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

May 10, 1985

OFFICE OF
THE ADMINISTRATOR

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

Dear Mr. Thomas:

The Science Advisory Board has completed its review of the Agency's revised Guidelines for Water Quality Criteria. The Board's review was carried out by its Environmental Effects, Transport and Fate Committee.

The Committee concludes that the Agency has made great progress in developing a more scientifically sophisticated and realistic set of Guidelines. It has identified additional areas of research to further improve the scientific data base in future years. These areas include:

- o Organisms used for future studies should be selected for the role they play in ecosystems, if ecosystem impact is to be reasonably approximated.
- o The family within which species are assumed to react similarly to toxicants should be abandoned as a unit of study in favor of the ecologically more relevant units of trophic levels or functional groups.
- o The Agency should reconsider the use of the acute/chronic ratio, or its validity should be examined within a range of exposure conditions normally found in field situations.
- o EPA should acknowledge that interactions are a reality that should be considered in criteria setting and should begin to examine the problem of mechanisms of toxicity.

The Board appreciates the opportunity to present its advice on these revised Guidelines and hopes that its review proves helpful to the Agency's criteria development efforts. We request that the Agency provide a formal response to our report.

Sincerely,

John M. Neuhold, Chairman
Water Quality Criteria Subcommittee
Environmental Effects, Transport
and Fate Committee

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

WATER QUALITY CRITERIA

A Report of the Water Quality Criteria Subcommittee
Environmental Effects, Transport and Fate Committee
Science Advisory Board
Environmental Protection Agency
April 1985

EPA NOTICE

This report has been written as a part of the activities of the Environmental Effects, Transport and Fate Committee of the Science Advisory Board, a public advisory group providing external scientific advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of the scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, its contents do not represent the views and policies of the Environmental Protection Agency, nor does mention of trade names or commercial products constitute endorsement or recommendations for use.

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I. INTRODUCTION

The Executive Committee of the Science Advisory Board agreed to review, beginning in the Spring, 1984, the Environmental Protection Agency's revised Guidelines for Water Quality Criteria as proposed by the Criteria and Standards Division in the Office of Water. The Executive Committee referred this issue to its Environmental Effects, Transport & Fate Committee (EETFC). The latter Committee carried out the review and developed a scientific report by creating a Subcommittee on Water Quality Criteria. (See Appendix A for a roster of Subcommittee members.) The specific assignment issued to the Subcommittee was to prepare a critique of the scientific rationale of and proposed modifications to EPA's Guidelines.

The initial presentation to the Environmental Effects, Transport and Fate Committee occurred in February, 1984 at a meeting at EPA's Gulf Breeze Environmental Research Laboratory. At that time, the Committee also formulated the charge of the Subcommittee on Water Quality Criteria. The Subcommitte held its first meeting at the Environmental Research Laboratory in Duluth, Minnesota where it was briefed by laboratory personnel responsible for providing scientific input to the Guidelines. The Subcommittee held subsequent meetings in July, 1984 in Corvallis, Oregon, where it received from EPA staff an update on the public comments submitted on the document, and that same month in Monterey, California where the EEFTC received a status briefing of the Subcommittee's review and preparation of a scientific report. The Subcommittee met in December 1984, in New Orleans, Louisiana to continue writing its report. The report was submitted to the SAB Executive Committee for its April 25-26, 1985 meeting at which time it was officially approved for transmittal to EPA.

The Science Advisory Board has followed the development of water quality criteria by the Agency since the Board's creation in 1974. The process of developing criteria has undergone considerable evolution since the Agency's initial efforts, which resulted in the "Blue Book" followed shortly by the "Red Book", that placed sole emphasis for the setting of criteria on the results of individual species' toxicity tests. Subsequent iterations of the Guidelines included consideration of such issues as mode of exposure, level of protectiveness and ecosystem protection. Each update has resulted in a more sophisticated and realistic set of Guidelines. To the credit of the scientists at the EPA laboratories and within the Office of Water, the latest edition of the Guidelines takes advantage of advances in research made over the past few years. The Subcommittee has identified some additional areas where the Guidelines can be improved, and this report presents those recommendations.

This report is organized into five sections. These include: 1) conclusions and recommendations; 2) a discussion of the philosophical and operational bases for water quality criteria; 3) a discussion and critique of the application of biological principles to such issues as the relationship of laboratory derived toxicity data to field realities, the role of organisms in ecosystems, the taxonomic family as a discriminant unit and acute/chronic ratios; 4) a review of chemical considerations, particularly the question of metal speciation; and 5) an evaluation of exposure considerations involving the concept of level of protection as well as a discussion of the validity of statistical approaches.

