Part I

Approach to the Derivation of Drinking Water Guidelines

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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 specific parameters in drinking water. 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. Consultations are recommended by the Subcommittee and may be carried out by the provinces and territories and/or the Subcommittee's Secretariat. 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.

The most common illness attributable to waterborne pathogens is gastrointestinal illness or diarrhoea. Although gastrointestinal illness is generally considered to be non–life threatening in normal, healthy adults, 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:

- 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; although infection does not always lead to illness, to protect the health of the most sensitive individuals (and hence all individuals), it is assumed for risk assessment purposes that infection equals illness.
- the volume of water ingested; it is assumed that the average daily intake is 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 aetiology 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 lower limit for the concentration of waterborne pathogens in drinking water. This essentially means that the recommended MAC for waterborne pathogens is zero (an approach similar to that used below for chemical carcinogens).

Therefore, the desired goal in terms of public health protection is zero risk of illness from waterborne pathogens. However, the desired goal 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^{-4}) 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 methods available for their direct detection are often difficult, costly and time consuming, as well as requiring well-trained personnel. Furthermore, the absence of one pathogen would not necessarily indicate that all other pathogens were absent.

For these reasons, the detection of surrogates or indicators that can warn of inadequate water treatment and hence the possible presence of pathogens in the water is usually used in place of detection of the actual pathogens. The characteristics of the ideal indicator organism include the following:

- 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.
- can be 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. The presence of these faecal indicators in a drinking water supply suggests that pathogenic bacteria could also be present. 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.

The absence of coliforms, on the other hand, while indicating that enteric bacteria are probably absent, is no 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. Viruses, for example, 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. In addition, the use of spores of sulphite-reducing clostridia (e.g., *Clostridium perfringens*) as an indicator of the presence of viruses and protozoan cysts has 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 the 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 water quality characteristics of the source and site-specific conditions are met. Treatment must achieve at least 99.9% and 99.99% removal or inactivation, or both, of *Giardia* and viruses, respectively, as 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 against the presence of waterborne pathogens is based on the degree of treatment required to remove or inactivate viruses and protozoan cysts rather than their detection, it avoids all the problems associated with the analytical methods. This approach for assuring pathogen-free water is the basic position of the Federal–Provincial Subcommittee on Drinking Water.

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. It should be emphasized that the health risk associated with the use of disinfectants (including the risk from their by-products) to keep drinking water microbiologically safe must also be considered.

* See Appendix B for definitions.

Chemical/Physical Parameters**

Introduction

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

There is uncertainty in the scientific database used in the derivation of guidelines for maximum exposure to chemical substances. 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 contribute to this uncertainty. 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 fundamental to the approach for derivation of guidelines outlined in this section is the need for application of sound scientific judgement on a case-by-case basis.

**This section is taken directly from the "Derivation of Maximum Acceptable Concentrations and Aesthetic Objectives for Chemicals in Drinking Water," as published in Part I of the 1989 *Guidelines for Canadian Drinking Water Quality — Supporting Documentation*.

Derivation of MACs

Different approaches were 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 were inadequate for evaluation. It was 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 was derived on the basis of the approach that led to the most stringent value. In most cases, this was the approach specified for carcinogenic chemicals.

Chemicals That Are Not Considered Carcinogenic

For chemicals classified as "probably not carcinogenic to humans" or for which data on carcinogenicity were "inadequate for evaluation" (Groups IV and V in Appendix A), the MAC was 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 was 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 was derived from a lifetime ingestion study or studies in the most sensitive subpopulation (e.g., teratological studies); data from acute or short-term studies were not used in calculating TDIs. The uncertainty factor was derived on a case-by-case basis; in general, however, a factor of 1 to 10 times was used to account for each of the following elements of uncertainty: intraspecies variation, interspecies variation, nature and severity of effect, adequacy of study and lowest-observed-adverse-effect level (LOAEL) versus NOAEL. An additional factor of 1 to 5 times was incorporated where there was information that indicated a potential for interaction with other chemicals. If the chemical was an essential nutrient at low concentrations, the dietary requirement was also taken into consideration in derivation of the uncertainty factor.

