



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 20, 1988

The Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

Dear Mr. Thomas:

The Water Quality Advisories Subcommittee of the Science Advisory Board's Environmental Effects, Transport and Fate Committee has completed its review of the Office of Water's guidelines for preparing water quality advisories. The review was requested by Edmund M. Notzon, Director of the Criteria and Standards Division of the Office of Water and the review was conducted on October 22 and 23, in Annapolis, Maryland.

The Subcommittee recognizes the potential that the advisory concept provides for bringing a greater number of pollutants under regulatory control in a relatively short period of time. The concept represents a preliminary step towards water quality criteria development and is designed to protect both ambient aquatic life and human health. The primary issue regarding ambient aquatic life protection involves defining and obtaining a minimum data base for advisory development. Data describing interactions in aquatic systems have not been developed for many pollutants. Data are more prevalent for characterizing human health risks, and obtaining a minimum data base is not of concern. Instead, the primary issue for human health protection via advisories is the appropriate depth of review of the existing data base.

In general, the Subcommittee has more support for the concept as it applies to ambient aquatic life protection than for application to human health protection, based on availability of data. Subcommittee cautions that advisories should not substitute for water quality criteria and recommends that a mechanism for advancing advisories to criteria status be specified to insure that emerging data are enfolded to reduce uncertainty. In addition, the Subcommittee feels that it is imperative that a review process and public comment period be incorporated to balance the increased uncertainty inherent in the advisory process.

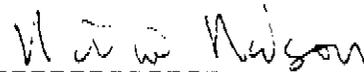
Regarding advisories for the protection of ambient aquatic life, an approach which the Subcommittee endorses, some suggestions for improving the guideline documents and the process

in general are provided. These suggestions include: specifying the data needed to advance understanding of the toxicity of the pollutant addressed, documenting uncertainty factors, employing quality ratings, and including modifications to address exposure duration, site-specific issues, and sensitive species rather than those that are commercially or recreationally important.

To guide decisions about human health, the Subcommittee prefers the use of the water quality criteria process, and has reservations with applying the advisory concept. Particular opposition is directed toward the restriction of literature searching to the most recent 5 years, and to the use of secondary literature sources. The risk assessment procedure described in the guideline documents focuses on data presentation rather than on analysis, and the use of modifying factors cannot be endorsed. Most of the Subcommittee's criticism is related to the error that results in assuming that a short risk assessment is easier, quicker and less expensive than a long one. In fact a properly prepared, concise advisory could take less paper, but require the same level of effort required for a criteria document.

The Subcommittee appreciates the opportunity to conduct this scientific review. We request that the Agency formally respond to the scientific advice transmitted in the attached report.

Sincerely



Norton Nelson, Chairman
Executive Committee
Science Advisory Board



Rolf Hartung, Chairman
Environmental Effects,
Transport and Fate
Committee



Kenneth Dickson, Chairman
Water Quality Advisories
Subcommittee

Enclosure

cc: A. James Barnes
Lawrence Jensen
J. Michael Conlon
Edmund Notzon
Frank Gostomski
Donald Barnes

United States

Office of the Administrator

SAB-EET&FC-88-032

Environmental Protection

Science Advisory Board

July, 1988

Agency

Washington, D. C. 20460

Final Report



Report of the Environmental Effects, Transport and Fate Committee

Review of the Guidelines for Preparing Water Quality Advisories

U.S. ENVIRONMENTAL PROTECTION AGENCY

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1.0 EXECUTIVE SUMMARY

Public pressure for control of pollutants, and the lack of resources to support the water quality criteria-setting process traditionally used for pollutant control have led EPA to propose the water quality advisory concept for protection of both ambient aquatic and human health. A water quality advisory (WQA) is a numeric recommendation that provides an estimate of the pollutant concentration in water which is unlikely to result in adverse effects to human health or the environment, even when exposures are continued for a lifetime. A WQA is similar to a water quality criteria (WQC) in that each is based on data describing toxicological effects; however, an advisory is provided when a lack of data prevents development of a WQC. Application of this concept clearly has the potential to bring a greater number of pollutants under regulatory control in a relatively short time. However, since advisories are based on fewer data, they are accompanied by increased uncertainty. The Subcommittee arrived at recommendations and conclusions regarding the advisory concept in general. In addition, specific findings that address the guidelines for ambient aquatic life and human health, respectively, are provided. The recommendations, conclusions and findings are summarized below.

1.1 The Advisory Concept

The Subcommittee endorses the advisory concept as it applies to development of ambient aquatic life advisories, provided they do not substitute for the development of water quality criteria. The uncertainty attending the advisory concept may cause under or over protection. Therefore, the advisory process should include mechanisms for reducing uncertainty as more data become available.

EPA should consider state standard-setting and management practices, carefully evaluating the problems that may result if

advisories are adopted as standards. In states where the law stipulates that water quality standards cannot be made less stringent once they are adopted, problems may arise as advisories progress to criteria that are based on more knowledge.

A procedure for selection of chemicals for evaluation should be incorporated into the advisory process. The Subcommittee recommends that the chemicals selected for advisory development be those for which there is evidence of potentially significant exposure in the environment.

The Subcommittee feels it is imperative that a review process and public comment period be incorporated into the advisory process. The increased certainty provided by the peer review process is necessary to balance the increased uncertainty inherent in the advisory process.

In general, the Subcommittee had more support for the concept of advisories applied to protection of ambient aquatic life than for application to human health protection, primarily based on the availability of data. A considerable body of evidence and expertise support procedures assessing risk to humans. The Subcommittee has reservations about basing advisories on only a subset of these resources. In contrast, less data are currently available to support decisions required to protect aquatic life. Therefore, a program designed to generate more data to support such assessments and fill in gaps in the knowledge base can be readily endorsed by the Subcommittee. Specific findings follow.

1.2 Ambient Aquatic Life Advisories

The Subcommittee endorses the concept of ambient aquatic life advisories and suggests some modifications to motivate advances in the area of aquatic effects prediction. First, the Subcommittee recommends that the Agency provide better guidance in the supporting documents to ensure that any additional data

collected in response to the advisory process also advances the understanding of the toxicity of the chemical in question.

In addition, the Agency needs to develop documentation to demonstrate the basis of each uncertainty factor used in developing an Advisory. A procedure should be developed to rate advisories on the basis of the quantity and quality of the data used to calculate and advisory. The value derived from the rating system should be presented in the Advisory statement.

The Agency should modify the guidelines to incorporate the concept of exposure duration and the flexibility to account for site-specific differences. Another recommended modification is determination based on effects produced in species that may be the most sensitive rather than on species that may have commercial or recreational importance.

The Subcommittee endorses the development of Advisory guidelines for specific chemical groups based on a justifiable rationale, such as structural activity relationships. Also, the Agency is encouraged to develop Water Quality Criteria and/or Advisories for wildlife protection.

1.3 Human Health Advisories

As previously stated, the Subcommittee has reservations with applying the advisory approach to human health protection. The Subcommittee has several recommendations that may improve the advisory process. For example, secondary sources, those that summarize the primary journal literature, are recommended for use only as directories to the primary literature, rather than as data sources themselves. Secondary synopses often omit pertinent data in the course of summarization.

The Subcommittee particularly opposes restricting the supporting literature search for advisories to the most recent 5 years. This restriction discourages the use of the complete body

of information that is available, including older studies at the foundation of toxicology, and studies that may report important clinical findings or industrial exposures in humans. In the opinion of the Subcommittee, a responsible risk assessment cannot be conducted without thorough collection, review and interpretation of all pertinent data.

Guidelines for preparing human health advisories differ from other risk assessment procedures in the use of modifying factors. The necessity for these factors is unclear, and the procedures for their use are not well developed; therefore, the Subcommittee cannot endorse their application to the advisory process. In addition, the risk assessment procedure described in the guidelines for human health advisories seems to emphasize presentation of facts, rather than analyzing and comparing them. Most of the Subcommittee's criticism is related to the error that results in assuming that a short risk assessment is easier, quicker and less expensive than a long one. In fact a properly prepared, concise advisory could take less paper, but require the same level of effort required for a criteria document.

2.0 INTRODUCTION

2.1 Origin of the Review

On June 30, 1987, EPA's Office of Water requested that the Science Advisory Board (SAB) review the draft guidelines developed for preparing water quality advisories for both human health and aquatic life protection. SAB reviews are conducted under the auspices of its Executive Committee. On July 21, 1987, the SAB received a preliminary briefing on the Water Quality Advisory Guidelines, given by Frank Gostomski, Chief, Water Quality Criteria Section, Office of Water Regulations and Standards. The SAB Executive Committee agreed to conduct the review and delegated responsibility to the Environmental Effects, Transport and Fate Committee, which established the Water Quality Advisories Subcommittee to conduct the review and appointed Dr. Kenneth L. Dickson as the chairman of the subcommittee. The request for this SAB review is presented in Appendix A.

