CHEMICAL MANUFACTURERS ASSOCIATION POSITION PAPER ON EPA'S 1980 WATER QUALITY CRITERIA

CHEMICAL MANUFACTURERS ASSOCIATION

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Geraldine V. Cox, Ph.D.
Vice President and Technical Director
Robert R. Romano, Ph.D.
Manager, Water Programs
Chemical Manufacturers Association
Washington, D.C. 20037
(202) 887-1260

Of Counsel

Edmund B. Frost
Vice President and General Counsel
David W. Carroll
Assistant General Counsel for Environmental Affairs
Chemical Manufacturers Association
Washington, D.C. 20037
(202) 887-1100

Theodore L. Garrett
Corinne A. Goldstein

Covington & Burling
888 Sixteenth Street, N.W.
Washington, D.C. 20006
(202) 452-6000

Counsel for
Chemical Manufacturers Association

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INTRODUCTION AND EXECUTIVE SUMMARY

On November 28, 1980, the U.S. Environmental Protection Agency ("EPA") published an announcement of its water quality criteria for 64 toxic pollutants pursuant to Section 304(a)(1) of the Clean Water Act (45 Fed. Reg. 79319). EPA stated in its announcement that ". . . these criteria present scientific data and guidance on the environmental effect of pollutants which can be useful to derive regulatory requirements based on considerations of water quality impacts." The Chemical Manufacturers Association (CMA) is concerned that scientific assumptions and judgments used in the methodology along with technical errors in EPA's water quality criteria are so serious that the criteria cannot serve their stated purpose.

EPA states (45 Fed. Reg. 79321) that "although this or other valid water quality criteria may be used by the states as developed, they may be modified to reflect local environmental conditions." CMA supports the need for modification to reflect local environmental conditions; however, this type of modification can never overcome faulty scientific

judgments in the criteria themselves. EPA also states (45 Fed. Reg. 79319) "Section 304(a)(1) criteria are not rules and they have no regulatory impact;" however, experience has shown that U.S. national ambient water quality criteria have been extensively used as state standards and have far reaching impacts in many ways -- even beyond the Clean Water Act.

As a result of their scientific shortcomings, the criteria present concentration levels that are much lower than necessary to protect human health and the environment, that will impose staggering compliance costs if utilized in water or other regulatory programs, and that in many cases are impossible of attainment. CMA's concerns are set forth in detail in this paper. These comments are preceded by a summary and a set of recommendations intended to address the serious problems that are presented by the EPA criteria.

Critique Of The Criteria

EPA is supposed to carry out its duties on the basis of good science and adequate data. The public is not served by the publication of EPA criteria that contain serious scientific deficiencies, including the following:

1. Judgments made by EPA in establishing criteria to protect human health from carcinogenic risk are scientifically inappropriate, overly restrictive, and contrary to other federal regulatory bodies. Many chemicals are improperly designated as carcinogens. A single model was used to predict carcinogenic risk for chemicals with very different properties

despite the existence of several equally valid models. EPA has failed to adequately use all the available data in their assessment of risk. The result has been that unnecessarily low levels for protection of human health have been set for 38 of the 64 chemicals (or classes of chemicals).

2. EPA's water quality criteria for the protection of aquatic life should not be directly used as a basis for water quality standards. Some of the criteria are not scientifically valid due to the methodology followed in their derivation and due to technical errors in the documents supporting the published criteria. EPA has not fully considered the relationship between toxicological response, concentration, and exposure duration in developing the maximum and 24-hour criteria, and has used mathematical procedures to calculate the criteria which do not properly incorporate all available data.

3. Water quality criteria should not be established for categories of chemicals. This procedure is not scientifically valid and resulted in unnecessarily restrictive criteria for a number of chemicals that differ markedly in toxicity to the most toxic member of a category.

4. The water quality criteria have not undergone review by the scientific community or the public. EPA's November 1980 criteria are very different from the draft criteria published in 1979. Major changes have been made in the methodology for deriving both aquatic life and human

health criteria. EPA has provided for neither peer review nor for public comments prior to establishing the national water quality criteria.

5. The states have primary authority for establishing water quality standards. The national criteria are for guidance only. The lack of scientific accuracy of the national criteria should be considered prior to using them as guidance for developing site specific criteria and standards.

CMA Recommendations

CMA believes the criteria are unnecessarily low for protection of human health and the environment. The implementation of criteria will needlessly alarm the public, will lead to false starts by federal and state regulatory officials, and will have serious adverse economic consequences, not only for the chemical industry, but for virtually every manufacturing and process industry in the United States. Our recommendations are as follows:

1. The EPA criteria announced in the November 28, 1980 Federal Register should not be used in their present form for regulatory purposes. CMA recommends that EPA formally withdraw the criteria.