Derivation of the MAC was 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 was 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) was 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 were used in the calculations. Where such information was unavailable, a value of 20% was 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 has been estimated to be similar to that by ingestion. However, in most cases, available data were 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, however, and should be sufficient to account for these additional routes of intake.

In some cases where the calculated total daily intake from all sources was less than 50% of the TDI, allocation to drinking water was based on consideration of additional factors, such as feasibility. In no case, however, could 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 was less than levels considered to be reliably measurable or achievable, an "interim MAC" (IMAC) was established, and improvement in methods of quantitation and/or treatment was 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 were estimated using the robust linear extrapolation model, applied to the tumour types considered to be most appropriate from a biological perspective. Wherever possible, information on pharmacokinetics, metabolism and mechanisms of carcinogenicity was 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 was applied, except in those cases where it was 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 were 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 was less than 10^{-5} to 10^{-6}, 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) was significant, the upper 95% confidence limit for the lifetime cancer risk associated with the MAC was less than or equal to 10^{-6}.
- The MAC must also be reliably measurable by available analytical methods.

Where estimated lifetime cancer risks associated with the MAC were greater than those judged to be essentially negligible (i.e., 10^{-5} to 10^{-6}), an IMAC was established, and improvement in methods of quantitation and/or treatment was recommended.

Chemicals That Are Possibly Carcinogenic

For compounds that are "possibly carcinogenic to humans" (Group III in Appendix A), the MAC was 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 was incorporated in the uncertainty factor to account for the limited evidence of carcinogenicity. In some cases where there were sufficient data (e.g., increased incidence of benign tumours at several sites in several

species), a quantitative estimate of tumour incidence was 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 chemical parameters. A number of pesticides considered to be "probably not carcinogenic to humans" or for which data on carcinogenicity were "inadequate for evaluation" (Groups IV and V in Appendix A) have been considered by the Food Directorate, Health Protection Branch, Health Canada (formerly Health and Welfare 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 (NDI), 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 in derivation of MACs and IMACs.

The World Health Organization (WHO), in conjunction with the Food and Agriculture Organization (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 the World Health Organization, MACs or IMACs were based upon FAO/WHO ADIs or provisional daily intakes, respectively.

Derivation of Aesthetic Objectives

In those cases where thresholds for organoleptic properties were less than the MAC, an "aesthetic objective" (AO) was derived, based on information on taste and odour thresholds reported in the literature.

Reference

Department of National Health and Welfare. Tap water consumption in Canada. 82-EHD-80, Environmental Health Directorate, Ottawa (1981).

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 levels of dose 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_R, multiplied by the sum of all the applicable radiation weighting factors, w_R:

$$H_T\ (Sv) = \Sigma\ w_R \times D_R\ (Gy)$$

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:

$$E\ (Sv) = \Sigma\ w_T \times H_T\ (Sv)$$

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, in addition to the possibility of hereditary effects, should be considered. 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^{-5} and 10^{-4} 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 6×10^{-3}.

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^{-6} per year, or about 6×10^{-4} 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:

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

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:

$$\frac{c_1}{MAC_1} + \frac{c_2}{MAC_2} + \ldots \frac{c_i}{MAC_i} \leq 1$$

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 were 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

Group I — 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

Group II — 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 VB — 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. 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) have been 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 were insufficient toxicological data to derive a maximum acceptable concentration (MAC) with reasonable certainty, interim values (IMACs) have been recommended, taking into account the available health-related data but employing a larger factor to compensate for the additional uncertainties involved. An interim value was also established for those substances for which estimated lifetime risks of cancer associated with the guideline (the lowest level that was practicably achievable) were 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) have been established for certain substances that are known or suspected to cause adverse effects on health. They have been 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, has been 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.