2.2 Purpose of the Review

The purpose of the review is to provide an independent, peer assessment of the scientific adequacy of the objectives, rationale and methodology included in the water quality advisory guideline documents presented to the SAB. The Subcommittee's objectives are to evaluate the concepts underlying the water quality advisory approach, and to provide the Agency with recommendations and suggestions for improvement.

2.3 Review Procedure

The Subcommittee received two guideline documents in advance of their meeting: 1) Guidelines for the Preparation of Office of Water Health Advisories, and 2) Guidelines for Deriving Ambient Aquatic Life Advisory Concentrations. These documents are included as Appendix B and C, respectively. In addition, the

Subcommittee received some examples of applications of the guidelines to specific chemicals, including ambient aquatic water quality advisories for xylene, styrene and tetrachloroethylene; and human health effects advisories for hexachlorobenzene and 2,4,5-trichlorophenol.

The Subcommittee met in public session on October 22 and 23, 1987 in the Laboratory Conference Room of EPA's Region 3, Annapolis office at 839 Bestgate Road, Annapolis, Maryland. David Sabock from EPA, Office of Water Regulations and Standards described the Agency's need for review and intended application of the Advisory guidelines. More detailed information was provided by Frank Gostomski. Specific methodologies and rationale for development of ambient aquatic advisory concentrations were presented by Dave Hansen (ERL-Narragansett) and Tom Purcell (WQC Section) while health methodologies and case studies were presented by Cindy Mullen (ECAO, Cincinnati).

Following these briefings, the Subcommittee discussed the principles underlying the derivation and use of advisory concentrations in a generic manner. This discussion was followed by sessions addressing specific aquatic and health issues by appropriate subgroups of the Subcommittee. These discussions formed the basis for recommendations, suggestions and comments on the advisory guidelines.

2.4 Description of This Report

The Subcommittee report provides general conclusions with regard to fundamental concepts, documenting their strengths and weaknesses. In addition, the report provides a discussion of specific issues that were identified during the review process, issues that pertain to both ambient aquatic advisories and health effects advisories as well as the field of water quality itself from National and state perspectives.

3.0 THE ADVISORY CONCEPT

Two forces -- public pressure for control of the increasing number of toxicants that cause concern, and lack of funds to produce the criteria documents that provide for control of these toxicants -- have pointed to the need for change in the water quality criteria-setting process. EPA's solution has been to develop the advisory concept together with accompanying guidelines for setting advisory concentrations.

Ten years ago the Agency signed a consent decree that obligated production of criteria documents for a list of some sixty substances. Even with court-granted continuances, criteria have been developed for only about half of the substances on the list. Though the remainder are substances of concern, data are not sufficient to support a full-fledged criteria effort and substantial laboratory and field testing will be necessary to obtain a complete data base.

Since there are many toxicants for which inadequate data or no data exist, application of the advisory concept would bring a greatly increased number of toxicants under regulation in a relatively short time. However, these advisories would necessarily be based on fewer data and, therefore, attended with greater uncertainty. The consequence of uncertainty is an increase in the likelihood of over or, in some circumstances, under protecting human health and/or ambient aquatic life.

Such tradeoffs give rise to concern among members of the Subcommittee. These concerns translate to reservations with the concept as expressed in the guidelines. The Subcommittee offers a series of conclusions and recommendations regarding the advisory concept in the four sections to follow.

3.1 Progressing from Advisories to Criteria

There is no trigger within the advisory guidelines for taking the concentration set by the advisory process to the higher level of certainty provided by the criteria process, when the data do become available. Therefore, there is no motivation to generate more data, and no means to reduce uncertainty once an advisory concentration is established. The setting of advisory concentrations is an appropriate first step in the criteria setting process; however, it is not an appropriate final step for either human health or ambient aquatic life protection. The Subcommittee believes that decision makers will be hampered with tools that do not reflect the current state of scientific knowledge and are, in addition, surrounded by uncertainty.

The Subcommittee recommends that a well defined mechanism for incorporating new data be included in the advisory guidelines. This mechanism should allow for an provide incentives for elevation of advisory concentrations to more certain and well founded criteria concentrations when sufficient data exist.

3.2 Antidegradation

The WQAs are likely to be used in a role roughly equivalent to that of the WQCs in related management programs. States are likely to develop water quality standards and NPDES (National Pollution Discharge Elimination Systems) permit programs around water quality advisories, just as they currently do with water quality criteria. However, there may be resistance to the advisory concept in some states.

Since EPA's guidance for developing advisories involves a conservative approach, they result in a more stringent number. If a WQC is subsequently developed, it is likely to be both more certain and less stringent. Some state Attorneys General have interpreted state laws to mandate that no water quality standard

may be made less stringent under the law. Therefore, even if EPA replaces an advisory concentration with a more certain but less stringent water quality criteria concentration, certain states could be required to maintain overly stringent WQA as the water quality standard. For this reason, some states are likely to resist adoption of a water quality standard based on an advisory, and are likely to wait for EPA to issue subsequent criteria to prevent establishment of overprotective standards.

3.3 Chemical Selection

Risk is a combination of exposure and effect. If there is no exposure to a chemical then even the most toxic chemical will pose no risk. Thus it would be a misuse of limited resources to prepared a advisory document on a chemical for which there was no established exposure. The extent of exposure may be determined through the use of on-going monitoring programs, such as those used by the states in support of the permitting process. For these reasons, the Subcommittee recommends that chemicals be selected for the advisory process only if there is evidence of a significant exposure to the aquatic environment.

3.4 Peer Review and Public Comment

The national guidelines for producing water quality criteria documents mandate peer review and public comment. The guidelines for advisories do not. The Subcommittee points out that this process for producing advisories depends on the opinion of a few, and believes that this would be a grave mistake. In light of the more restricted data base that will support advisories and the increased uncertainty that a restricted data base provides, the likelihood of producing an inappropriate advisory concentration is greatly increased, however expert the opinion behind it. The Agency must outline a process that provides for review by a range of external authorities in order to capture the best scientific thinking, broaden the scientific consensus, and minimize future criticism. Therefore, the Subcommittee recommends that a

procedure for peer review and public comment be incorporated into the advisory process, and that such a procedure be described in the guideline documents.

4.0 AMBIENT AQUATIC LIFE ADVISORIES; SPECIFIC ISSUES

4.1 Development, Certainty and Quality of the Data Base

4.1.1 Data Base Development

The development of water quality criteria has required an intensive review of the existing literature, but has also been characterized by the conduct of extensive laboratory research to fill perceived data gaps. From the proposed "Guidelines for Deriving Ambient Aquatic Life Advisory Concentrations" (Appendix B), it is clear that there will be dramatic differences in the quantity of data available for establishing an advisory and that the requirements for additional data will vary for each substance-specific advisory.

Given the potential for significant improvement in the quality and quantity of data developed in support of advisories, it is appropriate for the Agency to provide clear guidance to ensure the efficient collection of such data. For example, to comply with current guidelines, a discharger may conduct yet another generic acute toxicity test to strengthen the data base for a chemical where three generic tests have been previously performed, rather than producing data on species of particular relevance that would be more informative or site specific.

The guidelines recommend that dischargers seek guidance on development of data from appropriate regulatory agencies. The Subcommittee recommends that dischargers be guided to develop data that advance the understanding of the toxicity of the chemical in question and that advisory documents stipulate the advances that are needed to strengthen knowledge of the specific chemicals that they address.

4.1.2 Uncertainty

Since the data base contains gaps, there is uncertainty associated with every advisory estimated. Ideally, the uncertainty is quantified using a statistical, probabilistic approach. In the example provided to the Subcommittee, a species sensitivity factor of 11 and an acute to chronic ration of 25 were documented and used to estimate uncertainty. The Subcommittee recommends that additional documentation be provided in guideline documents to clearly define these terms and state their limits of applicability. In addition, distinctions need to be provided for application of these factors to fresh and salt water. Alternatively, generic uncertainty factors could be tested to provide the necessary refinements in documentation.

4.1.3 Quality Indicators

The Agency has recognized the differences in quality and quantity of data that are likely to be encountered in preparing advisories and has developed weighting factors based on the nature of the available data. Advisory documents will also contain disclaimers, alerting users that they must consider the technical basis of the advisory before application and that advisory values are derived less stringently than criteria. The Subcommittee believes that a quality designation should also be associated with the advisory concentration to indicate the certainty or confidence attached to the advisory number, and the fact that confidence varies. Such quality designations could take the form of descriptive statements or numerical indicators.

4.2 Considerations for Modifying the Advisory Process

4.2.1 Exposure Duration

As currently advanced a water quality advisory will consist of a single concentration below which aquatic life are assumed to be protected and above which adverse effects may occur. The

advisory concentration is designed to protect those exposed from chronic effects and is analogous to the Criterion Continuous Concentration (CCC) of a water quality criterion. However, an advisory does not contain the concept of exposure duration which is an integral part of the CCC of a water quality criterion. If advisories are used as surrogates for criteria as stated in the briefing to the Subcommittee, then the Agency should consider modifying the advisory to include the concept of exposure duration. The CCC of a water quality criterion states that ambient levels cannot exceed the CCC for more than four (4) days. The inclusion of duration of exposure recognizes that effects are a function of both concentration and time of exposure. This well established toxicological principal should be reflected in the water quality advisories particularly if they are used for regulatory purposes.