2. EPA should undertake a detailed review of the technical accuracy of the data and methodology used to develop the criteria. This includes a critical analysis of the original publications and studies on which EPA relied.

3. EPA should seek an independent scientific review of its methodology for deriving the criteria, and also of the

many judgments made to establish safe levels or estimates of risk. We recommend that the National Academy of Sciences be requested to undertake this task. Particular attention should be given to the issues raised below.

4. The criteria should be revised following this reassessment, published in draft form for public review, and finally published as national criteria.

5. The advisory nature of the criteria should be noted and the need for modification for site-specific characteristics for protection of both aquatic life and human health should be emphasized and developed.

6. EPA should continue to recognize the primary role and authority of the states for establishing water quality standards.

DETAILED COMMENTS

The Federal Clean Water Act requires each state to adopt water quality standards for surface waters. The standards are based on the uses designated by the state for various water bodies. The states are responsible for making sure that the standards are attained.

EPA has a limited role in this procedure. EPA is to publish water quality criteria, containing the latest scientific information, in order to assist the states in setting standards. The Agency also reviews state standards for consistency with the Act's requirements.

This paper discusses the statutory goals and requirements and raises questions as to EPA's current policy. It includes recommendations for a balanced approach that gives proper recognition to the primary role of the states. We also point out a number of flaws and inadequacies in the water quality criteria published by EPA in November 1980, including inappropriate scientific methodology and the failure to consider local conditions.

A nonprofit trade association, CMA has 186 United States member companies which together account for more than 90 percent of the production capacity for basic industrial chemicals in this country. CMA member companies have for years been reviewing the scientific literature concerning the health effects of the substances addressed in the EPA criteria. Since the criteria will undoubtedly have regulatory significance, even in areas not intended by EPA, CMA has a vital interest in the content and use of the criteria.

I. JUDGMENTS MADE BY EPA IN ESTABLISHING CRITERIA TO PROTECT HUMAN HEALTH FROM CARCINOGENIC RISK ARE SCIENTIFICALLY INAPPROPRIATE, OVERLY RESTRICTIVE, AND CONTRARY TO THOSE OF OTHER FEDERAL REGULATORY BODIES

CMA has great difficulty with EPA's excessively conservative approach to the estimation of a chemical's potential carcinogenic risk. For chemicals where limited animal data or chemical structure considerations suggest carcinogenicity, EPA has followed a procedure that: (1) sets criteria as if they were all confirmed human carcinogens; (2) fits data,

usually from a single study, into a single model in the same manner for every chemical; and (3) fails to use relevant data available in the technical literature in the assessment of risk. This procedure is different from that followed by other federal regulatory agencies and by other parts of EPA itself, and also is contrary to recommendations made by EPA's own Science Advisory Board and to publications of the National Academy of Sciences. The result is that the human health criteria for 38 out of the total 64 chemicals (or classes of chemicals) were set at levels far below those thought necessary by most scientists and regulatory authorities. These points are detailed below.

A. EPA Has Improperly Designated Many Chemicals as Carcinogens, Resulting in Unnecessarily Restrictive Criteria

It is extremely important that carcinogens be properly identified in accordance with accepted scientific methodology. EPA has failed to do this. It has treated as proven carcinogens chemicals that are only suspected as being carcinogenic, and in some cases included chemicals that are not even suspected as carcinogens. The criteria developed by EPA for many chemicals improperly designated as carcinogens will result in water limitations far more restrictive than may be necessary for protection of human health, and will be inconsistent with regulatory approaches taken under other federal laws and with judgments made by scientific advisory groups.

The Food and Drug Administration (38 Fed. Reg. 10458 and 39 Fed. Reg. 1355) has recognized that substantial insult to an animal's liver may well result in an increased incidence in liver cancer, even though the insulting agent itself is not a carcinogen. Thus for compounds that induce organ damage, and also cause tumors via an epigenetic mechanism, it may b possible to establish a threshold. EPA's approach estimates risks for these chemicals as if they had no threshold, resulting in extremely conservative criteria. OSHA has also addressed the consequences of exposure to many of the same chemicals. Table I shows the manner in which OSHA regulates the chemicals designated as carcinogens by EPA in their water quality criteria. Most of them are regulated by OSHA as if they were not carcinogens.

