Canadian Drinking Water Guidelines
Development Process

prepared by the
Federal-Provincial Subcommittee
on Drinking Water
# Table of Contents

1. Introduction .................. 3

2. Identification ................... 4

3. Assessment ...................... 4
   a) Field Monitoring Data ........... 4
   b) Criteria Summary Preparation ....... 5
   c) Criteria Summary Review .......... 5

4. Evaluation ...................... 6
   a) Cost-Benefit Analysis .......... 6
   b) Consultation ................... 6

5. Decision-Making and Approval ....... 6

6. Announcement and Publication ...... 7

7. Re-evaluation ................... 7

8. Communication .................. 7

Annex 1: Operating Rules for the Subcommittee on Drinking Water ........ 8
   Terms of Reference ................ 8
   Membership ........................ 8
   Financial Responsibilities ........... 8
   Secretariat Responsibilities ........... 8
   DWS Chairperson’s (Vice-Chairperson’s) Responsibilities ........... 9
   DWS Members’ Responsibilities ........... 9
   Liaison Members’ Responsibilities ........... 9

   Introduction ....................... 10
   Microbiological Parameters .......... 10
   Chemical/Physical Parameters .......... 12
   Radiological Parameters .............. 14
   Appendix A: Criteria for Classification of Carcinogenicity .......... 16
   Appendix B: Definitions .............. 17

An 1: Operating Rules for the Subcommittee on Drinking Water
   Terms of Reference
   Membership
   Financial Responsibilities
   Secretariat Responsibilities
   DWS Chairperson’s (Vice-Chairperson’s) Responsibilities
   DWS Members’ Responsibilities
   Liaison Members’ Responsibilities

Annex 2: Approach to the Derivation of Drinking Water Guidelines
   Introduction
   Microbiological Parameters
   Chemical/Physical Parameters
   Radiological Parameters
   Appendix A: Criteria for Classification of Carcinogenicity
   Appendix B: Definitions
1. Introduction

The Guidelines for Canadian Drinking Water Quality, published by Health Canada, provide a comprehensive set of drinking water quality guidelines that are scientifically defensible. The Guidelines address microbiological, chemical, physical and radiological parameters relevant to drinking water quality issues in Canada.

In 1983, a working group under the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH) began updating the 1978 edition of the Guidelines for Canadian Drinking Water Quality. In 1986, this working group was changed to a standing subcommittee, the Federal-Provincial Subcommittee on Drinking Water (DWS) (see Annex 1 for Operating Rules). Since then, DWS has been developing new, and revising existing, drinking water guidelines. Members of DWS include representatives of federal and provincial departments of health and environment. The Secretariat for DWS is provided by Health Canada – specifically, the Drinking Water Section of the Safe Environments Directorate (Healthy Environments and Consumer Safety Branch).

In May 1993, CEOH directed DWS to document the process it uses to develop these guidelines – specifically, the steps of identification, assessment, evaluation, decision-making and approval, announcement and publication and re-evaluation (see Figure 1) – while stressing the importance of communication among DWS, CEOH and the public at all stages of the process.

Throughout the entire guideline development process, DWS uses the criteria outlined in the publication, “Strategies for Population Health – Investing in the Health of Canadians” (prepared by the Federal, Provincial and Territorial Advisory Committee on Population Health for the Meeting of the Ministers of Health, September 14-15, 1994). These criteria cover the issues of national significance, impact, common directions, capacity, return on investment and flexibility.

The following sections contain a brief description of the steps involved in developing a Canadian drinking water guideline using a hypothetical Substance X for illustrative purposes. It must be stressed that the development of Canadian drinking water guidelines relies on a flexible process that must accommodate the diverse needs of various jurisdictions. Certain of the steps described below may be modified or circumvented in order to address the needs of the jurisdictions involved.

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1. The term “provinces” (“provincial”) as used throughout this document should be taken to include “territories” (“territorial”).

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![Figure 1: Canadian Drinking Water Guidelines Development Process](image-url)
2. Identification

In order to be considered for guideline development, the following questions regarding Substance X must be asked:

- Could exposure to the substance lead to adverse health effects?
- Is it frequently detected or could it be expected to be found in a large number of Canadian drinking water supplies?
- Is the level at which it is detected, or could be expected to be detected, of possible health significance?

If the answer to these questions is yes, Substance X would receive further consideration for guideline development. It should be noted, however, that the focus of DWS is on parameters of national significance (i.e., substances that are of interest and concern across the country and/or to multiple jurisdictions).

In deciding whether a need exists for a guideline, the DWS Secretariat must establish that controlling the substance in drinking water would have an impact (i.e., does control of Substance X have “clear potential, based on sound research evidence, to significantly improve population health and reduce disparities”?). In order to determine impact, the Secretariat must determine the availability of published literature and national field monitoring data on Substance X. Jurisdictions represented on DWS identify the availability of provincial field monitoring data on Substance X from existing, current or future sampling programs, as well as timelines for providing monitoring data summaries of this information. The provinces also identify additional information that may be needed (e.g., toxicity measurements, cost information, economic statistics) to assist in the assessment of the substance and possible subsequent guideline development process. Impact is verified through further research at the criteria summary preparation and review stages.

In setting the Priority List of substances to be reviewed, the Subcommittee uses a multiple rating system based on frequency and concentration of detection, health effects and professional judgement. DWS members are asked to rate each substance, first by rating how frequently it is detected in drinking water supplies, and then by rating the concentration at which it is usually detected in provincial drinking water supplies. Based on the first two ratings, DWS members rate the substance, using their professional experience and knowledge of water systems, within their jurisdiction. If no monitoring data are available to rate the substance, it is rated using only their experience and knowledge.

The Secretariat provides the health effects rating. Based on pre-health risk assessment or assessments from the U.S. Environmental Protection Agency (EPA) or World Health Organization (WHO), the Secretariat rates each substance (or group of substances) against its potential to cause adverse health effects.

With a summary of both exposure (e.g., concentration, frequency) and health ratings and provincial data, DWS establishes the Priority List through a consensus process. The Priority List is limited to the six substances that have the most impact on drinking water quality and public health. The list contains the substances the Subcommittee is currently evaluating, priority substances awaiting assignment to an evaluator, and suggested substances that may be given priority at a later date.

If Substance X meets the above criteria, it is placed on the DWS list of substances for assessment or reassessment. The list containing Substance X and other parameters that are under review or scheduled for review by DWS is also reproduced in the Guidelines for Canadian Drinking Water Quality booklet, published once every two or three years.

DWS reviews the list every fall, and then submits it to CEOH for approval. If CEOH agrees with DWS’s recommendation, further assessment of Substance X proceeds. If CEOH disagrees with DWS’s recommendation, either the substance is dropped from the assessment list or more information is collected on the substance to better justify the initial recommendation.

At this stage, the Secretariat also consults with its partners in other jurisdictions. The Secretariat has a long history of coordinating its evaluations with similar work being undertaken at Health Canada, the U.S. EPA and/or WHO. For instance, the Secretariat is waiting until the EPA concludes its extensive research on arsenic before re-assessing the current Canadian arsenic guideline. Similarly, the EPA deferred its evaluation on uranium until the Secretariat finished its research on this substance.

