Appendix J

Development of THM Guidelines

CANADIAN DRINKING WATER GUIDELINES

DEVELOPMENT PROCESS

prepared by the

Federal–Provincial Subcommittee
on
Drinking Water

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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[1] departments of health and environment. The Secretariat for DWS is provided by Health Canada — specifically, the Drinking Water Section of the Environmental Health Directorate (Health Protection 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.**

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

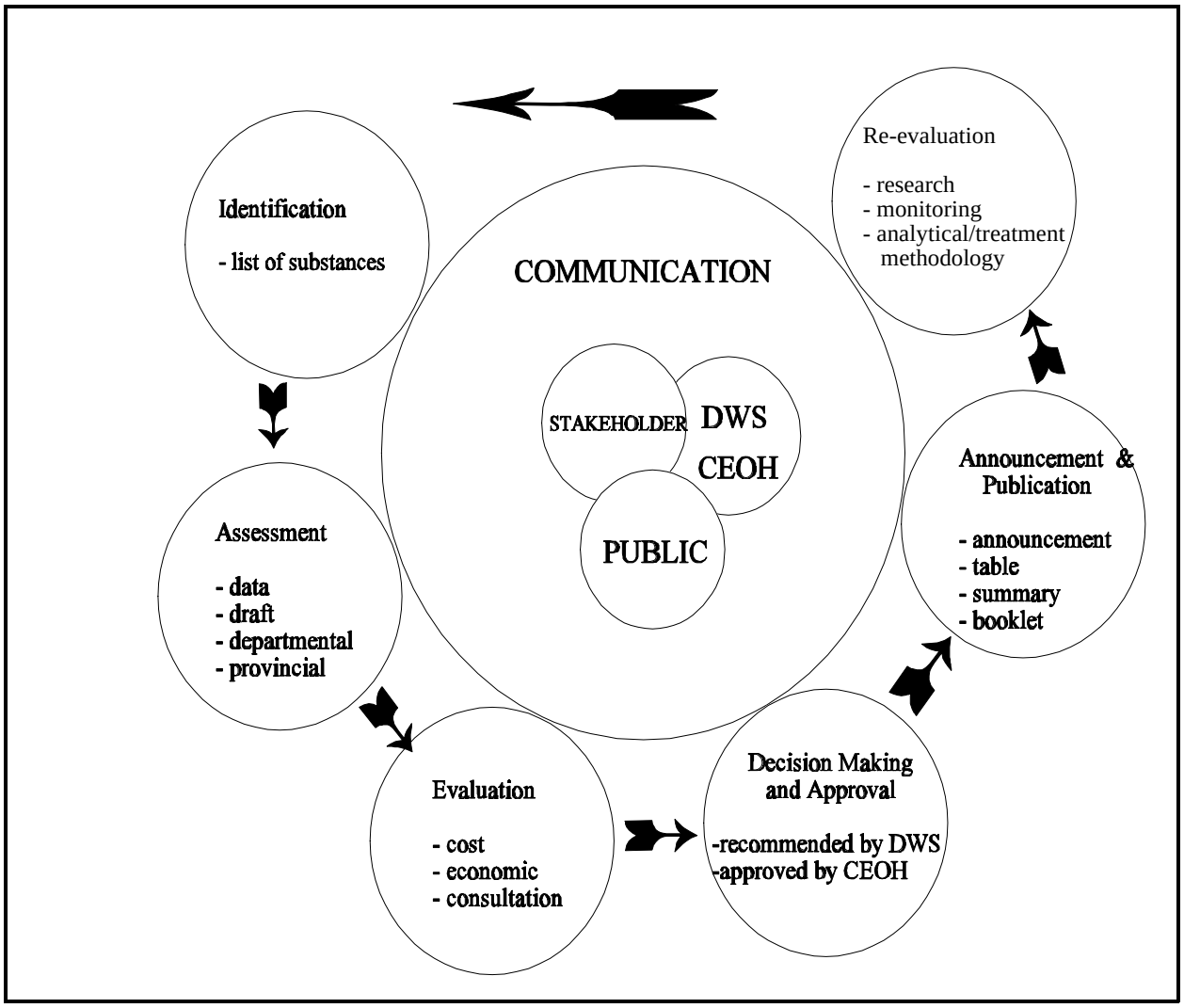

Figure 1 - Canadian Drinking Water Guidelines Development Process

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 timelier 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 on the level of concentration (elevated concentrations) 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 is available to rate the substance, it is rated using their experience and knowledge.

