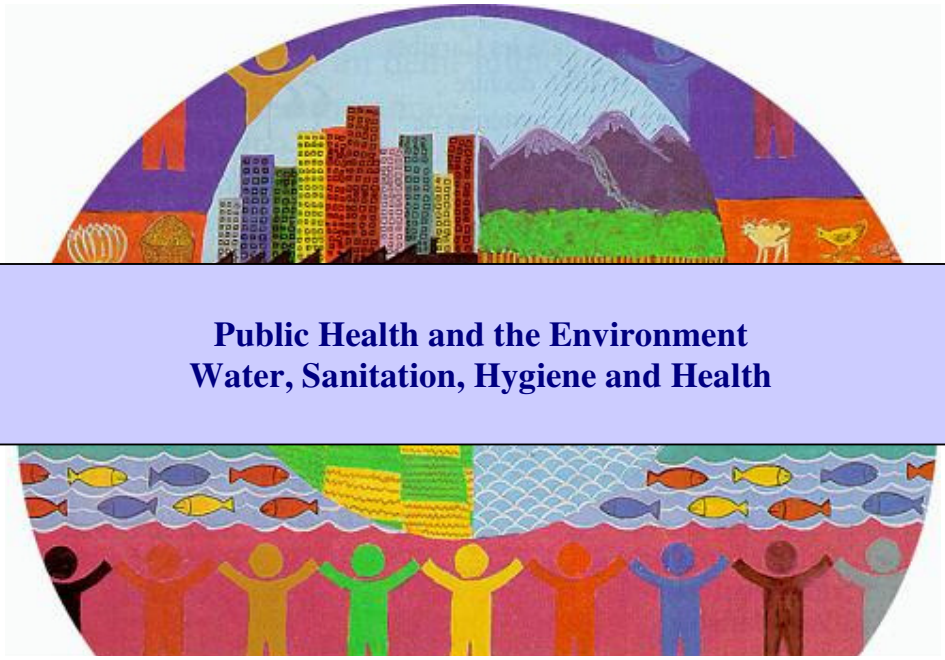
World Health Organization

WHO Guidelines for Drinking-water Quality

Policies and Procedures used in updating the WHO Guidelines for Drinking-water Quality



Public Health and the Environment
Water, Sanitation, Hygiene and Health

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List of abbreviations

ADI	Acceptable Daily Intake
BMD	Benchmark Dose
BMDL	Benchmark Dose Lower Confidence Limit
CICAD	Concise International Chemical Assessment Document
CSAF	Chemical-specific Adjustment Factor
DALY	Disability Adjusted Life Year
DWQC	(WHO) Drinking Water Quality Committee
EHC	(IPCS) Environmental Health Criteria document
FAO	Food and Agriculture Organization of the United Nations
FTF	Final Task Force
GDWQ	(WHO) Guidelines for Drinking-water Quality
GV	(WHO Drinking-water Quality) Guideline Value
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest Observed Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
PIC	Prior Informed Consent
POP	Persistent Organic Pollutants
TDI	Tolerable Daily Intake
UF	Uncertainty Factor
WG	Working Group
WHO (HQ, RO)	World Health Organization (Headquarters, Regional Office)
WHOPES	WHO Pesticides Evaluation Scheme

A Background

A.1 The first World Health Organization (WHO) publication dealing specifically with drinking-water quality was published in 1958 as International Standards for Drinking-water. It was subsequently revised in 1963 and in 1971 under the same title. In 1984-85, the first edition of the WHO Guidelines for Drinking-water Quality (GDWQ) was published in three volumes: Vol. 1 – Recommendations; Vol. 2 – Health Criteria and Other Supporting Information; and Vol. 3 –Surveillance and Control of Community Supplies. The second editions of the three volumes of the GDWQ were published in 1993, 1996 and 1997 respectively. Addenda to Volumes 1 and 2 were published in 1998 and 1999 (addressing selected chemicals only) and an addendum on microbiological agents in drinking-water in 2002. In 2004, the third edition of Volume 1 of the GDWQ was published, and the first addendum to this edition in 2006.

A.2 The main reason for promoting the adoption of guidelines, rather than international standards for drinking-water quality, is the advantage provided by the adoption of a risk-benefit approach whether quantitative or qualitative and of preventive management operating from catchment to consumer.

A.3 In developing standards and regulations, care should be taken to ensure that scarce resources are not unnecessarily diverted to the development of standards and the monitoring of substances of relatively minor importance. This approach should lead to standards and regulations that can be readily implemented and enforced and are protective of public health

Purpose and content of the GDWQ

A.4 The primary purpose of the GDWQ is the protection of public health. It is intended that the GDWQ be used as guidance to countries and to others as to what constitutes safe drinking-water and safe water supply.

A.5 The GDWQ are intended to be used in the development of risk management strategies. These may include national or regional standards developed from the scientific basis provided in the GDWQ, adapted to take account of local or national environmental, socio-cultural (including dietary) and economic conditions.

A.6 The GDWQ provide the scientific point of departure for standard setting and regulation. They may describe evidence-based guidance on reasonable minimum requirements of safe-practice to protect the health of consumers and progress towards improving water safety. They may also derive numerical “guidelines values” for constituents of water or indicators of water quality.

A.7 The GDWQ include an assessment of the health risk presented by the various microbial, chemical, radiological and physical constituents that may be present in drinking-water. The GDWQ define the criteria used to select the various constituents addressed.

A.8 The GDWQ describe the approaches used in deriving guidelines, including numerical “guideline values”, and explain how guidelines for drinking-water quality are intended to be used.

A.9 The GDWQ themselves may be accompanied by separate texts that provide background information substantiating or elaborating on the recommendations included in the GDWQ. A current list of such documents is in Annex A.

A.10 The GDWQ themselves may also be accompanied by separate texts providing guidance on good practice towards effective implementation of the guidelines. A list of such documents is in Annex A.

Development of the GDWQ

A.11 The GDWQ are kept up-to-date through an ongoing "rolling revision" process.

A.12 Guidelines are based upon the best available evidence and scientific consensus.[1]

A.13 The GDWQ are derived so as to take account of the needs of an individual through a normal lifetime, including changes in sensitivity that may occur between life stages. Those at greatest risk of waterborne disease are infants and young children, people who are debilitated or living under unsanitary conditions and the elderly. Exclusions, such as particularly sensitive sub-populations (including the sick and immunocompromised) may be specifically defined.

A.14 Exposure assumptions are adapted from those in the Environmental Health Criteria (EHC) monograph 170. . A daily per capita consumption figure of two litres of drinking-water for adults weighing 60 kg is used in the calculation. A 10 kg child is assumed to drink one litre of water per day and a 5 kg infant is assumed to consume 0.75 litres per day. The difference between boiled and unboiled water consumption may be important for some hazards especially microbial agents. It is assumed, where appropriate, that 50% of water consumed has been boiled, for example in food and beverage preparation.

A.15 The GDWQ *per se* are the collective product of many experts and of extensive recovered experience. While contributions are acknowledged, WHO is identified as the "author" of the GDWQ. For some technical substantiation and guidance on good practice published outside the GDWQ themselves, it is often appropriate to attribute authorship and/or editorship of contributions. This should not be allowed to detract from the pursuit of wide and balanced contribution.

Application of the GDWQ

A.16 The GDWQ are intended to be applicable to water used for all usual domestic purposes, including consumption, bathing and food preparation. They are applicable to large metropolitan or small community piped drinking water systems or to non-piped drinking water systems, including at household level. They are applicable to ice intended for human consumption. Exclusions are specifically defined (such as for dialysis, cleaning of contact lenses). Explanation is provided in the GDWQ regarding the application of the GDWQ in specific circumstances, such as for desalinated water, water for travellers, bottled/packaged water, water in health-care facilities etc.

[1] Consensus is defined by the International Organisation for Standardisation (ISO) as "General agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile conflicting arguments." NOTE: Consensus need not imply unanimity.

A.17 The judgement of safety - or what is a tolerable risk in particular circumstances - is a matter in which society as a whole has a role to play. The final judgement as to whether the benefit resulting from the adoption of any of the guidelines given in the GDWQ justifies the cost is for each country to decide. What must be emphasized is that the GDWQ have a degree of flexibility and enable a judgement to be made regarding the provision of drinking-water of acceptable quality. The advantage of a risk-benefit approach is emphasised (see A.2). When uncertainties exist, caution may be appropriate in setting drinking-water standards.

B Purpose of this document

B.1 This document describes the "rolling revision" process through which the GDWQ are developed and revised. The purpose of both the process and of this document is to maintain the relevance, quality, credibility and integrity of the GDWQ, while ensuring their continuing development in response to new, or newly-appreciated, information and challenges.

B.2 The procedures followed in the updating of the GDWQ are made accessible in order that interested parties may contribute at appropriate stages and in order that information and information needs may be fed into the process.

B.3 The document has no formal or legal status and is released for advisory purposes only. This version supersedes a previous version dated May 2005, and is subject to annual review and revision through the GDWQ Expert Consultation process.

C Basic principles

C.1 Water is essential to sustain life, and an adequate supply which is safe for lifetime consumption, should be available to all persons.

C.2 Every effort should be made to achieve a drinking-water quality as high as possible. The existence or implementation of a Guideline does not imply that a high quality supply should be allowed to degrade to a minimum requirement.

C.3 The quality of drinking-water may be controlled through a combination of protection of water sources, selection and control of treatment processes and management of the distribution and storage and handling of water.

C.4 Reliance on final product water quality determination alone is insufficient to protect public health. As it is neither physically nor economically feasible to test for all drinking-water quality parameters equally, monitoring effort and resources should be carefully planned and directed at significant or key characteristics identified using site specific risk assessments.

C.5 The potential consequences of microbial contamination, which usually include acute effects and may be widespread, are such that its control must always be of paramount importance and must never be compromised.

