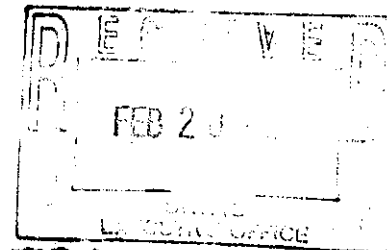




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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IX

**75 Hawthorne Street
San Francisco, CA 94105-3901**



FEB 18 2004

**Mr. Arthur Baggett
Chairman
State Water Resources Control Board
P.O. Box 100
Sacramento, CA 94912-0100**

Dear Mr. Baggett:

Thank you for the opportunity to review California's draft Water Quality Control Policy for developing the State's Clean Water Act Section 303(d) list. Because EPA is responsible for acting upon the State's Section 303(d) listing decisions that will be based on the assessment methodology contained in the Policy, we carefully evaluated the draft policy to determine whether it is consistent with applicable water quality standards, the Clean Water Act and associated federal regulatory requirements. EPA does not take formal action on the assessment methodology itself.

EPA is concerned that many provisions of the draft policy appear to conflict with applicable water quality standards and federal listing requirements. This letter summarizes these concerns; an enclosure provides more detailed comments and recommendations. We urge the State Board to make substantial revisions to the policy to ensure that it is fully consistent with water quality standards and Section 303(d) listing requirements.

Although the policy needs to be revised, we believe the draft policy represents a step in the right direction. We recognize that the State Board has devoted substantial effort in developing the draft listing policy and we understand that it is difficult to define policies that account for the full range of water quality assessment challenges that face California. We support the State's objectives to improve the quality of data supporting listing decisions, the clarity of assessment criteria, and the consistency with which assessment criteria are applied. We appreciate that the policy provides for the evaluation of all data and information types and the application of all numeric and narrative water quality standards in the assessment process. We also appreciate your staff's effort to solicit input from EPA during the initial phases of policy development.

It is difficult to identify elements of the proposed policy that would result in listing decisions that are inconsistent with applicable water quality standards and federal listing requirements for two reasons. First, it is unclear how many policy elements will actually be interpreted and applied by State and Regional Board staff because they are not explained clearly in the draft policy. The policy is inconsistent in its description of

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assessment methods as requirements or as discretionary guidelines. Second, the policy authorizes but does not require the State to consider listing waters under Section 303(d) that do not meet the explicit listing criteria through the subsequent application of professional judgment and “weight of evidence” analysis. It is unclear whether and how the State will actually apply these additional provisions. When the State develops its 2004 Section 303(d) list based on the adopted policy, EPA will carefully scrutinize the proposed listing decisions and associated assessment rationales. If the actual listing decisions are consistent with applicable water quality standards and federal listing requirements, the list will be approvable.

Inconsistencies With Federal Requirements

Based on our review of the policy, these provisions appear to be inconsistent with federal requirements:

- The policy includes provisions for excluding from consideration data and information that do not meet all of the State’s preferred tests of data quality and representativeness. These provisions appear to conflict with 40 CFR 130.7(b), which requires the state to gather and consider all existing and readily available data and information in the listing process. This requirement creates a strong presumption that data and information will be used in the assessment process unless it is completely unreliable. The data limitations and preconditions also seem substantially more stringent than the principles governing evidence admissibility and opportunity for public participation typically used in California administrative proceedings. The proposed policy and supporting documentation do not contain sufficient rationale for a decision to exclude available data and information from consideration, as required by 40 CFR 130.7(b)(6). Data and information are often useful within a “weight-of-evidence” assessment context even if they do not meet every quality assurance expectation.
- The proposed procedures for assessing exceedances of numeric water quality standards for many pollutants conflict with existing water quality standards provisions. Most procedures rely on a 10% allowable exceedance rate applied through a nonparametric binomial statistical test for most pollutant types and therefore appear to be much less stringent than existing state water quality standards, in conflict with federal listing requirements. For example, the proposed assessment procedure for toxic pollutants neglects the explicit recurrence intervals defined in the California Toxics Rule, which states that acute or chronic standards are not to be exceeded more than once in every three consecutive year period (see 40 CFR 131.38 (c)(2)(iii)).
- The policy does not describe clear provisions for identifying and listing threatened waters. Federal regulations at 40 CFR 130.7(b) and 130.2(j) require the identification of waters which do not or are not expected to meet applicable water quality standards. As described in EPA’s national listing guidance (EPA, 1997a and EPA, 2003), States are expected to assess potentially threatened waters and to

list waters which are expected to exceed applicable standards during the following 2-year period. The policy mentions but does not require the assessment of water quality trends that could identify threatened waters; moreover, it is not clear that the policy provides for evaluation of dilution calculations or modeling results to support potential listing determinations as required by federal regulations (see 40 CFR 130.7(b)(5)(ii)).