II. CONCLUSIONS AND RECOMMENDATIONS

1. The Subcommittee understands that the Congressional intent in adopting the concept of physical, chemical and biological integrity in amendments to the Clean Water Act was to lessen the Nation's dependence on water use specification criteria and to incorporate ecosystem principles into the promulgation of water quality criteria. To make this concept operationally possible, it is necessary to view the ecosystem in its entirety and focus attention on measures of stability.

2. Laboratory toxicity studies are useful in examining dose-response relationships and mechanisms of toxicity. Their applicability to predicting responses in the field, however, is limited. Thus, any criteria based on these studies, even with the application of safety factors, may not be protective. For the present, we are limited to using laboratory studies for the establishment of water quality criteria. In future revisions of the Guidelines, EPA should direct emphasis toward: a) laboratory examination of the effects of toxicants on the sensitivity of organisms; b) mesoscale ecosystem studies of the effects of toxicants on organisms and ecosystems; and c) demonstration of the impact of field variables in the laboratory.

3. Scientists have carried out toxicity studies, to a large extent, on organisms of utility (those that have value to society) or facility (those that easily adapt to laboratory conditions), but such studies provide little insight into ecosystem impacts. Organisms used for future studies should be selected for the role they play in ecosystems, if ecosystem impact is to be reasonably approximated.

4. The taxonomic family is not a unit within which species can be expected to react similarly to pollution insults. Classes of functional units within ecosystems would constitute a more suitable framework for analysis. The Subcommittee believes that EPA should abandon the family (within which species are assumed to react similarly to toxicants) as the unit for testing in favor of the ecologically more relevant units of trophic levels or functional groups.

5. The Subcommittee challenges the assumption that a simple relationship exists between acute and chronic toxicities on the basis that the mechanisms for, and behavior of, acute and chronic toxicities differ under a variety of environmental conditions. The Agency should reconsider the use of the acute/chronic ratio, or its validity should be examined within a range of exposure conditions normally found in field situations.

6. The proposed criteria for metal toxicity derive from empirical laboratory toxicity studies which take into account some environmental interaction effects, notably water hardness. They do not, however, consider the effects of pH on complexing or,

generally, metal ligand interactions on the toxicity of the metal. Also, the standard approach to determining metal concentrations has no bearing on the bioavailability of metals. The Agency should consider the proposed metal criteria as temporary, and it should develop new criteria based on methods that consider the mechanisms which dictate metal speciation, bioavailability, accumulation and toxicity.

7. Dissolved and particulate organic matter loadings of the aquatic ecosystem can have a pronounced effect on the toxicity of metals and xenobiotic organic compounds. EPA should initiate studies to establish the effect of organic matter on the toxicity of metals and xenobiotics.

8. The Guidelines' revisions address only individual toxicants. Organisms in the environment are exposed to complex pollutant mixtures including those that interact and produce results different from those expected from exposures to single compounds. The Agency should acknowledge that interactions are a reality to be considered in criteria setting and should begin to examine the problem of mechanisms of toxicity.

9. An apparent assumption in the Guidelines that EPA needs to assess further for its validity is that the 5th percentile based criterion protects 95% of the organisms or species or families in an ecosystem, and that this level of protection for organisms also protects both ecosystem function and integrity. The EPA studies conducted at the Monticello Research Field Station are developing a data base addressing the relative sensitivities of structural and functional properties of aquatic ecosystems, but they represent only a beginning.

10. The Guidelines generate criteria in two ways by: a) the application of formal procedures based on distributional concepts, and 2) the utilization of scientific judgment as to the reasonableness of the formal procedures. When distributional concepts are applied, EPA should include a measure of variability with each criterion to provide a basis upon which to decide whether more data points need to be collected or the methodology revised. When judgmental methodology is employed, the Agency should carefully articulate and document the scientific rationale for the judgment.

III. PHILOSOPHICAL AND OPERATIONAL BASES

The Congressional intent of the phrase "physical, chemical and biological integrity" in the 1972 amendments to the Federal Water Pollution Control Act was to incorporate the ecological concept of biochemical/geochemical cycling into the enforcement of the Act or, more specifically, to recycle anthropogenically generated substances to their places of origin (Jorling 1975). By implementing the concept, the land application of domestic sewage, for example, would return organic material and nutrients to the land for society's future use. Similarly, the reduction of synthetic organics to carbon dioxide and water, and the transformation of heavy metal products to parent metals for reuse, embody this concept of biochemical/geochemial recycling. Taken to its ultimate level of philosophical application to water quality issues, this approach would allow for no degradation of water quality.

This concept has a number of operational difficulties. Short of declaring a nondegradation policy, EPA must develop an operational definition of biochemical/geochemical recycling before establishing a philosophical basis for the promulgation of water quality criteria. An examination of what physical, chemical and biological integrity means in an ecosystem offers a start for such efforts.

