negative. Thus, some pathogens that are present will not be detected. Time sensitivity is not as critical with parasites, such as *Cryptosporidium* and *Giardia*, because parasites do not multiply outside the host. Once present in the environment, their dormant but viable forms (oocysts and cysts) are persistent. Concentrations of parasites are low, and large-volume samples (380 L for untreated water) are recommended. Transport of these large volumes makes filtration and collection of filtrates in the field

necessary. Very little is understood about the survival dynamics of pathogenic viruses in water.

Sample collection procedures should be specific and well documented. Staff must have access to these written procedures and should be adequately trained. For most microbiological testing, a sample is sent to the laboratory along with a requisition form. Accuracy is imperative, and sample information must include correct identification of the sample site, the collection time of the sample, the name of the ordering agency, and the contact persons. In many jurisdictions that deal with large numbers of regular sampling, electronic communication is being developed. For example, the B.C. Centre for Disease Control (BCCDC) Laboratory Services is exploring an electronic data interchange with computer ordering, bar coding of samples, and electronic reporting of results.

#### **4.3.2.2 *Analytical Phase of Testing***

Analysis should be carried out by specified methods using appropriate materials and equipment that have been properly maintained and calibrated. Staff should be properly trained in laboratory methodologies and in the operation of equipment.

*Turbidity testing* With the trend toward using lower turbidity levels for monitoring filter performance, it is important that turbidity meters are designed and calibrated to measure in the appropriate range and with the desired degree of accuracy.

*Bacterial indicator testing* A number of different testing methods for indicator bacteria are available. Multiple tube fermentation and membrane filtration techniques are the most commonly used laboratory methods. Increasingly, laboratories are adopting more rapid methods using defined substrate technology (DST) systems and multi-well plates to obtain a result more quickly and to reduce costs.

*Laboratory pathogen testing* Laboratory methods to detect pathogens characteristically include three general steps: concentration, separation, and characterization.

- **Concentration:** Because the numbers of pathogenic micro-organisms are generally low in water, techniques such as centrifugation, filtration, and chemical methods are used to concentrate the pathogens.

- **Separation:** Because pathogens may be mixed with numerous other non-pathogenic micro-organisms or debris, techniques such as density gradients, differentiation growth behaviours, and, most recently, antibody capture and flow cytometry are used to separate pathogens from other micro-organisms.
- **Characterization:** Once the pathogen has been concentrated and separated from other components of the water sample, it can be characterized using techniques such as culture, biochemical differentiation, microscopy, and, most recently, nucleic acid methods.

The specifics of direct testing methods vary with each microbial group and genus. There is no single method that can be applied to all bacterial water-borne pathogens.

Several general components in laboratory testing must be included as part of the TQMS approach. Laboratories carrying out reliable testing should participate in an external proficiency-testing program conducted by an independent body. Proficiency testing programs should be available for both water bacteriology and pathogen-specific testing. Certification of laboratories carrying out health-related testing is also a necessary element of TQMS. Certification requires inspection of facilities, equipment, and procedures, as well as assessment of external proficiency test results.

In British Columbia, water suppliers, private laboratories, and the BCCDC Laboratory Services carry out testing for microbial contamination. Under the authority of the British Columbia provincial health officer, a drinking water microbiological advisory committee carries out a certification program for all testing laboratories that report microbial results to the ministry. Members of the committee include water suppliers and public health persons. The committee reports to the provincial health officer.

#### ***4.3.2.3 Post-analytical Phase of Testing***

*Maintenance of records* Staff should keep adequate records to track samples, such as recording when the sample was collected, when it arrived at the laboratory, and when it was tested. Records should also include the names of staff performing the tests and relevant information about materials and equipment used in testing that might help explain anomalous results if they occur.

*Reporting responsibilities and methods* Procedures should be clearly established and documented to cover reporting responsibilities. Such procedures should detail the timelines for reporting results and the automatic triggering of follow-up or confirmatory tests. They should also specify the format of reports (e.g., telephone, fax, paper, or electronic).

*Notifications* Requirements for notifying water authorities and regulatory agencies of test results should also be documented and up-to-date contact details maintained.

*System of audits in British Columbia* Blind checks are conducted by British Columbia public health officials.

#### **4.3.3 Monitoring Within a Watershed-to-Tap Testing Framework**

Measurements of water quality may be considered in a Hazard Analysis Critical Control Point (HACCP) watershed-to-tap framework. The Australian Framework for Management of Drinking Water Quality (see subsection 6.4.3) incorporates the principles of HACCP. The focus of HACCP, developed as a generic, scientifically based system to ensure safe food production, is on critical control points. Critical control points (CCP) are points at which a failure will result in significant harmful events. Recent application of HACCP principles to drinking water supplies acknowledges the importance of water source quality, but identifies drinking water treatment as the prime CCP.

Water-borne cryptosporidiosis, reviewed from the HACCP perspective, identifies several possible CCPs. Protecting drinking water quality may take a multiple-barrier approach. That is, watershed-to-tap protection would involve testing raw water (watershed, source, and untreated supplies), testing treated water at defined points in the effluent stream, and testing within the distribution system. (Jurisdictions would have to consider the usefulness and interpretation of each test for different types of water, as well as variations in sampling frequencies and standards.)

A report on drinking water by the auditor general of British Columbia identified the lack of inter-jurisdictional communication,<sup>137</sup> and a committee representing seven ministries and two agencies was subsequently established. (See

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<sup>137</sup> British Columbia, Office of the Auditor General, 1998/1999, *Protecting Drinking-Water Sources*, Report 5 (Victoria, B.C.: Queen's Printer).

subsection 6.3 for more information on this report.) This committee reports to a standing committee of the British Columbia Legislative Assembly. Issues related to water testing should be considered by this committee. Microbial testing should be reviewed in a HACCP system by an inter-jurisdictional body.

#### 4.4 Measuring the Effect of Water Quality on Human Health

Water-borne outbreaks can have severe health effects and major economic impacts on affected communities. However, such events are rare. In recent years, questions have been raised about the possible involvement of water-borne pathogens in endemic disease, particularly gastroenteritis, even in supplies that meet conventional microbiological water quality criteria.<sup>138</sup> Endemic gastroenteritis refers to the amount of illness that occurs at relatively constant levels in a community, but the overall burden of illness and accompanying economic impact are very large. The pathogens that contribute to endemic gastroenteritis may potentially be transmitted by several routes, including drinking water, recreational water, food and beverages, person-to-person contact, animal-to-person contact, and indirectly through environmental contamination. Identification of the relative contribution of different factors is difficult and requires specific epidemiological studies.

A number of approaches have been adopted in an attempt to address this issue by measuring the effect of water quality on human health. These studies include:

- randomized but unblinded trials of point of use (POU) water treatment devices comparing gastroenteritis rates in people drinking highly treated water and normal tap water;<sup>139,140</sup>
- one randomized blinded trial of POU water treatment devices comparing gastroenteritis rates in people drinking highly treated water and normal tap water;<sup>141</sup>

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<sup>138</sup> P. Payment et al., 1991, "A randomized trial to evaluate the risk of gastro-intestinal disease due to consumption of drinking water meeting current microbiological standards," *American Journal of Public Health*, vol. 81, pp. 703–708.

<sup>139</sup> Payment et al., 1991.

<sup>140</sup> P. Payment et al., 1997, "A prospective epidemiological study of gastro-intestinal health effects due to the consumption of drinking water," *International Journal of Environmental Health Research*, vol. 7, pp. 5–31.

<sup>141</sup> M.E. Hellard et al., [2001], "A randomized blinded controlled trial investigating the gastro-intestinal health affects of drinking water quality," *Environmental Health Perspectives*, in press.

- serological surveys of *Cryptosporidium* antibodies in communities with different types of water supplies (e.g., groundwater vs. surface water);<sup>142</sup>
- time series serological studies of *Cryptosporidium* antibodies before and after changes in water treatment;<sup>143</sup> and
- studies of the relationship between water turbidity and rates of gastroenteritis in a community.<sup>144,145</sup>

To date, the studies have yielded conflicting results, and it is not clear whether micro-organisms in drinking water contribute to endemic gastroenteritis. It is possible, of course, that significant amounts of endemic illness may exist in some water supplies but not in others because of differences in microbiological water quality. While gastroenteritis imposes a significant morbidity and economic burden on a community, the costs of widespread improvements in water treatment are also potentially very large. Given the importance of the issue, jurisdictions should carefully assess the evidence and ensure that further well-designed studies are conducted to provide a better understanding of the relationship between water quality and health. This will allow regulatory authorities to make informed decisions about the levels of water treatment required for different qualities of source water, and to develop appropriate standards and guidelines to protect public health.

## 4.5 Drinking Water Monitoring in Ontario and Saskatchewan

### 4.5.1 Ontario

In August 2000, Ontario introduced the *Drinking Water Protection Regulation* (DWPR).<sup>146</sup> (See Appendix A1 for initiatives associated with the DWPR.) The

<sup>142</sup> Isaac-Renton et al., 1999.

<sup>143</sup> F.J. Frost et al., 2000, "A serological survey of college students for antibody to *Cryptosporidium* before and after the introduction of a new water filtration plant," *Epidemiology and Infection*, vol. 125, pp. 87–92.

<sup>144</sup> J. Schwartz et al., 1997, "Drinking water turbidity and paediatric hospital use for gastrointestinal illness in Philadelphia," *Epidemiology*, vol. 8, pp. 615–620.

<sup>145</sup> J. Schwartz et al., 2000, "Drinking water turbidity and gastro-intestinal illness in elderly Philadelphia," *Journal of Epidemiology and Community Health*, vol. 54, pp. 5–51.

<sup>146</sup> *Drinking Water Protection Regulation*, O. Reg. 459/00, under the *Ontario Water Resources Act*, RSO 1990, c. O-40, as am.

regulation specifies mandatory sampling requirements for waterworks in the *Ontario Drinking Water Standards (ODWS)*<sup>147</sup> and is associated with a number of initiatives that comprise part of Operation Clean Water, a comprehensive action plan designed to give Ontario residents the best drinking water in Canada.

The *DWPR* applies to every water treatment or distribution system that includes a waterworks established on or after August 8, 2000, and for which an approval would be required. All approval applications must be in accordance with the *ODWS*.

The *DWPR* covers a number of specific areas:

- It provides a definition of the minimum levels of treatment for surface and groundwater sources.
- It outlines the sampling and analysis requirements for waterworks; the procedure for notifying the medical officer of health and the Ministry of the Environment; corrective actions for exceedences and adverse water quality; and public information quarterly report requirements.
- It requires an engineer's report that analyzes the standard operational procedures in a waterworks; assesses the potential for microbiological contamination of that waterworks; and identifies operational and physical improvements necessary to mitigate this potential by using the multiple barrier concept. The engineer's report also identifies a monitoring regime for the entire waterworks to ensure compliance with the *DWPR*, and evaluates the waterworks' ability to comply with chlorination procedure B13-3, described below. To date, engineer's reports have been completed for all 680 supply/treatment/storage waterworks in Ontario.

The *ODWS* define the level of sampling and analysis requirements:<sup>148</sup>

Samples shall be taken from the point at which treated water enters the distribution system unless specifically noted.

- "Distribution samples" or samples to be taken "in the distribution system" shall be taken in the distribution system from

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<sup>147</sup> *Ontario Drinking Water Standards (ODWS)* [online], [cited November 19, 2001], <[www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf](http://www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf)>.

<sup>148</sup> *Ibid.*



a point significantly beyond the point at which treated water enters the distribution system.

- All sampling shall be done by grab samples unless “continuous monitoring” is specified. Continuous monitoring implies that sampling and analysis is done by continuous monitoring equipment that forms part of the water treatment or distribution system.
- Sampling and analysis is required for parameters indicated (which comprise microbiological, turbidity, chlorine residual, fluoride, volatile organics, inorganics and sodium, nitrate/nitrites, and pesticides and PCBs).

Samples must be analyzed by methods and laboratories accredited by the Standards Council of Canada, and the results must be made available to the public. However, some of the parameters set forth in the *ODWS* can be analyzed in the field by a licensed operator/water analyst at a waterworks.

The *ODWS* list specific drinking water standards, objectives, and guidelines, including operational parameters and aesthetic parameters (see subsection 5.3 of this report). They define indicators of adverse bacteriological water quality; the required notification procedure and corrective actions; the assessment procedures for chemical, physical, and radiological parameters; and the corrective actions required when a health-related parameter is exceeded. In addition, the *ODWS* discuss waterworks issues, such as source protection, treatment and operations, approval of waterworks, and where responsibility for water quality lies. (Generally, the municipality that distributes the drinking water is responsible for its quality).

The *ODWS* also provide a summary of water disinfection, discussing the disinfection agents commonly used in water treatment today (chlorine, chloramines, chlorine dioxide, ozone, and ultra-violet irradiation). The standards include a requirement for chlorine residual monitoring at the point at which treated water enters the distribution system from both surface and groundwater sources, as well as a requirement for turbidity monitoring.

The *ODWS* contain guidance on the use of chlorine for disinfection, with specific reference to the application of the CT disinfection concept. CT is the mathematical product of the disinfectant concentration and the effective contact

time with the water. This concept essentially evaluates the efficiency of disinfection, incorporating the concentration (C) of disinfectant and the effective disinfection contact time (T), a function of contactor geometry and flow rate. Tabular information defines the required reductions of pathogens achieved by a combination of filtration treatment and disinfection removal/inactivation. The CT concept was developed by the EPA and uses tables of information on inactivation of *Giardia* cysts and viruses for free chlorine at various temperatures and pHs.

The *ODWS* procedure B13-3, entitled “Chlorination of Potable Water Supplies in Ontario,” outlines disinfection of both surface water and well water supply facilities. It covers new watermains and watermains taken out of service for inspection, repair, or other activities that may lead to contamination before the watermains are placed in service.

The Environmental Monitoring and Reporting Branch conducts specific sampling and analysis surveillance for drinking water. The Drinking Water Surveillance Program (DWSP) was developed to provide reliable and current information on municipal drinking water (see Appendix A2). Data collected by the DWSP are used to monitor contaminant levels and trends, define the emergence of new contaminants, support drinking water standards development, and assess the efficiency of treatment processes in waterworks. Trained waterworks staff collect samples at various stages throughout the course of treatment and distribution. Samples are taken of source water, treated water entering the distribution system, and water from at least one location within the distribution system that is representative of water at the consumer’s tap. A free-flowing sample (water from a tap flushed for at least five minutes) is taken to ensure that the sample is representative of the water in the distribution main.

Waterworks using surface water sources are sampled more frequently than ‘true’ groundwater sources, because surface water is often of more variable quality. Waterworks are monitored for the presence of approximately 200 parameters, including those specified under the *ODWS*. Microbiological parameters that require a more intensive sampling schedule are covered by the sampling requirements of the *ODWS* and the certificates of approval for each municipality. Annually, one sample of the raw and treated water collected from each of the waterworks in the program is screened for the complete spectrum of organic chemicals. In this way, ‘emerging’ contaminants can be detected. If present in significant concentrations and frequency, these contaminants will be added to the suite of parameters tested for in the routine program.

The list of 200 parameters tested for in Ontario is continually reviewed and assessed. Any parameter that becomes of interest or concern can be added to the listing.

#### 4.5.2 Saskatchewan

The rationale for requisite monitoring of drinking water quality in Saskatchewan stems from section 25 of *The Water Pollution Control and Waterworks Regulations*<sup>149</sup> and ensures that microbiological contamination does not exceed levels deemed acceptable by the minister. Analysis is conducted for total coliform, fecal coliform, *E. coli*, or background bacterial growth.

Routine samples from water distribution systems are tested to detect potential problems with drinking water quality. Analysis of routine samples can indicate the presence of total coliform, background bacteria, overgrowth, or *E. coli*. Repeat samples are requested when the analysis yields positive results. Repeat samples indicate the presence or absence of the above micro-organisms and help determine whether the initial monitoring results occurred because of sampling errors or if bacteriological contamination actually exists in the water supply. Repeat samples are also used to determine if remedial actions have resolved water quality problems. Special samples are requested when analysis of the repeat samples shows positive results. Such samples are used to determine the extent of contamination within a water distribution system, and to check that remedial actions have resolved water quality problems.

Saskatchewan uses precautionary drinking water advisories and emergency boil water orders at various stages of monitoring follow-up to provide a greater level of safety while determining the solution to a water quality problem. (See Appendix A3 for additional information.) When a problem may exist and a public health threat is not yet identified, precautionary drinking water advisories are issued by an ecoregion, in consultation with a health district. When a threat to public health does exist, emergency boil water orders are issued by medical health officers or designates of local health districts in consultation with ecoregions.

Saskatchewan Environment and Resource Management (SERM), Saskatchewan Health, health districts, and the operators of communal waterworks regulated

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<sup>149</sup> *Water Pollution Control and Waterworks Regulations*, Saskatchewan Regulations 65187 and 49/2000, Charter E-10-2, Reg 2. (June 17, 1987).

by SERM share in the responsibility of providing water that is approved for human consumption.

- Operators of communal water systems are required to monitor drinking water quality and to notify SERM when chlorination equipment is not working. They are also required to act on directives or advice from ecoregions and health districts to resolve problems or to prevent health hazards.
- Head-office staff of SERM's Environmental Protection Branch receive analytical results from the provincial laboratory. They record these results in SERM's database, report all positive bacteriological results to respective ecoregions by telephone and email, and report negative results for repeat and special samples to ecoregions by email. The Environmental Protection Branch also notifies health districts about all positive results and negative results for repeat and special samples by email.
- Ecoregions, after receiving positive results from routine monitoring, will advise the operators of communal systems regulated by SERM about repeating samples and submitting information on recent operational status (such as recent watermain breaks and disinfection equipment condition). Ecoregions advise operators on steps and methods to resolve bacteriological water quality problems. Ecoregion staff also contact health districts to discuss public health concerns and whether to issue emergency boil water orders or precautionary drinking water advisories. They meet with municipalities or waterworks operators to discuss actions that must be initiated as a result of these advisories or orders. Ecoregions are responsible for issuing precautionary drinking water advisories in consultation with the health district. Ecoregion staff consult with health district staff when considering rescinding issue emergency boil water orders or precautionary drinking water advisories.
- Health district staff, including senior public health inspectors and medical health officers, work with ecoregion staff at various stages of monitoring and investigation to determine if risks to public health exist. As mentioned above, health district staff discuss issuing emergency boil water orders or precautionary drinking water advisories with ecoregion staff, and will attend meetings with waterworks operators to discuss any required actions. Medical health officers or designates are responsible for the issuing of emergency boil water orders in consultation with ecoregion staff. Health district staff may investigate plumbing at specific sites where necessary to

determine if cross connections occur. Health district staff work also consult with ecoregion staff when considering rescinding emergency boil water orders or precautionary drinking water advisories.

- The provincial laboratory analyzes routine, repeat, and special samples collected by the operators of communal water systems regulated by SERM, and reports these results promptly to the Environmental Protection Branch.

## 4.6 New Approaches for Water Quality Testing

The methods used today for measuring the microbiological quality of water and compliance with regulatory standards are based largely on techniques developed in the late 19th century, around the same time that modern water treatment techniques began to be implemented.

These methods have been effective in greatly reducing the risk of waterborne diseases in the developed world. However, it is evident that they do not adequately address all the microbiological hazards that are faced by water supplies.

In 2001, the American Academy of Microbiology released a report advocating a radical overhaul of current approaches for measuring microbial water quality. The report, “Reevaluation of Microbial Water Quality: Powerful New Tools for Detection and Risk Assessment,” was the outcome of a meeting of 22 international experts which took place in Florida during March 2000.<sup>150</sup> The report calls for the adoption of new technologies, particularly those based on molecular biology techniques, to provide more reliable methods of assessing human health risks, better early warning systems for hazardous events threatening water supplies, and improved ways of identifying and tracing contamination sources.

The report acknowledges the contribution of traditional water quality measurements based on coliform bacteria to the protection of public health over the last century, but underlines the inadequacy of this approach in assessing risks from pathogens other than fecal bacterial species. The traditional indicators are unreliable for assessing contamination risks for fecal viruses and protozoa, or for non-fecal pathogens such as *Legionella*. The chlorine-sensitive nature of

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<sup>150</sup> J.B. Rose and D.J. Grimes, 2001, *Reevaluation of Microbial Water Quality: Powerful New Tools for Detection and Risk Assessment* (Washington, D.C.: American Academy of Microbiology).

the coliform group also means that such measurements may provide a misleading assurance of safety for chlorinated supplies that are prone to contamination by more resistant organisms.

Over the last few decades, advances in microbiology and molecular biology have had a huge impact in medicine, agriculture, bioremediation, and many other areas. However, these technologies have been very slow to penetrate the field of water quality measurement. Since water supplies are often prone to contamination from multiple point and non-point sources, identification and tracing of pollution sources is needed for the implementation of effective management measures. Molecular techniques hold great promise in this area, and it is anticipated that direct detection of a range of micro-organisms in environmental samples will soon be possible.

While the practicality of advanced detection techniques, such as gene chip technology, have not yet been fully proven, the report concludes that adoption of the new methodologies is essential to advance microbial risk assessment and provide more effective risk management for water supplies in the future. The availability of such methods would provide a higher degree of sophistication in risk assessment, and enable the effectiveness of barriers to contamination and water treatment technologies to be more thoroughly characterized for different classes of pathogens. This in turn will provide better assurance that source-water protection and water treatment measures are appropriate for the level of risk, and that well-designed monitoring strategies are in place to provide process control and timely warning of hazardous situations.

## **4.7 Summary**

Methods for measuring microbiological water quality were developed in the late 19th century, around the same time as modern water treatment techniques began to be implemented. Because of limitations in knowledge about pathogenic micro-organisms, tests were based on the detection of coliform bacteria that did not cause disease, but which were always present in human and animal feces. Thus, the presence of these 'indicator bacteria' in water warned if fecal contamination had occurred and whether fecal pathogens might also be present.

The adoption of the total coliform group of bacteria as an indicator of fecal contamination was justified by historical conditions. However, changes in test methods and improvements in water management practices mean that these

organisms are no longer a valid indicator for this purpose. The fecal or thermotolerant coliform group has a stronger association with health risks from pathogens, but the most specific bacterial indicator of fecal contamination currently known is *E. coli*. Recent improvements in test methods have made routine monitoring for this organism both feasible and affordable, and there are increasing international trends to make *E. coli* the primary or sole indicator micro-organism for water quality monitoring. While *E. coli* is recognized as a good predictor of potential risks from bacterial pathogens, its correlation with risks from viruses and protozoa is relatively poor. Better indicators for these classes of pathogens are still being sought.

Direct measurement of pathogens in water has become increasingly possible as test methods are developed and improved. However, this type of testing has not been widely adopted as a routine monitoring tool for a range of reasons. The occurrence of pathogens in water supplies is intermittent and usually unpredictable. Their low numbers relative to non-pathogenic organisms make detection difficult; some test methods have poor reliability, and pathogen tests are generally more technically complex and expensive than indicator bacteria tests. From a public health viewpoint, the most significant limitation to pathogen testing is that uncertainties over the viability and infectivity of pathogens often means that a health risk cannot be accurately predicted. As well, the test result is usually not obtained until after the public has consumed the affected water.

As with all aspects of water supply management, microbiological testing requires a high standard of quality control to ensure the accuracy of results and comparability across different water supply systems. Routine microbiological monitoring of finished water from the distribution system is designed essentially to verify that the components of the water supply system are operating correctly and that water of the desired quality is being delivered to consumers. This is an important element of water supply management but is not the primary means of protecting public health. Monitoring of this nature cannot be a preventive management tool because of the time delay between sampling and obtaining the result. For this reason, implementing intensive microbiological monitoring schemes that emphasize more frequent sampling of finished water may not be a cost-effective approach to improving microbiological safety. More intensive microbiological sampling of finished water can improve future water quality only if it provides information to better system management.

Public health protection requires a preventive approach to detect and correct problems before they affect the quality of the finished water supply. The

development of a formal framework for water quality management incorporating preventive management principles and elements of internationally recognized risk management systems, such as HACCP, is discussed in subsection 6.4.3.1 of this report. Effective communication and cooperation between water utilities and public health and environmental regulators are also required to ensure the implementation of suitable monitoring programs, prompt communication of results, and initiation of appropriate investigations and public health responses in the event of adverse or unusual results.

Assessment of the microbiological safety of water supplies has traditionally relied on the measurement of indicator micro-organisms in water. In recent years, questions have also been raised about the possible involvement of water-borne pathogens in endemic disease, particularly gastroenteritis, even in supplies that meet conventional microbiological water quality criteria. A number of epidemiological studies have been undertaken to investigate this issue, but their results have been inconsistent, and it is not clear whether drinking water is a significant factor in endemic gastroenteritis. This issue is important both in terms of community illness and health costs, and the potential costs of improved water treatment methods. Further well-designed studies in this area are needed to allow informed decisions about the levels of water treatment required for different qualities of source water, and about appropriate standards and guidelines to protect public health.

## **5 The Development of Drinking Water Standards**

This section describes the approaches used by several jurisdictions for setting drinking water standards. Such standards play a key role in ensuring that water for drinking and food-preparation purposes is not only safe but also palatable and aesthetically pleasing. For drinking water, a standard or guideline value for each constituent or contaminant of concern is usually expressed as a numerical limit or concentration. Below this limit, there is no significant risk to the health of the consumer over a lifetime. However, it must be stressed that the existence of such limits does not in itself ensure the safety and well-being of the consumer. This requires judicious application of the standards through:

- regular monitoring for compliance;
- appropriate sampling regimes;
- use of accurate and reliable analytical methods;



- source water protection;
- adequate treatment and timely follow up; and
- corrective action when standards are exceeded.

Effective and efficient delivery of potable water also depends on trained and qualified personnel.

Two examples in Appendix A4 compare the steps typically taken to derive numerical limits for potentially harmful chemical constituents of drinking water with the approach used to set guidelines (or standards) for microbiological quality.

## **5.1 Current Practices for Setting Drinking Water Guidelines in Canada**

### **5.1.1 Jurisdictional Considerations**

The legal framework for matters relating to drinking water in Canada has evolved from the distribution of administrative and legal powers among the provincial, territorial, and federal governments as set out in the *Constitution Act*. In general, the provinces are responsible for matters such as protecting watersheds; constructing, operating, and maintaining water treatment plants; and ensuring that water quality standards or norms are met. The federal government (in particular, Health Canada) has an important role in catalyzing, conducting, and coordinating programs and studies related to drinking water quality.

Health Canada's work related to drinking water is part of a broader federal Water Quality Program designed to protect the public's health from microbiological, physical/chemical, and radiological contaminants found in drinking and recreational waters. This program has four components: research, evaluation, standards and regulations, and communication. Drinking water quality-related work is carried out in the Environmental Contaminants Bureau (formerly the Bureau of Chemical Hazards) in the Safe Environments Programme of the Healthy Environments and Consumer Safety Branch.

Health Canada usually collaborates or consults with the provinces and territories in conducting research and monitoring studies, and in evaluating the health risks of contaminants that may affect drinking water quality.

### 5.1.2 Historical Overview

Since 1968, a major area of federal, provincial, and territorial collaboration has been the development of guidelines for drinking water quality in Canada. Prior to 1968, federal and provincial authorities generally adopted and used the U.S. Public Health Service standards without considering the relevance of the parameters or values for the Canadian situation. The *Canadian Drinking Water Standards and Objectives, 1968* were the first comprehensive national set of 'made-in-Canada' drinking water quality standards. They were developed by the Joint Committee on Drinking Water Standards of the Canadian Public Health Association and the Advisory Committee on Public Health Engineering, convened by Health and Welfare Canada. The second national standards (or guidelines as they were subsequently called) were prepared by a federal-provincial working group of the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH) and were published in 1979 as the *Guidelines for Canadian Drinking Water Quality, 1978*.

In 1983, a new working group was convened to update the 1978 guidelines. Generally, the function of a working group under the CEOH is to complete a specific task after which the group is disbanded. However, in 1986, the Working Group on Drinking Water was reconstituted as a standing subcommittee to reflect the need to continuously scrutinize the quality of drinking water in Canada and to recommend timely changes to the guidelines in light of new information. Since the establishment of the Federal-Provincial Subcommittee on Drinking Water, the third (1987), fourth (1989), fifth (1993), and sixth (1996) editions of the guidelines have been issued.<sup>151</sup>

There has also been a change in emphasis since the 1968 standards were published. At that time, the primary aim of the water supply industry was to provide water free from bacterial contamination. Attention was also given to the presence of dissolved inorganic substances, many of which originated from natural sources. With the exception of a few biocides, the organic content of drinking water was of interest mainly with respect to problems of taste and odour. Some recommended limits were specified in terms of gross parameters such as phenolic substances, organic substances (such as carbon chloroform and alcohol extractibles), methylene blue active substances, and total dissolved solids. As such, these limits served merely as general indicators of the (chemical) quality of drinking water. In

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<sup>151</sup> Canada, Health Canada, 1996a.

preparing the *Guidelines for Canadian Drinking Water Quality, 1978*, the committee re-examined the criteria on which the 1968 standards had been based and retained, modified, or eliminated the earlier recommended values. Some parameters that had not been considered previously were examined, and some additional limits were set. In 1968, the guidelines for radioactive substances were specified in terms of total radioactivity (as a general indicator of contamination). In 1978, the guidelines began listing specific radionuclides.

Since 1978, increasing attention has been paid to the potential health significance of trace quantities of specific contaminants, in particular, synthetic organics, in drinking water. The *Guidelines for Canadian Drinking Water Quality* (third edition) included guidelines for some 94 parameters, an increase of 37 parameters over those listed in the 1978 document.<sup>152</sup> The number of pesticides and synthetic organic chemicals for which recommendations were developed rose to 55 compared with the 18 listed in 1978. The current (sixth) edition of the guidelines lists some 80 physical/chemical and 29 radiological parameters (both naturally occurring and artificial) along with those for microbiological characteristics.<sup>153</sup>

### 5.1.3 Current Perspective

The microbiological characteristics of drinking water continue to be viewed by the Subcommittee on Drinking Water as vital to public health protection, and these guidelines are under constant scrutiny. While the frequently encountered bacterial pathogens *Campylobacter*, *Salmonella*, and *Shigella* have traditionally influenced the development of guidelines for microbiological quality, the protozoans *Giardia* and *Cryptosporidium* have more recently emerged as public health threats. Another emerging concern, related to the microbiological contamination of surface waters, is the presence of species of blue-green algae (also known as cyanobacteria). These species produce potent toxins known as microcystins, of which the most commonly reported is microcystin-LR.

Concern about the presence of chloroform and other trihalomethanes (THMs), formed during the chlorination of drinking water, was first addressed in the 1978

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<sup>152</sup> Canada, Health and Welfare Canada, Federal-Provincial Subcommittee on Drinking Water, 1987, *Guidelines for Canadian Drinking Water Quality* (Ottawa: Supply and Services).

<sup>153</sup> Canada, Health Canada, 1996a.

guidelines.<sup>154</sup> Recently, attention has also been given to the potential health impacts of a range of other disinfection by-products and the use of alternative disinfectants. Substances known as haloacetic acids (HAAs), along with THMs, were the major disinfection by-products found in all facilities examined in a 1993 national survey of 53 Canadian drinking water supplies, where chlorine was used at some stage in the treatment process. The survey addressed the impacts of three distinct disinfection processes: chlorination, chloramination, and ozonation.<sup>155</sup>

Guidelines for bromate ion (a by-product from the use of ozone and hydrogen peroxide) and for the use of chloramines as a disinfectant in drinking water have been approved. Guidelines for disinfection by-products, haloacetic acids, and formaldehyde are in preparation.

#### 5.1.4 Guidelines Versus Standards

The current *Guidelines for Canadian Drinking Water Quality* comprise a set of recommended limits for the microbiological, chemical/physical, and radiological characteristics of potable water. These guidelines are intended to apply to all types of public and private supplies.

Since 1978, the word ‘guideline’ has been used to describe the limits recommended by the federal-provincial working groups and committees. The previous publication in 1968 was entitled *Canadian Drinking Water Standards and Objectives*. The change in designation was a conscious decision to make clear that the recommendations developed collaboratively by the federal and provincial governments do not automatically have standing in legislation and therefore are not legally enforceable as national standards. However, all the provinces have taken steps to ensure that the national guidelines are enforced in their respective jurisdictions.

These measures are in the form of specific drinking water legislation incorporating all or part of the national guidelines, operating permits to specific

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<sup>154</sup> Canada, Department of Health and Welfare, Federal-Provincial Working Group on Drinking Water. 1979, *Guidelines for Canadian Drinking Water Quality - 1978* (Ottawa: Minister of Supply and Services, Canadian Government Publishing Centre, Supply and Services Canada).

<sup>155</sup> Canada, Health Canada, 1995b, *A National Survey of Chlorination Disinfection By-Products in Canadian Drinking Water*, Report 95-EHD-197 (Ottawa: Communications and Consultation Directorate).

treatment facilities, or policy directives. For example, the current *Guidelines* do not have the force of law in British Columbia. Drinking water in British Columbia is regulated by the *Safe Drinking Water Regulation* under the *Health Act*.<sup>156</sup> The regulation governs:

- the construction and alteration of waterworks systems;
- the role of the medical officer of health and public health inspector in the determination of health hazards and the means of notification;
- approvals for operation of a water system;
- protection and monitoring of water potability and remediation; and
- requirements for disinfection.

The British Columbia regulation also requires the operator of a water system to have a written emergency response plan, and specifies legally mandated microbiological standards and penalties for contraventions of the regulation. The *Guidelines* form one set of parameters to which the B.C. Ministry of Health Services refers for chemical and radiological parameters. The ministry also refers to World Health Organization (WHO) guidelines,<sup>157,158</sup> the U.S. Environmental Protection Agency (EPA) standards, and general literature.<sup>159</sup> The role of the national guidelines in Ontario is described in subsection 5.2.

