

INTER-INDUSTRY ANALYTICAL GROUP

May 30, 1996

By UPS Overnight

Mr. Robert W. Perciasepe
Assistant Administrator
U. S. Environmental Protection Agency
401 M. Street, S.W. (Mail Code 4101)
Washington, DC 20460

Quantification Levels

Dear Mr. Perciasepe:

For almost two years now, the undersigned industry organizations have engaged in extensive research and analytical efforts to evaluate methods for reliably determining the concentrations of very low levels of pollutants in the NPDES process. After having made several formal presentations on this issue at meetings organized by EPA and others, we recently met with representatives of EPA's Engineering and Analysis Division ("EAD") to discuss its proposed approach (the "interim minimum level" or "ML") and a technically sound and readily implementable alternative developed by our experts (the "alternative minimum level" or "AML"). Following this meeting, we remain convinced that the ML is scientifically unsound, and an inadequate basis for setting regulatory standards.

In view of the serious penalties for permit violations, we are extremely concerned by EPA's continued commitment to the ML approach. Contrary to your letter of February 10, 1995, EPA has continued to implement the ML approach in a variety of policies and administrative rules (see the attached historical summary). We therefore request a meeting with you to discuss our concerns and explore the options available for resolving the issues.

From what we can gather, the EAD staff's reluctance to withdraw its proposed ML approach is based on three points, none of which is valid. First, they say that the method

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detection level ("MDL"), which is the basis of the ML,^{1/} has been used for several years and that it therefore has withstood the test of time. In fact, prior to the EAD proposal, MDLs had only been used for internal QA/QC purposes, never for setting enforceable compliance levels. Next, they say that their approach is administratively convenient. While that is correct, convenience must never be elevated above scientific soundness in EPA's decisionmaking.^{2/} Finally, based on an EAD assessment of new EAD data that have yet to be provided to us, the EAD reportedly has found that MLs will sometimes be larger and sometimes smaller than calculated AMLs. They use that finding to conclude that MLs and AMLs are comparable (i.e., "a wash"), thereby justifying the validity of MLs. We take issue with that conclusion. We believe the findings instead confirm that some of EAD's MLs are too high and some too low. The fact that MLs and AMLs may be similar on average does not justify use of an incorrect quantification value in any particular application.^{3/} In either case, the MLs are erroneous, too unpredictable for use in the NPDES process, and likely to yield undesirable consequences for regulators and dischargers alike.

Also, many or all of the MLs recommended by EPA seem to have been determined only for laboratory reagent water. Such MLs may be incorrect and irrelevant to quantification and compliance in more chemically complex actual effluents. While the policies and regulations

^{1/} The ML actually is the MDL times a factor of 3.18, or the standard deviation derived using the MDL procedure times a factor of 10.

^{2/} Moreover, the AML approach can be applied using a simple computer program that we have demonstrated to EAD staff. This program is less complex than those used to convert GC/MS signals into reported measurements.

^{3/} EAD's logic is flawed. It is like saying that a bank cash machine that gives some customers more cash than requested and some less is operating properly because, on average, the end result is the same. Dischargers are no more willing to accept the uncertainty of EAD's ML than customers would be willing to use the above cash machine.

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EPA has adopted using the ML ostensibly allow agencies to account for such matrix differences, the extent to which that relief will be available is unclear. And the policies and regulations do not require agencies to consider or account for matrix differences. This unduly encourages reliance on the reagent water MLs, and fails to ensure consideration of an obvious major technical factor.

Unless proper quantification levels are established, several undesirable consequences are inevitable. Permit and rulemaking proceedings will be delayed by disputes, ultimately leading to resource-intensive challenges at the administrative and judicial levels. Municipal and industrial dischargers, particularly those lacking the resources necessary to bring such challenges, will experience unavoidable episodes of permit excursions caused by analytical variability, rather than by the actual presence of pollutants above regulatory limits. These so-called "*false violations*" will encourage costly and unjustifiable enforcement actions, if not by EPA or state regulatory authorities, then by citizen groups. Ultimately, the enforcement authority of federal and state regulatory agencies could be undermined by the legally suspect and frequently contested nature of the grounds on which such enforcement actions would be based.