One interpretation of ecosystem integrity relates to the role that society assigns to the system. This may be a very functional role such as a highly managed sewage treatment lagoon, a power generation facility, an irrigation project, a shipping channel or a drinking water supply. The ecosystem might be valued in some completely natural or wild state for its aesthetic qualities such as a refuge for endangered species or as a recreational fishery. Whether these systems retain integrity depends upon how well they are managed to fulfill their role and function as assigned by society.

This interpretation of ecological integrity was applied in environmental policies, prior to passage of the 1972 amendments, in the form of specifying the use of water bodies. As Jorling (1975) pointed out, this application has a tendency toward a single user dominated policy which inevitably reduces the options available to decision makers. In this context, ecosystems are but an incidental consideration, while overall societal use is the primary concern.

The term "integrity" conveys the concept of wholeness. Within this concept, the terms physical, chemical and biological, taken in the context of water quality, encompasses the totality of the aquatic environment or the ecosystem. Thus, physical, chemical and biological integrity taken together mean ecosystem integrity.

Ecosystem/water characteristics are dynamic, that is, they change with time, whether in seasonal, geological or catastrophic senses. An ecosystem comprises states (species composition, biomass) and processes which act on those states through rate of movement or loss of energy and materials among the trophic levels which respond to seasonal forces (temperature, sunlight), geological forces (erosion of parent materials, gradients) or catastrophic forces (hurricanes, floods). In the strictest sense, an ecosystem never loses integrity but merely changes states. Given such an interpretation, any physical, chemical and biological quality of water is possible in a system which maintains its integrity. Therefore, basing water quality criteria on this concept is problematical, particularly if use is the dominant concern.

Most ecosystems are not static but develop along some trajectory to higher or lower levels of complexity and productivity. Loss of ecosystem integrity might be described as a greater than normal divergence from the natural path or trajectory in a new direction. In most cases, information does not exist to adequately define pathways, trajectories or normal divergence.

Ecosystem stability relates to its capability to withstand perturbations either through inertia, or high resilience and rapid return to equilibrium. Whether a perturbed ecosystem returns to the original trajectory or to some new pathway is related to the maintenance of ecosystem integrity.

Community composition indicates the state of ecosystem stability. The community evolved as a cohesive, compensating and regenerating unit. The loss or replacement of species from a community occurs frequently, but the ecosystem continues to function. Thus, a measure of how species work and function together through time becomes an important consideration. The presence of keystone species (species that play a critical role in the function of ecosystems) may be an important measure of ecosystem stability. Community respiration, productivity, nutrient turnover and nutrient loss are also measures of ecosystem stability and can be employed profitably in determining pollution effects on ecosystems.

Considerable knowledge of an ecosystem is necessary if its integrity is to be specified. The more knowledge of its component parts and functions, the better scientists are able to determine when impacts occur and if an ecosystem has lost integrity. Only in the simplest systems does the capability exist to understand these issues. As additional knowledge is obtained and synthesized, the definition of ecosystem integrity will become more sophisticated and more useful in the protection of our environment for current and future generations. Until such time, scientists must work with relatively crude measures of ecosystem stability.

IV. BIOLOGICAL CONSIDERATIONS

A. Laboratory to Field Relationships

Virtually all of the toxicity data available on aquatic organisms derive from laboratory studies although some minor "incident" data exist. The key scientific question is whether the data on organism sensitivities to toxicants gained from laboratory experiments accurately reflect the sensitivities that organisms experience in the environment, and whether the results of such experiments relate to the integrity of the ecosystem.

Laboratory toxicity studies of chemical compounds or mixtures are usually conducted on single species under closely controlled conditions. Such studies are designed to examine the responses to administered doses, over fixed periods of time, and to measure such factors as mortality, growth, reproduction, histopathological or biochemical changes. Such studies are particularly suitable for establishing cause and effect relationships between exposure to particular anthropogenic compounds and pathological or physiological alterations. The ability to control environmental and exposure variables represent the primary strengths of laboratory studies. Even though the design of laboratory studies can vary, the number of variables remains relatively small.

The applicability of laboratory studies to predicting the fate of individual organisms or populations exposed to pollutants in the environment is more difficult to establish because such organisms contend with more forms and degrees of stress under real world environmental conditions. These are presented in Table 1.

