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WHO Guidelines for Drinking Water Quality

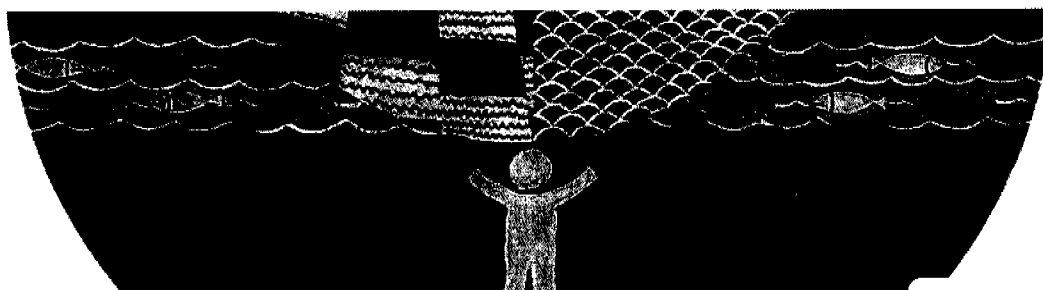
**Policies and Procedures for Preparing
and Updating of the WHO Guidelines
for Drinking-Water Quality**

Version at January 2002



**Protection of the Human Environment
Water, Sanitation and Health**

Geneva, 2002



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WHO GUIDELINES FOR DRINKING WATER QUALITY

**Policies and Procedures for Preparing and Updating of
The WHO Guidelines for Drinking-water Quality**

Version at January 2002

**World Health Organization
Geneva, Switzerland
2002**

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GDWQ Policies & Procedures – Version at January 2002

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List of Abbreviations

CICAD	Concise International Chemical Assessment Document
DALY	Disability Adjusted Life Year
DWQC	(WHO) Drinking Water Quality Committee
EHC	Environmental Health Criteria document
EMRO	WHO Regional Office for Eastern Mediterranean
EURO	WHO Regional Office for Europe
FAO	Food & Agriculture Organization of the United Nations
GDWQ	(WHO) Guidelines for Drinking Water Quality
GIV	(WHO Drinking Water Quality) Guideline Value
HACCP	Hazard Assessment Critical Control Point
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
P&C	Protection and Control (Working Group)
pGV	(WHO Drinking Water Quality) Provisional Guideline Value
PIC	Prior Informed Consent
POP	Persistent Organic Pollutants
SEARO	WHO Regional Office for South-East Asia
WG	Working Group
WWW	World-Wide Web
WHO (HQ,ROs)	World Health Organization (Headquarters, Regional Offices)

A. Background

A1. The first 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 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 Guidelines 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 a microbiological addendum was published in 2001.

A2. The main reason for not promoting the adoption of international standards for drinking-water quality is the advantage provided by the use of a risk-benefit approach (qualitative or quantitative) to the establishment of standards and regulations. In developing standards and regulations, care should be taken to ensure that scarce resources are not necessarily diverted to the development of standards and the monitoring of substances of relatively minor importance. Similarly, the adoption of drinking-water standards that are too stringent could limit the availability of water supplies that meet those standards. This approach should lead to standards and regulations that can be readily implemented and enforced and are protective of public health.

A3. The *Guidelines for Drinking-water Quality* (GDWQ) provide an assessment of the health risk presented by the various microbiological, chemical, physical and radiological constituents present in drinking-water. The resulting guidelines may describe reasonable minimum requirements of safe-practice to protect the health of consumers and/or may derive numerical “Guidelines Values” for constituents of water or indicators of water quality. The Guidelines are intended to be used in the development of risk management strategies, which can include national or regional standards developed in the context of local or national environmental, social, economic and cultural conditions. Such strategies, if properly implemented will ensure the safety of drinking-water supplies through the elimination or reduction to a minimum concentration of constituents of water that are hazardous to health.