EPA's designation of some of these chemicals as carcinogenic is also contrary to deliberations of a subcommittee of the Agency's own Science Advisory Board (SAB). For example, the SAB Subcommittee on Airborne Carcinogens reviewed the EPA Cancer Assessment Group's analysis of trichloroethylene and methylene chloride, and found that there was insufficient evidence to conclude that these compounds are carcinogenic. These findings are set forth in the following extracts from the transcripts of the Subcommittee's September 4 and 5, 1980, meetings:

> Trichloroethylene . . . it hasn't been shown that purified trichloroethylene is carcinogenic. And from my viewpoint, the evidence is not even suggestive.

> Methylene Chloride . . . My judgment here, there just aren't enough data to make any kind of decision . . . The animal data are really not sufficient to make any kind of decision at all. The epidemiology data are quite negative.1/

The Safe Drinking Water Committee of the National Academy of Sciences has also addressed some of the chemicals treated by EPA as carcinogens.2/ A review of the Committee's publication reveals major differences between their conclusions and EPA's conclusions regarding the carcinogenicity of many of the chemicals for which water quality criteria have been published.

The listing of asbestos as a carcinogen in EPA's water quality criteria is another example of inappropriate designation of carcinogens. While it has long been recognized that asbestos may be carcinogenic via inhalation, especially when smoking is a concurrent exposure, there is no substantial evidence to suggest asbestos is carcinogenic via ingestion. In fact all animal experiments, including an extensive study nearing completion sponsored by several agencies of the U.S. Government, have shown that asbestos is not carcinogenic by ingestion. Similarly, human epidemiological studies have not provided even reasonable evidence that exposure to asbestos

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1/ Dr. Sidney Weinhouse, Chairman, SAB Subcommittee on Airborne Carcinogens.

2/ Drinking Water and Health, Volume 3, page 70, National Academy Press, Washington, D.C., 1980.

via ingestion is carcinogenic to humans. To the best of our knowledge, when exposure is by ingestion, asbestos is not regulated or considered a carcinogen by any other U.S. Governmental agency or by foreign governmental agencies.

These examples of EPA's inappropriate designations of chemicals as carcinogens point up the need for further review of the human health criteria prior to their incorporation into water quality standards.

B. The Arbitrary Selection of a Single Model to Predict Carcinogenic Risk is Not Justified

The process of risk extrapolation is a procedure for predicting from known data that which might be expected to occur in a region where there are no data. In dealing with potential carcinogens, the evaluation of risk is often complex. Complications in the analysis can arise primarily due to four factors. First, the majority of cancer data are acquired through laboratory experiments with rodents, not primates or human populations. Second, the amount of material administered to induce cancer experimentally is usually many times the amount to which humans would be exposed. Third, the incidence of cancer has to be high in order to discriminate it from control populations with any statistical significance. Fourth, present scientific data do not provide a definitive answer to the issue of whether or not a threshold for carcinogenesis exists. Thus, it is uncertain precisely how to use

the known data, and the mathematical direction of the extrapolation line becomes a matter of belief rather than scientific fact.

Many theoretical dose.response models for the prediction of risk of carcinogensis have been proposed.[1/] Basically, all of these proposals differ in the steepness of the extrapolating slope, that is, the rate at which the line approaches zero. The mere fact that there are so many models questions the appropriateness of EPA's decision to use only one model. With the great chemical diversity of known carcinogens, it is not logical to expect that one mathematical model would serve as the best predictor of risk in all cases. Different models will provide drastically different estimat s of risk even though the same data are used in each. The choice of the appropriate model for a particular chemical must be determined by a scientific evaluation of the data for that

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1/ See, Mantel and Bryan, J. of Nat. Cancer Inst. 27, 455-470 (1961) Cancer Res. 35, 865-872 (1975) (Recommended by FDA); Armitage and Doll, Proc. of Fourth Berkley Symp. of Mathemical Statistics and Probability (1961); Druckrey, U.I.C.C. Monograph Series Vol. 7, Springer-Verlag (1967); Hoel, et al., J. of Environmental Health 1, 133-151 (1976); Guess and Peto, Cancer Res. 37, 3475-3483 (1977); Cornfield, Science 198, 693-699 (1977); Albert and Altshuler, AEC Symposium Series, CONF. 72050, NTIS (1973) 233-253; Chad and Hoel, Reliability and Biometry - Soc. for Industrial and Applied Math (1973); Hartley and Sielken, Biometrics 33, 1-30 (1977); Crump et al., Biom - trics, 33, 437-451 (1977); Reitz, et al., Fd. Cosmet. Toxicol. 16:511-514 (1978); Gehring and Blau, J. Environ. Pathol. Toxicol. 1:163-179 (1977).

chemical, and not on the basis of a blind adherence to a single model as a matter of policy.

