



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

February 11, 2015

Renee Spears
Senior Environmental Scientist Specialist-QA Officer
Office of Information Management & Analysis
State Water Resources Control Board
1001 I Street, 16-39D- Sacramento, CA 95814
P.O. Box 100- Sacramento, CA 95812

Dear Ms. Spears:

This letter addresses the EPA Region 9 Quality Assurance Office's March 17, 2014 approval of the State of California's request to use an Alternate Test Procedure (ATP), authorizing the use of two concentrations in lieu of the five concentrations plus a control specified in the WET test methods, when using the Test of Significant Toxicity (TST) statistical approach. EPA is withdrawing the approval of the Limited Use ATP, effective immediately, for a number of reasons. Please note that at this time, California's February 12, 2014 ATP request is no longer pending before EPA and should the State wish to pursue such an ATP, a new ATP application would be required.

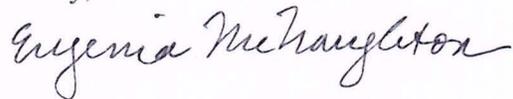
As you may know, the March 17, 2014 Limited Use ATP approval was challenged in the U.S. Eastern District Court of California in June 2014 by the Southern California Alliance of Publicly Owned Treatment Works (SCAP) and Central Valley Clean Water Association (CVCWA). As a result of the litigation, EPA has become aware of issues related to the State of California's February 12, 2014 request as well as EPA Region 9's approval. First, we note that the State's request cited 40 C.F.R. § 136.4, which describes the process for *nationwide* ATP approvals, rather than 40 C.F.R. § 136.5 for a Limited Use ATP. While we continue to believe this was a simple error, we acknowledge that it has created uncertainty and confusion among the regulated community.

Second, there is currently pending a proposed rulemaking to revise the ATP regulations at 40 C.F.R. Part 136. Please see <http://water.epa.gov/scitech/methods/cwa/mur2015.cfm>. The EPA Administrator signed a proposed rule on February 5, 2015, relevant portions of which are attached. One element of that rulemaking is a proposal to correct an inadvertent error in the 40 C.F.R. § 136.5 regulatory language regarding Limited Use ATPs. In revising 40 C.F.R. § 136.5 in 2012, EPA had inadvertently included the phrase "or permitting authority" after each instance that the phrase "Regional Alternate Test Procedure Coordinator" or "Regional ATP Coordinator" appears in Section 136.5. The effect of this inadvertent inclusion was to authorize State

permitting authorities to approve ATPs. This was not EPA's intention, and EPA has now proposed to delete the phrase "or permitting authority" from Section 136.5. It is EPA's position that the inadvertent error is not implicated in its approval decision here, but plaintiffs have raised arguments regarding the phrase "permitting authority" in Section 136.5. To the extent this error has created uncertainty in regards to the appropriateness of the March 17, 2014 ATP approval, EPA believes it is appropriate to withdraw that approval. However, withdrawal of the approval does not affect any aspect of the regulations at 40 C.F.R. Part 136 but concerns only the State's February 12, 2014 ATP request.

Third, plaintiffs have raised concerns with respect to the administrative record for the ATP approval. In light of some of the issues raised by plaintiffs, EPA has concluded that it is appropriate to withdraw its ATP approval. If you have any questions regarding this action, please contact me at (415) 972-3411.

Sincerely,

A handwritten signature in cursive script that reads "Eugenia McNaughton".

Eugenia McNaughton, Ph.D.
Manager, Quality Assurance Office

Cc: Rich Breuer

J. *Clarifications/Corrections to ATP Procedures in 40 CFR 136.4, 136.5 and Allowed Modifications in 136.6*

40 CFR 136.4 and 136.5 describe EPA procedures for obtaining approval to use an alternate test procedures either on a national basis, or for limited use by dischargers or facilities specified in the approval. In the 2012 Method Update Rule, EPA made several clarifying changes to the language of these sections. At the same time, however, in many places in 40 CFR 136.4 and 136.5 where the phrase “Regional Alternate Test Procedures Coordinator” or “Regional ATP Coordinator” appears, EPA inadvertently also inserted the phrase “or permitting authority” following the phrase. This error resulted from the use of the “search and replace” function on the computer. The effect of the change was to inadvertently authorize *State* permitting authorities to approve ATPs for limited use within the State. EPA never intended this result as is demonstrated by two facts. First, in its proposal for the 2012 Update, EPA did not propose to authorize State NPDES permitting authorities to approve limited use ATPs. Second, the rule states that the approval may be restricted to specific dischargers or facilities, or to all dischargers or facilities “specified in the approval *for the Region.*” (emphasis added). This language evidences EPA’s intent that the Region – not the state – would be authorized to issue any such limited use ATP approval. Finally, as further evidence of EPA’s intent, in several places, the text of the rule makes more sense if read to authorize only the Regional ATP Coordinator, and not the State permitting authority, to approve limited use ATPs. For example, 40 CFR 136.5(d)(1) provides as follows:

“After a review of the application by the Alternate Test Procedure Regional ATP Coordinator or permitting authority, the Regional ATP Coordinator or permitting

authority notifies the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure....”