A4. The GDWQ define the criteria used to select the various constituents addressed, describe the approaches used in deriving guidelines including guideline values, explain how guidelines for drinking-water quality are intended to be used and present brief summary statements either supporting the guidelines recommended, or explaining why no health-based guideline is required, or possible, at the present time.

A5. The GDWQ themselves may be accompanied by separate texts that provide background information substantiating the derivation of The Guidelines; and by texts intended to provide guidance on good practice towards effective implementation of the guidelines.

A6. Volume 3 of the GDWQ: *Surveillance and Control of Community Supplies* is distinct in orientation and is a document oriented toward “good practice”. The current edition is principally focused upon the situation in developing countries. Other “good practice” guidance linked to the GDWQ includes *Toxic Cyanobacteria in Water*.

A7. The GDWQ will be kept up-to-date through a rolling revision process.

B. Purpose of this document

B1. This document describes the process through which the GDWQ are developed. 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 continued development in response to new, or newly-appreciated, challenges.

B2. The procedures followed in the updating of the GDWQ are made publicly accessible in order that interested parties may contribute at appropriate stages and in order that information needs may be fed into the process.

B2. The document has no formal or legal status and is released for advisory purposes only.

C. Basic Principles

C1. Water is essential to sustain life, and an adequate supply which is safe for lifetime consumption, should be available to all persons.

C2. The primary purpose of the GDWQ is the protection of public health.

C3. It is intended that the Guidelines be used as guidance and advice to countries and to others as to what constitutes safe drinking-water and safe water supply. The GDWQ therefore provide the scientific point of departure for standard-setting, and provide evidence-based guidance on experience and best practice in moving towards safe drinking-water.

C4. 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 insanitary conditions and the elderly. Exclusions, such as particularly sensitive sub-populations, (including the sick and immuno-compromised), may be specifically defined.

C5. The GDWQ are intended to be applicable to water used for all usual domestic purposes including consumption, bathing and food preparation. Exclusions are specifically defined (such as for dialysis, cleaning of contact lenses).

[text on ice pending]

C6. Explanation will be provided in the GDWQ regarding the application of the Guidelines in specific circumstances, such as for desalinated water, water for travellers, bottled/package water, etc..

C7. Guidelines are based upon the best available evidence and scientific consensus. [N.B it has been proposed to develop a categorisation for strength of evidence for causality and for GV derivation and quantify each against these.]

C8. 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 guidelines have a degree of flexibility and enable a judgement to be made regarding the provision of drinking-water of acceptable quality. Authorities may decide to apply a precautionary approach in setting drinking-water standards.

C9. 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.

C10. Protection of water sources and supplies from contamination is the first line of defence. Source protection is almost invariably important in ensuring safe drinking-water and is to be preferred to extensively treating a contaminated water to render it suitable for consumption.

C11. 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.

C12. The health risks caused by toxic chemicals in drinking-water differ from those caused by microbial contamination. They arise primarily from the ability of chemicals to cause adverse health effects 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 usually becomes undrinkable owing to unacceptable taste, odour, and appearance. These factors place toxic chemicals in a lower priority category than microbial contaminants. Contaminants that are of particular concern are those that have cumulative toxic properties, such as heavy metals, and substances that are carcinogenic.

C13. 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.

C14. The radiological 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 these radionuclides is very small under normal circumstances.

C15. 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.

C16. 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. A daily per capita consumption figure of two litres of drinking-water for adults is used in the calculation.

C17. 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 Guidelines. For some technical substantiation and guidance on good practice published outside the GDWQ *per se*, it may be appropriate to attribute authorship and/or editorship of contributions. This should not be allowed to detract from the pursuit of wide and balanced contribution.

D. The Drinking-water Quality Committee and its Working Groups

D1. The revision of the GDWQ is guided and supported by the Department of Protection of the Human Environment (PHE) at WHO/HQ, in partnership with WHO's Regional Offices.

D2. 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 guidance so as to ensure that the product reflects best available evidence and scientific consensus, and/or the recovery and critical evaluation of experience.