Based on the information gathered from DWS members and other jurisdictions, the Secretariat establishes a schedule for the review of Substance X. It submits this schedule, along with schedules of other substances, to CEOH for review, comments and approval.

3. Assessment

a) Field Monitoring Data

During the assessment phase, the issue of flexibility (i.e., that the process “provides flexibility for each jurisdiction and stakeholder to implement the strategy in their own way”) is considered. For example, jurisdictions particularly concerned about Substance X may initiate monitoring programs. These additional monitoring data for Substance X are generally submitted to the
Secretariat for consideration when assessing Canadian exposure to the contaminant. This approach to additional data collection and sharing meets the common directions criterion, in that it “is consistent with the population health directions and priorities of provincial/territorial and federal governments.”

The flexibility and common directions criteria are also applied once a guideline has been established. For example, the provinces have the flexibility to choose how they want to incorporate and implement the new guideline into their drinking water quality management system. For the microbiological parameters in the Guidelines, there are, for example, varying strategies amongst provinces with respect to the number of samples required and the length of time before certain actions are taken (public warnings, boil water orders, etc.). This flexibility allows each province the opportunity to develop implementation criteria that best address the type of microbiological problems that are most likely to be encountered in their jurisdiction.

b) Criteria Summary Preparation

A Secretariat Evaluator verifies the availability of adequate toxicological and/or epidemiological data (i.e., substantiated published articles) with which to assess Substance X properly. The Evaluator then initiates a comprehensive literature and data search, critically reviews the literature and available monitoring data, and assesses Substance X in accordance with Health Canada’s published approach policy (Approach to the Derivation of Drinking Water Guidelines – see Annex 2).

Substance X has not been found to be carcinogenic to humans, so its recommended drinking water guideline is derived based on the application of an uncertainty factor, to account for inter- and intraspecies variation, to a no-observed-adverse-effect level observed in toxicological studies in which rats ingested Substance X in drinking water daily for two years. (Different procedures would have been used had Substance X been classified as a probable human carcinogen, a micro-organism or a radioactive contaminant.)

The Evaluator drafts a criteria summary on Substance X, incorporating the available health risk assessment information on Substance X, overall environmental exposure, the fraction of its exposure attributed to drinking water, existing analytical/treatment techniques and capabilities, and the recommended guideline value.

c) Criteria Summary Review

The first review of the draft criteria summary is internal: the Evaluator defends the classification of Substance X and its proposed guideline to a Senior Evaluator within the Drinking Water Section of the Safe Environments Directorate. The criteria summary is then revised to reflect the experience of the Senior Evaluator, who must be completely satisfied with the criteria summary before it is forwarded for an external review.

The Evaluator then sends the draft criteria summary to three external or “third-party” reviewers who have expert knowledge of Substance X. These third-party reviewers are from Canadian or American universities, the U.S. EPA Drinking Water Program or a Member State of WHO. These experts critically review the criteria summary in accordance with the Canadian published approach policy (see Annex 2) and respond to questions set out in a guide for peer reviewers. Their review focuses on the scientific component of the summary. This third-party review requires financial resources, as reviewers are paid under contract.

The written comments and any additional information identified by the reviewers are reviewed by the Evaluator. The Evaluator then revises the criteria summary and submits it for a final internal review.

The draft criteria summary, revised on the basis of the final internal review, is then submitted to the Standards & Guidelines Rulings Committee of the Safe Environments Directorate. This committee, composed of senior staff from all appropriate divisions within the Directorate and additional experts from within the Healthy Environments and Consumer Safety Branch, evaluates the document to ensure that it is scientifically sound and in keeping with Departmental (or Directorate) policies on health risk assessment. Taking into consideration comments from this committee, the Evaluator prepares a revised criteria summary for submission to DWS.

The criteria summary and an executive brief are then distributed to DWS members and to all members of the parent committee for review. Provincial reviews and assessments of the criteria summary vary from brief departmental (internal) reviews to detailed evaluations by external agencies or non-governmental organizations. Written comments from DWS members are forwarded to the Secretariat for consideration by the Evaluator. All comments are addressed and documented, and a revised criteria summary is drafted and redistributed to DWS members.
4. Evaluation

a) Cost-Benefit Analysis

Once the health risks associated with the ingestion of Substance X in drinking water have been evaluated by the jurisdictions represented on DWS, the feasibility of implementing the recommended guideline for Substance X in drinking water is evaluated. This process involves consideration of treatment cost and socio-economic factors (capacity and return on investment).

Jurisdictions concerned that their populations may be exposed to drinking water containing Substance X at concentrations exceeding the proposed risk-assessment-derived guideline value may conduct risk management assessments. These assessments may involve estimating the costs for water treatment plant improvements designed to reduce the concentration of Substance X in treated water supplies. The costs of controlling exposure to Substance X from sources other than drinking water may also be estimated in order to confirm that water treatment is in fact the most cost-effective way of reducing intake of Substance X. These costs may be weighed against the benefits of reducing exposure to Substance X via drinking water. For example, there may be direct savings in health care costs that would otherwise be incurred from a specific health problem associated with Substance X. There may also be indirect savings, which are the socio-economic benefits (e.g., savings in sick leave, work or production) associated with controlling Substance X in drinking water. Any side benefits that are an outcome of improved drinking water treatment to control Substance X (e.g., removal of other contaminants, extension of the life of the water distribution system) may also be considered in a cost-benefit analysis of Substance X.

These assessments are the responsibility of DWS members; the level of detail is left to their discretion.

b) Consultation

Consultation is closely linked with communication (section 8). Direct input from stakeholders and focus groups enables those directly affected by the health risks associated with Substance X to participate in the risk management process. This maximizes public understanding of the risk management decision-making process and increases the likelihood for public acceptance of the government’s final decision for the control of Substance X.

Consultation begins when Substance X is first identified in announcements and publications as being under evaluation by DWS. DWS members may solicit input at this point. Consultation becomes more structured once the criteria summary for Substance X has been submitted to DWS for evaluation. DWS members then identify the level of consultation required and inform CEOH of its recommendation. A national consultation on the proposed guideline is held. Regional or provincial consultations may also be recommended, depending on regional or provincial concerns. Each DWS member is responsible for consultation procedures or methods used within his or her own jurisdiction. The federal DWS member is responsible for national focus groups – federal departments and agencies, industries and manufacturers, and national organizations and associations.

DWS members are responsible for announcing the consultation on Substance X to their clients and requesting that interested parties submit their names to the Secretariat. At the same time, a consultation package on Substance X – containing the criteria summary, a treatment technology document describing commonly used or available control methods, available cost and economic analysis synopses, and any other relevant information – is drafted by the Secretariat and reviewed by DWS.

