The ''consensus principles'' described in this letter include the following:

- The definition of ''quantitation'' should account for both precision and bias.
- EPA should consider different uses of the MDL and ML in the Clean Water Act program (as a start-up test for a single laboratory, as a figure of merit to characterize an analytical method, as a permit compliance level, *etc.*), and evaluate the applicability of the MDL and ML to these uses.
- Definitions of and procedures for determining quantitation levels should take into account their use as regulatory compliance levels in NPDES permits, and the effects of routine variability within a laboratory on the results generated by the laboratory.

EPA notes that some of these ''consensus principles'' highlight existing aspects of approaches to detection and quantitation and provide a framework for future discussions with stakeholders. A more detailed description and additional discussion of these ''consensus principles'' is in Chapter 4 of the Revised Assessment Document.

C. Technical Issues

EPA considered, and is continuing to consider, several technical issues related to the development of detection and quantitation approaches. These issues are discussed in chapter 3 of the Revised Assessment Document. Commenters expressed concern regarding EPA's consideration of several of these technical issues, specifically how these issues are, or are not, addressed by EPA's MDL and ML. Specific concerns or suggestions expressed by commenters dealt with technical aspects of EPA's assessment, such as treatment of sample blanks, instrument data censoring, false positive and false negative rates, and calculation of MLs. EPA addressed these comments in the Revised Assessment Document and/or the Response-to-Comments Document, and the Agency expects to further address these issues in a continued consultation with stakeholders.

IV. Next Steps

It is clear that there is a strong interest in improving current procedures and uses, but no consensus for a specific procedure or procedures has emerged among the laboratory, industry, regulatory or regulated communities. The Agency looks forward to working with stakeholders. Based on an analysis of comments received on the 2003 assessment and proposed revisions to the MDL procedure, issues for consideration in future stakeholder consultations may include, but are not limited to, development of detection and quantitation procedures that:

- Vary in the nature and extent of statistical rigor and laboratory performance checks depending on the end use of a calculated limit in CWA programs;
- Account for more sources of variability, such as the variability between and within laboratories;
- Require more then seven samples and collect samples over a long period of time; and
- Use routine blank samples collected over long periods of time to account for background signals and temporal variability.

EPA has engaged a neutral third party to ask stakeholders for suggestions for additional issues, and about their interest in working with EPA to revise existing procedures and/or adopt one or more alternative procedures.

Dated: November 1, 2004.

Benjamin H. Grumbles,

Acting Assistant Administrator for Water.

[FR Doc. 04–24824 Filed 11–5–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 136

[OW–2003–0002; FRL–7834–9]

RIN 2040–AD53

Guidelines Establishing Test Procedures for the Analysis of Pollutants; Procedures for Detection and Quantitation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; withdrawal.

SUMMARY: On March 12, 2003, EPA published a document in the **Federal Register** that proposed revisions to the regulations for the definition and procedure for EPA's method detection limit (MDL). The document also proposed to add to these regulations a definition of minimum level of quantitation (ML) and a procedure for developing it. The proposed rule requested comment on the revisions and additions. The MDL and ML are used to characterize the capabilities of analytical test procedures applied under the Clean Water Act (CWA). The proposed revisions were based on EPA's 2003 assessment of approaches to determining detection and quantitation capabilities of analytical methods.

Today's document withdraws the proposed revisions. The proposed revisions were disfavored by the vast majority of commenters on the March 2003 proposed rule, and the Agency has determined that these proposed revisions do not represent the most effective way to address the public's and EPA's concerns regarding approaches to, and use of, detection and quantitation values. The Agency believes, preliminarily, that new approaches submitted in comments to the proposed rule might better address the issues EPA sought to address in its proposed revisions and that these new approaches warrant further consideration and refinement. Hence, EPA plans to work with stakeholders to evaluate one or more approaches to detection and quantitation that will satisfy the needs of programs, regulations, and initiatives at the Federal level for use of detection and quantitation procedures, and to revise its existing procedures, as appropriate.