At the federal level, the Canadian guidelines are generally used as a benchmark for the quality of water provided on common carriers that cross international and interprovincial borders, and on Indian reserves. Separate regulations exist under the *Canada Health Act*<sup>160</sup> that address the bacteriological quality of drinking water on common carriers. Regulations under the *Canada Labour Code*<sup>161</sup> require that federal employees be provided with potable water that meets the federal standards in *Guidelines for Canadian Drinking Water Quality*,

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<sup>156</sup> B.C. Reg. 230/92, O.C. 1072/92 under the *Health Act*, RSBC. 1996, c. 179.

<sup>157</sup> United Nations, World Health Organization (WHO), 1993, *Guidelines for Drinking Water Quality*, 2nd ed., vol. 2: *Recommendations* (Geneva: WHO).

<sup>158</sup> United Nations, World Health Organization, 1996.

<sup>159</sup> United States, U.S. Environmental Protection Agency, 1994, *Water Quality Standards Handbook*, 2nd ed., EPA 823-8-94-005a (Washington D.C.: EPA).

<sup>160</sup> R.S. 1985, c. C-6.

<sup>161</sup> Canada Labour Code, RSC 1985, c.I.L-2. Refer to the Sanitation Provisions in the Aviation Occupation Safety and Health Regulations; Occupational Safety and Health Regulations; On Board Trains Occupational Safety and Health Regulations; Oil and Gas Occupational Safety and Health Regulations; Marine Occupational Safety and Health Regulations listed at <laws.justice.gc.ca/en/L-2/index.html>.

1978 (amended in 1990). These measures are constantly under review and have received increasing scrutiny as a result of the Walkerton issue.<sup>162</sup>

### **5.1.5 Administrative Arrangements for Developing the National Guidelines**

Development of the *Guidelines for Canadian Drinking Water Quality* is a responsibility of the Federal-Provincial Subcommittee on Drinking Water of the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH). The subcommittee, which meets biannually, is made up of representatives from the federal, provincial, and territorial governments. Health Canada provides the secretariat for the subcommittee, and prepares the technical supporting documentation for the guidelines for review by subcommittee members. Subcommittee members are responsible for reviewing recommendations made by the secretariat and considering aspects such as the practicality, costs, and health benefits of implementing proposed guideline values.

The subcommittee's responsibilities are not confined to establishing the national guidelines. It also advises the CEOH on all matters that affect the provision of drinking water. Thus, the subcommittee carries out the following activities:

- collecting information on constituents of drinking water and evaluating their potential health effects;
- reviewing the adequacy of potable water treatment technology and the operating procedures of treatment plants;
- promoting the exchange of information on drinking water issues and co-operation with other organizations with related interests; and
- identifying research needs and promoting and encouraging research on drinking water issues in Canada.

Subcommittee members are nominated by CEOH health representatives, with one member from each of the federal, provincial, and territorial governments.

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<sup>162</sup> David Green, Secretary of the Secretariat to the Federal-Provincial Subcommittee on Drinking Water, Health Canada [personal communication with the authors, October 23, 2000].

Provincial and territorial members represent their agencies responsible for establishing drinking water quality parameters, or have the authority to make decisions on drinking water quality for the province or territory. A CEOH representative also attends the subcommittee's meetings to liaise between the two bodies and to ensure that the subcommittee operates within the CEOH's overall priorities.

The subcommittee normally arrives at decisions, conclusions, standards, guidelines, and procedures by consensus. In the event that consensus is not reached, a voting procedure is initiated. Each provincial/territorial jurisdiction represented has one vote; the Health Canada representative holds the federal vote.

### **5.1.6 Framework for Guideline Development**

The Subcommittee on Drinking Water bases its approach for developing drinking water guidelines on the *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks*. (See section 2 for a description of frameworks for managing risks that delineate the scientific and social aspects of risk assessment and risk management.) The subcommittee uses the following six steps (detailed in subsection 2.5) in developing drinking water guidelines for microbial, physical, chemical, and radiological parameters:

1. Identification and selection of parameters for review
2. Assessment of the health risks
3. Evaluation (cost-benefit analysis)
4. Decision making and approval
5. Announcement and publication
6. Re-evaluation

This framework acknowledges the importance of communication among all parties (including the general public at all stages of the guideline development process).

In health protection, the principal objective of science-based risk assessments is the initial development of exposure guidelines that fully protect health. In the provision of drinking water, assessment of health risks associated with contaminants results in the derivation of exposure levels (i.e., health-based drinking water guidelines) at or below which there is considered to be no or negligible risk. Such guidelines may have to be modified in light of economic

and social considerations. In that case, changes and the reasons for them should be transparent. The resulting measures should, of course, still protect health. In the approach followed by the subcommittee, these two broad stages correspond to step 2 (risk assessment) and steps 3 and 4 (evaluation and decision making).

### 5.1.7 Technical Approaches Used to Derive the Guidelines

This subsection describes in detail the principles and approaches used to develop health-based guidelines. It also provides a brief account of how such guidelines can be modified. Health risk assessments are prepared by staff of Health Canada (the secretariat to the subcommittee). Since provincial and territorial governments are responsible for the provision of drinking water, the provincial and territorial members of the subcommittee review the values proposed by Health Canada in terms of costs and practical considerations. Sometimes, as result of this review, the guidelines are modified.

#### 5.1.7.1 *Types of Limits*

While the primary purpose of the *Guidelines* is to define a quality for drinking water that protects health, aesthetic factors (taste, odour, and appearance) can affect the acceptability of water for consumers. Thus, the limits developed by the subcommittee are specified on the basis of health and/or aesthetic considerations. The subcommittee identifies three types of limits in the guidelines: maximum acceptable concentrations (MACs), interim maximum acceptable concentrations (IMACs), and aesthetic objectives (AOs).

A MAC is established for a substance that is known or suspected to cause adverse health effects. MACs are based on lifelong consumption and the use of the water for all usual domestic purposes, including personal hygiene. Water of higher quality may be required for some special purposes, such as renal dialysis.

The *Guidelines* explain how MACs are used in monitoring drinking water:<sup>163</sup>

Drinking water that continually contains a substance at a level greater than its MAC will contribute significantly to consumers' exposure

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<sup>163</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1996a, p. 10.



to the substance and may, in some instances, induce deleterious effects on health. However, short-term excursions above the MAC do not necessarily mean that the water constitutes an undue risk to health. The amount by which, and the period for which the MAC can be exceeded without posing a health risk must be assessed by taking into account the toxicity of the substance involved. When the MAC for a substance is exceeded, however, the minimum action required is immediate re-sampling. If the MAC continues to be exceeded, the local authority responsible for drinking water supplies should be consulted concerning the appropriate corrective action.

According to the *Guidelines*, an IMAC is recommended for “those substances for which there are sufficient toxicological data to derive a MAC with reasonable certainty.”<sup>164</sup> These interim values are set “taking into account the available health-related data, but employing a larger safety factor to compensate for the additional uncertainties involved.” IMACs are also established for those substances for which estimated lifetime risks of cancer associated with the guideline are greater than those deemed to be essentially negligible. (The guideline for a substance is the lowest concentration in drinking water that is practicably achievable using available analytical or treatment methods.) Because of their nature, IMACs will be reviewed periodically as new toxicological data become available.<sup>165</sup>

The third type of limit is an AO, which is established for substances or drinking water characteristics “that can affect [the water’s] acceptance by consumers or interfere with practices for supplying good-quality water.”<sup>166</sup> Some parameters may have both AOs and MACs. “Where only AOs are specified, these values are below those considered to constitute a health hazard.”<sup>167</sup>

#### 5.1.7.2 *Setting Guidelines for Microbiological Parameters*

Four primary factors influence the risk of illness from water-borne pathogens:

- the concentration of the pathogen in the drinking water;

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<sup>164</sup> Ibid.

<sup>165</sup> Ibid.

<sup>166</sup> Ibid., p. 11.

<sup>167</sup> Ibid.

- the minimum dose capable of producing an infection (human infectious dose) of the pathogen (an infectious dose may be a single virus particle or *Giardia* cyst, whereas much higher doses of bacterial pathogens are usually required to yield an infection);
- the virulence of the pathogen and the immune status of the host; and
- the volume of water ingested (average daily intake is assumed to be 1.5 L).

In order to protect the health of the most sensitive subpopulations (and hence all individuals), it is assumed that an infection will result in illness, even though it does not always lead to illness. From a human health-protection perspective, therefore, no tolerable lower limit exists for the concentration of pathogens in drinking water supplies. This essentially means that a health-based guideline for water-borne pathogens should be zero.

The complete removal of pathogens from drinking water, however, is rarely feasible both from an economic and a technological standpoint. Therefore, the approach used is to establish a practical limit, taking into consideration the need to reduce health risks to a level deemed 'acceptable' in light of economic and practical factors. A similar approach is used in setting limits for radiological and carcinogenic chemical contaminants. Annex 2 to the description of the development process for the current *Canadian Drinking Water Guidelines* refer to the U.S. *Surface Water Treatment Rule (SWTR)*.<sup>168</sup> In the *SWTR*, a risk of one infection (assumed to result in one case of illness) per 10,000 people per year (a risk of  $10^{-4}$ ) has been set as a health goal for exposure to *Giardia* in treated drinking water.

There are two main approaches for ensuring that the MACs for water-borne pathogens are not exceeded: (1) testing for the presence of indicator organisms, and (2) employing adequate water treatment methods. It is still generally considered impractical to monitor water for the presence of specific types of pathogenic organisms. (See section 4 for a detailed discussion of the measurement of microbiological quality.) For some pathogens, methods for direct detection have not yet been developed and, for others, available direct detection methods are difficult, costly, and time consuming, and require well-trained personnel. Furthermore, the absence of one pathogen does not necessarily indicate that all other pathogens are absent. Thus, the Subcommittee

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<sup>168</sup> 54 Federal Register 27486-27541 (June 29, 1989).

on Drinking Water continues to recommend the use of surrogate, or indicator, organisms to demonstrate whether water treatment is inadequate and pathogens may be present. Detecting the presence of indicator organisms is a signal that the water should be re-sampled. If the presence of an indicator is confirmed by re-sampling, corrective action should be taken.

Non-pathogenic fecal coliform bacteria, in particular *Escherichia coli* (*E. coli*) and total coliform bacteria, are usually used to indicate the possible presence of pathogenic bacteria. Other surrogates continue to be examined with a view to complementing, rather than replacing, the use of these coliform indicators. The *Guidelines* specify the MAC for coliform organisms in terms of numbers present per volume (100 mL) and frequency of detection. They also provide guidance on sampling frequency for the size of a population served, although other factors are also listed (e.g., quality of the source water, number of water sources, water quality history, size of the distribution system, and water treatment practices).

Coliform bacteria are not considered to be an appropriate indicator for water-borne viruses and protozoa; for example, viruses are more infective and more resistant to disinfection than most bacteria, and viruses survive longer in drinking water. Coliphages (viruses that infect coliform bacteria) and bacterial spores have been proposed as indicators for pathogenic enteric viruses.<sup>169</sup> The use of spores of sulphite-reducing clostridia (e.g., *Clostridium perfringens*) as an indicator of the presence of viruses and protozoan cysts has also been investigated. However, no guidelines are proposed for viruses and protozoa because of the impracticality of detecting and measuring these organisms. For example, the possibility of a guideline value (MAC) for protozoa has been examined by the subcommittee, but in March 2001, this was deemed not to be practical “based primarily on the inability of routine detection methods to provide information on their viability and human infectivity.”<sup>170</sup>

The subcommittee considers that a well-managed, adequately treated water system (e.g., effective disinfection and maintenance of a free chlorine residual) should ensure the removal or inactivation of such disease-causing organisms. The type and effectiveness of the disinfectant used depends on the type of pathogen present and the physical characteristics of the water being treated.

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<sup>169</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1999a, p 11.

<sup>170</sup> For more information, see <[www.hc-sc.gc.ca/ehp/ehd/bch/water\\_quality/consult/protozoa\\_memo.pdf](http://www.hc-sc.gc.ca/ehp/ehd/bch/water_quality/consult/protozoa_memo.pdf)>, [cited November 13, 2001].

In general, diligent monitoring of indicator organisms and the application of adequate water treatment are the primary means recommended in the *Guidelines* to safeguard against the presence of hazardous water-borne pathogens.

### 5.1.7.3 *Guidelines for Physical/Chemical Parameters*

Health-based guidelines for chemical contaminants in drinking water are derived by collecting and critically reviewing data from toxicological studies of laboratory animals, epidemiological studies of human populations, and clinical case reports. Effects from exposures to chemical contaminants vary depending on the dosage, route of exposure (e.g., ingestion, inhalation, or dermal exposure), frequency and duration of exposure, and the sex, susceptibility, and age of the exposed population or individual. These effects can be classified in the following broad categories: organ-specific, neurological/behavioural, reproductive, teratological, and oncogenic/carcinogenic/mutagenic. Effects may be brief or prolonged, reversible or irreversible, immediate or delayed, single or multiple. The nature, number, severity, incidence, and/or prevalence of specific effects in a population generally increase as the dose or exposure level to the substance increase. For most drinking water contaminants, the potential for chronic adverse effects following long-term exposures to low levels is of interest. Thus, studies in which animals or human populations have been exposed to contaminants over a significant part of their lives are considered the most relevant for guideline development.

For most chemically induced effects, there is generally believed to be a threshold level of exposure below which adverse effects will not occur. For other toxic effects, carcinogenesis in particular, it is often assumed that some probability of harm exists at any level of exposure; that is, no threshold exists. The setting of health-based exposure guidelines must, therefore, allow both for chemicals that are potential carcinogens and for chemicals that exert toxic effects other than cancer. In setting drinking water guidelines for chemical constituents, each chemical is first classified on the basis of its potential to cause cancer. Five classification groups are used in setting the guidelines for chemical constituents:<sup>171</sup> They are:

- Group I: carcinogenic to humans
- Group II: probably carcinogenic to humans

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<sup>171</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1999a, p. 16.

- Group III: possibly carcinogenic to humans
- Group IV: probably not carcinogenic to humans
- Group V: inadequate for evaluation

There are usually uncertainties in the scientific data used to assess the human health risks of exposures to chemical contaminants that affect how health-based guidelines or standards for drinking water are derived. Factors that contribute to this uncertainty include:<sup>172</sup>

- inadequate data on the level, frequency, and duration of exposure;
- differences in sensitivity between species and among individuals in the same species;
- inadequate experimental study design;
- potential for interactive effects between different contaminants; and
- variations in statistical models for extrapolating responses observed at high doses to those expected at low doses.

The subcommittee attempts to take these uncertainties into account and emphasizes that the application of sound scientific judgment on a case-by-case basis is fundamental for deriving guidelines for physical and chemical parameters.<sup>173</sup>

#### ***5.1.7.4 Setting Guidelines for Chemicals Deemed Not to Be Carcinogenic***

Chemicals that are classified as “possibly carcinogenic to humans” or “probably not carcinogenic to humans,” or as having “inadequate data for evaluation”<sup>174</sup> are generally considered to produce toxic effects that will not occur below certain levels of exposure. For such chemicals, these thresholds are ascertained from the scientific literature and are normally based on the results of studies using animals. The first step is to determine the highest dose in a toxicity study that does not result in any observed adverse effect. This is the no-observed-adverse-effect level (NOAEL). The NOAEL is then divided by an appropriate uncertainty factor to arrive at the tolerable daily intake (TDI) for human populations. Generally ranging from 1 to 5,000, uncertainty factors are applied to account for the uncertainties in factors such as:

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<sup>172</sup> Ibid., p. 12.

<sup>173</sup> Ibid.

<sup>174</sup> Ibid.

- the effects manifested within and between different species (intra- and inter-species differences);
- the nature and severity of the effects;
- the adequacy of the experimental study from which the NOAEL was derived; and
- the potential for interaction with other chemicals present in drinking water.

Sometimes the experimental data allow for ascertaining a lowest-observed-adverse-effect level (LOAEL) rather than a NOAEL, in which case an additional uncertainty factor is applied. An additional uncertainty factor is also applied for chemicals classified in Group III to account for the limited evidence of carcinogenicity.<sup>175</sup> In some cases, a quantitative estimate of tumour incidence is considered in deriving the MAC for chemicals deemed to be mostly carcinogenic.

Ideally, the NOAEL is derived from a lifetime ingestion study or studies of the most sensitive subpopulation. Data from acute or short-term studies are rarely used in calculating TDIs. If the chemical is an essential nutrient at low concentrations, the dietary requirement is also taken into consideration.<sup>176</sup>

Drinking water is usually not the only means by which populations are exposed to a contaminant (and often is a minor route of exposure). These other sources must be accounted for in setting the health-based guideline; that is, it is considered inappropriate from a health protection standpoint to ascribe contaminant exposure to drinking water alone, so only a portion of the TDI is allocated to drinking water. Where possible, the calculations use data on the proportion of total intake of a contaminant normally ingested in drinking water (based on mean levels in food, air, and treated municipal water supplies), or intakes estimated on the basis of physical/chemical properties. Where such information is unavailable, a value of 20% is used in deriving the MAC. Derivation of the MAC is generally based on an average daily intake of 1.5 L of drinking water by a 70-kg adult. Where appropriate, the MAC is derived based on intake in the most sensitive subpopulation (e.g., children, pregnant women).<sup>177</sup>

Contaminants present in drinking water may contribute to total exposure not only by ingestion, but also by inhalation or dermal exposure to water during

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<sup>175</sup> Ibid., p. 14.

<sup>176</sup> Ibid., p. 12.

<sup>177</sup> Ibid., p. 13.

bathing and other household activities. For some compounds, intake by these routes is estimated to be similar to that by ingestion. However, in most cases, exposure by inhalation and dermal absorption of contaminants in drinking water cannot be estimated because of insufficient data. The 20% allocation of total daily intake to drinking water is used to take into account these additional routes of intake.<sup>178</sup>

For chemicals deemed not to be carcinogenic, the objective of the guidelines is to ensure that the calculated total daily intake of a contaminant from food, air, drinking water, etc. does not exceed the TDI. (This assumes, as a worst case, that the water contains the contaminant at the MAC.)

MACs must be achievable by available treatment methods and measurable by existing analytical techniques. Where a health-based MAC is below levels that can be reliably measured or achieved, an interim MAC (IMAC) is established, and improvement in methods of quantitation and/or treatment is recommended.

#### ***5.1.7.5 Setting Guidelines for Chemicals Deemed to Be Carcinogenic***

It is generally accepted that carcinogenesis occurs through a non-threshold mechanism; that is, some probability of harm exists at any level of exposure. Consequently, no threshold of exposure exists below which adverse effects will not occur. Therefore, it is not possible to calculate a TDI for chemicals deemed to be carcinogenic. (The TDI described earlier was for chemicals deemed not to be carcinogenic.) Carcinogens should not be present in drinking water, and health-based guidelines should therefore be set at zero. Attaining zero exposure to a drinking water contaminant, however, is not feasible because no treatment technology can completely remove a chemical from water. Neither is it always feasible or practical to measure extremely low concentrations of chemicals. The incremental risks associated with exposure to low levels of carcinogens in drinking water can be sufficiently small that they are “essentially negligible” when compared with other risks commonly encountered in society.<sup>179</sup> The objective, therefore, is to set the MACs for potential carcinogens as close to zero as practical, taking into consideration the following factors:<sup>180</sup>

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<sup>178</sup> Ibid.

<sup>179</sup> Ibid.

<sup>180</sup> Ibid.

- The MAC must be achievable by water treatment methods at reasonable costs.
- Wherever possible, the lifetime cancer risk associated with the MAC must be less than  $10^{-5}$  to  $10^{-6}$  (upper 95% confidence limit), a range generally considered to be essentially negligible.
- The MAC must be reliably measurable by available analytical methods.

Quantitative risks associated with exposure to low levels of potential carcinogens are estimated by extrapolating the dose-response relationship observed at high doses in experimental studies (most often in animal species) to much lower dose ranges. These extrapolations are usually over many orders of magnitude, and it is normally assumed that the relationship between the level of exposure and risk is linear at these low-dose (or exposure) levels. Experimental data on tumour occurrence rates most relevant to humans are used to determine a MAC with an upper 95% confidence limit on lifetime cancer risk of between 1 in 100,000 ( $10^{-5}$ ) and 1 in 1,000,000 ( $10^{-6}$ ). (This range is considered to represent an essentially negligible risk.)<sup>181</sup> Wherever possible, information on pharmacokinetics, metabolism, and mechanisms of carcinogenicity is incorporated into the model for risk estimation. These mathematical extrapolations involve a number of uncertainties. However, the methods used are based on conservative assumptions, and therefore, in all likelihood, overestimate rather than underestimate the risks. The actual risks could be lower than those estimated by one to two orders of magnitude.<sup>182</sup>

As for MACs for non-carcinogens, the establishment of a MAC for a carcinogen also considers the relative contribution made by other sources of exposure to the substance. In cases where intake from sources other than drinking water is significant, the lifetime cancer risk (upper 95% confidence limit) should be less than or equal to the lower end of the range of risks considered to be essentially negligible (i.e.,  $10^{-6}$ ).<sup>183</sup>

Where estimated lifetime cancer risks associated with the MAC are greater than those judged to be essentially negligible (i.e.,  $10^{-5}$  to  $10^{-6}$ ), an IMAC is

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<sup>181</sup> Ibid.

<sup>182</sup> Ibid.

<sup>183</sup> Ibid.



established and improvement in methods of quantitation and/or treatment is recommended.<sup>184</sup>

#### **5.1.7.6 *Setting Guidelines for Pesticides***

Under the *Pest Control Products Act*,<sup>185</sup> the Pest Management Regulatory Agency (PMRA) of Health Canada is responsible for assessing pesticides and establishing maximum tolerable residue levels in foods as part of its process for registering pesticides for use in Canada. The assessments entail deriving acceptable daily intake (ADI) values (in a way similar to TDIs) or, where data are insufficient or of poor quality, negligible daily intake (NDI) values, which incorporate larger uncertainty factors. The approach for deriving MACs and IMACs for pesticides that are considered “probably not carcinogenic to humans” or for which data on carcinogenicity are “inadequate for evaluation” differs somewhat from that for other chemicals.<sup>186</sup>

The Health Canada secretariat to the Subcommittee on Drinking Water usually uses the ADIs and NDIs developed by the PMRA as the basis for deriving MACs and IMACs for pesticides. This ensures consistency in the establishment of food residue limits; takes advantage of detailed scientific assessments; and ensures that all relevant data are considered (including confidential data submitted under the *Pest Control Products Act*). The World Health Organization (WHO), in conjunction with the Food and Agriculture Organization (FAO) of the United Nations, also conducts evaluations of pesticide residues in foods to derive ADIs or, where data are insufficient, provisional daily intake (PDI) values, which incorporate a larger uncertainty factor. In some cases, Health Canada derives MACs and IMACs for pesticides based on ADIs or PDIs established by these international organizations.

#### **5.1.7.7 *Setting Guidelines for Aesthetic Parameters***

Aesthetic objectives (AOs) are derived where the taste, odour, and appearance (organoleptic properties) of substances in drinking water could affect consumer

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<sup>184</sup> Ibid.

<sup>185</sup> *Pest Control Products Act*, R.S. 1985, c. P-9 [online], [cited on November 14, 2001], <laws.justice.gc.ca/en/P-9/79987.html>.

<sup>186</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1999a, p. 14.

acceptance of a water supply and where thresholds for these properties are lower than the MAC. Published information on taste and odour thresholds is used as the basis for setting AOs.<sup>187</sup>

#### **5.1.7.8 *Setting Guidelines for Radiological Parameters***

The approach used by the subcommittee in deriving guidelines for radioactive parameters conforms to international radiation protection methodologies and focuses on the potential for induction of cancer in various organs and tissues. This approach takes into account both the risk from exposure to radioactive substances in drinking water and the unavoidable risk from natural background radiation. The *Guidelines* also consider the total dose received when several substances are simultaneously present in drinking water.

Assessment of the cancer risk from exposures to radiation requires a link between exposure and biological outcome (damage to cells). The fundamental dosimetric measure of this energy transfer is the *absorbed dose*, which is defined as the amount of energy imparted by ionizing radiation to a unit mass of tissue. The unit of measure is the gray (Gy), which is equal to one joule of energy per kilogram of tissue. Equal absorbed doses do not necessarily have the same biological effect in different types of tissue. The extent of damage depends on the rate at which energy is imparted to the tissue, which varies with the type and energy of the radiation. To account for the potential for different types of ionizing radiation to produce different degrees of biological damage, weighting factors are used to adjust the absorbed dose. It is this weighted, or equivalent, dose that is considered to be important in protecting health from the impacts of radiation. The *equivalent dose* in a tissue or organ equals the absorbed dose multiplied by the sum of all the applicable radiation weighting factors. The unit of measure of the equivalent dose is the sievert (SV), which is independent of the nature of the radiation.

Because radionuclides absorbed by the body can persist, exposure durations for internal organs can extend over many months or even years. Consequently, it is standard practice in establishing drinking water guidelines to integrate

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<sup>187</sup> A listing of background documents for parameters in the *Canadian Drinking Water Guidelines* is available online at <[www.hc-sc.gc.ca/ehp/ehd/catalogue/bch\\_pubs/dwgsup\\_doc.htm](http://www.hc-sc.gc.ca/ehp/ehd/catalogue/bch_pubs/dwgsup_doc.htm)>.

effective doses over a period of 50 years for adults and 70 years for lifetime exposures.<sup>188</sup> The resulting integrated dose is known as the *committed effective dose* (measured in Sv).

The International Commission on Radiological Protection (ICRP) has estimated that the lifetime probability for all fatal cancers, weighted non-fatal cancers, and hereditary disorders is 7.3% per 1 Sv. Based on this estimate, the ICRP recommends a limit on the effective and committed effective dose of 1 mSv (0.001 Sv) per year for the combination of external and internal doses, excluding both natural background radiation and medical/therapeutic doses. This annual dose presents a total lifetime (70 years) risk for all fatal and weighted non-total cancers and hereditary disorders of about  $6 \times 10^{-3}$ .<sup>189</sup>

Because radionuclides in drinking water generally contribute only part of the total radiation dose, MACs for radionuclides are based on one-tenth of the ICRP's recommended limit, or a committed effective dose of 0.1 mSv per year from drinking water. This dose represents a risk of fatal cancers, weighted non-fatal cancers, and hereditary disorders between  $10^{-5}$  and  $10^{-6}$  per year or about  $6 \times 10^{-4}$  for a lifetime exposure. This includes exposure to natural radionuclides and is based on the total activity of all radionuclides in the water supply.<sup>190</sup>

MACs for radionuclides are expressed in units of becquerels per litre (Bq/L). For each radionuclide, the MAC is calculated by multiplying the yearly drinking water intake (730 L for an adult) by the dose conversion factor (DCF) (measured in Sv/Bq) and dividing this into the committed effective dose (0.1 mSv per year). The National Radiological Protection Board (NRPB) calculates DCFs based on metabolic and dosimetric models. Each DCF provides an estimated 50-year or 70-year committed effective dose from a single intake of 1 Bq of a radionuclide. When two or more radionuclides affecting the same organ or tissue are present in the water supply, the sum of each radionuclide's observed concentration divided by its MAC should be less than or equal to 1.<sup>191</sup>

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<sup>188</sup> "Effective dose" is calculated by multiplying the equivalent dose in each organ by the accompanying tissue weighting factor ( $W_i$ ) and summing the result for each organ to give the total effective dose to the body  $E_{(sv)} = \sum W_i H_i(sv)$  (Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1999a, p. 15).

<sup>189</sup> Ibid., p 16.

<sup>190</sup> Ibid.

<sup>191</sup> Ibid.

## 5.2 Setting Drinking Water Standards in Ontario

In August 2000, Ontario announced its new *Drinking Water Protection Regulation* under the *Ontario Water Resources Act (OWRA)*.<sup>192</sup> The *Drinking Water Protection Regulation* requires:

- regular and frequent sampling and testing of water;
- stringent treatment for all drinking water;
- quarterly publication of public drinking water quality reports by large waterworks;
- conduct of microbiological and chemical testing exclusively by accredited laboratories;
- clear immediate person-to-person communication of reports of potentially unsafe water situations to the Ontario Ministry of the Environment, the local medical officer of health, and the waterworks owner; and
- public access to all records of large waterworks.

In conjunction with the *Drinking Water Protection Regulation*, the *Ontario Drinking Water Standards (ODWS)* were established.<sup>193</sup> The Ontario Ministry of Environment's Web site (<[www.ene.gov.on.ca](http://www.ene.gov.on.ca)>) lists the standards, as well as other essential information covering:

- the application of the standards;
- source protection, treatment, and operations;
- approval of waterworks;
- responsibility for water quality;
- sampling, analysis, and corrective action; and
- a summary of disinfection requirements.

This associated information must be used in conjunction with the standards to ensure that drinking water is safe and protects health.

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<sup>192</sup> *Drinking Water Protection Regulation*, O. Reg. 459/00, under the *Ontario Water Resources Act*, RSO 1990, c. O-40, as am.

<sup>193</sup> ODWS [online], [cited November 19, 2001], <[www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf](http://www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf)>.

### 5.2.1 Purpose and Application of the Standards

The primary purpose of the *ODWS* is to protect public health by ensuring the provision of safe drinking water. As stated in the *ODWS*, drinking water must not contain disease-causing organisms or unsafe concentrations of toxic chemicals or radioactive substances. The standards also point out that water should be aesthetically acceptable; thus controlling taste, odour, turbidity, and colour will result in water that is clear, colourless, and without objectionable or unpleasant taste or odour. Other aspects such as corrosiveness, a tendency to form incrustations, and excessive soap consumption should be controlled because of their effects on the distribution system and/or the intended use of the water. The *ODWS* are considered to provide the minimum level of quality for drinking water in Ontario. They should not be regarded as allowing degradation of a high quality water supply to this minimum level.

The categories of standards addressed in the *ODWS* reflect the above-mentioned considerations. These are listed below; the first three are based on the Canadian *Guidelines*.<sup>194</sup>

- A maximum acceptable concentration (MAC) is a health-related standard established for parameters that have known or suspected adverse health effects when present above a certain concentration. The length of time a MAC can be exceeded without injury to health will depend on the nature and concentration of the parameter.
- An interim maximum acceptable concentration (IMAC) is a health-related standard established for parameters when either insufficient toxicological data are available to establish a MAC with reasonable certainty, or it is not feasible for practical reasons to establish a MAC at the desired level.
- Aesthetic objectives (AOs) are established for parameters that may impair the taste, odour, or colour of the water or may interfere with good water quality control practices. For certain parameters, both AOs and health-related MACs have been derived.
- Operational guidelines (OGs) are established for parameters that must be controlled to ensure efficient and effective water treatment and distribution.

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<sup>194</sup> Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1996a.

The Ontario Ministry of the Environment applies the *ODWS* when approving the establishment of waterworks. The ministry also applies the *ODWS* when approving the extension of or a change in any existing waterworks capable of supplying water at a rate greater than 50,000 L per day or when approving waterworks that supply water to more than five private residences.

In general, the municipality is responsible for the quality of distributed drinking water. A third party contracted for the treatment and/or distribution of the water acts as a statutory agent for the appropriate municipality, and the municipality therefore remains ultimately responsible for ensuring that water of adequate quality is delivered to consumers. Private owners and operators of waterworks are subject to the provisions of the *OWR* and are fully responsible for the quality of water delivered to the consumer.

### **5.2.2 Ontario's Role in Setting National Guidelines**

Ontario sets the standards for safe drinking water, in effect, by implementing the *Guidelines* through the *ODWS*. With other provincial and territorial members of the Federal-Provincial Subcommittee on Drinking Water, the Ontario representative shares accountability for the various stages (identification, assessment, evaluation, decision-making and approval, and announcement and publication) of the national guideline development process. Ontario is also a member of the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH), the parent body of the subcommittee, which gives final approval for the guidelines.

In the identification stage of setting the national guidelines, Ontario provides input on identification of substances for consideration by the subcommittee. This input includes data from monitoring programs and specific project-related case studies. Such data can help to identify parameters of concern in terms of health impacts, elevated environmental concentrations, and frequency of detection. In particular, the Ontario Ministry of the Environment's Drinking Water Surveillance Program (DWSP) provides data for the identification of substances for consideration by the subcommittee. (See subsection 4.5.1 for more information on the DWSP.)

When enough data are available, Ontario participates as a member of the subcommittee in selecting and ranking priority substances for guideline development. Given that the priority list is currently limited to six, Ontario

may proceed unilaterally to set a standard for a substance that is of concern in Ontario (see subsection 5.3.3).

The Health Canada secretariat carries out the risk assessment and formulates a proposed guideline value for a substance (usually with only preliminary information on risk management aspects). Ontario then gathers information on exposure levels to the substance, treatment technologies, economic impacts of complying with the proposed guideline, and capability of analyzing the substance at the guideline level.

Ontario reviews the secretariat's summary of responses following national public consultation on a proposed guideline and advises on Health Canada's responses to the public's comments. Ontario may also conduct its own consultations in accordance with its policies regarding *ODWS* as described below (subsection 5.2.3).

With the other members of the subcommittee, Ontario votes on the post-public-comment revised guideline. If approved by the subcommittee, the guideline goes to the CEOH for final approval.

### **5.2.3 Ontario's Use of the National Guidelines**

Once the CEOH accepts a proposed guideline value, Ontario proposes the adoption of the guideline under the Environmental Bill of Rights (EBR).<sup>195</sup> At this time, Ontario conducts its own public consultation with respect to adopting the guideline. This consultation is broader than that carried out for the national guideline. Letters are sent to local health units, all water treatment plants (municipalities), and stakeholders such as the Ontario Water Works Association, the Association of Municipalities of Ontario, the Ontario Municipal Water Association, and Pollution Probe. The proposal to adopt the guideline is posted on the Ministry of the Environment's Web site (<[www.ene.gov.on.ca](http://www.ene.gov.on.ca)>) under the EBR. No announcement is made through newspapers or television.