The Secretariat provides the health effects rating. Based on pre-health risk assessment or assessments from the US 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 heath 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 2 or 3 years.

DWS reviews the list every fall, and then submits it to CEOH for approval. If CEOH agrees with DWS' recommendation, further assessment of Substance X proceeds. If CEOH disagrees with DWS's recommendations, the substance would either be dropped from the assessment list or more information would be 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. Environmental Protection Agency (EPA) and/or the World Health Organization (WHO). For instance, the Secretariat is waiting until 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. This additional monitoring data for Substance X is 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**

direction criteria 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 2 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 Environmental Health 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. Environmental Protection Agency Drinking Water Program or a Member State of the World Health Organization. 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 focusses 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 Environmental Health Directorate. This committee, composed of senior staff from all appropriate divisions within the Directorate and additional experts from within the Health Protection 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 request 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. 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 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

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Terms of Reference

The Subcommittee on Drinking Water (DWS) shall provide timely advice to the Federal-Provincial 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[1] 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.

[1] "Province" ("provincial") is understood to include "territory" ("territorial").

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 co-ordinating 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

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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 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)[1]

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^{-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 direct detection methods available are difficult, costly, 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

[1] See Appendix B for definitions.

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 depends 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.

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[1]

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/ 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, 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.

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[1] This section is taken 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 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 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. Wherever 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^{-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) is significant, the upper 95% confidence limit for the lifetime cancer risk associated with the MAC is 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 are greater than those judged to be essentially negligible (i.e., 10^{-5} to 10^{-6}), 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 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 (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 the World Health Organization, 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.

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

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

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:

$E\ (Sv) = Ó w_T \times H_T\ (Sv)$

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 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^{-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:

$$\frac{C_1}{} + \frac{C_2}{} + \ldots \frac{C_i}{} \leq 1$$

MAC_1 MAC_2 MAC_i

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 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 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.

Chlorinated Disinfection By-Products (CDBPs)

Prepared for the CDBP Task Group

Introduction

The goal of water disinfection is the inactivation of microorganisms, such as viruses, bacteria and protozoa, that can cause serious illnesses and death. Although disinfection can be accomplished to a significant extent by a number of physicochemical water treatment processes, such as coagulation, sedimentation, filtration, lime-soda softening and adsorption, a specific chemical disinfection step is usually incorporated into surface water treatment process trains (see Figure 1) to prevent the transmission of waterborne diseases.

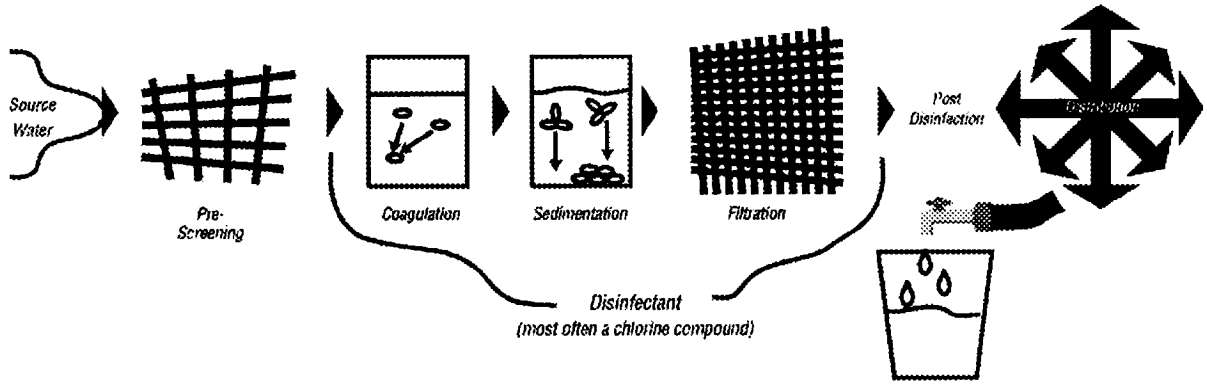

Figure 1: Conventional Treatment Process Train

The most commonly employed chemical disinfectant in drinking water treatment is chlorine. Because of concern over the health effects associated with the organic by-products of chlorination, however, the use of alternative disinfectants for primary or secondary (distribution system) disinfection, such as chloramines (secondary disinfectant only), ozone (primary disinfectant only) and chlorine dioxide (primary or secondary disinfectant), is increasing. However, each of these alternatives has also been shown to form its own set of disinfection by-products (DBPs).