D3. 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 Committee. Where possible, staff of WHO Collaborating Centres concerned with water are preferred.

D4. In selecting DWQC members, effort is also made to ensure reasonable geographic and gender balance and overall balance of expertise.

D5. Working Groups of the DWQC are established to respond to priorities and the need for development of guidance.

D6. The DWQC presently comprises the four or five persons who constitute each of three Working Groups (addressing microbial aspects, chemical aspects and aspects of protection and control of drinking-water quality).

D7. Members of Working Groups 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 Working Group 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 Working Group and ensures that proper records are kept of all necessary information.

In order to achieve proper functioning of the Working Groups, 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.

D8. 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 Working Groups.
- 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;
- Develop, jointly with WHO HQ, guidelines or aspects thereof, which are of specific regional interest.

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

D9. Experts supporting the programme of work of the DWQC may be invited to attend meetings of the DWQ Committee or its Working Groups, where they are actively engaged in associated activities and their contribution to the meeting is considered important.

D10. All members of the DWQC and its Working Groups are invited to serve as individual scientists and not as representatives of any government or other organization.

D11. All DWQC members and experts invited to meetings of the DWQC are expected to sign a statement regarding Conflict 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.

D12. Observers may be invited to meetings. They may be invited to comment on draft documents and to make their views known, but they do not participate in the final decision on guidelines. Observers will be identified (indicating their professional affiliations and potential interests) as such from the start.

E. Process for the Revision of the Guidelines

E1. 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.

E2. 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 International Programme on Chemical Safety; in the case of microbiological hazards, to be consistent with approaches of Water, Sanitation and Health 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.

E3. The overall scheme used to develop guidelines and guidance is outlined in Table 1 and is common to all aspects of GDWQ documentation.

Table 1: Process for GDWQ document preparation and adoption

Stage (Authority to proceed to next stage¹)	Status	Notes
Stage 0 (WHO Secretariat and Coordinator)	For 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 Drinking Water Quality Committee	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 ² .
Stage 2 (Drinking Water Quality Committee)	The Drinking Water Quality Committee either;	Decision to place an item on the programme of work (or not) would normally be taken at DWQC meeting. The decision and explanation would normally be made publicly available.
	<input type="checkbox"/> Recommends no action (with an explanation); or	A decision and explanation that a review was not needed would normally then be reviewed by the corresponding Working Group and published in the same way as a conclusion that a review was under way.
	<input type="checkbox"/> 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.

¹ A review document may move back at any stage and any number of stages in response to new information or other substantive change

² Pending - refer to Appendix with format for proposals.

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 ³
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 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 coordinator	For chemical review documents only, a truncated review, (excluding Guidelines Value derivation but including 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 (i) use is made of recent IPCS risk assessment monographs, where available, or one or more high quality national reviews, (ii) 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 and Unit risk (for non-threshold chemicals), 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 working group on reasonable technical achievability and from the chemical aspects WG on reasonable analytical achievability.

<p>Stage 6 (WG)</p>	<p>The WG is satisfied with the document and that proper process has been followed and recommends release to public domain for comment</p>	<p>This stage would normally be passed at a WG meeting. The document is then posted on the WWW site of WHO, with an invitation to comment; its availability is broadcast 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 WWW capability. ROs advise appropriate entities in Member States of its existence. Availability in the public domain for comment is normally six and not less than three months.</p>
<p>Stage 7 (Coordinator)</p>	<p>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)</p>	<p>This stage would normally be completed by correspondence, unless substantive comment had been received.</p>
<p>Stage 8 (WG)</p>	<p>The WG is satisfied with the document and that proper process has been followed and recommends it to the Drinking Water Quality Committee for adoption.</p>	<p>The stage would normally be completed by correspondence, unless substantive comment had been received.</p>
<p>Stage 9 (Drinking Water Quality Committee)</p>	<p>The Drinking Water Quality Committee is satisfied with the document and that proper process has been followed and recommends its publication.</p>	<p>This stage requires a Drinking Water Quality Committee meeting. Completion of stage 9 and all preceding stages constitutes adoption for substantiation documents and documents providing guidance on good practice in implementation. Where specific Guideline Values are under discussion the DWQC meeting takes the form of a "Final Task Force Meeting."</p>
<p>Stage 10 (Final Task Force Meeting)</p>	<p>For guidelines documents themselves including adoption of guideline requirements and Guideline Values</p>	<p>Endorsement by a Final Task Group meeting constitutes adopting for guidelines themselves, guideline requirements and guideline values</p>