The proposal remains on the EBR for 30 to 90 days. The Ministry of the Environment reviews and assesses the comments received and makes a decision to adopt or modify the guideline (to a more stringent level). For example, in September 2000, Ontario decided to lower the recommended level of fluoride,

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<sup>195</sup> The EBR provides a formal means of notifying the public of proposed laws, regulations, policies, and other documents, or changes to these. It also provides for public input.

where fluoridation (the addition of fluoride to drinking water) is practised, from the subcommittee's recommendation of 0.8-1.0 mg/L to 0.5-0.8 mg/L, following an additional 60-day comment period within the province. However, the MAC for fluoride (1.5 mg/L) proposed by the subcommittee and accepted by the CEOH was reaffirmed as a standard. The Ontario Ministry of the Environment posted a notice of the final decision for the fluoride standards on the EBR Web site.<sup>196</sup>

For substances that are not of national concern but for which Ontario wishes to set standards, the Standards Development Branch of the Ministry of Environment follows the process of risk assessment/risk management used by the Subcommittee on Drinking Water. The decision to begin this process unilaterally is based on data from programs, such as the DWSP, and on other information on how substances are being used in Ontario. Standards have been set unilaterally for two substances: an *ODWS* of 0.000009 mg/L for N-nitrosodimethylamine and an *ODWS* of 0.000000015 mg/L for dioxins and furans (as 2,3,7,8-tetrachlorodibenzodioxin equivalents).<sup>197</sup>

As with other standard-setting practices, re-evaluation of the MACs, IMACs, AOs, and OGs is an ongoing process in Ontario.

## 5.3 Current International Practices

### 5.3.1 United States Drinking Water Standards

The primary legislation addressing drinking water quality in the United States is the *Safe Drinking Water Act (SDWA)*.<sup>198</sup> Originally passed in 1974, the *SDWA* has been amended twice, in 1986 and 1996. The 1996 amendment represents a redirection of the U.S. Environmental Protection Agency's (EPA's) approach to drinking water protection.<sup>199</sup> Historically, several factors led to this

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<sup>196</sup> Ontario, Ministry of the Environment, 2000, *Notice of Decision for Policy: EBR Registry No. PA9E0007* [online], [cited November 19, 2001], <<http://204.40.253.254/envregistry/012023ep.htm>>.

<sup>197</sup> *ODWS* [online], [cited November 19, 2001], <[www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf](http://www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf)>.

<sup>198</sup> 42 United States Code (U.S.C.) s. 300(g) (1996).

<sup>199</sup> United States, Environmental Protection Agency, 1996, *National Drinking Water Program Redirection Strategy*, EPA document EPA 810-R-96-003 [online], [cited November 16, 2001], <[www.epa.gov/OGWDW/docs/toc.html](http://www.epa.gov/OGWDW/docs/toc.html)>.



redirection.<sup>200</sup> New requirements under the 1986 amendments for monitoring and enforcing drinking water quality resulted in financial burdens that many states were unable to meet. In addition, the cryptosporidiosis outbreaks in Milwaukee<sup>201</sup> and Las Vegas<sup>202</sup> demonstrated that even large, modern water treatment plants were potentially vulnerable to large-scale outbreaks. This added impetus to efforts to strengthen existing water regulations, particularly those related to microbial contaminants and watershed protection measures. The 1996 amendment features greater emphasis on strengthening the scientific basis of decision making during the standard-setting process; enhancing cooperative efforts among the states, local governments, regional EPA offices, and the public; and improving the effectiveness of source water protection.

### 5.3.1.1 *Federal Rule Making*

The rule-making process in the United States requires notifying the general public and providing opportunities for their involvement. Under the *Administrative Procedure Act*,<sup>203</sup> agencies proposing new regulations must publish the proposed rule in the *Federal Register* to allow for public comment. After this notice and comment period has been completed, and a public hearing has been held (if warranted), the final rule is also published in the *Federal Register*. This publication generally includes the agency's analysis of the public comments and provides an explanation of the final rule. With this process, critical issues of science and policy have often been resolved through written argument and judicial review after the proposed regulation was released.<sup>204</sup>

Since the 1990s, the EPA has shifted from the traditional rule-making process that involved agency-based standards development followed by release of a completed proposed rule for public comment. The EPA recognized that this process does not allow for meaningful stakeholder involvement at an early

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<sup>200</sup> F.W. Pontius and S.W. Clark, 1999, "Drinking water quality standards, regulations and goals," in *American Water Works Association Water Quality and Treatment* (New York: McGraw-Hill), pp. 1.1–1.45.

<sup>201</sup> MacKenzie et al., 1994.

<sup>202</sup> S.T. Goldstein et al., 1996, "Cryptosporidiosis: an outbreak associated with drinking water despite state-of-the-art water treatment," *Annals of Internal Medicine*, vol. 124, pp. 459–468 [published erratum appears in *Annals of Internal Medicine* July 15, 1996, vol. 125, p. 158].

<sup>203</sup> 5 U.S.C. s. 552 (1993).

<sup>204</sup> T.F.P. Sullivan, 1999, "Fundamentals of environmental law," in T.F.P. Sullivan, ed., *Environmental Law Handbook* (Rockville, Md.: Government Institutes).

enough phase in the development of new rules and standards. The agency now often employs a formal negotiated rule-making process that uses specially appointed federal advisory committees in the development of regulations. Authorized by the *Negotiated Rulemaking Act*,<sup>205</sup> the EPA may or may not adopt the wording of rules and standards developed through this process. However, the EPA believes that, even if the actual wording is not used, the process is valuable in achieving a greater understanding of the concerns of stakeholders.<sup>206</sup>

Procedures and rules for the use of federal advisory committees are established by the *Federal Advisory Committee Act*.<sup>207</sup> Committees must have a formal charter, a statement of purpose, and a balanced representation in terms of stakeholder interests.<sup>208</sup> The National Drinking Water Advisory Council advises on drinking water regulations. The council consists of representatives from academia, water utilities, state and local public health agencies, and environmental advocacy organizations. In addition, federal advisory committees and subcommittees have been formed to make recommendations for specific rules, such as the *Stage 2 Disinfectants/Disinfection Byproducts Rule* and the *Long Term 2 Enhanced Surface Water Treatment Rule*.<sup>209</sup>

### 5.3.1.2 *Types of Standards*

The *SDWA* authorizes the EPA to set two types of drinking water standards: primary and secondary. Primary standards are based on public health considerations; while secondary standards address aesthetic concerns. The process to establish the National Primary Drinking Water Regulations (NPDWRs) begins with the setting of maximum contaminant level goals (MCLGs). An MCLG is defined as “the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.”<sup>210</sup> While past methods of risk assessment

<sup>205</sup> 5 U.S.C. s. 561–570 (1990).

<sup>206</sup> United States, Environmental Protection Agency, 1992, *Research Plan for Microbial Pathogens and Disinfection By-products in Drinking Water*, EPA/6001/R-97/22 (Washington, D.C.: EPA).

<sup>207</sup> 5 U.S.C. App. 1997.

<sup>208</sup> F. Pontius, 1999, “Negotiating regulations for micro-organisms and disinfection by-products,” *Journal – American Water Works Association*, vol. 91, no. 10, pp. 14–28.

<sup>209</sup> 66 Federal Register (213)56537 (November 8, 2001).

<sup>210</sup> 42 U.S.C. s. 300(g) 1(b)(4)(A) (1996).

generally considered exposures of healthy adults to contaminants, risks posed to children and to adults with specific health conditions are now being increasingly and explicitly considered. However, methods to incorporate such considerations as susceptibility are still being developed. Because only risks to health, not the ability of water suppliers to treat contaminated water, are considered, MCLGs may be set at a level that is unattainable. They are therefore unenforceable in and of themselves, but they are the basis of the maximum contaminant levels (MCLs), which must be set as close to the MCLG goal as is “feasible.”<sup>211</sup> Feasibility is defined by the application of the best available treatment techniques. Emphasis is placed on actual field performance of available technologies rather than on laboratory results. Cost is taken into consideration, but no clear cost limit or cost-benefit ratio is stated. If a contaminant cannot be reliably measured at low concentrations, a treatment technique (TT) may be set in place of an MCL. A TT is an enforceable procedure or level of performance that public water systems must follow to ensure control of a contaminant.

#### 5.3.1.3 *Cost-Benefit Review and Use of Variances*

Once an MCL or TT has been established, it is subjected to further economic review. The EPA must perform a full cost-benefit analysis, identifying both quantifiable and non-quantifiable benefits of a particular standard or rule. The EPA is developing guidance manuals and standardized methods for performing full cost-benefit analyses.

If the benefits do not outweigh the costs, the EPA may adjust the MCL for a particular group or class of water systems to a level that “maximizes health risk reduction benefits at a cost that is justified by the benefits.”<sup>212</sup> Variances can also be used to mitigate the high costs of implementing a standard for a chemical. States, on their own authority, may grant variances from standards to small systems serving fewer than 3,300 people. With EPA approval, states may also grant variances to systems serving 3,300 to 10,000 people. Variances are not permitted for microbial contaminants.

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<sup>211</sup> 42 U.S.C. s. 300(g) 1(b)(4)(B) (1999).

<sup>212</sup> 42 U.S.C. s. 300(g) 1(b)(6)(A) (1999).

#### 5.3.1.4 *Selection of Contaminants for Setting Standards*

The 1996 amendment to the *SDWA* established a more formal process for selecting water-borne contaminants to be considered for regulation.<sup>213</sup> A contaminant is placed on the national Drinking Water Contaminant List if it both poses a significant health risk and is present, or anticipated to be present, in drinking water supplies. These two determinations are made by the National Drinking Water Advisory Council, which is composed of representatives from academia, health and environmental advocacy groups, and the regulated water industries.

The amendment requires the use of peer-reviewed literature for making determinations of health risk. Scientific methods used in studies on which regulatory determinations are made must be reliable and generally accepted. The amendment also specifies that the EPA's Science Advisory Board must be consulted on every new regulation proposed to ensure that regulations are based on 'food science.' The 1996 amendment also authorized the EPA to devote funds to create an occurrence database of contaminants of concern in drinking water. This database is used to assess whether the contaminants are present in drinking water to an extent that would merit regulation.

*MCLGs for microbial contaminants* At present, MCLGs for microbial contaminants are set at zero, as there is insufficient evidence to determine whether a single organism is capable of causing infection in a susceptible individual. In addition, current analytic methods for microbial contaminants are expensive, often inaccurate, and difficult to standardize, making it difficult to regulate specific types of microbial contaminants. For now, regulation of microbial contaminants is based on treatment techniques and the use of indicators, such as *E. coli* and turbidity. The EPA is currently conducting extensive research to investigate the dose-response relationships associated with microbial contaminants and to establish improved analytical techniques. It may move toward formal risk assessment for regulating specific micro-organisms.

*MCLGs for chemicals with non-cancer endpoints* For some contaminants, the health effect of concern is one other than cancer (e.g., neurotoxicity or developmental toxicity). These contaminants are assumed to have a threshold level below which exposure is considered adequately safe. A reference dose approach is used in setting MCLGs for these substances. The reference dose is

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<sup>213</sup> 42 U.S.C. s. 300(g) (1996).

usually established on the basis of animal toxicology studies from which a no-observed-effect level (NOEL) or no-observed-adverse-effect level (NOAEL) can be derived. In some studies, the lowest dose used may still show an effect on the study animals. If no other studies can demonstrate a lower dose at which there are no effects, this dose may be used as the basis for the reference dose; it is then termed the lowest-observed-effect level (LOEL) or lowest-observed-adverse-effect level (LOAEL). NOELs or LOELs are divided by a series of uncertainty factors to arrive at a reference dose that is deemed to provide an adequate margin of safety for humans. Uncertainty factors are included to allow for extrapolation from animal to human, from high dose to low dose, and for the quality of the database. Uncertainty factors are usually 10, but they may be lower when the quality and number of studies reduce the uncertainties. For drinking water, the reference dose derived from animal studies is multiplied by typical adult body weight and divided by daily water consumption to arrive at a drinking-water-equivalent level (DWEL). The DWEL is then multiplied by the percentage of the total daily exposure contributed by drinking water (often 20%) to determine the MCLG for that contaminant.<sup>214</sup>

*MCLGs for chemicals with cancer endpoints* For drinking water regulations, the EPA has established three categories of carcinogens related to chemicals:<sup>215</sup>

- Category I: “known probable human carcinogens via ingestion”
- Category II: “possible human carcinogens via ingestion”
- Category III: “substances for which insufficient or no evidence of carcinogenicity via ingestion exists”

This categorization is partly based on, but is separate from, the EPA’s general classification of carcinogens, which has five categories.<sup>216</sup> The regulatory classification also draws on classifications of other bodies, such as the International Agency for Research on Cancer, and on exposure data, pharmacokinetics, etc.

The MCLGs for Category I carcinogens are generally set at a default value of zero, unless scientific evidence indicates that there is a dose below which the chemical is considered safe. The ability of the EPA to determine that such a threshold dose exists depends on an understanding of the mode of action of

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<sup>214</sup> Pontius and Clark, 1999.

<sup>215</sup> 56 Federal Register 3526 (January 30, 1991).

<sup>216</sup> 51 Federal Register 33992 (September 24, 1986).

the chemical and on the assessment of risk based on the EPA's new carcinogen risk assessment guidelines (see subsection 5.3.1.5). As of September 2001, no carcinogen has had a MCLG set above zero. The MCLG of zero for chloroform, however, was successfully challenged in court after the EPA had concluded that chloroform was likely to cause cancer by a mode of action for which there is a threshold.<sup>217</sup>

The MCLGs for Category II carcinogens are based on one of two options. In the first option, the derivation is conducted as for non-carcinogens (see above), but an extra uncertainty factor for the possible carcinogenicity is added. In the second option, a risk assessment is conducted to estimate the concentration in drinking water associated with an excess lifetime cancer risk of  $10^{-5}$  to  $10^{-6}$ . This concentration serves as the MCLG.

### 5.3.1.5 *Revised Carcinogen Guidelines*

Advances in biological sciences since the 1980s have led the EPA to look into revising its methods for health risk assessment for carcinogens. In 1996, the agency published the *Proposed Guidelines for Carcinogen Risk Assessment*,<sup>218</sup> which replaced the 1986 *Guidelines for Carcinogen Risk Assessment*.<sup>219</sup> At the time of writing this report, the proposed guidelines remain provisional, and they have not been approved and implemented. The proposed guidelines differ from the 1986 guidelines in the following ways:

- They include data other than results of tumour assays in hazard characterization, including non-cancer effects if relevant, and structure-activity relationships.
- They require a two-part dose-response analysis: (1) modelling within the range of observed data from toxicological or epidemiological studies; (2) low-dose extrapolation below the range of observed data.
- They use a benchmark dose or the lower 95% confidence limit on the dose estimated to result in a 10% increase in cancer incidence as the point of low-dose extrapolation. The EPA has not decided whether this

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<sup>217</sup> *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. Ct. App. 2000).

<sup>218</sup> 61 Federal Register 17960 (April 23, 1996).

<sup>219</sup> 51 Federal Register 33992 (September 24, 1986).

lower 95% confidence limit or a measure of central tendency of the 10% effective dose will be used.

- They allow risk assessments to be conducted using either a linear or a non-linear low-dose extrapolation model or both (as opposed to using only linear low-dose extrapolation). The non-linear approach would use a margin-of-exposure (MOE) approach similar to that used for non-carcinogens. Information gathered for hazard characterization would be used to ascertain a mode of action that would help determine if the use of a non-linear dose response model is appropriate.

One controversy surrounding the *Proposed Guidelines for Carcinogen Risk Assessment* is what will constitute sufficient evidence to justify using a non-linear, low-dose extrapolation. This issue was addressed in a court case between the Chlorine Chemistry Council and the EPA.<sup>220</sup> The case was brought to court after the EPA published an MCLG of zero for chloroform,<sup>221</sup> despite having previously published a document stating that chloroform appeared to have a threshold below which exposure could be considered safe.<sup>222</sup> The District Court ordered the EPA to annul its chloroform rule, concluding that the rule was inconsistent with the requirement in the 1996 amendment to the *SDWA* to use the “best available science.”<sup>223</sup> Therefore, it was unlawful. This case is significant for establishing that agency regulations must consider the state of the science at the time of rule making, without consideration of future anticipated information or additional peer review.

#### **5.3.1.6 Citizen Enforcement and Consumer Confidence Reports**

Citizen enforcement of environmental laws, such as citizen lawsuits against polluters or water companies, was a part of the initial acts on which the EPA is based. Recent amendments have strengthened this aspect of environmental regulation. The 1996 amendments to the *SDWA* expand citizens’ ‘right to know’ by requiring water suppliers to notify their customers of any treatment failures or standards violations. Suppliers must provide a detailed description of the violation when there is the possibility of health effects from short-term exposure.

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<sup>220</sup> 206 F.3d 1286 (D.C. Cir. Ct. App. 2000).

<sup>221</sup> 63 Federal Register 69390 (December 16, 1998).

<sup>222</sup> 63 Federal Register 15674 (March 31, 1998).

<sup>223</sup> 42 U.S.C., s.300(g) (1996).

In addition, all water suppliers are required to send annual consumer confidence reports (CCRs) to all customers. The CCRs must include results of testing carried out in compliance with standards, information on the potential health effects of any contaminants found, and mandatory language on the risks of cryptosporidiosis for immunocompromised people.

### 5.3.1.7 *Environmental Justice and Drinking Water*

Executive Order 12898, 'Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'<sup>224</sup> directed federal agencies to develop environmental justice programs that would identify and remediate disproportionately adverse health or environmental effects from federal programs and policies. Included in the order were directives to make information more easily obtainable by members of minority or low-income communities, and to increase public participation in decisions potentially affecting those communities.

The first drinking water standard to address environmental justice issues explicitly is the proposed *Radon in Drinking Water Rule*.<sup>225</sup> This proposed standard recommends an MCL of 300 pCi/L (picoCurie per litre) and an alternative MCL (AMCL) of 4,000 pCi/L. Community water systems could choose to comply with the standard MCL or initiate a multimedia mitigation program that would remediate homes found to have high radon levels. Community water systems that chose to implement the multimedia mitigation program (reducing exposure to radon through indoor air rather than from drinking water). would then only have to comply with the AMCL.

As part of the rule-making process, the EPA conducted a video conference to solicit input from the various potentially affected communities. Participants in the conference noted that the alternative MCL option may discriminate against lower income individuals. They raised concerns over uneven implementation of home remediation plans, particularly for inner city residents. Such an uneven approach may benefit those whose homes are remediated while leaving the broader public potentially exposed to higher levels of radon in drinking water.<sup>226</sup>

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<sup>224</sup> 59 Federal Register 7629 (February 16, 1994).

<sup>225</sup> 64 Federal Register 59246 (November 2, 1999).

<sup>226</sup> F. Pontius, 2000, "Environmental justice and drinking water regulations," *Journal – American Water Works Association*, vol. 92, no. 3, pp. 14–20.



The proposed radon rule addresses these concerns primarily by requiring public participation at the local and state level in deciding how to comply with the radon rule. It also requires public notification in CCRs of radon levels, health effects of radon, and the multimedia mitigation approach to controlling radon risks. This degree of public education and participation may lead to equitable decision making at the local and state level.<sup>227</sup>

### 5.3.2 Australian Drinking Water Guidelines

The *Australian Drinking Water Guidelines (ADWG)* are the primary reference for drinking water quality in Australia. The *ADWG* are not legally binding, but they do provide a framework for identifying acceptable drinking water quality, while emphasizing flexibility and community consultation. The *ADWG* are widely used as the basis for a variety of regulatory arrangements in individual states and territories. The *ADWG* were first issued in 1980. The document has undergone major revisions in 1987 and in 1996. The most recent version (1996) is based largely on the 1993 WHO drinking water guidelines. The *ADWG* were developed by a joint committee of the National Health and Medical Research Council (NHMRC) and the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ).

The NHMRC National Health Advisory Committee decided in September 1997 that future revisions would be carried out by a rolling review process, in which sections of the *ADWG* are updated as warranted by new research knowledge. Previously, the *ADWG* would remain unchanged for several years, then would be revised after a major review. The online version of the *ADWG* will be updated as the rolling review proceeds and is available at <[www.health.gov.au/nhmrc/publications/synopses/eh19syn.htm](http://www.health.gov.au/nhmrc/publications/synopses/eh19syn.htm)>.

#### 5.3.2.1 Types of Guidelines

The *ADWG* contain both health-related and aesthetic guidelines. A health-related guideline value is defined as the concentration or measure of a water quality characteristic that, based on current knowledge, does not result in any significant risk to the health of the consumer over a lifetime of consumption. An aesthetic guideline value is defined as the concentration or measure of a

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<sup>227</sup> 64 Federal Register 59246 (November 2, 1999).

water quality characteristic that is associated with good quality water. In addition to the guideline values, the *ADWG* also provide fact sheets on each parameter. A fact sheet on a specific substance outlines the characteristics of the substance, its typical values in Australian water supplies, water treatment methods, measurement techniques, health considerations, the derivation of the guideline value, and key references. The *ADWG* also provide information and guidance on preventive management, including the multiple barrier approach, system management, monitoring, and performance evaluation.

### **5.3.2.2 *Economic Considerations***

The Australian process for establishing guidelines does not formally consider the economic impact of attaining guideline values. However, the guidelines do recognize that the ability to achieve good water quality is constrained by the availability of resources. The 1996 version of the *ADWG* emphasizes the role of community consultation in establishing agreed-to levels of service and programs for maintenance or improvement of water quality. The *ADWG* specifically include advice relating to system management, sanitary inspections, and monitoring programs for small water supplies. Cost-benefit analyses in the development of new or revised guideline values are expected to be incorporated into the *ADWG* in the near future.

### **5.3.2.3 *Selection of Contaminants for Guidelines***

The range of contaminants covered by the *ADWG* largely reflects those included in the WHO guidelines.<sup>228</sup> The rolling review process includes a publicly advertised call for submissions on the need for revisions and additions each year. These submissions are considered by a priority-setting group comprising representatives of ARMCANZ, NHMRC, and other stakeholders. This group selects a range of parameters for the revision of guideline values and/or fact sheets, depending on the amount of new available evidence. New parameters may also be added through this process. Working parties comprising members with relevant expertise from the health and environment sectors and the water industry review the information and formulate revised draft guideline values and/or fact sheets. These drafts are subject to a public consultation process before final approval by ARMCANZ and NHMRC.

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<sup>228</sup> United Nations, World Health Organization, 1993.

#### 5.3.2.4 *Guideline Values for Microbial Contaminants*

The *ADWG* set values for pathogenic micro-organisms at zero, stating that such organisms, if explicitly sought, should not be detected in drinking water. Water authorities are advised to seek advice from the relevant health authority if such organisms are detected.

The *ADWG* do not recommend routine testing for pathogenic micro-organisms. Microbiological water quality is assessed by routine monitoring for indicator organisms.

#### 5.3.2.5 *Guideline Values for Chemicals Where a Threshold Exists*

Guideline values are derived from available evidence from human and animal studies. Where appropriate human data are available, these are used to derive a guideline value. In the absence of human data, a guideline value is usually based on the highest observed dose (level) that causes no adverse effects (NOAEL) in long-term experiments on laboratory animals. It is calculated using the following formula:<sup>229</sup>

$$\text{Guideline} = \frac{\text{NOAEL} \times \text{human weight (70 kg)} \times \text{proportion of intake from water}}{\text{volume of water consumed (2 L/day)} \times \text{safety factor}}$$

Safety factors are used because of the uncertainty inherent in extrapolating from animal studies to human populations, or from a small human group to the general population. Safety factors generally applied are:

- 10 for variations between animals of the same species;
- 10 for variations between species;
- 10 if data from a sub-chronic<sup>230</sup> study are used in the absence of reliable data from chronic (long-term) studies; and
- 10 if adverse effects have been observed at the lowest doses.

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<sup>229</sup> Australia, National Health and Medical Research Council/Agriculture and Resource Management Council of Australia and New Zealand, 1996, *Australian Drinking Water Guidelines* [online], [cited November 19, 2001], <[www.health.gov.au/nhmrc/publications/pdf/eh19.pdf](http://www.health.gov.au/nhmrc/publications/pdf/eh19.pdf)>[www.health.gov.au/nhmrc/publications/pdf/eh19.pdf](http://www.health.gov.au/nhmrc/publications/pdf/eh19.pdf).

<sup>230</sup> The term 'sub-chronic' is used in toxicology to describe studies designed to determine adverse effects that may occur during repeated exposure of the test animals over a period of a few days up to three months (90 days).

An overall safety factor of 100 to 1,000 is common, although higher values may sometimes be used. Occasionally, individual safety factors lower than 10 are used where there is additional information to justify a reduction. This can occur, for instance, in the following cases:

- where information is available to clarify the mechanism of the effects on humans;
- where human epidemiological data are available;
- where the adverse effects observed are regarded as relatively benign; and
- where large amounts of animal and human data are available.

Guideline values for compounds for which carcinogenesis is deemed to occur only above a threshold dose are determined in the same way as for non-carcinogenic compounds, but with an additional safety factor incorporated for carcinogenic effects.

#### ***5.3.2.6 Guideline Values for Chemicals Where No Threshold Has Been Demonstrated***

With carcinogenic compounds for which no threshold can be demonstrated, a risk assessment approach based on that used by the WHO is used.<sup>231</sup> This approach estimates the risk associated with very low exposures by extrapolating from the dose-response relationship observed at higher doses. While a number of uncertainties are involved, the calculations tend to overestimate rather than underestimate the risk, and so provide a large margin of safety.

The outcome of this calculation is then considered together with other factors to derive the guideline value. These factors are:

- the limit of determination (i.e., limit of quantitatively meaningful measurement) based on the most common analytical method;
- the concentration that could give rise to a risk of one additional cancer per million people, if water containing the compound at that concentration were consumed over a lifetime (the WHO risk assessment model); and

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<sup>231</sup> United Nations, World Health Organization (WHO), 1993, p. 35.

- a value based on a threshold-effect calculation, with an additional safety factor for potential carcinogenicity.

Frequently, the values determined from the two types of calculations (i.e., where a threshold for carcinogenesis is or is not deemed to exist) are very similar. Provided the limit of determination gives an adequate degree of protection (i.e., within a factor of 10 of those values determined from health considerations), this is used as the guideline value. If the limit of determination is much lower than values determined from health considerations, then the lower of the two calculated values is used. Conversely, if the calculated value is much lower than the limit of determination, then the calculated value is used as the guideline, but with a note that it is lower than the practical limit of determination.

### **5.3.2.7 Risk Assessment and Risk Management**

As part of the rolling revision process for the *ADWG*, a risk management framework is used to provide additional guidance on a preventive management approach for water supplies. The framework was developed through a collaborative process involving major stakeholders and international experts, and will be subject to public comment prior to finalization. It provides a practical and comprehensive risk management system for drinking water quality management from catchment to consumer. The *Framework for Management of Drinking Water Quality: A Preventive Strategy from Catchment to Consumer* will be incorporated into the *ADWG* during 2001. Development of the framework is described in subsection 6.4.3, and a synopsis of the framework appears in Appendix A5.

### **5.3.2.8 Consumer Consultation**

The *ADWG* outline a suggested approach to ensure adequate public participation in the decision-making processes of water authorities.<sup>232</sup> Community involvement should be sought in deciding the levels of service to be provided and the time-frame during which the necessary changes in treatment

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<sup>232</sup> *Australian Drinking Water Guidelines*, 1996.

or distribution systems are to be implemented. While public health considerations must remain paramount, the financial implications of change will affect the operation of water authorities, and each community must decide its own priorities for the allocation of resources.

The public should have access to the following specific types of information:

- a drinking water management plan with details of system management, monitoring, performance assessment, reporting, planned improvements, contingency plans, and service levels;
- annual reports summarizing performance against agreed-to levels of service or the *ADWG*; and
- contingency plans for emergency situations, including procedures for notification when water quality poses a health risk.

### **5.3.3 The World Health Organization's Drinking Water Guidelines**

The WHO first published its *Guidelines for Drinking-Water Quality* in 1984 and 1985. The development of these guidelines was coordinated by the WHO headquarters and the WHO regional office for Europe (EURO). The International Programme on Chemical Safety (IPCS) played a key role in assessing health risks of the chemical constituents covered by the guidelines.

In preparing the guidelines, officials considered risk assessments already conducted by the IPCS, the International Agency for Research on Cancer, the Joint FAO/WHO Meetings on Pesticide Residues, and the Joint FAO/WHO Expert Committee on Food Additives.

Lead countries (Canada, Denmark, Finland, Germany, Italy, Japan, Netherlands, Norway, Poland, Sweden, United Kingdom, and United States) prepared draft health risk assessment documents. Several scientific institutions and selected experts reviewed these draft assessments before a review group made decisions about risk assessments and proposed guideline values for inclusion in the guidelines. More than 200 experts from almost 40 countries participated in preparing the current (second edition) of the WHO guidelines, published in 1993.<sup>233</sup>

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<sup>233</sup> United Nations, World Health Organization (WHO), 1993.

### 5.3.3.1 *Guidelines for Microbiological Parameters*

The 1993 WHO guidelines state that there is “no tolerable lower limit” for pathogens and that water for domestic purposes should contain no pathogenic agents. The guidelines note that pathogen-free water “is attainable by selection of high-quality uncontaminated sources of water, by efficient treatment and disinfection of water known to be contaminated with human or animal feces, and by ensuring that such water remains free from contamination during distribution to the user.”<sup>234</sup> The guidelines also state the need for treatments to ensure that the final disinfection stage is effective. Such treatments include removing or reducing, for example, turbidity and substances that exert a demand on the disinfection process or protect pathogens from disinfection.

*Bacterial quality* The WHO guidelines recommend using indicator bacteria (specifically *E. coli*) to test for the presence of fecal pollution or the efficiency of water treatment and disinfection. The thermotolerant coliform test is mentioned as an alternative to the test for *E. coli*. The guidelines also recommend thermotolerant coliform bacteria as indicators of the efficiency of water treatment processes in removing enteric pathogens and fecal bacteria, and for grading the quality of source waters in order to select the intensity of treatment needed.

The guidelines state that *E. coli* or thermotolerant coliforms should not be present in 100 mL samples of any water intended for drinking. Also, *E. coli* or thermotolerant coliform bacteria and total coliform bacteria must not be detectable in any 100 mL sample of treated water entering the distribution system or in the distribution system. The guidelines allow for the occasional occurrence of coliforms in the distribution systems of large supplies provided *E. coli* is not present, but total coliform bacteria must not be present in 95% of samples taken throughout any 12-month period.<sup>235</sup>

The presence of *E. coli* or total coliform bacteria in water supplies is a signal to undertake immediate action to confirm their presence, determine the cause of their presence, and take remedial action to eliminate them.

*Virological quality* Water treatment can considerably reduce the levels of viruses but may not eliminate them completely from very large volumes of water. The WHO considers that there is insufficient information from which to derive

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<sup>234</sup> Ibid., p. 14.

<sup>235</sup> Ibid., p. 22.

virological criteria. Specific guidelines are not recommended for routine use because of the cost, complexity, and time required for virological analyses. Moreover, these analyses are unable to detect the most relevant viruses.

*Parasitological quality* The analytical methods for protozoan pathogens are expensive and time consuming, and cannot be recommended for routine use. Therefore, guideline values for pathogenic protozoa, helminths, and free-living micro-organisms have not been established, although the guidelines state that these agents should not be present in drinking water.

### **5.3.3.2 Guidelines for Chemical Parameters**

The WHO uses two principal sources of information for deriving guideline values: studies on human populations and studies using laboratory animals. The latter are most often used but are generally limited because of:

- the relatively small numbers of animals used;
- the relatively high doses administered; and
- the need to extrapolate the results to the low doses human populations are usually exposed to.

Data from well-conducted studies where clear dose-response relationships have been demonstrated are preferred. Expert judgment is exercised in the selection of the most appropriate studies.

The WHO uses different approaches in developing guidelines, depending on whether a chemical does or does not have a threshold for the critical adverse effect.

*Threshold effects* A tolerable daily intake (TDI) is derived by dividing a NOAEL or LOAEL from experimental studies by an uncertainty factor. A group of experts selects, by consensus, the NOAEL or LOAEL most biologically significant for the response. Expert judgment is used to apply uncertainty factors, each in the range of 1 to 10, to allow for variations between animals and humans, and between individuals; the adequacy of studies or the database; and the nature and severity of the effect. The guideline value (as a concentration in drinking water) is derived from the TDI by allocating a fraction of the TDI to drinking water and taking into account the volume of water consumed. Allowances are made for differences between children and adults. The fraction of the TDI



allocated to drinking water is, where possible, determined by the relative contribution made by drinking water to the total amount of a substance ingested daily. If such data are lacking, a default value of 10% is used.<sup>236</sup>

If the total uncertainty is deemed to exceed 10,000, the resulting TDI is considered to be so imprecise as to lack meaning. Where uncertainty factors are greater than 1,000, the guideline values are designated as ‘provisional’ to emphasize the high level of uncertainty.

*Non-threshold effects and potential carcinogens* The evaluation of the potential carcinogenicity of chemical substances is usually based on long-term studies in animals. The WHO takes into consideration how the International Agency for Research on Cancer (IARC) classifies chemicals with respect to potential carcinogenicity; that is, whether IARC considers a substance (agent) to be one of the following:<sup>237</sup>

- Group 1: “carcinogenic to humans”
- Group 2A: “probably carcinogenic to humans”
- Group 2B: “possibly carcinogenic to humans”
- Group 3: “not classifiable as to its carcinogenicity to humans”
- Group 4: “probably not carcinogenic to humans”

Generally, chemical carcinogens are considered to act through a genotoxic mechanism for which no threshold exists; that is, there is a probability of harm at any level of exposure. Therefore, the WHO considers the development of a TDI for such substances to be inappropriate, and a mathematical procedure is used to estimate the cancer risks at low doses (exposure levels). Guideline values are presented as the concentration in drinking water associated with an estimated excess lifetime cancer risk of  $10^{-5}$  (i.e., one additional cancer case per 100,000 of the population ingesting drinking water containing the substance at the guideline value for 70 years). The guidelines note that concentrations associated with estimated excess lifetime cancer risks of  $10^{-4}$  and  $10^{-6}$  may also be calculated. Where it is not practical to reduce concentrations to a level associated with a  $10^{-5}$  excess lifetime cancer risk, or where such levels cannot be measured because of inadequate analytical methods, a provisional guideline value is set at a practicable level, and the estimated cancer risk presented.<sup>238</sup>

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<sup>236</sup> Ibid., p. 32.