Consultation packages are mailed out by the Secretariat to those parties who ask to participate and are posted to Health Canada’s website for a six-month consultation period. After the review period, DWS members and members of the Secretariat summarize the responses they have received, and the Secretariat prepares, from jurisdictional summaries, a brief summary of common comments. This national summary report is reviewed by all DWS members, revised by the Secretariat and redistributed to DWS and CEOH members and consultation participants.

5. Decision-Making and Approval

A package containing all the consultation package materials as well as the results of the consultation (i.e., the summary of all results) is distributed to DWS members one month in advance of the DWS meeting at which discussions are to commence on a recommended approach for controlling Substance X in drinking water.

At the meeting, DWS members decide whether or not a guideline for Substance X is needed and formulate a recommendation. This recommendation is then forwarded to CEOH for endorsement. CEOH assesses the recommendation based on the information contained in the executive brief, the cost and economic analysis synopses, and the national consultation summary report.

If the recommendation for a new drinking water guideline is approved by CEOH, it is reported to the Conference of Deputy Ministers of Health via its Population Health Advisory Committee. If the recommendation to establish a guideline is rejected, the item is returned to DWS with directions as to what additional information is required.
6. Announcement and Publication

After obtaining CEOH’s approval for a new guideline, the Secretariat prepares a public announcement for the news media. This brief statement on CEOH’s decision concerning the proposed drinking water guideline for Substance X is made available to all DWS members. Each DWS member is responsible for the release of this statement within his or her own jurisdiction.

As the new guideline has been approved by CEOH, the Secretariat Evaluator makes all required revisions to the criteria summary in preparation for publication in the Guidelines for Canadian Drinking Water Quality – Supporting Documentation binder. The final criteria summary is published in both official languages within one year of CEOH’s approval.

The new guideline is included in the summary table of drinking water guidelines found in the Guidelines for Canadian Drinking Water Quality – Supporting Documentation binder and is posted on Health Canada’s website. This table is updated annually, if required. The guideline is also included in the Guidelines for Canadian Drinking Water Quality booklet, updated every two or three years.

7. Re-evaluation

Re-evaluation of existing guidelines is an ongoing process. The Secretariat has the responsibility for identifying outdated guidelines each year when the DWS list of substances is established, but any DWS member or interested party may identify an outdated guideline. The availability of new research, monitoring data, analytical methodology or treatment process may prompt a re-evaluation of an existing guideline.

8. Communication

Communication between DWS and CEOH members is essential throughout the guideline development process to ensure that proposed guidelines are in line with current policies. Communication begins with the annual review of the DWS list by CEOH and ends with the final approval of the recommended guideline by CEOH. A summary of DWS activities and meeting minutes are posted on Health Canada’s website and made available to CEOH members after every DWS meeting.

In an effort to keep the public informed on the development of drinking water guidelines, a public announcement following each DWS meeting is made available to DWS members for distribution to interested parties, and is posted on Health Canada’s website. These announcements are the summaries of DWS activities prepared for CEOH. These summaries do not provide specific guideline values, as early disclosure of a proposed value could hinder the approval of that guideline.

Challenges to a new or existing guideline are managed through an established formal process.
Annex 1:
Operating Rules for the
Subcommittee on Drinking Water

Terms of Reference
The Subcommittee on Drinking Water (DWS) shall provide timely advice to the Federal-Provincial-Territorial Committee on Environmental and Occupational Health (CEOH) on all matters that can affect the provision of wholesome drinking water, with emphasis on:

- collecting, collating and evaluating national and international information on constituents of drinking water and their potential health effects;
- developing and recommending guidelines for potable water quality based on health assessment, treatment costs and economic analysis;
- reviewing and evaluating the adequacy of potable water treatment technology and operating procedures in treatment plants;
- promoting the exchange of information on drinking water issues and promoting co-operation with other organizations with related interests; and
- identifying research needs and promoting and encouraging research on drinking water issues in Canada.

Membership
1. Members shall be nominated by CEOH health representatives according to the following protocol: one member from each of the federal and provincial governments. Provincial DWS members should be represented by the provincial agencies responsible for establishing drinking water quality parameters, or have the authority to speak and make decisions for that jurisdiction on drinking water quality. If a DWS member cannot attend a meeting, the DWS member may nominate an alternate for backup and continuity at that specific meeting.

2. The Chairperson and Vice-Chairperson shall be elected from and by the members to serve a term of 2 years. The Chairperson and Vice-Chairperson may be re-elected to serve a second term but shall not serve more than two consecutive terms.

3. In order to ensure DWS operates within the overall priorities of CEOH, DWS shall be assigned, on a rotational basis, a CEOH Liaison, who shall be responsible for providing a liaison function between CEOH and DWS. The CEOH Liaison shall be appointed through CEOH.

Financial Responsibilities
4. Secretariat support for DWS shall be provided by Health Canada.

5. Health Canada shall be responsible for transportation costs for the DWS meetings of the members nominated pursuant to paragraph 1, to the limit of one person per province.

6. Members shall bear their own subsistence costs while attending the DWS meeting.

7. Additional persons from the provinces may participate in these meetings, but all costs for these participants shall be the responsibility of the provincial governments.

8. It is expected that Health Canada will pay for meeting room costs and refreshment services during the meeting. All other hospitality is optional in accordance with the policy of the host jurisdiction.

9. DWS is entitled to hold two meetings per year – the location alternating between Ottawa and a province – with due consideration of costs involved.

Secretariat Responsibilities
10. The Secretariat shall provide advance notification of all DWS meetings to the CEOH Secretariat.

11. The Secretariat shall make available, to the CEOH Secretariat, decision or information items, annual reports outlining achievements and status of work in progress, and a list of substances for the coming
year, for approval by CEOH. Copies shall be forwarded to the DWS Chairperson and the CEOH Liaison.

12. The Secretariat shall be responsible for the development of risk assessments for substances under review or scheduled for review (e.g., gathering and evaluating data on the health effects associated with exposure to a substance and developing options to reduce any perceived risks), including preparing a risk management criteria summary and coordinating other summary reports or synopses for presentation to DWS members.

13. The Secretariat
   a. shall solicit the views of members on the agenda for the forthcoming meeting,
   b. may request members to prepare and submit background information for agenda items at least 4 weeks prior to the meeting, and
   c. may request members to complete an Information Exchange form (to be provided by the Secretariat) at least 4 weeks prior to the meeting for distribution to the members.

14. The Secretariat shall distribute the agenda and background information to DWS members approximately 4 weeks prior to the meeting.

15. The Secretariat shall submit, to the CEOH Secretariat, draft minutes of its meetings within 30 days of the meeting having taken place and final bilingual minutes of its meetings within 60 days. The Secretariat shall make available to DWS and CEOH a public announcement (summary) prepared from the minutes and shall post it on Health Canada’s water quality website also within 60 days of the meeting.

DWS Chairperson’s (Vice-Chairperson’s) Responsibilities

16. The Chairperson (Vice-Chairperson) shall
   a. give direction to the Secretariat on the details of forthcoming meetings,
   b. ensure DWS meetings are run in an efficient and effective manner, and
   c. keep the CEOH Liaison informed of progress on an ongoing basis.