E4. 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.

E5. DWQ Committee 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.

E6. Data in the public domain, published in the peer-reviewed literature are the principal and preferred sources of information for use in deriving drinking-water quality guidelines if they 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 IARC, or by a similar recognized, international organization.

F. Guidelines for Microbiological Safety

F1. Overall Approach [pending, in response to ongoing revision]

F2. Significance and interpretation of a microbiological guideline
[pending, in response to ongoing revision]

G. Guidelines on Chemical Safety

G1. Overall approach

G1.1 In general, approaches to the management of chemical hazards vary between those where the source water quality is a significant contributor and those others where materials and chemicals (“additives”) are the dominant source.

G1.2 Chemical assessments are generally conducted on the basis of chronic exposures. For chemicals where exposure leads to acute rather than cumulative health effects; for chemicals such as larvicides added deliberately to drinking-water; and for toxins of cyanobacteria; special management approaches are required.

G1.3 Because of the large number of chemicals, guidance is required on priority identification, and this is undertaken in the GDWQ through a “chemical monitoring protocol”. [presently in development]

G1.4. Guideline Values are devised for many 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.

G1.5 Most chemicals arising from source waters are of health concern only after extended exposure and quality typically varies progressively. 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.

G1.6 Some chemicals arise principally from materials and chemicals and in the production and distribution of drinking-water ("additives"). The preferred method of control for such chemicals is through control of the materials and chemicals from which they arise. Many agencies undertake such certification and a GDWQ-related monograph (in preparation) describes the overall approach. Guideline Values may be derived for chemicals of this type, and are intended to inform and support such control and certification.

G1.7 Few chemicals are likely to lead to human health effects following short-term exposures without causing aesthetic rejection (see C15). Such chemicals include nitrate and nitrite. While routine monitoring may assist in identifying trends of concern, it does not provide an adequate management tool alone. GVs are prepared for such chemicals, but management strategies should not rely on detection and subsequent remediation of unsafe conditions, because of the acute nature of the health effects.

G1.8 Management of health hazards arising from the toxins of toxic cyanobacteria requires approaches similar to those for microbiological hazards. GVs may be derived for these toxins and should be used within the context of wider assessment and management approaches.

G1.9 [Paragraph on pesticides used for public health purposes pending.]

G1.10 The criteria used for deciding whether to review a chemical or not are, for chemicals not yet considered in the GDWQ:

- evidence for occurrence in drinking-water combined with evidence of actual or potential toxicity;
- significant international concern.

For constituents already considered in the GDWQ:

- for substances with provisional guideline values, new evidence that might affect "provisional" status;
- new health risk evaluation made available by the IPCS;
- new evaluation of the carcinogenic risk of a chemical by IARC;
- listing of a chemical in relevant PIC or POP listings.

G1.11 The criteria to determine whether to derive a GLV are:

- evidence for occurrence in drinking-water combined with evidence of actual toxicity.

G1.12 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 value to define a minimum desirable concentration of such substances in drinking-water.

G2. Risk Assessment

G.2.1 In deriving a guideline value for exposure to a chemical substance it is preferable to use data obtained from studies on human populations for assessing the health effects from exposure to a chemical but, in most cases, such information is not available or is limited in its scope. Where reliable and adequate epidemiological data are available, they should be used in preference to data from animal studies. In most cases, data derived from studies with laboratory animals are used to assess the health effects of the chemical. In order to do this, it is desirable to have access to one or more well-conducted animal studies with a clear dose-response relationship.