As currently written, if the State is acting on a request for approval, the regulation would require the State to inform itself of its own action in approving or rejecting the ATP, a somewhat superfluous requirement.

Consequently, EPA proposes to delete all instances of “or permitting authority” from 40 CFR 136.4 and 136.5 to correct this error and revise the rule text to its original intent. Based on this revision, EPA and EPA alone would have the authority to approve limited use ATPs.

EPA also proposes changes to 40 CFR 136.4 and 136.5 to clarify the process for nationwide approval and the Regional ATP Coordinator’s role in limited use ATP approvals. These changes do not significantly change the process, the intent is to make wording simpler and clearer.

Finally, EPA proposes to add language to 40 CFR 136.6(b)(1) to clarify that if a method user is uncertain whether or not a modification is allowed under 40 CFR 136.6, the user should contact either its Director or EPA Regional ATP Coordinator.

K. Changes to Appendix B to 40 CFR part 136 - Definition and Procedure for the Determination of the MDL

EPA proposes revisions to the procedure for determination of the MDL primarily to address laboratory blank contamination and to better account for intra-laboratory variability. EPA’s consideration of revisions to the MDL procedure for this rulemaking is specific to these revisions, and other changes to the procedure are outside the scope of this action. The proposed changes originated from The National Environmental Laboratory Accreditation Conference

5. Section 136.4 is amended by revising paragraphs (a) introductory text, (b), and (c) to read as follows:

§ 136.4 Application for and approval of alternate test procedures for nationwide use.

(a) A written application for review of an alternate test procedure (alternate method) for nationwide use may be made by letter via email or by hard copy in triplicate to the National Alternate Test Procedure (ATP) Program Coordinator (National Coordinator), Office of Science and Technology (4303T), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Any application for an ATP under this paragraph (a) shall:

* * * * *

(b) The National Coordinator may request additional information and analyses from the applicant in order to evaluate whether the alternate test procedure satisfies the applicable requirements of this part.

(c) Approval for nationwide use.

(1) After a review of the application and any additional analyses requested from the applicant, the National Coordinator will notify the applicant, in writing, of whether the National Coordinator will recommend approval or disapproval of the alternate test procedure for nationwide use in CWA programs. If the application is not recommended for approval, the National Coordinator may specify what additional information might lead to a reconsideration of the application and notify the Regional Alternate Test Procedure Coordinators of the disapproval recommendation. Based on the National Coordinator's recommended disapproval of a proposed alternate test procedure and an assessment of any current approvals for limited uses for the

unapproved method, the Regional ATP Coordinator may decide to withdraw approval of the method for limited use in the Region.

(2) Where the National Coordinator has recommended approval of an applicant's request for nationwide use of an alternate test procedure, the National Coordinator will notify the applicant. The National Coordinator will also notify the Regional ATP Coordinators that they may consider approval of this alternate test procedure for limited use in their Regions based on the information and data provided in the application until the alternate test procedure is approved by publication in a final rule in the Federal Register.

(3) EPA will propose to amend 40 CFR part 136 to include the alternate test procedure in §136.3. EPA shall make available for review all the factual bases for its proposal, including the method, any performance data submitted by the applicant and any available EPA analysis of those data.

(4) Following public comment, EPA shall publish in the FEDERAL REGISTER a final decision on whether to amend 40 CFR part 136 to include the alternate test procedure as an approved analytical method for nationwide use.

(5) Whenever the National Coordinator has recommended approval of an applicant's ATP request for nationwide use, any person may request an approval of the method for limited use under §136.5 from the EPA Region.

6. Section 136.5 is amended by revising paragraphs (a), (b), (c), and (d) to read as follows:

§136.5 Approval of alternate test procedures for limited use.

(a) Any person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.

(b) When the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator with a recommendation for or against approval.

(c) Any application for approval of an alternate test procedure for limited use may be made by letter via email or by hard copy. The application shall include the following:

(1) Provide the name and address of the applicant and the applicable ID number of the existing or pending permit(s) and issuing agency for which use of the alternate test procedure is requested, and the discharge serial number.

* * * * *

(d) Approval for limited use. (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. The approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.

(2) The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National Alternate Test Procedure Coordinator.

7. In Section §136.6:

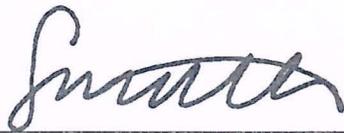
Clean Water Act Methods Update Rule for the Analysis of Effluent

List of Subjects in 40 CFR part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Test procedures, Water pollution control.

Dated:

FEB 05 2015



Gina McCarthy, Administrator.