Table 1

VARIABLE	LABORATORY	ENVIRONMENT
Type of toxicant	Single/known	Multiple/unknown
Toxicant concentration	Constant	Variable/intermittent
Exposure	Single toxicant	Multiple toxicants
Interspecific competition	Absent	Present
Disease/parasites	Absent	Present
Population density	Extreme/controlled	Variable
Space	Constrained	Adequate/unconstrained
Temperature	Constant	Fluctuating
Structure	Glass/impoverished	Plants/stones/cover

The stresses organisms experience in the laboratory and the environment also differ and, because stresses affect the response of organisms, the responses examined in the laboratory may not directly translate to the environment. Studies such as those conducted by EPA at the Monticello Research Field Station can provide useful information on the relationships between laboratory data and the field. The experimental streams utilized provide an opportunity to assess the effects of chemicals on structural and functional relationships. Information presented to the Subcommittee by EPA regarding research at the Monticello Research Field Station demonstrated ecosystem responses not predicted by laboratory toxicity test data. Such studies are especially valuable in developing a better understanding of how to translate laboratory studies to the field setting, and EPA should continue its work in this area.

In spite of the shortcomings of laboratory testing for predicting environmental effects, such studies have advantages in defining the problem, in their ease of execution, in the potential clarity of interpretation and in verification. If the full potential of laboratory studies for environmental assessments is to be realized, EPA should address several major research needs. These include: 1) examination of the effects of some environmental components in the laboratory (e.g., the influence of multiple biological species interactions); 2) extension of these studies to mesoscale ecosystem studies which, to a degree, duplicate field conditions; and 3) an examination of the effects of multiple contaminants as is most often encountered in the environment.

B. The Role of Organisms in the Ecosystem

Most toxicity tests utilize organisms that either easily adapt to laboratory conditions (organisms of facility) or those that have value to society (organisms of utility). A few species, such as the bluegill (*Lepomis macrochirus*) and the fathead minnow (*Pimephales promelas*), represent a relatively wide geographic distribution. Seldom, if ever, have test organisms been selected for the role they play in the environment. Yet, ecosystems change states depending upon the organisms most affected by the intrusion of a toxicant.

The Agency should consider the different concentrations at which community perturbation(s) affects various organisms and which different organisms discriminate toxicant concentrations. This is particularly important for "keystone" species which perform roles that determine the makeup of the community of which they are a part. The alewife (*Alosa pseudoharengus*), for example, controls the quality of the plankton population upon which it feeds in northeastern ponds (Brooks and Dodson, 1965). A starfish (*Pisaster spp.*) of the intertidal shores in the Pacific Northwest controls the makeup of the intertidal community in which it exists (Paine, 1969). A pollutant that affects either the alewife or the starfish will have marked effects on ecosystem composition. The

Guidelines should reflect recognition of the role of keystone species in communities and of the effect on communities in their absence.

C. The Family Concept in Toxicity Testing

The Guidelines assume that, as a unit, the taxonomic family contains species whose sensitivites to pollutants are essentially interchangeable. In other words, EPA believes that the species within families can serve as surrogates for one another in their response to pollutant insults. The Agency has not documented this contention and sound reasons, discussed below, exist suggesting that it might not be true.

Taxonomic designations of orders, families, genera and species represent constructs which attempt to relate organisms phylogenetically. They do not delineate how organisms are organized in ecosystems, the functional role they play or their potential response to pollutant exposures. Scientists constantly analyze new species and reorganize taxonomic relationships and, in some instances, rename species and genera or recognize new families. Although the system of nomenclature conveniently describes plants and animals, it is not useful for presenting the terms of ecosystem relationships and has limited utility for testing toxicants.

The number of subfamilies, genera and species comprising a given taxonomic family varies considerably. Family designation does not assure a broad spectrum of function or role of an organism in an ecosytem. A salient issue is whether any given number of families from which test species are drawn will assure a cross section of oganisms important to the continued function, stability and productivity of ecosystems.

Trophic levels (reducer, producer and consumer) and feeding strategies perform a more important role in determining the transfer, accumulation and concentration of toxic substances in ecosystems. All species in a single family, however, may not act as reducers, herbivores or predators or have similar feeding strategies. Certain widely distributed families, such as members of the family Cyprinidae (minnows) have diverged into many species representing all trophic levels and an abundance of feeding strategies.

Detailed knowledge of how organisms are exposed to pollutants, given their role in the ecosystem, and how organisms defend against intrusion of environmental insults (e.g., regulation of uptake, excretion and detoxification), might provide the basis for selecting species for toxicity testing.

Exposure of aquatic organisms occurs in two major ways: 1) ingestion with food or water, and 2) active or passive absorption through epithelial membranes. The role an organism plays in the ecosystem determines, to a large extent, the level of exposure it receives through the food it ingests. For toxic substances that biomagnify, predators will receive greater exposures than herbivores. Predators, herbivores and reducers also have differing behavioral, anatomic and, most likely, physiological characteristics that relate to exposure, metabolism and, consequently, their sensitivity to toxicants.

