Straw Proposal

June 1, 2006

The Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs (FACDQ) discussed uses at its March 29-30, 2006 meeting. A subgroup of representatives from each caucus was assigned to develop a straw proposal on uses.

The assignment was to develop a "straw" proposal that could be floated to each caucus' constituencies as a possible FACDQ agreement on uses of detection and quantitation approaches in Clean Water Act programs. The straw includes the uses that have been discussed in FACDQ meetings:

- Permit limits
- Compliance enforcement limits
- Data reporting for compliance/enforcement, and
- Data reporting for reasonable potential analyses.

Attention was given to the situation when the water quality-based effluent limit (WQBEL) is below L_Q.

Using documents from the committee's March meeting and several state and federal approaches, the subgroup developed the following "straw" proposals for each of the uses. In some cases, the subgroup felt it was important to include the discussion illuminating its proposals. The straw also includes a proposal and discussion for the prescriptive/descriptive approach for the committee's consideration in July. All proposals assume that detection and quantitation levels will be determined in a scientifically-defensible manner.

Although this document does not represent an endorsement of the proposals by the constituents from each caucus, it includes proposals as a starting point for FACDQ discussion in July. Where there are different perspectives on a proposal, they are indicated. The subgroup expects that caucuses will review these proposals with their constituents to support decision-making at the July meeting. Where caucus members and their constituents disagree with a proposal, it is hoped that they will consider ways to revise proposals to help the FACDQ reach consensus.

1. Setting Permit Limits

Proposal: Set permit limits at the WQBEL.

- Another opinion was that permit limits should be set at L_Q when the WQBEL is less than L_Q.

The subgroup used the committee's discussions at its last two meetings (December 2005 and March 2006) to inform this proposal. The near unanimous line of thought is to set

the permit limit equal to the WQBEL at all times. Another opinion is that permit limits should be set at the L_Q when the WQBEL is below the L_Q.

2. Calculating Averages for Compliance and Enforcement

Proposal: Above or equal to L_Q, use the actual value obtained in the analytical test. Below L_Q, assign "0".

- Another opinion is to assign a numerical value or to use a value substitute, e.g., 1/2 L_C, L_C, or possibly a multiple of L_C.

The subgroup discussed the practice of calculating monthly averages for compliance and enforcement purposes. Above or equal to L_Q, there is unanimity that the value is used in calculating the monthly average. There are different opinions in how values are treated below L_Q, particularly in the "delta" between L_Q and L_C. One line of thought is to use zero (0) for reporting below L_Q and in calculating monthly averages. Another line of thought is to assign a numerical value or to use a value substitute for reporting below L_Q and in calculating monthly averages.

3. Evaluating Compliance and Enforcement

Proposal: Use L_Q for daily limits.
Use the WQBEL for monthly averages calculated using the approach in #2 above.

- Another opinion is that L_Q should be used for all cases.

In evaluating compliance and enforcement, the subgroup proposes using L_Q for evaluating daily limits and the WQBEL for monthly averages. An assumption was made that a robust process would be used to assess the reasonable potential that a permittee would cause or contribute to exceed a limit. Another assumption was that when the WQBEL is below L_Q, a Pollutant Minimization Program (PMP) would already be in place when compliance was evaluated or enforcement action contemplated. Another opinion is that L_Q should be used for evaluating compliance in all cases. Additional discussion points on this topic are included below to array the thought that went into the current proposal.