G.2.2 Procedures for deriving exposure guidelines are described in Environmental Health Criteria monograph 170, published by the International Programme on Chemical Safety (IPCS). However, there have been further developments with respect to methodologies for risk assessment of chemicals. These are described in Environmental Health Criteria monograph 210. Many of these developments require an extensive toxicological database, which is seldom available. The risk assessment process can be modified for specific substances by making use of scientific developments when appropriate.

[Text from existing GDWQ Vol. 2 pending review and insertion]

G.2.3 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 IPCS, e.g. an Environmental Health Criteria monograph (EHC) or a Concise International Chemical Assessment Document (CICAD).

In the absence of a suitable IPCS assessment, a new drinking-water guideline 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 IPCS assessment or a recent high-quality peer-reviewed national assessment, a new assessment is developed.

[Pending back-reference concerning evaluation where data is confidential]

G.2.4 Revisions of, or additions to, the guideline values for pesticides should be derived from the most recent recommendations of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR). In the absence of a JMPR assessment of a pesticide for which a guideline value is necessary, a request is made to JMPR to develop such an assessment.

G.2.5 Information for each chemical on the routine analytical techniques and practical quantitation limits, as well as on the technical feasibility of control by treatment or other means, is included in the assessment document when deriving a drinking-water guideline. The latter is provided by the Working Group on Aspects of Protection and Control.

G.2.6 For most types of toxic effects, it is believed that a threshold level of exposure exists, i.e. a level below which adverse effects will not occur even after long-term exposure. For other toxic effects, notably carcinogenesis (and mutagenesis), it is assumed

that there is some probability of harm at any level of exposure, i.e. that no threshold exists. 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 threshold or non-threshold chemicals.

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, often from occupational exposure.

On the basis of the available evidence, the International Agency for Research on Cancer (IARC) categorizes chemical substances with respect to their potential carcinogenic risk into the following groups:

- 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 a genotoxic activity, but acting through an indirect mechanism. It is generally believed that a threshold dose exists for these non-genotoxic carcinogens.

In order to make the distinction with respect to the underlying mechanism of carcinogenicity, each compound that has been shown to be a carcinogen is evaluated on a case-by-case basis, taking into account the IARC categorization, the evidence of genotoxicity, the range of species affected, and the relevance to humans of the tumours observed in experimental animals to determine the mode of action and therefore approach taken. For carcinogens for which there is convincing evidence to suggest a non-genotoxic mechanism, guideline values are derived using the approach for threshold chemicals.

G2.7 [text explaining uncertainty factors policy - pending]

G3. Threshold Chemicals

G3.1 In the case of threshold chemicals, a tolerable daily intake (TDI) is calculated from the No-Observed-Adverse-Effect-Level (NOAEL) or in some cases from the Lowest-Observed-Adverse-Effect-Level (LOAEL) for the effect considered to be most biologically significant. This is done by dividing the NOAEL or LOAEL by an uncertainty factor (UF)

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

G3.2 The drinking-water guideline value (GV) is then calculated from the TDI, according to the following formula:

$$GV = \frac{TDI \times bw \times P}{C}$$

Where bw is the body-weight, a body-weight of 60 kg is used for the calculation. In some cases where children or infants are thought to be at particular risk, guideline values are calculated based on either a 10 kg child or a 5 kg infant.

C is the daily consumption of drinking-water (see C16).

The portion (P) of the TDI allocated to drinking-water is based, where available, on mean levels of the chemical in food, air and water. When such information is not available, a default value of 10% is used for the allocation to drinking-water.

G3.3 Guideline values are generally derived for a lifetime of exposure

G3.4 In preparing the third edition of the GDWQ and subsequent revision, default values will be harmonized with those in EHC 170 where appropriate.