The Subcommittee recommends that the Agency abandon use of the family as a unit for testing in favor of ecologically more tractable units such as trophic levels or functional roles.

D. Acute/Chronic Ratios

The proposed revisions of the Guidelines allow for the use of acute/chronic ratios to estimate chronic toxicity of a compound from acute toxicity data. The Agency adopted this approach apparently because of the difficulties and expense associated with conducting chronic toxicity studies. This underlying assumption derives from the belief that a precise and predictable relationship exists between the acute and chronic toxicities of a compound.

As the Subcommittee's understanding of the toxicity of metals and organic compounds has developed, however, it has become clearer that physiological mechanisms differ by which acute and chronic exposures affect organisms. For example, acute metal exposures in fish will primarily affect the gills. The rate limiting steps appear to be the availability of metal ligands in the blood that serve to clear the gill epithelia and ability of the gill to detoxify or transport accumulated metals. Chronic exposures, however, have their greatest impact on the kidney, with the rate limiting steps being the ability of the liver to detoxify circulating metals and to detoxify any accumulated metals.

Because of these differences in underlying mechanisms, the relationship between acute and chronic toxicity might be constant only under carefully controlled laboratory conditions. Extrapolations to field situations in which numerous uncontrolled variables exist are highly questionable.

The Agency should reconsider the use of acute/chronic ratios as a substitute for performing chronic toxicity tests. If it retains this approach, however, EPA should examine its validity with a range of exposure conditions that more accurately reflect the variables encountered in actual field situtations.

V. CHEMICAL CONSIDERATIONS

A. Metal Speciation

The Guidelines do not effectively address the problem of metal speciation in aqueous systems. Metals in solution exist as a variety of chemical species including free ions and a number of inorganic and organic complexes. They may also adsorb to particulates such as fine clays and detritus (Stumm and Morgan, 1981). Not all of these species are available or toxic to the organism (Sunda and Guillard, 1976; Sunda, et.al., 1978; Cross and Sunda, 1978).

For metals such as Cd, Cu and Zn, bioaccumulation and toxicity relate to free ion activity rather than the total concentration of dissolved metals. This relationship appears to result from thermodynamic and biochemical considerations (Cross and Sunda, 1978). Free metal ion activity is a measure of the free energy of the system and reflects the potential for interactions between the metal and available ligands. The various complexes of metals, such as Cd, have very low permeability coefficients for lipid bilayers and do not enter cells at a significant rate (Gutknecht, 1983). As a consequence, transport of these metals may be mediated by membrane-bound transport proteins. Uptake of these metals is a function of the interaction beween the metal and the transport protein, and the potential for this interaction is reflected in the free metal ion activity.

Metals such as Hg and Ag, however, form complexes (e.g., $HgCl_2$ and $AgCl^0$) that pass rapidly across membranes (Gutknecht, 1981). For these metals, the membrane-permeable complexes dictate bioavailability and toxicity, not free ion activity (Engel, et.al., 1981).

Regardless of mode of uptake, any attempt to define the toxicity of a metal in an aqueous environment should take into account the metal speciation which, in turn, determines bioavailability. The revised criteria do not address these mechanisms.

The Guidelines do attempt to account for alterations in the toxicity of metals (e.g., Cd, Cu and Pb) due to variations in water hardness defined as the concentration of $CaCO_3$. Changes in $CaCO_3$, however, can alter metal speciation via a number of mechanisms including increased complexation, competition with Ca^{2+} for available ligands or modification of complexation due to changes in pH. Any extrapolation from laboratory toxicity studies to actual field situations requires an understanding of these mechanisms and other potential metal-ligand interactions that could modify availability and toxicity. The proposed Guidelines, however, utilize empirical data while largely ignoring the basic mechanisms. As a consequence, they can only be expected to provide useful information for a limited number of metals and under carefully controlled conditions.

The Guidelines also attempt to distinguish between total recoverable metal concentrations and "active" metal concentrations. Active metal concentrations are operationally defined as the concentration of metals that passes through a 0.45 um filter after the sample is acidified to pH 4.0 with nitric acid. This approach does provide a standard method for determining metal concentrations, but it has no bearing on the actual concentrations of bioavailable metals. Because it has no mechanistic basis, it does not allow useful quantitative comparisons of metal toxicity between different water samples. Thus, it has limited predictive potential.

The Subcommittee believes that Agency staff have worked diligently to refine the existing Guidelines to their logical limits. However, this approach does not consider the underlying metal chemistry, and any further refinements are unwarranted. The Subcommittee recommends that the Agency regard its proposed metal criteria and the methods used in their development as temporary. Future revisions of the Guidelines should rely on new methods that take advantage of increased understanding of the mechanisms that dictate metal speciation, accumulation and toxicity. The Subcommittee recognizes that adoption would require a basic reevaluation of EPA's current approach to determining metal toxicity and developing metal criteria, but it considers these changes essential.