C. EPA Has Failed Adequately to Use all of the Available Data in its Assessment of Risk

The extrapolation of animal data to the human situation is a difficult task. EPA's procedure for assessing the potential for human risk neither takes into account existing data on metabolism and pharmacokinetics, nor evaluates the ability of cells to repair chemical damage. EPA's extrapolation model is capable of using these types of data, but the Agency has not used the model's full capability. Where pertinent data exist they should be used.

In addition, the approach taken by EPA assumes that man is more sensitive than animals on a mg/kg/day basis either explicitly by calculating a factor based upon relative body weights, or implicitly by extrapolating on equal concentrations in the diet. EPA uses this assumption even when there are available data that provide a more accurate and realistic estimate of human risk. For example, animal and epidemiological studies on chloroform and vinyl chloride exposure indicate that man is less sensitive than animals to these compounds.[1/] These studies should be reflected in EPA's

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1/ See, P. J. Gehring, P. G. Watanabe, and C. N. Park, Toxicology and Applied Pharmacology 44, 581-591 (1978); id. at 49 (1979); P. G. Watanabe, G. R. McGowan, and P. J. Gehring, Toxicology and Applied Pharmacology 36, 339-352 (1976).

methodology for carcinogen assessment, but they have been ignored by the Agency.

II. EPA'S WATER QUALITY CRITERIA FOR THE PROTECTION OF AQUATIC LIFE SHOULD NOT BE DIRECTLY USED AS A BASIS FOR WATER QUALITY STANDARDS

CMA has serious reservations concerning: (a) the methodology employed by EPA in deriving the aquatic life criteria, (b) the technical accuracy of the criteria for specific chemicals, and (c) the suitability of national criteria for chemicals whose toxicity is influenced by their chemical form and bioavailability. Failure to consider thes points could result in site specific criteria and water quality standards which are overly and unnecessarily conservative.

A. The Methodology Used by EPA Can Lead to Criteria Which Are Overly Protective

The methodology used by EPA for deriving water quality criteria is overly protective of ambient water concentrations for at least two reasons: (1) the time periods associated with the criteria (instantaneous maximum and 24-hour average) and the toxicity tests upon which the criteria are based are different; and (2) the statistical procedures used to calculate the final acute criterion value does not utilize all of the available acute toxicity data base, but rather emphasizes the lowest LC_{50} values.

1. The aquatic life criteria are presented in terms of maximum and 24-hour average concentrations. The maximum or instantaneous criteria are based on acute toxicity tests in

which aquatic organisms are continuously exposed to toxicant for 48 to 96 hours. The 24-hour average criteria are based on chronic or subchronic toxicity tests which last for several weeks or months. By establishing time specific criteria based on toxicity data generated during significantly longer time frames, EPA has built a safety factor into the calculation. This procedure can result in overly conservative criteria, particularly for chemicals which are not cumulatively toxic. Since the relationship between toxicological response, concentration, and exposure duration is compound specific, it is logical to develop criteria for individual chemicals over time periods that reflect the latest scientific knowledge regarding the relationship between toxicological response, concentration, and exposure duration. EPA has stated that "these two specific time frames [maximum and 24-hour average] were chosen because they match the two kinds of samples that are commonly collected: grab samples and 24-hour composite samples (45 Fed. Reg. 79362)." If scientifically defensible criteria are to be developed, CMA believes that the time frames for criteria should not be based upon convenient sampling schemes but rather on the toxicological properties of the specific chemicals.

2. The EPA mathematical procedure to calculate the final acute criteria values does not use the entire data base. Although EPA's methodology requires acute toxicity data for at least eight aquatic species before a criterion can be derived, the extrapolation/interpolation procedure followed by EPA to

calculate the maximum criterion uses data on only the lowest LC_{50} values. By relying on only a few data points, there is a great potential for deriving an erroneous criterion if these data are faulty. For example, the maximum criterion for mercury is largely based upon a reported crayfish LC_{50} of 0.02 ug/l. As discussed in detail in section III(B) of this document, this datum is incorrect and resulted in an EPA published criterion that is overly conservative.

CMA recommends that a statistical procedure be adopted which incorporates all of the data. For example, by assuming that the distribution of species LC50 values is log normal (or another appropriate distribution), a criterion can be calculated which uses the entire data base.

B. EPA's Aquatic Life Criteria Require a Detailed Scientific Review to Insure Technical Accuracy

EPA's criteria support documents for individual pollutants have not received a sufficient detailed peer review to insure that they are technically accurate prior to their publication in the Federal Register. If EPA criteria are used as guidance in regulatory proceedings, it is appropriate that states and other regulatory agencies carefully review these documents prior to their use. CMA has reviewed a limited number of the aquatic life criteria documents and has found significant errors.