- The policy contains provisions that would exclude from listing waters impaired due to pollutant discharges from naturally occurring sources and these provisions conflict with applicable state water quality standards, which do not contain such an exemption. Moreover, the policy would appear to exclude from listing impaired waters that receive pollutant discharges from anthropogenic sources if naturally occurring sources alone were sufficient to cause water quality standards exceedances, a provision that also conflicts with state water quality standards. The draft listing policy conflicts with the State's draft S.B. 469 TMDL Guidance document, which correctly observes that water quality standards would need to be revised in order to avoid listing or developing TMDLs for waters whose natural background pollutant levels exceed water quality standards (SWRCB, 2003, section 6). Finally, the provision that encourages application of a reference watershed approach to assessment of bacteria standards exceedances is inconsistent with state water quality standards except in Region 4, the only Region in which a reference watershed approach to bacteria standards implementation has been adopted as a component of its water quality standards. The state would need to adopt and receive EPA approval of water quality standards changes pursuant to Section 303(c) in order to apply natural source exclusions or the reference watershed approach to implementing bacteria standards as part of the Section 303(d) listing methodology.
- For toxicity assessments, it is uncertain if the policy would require listing a water body with evidence of toxicity but the pollutant is unknown. Recent EPA listing guidance clarifies states must list impaired or threatened waters based on biological assessments, or toxicity testing that demonstrate violations of narrative or numeric criteria adopted to protect designated uses even if the specific pollutant is not known (see EPA, 2003.)
- The policy provides that impaired waters need not be listed if other enforceable programs are available to address the impairment causes. This provision is generally consistent with the requirements of 40 CFR 130.7(b). However, in order for this provision to apply, the policy states that the discharge source subject to the enforceable program need only comprise the majority of the pollutant load causing the impairment. This provision is potentially inconsistent with federal regulations because minority sources not covered by the enforceable program may be sufficient to cause water quality standards violations even if the majority source is controlled. This part of the enforceable programs provision should be revised to require that enforceable programs that address impairments sources must be sufficient to result

in full attainment of water quality standards, taking into account all pollutant sources in addition to the regulated source(s).

Other Key Concerns About the Draft Listing Policy

Several other listing provisions either appear to conflict with federal listing requirements, are too vague to enable us to adequately evaluate their consistency with federal requirements, or have not been supported by adequate technical rationales. EPA is concerned about the following aspects of the policy, most of which are also discussed in greater detail in the enclosure to this letter:

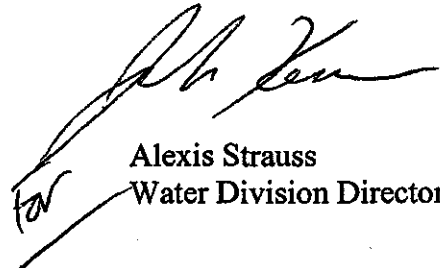
- The policy does not require verification that data sets are suitable for analysis through the proposed binomial statistics method. Unless evaluated data exhibit particular characteristics (e.g. normal distribution, sample independence, absence of systematic biases) it may be invalid to draw valid statistical inferences based on binomial statistical tests (see Lin, *et al.*, 2000). With the exception of monitoring programs based on random sample designs, most monitoring programs in California are not designed to collect data that exhibit these characteristics.
- The policy is unclear as to whether and how alternative data evaluation and weight of evidence analysis procedures will be applied in the assessment process. The policy should include a firm commitment to apply a weight of evidence approach that would provide for listing of waters in cases where multiple lines of evidence combine to demonstrate water quality standards exceedances even if a single line of evidence provides insufficient evidence of exceedances. The policy should explain more clearly the procedures to be followed to conduct weight of evidence analysis. As proposed, the policy takes too narrow a view of weight of evidence analysis and thereby creates the potential that standards exceedances and associated listings will be missed in the assessment process.
- The policy is unclear about how priority ranking and scheduling decisions will be made. Moreover, scheduling provisions should be modified to be consistent with EPA's national policy that TMDLs are to be completed within approximately 8-13 years of the date of initial listing or 1998, whichever is later (see EPA, 1997b).

