California Environmental Protection Agency (Cal/EPA)
External Scientific Peer Review Guidelines

Gerald W. Bowes, Ph.D.

November 2006

Background

In 1997, the Governor signed into law Senate Bill 1320 (Sher 1997). The language is now incorporated into Health and Safety Code Section 57004. The statute requires the six Cal/EPA organizations* to submit for external scientific peer review all proposed rules that have a scientific basis or components.

The guidance described herein was developed to implement the statute requirement for the California State Water Resources Control Board and nine Regional Water Quality Control Boards. This original Water Board focus in no way limits its use by all Cal/EPA organizations, for which it is now intended. In future updates, references and examples relating to media topics beyond water quality will be included if considered useful.

These guidelines also shall apply to all subjects chosen for external peer review, whether or not they are subject to the statute requirement, as described below. Reviewer candidates for all reviews must meet the same no conflict of interest provisions.

The Statute Requirement for External Scientific Peer Review

The language from Health and Safety Code Section 57004 that relates to external scientific peer review is provided here as Attachment A. It defines the essence of our challenge, and describes the responsibilities of both the organization requesting the review, and the reviewers. As noted, the requirement refers to all proposed rules that have a "scientific basis" or "scientific portions," and these phrases are defined in the code. The "agency" referred to is Cal/EPA. The statute notes that no Cal/EPA organization shall take any action to adopt the final version of a rule unless several conditions are met. One of these is that **"The board, department or office submits the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation."**

With respect to proposals involving water quality objectives, we interpret this to include the soundness of the scientific basis of the objectives themselves, and the context in which they are to be implemented.

The peer review process described in these guidelines includes independent identification of external peer reviewer candidates by an outside party. This is achieved through a contractual arrangement Cal/EPA has with the University of California, Berkeley. All candidates must complete and sign a Conflict of Interest (COI) Disclosure form that is reviewed by an independent entity identified by Cal/EPA. Only approved candidates can serve as external peer reviewers.

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* (1) Air Resources Board; (2) Department of Pesticide Regulation; (3) Department of Toxic Substances Control; (4) Integrated Waste Management Board; (5) Office of Environmental Health Hazard Assessment; and (6) State Water Resources Control Board and nine Regional Water Quality Control Boards

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Do all Proposed Rules or Amendments with Scientific Components Require Scientific Peer Review?

Sometimes the answer is No, peer review is not needed, or, at least, not for all of it. A Cal/EPA document provides some assistance for making this decision. It is titled, *Unified California Environmental Protection Agency Policy and Guiding Principles for External Scientific Peer Review*, March 13, 1998 (Cal/EPA Guiding Principles). It notes that there are several circumstances where work products do not require peer review under SB 1320 (Health and Safety Code Section 57004), including the following:

> *A particular work product that has been peer reviewed with a known record by a recognized expert or expert body. Additional review is not required if a new application of an adequately peer reviewed work product does not depart significantly from its scientific approach. These types of work products would include standards developed by the U.S. EPA, which Cal/EPA adopts. These U.S. EPA standards are presumed to have been sufficiently peer reviewed unless additional peer review is required by law.*

The "USEPA standards" are those that appear in a final (not draft) EPA document, which is understood to have met EPA adoption requirements. That is, the draft document was sent out for scientific peer review, and the final document satisfactorily addressed reviewers' comments, as EPA considered appropriate and necessary.

Note the caveat to this and other potential exceptions described in the "Implementing Language" section below.

Consideration Should be Given to Whether the Scientific Basis for a Specific Rule, Major Scientific Initiative, or Method not Subject to Health and Safety Code Section 57004 Should be Submitted for External Scientific Peer Review

The Cal/EPA Guiding Principles document identifies such categories of work products (pp 6-7), as described below. The distinguishing feature of these is that they address important scientific topics which would have statewide significance. Examples are as follows:

1) *Products that Address Emerging or Controversial Issues, Have Significant Cross-Media Implications, or Establish a Significant Precedent*
   e.g., Application of new scientific findings in hazardous waste classification.
   e.g., Risk assessment methods, development, and findings. (For example, impacts concerning children or new environmental chemical fate transport models that substantially modify risk outcomes.)

2) *Scientific Products that Support Regulations, Standards, or Rules*
   e.g., Critical technical guidance documents for the regulated community.

3) *New Decision Criteria, Analytical Tools, or Models of Significance or Changes in Assessment Methodologies to be Used Routinely in Risk Assessment*
e.g., Significant new or revised models and other techniques designed to predict exposure, simulate transport, etc.
e.g., Changes or innovations in analytical measurement techniques for pollutants.

Work Products Not Requiring Peer Review

The Cal/EPA Guiding Principles document referred to above notes that there are several circumstances where peer review is not required under Health and Safety Code Section 57004. These are in addition to the EPA standards example given in the section above titled, *Do All Proposed Rules . . . .* Peer review is not required for permits, variances, enforcement actions, and similar types of activities, unless they are accomplished through rulemaking.

Implementing Language Must Be Submitted For External Review

The context in which the "science" is to be applied must be understood by the reviewer. With respect to water quality objectives, their implementation in a proposed rule is an integral part of the rule's scientific basis. This use of the objectives must be submitted for external review even if the objectives themselves had previously been accepted as scientifically sound.