C.6 The health risks caused by toxic chemicals in drinking-water differ from those caused by microbial contamination. They arise primarily from the fact that chemicals frequently cause adverse health effects only after prolonged periods of exposure. There are few chemical constituents of water that can lead to acute health problems except through massive accidental contamination of a supply. In such incidents, the water often becomes undrinkable owing to

unacceptable taste, odour, and appearance. These factors place toxic chemicals in a lower priority category than microbial contaminants. Chemical contaminants that are of particular concern are those few that have been shown to cause adverse effects in human populations through drinking-water.

C.7 The use of chemical disinfectants in water treatment usually results in the formation of chemical by-products, some of which are potentially hazardous. However, the risks to health from these by-products are extremely small in comparison with the risks associated with inadequate disinfection. Disinfection should not be compromised in attempting to control such by-products.

C.8 The health risk associated with the presence of naturally occurring radionuclides in drinking-water should also be taken into consideration, although the contribution of drinking-water to total exposure to radionuclides is very small under normal circumstances.

C.9 Biological, chemical and physical constituents of water may affect the appearance, odour, or taste of water, and the consumer will often evaluate the quality and acceptability of the water on the basis of these criteria. Water that is highly turbid, is highly coloured, or has an objectionable taste or colour may be regarded by consumers (rightly or wrongly) as being unsafe, and may be rejected for drinking purposes. It is therefore important to maintain a quality of water that is acceptable to the consumer, in addition to ensuring its safety. Aesthetic and organoleptic characteristics are subject to individual preference as well as social, economic and cultural considerations. For this reason, although general guidance can be given on the levels of substances that may be aesthetically unacceptable, in the GDWQ no guideline values are set for such substances where they do not represent a potential direct hazard to health.

C.10 Where it is appropriate to apply a "reference level of risk"[2] in guideline derivation, the reference level used is 10^{-6} disability adjusted life years (DALYs) per person per year. This is applied to microbial pathogens. Reference risk may also be applied to carcinogens for which there is no evidence of a threshold. The reference risk used in this case, is approximately equivalent to a lifetime excess cancer risk of 10^{-5}. The application of DALYs requires sufficient exposure and epidemiological data.

D The Drinking-water Quality Committee, its Working Groups and Coordinators

D.1 The rolling revision of the GDWQ is guided and supported by the WHO Secretariat, housed within the "Water, Sanitation, Hygiene and Health " unit, at WHO Headquarters (HQ), in partnership with WHO's Regional Offices (ROs).

D.2 The Drinking-Water Quality Committee (DWQC) advises the WHO Secretariat on the development and revision of the GDWQ and associated guidance. Its specific purposes are:

- To identify areas in which WHO should develop or revise guidelines and/or guidance on good practice concerning drinking-water quality.
- To oversee the process of development of such guidelines and/or guidance so as to ensure that the product reflects best available evidence and scientific consensus, and/or the recovery and critical evaluation of experience.

[2] The term "reference level of risk" is used because this risk has been adopted for the purposes of comparing the overall health burden in populations.

The DWQC acts through full meeting and through meetings of one or two of its Working Groups (WGs), where the subject at hand is fully within their remit.

D.3 Individual experts are invited to serve as members of the DWQC. Members are selected primarily on the basis of excellence, independence, relevance of their expertise, and willingness to support the work of the DWQC. Where possible, staff of WHO Collaborating Centres concerned with water is preferred. In selecting DWQC members, effort is also made to ensure overall balance of expertise and reasonable geographic and gender balance.

All members of the DWQC and its WGs are invited to serve as individual scientists and not as representatives of any government or other organization.

All DWQC members and experts invited to meetings of the DWQC are expected to sign a Declaration of Interest, demonstrating their ability to participate impartially in the conduct of the meeting, as a prerequisite to participation. Any potential conflict of interest should be declared in advance to WHO. This does not necessarily exclude the person from participating in debate. They will, however, refrain from participating in decision-making processes related to their particular area of conflicting interest.

D.4 WGs of the DWQC are established to respond to priorities and the need for development of areas of guidance.

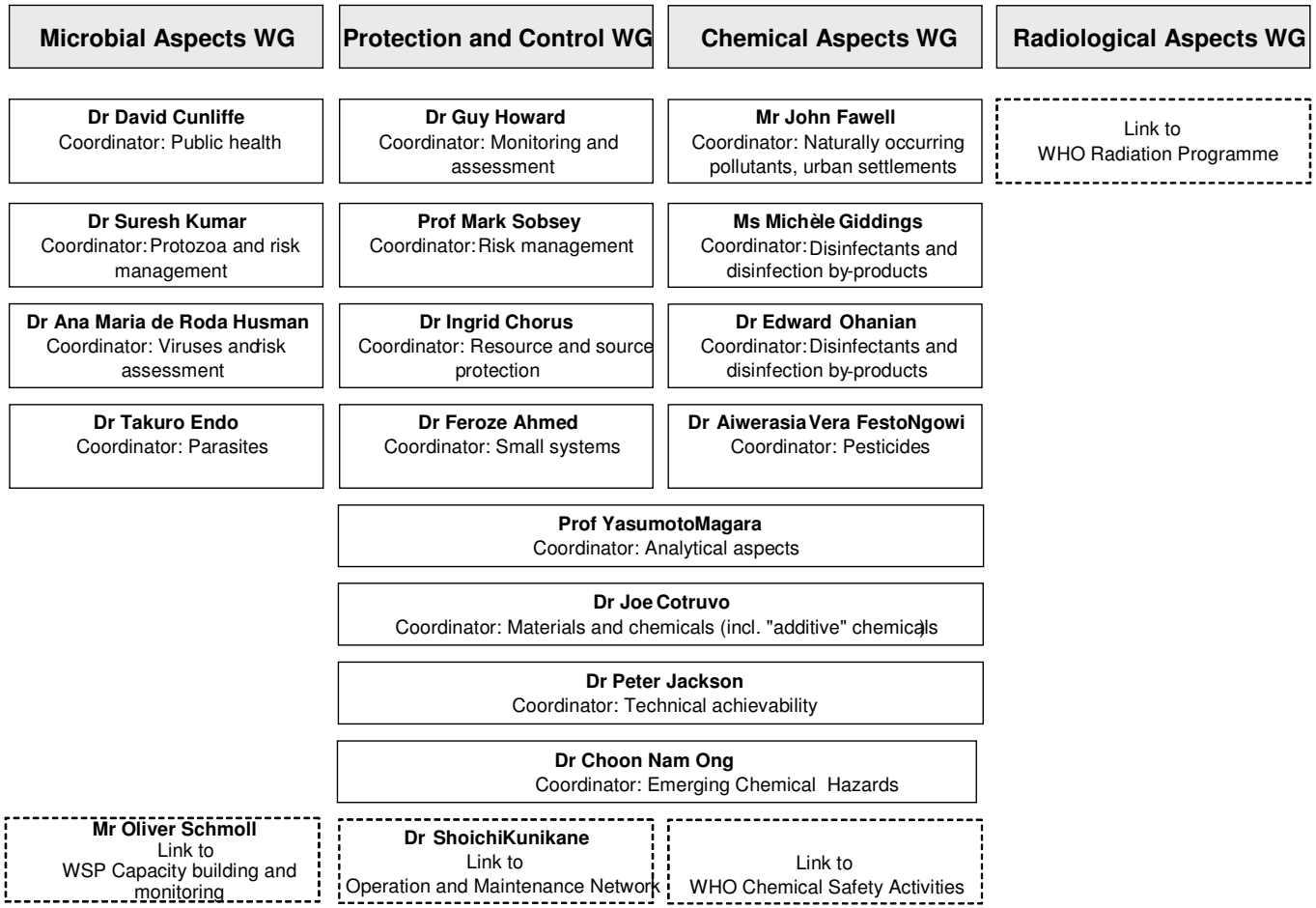
D.5 The DWQC presently comprises the four or five experts who constitute each of three WGs (addressing microbial aspects, chemical aspects and aspects of protection and control of drinking-water quality) as summarised in Figure 1.

D.6 Members of WGs are referred to as “coordinators” inasmuch as they coordinate the task of preparing documents for specific areas of the guideline development work (i.e. each item of the work programme is coordinated by a WG member). A Coordinator, in collaboration with the WHO Secretariat:

- Advises and guides the author(s);
- Ensures time targets are met;
- Communicates and collaborates with both author(s) and reviewer(s);
- Passes reviewer comments to author(s) for response, as appropriate and assists in their resolution and preparation of comment reconciliation statements, if required;
- Ensures background materials are available to the WG and ensures that proper records are kept of all necessary information.

In order to achieve proper functioning of the WGs, it is essential for the Coordinators to interact with each other on specific topics, as required. A Coordinator should have expertise in the particular technical area for which he/she is responsible. It is expected that coordinators communicate with authors and reviewers mainly through electronic means.

Figure 1: Drinking-water Quality Committee structure



D.7 Representation from each of the WHO Regions on the DWQC is encouraged - whether through Regional Office staff or through nominated experts at DWQC meetings. Individuals serving in this capacity are expected to:

- Bring regional views and concerns to the attention of the DWQC and its WGs;
- Ensure participation of suitable regional experts and collaborating institutions within the region and seek their positive involvement in the process, including identification of priorities and the development and review of documents;
- Seek to promote the awareness of the GDWQ and their review process in the region, particularly in those areas with poor access to the internet;
- Ensure feedback on important developments related to drinking-water quality matters to the region;
- Disseminate the GDWQ and assist countries in their implementation; and
- Develop, jointly with WHO HQ, guidance or aspects thereof, which is of specific regional interest.

To perform these roles appropriately, a long-term focal point for GDWQ-related activities in each Region is preferred.