For example, EPA's instantaneous maximum criterion for mercury is largely based on a reported crayfish LC_{50} value of 0.02 ug/1.[1/] Using this datum, EPA calculated a national water quality criterion for mercury of 0.0017 ug/1. A CMA review of the mercury document revealed that this crayfish LC50 value is incorrect. When this datum is replaced by the correct value of 20 ug/1 and the criterion recalculated following EPA Guidelines (45 Feg. Reg. 79341; Appendix B), the resulting instantaneous criterion becomes 3.65 ug/1, a value which is over three orders of magnitude greater than EPA's published criterion. If EPA had submitted the final documents for public and peer review, errors of this type could have been eliminated prior to final publication. CMA recommends that such a review be made immediately and that regulatory agencies not use the criteria without careful review of the water quality criteria support documents.

C. National Water Quality Criteria May Not Adequately Reflect Site Specific Environmental Conditions

In the November 28, 1980 Federal Register notice, EPA acknowledged that the national water quality criteria may require modification "to reflect local environmental conditions." (45 Fed. Reg. 79321) National criteria are based on laboratory toxicity tests. The toxicity data on laboratory-tested species are not directly applicable to aquatic species

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1/ Heit, M. and M. Fingerman. 1977. Bull. Environ. Contam. Toxicol. 18: 572.

in specific water bodies because of differences in species composition and sensitivity, chemical and physical water quality variables, chemical form or composition of pollutant being tested, and other physical factors such as flow and substrates.

Historically, EPA water quality criteria (in particular, the "Red Book" criteria) have been directly used by various regulatory agencies as the basis for setting water quality standards. A growing body of information in the field of aquatic toxicology exists which indicates that the toxicity of many chemicals is altered by local environmental conditions. Experts within and outside EPA now recognize that scientifically valid criteria can be developed only when these site-specific factors are considered. As indicative of this realization, EPA has stated that it is ". . . examining a series of environmental factors or water quality parameters which might realistically be expected to affect the laboratory derived water quality criterion recommendation for a specific pollutant. . . . The purpose of this effort [criteria modification process] is to assist states in adopting the Section 304(a) criteria to local conditions where needed, thereby precluding the setting of arbitrary and perhaps unnecessary stringent or underprotective criteria in a water body." 45 Fed. Reg. 79,321 (emphasis added).

Criteria modification for site specific conditions is important, and CMA recommends the use of water quality

criteria for determining allowable discharge levels of individual chemicals be delayed until the national criteria are corrected for scientific validity and the modification procedures are defined.

III. WATER QUALITY CRITERIA HAVE IMPROPERLY BEEN ESTABLISHED FOR CATEGORIES OF CHEMICALS

Many of EPA's water quality criteria are for categories of chemicals rather than single substances. Criteria were derived for human health for 16 categories of compounds. For aquatic life narrative criteria were set forth for most of these categories. EPA's use of categories is not scientifically justifiable, and has resulted in unnecessarily restrictive criteria levels for a number of chemicals that differ markedly in toxicity relative to the most toxic member of the group.

EPA outlined its methodology for deriving water quality criteria for aquatic life in Appendix B of the November 1980 criteria announcement. The outline states that categories of chemicals were used only when certain clearly defined circumstances existed:

> Each separate chemical which would not ionize significantly in most natural bodies of water should usually be considered a separate substance, except possibly for structurally similar organic compounds that only differ in the number and location of atoms of a specific halogen, and only exist in large quantities as commercial mixtures of the various compounds, and apparently have similar chemical, biological, and toxicological properties. (45 Fed. Reg. 79342)

Unfortunately, EPA's categorization of chemicals did not follow its own guidelines. EPA has published restrictive criteria for categories of chemicals based on single toxicity tests for an individual chemical within the categories.

The "halomethane" category is an example of an inappropriate "generic" grouping adopted by the Agency. EPA has included in this category the following chemicals: methylene chloride, bromoform, methyl bromide, methyl chloride, trichlorofluoromethane, dichlorodifluoromethane, and bromodichloromethane. None of EPA's requirements for categorization are met by this group of chemicals. Despite the lack of similarity among the individual chemicals contained within the halomethane category, EPA set forth single narrative criteria for this class of compounds treating all halomethanes as though they were as acutely toxic as methylbromide and as chronically toxic as bromoform. If these narrative criteria for the protection of aquatic life were used as a guide for setting standards, unnecessarily restrictive levels will result for all the commercially significant halomethanes.

