

CMA EXHIBIT A ADDENDUM

Supplementary Comments
on Water Quality Criteria
(FR, 44:15926-15981, March 15, 1979)

James L. Peterson, Ph.D.
Director
Division of Limnology and Ecology

and

John A. Hendrickson, Jr., Ph.D.
Associate Curator
Division of Limnology and Ecology

Academy of Natural Sciences
Nineteenth and the Parkway
Philadelphia, PA 19103

May 1979

CMA 049425

On the basis of the preamble to the March 15, 1979, FR document (p. 15928, columns 2 and 3), we have high hopes that the Agency will substantially improve the guidelines methodology in terms of adherence to the normal standards of scientific inference. We are aware of a few of the formal comments which have been summarized in Appendix D (FR, 44: 15980-1), and we concur with much of the substance of such comments. These comments address five areas.

1. The following comments on the methodology employed in developing guideline numerical factors are believed to be new. We offer them in the anticipation that they will be taken as constructive criticism, since we hope for a scientific rather than an adjudicatory determination of "scientifically based" water quality criteria.

1. One major issue to be addressed in data for the calculation of guidelines numerical factors is data quality. It seems to us to be reasonable to require that the data used in developing any numerical conversion factors should meet the standards required for all data routinely considered available under the guidelines. It appears to us as though many of the data values that were used in the May 18th document have not been (or will not be) judged available under the guidelines; certainly very few have also been used in the relevant criteria documents.

It appears to us that the data of Table 1 of the May 18th 1978, document warrant stratification at least on the basis of saltwater versus freshwater, as indicated by the occurrence of footnotes pointing out the saltwater values within the table. It would be preferable for the correction factor for measured versus nominal concentrations to be overridden for specific pollutants on the basis of pollutant-specific data on measured concentrations, either for all waters or for waters of particular quality with respect to important determinants of measured concentrations.

The admixtures of data points in all the tables seem to suggest that these have been treated as "numbers" rather than "data" in the sense used by Finney (1975). Certainly there is no discussion of whether the resulting numbers are reasonable in terms of principles of chemistry or toxicology. As one example, let us consider the numbers which result from the averaging processes in Table 2 and Table 6. The geometric means from Table 2 suggest that LC_{50} times log of exposure time might be approximately a constant, while the geometric means in Table 6 would be more nearly approximated by suggesting that LC_{50} times (exposure time)^K might be a constant, where $K \geq 1$. The geometric means are probably so far removed from qualifying as credible data that even this level of inference would be judged unscientific, but perhaps the thought can be gleaned that pollutant-organism pairs could be grouped first

by probable toxic mechanism in order to develop scientifically plausible adjustment factors.

Neither Table 3 nor Table 7 specifically addresses renewal tests, yet these are assigned the same adjustment factors as static tests on the basis of Tables 3 and 7. The data in Table 7 do not seem to support any conversion from flow-through to static in that no observation is anywhere near the geometric mean, and the geometric mean is not appreciably (let alone significantly) different from 1.00. In Table 3, the geometric mean of 0.71 is much lower than the sample median (0.91), which might be an indication that the ratios represent a mixture of numbers which is not well-approximated by a log-normal distribution.

It is difficult to evaluate what would be the results if the "comparable" data entries used in computations in Tables 4, 5, 8 and 9 were to be based on the data available under the guidelines, although it appears that very few of the logarithmic variances sampled from tables in the criteria documents even equal the average variances from those four tables, and most seem to be much smaller.

2. Many surface waters contain "natural background" concentrations of several of the 65 "toxic pollutants". Provision is made in the March 15th preamble (44 FR, 15926-7) for the consideration, in developing a water quality standard for a given water body, of scientific evidence of ecosystem adaptation to "high natural background levels of certain pollutants".

However, these background levels are not addressed in the development of guidelines, and any data based on organisms previously exposed to such levels are excluded by the guidelines methodology. The guidelines methodology does not take into account even the background levels associated with seawater, which are certainly considerable (relative to the proposed criteria) for at least some of the inorganic "pollutants" studied.

The Agency should modify the guidelines methodology to consider natural background levels of appropriate substances among the 65 toxic pollutants, for at least two cases: (a) those cases in which natural background levels are in the no effect range for all studies available under the guidelines prior to adjustment for the guidelines sensitivity and protection factors; (b) those cases in which field studies indicate that natural background levels of certain pollutants are tolerated by locally adapted populations of tested species (or closely related taxa) at levels which may show adverse effects in laboratory populations not previously exposed to the pollutant. It is our hope that the Agency will proceed in a more nearly rational and scientific fashion in this necessary modification of the guidelines.