17. The Chairperson (Vice-Chairperson) may convene an informal meeting of the Secretariat and other DWS members, as appropriate, immediately prior to the meeting to review the agenda and to attend to any last-minute details.

DWS Members’ Responsibilities

18. DWS is responsible for the risk management of substances (e.g., evaluation of the impact of the health data, as well as assessment of the practicability, cost and potential benefits of a particular proposed guideline in light of other health protection priorities in the jurisdictions) and derivation of guidelines that are both practicable and protective of health.

19. DWS shall normally arrive at decisions, conclusions, standards, guidelines and procedures by consensus. In the event that it becomes necessary to vote, each provincial jurisdiction represented shall have one vote. The federal vote shall be held by Health Canada.

20. Voting shall be by ballot. A quorum shall be attained if at least three-quarters of the eligible jurisdictions vote (this includes negative votes, affirmative votes and abstentions). A motion shall be passed if at least two-thirds of those casting votes are affirmative votes. Reasons for negative votes or abstentions shall be recorded. If adequate information or data are available and a member prefers to defer the decision or vote on an issue for further evaluation, the issue may be deferred once until the next meeting. A write-in vote approximately 2 months following the meeting may be held, but it shall not be considered a deferral.

21. When possible, the local DWS member will attend any CEOH meeting held in that DWS member’s jurisdiction for assisting the CEOH Liaison and DWS Secretariat in presentation of items and responding to questions on DWS activities.

Liaison Members’ Responsibilities

22. To improve communication between DWS and CEOH or the Canadian Advisory Council on Plumbing (CACP), the Liaison will review all issues discussed by DWS from CEOH’s or CACP’s perspective, and will keep the latter groups up-to-date on DWS activities and responsibilities.

23. At, and in between, CEOH or CACP meetings, the Liaison will report on issues of interest to the group in question. Upcoming CEOH and CACP issues and priorities of concern to DWS should be noted and brought to the attention of the Secretariat and to other DWS members in a timely manner.

24. At CEOH meetings, the CEOH Liaison will present and report on formal Subcommittee issues and activities. The DWS Secretariat and local DWS member, if possible, will assist in the presentation.
Annex 2:
Approach to the Derivation of Drinking Water Guidelines

Introduction
The process of developing drinking water guidelines for microbiological, chemical/physical and radiological parameters is based on risk management concepts and involves several steps: i) identification, ii) assessment, iii) evaluation, iv) approval and v) announcement and publication of the guidelines. It is a flexible process that must accommodate the diverse needs of various jurisdictions (i.e., provincial, territorial and federal). Certain steps may be modified in order to satisfy the needs of the jurisdictions involved.

The second step in the drinking water guidelines development process involves the scientific assessment of the health risk associated with the ingestion of drinking water containing specific parameters. Health Canada is responsible for preparing these health risk assessments, based on careful consideration of the available scientific data, and for recommending guideline values for microbiological, chemical/physical and radiological parameters in drinking water, according to the different principles and approaches outlined in the following sections.

As provincial and territorial governments are responsible for the provision of safe drinking water and the implementation of drinking water guidelines, members of the Federal-Provincial Subcommittee on Drinking Water are accountable for the evaluation and approval steps of the drinking water guidelines development process. Each recommended guideline value and its accompanying health risk assessment are evaluated for their practicality and impacts. National consultations are carried out by the Secretariat; provincial or regional consultations may be carried out by the provinces and territories. Through this consensus-based development process, a guideline is established, and the associated health risk assessment is modified to create a criteria summary that reflects the risk management decisions involved in the guideline’s development.

Microbiological Parameters

Introduction
Pathogens that commonly occur in polluted surface water include protozoa (e.g., Giardia, Cryptosporidium), bacteria (e.g., Salmonella, Shigella, Campylobacter, Yersinia, Legionella) and enteric viruses (e.g., Norwalk virus, rotaviruses, hepatitis A and E viruses [HAV/HEV]). Only enteric viruses and bacteria are found in contaminated groundwater.

Gastrointestinal illness or diarrhoea is the most common illness attributable to waterborne pathogens. Although such illness is generally considered to be non-life threatening in normal, healthy adults, low mortality rates (3-5%) have been observed in sensitive subpopulations, including infants and the elderly. More serious illness, including jaundice, liver damage and, potentially, death (0.6% mortality), may be caused by other waterborne pathogens, such as HAV.

Four primary factors influence the risk of waterborne illness to human health:

- the concentration of the pathogen in the drinking water.
- the 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. To protect the health of the most sensitive individuals (and hence all individuals), it is assumed for risk assessment purposes that infection equals illness, although infection does not always lead to illness.
- the volume of water ingested. Average daily intake is assumed to be 1.5 L.

Between 1974 and 1987, 32 waterborne outbreaks of bacterial origin (1133 cases) and 10 waterborne outbreaks of giardiasis (315 cases) were reported in
Canada. During the same period, five waterborne viral (Norwalk virus and HAV) outbreaks, associated with 229 cases, were reported. Gastroenteritis of unknown etiology accounts for most waterborne disease outbreaks (1587 cases associated with 15 outbreaks over the period), but evidence is accumulating that in many cases the aetiological agents are viruses. It is likely that these reported outbreaks represent only a fraction of the true number of outbreaks of waterborne illness. Information for the period since 1987 has not yet been compiled, but significant waterborne disease outbreaks have occurred.

### Derivation of Maximum Acceptable Concentrations (MACs)

For some waterborne pathogens (e.g., certain viruses and protozoa), one infectious unit can yield illness. To protect sensitive subpopulations, therefore, it is generally assumed in risk assessment that infection will result in illness. As a result, there is no tolerable concentration of waterborne pathogens in drinking water. This essentially means that the recommended MAC for waterborne pathogens is zero (similar to the approach used for chemical carcinogens).

Even though the desired goal for public health protection is zero risk of illness from waterborne pathogens, this is rarely technically and economically feasible. Instead, “acceptable” microbial risks are derived and used in risk assessment. The U.S. Surface Water Treatment Rule (SWTR), for example, has set a risk of one infection (assumed to result in one case of illness) per 10,000 people per year (a risk of 10⁻⁶) as a health goal for exposure to Giardia in treated drinking water.

In order to apply health protection goals to water management, it is necessary to determine whether there are any pathogens present in the water supply. However, it is impractical to monitor water for the presence of pathogenic organisms, for several reasons. For some pathogens, methods for direct detection have not yet been developed. For others, the direct detection methods available 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.

For these reasons, surrogates or indicators that can warn of inadequate water treatment, and hence the possible presence of pathogens in the water, are usually monitored for instead of the actual pathogens. The ideal indicator organism would have the following characteristics:

- Present only when the pathogen is present, and more numerous than the pathogen
- Exclusively associated with faecal wastes and therefore absent from non-polluted waters
- Incapable of growth in the environment
- Similar resistance to stress (e.g., similar survival characteristics, similar resistance to disinfection) as the pathogen
- Easily and accurately enumerated

Faecal coliform bacteria, in particular Escherichia coli and total coliform bacteria – micro-organisms that are not normally pathogenic themselves – are usually used to indicate the potential presence of pathogenic bacteria. For this reason, faecal indicator bacteria must never be present in treated water. If they are detected, steps should be taken immediately to rectify the situation.