4.2.2 Species Beyond Commercially or Recreationally Important Ones

The Subcommittee believes that a reduction in advisory concentrations is warranted if laboratory or field data for any species, regardless of whether or not it is considered commercially or recreationally important, indicate that it is affected at concentrations below the calculated advisory concentration. Both the national water quality criteria and the aquatic life advisory concentrations must be reduced if "commercially or recreationally important species" are found to be affected at lower levels than predicted by the final acute or chronic values. Restricting this adjustment to only important species is inappropriate for the advisory concentrations. Because advisory concentrations may be based on only three species, the potential for missing important species is increased greatly.

4.2.3 Site-Specific Modifications

The guidelines for deriving water quality advisories are designed to produce a conservative value, thus, advisories may be over protective at many sites. A procedure for site-specific modifications, which could require generation of additional acute and/or chronic data for species appropriate to the site, would not only increase the data base for the chemical but would account for water quality interactions which may affect the bioavailability of the chemical. A site specific modification approach would be especially applicable to metals, organic compounds that ionize, and those that have high partition coefficients, and could also be adapted from the existing procedure for site-specific modification of water quality criteria.

4.3 Considerations for Developing Other Advisories

4.3.1 Guidelines for Specific Chemical Groups Versus Generic Guidelines

The Subcommittee endorses the development of guidelines for specific chemical groups, such as the guidelines reviewed by the Subcommittee for low molecular weight, non-ionizable organics. The Subcommittee agrees with EPA that, because of varying fate and effects among groups of chemicals, initial development of generic guidelines is inappropriate. Guidelines for specific groups of chemicals should clearly indicate the chemical group addressed in the document title, as well as in supporting text.

The Subcommittee suspects that differences in guidelines between most different groups of chemicals will be small. The acute to chronic ratio (ACR) of 25 used in the guidelines may serve for a broad range of chemicals, since a variety of chemicals were used to derive it. Similarly, the factors used to calculate the advisory acute value (AAV) are related to the number of Genus Mean Acute Values (GMAV) available, and should

not be significantly different among chemical groups. The use of these parameters generically for chemical groups may be substantiated by clarifying and justifying their derivation in supporting documentation.

The major differences between guidelines for different chemicals will likely be in numbers and kinds of species to be tested. The AAV for ionizable molecules, metals and perhaps other groups of chemicals may need to be based on a larger number of representative species from both fresh and salt water. Also, water quality characteristics such as hardness and pH may need to be considered. If there is potential for a greater effect on aquatic plants than animals, as with herbicidal chemicals, then at least one acute test with plants must be required.

4.3.2 Development of Advisories for Wildlife

The Subcommittee points out the fact that waterfowl, birds, mammals, reptiles, and amphibians are valued environmental resources and that they are exposed to chemicals via food, water and other routes. Water quality criteria incorporating bioaccumulation, whether based on risk assessment assumptions or FDA action levels for human consumption of fish, may not be adequate for wildlife protection. The reasons include important differences in metabolism, feeding requirements and body weight. For these reasons, the Subcommittee recommends that the EPA consider the development of water quality advisories for wildlife.

5.0 HEALTH EFFECTS: SPECIFIC ISSUES

5.1 Data Base Development

The basic methodology for risk assessment outlined in the "Guidelines for the Preparation of Office of Water Health Advisories" (Appendix C) do not differ markedly from those currently used by the Agency for setting drinking water health advisories. Current methods for developing health advisories to protect human health are based largely upon an intensive collection and review of the existing literature. Research needs may be identified, but, unlike establishment of criteria for protecting aquatic life, additional laboratory research is almost never conducted.

5.1.1 Secondary Sources

The guidelines call for the use of secondary sources, which summarize, annotate and compile primary or journal literature, in preparing health advisories. While the Agency should use the existing literature efficiently, misconceptions and confusion can arise for the use of secondary sources. Misconceptions can be introduced due to the fact that the studies likely to be summarized in secondary sources were originally designed for purposes other than safety evaluation. Confusion arises because the details necessary for appropriate integration, understanding and analysis of the data are often omitted in such summaries. Although they may serve as efficient directories to primary literature, the exclusive use of secondary sources can not be supported by the Subcommittee.

5.1.2 Literature Searches

The Subcommittee considers the restriction of the literature search to the most recent 5 years, as prescribed in the guidelines, to be a major problem. Such a restriction discourages and may prevent the use of many older studies that report significant

exposures and effects in humans, especially as a result of industrial exposures. These studies are often supported by experimental studies in animals which provide basic information on acceptable levels of industrial exposure in humans. While concise presentations may be appropriate, responsible development of a risk assessment requires thorough collection, review and critical interpretation of all pertinent data.

5.2 Modifying Factors

The proposed use of "modifying factors" appears to the Subcommittee as a major methodological feature that differentiates the advisory-setting procedure from other risk assessment procedures previously reviewed by the Science Advisory Board. As presented in the guidelines, the purpose and necessity for this feature is unclear. The presently used methodology for establishing water quality criteria encourages the use of scientific judgment in the selection of the most appropriate data for assessing risk and uses four uncertainty factors which can vary depending on the quality of the data. Data on pharmacokinetics and bioavailability are also used quantitatively to adjust data in risk assessments. However, the proposed modifying factor appears to be little more than a "fudge factor" which has a high potential for abuse in "adjusting" the outcome to preconceived values, rather than values that are consistent with scientific and toxicologic data. In the opinion of the Subcommittee, the proposal to use modifying factors is not well developed, is not necessary, and can therefore not be endorsed.

5.3 Data Analyses

Since the proposed guideline documents are similar in purpose and methodology to water quality criteria documents, it is reasonable that the outline and topics included therein are also similar. However, the tone and tenor of the guidelines reflects a substantial degradation of the risk assessment process. The document discourages the critical analysis and synthesis of data

where it should be encouraged. The guidelines call for an encyclopedic presentation of facts in a rigid format, followed by a risk assessment protocol which emphasizes arithmetic rather than analysis.

The Subcommittee encourages guideline revisions that promote standardization within sections to encourage comparison between studies. In addition, it recommends that discussions be included to relate the elements of the outline to the derivation of advisory concentrations.

5.4 Conclusion

Most of the criticism raised by the Subcommittee can be related to a fundamental flaw in the basic assumptions underlying the development and use of water quality advisories to protect health. Namely, this assumption is that a good, short risk assessment is substantially easier, quicker, and less expensive to prepare than are long reviews and risk assessments. While a properly prepared and appropriately concise health advisory could save paper, it will require the same level of analysis and effort needed for a criteria document. In many respects, the imposition of an economy of words requires more effort in preparation than longer detailed reviews. In fact, the advisory process used for health effects assessments may compromise the Agency's efforts to provide sound guidance on tolerable levels of compounds in ambient water.

APPENDIX A

Request for the Review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 30 1987

OFFICE OF
WATER

MEMORANDUM

SUBJECT: Request for SAB Review of Water Quality Advisory Guidelines

FROM: Edmund M. Notzon, Director *Edmund M. Notzon*
Criteria and Standards Division (WH-585)

TO: Terry Yosie, Director
Science Advisory Board (A-101)

I am requesting the Science Advisory Board review draft guidelines developed for preparation of water quality advisories for both human health and aquatic life protection. The draft guidelines are attached as are copies of completed advisories which were developed using the draft guidelines.

Water quality advisories are intended to be used as a supplement to our efforts to develop water quality criteria recommendations under Section 304(a) of the Clean Water Act. Advisories are designed to fill the gap between the large number of pollutants and the limited number of criteria documents we are able to produce. Advisories basically provide the Agency's best scientific judgment applied to existing information.

Please let me know as soon as possible when the Science Advisory Board will be able to conduct a review of the advisory guidelines. Dr. Frank Gostomski (475-7321) may be contacted for further information.

Attachments

APPENDIX B

Guidelines for Deriving Ambient Aquatic Life

Advisory Concentrations

WQA Subcommittee

GUIDELINES FOR DERIVING AMBIENT AQUATIC LIFE
ADVISORY CONCENTRATIONS

DRAFT

Office of Water Regulations and Standards
Criteria and Standards Division
Washington, D.C.

