METHODOLOGY AND FORMAT FOR UPDATING AND REVISING THE AIR QUALITY GUIDELINES FOR EUROPE

WORLD HEALTH ORGANIZATION
Regional Office for Europe
COPENHAGEN

TARGET 21

AIR QUALITY

By the year 2000, air quality in all countries should be improved to a point at which recognized air pollutants do not pose a threat to public health.

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Report on a WHO Working Group

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ABSTRACT

Within the framework for updating and revising the WHO *Air quality guidelines* for Europe, a meeting of the Working Group on Methodology and Format was held at the WHO European Centre for Environment and Health in Bilthoven, Netherlands, from 20 to 22 September 1993 to discuss such topics as the types of health effect to be considered, the methods to apply in order to assess the risk of threshold and non-threshold effects, and the effects of air pollutants at different levels of exposure (and/or dose) and how these should be demonstrated. The participants also discussed the structure of the individual chapters of the second edition of the guidelines, the possibilities for illustrating dose–response relationships and the methods to be applied in deriving guideline values or risk estimates for carcinogens and non-carcinogens. The Group emphasized the need to make a clear distinction between guidelines and standards and to advise on how to move from guidelines to standards. They felt that including a separate chapter on standard setting would be inappropriate, but that an account of the factors that could be considered in standard setting should be included in the introductory chapters of the second edition.

Keywords

ENVIRONMENTAL EXPOSURE
AIR POLLUTION – prevent/control
AIR POLLUTANTS – adverse effects
AIR QUALITY
EVALUATION STUDIES
EUROPE

CONTENTS

INTRODUCTION

The WHO *Air quality guidelines* for Europe were published in 1987. Since then they have been a valuable source of information on the adverse effects on health of air pollutants, and have been used as a basis for setting standards. At a planning meeting held in January 1993 it was decided to revise the guidelines in the light of recent advances in toxicology and new information on pollutants of significance, and a number of working groups were established to that end. The first working group held a meeting on the methodology and format for updating and revising the air quality guidelines for Europe at the WHO European Centre for Environment and Health in Bilthoven, Netherlands, from 20 to 22 September 1993. The meeting was attended by 10 scientists from 8 countries, a representative of the Commission of the European Communities (DG-XI), representatives of the International Programme on Chemical Safety (IPCS) and the International Agency for Research on Cancer (IARC), as well as WHO staff. Dr Peter Rombout was elected Chairperson and Dr Robert Maynard Rapporteur. The working papers and participants are listed in Annexes 2 and 3, respectively.

The objectives of the Working Group were to provide guidance on:

- the types of health effect to be considered;
- the methods to apply with respect to assessing the risk of threshold and non-threshold effects;
- the effects of air pollutants at different levels of exposure (and/or dose) and how these should be demonstrated;
- the appropriate averaging times for guidance values in relation to observed exposure–response relationships;
- the means of combining risk estimates for predicting effects of mixtures of pollutants and combined exposures;
- the need to incorporate confidence limits in unit risk estimates and to consider recent developments in physiologically based pharmacokinetic/pharmacodynamic modelling (PBPK).

Dr Van der Heijden, Director of the Bilthoven division of the WHO European Centre for Environment and Health opened the meeting. He underlined the usefulness of the air quality guidelines (AQGs) and the importance of the first edition, but recognized the need to produce a second edition. He emphasized in particular the value of the AQGs to countries in central and eastern Europe. The second edition would involve to a greater degree the International Programme on Chemical Safety (IPCS) and the Commission of the European Communities (CEC). CEC intends to use the guidelines as a basis for setting values in the planned Framework Directive on Air Quality in Europe.

DISCUSSION

The need for more guidance on how to move from guidelines to standards was stressed. It was also pointed out that provision of a range rather than a single value for a guideline might be valuable, and, where possible, information should be provided on the dose/exposure–response curve for individual chemicals.