EPA also dealt with the question of class criteria for human health:

> Because relatively minor structural changes within a class of compounds can have pronounced effects on their biological activities, class criteria should be avoided. Whenever sufficient toxicologic data are available on a chemical within a class, a compound specific criteria for that chemical should be developed. (45 Fed. Reg. 79370)

In view of this statement, the derivation of human health criteria for halomethanes is even more startling. Recognizing an absence of sufficient carcinogenicity data on some of the halomethanes, EPA nonetheless has treated the entire category as if all halomethanes are carcinogens. EPA states in the Halomethane Criteria Document:

> Carcinogenicity data currently available for the halomethanes are not adequate for the development of water quality criteria. We suggest that the criteria level be the same as that for chloroform (1.9 ug/L) in order to keep the individual lifetime cancer risk below 10^{-5}. (at C-110 and C-111)

Thus, based on the reported carcinogenicity of chloroform, which is not even included by EPA in the halomethane category, and in the absence of data indicating that any member of the halomethane category is carcinogenic, the water quality criteria for all the halomethanes has been set at 1.9 ug/l. There is simply no justification for such a procedure, and no scientific basis for the criterion.

The impact of classifying the halomethanes as carcinogens is severe. The criteria for human health in the absence of carcinogenic effects as derived by EPA and published in the Halomethane Criteria Document (at p. C-78) are as follows:

In summary, criterion levels intended to protect the public against noncarcinogenic effects resulting from exposure to selected halomethanes are as follows:

Compound	Concentration in ug/l
Chloromethane	3890
Bromomethane	1400
Dichloromethane	12400
Tribromomethane	*
Bromodichloromethane	*
Dichlorofluoromethane	2800
Trichlorofluoromethane	32300

In contrast, EPA's human health criteria for halomethanes as a category (1.9 ug/l), based on assumed carcinogenicity, is at least 1000 times lower than the level derived based on noncarcinogenicity. CMA feels that EPA does not have the data to support the 1.9 ug/l categorical number for all halomethanes.

Other categories used by EPA in setting water quality criteria may be similarly inappropriate. For example, the data base used for Polynuclear Aromatic Hydrocarbons has been derived almost exclusively from studies on benzo(a)pyrene. Criteria levels based on data relating to one chemical should be restricted to the chemical on which the studies were performed and not broadened to a wide variety of chemicals. EPA's inappropriate categorization does not reflect the best scientific knowledge and has no place in the development of water quality criteria.

IV. THE EPA WATER QUALITY CRITERIA HAVE NOT UNDERGONE REVIEW BY THE SCIENTIFIC COMMUNITY OR THE PUBLIC

EPA's November 1980 criteria have changed significantly from the draft criteria published in 1979. These changes include EPA's minimum data base requirements, new methodology for deriving the criteria, and changes in the data base for many pollutants. The human health criteria for almost all of the substances were changed from the drafts. Accordingly, it is incumbent on EPA to provide for further peer and public review of the criteria before any use is made of them. Two examples in addition to those already discussed in this paper highlight the need for such peer and public review.

First, a striking change has been made in the manner in which EPA calculates and uses the Acceptable Daily Intake (ADI) of a particular chemical to derive a water quality criterion. As originally proposed (for noncarcinogens) in March 1979, EPA stated:

> Once an ADI is established, assumptions are made concerning the relative contribution of water to total human exposure. In some cases, criteria are developed in a manner analogous to that used in carcinogenicity studies:
>
> $$C = ADI/2 + 0.0187 \times R$$
>
> In other cases, the biocentration term is omitted and an approximation is made of the proportion of the exposure attributed to water and nonwater sources. For all compounds, criteria are based on an assumed daily water consumption of 2 liters. (44 Fed. Reg. 15980)

Thus, the Agency proposed to calculate a criterion by dividing the ADI by two (2 liters), using the biocentration factor when indicated. However, EPA changed this approach significantly in developing the 1980 criteria. In its notice of November 28, 1980, the Agency describes its new approach as follows:

> For noncarcinogens, ADIs and criteria derived therefrom are calculated from total exposure data that included contributions from the diet and air. The equation used to derive the criterion (C) is:
>
> C = ADI-(DT+IN)/(2 1+(0.0065 kg x R)
>
> where 2 1 is assumed daily water consumption, 0.0065 kg is assumed daily fish consumption, R is bioconcentration factor in units of 1/kg, DT is estimated non-fish dietary intake, and IN is estimated daily intake by inhalation. (45 Fed. Reg. 79354)

CMA questions the basis on which EPA has introduced the factors of daily dietary intake and daily intake by inhalation into the formula used to calculate water quality criteria. It appears that EPA intends to control total exposure to chemicals via the Clean Water Act. Clearly, the appropriateness of this new formula should be thoroughly debated.