Discussion:

a. In evaluating compliance and enforcement:
   1) Assume there is a reliable, robust process for determining reasonable potential and that a permit limit would not be needed unless there was a firm basis to conclude there was reasonable potential.
   2) Assume the objective of a permitting process is to get to the source of the problem, not to punish a permittee.
b. If reasonable potential for a pollutant is established and the WQBEL is less than L_Q, besides the imposition of a numerical WQBEL, assume that the permit is

drafted with an enforceable requirement to plan and implement a Pollutant Minimization Program (PMP). A PMP includes the following concepts:

1) A cost-effective PMP is an activity that has as its goal the reduction of all potential sources of the pollutant for the purpose of maintaining the effluent at or below the WQBEL.
2) A PMP includes investigation of treatment technologies and efficiencies, process changes, wastewater reuse or other pollution prevention techniques that are appropriate for that facility, taking account of the permittee's overall treatment strategies, facilities plans and operational circumstances. For example, in Wisconsin past documented pollution prevention or treatment efforts may be used to satisfy all or part of a pollution minimization program requirement. (S. 106.04(5), Wisconsin Administrative Code).
3) The PMP requirement may take the form of a schedule of actions, as follows:
    a. Develop and submit to the regulatory agency a cost-effective PMP plan by (date) – The Plan may be thought of as the heart of the PMP. Generally, the best approach will be to investigate the simplest, least costly potential solutions first. The Plan will map out steps to be taken to arrive at the PMP goal in an orderly fashion. Besides effluent monitoring (required elsewhere), the Plan may call for treatment system influent or source stream monitoring to aid in locating sources of the pollutant.
    b. Implement the PMP as detailed in the plan or as amended by agreement of the permittee and the regulatory agency by (date).
    c. Submit to the regulatory agency an annual status report on the progress of the PMP. The first annual report is due by (date). The status reports may be considered to be updates of the Plan.
4) In addition to the PMP, the permit should require regular monitoring for the pollutant using the method capable of the lowest L_Q. Since the determination of reasonable potential has already been made (we believe the pollutant to be present), it can be expected that the pollutant will be detected (some measurements will result in non-zero values), even if we can't quantify. As long as serious progress of the PMP is demonstrated, these "hits" should not cause further regulatory action.
5) An assumed or explicitly stated off-ramp would allow elimination of the PMP requirement once conditions that caused the determination of reasonable potential ceased. This conclusion is implicit in the stated goal of a PMP which, in the Great Lakes Initiative, is "…to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL." (GLI, Appendix F Procedure 8)
6) If the permittee does not take the PMP requirement seriously, the regulatory agency should consider either enforcement action or modifying (or waiting until the next re-issuance of) the permit to require more specific actions or alternative requirements.

4. Analytical Data Reporting for Reasonable Potential Analyses (by permittee)

Proposal: Assuming a robust reasonable potential evaluation process is in place:

- All values will be reported above L_Q.
- Information below L_Q will be reported as "Detected but Not Quantified (DNQ)," for example.
- Information below L_C will be reported as Not Detected (ND).

The subgroup discussed the reporting of analytical data by the permittee and also discussed how that data could be used for determining reasonable potential to exceed a limit. The proposal addresses the first issue: how analytical data are reported by the permittee. The discussion points below array opinions concerning how that data could then be used to determine reasonable potential.

Discussion:

a. Threshold #1: Should the FACDQ make recommendations regarding how data are used in reasonable potential analyses? YES or NO
b. Threshold #2: If yes, then reasonable potential data reporting may need to be separated from compliance/enforcement data reporting. The following should be considered in putting numerical limits in permits.
    1) Decisions based on pollutant test data are determined on a case-by-case basis. Decisions may have more subjective components than simply using straight statistical calculations. Processes for determining reasonable potential vary by state.
    2) A number of other factors are considered when determining reasonable potential to cause or contribute to exceedance of a water quality standard. Those other factors include (where applicable):
        a. Biological indicators (for example fish or other aquatic organisms), such as when the relevant water quality standard is an acute or chronic aquatic toxicity criterion, or if the relevant standard is protective of human health or wildlife from fish contaminants.
        b. Whole effluent toxicity (WET) testing (e.g. if the relevant water quality standard is an acute or chronic aquatic toxicity criteria).
        c. TMDLs and/or waste load allocation issues.
        d. Industrial processes or raw materials used by a facility.
    3) Lacking these other considerations, decisions should be based on multiple analyses.
        a. Sometimes decisions are made using initial screening based on as little as a single data point.
            ⇒ If no-detect, there may be a concern for false negative rates.
            ⇒ If there is a "DNQ", additional testing should be implemented before a reasonable potential determination is made.