DBPs are formed when chemical disinfectants react with DBP precursors. Natural organic matter (e.g., humic and fulvic materials, algal-derived organic matter), commonly measured by total organic carbon (TOC), serves as the organic precursor, while bromide ion serves as the inorganic precursor. In general, therefore, levels of DBPs are highest in treated water from sources with high organic matter content, such as rivers and lakes, and low when the source water is groundwater. Within a single water supply, however, DBP levels can vary greatly, depending on both water quality (e.g., TOC, bromide, pH, temperature, ammonia, carbonate alkalinity) and treatment conditions (e.g., disinfectant dose, contact time, removal of natural organic matter before the point of disinfectant application, prior addition of disinfectant).

Each individual chemical disinfectant can form a mixture of DBPs, and combinations of chemical disinfectants can form even more complex mixtures. Human exposure to DBPs is a function of both DBP concentration, exposure intensity (e.g. volume of water drunk per day) and exposure time. More specifically, human health effects are a function of exposure to complex mixtures of DBPs that can change seasonally/temporally (e.g., as a function of temperature,

nature and concentration of natural organic matter) and spatially (i.e., throughout the distribution system).

DBPs can be controlled through the removal of DBP precursors and through modifications of disinfection practice. Coagulation, granular activated carbon, membranes and ozone-biofiltration can all remove natural organic matter. Source water protection and control represent non-treatment alternatives to precursor control. Optimized use of combinations of disinfectants, functioning as primary and secondary disinfectants, can further control DBPs.

Although research continues to develop new treatment methods that will reduce the levels of by-products produced during disinfection, it is generally accepted that risks to health from these by-products at the levels at which they occur in drinking water are small in comparison with risks associated with inadequate disinfection. Thus, it is important that disinfection not be compromised in attempting to control such by-products.

Canadian Drinking Water Guideline for Trihalomethanes (THMs)

In 1993, the Federal-Provincial Subcommittee on Drinking Water (DWS) established a Canadian drinking water guideline of 100 μg/L for trihalomethanes (THMs), which are by-products of chlorine disinfection and which consist of chloroform, bromoform, bromodichloro-methane and dibromochloromethane. The guideline was based on the risk of cancer reported in animal studies from chloroform, the THM most often present and in greatest concentration in drinking water. It was also based on an annual average, to account for the fact that THM levels are generally highest in the summer and lowest in the winter. The guideline was designated as interim until such time as the risks from other DBPs are established; risk assessments for many other DBPs are still in preparation in Canada and other countries. It was not expected that all water systems would be able to meet the revised THMs guideline immediately. It was recommended that when water systems are expanded or upgraded, every effort should be made, not only to meet the revised guideline, but to reduce concentrations of THMs to as low a level as possible. Although the preferred method of controlling DBPs is precursor removal, it was emphasized that any method for DBP control employed must not compromise the effectiveness of water disinfection.

By 1998, new epidemiological studies had been published (including a Great Lakes basin cancer study sponsored by Health Canada) that reported associations between THMs and cancer (e.g., bladder, colon) and adverse pregnancy outcomes (e.g., miscarriage, birth defects, low birth weight). In response to these new findings, which raised concerns that the THMs guideline may not be sufficiently protective of human health, the DWS decided in April 1998 to reopen the THMs guideline.

In its role as Secretariat to the DWS, Health Canada (Environmental Health Directorate and Laboratory Centre for Disease Control) established a multi-stakeholder Chlorination Disinfection By-Products (CDBP) Task Group in July 1998 to oversee a comprehensive update of health risk information on THMs and to develop recommendations for controlling the risks (see Figure 2). This is being done through a series of subgroups that are evaluating human (epidemiological) and laboratory animal (toxicological) evidence of health effects from THMs, drinking water quality data and water treatment facility characteristics and costs for communities across Canada. The subgroups are likely to complete their interim reports by late 2000.

Ultimately, a risk/cost/benefit analysis will be conducted, and recommendations for health-based guidelines and treatment options for THMs and/or CDBPs will be developed. Following approval by the Task Group, these recommendations will be submitted for consideration by DWS. If necessary, the DWS could revise the THMs drinking water guideline as early as fall 2001.

