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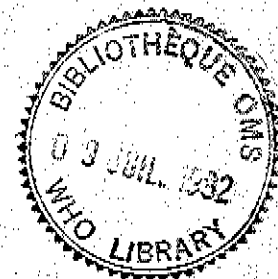
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## REVISION OF THE WHO GUIDELINES FOR DRINKING-WATER QUALITY

Report on the  
Consolidation Meeting on  
Organics and Pesticides

Medmenham, United Kingdom  
30 – 31 January 1992



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EUR/HFA TARGET 20

This activity was organized by the WHO Regional Office for Europe to promote work aimed at achieving the following target in the health for all strategy.<sup>a</sup>

## TARGET 20

### WATER QUALITY

*By the year 2000, all people should have access to adequate supplies of safe drinking-water and the pollution of groundwater sources, rivers, lakes and seas should no longer pose a threat to health.*

### Keywords

PESTICIDES  
HAZARDOUS SUBSTANCES  
DRINKING WATER  
WATER QUALITY  
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<sup>a</sup> Updating of the European HFA targets. Copenhagen, WHO Regional Office Europe, 1991 (document EUR/RC41/Inf.Doc./1 Rev.1).

## 1. Introduction

As part of the revision of the WHO Guidelines for Drinking-Water Quality, four Review Group Meetings were convened by the World Health Organization Regional Office for Europe (EURO) to evaluate certain organic chemicals and pesticides in drinking-water. The venues, dates and meeting reports are as follows:

Pesticides I:	Milan, 25-30 June 1990, EUR/ICP/CWS 027
Pesticides II:	Rennes, 2-6 September 1991, EUR/ICP/CWS 031
Organics I:	Copenhagen, 6-10 November 1990 EUR/ICP/CWS 030
Organics II:	Copenhagen, 8-12 April 1991, EUR/ICP/CWS 032

At the Coordination Group Consultation held in Geneva, 13-14 May 1991 (WHO/PEP/91.17) it was agreed that there was a need to convene an overall consolidation meeting to review and harmonize the approaches used by each of these Review Groups in assessing the risk and deriving guideline values.

The aims of the Consolidation Meeting were:

- To review all the evaluation documents on organics and pesticides;
- To review the derivation of the proposed guideline values checking the consistency in the approaches used;
- To give guidance to the scientific editor and answer her questions regarding the evaluation documents already received.

The meeting was held at the Water Research Centre, Medmenham, United Kingdom, 30-31 January 1992. Dr R. van Leeuwen acted as moderator, Mrs Wendy Young took the main notes of the meeting and WHO representatives acted as secretariat and rapporteurs. Mrs Marla Sheffer, scientific editor of the Guidelines, attended the meeting together with the Coordinators (See Annex 1 for list of participants).

At present, approximately 50 revised shortened evaluation documents have been received from the lead countries. There are about 50 outstanding chemicals but it is envisaged that many of these outstanding documents will be received by end of February 1992.

It was proposed that in the event the revised shortened versions from the lead countries were not received, Mrs Sheffer would proceed to edit the original draft evaluation documents. The documents edited by Mrs Sheffer will be returned to the coordinators only. Should significant modifications or problems arise, the Coordinators are to contact the lead countries. Dr Hend Galai-Gorchev will revise the document on DDT and will also send reminders to those countries whose documents have not been received.

## 2. Review of proposed guideline values

The group agreed on the following rounding principle: The tolerable daily intake (TDI) should be expressed numerically using only one significant figure and the TDI-derived guideline values should also have only one significant figure. Following this principle, slight differences may appear

between the guideline value derived without rounding and the one derived after rounding. Nevertheless, and in order to be consistent throughout the entire document, it was agreed to strictly adhere to this rounding rule. Attached to this report is the list of compounds with agreed TDI or ADI (Acceptable Daily Intake) and proposed guideline values. (Annex 2).