4) There are some options other than numerical limits when there is a "hit" or "detect" (below L_Q) when doing permit application testing. The FACDQ may want to suggest guidance that allows flexibility for the regulatory agency to explore alternatives to immediately imposing an effluent limitation based on the single hit. For example:
   a. Suggest that the permittee perform additional monitoring prior to permit issuance for the purpose of expanding the data set.
   b. Require additional monitoring in the permit to expand data set following issuance of the permit. If this monitoring continues to indicate exceedance of the permit, the regulatory agency could re-open and modify permit.
   c. Not impose the limit but put a special study requirement in the permit, where data are not reported on the Discharge Monitoring Report (DMR) the same as for compliance/enforcement. However, once per year (for example) the permittee submits a special report to the agency with information on any hits below L_Q. This study might also include pollution minimization work where potential sources are identified and reduced.

5. Analytical Data Reporting for Compliance and Enforcement

Proposal:

- From the lab to the permittee and from the permittee to the regulator (for daily limits): Assuming a robust reasonable potential evaluation process is in place:
  - All values will be reported above L_Q.
  - Information below L_Q will be reported as "Detected but Not Quantified (DNQ)," for example.
  - Information below L_C will be reported as Not Detected (ND).
  - From the permittee to the regulator only, another opinion was that nothing below L_Q should be reported for compliance and enforcement purposes.
- From the permittee to the regulator (for monthly averages): report the individual test results and the numerical value of the monthly average per the sub-bullets above.

Analytical data reporting for compliance and enforcement purposes parallels how analytical data are reported for reasonable potential analyses. In the proposal, the subgroup suggests how data should be reported for compliance and enforcement purposes from the lab to the permittee, and then from the permittee to the regulator (for both daily limits and monthly averages).

6. Analytical Data Reporting for Listing Impaired Water Bodies

Proposal: Do not develop recommendations for how to use data for 303(d) listings based on the following reasons:

- This is a complex process that does not totally depend upon Part 136 analytical methods, and would require an effort to fully educate the committee on this process.
- However, if an opportunity arises to link this process to uses and approaches for detection and quantitation, and if the FACDQ has an education process about 303(d), then the FACDQ could revisit this issue prior to the final recommendations.

The subgroup discussed whether the FACDQ should develop recommendations for how to deal with data for 303(d) listing purposes, and if so, what those recommendations may include. The subgroup did not discuss the latter point because its proposal is that the FACDQ not develop recommendations in this area.

7. Considerations for Prescriptive and Descriptive Approaches[1]

Proposal:

- Promulgate national detection and quantitation limits.
- Include a robust procedure in the promulgation (i.e. the procedure is a result of FACDQ pilot testing and analysis).
- Publish a table with the rule describing the most sensitive methods.
- Identify and prioritize the analytical methods for updating.

The subgroup included a proposal and discussion of prescriptive and descriptive approaches because it impacts uses and is therefore a fundamental decision the FACDQ needs to make.

The group acknowledged a lack of clarity in the way that EPA carries out its programs under the Clean Water Act with respect to descriptive and prescriptive approaches and agreed that there is a need for more clarity. EPA's current recommended approach for setting permit limits when a WQBEL is below analytical detection levels is as follows: EPA promulgates a quantitation level (e.g., the Minimum Level or ML as part of many methods approved in 40 CFR Part 136), and recommends the use of the most sensitive method approved in Part 136. Labs demonstrate initial capability (e.g. currently through demonstrating a MDL using Appendix B and an initial Precision and Accuracy demonstration), and the ML of the most sensitive method is set as the permit compliance evaluation level in the permit.