DATES: For judicial review purposes, this action is considered issued as of November 8, 2004. Under section 509(b)(1) of the Clean Water Act, judicial review of the Administrator's action regarding guidelines establishing test procedures for analysis of pollutants can only be had by filing a petition for review in the United States Court of Appeals within 120 days after the decision is considered issued for purposes of judicial review. Under 40 CFR 23.12, if within ten days of the issuance date of this action for purposes of judicial review EPA's General Counsel receives two or more petitions filed in two or more United States Courts of Appeals, the General Counsel will notify the United States Judicial Panel of Multidistrict Litigation of all petitions received within the ten day period.

ADDRESSES: The docket for today's action is available for public inspection under Docket ID No. OW–2003–0002 at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: William A. Telliard; Engineering and Analysis Division (4303T); Office of Science and Technology; Office of Water; U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, NW., Washington, DC 20460, or call (202) 566–1061 or E-mail at *telliard.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Entities Are Potentially Interested in This Action?

Because EPA is withdrawing proposed regulatory changes, this action should not have any concrete effects on any entity. Various groups may, however, be interested in today's decision. EPA regions, as well as States, Territories and Tribes authorized to implement the National Pollutant Discharge Elimination System (NPDES) program, issue permits that comply with the technology-based and water quality-based requirements of the Clean Water Act (CWA). In doing so, NPDES permitting authorities, including authorized States, Territories, and Tribes, make a number of discretionary choices associated with permit writing, including the selection of pollutants to be measured and, in many cases, limited in permits. If EPA has ''approved'' standardized testing procedures under 40 CFR part 136 for the measurement of a given pollutant, the NPDES permit must require such analysis to be done in accordance with one of the approved testing procedures or an approved alternate test procedure. Many of the testing procedures approved by EPA include a specification for detection and quantitation levels that laboratories can be expected to achieve. Therefore, entities with NPDES permits may be interested in EPA's withdrawal of the proposed revisions to the detection and quantitation procedures. In addition, States, Territories and Tribes must use the standardized testing procedures and achieve the associated detection and quantitation levels when providing certification of Federal licenses under Clean Water Act section 401. Categories and entities that may be interested in today's decision include:

Category	Examples of potentially interested entities
State, Territorial, and Indian Tribal Governments	States, Territories, and Tribes authorized to administer the NPDES permitting program; States, Territories, and Tribes providing certification under Clean Water Act section 401.
Industry	Facilities that must conduct monitoring to comply with NPDES permits.
Public	Individuals and groups that follow, comment on, or otherwise participate in NPDES permit proceedings.
Municipalities	POTWs that must conduct monitoring to comply with NPDES permits.
Environmental Laboratories	Public or private laboratories that conduct compliance-monitoring analyses for NPDES permits.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this decision. This table lists the types of entities that EPA believes may potentially be interested in this decision. Other types of entities not listed in the table may also be interested. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. Docket. We have established an official public docket for this document under Docket ID No. OW–2003–0002. The official public docket consists of the documents specifically referenced in this action, any public comments received, the March 12, 2003, document, and other supporting information related to this action. Information claimed as CBI and other information whose disclosure is restricted by statute, or which is not included in the official public docket, will not be available for public viewing in EPA's public docket. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20460. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. To view docket materials, please call ahead to schedule an appointment. Every user is entitled to copy 266 pages per day before incurring a charge. The Docket may charge 15 cents for each page over the 266-page limit plus an administrative fee of $25.00.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number. Information claimed as CBI and other information whose disclosure is restricted by statute, or which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in I.B.1.

C. What Other Information Is Available To Support This Action?

You can obtain electronic copies of this document as well as copies of major supporting documents at EPA Dockets at *http://www.epa.gov/edocket/* and *http://www.epa.gov/waterscience.*

II. Legal Authority

This action withdraws EPA's March 12, 2003, proposed revisions to 40 CFR part 136 and the proposed addition to 40 CFR part 136.2. We take this action pursuant to sections 301(a), 304(h), and 501(a) of the Clean Water Act, 33 U.S.C. 1311(a), 1314(h) and 1361(a).