Resolution of the quantification issue cannot be delayed any longer. Increasingly stringent water quality standards are resulting in WQBELs below the concentrations at which reliable measurement is possible. Permit writers need valid quantification levels in order to properly set and determine compliance with those limits. The Great Lakes States have a particularly acute need for valid quantification levels. They are subject to a rigid schedule for developing GLI implementation regulations, which will require quantification levels for the many pollutants that have not already been assigned such levels in 40 C.F.R. Part 136.⁴

⁴ The EPA quantification levels in 40 C.F.R. Part 136 were not derived using the EAD proposal. They reportedly are based on values derived years ago using best professional judgment.

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The undersigned organizations have committed extensive resources to assist EPA with this matter. We had hoped that the discussions between EPA and our statisticians, analytical chemists, and other nationally renowned experts would serve as a model and incentive for future cooperative efforts between government and the private sector. Unfortunately, this has not been the result.

It is in this effort to cooperate and to find a basis for agreement that we believe a meeting with you is critical. One of our representatives will contact your office in the next few days to make the appropriate arrangements.

David E. Coleman /mek
Aluminum Company of America

Donald J. Edwards
American Automobile
Manufacturers Association

John Schmitt
American Forest & Paper
Association

Paul Bailey
American Petroleum Institute

Anthony D. Wagner
Chemical Manufacturers Association

William A. Sonntag, Jr. /psw
National Association of Metal Finishers
American Electroplaters & Surface
Finishers Society
Metal Finishing Suppliers' Association

Jim T. Stine
Utility Water Act Group

Attachment

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US EPA/EAD Washington DC

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cc: Dr. Tudor T. Davies
Mr. Michael B. Cook
Mr. James F. Pendergast
Mr. James D. Taft
Mr. William A. Telliard
Steven J. Koorse, Esquire

Attachment to
Letter to Robert Perciasepe
Dated May 30, 1996

Quantification Issue: Historical Overview

Following is a brief history of events leading to the current dispute over what constitutes an appropriate quantification level.

- EPA first raised the quantification issue for general application at the national level in its Technical Support Document For Water Quality-based Toxics Control ("TSD") (1991). The TSD only discussed the quantification issue conceptually, however; no specific approach for calculating quantification levels was offered.
- In March 1994, EPA's Engineering and Analysis Division ("EAD") proposed an approach for calculating quantification levels (called "interim minimum levels" or "MLs") in a draft guidance document entitled, "National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limitations Set Below Analytical Detection/Quantitation Levels."
- In May 1994, an industry coalition^{1/} submitted an extensive "white paper" in response to the draft guidance. That paper described serious deficiencies in the ML, and the MDL on which it is based. That paper and voluminous technical materials prepared for subsequent meetings with EPA on this issue are available upon request.
- At the request of the industry coalition, the Agency hosted a meeting in December 1994, at which members of that coalition, the Water Environment Federation, and the Association of Metropolitan Sewerage Agencies, informed the Agency unanimously that the EAD's proposed ML approach was scientifically unsound and thus unacceptable for use in the NPDES program.^{2/} The

^{1/} Members of the coalition include Aluminum Company of America, American Automobile Manufacturers Association, American Forest and Paper Association, American Petroleum Institute, Chemical Manufacturers Association, National Association of Metal Finishers, American Electroplaters & Surface Finishers Society, Metal Finishing Suppliers' Association, and Utility Water Act Group.

^{2/} The primary reason for concluding that the ML is unacceptable is that it is based on the "method detection limit" ("MDL"). By the Agency's own admissions, the MDL is not sufficiently reliable for setting regulatory standards. For example, EPA stated that MDLs are "the result of measurements made by one or several of the most experienced laboratories under non-routine and controlled ideal research-type conditions. MDLs vary with the . . . analyst, and other factors. The MDLs, although useful to individual laboratories, do not provide a uniform measurement concentration that could be used to set standards." 56

(continued...)

participants at that meeting requested a subsequent meeting at which their concerns could be fully discussed amongst all interested parties.