Office of Research and Development
Environmental Research Lab
Duluth, MN
Environmental Research Lab
Narragansett, RI

June 1987

I. Introduction

- A. Aquatic life advisories will be issued for selected chemicals for which not enough toxicity, bioaccumulation and/or field data are available to allow derivation of ambient water quality criteria for aquatic life using the procedures described in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (Stephen et al. 1985), hereinafter referred to as the "National Guidelines". Aquatic life advisories will contain compilations and interpretations of available data that are directly pertinent to the derivation of aquatic life advisory concentrations.
- B. Aquatic life advisory concentrations are intended to be used mostly for evaluating the aquatic toxicity of concentrations of pollutants in effluents and ambient waters, whereas water quality criteria for aquatic life provide a stronger basis for regulating concentrations of pollutants in effluents and ambient waters. Advisory concentrations have the following two intended uses:
 1. Advisory concentrations are intended to be used to interpret data on concentrations of chemicals in ambient water. If the concentration of a chemical in ambient water is equal to or below the aquatic life advisory concentration for that chemical, there is probably no cause for concern about effects on aquatic organisms and their uses. If, however, the ambient concentration is above the advisory concentration, the discharger should quickly evaluate the available exposure and effect data to determine whether it is prudent to:
 - a. obtain additional data concerning the concentration of the chemical in the effluent and/or ambient water;
 - b. obtain additional laboratory and/or field data on the effect of the chemical on aquatic organisms and their uses so that a more accurate, and usually higher, aquatic life advisory or a water quality criterion can be derived;
 - c. conduct acute and/or chronic toxicity tests on the effluent; and
 - d. reduce the ambient concentration of the chemical.

After a reasonable period of time, the appropriate regulatory agency should evaluate all available pertinent data concerning the ambient concentration and the effects of the pollutant on aquatic life to determine whether it is appropriate to take any action such as establishing a permit limit for the pollutant or requiring toxicity tests on the effluent. Such agency may choose to regulate either before or after collecting additional data.

2. Advisory concentrations are intended to be used to help the U.S. EPA select chemicals for which water quality criteria for aquatic life should be derived. Any chemical that is found to be present in a considerable number of ambient waters at concentrations similar to or exceeding the advisory concentration may become a candidate for derivation of water quality criteria for aquatic life. Thus advisories will provide dischargers with advance notice of chemicals for which criteria might be derived so that they can generate additional data that might be useful for revising the advisory concentration or for deriving water quality criteria for aquatic life.

Additional guidance on appropriate regulatory uses of advisory concentrations and criteria should be obtained from the Criteria and Standards Division, Office of Water Regulations and Standards, U.S. EPA.

- C. The procedures described in the National Guidelines will be used as much as possible in the derivation of aquatic life advisory concentrations. Whenever a procedure described in the National Guidelines cannot be used (usually because some required data are not available), a procedure that (a) follows as closely as possible the procedures described in the National Guidelines and (b) is compatible with the intended uses of advisory concentrations will be developed for use in deriving advisory concentrations. Aquatic life advisory concentrations can be based on fewer data than can water quality criteria for aquatic life because advisory concentrations are not intended to have as much regulatory impact as criteria. However, to be compatible with the first intended use, advisory concentrations must be derived so as to ensure that

they are rarely, if ever, higher than what the Criterion Continuous Concentration (CCC) would be if enough data were available to allow derivation of a national aquatic criterion for the chemical. The data requirements and procedures used for deriving aquatic life advisory concentration is rarely, if ever, above what the CCC would be. Thus, whenever a national criterion is derived for a pollutant for which an advisory concentration is already available, the CCC will almost always be higher than the advisory concentration. On the other hand, an advisory concentration that is too much lower than the CCC will cause unnecessary concern about various chemicals, effluents and ambient waters. To be most useful, the advisory concentration should never be above what the CCC would be and should rarely be more than a factor of 10 less than the CCC.

- D. In order to obtain acceptable advisory concentrations for the least cost, the data requirements and procedures used for deriving aquatic life advisory concentrations will be different for different classes of chemicals. When possible, classes will be defined so that data requirements and procedures can be appropriately based on the biological, chemical, physical and toxicological properties used to define the class.

II. Low Molecular Weight Non-ionizable Organic Chemicals

- A. This class of chemicals is not very well defined yet. It is expected, however, that all low molecular weight non-ionizable organic chemicals will be in this class after an upper limit on molecular weight has been established. It might be possible to expand this class to include a wider range of chemicals within certain limits.
 1. This class is intended to be limited to chemicals for which there is no reason to suspect that the range of acute or chronic sensitivities of saltwater species will differ substantially from those of freshwater species. Therefore, unless there is substantial evidence to the contrary, the data available for freshwater and saltwater species should be considered together in order to derive an advisory concentration that will apply to both fresh and salt water. Because of the differing ionic compositions of the waters, it seems reasonable to assume that the toxicities and BCFs of organic

chemicals that ionize and inorganic chemicals are likely to differ in fresh and salt water.

2. This class is also intended to be limited to chemicals whose range of toxicities to aquatic animal species is relatively small, so that the requirements for acute values do not have to include very many species and do not have to be very specific. Thus this class of chemicals should not include any pesticides that are intended to be effective against any aquatic or terrestrial animals or any metals.
 3. This class is also intended to be limited to chemicals that are not especially toxic to plants, so that tests with aquatic plants do not have to be required. Thus this class of chemicals should not include any herbicides.
- B. An aquatic life advisory concentration should not be calculated for a chemical unless data are available from acceptable acute tests with at least three animal species, such that:
1. at least one species is a fish in the class Osteichthyes in the phylum Chordata.
 2. at least two species are invertebrates such that:
 - a. at least one species is in the class Crustacea in the phylum Arthropoda.
 - b. the other species is either in the phylum Mollusca (test with embryos and larvae leading to a 96 hour EC50 or LC50) or in a different family of the phylum Arthropoda.
 3. at least one is a freshwater species.
 4. at least one is a saltwater species.

Available data from foreign species should be included in the advisory, but not utilized to derive an advisory recommendation unless other required data is not sufficient.

Because many of the chemicals in this class are highly volatile or degradable, acute tests with animals and tests with plants that are otherwise acceptable (in terms of acclimation, control mortality, etc. as described in the National Guidelines) are acceptable for this class of chemicals only if:

1. For flow-through tests, the concentrations were measured. If concentrations fluctuated unreasonably, the test should not be used.
 2. For renewal tests, the organisms were exposed to fresh test solution at least once every 24 hours and either (a) the properties of the chemical indicate that its concentration in water should not decrease by more than 50% in 24 hours or (b) measurements on tests solutions showed that the concentration of test material did not decrease by more than 50% in 24 hours.
 3. For static tests, either (a) the properties of the chemical indicate that its concentration in water should not decrease by more than 50% in 96 hours; (b) measurements on test solutions showed that the concentration of test material did not decrease by more than 50% from the beginning to the end of the test or (c) results of a nominal or measured static test should be multiplied by a factor obtained by dividing a flow-through 96-hr LC50 by a comparable static 96-hr LC50. The comparable flow-through and static tests must be conducted on the chemical in the same laboratory using the same water and organisms from the same sources. The results of the flow-through tests must be based on the time-weighted average measured concentrations of test material and the results of the static test must be based on the concentrations measured at the beginning of the test.
- D. Although data from tests with aquatic plants are desirable they are not required because for many chemicals it appears that aquatic plants are adequately protected if aquatic animals are adequately protected.
- E. For each species for which at least one acceptable acute value is available, determine a Species Mean Acute Value (SMAV) using the procedure described in

the National Guidelines. (If data from tests in both fresh and salt water are available for a species such as striped bass, all the data should be used together when determining the SMAV for that species.) Then calculate a Genus Mean Acute Value (GMAV) for each genus for which at least one SMAV is available.

- F. An FAV should be calculated using the procedure described in the National Guidelines if GMAVs are available for at least one animal species in at least eight different families, such that either:
1. the acute data requirements specified in the National Guidelines for either fresh or salt water are met, or
 2. all the following are included:
 - a. three families in the phylum Chordata such that:
 - (1) at least one species is in the family Salmonidae.
 - (2) at least one is a freshwater species.
 - (3) at least one is a saltwater species.
 - b. a saltwater penaeid shrimp or mysid.
 - c. a freshwater cladoceran.
 - d. a family in a phylum other than Chordata or Arthropoda.
 - e. two other families not in the phylum Chordata.

As described in the National Guidelines, in some situations a calculated FAV should be lowered to protect an important animal species.

- G. If the requirements for calculating an FAV are not met, calculate an Advisory Acute Value (AAV) by dividing the lowest available GMAV by the appropriate factor:

<u>Number of GMAVs</u>	<u>Factor</u>
3	11.0
4	10.0

<u>Number of GMAVs</u>	<u>Factor</u>
5	9.0
6	8.0
7	7.0
8	6.0
9	5.0
10	4.0
11	3.8
12	3.6
13	3.4
14	3.2
15	3.0
16	2.8
17	2.6
18	2.4
19	2.2
20 or more	2.0

The AAV is intended to be equal to or slightly below what the FAV would be if one could be calculated. Since the factors for 8 GMAVs and above are only to be used when those GMAVs are not acceptable under the National Guidelines, the lowest factor has been set at 2, to provide a conservative estimate for the advisory concentration. If there are 8 acceptable GMAVs, then an FAV can be calculated directly.