D.8 Coordination with the International Programme on Chemical Safety (IPCS) is especially important for the Chemical Aspects WG and some areas of work of the Protection and Control WG. The roles of IPCS in respect of the GDWQ include:

- Bringing to the attention of the WG information concerning ongoing activities in IPCS and amongst its contacts which would indicate that the WG should consider or reconsider a specific chemical or general issue in risk assessment of guideline value derivation;
- Taking account of the information requirements of the WG and its processes (especially chemical reviews/risk assessments) and to follow-up in securing them in a timely manner;
- Between WG meetings to monitor and follow-up the above and inform WG members of progress and developments; and
- For substances referred to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), to follow-up progress and activity, to attend corresponding meetings and to liaise with WG members accordingly.

In order to satisfy the above, a specific contact person from the IPCS programme is identified and normally attends chemical WG, DWQC and Final Task Force (FTF) meetings.

Coordination with other WHO programmes, for example those dealing with nutrition, infant health, dental health and vector control is also essential because of their relation to the GDWQ.

D.9 Experts supporting the programme of work of the DWQC may be invited to attend meetings of the DWQC or its WG, where they are actively engaged in associated activities and their contribution to the meeting is considered important.

D.10 Observers may be invited to meetings. They may be invited to comment on draft documents and to make their views known, but they may not participate in the final recommendation on guidelines. Observers will be identified (indicating their professional affiliations and potential conflicts of interest) as such from the start.

D.11 Expert consultation meetings may be organized to provide detailed advice to the DWQC on a particular topic.

E Process for revision of the Guidelines for Drinking-water Quality

E.1 A transparent process has been adopted for the revision of the GDWQ including making provision for comments through open consultation. The process is described in this document.

E.2 The process of revising the GDWQ should be consistent with processes used in other parts of WHO, especially with those for normative work. Every effort is made in the case of the derivation of guidelines for chemical parameters to be consistent with the processes of the IPCS; in the case of microbial hazards, to be consistent with approaches of the Assessment and Management of Risks Programme more broadly and the Food Safety Programme; and in the case of radiological hazards, to be consistent with the approaches of the WHO Radiation Programme. Consistency is also sought with the International Health Regulations.

E.3 The overall scheme used to develop guidelines and guidance is outlined in Table 1 and is common to all aspects of GDWQ documentation.

E.4 DWQC members and meeting attendees are expected to respect the flow of consultation outlined in Table 1 and, for example, would be expected not to release documents for wider view prior to Stage 7.

E.5 Data in the public domain, published in the peer-reviewed literature are the principal and preferred sources of information for use in deriving guidelines. For derivation of chemical guideline values they should meet well-defined content and data presentation criteria. Confidential, unpublished data, are accepted only when they have undergone evaluation and peer-review by a WHO body, such as JMPR, or by a similar recognized, international organization.

E.6 FTF meetings (see Table 1) are attended by the DWQC and government-nominated experts. FTF experts are nominated by countries to serve in that capacity and selected on the basis of technical excellence and relevance of expertise. Geographic and gender balance are taken into account as far as possible in selection of experts to participate in FTF meetings.

Table 1: Process for GDWQ document preparation and adoption

Stage[3]	Status	Notes
Stage 0 (WHO Secretariat and Coordinator)	Proposals received from external source	Proposal evaluated by WHO Secretariat and corresponding Coordinator and either direct response prepared or proposal to DWQC prepared.
Stage 1 (WG)	A Coordinator, through the WG, submits a proposal to the DWQC	A proposal would normally comprise justification, proposed action, proposed author – already approached regarding willingness to contribute – and tentative list of peer-reviewers, and would not normally exceed one page.
Stage 2 (DWQC)	The DWQC reviews the proposal and either	Decision to place an item on the programme of work (or not) would normally be taken at DWQC meeting.
	• Recommends no action (with an explanation); or	A decision and explanation that a review was not needed would normally be reviewed by the corresponding WG and published in the same way as a conclusion that a review was under way.
	• Agrees to the proposal (with comment if appropriate)	The agreed course of action (document description) is recorded in the report of the meeting. The agreed author then prepares the first draft of the document.
Stage 3 (Coordinator)	A review/document has been prepared to the satisfaction of the Coordinator and author(s) and a list of proposed peer-reviewers prepared	For chemical review documents, see footnote[4].
Stage 4 (WG)	The WG has reviewed the draft document and proposed list of reviewers and agreed that it is suitable for release for peer-review	This stage would normally be conducted by correspondence and would not require a WG meeting. The Coordinator initiates peer-review[5] immediately this stage is reached and liaises with the authors in taking account of the comment received.
Stage 5 (Coordinator)	The review document has been subject to peer-review, revised to take account of comments received (and peer-review reconciliation prepared if necessary) to the satisfaction of author(s) and the Coordinator[6]	For chemical review documents only, a truncated review (including the guideline value and identification of the critical study) is made available for public domain comment for a minimum of three and normally six months in parallel with peer-review and comments received are treated alongside peer-review comments.

[3] Passing of stage indicates authority to proceed to next stage. A document may move back at any stage and any number of stages in response to new information or other substantive change.

[4] (i) Use is made of recent IPCS risk assessment monographs, where available, or one or more high quality national reviews; (ii) any new evidence, especially epidemiological evidence relevant to drinking-water, is added or highlighted; (iii) the text should propose the critical study and a value for the TDI or equivalent or unit risk as appropriate, drawing on IPCS conclusions, if any, and on the method in EHC 170 Guidance Values for Human Exposure Limits; (iv) the list of peer reviewers would automatically include all IPCS contact points, the review will have incorporated information from the Protection and Control WG on reasonable technical achievability and from the Chemical Aspects WG on reasonable analytical achievability.

[5] Terms of reference for peer-review are given in Annex D.

[6] Instructions to authors on how to respond to peer-review comments are given in Annex E.

Stage[3]	Status	Notes
Stage 6 (WG)	The WG is satisfied with the document and that proper process has been followed and recommends release to public domain for comment	This stage would normally be passed at a WG meeting. The document is then posted on the internet site of WHO, with an invitation to comment; its availability is announced via listserve message including to all DWQC members and WHO Collaborating Centres concerned with water; hard copies are available from WHO HQ and ROs on request for countries with low internet capability. ROs advise appropriate entities in Member States of its existence. Availability in the public domain for comment is normally three months and not less than six weeks.
Stage 7[7] (Coordinator)	The document has been revised to take account of appropriate comments received (and a comment reconciliation statement prepared if needed) to the satisfaction of the coordinator and author(s)[8]	This stage would normally be completed by correspondence, unless substantive comment had been received.
Stage 8 (WG)	The WG is satisfied with the document and that proper process has been followed and recommends it to the DWQC for adoption.	The stage would normally be completed by correspondence, unless substantive comment had been received.
Stage 9 (DWQC)	The DWQC is satisfied with the document and that proper process has been followed and recommends its publication.	This stage requires a DWQC meeting. Completion of stage 9 and all proceeding stages constitutes adoption for substantiation documents and documents providing guidance on good practice in implementation. Where specific guideline requirements or guideline values are under discussion, this takes place at the annual DWQC meeting and is subsequently endorsed at a FTF meeting.
Stage 10 (FTF meeting)	For GDWQ documents themselves including adoption of guideline requirements and guideline values	Endorsement by a FTF meeting constitutes adopting for GDWQ themselves, guideline requirements and guideline values.

[7] On rare occasions, when document finalization is legitimately urgent and where no substantive change is likely to emerge from peer-review (stage 5) it may be appropriate to undertake peer-review and public domain review in parallel. Were this to be done and substantive changes arise from the peer-review process, then the public domain review is repeated.

[8] Instructions to authors on how to respond to public domain comments are given in Annex E.

F Guidelines for microbial safety

F.1 The GDWQ for microbial safety incorporate the use of quantitative microbial risk assessment and epidemiological evidence as a basis for estimating effects of improved drinking water quality and for setting health based targets. The GDWQ describe an approach for calculating performance targets to reduce concentrations of microbial pathogens present in source waters to achieve specified levels of acceptable risk. Measures to achieve microbial reductions and reduce risk, including catchment protection and treatment processes are provided. The GDWQ also provide guidance on the use of health outcome targets, water quality targets, and specified technology targets

F.2 It is impractical to set targets for all microbial pathogens due to lack of sufficient information to enable calculation of health risk or data on occurrence in source water. A more practical approach is to use appropriate reference pathogens. Reference pathogens should be significant water-borne organisms for which sufficient data of appropriate quality is available to enable a quantitative risk assessment to be performed as well as information on occurrence in source waters and removal by treatment processes.

Control of reference pathogens should be indicative for all pathogens of concern and typically means inclusion of representative bacteria, virus and parasites.

F.3 The GDWQ describe how to perform microbial risk assessments, include summary data for *Cryptosporidium*, *Campylobacter* and rotavirus as reference pathogens, and illustrate how to use this data to calculate performance targets.

Microbial risk assessment requires information on dose response, risk of illness following infection, disease burden (DALYs per case) and the fraction of the population that is susceptible to infection. Dose response information generally comes from human volunteer studies or epidemiological investigations. Information on risk of illness following infection, disease burden and the fraction of the population that is susceptible to infection can be obtained from a number of sources including investigations, medical registries and national data bases. Disease burdens need to include all outcomes including acute and chronic responses and the incidence and severity of each response. Disease burdens can vary widely in different areas and regions and data needs to be relevant to local circumstances. Further information on quantifying disease burdens in terms of DALYs is described in the supporting document “Quantifying Public Health Risk in the WHO Guidelines for Drinking-water Quality”.

Existing examples in the GDWQ can be revised and additional examples can be included subject to availability of sufficient data of appropriate quality. Additions should meet the requirements of a reference pathogen.

Detailed microbial risk assessments for individual reference pathogens can also be developed as stand alone documents (see F.8 below).

F.4 Default values based on available data are presented on concentrations of a limited number of pathogens and index micro-organisms in source waters. The values are provided as a guide for use in the absence of source specific data. High quality published data is limited with results on pathogen occurrence often not being published or accessible.