Conclusion

EPA expressed these concerns in comments to State Board staff dated June 2003 on the previous draft of the proposed policy. We are concerned that most of the inconsistencies with federal listing requirement identified in our previous comments remain in the December 2003 draft policy. Unless the policy is modified to address our remaining concerns, it appears likely that the State will develop Section 303(d) listing decisions that do not comply with federal listing requirements. EPA would be compelled to disapprove any listing decision that conflicts with these requirements. EPA partially

disapproved and added waters and pollutants to the California Section 303(d) lists submitted in 1992, 1996, 1998, and 2003—an outcome we want to avoid in future listing decisions. We would greatly prefer to work with the State Board and your staff to identify policy modifications that comply with state water quality standards and federal listing requirements. We do appreciate your efforts to develop this policy and look forward to working with you in the coming months to help strengthen the policy. If you have questions concerning these comments, please call me at (415) 972-3752 or David Smith at (415) 972-3416.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alexis Strauss".

Feb. 18, 2004

Alexis Strauss
Water Division Director

Enclosure

Enclosure: Specific Concerns About California's Proposed Section 303(d) Listing Policy

Data Quality, Quantity and Representativeness

The draft listing policy proposes to use minimum sample sizes for assessing certain pollutants (e.g., $n > 20$ for water samples and $n > 10$ for tissue or sediment samples). EPA's recent listing guidance states "EPA does not recommend the use of rigid, across the board, minimum sample size requirements in the assessment process. Small sample sets often provide sufficient information to support decisions to list waters because the frequency and/or magnitude of observed excursions and digressions are high enough to support a reliable impairment determination." (EPA 2003, pp. 25-26). The policy appears to allow assessments of smaller data sets on case-by-case basis, but the policy should more clearly require assessment of data sets with fewer than the suggested "minimum" sample sizes.

The policy also requires only "high quality" data to be considered for listing impaired waters; i.e., monitoring data associated with a Quality Assurance Project Plan or equivalent. Other data will be considered only in combination with "high quality data"; however other data cannot be used by itself. EPA agrees that "high quality" data should be accorded the greatest weight to support listing and de-listing decisions. However, all data and information must be considered (see EPA, 1997a and EPA, 2003). We encourage the State to define the basic QA/QC components that correspond to the "equivalent" of a QAPP. For example, if a monitoring group were to provide documentation of study objectives, rationale for selection of sampling sites, sampling frequency, field techniques, analytical methods, and personnel training, then we see no legal rationale to exclude the analytical results and monitoring data from the assessment.

The policy lists major monitoring programs in California considered to be of high quality. We recommend the State include all EPA monitoring data (not just EMAP) as well as other agencies that operate high quality sampling programs (e.g., US Fish and Wildlife Service, US Department of Agriculture, US Army Corps of Engineers, and National Oceanic and Atmospheric Administration).

The policy's minimum sample size and high quality data provisions and supporting rationale do not provide a "good cause" rationale for excluding data and information from consideration (see 40 CFR 130.7(b)). These regulatory provisions create a rebuttable presumption that all readily available data and information will be used in the assessment process. A great deal of useful data from STORET, academic and agency reports, and volunteer monitoring groups would appear to be excluded from consideration under the proposed rule, an outcome which appears inconsistent with the federal requirements.

Moreover, these requirements appear to be more stringent than the principles governing the admissibility of evidence and opportunities for public participation typically used in California administrative proceedings. See, e.g., *Gaytan v. Workers' Compensation Appeals Board*, 134 Cal.Rptr.2d 516, 529-530 (2003) (discussing party's opportunity to present evidence and have it considered); *McBail & Co. v. Solano County*

Local Agency Formation Comm., 72 Cal .Rptr.2d 923, 926-28 (1998) (discussing agencies' obligation to adequately consider "all relevant factors", and disapproving agency's effort to require a party to make a factual showing beyond that required by statute); *Mohilef v. Janovici*, 58 Cal.Rptr.2d 721, 736 (1996) ("it is well established that a 'presentation to an administrative agency may properly include evidence that would not be admissible in a court of law'"); *Desmond v. County of Contra Costa*, 25 Cal.Rptr. 840, 846-847 (1993) (approving use of non-expert opinion testimony in agency proceeding); *County of San Diego v. Assessment Appeal Board*, 195 Cal.Rptr. 895, 900-901 (1983) (setting aside Board's decision because "it chose to disregard competent evidence"; *Calif. Hotel and Motel Assn.*, 157 Cal.Rptr. 840 (1979) (discussing public participation objectives of California's Administrative Procedures Act); see also *California Optometric Assn.* 131 Cal.Rptr. 744 (1976) and *Carmel Valley View, Ltd.*, 130 Cal.Rptr. 249 (1976).