For example, proposed numerical water quality objectives for recreational shellfish harvesting waters may be identical to those recommended by the California Department of Health Services and the U.S. Food and Drug Administration. Peer review could be assumed to be not needed. However, these numbers are integral to a specific sampling strategy and statistical context and, if any of the associated parameters are different in the regulatory action proposed for adoption a peer review must be performed.

For a Water Board Basin Plan Amendment for example, the material to be reviewed must include the amendment language. Where some uncertainty exists, staff should contact me in writing. I may seek input from legal counsel, before responding in writing for the project record.

The Decision to Request External Reviewers: Who is Responsible?

Management in the Cal/EPA organizations is responsible for deciding whether or not a proposal should be submitted for external scientific peer review. Management must be familiar with and have approved the detail of the request letter and its attachments, described below. One of the attachments highlights the essential scientific topics to be reviewed and commented upon.

Another reason for ensuring that the proposal is a solid product with committed organization support is that a considerable effort is directed to identifying willing and conflict-of-interest free candidates who are noted experts in their fields. Candidates are drawn from academic institutions across the country.

The external review is not a time for seeking technical advice. The process is not a collaboration. The proposed rule sent out for external review is draft final and based on sound scientific

principles, in the best professional judgment of management and staff. The proposal must be clearly expressed and based on defensible logic.

Staff are encouraged to find colleagues who are preparing, or who have prepared, similar requests to gain from an exchange of ideas. Also, other entities within the organization making the request will have a role in review of the proposal in the path leading to adoption. Inform them, including legal counsel, about the intended proposal and solicit comment as necessary.

If a decision is made that peer review is not necessary, that conclusion must stand up to future challenge which could stop the proposed action in its tracks. A successful challenge would result in initiation of the peer review process. All of this could add months to the original adoption schedule. The decision to go ahead with peer review, or not, should be well thought out.

The external scientific peer review should take place and changes made which staff consider necessary, before documents are sent out for public comment. Demanding schedules sometimes require both reviews to take place simultaneously. Avoid this if possible.

Signing the Request for External Reviewers

Within the State and Regional Water Boards, the level of the person signing the request has been left to the discretion of the respective organizations. Some prefer that the Executive Officer or Assistant Executive Officer sign. At the minimum, the request should be signed by the second supervisory level or above.

The request includes a clear and detailed description of the scientific basis of the proposal, and it highlights the individual topics that later will be the focus of each reviewer's attention. Those topics, the comments on them by noted experts, and subsequent Cal/EPA organization response all will become part of the public record and the administrative record which is the legal basis for a Cal/EPA organization action.

This signoff by management is the most effective and consistent way of ensuring that staff and management are equally familiar with the details of the request. The reference to consistency is based in part on an observed flux in staff in the organizations, which has shown that the peer review mandate and the details for carrying it out continues to be a new learning experience for many. The need for management signature is based also on the assumption that management is familiar with the peer review process and will provide guidance to staff, as necessary.

Submitting the Request for External Reviewers

The request is initiated by writing a letter to me with the information listed below. It should be sent in draft email form, with three attachments.

This draft can be sent by staff after management review. The letter itself will:

(a) describe the purpose of the request, noting that if the proposal for review is intended for eventual adoption, the proposed adoption date will be identified;

(b) indicate the date the documents will be ready for review, and your preferred period of review (I suggest 30 days). Please be as accurate as you can about document availability. Often, reviewers agree to do the work within a certain time frame;
(c) emphasize the importance of keeping to the review schedule. (As noted above, the external scientific peer review should take place before the public comment period.)
(d) recommend the kinds of expertise staff believes is appropriate for the review (Highlight the expertise considered essential); **Recommendations for reviewers are not permitted.**
(e) provide the name, phone number, and e-mail address of the staff contact for the project.

The three attachments will provide the information described below:

Attachment 1: A plain English summary of the proposal, which is intended for future organization action. This could be done on one page.

Attachment 2: The scientific issues you want the reviewers to address and comment on.

The following two paragraphs will precede the list of scientific issues:

"The statute mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

We request that you make this determination for each of the following issues that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review."

The following paragraph must be added here if a proposed rule is not the subject of review: **"For those work products which are not proposed rules, reviewers must measure the quality of the product with respect to the same exacting standard as if it was subject to Health and Safety Code Section 57004 requirements."**

An explanatory paragraph or two must be provided to the reviewers for each issue you are presenting to them. This will make it much easier for reviewers to know what your challenge is, and how you have addressed it.

The last scientific issue should be followed by this statement to ensure the reviewer is given an opportunity to comment on the proposed Board action as a whole:

"The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the following questions.

(a) In reading the staff technical reports and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.

(b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the proposed Board action. At the same time, reviewers also should recognize that the Board has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed."

An excellent example of the suggested format is attached (Attachment B to this guidance). It describes a proposed site-specific objective. Note that questions are not asked. Independent scientific peer review is not a vehicle for seeking technical advice.

Attachment 3: A listing of people who have participated in the development of the proposal. The intent here is to identify academicians and other researchers from any of the California university systems, public or private, and outside them, that have participated in any stage of project development. The peer review statute forbids any such participant from taking part in the review. So we want to know who they are: **"No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule."**

How Long will it Take to Have Reviewers Identified and Cleared for the Review Assignment?