The participants also discussed the need to examine and identify sources of pollutants. This was considered a difficult task. Sources and key routes of exposure and intake would inevitably differ from country to country. It was suggested that the identification of sources should be qualitative but systematic.

Groups were formed according to agenda item, and their conclusions were discussed in plenary.

Review of health effects

With respect to revising the chapters dealing with individual compounds, the following categories of health effect were identified: annoyance, non-cancer effects and cancer effects.

Various annoyance problems were reviewed. The group acknowledged that annoyance effects are complex, embracing both irritation and odour. It was decided that, although it should be

tackled in detail on a compound-to-compound basis, a separate section in the introductory chapters should provide an overview of this topic. Headache was considered a non-cancer health effect rather than an annoyance.

There was a lengthy discussion of the meaning and value of the terms threshold and non-threshold effects. The confusing nature of the terms was stressed and the view that threshold reflected knowledge at a given time, more than mechanisms, was put forward. Ozone was discussed as an example.

The need to separate minor effects from effects of major concern to health was emphasized. The concepts of negligible effects and *de minimus* effects were mentioned. A discussion of the effects associated with changes in levels of fine particles led to the question of which effects were actually important. The idea that the advance of death by a few days for the mortally ill may *not* be an effect of overwhelming importance was discussed. The importance of using a recent IPCS document on guidance values for setting environmental health criteria was noted.

In summing up this part of the discussion the Chairperson suggested abandoning the terms threshold and non-threshold and using carcinogenic and non-carcinogenic effects instead. He further suggested that the non-carcinogenic group could be divided into those chemicals about which a good deal was known and to which expert judgement and experience could be applied in deriving a guideline, and a second group for which much more data were needed to remove major uncertainties.

Non-carcinogens

It was agreed that the draft IPCS document on the derivation of guidance for health-based exposure limits was a valuable source of information. Difficulties in using a standard methodology were explored as were the dangers of using the concepts average exposures and average recipients. It was pointed out that routes of exposure may vary from country to country for each particular chemical, and those responsible for setting standards should be encouraged to take this into account in moving from guidelines to

standards. The interdependence of media was illustrated with regard to lead and dioxins.

Proposals were made on what methods to include on risk assessment in connection with establishing air quality guidelines for Europe, including the reference concentration (RfC) approach. The concept of not needing a standardized method when good data were available and expert judgement could be safely applied was discussed. Table 1 indicates how the size and completeness of the database relates to assessment methods, and it was agreed that this should be considered for inclusion in the second edition of the guidelines.

Table 1. Size and completeness of database in relation to assessment methods

Completeness/ Size of database	Examples	Uncertainties	Feasibility of expert judgement approach	Need for standardized approach
+++	Ozone, nitrogen dioxide, lead	+	+++	+
++	Manganese, nickel	++	++	++
+	Volatile organic compounds	+++	+	+++

Key: +++ Large
++ Medium
+ Small

The dangers of replacing expert opinion and common sense with advanced, complex and sometimes not intuitively obvious statistical methods were discussed and caution was advised. The apparent paradox of *not* using a standard method when many data

were available but using one when few data were available needs to be explained.

In summary, it was agreed that the chapters from the first edition should be taken as a starting point and updated where necessary. Fundamental changes would be unnecessary. Other approaches including meta-analysis, the RfC approach and the use of bench-mark doses should be considered. These would be discussed in the introductory chapters of the second edition.

The term protection factor should be abandoned and replaced with uncertainty factor. It was agreed that the sources of the implied uncertainty need to be explained.

There is also a need to provide guidance where appropriate on dose/exposure–response relationships. The group stressed that, where feasible, the severity and adversity of health effects should be described for exposure levels by a range around the suggested guideline.

The importance of assessing the contribution to total dose of different routes of exposure should also be kept in mind.

Carcinogens

A draft paper by the US Environmental Protection Agency was considered by the group. It dealt with the viewpoint that a move away from oversimplistic application of a given extrapolation model was desirable. It was made clear that the newer, modified approach would not always lead to a unit risk assessment: indeed extrapolation to zero dose cannot always be advised.