B. Organic Matter and Dynamics

The need for site-specific criteria in considering limiting concentrations of heavy metals and xenobiotic organic chemicals that a given body of water can carry without degrading the intended uses of that water, or the well being of the indigenous biota, can be substantiated. One of the variables that influences the effects of xenobiotics in various bodies of water is the concentration of dissolved and particulate organic matter. Prime activities of dissolved organic matter (humic acids, particulate organic matter) affecting the bioavailability of toxic heavy metals to aquatic organsims include chelation, sulfhydryl binding and other complexation mechanisms. As considered in the above discussion of metal speciation, the toxicity of a heavy metal in the aqueous environment is less a function of its total concentration than its bioavailability. Heavy metal ions may be complexed by other inorganic ions, primarily sulfates, chlorides and bicarbonates. These inorganic anions vary from one water mass to another and should be considered in establishing site-specific criteria for heavy metal concentrations. The concentration of these inorganic anions will, however, remain relatively constant for a given body of water. The total concentration of organic matter may also remain fairly constant, but various components exist in a dynamic state since both terrestrial sources and biota continuously add fresh organic materials. The complexation of heavy metals by organic matter undergoes constant flux as organic matter is degraded by bacteria. Because microbial metabolism is temperature sensitive, the rate of this flux will vary diurnally and seasonally.

In contrast to the direct effect of dissolved organic matter on the bioavailability of heavy metals, little is known of the effects of naturally dissolved organic matter on the bioavailability and toxicity of xenobiotics. While it might be expected that xenobiotics partition onto particulate organic matter, this effect is probably minor in comparison to their partition onto inorganic clay suspensoids. Differences in the load of dissolved and particulate organic matter between various bodies of water may have a greater indirect effect on the fate of xenobiotics. A heavy input of organic matter into a body of water may sustain an abundant and diverse microbial population. This condition would be reflected in a faster rate of microbial detoxification of many xenobiotics in organically rich waters. The Subcommittee recommends that EPA initiate studies to establish the effect of organic matter on the toxicity of pollutants.

C. Contaminant Interactions

The proposed Guidelines' revisions, like all previous water quality criteria development efforts, deal only with individual contaminants. This approach, while simplifying the analytical task of the regulator, ignores the complex realities that organisms must routinely face in their environments. These include non-additive or synergistic effects on toxicity. Different metals compete for organic and inorganic ligands as well as membrane transport proteins that regulate their bioaccumulation. As a consequence, alterations in the concentration of one metal may change the speciation and toxicity of another. Scientists have documented changes for phytoplankton where Zn, Cu and Mn all compete for common transport sites (Jenkins, et. al., 1983). Reduced concentrations of Zn or Mn dramatically increase the apparent toxicity of Cu because this substance effectively competes with these essential metals, and organisms quickly become deficient in Zn and Mn. Similar interactions occur between organic hydrocarbons, and recent data suggest that metals and hydrocarbons may also interact and modify each other's availability and toxicity in precise ways (Jenkins, 1985).

In short, the Subcommittee believes it is important for EPA to: 1) begin to examine the impact of mechanisms upon contaminant interactions in a thorough manner, and 2) point out the potential for interactions between contaminants and their relationship to criteria development.

VI. EXPOSURE CONSIDERATIONS

A. Level of Protection

The Guidelines for deriving National Water Quality Criteria for the protection of aquatic life and its uses assume that criteria based on the 5th percentile of the distribution of the geometric mean, species geometric mean, or EC50 or LC50 values will result in protection of the biological integrity of aquatic resources. Implicit in this assumption is the belief that water quality criteria derived from toxicity data for fish, invertebrates, and plants protect the myriad of other aquatic organisms in aquatic ecosystems, and that protection of the structure (i.e., organisms) of the ecosystem will protect the functional properties of the ecosystem.

The approach taken in the Guidelines represents a positive step toward protecting the integrity of aquatic resources, but it is incomplete because the above assumptions have not been totally validated. In addition, EPA has not demonstrated what current level of protection adequately protects the integrity of aquatic ecosystems. If one of the unprotected species is a keystone species in the ecosystem, collapse of the structure of the aquatic community may occur. In their present form, the Guidelines do not address the keystone species concept nor did the Agency staff present data to the Science Advisory Board demonstrating, through field validation experiments, that they could address the keystone species issue. An example of a keystone species is smooth cordgrass (Spartina alterniflora) in a salt marsh. Elimination of cordgrass would cause collapse of the salt marsh ecosystem. Yet cordgrass is not a routine test species, and its sensitivities to chemicals are largely unknown.