Chlorine and Chloramine Disinfectants and their By-Products

Chlorine

Chlorine (Cl_2), in the form of hypochlorous acid/hypochlorite ion ($HOCl/OCl^-$), reacts with bromide ion, oxidizing it to hypobromous acid/hypobromite ion ($HOBr/OBr^-$). HOCl and HOBr react collectively with natural organic matter to form a variety of chlorinated DBPs, including THMs (chloroform, bromoform, bromodichloromethane and dibromochloromethane), haloacetic acids (HAAs: up to nine chlorinated/brominated species), haloacetonitriles (HANs: several chlorinated/brominated species), chloral hydrate and 3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone, or MX. The order of dominance is generally THMs > HAAs > HANs. Chlorinated THM, HAA and HAN species usually dominate over brominated species, except in waters with high bromide levels.

Trihalomethanes (THMs)

Levels of total THMs in treated water supplies often exceed 100 µg/L; however, average exposure to total THMs in chlorinated drinking water, from limited surveys, are about 35–50 µg/litre, with chloroform and bromodichloromethane being the first and second most dominant species.

The health effects associated with exposure to THMs are described in detail in Health Canada's *Guidelines for Canadian Drinking Water Quality — Supporting Documentation.*

Haloacetic Acids (HAAs)

A recent national survey suggests that the monitoring range for HAAs is 10–100 µg/L, with average levels of less than 50 µg/L; dichloroacetic acid (DCA) and trichloroacetic acid (TCA) are the first and second most dominant species.

HAAs are considered harmful to human health by both the U.S. Environmental Protection Agency (EPA) and the World Health Organization (WHO). DWS recommended that these DBPs be assessed due to their potential health hazard. The DWS Secretariat is currently in the midst of their evaluation of these DBPs.

HAAs have diverse toxicological effects in laboratory animals, including carcinogenic, reproductive and developmental effects. WHO has concluded that the induction of mutations by DCA is very improbable at the low doses that would be encountered in chlorinated drinking water. Most evidence suggests that the tumorigenic effects of DCA and TCA may depend on modifying processes of cell division and cell death rather than their very weak mutagenic activities.

DCA differentially affects the replication rates of normal hepatocytes and hepatocytes that have been initiated. At the low doses used in chronic animal studies, DCA initially stimulates the division of normal hepatocytes, but the cells' replication rate is eventually sharply inhibited. This indicates that normal hepatocytes eventually down-regulate those pathways that are sensitive to stimulation by DCA. Altered cells, particularly those that express high amounts of a specific immunoreactive protein, are unable to down-regulate this response, so that rates of replication in pre-neoplastic lesions with this phenotype are very high at doses that cause DCA tumours to develop with a very low latency. This continued alteration in cell birth and death rates may also be necessary for the tumours to progress to malignancy. WHO has suggested that currently available cancer risk estimates for DCA be modified by incorporation of newly developing information on its comparative metabolism and modes of action to formulate a biologically based dose–response

model; these data are not available at this time but should become available within the next 2–3 years.

TCA is a very weak activator of peroxisome proliferator activated receptor. Data suggest that TCA presents little carcinogenic hazard to humans at the low concentrations found in drinking water. From a broader toxicological perspective, the developmental effects of TCA are the endpoint of concern.

Data on the carcinogenicity of brominated acetic acids are too preliminary to be useful in risk characterization. Dibromoacetic acid has effects on male reproduction (e.g., marked atrophy of seminiferous tubules).

Only one epidemiological study has considered exposures to HAAs and various adverse pregnancy outcomes, but the study has not yet been published in the peer review literature.

Haloacetonitriles (HANs)

Concentrations of the various HAN compounds range from 1 to 40 µg/L; however, HANs are also formed *in vivo* following ingestion of chlorinated water.

There are no long-term toxicity studies for dichloroacetonitrile and dibromoacetonitrile; however, these DBPs, together with trichloroacetonitrile, are associated with developmental health effects. Health Canada is currently conducting animal toxicological studies on HANs.

One epidemiological study has considered exposures to HANs and various adverse pregnancy outcomes, but it has not yet been published in the peer review literature.

There are no appropriate human data or data from chronic animal studies with which to estimate carcinogenic risk from HANs.

WHO has concluded that there are no new data to suggest that the TDIs calculated for dichloroacetonitrile and dibromoacetonitrile in the 1993 *Guidelines for Drinking-Water Quality* should be changed. It has also concluded that no TDI can be established for trichloroacetonitrile.