F.5 Reductions of enteric bacteria, viruses and parasites achieved by typical and enhanced treatment processes are presented. The information, together with information on microbial pathogen reductions resulting from source water protection measures, will be revised or expanded to include additional processes subject to availability of information including performance data. This includes validated data on removal of microbial hazards.

F.6 The traditional approach to assessing faecal pollution and verifying safety of drinking water has been based on testing of indicator organisms. The organism of choice is *E. coli* (or thermotolerant coliforms). However, *E. coli* has shortcomings as an indicator of viruses and parasites that are more resistant to treatment. In addition it has become clear that no single organism can indicate both faecal pollution and treatment efficiency. To deal with these requirements two types of organism have been identified:

- index organisms (e.g. *E. coli*) which point to the presence of faecal pathogens; and
- indicator organisms which measure the effectiveness of treatment processes.

Information on index and indicator organisms is included in fact sheets. The use of indicator and index organisms is an expanding and changing area.

F.7 Reviews of waterborne bacteria, viruses, parasites, helminths and hazardous cyanobacteria are included in GDWQ fact sheets. The selection of organisms for review is based on documented evidence of waterborne transmission in multiple countries or frequently expressed concern. Fact sheets need to include a description of the organism and information on human health effects, source and occurrence, routes of exposure, significance in water and mechanisms for controlling risk and reducing burden of disease.

F.8 Specific microorganisms warranting more detailed discussion than that provided in fact sheets are dealt with in stand-alone background documents. These can include reference pathogens, organisms identified as causing a substantial burden of disease through waterborne transmission and organisms of sustained concern expressed from multiple regions. A standard format for these documents is included in Annex C.

G Guidelines on chemical safety

G1 Overall approach

General

G1.1 Guideline values are derived for appropriate chemical constituents of drinking-water. A guideline value represents the concentration of a constituent which does not result in any significant risk to health over a lifetime of consumption.

G1.2 Because of the large number of chemicals which may occur in drinking-water, guidance is provided on priority identification to take account of specific conditions at local/regional/national levels.

G1.3 In the third edition of the GDWQ, the term “technical achievability” is used for chemicals used in water treatment or for chemicals from materials in contact with drinking-water. The main consideration for these chemicals is the management of contamination, which will relate to the way in which these devices and materials are used. For this reason, the term “practical considerations” will now be used.

Default assumptions for chemical guideline derivation

G1.4 It is necessary to make some assumptions in developing guideline values for chemicals, because a guideline value cannot take into account all of the variation and limitations relating to the available data on aspects such as exposure and observed health effects. In preparing guidelines, a number of values and approaches are applied. It is permissible to move from these values, but this requires appropriate justification in the discussion of the guideline derivation in the background document.

Drinking-water consumption and body weight

G1.5 Global data on the consumption of drinking-water show large variation in intake in different parts of the world. Data from studies carried out in temperate countries including, Canada, the Netherlands, the United Kingdom and the USA indicate that average daily per capita consumption is usually less than 2 litres, but there was considerable variation between individuals, particularly for those who have a high level of physical activity. A significant proportion of water required for hydration will come from food but this will also vary in different parts of the world. The range of water intake, in food and fluids, required for hydration ranges from 2 to greater than 4 litres depending on climate and physical activity. There is also a sharp rise in fluid intake at temperatures above 25°C, largely to meet the demands of an increased sweat rate (Howard and Bartram 2003).[9]

In developing guideline values for chemicals, assumptions for daily per capita water consumptions and body weight are used as specified in A.14. For some chemicals it is important to highlight in the guideline derivation that member states should consider modifying the guideline value to take their local circumstances of water consumption into account.

Management approaches

G1.6 In general, approaches to the management of chemical hazards vary according to the principal source of the hazard e.g. where the source water quality is a significant contributor or where materials and chemicals ("additives") are the dominant source.

G1.7 Most chemicals arising from source waters (naturally occurring, diffuse-source pollutants; industrial pollutants) are of health concern only after extended exposure. However, it should be recognised that concentrations can vary significantly over time. Naturally occurring and anthropogenic chemicals can show very stable concentrations but they can also change concentration as a consequence of physical conditions, e.g. seasonally or as a consequence of exploitation of the water source. Periodic monitoring, analysis of trends and comparison with guideline values, is a rational approach to monitoring of such chemicals. Guideline values are set for such hazardous water constituents and provide a basis for assessing drinking-water quality.

G1.8 Some chemicals arise principally from materials and chemicals used in the production and distribution of drinking-water ("additives"). The preferred approach to control for such chemicals is through use of materials and chemicals determined or certified to be of suitable quality and type for drinking-water applications.

[9] Howard G and Bartram J (2003) *Domestic water quantity, service level and health*. Geneva, World Health Organization.

G1.9 Few chemicals are likely to lead to human health effects following short-term exposures without causing aesthetic rejection (see also C9); exceptions include chemicals nitrate and nitrite. While routine monitoring may assist in identifying trends of concern, it does not provide an adequate management tool alone. Guideline values are prepared for such chemicals, but management strategies should rely on detection and subsequent remediation of unsafe conditions, because of the acute nature of the health effects.

G1.10 Management of health hazards arising from the toxins of toxic cyanobacteria requires approaches similar to those for microbial hazards. Guideline values may be derived for these toxins but should be used within the context of wider assessment and management of algal growth approaches**.**

G1.11 In areas where spread of disease by water-based insect vectors occurs or is a risk, larvicides may be applied to household and community water sources. The need for balancing of risks from insect vectors and larvicides implies the need for specific management approaches.

General scheme and criteria

G1.12 The general scheme for development of GDWQ chemical risk assessments, guideline values and summary statements is summarised in Figure 2.

G1.13 The criteria used for deciding whether to review a newly proposed chemical in the GDWQ, which has so far not been considered, are:

- evidence for reasonably widespread actual or potential occurrence in drinking-water at levels that may be of health significance, combined with evidence of actual or potential toxicity; or
- significant international concern; or
- inclusion in or proposal to the WHO Pesticides Evaluation Scheme (WHOPES) (see G7);
- listing of a chemical in relevant Prior Informed Consent (PIC) or Persistent Organic Pollutant (POP) listings.

Where there is significant international concern but lack of data regarding the occurrence of a particular substance in drinking water it is possible to post a request for such data on listserve message as a means of eliciting occurrence data.

G1.14 The criteria used for deciding whether to revise the review for a constituent already considered in the GDWQ are:

- for substances with provisional guideline values, new evidence that might affect "provisional" status (see G6);
- new health risk evaluation made available by WHO;
- new evaluation of the carcinogenic risk of a chemical by the International Agency for Research on Cancer (IARC);
- listing of a chemical in relevant PIC or POP listings.

G1.15 The criteria to determine whether to derive a guideline value are evidence of actual toxicity combined with evidence for occurrence in drinking-water at concentrations close to or above those of health concern.

G1.16 There are also a number of chemicals that do not warrant the development of a formal guideline value but for which a health-based reference value is discussed in the text. In these cases the concentrations normally found in drinking-water are well below the health-based reference value but they may be commonly detected and the reference-value provides a means of both judging the margin of safety in the absence of a specific guideline value and a level of interest for establishing analytical methods. Alternatively there may be a significant possibility of spills to drinking-water sources and health-based reference values provide assistance in determining whether concentrations encountered pose a significant risk to health.

G1.17 Several of the inorganic elements for which guideline values are recommended are recognized to be essential elements in human nutrition. No attempt is made in the GDWQ in recommending guideline values to define a minimum desirable concentration of such substances in drinking-water but there is a need to ensure that a reasonable balance is maintained between consideration of potential toxicity and essentiality.

G1.18 For some contaminants, drinking-water can also contribute to exposure by skin absorption and inhalation as a consequence of bathing and showering and potentially through other household uses. The level of this exposure varies significantly in different parts of the world. Generally, the portion of the tolerable intake allocated to drinking-water is sufficient to allow for these additional routes of exposure, and so it is not separately accounted for in the calculation of the guideline value. However, where such a chemical is being considered, it is important to identify that this is the case in the background document and to point out that if national authorities have reason to believe that potential inhalation of volatile compounds and dermal exposure from various indoor uses are not adequately addressed in the development of the guideline value, they could consider taking this into account in setting national standards or guidelines.