An apparent assumption in the Guidelines that EPA needs to assess furthur for its validity is that the 5th percentile based criterion protects 95% of the organisms or species or families in an ecosystem, and that this level of protection for organisms also protects both ecosystem function and integrity. Data supporting this assumption are scarce, in part due to the difficulties in assessing ecosystem functional responses to stresses caused by chemicals. The EPA studies conducted at the Monticello Research Field Station are developing a data base addressing the relative sensitivities of structural and functional properites of aquatic ecosystems, but they represent only a beginning. If, in fact, essential ecosystem functions exhibit more sensitivity to chemical stresses than the fish, invertebrates, and plants used to develop the water quality criteria data bases, then it is possible that the criteria will underprotect the integrity of aquatic ecosystems. Inclusion of test results that evaluate responses of functional processes to chemicals should be included in the approach advanced by EPA for establishing water quality criteria.

B. Statistical Issues

From 1976 to the present, the Agency developed and revised technical guidance for calculating water quality criteria. This guidance has taken the form of methodologies using laboratory studies of the toxicity of pollutants. The Agency has also generated new data from laboratory experiments, field studies and field experiments. As new data became available, the Agency periodically modifies the Guidelines so that they reflect current scientific judgment on the factors that protect designated uses.

Among the important developments in the Agency's evolutionary development of Guidelines include efforts to: 1) correctly state the scientific assumptions of its criteria development methods; 2) demonstrate how these assumptions will achieve the degree of protection sought; and 3) verify that the predicted result and protection do occur.

Each of these three areas has a statistical component to the extent that analyses supporting the methodology are based on distributional descriptions of relevant data. The current Guidelines (Federal Register, February 7, 1984, p. 4553) rely heavily on the distribution of species' EC50's and LC50's in setting criteria. In the following sections, the Subcommittee reviews the statistical basis of the current Guidelines in terms of the three preceding points.

1. Statement of Scientific Assumptions

The Guidelines for deriving water quality criteria consist of a formal procedure using laboratory data to calculate numerical criteria and less formal techniques on the use of professional judgment in applying the calculations. The formal procedure, which uses laboratory data from many areas of aquatic toxicology, is designed to provide criteria that are comparable among laboratories and for different pollutants. These data represent primarily EC50's and LC50's for acute tests and no observable effect levels for chronic tests. The assumptions that underlie the formal method are limited by the capabilities of low cost field monitoring and by the uncertainties of extrapolating observed effects in laboratory tests to effects that may occur in the same species in field situations.

The ideal National Water Quality Criteria for a compound or element is the highest concentration of the toxicant which, when placed into a wide variety of unpolluted bodies of water, results in no adverse effects. Field testing represents the ideal method for establishing these concentrations. Since scientists experience technical difficulties in conducting such studies, one of the implied advantages of the current Guidelines is their reliance on better understood laboratory results.

The major distributional feature of the Guidelines stems from the use of the fifth percentile of the distribution of family geometric mean, species geometric mean, or EC50 or LC50 values in setting the criteria. These means are calculated from a data base that provides a range of family mean values by taxonomic and functional groups which EPA assumes represents the range of sensitivities seen in a field situation.

Because no statistical sampling of individuals within species, or of species within families or of families has occurred, the assumption of representativeness is not supported by sampling theory but relies instead upon the scientific judgment of the Guidelines' authors. Since all types of generalization do not require random sampling, this feature of the Guidelines should not be criticized. Because EPA provides no factual basis for the claim of representativeness, however, the use of a distributional approach might be misread as implying that the distribution of EC50's and LC50's was representative on statistical, rather than some other basis.

One reason why EPA cites no field data to establish representative results is the difficulty of relating the fifth percentile of the distribution of the geometric mean EC50's and LC50's to protectiveness in the field. The Guidelines state that the fifth percentile number should not be used to decide, in a field situation, whether the criteria determines protectiveness. This point is discussed further in the next section.

2. Achievement of Protection

One of the important provisions of the Guidelines is the argument, however idealized, that the numeric criteria achieve protection of aquatic life. Based on the ideal criteria proposed in the Guidelines one might conceive of an idealized study, discussed below, to verify protectiveness.

A toxic compound, for which criteria exist, is introduced into a nonpolluted lake. A field study is performed before and after introduction of the compound. Based on the field study, the proportion of individuals affected is calculated for each species, and from these data scientists estimate the LC50's and EC50's. Finally, EPA determines that, as predicted from the laboratory data, 5% of the family geometric mean LC50's and EC50's are less than the criteria. (This assumes that at least 100 families inhabit the lake.)