The period of time from my receipt of the final request to my contacting you later with names of approved reviewers, can range up to two months. This covers the period for finding candidates by the University of California (UC) Project Director; completing the COI Disclosure form and review by an independent entity. The UC Project Director and I receive a letter from the reviewing authority indicating whether or not the candidates have passed the test. If a candidate has not been approved, a search for a replacement with comparable expertise is initiated. On these occasions, the two-month period could be exceeded.

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What Happens After the Draft Request is Submitted?

I will review the draft to ensure that all the required topics are covered and that they are clearly presented to minimize questions of clarification by the UC Project Director, potential reviewer candidates, and selected reviewers once the review is underway. This reading of the draft will be done quickly. After the review, I will contact the person who sent the request, suggest changes if any are thought to be necessary, and ask that the final request (letter and three attachments) be sent to me electronically with a signed, hard copy in the mail to follow. Then I will send the electronic copy to the UC Project Director. This person is not identified in this guidance to emphasize the importance of the independence afforded the University in selecting reviewers for Cal/EPA following strict conflict-of-interest considerations.

The UC Project Director sends the same request information to potential reviewer candidates. This opens a communication to determine if the candidates are interested and qualified. Once suitable candidates are identified, they are asked to complete and sign the COI Disclosure form.

My Response Letter to You

When candidates are approved as reviewers, I will write a letter to the Cal/EPA organization representative who requested the external reviewers. The letter will identify reviewers and provide contact and biographical information. An example of this letter is included here as Attachment C. From this point forward, all subsequent communications will be directly between the organization requesting the review, and the reviewers.

My letter will tell you to contact reviewers **immediately**, and let them know you have been informed that they have been approved as reviewers. The letter also will tell you to let them know your latest schedule for sending the review materials to them. Keep them current on changes to this schedule. Their acceptance of the assignment often is conditional upon the original schedule, so you will have to determine if changes are acceptable to them. Keep me informed of significant schedule changes as I am sometimes contacted by the University or the reviewers when delays occur.

Providing Guidance to Reviewers

Your second contact with reviewers will take place when you send them the material to be reviewed. A cover letter and attachments providing guidance to the reviewers must accompany this material. The three attachments originally sent with the letter of request for reviewers must be included with this cover letter. The reviewers must clearly understand that the focus of the review will be the topics identified in Attachment 2. Reviewers should have been sent this information by the UC Project Director during the initial search for candidates. Regardless, it now should be sent directly from the Cal/EPA organization to provide direction and context for the review.

Reviewers' Responsibility

From Health and Safety Code Section 57004:

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"The external scientific peer review entity, within the timeframe agreed upon by the board, department, or office and the external scientific peer review entity, prepares a written report that contains an evaluation of the scientific basis of the proposed rule. If the external scientific peer review entity finds that the board, department, or office has failed to demonstrate that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices, the report shall state that finding, and the reasons explaining the finding, within the agreed-upon timeframe."

Response to Reviewers: Cal/EPA Organization Responsibility, and Flexibility in Response

From Health and Safety Code Section 57004:

"The board, department, or office may accept the finding of the external scientific peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the Board, department, or office disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices."

Such a determination and supporting rationale must be brought to the attention of the Board, Department, or Office at the time the Rule is proposed for adoption. In adopting the proposed Rule, the Board, Department, or Office would be concurring with staff's rationale.

Additional Information: Questions and Responses

1. **How many reviewers are assigned to a project?**

   The complexity of the proposal and essential expertise identified for its review will provide a basis for the number of reviewers identified for a proposal. The number assigned, and the expertise, is determined by the UC Project Director after careful consideration of the information provided in the request letter and its attachments. For Water Board proposals, the number of reviewers has ranged from one to eight.

2. **Do reviewers interact with one another as a committee?**

   Normally, reviewers act independently and are not organized as committees. This has proved to be the most efficient way of getting the Water Boards the information they need as they move forward to consider adoption of a science-based regulation. Committees can be formed, but the potential need for members to interact would extend the suggested 30-day review period.

3. **Does a Cal/EPA organization have any right to reject a reviewer if it feels that person is not appropriate for the assignment?**

As noted in (1) above, the University Project Director identifies reviewer candidates based on the information provided in the letter of request for reviewers. This includes a description of recommended reviewer expertise. If the requesting organization feels that essential expertise is not represented by the identified reviewers, then I should be informed in writing with the reasons for this conclusion. I will forward this statement to the University Project Director and, if justification is sound, an additional reviewer will be found for the assignment.

4. **Are discussions between staff and reviewers permissible?**

No. There is one exception - the reviewers' need for clarification of certain aspects of the documents being reviewed, where this need has been expressed. Clarification questions and responses to them must be transmitted in writing. These communications will become part of the administrative record. Independent peer review is characterized by no interactions, or a limited number of them. The organization requesting independent review should be careful that staff-reviewer communications do not become a collaboration, or are perceived by others to have become so. The reviewers are not technical advisors.

5. **If a proposal has been revised significantly, and a Cal/EPA organization wants it reviewed again, can the organization send it back to the same reviewers for another look?**

No. This could unintentionally lead to collaboration, or the appearance of such, which must be avoided. Write me a letter stating the nature of the changes and identify the original reviewers. Add anything else that is relevant to the revision. I will contact the UC Project Director and transmit the justification for the request. The Project Director will decide who should review the revised documents. If different from the original reviewers, each would have to complete a COI Disclosure form. I will contact you after this decision has been made.