While the absence of coliforms indicates that enteric bacteria are probably absent, it does not guarantee that enteric viruses and parasitic cysts are also absent. This is because the coliform bacteria are not an appropriate indicator for waterborne viruses and protozoa. For instance, viruses survive longer in water, are more resistant to disinfection, and are more infective than most bacteria. For these reasons, coliphages (which are viruses that infect coliform bacteria) and bacterial spores have been proposed as indicators for enteric viruses in drinking water. 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.

The use of indicator organisms is only one means of guarding against the presence of waterborne pathogens. Adequate treatment of drinking water to remove or inactivate these pathogens is often the primary method used to ensure against their presence in drinking water. The U.S. SWTR requires all public water systems using any surface water, or groundwater under the influence of surface water, to disinfect as well as provide filtration unless certain characteristics of the source water and site-specific conditions are met. Treatment must achieve at least 99.9% and 99.99% removal and/or inactivation of Giardia and viruses, respectively, measured by compliance with specified disinfectant residual concentrations and contact times. The type and effectiveness of the disinfectant to be used depend on the type of pathogen present and the physical characteristics of the water being treated.

As this method for ensuring waterborne pathogens are not present in drinking water supplies is based on the degree of treatment required to remove or inactivate viruses and protozoan cysts rather than detection, it avoids all the problems associated with the analytical methods. This approach for assuring pathogen-free water is used by the Federal-Provincial Subcommittee on Drinking Water.

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1. See Appendix B for definitions.
In general, then, the application of adequate water treatment and the absence of indicator organisms are the primary means used to safeguard against the presence of hazardous waterborne pathogens. Health risks associated with the use of disinfectants (including the risk from their by-products) to keep drinking water microbiologically safe must also be considered.

**Chemical/Physical Parameters**

**Introduction**

Data on the effects of exposure to chemical agents are obtained in toxicological studies in animal species and occasionally in epidemiological studies of human populations. Effects vary depending upon the dosage, route of exposure (e.g., ingestion, inhalation or dermal), frequency or duration of exposure and the species, sex and age of the exposed population. Effects of exposure to chemicals are generally classified in the following broad categories: organ-specific, neurological/behavioural, reproductive, teratological and oncogenic/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 with increasing dose; this is commonly referred to as the dose-response relationship.

For some types of toxic effects that result from exposure to chemicals, it is believed that there is a dose (or threshold) below which adverse effects will not occur. For other types of toxic effects, there is assumed to be some probability of harm at any level of exposure (i.e., no threshold). At present, the latter assumption is generally considered to be appropriate for carcinogenesis only. For some types of carcinogens (i.e., those that induce tumours by particular mechanisms, such as promotion), however, there may be a threshold dose below which tumours will not occur.

Uncertainty exists in the scientific database used to derive guidelines for maximum acceptable exposure to chemical substances. Contributing to this uncertainty are inadequate data on the level, frequency and duration of exposure; differences in sensitivity between species and among individuals in the same species; inadequate study design; potential for interactive effects; and variations in statistical models for extrapolation of responses observed at high doses to those expected at low doses. Every effort has been made to take these uncertainties into account in the approaches for deriving MACs for chemical parameters described in this section and the supporting documents. It should also be emphasized that the application of sound scientific judgment on a case-by-case basis is fundamental to the approach for deriving guidelines outlined in this section.

Probabilistic methods can be used in the risk assessment of drinking water parameters (microbiological, chemical/physical and radiological) in order to characterize the uncertainty and variability in those assessments and to provide more information for decisions about drinking water guidelines. Since probabilistic methods are still being evaluated by Health Canada, they are currently used to supplement the existing deterministic (point estimate) approaches to the risk assessment of chemical parameters (described in this section) on a case-by-case basis. The information that these methods provide about risk ranges for chemical parameters can allow point estimates of risk and exposure to be put into context. However, caution must be exercised in the interpretation of the results of probabilistic methods; their successful application is dependent upon the availability and quality of the necessary data and the use of complex analyses.

**Derivation of MACs**

Different approaches are adopted for the derivation of guidelines for compounds considered to be carcinogenic and probably carcinogenic, compounds considered to be possibly carcinogenic, and those considered to be probably not carcinogenic or for which data are inadequate for evaluation. It is necessary, therefore, to classify chemicals with respect to their potential carcinogenicity into various groups (as outlined in Appendix A) on the basis of rigorous examination of the quantity, quality and nature of the results of available toxicological and epidemiological studies. Chemicals classified as carcinogenic often also induce toxic effects other than malignant tumours; for these substances, the guideline is derived on the basis of the approach that leads to the most stringent value.

**Chemicals That Are Not Carcinogenic**

For chemicals classified as “probably not carcinogenic to humans” or for which data on carcinogenicity are “inadequate for evaluation” (Groups IV and V in Appendix A), the MAC is derived based on a tolerable daily intake (TDI) (formerly called the acceptable daily intake, or ADI) for organ-specific, neurological/behavioural, reproductive or teratological effects. Where possible, the TDI is derived by division of the lowest no-observed-adverse-effect level (NOAEL) for a response considered to be biologically significant by an uncertainty factor. Ideally, the NOAEL is derived from a lifetime ingestion study or studies in the most sensitive subpopulation (e.g., teratological studies). Data from acute or short-term studies are rarely used in calculating TDIs. The uncertainty factor is derived on a case-by-case basis, though in general a factor of 1 to 10 times is

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used to account for each of the following elements of uncertainty: intraspecies variation, interspecies variation, nature and severity of effect, adequacy of study and use of a lowest-observed-adverse-effect level (LOAEL) versus a NOAEL. An additional factor of 1 to 5 times is incorporated where there is information that indicates a potential for interaction with other chemicals. If the chemical is an essential nutrient at low concentrations, the dietary requirement is also taken into consideration.

Derivation of the MAC is generally based on an average daily intake of 1.5 L of drinking water by a 70-kg adult (Department of National Health and Welfare 1981). However, where appropriate, the MAC is derived based on intake in the most sensitive subpopulation (e.g., pregnant women, children). Human exposure from sources other than drinking water (e.g., air, food, consumer products) is taken into account by apportioning a percentage of the TDI to drinking water. Where possible, data concerning the proportion of total intake normally ingested in drinking water (based on mean levels in food, air and treated municipal water supplies) or intakes estimated on the basis of consideration of physical/chemical properties are used in the calculations. Where such information is unavailable, a value of 20% is used in the derivation of the MAC.

Contaminants present in drinking water may contribute to total intake not only by ingestion, but also by inhalation or dermal exposure to water during 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, available data are insufficient to enable estimation of exposure by inhalation and dermal absorption of contaminants present in drinking water. The 20% allocation of total daily intake to drinking water is believed to be generous and should be sufficient to account for these additional routes of intake.