The group then reviewed summary reports on each compound, answered the questions of the scientific editor and agreed upon certain points:

The following compounds have been highlighted as having associated problems with the proposed guideline values:

## 2.1 Organics

- a) In the summary statement on carbon tetrachloride:  
Change paragraphs 3 and 4 around

Changes to paragraph 4 (which will become paragraph 3) are:

Carbon tetrachloride is not genotoxic in most available studies and it is possible that it acts as a non-genotoxic carcinogen. A guideline value derived from the division of a NOAEL by an uncertainty factor would be in the same range as one calculated by estimating the risk of cancer by applying a low dose extrapolation model to the animal data.

- b) The guideline value for 1,1,1-trichloroethane is provisional.
- c) It was recommended that the summary for trichloroethene be revised. It now reads as follows:

"Paragraph 4, line 3

...of 100 mg/kg body weight for minor effects on relative liver weight in a 6 week reproduction study in rats with 5 day-dosing (100 for inter and intraspecies variation and 10 for limited evidence of carcinogenicity). An additional factor of 3 was applied in view of the short duration of the study and the use of a LOAEL rather than a NOAEL. This was considered adequate since this LOAEL was lower than a NOAEL from a less well-documented long-term study in which drinking-water was the vehicle. The guideline value derived from this TDI based on 10% allocation to drinking water is 60µg/litre. However, the lowest reported odour threshold for trichloroethene is 300 µg/litre."

The last sentence of the original paragraph is to be deleted.

- d) For tetrachloroethene, rounding of figures results in the proposed guideline value of 49 being reduced to 30µg/l.
- e) It was recommended that the summary for benzene should be redrafted to place more emphasis on the human data from inhalation studies. The animal data where exposure is via the oral route is also to be included as both approaches result in comparable guideline values. The new version reads as follows:

"...Owing to the unequivocal evidence of the carcinogenicity of benzene in man and animals and the documented chromosomal effects, quantitative risk extrapolation was used to calculate reference lifetime risks.

Based on risk estimate of data on leukemia in epidemiological studies with respect to inhalation exposure, it was calculated that a drinking-water concentration of 1µg/l was associated with a lifetime excess cancer risk of  $10^{-6}$  (10 µg/l is associated with a  $10^{-5}$  lifetime risk).

Since data on the carcinogenic risk to humans following ingestion of benzene are not available, risk estimates have also been carried out on the basis of a 2-year gavage study in rats and mice.

The robust linear extrapolation model was used since there was a statistical lack of fit of some of the data with the linearized multistage model. The estimated ranges of concentrations, based on separate tumour sites, in drinking water corresponding to lifetime excess risks of  $10^{-4}$ ,  $10^{-5}$  and  $10^{-6}$  are, 15 - 160 µg/l, 1.5 - 16 µg/l and 0.15 - 1.6 µg/l, respectively. These estimates are similar to those that have been derived from epidemiological data, and formed the basis for the previous guideline value of 10 µg/l associated with a  $10^{-5}$  lifetime risk. Concentrations corresponding to lifetime excess risks of  $10^{-4}$ ,  $10^{-5}$  and  $10^{-6}$  are, therefore, 100, 10 and 1 µg/l, respectively.

- f) In the revised shortened evaluation document for styrene, duration of exposures are to be added.
- g) It is recommended that 1% allocation to water be used for di(2-ethylhexyl)phthalate (DEHP).
- h) The basis of NOAEL for MCB (Monochlorobenzene) is neoplastic nodules in the liver.
- i) It was decided that the DCBs (Dichlorobenzenes) should be discussed in detail incorporating the International Programme on Chemical Safety (IPCS) Environmental Health Criteria (EHC) document. Use of the 10 000 uncertainty factor was criticized and it was suggested that the guideline for 1,4-DCB be provisional. In contrast, the EHC document uses an uncertainty factor of 1000.

The modified summary for 1,4 DCB reads now as follow:

"1,4-DCB is not considered genotoxic; it is therefore valid to calculate a guideline value using the TDI approach. A TDI of 0.01 mg/kg body weight was calculated by allocating a very conservative uncertainty factor of 10 000 etc.....).

The provisional guideline value is 30µg/l based on an allocation of 10% of the TDI to drinking-water but this value exceeds the lowest reported odour threshold of 0.3µg/l.