<sup>237</sup> Ibid., p. 35.

<sup>238</sup> Ibid., p. 35.

Some carcinogens are capable of producing tumours in animals or humans by an indirect mechanism for which a threshold dose is believed to exist. Where there is convincing evidence to suggest a non-genotoxic mechanism, the WHO derives guideline values using a TDI approach.

### **5.3.3.3 *Guidelines for Radioactive Parameters***

The WHO drinking water guidelines describe the introduction by the International Committee on Radiological Protection (ICRP) of radiation and tissue weighting factors for rationalizing the biological impacts of different types of radiation on different organs and tissues.<sup>239</sup> The sum of the (doubly) weighted dose of radiation received by all the tissues and organs of the body gives a measure of the total harm and is referred to as the effective dose. Since radionuclides may persist in the body, the committed effective dose, expressed in sieverts (Sv), is a measure of the total effective dose (or exposure) incurred over a lifetime following the intake of a radionuclide. An estimate of the risk (i.e., the mathematical expectation) of a lifetime fatal cancer for the general population has been estimated by the ICRP to be  $5 \times 10^{-2}$  per sievert (excluding a small additional health risk from non-fatal cancers or hereditary effects).

The WHO recommends a reference level of a committed effective dose of 0.1 mSv from one year's consumption of drinking water. This represents less than 5% of the average effective dose attributable annually to natural background radiation. Below this reference level, drinking water is considered to be acceptable for human consumption. The recommended guideline levels are 0.1 becquerel per litre (Bq/L) for gross alpha activity and 1 Bq/L for gross beta activity; the recommendations do not differentiate between natural and artificial radionuclides. If either the gross alpha activity concentration of 0.1 Bq/L or the gross beta activity concentration of 1 Bq/L is exceeded, specific radionuclides should be identified and their individual activity concentrations measured.

The WHO notes that the guidelines for radioactivity apply to the routine operating conditions of water supplies, not to those water supplies that are contaminated during an emergency situation when radionuclides are released into the environment.

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<sup>239</sup> Ibid., p. 115.

## 5.4 Summary

The establishment of standards or guidelines for drinking water quality is critical for protecting the health of consumers. However, the existence of such limits alone cannot ensure protection unless other measures are practised. Source water protection, adequate water treatment, monitoring of treated water for compliance with the limits, and taking corrective action when limits are exceeded are all important aspects of providing quality drinking water.

In Canada, responsibility for developing and implementing guidelines or standards for drinking water is shared between the provincial, territorial, and federal levels of government. Collaborative arrangements between these governments have been in place for many years, and the development of national guidelines (the *Guidelines for Canadian Drinking Water Quality*) is conducted under the auspices of the Federal-Provincial Subcommittee on Drinking Water. Six editions of the guidelines have been issued since 1968. The current (1996) edition includes recommendations for over 100 microbiological, chemical, physical, and radiological parameters. The Subcommittee on Drinking Water follows a risk assessment/risk management model for developing the guidelines. Health Canada provides the secretariat for the subcommittee and, in general, carries out the health risk assessments of the parameters and prepares the technical documentation. The provinces and territories are responsible for considering aspects such as the practicality, costs, and benefits of implementing proposed new or updated guideline values.

Maximum (or interim maximum) acceptable concentrations (MACs and IMACs) are specified for substances that could cause adverse health effects. Aesthetic objectives (AOs) are specified for certain substances or characteristics of drinking water that can affect its acceptability by consumers or interfere with water supply practices. The guidelines recommended by the subcommittee are not legally enforceable as national standards. The decision to implement and enforce them rests with each province and territory. The provinces and territories have adopted a variety of measures including enacting specific legislation encompassing all or part of the guidelines, issuing operating permits to specific water treatment facilities, or issuing policy directives to implement the guidelines. The national guidelines have also been used at the federal level as a benchmark for the quality of water provided to federal employees, on Indian reserves, and on common carriers that cross international and interprovincial borders.

The national guidelines specify two main approaches for ensuring the microbiological quality of drinking water: (1) testing for the presence of indicator organisms, in particular *E. coli*, and (2) employing adequate water treatment methods. The approach for setting health-based guidelines for chemical contaminants depends on the nature of the toxic effect. In general, for non-carcinogenic chemicals, limits are set to ensure that exposure to a substance (from drinking water and other sources combined) does not exceed the tolerable daily intake. For carcinogenic substances, limits are set as close to zero as reasonably practical, taking into account the calculated cancer risk, the ability to achieve the level at a reasonable cost, and the ability to analyze for the substance at the specified limit. The approach used for radioactive parameters conforms to the international radiation protection methodologies, which focus on substances' potential to cause cancer.

In August 2000, Ontario announced its *Drinking Water Protection Regulation (DWPR)*<sup>240</sup> and established the *Ontario Drinking Water Standards (ODWS)*.<sup>241</sup> The primary purpose of the *ODWS* is protection of public health. The standards stipulate that drinking water must not contain disease-causing organisms or unsafe concentrations of toxic chemicals or radioactive substances. The standards are divided into the following categories: maximum acceptable concentrations (MACs), interim acceptable concentrations (IMACs), aesthetic objectives (AOs), and operational guidelines (OGs). In effect, Ontario sets the standards for safe drinking water quality by implementing the current *Guidelines*. However, standards for parameters of particular interest in Ontario may also be established in addition to those in the national standards. Data obtained from monitoring programs, such as the Drinking Water Surveillance Program, are used as support for the standard-setting process.

Ontario consults with the public before accepting a national guideline, and these consultations are considered to be broader than those carried out for the national guidelines. The Ontario Ministry of Environment contacts various organizations and stakeholders, and posts proposals to adopt a guideline on its Web site.

In the United States, the process for setting standards is marked by substantial public involvement. Since the 1970s, the public in choosing contaminants for

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<sup>240</sup> *Drinking Water Protection Regulation*, O. Reg. 459/00, under the *Ontario Water Resources Act*, RSO 1990, c. O-40, as am.

<sup>241</sup> *ODWS* [online], [cited November 19, 2001], <[www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf](http://www.ene.gov.on.ca/envision/WaterReg/Pibs4065.pdf)>.

regulation, setting standards, and even enforcing standards has formalized and grown. Consultation methods include publishing proposed contaminant lists and standards in the *Federal Register* to allow:

- open public comment;
- the chartering of formal advisory committees to recommend specific approaches and concentrations for standards; and
- the provision of detailed chemical release and contaminant monitoring data to the general public.

Unenforceable goals for microbial contaminants are currently set at zero. The development of microbial risk assessment methods may allow specific microbial contaminant standards to be set, but currently, standards exist only for coliforms and turbidity as indicators of contamination. Required types and performance levels of water treatment are used to control levels of other microbial contaminants in drinking water.

New guidelines being finalized for carcinogen risk assessment emphasize mechanisms of carcinogens and allow for departure from long-held assumptions that dose response is linear.

The Australian situation is similar to Canada's in that the states are responsible for regulating water quality. However, the national *Australian Drinking Water Guidelines (ADWG)* are used as the basis for a variety of regulatory arrangements. The approaches used in deriving the limits are also similar to those used by the Canadian Subcommittee on Drinking Water and the World Health Organization (WHO).

The WHO's guidelines for drinking water quality are developed to guide individual countries and are intended to be used as a basis for the development of national standards. The technical approaches used in setting limits for the parameters are similar to those followed in setting Canada's national guidelines.

## **6 Strengthening Drinking Water Management Practices**

This section examines state-of-the-art practices for assessing the risks of microorganisms, population health and disease surveillance systems, and water quality management, with a view to their possible application to water quality

management in Canada. The section begins with a review of scientific advances in assessing the health risks of micro-organisms, including risks posed to individuals who may be especially vulnerable, and an examination of how risk assessment/risk management models can be applied in quantifying the health risks posed by micro-organisms. It also examines the possible role of enhanced population health surveillance systems in detecting and preventing disease outbreaks from microbial contamination, and describes systems for the early detection of infectious disease outbreaks in Canada and Australia. We review the concept of comprehensive water quality management systems as a possible approach to further improve water quality management, and conclude with some specific suggestions for how such developments could be of value in further strengthening water quality management practices in Ontario.

## 6.1 Recent Developments in Microbiological Risk Assessment

Guidelines for the microbiological quality of drinking water are set using indicator organisms, most often the coliform group (either total or fecal). The same approach has been used for contact recreational and shellfish harvesting waters. With the development of better methods for the direct measurement of pathogens in water<sup>242,243,244,245,246,247</sup>, it is timely to review advances made in quantitative microbiological risk assessment and how these advances can be incorporated into risk assessment frameworks for setting microbiological standards for drinking water. Direct measurements of pathogens could supplement or replace traditional indicator measurements.

The quantitative microbiological risk assessment (QMRA) approach follows the framework proposed by the U.S. National Research Council (NRC) for

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<sup>242</sup> L.Y.C. Leong, 1983, "Removal and inactivation of viruses by treatment processes for potable water and wastewater: A review," *Water Science and Technology*, vol. 15, p. 91.

<sup>243</sup> J.E. Ongerth, 1989, "*Giardia* cyst concentrations in river water," *Journal – American Water Works Association*, September, pp. 81–86.

<sup>244</sup> C.P. Gerba and J.B. Rose, 1990, "Viruses in source and drinking water," in G.A. McFeters, ed., *Drinking Water Microbiology* (New York: Springer-Verlag).

<sup>245</sup> J.B. Rose, 1990, "Pathogens in water: Overview of methods, application limitations and data interpretation," in G.F. Craun, ed., *Methods for the Investigation and Prevention of Waterborne Disease Outbreaks* (Cincinnati, Ohio: U.S. Environmental Protection Agency, Health Effects Research Laboratory), pp. 223–234.

<sup>246</sup> J.B. Rose et al., 1991a, "Survey of potable water supplies for *Cryptosporidium* and *Giardia*," *Environmental Science and Technology*, vol. 25, pp. 1393–1400.

<sup>247</sup> J. Gregory, 1994, "*Cryptosporidium* in water: Treatment and monitoring methods," *Filtration and Separation*, vol. 31, pp. 283–289.

chemical risk assessment; thus the steps hazard assessment, exposure assessment, dose-response analysis, risk characterization, and risk management are included. In the 1983 approach, the technical tasks of risk analysis (encompassing the hazard assessment, exposure assessment, dose-response analysis, and risk characterization phases) and the policy-making tasks of risk management are separate. However, it is now understood that subjective factors are embodied within risk analysis (which may be called risk analysis policy), and that a good risk analysis requires problem-scoping by the risk manager. Thus, the analysis and management phases are of necessity interconnected in the QMRA.

Alternative protocols specifically for microbiological risk assessment have been presented, for example, by the International Life Sciences Institute (ILSI).<sup>248</sup> A schematic of the ILSI protocol is shown in Figure 6.1. This protocol emphasizes more clearly the interrelationships between the technical and policy-making components surrounding the risk assessment process, particularly at the problem formulation stage.

Microbial risk assessment methods, both qualitative and quantitative, have been gaining acceptance in the international arena. The World Health Organization (WHO), in conjunction with the Food and Agriculture Organization (FAO), has organized a major multi-year effort to prepare documents relating to the risk posed by food-borne pathogens.<sup>249</sup>

The European Commission (through its Scientific Committee on Food) adopted principles for microbiological risk assessment in 1997.<sup>250</sup> The Sanitary and Phytosanitary (SPS) Agreement, under the aegis of the World Trade Organization (WTO), also provides for the use of risk assessment methods to determine protective measures.<sup>251</sup>

### 6.1.1 Differences in Assessing Microbial and Chemical Risks

Several substantive differences exist between assessing the risks of micro-organisms and those of chemicals. Some of these differences are the subject of

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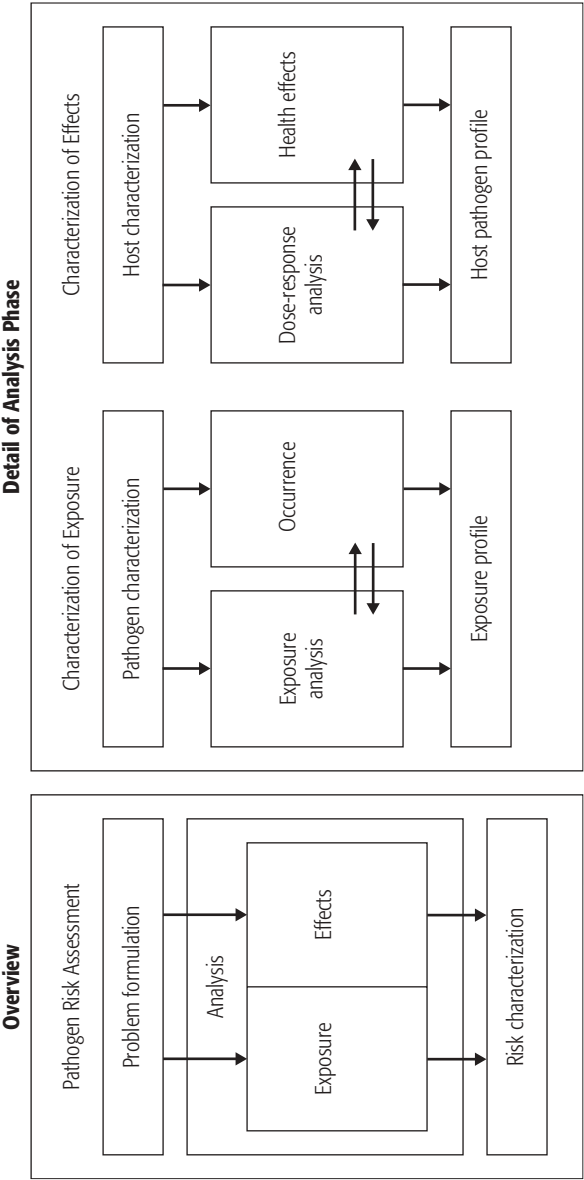
<sup>248</sup> International Life Sciences Institute (ILSI), Risk Science Institute, Pathogen Risk Assessment Working Group, 1996, "A conceptual framework to assess the risks of human disease following exposure to pathogens," *Risk Analysis*, vol. 16, pp. 841–848.

<sup>249</sup> World Health Organization Web site: <[www.who.int/fsf/mbriskassess/index.htm](http://www.who.int/fsf/mbriskassess/index.htm)>.

<sup>250</sup> EU Web site: <[europa.eu.int/comm/food/fs/sc/oldcomm7/out07\\_en.html](http://europa.eu.int/comm/food/fs/sc/oldcomm7/out07_en.html)>.

<sup>251</sup> The Sanitary and Phytosanitary (SPS) Agreement Web site: <[www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)>. See, particularly, article 5.

Figure 6.1 Schematic of the Microbial Risk Analysis Protocol of the International Life Sciences Institute (ILSI)





research, which is summarized at the end of this section. The first difference is that exposure to micro-organisms from water generally involves ingesting low numbers (up to tens or hundreds) of micro-organisms. Exposure to chemical agents even at very low doses involves ingesting much larger numbers (thousands or much greater) of molecules. When exposures to relatively low numbers of micro-organisms occur, there may be large differences in the actual number of organisms ingested by different individuals as a consequence of statistical sampling variability. In the case of the large numbers of chemical molecules, this variability is quite small compared to other variabilities. Hence, this intrinsic sampling variability must be taken into account in assessing exposure to and dose-response relationships for micro-organisms.

The second difference is that one micro-organism has the potential to cause harm, whereas many molecules of a chemical agent are necessary to provoke an effect (depending on the agent and the mode of action). Generally, an ingested micro-organism has the potential to multiply within the body, thereby producing sufficient numbers *in vivo* to result in illness. This does not mean that ingesting a single organism will always result in illness, because an organism may be killed by the body's defence processes (e.g., by the acidity of the gastrointestinal tract or by the immune system) before reproducing in sufficient amounts to cause an effect. But one organism *does* have the potential to produce an effect.

The third difference is that exposure of an individual to micro-organisms may subsequently affect the broader population, including those individuals who have not ingested pathogenic micro-organisms from water. Once infected (even if not symptomatic), an individual may infect others by person-to-person contact and cause others to become ill. The degree of secondary spread depends on the organism's infectivity and excretion pattern, and on the behaviour of infected individuals. For example, infected adults are believed to follow better hygienic practices, such as hand-washing, as compared to children, and, therefore, infected adults may produce fewer secondary cases than children do. In addition, the number of susceptible persons that an infected person may come in contact with is an important factor. A summary of selected secondary attack rates is shown in Table 6.1.

Another population factor is that prior exposure to a micro-organism (whether via water or other routes) may induce partial or complete immunity in an individual; that is, the individual may become less susceptible (partial immunity)

or completely resistant (complete immunity) to subsequent exposures. This immunity may be permanent or temporary. However, insufficient data exist to permit the quantitative evaluation of *either* secondary transmission or immunity in performing a quantitative microbial risk assessment. This inability to consider secondary transmission and immunity in a quantitative way constitutes, in effect, a neglect of compensating factors.

**Table 6.1 Secondary Attack Rates in Selected Outbreaks**

| Organism               | Secondary Attack Ratio <sup>a</sup> | Secondary Prevalence in Households <sup>b</sup> | Remarks                                      | Reference                            |
|------------------------|-------------------------------------|---|--|--------------------------------------|
| <i>C. parvum</i>       | N/A                                 | 0.042   | Drinking water outbreak (Milwaukee)          | (MacKenzie et al. 1995) <sup>d</sup> |
| Viral gastroenteritis  | 0.22                                | 0.11 <sup>a</sup>                               | Drinking water outbreak                      | (Morens et al. 1979) <sup>e</sup>    |
| Viral gastroenteritis  | 0.56                                | N/A   | Drinking water outbreak (Denmark)            | (Laursen et al. 1994) <sup>f</sup>   |
| Norwalk virus          | 0.5–1.0                             | 0.19  | Swimming outbreak                            | (Baron et al. 1982) <sup>g</sup>     |
| Norwalk virus          | N/A                                 | 0.44  | Food-borne outbreak in children and teachers | (Heun et al. 1987) <sup>h</sup>      |
| Norwalk virus          | 0.4                                 | N/A   | Food-borne outbreak                          | (White et al. 1986) <sup>i</sup>     |
| <i>E. coli</i> O157:H7 | N/A                                 | 0.18 c  | Daycare centre outbreak in children          | (Spika et al. 1986) <sup>j</sup>     |

N/A – information not available.

<sup>a</sup> Ratio of secondary cases to primary cases.

<sup>b</sup> Proportion of households with one or more primary cases who have one or more secondary cases.

<sup>c</sup> Proportion of persons in contact with one or more primary cases who have a secondary case.

<sup>d</sup> W.R. MacKenzie et al., 1995, "Massive outbreak of water-borne *Cryptosporidium* infection in Milwaukee, Wisconsin: Recurrence of illness and risk of secondary transmission," *Clinical Infectious Diseases*, vol. 21, pp. 57–62.

<sup>e</sup> D.M. Morens et al., 1979, "A waterborne outbreak of gastroenteritis with secondary person to person spread," *Lancet*, May 5, pp. 964–966.

<sup>f</sup> E. Laursen et al., 1994, "Gastroenteritis: A waterborne outbreak affecting 1600 people in a small Danish town" *Journal of Epidemiology and Community Health*, vol. 48, pp. 453–458.

<sup>g</sup> R.C. Baron, 1982, "Norwalk gastrointestinal illness: An outbreak associated with swimming in a recreational lake and secondary person-to-person transmission," *American Journal of Epidemiology*, vol. 115, pp. 163–172.

<sup>h</sup> E.M. Heun et al., 1987, "Risk factors for secondary transmission in households after a common source outbreak of Norwalk gastroenteritis," *American Journal of Epidemiology*, vol. 126, pp. 1181–1186.

<sup>i</sup> K.E. White et al., 1986, "A food-borne outbreak of Norwalk virus gastroenteritis," *American Journal of Epidemiology*, vol. 124, no. 1, pp. 120–126.

<sup>j</sup> J.S. Spika et al., 1986, "Hemolytic uremic syndrome and diarrhea associated with *Escherichia coli* O157:H7 in a day care center," *Journal of Pediatrics*, vol. 109, pp. 287–291.

## 6.1.2 Case Studies

A number of case studies of the application of microbial risk assessment have been published since the 1980s. Four examples are described here: one involves risk from ingesting pathogens in food and three involve drinking water.

### 6.1.2.1 *Risk from Ingesting Giardia lamblia in Drinking Water*

A dose-response relationship for infection from ingesting *Giardia lamblia* (*G. lamblia*) has been developed using data from human volunteer studies.<sup>252</sup> This was compared with attack rates observed in water-borne outbreaks to assess the likelihood that an infected person would become ill.<sup>253,254</sup>

Using a target risk of 1 infection in 10,000 persons per year – acceptable according to the U.S. *Surface Water Treatment Rule (SWTR)*<sup>255</sup> – and an average daily water consumption of 2 L per person per day, an acceptable finished water concentration would be  $6.75 \times 10^{-6}$  organisms per litre (i.e., one organism in 148,000 L). The verification of such a low level of microbial occurrence is technologically impossible, and so a graphical relationship between the microbial quality of a source water and the log reduction required to reduce the microbial level to the acceptable value was developed. The term ‘log reduction’ refers to the orders of magnitude by which a micro-organism concentration is reduced. For example, a reduction by a factor of 10 is ‘1 log,’ a factor of 100 is ‘2 logs,’ and so on.

In the initial proposal of the *SWTR*, a tiered treatment requirement incorporating the above approach was proposed. However, in the final regulation, a single fixed value of log reduction was required (based on an estimated upper value of source water microbial levels across the United States).

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<sup>252</sup> S. Regli et al., 1991, “Modelling risk from Giardia and viruses in drinking water,” *Journal – American Water Works Association*, vol. 83, no. 11, pp. 76–84.

<sup>253</sup> Ibid.

<sup>254</sup> J.B. Rose et al., 1991b, “Risk assessment and the control of water-borne Giardiasis,” *American Journal of Public Health*, vol. 81, pp. 709–713.

<sup>255</sup> 54 Federal Register 27486–27541 (June 29, 1989).

### **6.1.2.2 *Netherlands: Cryptosporidium and Balancing the Risks from Disinfection By-products***

Teunis et al. evaluated the risk to consumers from ingesting *Cryptosporidium parvum* (*C. parvum*) in treated water from a plant in the Netherlands.<sup>256</sup> They based the underlying dose-response relationship on data from human volunteer studies.<sup>257</sup> In the risk assessment, they also used the uncertainties associated with analysis and recovery of oocysts and an underlying distribution of source water quality and treatment efficiencies. The authors concluded that the median annual risk of infection from *Cryptosporidium* was slightly greater than 1 in 10,000.<sup>258</sup>

In subsequent work, the same research group extended the use of its risk assessment to consider the potential effect of increases in ozone dose to augment *Cryptosporidium* removal, which also increases the formation of disinfection by-products (especially bromate).<sup>259</sup> Havelaar et al. considered the public health consequences in terms of change in prevalence, duration, and severity of illnesses in the general and AIDS populations. They concluded that the addition of ozone resulted in a net public health benefit even allowing for the enhanced (cancer) risk from disinfection by-products. However, in performing this work, Havelaar et al. had to make a number of assumptions that are not yet fully grounded in data. For example, the relative susceptibility of the general and AIDS populations to infection by *Cryptosporidium* is not yet quantitatively characterized. In addition, assumptions about the risk of mortality from cryptosporidiosis in people with AIDS may no longer be valid because of advances in HIV treatment.

### **6.1.2.3 *New York City: Cryptosporidium***

The New York City water system uses chlorination alone and has been exempted from filtration under an agreement between New York City, New York State, and the U.S. Environmental Protection Agency (EPA). An intensive watershed

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<sup>256</sup> P.E.M. Teunis et al., 1997, "Assessment of the risk of infection by *Cryptosporidium* in drinking water from a surface water source," *Water Research*, vol. 31, pp. 1333–1346.

<sup>257</sup> H. Dupont et al., 1995, "Infectivity of *Cryptosporidium parvum* in healthy volunteers," *New England Journal of Medicine*, vol. 332, p. 855.

<sup>258</sup> Teunis et al., 1997, pp. 1333–1346.

<sup>259</sup> A.H. Havelaar et al., 2000, "Balancing the risks and benefits of drinking water disinfection: disability adjusted life-years on the scale," *Environmental Health Perspectives*, vol. 108, pp. 315–321.

protection and monitoring program has been mandated to assure the water quality of its Catskill and Delaware supplies. At the request of New York City's comptroller, a committee of the NRC performed a study on the effectiveness of this program in assuring future water quality.<sup>260</sup>

As part of this study, monitoring data for *C. parvum* were used to conduct a risk assessment of the water from these two supply systems. A dose-response relationship developed from human feeding studies was employed.<sup>261</sup> Based on a consideration of the variability and uncertainty of the inputs, it was concluded that the estimated risk to consumers from a *Cryptosporidium* infection was in excess of 1 in 10,000 per year.<sup>262</sup> Thus, if the level of illness was regarded as 'acceptable,' additional reduction of oocyst levels would be necessary.

#### 6.1.2.4 *Escherichia coli* O157:H7 in Hamburgers

Cassin et al. developed a risk assessment for illnesses from consuming hamburgers containing *Escherichia coli* O157:H7 (*E. coli* O157:H7).<sup>263</sup> In this situation, a complex train of events must be considered: from the pathogen's occurrence through the dynamics of increases and decreases during the slaughter, processing, transport, storage, and cooking. In the absence of a dose-response relationship based on human data, the relationship for *Shigella* was used.<sup>264</sup> Use of *Shigella* as a surrogate for *E. coli* O157:H7 was justified by the similarity between the toxins in the organisms. Subsequent knowledge, including the assessment of dose-response in animals, suggests that *E. coli* O157:H7 is somewhat less infectious than *Shigella*.<sup>265</sup> Using this model, the potential impacts of controls, such as reducing storage temperature or increasing cooking temperature and time, were explored.

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<sup>260</sup> United States, National Research Council, 2000, *Watershed Management for Potable Water Supply: Assessing the New York City Strategy* (Washington, D.C.: National Academy Press).

<sup>261</sup> C.N. Haas et al., 1996, "Infectivity of *Cryptosporidium parvum* oocysts," *Journal – American Water Works Association*, vol. 88, no. 9, pp. 131–136.

<sup>262</sup> Ibid.

<sup>263</sup> M.H. Cassin et al., 1998, "Quantitative risk assessment for *Escherichia coli* O157:H7 in ground beef hamburgers," *International Journal of Food Microbiology*, vol. 41, pp. 21–44.

<sup>264</sup> C.N. Haas et al., 2000, "Development of a dose-response relationship for *Escherichia coli* O157:H7," *International Journal of Food Microbiology*, vol. 56, nos. 2–3, pp. 153–159.

<sup>265</sup> C. Crockett et al., 1996, "Relevance of Shigellosis in the U.S.: Consistency with dose-response information," *International Journal of Food Microbiology*, vol. 30, pp. 87–100.

### 6.1.3 Data Gaps and State of Knowledge

#### 6.1.3.1 *Elements of Dose-Response Assessment*

One intrinsic feature of risk assessment is that the data used to define a dose-response relationship are most often, by necessity, obtained at relatively high dose (and risk) levels.<sup>266</sup> Hence to estimate the risk at lower exposure levels, a mathematical relationship is necessary for extrapolation. This problem occurs in the assessment of both chemicals and microbial agents.

Scientists have long known that different dose-response relationships may yield quite different low-dose risk levels.<sup>267</sup> Hence, the use of a particular mathematical relationship depends on the belief that it represents a plausible concept. (The word ‘belief’ is used deliberately here, since it is fundamentally impossible to prove the truth of a particular relationship, rather than to fail to disprove its applicability.) The demonstration of this phenomenon for microbial agents was made by Holcomb et al.<sup>268</sup> Hence, it is important to develop appropriate specifications for the characteristics of plausible dose-response models for infectious micro-organisms.

Initial attempts at expressing such characteristics have been made.<sup>269</sup> The two most successful models have been the exponential and the beta-Poisson models, both of which share the characteristic that the risk at low doses is a linear function of dose. Consistency between outbreak data and risks extrapolated from human volunteer trials has been demonstrated in a number of situations (see, for example, Rose et al.,<sup>270</sup> Haas and Rose,<sup>271</sup> and Crockett et al.<sup>272</sup>).

A second facet of dose-response assessment that is undergoing intensive study is the relationship between the ingested dose and the severity of the consequence

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<sup>266</sup> J. Van Ryzin, 1980, “Quantitative risk assessment,” *Journal of Occupational Medicine*, vol. 22, pp. 321–326.

<sup>267</sup> This is due to the limitation of the number of subjects (either animals or humans) that are used in testing. For example, if 50 (a large number) subjects are used at a low dose, the resulting lowest measurable risk level is 1/50 (0.02).

<sup>268</sup> D.L. Holcomb et al., 1999, “Comparison of six dose-response models for use with food-borne pathogens,” *Risk Analysis*, vol. 19, pp. 1091–1100.

<sup>269</sup> C.N. Haas et al., 1999a, *Quantitative Microbial Risk Assessment* (New York: John Wiley), see chapter 4.

<sup>270</sup> J.B. Rose et al. 1991b.

<sup>271</sup> C.N. Haas and J.B. Rose, 1994, “Reconciliation of microbial risk models and outbreak epidemiology: The case of the Milwaukee outbreak,” paper presented at the *Annual Conference of the American Water Works Association*, New York.

<sup>272</sup> Crockett et al., 1996.

(duration and/or intensity of symptoms). In most cases, even when there is a highly diverse spectrum of outcomes, the likelihood of an outcome of a particular severity is regarded as being a fixed proportion of the total infections (or total cases).

It is becoming clear that, at least for some pathogens, the severity of the outcome may depend on the initial dose ingested. Severity may either be an increasing or decreasing function of dose, depending on the underlying biological processes that occur.<sup>273</sup> The nature of the relationship between severity of response and initial dose needs to be given careful consideration in microbiological risk assessment.

### 6.1.3.2 *Elements of Exposure Assessment*

In assessing risk to a population, it is important to consider differences in exposure level to pathogenic organisms. Such differences may arise because of variability in concentrations of pathogens or in consumption patterns.

In raw and treated drinking water, pathogens are frequently *not distributed randomly*.<sup>274,275,276</sup> This may be due to raw water factors such as variability in rainfall or runoff, as well as to additional variability resulting from treatment processes and distribution. Some of these factors have temporal dimensions, while others have spatial dimensions. An example of the latter is that the travel time from a water treatment plant to a customer is a function of the distance of the customer from the plant. Hence, if a particular pathogen continues to decay, (promoted, for example, by the presence of a disinfectant residual in the water), customers at the far end of a water system would be exposed to a lower level of pathogens than customers at the near end of the system. However, if pathogens entered the system during distribution (e.g., by leaky or broken pipes), customers closer to such disturbances would tend to have greater exposure. To describe the distribution of risks more precisely, such spatial and temporal factors resulting in variability must be better characterized.

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<sup>273</sup> P.F.M. Teunis et al., 1999, "Dose response models for infectious gastroenteritis," *Risk Analysis*, vol. 19, pp. 1251–1260.

<sup>274</sup> W.O. Pipes, 1977, "Frequency distributions for coliform bacteria in water," *Journal – American Water Works Association*, vol. 69, p. 664.

<sup>275</sup> A.H. El-Shaarawi et al., 1981, "Bacterial density in water determined by Poisson or negative binomial distributions," *Applied Environmental Microbiology*, vol. 41, pp. 107–116.

<sup>276</sup> P. Gale et al., 1997, "Drinking water treatment increases micro-organism clustering: The implications for microbiological risk assessment," *Journal of Water Supply Research and Technology-Aqua*, vol. 46, pp. 117–126.

Individuals in a population consume different amounts of water because of various behavioural or physiological factors. With increasing consumption of bottled water, estimating tap-water consumption has become more problematic.<sup>277</sup> In Canada, the best available data set appears to be from a survey conducted in the 1970s,<sup>278</sup> although at that time, the penetration of bottled water consumption was small. That survey estimated total tap-water consumption at 1.34 L per person per day, with about 50% representing tea and coffee consumption. Tea, coffee, and other boiled uses of tap water (e.g., reconstitution of soups) should generally be excluded, where possible, from an exposure estimate, since infectious micro-organisms are quite effectively reduced by boiling.

Finally, the assessment of exposure, and in particular pathogen concentration, relies on the adequacy of microbiological methods. In general, these methods are tedious to develop and perform, and are not perfect with respect to specificity (the ability to detect *only* the organism of interest), sensitivity (the ability to detect *any* amount of the organism of interest), and assessment of organism viability. For example, in the United States, the *Information Collection Rule*<sup>279</sup> requires data collection on the occurrence of *Cryptosporidium* in larger water supplies. Sample collection requires several hours and approximately one day of processing before obtaining results. Frequently, the recovery of oocysts using this method is under 15%, and both non-viable and non-pathogenic oocysts are detected. In addition, this collection method is expensive to perform (several hundred U.S. dollars per sample).

It is possible that advances in the application of molecular biological tools to water microbiology will permit the development of better methods; however, these remain at the research stage.

### 6.1.3.3 *Strain Differences*

The ability to perform a risk assessment depends on the availability of information about a dose-response relationship for the organism of interest. There may be significant species and subspecies differences in infectivity (and in the severity of resulting illness) that must be considered. Ideally, a dose-

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<sup>277</sup> L.J. Davis et al., 1998, "A survey of risk factors for Cryptosporidiosis in New York City: Drinking water and other exposures," *Epidemiology and Infection*, vol. 121, pp. 357–367.

<sup>278</sup> Canada, Health and Welfare Canada, Environmental Health Directorate, 1981.

<sup>279</sup> 61 Federal Register 24354 (May 14, 1996).



response relationship for a particular subspecies or strain should be obtained. However, this may not be possible in practice.