In some cases where the calculated total daily intake from all sources is less than 50% of the TDI, allocation to drinking water is based on consideration of additional factors, such as feasibility. In no case, however, can the calculated total daily intake from food, air and drinking water (containing levels at the MAC) exceed the TDI.

Maximum acceptable concentrations must be achievable by available treatment methods and measurable by existing analytical techniques. Where a MAC is less than levels considered to be reliably measurable or achievable, an “interim MAC” (IMAC) is established, and improvement in methods of quantitation and/or treatment is recommended.

Chemicals That Are Carcinogenic

As it is generally accepted that carcinogenesis is a non-threshold phenomenon, it is assumed that there is a probability of harm at any level of exposure to carcinogenic chemicals. Ideally, therefore, carcinogens should be absent from drinking water. However, the incremental risks associated with exposure to low levels of these chemicals in drinking water may be sufficiently small so as to be essentially negligible compared with other risks commonly encountered in society.

Quantitative risks associated with exposure to low levels of potential carcinogens are estimated by extrapolation (usually over many orders of magnitude) of the dose-response relationship observed at high doses in experimental studies (most often in animal species) to the low dose range. There are a number of uncertainties involved in these mathematical extrapolations; the methods used are, however, based on conservative assumptions and probably tend to overestimate rather than underestimate the risks. The actual risks at low levels of exposure may, therefore, be lower than the estimated values by 1 to 2 orders of magnitude.

For chemicals classified as “carcinogenic to humans” or “probably carcinogenic to humans” (Groups I and II in Appendix A), lifetime cancer risks are estimated using the robust linear extrapolation model, applied to the tumour types considered to be most appropriate from a biological perspective. Whenever possible, information on pharmacokinetics, metabolism and mechanisms of carcinogenicity is incorporated into the model for risk estimation. To account for differences in metabolic rates between animals and humans, a surface area to body weight correction is applied, except in those cases where it is not justified on the basis of available data on pharmacokinetics and metabolism.

For many carcinogenic compounds (substances classified in Groups I and II in Appendix A), available treatment technology is inadequate to completely eliminate exposure from drinking water. In addition, available analytical methods may be inadequate for reliable determination at extremely low levels. Therefore, MACs are set as close to zero as reasonably practicable, on the basis of consideration of the following factors:

- The MAC must be achievable by available water treatment methods at reasonable cost.
- Wherever possible, the upper 95% confidence limit for the lifetime cancer risk associated with the MAC is less than $10^{-7}$ to $10^{-8}$, a range that is generally considered to be “essentially negligible.” In cases where intake from sources other than drinking water (e.g., food, air and consumer products) is significant, the upper 95% confidence limit for the lifetime cancer risk associated with the MAC is less than or equal to $10^{-8}$.
- The MAC must also be reliably measurable by available analytical methods.
Where estimated lifetime cancer risks associated with the MAC are greater than those judged to be essentially negligible (i.e., $10^{-5}$ to $10^{-3}$), an IMAC is established and improvement in methods of quantitation and/or treatment is recommended.

**Chemicals That Are Possibly Carcinogenic**

For compounds that are “possibly carcinogenic to humans” (Group III in Appendix A), the MAC is based upon a TDI determined as described in the section entitled “Chemicals That Are Not Carcinogenic”; however, an additional factor of 1 to 10 times is incorporated in the uncertainty factor to account for the limited evidence of carcinogenicity. In some cases where there are sufficient data (e.g., increased incidence of benign tumours at several sites in several species), a quantitative estimate of tumour incidence is considered in derivation of the MAC.

**Pesticides**

The approach to derivation of the MACs and IMACs for pesticides included in the Supporting Documentation differs somewhat from that for other chemicals. A number of pesticides considered to be “probably not carcinogenic to humans” or for which data on carcinogenicity are “inadequate for evaluation” (Groups IV and V in Appendix A) have been considered by the Food Directorate, Health Products and Food Branch, Health Canada, to establish maximum tolerable residue levels in foods, as part of their registration under the *Pest Control Products Act*. These evaluations include an extensive assessment of data for establishment of either ADIs or, where there are data gaps or data of poor quality, negligible daily intakes (NDIs), which incorporate a larger uncertainty factor. Wherever possible, these ADIs or NDIs established by the Food Directorate have been used in the derivation of MACs or IMACs, respectively, for the pesticides included in the Supporting Documentation, for the following reasons:

- To ensure consistency of approach in relation to the establishment of residue limits in foods
- To take advantage of the very detailed scientific assessment already available in most cases
- To ensure that all relevant data (including confidential data submitted under the *Pest Control Products Act*) are taken into consideration when deriving MACs and IMACs

The World Health Organization (WHO), in conjunction with the Food and Agriculture Organization of the United Nations (FAO), also conducts evaluations to derive ADIs or, where data are insufficient, provisional daily intakes, which incorporate a larger uncertainty factor, for pesticide residues in foods. For chemicals that fall into Groups IV and V in Appendix A (“probably not carcinogenic to humans” or for which data on carcinogenicity are “inadequate for evaluation”) and that have been evaluated by WHO, MACs or IMACs are based upon FAO/WHO ADIs or provisional daily intakes, respectively.

**Derivation of Aesthetic Objectives**

In cases where thresholds for organoleptic properties are less than the MAC, an “aesthetic objective” (AO) is derived, based on information on taste and odour thresholds reported in the literature.

**Radiological Parameters**

The derivation of radiological guidelines conforms to international radiation protection methodologies. These methodologies are based on an annual dose limit that takes into consideration both the risk from exposure and the level of unavoidable dose due to natural background radiation. As a result, the levels of risk associated with the guideline dose for radionuclides, although low, are somewhat higher than the basic risk criteria for individual chemical carcinogens in drinking water. However, the guideline dose for radionuclides applies to the total dose received from all radionuclides in the water supply. Owing to extensive human epidemiological data and well-documented dose-effect data, radiation risk estimates contain considerably fewer uncertainties than chemical risk estimates.

In order to assess the risk to health from radiation exposure, a link is required between exposure and biological outcome. At low doses received over an extended period of time, the biological outcome of greatest importance is the induction of cancer in the various organs and tissues of the body.

Irradiation of tissue results in damage to exposed cells as energy is transferred from the radiation to the tissue. The fundamental dosimetric measure of this energy transfer is the *absorbed dose*, D, which is defined as the amount of energy imparted by ionising 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. The absorbed dose is independent of the type and energy of the radiation; however, equal absorbed doses do not necessarily have the same biological effect. 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 put all ionising radiations on an equal basis in terms of potential for causing harm, a set of radiation weighting factors has been introduced. These factors take into account the differing degrees of biological
harm produced by the same dose of the different radiations. In radiological protection, it is this weighted dose, referred to as the equivalent dose, that is of interest. The equivalent dose in a tissue or organ, $H_T$, equals the absorbed dose, $D$, multiplied by the sum of all the applicable radiation weighting factors, $w_T$:

$$H_T (\text{Sv}) = \sum w_T \times D \text{ (Gy)}$$

The unit of equivalent dose is the sievert (Sv), which is equal to one joule per kilogram and is radiation independent.