- H. If three or more experimentally-determined acute-chronic ratios (ACR) which are acceptable based on the

National Guidelines are available for the chemical, determine the Final Acute-Chronic Ratio (FACR) using the procedure described in the National Guidelines. If fewer than three acceptable experimentally-determined ACRs are available, use enough assumed ACRs of 25 so that the total number of experimentally-determined and assumed ACRs equals three (over 90% of the ACR reported by both Kenaga (1982) and Call et al. (1985) were less than 25 and nearly all the FACRs used to derive water quality criteria for aquatic life have been less than 25). Calculate the Advisory Acute-Chronic Ratio (AACR) as the geometric mean of the three ACRs. Thus if no experimentally-determined acute-chronic ratios are available, the AACR is 25.

- I. Calculate the advisory concentration by dividing the FAV (or the AAV if an FAV cannot be determined by the FACR (or the AACR if an FACR cannot be determined)).
- J. If necessary, the advisory concentration should be lowered to one-half of the lowest EC50 for an important aquatic plant species for which the EC50 is available from an acceptable test, based on the National Guidelines, in which the concentrations of test material were measured and the effect was biologically important.
- K. If a Maximum Permissible Tissue Concentration (either an FDA or other regulatory action level for seafoods or from wildlife feeding studies, as described in the National Guidelines) is available, back-calculate to a concentration in water using a measured BCF (or a predicted BCF if a measured BCF is not available). If necessary, the advisory concentration should be lowered to be equal to the calculated concentration.
- L. The advisory should be stated as:

If the measured or estimated ambient concentration of (a) exceeds (b) in fresh or salt water, one or more of the following options must be completed as quickly as possible:

1. obtain additional data concerning the concentration of (a) in the effluent and/or ambient water;
2. obtain additional laboratory and/or field data on the effect of (a) on aquatic organisms and their uses so that a new aquatic life advisory or a water quality criterion can be derived;

3. conduct acute and/or chronic toxicity tests on the effluent;

4. reduce the concentration.

After a reasonable period of time, unless a consideration of all available data concerning the ambient concentration and the effects of (a) on aquatic life demonstrate that the ambient concentration is low enough, it must be reduced.

where (a), = insert name of chemical and

(b) = insert advisory concentration

M. Caveats should be added to the advisory statement in some situations:

1. If data for a commercially or recreationally important species indicate that the species might not be adequately protected by the advisory concentration, but the data do not justify lowering the advisory concentration (for example, because the concentration of test material were not measured), caveat should be added stating that the species might not be adequately protected.
2. If EC50s for a variety of species of algae (or aquatic plants in general) are below the advisory concentration, a caveat should be added stating that algae (or aquatic plants) might not be adequately protected.

References

- Call, D.J., L.T. Brooke, M.L. Knuth, S.H. Poirier and M.D. Hoglund. 1985. Fish subchronic toxicity prediction model for industrial organic chemicals that produce narcosis. *Environ. Toxicol. Chem.* 4:335-341.
- Kenaga, E.E. 1982. Predicatability of chronic toxicity from acute toxicity of chemicals in fish and invertebrates. *Environ. Toxicol. Chem.* 1:347-358.
- Stephan, C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman and W.A. Brungs. 1985. Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. PB85-227049. National Technical Information Service, Springfield, Va.

APPENDIX C

Guidelines for the Preparation of Office of Water
Health Advisories

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Health Advisories

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**GUIDELINES FOR THE PREPARATION OF OFFICE OF WATER
HEALTH ADVISORIES**

**U.S. Environmental Protection Agency
Environmental Criteria and Assessment Office
Cincinnati, OH 45268**

May 6, 1987

INTRODUCTION

These guidelines were prepared to assist authors and others involved in the preparation of Health Advisory (HA) documents for the U.S. Environmental Protection Agency (EPA), Office of Drinking Water (ODW) and the Office of Water Regulations and Standards (OWRS).

The HA document provides a quick review and summarization of the key literature on the physical, chemical and toxicological properties of the specified chemical. Key literature contains information having a direct effect on the estimation of an HA or provides basic scientific information on the chemical of interest. When available, existing documents and reports will be heavily relied upon to complete this document. The HA document is used by EPA to aid in determining control priorities when the chemical is present in ambient or drinking water. The calculated and extrapolated HA values included within the HA document are not legally enforceable ambient or drinking water standards.

LITERATURE SEARCH

To provide literature search and acquisition support consistent with the magnitude of the entire effort, the literature search for a HA document will rely heavily upon those searches already performed in support of available, good quality primary references or summary documents on the chemical. As a minimum, a limited (last five years or 2-3 years prior to most recent reference cited in an existing document) automated literature search will be performed to ensure identification of the more recent technical literature. Typically, the available summary documents and literature search outputs will then be forwarded to the author for his selection of the key primary literature references to be acquired during preparation of the HA. On occasion, an initial selection of the key literature will be performed by EPA staff prior to the author's involvement. The contractor's support staff will acquire copies of the selected references and these will be forwarded to the author to permit initiation of the original writing tasks.

Primary References

Due to the magnitude of the effort, existing documents and reports must be heavily relied upon. To avoid transferring interpretational or typographical errors to the HA from secondary references spot checks will be done. Secondary references (e.g., chemistry texts) may be used in the preparation of Section II (General Information and Properties). Secondary references will be cited when they are the original source of information. For example, an existing EPA document may be a secondary reference for toxicology data but the primary source for extrapolations from that data to humans (i.e., primary reference for existing guidelines or standards).

Key Reference

Only a limited number (average of 20) of literature references are usually specifically cited in the HA document. The selection of references to be

considered possibly the most critical step in the preparation process. The HA documents are not comprehensive reviews of all of the literature on each ambient or drinking water contaminant. Conciseness is maintained by selecting only the most important/valid references for citation. Emphasis must be on the determination of the NOAEL and/or the LOAEL. This establishes the overall scope and technical emphasis of the HA.

The selection of key references is also influenced by the technical "emphasis" on oral exposure. Preferably, studies selected for inclusion into the HA will involve (1) oral exposure-food, drinking water, gavage, (2) dermal exposure/absorption and (3) inhalation exposure if pertinent information on the chemical is provided or if there are no other data available. Studies involving other types of exposure are only useful when more pertinent data are lacking.

Pesticides/Confidential Business Information

For HA documents on pesticides, etc., a special consideration is often encountered. Much of the toxicology and pharmacology data may have been developed by industry and, for proprietary business reasons, classified as Confidential Business Information (CBI). This CBI information cannot be released to the public unless specific authorization is provided by the submitting industry. When such a situation is encountered, the document will use the CBI information in calculating the advisory, and non-CBI summaries will be included. Sanitized copies of any literature that is of importance should be on file. The author will be authorized to access the CBI and instructed to incorporate non-CBI summaries into the HA from the CBI sources. Here a disclaimer is employed to explain why certain details (CBI) are not included. Special instructions are provided to the author regarding the preparation of non-CBI summaries for inclusion in the HA document.

Reference Hard Copies

Two copies of every cited reference will be obtained and submitted to EPA. The author may cite references from his/her personal reference collection or other readily accessible sources. It is emphasized that two legible copies of each reference must be provided with the HA document draft.

Translations

Due to the significant costs that can be incurred, translations of foreign language references are generally avoided and, if absolutely needed, are dealt with on a case-by-case basis. The author must identify all desired translation requirements early in the HA preparation process and check with the EPA HA manager to see if EPA already possesses a translation or if EPA chooses to translate the reference itself.

DOCUMENT ORGANIZATION

The organization of an HA document is designed to achieve a uniform and effective summary of the pertinent data needed to determine a HA. An outline

of the major sections is given later including suggested contents of each sections. More information is described here concerning the technical emphasis, presentation format, and document tone desired for the document.

This rigid structure frequently poses organizational problems with respect to presenting the results of experimental studies, since data pertinent to two or more sections of the outline are often presented in a single research paper. Experience has shown that the best way to solve this problem is to "summarize" the results of each study, presenting the results of individual experiments (or groups of similar experiments) under the appropriate outline headings. This plan does lead to some redundancy with regard to the description of experimental conditions (see below), but nevertheless it is the format that is most useful to the various users of the HA documents.

TECHNICAL EMPHASIS

The HA document must be a technical document. EPA science policy, economic or political considerations are not an issue during the selection of references or the preparation of the document. The technical emphasis in the HA document is with the presence of the specified chemical in water. Thus, all chemistry related portions of the document (physical, chemical properties, chemical analysis) should emphasize the chemical's properties and behavior in water and accumulation in aquatic life. The health effects portions of the document should emphasize the compound's toxicological properties by the most relevant route of exposure, (i.e., oral and dermal exposure). Toxicology information for other routes of exposure may be included as background material for toxicological discussion. However, due to the limited scope of these documents and magnitude of the effort, such discussion will be minimal should it occur at all.

FORMAT FOR PRESENTING EXPERIMENTAL RESULTS

Each experiment (or group of related experiments) should be described in a paragraph that is an independent unit, able to stand alone. This format is needed to provide a concise summary of the key information and for locating items of interest relative to a specific exposure situation. The format is also useful during HA revisions when additions, deletions or rearrangements may be made.