We are also concerned that the proposed policy appears to set a higher burden of proof than typically used in California's administrative proceedings. We understand that "preponderance of the evidence" is the burden of proof typically used in the State's administrative proceedings. See, e.g., *Mann v. Dept. of Motor Vehicles*, 90 Cal.Rptr. 2d 277, 282-283 (1999) ("Evidence Code section 115 provides in part that '[e]xcept as otherwise provided by law, the burden of proof requires proof by a preponderance of the evidence', rejecting argument that department "had the burden of producing 'clear and convincing [proof] to a reasonable certainty' in administrative proceeding); *San Benito Foods v. Veneman*, 58 Cal.Rptr.2d 571 (1996) (rejecting argument that agency's hearing officer was required to apply a "clear and convincing evidence" standard of proof in administrative proceeding); *In the Matter of Permits 19259 and 19260*, State Water Resources Control Board, 1987 WL 54550 (1987) ("Permittee asserts that the standard of proof in this case should be that of clear and convincing proof to a reasonable certainty." "Generally, the proper standard of proof in cases where no fundamental vested right is involved is the preponderance of the evidence standard....We conclude that changes in water right permits likewise are subject to the preponderance standard and substantial evidence review."); *Rosas v. Workers' Compensation Appeals Board*, 20 Cal.Rptr.2d 778, 783-87 (1993) (the burden of proof in a workers' compensation proceeding "manifestly does not require the applicant to prove causation by scientific certainty"); and *Western Oil and Gas Assoc. V. Air Resources Board*, 208 Cal.Rptr. 850, 858 (1984) ("The Board therefore should not be required to wait until substantial adverse effects are scientifically verified before adopting appropriate standards.")

In section 6.2.5, the draft policy states "information that is descriptive, estimated, modeled or projected may be used as ancillary lines of evidence for listing or de-listing decisions." We request the State modify this to remove the notion that such information will be treated only as supplementary information for assessment decisions. We find it inconsistent with federal guidance that water quality modeling results by themselves are sufficient means of assessing water quality conditions. Federal regulations require the consideration of information from dilution calculations or predictive models in the assessment process (40 CFR 130.7(b)(5)(ii)).

Statistical Methods

As discussed in our letter, it is important that data sets exhibit certain characteristics in order to validly apply statistical analysis procedures such as nonparametric binomial methods to describe potential sources of analytical error. In order for these statistical tests to yield reliable results, evaluated data should be independent, normally distributed, and without bias (e.g., serial correlation or autocorrelation). The policy should be modified to provide for the verification that available data sets exhibit these characteristics prior to applying the binomial approach. We expect that the State will document its analysis which shows these assumptions are met to a reasonable degree. Not all data sets must meet every assumption completely, but the State should discuss potential errors associated with application of binomial analysis methods to data sets that do not meet one or more key assumptions. We want to stress that the data should be assessed through another assessment method if the assumptions necessary to carry out a binomial assessment are not met.

The listing policy relies heavily on the binomial approach, its limitations, or the policy choices reflected in its design with respect to management of type 1 and type 2 decision error. Instead the policy uses footnotes to provide some background information and relies on the notion that other states have already adopted the binomial parameters and therefore they are acceptable. For example, the policy discusses the null hypothesis yet it does not clearly define the state's definition of the null hypothesis for listing waters (which is buried in the FED). This is especially critical for the de-listing section of the policy. Moreover, the proposed approach to applying binomial statistics infers a policy choice by the state to minimize type 1 error (the likelihood of incorrectly assessing a water as impaired) at the cost of maximizing type 2 error (the likelihood of incorrectly concluding that an impaired water is attaining standards). EPA guidance and professional literature recommend that type 1 and type 2 error rates should be balanced if there is no clear agreement that one form of error is more important than the other, as a policy matter, in that state (see EPA, 2001, EPA 2003, and Smith, *et al.*, 2001).