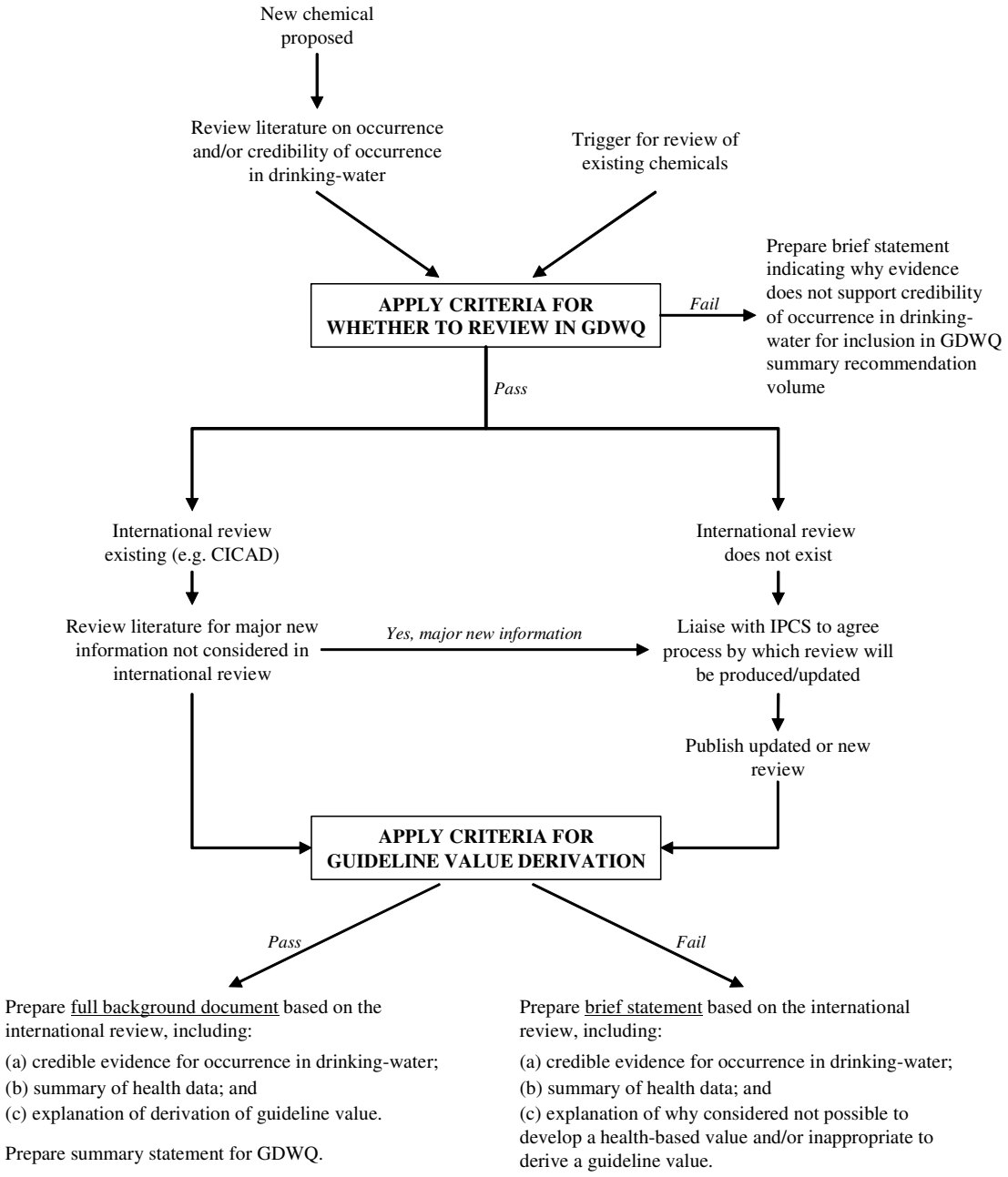
G1.19 For all chemicals included in the GDWQ a chemical risk assessment (or background document) is prepared. The content of such documents is specified in Annex B. These documents provide a summary of the toxicity and where suitable summaries exist, such as JMPR valuations in which the comment and evaluation sections may be reproduced and the reader directed to the original document for the detailed toxicological review. This document also includes information on analytical determination and practical consideration of control.

G1.20 For pesticides considered for WHOPES no guideline or health-based value is prepared. Information on any potential risk is given by comparing exposure to the pesticide, estimated from consumption of the recommended dose to drinking water in containers, to the ADI .

G1.21 Where there is a significant change in the position in the GDWQ on a specific chemical, such as a change in a guideline value, or a change in status of a guideline value (e.g. provisional or not), then a short explanatory statement is included when published.

G1.22 Some chemicals are the subject of formal international initiatives, such as POPs through the Stockholm Convention (2001) or PIC through the Rotterdam Convention (1998). Where this is the case, a brief explanatory note is included in the background document and the summary statement.

Figure 2: Outline scheme for development GDWQ reviews, background documents, guideline values and summary statements



G1.23 A small number of chemicals are considered to be of particular significance for health. Where the DWQC considers that this is the case for a particular chemical then it can determine that an extended summary is prepared for the GDWQ in order to provide an immediate source of more extensive information.

G1.24 Fact sheets are prepared for individual chemical contaminants. These generally include a brief toxicological overview, the basis of guideline derivation, treatment achievability, and analytical limits of detection. These follow four distinct formats:

- A formal guideline value is established for a chemical that may be a concern in certain situations, target length is 1-1-5 pages ("classic" fact sheet)
- A formal guideline value is established for a chemical of major health concern, target length is 3-4 pages, with an additional focus on risk management, or "practical considerations" ("extended coverage" fact sheet)
- A health-based reference value is established (but no formal guideline value), target length is approximately 1 page.
- No guideline value is established, because the chemical does not meet the requisite criteria the target length is 0.5 page). If it is the case where no guideline value is established because it is a pesticide used for public health purposed the target length is 1 page.

G2 Risk assessment

G2.1 In deriving a guideline value for exposure to a chemical substance it is preferable to use data obtained from investigations in human populations for assessing the health effects from exposure to a chemical. In most cases, such information is not available or is limited in its scope. Where reliable and adequate epidemiological data are available, they are used in preference to data from animal studies but where the data are inadequate, these may be used to support data from animal studies. In most cases, data derived from studies with laboratory animals are used to assess the human health effects of the chemical. In order to do this, it is desirable to have access to well-conducted animal studies. The overall database needs to be considered and clear dose-response relationships established.

Epidemiological and clinical studies, when available, are an important source of human data; however, consideration is required as to whether these are sufficiently representative to cover any sensitive subpopulations for the toxicological end-point in question. An uncertainty factor of 1–10 may be applied to data that provide a no-effect level in epidemiological studies to make allowance for sensitive subpopulations where this is appropriate. Clinical studies almost invariably use healthy individuals, and so sensitive subpopulations will not be accounted for. However, clinical studies rarely identify an effect level, and the margin of safety (i.e. the margin that is available between a guideline value and the level at which effects might be observed) is frequently unknown. It is therefore important that when such data are used, excessively stringent guideline values are not derived from the application of inappropriate uncertainty factors. Epidemiological and clinical studies are often a valuable contributor to building a weight of evidence for a particular value or approach.

Section E.5 describes general priorities amongst data sources.

G2.2 Methodologies for risk assessment of chemicals are described in Environmental Health Criteria monographs including 70, 104, 170, 210 and 237. The risk assessment process can be modified for specific substances by making use of scientific developments when appropriate**.**

G2.3 Revision of, or addition to, the guidelines values for chemicals (other than pesticides) are, where possible, based on a recent assessment carried out by the WHO, e.g. an EHC monograph or a Concise International Chemical Assessment Document (CICAD). In the absence of a suitable WHO assessment, a new drinking-water guideline value may be based on one or more recent, high-quality, peer-reviewed national assessment.

Where it is necessary to develop a guideline in the absence of either a recent WHO assessment or a recent high-quality peer-reviewed national assessment, a new risk assessment is developed and undergoes formal peer-review.

G2.4 Revisions of, or additions to, the guideline values for pesticides are derived from the most recent recommendations of the JMPR.

In the absence of a JMPR assessment of a pesticide for which a guideline value is considered necessary, a request is made to JMPR to develop such an assessment. The request to JMPR would normally be to perform a risk assessment and to establish a tolerable daily intake (TDI); and information on any scientific concerns relating to short versus long-term exposure. This is used by the Chemical Aspects WG, alongside information on aspects of risk management and policy towards guideline value derivation to determine whether and how it should be addressed in GDWQ.

G2.5 For most types of toxic effects, it is believed that a level of exposure exists, below which adverse effects will not occur even after long-term exposure, often termed a threshold of toxicity. For other toxic effects, notably carcinogenicity induced via a genotoxic mechanism and mutagenicity, it is assumed that there is some finite, although very low, probability of harm at even low levels of exposure, although the distinction is not always simple or clear. For this reason, two distinct approaches are adopted for deriving guidelines. The first step in the process is to classify chemicals, on the basis of available evidence, as to which category in which the substance is most likely to fall.

The evaluation of the potential carcinogenicity of chemical substances is usually based on long-term animal studies. Sometimes data are available on carcinogenicity in humans, such as from occupational exposure.

On the basis of the available evidence, the IARC categorizes chemical substances with respect to their potential carcinogenic risk into the following groups[10]:

Group 1: the agent is carcinogenic to humans
Group 2A: the agent is probably carcinogenic to humans.
Group 2B: the agent is possibly carcinogenic to humans
Group 3: the agent is not classifiable as to its carcinogenicity to humans
Group 4: the agent is probably not carcinogenic to humans

There are carcinogens that are capable of producing tumours in animals or humans without exerting direct genotoxicity, but acting through an indirect mechanism, e.g. cytotoxicity or physiological or hormonal disruption. Such substances cause cancer through a mechanism that is based on toxicity and a dose (i.e. a threshold), below which there is no toxicity, will not result in cancers.

In order to make the distinction with respect to the underlying mechanism of carcinogenicity, each compound that has been shown to be a carcinogen (including all chemicals classified in group 1 or group 2A by IARC) is evaluated on a case-by-case basis. The evidence of genotoxicity, the range of species affected the relevance to humans of the tumours observed in experimental animals and the toxicokinetics of the substance are

[10] IARC policy is that its classification should not be used to directly inform regulatory activity. This is because of the importance of taking account of underlying mechanism.

considered to determine the mode of action and therefore approach taken. For carcinogens for which there is convincing evidence to suggest a non-genotoxic mechanism or to suggest that detoxification mechanisms require to be overwhelmed by high doses, guideline values are derived using the approach for threshold chemicals.

G3 Threshold chemicals

G3.1 Increasingly the preferred approaches for the derivation of tolerable daily intakes (TDIs)/acceptable daily intakes (ADIs) for threshold effects include the benchmark dose (BMD) or the benchmark dose lower confidence limit (BMDL) (IPCS 1994) [11] and chemical-specific adjustment factors (CSAFs) (IPCS 2005).[12]

G3.2 The BMDL is the lower confidence limit of the dose that produces a small increase in the level of adverse effects (e.g. 5% or 10%) to which uncertainty factors can be applied to develop a tolerable intake.