The text describing the results of important experimental studies must provide sufficient experimental detail to allow the reader to form an independent opinion regarding the quality and importance of the results. (Such opinions may be offered by the author of the HA but must be clearly identified as such). If available, the following information must be included (more or less in order) in the paragraph describing an experiment or series of related experiments.

1. The literature citation (in proper format) is contained in a brief introductory sentence. The format for citing references will be provided and examples are given later.

2. Species of test animals (and strain, sex, age, body weight, if critical to the results interpretation).
3. Chemical form (e.g., "copper as CuSO_4 ").
4. Route of exposure and vehicle if used (in drinking water, in food, by gavage in corn oil, intraperitoneal injection, dermal application, etc.).
5. Frequency of exposure (single administration, multiple administration, intermittent or continuous exposure, hours per day, days per week, weeks per year, etc.).
6. Total duration of exposure and study (including any post-exposure observation periods), and total cumulative dose (if relevant).
7. The dose range (in $\mu\text{g}/\text{kg}/\text{day}$, and the number of animals per dose group. A more detailed description of this requirement is presented below (see "Dose Units").
8. Experimental methods and explanatory information if required to fully understand the results or limitations of the study being cited.
9. Parameters measured or observed (survival, blood pressure, liver weight, and other toxicological endpoints.).
10. Summary statement, explicitly giving the No-Observed-Adverse-Effect Level (NOAEL) (if identified) or Lowest-Observed-Adverse-Effect Level (LOAEL). This should be expressed in the dose units used in the cited reference, as well as converted to the standardized units of ($\text{mg}/\text{kg}/\text{day}$).

DOSE UNITS

To permit a common basis for the risk assessment process, all animal and human doses must be stated in terms of milligrams per kilogram body weight per day (mg/kg bw/day). Concentrations of a substance in water and other liquids must be expressed in terms of milligrams per liter (mg/l), and the concentration of substance in the diet must be expressed as milligrams of substance per kilogram of food. Whenever there is ambiguity whether " mg/kg " refers to kg body weight or kg food, use " mg/kg bw" or " mg/kg food" to prevent confusion, and only use " mg/kg bw/day" if the data are presented. Where appropriate, units of micrograms (μg) and grams (g) may be used.

When describing the results of an experiment, the units reported by the authors must always be stated. This allows direct validation of the text of the HA document by comparison with the cited reference. If the units reported in the reference are other than $\text{mg}/\text{kg}/\text{day}$, a conversion to mg/kg must be calculated and also stated in the text. When a salt of a compound is administered, the dose of the ion of interest should be expressed, not the dose of the compound. When intermittent dosing is used (e.g., five days per

week), calculate the average daily dose (mg/kg/day) over the duration of the study. In calculating the dose in mg/kg/day, carry only as many significant figures as are reported by the authors. Often, all information required for calculating the dose in $\mu\text{g}/\text{kg}$ units is not available in the cited reference, and assumptions must be made. All such assumptions must be clearly labeled as such. In order to keep track of all experimental details and the dose calculations, it is suggested that a worksheet be filled out for each literature report used, providing the basis for all details and mathematical conversions made. These worksheets, as well as other supportive materials, should become part of the document file and a copy provided to EPA.

TONE

All sections of the HA document must be concise, accurate, factual, objective and neutral summaries of the important work that has been reported in the literature. The author of the HA document is not permitted to make deductions or extrapolations from the data into the report, regardless of the logic and accuracy of the extrapolation. Deductions and extrapolations made by the author of the citation may be reported, but must be clearly indicated as such. It is emphasized that the HA author's technical expertise and judgement is required to make critical decisions during the selection of those key references to be reviewed and cited in the HA. But, with the exception of the section on "Quantification of Toxicological Effects" the HA document is to be only a summary (not an extensive critical review) of the key information.

Example text

The following paragraphs are offered as examples of the organization, content and style that is desired in descriptions of experimental results.

Single doses of compound X at 1.0, 2.5, 5 and 10 mg/kg administered by intravenous injection in (vehicle) to rats (age, sex, strain), 10 animals per dose, were shown to cause (effect) at doses ≥ 2.5 mg/kg. A dose of 1.0 mg/kg caused no (effect) (Miller et al., 1983).

Adult Sprague-Dawley male rats were administered compound X in their drinking water at doses of 0, 200 or 2,000 ppm (0, 10 or 100 mg/kg/day) for 14 consecutive days (Smith, 1977b). The number of animals used was not reported. A NOAEL of 200 ppm dose (10 mg/kg/day) was identified showing no effect(s) on _____. The 2,000 ppm dose (100 mg/kg/day) caused (effect). In a later review of the study, U.S. EPA (1980) identified several problems with the study, which may have compromised the results.

The format specifications should be approached as the maximum requirement for each summary. Typically, some abbreviation is acceptable to make the HA concise and describe those aspects of each study that contribute the important information. The author, however, should be conservative in preparing abbreviated summaries. The EPA reviewers have final authority over HA document content. The deletion of "unnecessary" experimental details is easier than later reevaluation of the primary reference to expand the text.

The section on "Quantification of Toxicological Effects", however, does require that the author make scientific judgments and thus, departs from the objective, neutral and factual summary tone of all other HA document sections. In this section, the author must select specific sets of data to be used for each HA calculation. This data is then used with EPA established guidelines to estimate acceptable levels.

HEALTH ADVISORY CALCULATIONS

Calculations of HA values are required for 1-day and 10-day periods as well as longer-term and lifetime HA values if adequate subchronic and chronic toxicity data are available. For all such calculations, extrapolation of animal toxicity data to humans will probably be required. The 1-day, 10-day and longer-term for a child HA calculation shall be based on a 10-kg child who consumes one liter of water per day. The adult longer-term and lifetime health calculations shall be based on a 70-kg adult who consumes two liters of water per day. Each HA calculation requires the selection of the best single data-set. These data must be (1) of high quality, (2) from a study where evaluations of target organ effects have been observed, (3) from a study using the most relevant route of exposure and (4) for a study duration comparable to that for the HA value being calculated. A 1-day HA can use up to a 7-day study; a 10-day HA can use up to a 30-day study; a longer-term HA can use a 30 to <90-day study or 10% of the animals' lifetime; a lifetime HA can use >90 day study. Appropriate uncertainty factors are then applied to derive the calculated HA exposure levels discussed below.

Data-Set Quality

The quality of available data-sets will be a judgment resting primarily with the HA author. Publication of toxicity data in reputable "peer-reviewed" toxicology or medical journals should be used as one measure of data quality. Informal coordination with the study authors or other experts active in this technical field may also be required to assist in assessing the quality of data being considered as the basis for an HA calculation. Discussion with the EPA staff is encouraged during the course of the assignment to review the quality aspects of data being considered.

Target Organ Effects Data

The selected data-sets must be from studies where observations for "target organ effects" (e.g., observations for effects other than or in addition to lethality) have been made. The following priorities should be applied in the selection of studies for use in calculating HA values (1) dose-response studies in which a NOAEL is identified, (2) studies employing a single dose or multiple dose that did not produce an effect (a minimum NOAEL) and (3) dose-response studies in which the lowest dose tested still produced an effect (LOAEL only). In cases where there are two or more sets of reliable animal toxicity data, the data set that represents the highest NOAEL or the lowest LOAEL will be used.

Lethality data (regardless of quality) should not be used as the basis for an HA calculation since the dose at which no deaths were observed during an LD or LC50 study is not an adequate basis for calculating an HA value, unless the study included definitive observations for a number of nonlethal adverse effects. In addition, organoleptic effects (taste and odor threshold levels) are also not a good basis for calculating an HA value although they should be discussed in the appropriate section.

The Route of Exposure

The selected data shall be from a study where the route of exposure most closely mimics the route of concern for contaminants in water. Therefore, a study where chemical exposure has been by addition to the animals drinking water represents an excellent data source. Alternatively, studies employing other means of oral exposure are also acceptable for use in calculating HAs. Data from other routes of exposure (e.g., i.v., dermal, inhalation, etc.) shall be selected only when there is an absence of oral data. In this regard consultation with EPA staff should take place to assure adherence to the most recent EPA directives on route-to-route extrapolations.

Study Duration

Although it often becomes a judgment call of the scientist performing the analyses, this aspect of the HA determination is of paramount importance. Therefore, guidelines are helpful in making this determination and necessary in order to maintain consistency in format, content and HA determinations.

The data used for an HA calculation should be for a study of comparable duration to the HA time period being calculated. Ideally, the no-effect dose observed following a single exposure should be selected for the calculation of the 1-day HA. All other factors being equal, the study with the longest post-exposure period for observation of acute toxic effects should be up to 7 days.

The data for the 10-day HA calculation should be selected from a study during which multiple doses were administered for a duration of 30 or fewer days. As with the data for a 1-day HA, the post-exposure observation period following animal exposure may extend beyond this period.

Data selected for the longer-term HA should be from ~10% of an animals lifetime (i.e., 90 days for rodents).