For many pollutant types (toxics, conventional, bacteria, tissues, etc), the policy proposes the State will list waters in cases where there was greater than 90% statistical confidence that a numeric standard has been exceeded at least 10% of the time (i.e., the binomial approach). The policy refers to EPA guidance to defend its decision criteria, most specifically a 10% allowable exceedance level, and yet this is based on an incorrect reading of EPA guidance concerning allowable water quality exceedance rates. The assertion that EPA endorses the use of a 10% standards exceedance rate is incorrect. The EPA 305(b) guidance (EPA, 1997a, as clarified in EPA, 2003) refers to the 10% exceedance rate as a method for assessing data sample sets-- not as an acceptable exceedance rate in the "population". The use of this exceedance rate in a binomial assessment method has not been shown to be protective of water quality nor consistent with water quality standards requirements. With a few exceptions, California water quality standards do not authorize a 10% exceedance frequency as proposed in this policy. It is likely that use of this exceedance rate would increase the number of water bodies that do not meet water quality standards that are missed in the listing assessments. The 10%

binomial analysis approach must be changed in order for the policy to be consistent with state water quality standards and federal listing requirements.

The proposed policy applies the binomial approach to certain sized data sets, and then for smaller data sets it defines arbitrary required exceedance frequencies in order to support listing determinations. For example, some water parameters are evaluated via the binomial approach for $n > 20$ and refers to Table 4.2 for the maximum allowable number of exceedances. For smaller sample sets, $n < 20$, only if 5 or more exceedances have been observed will the water body be deemed impaired. The policy and supporting documentation do not demonstrate that this approach is consistent with State water quality standards or technically defensible.

Toxic Pollutants

The proposed binomial approach as applied to toxic pollutants in water does not meet federal requirements for assessing water bodies designated with the aquatic life beneficial use. EPA's guidance for the 2004 cycle states, "Use of the 10% rule when performing attainment determinations regarding effects of toxics is not appropriate unless the State's WQS regulations specifically authorizes use of this rule for such pollutants" (EPA 2003, pg. 30). The State needs to modify this approach to be consistent with the allowable exceedance frequency explicitly stated in California Toxics Rule (which includes most of the toxic pollutant standards in effect in California) and which served as the analytical basis for most other toxic pollutant objectives in the Basin Plans. The California Toxics Rule (EPA, 2000a) states that numeric standards designated for aquatic life uses are not to be exceeded more than once every three years, regardless of sample size. In order to ensure consistency with this provision, the listing policy should be modified to provide for listing in cases where 2 or more independent samples exceed the acute or chronic water quality standards in any 3 consecutive year period. An allowable 1 in 3 year exceedance rate would correspond to approximately 0.1% of the days in any 3-year period. If the State wants to apply a binomial assessment method to identify toxic pollutant impairments, then a 0.1% allowable exceedance rate would be consistent with the requirements of the California Toxics Rule.

Conventional Pollutants

For conventional pollutants, the proposed policy cites EPA's 305(b) guidance as part of its rationale for using an allowable 10% water quality standards exceedance rate as part of its binomial assessment methodology. The policy misinterprets this EPA guidance. EPA's 1997 guidance recommends methods for evaluating relatively small-sized sample sets to assess compliance with the applicable water quality standards, which specify allowable exceedance rates in the entire water body. The guidance does not directly identify allowable water quality standards exceedance rates. Excursion rates used to evaluate small sample sets are not directly comparable to allowable water quality standards exceedance frequencies in the underlying "population". Most of California's water quality standards for conventional pollutants do not authorize 10% exceedance frequencies.

Because the binomial approach already accounts for and directly manages uncertainty associated with assessments based on small sample sizes, including type 1 error in particular, it would be inappropriate to apply the 10% exceedance rate directly within the context of a binomial assessment approach unless the underlying water quality standards authorize a 10% exceedance frequency.