There are no useful data for risk characterization purposes for other HANs.

Chloral Hydrate

Chloral hydrate can be found in drinking water at concentrations up to 100 µg/L, although concentrations in Canada are generally less than 25 µg/L, with an average of less than 10 µg/L.

Chloral hydrate is the one member of the haloaldehydes and haloketones group of DBPs for which there are limited toxicity data. There are no long-term studies. Health Canada and the U.S. EPA are conducting animal toxicological studies on this by-product.

Chloral hydrate has been shown to induce chromosomal anomalies in several *in vitro* tests but is largely negative when evaluated *in vivo.* It has been reported to cause hepatic tumours in mice after a 2-year exposure at 1 g/L drinking water. The liver tumours induced by chloral hydrate probably involve its metabolism to TCA or DCA, which are tumour promoters.

3-Chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone (MX)

WHO reports that levels of MX in drinking water are in the range 2–67 ng/L; no data are available on levels in Canadian drinking water supplies.

The critical effects of MX appear to be its mutagenicity (both *in vitro* and *in vivo*) and carcinogenicity.

MX caused chromosomal aberrations and induced DNA damage in isolated liver and testicular cells and sister chromatid exchanges in peripheral lymphocytes from rats exposed *in vivo.* Several *in vitro* studies have revealed that MX is mutagenic in bacterial and mammalian test systems.

A carcinogenicity study in rats showed increased tumour frequencies in thyroid and bile duct. Induction of thyroid follicular tumours could involve modifications in thyroid function or a mutagenic mode of action. A dose-related increase in the incidence of cholangiomas and cholangiocarcinomas was also observed.

Chloramines

Monochloramine is a secondary disinfectant, being added to maintain residual disinfection activity in potable water distribution systems. Mono-, di- and trichloramines are also by-products of drinking water chlorination, formed when water containing ammonia is chlorinated. Monochloramine is the most abundant and the most extensively studied chloramine. It can form cyanogen chloride (CNCl) and lower levels of chlorinated DBPs. The production of nitrite and nitrate in chloraminated distribution systems has also raised concern.

Cyanogen chloride is found in drinking water at concentrations ranging from 0.4 to 1.6 µg/L. It is metabolized to cyanide in the body. There are no health data available on cyanogen chloride for exposure via the oral route. EPA does not have a guideline for cyanogen chloride, and WHO, in its 1993 *Guidelines for Drinking-Water Quality*, recommended that the guideline value of 70 µg/L for cyanide be used as the guideline for total cyanogen compounds. Health Canada is currently assessing and evaluating the health effects database for this by-product.

Other Disinfectants and their By-Products

Chlorine Dioxide

Chlorine dioxide forms chlorite ion (ClO_2^-) and chlorate ion (ClO_3^-) by-products; organohalogen DBPs are not directly formed. Unlike the other disinfectants, the major chlorine dioxide DBPs are derived from decomposition of the disinfectant as opposed to reaction with precursors.

Chlorite is the predominant species formed. Formation of chlorite can be estimated by a simple percentage (50–70%) of the applied chlorine dioxide dose.

The toxic damage of chlorite is primarily in the form of oxidative damage to red blood cells at doses as low as 10 mg/kg body weight. There are also indications of mild neurobehavioural effects in rat pups and conflicting data on genotoxicity. Chlorite does not increase tumours in laboratory animals in chronic exposure studies.

The toxicity of chlorate is similar to that of chlorite, but chlorate is less effective at inducing oxidative damage. Chlorate does not appear to be teratogenic or genotoxic *in vivo*, and there are no data from long-term carcinogenicity studies.

Epidemiological studies to investigate the possible cancer risks that may be associated with drinking water disinfected with chlorine dioxide have not been conducted.

WHO has calculated a TDI for chlorite using a two-generation study in rats. A TDI was not derived for chlorate because a long-term study is in progress, which should provide more information on chronic exposure to chlorate.

Ozone

Ozone can react directly or indirectly with bromide to form brominated ozone DBPs, including bromate ion (BrO_3^-). In the presence of natural organic matter, non-halogenated organic DBPs such as aldehydes (e.g., formaldehyde), ketoacids and carboxylic acids are formed during ozonation. If both natural organic matter and bromide are present, ozonation forms HOBr, which, in turn, leads to the formation of brominated organohalogen compounds (e.g., bromoform).