The BMD has a number of advantages over the no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL):

- It is derived on a quantitative basis using data from the entire dose-response curve for the critical effect rather than from the single dose group at the NOAEL or LOAEL (i.e. one of the few pre-selected dose levels).
- Use of the BMD facilitates the use and comparison of studies on the same agent or the potencies of different agents.
- The BMD can be calculated from data sets in which a NOAEL was not determined, eliminating the need for an additional uncertainty factor to be applied to the LOAEL.
- Definition of the BMDL as a lower confidence limit accounts for the statistical power and quality of the data. That is, the confidence intervals around the dose–response curve for studies with small numbers of animals and, therefore, lower statistical power would be wide; similarly, confidence intervals in studies of poor quality with highly variable responses would also be wide. In either case, the wider confidence interval would lead to a lower BMD, reflecting the greater uncertainty of the available data. On the other hand, narrow confidence limits (reflecting better studies) would result in higher BMDL values.

G3.3 Approaches to the derivation of TDIs are increasingly being based on understanding of a chemical's mode of action in order to reduce reliance on default assumptions. This approach provides a departure from the use of default uncertainty factors (such as a simple 10 for interspecies extrapolation and 10 for intraspecies variation) and relies on the use of quantitative toxicokinetic and toxicodynamic data and CSAFs to assess interspecies and interindividual extrapolations. Previously, CSAFs were called "data-derived uncertainty factors." The part of the CSAF approach that is at present best developed is the use of physiologically based pharmacokinetic models to replace the default values for extrapolation between species and between routes of exposure.

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[11] IPCS (1994) *Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits.* Geneva, World Health Organization, International Programme on Chemical Safety (Environmental Health Criteria 170).

[12] IPCS (2005) *Chemical-specific adjustment factors for interspecies differences and human variability: Guidance document for use of data in dose/concentration–response assessment*. Geneva, World Health Organization, International Programme on Chemical Safety (Harmonization Project Document No. 2).

G3.4 For threshold chemicals, a TDI is calculated from the BMDL or the NOAEL or in some cases from the LOAEL for the effect considered to be most biologically significant. This is done by dividing the BMDL, NOAEL or LOAEL by an uncertainty factor (UF).

$$\text{TDI} = \frac{\text{NOAEL or LOAEL or BMDL}}{\text{UF}}$$

G3.5 The drinking-water guideline value (GV) is then calculated from the TDI, according to the following formula:

$$\text{GV} = \frac{\text{TDI x bw x P}}{\text{C}}$$

Where *bw* is the body-weight (see A.13); *C* is the daily consumption of drinking-water (see A.13); and *P* is the fraction of the TDI allocated to drinking-water.

Nutrient minerals in drinking-water

G3.6 A number of minerals that are found in drinking-water are essential for human nutrition (see also G1.17) There are a number of issues that need to be taken into account in considering guidelines for these minerals (IPCS 2002; FAO and WHO 2006).[13] The issue of essentiality and recommended minimum intakes should be covered in depth in the background document. Intake of the mineral from other sources needs to be considered in relation to the potential contribution from drinking-water in relation to all other sources. Care must be taken that the guideline value is consistent with total daily consumption and the recommended minimum intake of the mineral.

In examining such substances, it is important to record in the exposure section if the substances are taken in supplements, although no allowance for this is made in the derivation of the guideline value.

Allocation factors

G3.7 For threshold chemicals, the TDI/ADI covers total intake from all sources. It is, therefore, necessary to allocate a proportion of the TDI/ADI to drinking-water to derive a guideline value. In general the primary sources of exposure are food and water. Where sufficient data are available on the exposure from sources other than drinking-water to provide an accurate assessment of actual exposure from different sources, consideration of the proportion of the TDI/ADI available for drinking-water should be taken into account so that a more appropriate allocation can be made to drinking-water. In the absence of adequate exposure data, the normal allocation to drinking-water is 20%. This value is a change from the previous allocation of 10% used in the first, second and third editions of the GDWQ, which was found to be excessively conservative, and will be incorporated in new guidelines and existing guidelines as they are revised. For substances where the exposure from food is very low, such as some of the disinfection by-products, the allocation may be as high as 80%. In the

[13] IPCS (2002) *Principles and Methods for the Assessment of Risk from Essential Trace Elements.* Environmental Health Criteria 228. Geneva, World Health Organization, International Programme on Chemical Safety.

FAO and WHO (2006) *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances: Report of a Joint FAO/WHO Technical Workshop on Food Nutrient Risk Assessment, WHO Headquarters, Geneva, Switzerland, 2-6 May 2005*. Geneva, World Health Organization.

case of some pesticides, for which exposure from food is high, the allocation may be as low as 1%.

Uncertainty factors

G3.8 Uncertainty factors are used in the derivation of the TDI/ADI. The derivation of these factors requires expert judgement and a careful sifting of the available scientific evidence.

G3.9 In the derivation of the WHO drinking-water quality guideline values, uncertainty factors are applied to the BMDL or the lowest credible NOAEL or LOAEL for the response considered to be the most biologically significant and were determined by consensus using the approach outlined below:

Source of uncertainty	**Factor**
Interspecies variation (animals to humans)	1 – 10
Intraspecies variation (individual variations)	1 – 10
Adequacy of studies or database	1 – 10
Nature and severity of effect	1 – 10

Factors lower than 10 may be used, for example for interspecies variation when humans are known to be less sensitive than the animal species studied.

Inadequacies in the database include studies for which only a LOAEL and no NOAEL could be identified, and studies of insufficient duration, i.e. absence of a relevant long-term study.

Situations in which the nature or severity of effect might warrant an additional uncertainty factor include studies in which the end-point was malformation of a fetus or in which the end-point determining the NOAEL was directly related to possible carcinogenicity. An additional uncertainty factor may be applied for carcinogenic compounds for which a guideline value was derived using a TDI approach where the toxic endpoint is relevant to the carcinogenicity and there is a justifiable level of uncertainty.

G3.10 The total uncertainty factor should not exceed 10 000. If the risk assessment would lead to a higher uncertainty factor, then the resulting TDI would be so imprecise as to lack meaning. For substances for which the total of uncertainty factors is greater than 1000, guideline values are designated as provisional in order to emphasize the higher level of uncertainty inherent in these values.

G3.11 The derivation of the uncertainty factor used in calculating a guideline value should be clearly presented as part of the review. This helps authorities in determining the urgency and nature of the action required in the event that a guideline value is exceeded.

G3.12 Under some circumstances, the end-point used in the critical study will be a sensitive biochemical end-point. In a number of cases, the long-term biological significance of such end-points may be uncertain and it may, therefore, be appropriate to use a smaller uncertainty factor. Should insufficient guidance be available, then IPCS should be consulted by the coordinator concerned for advice.

Use of sensitive sub-groups in deriving guideline values

G3.13 Where the critical study relates to a specific human population that is considered to be a particularly sensitive subgroup, it may be appropriate to apply an uncertainty factor of 1 to the NOAEL or LOAEL. The reasoning, where used, should be included in the discussion of the guideline in the background document.

G4 Non-threshold chemicals

G4.1 For some chemicals, it has generally been assumed that there is a theoretical probability of harm at even very low levels of exposure for particular toxic endpoints such as cancer. Although, this is a simplistic assumption, the development of a TDI is often considered inappropriate and mathematical low-dose extrapolation may be applied. Where available, dose-response characterisations developed by WHO expert groups in documents such as CICADs should normally be used as the basis for the determination of guideline values.

G4.2 In the case of compounds considered to be non-threshold chemicals, cancer risks are typically estimated using a conservative linear non-threshold model at low doses that places an upper bound on risks. The actual cancer risks are not likely to be higher than the upper bound but could be lower and even zero. The recognition that the cancer risk may approach zero or be indistinguishable from zero stems from the uncertainties associated with mechanisms of carcinogenesis, including the role of the chemical in the cancer process and the possibility of detoxification and repair mechanisms.

The mathematical model used normally is the linearised multi-stage model. This extrapolation assumes linearity at low doses, and there are several variants of the model. The variant used is specified and does not include allowance for exposure through showering, bathing and other household uses, but attention should be drawn to the possibility of exposure from these sources where appropriate. Dose is based on body weight rather than body surface area. Where an alternative model is used, an appropriate explanation is provided.

The guideline value recommended is the concentrations in drinking-water associated with an estimated upper bound (e.g. 95th percentile value) excess lifetime cancer risk of 10^{-5} (i.e. one additional cancer per 100,000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years).

G5 Health-based reference values for short-term exposure

G5.1 Some substances may be subject to spills into drinking-water sources, particularly surface water and when this occurs there is a significant potential for high concentrations to enter the drinking-water supply. This could be for a few hours or for a longer period of a few days. When the substance has entered distribution it may take several days to clear unless there is a formal and structured programme of flushing.

G5.2 Where there is a requirement for health-based values related short-term exposure the approach used to derive long-term guideline values may be adapted by using data from shorter-term studies of up to 90 days, depending on what data is available. Care needs to be taken that the endpoint selected is not one that can only occur after prolonged exposure. This does not include the use of acute studies, such as single dose studies to determine an LD50,

since there are rarely sufficient endpoints considered for the study to be of value in establishing formal guideline values that may be used with little expert input.

G5.3 For threshold chemicals, the following toxicological effects that relate particularly to short-term exposure need to be considered in establishing a TDI to develop guidelines for short-term exposure:

- Clinical signs and the nature of the clinical signs;
- Neurotoxicity (includes delayed neurotoxicity and ACh inhibition);
- Haematotoxicity (includes methaemoglobinaemia, haemolysis and anaemia);
- Reproductive effects (particularly developmental effects);
- Direct effects on the GI-tract/stomach;
- Biochemical effects (includes increased plasma enzyme levels, mitochondrial uncoupling, pharmacological effects); and
- Whether the substance is genotoxic.

G5.4 In developing management approaches for short-term exposure, it is reasonable to consider a higher allocation of the TDI to drinking-water, up to 100%. However comments should be included in the discussion of the guideline value in the background document with regard to authorities taking into account exposure from other sources in case this is significant.

G5.5 Where JMPR has developed short-term exposure values for pesticides, these could be used but account must be taken of the studies forming the basis of the JMPR value, as this is intended for exposure over a maximum of 24 hours.