Second, the Agency has changed its risk extrapolation model. In effect, this is a change in basic policy. In 1979, EPA stated:

> Since the experimental tumor incidence data generally provide no clue as to which model is correct, the choice must be made on the basis of policy. The Agency has chosen the

> one-hit model because it is consistent with the three basic facts previously mentioned and because it gives greater risk estimates than other plausible models. (44 Fed. Reg. 15978)

EPA has now changed to a multistage model. This model employs enough arbitrary constants to be able to fit most dose-response data. However, the Agency now uses a 95 percent upper confidence limit on the extra risk and lower 95 percent confidence limit on the dose. This procedure was not used in the one-hit model as originally proposed in March 1979.

These major changes in the model and in the utilization of confidence limits in the estimation of risk have been made without the benefit of public comment. This is not sound practice, and is inconsistent with both the Administrative Procedure Act and EPA's stated policy of seeking maximum public participation in Agency decision-making.

In addition to the major changes there have also been a variety of more subtle alterations that could be regarded as simple oversights. However, these alterations lead to inconsistencies within the criteria, for example, the cyanide criterion document. The cyanide water quality criterion for the protection of both aquatic and human health should be based on free cyanide. Indeed this is the approach EPA followed in their proposed cyanide criterion of July 29, 1979. However, a subtle change has occurred in the human health criterion for cyanide -- from free cyanide to total cyanide. This change did not have the benefit of public comment. In

July of 1979 EPA proposed a human health criterion of 0.2 mg CN^-/1, stating:

> Human Health. For cyanide, the criterion to protect human health from the toxic properties of cyanide ingested through water and through contaminated aquatic organisms is 0.2 mg CN^-/1. (44 Fed. Reg. 43666).
>
> * * *
>
> No new additional evidence was encountered to suggest that the 1962 PHS Drinking Water Standard for cyanide should be lowered. The concentration of 0.2 mg/1 or less is easily achieved by proper treatment and concentrations in excess of that amount have been encountered only on rare occasions in U.S. water supplies. The experience since 1962 suggests that 0.2 mg CN^-/1 is a safe criterion not only for man but for most species of fish as well. (Id. at 43667)

Thus, in July of 1979 EPA had strongly supported a scientifically appropriate criterion of 200 ug CN^-/1 to protect human health. However, on November 28, 1980 (45 Fed. Reg. 79331) the final human health criterion for cyanide was announced as 200 ug/1. The criterion for aquatic life (45 Fed. Reg. 79331) was still clearly defined as representing free cyanide (sum of cyanide present as HCN and CN^-). However, that definition was not clearly stated in the criteria for human health as it had been in 1979. In order to be consistent with the aquatic criterion and current scientific thinking, EPA should have presented the final human health criterion for cyanide as 200 ug CN^-/1, clearly defining that free cyanide (sum of cyanide present as HCN and CN^-) represent the toxic entity of concern in ambient water.

For these reasons, and for the other reasons discussed in this paper, a thorough review by both EPA's Science Advisory Board and the National Academy of Sciences should be undertaken before the criteria are used as guidance by states in determining acceptable levels of human and environmental exposure and in developing water quality standards.

V. THE STATES HAVE PRIMARY AUTHORITY FOR ESTABLISHING WATER QUALITY STANDARDS

A review of the language and history of the Clean Water Act demonstrates that Congress intended to give the states the primary authority to designate uses for various water bodies and to establish water quality standards appropriate for those uses. EPA's water quality criteria were intended to be a guide to the states, setting forth the latest scientific information on factors affecting water quality for water bodies in different locations and for various uses.

Section 304(a) of the Clean Water Act, 33 U.S.C. § 1314(a), sets forth the basis for EPA's publication of water quality criteria:

> The Administrator . . . shall develop and publish . . . criteria for water quality accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare . . . which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability . . . for varying types of receiving waters.

It is significant that nothing in the statutory language requires a single set of national water quality standards based on any particular water uses. Instead, the Act simply contemplates that EPA will furnish scientific information to the states pertaining to the effects of pollutants on water quality under various circumstances.

Section 303 water quality standards under the 1972 Act are defined in three stages. First of all, the statute provides that the water quality standards adopted prior to 1972 by the states shall remain in effect. 33 U.S.C. § 1313(a)(1). Secondly, in the event that a state's standard is not consistent with prior law, the Administrator must give the state notice and an opportunity to make necessary changes. If the state does not do so, the Administrator is authorized under Section 303(b)(2) to publish a standard which he determines to be in accord with Section 303(a), i.e., consistent with the law in effect prior to the 1972 Act. Third, if a state decides to adopt new or revised standards, these standards must be submitted to EPA for review. Section 303(c)(2) of the Act provides as follows regarding any such state standards:

> Such revised or new water quality standard shall consist of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses. Such standards shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural,

> industrial, and other purposes, and also taking into consideration their use and value for navigation.1/

Several points should be noted regarding these provisions. Most importantly, the states have the primary role in adopting water quality standards. EPA's role is to review such standards for compliance with the Act. The statute does not permit EPA to substitute its judgment for that of the states, so long as the requirements of the Act are met. In addition, nothing in the statutory language requires or authorizes the imposition of a national standard. The language of Section 303(c) above makes clear that standards are to be set "for the navigable waters involved" and not for some hypothetical national receiving water.