6. **Do we need to respond to reviewers?**

As a matter of courtesy, the Cal/EPA organization should acknowledge receipt of the comments and thank the reviewers for taking time to review the scientific basis of the proposed rule or other work product.

Reviewers also will be interested to know how the organization responded to their comments. As required by statute, the Cal/EPA organization can agree with critical comments, and make adjustments to meet this criticism, or it can disagree, but it is required to state why for each point of contention, the organization's proposal is based on sound scientific principles.

If the organization provides this follow-up information to the reviewers, I recommend that it be done when the proposal has been revised as necessary, and it is ready to be sent out for public comment. This courtesy communication to reviewers is not meant to establish a dialogue or collaboration that could influence subsequent Board action.

7. **If we are asked for a copy of reviewers' comments, at what point in the process should they be released?**

   Legal counsel advises that reviewers' comments are a matter of public record at the time they are received by the Cal/EPA organization, and should be given to a requestor at that time.

   Cal/EPA staff may feel more comfortable by first preparing responses to the comments and adjusting the proposed rule or work product as necessary prior to release for public comment, before releasing the comments. Staff may suggest this as an alternative to a requestor. However, if this person wants them upon receipt by the Cal/EPA organization, the review comments must be provided at that time.

8. **If a reviewer sends an invoice with a copy of the review to the Cal/EPA organization requesting the review, what should be done with the invoice?**

   The Cal/EPA organization should keep the review, but return the invoice to the reviewer.

   All reviewers previously have been instructed that upon completion of the assignment, they shall send one full set copy of the peer review directly to the Cal/EPA requesting organization and one full set copy to the UC Project Director. The reviewers shall **only** send their invoices directly to the UC Project Director for review/approval, and not to the Cal/EPA organizations. The UC Project Director will authorize payment for completed reviews.

9. **Should there be any contact between Cal/EPA organizations requesting a review and the UC Project Director, at any time?**

   No. This person is a neutral third party whose responsibility it is to identify reviewer candidates based on material prepared by a Cal/EPA organization. The strength of our peer review process is the independence afforded this individual. This keeps Cal/EPA organizations free of any perception that they might influence selection of reviewer candidates for the current proposal and those in the future.

Gerald W. Bowes, Ph.D.
Staff Toxicologist (Sup.)
Manager, Toxicology and Peer Review Section
Division of Water Quality
State Water Resources Control Board
1001 I Street
Sacramento, CA 95814
Telephone: (916) 341-5567
FAX: (916) 341-5463
Email: gbowes@waterboards.ca.gov

Health and Safety Code

§57004. Scientific Peer Review

(a) For purposes of this section, the following terms have the following meanings:
  (1) "Rule" means either of the following:
    (A) A regulation, as defined in Section 11342.600 of the Government Code.
    (B) A policy adopted by the State Water Resources Control Board pursuant to the Porter-Cologne Water Quality Control Act (Division 7 (commencing with Section 13000) of the Water Code) that has the effect of a regulation and that is adopted in order to implement or make effective a statute.
  (2) "Scientific basis" and "scientific portions" mean those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

(b) The agency, or a board, department, or office within the agency, shall enter into an agreement with the National Academy of Sciences, the University of California, the California State University, or any similar scientific institution of higher learning, any combination of those entities, or with a scientist or group of scientists of comparable stature and qualifications that is recommended by the President of the University of California, to conduct an external scientific peer review of the scientific basis for any rule proposed for adoption by any board, department, or office within the agency. The scientific basis or scientific portion of a rule adopted pursuant to Chapter 6.6 (commencing with Section 25249.5) of Division 20 or Chapter 3.5 (commencing with Section 39650) of Division 26 shall be deemed to have complied with this section if it complies with the peer review processes established pursuant to these statutes.

(c) No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule.

(d) No board, department, or office within the agency shall take any action to adopt the final version of a rule unless all of the following conditions are met:
  (1) The board, department, or office submits the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation.
  (2) The external scientific peer review entity, within the timeframe agreed upon by the board, department, or office and the external scientific peer review entity, prepares a written report that contains an evaluation of the scientific basis of the proposed rule. If the external scientific peer review entity finds that the board, department, or office has failed to demonstrate that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices, the report shall state that finding, and the reasons explaining the finding, within the agreed-upon timeframe. The board, department, or office may accept the finding of the external scientific peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.

(e) The requirements of this section do not apply to any emergency regulation adopted pursuant to subdivision (b) of Section 11346.1 of the Government Code.

(f) Nothing in this section shall be interpreted to, in any way, limit the authority of a board, department, or office within the agency to adopt a rule pursuant to the requirements of the statute that authorizes or requires the adoption of the rule.

California Regional Water Quality Control Board

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The Regents of the University of California, Berkeley
SWRCB Contract # 11-135-240, EXHIBIT A, ATTACHMENT 2

To: Dr. Gerald W. Bowes

From: Renee Purdy DeShazo
Staff Environmental Scientist

Re: Request for External Peer Review of Proposed Basin Plan Amendment to Adopt Site-Specific Ammonia Objectives

Date: April 15, 2004

The Los Angeles Regional Water Quality Control Board (LA Regional Board) requests by transmittal of this memo that State Board identify and assign reviewers to provide external peer review of a proposed Basin Plan amendment per the requirements of Health and Safety Code section 57004.