In the case of *Salmonella* and *Shigella*, differences in infectivity of different species have been demonstrated.<sup>280,281</sup> For *E. coli*, the different *subspecies* manifest different dose-response relationships.<sup>282</sup> In the case of *C. parvum*, documented differences in infectivity of subspecies are also likely the result of differences in the mechanisms of pathogenicity.<sup>283</sup> In the particular case of *E. coli* O157:H7, the acquisition of Shiga-like toxin by this organism is at least in part responsible for differences in infectivity.<sup>284</sup> The degree to which biochemical markers may be used to predict infectivity.

#### 6.1.3.4 Sensitive Subpopulations

Public policy generally desires a level of protection for more sensitive or susceptible subpopulations. However, exactly what constitutes ‘more susceptible’ has not been rigorously defined. Individuals or populations exposed to or immunized against microbial pathogens are assumed to develop immunity to these pathogens. Individuals or populations without such immunity would be considered ‘susceptible.’ It is clear, however, that a variety of factors beyond the presence or absence of prior immunity can produce variation in the risk of an adverse health outcome from exposure to a microbial pathogen. An expert working group proposed this definition: “Susceptibility is a capacity characterizable by a set of intrinsic and extrinsic factors that modify the impacts of a specific exposure upon risks/severity of outcomes in an individual or population.”<sup>285</sup>

This definition contains several important points related to risk assessment and public health regulation. First, the definition allows that some factors may

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<sup>280</sup> Crockett et al., 1996.

<sup>281</sup> A.M. Fazil, 1996, *A Quantitative Risk Assessment Model for Salmonella* (Philadelphia, Penn.: Drexel University, Environmental Studies Institute).

<sup>282</sup> See Chapter 9 in Haas et al., 1999a.

<sup>283</sup> P.C. Okhuysen et al., 1999, “Virulence of three distinct *Cryptosporidium parvum* isolates for healthy adults,” *Journal of Infectious Diseases*, vol. 180, pp. 1275–1281.

<sup>284</sup> P.M. Griffin and R.V. Tauxe, 1991, “The epidemiology of infections caused by *Escherichia coli* O157:H7, other enterohemorrhagic *E. coli* and the associated hemolytic uremic syndrome,” *Epidemiology Review*, vol. 13, pp. 60–98.

<sup>285</sup> J. Balbus et al., 2000, “Susceptibility in microbial risk assessment: Definitions and research needs,” *Environmental Health Perspectives*, vol. 108, pp. 901–905.

be intrinsic to the person or population at risk, such as prior immunity, nutritional status, or age, while other factors may be extrinsic, such as access to health care. Second, susceptibility can be considered at both the individual level and at the population level. Third, susceptibility to one organism or group of pathogens does not necessarily imply susceptibility to all water-borne pathogens. The factors associated with increased risk are often limited to specific pathogens or specific exposure scenarios. Similarly, a given individual may become more or less susceptible to microbial pathogens at different times of his or her life, depending on the particular combination of various factors associated with infectious disease risk.

Factors associated with increased risk from water-borne microbial pathogens can be categorized in several ways:

- Factors that are associated with increased probability of exposure.
- Factors that are associated with increased risk of infection given exposure.
- Factors that are associated with increased probability or severity of an adverse health outcome given infection.

In the first category are social and behavioural factors, such as population crowding, primary water source, and poor hygiene (fecal-oral), especially in young children. In the second category is the lack of prior exposure to a pathogen, the most classic aspect of microbial susceptibility, which increases the risk that an ingested organism will survive long enough to establish an infection in the body. Also in the second category are factors that reduce the effectiveness of the body's non-specific defences. Populations that exemplify this are newborn babies and people on antacid therapies, both of whom have reduced stomach acidity, which increases the risk of infection from ingested bacteria. In the last category are diseases or treatments that suppress the immune system and prevent it from containing and eliminating infections that have started. AIDS and intensive cancer chemotherapy are examples of factors in this category. In addition, extremes of age, dehydration, or underlying illness may increase the risk of a severe health outcome from water-borne pathogens that cause diarrhea.<sup>286</sup>

The host susceptibility factors of the pathogen *C. parvum* have been studied extensively. The disease cryptosporidiosis is one of the AIDS-defining illnesses,

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<sup>286</sup> C.P. Gerba et al., 1996, "Sensitive populations: Who is at the greatest risk?" *International Journal of Food Microbiology*, vol. 30, pp. 113–123.

and patients with AIDS have far greater morbidity and mortality than people without AIDS. More specifically, it has been demonstrated that the inability of AIDS patients to recover from cryptosporidiosis is associated with a decline in their T4 helper cells below 180–200 cells/mm<sup>3</sup>.<sup>287,288</sup> (A T4 helper cell is a type of T lymphocyte that is particularly depleted in AIDS patients and is used as a marker of disease progression.) Additional studies with *C. parvum* have demonstrated that prior exposure leads to variable immunity to future infection, so that the number of organisms required to cause an infection may or may not increase after a single, previous exposure.<sup>289</sup> Case studies of microbial risk assessments for *C. parvum* have incorporated this data on variation in susceptibility to some degree.<sup>290, 291, 292</sup> Most have derived the dose-response parameter from the work of Dupont et al. on immunocompetent hosts (people capable of a normal immune response).<sup>293</sup> Perz et al. used a semi-quantitative factor of 3 to characterize the increased risk of infection for people with AIDS who have been exposed to a microbial pathogen.<sup>294</sup> And most have used epidemiological data to characterize the increased risk of death and severe illness for people with AIDS. None has explicitly taken into account variability in immunity from prior exposure among immunocompetent people. Thus, while pioneering efforts to incorporate susceptibility into microbial risk assessment have been made, much still must be done before we can confidently characterize the variation in susceptibility in populations.

Given the complexity of susceptibility, it is difficult to characterize specific groups of people as being more or less susceptible than others. Risk assessments

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<sup>287</sup> T.P. Flanagan et al., 1992, "Cryptosporidium infection and CD4 counts," *Annals of Internal Medicine*, vol. 116, pp. 840–842.

<sup>288</sup> E. Pozio et al., 1997, "Clinical cryptosporidiosis and human immunodeficiency virus (HIV)-induced immunosuppression: Findings from a longitudinal study of HIV-positive and HIV-negative former injection drug users," *Journal of Infectious Disease*, vol. 176, no. 4, pp. 969–975.

<sup>289</sup> C.L. Chappell et al., 1999, "Infectivity of *Cryptosporidium parvum* in healthy adults with pre-existing anti-*C. parvum* serum immunoglobulin G," *American Journal of Tropical Medicine and Hygiene*, vol. 60, pp. 157–164.

<sup>290</sup> J.F. Perz, F.K. Ennever, and S.M. Le Blancq, 1998, "Cryptosporidium in tap water: Comparison of predicted risks and observed levels of disease," *American Journal of Epidemiology*, vol. 147, no. 3, pp. 289–301.

<sup>291</sup> P.F.M. Teunis and A.H. Havelaar, 1999, *Cryptosporidium in Drinking Water: Evaluation of the ILSI/RSI Quantitative Risk Assessment Framework* (Washington, D.C.: National Institute of Public Health and the Environment).

<sup>292</sup> Gale et al., 1997.

<sup>293</sup> H. Dupont et al., 1995, "Infectivity of *Cryptosporidium parvum* in healthy volunteers," *New England Journal of Medicine*, vol. 332, p. 855.

<sup>294</sup> Perz, Ennever, and Le Blancq, 1998.

and regulations designed explicitly to protect susceptible subpopulations must be very deliberate in defining the goals and parameters of the risk assessment or regulation at the beginning of the process. The specific pathogens, subpopulations, and adverse health outcomes of interest must be defined at the outset, and the definition of susceptibility and methods for quantifying that susceptibility should be agreed on by all stakeholders.<sup>295</sup> For most situations, it is unlikely that sufficient data for quantitative risk estimates will exist that comprehensively address susceptibility. Instead, it is more likely that semi-quantitative estimates and default assumptions will be required to address variations in susceptibility within a particular population.

### 6.1.3.5 *Population-level Dynamics of Infectious Disease*

The effect of exposure of a population to a water-borne infectious agent may extend beyond the number of primary cases that occur. Both asymptomatic and symptomatic individuals may produce additional cases by secondary transmission routes. As well, a primary infection may result in partial or complete immunity to subsequent exposure. This primary infection may be symptomatic or asymptomatic; and the resulting immunity may be temporary or permanent. This necessitates describing an exposed population using a complex dynamic model.<sup>296,297,298</sup> The parameters in these models describe incubation time, duration and intensity of immunity, effectiveness of person-to-person contact, etc. However, these parameters remain poorly characterized for water-borne diseases of interest. Thus, the use of such models is still at the research stage. For example, it is known that for *Cryptosporidium*, an infection may produce partial immunity for at least one year following the initial exposure.<sup>299</sup> It is also known that an underlying endemic baseline of illness may exist on which an outbreak is superimposed.<sup>300</sup>

<sup>295</sup> R.T. Parkin and J.M. Balbus, 2000, "Variations in concepts of 'susceptibility' in risk assessment," *Risk Analysis*, vol. 20, no. 5, pp. 603–611.

<sup>296</sup> J. Eisenberg et al., 1996, "Quantifying water pathogen risk in an epidemiological framework," *Risk Analysis*, vol. 16, pp. 549–563.

<sup>297</sup> J. Eisenberg et al., 1998, "An analysis of the Milwaukee cryptosporidiosis outbreak based on a dynamic model of the infection process," *Epidemiology Research*, vol. 9, pp. 255–263.

<sup>298</sup> See Chapter 8 in Haas et al., 1999a.

<sup>299</sup> P.C. Okhuysen et al., 1998, "Susceptibility and serologic response of health adults to reinfection with *Cryptosporidium parvum*," *Infection and Immunity*, vol. 66, pp. 441–443.

<sup>300</sup> R.D. Morris et al., 1998, "Did Milwaukee experience water-borne Cryptosporidiosis before the large documented outbreak in 1993?" *Epidemiology*, vol. 9, pp. 264–270.

As additional data become available, it may become possible to perform full population-based risk assessments to judge the implications of policy shifts related to controlling infectious micro-organisms in drinking water.

#### **6.1.3.6 Use of Animal Models for Developing Dose-Response Curves**

While some dose-response relationships have been developed using human subjects, it is impossible to rely solely on such data in all circumstances. The effects of some pathogens (e.g., hepatitis A virus) are severe enough to preclude such studies for ethical reasons. Furthermore, ascertaining the impact of susceptibility on outcome would likely be impossible if only animal data were relied on (again on ethical grounds). Hence, using animal data is desirable for developing dose-response relationships and ascertaining the impact of various modifying factors on outcome.

In regulating chemical agents, animal model data are frequently relied on as a source of dose-response or potency information. The term ‘animal model’ refers to experiments using a particular animal species and strain as a host for a specific pathogen. Biologists use the term ‘model’ to mean a system in which such animal species provide useful data applicable to humans. This is a separate and distinct use of the term ‘model’ in much of risk assessment, wherein it implies a mathematical or quantitative relationship. There are well-developed principles for extrapolating results obtained in animal studies to humans.<sup>301</sup>

Two recent studies using animal dose-response data to develop human dose-response information are promising.<sup>302,303</sup> These involve *Listeria monocytogenes* (a food-borne pathogen) and *E. coli* O157:H7. The studies considered outbreaks in which human exposure to the pathogens could be estimated and attack rates recorded. These were compared with estimated attack rates based on animal dose-response data. The comparison validated the use of animal data as a quantitative predictor of human response. As additional animal trials and validations are performed, the amount of information will increase.

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<sup>301</sup> United States, Interagency Staff Group on Carcinogenesis, 1986, “Chemical carcinogens: A review of the science and its associated principles,” *Environmental Health Perspectives*, vol. 67, pp. 201–282.

<sup>302</sup> C.N. Haas et al., 1999b, “Development and validation of dose-response relationship for *Listeria monocytogenes*,” *Quantitative Microbiology*, vol. 1, pp. 89–102.

<sup>303</sup> Haas et al., 2000.

### 6.1.3.7 *Micro-organisms Inducing Illness by Pre-formed Toxins*

The focus of this section (and indeed of the entire field of microbial risk assessment to date) has been on the proliferation of micro-organisms *inside* the body, resulting in illness. In some situations, the proliferation of micro-organisms *outside* the body can result in the production of toxins that may cause illness when ingested. Perhaps the toxins of most concern related to exposure from drinking water are algal hepatotoxins, such as microcystins. The guideline values for such toxins are set by reference to a no-observed-adverse-effect level (NOAEL) or lowest-observed-adverse-effect level (LOAEL) from animal testing, frequently using mortality as an endpoint, along with various uncertainty factors. This is a similar approach to that used by the United States to develop regulatory levels for non-carcinogens. However, a dose-response-based method is superceding this approach in the United States and elsewhere.<sup>304</sup> The process currently used for setting these guideline values for such toxins is empirical and must be developed to a level that is consistent with that for other microbial risk assessments. Duy et al. have reviewed this field.<sup>305</sup>

## 6.2 Enhanced Population Health Surveillance

### 6.2.1 The Significance of Health Surveillance

In 1999, the National Health Surveillance Network Working Group described health surveillance as “tracking and forecasting any event or health determinant through the ongoing collection of data, the integration, analysis and interpretation of that data into surveillance products, and the dissemination of that resultant surveillance product to those who need to know. Surveillance products are produced for a predetermined public health purpose or policy objective. In order to be considered health surveillance, all of the above activities must be carried out.”<sup>306</sup>

Surveillance serves several purposes.

<sup>304</sup> K.S. Crump, 1995, “Calculation of benchmark doses from continuous data,” *Risk Analysis*, vol. 15, pp. 79–89.

<sup>305</sup> T.N. Duy et al., 2000, “Toxicology and risk assessment of freshwater cyanobacterial (blue-green algal) toxins in water,” *Review of Environmental Contamination and Toxicology*, vol. 163, pp. 113–185.

<sup>306</sup> Canada, Health Canada, Federal-Provincial-Territorial Working Groups: National Health Surveillance Network Working Group; Integration Design Team, 1999b, *Proposal to Develop a Network for Health Surveillance in Canada* (Ottawa: Health Canada), p. iv.

- It provides early warning of impending danger.
- It is evidence for the developing understanding of new and evolving diseases and problems.
- It serves as an essential part of the scientific basis for needs assessment, planning, and evaluation.
- It is a core part of the system for protecting and promoting health, and preventing disease and injury.

Focusing on how the pieces of a surveillance system work together is worthwhile, because the whole is more important than any single part. Each part of a surveillance system backs up or substantiates the other parts. Different sectors or people have responsibilities, and when these sectors or people work well, they both prevent illness and limit the effects of illness.

Surveillance is not an end in itself. It is a tool to further efforts in understanding disease processes, to identify needs, to follow trends, and to recognize emerging problems. Thus, it is an important part of developing and evaluating programs and policies in order to improve the health and well-being of the population.

Surveillance is a key contributor to the triumvirate of assessment, policy development, and assurance. It is also one of the five prime functions of public health: surveillance, health promotion, health protection, disease prevention, and injury prevention. This subsection reviews some of the context for surveillance generally and the practical implications of surveillance as it relates to water-borne diseases specifically.

Health surveillance is used to:

- identify trends in conditions and factors related to health;
- identify, locate, and quantify emerging problems as early as possible;
- support generation of hypotheses and preliminary assessment for research and for understanding of health problems;
- provide feedback to clinical and public health practitioners on incidence, prevalence, and other indicators; and
- support the evaluation of policies, programs, and services.

Groups and organizations that have an interest in surveillance are local health departments and practitioners; federal, territorial, and provincial governments; voluntary and other organizations; researchers; and communities.

Surveillance data help local health departments and practitioners better understand the population they serve. Such data can be used to guide the allocation and focus of resources. These data are part of an early warning system for identifying emerging problems, and can be used for advocating priorities both within and outside the formal health system. Ongoing surveillance can help in following and evaluating efforts to change risk factors, behaviours, or outcomes. A key concern in surveillance is data collected at the local level. The products of this surveillance should be of interest and use to those charged with collecting it.

Federal, provincial, and territorial governments use surveillance data to gain a better understanding of a particular situation and the impact of any actions taken. Policy and program officials and the public find surveillance data helpful in comparing the different jurisdictions. Surveillance data can help federal, provincial, and territorial governments assess accountability within the systems they fund and maximize the health and social benefits of tax dollars expended. Additionally, many relationships that would not be recognized from data collected locally become apparent at the provincial, territorial, or national level (e.g., a small increase in a disease may not be considered significant without the larger numbers of cases reported).

Voluntary and other organizations recognize the importance of having good quality surveillance data for their work in research, advocacy, and service. Researchers use surveillance data to generate hypotheses and include it as part of the range of information contributing to a better understanding of complex problems. Communities can use surveillance data to assess their performance, especially in dealing with their most important health problems.

### **6.2.2 General Principles of Health Surveillance**

A coordinated system for surveillance could be thought of as a transportation infrastructure. Many different roads allow providers to offer a variety of services using different vehicles moving at different rates. The underlying infrastructure can offer that flexibility only if its development is coordinated among users, and related policies do not create unnecessary barriers to its efficiency. In addition, while end users may not need to understand the intricacies of a surveillance system, the system must be sufficiently transparent to ensure fairness and coherence. The best surveillance data gathering is of little use unless it can



be analyzed, evaluated, disseminated, and applied to programs and policy. It is crucial that data quality, evaluative abilities, and resource use are maximized to enhance the capacity for carrying out health surveillance. The underlying principles of health surveillance are listed below.

- Purpose of surveillance
  - Surveillance is done for a purpose that is understood and has application to a need, a problem, or potential problem, or to the definition of future research questions.
  - Surveillance is more than the collection of data; it also involves analysis and dissemination of information to practitioners and policy and decision makers.
- Construction of surveillance systems
  - Surveillance systems are usually best built from the local level up. In that way, they serve the needs of those at the local level (the data source) and can then be rolled up with data from many areas for use at other levels of government to meet broader needs. Thus, information and analysis from local surveillance can be fed back to local practice, as appropriate. Where surveillance covers a broader area, information and analysis can be shared among the federal, provincial, and territorial levels, or between international and national levels. Such links benefit both the collectors and the end users of the data.
  - An important federal, provincial, and territorial role is to facilitate national coordination among jurisdictions and to support common identification of needs and appropriate responses.
  - “One size does not fit all.” While certain aspects of a surveillance system will be negotiated by all jurisdictions, the different needs and interests of various jurisdictions must be respected. Any system must be flexible enough to account for varying approaches.
  - “Do not let the best be the enemy of the good.” It is important to do what is possible now and not wait for the ultimate solution before moving forward.

- As surveillance systems are developed or modified, improving their ability to connect with other surveillance activities is an important consideration.
- Surveillance systems must be sustained with ongoing support and resources.
- Data collection and management
  - Different information needs and methods are determined by considering, for example, the purpose, cost, and ease of gathering data (some events will require reporting on the whole population; other events will require only population sampling).
  - Although better data gathering does not remove the risk of public criticism, or guarantee better decisions, they improve the likelihood of less criticism and better decisions.
  - Where possible, it is important to reduce duplication and maximize value by having common data collection for multiple uses.
  - Common definitions and compatible databases will allow data sets to be compared and combined.
  - Diseases and health determinants do not act in isolation. Thus, the ability to link databases and create more comprehensive disease profiles will result in a clearer understanding of complex interactions.

### **6.2.3 Water Quality Surveillance**

Water quality (or lack of it) has the potential to turn a relatively healthy community into a very sick one. Local public health authorities have the expertise and mandate for public health protection. They work with their municipalities, the provincial environment ministry, and individual landowners to interpret test results related to human health and provide advice. Depending on the legislation or jurisdiction, the authority for issuing a boil water order or a boil water advisory will rest with the public health authority, the municipality, or the environment ministry. The decision is normally made in consultation with the medical officer of health and

the senior inspector. Larger municipalities are usually under the authority of the environment ministry, while smaller systems (e.g., private wells for rural restaurants, apartments, and trailer parks) are regulated by the local public health authority. Individual landowners who do not provide water to others are usually not regulated. However, the public health authority provides a consultation service and advice on maintaining and testing wells.

It should be noted in this context that smaller communities often face greater resource challenges in addressing water treatment and monitoring needs. Communities with small populations are less likely to have trained managers and the costs of treatment per resident are higher. Large distances also complicate the challenges of sampling and surveillance. Thus, protection of source water becomes a particularly important strategy as the costs of full treatment for small systems may be prohibitively high.

Surveillance takes place at several levels. While some may regard the term 'compliance monitoring' as being distinct from 'health surveillance,' it is helpful in this context to think of both practices as comprising surveillance at various points in the process. Such an approach permits risk management practices (interventions) to protect human health.

Surveillance encompasses microbiological, chemical, and physical water quality. In general, bacteria, viruses, and parasites cause harm in the short term, whereas certain chemicals may increase the risk of certain diseases, such as cancer, over the long term.

Water quality surveillance or monitoring has three objectives:

1. to protect the water supply;
2. to detect problems at an early stage, thereby allowing intervention to reduce or eliminate the risk of human disease; and
3. to identify patterns of human illness suggestive of water-borne illness, prompting further investigation and precautionary measures.

Basic surveillance involves a number of complementary processes that build on the evidence each provides to create a diagnostic picture for identifying problems and likely solutions.

The primary focus of surveillance is to ensure the safety of the water supply. Thus, regular sampling of water quality and testing for residual chlorine levels at different points in the system allow appropriate changes to be made to the purification processes. For example, inadequate chlorine levels can be rectified. If there is an unknown reason for continuing low levels of chlorine at points in the distribution system, then a precautionary boil water order is a prudent measure while the problem is being identified and resolved. Some problems can be resolved through filtration or other treatments, while others can be addressed only by finding an alternative supply source. Monitoring water quality is essential not only for identifying potential problems or failures in the treatment system; it is also a way of verifying the effectiveness of treatment.

Surveillance of communicable diseases involves reporting by physicians and laboratories to public health authorities. The response may be either routine or urgent depending on the disease. A common disease (and one that rarely has complications, such as chickenpox) is usually reported in writing using a form. However, such reporting may be incomplete because only a small percentage of these cases are actually reported unless there is something unusual about them. Other events, such as meningitis, suspected food poisoning, or serious disease outbreaks, are usually reported to public health authorities by telephone for immediate advice and action.

An outbreak may occur even when treatment processes seem to be functioning properly. For example, in a chlorinated, non-filtered surface supply, an outbreak of *Giardia* can occur even though chlorine levels are appropriate and no fecal coliforms are detected. This is possible because *Giardia* cysts are resistant to chlorine, and may be infective at such a low level that they or fecal coliform bacteria are not measurable in usual samples. They can, however, be removed by adequate filtering.

#### **6.2.3.1 *Surveillance and Decision Making***

Each piece of surveillance information contributes to the overall picture when public health authorities, environment ministries, and municipalities must make decisions and develop practical solutions to protect the public's health. Decisions are often contextual and depend on the decision makers' knowledge of the water system, their expertise in assessing disease risk, the data available, the system's prior history (based on ongoing testing), and other factors. Knowledge

of the water distribution system (e.g., potential dead spots that receive little flow or areas most distant from the chlorination source) is also important in understanding potential problems and developing solutions.

The history of the water supply is important because it provides a context for decision making. For example, if testing has always yielded negative results and nothing else in the system has changed, a positive test may indicate that a sample was taken inappropriately. Thus, it is reasonable for decision makers to wait until a new sample is tested immediately and the results are available. However, if the system has had intermittent positive test results for coliforms, fecal coliforms are detected, and the residual chlorine levels are inadequate, decision makers should announce a boil water advisory. And, if the chlorinator is down and no other clean water source is available, a boil water order is warranted.

Regular monitoring according to existing guidelines alerts water authorities to emerging problems and provides baseline data for evaluating any changes in a water system. In many jurisdictions, a public health laboratory does the testing. In others, such as Ontario, privately owned laboratories perform tests. Whatever the laboratory, if an adverse test is found, the laboratory notifies the municipal authorities, the environment ministry, and the public health unit. The sequence of notification and level of involvement of each organization vary depending on their relative responsibilities and the situation. However, communication is established quickly, and a meeting or phone consultation is conducted to determine the scope of the situation and decide on a course of action. Such communication usually takes place on the same day as test notification is received.

Another point of detection is physicians who may recognize a cluster of similar cases and call the medical health officer. Less obvious outbreaks may be recognized by a public health laboratory, for example, when an increase in requests for testing is encountered (e.g., for cultures of human feces). In addition, a laboratory or a communicable disease unit may notice an increased rate of a particular disease. If the disease appears to be community-based and potentially water-borne, the environment ministry and the affected municipality would be contacted regarding water quality. This would also trigger an investigation for other links, such as other water sources, food, or a particular event at which individuals might have become infected. Infections can be spread by food or water, respiratory or person-to-person contact, an environmental source such as disturbed soil, or other means – all of which could be explored.

Certain infections can point the investigator in a specific direction, based on the nature of the disease. For example, Norwalk virus is usually associated with an institutional outbreak, and giardiasis is usually related to an infected water source or a location where small children congregate, such as a daycare centre. *E. coli* O157:H7 infections usually originate in food (e.g., meat, unpasteurized juice, or milk). Less commonly, *E. coli* O157:H7 is water-borne, but this type of transmission is of great concern because of the large numbers of persons who may be exposed.

This subsection of the report has outlined the general context for health surveillance and the particular issues related to water supplies and human health. When surveillance is in place, officials are better able to make an appropriate analysis of a risk and respond to it. When a problem is encountered, they can address it quickly and effectively to eliminate or minimize the risk to the public's health.

#### **6.2.4 Infectious Disease Surveillance in Canada**

Mortality statistics and health surveillance first made an impact in the 1600s when they were used in England to guide efforts that resulted in improved sanitation, housing, and drinking water quality. These efforts were successful in reducing the spread of and preventing infectious diseases. Today, resources worldwide are applied to surveillance and research programs that can provide answers to currently vexing policy and program questions. These resources are most effective when used in collaborative efforts.

In Canada, many activities are underway to better define and enhance surveillance activities. At the national level, Health Canada has specific activities and strategies related to the development of a Network for Health Surveillance as well as in-house tools and systems for the surveillance of public health and infectious diseases. For example, Health Canada reviews provincial data to monitor trends and to identify new or emerging issues. Also nationally, the Canadian Food Inspection Agency is responsible for food safety from raw materials through consumption. This agency coordinates with Health Canada, the provinces, and the territories in monitoring disease trends and identifying potential outbreaks. Such coordinated reviews monitor the outbreak and spread of disease. At the local level, an outbreak may seem unusual or rare, and represent only a small increase in disease. Seen from a national perspective, it becomes obvious as an extraordinary occurrence. Thus, outbreaks can be detected, the

cause determined, and interventions taken sooner than would be possible at the local or provincial level alone.

Statistics Canada has a number of programs to collect data on everything from health surveys to education and economics. The Canadian Institute for Health Information, a federally chartered not-for-profit organization, also collects and analyzes a range of health statistics and utilization data.

Each province and territory maintains surveillance programs appropriate to its needs and available resources. Reportable disease information (which includes the most common water-borne diseases of concern) is collected by health authorities. Cumulative statistics are then forwarded to the province. Usually, a second level of review identifies trends and anomalies.

The Federal-Provincial-Territorial Advisory Committee on Health Infostructure (which reports to federal, provincial, and territorial deputy ministers of health), its Health Surveillance Working Group, and other groups are now focusing on what is needed for effective surveillance in general.

In February 2001, the Health Surveillance Working Group reported to the Advisory Committee on Health Infostructure on its Health Surveillance Tactical Plan.<sup>307</sup> This report encompassed a number of initiatives related to the function of health surveillance within the realm of public health services.

The report notes that provincial and territorial legislation exists for controlling communicable diseases, reporting notifiable diseases, and acting on the results. Various systems are in place within the provinces and territories for tracking and reporting communicable disease, recording immunizations, and managing cases. Formal and informal networks of people and organizations also exist that can act on the results from these various systems. However, not all components are in place in Canada to support a comprehensive communicable disease surveillance system that would contribute to and make use of electronic health records.

To advance the concept of a national health surveillance infostructure, Health Canada and some provinces and territories have set up pilot projects. The scope

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<sup>307</sup> Canada, Health Canada, Health Surveillance Working Group, 2001, *Canadian Health Infostructure Health Surveillance Tactical Plan*, Summary of the Final Report to the Advisory Committee on Health Infostructure (Ottawa: Health Canada).

of these projects is not confined to communicable diseases but also encompasses information on risks from exposures to hazardous consumer products, drugs, and other agents of concern.

One significant pilot project about communicable diseases is the Canadian Integrated Public Health Surveillance (CIPHS) project.<sup>308</sup> The underlying concept of this project is the development of a suite of computer applications and databases that will enable public health agencies to collect and collate public health surveillance data systematically. The goal is to facilitate data sharing at the local level between a laboratory data system and a public health information system. The major components of the suite of applications are listed below.

- **Laboratory Data Management System (LDMS):** The initial focus of the LDMS is to demonstrate 'proof-of-concept' for producing laboratory results in one part of laboratory activities (enterics). Subsequently, the scope will expand to include other laboratory areas and a full research laboratory information system.
- **Public Health Information System (PHIS):** This collaborative project between Health Canada and the B.C. Centre for Disease Control is intended to enhance and incorporate these organizations' public health case management system into the CIPHS initiative. Antimicrobial resistance surveillance and tuberculosis case management modules are also under development.
- **Outbreak Modules:** These are Internet-enabled for alerts and outbreak management. Outbreak modules include a number of existing or planned functions both within the PHIS and as stand-alone Internet-based applications. The Internet-enabled applications are those that may be accessed by authorized persons using a Web browser such as Internet Explorer. Thus, early alerts or summaries of known outbreaks may be posted by local or provincial public health workers and released for national viewing by a provincial authority.

Both PHIS and LDMS have database structures that allow individual cases or results to be associated with a particular outbreak. The postings of early alerts or summaries of known outbreaks may be generated with the assistance of

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<sup>308</sup> Ibid., p. 7. Information about CIPHS can be found online at <[www.hc-sc.gc.ca/ohih-bsi/whatfund/hihsp/comp\\_award/an-integrated-health-surveillance\\_e.html](http://www.hc-sc.gc.ca/ohih-bsi/whatfund/hihsp/comp_award/an-integrated-health-surveillance_e.html)>.



functions built into a broader public health information system. This is the case with the generation of outbreak summaries and the PHIS application in British Columbia. A user of PHIS may create an outbreak summary and have the system calculate tables of the age/sex distribution, symptoms, laboratory confirmation, and exposures. The system can then transmit the data to the federal database for viewing by others.

Currently, there are two national surveillance initiatives specific to enteric disease outbreaks in Canada: the Canadian Enteric Outbreak Surveillance Centre Web site project, and the National Enterics Surveillance Program.<sup>309</sup>

#### **6.2.4.1 *The Canadian Enteric Outbreak Surveillance Centre***

The Canadian Enteric Outbreak Surveillance Centre (CEOSC) is an initiative of Health Canada's Division of Enteric, Foodborne and Waterborne Diseases. The CEOSC initiative is intended to enable public health professionals from across Canada to access information on disease outbreaks efficiently so that they can better protect public health. As of September 2001, the CEOSC is at the pilot stage and has not been fully implemented on a national scale.

The CEOSC consists of two Web-based applications, the Early Alert System and the Enteric Outbreak Summary Reporting System, which allow outbreak information to be shared in confidence among regional, provincial, territorial, and federal public health officials.

The Early Alert System provides a Web site for posting alerts about outbreaks or suspected outbreaks currently under investigation. These alerts may be significant to public health professionals in neighbouring regions or in other jurisdictions across Canada.

The Enteric Outbreak Summary Reporting System provides a centralized reporting Web site for public health professionals where they can post a final

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<sup>309</sup> F. Pollari, Head, Surveillance Section, Division of Enteric, Foodborne and Waterborne Diseases, Centre for Infectious Diseases Prevention and Control, Population and Public Health Branch, Health Canada, Guelph, Ont. [personal communication with the authors, November 19, 2001]; and S. Isaacs, Senior Epidemiologist, Outbreak Response and Issues Management, Division of Enteric, Foodborne and Waterborne Diseases, Centre for Infectious Diseases Prevention and Control, Population and Public Health Branch, Health Canada, Guelph, Ont. [personal communication with the authors, November 19, 2001].

report of an enteric outbreak. Regional, provincial, territorial, and national public health professionals can access this site. As a result, current information on outbreak trends and occurrence information (time, place, source, and populations affected) is available to public health professionals at all levels of authority.

#### **6.2.4.2 *The National Enterics Surveillance Program***

The National Enterics Surveillance Program (NESP) is a joint project of Health Canada's Division of Enteric, Foodborne and Waterborne Diseases and the National Laboratory for Enteric Pathogens. This project is designed to provide timely information on sporadic enteric disease cases and outbreaks across the country. The NESP has been operating on a national scale since 1997 and is considered to be the most up-to-date enteric disease outbreak reporting system in Canada today. Analyses are conducted and reports issued weekly resulting in an outbreak being reported within one to two weeks of its occurrence.

Provincial laboratories send weekly totals of isolates to the National Laboratory for Enteric Pathogens in Winnipeg. Each weekly report from a provincial laboratory has the number of new isolates recorded that week for *Salmonella*, *Shigella*, *Campylobacter*, *E. coli*, *Vibrio*, *Yersinia*, *Cryptosporidium*, *Giardia*, and *Entamoeba*, as well as rotaviruses and caliciviruses (Norwalk-like viruses). The weekly report includes the pathogen's name and the number of related cases identified that week in the province. Additional information may be supplied indicating that some of the cases are associated with an outbreak, travel, unusual outcomes (e.g., death) unusual specimen source, or antimicrobial resistance.

The National Laboratory generates a weekly report directed at laboratory personnel. The Division of Enteric, Foodborne and Waterborne Diseases generates weekly, monthly, and annual reports directed at epidemiologists and public health personnel.

#### **6.2.5 Infectious Disease Surveillance in Australia**

As in other developed nations, surveillance for infectious diseases in Australia is based primarily on the detection and reporting of specific pathogens in clinical specimens. In addition, cases of suspected food- or water-borne disease are also reported to health authorities.