G4. Non-threshold chemicals

G4.1 For non-threshold chemicals, there is a probability of harm at any level of exposure. The development of a TDI is considered inappropriate and mathematical low-dose extrapolation is applied.

G4.2 In the case of compounds considered to be [genotoxic carcinogens/non-threshold chemicals], guideline values are determined using a mathematical model, and the guideline values recommended are the concentrations in drinking-water associated with an estimated upper bound (e.g. 95 or 99 percentile value) excess lifetime cancer risk of 10^{-5} (one additional cancer per 100,000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years).

[Sentence to be added explaining that the choice of a 1:100000 does not imply that WHO considers this risk to be acceptable, but rather as an indicative figure. Decisions on acceptability of risks must be made by standard-setting authorities.]

[expanded explanation of "upper bound" pending insertion]

G4.3 Although several models exist, the linearized multi-stage model is generally adopted in the derivation of GVs for non-threshold chemicals.

G4.4 Guideline values for [carcinogenic compounds/non-threshold chemicals] computed using mathematical models must be considered at best as a rough estimate of the cancer risk. These models do not usually take into account a number of biologically important considerations, such as pharmacokinetics, DNA repair, or immunological protection mechanisms. The models used are conservative and probably err on the side of caution.

G5 Provisional Guideline Values

G5.1 When the health-based GV is less than the level that can be determined by a routine analytical method, the GV is set at the analytical level that can be reasonably achieved (practical quantitation limit). From the 3rd edition of the GDWQ, such values will be denoted with an "A" in the summary table (rather than a "P", as was done earlier) and an explanatory footnote added.

G5.2 If the health-based GV can not be achieved through realistic technical means such as treatment, then the GV is set at the health-based limited. From the third edition of the GDWQ, these values will be denoted with a "T" in the summary table, rather than a "P" as was done previously and an explanatory footnote added.

G5.3 Guideline values for disinfectants and disinfectant by-products are not established where their establishment would discourage disinfection. This follows from the principles of protection of public health and giving priority to microbiological contaminants. Where such conflict might occur, GVs are set at the health-based value and have been designated as provisional. From the third edition of GDWQ they will be denoted with a "D" in the summary table, with an explanatory footnote.

H. Guidance on Good Practice/Implementation of the Guidelines

H1. The development of narrowly defined norms/standards alone will have a limited impact upon public health, unless other supportive guidance is available. 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 areas) and more detailed guidance on management of certain hazards than is possible in the Guidelines themselves.