The proposed amendment would incorporate site-specific ammonia objectives (SSOs) for select inland fresh waters, including various reaches of the Santa Clara River, San Gabriel River and its tributaries, and Los Angeles River and its tributaries. The proposed amendment would change the current 30-day average (i.e. chronic) ammonia objective set to protect aquatic organisms for this subset of inland fresh waters. (The current Basin Plan objective is based on US EPA's most recent recommended federal CWA section 304(a) criteria for ammonia, published in 1999.) The goal of this amendment is to take into account site-specific conditions that may alter the toxicity of ammonia to aquatic life. The proposed site-specific objectives are based on water effect ratios (WERs), which take into account the difference in ammonia toxicity observed in local water bodies as compared to that observed in laboratory water.

The Los Angeles Regional Board at its regularly scheduled meeting on August 5, 2004 will consider the proposed amendment. The staff report and supporting technical reports will be ready for review by May 3, 2004. Given the importance of this amendment, we request that the reviewers provide comments within 30 days of receipt of the staff report and supporting documents.

We recommend that State Board solicit reviewers with expertise in toxicity and water chemistry and a familiarity with standards development and, specifically, methods for deriving site-specific objectives.

Additional background information for the proposed basin plan amendment is provided in Attachment 1. Scientific issues to be addressed by peer reviewers are listed in Attachment 2. Individuals involved in development of the proposed amendment are identified in Attachment 3.

The staff contact for this amendment is Renee DeShazo, who can be reached at (213) 576-6783 or via e-mail at rdeshazo@rb4.swrcb.ca.gov. Please feel free to call me if you have any questions about this request, and thank you for your assistance.

Proposed Ammonia Site-Specific Objectives for the Los Angeles, Santa Clara and San Gabriel Rivers and their Tributaries

Summary of Proposed Action

I. Summary

The Regional Board staff proposes an amendment to the Basin Plan to incorporate site-specific ammonia objectives (SSOs) for select inland fresh waters, including various reaches of the Santa Clara River, San Gabriel River and its tributaries, and Los Angeles River and its tributaries. The proposed amendment would change the current 30-day average (i.e. chronic) ammonia objectives set to protect aquatic organisms for this subset of inland fresh waters. (Current Basin Plan objectives are based on US EPA's most recent recommended federal CWA section 304(a) criteria for ammonia, published in 1999.) The goal of this amendment is to take into account site-specific conditions that may alter the toxicity of ammonia to aquatic life. The proposed site-specific objectives are based on water effect ratios (WERs), which take into account the difference in ammonia toxicity observed in local water bodies as compared to that observed in laboratory water.

II. Rationale

In 1999, the US EPA issued an update to the 1984 Ambient Water Quality Criteria for Ammonia (1999 Update). In both of the criteria documents, the US EPA acknowledged that ammonia toxicity may be dependent on the ionic composition of the exposure water, but the effects and understanding of these effects were insufficient to allow inclusion of them in the national criteria derivation. The 1999 Update states that these effects will "have to be addressed using water-effect ratios or other site-specific approaches" (US EPA, 1999). EPA acknowledges that it is possible that WERs for ammonia might be substantially different from 1 if there is an interaction with other pollutants or if there is a substantial difference in ionic composition (US EPA, 1999, Appendix 9). Studies cited in the 1999 Update include several studies done to investigate the impacts of the ionic composition of the exposure water on the toxicity of ammonia to a number of species, including Atlantic salmon, lake trout, rainbow trout, *Ceriodaphnia dubia*, and *Hyalella azteca*.

The results of these studies indicate that the toxicity of ammonia may be reduced in waterbodies similar to those found in Southern California with high hardness and elevated concentrations of certain ions (calcium, sodium, and potassium). Because the waterbodies in Los Angeles County are primarily effluent-dominated, the hardness and ionic concentrations in these waterbodies are much higher than the concentrations found in the laboratory dilution water used in the studies that were the basis for the ammonia criteria. For this reason, there is a potential to develop a WER for ammonia in these waterbodies.

III. Methodology

When developing WERs for ammonia, the US EPA recommends the procedures outlined in "Interim Guidance on Determination and Use of Water-Effect Ratios for Metals" (US EPA, 1994). The methodology used to develop the proposed site-specific objectives is consistent with this guidance and with US EPA's "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985).

(Original language edited to relate statute requirement for external scientific review clearly to topics that will be subject to review)

PROPOSED AMMONIA SITE-SPECIFIC OBJECTIVES FOR THE LOS ANGELES, SANTA CLARA AND SAN GABRIEL RIVERS AND THEIR TRIBUTARIES

Description of Scientific Issues to be addressed by Peer Reviewers

The statute mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

We request that you make this determination for each of the following issues that constitute the scientific portion of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review.

1. **Use of the WER approach along with the "Guidelines for Deriving Numerical Water Quality Criteria for Protection of Aquatic Organisms and their Uses" to develop SSOs for these waters.**

   In both of the 1999 Update and the earlier 1984 Criteria Document, the US EPA acknowledged that ammonia toxicity may be dependent on the ionic composition of the exposure water, but the effects and understanding of these effects were insufficient to allow inclusion of them in the national criteria derivation. The 1999 Update states that these effects will "have to be addressed using water-effect ratios or other site-specific approaches" (US EPA, 1999). EPA acknowledges that it is possible that WERs for ammonia might be substantially different from 1 if there is an interaction with other pollutants or if there is a substantial difference in ionic composition (US EPA, 1999, Appendix 9). Studies cited in the 1999 Update include several studies done to investigate the impacts of the ionic composition of the exposure water on the toxicity of ammonia to a number of species, including Atlantic salmon, lake trout, rainbow trout, *Ceriodaphnia dubia*, and *Hyalella azteca*.