Each state or territorial health department designates which pathogens are 'notifiable' under health regulations. Pathology laboratories and physicians who diagnose these pathogens must notify the health department using a standard reporting form. The reporting form also contains the patient's contact and demographic information and details about the physician treating the case. Health authorities must also be notified of suspected cases of food- or water-borne disease.

Following notification, the affected person (or the parent in the case of a child) is contacted by health department personnel and interviewed about possible sources of exposure before the onset of illness, including food and drinking water. If two or more cases appear to be linked to a common exposure, further investigations into the potential outbreak ensue, and public health action may be taken.

State surveillance data are supplied to the Australian federal health department for collation every two weeks. Surveillance for over 40 communicable diseases reported by all states and territories is coordinated by the National Notifiable Diseases Surveillance System. Surveillance figures are published in a monthly newsletter and on the Internet about two months after the states submit their reports.

#### **6.2.5.1 *Specialized Surveillance Schemes***

Australia also has a number of specialized surveillance schemes. These provide supplementary surveillance data and information on utilization patterns of medical services and costs. The Australian Sentinel Practice Research Network (ASPREN) involves about 120 general practitioners throughout Australia, although not all report every week. Data on 7,000 to 8,000 patient consultations are reported weekly with particular attention focused on 14 conditions chosen for sentinel surveillance. In the Virology and Serology Laboratory Reporting Scheme (LabVISE), 17 state sentinel laboratories contribute data on the laboratory identification of viruses and other organisms. In the National Influenza Surveillance Scheme, data are collated from sentinel general practice consultations for influenza-like illness, laboratory reports of influenza, and absenteeism rates from a large national employer.

### **6.2.6 Limitations of Current Surveillance Systems for Outbreak Detection**

Current surveillance systems have significant limitations in their ability to rapidly and efficiently detect outbreaks of disease.

These limitations are detailed below.

#### **6.2.6.1 *Speed of Detection***

Infectious disease agents have variable incubation periods, so several days may pass between infection and the development of symptoms. If the affected person visits a medical practitioner, a clinical specimen may not be requested at the first visit by the physician unless the patient has reported intense or prolonged symptoms. Once a specimen has been obtained and sent to the pathology laboratory for analysis, testing and confirmation may take from one to a few days to complete before a positive result is reported to health authorities. Establishing contact with the patient to conduct a telephone interview about exposures and risk factors may then take a further few days. If an outbreak is suspected, further investigations and clinical or environmental sampling to locate or confirm the source may require several days.

In some instances, outbreak detection may circumvent the usual process. For example, illness among a group of people with social or occupational links may lead to more rapid reporting to health authorities, as group members become aware that others have also become ill after a common exposure. Outbreaks may also be detected earlier if the pathogen produces distinctive or uncommon symptoms (e.g., bloody diarrhea with toxigenic *E. coli*). Occasionally, a localized outbreak of illness is detected by a sudden increase in the number of people attending hospital emergency departments or local doctors.

#### **6.2.6.2 *Limited Sensitivity***

Not all exposed people will become infected with a pathogen and not all infected people will experience symptoms. Among those who are infected, the severity of symptoms will vary, and only those with relatively severe symptoms are likely to seek any medical attention. Practices in requesting clinical specimens for diagnosis vary between and within countries and generally only a minority of patients will have a specimen analyzed.

Pathology tests are limited in sensitivity, and not all infections from the tested pathogens will be detected. Experiments using human volunteer subjects have shown that some gastrointestinal pathogens are characterized by an intermittent shedding pattern in the feces, so a single specimen may contain only low numbers of the pathogen that may not be detected. Thus, the number of positive specimens detected by a pathology laboratory represents a minimum estimate of the true infection rate among the people submitting specimens.

#### **6.2.6.3 *Incompleteness of Data***

The types of pathogens designated as ‘notifiable’ may vary from one jurisdiction to another and also may change over time depending on their perceived public health importance. Testing practices in laboratories are variable. While all laboratories will test gastroenteritis fecal specimens for the common bacterial pathogens, many will not test for viruses or protozoa unless specifically requested to do so by the physician treating the affected individual. Alternatively, individual laboratories may apply certain criteria to determine which specimens are subjected to a wider range of tests (e.g., age, recent overseas travel, immunodeficiency). For some pathogens, no routine testing method is available. The lack of uniformity in testing practices means that the frequency of some pathogens is underestimated relative to others. Finally, when a notifiable pathogen is detected, notification to health authorities may not always occur or may be significantly delayed.

#### **6.2.6.4 *The Reporting Pyramid***

The reporting pyramid is the relationship among rates of illness in the community, cases seeking medical attention, cases where a pathogen is identified, and cases eventually reported to surveillance schemes. A recent study in England found that, for every single identified pathogen reported to the national surveillance system, 23 people had sought medical attention from a medical practitioner, and 136 cases of gastroenteritis had occurred in the community.<sup>310</sup> The ratios of this reporting pyramid varied for individual pathogens; those tending to cause mild or short duration illness (e.g., viruses) had a larger ratio

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<sup>310</sup> J.G. Wheeler et al., 1999, “Study of infectious intestinal disease in England: Rates in the community, presenting to general practice, and reported to national surveillance,” *British Medical Journal*, vol. 318, pp. 1046–1050.

of community cases to physician-reported cases. These ratios are likely to vary in different countries because of different patterns of pathogen prevalence, variability in access to medical care, differences in specimen collection and screening practices, and differences in surveillance systems.

#### **6.2.6.5 Performance of Current Systems**

The slowness and low sensitivity of current surveillance systems mean that the delay between exposure of the population and detection of an outbreak is likely to be at least two to three weeks. By this time, many people may have become infected and developed illness. Some outbreaks may pass undetected or be detected only in retrospect after the exposure has passed and the outbreak is over. In some instances, the delay may mean that determination of the exact circumstance leading to the outbreak is not possible. Earlier detection would facilitate public health intervention to reduce case numbers. It would also assist in finding the causes of outbreaks so that better preventive measures can be developed in future.

The lack of sensitivity of current surveillance systems was clearly demonstrated in the Milwaukee *Cryptosporidium* outbreak in 1993. Over 400,000 people (about 25% of the population of the greater Milwaukee area) are believed to have experienced gastroenteritis following contamination of the water supply. The outbreak was recognized on April 5 owing to large-scale absenteeism among workers. However, by this stage it is likely that almost half the cases of illness had already occurred, and many more people had already been infected but had not yet developed symptoms.<sup>311</sup> Water was not identified as the cause of the outbreak until two days later, and a boil water notice was issued. Subsequent computer modelling and analysis suggested that a smaller water-borne outbreak had occurred in early March prior to the main outbreak, and had this been detected, about 85% of subsequent cases might have been prevented.<sup>312</sup>

#### **6.2.7 Options for Improving Surveillance**

Efforts to improve surveillance must aim at increasing sensitivity and decreasing the delay between population exposure and recognition of a disease outbreak.

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<sup>311</sup> MacKenzie et al., 1994.

<sup>312</sup> Eisenberg et al., 1998.

This will assist in reducing case numbers by allowing earlier public health intervention. It will also help in gaining better knowledge about the causes of outbreaks so that more effective preventive measures can be developed. These aims may be achieved by moving further down the reporting pyramid for infectious disease surveillance and by using related data sources, such as those described below.

The strengths and weaknesses of surveillance, as indicated by various measures of community illness and water quality, were examined after the Milwaukee *Cryptosporidium* outbreak.<sup>313</sup> The data sources were water treatment plant turbidity logs, clinical laboratory diagnoses, nursing home diarrheal rates, hospital emergency room logs, random dialling telephone surveys, water utility complaint logs, school absentee logs, and pharmacy sales of over-the-counter antidiarrheal drugs. Researchers found that several of these data sources might have provided earlier warning of the outbreak, but most had limitations relating to ease of acquiring and collating data.<sup>314</sup>

## 6.2.8 Enhanced Surveillance Systems

### 6.2.8.1 *Surveillance System Development in Australia*

The Australian Cooperative Research Centre (CRC) for Water Quality and Treatment has undertaken a research project to develop a new system for the detection of water-borne disease outbreaks. The aims of this project are to:

- identify new sources of information related to the detection of water-related diarrheal disease incidence in Australia;
- create computer programs to acquire, store, and analyze such information daily to predict or detect outbreaks of diarrheal disease; and
- investigate effective ways of presenting data from the new sources to make them accessible to working epidemiologists and water authorities throughout Australia.

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<sup>313</sup> M.E. Proctor et al., 1998, "Surveillance data for water-borne illness detection: An assessment following a massive water-borne outbreak of *Cryptosporidium* infection," *Epidemiology and Infection*, vol. 120, pp. 43–54.

<sup>314</sup> Ibid.

Padiglione and Fairley evaluated potential data sources in a pilot study.<sup>315</sup> They concluded that to be of practical use in outbreak detection, data sources should ideally be available in real time or daily and in electronic format for computer acquisition and analysis. In addition, data sources should be compiled and available at minimal cost to health authorities. At present, the two main data sources relating to health outcomes that fulfill these criteria are hospital admissions of children with gastroenteritis and the numbers of gastroenteritis fecal specimens received by pathology laboratories. Water quality data sources include the results of routine microbiological and physicochemical monitoring of the distribution system. Australian water authorities are making increased use of on-line monitoring for turbidity and particle counts, and these may also prove to be useful data sources.

The new data sources are less specific than traditional surveillance methods because they relate to gastroenteritis or general rates of community illness rather than to identification of infection by specific pathogens. The new sources also generate much larger amounts of data on a daily basis than conventional surveillance systems. Thus, better methods of data analysis and more sophisticated display tools are needed to assist with the interpretation of this information.

The CRC's project uses artificial neural network programs for data analysis. An artificial neural network is a computer software program composed of subunits arranged in logical layers (input, hidden, and output) that interact with one another in a way crudely analogous to the interaction of nerve cells in an animal brain. Neural network programs 'learn' by examining a training set of known inputs and their corresponding outcomes. Starting with random weightings of the interactions, a network gradually adjusts the weightings until it can closely approximate output, given the appropriate input variables. Such a 'trained' network can then be used to predict unknown outcomes given new inputs.

Artificial neural networks are already in use in many diverse fields. For example, they are used to clean electrical noise from ECG signals, predict electric load requirements in UK cities, and enable personal computers to understand spoken words. The advantage of artificial neural networks is that they can often recognize relationships within a data set that are too subtle for a human observer to

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<sup>315</sup> A. Padiglione and C.K. Fairley, 1998, "Early detection of outbreaks of water-borne gastroenteritis. Water," *Journal of the Australian Water Association*, vol. 25, no. 6, pp. 11–15.



detect. They are intrinsically non-linear in nature and compare well against the standard statistical methods for analyzing disease occurrence data. When linked to geographic information systems (GIS), neural network programs can analyze time-series data on water quality and disease incidence on a geographic basis related to water distribution areas. Patterns of normal variation can be recognized, and future diarrheal disease rates can be predicted from current data. When such predictions are significantly above that expected through normal variation, the neural network can alert the surveillance authorities to the existence of abnormal conditions that may signal an outbreak.

The CRC's project also involves the development of other computing tools to analyze and present data in a form that water authorities and health agencies can easily access. One such component, called MapMovie, is a tool that allows for rapid scanning of both the spatial and temporal relationships in a database by rapidly re-drawing a colour-coded map several times per second on a computer screen. The result is a 'movie' of the development over time of an outbreak or other event in the study area. Mechanisms for the automatic acquisition of pathology laboratory results and numbers of fecal specimen requests by state health departments are also being developed.

Ultimately, researchers envisage that direct communication between computers will be established so that daily or on-line reporting of relevant parameters to health authorities will be carried out automatically. The neural network surveillance program may then run the analysis and present the results daily, or may be programmed to alert health officials only if one or more parameters exceed the expected range. Health officials may then initiate further data analysis or health investigations. This will provide an integrated system capable of detecting outbreaks of gastroenteritis at the earliest possible stage and determining whether they are likely to be related to drinking water supplies.

#### **6.2.8.2 *Predicting Outbreaks***

All types of surveillance that rely on detecting parameters relating to illness are capable of detecting outbreaks only after the event has already occurred. The best that can be achieved with this kind of system is to detect outbreaks earlier and reduce their impact. In theory, it should be possible to predict water-borne outbreaks before human exposure occurs if the causative factors can be determined and monitored. For example, if enhanced surveillance shows that unrecognized disease outbreaks have been occurring, and they are strongly

associated with heavy rain several weeks previously in a catchment area, then, in theory, intervention to prevent exposure would be possible. Where multiple water sources are available, it may be possible to stop using the affected source temporarily when such rainfall occurs. Alternatively, a boil water notice might be issued until the danger is past.

### **6.3 Recommendations of the Auditor General of British Columbia**

In the wake of the water-borne outbreaks of the mid-1990s, the auditor general of British Columbia undertook a study of the governance of drinking water in British Columbia. The study concluded that:<sup>316</sup>

- water source management was not integrated;
- improvements were needed in managing the effects of other resource uses on drinking water sources;
- the absence of groundwater management had resulted in increasing problems; and
- small water systems were particularly vulnerable to the impacts of inadequate water source protection.

In light of these broad conclusions, the auditor general made 26 recommendations in the report *Protecting Drinking Water Sources*. First was a recommendation to ensure that, in integrated management processes dealing with drinking-water issues:

- drinking-water consumers and suppliers are meaningfully represented;
- decisions are grounded in sufficient reliable information about natural conditions in the watershed and the values and impacts of competing resource uses; and
- findings and recommendations are handed off to elected or appointed officials who have the authority to act on them.

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<sup>316</sup> British Columbia, Office of the Auditor General, 1998/1999.

The auditor general further recommended that a lead agency be designated to coordinate policy and action on drinking water issues, and that the provincial government issue a comprehensive set of guidelines for good quality drinking water. Such guidelines would help decision makers and citizens better understand the information they receive about drinking water quality.

Given that approximately 80% of people in British Columbia receive their drinking water from surface sources, and that watersheds may also be areas of logging, the auditor general was especially concerned with the impacts of forestry practices on water sources. While the specifics of these recommendations may not apply in all situations, the principles of water quality monitoring and clearly defined accountability are generally applicable. Within the context of British Columbia's *Forest Practices Code*,<sup>317</sup> the auditor general recommended that:

- water quality objectives be developed for all community watersheds as a matter of priority;
- responsibility for monitoring whether water quality objectives are being met be clearly defined; and
- consideration be given to widening the range of results-based monitoring in community watersheds.

The auditor general also addressed the impact of agricultural practices on watershed health. Within the context of British Columbia's *Code of Agricultural Practice for Waste Management*,<sup>318</sup> the auditor general recommended that:

- region-specific regulations for agricultural sources of nutrients be developed; and
- priority be given to monitoring compliance with the *Code of Agricultural Practice for Waste Management* and to enforcing actions that encourage compliance with the code in order to maintain the incentive for voluntary compliance.

In light of the observation that groundwater management was inadequate, the auditor general recommended that the British Columbia provincial government:

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<sup>317</sup> *Forest Practices Code Act*, R.S.B.C. 1996, c. 159.

<sup>318</sup> B.C. Reg. 131/92, O.C. 557/92 under the *Waste Management Act*, RSBC 1996, c. 482, and the *Health Act*, RSBC 1996, c. 179.

- ensure regular monitoring of groundwater usage and levels in all developed aquifers; and
- ensure that monitoring of groundwater quality occurs regularly in all developed aquifers and more frequently in all vulnerable aquifers.

## **6.4 Comprehensive Water Quality Management Systems**

There is increasing recognition that compliance with conventional numerical water quality parameters is not, in itself, sufficient to guarantee the safety and quality of drinking water supplies. Evidence from outbreaks of water-borne diseases in developed nations suggests that occasional failure, overwhelming of protective barriers, and periods of poor system performance constitute increased risks to public health. These risks are unlikely to be effectively prevented by adopting more stringent numerical standards for treated water quality. This has spurred international interest in developing comprehensive water quality management systems for drinking water supplies that emphasize holistic and preventive management. Australia has developed a system of this type and is in the process of incorporating it into the national drinking water guidelines. This subsection discusses the motivation for developing the system, the system's structure and purpose, and its relationship to other quality management systems. A synopsis of the Australian framework is presented in Appendix A5.

### **6.4.1 Limitations of Microbiological Water Quality Monitoring**

Microbiological contaminants that create acute health risks remain the most important threat to drinking water supplies. Contaminated water supplies have the capacity to expose a large sector of any community to infectious disease agents within a short period of time, sometimes resulting in severe health consequences and major economic impact.

Microbiological water quality measurement relies on the detection of fecal indicator organisms in finished water. Traditional indicator organisms (*E. coli*, fecal/thermotolerant coliforms) correlate fairly well with risks from bacterial pathogens, but less well with risks from viruses and protozoa. As of September 2001, no satisfactory and practical surrogate has been identified for viruses and protozoa, and it is possible that other as yet unrecognized pathogens may also be present in water supplies. Routine monitoring for specific pathogens is

also problematic because test methods are often expensive and may be unreliable. In addition, public health implications of a positive result are not well understood. These uncertainties have resulted in several high-profile incidents where public health alerts have been issued following the detection of apparently high levels of pathogens in water supplies, but subsequent investigations showed no evidence of water-related illness.<sup>319</sup>

The delay between sampling and obtaining the test result means that in most water supply systems the affected water will have already been distributed to consumers before the result is known. Advances in test methods may substantially shorten this delay, but microbiological monitoring of finished water will always remain a reactive management tool that can prompt corrective action only after a problem has occurred.

Finished water monitoring also has another significant limitation: it is often uninformative about the nature, location, or timing of the problem that led to the unacceptable finished water quality. Remedial action tends to focus on localized short-term measures to regain compliance with numerical limits (e.g., hyperchlorination, flushing). Little helpful knowledge may be gained to prevent future recurrences.

#### **6.4.2 The Need for a New Approach to Water Quality Management**

Reliance on the monitoring of finished drinking water for managing drinking water quality and safety has important limitations. Monitoring for compliance with numerical values is limited in scope. It can lead to reactive rather than preventive management as corrective actions are initiated after monitoring reveals that standards have been exceeded. Furthermore, it cannot be used to deal with drinking water contamination by known contaminants that do not have prescribed numerical standards, or by unknown contaminants that may correlate poorly with indicator organisms or other routinely measured parameters. Additionally, reliance on finished water monitoring assumes that the numerical guideline values are, by themselves, a sufficient measure of drinking water quality. In reality, substantial limitations remain in our knowledge of the relationship between those parameters and public health outcomes. Even if it were possible and feasible to accurately measure individual pathogens, the biological variability in their capacity to cause infection and

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<sup>319</sup> Clancy, 2000.

illness means that reliable predictions could not be made about the public health consequences of exposure to any given level of contaminant.

Recognition of these limitations has led to the realization that health authorities and water suppliers must adopt a more preventive approach to water quality management that emphasizes the importance of good management practices throughout the water supply system. This approach does not eliminate the requirement for compliance monitoring of finished water, but allows it to be viewed in the proper perspective – confirming that management systems are effective rather than being the primary means of public health protection.

#### **6.4.3 Australian Framework for Management of Drinking Water Quality**

Australia has developed a prototype comprehensive water quality management system for drinking water supplies and is incorporating it into the national drinking water guidelines. Although the system focuses on microbiological contaminants, it also provides an effective methodology for minimizing risks from chemical contaminants.

Control of water quality in Australia is based on the *Australian Drinking Water Guidelines* (ADWG), which are voluntary national guidelines developed jointly by the National Health and Medical Research Council (NHMRC) and the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ). The ADWG are used as the basis for a variety of different regulatory arrangements in individual states and territories. (For further information on the ADWG, see subsection 5.3.2.) While the ADWG recognize the merits of a preventive management approach, much of the related supporting information is not developed in detail or organized in a cohesive manner. The ADWG do provide a great deal of information pertaining to numerical criteria for water quality parameters, with an implied emphasis on monitoring finished water quality. As a result, the ADWG are often used as a focus for compliance-based management strategies, which tend to use guideline values as standards. This is not the intent of the ADWG, and such use overshadows the importance of overall system management for assuring safe drinking water.

As part of the rolling revision process for the ADWG, relevant information on preventive management has been reorganized and expanded to form a practical and comprehensive risk management system for drinking water quality management. This system, *Framework for Management of Drinking Water*

*Quality: A Preventive Strategy from Catchment to Consumer*, will be incorporated into the *ADWG* in 2002.<sup>320</sup> The draft framework was developed in a collaborative process involving major stakeholders and international experts, and will be subject to public comment prior to finalization. Australian water authorities are also developing additional documentation to support the implementation of the framework. The CRC for Water Quality and Treatment, in collaboration with ARMCANZ and NHMRC, is largely responsible for the development of the framework and supporting documentation.

#### 6.4.3.1 The Development Process

The development of the framework involved nine steps.

1. *Identification of existing preventive elements in the ADWG* The preventive elements in the *ADWG* provide an important foundation for developing a framework for drinking water quality management.<sup>321</sup> These include, for example, the following measures for guaranteeing the safety of water supplies:

- the use of effective barriers to prevent contamination of the water supply system;
- regular inspections of catchment areas to identify the chemicals being used and how they are applied;
- registration of chemicals, such as pesticides and other toxic organic and inorganic compounds;
- control of industrial, mining, forestry, agricultural, and human activities within catchment boundaries;
- an effective maintenance program for the plant and equipment used in the water supply system;
- management of activities in the distribution system to ensure cross connections do not occur;
- choice and use of approved water treatment chemicals;
- use of approved materials in contact with water;
- use of appropriately skilled and trained personnel in the operation of water supply systems; and

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<sup>320</sup> For more information, see Web site: <<http://health.gov.au:80/hfs/nhmrc/publications/synopses/eh19syn.htm>>.

<sup>321</sup> Australia, National Health and Medical Research Council/Agriculture and Resource Management Council of Australia and New Zealand, 1996, Chapter 1.7.

- public awareness and education programs so that people know what is being done to protect their water supply and whom to contact if unauthorized activities are suspected.

Further elements of a preventive management approach include the following aspects of system management:<sup>322</sup>

- an agreed level of service;
- effective treatment processes, including disinfection;
- regular inspection and maintenance of the system;
- practices that identify likely external sources of contamination;
- ongoing evaluation and refinement of the overall operation of the system;
- monitoring programs that assess water quality throughout the system and identify the location and nature of any water quality problem within the system;
- validation procedures for sampling and laboratory testing programs;
- the use of monitoring information both to facilitate day-to-day management of the supply and to assess its performance over time;
- appropriate procedures for immediate correction of any serious water contamination and resolution of longer-term water quality problems that might be costly to address;
- defined lines of responsibility for remedial action;
- use of appropriately skilled and trained personnel;
- transparent auditing procedures; and
- reporting to consumers.

*2. Review of systems for quality management and risk assessment/risk management* Quality management embodies the philosophy of continuous improvement and consists of generic elements, such as policy development, assessment, planning, implementation and operation, monitoring, corrective and preventive action, and evaluation. A number of established systems and processes also exist for the systematic assessment of hazards and risks, and the development and implementation of risk management procedures.

The existing quality management systems listed below were reviewed to help identify the appropriate scope and structure of a framework for drinking water quality management. Details of these systems are summarized in Appendix A6.

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<sup>322</sup> Australia, National Health and Medical Research Council/Agriculture and Resource Management Council of Australia and New Zealand, 1996, Chapter 5.



- International Organization for Standardization (ISO) 9001 (Quality Systems)
- International Organization for Standardization (ISO) 14001 (Environmental Management Systems)
- Water Services Association of Australia (WSAA) Environmental Management Guidelines (EMG)
- Hazard Analysis Critical Control Point (HACCP)
- Australia/New Zealand RM 4360 (Risk Management)
- American Water Works Association (AWWA)/EPA Partnership for Safe Water

Areas of equivalence among the different systems were identified, and the relevance and applicability of each component to the management of drinking water quality was assessed.

Particular attention was given to the ISO 9001 system, which increasingly is being adopted by Australian water authorities, and the HACCP system, which is used in the food industry. The ISO 9001 system is a generic model for quality assurance. It is designed to ensure that a product conforms to specified requirements by controlling aspects of production, such as materials, procedures, testing, traceability, and documentation. HACCP is an internationally recognized system used to reduce or prevent health risks associated with food processing. A preventive system of control to assure product safety, HACCP focuses efforts on preventing hazards as close to their sources as possible. Key features of HACCP are the identification of hazards and the specific measures to control hazards. These measures emphasize the use of parameters that can be monitored and verified in real time, and documentation to demonstrate that the critical control activities are working. The application of HACCP to drinking water supply has been suggested by a number of authors because of the existence of many parallel risk management issues in food and water supply.<sup>323, 324</sup> Several Australian water authorities have already achieved HACCP certification.

The review of available systems demonstrated that, while existing quality management systems contained many components relevant to water supplies, no single system had all the components required to address the unique and

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<sup>323</sup> A.H. Havelaar, 1994, "Application of HACCP to drinking water supply," *Food Control*, vol. 5, no. 3, pp. 145–152.

<sup>324</sup> D. Deere and A. Davison, 1998, "Safe drinking water: Are food guidelines the answer?" *Water*, vol. 25, no. 6, pp. 21–24.

difficult challenges of drinking water quality management. Thus, it was necessary to develop a system specifically for water supplies, drawing on useful aspects of existing quality management systems and supplementing these with additional elements to provide the comprehensive coverage needed.

*3. Development of a draft framework and discussion paper* A draft framework was developed that incorporated the existing preventive elements of the *ADWG* and relevant elements from various risk assessment, risk management, and quality management systems. A discussion paper outlining the derivation process and describing the draft framework was circulated to major stakeholders, including representatives of NHMRC and ARM CANZ, the water industry, federal and state health regulators, catchment and environmental organizations, and the Consumers' Health Forum.

*4. Participation by stakeholders in a national workshop* A national workshop was convened in October 1999 by the NHMRC/ARM CANZ Drinking Water Review Coordinating Group to discuss the draft framework and develop a working plan for its further development and testing. There was consensus that the adoption of a national approach to drinking water quality management offered many benefits. A comprehensive and preventive framework jointly developed by major stakeholders would provide a flexible and effective means of assuring the protection of public health. It would also increase communication among and define the responsibilities of the various agencies and stakeholders involved in the supply of water. The framework would provide a common and unified approach throughout the industry that would establish due diligence and credibility.

*5. Participation by water authorities and other stakeholders in desktop trials* Four teams representing water supply systems with different characteristics assessed the draft framework. The objectives of the trials were to:

- critically assess the framework through practical application to different types of water supply systems (e.g., groundwater versus surface water, medium supply versus large supply, protected catchment versus unprotected catchment, minimal treatment versus conventional treatment);
- obtain constructive comments to improve and modify the framework;
- develop increased guidance by conceptually demonstrating how implementation could be achieved in these organizations; and

- provide a broader base of input into the development of the framework.

Each participating water authority nominated team leaders and team membership, including representatives from operations, land-use/catchment boards, and local state/territory health and water resource departments. It was important that the team include the range of skills required for assessing all elements of the framework. Each project team was asked to identify and describe their water supply system (from catchment to consumer) and assess how the framework would apply to their practices and operations for that system. Teams were asked to comment on the framework's comprehensiveness, coherency, deficiencies, and difficult aspects. They were also asked to identify possible benefits from its use and elements that could be added to make the framework more effective. Feedback from these assessments helped refine the framework.

The assessment confirmed that the draft framework provided broader and more effective coverage of drinking water quality management issues than that provided by simply combining the elements of ISO 9001 and HACCP. The framework steps identified as not being well covered by ISO 9001 and HACCP are those associated with stakeholder involvement (beyond customers), research and development, management of large-scale emergencies, and procedures for reporting. The teams also identified other advantages of the framework, including an enhanced profile of drinking water quality management, specific guidance on preventive measures, and an emphasis on the importance of communication. Appendix A6 presents a table summarizing areas of overlap of the framework with other quality management systems.

6. *Incorporation of the framework into the ADWG (in progress)* Following refinement of the draft framework as a result of feedback from the desktop trials, an NHMRC working party is making final modifications. Revisions to the ADWG to incorporate the framework are being planned. The framework was released for public comment in May 2001. A public workshop on the framework was held in conjunction with a WHO drinking water guidelines meeting in Australia in May 2001. Completion of revisions to the ADWG and incorporation of the framework is expected in 2002.

7. *Development of supplementary documentation* The framework must be generic and flexible in order to be applicable to a range of water supply types, and to function effectively in different jurisdictions with differing structural and regulatory arrangements. While a number of case studies are incorporated into

the framework, specific details relevant to implementation in individual water supply systems are not included. Most larger water authorities have the resources to apply risk assessment and risk management approaches to their systems, and many are already using quality management systems, such as ISO 9001. However, the areas of systematic risk assessment and review of management controls are complex and highly technical, and may be beyond the capability of small to medium-sized water authorities. Therefore, a number of additional documents are under development to assist with implementation of the framework. They will also enhance the understanding and application of the *ADWG* by the water industry and other organizations involved in water supply and regulation.

*8. Integration with other quality management systems* The framework contains several elements analogous to components of existing quality management systems. Water authorities can integrate the ‘missing’ elements into the systems they are already using, thus facilitating implementation of the framework.

*9. Third-party audit and certification* Since the *ADWG* are voluntary, they are not intended to mandate the adoption of the framework or the establishment of third-party audit or certification mechanisms. Nevertheless, a number of larger water authorities have expressed interest in the development of formal independent audit and/or certification processes. They feel that audit by independent parties will ensure consistency in the application of the framework and increased credibility with consumers.

#### **6.4.3.2 *The Draft Australian Framework for Management of Drinking Water Quality***

Table 6.2 lists the major elements of the framework and the components within each element. (Appendix A5 provides a synopsis of the framework.) The framework is still in draft form and may undergo further revisions prior to finalization and inclusion in the *ADWG*.

### **6.5 Strengthening Drinking Water Management in Ontario**

This report has demonstrated that the scientific basis underlying Ontario’s drinking water standards is comparable to that in other jurisdictions, including the United States, Australia, and the World Health Organization. Since August

2000, drinking water safety in Ontario has been governed by the *Drinking Water Protection Regulation* and the *Ontario Drinking Water Standards (ODWS)*; the *ODWS* are based on the guidelines developed by the Federal-Provincial Subcommittee on Drinking Water of the Federal-Provincial-Territorial Advisory Committee on Environmental and Occupational Health. Administration of this legislation, in concert with the *Guidelines for Canadian Drinking Water Quality*, takes advantage of many of the best procedures for assessing and managing risks of drinking water supplies.

As in all areas of risk assessment and risk management, opportunities exist for capitalizing on recent developments to further strengthen drinking water safety systems in Ontario. Areas that merit consideration include the following.

**Table 6.2    Framework for Management of Drinking Water Quality:  
A Preventive Strategy from Catchment to Consumer**

|   |   |
|---|---|
| <p><b>1 Commitment to Drinking Water Quality Management</b><br/><i>Drinking Water Quality Policy</i><br/><i>Requirements</i><br/><i>Partnership Agencies</i></p> <p><b>2 Assessment of the Drinking Water Supply System</b><br/><i>Water Supply System Analysis</i><br/><i>Review of Drinking Water Quality Data</i><br/><i>Hazard Identification and Risk Assessment</i></p> <p><b>3 Planning: Preventive Strategies for Drinking Water Quality Management</b><br/><i>Multiple Barriers</i><br/><i>Critical Control Points</i></p> <p><b>4 Implementation: Operational Procedures and Process Control</b><br/><i>Operational Procedures</i><br/><i>Equipment Capability</i><br/><i>Materials and Chemicals</i><br/><i>Operational Monitoring</i><br/><i>Operational Preventive and Corrective Action</i></p> <p><b>5 Verification of Drinking Water Quality</b><br/><i>Drinking Water Quality Monitoring</i><br/><i>Consumer Satisfaction</i><br/><i>Short-term Evaluation of Results</i><br/><i>Corrective Action</i></p> | <p><b>6 Incident and Emergency Response</b><br/><i>Communication</i><br/><i>Incident and Emergency Response Protocols</i></p> <p><b>7 Employee Awareness and Training</b><br/><i>Employee Awareness and Involvement</i><br/><i>Employee Training</i></p> <p><b>8 Community Involvement and Awareness</b><br/><i>Community Consultation</i><br/><i>Communication</i></p> <p><b>9 Research and Development</b><br/><i>Investigative Studies and Research Monitoring</i><br/><i>Validation of Processes and Critical Limits</i><br/><i>Validation of Equipment</i></p> <p><b>10 Documentation and Reporting</b><br/><i>Documentation and Records Management</i><br/><i>Reporting</i></p> <p><b>11 Evaluation and Audit</b><br/><i>Long-term Evaluation of Results</i><br/><i>Drinking Water Quality Management Audit</i></p> <p><b>12 Review and Continual Improvement</b><br/><i>Management Review</i><br/><i>Drinking Water Quality Improvement Plan</i></p> |
|---|---|

### **6.5.1 Enhanced Population Health Surveillance**

Recent developments in surveillance methodology and the steps taken to establish the development of a National Health Surveillance System in Canada provide the basis for more closely monitoring trends in infectious and non-infectious disease outbreaks. These recent advances may afford opportunities to strengthen surveillance of enteric diseases, which may enable risk managers to better anticipate and prevent water-borne disease outbreaks.

### **6.5.2 Scientific Methods for Characterizing Microbiological Risks**

Risk assessment methodology for microbiological hazards is not well developed, unlike that for chemical and radiation risks. Attempts are being made to develop new dose-response models that include better exposure assessments and identification of sensitive subpopulations. This ongoing scientific work offers promise for strengthening our ability to estimate levels of risk associated with microbiological contaminants in drinking water.

### **6.5.3 Source Water Protection**

The most effective approach for managing microbiological risks from drinking water is source water protection. Enhanced population health surveillance can provide an early warning of disease outbreaks, but it is not a substitute for good water quality management, which will prevent the occurrence of outbreaks. The advantage of good source water protection is that it can prevent water contamination ('pollution prevention'). Good source water protection can eliminate the need to deal with contamination after it becomes a problem ('react and cure').