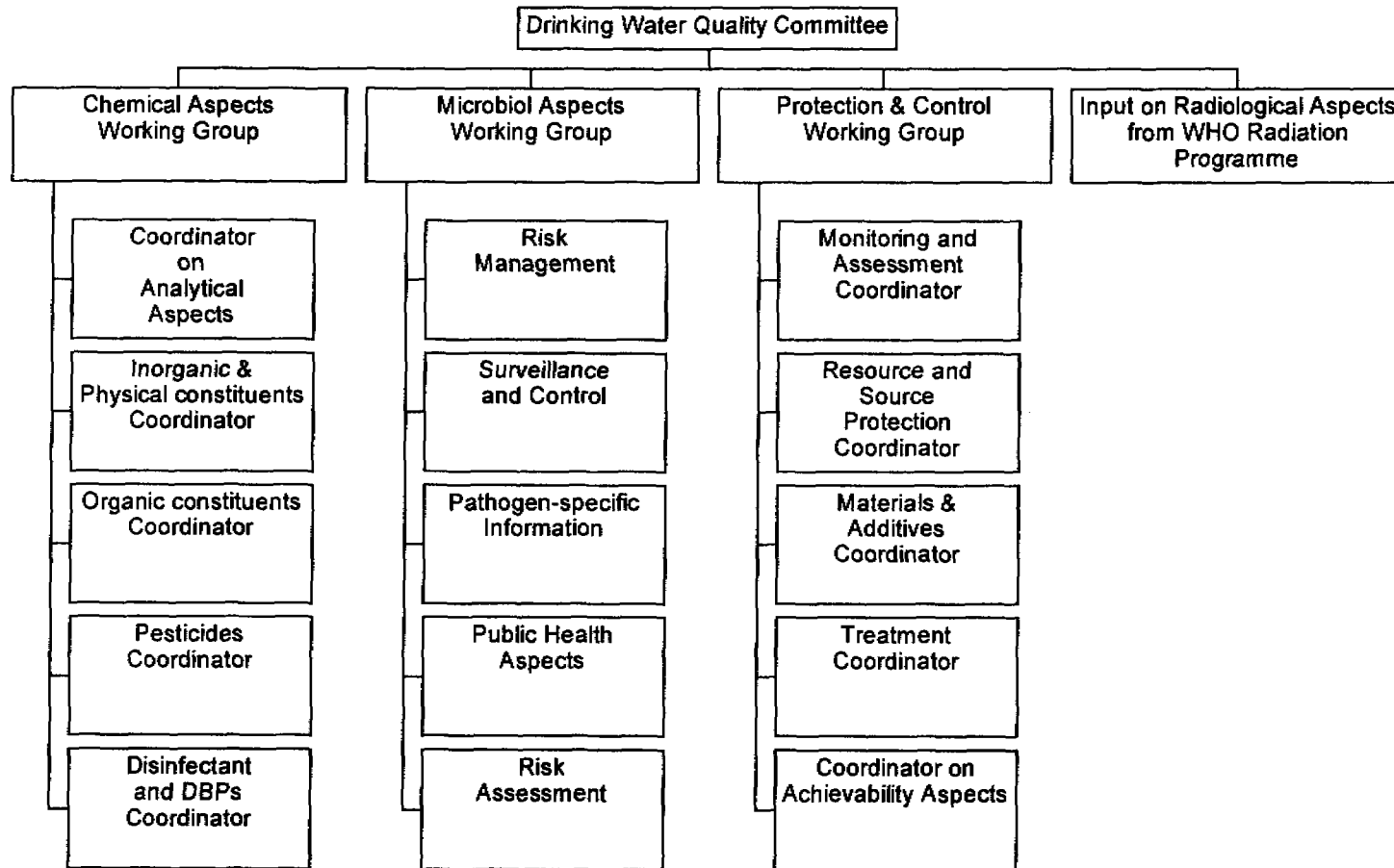
H2. The preparation of guidance of this sort is not necessarily a component of the GDWQ *per se* and such supportive guidance may, in some cases, therefore, be published outside the GDWQ and may be developed and published in cooperation with other agencies.

H3. 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.

H4. 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, therefore, (Table 1) it is important that input from practitioners with relevant field experience be sought and properly accommodated.

I. Radiological Aspects

[Pending]



Appendix 2

Glossary of Terms

Adverse effect change in morphology, physiology, growth, development or life-span of an organism, which results in impairment of functions, capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. Decisions on whether or not any effect is adverse requires expert judgement.

Critical effect(s):the adverse effect(s) judged to be most appropriate for determining the TI.

No-observed-adverse-effect-level (NOAEL): greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration or morphology, functional capacity, growth, development or life-span of target organisms distinguishable from those observed in normal (control), organisms of the same species and strain under the same defined conditions of exposure.

Lowest-observed-adverse-effect-level (LOAEL): greatest concentration or amount of a substance, found by experiment or observation, that causes no aberrations of morphology, functional capacity, growth, development or life-span of the target organism distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure.

Benchmark dose: the lower confidence limit of the dose calculated to be associated with a given incidence (e.g. 5 or 10% incidence) of effect estimated from all toxicity data on that effect within that study (Crump, 1984).

Uncertainty factor (UF): a product of several single factors by which the NOAEL or LOAEL of the critical effect is divided to derive a TI. These factors amount for adequacy of the pivotal study, interspecies extrapolation, inter-individual variability in humans, adequacy of the overall data base, and nature of toxicity. The term “uncertainty factor” was considered to be a more appropriate expression than “safety factor” since it avoids the notion of absolute safety and because the size of this factor is proportional to the magnitude of uncertainty rather than safety. The choice of UF should be based on the available scientific evidence.