Participants also discussed an alternative to quantitative risk assessment (QRA) for setting standards for carcinogens. This approach is based on the identification of a no demonstrable effect level (NDEL) or no expected human effect level (NEHEL), and the application of uncertainty factors. Comparison with ambient concentrations and index compounds was also considered. The group felt this method was *not* generally applicable, although its use on a national or smaller scale was possible. It was not possible, however, to reach complete agreement on the value of a non-QRA approach.

The group agreed on the need to consider the role of biomarkers of exposure and early, possible, pre-carcinogenic effects. Cellular proliferation and the effects of combined or sequential exposure to irritants and carcinogens were considered. Research into the use of biomarkers was advancing, and a note on this area should be included in the introductory chapters.

There was a need to consider the effects of air pollutants on susceptible groups in the population, and this should be pointed out in the instructions provided with chapters dealing with individual pollutants.

A distinction must be made between genotoxic and non-genotoxic carcinogens.

There was a long discussion on extrapolation of the effects of low doses of carcinogens. The lack of a perfect model was acknowledged, and it was resolved to wait for the conclusions of an IARC meeting on extrapolation and QRA. The need to recommend a standard approach was discussed. It was agreed that this would be worth while, although flexibility for expert judgement by the individual working groups and freedom to adopt, if suitable, the latest methods were also considered necessary.

Annex 1 contains a valuable note on the QRA/uncertainty factor method for deriving a guideline.

Discussion of the value of unit risk estimates made clear that this approach could have been better explained in the first edition. It was felt that the unit risk approach should be retained but that note be taken of the imprecision of the estimates. All sources of error and bias should be addressed. It was agreed that in some cases methods of extrapolation would render the unit risk approach unnecessary, and that this approach should be regarded as the default option. It was also agreed that a table indicating dose or exposure concentration and corresponding calculated risk should be provided when unit risk or other extrapolation techniques are applied.

Combined exposures

Although evidence on the effects of combined exposure to pollutants must be considered, it was pointed out that data were

available for only a limited series of combinations of media and routes. Detailed work should therefore be limited to these chemicals. The significance of indoor versus outdoor exposure was touched on. It was stressed, however, that while for some compounds a brief outdoor exposure would likely be unimportant, for other compounds it would be important.

Since combinations of pollutants in summer and winter smog have significant effects, it was agreed that controlling levels of a range of pollutants by controlling sources of smog should be pursued.

A short note on combined exposures should be included in the introductory chapters with detailed accounts as necessary in the compound-specific chapters.

Illustration of effects of different levels of exposure

The need for guidance on the dose/exposure–response curve for compounds was recognized, and it was recommended that this be indicated in the instructions to authors of chapters dealing with individual pollutants. As an example, the extent and character of health effects to be anticipated at 0.5, 1.0, 2.0 and 4.0 times the guideline could be provided. The idea of using graphical illustrations was considered. It was agreed that such an approach was not feasible or even desirable for all compounds.

The idea of using tables was considered. It was agreed that some form of table illustrating effects against exposure would be valuable for some compounds, and that action or alert levels should be included. The need to identify high-risk groups was stressed: this would be difficult in a simple table, although it might be achieved with specific classes of compounds or population subgroups such as asthmatics. There was a good deal of concern regarding the possible misinterpretation of a table giving action or alert levels. Measurements of individual pollutants were thought not to reflect in an identical way the effects of air pollution mixtures in different areas.

The idea of a two-tier system was considered: guidelines for air quality and emergency response levels.

Some members were very uneasy with the idea of providing advice on action levels as they felt that this was a problem for individual countries. Others felt that advice on this was important. The desirability of providing an indication of likely effects of exposure to levels of pollutants lower than those recommended as air quality guidelines was considered. This was agreed to be important as research on a number of compounds suggested that effects could be recorded at low close to background levels.