### **6.5.4 Total Water Quality Management**

Ultimately, effective management of health risks associated with drinking water should be based on some form of total or comprehensive water quality management system, such as the Australian framework. The need for such a system arises in part from the realization that reliance on the monitoring of

treated drinking water for managing health risks is reactive and, therefore, has important limitations. In total quality management, a preventive approach emphasizes good management practices throughout the water supply system from catchment to consumer. Key components of this approach include:

- ongoing assessment of water quality and potential health risks;
- planning of preventive strategies;
- implementation of effective operational procedures and process control;
- employee awareness and training;
- involvement of community members;
- research and development;
- documentation and reporting; and
- continual improvement of all aspects of water quality management.

#### **6.5.5 No Assurance of ‘Zero Risk’**

Although the strategies discussed above can be expected to maximize drinking water quality in Ontario, it must be recognized that the ideal goal of ‘zero risk’ to human health is unreachable in practice. Implementation of improved water quality management practices can significantly lower the health risks associated with pathogenic micro-organisms. However, no absolute assurance can be given that disease outbreaks will not occur in the future. The objective, therefore, is to reduce the health risks from drinking water to the extent possible using the best available risk assessment and risk management methodologies.

## **Appendix A1: Initiatives Associated with Ontario's *Drinking Water Protection Regulation* (O. Reg. 459/00)**

Ontario's new *Drinking Water Protection Regulation* is part of Operation Clean Water, a comprehensive action plan to give Ontario residents the best, safest drinking water in Canada. Details of individual programs are presented in the documents listed below which can be obtained from the Ontario Ministry of the Environment Web site ([www.ene.gov.on.ca](http://www.ene.gov.on.ca)).

### **General**

- Comment Form – Drinking Water Protection, Sept. 4, 2001.
- Harris government action plan to improve water quality includes tough new regulation (in .pdf format 40K/2 pages)
- Operation Clean Water (in .pdf format 9K/1 page)
- Protecting Ontario's drinking water (in .pdf format 28K/6 pages)
- Speaking notes for the Honourable Dan Newman, August 8, 2000, 12:45pm (in .pdf format 9K/2 pages)
- Frequently Asked Questions (FAQs) (in .pdf format 21K/10 pages)
- *Drinking Water Protection Regulation* (in .pdf format 75K/28 pages)
- Licensing of water and wastewater operators: Proposed amendments to Ontario Regulation 435/93. Environmental Bill of Rights Registry Number RA00E0015

### **Discussion Papers**

- Ontario launches consultation on additional measures for drinking water protection
- Protecting drinking water for small waterworks in Ontario (in .pdf format 32K/8 pages)

### **Technical Briefs**

- Update – Technical Clarifications to O. Reg. 459/00 – This document provides clarification of certain schedules in the Drinking Water Protection Regulation. (in .pdf format 23K/4 pages) posted July 10, 2001
- *Ontario Drinking Water Standards (ODWS)* (in .pdf format 18K/2 pages)
- Engineers reports for waterworks (in .pdf format 27K/3 pages)



- New sampling requirements for waterworks (in .pdf format 20K/2 pages)
- Water sampling and testing for microbiological parameters (in .pdf format 26K/3 pages)
- Licensing of staff conducting analytical tests at waterworks (in .pdf format 18K/2 pages)
- Laboratory accreditation requirements (in .pdf format 33K/5 pages)
- Minimum Treatment requirements (in .pdf format 21K/2 pages)
- Adverse drinking water quality – corrective actions (in .pdf format 15K/1 page)
- Notification requirements (in .pdf format 19K/2 pages)
- Posting a public notice (in .pdf format 18K/2 pages)
- Waterworks quarterly reports for consumers (in .pdf format 41K/6 pages)

## Other Key Documents and Links

- Drinking Water Laboratory Submissions and Waterworks Notification
- Terms of reference engineer's reports for water works (in .pdf format 32K/6 pages)
- Submission dates for first engineer's reports (in .pdf format 46K/17 pages)
- Electronic Submission of Engineer's Report for Water Works under Drinking Water Protection Regulation 459/00
- Canadian Commercial Laboratories Accredited For and Testing Ontario
- *Ontario Drinking Water Standards (ODWS) Parameters* [PDF]
- Ontario Provincial/Municipal Laboratories Accredited For and Testing *Ontario Drinking Water Standards (ODWS) Parameters* [PDF]
- Ontario drinking water standards in .pdf format 194K/72 pages)
- Guide for applying for approval of municipal and private water and sewage works (in .pdf format 389K/100 pages)
- Model conditions for certificate of approvals: groundwater supply with treatment (in .pdf format 134K/10 pages)
- Model conditions for certificates of approval: surface water supply (in .pdf format 135K/10 pages)
- Model conditions for certificates of approval: groundwater supply with chlorination only (in .pdf format 127K/8 pages)
- Model conditions for certificates of approval: Re-chlorination facility tapping another municipality's water supply system (in .pdf format 139K/7 pages)

## **Forms**

- Notice of drinking water analysis and remedial actions for waterworks (in .pdf format 27K/2 pages)
- Notification of laboratory services provided to waterworks (in .pdf format 37K/4 pages)
- Notification for water works without disinfection, chlorination or filtration facilities (in .pdf format 34K/4 pages)

## **Private Well Owners**

- Green Facts: Important facts about water well construction (in .pdf format 124K/2 pages)
- Green Facts: Installation of well pumps (in .pdf format 43K/4 pages).
- Green Facts: The protection of water quality in drilled wells (in .pdf format 86K/3 pages)
- Green Facts: The protection of water quality in bored and dug wells (in .pdf format 109K/3 pages)

## **Appendix A2: Ontario Ministry of the Environment Drinking Water Surveillance Program**

### **Background Information**

The Drinking Water Surveillance Program (DWSP) began in 1986 at 22 water supply systems. By the end of 1999, 162 municipal waterworks were being monitored. They account for over 88% of the population served by municipal water supplies. The DWSP is a monitoring program developed to provide reliable and current information on municipal drinking water. Collected data are used to:

- monitor levels of chemicals and establish trends;
- define and track the occurrence of new chemicals;
- provide data in support of drinking water standards setting; and
- assess treatment plant operations.

Water supply systems are included in the program based on population served, geographical location, and risk of contamination.

DWSP is not a compliance monitoring program. That responsibility lies with the operating authority for each municipal water supply, which is required to monitor the quality of the drinking water provided to the consumer and ensure its safety. Participation of operating authorities in DWSP is voluntary and DWSP data are routinely sent to them once the laboratory has completed the analysis.

Results show that the municipalities that were monitored by DWSP for the period 1998 to 1999 produced good quality water for their communities. Over 309,000 analytical tests (inorganic, organic, and radiological) were performed on raw water, treated drinking water, and water in the distribution systems. Ninety-one test results in the 1998 and 1999 period of DWSP sampling were above a health-related *Ontario Drinking Water Objectives (ODWO)*. The health-related objectives for flouride, turbidity, nitrates, lead, selenium, total trihalomethanes, N-nitrosodimethylamine (NDMA), and chloramines were exceeded on at least one occasion at 26 locations for the 1998 and 1999 monitoring period.

## **Drinking Water Characteristics**

In Ontario, drinking water is provided by rivers, lakes, streams, ponds, reservoirs, springs, and wells. As water travels through the ground or over the surface, it dissolves naturally occurring minerals and radioactive material and can absorb substances resulting from the presence of animals or human activity.

Categories of substances that may be present in source waters include:

- Microbiological substances, such as viruses and bacteria, which may come from sewage treatment plants, septic systems, agricultural livestock operations, and wildlife.
- Inorganic substances, such as salts and metals, which can be naturally occurring or result from urban storm water runoff, industrial or domestic wastewater discharges, oil and gas production, mining or farming.
- Pesticides and herbicides that may come from a variety of sources such as agriculture, stormwater runoff, and residential use.
- Organic substances, synthetic and volatile, are by-products of industrial processes and petroleum production and can come from gas stations, urban stormwater runoff, and septic systems.
- Radioactive materials that can occur naturally or result from nuclear power production and mining activities.

## **DWSP Parameter Groups**

The following paragraphs describe the parameters (physical characteristics, such as colour, pH and temperature or chemical substance) that DWSP monitors.

## **Inorganic parameters**

### ***Physical/chemical***

Physical/chemical parameters, for the most part, are naturally occurring in the source water. The water treatment process is designed to reduce the levels of these parameters.

*Fluoride* is a chemical substance that may be added to municipal water during the treatment process to promote strong teeth. Fluoride can also be present in the source water as a result of erosion of natural deposits or discharge from fertilizer and aluminum factories. Eight tests for fluoride were detected above the *ODWO* in 1998 and 1999.

*Nitrates* are present in source water as a result of run-off from fertilizer use, leaching from septic tanks, sewage and erosion from natural deposits. Two tests for nitrate were detected above the *ODWO* in 1998 and 1999.

*Turbidity* in water is caused by the presence of suspended matter such as clay, silt and microscopic organisms and is commonly present in the source water as a result of soil runoff. Turbidity can serve as a source of nutrients for micro-organisms and interfere with their enumeration. A total of 38 turbidity tests were detected above the *ODWO* of one nephelometric turbidity unit (NTU) for water entering the distribution system in 1998 and 1999. Three sites with groundwater sources accounted for 17 turbidity tests detected above the *ODWO* and 10 sites with surface water sources accounted for 21 turbidity tests detected above the *ODWO*. Turbidity in treated surface water may be an indication that the treatment process is not optimized to remove particles. The risk that the turbidity could consist of cysts or other matter that could shield bacteria from disinfection is greater in surface water sources than in ground water sources.

### ***Metals***

Metals, for the most part, are naturally present in source water, or are the result of industrial activity. Some, such as copper and lead, may enter the drinking water from plumbing in the distribution system.

*Lead* can occur in source water as a result of erosion of natural deposits. The most common source of lead is corrosion of household plumbing. First flush

water at the consumer's tap may contain higher concentrations of lead than water that has been flushed for several minutes. Ten tests for lead were detected above the *ODWO* in 1998 and 1999.

*Selenium* occurs naturally in waters at trace levels as a result of geochemical processes such as weathering of rocks and soil erosion. It is difficult to establish levels of selenium that can be considered toxic because of the complex interrelationships between selenium and dietary constituents such as protein, vitamin E, and other trace elements. Four tests for selenium were detected above the *ODWO* in 1998 and 1999.

*Mercury* and *cyanide* have never been detected above a trace level in DWSP results for treated water.

### **Organic parameters**

Organics make up 83% of the total number of parameters tested by the DWSP, yet they are seldom detected in drinking water. Organic parameters are grouped accordingly:

#### ***Chloroaromatics***

Parameters classified as chloroaromatics are present in surface water as a result of industrial activity. They are by-products of certain processes of chlorination of hydrocarbons.

#### ***Chlorophenols***

The *ODWO* for total phenols was replaced by *ODWOs* for specific, more sensitive individual chlorophenols. Ten individual chlorophenols are tested for in the DWSP.

### ***N-nitrosodimethylamine (NDMA)***

*N-nitrosodimethylamine* (NDMA) or its precursors may be present in the source water as a result of industrial discharge or from sewage/animal waste effluents combined with nitrite from anaerobic decay of organic waste matter. NDMA has been detected as a by-product in a certain blend of coagulant and polymer used in the treatment process. Four tests for NDMA were detected above the *ODWO* in 1998 and 1999.

### ***Disinfection by-products***

*Chloramines* (Combined Chlorine) are produced during the disinfection process when aqueous chlorine and ammonia are mixed. Chloramines can be used to maintain a chlorine residual for long periods of time in the distribution system. Chloramines assist in the control of certain taste and odour problems caused by chlorination and keep trihalomethane formation to a minimum. Two tests for chloramine were detected above the *ODWO* in 1998 and 1999.

*Trihalomethanes* (THMs), by-products of drinking water chlorination, occur during the treatment process. Trihalomethanes are comprised of *bromoform*, *chloroform*, *bromodichloromethane* and *chlorodibromomethane*. THMs do not exceed the *ODWO* on the basis of a single test result, but on a running average of four quarterly test results in the distribution system. THMs were detected above the *ODWO* criteria on 23 occasions in 1998 and 1999.

*Haloacetic Acids* (HAAs) are another category of disinfection by-products that will occur in chlorinated waters as a result of the water treatment process. Haloacetic acids are comprised of *monochloroacetic acid*, *dichloroacetic acid*, *trichloroacetic acid*, *monobromoacetic acid*, *bromochloroacetic acid*, and *dibromoacetic acid*. Results are reported for the individual compounds as well as for total HAAs. There is presently no Ontario Drinking Water Objective (*ODWO*) for HAAs.

### ***Polycyclic aromatic hydrocarbons (PAHs)***

The presence of *PAHs* in the environment is principally associated with the combustion of organic matter, including fossil fuels tested for in DWSP.

Benzo(a)pyrene is the only PAH for which an *ODWO* has been established and no detections above the *ODWO* were observed.

### ***Polychlorinated biphenyls (PCBs)***

*PCBs* are among the most ubiquitous and persistent pollutants in the global ecosystem. In the past, *PCBs* have been marketed extensively for a wide variety of purposes but their use in Canada is currently being phased out. Results of the DWSP show that *PCBs* have never been detected in either the treated drinking water or the raw water.

### ***Volatiles***

*Volatile* organics are generally present in source water as a result of recreational and industrial activity. Twenty-six volatiles, in addition to disinfection by-products discussed above, are tested for in DWSP.

### ***Pesticides***

*Atrazine* is the pesticide most commonly detected in Ontario's municipal drinking water. The presence of atrazine and other pesticides at trace levels indicates that the raw water source is affected by agricultural activity. No pesticides were detected at levels greater than the *ODWO* in 1998 and 1999.

### ***Radionuclides***

There are more than 200 radionuclides, some of which occur naturally and others that originate from the activities of society. The radionuclide of concern in Ontario drinking water supplies is tritium. *Gross beta* and *gross alpha* determinations are preliminary screens for all radionuclides with the exception of tritium, which must be measured separately. Results of the DWSP show that tritium has never been detected above the *ODWO* in either the treated drinking water or the raw water.



## **Taste- and odour-causing parameters**

Taste and odour episodes in drinking water have become more prevalent in Ontario over the past five years. They are caused by the decomposition of blue-green algae and generally occur after the algae blooms in the late summer. The compounds most frequently associated with taste and odour are *Geosmin* and *MIB* (*2-methylisoborneol*). Although geosmin and MIB can impart nuisance taste and odour at very low levels, no health related or aesthetic guidelines have been established.

*Geosmin* and *MIB* are not monitored routinely under the DWSP. However, special surveys are conducted at selected sites during specific times of the year. When water works experience taste and odour problems, they can request special sampling for these parameters.

## **Appendix A3: Saskatchewan Guidance for Issuing and Rescinding Emergency Boil Water Orders and Precautionary Drinking Water Advisories**

### **Introduction**

Eliminating pathogens should be the primary focus when treating and operating public water supplies. The most common form of disease from water-borne pathogens is gastrointestinal illness. The onslaught of this disease, as a result of drinking contaminated water, is sudden. Related health outcomes are not restricted to diarrhea; they can include other illnesses such as reactive arthritis, meningitis, impairment of neurological development, and hemolytic-uremic syndrome. In extreme cases, ingestion of pathogens can lead to death; some pathogens have mortality rates as high as 1% of cases. This contrasts with chemicals (many of which have established guidelines), as no acute health effects are sustained from chemical substances at the levels normally found in drinking water.

In order to provide the safest possible drinking water to consumers, all aspects of the multi-barrier approach are necessary. These aspects include treatment via chemically assisted filtration and disinfection (or slow sand filtration and disinfection); source protection; good operation and maintenance of the waterworks; comprehensive drinking water quality monitoring program; and appropriate abatement and enforcement measures.

*Treatment* Appropriate treatment including disinfection of drinking water supplies is crucial with respect to immediate health protection. The recommended minimum treatment requirement for all surface water includes coagulation-flocculation, sedimentation, filtration, taste/odour control, and disinfection. Although taste and odour control is an aesthetic process requirement instead of a health related one, it often has a major impact on the public's view about the safety of the drinking water. The public often rejects highly coloured water and turn to alternative supplies of questionable safety. The recommended minimum treatment requirement for groundwater includes continuous disinfection. Special or uncommon treatment process such as lime softening, demineralization, etc., have to be evaluated on a case-by-case basis.

*Source Protection* Intake works and wells should be properly located and constructed to protect against contaminants that will be present regardless of protection measures. Surface water and groundwater should be protected

through control of waste disposal and restricted land use. Land management practices, watershed/well protection (e.g., well decommissioning), and associated assessment and monitoring activities also play a key role in protecting the integrity of drinking water sources.

*Operation and Maintenance* Utility operators should adhere to recognized operation and maintenance programs to ensure that all aspects of the waterworks (source, treatment and distribution) are operating optimally. Distribution system programs should include maintenance of appropriate pressure regimens, main assessment, cleaning, repairing and replacement, leak detection and cross-connection control. Industrial customers should be advised of cross-connection control concerns. Programs should also include provisions for operator training/certification and the assessment of operational needs of a waterworks.

*Monitoring* System owners should verify the efficacy and the liability of their waterworks by routinely and systematically conducting water quality monitoring (microbiological, chlorine residual, turbidity and other chemical parameters) and evaluating treatment components. The minimum monitoring requirements are specified in the Minister's Orders.

When all the above public health principles are in place and a system failure or emergency occurs, rapid communication of the problem to the community is crucial. Problems requiring immediate attention include drinking water samples that test positive for microbiological contaminants, failure of a chlorinator, or other major treatment plant components. These problems may warrant actions such as the issuance of an "Emergency Boil Water Order" (EBWO) or a "Precautionary Drinking Water Advisory" (PDWA). *EBWOs are issued by the medical health officer of the local health district (HD)*, in consultation with Saskatchewan Environment and Resource Management's ecoregion when a threat to the public health exists. *PDWAs are issued by the ecoregion*, in consultation with HD, when there is a concern that problems may exist, but the immediate public health threats have not yet been identified.

SERM sets objectives for the bacteriological quality of drinking water. The maximum acceptable concentrations for the bacteriological quality are as below:

- 0 total coliforms per 100 mL; or
- 0 fecal coliforms per 100 mL; or
- No overgrowth or <200 colonies of background bacteria per 100 mL.

## **Emergency Boil Water Orders and Precautionary Drinking Water Advisories**

There are certain water quality problems that cannot be rectified by boiling yet for which boiling has been considered or advised as a solution. For example boiling will not destroy the heat-stable cyanobacterial toxins. Boiling drinking water may remove some disinfection byproducts (DBPs) but the exact conditions for their complete removal are unknown at this time. Many DBPs are not volatile and are not removed by boiling. For these reasons the most appropriate position to take is that boiling has not been shown to reduce the health risks related to cyanobacterial toxins and DBPs and therefore cannot be recommended as a solution at the present time. However, boiling is an effective way to inactivate all water-borne pathogenic micro-organisms.

The presence of fecal coliforms can be used as a trigger for the issuance of EBWO. However, care should be taken as some species in this group are not indicators of contamination by sewage. For example, *Klebsiella pneumoniae* occur naturally in vegetation and soils as well as in feces. The adequacy of the treatment and distribution process as well as proper sampling technique should be assessed before issuing an EBWO.

If further tests conducted by swabbing a fecal coliform or a total coliform plate shows that *E. coli* is present, then the water is very likely contaminated with human or animal fecal matter and pathogenic micro-organisms may be in the water. If it is determined that the water sample was collected properly, then an EBWO should be issued immediately.

The mere presence of parasitic cysts or oocysts in treated drinking water is not usually sufficient justification for issuing a boil water advisory. Because the current methods for the routine detection of cysts or oocysts do not measure viability or human infectivity, their public health significance is unknown. Nevertheless, the presence of cysts or oocysts in drinking water receiving full conventional treatment may indicate inadequate filtration, a malfunction in treatment or penetration of sewage into the distribution system. In such cases health officials may wish to monitor the public for the associated gastrointestinal illnesses before considering issuance of an advisory. Certain parasitic illnesses such as cryptosporidiosis, may pose a more serious threat to people who have weakened immune systems. Severely immunocompromised individuals should be advised to discuss these risks and remedial measures with their physicians.

The confirmed presence of total coliforms or overgrowth or >200 of background colonies in drinking water indicates that treatment may be inadequate or the distribution system is experiencing bacterial regrowth problems or infiltration. Total coliforms are not necessarily an indication of the presence of fecal contamination. However, the presence of total coliforms in drinking water certainly demonstrates a health risk. If remedial measures such as flushing water mains and increasing chlorine residuals do not correct this problem, then the local health district and the ecoregion may wish to discuss the issuance of a PDWA advising the public to boil their drinking water.

## Emergency Boil Water Orders

Emergency boil water orders should only be issued to mitigate confirmed public health threats due to microbial contamination of drinking water. EBWOs should be issued on evidence of:

- confirmed presence of fecal coliforms combined with inadequate treatment;
- confirmed presence of *E.coli*; or
- where epidemiological evidence indicates that the drinking water is responsible for an outbreak of illness (such as gastrointestinal illnesses).

## Precautionary Drinking Water Advisories

PDWAs could be issued when there is a concern that problems (due to microbial or chemical contamination) may exist. In a case of possible microbial contamination, the PDWA should be used to advise the public to boil the water. In a case where there is chemical contamination, the public will not be advised to boil the water, but may be advised to look for alternative water sources of confirmed acceptable quality. PDWAs should be issued on evidence of:

- significant deterioration in source water quality (i.e., high turbidity<sup>325</sup> due to runoff and other events);
- persistently low chlorine/disinfectant residuals (i.e., < 0.5 mg/L of total chlorine residual or < 0.1 mg/L of free chlorine residual);

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<sup>325</sup> The maximum acceptable concentration for turbidity is 1 NTU.

- the bacteriological monitoring results show a persistent total coliforms and overgrowths;
- lack of adequate treatment component(s) or equipment malfunctions in the treatment plant or distribution system; or
- persistently high concentration of chemical parameters such as arsenic, boron, or trihalomethanes.

## Rescinding Boil Water Orders or Advisories

EBWO or PDWAs are usually rescinded as soon as the microbiological quality, turbidity, particle counts and disinfection residual of the treated water in at **least two consecutive sets of samples**<sup>326</sup> have returned to acceptable levels or when the treatment or distribution malfunction has been corrected and sufficient water displacement, with water of confirmed acceptable quality, has occurred in the distribution system to eliminate any remaining contaminated water.

In the case of a disease outbreak, boil water orders are usually rescinded after the above conditions have been met and when surveillance indicates that the incidence of the illness in the community has returned to background levels. Owing to lengthy incubation periods for some pathogens and their secondary spread, new cases of illness may occur after the period of contamination has passed. Conversely, a lack of new cases may indicate that the advisory is being followed and not that the causative situation has been rectified.

## Communication

An emergency team consisting of those responsible for treatment plant operation and distribution, water quality monitoring and public health surveillance should be in place to quickly respond to any drinking water related incident that has had or may have had an affect on water quality or public health. The team should also have criteria in place to determine when an order/advisory can be rescinded. The arrangement should also allow for prompt communication of the order/advisory and related health risks between elected officials and the public through the services of the news media.

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<sup>326</sup> The two sets of samples should be taken at least one day apart. A set of samples should consist of least two samples, collected in the same day, from two different representative locations in the distribution system.

When an EBWO or a PWDA is issued, SERM's Environmental Protection Branch and Saskatchewan Health's Population Branch should be advised.

## Appendix A4: Guidelines for Tetrachloroethylene and Microbiological Parameters

These two examples have been selected to illustrate and contrast how drinking water guidelines for chemical and microbiological agents are derived. The description of the derivation for the guideline for perchloroethylene is adapted from the Supporting Documentation for the Canadian Guidelines (Canada, Health Canada, Federal-Provincial Subcommittee on Drinking Water, 1996b); that for microbiological parameters is based on the Supporting Documentation for the World Health Organization's Guidelines for Drinking Water Quality (United Nations, World Health Organization, 1996). The approaches are similar to those used by many other jurisdictions.

### Tetrachloroethylene

*The Canadian maximum acceptable concentration (MAC) for tetrachloroethylene in drinking water is 0.03 mg/L.<sup>327</sup>*

Tetrachloroethylene (also known as perchloroethylene or PERC) is a non-flammable liquid that is no longer produced in Canada, but continues to be imported primarily as a solvent for use in the dry-cleaning and metal-cleaning industries. Most of the tetrachloroethylene used in Canada is expected to be released to the atmosphere. However, it has been found in groundwater, primarily as a result of the improper disposal or dumping of cleaning solvents; it has been detected in some samples of drinking water across Canada and in contaminated surface water and groundwater. From a survey representing about 1.7 million of the 7.1 million Canadians who rely on groundwater for household use, it has been estimated that tetrachloroethylene was detectable in water supplying about 40% of the surveyed population.

Drinking water contributes approximately 1.0% to the total daily intake of tetrachloroethylene for the general population, or 1.9% if the contribution from incidental dermal intake (i.e., absorption through the skin from contact with water) is included. Total daily intake can be much larger for individuals whose drinking water comes from contaminated wells; for example, the contribution rises to 8.2% (or 16% if incidental dermal intake is considered) at a tetrachloroethylene concentration of 0.005 mg/L in drinking water.

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<sup>327</sup> One milligram is 1/1,000 of a gram.



Increases in illness and death due to various types of cancer have been observed in persons exposed to tetrachloroethylene in an occupational setting; however, the available information from human studies is considered inadequate to assess the carcinogenicity of tetrachloroethylene in humans. Increased incidences of kidney tumours, leukemias and liver tumours have been observed in experimental studies in which rats and mice were exposed to tetrachloroethylene in air; the types of tumours differed between species and sexes. Generally, a substance for which there is adequate evidence of carcinogenicity in two species of laboratory animals is often categorized as being “probably carcinogenic to humans.” However, a consideration of information on the mechanisms of carcinogenesis reduces the relevance of several of the increases in tumour incidence observed in these animal studies in assessing the weight of evidence for the carcinogenicity of tetrachloroethylene in humans. Thus, the induction of kidney tumours in (specifically) male rats and liver tumours in mice exposed may not be relevant to humans. The results considered most pertinent in assessing the weight of evidence for carcinogenicity are the small increase in the incidence of leukemias in (male and female) rats. On the basis of these observations, tetrachloroethylene was classified as possibly carcinogenic to humans.

Generally, for chemicals classified in this way, a tolerable daily intake (TDI) is derived by dividing a no-observe-adverse-effect-level (NO(A)EL) or a lowest-observed-(adverse)-effect-level (LO(A)EL) (for an effect with a threshold) by an uncertainty factor, which, when deemed appropriate, takes into account the limited evidence of carcinogenicity. A TDI was derived on the basis of results from the longest-term study of adequate design in which tetrachloroethylene was administered orally to laboratory animals. The TDI is derived as follows:

$$\text{TDI} = \frac{14 \text{ mg/kg bw per day}}{1000} = 0.014 \text{ mg/kg bw per day, where:}$$

- bw is body weight;
- 14 mg/kg bw per day is the NOEL in the longest-term adequate study in which tetrachloroethylene was administered in drinking water; the critical effects in this study were increased liver and kidney to body weight ratios in rats; and
- 1000 is the uncertainty factor (x10 for interspecies variation, x10 for intraspecies variation and x10 for use of a subchronic study, in the absence of adequate chronic [longer-term] studies). An additional factor for the

limited evidence of carcinogenicity has not been incorporated, as the evidence (leukemias in rats) is not related to the critical effect on which the TDI is based; moreover, the weight of evidence from a battery of other tests indicates that this tetrachloroethylene is not a direct acting carcinogen in humans.

The maximum acceptable concentration (MAC) in drinking water is derived from the TDI as follows:

$$\text{MAC} = \frac{0.014 \text{ mg/kg bw per day} \times 70 \text{ kg bw} \times 0.1 \times 0.5}{1.5 \text{ L/d}} = 0.03 \text{ mg/L},$$

where:

- 0.014 mg/kg bw per day is the TDI;
- 70 kg is the average body weight of an adult;
- 0.1 is the proportion of total tetrachloroethylene intake allocated to drinking water;
- 0.5 is an additional modifying factor applied to account for dermal absorption; and
- 1.5 L/d is the average daily consumption of drinking water for an adult.

The available data indicate that the intake of tetrachloroethylene through ingestion in drinking water normally contributes approximately 1% of total intake. However, an allocation factor based on average exposures was not considered to be meaningful for developing the guideline for tetrachloroethylene since this substance occurs sporadically in drinking water at concentrations at least one order of magnitude above the average as a consequence of gross pollution; in this case intake through drinking water is more likely to approach 10% of total intake. Moreover, such contamination is likely to persist for years.

## Microbiological Criteria

While a numerical guideline of standards can be derived for chemical parameters (as illustrated above), the same approach is currently not employed for the microbiological characteristics of drinking water. To date, the results of studies in human populations are not adequate for assessing the risk to health posed by any particular level of pathogens in water and hence for deriving numerical guidelines (or standards) for specific micro-organisms.

Risks from exposure to micro-organisms from drinking water depend not only on the infectivity and invasiveness of the pathogen but also on the inherent and acquired immunity of the individuals. It is generally assumed, therefore, that water in which pathogenic micro-organisms, however low the concentration, can be regarded as safe. Furthermore, only certain water-borne pathogens can be detected reliably and easily in water; some cannot be detected at all. Thus the approach that has generally been adopted is the monitoring of fecal coliforms as indicators of the presence of pathogens in drinking water. There is widespread agreement that the most specific and suitable bacteriological indicator of fecal pollution is *Escherichia coli*. Water that contains *E. coli* is regarded as contaminated and unsafe, thereby requiring immediate remedial action.

Protection of source water and proper design and operation of treatment and distribution system are critical in ensuring that pathogens are absent from drinking water. The quality of the source water should serve as a guide in selecting the required degree of treatment to remove any pathogens that may be present. A measure of the adequacy of the treatment processes in removing pathogens is provided by monitoring source water, treated water entering the distribution system and treated water at points in the distribution system for the presence of indicator species; these are normally *E. coli* or thermotolerant bacteria and total coliform bacteria. The need for any re-sampling and/or actions to rectify a situation is specified depending on whether, and/or at what levels, these indicator species are detected.

The selection and design of water-treatment processes and the proper operation of these processes to control fecal and pathogenic agents is seen as the only approach that can be used in the case of pathogens, such as *Giardia*, *Cryptosporidium*, and viruses that are more resistant than *E. coli* to terminal disinfection.

## **Appendix A5: Synopsis of the Elements of the Australian Draft Framework for Management of Drinking Water Quality**

### **A Preventive Strategy from Catchment to Consumer, January 2001**

This synopsis provides a brief description of each of the elements in the draft Framework for Management of Drinking Water Quality that has been developed by the Australian National Health and Medical Research Council and the Agriculture and Resource Management Council of Australia and New Zealand.

The draft framework is presently undergoing minor revisions by an NHMRC Working Party, prior to review by water industry stakeholders. It is anticipated that the framework will be released for public comment in March 2001. A public workshop on the framework will be held in conjunction with a WHO Drinking Water Guidelines meeting in Australia in May 2001. Completion of revisions to the *ADWG* and incorporation of the framework is expected to occur in late 2001.

### **Commitment to Drinking Water Quality Management**

#### **Water Quality Policy**

Development of a water quality policy is an important step in formalizing the level of service to which the water authority is committed and it provides the basis for which all subsequent actions can be judged. Employees must be assured that senior management is committed to achieving the policy, and mechanisms should be established to ensure that this policy is continually communicated and understood at all levels of the organization.

#### **Multi-agency Involvement**

Several aspects of drinking water quality management require commitment and involvement with other agencies such as health and environmental regulators, catchment management organizations, and other bodies that control or influence land use and planning requirements. As a lead agency in the

management of drinking water quality, a water authority should identify all key stakeholders and develop appropriate mechanisms for their commitment and involvement. Effective multi-agency involvement is of particular importance in the area of catchment management where few water authorities have direct control over activities that may impact on source water quality.

## **Requirements**

Drinking water quality requirements may be specified by regulatory authorities as mandatory criteria or negotiated as voluntary objectives. Water authorities may also set internal performance targets as a mechanism for driving and measuring improvement.

## **Assessment of the Drinking Water Supply System**

### **Water Supply System Analysis**

Effective system management involves, first and foremost, understanding the nature of the water supply system from source to consumer. An analysis should be performed to appropriately characterize each element of the water supply system with respect to drinking water quality and the factors that affect it. This characterization not only serves understanding of the water supply system, but also assists with identification of hazards and assessment of risks to water quality. It is important to recognize that the purpose of this step is to develop a broad overview and basic understanding of the water supply system. It is not intended that it be extremely time-intensive or a massive data collection exercise but rather the characterization of the system at an appropriate level of detail to provide a useful information base on which to make effective decisions.

### **Review of Drinking Water Quality Data**

A detailed review of retrospective drinking water quality data can provide a greater understanding of source water characteristics over time and following specific events (e.g., heavy rainfall). This investigation also assists the identification of hazards and the aspects of the drinking water system for which performance needs improvement.

## **Hazard Identification and Risk Assessment**

Events, scenarios and causes that might give rise to these health hazards and affect drinking water quality (what can happen and how) should be identified and documented for each water supply system component and their risk assessed so that appropriate strategies can be planned for their prevention. The information provided by the *Water Supply System Analysis and Review of Water Quality Data* should be incorporated into this analysis.

All potential hazards and hazardous events should be included regardless of whether or not they are under the direct control of the water supplier. Potential continuous, intermittent or seasonal pollution patterns should also be determined and in addition to normal seasonal conditions, extreme and infrequent events such as droughts or floods should be considered.

Once potential hazards and their causes have been identified, the level of risk associated for each hazard/scenario must be estimated so that priorities for risk management action can be established and documented. The level of risk for each hazard/scenario can be estimated by identifying the likelihood of occurrence (e.g., certain, probable, improbable) and evaluating the severity of consequences if the hazard occurred (e.g., insignificant, major, catastrophic). Rarely will enough knowledge be available to complete a meaningful, detailed quantitative risk assessment; thus, in most cases it is better to use fully understandable, qualitative or semi-quantitative approaches that are transparent and fully understood by involved parties.