   The results of these studies indicate that the toxicity of ammonia may be reduced in waterbodies similar to those found in Southern California with high hardness and elevated concentrations of certain ions (calcium, sodium, and potassium). Because the waterbodies in Los Angeles County are primarily effluent-dominated, the hardness and ionic concentrations in these waterbodies are much higher than the concentrations found in the laboratory dilution water used in the studies that were the basis for the ammonia criteria. For this reason, there is a potential to develop a WER for ammonia in these waterbodies.

2. **Selecting *Hyalella azteca* as the primary species and fathead minnow as the secondary species in the WER study.**

Based on requirements in the WER guidance (US EPA, 1994), *Hyalella azteca* was chosen as the primary test species for the study. In the 1999 Update, the 30-day average (chronic) criterion was developed based on a limited number of chronic toxicity studies. The most sensitive species used in the development of the criterion was *Hyalella azteca* (see 1999 Update, p. 76). Uwe Borgmann conducted the chronic study used in the development of the criteria in 1994. Borgmann also conducted acute toxicity tests on *Hyalella* that indicate that hardness and concentrations of certain ions may have a significant impact on the toxicity of ammonia to *Hyalella*. As required in the WER guidance, the endpoint of the *Hyalella* chronic toxicity test is close to, but not lower than, the chronic criterion for these waterbodies at the pH values observed in the waterbodies. The *Hyalella* acute toxicity endpoint value is higher than the acute criterion for these waterbodies. Additionally, initial tests have demonstrated that the conditions in these rivers significantly affect the toxicity of ammonia to this species. For these reasons, *Hyalella* is an appropriate species to use in the development of a WER for these waterbodies.

The WER guidance requires that at least one test be conducted with a secondary species to confirm the results with the primary species. Based on a review of the 1999 Update and other studies that have been conducted and given that all the waterbodies in question are designated as warm water habitat (WARM), the secondary species used in the study was the fathead minnow (*Pimephales promelas*). The fathead minnow is the 4th most sensitive species used in the development of the chronic criterion in the 1999 Update.

3. **Use of acute tests to develop chronic WERs.**

The magnitude of a WER is likely to depend on the sensitivity of the test used to determine the WER. More sensitive tests are expected to result in higher WERs and less sensitive tests will result in WERs closer to 1 (USEPA, 1994). For the purposes of this study, acute *Hyalella* studies are the basis of the development of the chronic WER. As expected, the acute toxicity tests resulted in a lower WER than the chronic studies. The resulting SSO is therefore conservative. Additionally, the shorter and less costly acute studies allowed more studies to be conducted. Finally, the acute toxicity test for *Hyalella* is a more frequently used and established test than the chronic toxicity test so there are more data from other laboratories to compare to the monitoring results. The WER guidance specifically outlines that the endpoint of the test is the determining factor for selecting the test, not whether or not the test is chronic or acute. As a result, according to the guidance, a WER developed using acute toxicity tests may be applied to a chronic criterion and vice versa as long as the endpoint of the primary test is not lower than the criterion being adjusted (see discussion under #2 above).

4. **The decisions regarding the sampling design (i.e. sampling locations, frequency and seasonality).**

The *Interim Guidance for the Development of Water Effects Ratios for Metals* (EPA, 1994) specifies the minimum number of samples and types of samples to be collected for the development of a WER. The guidance requires at least three samples, two of which should be collected within 1 to 2 times the design flow of the waterbody and one collected in flows 2 to 10 times the design flow. The guidance does not have specific

requirements for the number of sampling locations that are required. The only requirement is that the number of sampling locations be "sufficient to characterize the site to which the SSO will apply." To avoid dilution of the site water samples during toxicity testing, the ammonia concentration in the site water needs to be as low as possible. This requirement limits the choice of sampling locations to sites with sufficiently low ammonia concentrations. Additionally, site access is a consideration, especially for wet weather sampling, further restricting the choices of sampling locations. For this reason, only one location is used for each discharger at a location downstream of the discharge.

Samples were collected at ten stations, each downstream of a wastewater treatment plant. At all but one station, four acute *Hyalella azteca* toxicity tests and one chronic *Pimephales promelas* (fathead minnow) test were collected. Additionally, at five stations, a chronic *Hyalella azteca* test was conducted to confirm that the use of acute tests to establish WER values was appropriately conservative for the purposes of this study. As a result of some QA/QC problems with the analysis of some samples, four acute *Hyalella* tests, two chronic *Hyalella* tests and three chronic fathead minnow tests were rejected and not used in the study analysis. Therefore, a total of 35 acute *Hyalella* tests, three *Hyalella* chronic tests, and seven chronic fathead minnow tests were successfully conducted during this study. The acute *Hyalella* tests were conducted during both dry and wet weather to assess the impacts of different seasons on the WER. Sampling began in January 2002 and was completed in February 2003. In addition, an initial study to assess the potential for developing a WER for ammonia was conducted in October 2000 at two sites on the Los Angeles River and at two sites on the San Gabriel River.

5. **(a). Use of the laboratory toxicity tests in the final calculation of the WERs and SSOs.**
   (b). The decisions to retain or reject problematic toxicity tests.