Bromide concentration and ozone dose are the best predictors of bromate formation during ozonation, with about 50% conversion of bromide to bromate; brominated organic DBPs formed on ozonation generally occur at low levels.

Bromate induced a dose-related increase in benign and malignant renal cell tumours in both sexes of F344 rats when administered in drinking water. It gave largely negative results in bacterial mutagenicity tests, whereas positive results were obtained for clastogenic effects and DNA damage in all *in vivo* tests to date.

Health Canada has estimated cancer risks for bromate on the basis of renal cell tumours using the model-free extrapolation method. Although there is some discussion as to whether bromate carcinogenesis is a result of a threshold effect and whether rat toxicity data are relevant to humans given that bromate may be genotoxic via an indirect mechanism (lipid peroxidation) with a threshold, Health Canada has concluded that bromate must be considered a non-threshold carcinogen until additional research provides sufficient evidence to prove otherwise.

An interim maximum acceptable concentration (IMAC) of 10 µg/L for bromate was established, based on the ability of laboratories to measure bromate within reasonable limits of precision and accuracy using EPA Method 300.0, which has a practical quantitation limit of 10 µg/L. It is an interim guideline because the lifetime renal cancer risk associated with the ingestion of drinking water containing bromate at the IMAC is greater than the range that is considered generally to be essentially negligible. The IMAC will be reviewed periodically in light of developments in analytical and treatment technology and additional data on health risks associated with exposure to bromate in drinking water.

Conclusions

The predominant chlorinated DBP group has been shown to be THMs, with chloroform and bromodichloromethane as the first and second most dominant THMs. HAAs are the second predominant group, with DCA and TCA being the first and second most dominant species.

In contrast to THMs, which have been monitored over longer time frames because of regulatory scrutiny, monitoring data for HAAs, HANs and other DBP species in finished water and distribution systems are much more recent and hence sparse.

There are few long-term toxicological or epidemiological data available for DBPs other than THMs, bromate (for which a drinking water guideline has already been developed by Health Canada) and, to a lesser extent, HAAs. Several studies are in progress, which should provide toxicological data for many of the other DBPs over the next few years.

Although THMs are only one subgroup of the many DBPs formed during chlorination, they are useful as indicators of overall CDBP formation. It is concluded that, given the current state of knowledge, a risk assessment based on THMs would provide the greatest level of confidence regarding the ability of a drinking water guideline to protect against risks of cancer and other health effects.