- In a letter of February 10, 1995, Mr. Perciasepe agreed to the request for a follow-up meeting. In his letter, Mr. Perciasepe agreed not to finalize the draft policy until the dispute had been resolved.
- On August 2-3, 1995, EPA sponsored a meeting at which interested parties were given the opportunity to express their views on the proposed EAD approach, and to offer alternatives.
- At that meeting, a broad cross section of American industry, with support from a group of highly renowned statisticians, analytical chemists, engineers, lawyers and other experts, explained why the EAD approach was unacceptable. That industry group also presented an alternative approach (the "AML") for properly deriving quantification levels.
- EPA's participation at that meeting was limited essentially to listening. The EPA representatives did not attempt to respond to industry's criticism of the proposed EAD approach. Nor did EPA comment on the industry group's proposed alternative, notwithstanding that ample materials on both issues were presented to the Agency over a month before the meeting. Materials were provided in advance with the express purpose of allowing EAD adequate time to consider and respond to industry's position.
- At the request of the industry group, a subsequent meeting to discuss the issues was scheduled for April 26, 1996. Several months prior to that event, the group provided to EPA detailed procedures describing how to apply its alternative approach. Only ten days before the meeting, and almost two years since industry first commented on deficiencies in the EAD proposal, EAD provided the industry group with a list of its concerns over the AML.
- At the meeting on April 26, the EAD staff and some, but not all of their consultants, reiterated their continued support for EAD's proposed approach. The staff also presented their concerns over the AML to the industry group's technical experts. The technical experts were able to explain why those concerns were either unsubstantiated or capable of being quickly resolved.

^{2/} (...continued)

Fed. Reg. 60,949 (Nov. 29, 1991) (emphasis added). EPA has made similar statements elsewhere.

- At an EPA conference in Norfolk, Virginia, on May 15, 1996, EAD staff again reiterated support for their proposed approach, offered subjective and unsubstantiated criticism of the industry alternative, and provided a totally inadequate opportunity for industry to respond.
- During the course of the above events, the Agency proposed several actions in the *Federal Register* and elsewhere in which the proposed EAD approach was applied, notwithstanding the commitment not to do so in Mr. Perciasepe's letter of February 10, 1995. Following is a list:
 1. Water Quality Guidance for the Great Lakes System: Supplementary Information Document, March 1995 at pg. 419.
 2. EPA Method 1637: Determination of Trace Elements in Ambient Waters by Chelation Preconcentration with Graphite Furnace Atomic Absorption EPA 821-R-95-030, April 1995.
 3. EPA Method 1638: Determination of Trace Elements in Ambient Waters by Inductively Coupled Plasma-Mass Spectrometry EPA 821-R-95-031, April 1995.
 4. EPA Method 1639: Determination of Trace Elements in Ambient Waters by Stabilized Temperature Graphite Furnace Atomic Absorption EPA 821-R-95-032, April 1995.
 5. EPA Guidance on the Documentation and Evaluation of Trace Metals Data Collected for Clean Water Act Compliance Monitoring EPA 821-B-95-002, April 1995.
 6. EPA Method 1640: Determination of Trace Elements in Ambient Waters by On-Line Chelation Preconcentration and Inductively Coupled Plasma-Mass Spectrometry EPA 821-R-95-033, April 1995.
 7. EPA's proposed effluent limitations guidelines, pretreatment standards, and NSPS for the pharmaceutical manufacturing category. 60 Fed. Reg. 21,592 (May 2, 1995).
 8. EPA's Multi-Sector Storm Water Permit. 60 Fed. Reg. 50,804 (Sept. 29, 1995).
 9. EPA's proposed Oil & Grease 40 C.F.R. Part 136 rule. 61 Fed. Reg. 1730 (Jan. 23, 1996).