It was agreed that, in addition to defining a guideline value, the consequences on health of exceeding the guideline should be indicated. Individual countries would then be able to make use of this information in establishing action or alert levels, if they wished, as part of their risk management strategies.

The group pointed out the need to separate scientific opinion on the likelihood of occurrence of effects from comments on the importance of these effects. Mere expression of concern about a certain level of exposure was agreed to be undesirable, as such statements involved value judgements not easily made without a detailed knowledge of the circumstances under which such effects might occur.

The concept of an overall exposure–response relationship for an individual compound or pollutant was questioned. It was pointed out that, for fine particles, effects on sensitive individuals, including premature death, might occur at very low levels of exposure and that at these levels few effects might occur in normal individuals. The idea of a series of overlapping exposure–response relationships was developed. It was agreed that this would be difficult to illustrate in a simple table.

Authors should be encouraged to present their findings in tabular form, but clear instructions should be provided that warn against mixing value judgements with scientific judgements of likely effects. It was agreed that it would be much easier to design tables of effects for some compounds than for others.

Averaging times for guidelines

An understanding of mechanisms of effect and the effects of exposure, i.e. biological factors, should guide the selection of averaging times. This should be done on a compound-to-compound basis. Monitoring technology was better developed in some areas than others, but inappropriate monitoring strategies should not be allowed to constrain the definition of the guidelines. They must be based on the concentrations of exposure necessary to cause a specific effect. The group did not, however, underestimate the difficulties likely to be encountered, including the lack of measurement techniques that would allow reporting data over appropriate averaging periods.

Derivation of standards from guidelines

Although it had been clearly advised against, guidelines defined in the first edition had been widely interpreted as standards. The group agreed that this was undesirable. The suggestion that a separate chapter providing advice on how to move from guidelines to standards be included was considered. The scientific nature of the guidelines was stressed as was the difference between these and standards, since the derivation of the latter would often involve the consideration of sociopolitical factors.

The setting of standards depends on risk management strategies, and thus was not within the scope of the discussion. It was also felt that the overwhelming importance of legislative and country-specific factors would make the task of recommending general approaches for moving from guidelines to standards all but impossible. It was, however, agreed that a number of scientific factors that should be taken into account when trying to set standards for air pollutants could probably be defined. These factors may be better referred to as principles.

It was noted that WHO had published a book dealing with standard setting in 1987.[a] The group recommended that WHO establish a group to review and update it, and that the introductory section of the second edition include an account of the scientific factors that could be included in a standard setting exercise. It was also recommended that WHO take steps to communicate better the intended purpose of the AQGs, and abandon the idea of a separate chapter on standard setting.

The group considered the need to take sustainable development into account in writing the second edition. It was agreed, however, that sustainable development was a complex concept involving economic, political, toxicological and ecotoxicological concepts. The idea of an appendix or a separate chapter dealing with some of these broader issues was suggested. The planned contributions on ecological effects of air pollutants would need to be seen before any action could be specified.

It was stressed that the definition of the term exposure must be extremely clear, as should how it will be used in the guidelines. It should be defined in terms of both concentration and duration of contact.

Peer-reviewed literature should be drawn on in deriving the guidelines, as well as other relevant reviews and available documents.

A chapter length of about 20 pages was considered appropriate. Contributions on individual pollutants should be kept at about the same size as those in the first edition.

Sulfur dioxide and particulate matter

It had been agreed at the planning meeting in January 1993 to consider sulfur dioxide and particles both as separate pollutants and in combination. It was agreed during the discussion that sulfur dioxide and particles should be treated separately because sulfur dioxide concentrations have gone down considerably in many areas,

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[a] Koning, de H.W., ed. *Setting environmental standards. Guidelines for decision-making.* Geneva, World Health Organization, Geneva, 1987 (ISBN 9241542144).

whereas particle concentrations (measured as PM_{10}) have remained stable, and concentrations of small particles may even have gone up. Further, the understanding of the effects of sulfur dioxide and particles has advanced. There are significant new data on effects of pure sulfur dioxide on asthmatics, for instance, and in the past five years, many epidemiological studies have been published that allow estimation of effects of particles, sometimes in conjunction with other pollutants, but in a good many cases also alone.