All tests were reviewed and a summary of all the QA/QC requirements in the WER is included in the technical report. Although a number of deviations from the testing protocol were determined, only a few were considered to have a significant impact on the test results. Listed below are the two criteria used to determine if a test was unacceptable for the purposes of the study:

1. Survival in the laboratory dilution water control test was below the acceptable level for the test.
2. Dissolved oxygen levels in the test were below the minimum required value for more than 10% of samples collected during the testing period.

In some cases, control survival in the site water was below the required survival rate. These tests were still considered acceptable as long as the survival rate in the laboratory dilution water control was acceptable, because the control samples in site water all contained some ammonia that might have impacted the survival of the test organisms. These two criteria were used to eliminate unacceptable test results from the WER analysis because the EPA ammonia criteria documents used both the control survival and the dissolved oxygen levels to determine whether or not a particular study would be included in the calculation of the national ammonia criteria. Additionally, it was clear from the data review that these two issues had impacted the results of at least some of the tests that failed the criteria.

6. **The methodology for calculating the final WERs and SSOs.**

The calculation of the final WER for the study is based on the process outlined in the WER guidance document. The process involves calculating WERs for each of the dry weather events and taking the adjusted geometric mean of those WERs. That result is then compared to the WER calculated for wet weather events (hWER) to determine the final WER (fWER).

The WER guidance procedure places a large emphasis on the wet weather sample and the results obtained during wet weather. During the calculation of the wet weather hWERs, it became clear that the determination of the hWER was significantly impacted by the assumptions used in calculating the hWER, especially the flow conditions. Because the flow conditions are highly variable in Southern California, the use of a hWER based on a flow condition that could change dramatically over a very short period of time is difficult to justify. Consequently, the appropriateness of using the wet weather hWER versus the adjusted geometric mean of the dry weather WERs was evaluated.

The hWER calculations generally result in wet weather hWERs that are significantly higher than the adjusted geometric mean of the dry weather WER. The one exception is LA2 where the hWER drives the fWER using the calculation conditions chosen. However, because the choice of calculation conditions causes such variability in the hWER, under other wet weather conditions, the hWER may not be the lowest value. Over the course of the storm at LA2, the hWER was estimated to range from 1.0 to 409 based on the changing flow conditions in the river.

Additionally, the chronic objective is the only objective being adjusted by the fWER. The chronic objective is based on a 30-day averaging period. Wet weather events in Southern California occur over a matter of hours to days, but generally do not last for weeks at a time. Therefore, the application of a hWER based on a short-term condition to a 30-day chronic objective is not appropriate. Therefore, it was determined that the appropriate approach for this study was to use the adjusted geometric mean of the dry weather events as the fWER for all of the sites.

To calculate the SSOs for a waterbody reach, a new criteria equation was developed. Each equation was calculated based on EPA guidance for determining aquatic life criteria (US EPA, 1985). The SSOs are all equal to the pH relationship multiplied by the lower of 1) the *Hyalella* value adjusted by the WER or 2) the lowest fish value. This ensures that the SSOs are protective of both fish and invertebrates.

7. **The rationale of only adjusting the invertebrate data (GMCVs) in the national dataset to derive site specific objective equations given the differences in observed WERs between fish and invertebrates.**

During the testing, it became clear that a WER greater than 1.0 for the sensitive invertebrate species, *Hyalella*, occurred in the waterbodies, but a WER for a sensitive fish species, fathead minnow, was closer to 1. Consequently, an adjustment was made to the analytical approach, based on discussions with the Technical Advisory Committee (TAC) for the study, to take this fact into consideration. Specifically, to develop the SSOs for ammonia, the final WERs calculated from the *Hyalella* toxicity tests were used to

revise the invertebrate portion of the criterion equation, whereas the fish portion of the equation was not revised. After the adjustments to the invertebrate portion of the equation, the criterion was recalculated to determine the SSO. In these calculations, the objective is determined by the lower of 1) the temperature-adjusted *Hyalella* Genus Mean Chronic Value (GMCV) and 2) the lowest fish GMCV. This approach results in a SSO that is protective of both invertebrate and fish species.

8. **The decision to use the criteria pH relationship (from the US EPA 1999 Update) rather than a study-specific pH relationship for *Hyalella* to calculate the fWERs and SSOs for the study.**

   The TAC requested that the pH relationship for *Hyalella* be examined to determine whether or not it matched the pH relationship developed in the 1999 Update. The pH relationship is a critical part of the study because it is used to adjust the results from the laboratory dilution water tests to equivalent results at the same pH as the site water (before the WER is calculated). A separate pH study was conducted and the results of that study as well as the results from all of the laboratory dilution water tests were compared to the criteria pH relationship to determine if differences existed that justified the development of a separate pH relationship for *Hyalella*. The comparison demonstrated that, at least for the average pH values found in the waterbodies in this study (7.34 to 8.05), the *Hyalella* pH relationship does not appear to be significantly different from the criteria pH relationship. Additionally, the use of a pH relationship developed based on the study would have resulted in WERs that are higher than the WERs calculated using the EPA pH relationship. So the use of the EPA pH relationship is a conservative approach to developing the WERs and SSOs for the study. As a result, a separate pH relationship was not used to calculate the WERs and SSOs for the study.