III. Background

A. Test Procedures Used for Clean Water Act Programs

EPA proposes and promulgates test procedures at 40 CFR part 136 in accordance with section 304(h) of the CWA, which requires that the EPA Administrator ''promulgate guidelines establishing test procedures for the analysis of pollutants'' to be monitored and regulated under the National Pollutant Discharge Elimination System (NPDES). Test procedures are also known as analytical methods. EPA draws the analytical methods from a variety of sources, including methods developed by commercial vendors, EPA, and other government agencies, as well as methods from voluntary consensus

standards bodies (VCSBs) such as the American Public Health Association (APHA), the Water Environment Federation (WEF), and the American Water Works Association (AWWA), which jointly publish Standard Methods for the Examination of Water and Wastewater, the Association of Official Analytical Chemists (AOAC-International); and the American Society for Testing and Materials (ASTM International). An analytical method promulgated by EPA under CWA section 304(h) is considered approved by EPA for purposes of EPA's NPDES permitting regulations.

Among considerations for approval of an analytical method at 40 CFR part 136 are the demonstrated performance characteristics of precision, bias, and sensitivity (*i.e.*, detection and quantitation). EPA generally evaluates each of these characteristics to determine if the analytical method will yield results at concentrations of concern that are reliable enough to meet Agency needs for permitting and compliance monitoring under the CWA. Detection and quantitation limits have been the most controversial of these characteristics, particularly among members of the regulated community.

B. Settlement Agreement

Following promulgation of a new EPA analytical method at 40 CFR part 136 on June 8, 1999 (64 FR 30417), the Alliance of Automobile Manufacturers, the Chemical Manufacturers Association, and the Utility Water Act Group (''Petitioners'') and the American Forest and Paper Association (''Intervenor'') filed a lawsuit challenging the method. This lawsuit challenged specific aspects of the analytical method and the procedures used to establish method detection limits (MDLs) and minimum levels of quantitation (MLs) in all chemical analytical methods under the CWA. On October 19, 2000, EPA entered into a settlement agreement, with the Petitioners and Intervenor (*Alliance of Automobile Manufacturers, et al.* v. *EPA*, No. 99–1420 (D.C. Cir.); the ''settlement agreement'').

Under the settlement agreement, EPA agreed to assess the procedures currently used by the Agency for determining detection and quantitation limits, as well as consider alternate procedures. EPA agreed to sign a notice for publication in the **Federal Register** on or before February 28, 2003, and to invite public comment on its assessment. The settlement agreement also stated that EPA may propose modifications to the existing procedures for detection and quantitation. EPA signed the notice by the agreed date and, on March 12, 2003 (68 FR 11791), published a notice announcing the availability of its assessment. The document was entitled Technical Support Document for the Assessment of Detection and Quantitation Approaches (EPA–821–R–03–005, February 2003). In a separate document on the same day, EPA proposed revisions to the Agency's existing MDL procedure at 40 CFR part 136 (68 FR 11770). EPA provided a 120-day public comment period on both documents, and reopened the comment period for an additional 30 days, in response to requests from the Petitioners. Today's document announces EPA's final action withdrawing the revisions to 40 CFR part 136 that were proposed on March 12, 2003.

Under the settlement agreement, as amended, EPA also agreed to sign a notice taking final action on the assessment described above on or before November 1, 2004. In a separate **Federal Register** notice, EPA is also announcing the availability of a revised assessment document that addresses comments and procedures submitted in response to the 2003 assessment.