Moreover, nothing in Section 303 of the Act requires the setting of standards for only one particular water use, such as a fishable/swimmable use. Section 303(a) of the Act incorporates prior law, which expressly envisioned the classification of waters for various uses, including industrial use, and the establishment of standards reflecting those designated uses. Similarly, Section 303(c) of the Act provides that new or revised standards shall consist of "the designated uses of the navigable waters involved" and "water quality criteria for

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1/ In the event that the Administrator determines that a new standard is not consistent with these requirements, he is to give the state notice and an opportunity to make specified changes. 33 U.S.C. § 1313(c)(3). If such changes are not adopted, EPA is required to promulgate the standard. Id., § 1313(c)(4).

such waters based upon such uses." The Senate Report on the 1965 Act explained this system of multiple use as follows:

> It will be necessary for us to use many rivers for multiple purposes, including industrial, agricultural, recreational, public water supply, and fish and wildlife uses. In other cases, the uses on a given river or portion of a river will be more limited, depending upon the nature of the waterway, the intensity and history of use, and alternative sources of water in the area. S. Rep. No. 10, 89th Cong., 1st Sess. 8.

Finally, Section 303 of the Act neither authorizes nor requires the states to base water quality standards on EPA's Section 304 water quality criteria. There is no statutory language providing that EPA's criteria have either mandatory or presumptive applicability to water quality standards adopted by the states under Section 303 of the Act.[1/]

It cannot be over emphasized that Congress placed primary responsibility for establishing water quality standards on the states. Section 101(b) of the 1972 Act provides: "It is the policy of the Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution, to plan the development and use (including restoration, preservation, and enhancement) of land and water resources . . . ." Such state

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1/ One court has held that EPA lawfully disapproved a state's water quality standard where the state failed to justify adequately its departure from EPA's Quality Criteria for Water, also known as the Red Book. Mississippi v. Costle, 15 ERC 1256 (5th Cir. 1980). Nothing in the Clean Water Act, however, requires states to adopt EPA's criteria.

primacy is particularly appropriate since standards based on water usage are to be established for individual water segments. Such uses and standards may only be derived from hydrological and biological data specific to the particular water segment involved. Congress recognized that this task is better accomplished by the states on an individual basis with review by EPA to determine compliance with the Clean Water Act, rather than by EPA on a national basis.

Congress was also concerned, as evidenced by Section 101(b) above, with protecting states' rights to exercise traditional land-use powers. Section 101(g), added in 1977, provides that "the authority of each state to allocate quantities of water within its jurisdiction shall not be . . . impaired by this Act." The amount of water available for allocation is, of course, directly related to the permissible uses of that water segment. If EPA mandates that use, states' authority to allocate water would be impaired in contravention of the Act.

TABLE I. OSHA Designation of Priority Pollutants Considered to be Carcinogens by EPA

OSHA-Designated Carcinogens	Regulated by OSHA, but not as Carcinogens	Not Regulated by OSHA
Acrylonitrile	Aldrin	HCB
Benzidine	Dieldren	Bis-(2-chloroethyl)-ether
Inorganic arsenic	Beryllium	1,2-Diphenylhydrazine
Bis-(chloromethyl)-ether	Carbon tetrachloride	Bromodichloromethane
Vinyl chloride	Chlordane	Tribromomethane
N-Nitrosodimethylamine*	1,1,2-Trichloroethane	Hexachlorobutadiene
Asbestos	1,1,2,2-Trichloroethane	1,1-Dichloroethylene
Benzene	Hexachloroethane	
	2,4,6-Trichlorophenol	
	Chloroform	
	DDT	
	2,4-Dinitrotoluene	
	Chloromethane	
	Bromomethane	
	Dichloromthane	
	Dichlorodifluoromethane	
	Trichlorofluoromethane	
	Tetrachloroethylene	
	Toxaphene	
	Trichloroethylene	
	1,2-Dichloroethane	
	PCB	
	PAH (coal tar pitch)	

*OSHA regulates one specific nitrosamine as a carcinogen, but not the broad category of nitrosamines.