The Assessment of the Drinking Water Supply System should be reviewed on a periodic basis to incorporate any changes that occur, for example in land use, treatment processes, consumer distribution, institutional and organizational arrangements, and to take account of new scientific knowledge.

## **Planning Preventive Strategies for Drinking Water Quality Management**

Preventive strategies are those actions and activities that are required to eliminate hazards or reduce their impact to acceptable levels. Preventive strategies should be comprehensive from catchment to the consumer and should be based on validated science and best practice management. In determining preventive

strategies, the level of preventive action planned to control a hazard should be proportional to the associated risk. Furthermore, some preventive measures cover a broad spectrum and may control more than one hazard.

## **Multiple Barriers**

Application of multiple barriers is universally recognized as a fundamental tenet for effective drinking water quality management and for ensuring the supply of safe drinking water. The multiple barrier approach involves the use of a series of barriers from catchment to consumer to prevent contaminants from entering the water supply system, and where they occur, control their transmission through the system. Barriers should be effective and capable at all times; however, the basic principle is that if multiple barriers are provided, any contaminant passing through one process can be removed in the next thereby minimizing the likelihood of contaminants passing through the entire treatment system and being present in sufficient amounts to cause harm to consumers.

## **Critical Control Points**

A Critical Control Point (CCP) is defined as a point, step or procedure at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level (Codex). In determining whether a step or process should be considered a CCP, a practical explanation is whether loss of control at that point will result in a high probability of an unacceptable health risk.

Ideally for critical control points:

- operating criteria are specific, quantifiable and provide a yes/no response;
- operating criteria are validated by research and technical literature;
- the technology for controlling the CCP is readily available at reasonable cost;
- monitoring of criteria is continuous and real time and the operation can automatically be adjusted to maintain control;
- there is a favourable history of control; and
- the potential hazard is prevented or eliminated.

It is recognized, however, that ideal CCPs are often not achievable and clearly defined criteria may not be available and may be based upon judgement and operational experience. Also, in many cases it may not be possible to prevent a hazard but rather minimize it to an acceptable level.

Key components of water supply systems that may serve as CCPs include:

- selective use of water sources
- selective withdrawal tower/reservoir draw-off
- coagulation, flocculation and/or sedimentation
- filtration
- disinfection

CCPs will be different for each water supply system depending on the levels of barriers and the treatment processes used. For each CCP, critical limits must be defined which ensure the CCP is under control. A critical limit is defined as a prescribed tolerance that must be met to ensure that a CCP effectively controls a potential health hazard. When critical limits have been exceeded, a potential health hazard may exist or could develop and should automatically result in a corrective action being instituted to resume control of the process.

## **Implementation – Operational Procedures and Process Control**

To consistently achieve a high quality water supply it is essential to have the proper controls over the processes and activities that govern drinking water quality and safety, particularly for those activities that have been defined as critical control points. It is imperative that operations are optimized and controlled on a continuous basis as even short periods of sub-optimal performance are now well documented as being of particular risk to public health. Therefore, continuous performance and ensuring that barriers are capable at all times are a critical requirement for the provision of a safe drinking water supply.

### **Operational Procedures**

Operating procedures formalize the activities that are essential to ensure consistent drinking water quality. These procedures need to be properly defined, documented and implemented and their effectiveness verified. Operating



procedures are particularly important for those activities established as Critical Control Points. For these activities, processes should be validated and every aspect of operation should have detailed operating procedures provided. Furthermore, these processes should be carried out by qualified operators and require continuous monitoring of operational parameters.

Appropriate training and adherence to documented operating procedures are also important considerations in maintaining controlled operations. Procedures are most effective when operations staff are involved in their development, documentation and verification. This participation will help ensure that all relevant activities are included, and will enhance operator training and awareness in addition to creating commitment to operational and process control.

### **Equipment Capability**

The capability of existing equipment is a fundamental aspect to achieving the level of performance required. This is particularly relevant to the operation of water treatment plants, and should include the aspects of design, operation within design limits, maintenance, monitoring and alarm systems to indicate malfunction. Treatment plant equipment must also be capable of providing process flexibility and controllability, and backup equipment should be available for critical processes in case of equipment failure. For CCPs in particular, it is desirable that monitoring is on-line and continuous, and alarms be provided to indicate when operational limits have been exceeded. Control of monitoring equipment, including regular calibration and maintenance, must be performed to ensure that data collected is representative and accurate. Design of new equipment and processes should undergo validation through appropriate research and development.

### **Materials and Chemicals**

Given that the materials and chemicals used in water treatment have the potential to affect drinking water quality, the choice and use of water treatment chemicals and the materials that come into contact with water are important process control considerations. Only approved chemicals and materials should be used in water treatment. The products used in drinking water treatment and supply should be subjected to a system of continuous quality control.

Chemical suppliers should be evaluated and selected based on their ability to supply product in accordance with required specifications. Documented procedures for control of chemicals including the purchasing, verification, handling, storage and maintenance of chemicals should be established to assure quality at the point of application.

### **Operational Monitoring**

Operational monitoring includes the planned sequence of measurements and observations to assess and verify the performance of preventive strategies. Effective operational monitoring is critical for confirming that the barriers for controlling hazards from catchment to consumer are functioning properly and effectively. Data from operational monitoring are used as triggers for immediate short-term corrective actions to operational processes to improve drinking water quality. They are not used for assessing compliance with standards/guidelines or agreed levels of service.

An operational monitoring plan should be developed and documented to monitor control of CCPs and other preventive strategies from catchment to consumer by scheduled measurement or observation. The use and maintenance of suitable monitoring equipment are important aspects to providing accurate process control information. Monitoring equipment must be maintained and be accurate. Procedures and records for calibration and maintenance of equipment should be established and documented. Additionally, failure of monitoring equipment should not compromise the system. Particularly at CCPs, a system should be in place to detect failure and provide backup of monitoring equipment.

### **Operational Preventive and Corrective Action**

Preventive and corrective action includes planning of appropriate procedures in advance for immediate corrective action to re-establish process control when operational monitoring indicates that target levels and critical limits have not been met for a particular operational activity or CCP. These operating procedures should be documented and include instructions on required adjustments and process control changes, and should clearly define responsibilities and authorities.

Prior to implementation of a corrective action when operational monitoring indicates that critical limits have been exceeded, the first action should always be to investigate by re-sampling, additional monitoring and/or checking other operational monitoring. Then, where appropriate, a corrective action should be implemented to re-establish process control and then verified to ensure its effectiveness. The effect of the corrective action and what adjustments or action may be needed further along in the supply system should also be considered as well as the planning and preparation of incident and emergency response procedures if corrective actions cannot rectify operational performance.

Where possible, the underlying cause of the problem should be identified and measures should be planned to prevent future occurrences. An analysis of the causes may define some solutions such as modifying an operating procedure, treatment plant adjustments, training etc. Finally, records and reporting (internal and external) of the occurrence is necessary and protocols should be developed.

## **Verification of Drinking Water Quality**

### **Drinking Water Quality Monitoring**

Drinking Water Quality Monitoring (or compliance monitoring) comprises the regular testing performed for assessing compliance with guideline levels, regulatory criteria and/or agreed levels of service. Monitoring of drinking water quality constitutes the final check that the barriers and preventive strategies implemented are working effectively and compliance must be demonstrated to provide regulators and consumers with confidence about the safety of the water.

Compliance monitoring differs from operational monitoring not only in purpose but also in terms of the water quality characteristics to be measured, sampling locations, frequency of sampling, etc. As it is neither physically nor economically feasible to test on an ongoing basis for all drinking water quality parameters, monitoring is generally performed for a select range of microbiological, chemical and aesthetic parameters.

## **Consumer Satisfaction**

Consumer satisfaction with drinking water is largely based on a judgement that the aesthetic quality of tap water is “good” which usually means that it is colourless and free from unpleasant taste and odour. From the consumer’s point of view, changes from the norm are particularly noticeable. Monitoring of consumer comments and complaints can provide valuable information on potential problems that may have gone unidentified in performance monitoring of the water supply system. A consumer complaint and response program which detail mechanisms for logging, recording and evaluating consumer complaints should be established and documented to promptly respond to any potential problems in the water supply system.

## **Short-term Evaluation of Results**

Drinking water quality performance evaluation entails the daily reviewing of compliance monitoring to assess the day-to-day management of the drinking supply. It is an important element for verifying that the quality of water supplied to consumers is in compliance with relevant requirements. When monitoring results become available, they should be reviewed and compared with previous results and drinking water quality objectives. Procedures for performance evaluation and how results should be recorded and interpreted should be established and documented including responsibilities and reporting mechanisms.

## **Corrective Action**

If the review of drinking water quality performance indicates that compliance requirements have been violated, an investigation should be initiated and, if necessary, a corrective action implemented. If the corrective action cannot remediate the problem, then incident and emergency response protocols should be followed. Implementation of corrective action could also be required in response to consumer feedback.

## **Incident and Emergency Response**

Considered and controlled responses to incidents or emergencies that can compromise water quality are imperative for protecting public health, as well as maintaining customer confidence and company reputation. While preventive strategies including backup equipment and facilities are intended to prevent incidents and emergency situations from occurring, some events cannot be anticipated or controlled, or have such a low probability that providing backup would be too costly. Water suppliers should regard incident and emergency response as a priority and commit the necessary resources to developing emergency response plans. Actions and protocols should be developed in consultation with relevant regulatory agencies and other stakeholders, and should be regularly reviewed and updated. Plans should be consistent with existing government emergency response arrangements.

### **Communication**

Effective communication is critical to managing incidents and emergencies. Clearly defined protocols for both internal and external communications should be established in advance with involvement of relevant agencies including health and regulatory agencies. These protocols should include a contact list of key people, agencies and businesses, detailed notification forms and procedures for internal and external notification, and a reporting and decision making structure both within and outside the organization (definition of responsibilities and authorities).

Maintaining customer confidence and trust during and after an incident or emergency is essential and this can largely be affected by how a water supplier responds to such events. Public and media communications should be given careful consideration in advance of any incident or emergency situation occurring. Draft public and media notification for different scenarios should be prepared in advance. An appropriately trained media liaison contact should be designated to handle all communications in the event of an incident or emergency. Regular updates on investigations and actions during incidents should be issued to staff, other agencies, the media and the public.

## **Incident and Emergency Response Protocols**

Potential emergency scenarios should be identified and incident and emergency responses, including communication and notification procedures, should be planned and documented. This preparation in advance of any incident or emergency is essential for the efficient, effective and rapid response to an emergency situation and will minimize the impacts on the community.

The development of an appropriate incident and emergency response plan involves a review of the hazards and events that can lead to emergency situations. These include events such as:

- non-compliance with regulatory criteria;
- accidents which increase levels of contaminants (e.g., spills in catchment, incorrect dosing of water treatment chemicals);
- equipment breakdown and mechanical failure, prolonged power outages;
- extreme weather events and natural disasters; and
- human actions (e.g., sabotage, acts of war).

Training in emergency response, including simulated incidents, is important to ensure that plans are appropriate and employees have the skills and knowledge to effectively apply them. After any incident, a review of events and a debriefing with all involved staff should be conducted to discuss performance and address any issues or concerns.

## **Employee Awareness and Training**

### **Employee Awareness and Involvement**

Increasing awareness and understanding of drinking water quality management are essential elements in empowering and motivating employees to make effective decisions. All employees should be aware of the organization's drinking water quality policy, the characteristics of the water supply system, what preventive strategies are in place throughout the system, regulatory and legislative requirements, roles and responsibilities of employees and departments, and how their actions can impact on public health.

Employee participation and involvement in decision making is also an important feature for establishing the commitment necessary for continuous improvement of drinking water quality management. Employees should be encouraged to participate in decisions that affect their jobs and areas of responsibility. Allowing employees to participate in decision-making gives employees the motivation and a sense of ownership for decisions made and their implications. Open and positive communications with employees is key to creating this participatory culture and employees should be encouraged to communicate with management to discuss issues and initiate actions.

## **Employee Training**

Employees should have a sound knowledge base to make effective operational decisions. This includes the training in the methods and skills required to perform their tasks in an efficient and competent manner as well as the knowledge and understanding of the impact their activities can have on public health. Particularly with respect to operational procedures and the activities and processes that are critical in controlling significant hazards (i.e., CCPs), operations personnel must understand water treatment concepts and have the confidence to apply these concepts and adjust plant operations appropriately to respond to periods of poor raw water quality.

Water suppliers should also ensure contractors employed to work in the water supply system are qualified and have undergone appropriate training related directly to their task or role. Contractors must also be aware of and comply with the organization's policy and operational protocols.

## **Community Involvement and Awareness**

### **Community Consultation**

Decisions on drinking water quality made by a water authority and the relevant regulatory authorities must be aligned with the needs and expectations of its consumers. Therefore, community involvement, including appropriate industry sectors, should be sought during decision making processes including those relating to levels of service to be provided, costs, changes in water treatment or infrastructure.

## **Communication**

Management of public communications is an essential element of an effective quality management system. Active, two-way communication with consumers should be established to ensure that their needs and expectations are understood and are being satisfied.

Information on drinking water quality, including how it may be affected in household distribution, should be readily accessible to consumers. A water authority should establish procedures for disseminating information to promote awareness of drinking water quality issues.

## **Research and Development**

Research and development are directed toward the innovation, introduction and improvement of product and processes. Participation in research and development activities through industry-wide co-operation is essential to ensure that new technologies and improved methods are developed to enhance drinking water quality and treatment. Ongoing research at a local level is also beneficial in that it increases understanding of the specific characteristics of individual water supply systems and supports continuous improvement of drinking water quality and processes.

## **Investigative Studies and Research Monitoring**

Strategic investigative studies and research monitoring includes the broader monitoring (e.g., baseline monitoring and event-based monitoring) designed to identify hazards, develop effective controls and improve performance.

## **Validation of Processes and Critical Limits**

Water treatment processes should be experimentally validated to ensure that actual performance under local conditions, water types etc is satisfactory, and that processes and chemical doses are optimized. Critical limits for CCPs should also be verified to ensure they have been set at appropriate levels to provide adequate warning and allow regaining of process control in a satisfactory time frame.



## **Validation of Equipment**

Equipment used in water treatment and process monitoring and control should be validated to ensure that the design performance and required level of accuracy is achieved.

## **Documentation and Reporting**

### **Documentation and Records Management**

The existence of documentation supports the establishment of drinking water quality management systems, serves as a reference for the implementation of the system, enables evaluation and provides a means for effective communication with the public and various stakeholders. Documentation should be established for all aspects of a water authority's management system including the specific plans and operating procedures for effective implementation. Records of all results from operational and compliance monitoring should be effectively managed to allow ease of access and review. Procedures for information collection, management and internal reporting should be established and documented.

### **Reporting**

Drinking water quality management should be open and transparent. External reporting should be established in consultation with relevant regulatory authorities and consumers. Annual reports which summarize drinking water quality performance over the preceding year against standards/guidelines or agreed levels of service should be produced and be publicly available. A water authority should also provide the relevant regulatory authorities with regular reports summarizing performance and water quality data, and event reports covering specific incidents or failures.

Internal reporting procedures should also be established and results regularly reported to senior management. A water authority should establish procedures for monthly or quarterly internal operational reporting, including summaries of monitoring data, performance assessment and significant operational problems for the period.

## **Evaluation and Audit**

### **Long-term Evaluation of Results**

An evaluation of drinking water quality performance (long term) by water authorities is an important element in verifying that control measures are being implemented appropriately and are functioning effectively.

### **Drinking Water Quality Management Audit**

Auditing is required to confirm the performance of a water authority with respect to the implementation of its drinking water quality management system. All aspects of the management system, including the suitability of the drinking water quality policy with respect to changing customer expectations and regulatory requirements, should be regularly evaluated by senior staff.

Water authorities may also seek to establish and formalize external auditing procedures for their drinking water quality management systems. In addition to demonstrating the commitment of a water authority to the highest standards possible, external auditing by independent agencies may provide increased credibility and customer confidence.

## **Review and Continual Improvement**

Management support and commitment to improve the performance of an authority's activities relating to water quality are vital. A review of the approaches used to manage drinking water quality with the objective of improving the operational processes and overall drinking water quality performance should be conducted on a regular basis.

### **Management Review**

The outcome of water quality performance evaluation and audits should be reviewed annually by senior management.

**Drinking Water Quality Improvement Plan**

An Improvement Plan should be formulated to address the long-term resolution of any existing or potential drinking water quality problems.

Appendix A6: Comparison of Various Management Systems and Programs

Table A6.1 Outline of the Requirements for Various Management Systems and Programs

| ISO 9001 | PURPOSE   | PRE-REQUIREMENTS | REQUIREMENTS   |
|----------|---|------------------|--|
|          | <ul style="list-style-type: none"><li>• a model for quality assurance for use when conformance to specified requirements is to be assured</li><li>• achieving customer satisfaction by preventing nonconformity at all stages</li></ul> |                  | <p><i>Management Responsibility:</i></p> <ul style="list-style-type: none"><li>• quality policy</li><li>• organization (responsibility, authority, resources, management representative)</li><li>• management review</li></ul> <p><i>Quality System:</i></p> <ul style="list-style-type: none"><li>• quality manual</li><li>• quality system procedures, manual</li><li>• quality planning</li></ul> <p><i>Contract Review:</i></p> <ul style="list-style-type: none"><li>• review</li><li>• amendments</li><li>• records</li></ul> <p><i>Design Control:</i></p> <ul style="list-style-type: none"><li>• research and development</li><li>• planning</li><li>• design considerations</li></ul> <p><i>Document and Data Control:</i></p> <ul style="list-style-type: none"><li>• document control procedure</li></ul> <p><i>Purchasing:</i></p> <ul style="list-style-type: none"><li>• evaluation of subcontractors</li><li>• purchasing data</li><li>• verification of purchased products</li></ul> <p><i>Control of Customer-Supplied Product:</i></p> <ul style="list-style-type: none"><li>• Product identification &amp; traceability</li></ul> <p><i>Process Control:</i></p> <ul style="list-style-type: none"><li>• identify and plan process control procedures</li><li>• document</li><li>• special processes</li></ul> <p><i>Inspection and Testing:</i></p> <ul style="list-style-type: none"><li>• document procedures for inspection and testing (receiving, in-process, final)</li><li>• document records</li><li>• appropriate sampling plan, suitable equipment, approved sampling and test methods, qualified personnel</li></ul> |
|          |   |                  | <p><i>Control of Inspection, Measuring, and Test Equipment:</i></p> <ul style="list-style-type: none"><li>• control procedure (identify all equipment, calibrate equipment)</li></ul> <p><i>Inspection and Test Status:</i></p> <ul style="list-style-type: none"><li>• indicators for stages of operation</li></ul> <p><i>Control of Non-conforming Product:</i></p> <ul style="list-style-type: none"><li>• procedures for non-conforming product</li><li>• notification, action</li><li>• responsibility and authority</li><li>• document, record</li></ul> <p><i>Corrective and Preventive Action:</i></p> <ul style="list-style-type: none"><li>• corrective action</li><li>• preventive action</li></ul> <p><i>Handling, Storage, Packaging and Delivery:</i></p> <ul style="list-style-type: none"><li>• documented procedures</li></ul> <p><i>Control of Quality Records:</i></p> <ul style="list-style-type: none"><li>• organized and systematic approach to the maintenance of records/results</li><li>• computer-based records</li></ul> <p>Internal Quality Audits</p> <p><i>Training:</i></p> <ul style="list-style-type: none"><li>• identify training needs</li><li>• provide, document</li></ul> <p><i>Servicing:</i></p> <ul style="list-style-type: none"><li>• provision of technical information, product literature</li><li>• complaint handling</li></ul> <p><i>Statistical Techniques:</i></p> <ul style="list-style-type: none"><li>• identify the need for statistical techniques (e.g., sampling rates, plans, acceptance criteria, etc.)</li></ul>   |

Table A6.1 Outline of the Requirements for Various Management Systems and Programs, cont'd.

|                      |  |                  |   |  |
|----------------------|--|------------------|---|--|
| ISO 14001            | <p>PURPOSE</p> <ul style="list-style-type: none"><li>• a model for an environmental management system to minimize the impacts of business operations to the environment and foster environmental sustainability</li></ul>  | PRE-REQUIREMENTS | <p>REQUIREMENTS</p> <p><i>Commitment and Policy:</i></p> <ul style="list-style-type: none"><li>• top management and leadership</li><li>• initial environmental review</li><li>• environmental policy</li></ul> <p><i>Planning:</i></p> <ul style="list-style-type: none"><li>• identification and evaluation of environmental impacts (risk assessment)</li><li>• legal and other requirements</li><li>• internal performance criteria</li><li>• environmental objectives and targets</li><li>• environmental management programs</li></ul> <p><i>Implementation:</i></p> <p><i>Ensuring the capability and supporting actions such as:</i></p> <ul style="list-style-type: none"><li>• resources</li><li>• accountability and responsibility</li><li>• environmental awareness and motivation</li></ul>  | <p><i>Implementation: (cont.)</i></p> <ul style="list-style-type: none"><li>• knowledge, skills, and training</li><li>• communication and reporting</li><li>• EMS documentation</li><li>• operational procedures and controls</li><li>• emergency preparedness and response</li></ul> <p><i>Measurement and Evaluation:</i></p> <ul style="list-style-type: none"><li>• measurement and monitoring</li><li>• reliability of data (calibration)</li><li>• corrective and preventive action (longer term)</li><li>• EMS records and information management</li><li>• audits of EMS system</li></ul> <p><i>Review and Improvement:</i></p> <ul style="list-style-type: none"><li>• review of EMS</li><li>• continual evaluation and improvement</li></ul> |
| WSAA EMG (Australia) | <p>PURPOSE</p> <ul style="list-style-type: none"><li>• guidelines for the water industry on how to implement an environmental management system to minimize the impacts to the environment from their operations</li></ul> |                  | <p>REQUIREMENTS</p> <p><i>Assessment:</i></p> <ul style="list-style-type: none"><li>• environmental impacts and their significance (risk assessment)</li><li>• regulatory and other requirements</li></ul> <p><i>Environmental Policy:</i></p> <p><i>Plan:</i></p> <ul style="list-style-type: none"><li>• environmental management program (including objectives, targets, responsibilities, roles, resources, reporting requirements, timeliness)</li><li>• improvement plans (to mitigate impacts and achieve environmental policy)</li><li>• environmental impact assessment (new developments)</li><li>• emergency preparedness and response</li></ul> <p><i>Implement Policy and Plans:</i></p> <p><i>Enabling Tools:</i></p> <ul style="list-style-type: none"><li>• organizational structure and integration (responsibilities and roles, communication)</li><li>• employee awareness, involvement and training</li><li>• community involvement/consultation</li><li>• research and development activities</li><li>• monitoring</li></ul> <p><i>Evaluate and Review:</i></p> <ul style="list-style-type: none"><li>• environmental performance evaluation</li><li>• management review (improvement)</li></ul> <p><i>Documentation, Records and Reporting:</i></p> <ul style="list-style-type: none"><li>• annual environmental performance report</li></ul> |  |

Table A6.1 Outline of the Requirements for Various Management Systems and Programs, cont'd.

|                |  |   |   |   |
|----------------|--|---|---|---|
| <b>HACCP</b>   | <p><b>PURPOSE</b></p> <ul style="list-style-type: none"><li>• a systematic approach to identify specific hazards and preventive measures for their control (food industry)</li></ul>   | <p><b>PRE-REQUIREMENTS</b></p> <ul style="list-style-type: none"><li>• HACCP team</li><li>• product and distribution description</li><li>• intended use and customer identification</li><li>• flow diagram construction</li><li>• flow diagram verification</li></ul>   | <p><b>REQUIREMENTS</b></p> <p><i>Hazard Analysis:</i></p> <ul style="list-style-type: none"><li>• scope</li><li>• hazard identification</li><li>• hazard analysis (risk/severity)</li><li>• preventive measures</li></ul> <p><i>Critical Control Points (CCPs):</i></p> <ul style="list-style-type: none"><li>• CCP decision tree tool</li></ul> <p><i>Critical Limits for Preventive Measures:</i></p> <ul style="list-style-type: none"><li>• for each CCP</li></ul> <p><i>CCP Monitoring Requirements:</i></p> <ul style="list-style-type: none"><li>• planned procedures (what, when, where, how, who)</li><li>• training</li><li>• sampling plans (statistics, etc.)</li><li>• calibration and equipment reliability</li></ul> <p><i>Corrective Action:</i></p> <ul style="list-style-type: none"><li>• actions – immediate, long term</li></ul> | <p><i>Corrective Action: (cont.)</i></p> <ul style="list-style-type: none"><li>• responsibilities</li><li>• training</li><li>• documentation</li></ul> <p><i>Verification Procedures:</i></p> <ul style="list-style-type: none"><li>• supplementary tests</li><li>• industry verification (CI, HACCP plan, re-validation)</li><li>• regulatory verification</li></ul> <p><i>Record-keeping Procedures:</i></p> <ul style="list-style-type: none"><li>• system of record-keeping</li><li>• recording of types (development, plans procedures, records)</li></ul> <p><i>Other:</i></p> <ul style="list-style-type: none"><li>• standard operating procedures</li><li>• training</li><li>• crisis management</li></ul> |
| <b>RM 4360</b> | <p><b>PURPOSE</b></p> <ul style="list-style-type: none"><li>• a generic framework for the establishment and implementation of the risk management process involving the identification, analysis, assessment, treatment, and on-going monitoring of risk</li></ul> | <p><b>PRE-REQUIREMENTS</b></p> <ul style="list-style-type: none"><li>• <i>Risk Management Policy</i></li></ul> <p><i>Organization:</i></p> <ul style="list-style-type: none"><li>• management representative</li><li>• responsibility and authority</li><li>• resources</li></ul> <p><i>Management Review:</i></p> <p><i>Implementation Program</i></p> | <p><b>REQUIREMENTS</b></p> <p><i>Establish the context:</i></p> <ul style="list-style-type: none"><li>• strategic, organizational, and risk management context</li><li>• develop risk assessment criteria</li><li>• define structure of analysis (separating activity into elements)</li></ul> <p><i>Risk Identification:</i></p> <ul style="list-style-type: none"><li>• what can happen</li><li>• how can it happen</li></ul> <p><i>Risk Analysis:</i></p> <ul style="list-style-type: none"><li>• establishment of level of risk</li><li>• determination of existing controls</li><li>• determination of likelihood, consequences</li></ul> <p><i>Risk Assessment:</i></p> <ul style="list-style-type: none"><li>• risk/criteria assessment</li><li>• risk prioritization</li></ul>  | <p><i>Risk Treatment:</i></p> <ul style="list-style-type: none"><li>• identification of and evaluation of options for treatment</li><li>• development of treatment plans</li><li>• implementation of plans</li></ul> <p><i>Monitoring and Review:</i></p> <ul style="list-style-type: none"><li>• monitoring of risks and effectiveness of risk treatment plan</li><li>• ongoing review</li></ul> <p><i>Documentation:</i></p> <ul style="list-style-type: none"><li>• documentation of each stage of risk management process (including assumptions, methods, data sources, and results)</li></ul>   |

Table A6.1 Outline of the Requirements for Various Management Systems and Programs, cont'd.

| Partnership for Safe Water | PURPOSE   | PRE-REQUIREMENTS | REQUIREMENTS  |   |
|----------------------------|---|------------------|---|---|
|                            | <ul style="list-style-type: none"><li>a program for water utilities to identify those factors that are limiting performance and to voluntarily implement improvement activities (primary focus on water treatment plant operations)</li></ul> |                  | <p><b>Commitment:</b></p> <ul style="list-style-type: none"><li>program requirements</li><li>eligibility</li></ul> <p><b>Data Collection:</b></p> <ul style="list-style-type: none"><li>performance data and plant information</li></ul> <p><b>Self-Assessment and Correction:</b></p> <ul style="list-style-type: none"><li>identification and correction of performance-limiting factors</li><li>performance assessment</li></ul> | <p><b>Self-Assessment and Correction:</b> (cont.)</p> <ul style="list-style-type: none"><li>major unit process evaluation</li><li>design</li><li>operation</li><li>administration (policies, staffing, funding)</li><li>implement performance improvement activities</li><li>assess performance improvements</li></ul> <p><b>Composite Correction Program:</b></p> <ul style="list-style-type: none"><li>third party assessment</li></ul> |

Table A6.2 Comparison of Management Systems and Programs

| Framework for Management of Drinking Water Quality                       | ADWG | ISO 9001* | ISO 14001 | WSAA EMG | HACCP | RM 4360 | Partnership for Safe Water |
|--|------|-----------|-----------|----------|-------|---------|----------------------------|
| 1 Commitment to Drinking Water Quality Management                        | +    | +++       | +++       | +++      | +     | +++     | +++                        |
| Drinking Water Quality Policy  |      | +++       | +++       | +++      |       | +++     | +                          |
| Requirements   | ++   | +         | +++       | +++      | +++   |         | +                          |
| Partnership Agencies   |      |           |           |          |       |         |                            |
| 2 Assessment of the Drinking Water Supply System                         | ++   |           | ++        | +++      | +++   | +       | +++                        |
| Water Supply System Analysis   | +++  |           | ++        | +++      | +++   |         | +                          |
| Review of Drinking Water Quality Data                                    | +++  |           |           | ++       |       |         | +++                        |
| Hazard Identification and Risk Assessment                                | ++   |           | ++        | +++      | +++   | +++     | +                          |
| 3 Planning – Preventive Strategies for Drinking Water Quality Management | +    | +++       | +++       | +++      | +++   | +++     | +++                        |
| Multiple Barriers  | +++  |           |           |          |       |         | +++                        |
| Critical Control Points  |      |           |           |          | +++   |         |                            |
| 4 Implementation – Operational Procedures and Process Control            | ++   | +++       | +++       | +        | +++   | +       | +++                        |
| Operational Procedures   | +    | ++        | ++        | +        | +++   |         | ++                         |
| Equipment Capability   |      | ++        |           |          | ++    |         | +++                        |

\* ISO 9001:1994

- +++ Aspect explicitly stated and covered.
- ++ Aspect mentioned but not covered in detail.
- +
- Aspect not explicitly stated but could be interpreted as being included.



Table A6.2 Comparison of Management Systems and Programs, cont'd.

| Framework for Management of Drinking Water Quality | ADWG | ISO 9001* | ISO 14001 | WSAA EMG | HACCP | RM 4360 | Partnership for Safe Water |
|--|------|-----------|-----------|----------|-------|---------|----------------------------|
| Materials and Chemicals                            | ++   | ++        |           |          | ++    |         | ++                         |
| Operational Monitoring                             | +++  | ++        | +++       | +++      | +++   | +       | +++                        |
| Operational Preventive and Corrective Action       | ++   | +++       | +++       |          | +++   |         | +++                        |
| 5 Verification of Drinking Water Quality           | +++  | +++       | +++       | +++      | +++   | +++     |                            |
| Drinking Water Quality Monitoring                  | +++  | +++       | +++       | +++      | +++   | +++     |                            |
| Consumer Satisfaction                              | +++  | +         | +         |          | +     |         |                            |
| Short-term Evaluation of Results                   |      | +         | +         | +        | ++    | ++      |                            |
| Corrective Action                                  |      | +         | +         | +        | ++    | ++      |                            |
| 6 Incident and Emergency Response                  | ++   | +         | +++       | +++      | +     |         |                            |
| Communication                                      | +    |           | +++       | +++      |       |         |                            |
| Incident and Emergency Response Protocols          | ++   | +         | +++       | +++      | +     |         |                            |
| 7 Employee Awareness and Training                  | ++   | +++       | +++       | +++      |       |         | +++                        |
| Employee Awareness and Involvement                 |      |           | +++       | +++      |       |         | +++                        |
| Employee Training                                  | ++   | +++       | +++       | +++      |       |         | +++                        |
| 8 Community Involvement and Awareness              | +++  | +         | +         | +++      |       | +       |                            |

\* ISO 9001:1994

- +++ Aspect explicitly stated and covered.
- ++ Aspect mentioned but not covered in detail.
- +
- Aspect not explicitly stated but could be interpreted as being included.

Table A6.2 Comparison of Management Systems and Programs, cont'd.

| Framework for Management of Drinking Water Quality | ADWG | ISO 9001*ss | ISO 14001 | WSAA EMG | HACCP | RM 4360 | Partnership for Safe Water |
|--|------|-------------|-----------|----------|-------|---------|----------------------------|
| Communication                                      | +++  | +           | +++       | +++      |       | +++     |                            |
| 9 Research and Development                         | +    | +           |           | +++      |       |         | +++                        |
| Investigative Studies and Research Monitoring      | +++  |             |           |          |       |         | +++                        |
| Validation of Processes and Critical Limits        |      | +++         |           |          | +++   |         | +                          |
| Validation of Equipment                            |      | +++         |           |          | +++   |         | +++                        |
| 10 Documentation and Reporting                     | +++  | +++         | +++       | +++      | +++   | +++     | +                          |
| Documentation and Records Management               | +    | +++         | +++       | +++      | +++   | +++     | +                          |
| Reporting  | +++  | +           | ++        | ++       | +     | +++     | +                          |
| 11 Evaluation and Audit                            | +++  | +++         | +++       | +++      | +++   | +++     | +++                        |
| Long-term Evaluation of Results                    | +++  | +           | +         | +++      | +     | +       | +++                        |
| Drinking Water Quality Management Audit            | ++   | +++         | +++       | +++      | +++   | +++     | +++                        |
| 12 Review and Continual Improvement                | ++   | +++         | +++       | +++      |       | +++     | +++                        |
| Management Review                                  | ++   | +++         | +++       | +++      |       | +       |                            |
| Drinking Water Quality Improvement Plan            |      |             |           | +++      |       |         |                            |

\* ISO 9001:1994

- +++ Aspect explicitly stated and covered.
- ++ Aspect mentioned but not covered in detail.
- +
- Aspect not explicitly stated but could be interpreted as being included.

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