The relationship between the probability of a cancer and equivalent dose is found also to depend on the organ or tissue irradiated. To account for the various susceptibilities of the different organs and tissues to cancer induction, an additional set of tissue weighting factors is applied. These factors are derived from estimates of the probability of fatal and non-fatal cancer induction in the organs and their relative contributions to the total detriment following exposure to radiation. The effective dose, $E$, is obtained by multiplying the equivalent dose in each organ by the corresponding tissue weighting factor, $w_T$, and summing the result for each organ to give a total effective dose to the body:

$$E (\text{Sv}) = \sum w_T \times H_T (\text{Sv})$$

The set of tissue weighting factors has been chosen such that a uniform equivalent dose over the whole body will give an effective dose numerically equal to the equivalent dose. The total effective dose is a broad indicator of the risk to human health for any type of radiation and any distribution of dose in the body, whether the dose is received internally or externally. However, both the equivalent and effective doses provide a basis for estimating the probability of stochastic effects only for absorbed doses well below the thresholds for deterministic effects.

Radionuclides taken into the body by inhalation or ingestion may persist for extended periods of time; in some cases, the resulting dose to the internal organs may extend over several months or years. Internal exposures are therefore measured in terms of the integrated, or committed, dose delivered to an organ or the whole body over a period of time. Standard periods of integration are 50 years for the adult population and 70 years for a lifetime exposure. This dose is termed the committed effective dose and is measured in sieverts. It is this measure of extended internal exposure that is relevant to the establishment of drinking water guidelines.

The greatest body of information on the effects of ionising radiation comes from ongoing epidemiological studies of high dose and high dose rate exposures, primarily studies of the Japanese atomic bomb survivors. Based on these studies, the U.S. National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR V) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) have calculated lifetime risk estimates for fatal cancer of 8% and 11% per 1 Sv, respectively, following an acute whole-body exposure to high dose and high dose rate radiation. Both BEIR V and UNSCEAR state that these risks should be reduced by a factor of 2 for low dose exposures protracted over several months or years. After applying a single reduction factor of 2, UNSCEAR recommends a lifetime risk estimate following a protracted exposure to the whole body of low dose and low dose rate radiation of 5% per 1 Sv, distributed among the various body organs. The International Commission on Radiological Protection (ICRP) has also recommended the use of this risk estimate for low-level exposures.

The ICRP has also recognized that not all cancers are fatal, and that this should be considered, along with the possibility of hereditary effects. In order to make an assessment of the total detriment from radiation exposure, the ICRP has incorporated not only the risk of fatal cancer but also an allowance for differences in latency periods, the risk of non-fatal cancers weighted for severity and ease of curing and a risk of serious hereditary disease in all future generations. For non-fatal cancers, the weighted number is about 20% of the number of fatalities. The weighted figure for hereditary conditions is uncertain but is estimated to be about 27% of the number of fatalities for the whole population. The estimated lifetime probability for all fatal and weighted non-fatal cancers and hereditary disorders is 7.3% per 1 Sv. Values for the tissue weighting factors used in calculating effective dose have been derived from the total risk coefficients for all fatal and weighted non-fatal cancers in the individual organs.

Based on the risk coefficients for stochastic effects, the ICRP has established radiation dose limits for public exposures. The basic framework is intended to prevent the occurrence of deterministic effects by keeping doses below the relevant thresholds and to ensure that all reasonable steps are taken to reduce the induction of stochastic effects. In selecting the limit on effective dose, the ICRP has sought a value that it considers just short of unacceptable for continued exposure. In order to decide where the boundary between unacceptable and tolerable is to be set, the ICRP has taken into account a range of quantifiable factors of health detriment. Dose limits are therefore based on the risk of fatal and weighted non-fatal cancer and hereditary conditions.

For members of the public, the boundary between unacceptable and tolerable is based on levels of risk between $10^{-4}$ and $10^{-8}$ per year and on the variations in the dose from natural background radiation. Natural background radiation, although not harmless, makes only a small contribution to the total health detriment experienced by the public. Excluding the highly variable radon exposure, the annual effective dose from natural
sources is about 1 mSv. On this basis, the ICRP recommends a limit on effective and committed effective dose of 1 mSv for any combination of external and internal doses, respectively, received or committed in one year, excluding natural background radiation and medical or therapeutic exposures. At a rate of exposure of 1 mSv/year over a lifetime (70 years), the total lifetime risk for all fatal and weighted non-fatal cancers and hereditary defects is $6 \times 10^{-5}$.

In setting dose guidelines for radionuclides in drinking water, it is recognized that water consumption contributes only a portion of the total radiation dose and that some radionuclides present are natural in origin and therefore cannot be excluded. Consequently, MACs for radionuclides in drinking water have been derived based on a committed effective dose of 0.1 mSv from one year’s consumption of drinking water, or one-tenth of the ICRP’s recommendation on public exposure. This dose represents less than 5% of the average annual dose attributable to natural background radiation (i.e., 2.6 mSv).

The guideline reference dose is based on the total activity in a water sample, whether the radionuclides appear singly or in combination, and includes the dose due to natural radionuclides, in contrast to the ICRP guideline. The risk of fatal and weighted non-fatal conditions at a lifetime exposure of 0.1 mSv/year is between $10^{-5}$ and $10^{-4}$ per year, or about $6 \times 10^{-5}$ over a lifetime. The guideline dose limit is based solely on health considerations and has not been adjusted to incorporate any limitations in the sampling and treatment capability of water supplies.

To facilitate the monitoring of radionuclides in water, the reference level of dose is expressed as an activity concentration, which can be derived for each radionuclide from published radiological data. The National Radiological Protection Board (NRPB) has calculated dose conversion factors (DCFs) for radionuclides based on metabolic and dosimetric models for adults and children. Each DCF provides an estimate of the 50-year or 70-year committed effective dose resulting from a single intake of 1 Bq of a given radionuclide.

The MACs of radionuclides in public water supplies are derived from adult DCFs, assuming a daily water intake of 2 L, or 730 L/year, and a maximum committed effective dose of 0.1 mSv, or 10% of the ICRP limit on public exposure:

$$\text{MAC (Bq/L)} = \frac{1 \times 10^{-4} \text{ (Sv/year)}}{730 \text{ (L/year)} \times DCF \text{ (Sv/Bq)}}$$

Adult consumption of drinking water containing a single radionuclide at its MAC for one year would result in a committed effective dose of 0.1 mSv.

Where two or more radionuclides that affect the same organ or tissue are found to be present in drinking water, the following relationship should be satisfied:

$$\frac{c_1}{\text{MAC}_1} + \frac{c_2}{\text{MAC}_2} + \ldots + \frac{c_i}{\text{MAC}_i} \leq 1$$

where $c_i$ and MAC$_i$ are the observed and maximum acceptable concentrations, respectively, for each contributing radionuclide.