Nevertheless, situations remain in which particles and sulfur dioxide are both elevated, and in which it is reasonable to evaluate their effects jointly for manifestations of classic, London-type smog.

It was decided that a future working group should evaluate sulfur dioxide and particles separately, but pay attention also to their joint effects.

A second, more difficult question arose on the importance of composition and size distribution of the particles. With regard to composition, specific pollutants (such as polycyclic aromatic hydrocarbons and some metals) that may form part of the particulate mass have to be treated separately. It is more difficult to resolve to what extent the available data would permit some evaluation of the relative importance of small particles ($PM_{2.5}$) in causing the effects generally ascribed to particulate matter and the particular contributions of acid aerosols and organic particles. However, when WHO and the US Environmental Protection Agency decided to formulate guidelines and standards for PM_{10}, there were no direct data available on the health effects of PM_{10} either. It was proposed that a future working group on particles take into consideration the question as to what extent guidance values could be formulated for, e.g. small-size particles and acid aerosols.

Finally, a discussion arose on whether sulfur dioxide and particles should be treated by an expert group separately from a group treating carbon oxide, nitrogen dioxide and ozone. It would be useful to have one working group treat all of these major ambient air pollutants, as was done in the preparation of the first edition of the AQGs.

Instructions to authors: methods and procedure

Authors of chapters dealing with individual compounds should be given clear guidance. Further, an explanation of the methods used in establishing the guidelines should be provided in the introductory chapters to the second edition. The procedure for preparing drafts 1 and 2 of the second edition was discussed. The drafts should be prepared by WHO staff, based on the findings of this meeting, and circulated to both the Steering Group and the Working Group. When the chapters dealing with the individual pollutants have been completed a final draft of the introductory chapters should be prepared for inclusion in the second edition.

The participants agreed on a procedure for commissioning and editing chapters dealing with individual pollutants. It was recognized that identifying suitable authors with sufficient time available to prepare a first draft would be a difficult task. Senior authors will be responsible for producing the first draft of the chapter dealing with their compound. The responsibility for each chapter will rest firmly on the senior author. In the three months following receipt of the drafts, working group meetings will be held to finalize chapters dealing with compounds in their groups.

CONCLUSIONS AND RECOMMENDATIONS

1. The following categories of health effect should be considered: annoyance, non-carcinogenic effects and carcinogenic effects.

2. The terms threshold and non-threshold should be abandoned. Non-carcinogenic and carcinogenic should be used instead.

3. The non-carcinogenic group could be divided into those about which a good deal was known and where expert judgement and experience and a small uncertainty factor could safely be used in establishing a guideline value, and those which were

much less well understood and where standard methods and a large uncertainty factor might be needed.

4. The term protection factor should be replaced by uncertainty factor.

5. Every effort should be made to define clearly what is meant by the term exposure in considering individual compounds. Exposure should be defined at least in terms of concentration of pollutant and duration of exposure and preferably in terms of duration and concentration in micro-environments and level of physical exercise.

6. No firm guidance on choice of method for estimating the effects of exposure to low concentrations of genotoxic carcinogens could be provided in advance of the IARC meeting due to be held in October 1993.

7. Attention should be paid to the importance of differential exposure by varying direct and indirect routes.

8. Guidance regarding the exposure–response relationship for individual pollutants and mixtures should be provided as appropriate.

9. In addition to defining guideline values, indication should be made of the health consequences of exceeding these values. Individual countries would then be able to make use of this information in establishing action or alert levels if they wished, as part of their risk management strategies.

10. In deriving guidelines the value of biomarkers should be assessed by authors of individual chapters.

11. Whatever method for extrapolation to low levels of exposure was recommended, a flexibility of approach should be retained to allow expert judgement to be used.