- j) Acrylamide cannot be measured at the proposed guideline value and it is recommended that the following be added: "generally acrylamide cannot be detected at 1µg/l or less, but can be controlled by product specification". The reference on the induction of scrotal mesotheliomas (company information) should be identified and incorporated in the revised shortened evaluation document.

- k) It was agreed that additional comment on difficulty of detection be included for hexachlorobutadiene since "it is difficult to analyse except by using sophisticated techniques" (Mr Fawell to draft). The animal study used for the derivation was queried and the first draft evaluation document is to be sent to Marla Sheffer for clarification.
- l) It was recommended that Marla Sheffer should compare the limits of detection in the revised shortened evaluation documents with the lowest limit of detection identified in the Consultation on Analytical and Water Treatment Methods.
- m) For NTA, a 50% allocation of the TDI to water gives a guideline value of 150 µg/l but after rounding a value of 200 µg/l is derived. It was recommended that appropriate wording should be added to indicate that the TDI and guideline value are rounded.
- n) Confirmation that the working group identified a TDI of 1.9 mg/kg bw for EDTA (free acid) is required. If this is the case the guideline value should be rounded to 200 µg/l. However, if this is an ADI established by JECFA, the value should not be rounded up.

## 2.2 Pesticides

- a) The guideline value for 1,2-dichloropropane is provisional.
- b) The guideline for epichlorohydrin is provisional.
- c) All first draft evaluation documents are to be sent to Marla Sheffer and, where appropriate, information will be reintroduced into the revised shortened versions.
- d) For aldicarb, the guideline value of 1µg/l (based upon 1% allocation of the TDI to water), is close to the detection limit. The actual food contamination is generally low and therefore it was recommended that a 10% allocation to water is more appropriate which results in a guideline value of 10µg/l. However, where illegal use of aldicarb has occurred, then the 1% allocation should be used. These proposals are to be presented to the drafting group.
- e) For 2,4-D, it was recommended that Dr van Leeuwen summarizes the results from recent carcinogenicity studies in rodents. These are to be sent to Mrs Sheffer and incorporated and referenced in the evaluation document. The results are to be presented to the drafting group should the guideline value be affected.
- f) For ethylene dibromide none of the guideline values proposed can be measured. It was recommended to add: "However, the present limit of detection is below 0.01µg/l". The guideline values are very low and based on a low dose extrapolation model, and it was recommended that Marla Sheffer should obtain the original studies and clarify the results. These should be presented to the drafting group.
- g) A general statement on pesticides and the aquatic environment is to be included in Volume 1. In the DDT summary, the final paragraph emphasizing this aspect should remain.

- h) It was recommended that definitions of abbreviations should be included in Volume 2.
- i) It was recommended that Marla Sheffer should compare the limits of detection in the revised shortened evaluation documents with the lowest limit of detection identified in the Consultation on Analytical and Water Treatment Methods.

3. Conclusions and recommendations

The Group agreed on the following:

3.1 Principles to be incorporated in Volume 1

- a) The definition of guideline values can be copied from Volume 1. However, it was agreed that improvements can be made on what the guidelines actually mean (emphasizing that they are not standards). Mr Fawell and Dr van Leeuwen are to draft a section on the use of uncertainty factors and give guidance on interpretation should a guideline value be exceeded.
- b) The drafting group (Canada) will prepare a section on sampling and monitoring as in the present Volume 1. Mr Fawell will prepare a draft version of this section which will be submitted for the consideration of the drafting group.
- c) It was recommended that a section on possible means of prevention of contamination be included.
- d) It was recommended that a section on corrosion control be included.
- e) There are some well established treatment principles for various types of chemicals. It was recommended that a section on the technical principles for removal be included (may involve the use of consultants).
- f) It was recommended that there should be an introductory paragraph on the use of different mathematical models and their limitations. It was agreed that it was outside the scope of the group to evaluate these models in detail which was the responsibility of the IPCS.
- g) It was recommended that a general paragraph on the use and problems associated with surface area correction be included. Mr Fawell agreed to draft this section.

3.2 Derivation of guideline values

- a) A 60 kg adult is to be used in the derivation of the guideline values as opposed to 70 kg adult.
- b) Where an uncertainty factor of 10 000 is used, the guideline value should be termed "provisional".