In order for California to apply a 10% exceedance frequency within a binomial analysis framework, the State would need to document that the applicable water quality standards for each pollutant authorize a 10% exceedance rate. Some Regional Basin Plans include water quality objectives that provide for 10% (or other specified percentage) exceedance frequencies. It would be appropriate to apply the proposed 10% (or other specified percentage) exceedance frequency within a binomial analysis framework in these cases. However, most Basin Plan objectives for conventional pollutants are expressed as values not to be exceeded. The 10% binomial approach is much less stringent than these objectives provide in these cases. In cases in which the Basin Plans are silent with respect to allowable exceedance frequencies, the State would need to provide a stronger rationale for its selected method. As discussed above, it is inappropriate to cite EPA guidance as a rationale for the proposed 10% exceedance frequency. Nor is it appropriate to cite other state methodologies as a basis for the proposed approach because other state water quality standards often are expressed in terms that authorize use of an underlying 10% exceedance rate for particular conventional pollutants.

Some California standards (e.g., for bacterial indicators) are expressed both in terms of 10% exceedance frequencies and as instantaneous maximum values not to be exceeded. It is invalid to ignore the "not be exceeded" element of the standards in the assessment process, and the State should revise the policy to explain how these two-part standards will be assessed.

"Nuisance" Pollutants

The policy should be modified to clarify that many of the pollutants characterized as "nuisances" may pose serious threats to aquatic habitat, recreation, fishing, and other important beneficial uses. The proposed assessment criteria for the impairment types covered in this section lack sufficient detail to guide consistent application of assessment methods. As discussed in the preceding section, the policy would need to provide a more persuasive rationale to support application of the 10% binomial approach to assessment of these pollutants. Many of the Basin Plans contain water quality objectives that do not appear to authorize such high exceedance frequencies.

Bacteria

The policy provisions for assessing bacterial standards exceedances should be revised because the proposed criteria appear to conflict with the State's current two-number water quality standards or objectives which have both an instantaneous maximum as well as specific data requirements and 30-day evaluation periods. The 10% binomial aspect would potentially be consistent with the numeric standard using the 30-day

geometric mean averaging period. The policy should more clearly explain how 30-day geometric mean objectives are to be interpreted. Several potential interpretations are possible:

- monthly geometric means for each month would be calculated then compared with this component of the objective through the binomial method,
- rolling 30-day geometric means would be calculated and applied through the binomial method,
- the geometric mean of all samples would be calculated and compared directly to the numeric objective.

The policy should more clearly explain how data would be evaluated in cases in which fewer than 4-5 samples are available in any particular month. We are concerned that exclusion of data from further consideration simply because the minimum monthly sample sizes are not available could result in incorrect conclusions that the objectives are attained. We recommend the data should be evaluated through a weight of evidence approach that considers the frequency, duration, and magnitude of bacterial standards excursions along with information about potential bacteria discharge sources.

Bioaccumulative Toxins

The policy should provide a more robust rationale supporting the proposed use of the 10% binomial approach for assessment of bioaccumulative toxins. We are concerned that the proposed approach is probably not sufficient protective of aquatic life uses and appears to be inconsistent with the language in Basin Plan narrative objectives applicable to bioaccumulative pollutants. The minimum data size (n=10) should be lowered since this sample media is most likely to represent water quality conditions over long term. Fewer fish tissue measurements are required to make a more accurate analysis, especially if composite results are provided. In essence, an assessment based on as few as 3 composite fish sample results can be completed with sufficient confidence and it is probably more accurate than assessments made using 10 individual samples. (Composites generally consist of 3 or more individuals of the same species, where the smallest is 75% in length of the largest.) We encourage the State to include more explicit language about interpretation of individual versus composite results, and to include guidelines on evaluating magnitude of tissue results. We concur that tissue results from muscle or whole body should be used in the assessment and that kidney or liver tissue alone are not suitable measures. Finally, the State should rectify Table 3 and use the most appropriate screening value for arsenic in fish tissue—1.2 mg/kg ww for inorganic arsenic (see EPA 2000b, pg. 5-11 and discussion in Newport Bay Toxic Pollutant TMDLs pp. 69-70).

Toxicity

The toxicity section of the policy is also inconsistent with existing Basin Plan standards. Each Basin Plan has standards that address toxicity by authorizing, in essence, “no toxics in toxic amounts”. The policy should be revised to incorporate more protective assessment criteria for evaluating toxicity data that are consistent with Basin Plan

requirements. The proposed toxicity evaluation method also needs to be revised to better account for the complexities of assessing the presence and magnitude of acute and chronic toxicity in multiple species tests. We will provide additional technical recommendations for improving the toxicity assessment methodology in the next week.