IV. Summary of Proposed Rule

In the March 2003 proposed rule, EPA proposed to revise certain aspects of the existing procedure for determining the MDL in 40 CFR part 136, appendix B (Definition and Procedure for the Determination of the Method Detection Limit). EPA also requested comment on whether to add a definition of quantitation limit to part 136, and whether to add a procedure for determining the ML to appendix B. Details of the proposed revisions are presented and discussed in section VII of the March 2003 proposed rule, and include: (1) Proposed revisions to the definition of the MDL; (2) proposed technical revisions to the MDL procedure; (3) proposed clarifications and other minor editorial changes to the MDL procedure codified in part 136; and (4) a proposed definition of quantitation limit (ML) and a proposed procedure to calculate the ML.

In section VII.E of the preamble to the March 2003 proposed rule, EPA explained that the Agency continues to approve analytical methods from organizations that do not necessarily use EPA's MDL and ML procedures. EPA also recognized that there are alternative detection and quantitation approaches that may be used by method developers to determine analytical method sensitivity, and noted that the Agency includes analytical methods at 40 CFR part 136 that employ alternative approaches. In the preamble to the proposed rule, EPA specifically stated that ''the use of detection and quantitation approaches from voluntary consensus standards bodies and other organizations is encouraged under the National Technology Transfer and Advancement Act.'' EPA also included in the proposed revisions to appendix B the statement that ''an alternative procedure may be used (*e.g.*, from a voluntary consensus standards body) to establish the sensitivity of an analytical method, provided the resulting detection limit meets the sensitivity needs for the specific application.''

V. Summary of Major Comments

EPA received more than one hundred comment letters raising issues, concerns or suggestions on the proposed rule. EPA received comments from 23 laboratories, 31 wastewater treatment plants, three Federal agencies, 11 State and county agencies, 23 industrial firms, three instrument manufacturers, 19 trade organizations, four consultants, eight individuals, and one law firm representing the Petitioners. A summary of public comments and EPA's responses are included in the Response to Comments document, which is in the official public docket supporting this action.

Although a few commenters suggested that EPA adopt the revisions as proposed, most commenters noted that the proposed modifications are minor and do not attempt to make the fundamental changes that these commenters believe would be more appropriate. For example, some commenters stated that EPA's proposed MDL revisions do not sufficiently account for all sources of routine inter- and intra-laboratory variability. Many of these commenters expressed support for concepts that were included with comments submitted by the U.S. Geological Survey and the American Council of Independent Laboratories. Other commenters suggested that EPA adopt detection and quantitation procedures published by ASTM International's Committee D19 on Water (*i.e.*, interlaboratory detection and quantitation estimates, known by the acronyms IDE and IQE.)

Commenters also questioned the appropriateness of the MDL and ML for all of the different uses for which the MDL and ML are employed in Clean Water Act programs. Commenters asserted that a single procedure is not appropriate for determining detection or quantitation limits that can appropriately support all CWA uses, such as a start-up test in a single laboratory, a value characterizing a given analytical method, a benchmark

for approval of a method modification or alternate test procedure, and a reporting or compliance limit. Several commenters stated that EPA, permit holders, and laboratories would be better served if detection and quantitation were determined through approaches quite different from those proposed.

Some commenters encouraged EPA to allow use of alternative procedures for determining detection and quantitation levels. Some commenters suggested that, like EPA's MDL and ML, other available concepts fall short of providing optimal procedures. For example, comments submitted by some laboratories indicated that the proposal submitted by the Inter-industry Analytical Group, which was discussed in the preamble to the March 2003 proposed rule, would be useful only during initial phases of method development, but not as a routine laboratory tool to assess lab performance. Other commenters noted that the IDE and IQE procedures published by ASTM's D19 committee, which were discussed in the 2003 assessment of detection and quantitation approaches, also are intended only for interlaboratory use and are not appropriate for use in a single laboratory.

Other commenters recommended that EPA contact the editorial committees of voluntary consensus standards bodies to begin a process of developing detection and quantitation procedures. Several commenters requested that EPA reconsider the proposal and work with stakeholders to devise an approach that meets the Agency's needs, rather than proceeding with the proposed revisions to the MDL.

