

XI. References

Appendix A: Definitions, Acronyms, and Abbreviations Used in This Document

I. Statutory Authority

This action is being proposed pursuant to the authority of sections 301(a), 304(h), and 501(a) of the Clean Water Act ("CWA" or the "Act"), 33 U.S.C. 1311(a), 1314(h), 1361(a). Section 301(a) of the Act prohibits the discharge of any pollutant into navigable waters unless the discharge complies with a National Pollutant Discharge Elimination System (NPDES) permit issued under section 402 of the Act. Section 304(h) of the Act requires the Administrator of the EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to [section 401 of this Act] or permit application pursuant to [section 402 of this Act]." Section 501(a) of the Act authorizes the Administrator to "prescribe such regulations as are necessary to carry out this function under [the Act]." EPA publishes analytical test method regulations for use in CWA programs at 40 CFR part 136. The Administrator has made these test methods applicable to monitoring and reporting of NPDES permits (40 CFR 122.21, 122.41, 122.44, and 123.25), and implementation of the pretreatment standards issued under section 307 of the Act (40 CFR 403.10 and 403.12).

II. Purpose of This Action

EPA recently completed an assessment of procedures for determining the sensitivity of analytical test methods (*i.e.*, procedures for determining detection and quantitation) and their application to Clean Water Act Programs. That assessment was conducted pursuant to a settlement agreement with the Alliance of Automobile Manufacturers, *et al.* (See III.B. below for details.) The assessment is contained in a document entitled, Technical Support Document for the Assessment of Detection and Quantitation Concepts or "Assessment Document" (EPA 821-R-03-005, February, 2003). A draft of the Assessment Document was peer-reviewed in August 2002 in accordance with EPA peer review guidelines. Following peer review, EPA incorporated peer review comments into the Assessment Document. EPA is providing an opportunity for public review and comment on the assessment and the Assessment Document through this notice and also in a separate notice in this **Federal Register** (see Notice of

Document Availability and Public Comment Period on the Technical Support Document for the Assessment of Detection and Quantitation Concepts).

Based on findings from the assessment, EPA is proposing revisions to the method detection limit procedure codified at 40 CFR part 136, Appendix B and is seeking comment on the revisions proposed in this notice. EPA also is proposing to revise the definition of "Detection limit" at 40 CFR 136.2 and to add a definition of the "Minimum level of quantitation (ML)" for consistency with the proposed revisions to Appendix B.

III. Background

A. Analytical (Test) Methods Used for CWA Programs

Section 304(h) of the Clean Water Act 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). EPA proposes and promulgates test methods at 40 CFR part 136 in accordance with section 304(h). The approved test methods have been drawn 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).

Among considerations for approval of a test 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 test method will yield results at concentrations of concern that are reliable enough to meet EPA needs for permitting and compliance monitoring under the CWA. Detection and quantitation limits have been among the most controversial of these characteristics, particularly among members of the regulated community.

B. Settlement Agreement

On June 8, 1999, EPA published a final rule adding EPA Method 1631,

Revision B: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry (Method 1631B) to the "Guidelines Establishing Test Procedures for the Analysis of Pollutants" under section 304(h) of the Clean Water Act. This method was developed specifically to measure concentrations of mercury at low (*i.e.*, ambient water quality criteria) levels. Following promulgation, 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. (*Alliance of Automobile Manufacturers, et al. v. EPA*, No. 99-1420 (D.C. Cir.)). The challenge addressed specific aspects of EPA Method 1631 as well as the general procedures used to establish the method detection limit (MDL) and the minimum level of quantitation (ML) specified in the method. On October 19, 2000, EPA entered into a settlement agreement with the Petitioners and Intervenor (the "settlement agreement"). The settlement agreement included six clauses. EPA has already satisfied the requirements of clauses 1 through 5, which addressed clarification and revision of specific method procedures and requirements. This proposal partially fulfills the requirements of clause 6 of the settlement agreement, which addresses procedures for determining the sensitivity of analytical test methods.

Clause 6 provides for EPA to assess existing Agency and alternative procedures for determining detection and quantitation limits under the Clean Water Act and to sign a notice for publication in the **Federal Register** on or before February 28, 2003, inviting public comment on the assessment. The assessment is to include, at a minimum, evaluation of the "Definition and Procedure for Determination of the Method Detection Limit" published at 40 CFR part 136, Appendix B and used in Method 1631, and evaluation of the corresponding "minimum level" of quantitation procedures.

Clause 6 further provides for EPA to submit its assessment to formal peer review by experts in the field of analytical chemistry and in the statistical aspects of analytical data interpretation. EPA conducted peer review of its assessment in August 2002. A summary of the results of the peer review is provided in section VI of this proposal; the peer reviewers' comments and EPA's responses are included in the docket for this proposal. As stipulated in the settlement agreement, EPA