- c) It was agreed that an ADI or TDI should be expressed numerically using only one significant figure, and this figure be used to derive the guideline value. The guideline value should also be rounded to one significant figure. When the second significant figure is 5 the value should be rounded up.
- d) The ADI or TDI should be expressed as one figure and not as a range.
- e) It was recommended that units should be chosen as appropriate to enable easy understanding.
- f) It was thought that there should be no problem in using manufacturers' data.
- g) It was agreed that studies less than 1 year in rodents would be classified as "short-term" and those over 1 year as "long-term".
- h) Where omitted, IARC classification should be incorporated into the shortened revised evaluation documents.
- i) Where no guideline value can be derived, it was agreed that the compound should still appear in the table (Volume 1). It was agreed that the wording "data available did not allow establishment of a guideline value" should be incorporated.
- j) Where applicable, it should be stated whether surface area correction was used in deriving guideline value. Although likely, it is uncertain whether it is used in the USA studies. If difficult to ascertain, it was agreed that unless the compound was controversial, the model should not be rerun as this would prove too time consuming.
- k) Iodine is included in the disinfectants and disinfectant by-products group of chemicals rather than in the inorganics group.
- l) Depending on the mathematical model used, a large range of guideline values can be derived for bromate. In conjunction with the risk-benefit of using ozone treatment, it was agreed that the proposed guideline value for bromate should be reviewed by the drafting group in Canada.

Annex 1

List of Participants

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Annex 2

Compound	TDI µg/kg-bw	Guideline Value µg/l
Alachlor	-	30/3/0.3
Carbofuran	2	6
Dichlorprop	40	100
2,4-DB	30	90
2,4,5-T	3	9
Silvex	3	9
Mecoprop	3	9
DDT	20	2
1,2-Dibromo-3-chloropropane	-	2/0.2/0.02
2,4-Dichlorophenoxyacetic acid	10	30
MCPA 0.5	2	
Methoxychlor	5	20
Aldicarb	4	10
Aldrin/Dieldrin	0.1	0.03
Atrazine	0.7	2
Bentazon	100	30
Chlordane	0.5	0.2
Chlortoluron	10	30
1,2-Dichloropropane	7	2 (provisional)
1,3-Dichloropropene	-	20/2/0.2
Ethylene dibromide	-	0.03/0.003/0.0003
Heptachlor and -epoxide	0.3	0.09

Annex 2

Compound	TDI µg/kg-bw	Guideline Value µg/l
Hexachlorobenzene	-	2/0.2/0.02
Isoproturon	3	9
Lindane	5	2
Permethin	50	20
Metolachlor	1	3
Molinate	2	6
Pendimethalin	5	20
Propanil	5	20
Pyridate	40	100
Simazine	0.5	2
Trifluralin	8	20

Compound	TDI µg/kg-bw	Guideline Value µg/l
Carbon tetrachloride	0.7	2
1,2-Dichloroethane	-	30/3/0.3
1,1,1-Trichloroethane	400	1000 (provisional)
Dichloromethane	6	20
1,1-Dichloroethane	-	-
1,1-Dichloroethene	5	20
1,2-Dichloroethenes	20	60
Trichloroethene	20	60
Tetrachloroethene	10	30
Vinyl chloride	-	20/2/0.2
Styrene	8	20
Toluene	200	600
Xylenes	200	600
Monochlorobenzene	90	300
1,2-Dichlorobenzene	400	1000
1,4-Dichlorobenzene	10	30
Trichlorobenzenes	8	20
Acrylamide	-	1/0.1/0.01
Hexachlorobutadiene	0.2	0.6
Epichlorohydrin	0.1	0.3 (provisional)
Di(2-ethylhexyl)adipate	300	90
Nitrilotriacetic acid	10	200
EDIA	-	200 (provisional)

Annex 2

Compound	TDI µg/kg-bw	Guideline Value µg/l
Benzo(a)pyrene	-	7/0.7/0.07
Tributyltin oxide	0.3	2
Ethylbenzene	100	300
Benzene	-	100/10/1
Di(2-ethylhexyl)phthalate	30	9