Should EPA conclude that the criteria protect the lake for its intended uses? The Guidelines, as noted above, state that this inference should not be made. Attainment of the criteria is neither necessary nor sufficient for protection but is believed to be positively associated with protection. The Guidelines explain that this situation occurs because aquatic organisms do not interact in the laboratory but, rather, in the field, and in the latter they are influenced by factors typically absent in the laboratory. Such factors are predator-prey relationships, disease, contamination of food, and extreme environmental conditions like high temperatures and unusual conditions of water flow. In addition, some community functions and species' interactions may be adversely affected at concentrations lower than indicated by standard toxicity tests.

The Guidelines state that attainment of the criteria will probably result in a reasonable level of protection in the field. The protectiveness is an anticipated consequence of setting the criteria such that, in the laboratory data, only a small fraction of families tested would have LC50's or EC50's less than the criteria. The small fraction was set at 5% because using other fractions resulted in criteria that "seemed too high or too low in comparison to the data from which they were calculated." It is apparent that the distributional nature of the criteria is not intended as a consequence of an operational definition of protection appropriate to field situations. It is, rather, a means of quantifying the authors' judgments of what numerical criteria would be associated with protection, based on laboratory data that are judged as representative of the taxonomic and functional groups of aquatic organisms found in the United States.

The only basis for criticizing this method of quantifying the authors' judgment would be that the fifth percentile criterion does not reflect the authors' concepts, in the absence of an effective method, to test not only the fifth percentile criterion but any other criterion that might be proposed.

3. Verification

The Guidelines recognize that field verification of national criteria should be based on an operational definition of protection of aquatic life and its uses that takes into account the practicalities of field monitoring and public concerns. The Guidelines also state that the amount of decrease in the number of taxa and of individuals defined as unacceptable should take into account the features of the body of water and its aquatic community.

The Guidelines do not state how this definition would he developed or utilized in practice. They express the opinion that moderate cost field studies are not sensitive enough to detect unacceptable changes and that only highly reliable, extensive testing could show that the criteria do not allow unacceptable effects. These arguments suggest that, except for extreme cases, the protectiveness of the numerical criteria is unverifiable.

In the absence of methods to effectively verify the criteria, it is difficult to rely on the usual procedure for establishing scientific truths. This procedure invariably involves prediction and rejection (or confirmation) as a means for establishing the factual basis for decision making.

Based on these considerations and on the informal guidance on the use of professional judgment, the Subcommittee infers that the criteria resulting from this guidance are intended to be used pragmatically, not dogmatically. The implications of this statement for the statistical approach are discussed next.

4. Implications for Statistical Analysis

It is often easier to evaluate a pragmatic calculating procedure than one that depends exclusively on theory for its justification. This is because a pragmatic procedure is evaluated by its success at achieving measurable objectives. The present Guidelines are actually predicated on the assumption that, except in extreme cases, cost-effective efforts to establish the criteria's protectiveness will fail. Assuming the truth of this, the validity of the Guidelines has to be assessed primarily on its biological reasonableness as discussed in the previous sections.

A major issue is the use of the distributional approach. As discussed above, this method reflects the Guidelines authors' judgment of what would constitute an effective statistical procedure. As such, it cannot be criticized from the point of view of sampling theory; if not misinterpreted, this use of distributional concepts is acceptable.

A second issue is that of the uniqueness of a criteria for a given pollutant. There are many combinations of acute and chronic species data satisfying the required minimum data base. For each data base there is a possibly different criteria because it is not required that, if more than the minimum data is available, all data must be used. Thus, for a given pollutant, the Guidelines can be thought of as leading to a distribution of the criterion for the pollutant, with one point in the distribution for each combination of data that satisfies the minimum data base. Where sufficient data exist, this distribution should be evaluated. If it happens that the Guidelines lead to distributions of criteria that are not concentrated around a single reasonable value, the cause should be investigated and, if necessry, EPA should alter the Guidelines. A simple approach to this could be based on jack-knifing (Mosteller and Tukey, 1977), which is one way of estimating the sampling error of complex statistics.

In evaluating the distribution of a criteria, EPA should ensure that all sources of variability, such as those associated with acute/chronic ratios, are reflected. Since the basic acute and chronic data represent point estimates, their variability should be reflected in the final distribution.

The Guidelines propose that the ideal criteria should derive from field tests although they argue that obtaining truly informative results is difficult with such tests. Based on this argument, the Subcommittee recommends that as field test methodology becomes more refined, EPA should modify the Guidelines to include such methods and their results. This will help incorporate pragmatic methods of criteria development in terms of measurable environmental outcomes.

A useful step in achieving the integration of the Guidelines' criteria and the ideal criteria would be to use data generated by the Monticello test streams. This would provide a means to validate the criteria in situations that more closely approximate those existing in the field.

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