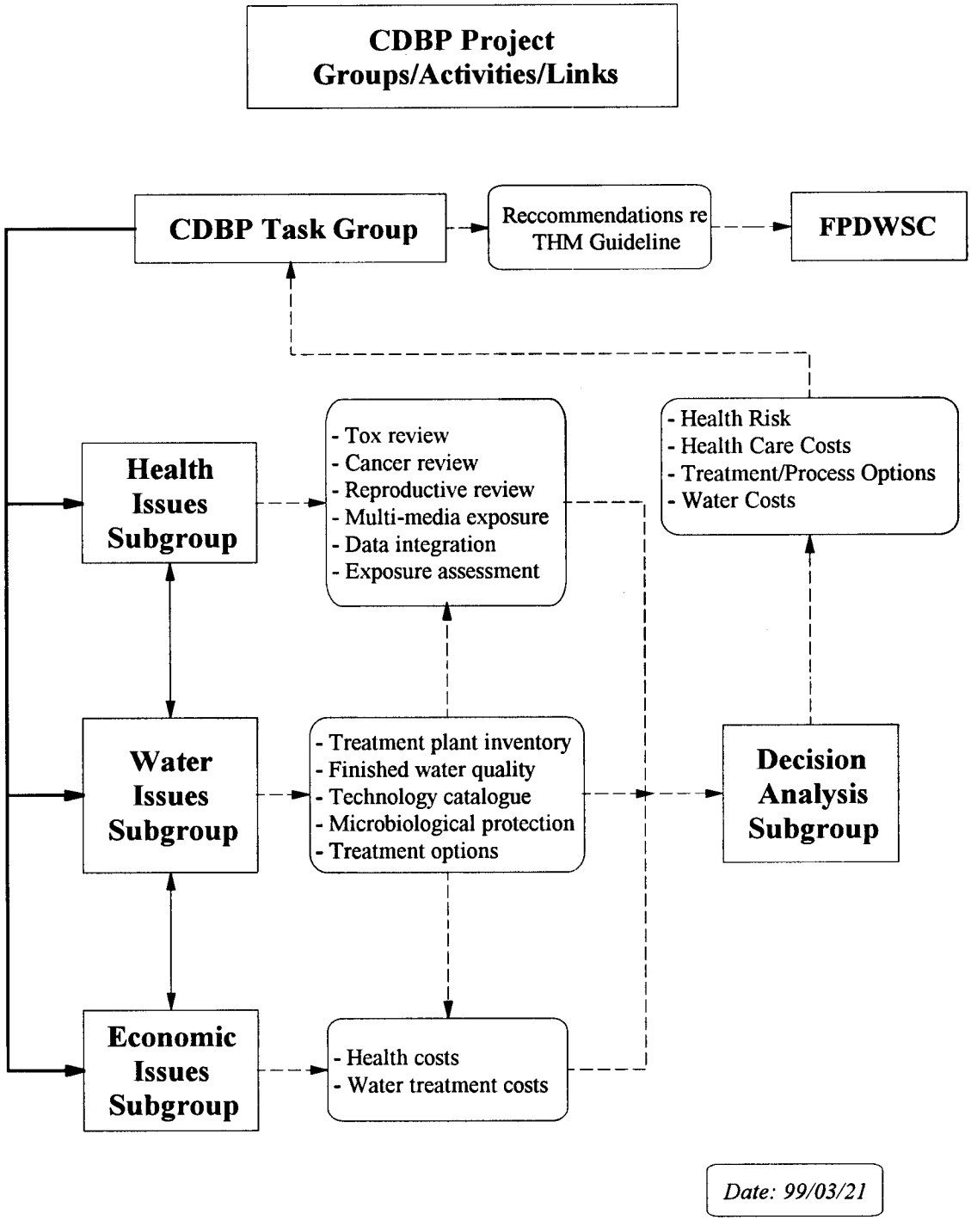

Figure 2. CDBP Task Group Project

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Health Canada Chlorinated Disinfection By-Products (CDBP) Task Group

The chlorine used to disinfect drinking water reacts with naturally occurring organic matter in water to form chlorinated disinfection by-products (CDBPs). Trihalomethanes (THMs) are a major group of CDBPs found in Canadian drinking water supplies and are frequently used as indicators for the presence of all CDBPs in drinking water. In 1993, the Federal-Provincial Subcommittee on Drinking Water (DWS) established a Canadian drinking water guideline for THMs (100 parts per billion) based on laboratory animal studies showing a risk of cancer from one of these compounds (chloroform).

Studies conducted since 1993, including a Great Lakes Basin cancer study sponsored by Health Canada have raised concerns that the THMs guideline may not be sufficiently protective against risks of cancer and other health effects. In response to these concerns, Health Canada has established a CDBP Task Group to comprehensively assess the risks from THMs in Canadian drinking water supplies and develop risk management recommendations.

The CDBP Task Group will oversee the updating of existing health risk estimates for THMs, the estimation of potential health care costs, an examination of available water treatment options and costs and the identification of additional benefits from improved water treatment. Ultimately a risk/cost/benefit analysis will be conducted and recommendations for an appropriate health-based THMs guideline and treatment options will be developed.

The document "Chlorinated Water and Health Effects" provides information on studies of health effects from CDBPs, the CDBP Task Group project and answers to commonly asked questions about the chlorination of drinking water.

As the work of the CDBP Task Group is just getting underway, this page will be updated periodically with progress reports and other information on the work of the Task Group.

For further information:

Water Chlorination - IYH

Water Treatment Devices (For Microbiological Purification of Water) - IYH

Drinking Water Guidelines - IYH

Summary of Guidelines for Canadian Drinking Water

Chlorinated Disinfection By-Products (CDBPs) (pdf format)

Water Treatment Devices – for the Removal of Taste, Odour and Chemicals - IYH (pdf format)

Undiluted Truth About Drinking Water

Health Risks of Drinking Water Chlorination By-products: Report of an Expert Working Group

National Survey of Chlorinated Disinfection By-Products in Canadian Drinking Water

A One-Year Survey of Halogenated Disinfection By-Products

Assessing Exposure to Disinfection By-Products in Epidemiologic Studies

Great Lakes Water and Your Health (pdf format)

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