G5.6 Short-term guidelines for those substances that are considered to be in vivo genotoxins should consider the necessity of including an uncertainty factor to take the potential for in vivo genotoxicity into account.

G5.7 Health-based reference values are developed for periods of 24 hours and a longer period of either 5 or 7 days that could reflect the situation if a substance has penetrated distribution or a plume of a contaminant takes that time to pass the intake. In such circumstances consideration is required as to whether there is likely to be chronic low-level exposure to the compound in drinking-water supplies and if so it should be noted in the discussion of the guideline in the background document.

G6 Provisional guideline values and aesthetic aspects

G6.1 When the health-based guideline value is less than the level that can be determined by a routine analytical method, the guideline value is set at the analytical level that can be reasonably achieved (practical quantification limit) and considered "provisional". From the 3rd edition of the GDWQ, such values are denoted with an "A" in the summary table (rather than a "P", as was done in earlier editions) and an explanatory footnote added.

G6.2 If the health-based guideline value can not be achieved through realistic technical means such as catchment protection or treatment, then the guideline value is set at the health-based limit and considered "provisional". From the third edition of the GDWQ, these values are denoted with a "T" in the summary table (rather than a "P" as was done in the first and second editions) and an explanatory footnote added.

G6.3 Guideline values for disinfectants and disinfectant by-products are not established where their establishment might discourage disinfection (See section C.7). This follows from the principles of protection of public health and giving priority to microbial contaminants. Where such conflict might occur, guideline values are set at the health-based value and have been designated as provisional. From the third edition of GDWQ they are denoted with a "D" in the summary table, with an explanatory footnote.

G6.4 Some substances of health concern have aesthetic effects that would normally lead to rejection of water at concentrations significantly lower than those of concern for health. Such substances are not normally appropriate for routine monitoring. Nevertheless, health-based reference values are needed to interpret data collected in response to customer complaints. In these circumstances, a health-based summary statement is prepared and guideline value derived in the usual way. In the summary statement, the relationship between concentrations relevant for health and aesthetic concern is explained. In tables of guideline values, the health-based guideline value is designated "C". In footnotes to tables it is explained that whilst of health significance, because water would normally be rejected by consumers they would not normally be considered appropriate for routine monitoring; but that they would be of importance in responding to customer complaints and guideline values are included for this purpose.

G7 Assessment of the safety and efficacy of the direct addition of larvicides to drinking-water for the control of vector-borne diseases

G7.1 Mosquitoes are a significant vector of some serious diseases and they may breed in a range of standing water bodies, which include containers in which drinking-water is stored. Specific consideration is required in circumstances where there is a need to control mosquito larvae by applying larvicides directly to drinking-water.

G7.2 Generic guidelines for the safe use of larvicides in drinking-water in the context of water quality management are published in the GDWQ and the respective background documents.

G7.3 WHO Pesticide Evaluation Scheme (WHOPES) assesses the efficacy of and develops specifications for such larvicides. If WHOPES determines that the product is likely to be efficacious, the manufacturer is invited to submit data to JMPR for a safety assessment. This safety assessment, which is published by FAO and WHO in the JMPR report which forms the basis for a short background document, which also takes into account the properties of the pesticide and its likely behaviour in water to provide additional information that can be used by local health authorities in assessing the suitability of different pesticides in their specific circumstances. If available, field data on levels in drinking-water in drinking-water containers treated for vector control are used in the development of the background documents to determine probable levels of exposure. Where these data do not exist assumptions are made that the dose recommended by WHOPES will be the concentration that will be drunk. Data on potential ameliorating factors, such as solubility and octanol-water partition coefficient are noted to assist local health authorities in taking decisions regarding the local application of vector control agents.

G7.4 A guideline value is not developed but comparison is made to the ADI. Although the ADI does not normally apply to bottle-fed infants, this comparison includes a 10 kg child and a 5 kg bottle-fed infant. Where the ADI will theoretically be exceeded this is noted to enable

local health authorities to determine whether it is possible or necessary to provide alternative sources and whether risks from vector borne disease are likely to outweigh the theoretical risks from exposure to the pesticide under the particular circumstances.

H Guidance on good practice/implementation of the Guidelines for Drinking-water Quality

H.1 The development of narrowly defined norms/standards alone may have a limited impact upon public health, unless other supportive guidance is available to inform public health policy-making and water management practices. Such guidance may address, for instance, aspects of development and application of law, regulation and standards, aspects of their progressive implementation, aspects of monitoring, surveillance and assessment, information concerning application in certain geographic areas, or application to certain population groups (such as in rural and urban areas) and more detailed guidance on management of certain hazards than is possible in the GDWQ themselves.

H.2 The preparation of guidance of this sort is not necessarily a component of the GDWQ *per se* and such supportive guidance may, therefore, be published outside the GDWQ and may be developed and published in cooperation with other agencies**.** A list of guidance materials associated with the GDWQ is included in Annex A.

H.3 The decision to develop and publish guidance of this type is determined, to a significant extent, by the absence of adequate information from other sources, the likely impact such information would have on policy and practice, and the likely impact of such change on public health.

H.4 In contrast to some other aspects of the GDWQ *per se*, recovery and critical analysis of experience is a significant contributor to overall quality of guidance on good practice. In selection of peer-reviewers (Table 1), therefore, it is important that input from practitioners with relevant field experience be sought and properly accommodated.

I Radiological aspects

I.1 Radioactive contaminants are considered differently to other chemical contaminants because of significant differences in the way in which radiological contaminants are measured. Radioactivity is measured by counting alpha or beta particles emitted from the disintegration of atomic nuclei during radioactive decay.

Because of the large number of possible radioactive substances it is not practical or necessary to carry out specific analysis to determine the actual radionuclides that are present routinely in water samples. Instead the GDWQ rely on screening values for gross beta and gross alpha emissions. When these are exceeded it is necessary to carry out analysis to determine which radioactive substances are the source or sources of the emissions and the relative hazard of these substances can be determined from information and data provided in the GDWQ.

I.2 The exception to I.1 is radon. Radon is a gas that is relatively easily lost from water and can contribute to the content of radon in indoor air. Radon will only be found at significant concentrations in drinking-water derived from groundwater. The potential for radon to be present in drinking-water can be ascertained from the geology of the region and this

would be the first step in assessing the likely presence of radon as a hazard. It would not be expected that radon would be identified in the screening process or that it would be routinely monitored in drinking-water.

ANNEX A: GDWQ-associated publications

List of present documents current at May 2007:

Guidelines for Drinking-water Quality[14]

- Guidelines for Drinking-water Quality, Volume 1, 3rd edition, 2004
- Guidelines for Drinking-water Quality, First Addendum to Volume 1, 3rd edition, 2006
- Guidelines for Drinking-water Quality, Addendum: Microbiological agents in drinking water, 2nd edition, 2002
- Guidelines for Drinking-water Quality, Volume 3, 2nd edition, 1997

Supporting documents (in alphabetical order)

Document title	URL
Arsenic in Drinking-water: Assessing and Managing Health Risks (in preparation)	
Assessing Microbial Safety of Drinking Water: Improving Approaches and Methods (2003)	http://www.who.int/water_sanitation_health/dwq/9241546301/en/
Chemical Safety of Drinking-water: Assessing Priorities for Risk Management (in preparation)	
Desalination for Safe Drinking-water Supply (draft available, but in revision)	http://www.who.int/entity/water_sanitation_health/gdwqrevision/desalination.pdf
Domestic Water Quantity, Service Level and Health (2003)	http://www.who.int/water_sanitation_health/diseases/wsh0302/en/
Evaluation of the H_2S Method for the Detection of Fecal Contamination of Drinking-water (2002)	http://www.who.int/water_sanitation_health/dwq/wsh0208/en/
Guide to Hygiene and Sanitation in Aviation (in revision)	
Guide to Ship Sanitation (in revision)	
Health Aspects of Plumbing (2006)	http://www.who.int/water_sanitation_health/publications/plumbinghealthasp/en/
Heterotrophic Plate Counts and Drinking-water Safety: The Significance of HPCs for Water Quality and Human Health (2003)	http://www.who.int/water_sanitation_health/dwq/hpc/en/
Legionella and the Prevention of Legionellosis (2007)	http://www.who.int/water_sanitation_health/emerging/legionella/en/index.html
Managing Water in the Home: Accelerated Health Gains from Improved Water Supply (2002)	http://www.who.int/water_sanitation_health/dwq/wsh0207/en/
Pathogenic Mycobacteria in Water: A Guide to Public Health Consequences, Monitoring and Management (2004)	http://www.who.int/water_sanitation_health/emerging/pathmycobact/en/
Protecting Groundwater for Health: Managing the Quality of Drinking-water Sources (2006)	http://www.who.int/water_sanitation_health/publications/protecting_groundwater/en/index.html

[14] Documents available at http://www.who.int/water_sanitation_health/dwq/guidelines/en/index.html

Document title	URL
Protecting Surface Waters for Health: Managing the Quality of Drinking-water Sources (in preparation)	
Quantifying Public Health Risk in the WHO Guidelines for Drinking-water Quality: A Burden of Disease Approach (2003)	http://www.who.int/water_sanitation_health/dwq/quantifyinghealthrisks/en/index.html
Rapid Assessment of Drinking-water Quality: A Handbook for Implementation (in preparation)	
Safe Piped Water: Managing Microbial Water Quality in Piped Distribution Systems (2004)	http://www.who.int/water_sanitation_health/dwq/9241562251X/en/index.html
Toxic Cyanobacteria in Water: A Guide to their Public Health Consequences, Monitoring and Management (1999)	http://www.who.int/water_sanitation_health/resources/toxicyanbact/en/index.html
Upgrading Water Treatment Plants (2001)	http://www.who.int/water_sanitation_health/hygiene/om/treatplants/en/index.html
Water Quality: Guidelines, Standards and Health: Assessment of Risk and Risk Management for Water-related Infectious Disease (2001)	http://www.who.int/water_sanitation_health/dwq/whoiwa/en/index.html
Water Safety Plans: Managing Drinking-water Quality from Catchment to Consumer (2005)	http://www.who.int/water_sanitation_health/dwq/wsp0506/en/index.html
Water Treatment and Pathogen Control: Process Efficiency in Achieving Safe Drinking-water (2004)	http://www.who.int/water_sanitation_health/dwq/9241562552/en/index.html
Waterborne Zoonoses: Identification, Causes and Control (2004)	http://www.who.int/water_sanitation_health/diseases/zoonoses/en/index.html

ANNEX B: Content and format of chemical background documents

The content of chemical background documents is shown below. All of the headings may not, however, be required in every document.