The preamble (44 FR 15927) refers to current EPA policy on Red Book criteria, with respect to the need for a State to provide "adequate technical justification" before adopting

a water quality standard less stringent than the Red Book number, and it is stated that the Agency may extend this policy to the toxic pollutant criteria once these are final. This policy, if extended to these toxic pollutant criteria, would transfer to an individual State the onus of developing an adequate methodology for establishing criteria in waters with natural background levels; it is certainly not clear that the Agency, with its vastly greater budgetary resources for the employment of staff and contractors, has performed even the conceptually simpler task of developing an adequate technical justification for the guidelines methodology. It seems to us inadvisable to extend the current Red Book policy to any of the 65 toxic pollutants without an advance development by the agency of an adequate methodology for the States to use in providing "adequate technical justification" for a standard less stringent than a section 304(a) criteria value.

3. The determination of the relationship of toxicity to other water quality variables is presented in the guidelines with undue restrictions on the mathematical forms to be considered (only linear regression of natural logarithm of toxicity on natural logarithm of the chosen water quality characteristics), and with an exhortation to unscientific extrapolation in the absence of confirmatory data. The application of the guidelines methodology to specific instances (beryllium, cadmium and lead) provides examples of the abuse of extrapolation and the failure to consider the full set of available data.

Section VII does not distinguish between not finding a meaningful relationship for one of the four kinds of toxicity data, as one case, and finding that there is no meaningful relationship for one of the four kinds of data as another case. Thus, a slope with a best estimate of zero (no meaningful relationship) is treated as if there is no information on the relationship for data of that kind and thus, under VII. D, a positive slope from data of another kind is imputed even to data which support the null hypothesis of no meaningful relationship.

The guidelines not only encourage extrapolation from data of one kind to data of another kind, but also across the full range of pollutant concentrations, even though the allegedly meaningful slopes are usually from studies at very high concentrations of the pollutants. This extrapolation across the concentration ranges for a pollutant ignores basic information on thermodynamic chemistry, namely that concentration is one of the determinants of a chemical equilibrium.

It is also plausible that different functional forms could apply to relationships between certain pollutants and such water quality variables as salinity; an asymptotic relationship in particular emerges as a likely candidate for an alternative functional form.

The methods for estimating a meaningful relationship in VII. B. and D. are no better than the methods used in developing the guidelines adjustment factors, and as methods they

are probably less defensible on scientific grounds because they blatantly invoke extrapolation.

Section VII. D. should be stricken, and an appropriate change made in Section VII. C. to employ the methods of sections VIII. through XI, as appropriate, to estimate those final values for which meaningful non-zero slopes are not available.

4. The alternative procedures in Appendix B-1 (44 FR 15974) are of two kinds. The first is simply a statement that, when convenient to the Agency, scientific peer review will be bypassed in order to expedite criteria formulation. The other three methods are unsupported extrapolations in order to expedite criteria formulation by suggesting that the answer is known before the question is even asked. All those alternative procedures should be stricken.

All four of these procedures have apparently been used, with three of them leading to the completion of freshwater (or saltwater) criteria formulation on the basis of the criteria formulation process in the other water. For only eleven of the pollutants considered in the March 15th publication do we have both freshwater and saltwater criteria formulation completed, and some of these eleven have at least one criteria pair subject to challenge in comments now being submitted. Therefore, it certainly does not appear to be the case that there are enough pollutants with both freshwater and saltwater criteria values from the guidelines alone to begin to evaluate

the frequency with which alternates 2, 3 or 4 would yield similar criteria formulations to what occurs under the guidelines.

5. We are in general agreement with the guidelines methods used to select data (Section II). We believe that reasonable flexibility should be used in determining whether data are sufficiently questionable to warrant being discarded.

It is not clear to us as to what the relative scientific merits would be in comparing the use of questionable data (as described in II.E) with the use of extrapolation in the absence of data, for those instances in which a comparison might be available. If such instances do arise in which the choice would be meaningful in criterion formulation, it would seem prudent for the agency to defer criterion formulation until fully acceptable data can replace the questionable data, rather than to use extrapolation.

Additional Reference

Finney, D.J. 1975. Numbers and data. Biometrics, 31:575-586.