12. The unit risk approach should be retained, at least as a default option. The imprecision of estimated unit risks should be made known, including an assessment of all sources of error and bias and their likely magnitudes.

13. In deciding on appropriate averaging times for guidelines biological factors must take precedence over questions of feasibility of monitoring.

14. Setting standards depends on risk management strategies, and this topic was outside the competence of the group. It was also felt that the overwhelming importance of legislative and country-specific factors would make the task of recommending general means of moving from guidelines to standards all but impossible.

15. The inclusion of a separate chapter on standard setting in the second edition of the guidelines would be inappropriate. However, an account of the factors that could be considered in standard setting should be included in the introductory chapters.

16. Clear explanations should be provided on how guidelines were derived. This was seen as particularly important in situations when complex statistical techniques are employed.

17. WHO should establish a group to review and update the WHO book on standard setting.

18. Authors should be provided with a set of instructions.

19. A revised draft of the introductory chapters to the second edition should be supplied to chapter authors.

20. In preparing chapters dealing with individual pollutants the relevant chapters of the first edition should be taken as a starting point and amended as necessary.

21. The authors of individual chapters should clearly explain the basis for their decisions on averaging times.

22. The use of illustrations and tables as means of showing exposure–response relationships should be encouraged. It was noted that such methods would be appropriate for only some of the compounds considered.

23. Scientific literature should be widely consulted in preparation of the second edition of the guidelines.

24. WHO should take steps to communicate better the intended purpose of the guidelines.

Annex 1

QRA/UNCERTAINTY FACTOR METHOD FOR DERIVATION OF GUIDELINE

The IARC classification has been revised since the first air quality guidelines (printed on page 12 of the first edition). It is suggested that the relevant paragraphs be replaced with the following.

General rule

For compounds in groups 1 and 2A (i.e. proven human carcinogens, carcinogens with at least limited evidence of human carcinogenicity, and compounds for which there is strong evidence that the carcinogenesis observed in experimental animals is mediated by a mechanism that also operates in humans), guideline values are derived with the use of low-dose extrapolation (QRA). For compounds in groups 2B, 3 and 4, guideline values are derived with the use of an uncertainty factor method. For compounds in group 2B this may incorporate a separate factor for the possibility of a carcinogenic effect in humans.

Exceptions from the general rule

Exceptionally, it may be justified to deviate from the general rule. Firstly, a compound classified in group 1 or 2A may be assessed with the use of the uncertainty factor methodology, provided that *there is strong evidence from exposed humans that the mechanism of carcinogenicity is a threshold phenomenon*, i.e. that it can be established with certainty that an increase in exposure to the compound is only associated with an increase in cancer incidence above a certain level of exposure. The Working Group on Methodology and Format did, however, consider that this required a level of understanding of the mechanism of action not presently

available for the compounds in groups 1 and 2A on the current agenda.

Secondly, a compound in group 2B may be assessed with the use of QRA methods instead of the uncertainty factor approach. This may be considered appropriate where the mechanism of carcinogenesis in animals is likely to be a non-threshold phenomenon as indicated, for example, by genotoxic activity of the compound in several, different short-term test systems for gene mutation, DNA damage, etc. The Working Group on Methodology and Format considers that this may be discussed as a possible option for 1,2-dichloroethane, styrene and mercury [?].

Annex 2

WORKING PAPERS AND BACKGROUND MATERIAL

Working papers

ICP/CEH 230/6	Principles and procedures applied in establishing AQG 1984–1987, by Dr M.M. Younes
ICP/CEH 230/7	Draft outline for chapters in updated AQG, by Dr M.M. Younes

Background material

Planning meeting on the update and revision of the air quality guidelines (AQGs) for Europe, Bilthoven, Netherlands, 11–13 January 1993 (unedited report).

Smith, E. *Derivation of guidance values for health-based exposure limits* (draft IPCS document).

Annex 3

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