Data selected for the lifetime HA should be from a study in which the animals were dosed for a substantial period of their lifetime (generally two years for mice and rats).

The 1-day, 10-day and longer-term HA calculations shall ignore the carcinogenic potential of the chemical. The HAs for lifetime exposures may not be recommended, however, if the chemical is a known or probable human carcinogen.

Uncertainty Factors

A NOAEL or LOAEL is determined from animal toxicity data or human effects data. For animal data, this level is modified by an uncertainty factor mainly because there is no universally acceptable quantitative method to extrapolate from animals to humans. The possibility must be considered that humans are more sensitive to the toxic effects of chemicals than are animals. For human data, an uncertainty factor is also used to account for the heterogeneity of the human population in which persons could exhibit differing sensitivity to toxic chemicals. The suggested modification of the guidelines set forth by the National Academy of Sciences and modified by the U.S. EPA 1986a typically used in establishing uncertainty factors are as follows:

Standard Uncertainty Factors (UFs)

- Use a 10-fold factor when extrapolating from valid experimental results from studies using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population. [10H]
- Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty in extrapolating animal data to the case of humans. [10A]
- Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there is no useful long-term human data. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs. [10S]
- Use an additional 10-fold factor when deriving an RFD from a LOAEL instead of a NOAEL. This factor is intended to account for the uncertainty in extrapolating from LOAELs to NOAELs. [10L]

Modifying Factor (MF)

- Use professional judgment to determine another uncertainty factor (MF) that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above, e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

If the investigator feels that a modifying factor should be used, he is instructed to get in touch with the appropriate EPA contact for clarification.

REFERENCES

References cited in the document are to be complete and follow a standard format. When citing primary data given in a secondary or review document the original citation must be given along with the secondary source (i.e., Stair et al., 1978, as cited in U.S. EPA, 1986). The appropriate format for the citation in the bibliography is as follows:

Bansal, O.P. 1983. Adsorption of oxamyl and dimecron in montmorillonite suspensions. Soil Sci. Soc. Am. J. 47:887-882.

U.S. EPA. 1969. Thirteen week feeding study - dog. Project #210-239, Acc. #66910. October. Office of Toxic Substances, Washington, D.C.

U.S. EPA. 1986. Guidelines for carcinogen risk assessment. Federal Register. 51(185):33992-34003.

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 1. Water Exposure
 - a. 1-day HA (for drinking water)
 - b. 10-day HA (for drinking water)
 - c. Longer-term HA (for drinking water)
 - d. Lifetime HA (for drinking water, fish and drinking water, fish)
 - e. Cancer Risk Assessment (for drinking water, fish and drinking water, fish)

VII. Other Criteria and Standards (including organoleptic data)

VIII. EPA Contacts

1. Aquatic Life Advisories
2. Drinking Water Advisories

IX. References

I. EXECUTIVE SUMMARY

II. GENERAL INTRODUCTION

[This section of the HA document is standard EPA "boilerplate" that is included verbatim in all such documents. Normally, a typed version of this section will be included in the initial package to the author.]

[The Health Advisories that have been derived in the document should be summarized here as presented in the OWRS format]

III. GENERAL INFORMATION

[This section provides an identification of the contaminant and a concise summary of its physical and chemical properties. In general, the emphasis of this section is on the identification or characterization of various water contaminants. It should include the following information:]

Chemical and Physical Properties

[A list of fundamental physical and chemical properties that may be useful in assessing hazards associated with contaminants of interest.]

- * CAS #
- * CAS name
- * Chemical formula
- * Chemical Structure
- * Molecular weight
- * Physical state (at 25 degrees C)
- * Melting point
- * Boiling point
- * Vapor pressure (25 degrees C)
- * Specific gravity (25 degrees C)
- * Water solubility (25 degrees C)
- * Octanol/water partition coefficient (log Kow)
- * Taste threshold (water)
- * Odor threshold (water)
- * Odor threshold (air)
- * BCF (range of BCF for illustrative purposes only)

Synonyms

[A list of related names that are applied to the chemical of interest.]

Occurrence

[A brief description of the common uses and application of the substances of interest along with an indication of the amount of the substance that the public could be exposed to, especially those that lead to contamination of ambient and drinking water.]

Environmental Fate and Human Exposure

[A brief description summarizing the current information on the transport, fate, and distribution of the substance in the environment. This section should allow a relative source contribution determination.]

IV. AQUATIC TOXICITY

This section will be provided by the EPA.

V. PHARMACOKINETICS

[This section should be brief (even if the technical literature is extensive in this area). The pharmacokinetics data may provide supporting evidence of the quality or relevance of the selected toxicity data. This section is divided into four subheadings, the contents of which are detailed below.]

Absorption

[This section should present data that provide a quantitative estimate of the fraction of an oral dose that is absorbed from the GI tract into the body and for inhalation, if the chemical is volatile, and dermal, even if the chemical is or is not absorbed through the skin. Data regarding the time course of absorption should be presented, but should not be confused with the contents of the section on excretion.]

Distribution

[This section should provide data regarding tissue uptake of the substance, with special reference to the question of whether any preferential accumulation in a target organ occurs. To this end, results expressed as (amount substance)/g tissue are preferred to those that express results as total amount of substance in each tissue, although both are useful.]

Metabolism

[This section should focus on covalent reactions that the substance undergoes in the body, with special enzymatic reactions (activation, conjugation, etc.) and non-enzymatic ones (oxidation, hydrolysis, etc.). Where relevant, noncovalent reactions (binding, adsorption) should also be covered.]

Excretion

[This section should provide quantitative data regarding the percent of a dose that is excreted from the body via feces, urine, bile, expired air or sweat. Half-life data need to be included in appropriate sections to provide sense of "residence times" with continuous or intermittent exposures.]

VI. HEALTH EFFECTS

[This section is the most important part of the document, since it is from these studies that the quantitative assessment of risk (section V) is made. Since many substances show cumulative effects, studies (or individual experiments from more extensive studies) are organized according to the duration of exposure. Each study discussed should be well explained providing information on dose, exposure concentration, duration and route of exposure and species differences that are seen in the available results.]

[Human and animal data shall be described in separate sections with the human data presented first. Additional subheadings should be included in this section of the document to discuss the available information on systemic toxicity (as a function of short and long-term exposure time) reproductive/developmental toxicity, teratogenicity, mutagenicity, and carcinogenicity. The contents of these headings and subheadings are discussed below. When there are no data concerning any of these toxic effects, a general statement should be made to that effect.]

Human

[Much of the data on human exposure are derived from clinical case studies and epidemiologic studies. These studies should be briefly summarized with critical effects identified.]

Short-Term Exposure (Acute Exposure)

[Studies involving a single acute exposure or multiple exposure up to 30 days are included in this section. Adverse effects on various tissues and organ systems (e.g., hepatic effects, renal effects, etc.) are presented.]

Long-Term Exposure (Subchronic and Chronic Exposures)

[Studies presented in this section involve exposure periods in excess of 30 days. Effects reported are those other than reproductive/developmental, mutagenic and carcinogenic responses. If there is evidence for or against occurrence of these endpoints, they should be described under the specific subheadings.]

Animals

Short-Term Exposure (Acute Exposure)

[Studies involving a single acute exposure (including LD₅₀s, LD₁₀₀s, etc.) or multiple exposures up to 30 days are presented. Studies demonstrating adverse effects on tissues or organ systems (e.g., hepatic effects, renal effects, etc.) as well as irritant properties are presented. Data presented in these studies (other than lethality) serve as the basis for deriving 1-day and 10-day HAs.]

Dermal/Ocular Exposure

[This section should contain descriptions of data on eye and skin irritation and skin sensitization, if available. Expectation of systemic toxicity following dermal exposure, if different only by degree, should be addressed in the section on Pharmacokinetics: Absorption.]

Longer-Term Exposure (Subchronic and Chronic Exposures)

[Studies presented in this section involve long-term exposure (from 30 days up to 12 months) or lifetime (24 months for rats or mice). Effects reported are those organ system effects other than reproductive, developmental, mutagenic and carcinogenic responses. Further, the effect that is the most appropriate as an index of chronic toxicity should be identified. Data presented in the studies included in this section will usually be used in deriving the longer-term and lifetime NAs.]

Reproductive Effects

[This section should contain data describing the effects of the substance on the reproductive success of exposed parents and on the survival of offspring. This section should also include data regarding any increased frequency in structural anomalies in offspring. Scientific guidelines to be followed are given in FR 51(185):34027.]

Mutagenicity

[This section should contain the results of experiments designed to assess the mutagenic potential of the substance. Commonly, results from tests in bacterial systems (such as the Ames test) will be reported in this section, as well as various in vitro tests in eukaryotic cells. Scientific guidelines to be followed are given in FR 51 (185):34005.]

Carcinogenicity

[This section should contain the results of experiments designed to assess the potential of selected chemicals of interest to produce tumors in the various organs/systems. Scientific guidelines to be followed are given in FR 51 (185):33992 U.S. EPA, 1986.]