1. GENERAL DESCRIPTION
    - 1.1 Identity
    - 1.2 Physicochemical properties
    - 1.3 Organoleptic properties
    - 1.4 Major uses and sources in drinking-water
    - 1.5 Environmental fate

2. ENVIRONMENTAL LEVELS AND HUMAN EXPOSURE
    - 2.1 Air
    - 2.2 Water
    - 2.3 Food
    - 2.4 Estimated total exposure and relative contribution of drinking-water

3. KINETICS AND METABOLISM IN LABORATORY ANIMALS AND HUMANS

4. EFFECTS ON EXPERIMENTAL ANIMALS AND *IN VITRO* TEST SYSTEMS
    - 4.1 Acute exposure
    - 4.2 Short-term exposure
    - 4.3 Long-term exposure
    - 4.4 Reproductive and developmental toxicity
    - 4.5 Genotoxicity and related end-points
    - 4.6 Carcinogenicity

5. EFFECTS ON HUMANS

6. PRACTICAL ASPECTS
    - 6.1 Analytical methods and analytical achievability (including information on field test-kits, if available).
    - 6.2 Treatment and control methods and technical achievability (both municipal-scale treatment technologies and household or residential-scale treatment should be included where this information is available).

7. GUIDELINE VALUE [or CONCLUSIONS, if no guideline value derived]

    Additional advice on the application of the guideline value should be included as appropriate. This can relate to a number of issues such as whether the substance only occurs in groundwater, whether control should be through product or product use specifications, the importance of drinking-water intake (e.g. for WHOPES pesticides) etc.

8. REFERENCES

The format of chemical background documents is shown below.

1. Documents are transferred mainly by electronic means, and authors are requested to follow these guidelines as far as possible in order to minimize problems in transferring documents from one format to another.
2. The "master documents" are held by the WHO Secretariat.
3. Abbreviations should be presented in parenthesis where they are first introduced.
4. The full name of the chemical should be used throughout the document; the use of non-standard abbreviations for chemicals should be avoided.
5. **Font**. The text should be in Times New Roman 12p (with 10pt allowed for tables).
6. **Tabs**. Set at every 0.5 inch (12.5 mm). They should not be changed within the document.
7. **Paragraphs**. For ease of reference during peer-review, paragraphs should be numbered manually (not using the automatic paragraph numbering facility, which causes loss of paragraph identification in the editing of the document), restarting within each section/section (the WHO Secretariat will remove these numbers when the document is finally approved). The paragraphs should be left-justified, with no special treatment for the first line.
8. **Headings**. The first two levels in **bold**. The first level should be in CAPITALS.
9. **Page Numbering**. Pages should be numbered consecutively, starting from the first page, in the header at the right upper corner of the page.
10. **Table of Contents**. This should be located at the beginning, showing section/subsection headings at three levels, and should be done using the table of contents-facility of Word.
11. **Margins**. One inch (25 mm) margins should be used all round.
12. **Tables**. These should be fitted within the normal margins, and preferably be oriented in portrait mode. They should be placed after the main text. Table auto-formatting format I should be used.
13. **Figures/Diagrams**. The use of figures and diagrams should be avoided, where possible, as, generally, conversion between formats is not possible.
14. **Page size**. Draft documents should be formatted using either A4 (8.27 x 11.69 inches, 210 x 297 mm) or US letter size (8.5 x 11 inches; 215 x 279 mm) paper size.
15. **Literature Citation and List of References**. For citations in the text, the name-and-year system is used; two different styles are possible:
    (a) Renbert et al. (1980) have used reversed phase TLC to determine TCP in edible oil.
    (b) Capillary GLC is frequently used for analysing TAPs in environmental samples (Lebel et al., 1981, 1982; Lebel & Wlliams, 1983a,b; Ofstad & Sleten, 1985).

    Where a report has more than two authors, the first author is followed by "et al.". It should be noted that "et al." is <u>not</u> underlined or italicized; "&" replaces "and", the punctuation must be correct, and that several references to the same statement (including more than one by the same author(s)) are placed in chronological order.

    Citations in the list of references are listed in alphabetical order. All authors of the citation should be listed. Journal names should be written in full and italicized. The names of authors are not always provided, in which case the name of the organization associated with the data, followed by the year, should be cited, for example, (IARC, 1983) or (WHO, 1976).

    Personal communications should be cited only in the text, not within the list of references. The name of the author, the recipient, and the date should be given. If the original recipient was not the WHO, the submitter of the communication should be included.

ANNEX C: Content of microbial background documents

The content of microbial background documents is shown below. All of the headings may not, however, be required in every document.

1. DESCRIPTION
   - Basic biology

2. HEALTH EFFECTS
   - Infective dose, variability, infection/illness ratio, susceptibility
   - DALYs per case, severity, duration, proportion

3. SOURCE/OCCURRENCE
   - Hosts/environment

4. ROUTES OF EXPOSURE

5. EVIDENCE OF DRINKING-WATER INVOLVEMENT

6. MONITORING AND ASSESSMENT
   - Detection, quantification, typing, recoveries, etc.

7. PREVENTION AND MANAGEMENT
   - Catchment management, treatment, etc.

8. CONCLUSIONS

ANNEX D: Terms of reference for peer-review

As part of the GDWQ document preparation and adoption process, all documents are subject to international peer-review (as outlined in Table 1).

Once a document is ready for peer-review and has received prior in-house clearance, the responsible WG Coordinator is asked to liaise with the WHO Secretariat in order to initiate peer-review by formally contacting identified reviewers and requesting the review.

The (electronic) letter of request to reviewers will cover the following issues:

- Introduction to the GDWQ rolling revision process.
- Introduction to the document for which review is requested, including document title, name of authors/editors and a brief description of the scope and purpose of the document.
- Time frame for review (not longer than three months), including a request that the reviewer contacted indicate his/her willingness/availability to carry out the review within that time frame.
- Reference to the response format to be used by the peer reviewer.
- Contact point and contact details at the WHO Secretariat.
- Reference to the confidentiality of the draft document.
- Reference to the fact that contributors to the development of the GDWQ are mentioned in each publication in recognition of their work.

A response form detailing the type of review that is sought will be attached to the letter. The form is provided electronically, and reviewers will be asked to submit their comments using this form.

The response form should cover the following fields of review or questions to the reviewer (as a minimum):

A) General comments on the document as a whole:

1. Does this text respond to an issue of concern?
2. Does this text compete with or complement other publications in the area? If so, which ones?
3. Is the level of guidance and information provided appropriate?
4. Are there major omissions that should be corrected?
5. Is there superfluous information that could be omitted?
6. Are there errors of fact or interpretation that should be corrected? If so, what?
7. Are there any additional comments?

B) Specific comments on a chapter-by-chapter basis (if applicable):

1. Is the level of guidance and information provided appropriate?
2. Are there major omissions that should be corrected?
3. Is there superfluous information that could be omitted?
4. Are there errors of fact or interpretation that should be corrected? If so, what?
5. Do the case-studies and illustrations sufficiently support points made in the text (if applicable)?
6. Are more or different case-studies and illustrations needed? If so, do you have access to any (if applicable)?

C) Document-specific technical issues and/or questions for which input is sought from the reviewer

ANNEX E: Instructions to authors on how to respond to peer-review and public domain comments

As part of the review and approval process (as outlined in Table 1), authors are required to review all comments received during the international peer-review and public domain review of the draft document and to adequately respond to them.

Authors can either be in agreement with a reviewer's comment or in disagreement, the former leading to a change of the draft document in order to address the reviewer's comment.

Authors are requested to prepare a summary table which lists the comments received and provides a brief response or reconciliation statement for each comment (see example outlined below). To expedite review by the respective WG, authors are encouraged to be as informative as is reasonably possible in outlining how comments were dealt with. For example, where a relatively simple change (e.g. deletion of some text) suggested by a reviewer was made within the text, the author could merely indicate the change (e.g. "text deleted") at the appropriate column entry within the summary table. Where text has been modified on the basis of a comment, authors are encouraged to clearly indicate in the summary table, where the revised text appears in the document. Where an author disagrees with a reviewer's comment, the reason(s) for the disagreement should be briefly outlined in the summary table.

To facilitate the review, the WHO Secretariat will provide to authors an electronic file containing a tabulated list of the review comments received, as well as copies of all correspondence received from peer-reviewers.

The reviewed draft document and accompanying summary table are forwarded by authors to the WHO Secretariat for distribution to members of the WG for review and approval.

The summary table is not part of the published document; however, it is retained by the WHO Secretariat for distribution to members of the respective WG for review and approval.

Section (paragraph/page)	Comment (issue)	Response
Section 1, paragraph 2	Sentence related to disposal of the chemical should be deleted	Sentence has been deleted in both locations
Section 1	Add text related to guidance value to conclusion	Text on guidance value has been added to paragraph 3 of conclusion
Section 8.5, paragraph 4	The conclusion that "this chemical is mutagenic" may be misleading, owing to its rapid hydrolysis	Disagree, *in vitro* and *in vivo* studies have clearly revealed that this chemical causes genetic damage