9. **Use of the recommended SSOs to protect Threatened and Endangered species.**

   After the SSO values were calculated, the results were compared to the toxicity thresholds for any rare, endangered, threatened, or locally important species present in the waterbodies to ensure that the results were protective of those species.

10. **The decision by Regional Board staff, based on the results of the study, to recommend that the Board adopt reach-specific 30-day average objective equations (rather than watershed-wide SSOs or one SSO for all three watersheds).**

    The variability in fWERs between sites and watersheds is not very significant, ranging from 1.395 to 2.303. For the most part, the watershed fWERs and overall fWER for the study are all around 2. To determine whether or not the differences between the sites were significant, an analysis of variance (ANOVA) was conducted. This analysis basically compares the means of the WERs collected at each site, the variance of the WERs, and information about the entire dataset to determine if the results are statistically different at a 95% confidence level. The results demonstrated that all of the WERs were statistically similar at the 95% confidence level except BW1 and SGR2. Because differences were seen between the Burbank Western Wash and the San Gabriel River, the chosen approach for this study was to use a site-by-site approach to account for the variability observed in the waterbodies and account for the possible differences in the ions causing the WER as demonstrated by the water quality analysis comparison.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the broader perspective.

(a) In reading the staff technical reports and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.

(b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the proposed Board action. At the same time, reviewers also should recognize that the Board has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed."

PROPOSED AMMONIA SITE-SPECIFIC OBJECTIVES FOR THE LOS ANGELES, SANTA CLARA AND SAN GABRIEL RIVERS AND THEIR TRIBUTARIES

Individuals Involved in Development of Basin Plan Amendment

Consultant
Larry Walker Associates - Ashli Cooper Desai

Technical Advisory Committee
Charles Delos, US EPA Headquarters
Gary Chapman, Paladin Water Quality Consulting
Steve Bay, SCCWRP

Regulated Community
Los Angeles County Sanitation Districts – Beth Bax
City of Los Angeles, Bureau of Sanitation – Shahrouzeh Saneie
City of Burbank – Rodney Andersen

US EPA Region IX
Robyn Stuber
Terry Fleming

Coordinating Committee

Name	Organization
Ron Bottorff	FOSCR
Jacqueline Lambrichts	FOSGR
Rick Harter	LASGWRC
Leslie Mintz	Heal the Bay
Bill Depoto	LACDPW
Mauricio Cardenas	DFG
Bill Reeves	SWRCB
(No individual identified)	FOLAR
Denise Steurer	USFWS
Karen Evans	USFWS
Heather Merenda	City of Santa Clarita

State Water Resources Control Board

Division of Water Quality

1001 I Street · Sacramento, California 95814 · (916) 341-5455
Mailing Address: P.O. Box 100 · Sacramento, California · 95812-0100
Fax (916) 341-5584 · http://www.waterboards.ca.gov

Alan C. Lloyd, Ph.D.
Agency Secretary

Arnold Schwarzenegger
Governor

The Regents of the University of California, Berkeley
SWRCB Contract # 11-135-240, EXHIBIT A, ATTACHMENT 2

TO: John H. Robertus
Executive Officer
San Diego Regional Water Quality Control Board

Original Signed By
FROM: Gerald W. Bowes, Ph.D.
Chief, Toxicology and Peer Review Section
DIVISION OF WATER QUALITY

DATE: October 14, 2005

SUBJECT: PEER REVIEWERS FOR PROPOSED BASIN PLAN AMENDMENT INCORPORATING THE TMDLs FOR INDICATOR BACTERIA AT SAN DIEGO BAY AND DANA POINT HARBOR SHORELINES

In response to your request for peer reviewers for the proposed Basin Plan Amendment identified above, I am pleased to send you the name of two reviewers who have been selected to perform this review. These people have been approved by the University of California, Office of the President (UCOP), based on its review of a COI Disclosure form that each was required to complete.

The reviewers' names are given below. Please confirm with them that the review material should be sent to the address indicated:

1. Name and contact information for Peer Reviewer No. 1

2. Name and contact information for Peer Reviewer No. 2

I am providing biographical information for Professors _____ and _____ with this letter.

You should now contact Professors _____ and _____ immediately. Let them know you have been notified that they will be the external reviewers for your proposed

Board action. Also, tell them when to expect the material for review. The letter of request to me provided this information, and reviewer candidates' acceptance of the assignment often is conditional on their availability at that time. If the date has changed, confirm with the reviewers that the new date is acceptable. Keep in periodic contact with each reviewer if the date is expected to change again. I would like to receive copies of these email transmittals to keep up-to-date. I am always contacted by reviewers and the University when delays in the process arise.

[* Language containing additional conflict of interest questions deleted.]

Your letter to the reviewers should include the same three attachments that you provided in your request letter to me. Be clear to them that the second attachment, which lists the components of the scientific basis of the proposed rule, will be the focus of the review.

When all interactions with them have been completed, please let me know for the peer review files I keep here. This information also is essential for the peer review tracking report I write each month, which is provided to Division management and our Executive Office. . .

My files also should include the peer reviewers' comments and Board responses, and I request that you send this information to me for the record as well.

If I can provide additional help, feel free to contact me at any time during the review process.

Attachments

* The conflict of interest review procedure for this new Interagency Agreement (#06-104-600-0) includes coverage of the two topics highlighted. There is no longer any need for Cal/EPA organizations to contact reviewers on them.

W:\Standards Section\other\Exhibit F Peer Review Guidance 101006.doc