In response to these comments, EPA has decided to withdraw the proposed rule and has initiated a process to work with stakeholders on revisions to MDL and ML procedures. See Potential Stakeholder Process for Detection and Quantitation Procedures, 69 FR 55547, September 15, 2004.

VI. Decision To Withdraw Proposal

In today's action, EPA is withdrawing the March 12, 2003, proposal to revise the MDL definition and procedure and to add a definition and procedure for determining the ML. EPA has decided to withdraw these proposed revisions because the Agency has concluded that approaches other than those set forth in the 2003 proposal have the potential for addressing concerns regarding development and use of detection and quantitation limits, and that those approaches warrant further consideration and refinement. The Agency generally sees merit in comments suggesting that EPA should continue to work collaboratively with stakeholders on these issues. EPA also notes that the comments generally disfavored the proposed revisions, and that there is no agreement among critics of the existing MDL and ML procedures about what changes should be adopted by the Agency for use in CWA programs.

VII. Effect of Today's Action on Existing MDL Procedure

EPA plans to explore alternative concepts and approaches submitted in response to the two March 2003 **Federal Register** documents. These comments included sometimes detailed alternative approaches or other revisions to current EPA detection and quantitation procedures. EPA intends to further evaluate issues and detection and quantitation approaches suggested by commenters, and to solicit additional stakeholder input through consultations. The Agency believes that the body of public comment on the proposed rule provides a strong starting point for a continued collaborative consultation with stakeholders representing constituencies such as citizens, environmental organizations, permit writers, regulators and regulated industries. In a **Federal Register** notice published on September 15, 2004 (69 FR 55547), EPA announced that a neutral party is seeking a broad group of stakeholders willing to work together to define and address concerns about the way detection and quantitation values are calculated and used to support CWA programs. Such a process, if feasible, could begin as early as December 2004.

The existing MDL procedure has been in place since 1984. Individual MDLs and MLs are included in many EPA-approved methods at 40 CFR part 136, and have provided laboratories and data users with limits for evaluating results of analytical measurements or analytical method selection. Although several commenters expressed concern with a number of technical and applicability issues regarding EPA's current MDL and ML procedures (and EPA finds merit in this concern), other commenters supported their continued use because, in their experience, the MDL and ML values published in many of the approved EPA methods have served acceptably as default detection and quantitation levels for permits. By today's action, EPA leaves the existing MDL procedure unchanged while it further considers the concerns raised by commenters.

VIII. Statutory and Executive Order Reviews

Today's action does not constitute a rule under section 551 of the Administrative Procedure Act, 5 U.S.C. 551. Hence, requirements of other regulatory statutes and Executive Orders that generally apply to rulemakings (*e.g.*, the Unfunded Mandate Reform Act) do not apply to this action.

Dated: November 1, 2004.

Michael O. Leavitt,

Administrator.

[FR Doc. 04–24823 Filed 11–5–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH40

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for the Sacramento Mountains Checkerspot Butterfly and Proposed Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of public comment period, notice of availability of draft economic analysis and draft environmental assessment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the draft economic analysis and draft environmental assessment for the proposal to designate critical habitat for the Sacramento Mountains checkerspot butterfly (*Euphydryas anicia cloudcrofti*) (butterfly) under the Endangered Species Act of 1973, as amended (Act). We are reopening the public comment period for the proposal to list this species as endangered with critical habitat to allow all interested parties to comment on the proposed listing and critical habitat designation, as well as the associated draft economic analysis and draft environmental assessment. Comments previously submitted on the September 6, 2001 (66 FR 46575), proposed rule to list the butterfly as endangered with critical habitat need not be resubmitted as they have been incorporated into the public record and will be fully considered in preparation of the final listing and critical habitat determination. We invite all interested parties to submit comments on this proposal.

DATES: Comments must be submitted directly to the Service (*see* **ADDRESSES**