Other Effects

[If any other pertinent information is detected in the literature, it should be presented here. For example, synergistic or antagonistic effects with other compounds may be summarized.]

VI. QUANTIFICATION OF TOXICOLOGICAL EFFECTS

Health Advisories are based upon the identification of adverse health effects associated with the most sensitive noncarcinogenic endpoint of toxicity. The induction of this/these effect(s) is/are related to a particular exposure dose regime over a specified period of time. The effect is usually determined from an animal toxicological study. Standardized risk characterization methodology for threshold toxicants is applied in HA development. The general formula is as follows:

$$HA = \frac{(\text{NOAEL}) (\text{BW})}{[\text{UF}(s)] (\text{L/day})} = \text{mg/L} \quad (\text{ug/L})$$

where: NOAEL = No-Observed-Adverse-Effect Level

or

LOAEL = Lowest-Observed-Adverse Effect Level
(the exposure dose in mg/kg bw/day)

BW = assumed body weight of protected individual
(10-kg for child or 70 kg for an adult)

UF(s) = uncertainty factor, chosen using U.S. EPA, 1986a guidelines to compensate the uncertainty of NOAEL extrapolations from animal/human studies to human populations taking into consideration the amount, type, and nature of the data

L/day = assumed daily water consumption (1 L/child; 2 L/adult)

1-day Health Advisory

The study by _____ has been selected to serve as the basis for the 10-kg child 1-day HA because...[add reasons why this study was selected. Factors to be considered include appropriateness of exposure route, exposure period, age of test animals (or humans), sensitivity of the parameter measured, experimental limitations, etc. High risk populations, chemical interactions, beneficial effects and other special considerations should also be included, as appropriate, in the selection of studies and/or the calculation.]

Longer-Term Health Advisory

The study by _____ has been selected to serve as the basis for the longer-term HA because....[add reasons why this study was selected]

The longer-term HA for the 10-kg child is calculated as follows:

$$\text{Longer-term HA} = \frac{(\text{NOAEL}) (10 \text{ kg})}{(\text{UF}) (1 \text{ L/day})} = \text{___ mg/L (___ } \mu\text{g/L)}$$

where:

NOAEL = (in $\mu\text{g/kg/day}$) is based on absence of [effect] in [species] exposed to [substance] via [route] for [duration]

10 kg = assumed weight of child

UF = uncertainty factor, chosen in accordance with U.S. EPA 1986a guidelines

1 L/day = assumed daily water consumption by a child

The longer-term HA for the 70-kg adult is calculated as follows:

$$\text{Longer-term HA} = \frac{(\text{NOAEL}) (70 \text{ kg})}{(\text{UF}) (2 \text{ L/day})} = \text{___ mg/L (___ } \mu\text{g/L)}$$

where:

NOAEL = (in mg/kg/day) is based on absence of [effect] in [species] exposed to [substance] via [route] for [duration]

70 kg = assumed weight of adult

UF = uncertainty factor chosen in accordance with U.S. EPA, 1986a guidelines

2 L/day = assumed daily water consumption by an adult

Lifetime Health Advisory

The lifetime HA represents that portion of an individual's total exposure that is attributed to drinking water and is considered protective of noncarcinogenic adverse health effects over a lifetime exposure. The lifetime HA is derived in a three step process. Step 1 determines the Reference Dose (RfD), formerly called the Acceptable Daily Intake (ADI). The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious health effects during a lifetime, and is derived from the NOAEL (or LOAEL), identified from a chronic

(or subchronic) study, divided by an uncertainty factor(s) times a modifying factor. From the RfD, a Drinking Water Equivalent Level (DWEL) can be determined (Step 2). A DWEL is a medium-specific (i.e., drinking water) lifetime exposure level, assuming 100% exposure from that medium, at which adverse, noncarcinogenic health effects would not be expected to occur. The DWEL is derived from the multiplication of the RfD by the assumed body weight of an adult and divided by the assumed daily water consumption of an adult. The lifetime HA in drinking water alone is determined in Step 3 by factoring in other sources of exposure, the relative source contribution (RSC). The RSC from drinking water is based on actual exposure data or, if data are not available, a value of 20% is assumed for synthetic organic chemicals and a value of 10% is assumed for inorganic chemicals. If the contaminant is classified as a Group A or B carcinogen, according to the Agency's classification scheme of carcinogenic potential (U.S. EPA, 1986b) then caution should be exercised in assessing the risks associated with lifetime exposure to this chemical.

The study by _____ has been selected to serve as the basis for the lifetime HA because ...(state reasons as to why study was selected).

Using this study the lifetime HA is derived as follows:

Step 1: Determination of the Reference Dose (RfD)

$$\text{RfD} = \frac{\text{NOAEL (or LOAEL) mg/kg/day}}{\text{UF(s)} \times \text{MF}} = \text{_____ mg/kg/day}$$

where:

NOAEL = (or LOAEL) is based on the absence of [effect] in [species] exposed to [substance] via [route] for [duration].

UF = 10, 100, 1000, or 10,000 according to U.S. EPA, 1986a guidelines

MF = Modifying factor >0 to ≤10

Step 2: Determination of the Drinking Water Level (DWEL)

$$\text{DWEL} = \frac{(\text{RfD}) \times 70 \text{ kg}}{(2 \text{ l/day})} = \text{_____ mg/l (_____ } \mu\text{g/l)}$$

where:

RfD = is given $\mu\text{g/kg/day}$

70 kg = body weight of protected individual

2 l/day = Assumed daily water consumption by an adult

Step 3: Determination of lifetime HA for drinking water only

$$\text{Lifetime HA} = \text{DWEL} \times \text{RSC} = \text{---mg/l (---ug/l)}$$

where:

RSC = Relative Source Contribution (10% or 20% unless more information is available that allows more concise determinations)

If the available data provide information on the exposure potential from fish along with the bioconcentration factors involved, the author will also calculate a health advisory for ambient water. This approach allows one to calculate the lifetime acceptable concentration in ambient water based on intake resulting from the consumption of fish only (consumed at a rate of 0.0065 kg/day) and that contributed by the consumption of fish plus ingestion of potable water (2 l/day).

The two procedures are described as follows:

a. Fish Only

$$\text{HA} = \frac{(\text{RFD (BW)})}{(\text{BCF})(\text{fish consumption})}$$

b. Fish plus potable water

$$\text{HA} = \frac{(\text{RFD (BW)})}{2 \text{ l/day} + (\text{BCF})(\text{fish consumption})}$$

where:

BW = body weight (70 kg/adult)

BCF = Bioconcentration factor (to be supplied)

2 l/day = water consumed per adult/day

fish consumption = 0.0065 kg/day

Depending upon the amount of data available, a relative source contribution may also be utilized to further refine the HA calculated above. This is done by multiplying the final number by the percentage assumed to be contributed by ambient water. The assumptions used in these calculations must be thoroughly documented.

Cancer Risk Assessment

[The HA document author is not required to develop the actual quantitative carcinogenic risk assessment. However the author will report to the EPA any data that can be used in the risk assessment calculations by the EPA. From these data, the EPA can determine the concentration of the chemical in

water (mg/l) that is equivalent to the exposure (mg/kg/day) for each excess cancer risk level (10^{-4} , 10^{-5} , 10^{-6}). The basic assumption used as well as the general procedures followed in the determination of these risk levels should accompany the final results. If there are no carcinogenic data available, a negative statement to that effect should be made. If the chemical has been classified by EPA or IARC (EPA is preferred) then the boiler plate caveats stating the chemical's classification should be included. The EPA reference to use is U.S. EPA, 1986b.

VII. OTHER CRITERIA, GUIDANCE AND STANDARDS

[Briefly summarize any existing guidelines by EPA, National Institute for Occupational Safety and Health (NIOSH)/Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), other Federal agencies, states and/or foreign nations, including organoleptic data. Also summarize any guidelines promulgated by the National Academy of Sciences (NAS), World Health Organization (WHO), etc.]

VIII. EPA CONTACTS

A. AQUATIC LIFE ADVISORIES

For further information regarding the aquatic life and fish and water exposure advisories contact:

_____ FTS 475-7315 (202)475-7315

_____ FTS 475-7315 (202)475-7315

B. DRINKING WATER ADVISORIES

For further information regarding the drinking water human health advisories contact:

_____ FTS 382-____ (202)382-____

_____ FTS 382-____ (202)382-____

IX. REFERENCES

[This section contains a listing of all references cited in the HA document in the proper format.

NAS (National Academy of Sciences). 1977. Drinking Water and Health. Vol. 1, p. 19-63.

NAS (National Academy of Sciences). 1980. Drinking Water and Health. Vol. 3, p. 25-67.

U.S. EPA. 1986a. Appendix A. Reference Dose (RfD): Description and Use in Health Risk Assessment. Integrated Risk Information System (IRIS). Online. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH.

U.S. EPA. 1986b. Guidelines for Carcinogen Risk Assessment. Federal Register 51(185):33992-34003.