Tolerable intake (TI): an estimate of the intake of a substance which can occur over a lifetime without appreciable health risk. It may have different units, depending upon the route of administration. Though not strictly an “intake”, TIs for inhalation are generally expressed as airborne concentrations (i.e. ug or mog per m³).

Default value :pragmatic, fixed or standard value used in the absence of relevant data.

Guidance values: values, such as concentrations in air or water, which are derived after appropriate allocation of the TI among the different possible media of exposure. Combined exposures from all media at the guidance values over a lifetime would be expected to be without appropriate health risk. The aim of the guidance value is to provide quantitative information from risk assessment for risk managers to enable them to make decisions concerning the protection of human health.

[More to be added]

APPENDIX 3

FORMATTING OF DRAFT CHEMICAL REVIEW DOCUMENTS

[N.B. pending formatting ref. Author, contributor attribution]

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 in Word 97 format. If possible, authors are asked to prepare documents in this format. WordPerfect (6/7/8 & 9) is also acceptable. If the author cannot use Word or WordPerfect, he/she should discuss the best alternative with the Secretariat.
3. Abbreviations should be presented in parenthesis where they are first introduced.
4. The full name of the chemical or organism 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 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 & Williams, 1983a,b; Ofstad & Sletten, 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 not 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 World Health Organization, the submitter of the communication should be included.

The format to be used for the monographs is shown below. All of the headings may not, however, be required in every monograph.

GENERAL DESCRIPTION

Identity
Physicochemical properties
Organoleptic properties **Major uses**
Environmental fate

ANALYTICAL METHODS

ENVIRONMENTAL LEVELS AND HUMAN EXPOSURE

Air
Water
Food
Estimated total exposure and relative contribution of drinking-water

KINETICS AND METABOLISM IN LABORATORY ANIMALS AND HUMANS

EFFECT ON HUMANS

EFFECTS ON LABORATORY ANIMALS AND *IN VITRO* TEXT SYSTEMS

Acute exposure
Short-term exposure
Long-term exposure
Reproductive toxicity, embryotoxicity, and teratogenicity
Mutagenicity and related end-points
Carcinogenicity

GUIDANCE VALUE

ACHIEVABILITY OF HEALTH-BASED GUIDELINE

ANALYTICAL ACHIEVABILITY

TREATMENT ACHIEVABILITY

APPENDIX 4

As part of the review and approved process, authors are required to provide a summary of the disposition of comments received during the international peer-review of the draft document.

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

To facilitate the review with respect to the way in which peer-review comments were dealt with by authors during their revision of the draft document, the Coordinator/Secretariat will provide to authors an electronic file containing a tabulated list of the peer-review comments received (see example outlined below), as well as copies of all correspondence received from peer-reviewers. Authors are required to indicate (in the "RESPONSE" column of the electronic file) how the peer-review comments were dealt with.

To expedite review by the Working Group, authors are encouraged to be as informative as is reasonably possible in outlining how the peer-review 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 peer-review 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 comments, the reason(s) for the disagreement should be briefly outlined in the summary table.

**SUMMARY TABLE OF PEER-REVIEW COMMENTS AND RESPONSES
FOR CHEMICAL REVIEW DOCUMENTS**

COMMENT (ISSUE)	RESPONSE	FINAL REVIEW BOARD OUTCOME
Completed by the Coordinator / Secretariat, based upon comments received during the institutional peer-review stage	Completed by authors during revision of the draft document	Completed by the Secretariat based upon deliberations of the Working Group
Section 1.0, 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, <i>in vitro</i> and <i>in vivo</i> studies have clearly revealed that this chemical causes genetic damage.	

C:\Guidelines for Drinking Water Quality (Sham 20/xi)