Alternate Data Evaluations

The listing policy includes provisions for listing waters based on alternate data evaluation and we support this general concept of multiple lines of evidence to determine impairment. However, the proposed policy is too vague both in terms of the scope of data and information to be considered and the specific methods to be applied to consider multiple lines of evidence. These provisions should more clearly apply to all data types including sediment, tissue, toxicity, and biological response data. The policy should more clearly explain how alternate data sources would be evaluated. We are concerned that the draft policy currently states "the measurements can be analyzed using a scientifically defensible procedure that provides an equivalent level of confidence as the listing factors in section 3.1." This seems to require any and all data must have 90% confidence level to be used in assessing impaired waters, which may be inconsistent with the concept of a weight of evidence approach. Also, it is unclear if sample magnitude can be sufficiently influential to cause listing the water body based on sediment and/or tissue results.

The State should consider adopting weight of evidence approaches that more clearly explain how different lines of evidence will be evaluated in conducting individual assessments. There are available analytical options between the purely qualitative method proposed in the policy and the option of reducing all lines of evidence to a single quantitative measure, as discussed in the FED. For example, EPA developed and applied a semi-quantitative method of evaluating water column, sediment, and fish tissue data for toxic pollutants in the process of developing several TMDLs for Newport Bay, CA. We recommend that the State consider the use of this type of approach as part of the listing policy.

Natural Source Exemptions

The proposed policy states that water body impairment due to natural sources will be exempt from inclusion on the 303(d) list. In order for waters impaired due to natural sources to be excluded, the adopted water quality standards must clearly contain such exclusions. Our review of the Basin Plans found no such exclusions. The State's draft TMDL guidance properly notes that standards would need to be changed in order to avoid listing waters impaired by natural sources, and approach that was taken by the Lahontan RWQCB. If appropriate, the State may consider adoption of a natural sources exclusion and submit it for EPA approval pursuant to Section 303(c). However, until the standards are modified, this provision should be deleted from the policy. Impaired waters should be listed and may appropriately be assigned a lower priority ranking in order to reflect the State's preference for revising the applicable water quality standards, which may obviate the need to develop TMDLs for these waters.

We are also concerned that the policy provides that waters influenced by anthropogenic sources needed not be listed if natural sources by themselves would be sufficient to cause water quality standards violations. This provision must also be deleted, and would not be approvable if adopted as part of a water quality standards change pursuant to Section 303 (c). The same issue arose in the State of Arizona's development of a Section 303(d) assessment methodology, and following discussion of the issue with EPA, the State decided not to apply this provision because they agreed that it is inconsistent with Arizona's water quality standards, that do contain a natural sources exclusion.

The policy proposes the application of a reference watershed approach to assessing bacterial standards exceedances, similar to the approach adopted for Santa Monica Bay. We note that in the case of Santa Monica Bay, the State properly adopted the reference watershed approach as a water quality standards modification; this was subsequently approved by EPA pursuant to Section 303(c). These provisions should also be deleted until the State decides to adopt reference watershed approaches to bacterial standards implementation.

Listing of Threatened Waters

The proposed policy provides no clear provisions for assessing and listing threatened waters. Pursuant to the requirements of 40 CFR 130.7, as interpreted in our 1997 and 2003 guidance documents, EPA expects each state to describe how it will assess whether waters which currently attain standards will likely fall out of attainment during the next listing cycle. The proposed policy makes reference to the use of certain types of data for trend analysis purposes, but does not actually describe how or if such data analysis will lead to listings of threatened waters. We expect the listing policy to clearly show how the requirement to list threatened waters was addressed. We are concerned by the proposed requirement that evidence of current beneficial use impairment be available to support a threatened waters designation because that requirement appears to conflict with federal regulations. This provision requiring evidence of current effects to support threatened waters designations should be deleted.

De-listing Provisions

For de-listing waters from the 303(d) list, the proposed policy appears to utilize the same statistical approach and underlying assumptions (fewer than 10% exceedances with 90% confidence level) as described in the listing methodology. We support the State's decision to apply a different null hypothesis in assessing potential delisting decisions (see Lin, *et al.*, 2000). The same concerns expressed above about the proper use of binomial statistical methods, issues of data characteristics, and proper interpretation of water quality standards also apply to the use of the proposed process for delisting waters.