[1] See also Document #8 from the 4th FACDQ meeting (March 29-30), titled "Prescriptive and Descriptive Approaches for Detection and Quantitation in Clean Water Act Programs."

The straw proposal above is included for discussion at the July meeting, and the points below are meant to inform the discussion.

Prescriptive Approaches

a. There are advantages to a prescriptive approach for compliance and enforcement purposes.
    1) These values would not change over time or between laboratories.
    2) Laboratories would not need to do separate MDL-like studies.
    3) If L_Q and/or L_C are used as a CET, the CET is the same for all permit holders irrespective of which laboratory or instrumentation they use or changes over time. This provides greater uniformity and consistency in the Clean Water Act program.
    4) Verification of L_Q and L_C can occur with each batch; for individual compliance sample results there is a matching L_Q and L_C quality control result.
    5) This approach does not require statistical or theoretical assumptions about the distribution of data that are often not met in reality.
b. Some disadvantages of a prescriptive approach include the following.
    1) Without a built-in mechanism for lowering L_Q and L_C, these values become locked in and cannot be changed without a change in regulation.
    2) If new L_Q and L_C are set for all 40 CFR 136 analytes, it will require considerable regulatory change.
    3) Rulemaking (including updates or revisions of existing regulations and methods) is costly and time consuming for the EPA.
    4) For laboratories that are not familiar with quality control in the 1600 series methods or ICR procedures, verification of L_C and L_Q will be a dramatic change.

Descriptive Approaches

a. Some states have implemented a descriptive approach to setting compliance limits at a laboratory specific MDL.
    1) The State specifies that the permittee's lab must determine values for L_Q and L_C using a given procedure or by one of the accepted procedures.
    2) The permit requires that the selected analytical method must be capable of quantifying the result, or if not possible using the most sensitive method, that the most sensitive method must be used.
    3) Labs must achieve certain data quality requirements set by a lab accreditation program.
    4) If data are submitted that does not meet sensitivity requirements or reporting limit targets (set by the State based on federal ML or MDL information or other information available to the State), the data are rejected or the permittee is instructed to find a lab that can meet expected standards.
    5) The State sets criteria by rule or in the permit for determining how compliance is judged when values fall below the L_Q and the WQBEL is close to or below the L_Q.

b. There are advantages to a descriptive approach for compliance and enforcement purposes.
   1) It allows for characterization of individual laboratory performance. This information may be pooled to develop a realistic expectation of future performance by qualified laboratories.
   2) A range of descriptive laboratory performance is used to develop prescriptive requirements for various uses (regulatory, monitoring, laboratory accreditation, method equivalency studies, etc.).
   3) It may more effectively drive development of increasingly sensitive analytical methods and better technologies.
   4) It may be more efficiently updated or maintained with current technologies.
   5) The process is conducive to accounting for matrix effects if a lab applies detection and quantitation procedures to a matrix of an individual permittee or group of permittees.

c. Some disadvantages of a descriptive approach include the following.
   1) Descriptive estimates of detection and quantitation limits vary with time (laboratory, analyst, instrument, etc.). Thus, using them as mandatory (prescriptive) benchmarks requires that a representative set of estimates that address laboratory, temporal and other sources of variability be obtained to prescribe acceptable future performance.
   2) For some types of methods (e.g., censored), spiking experiments to describe a laboratory's performance may differ depending on whether (a) acceptable performance at a specific (i.e., prescriptive) detection or quantitation limit is required, or (b) laboratory simply describes its best performance.
   3) If L_C or L_Q were used for compliance evaluation, the permittee would have different permit limits for each lab and each instrument, and then again every time the lab updated its estimates of L_C or L_Q.
   4) There is potentially less consistency and or knowledge of what is expected.
   5) The permittee could "shop" for a desired limit.
   6) States have difficulty coming up with or maintaining the list of reporting limit targets.