### Appendix A: Criteria for Classification of Carcinogenicity

Chemicals are classified into four main categories on the basis of the following criteria (modified from those of the International Agency for Research on Cancer):

**Group I – Carcinogenic to Humans**

Data from adequate epidemiological studies indicate that there is a causal relationship between the agent and cancer in humans (i.e., the observed association is unlikely to be due to chance, bias or confounding). Confidence in inferring a causal relationship is increased when the association is strong and observed in several studies, when there is a dose-response relationship, or when a reduction in exposure is followed by a reduction in the incidence of cancer.

**Group II – Probably Carcinogenic to Humans**

Data from epidemiological studies are inadequate to assess carcinogenicity either because there are few pertinent investigations or because chance, bias or confounding cannot be excluded as a possible explanation for the results. However, there is sufficient evidence of carcinogenicity in animal species (i.e., there is an increased incidence of malignant tumours in multiple species or strains or in multiple experiments with different routes of exposure or dose levels, or the incidence, site or type of tumour at age of onset is unusual). Confidence in the sufficiency of the data from animal studies is increased when there is evidence of a dose-response relationship, supporting results from in vitro studies or limited carcinogenicity bioassays, evidence of structure-activity relationships or supporting data on mechanisms of toxicity.

**Group III – Possibly Carcinogenic to Humans**

**Group IIIA** – Data from epidemiological studies indicate an association between exposure and human cancer, but alternative explanations such as chance, bias or confounding cannot be excluded.

**Group IIIB** – Data from epidemiological studies are inadequate to assess carcinogenicity. There is some evidence of increased tumour incidence in animals, but the data are limited because the studies involve a single
species, strain or experiment; study design (i.e., dose levels, duration of exposure and follow-up, survival, number of animals) or reporting is inadequate; the neoplasms produced often occur spontaneously and have been difficult to classify as malignant by histological criteria alone (e.g., lung and liver tumours in mice); there is an increase in the incidence of benign tumours only, or it is believed on the basis of information on the mechanism of action that increased tumour incidence is observed only at very high doses, or that it is species-dependent.

**Group IV – Probably Not Carcinogenic to Humans**

*Group IVA* – There is no evidence of carcinogenicity in sufficiently powerful and well-designed epidemiological studies; there is no evidence of carcinogenicity in adequate studies in two animal species.

*Group IVB* – There is no evidence of carcinogenicity in sufficiently powerful and well-designed epidemiological studies; data in animal species are inadequate.

*Group IVC* – There are no adequate epidemiological data; there is no evidence of carcinogenicity in adequate animal studies in two different species.

**Group V – Inadequate Data for Evaluation**

*Group VA* – Data from epidemiological and/or animal studies are inadequate (i.e., because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of carcinogenicity).

*Group VIB* – There are no data available for evaluation.

**Appendix B: Definitions**

**Acceptable Daily Intake (ADI):** This term is used for pesticides that have been previously evaluated by the Food Directorate of Health Canada or by the World Health Organization in conjunction with the Food and Agriculture Organization of the United Nations. An acceptable daily intake (ADI) is the amount of a substance that can be consumed from all sources each day by an adult, even for a lifetime, without any significant increased risk to health.

**Aesthetic Objective (AO):** An aesthetic objective (AO) applies to certain substances or characteristics of drinking water that can affect its acceptance by consumers or interfere with practices for supplying good water. For certain parameters, both AOs and health-related guidelines (maximum acceptable concentrations, or MACs) are derived. Where only AOs are specified, the values are below those considered to constitute a health hazard.

**Committed Effective Dose:** The committed effective dose is the effective dose that will be accumulated over a period of time following a single intake of radioactive material into the body. Standard periods of integration are 50 years for adults and 70 years for a lifetime exposure.

**Dose Conversion Factor (DCF):** The dose conversion factor is the committed effective dose resulting from the inhalation or ingestion of 1 Bq of a given radionuclide (units are sievert per becquerel, or Sv/Bq).

**Interim Maximum Acceptable Concentration (IMAC):** In those instances where there are insufficient toxicological data to derive a maximum acceptable concentration (MAC) with reasonable certainty, interim values (IMACs) are recommended, taking into account the available health-related data but employing a larger factor to compensate for the additional uncertainties involved. An interim value is also established for those substances for which estimated lifetime risks of cancer associated with the guideline (the lowest level that is practicably achievable) are greater than those deemed to be essentially negligible. Because of the nature of IMACs, they will be reviewed periodically as new toxicological data and developments in methods of quantitation and/or treatment become available.

**Lowest-Observed-Adverse-Effect Level (LOAEL):** The lowest-observed-adverse-effect level (LOAEL) is the lowest dose in a toxicity study that results in an observed adverse effect (usually one dosage level above the no-observed-adverse-effect level, or NOAEL). An adverse effect significantly alters the health of the target animal for a sustained period of time or reduces survival.

**Lowest-Observed-Effect Level (LOEL):** The lowest-observed-effect level (LOEL) is the lowest dose in a toxicity study that results in an observed, but not adverse, effect (usually one dosage level above the no-observed-effect level, or NOEL). For example, the dose that induces a transient increase in organ weight without accompanying biochemical or histopathological effects would generally be considered a LOEL.

**Maximum Acceptable Concentration (MAC):** Maximum acceptable concentrations (MACs) are established for certain substances that are known or suspected to cause adverse effects on health. They are derived to safeguard health on the basis of lifelong consumption. To the extent possible, the use of drinking water for all usual domestic purposes, including personal hygiene, is considered in the derivation of the guidelines. However, water of higher quality may be required for some special purposes, including renal dialysis.

Drinking water that continually contains a substance at levels greater than the MAC will contribute significantly to consumers’ exposure to this substance and may, in some instances, be capable of inducing 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 contaminant is exceeded, however, the minimum action required is immediate resampling. If the MAC continues to be exceeded, the authorities responsible for public health should be consulted concerning appropriate corrective action.

Negligible Daily Intake (NDI): This term is used only for pesticides that have been previously evaluated by the Food Directorate of Health Canada. When insufficient toxicological data are available to derive an acceptable daily intake (ADI) from all sources with reasonable certainty, a provisional value has been recommended by the Food Directorate that takes into account the available health-related data.

No-Observed-Adverse-Effect Level (NOAEL): The no-observed-adverse-effect level (NOAEL) is the highest dose in a toxicity study that does not result in any observed adverse effect. An adverse effect significantly alters the health of the target animal for a sustained period of time or reduces survival.

No-Observed-Effect Level (NOEL): The no-observed-effect level (NOEL) is the highest dose in a toxicity study that results in no observed effects.

Radionuclide: A radionuclide is an unstable nuclide that emits ionising radiation.

Tolerable Daily Intake (TDI): A tolerable daily intake (TDI) is the amount of a substance that can be consumed from all sources each day by an adult, even for a lifetime, without any significant increased risk to health. The term is now used instead of acceptable daily intake (ADI), except for pesticides, as it signifies permissibility rather than acceptability.