Scheduling Considerations

The draft policy briefly discusses the State's proposed process for prioritizing and scheduling TMDLs. We concur with the policy that high priority TMDLs will be

developed within two years; however the description of medium priority and low priority designations and associated schedule implications should be clarified. EPA's 1997 policy indicates that states are expected to schedule TMDLs for completion within approximately 8-13 years of their initial listing dates, or the 1998 listing date, whichever is later (EPA, 1997b).

The State should describe more clearly the process for making individual priority ranking decisions. Some of the more pertinent factors might be: degree of threat to human health, aquatic life or wildlife, timeframe for NPDES permit revisions, unique water bodies, presence of threatened and endangered species, significant public interest and support of TMDL, important recreation and economic significance of water body, number of water quality standards exceedances per water body or number of unmet designated beneficial uses. We recommend that the State Board review Arizona's priority ranking process as an example of a much clearer and rigorous priority ranking and scheduling methodology. Upon request we would be happy to discuss other more rigorous priority ranking methods.

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- USEPA 1997a. *Guidance for Preparation of the Comprehensive State Water Quality Assessments (305(b) Reports and Electronic Updates)* EPA 841-B-97-002A. U.S. Environmental Protection Agency, Office of Water, Washington DC.
- USEPA 1997b. *New Policies for Establishing and Implementing Total Maximum Daily Loads (TMDLs)* – Policy Memorandum from Robert Perciasepe, August 8, 1997, U.S. Environmental Protection Agency, Office of Water, Washington DC.

EPA Region 9 comments on Calif. SWRCB listing policy—technical comments regarding toxicity assessment methods.

1. Tables 5 and 6 must be updated with these following methods to be consistent with CFR Part 136.
 - 4th edition freshwater short-term test methods (USEPA 2002a)
 - 5th edition freshwater and marine acute test methods (USEPA 2002b)
 - 3rd edition marine and estuarine short-term test methods (USEPA 2002c)
2. Under the discussion of toxicity test methods, the text needs to be clarified that the ambient water tests are compared to either standard control waters or uncontaminated receiving water as specified in the testing manuals whereas the sediment tests are compared to a reference condition.
3. Reword the sentence on page 103, “Currently no single toxicity test can adequately characterize the toxicity pollutants may cause in water or sediment. Change to testing with multiple test species of fish, invertebrates and plant species is important as no one test species is most sensitive to all toxicants all the time (see page 59 of the TSD).
4. Reword the sentence on page 103, “Currently no single toxicity test can adequately characterize the toxicity pollutants may cause in water or sediment. Change to testing with multiple test species of fish, invertebrates and plant species is important as no one test species is most sensitive to all toxicants all the time (see page 59 of the TSD).
5. Under the discussion of assessing significant toxicity, the 2nd paragraph is an approach for the sediment testing scenario. However, for ambient toxicity (see USEPA 2000 section 6.4), should recommend a percent MSD (PMSD) to minimize within-test variability (Denton et al., 2003). As stated on page 108, “The MSD considers lab variation only and is specific to each toxicity test protocol.” The MSD provides an indication of within-test variability and smaller values of MSD are associated with increased power to detect a toxic effect (Denton et al., 2003). The minimum significant difference (MSD) represents the smallest difference between the control mean and a treatment mean that leads to the statistical rejection of the null hypothesis (i.e., no toxicity) at each concentration of the toxicity test dilution series.
6. On page 109, it cites Denton and Narvaez 1996, as finding that toxicity measurements should be obtained quarterly, for three years, to provide a good basis of health of the system, this sentence is taken out of context and needs to be clarified.
7. The section on persistence of toxicity (page 108-109) needs to be rewritten to be accurate. Persistence of toxicity is typically examining whether a sample is persistent on the day of collection (baseline toxicity) compared to the sample being re-tested days later after being stored. What is needed is assessing the magnitude and frequency of toxicity. We disagree a higher false acceptance (alpha error) is not acceptable and appropriate for toxicity. The alpha error must be set at the specified

level as discussed in the toxicity testing manuals of alpha error rate of 0.05. If any, regulators should be concerned with the beta error, that is not detecting toxicity when toxicity is present (USEPA 2000).

REFERENCES

Denton DL, Fox JF, Fulk FA. 2003. Enhancing toxicity test performance by using a statistical criterion. *Environ Toxicol Chem* 22(10)2323-2328.

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U.S. Environmental Protection Agency. 2002c. Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms. 3rd Edition. EPA/821-R-02-014. Office of Water.