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Attached are the Comments of the Inter-Industry Analytical Group and WET Coalition on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulation.

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- Comments on 2004 Draft Report to Congress.PDF

May 20, 2004

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202
725 17th Street, N.W.
Washington, DC 20503

Comments of Inter-Industry Analytical Group and WET Coalition on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulation 69 Fed. Reg. 7987 (February 20, 2004)

Dear Ms. Hunt:

OMB has requested comments on its 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulation, available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html. 69 Fed. Reg. 7987-88 (February 20, 2004). The following comments on the Draft report are submitted by the Inter-Industry Analytical Group (IIAG) and WET Coalition.[1]

The Draft Report is prepared pursuant to the Regulatory Right-to-Know Act, which requires OMB to submit a report on the costs and benefits of federal regulations, together with recommendations for reform. For the 2004 report, OMB requests nominations of promising regulatory reforms relevant to the manufacturing sector. In particular, OMB requests comments suggesting specific reforms to rules, guidance documents, or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, embracing competitiveness, reducing uncertainty, and increasing flexibility.

Among the lessons reported in the 2004 Draft report are that government regulation can have a disproportionately large burden on small businesses and that the cumulative costs of regulation on the manufacturing sector are large compared to other sectors in the economy (Draft

[1] The Inter-Industry Analytical Group consists of ALCOA, Alliance of Automobile Manufacturers, American Chemistry Council, American Forest & Paper Association, American Petroleum Institute, General Electric, and Utility Water Act Group. The WET Coalition consists of the following members: Alliance of Automobile Manufacturers, American Chemistry Council, American Forest & Paper Association, American Petroleum Institute, AMSA, Rubber Manufacturers Association, Utility Water Act Group, VAMWA, WESTCAS, Alcoa, General Electric, Kennecott Utah, and Milliken Company.

Report, Executive Summary p. 1). The report also points out that, based on four major studies that reach similar conclusions, economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence (Draft Report p. 31).

The continuing concern of the IIAG and WET Coalition is the implementation of U.S. environmental laws. In particular, the IIAG and WET Coalition focus their activities on the methods of measuring pollutants, especially for the purpose of making regulatory decisions. IIAG concentrates on analytical methods generally, including those used to detect and to measure individual chemicals such as mercury and congeners of PCBs. The WET Coalition concentrates on "whole effluent toxicity" or WET test methods that use living organisms to test water samples for toxicity. Our goal is to ensure that analytical methods are validated before being approved for regulatory use, so that their limitations and variability can be taken into account. Our preferred approach is to work with the Environmental Protection Agency (EPA) to develop consensus approaches to measurement issues that both serve EPA's purposes and protect NPDES permittees from decisions with regulatory and legal consequences based on unreliable or poor-quality data.

The IIAG and WET Coalition believe OMB's involvement in analytical procedures issues could be useful because the long history of these issues at EPA suggests the need for a fresh look. Industry and EPA have engaged in protracted negotiations, and sometimes litigation, over analytical methods and WET methods for years, and progress has been slow. We remain locked in litigation over WET methods, and in the ongoing rulemaking over detection and quantitation levels, industry has found EPA's latest proposal to be unacceptable, although recent discussions with the agency have been more productive. OMB might be helpful in this area, where data quality, one of OMB's ongoing concerns, is a central issue.

Summary of Comments

The IIAG and WET Coalition wish to call OMB's attention in these comments to three issues of great importance to the federal government's environmental regulatory programs. These three issues are the following:

1. Adequate Validation of all Analytical Methods Used to Measure Pollutants for Making Regulatory Decisions

"Validation" includes determining and publishing the variability of an analytical method by running a controlled test using an adequate selection of wastewater samples and multiple laboratories. It includes using appropriate methods for calculating the "quantification level," now represented by EPA's "Minimum Level" (ML), which in turn is derived from the "Method Detection Limit" (MDL), which EPA intends as a "detection level." IIAG has submitted comments, along with a coalition of stakeholders, suggesting that EPA's method for calculating

the MDL and ML is not suitable. See EPA Docket No. OW-2003-0002. As stated, we recently engaged EPA in discussions on the MDL/ML rule.

2. Whole Effluent Toxicity (WET) Methods Must be Suitably Validated, Like Other Analytical Methods

Because of the inherent variability in using living organisms for testing, appropriate precautions should be taken when using WET methods for regulatory decisions, such as whether a wastewater discharge has the "reasonable potential" to cause or contribute to an exceedance of a water quality standard. For example, the WET Coalition opposes using single WET tests as a simple pass-fail test of whether there are "violations" of environmental laws that can result in penalties.

3. EPA Needs a Systematic Process for Determining What New or Improved Analytical Methods to Develop, and It Needs Criteria for Including an Analytical Method in its Collection of Approved Analytical Methods, 40 C.F.R. Part 136

For well over 10 years there has been contention between the private sector and EPA's Office of Water over the Office of Water's development and approval of analytical methods for measuring pollutants in water. Some of this controversy might be avoided if the regulated community had a clearer idea of (1) how EPA decides what analytical procedures should be developed to measure what pollutants and (2) what are the criteria for deciding that an analytical method is acceptable for use in making regulatory compliance decisions. We believe a more systematic development and approval process would also make it easier for EPA to budget resources for developing and validating analytical methods.

Detailed Comments

As we explain below, all three of these issues are important for ensuring that environmental regulatory decisions are made using high-quality data. These issues are also important for the sensible allocation of resources, both of the government and the private sector. If poor measurement techniques cause the government and regulated companies to spend resources on minor or nonexistent environmental problems, they detract from addressing more serious issues.

1. EPA Needs to Change its Proposed Method of Calculating the Quantitation Level ("Minimum Level" or ML)

EPA is engaged in a rulemaking that proposes to make minor changes in EPA's method for calculating the MDL and minimum level of quantitation (ML). The former is used as a "detection limit" and the latter as a "quantitation level." A coalition of interests representing

laboratories, municipalities, trade associations, and NPDES dischargers has told EPA in rulemaking comments that the proposed MDL and ML are "unacceptable." See letter to G. Tracy Mehan, III, from 36 stakeholders (August 15, 2003) in EPA rulemaking Docket OW-2003-0002.

The detection limit for an analytical method is a concentration of pollutant where one can be 99% certain that if the test results indicate the presence of the analyte, then it is really present – in other words, that the analyte is not being identified because of method error. EPA uses the method detection limit (MDL) as a detection limit, though industry has commented that the MDL does not really satisfy the definition of detection limit.

The quantitation level is the concentration above which the concentration of an analyte can be accurately and precisely measured with a known degree of confidence. EPA uses the minimum level of quantitation (ML) for this purpose.

Determining the ML or quantitation level is particularly important to NPDES permittees because when a permit limit is lower than the quantitation level of the method used to measure it, the quantitation level is used as a *de facto* compliance level. Some states have taken the irrational position that they can enforce permit limits using measurements below the quantitation level, at a level where the method cannot reliably determine the quantity of pollutant present, but that is a separate issue from determining the correct quantitation level in the first place. IIAG is concerned that an incorrect quantitation level will cause penalties to be assessed for apparent "violations" of NPDES permits that are really due to instrument "noise."

Since the quantitation level of an analytical method serves as a compliance level when a water quality standard-based permit limit is lower than the quantitation level (and thus cannot be reliably measured), it is extremely important that it be determined in a scientifically sound way. Compliance limits set at the extremely low levels at which some analytical methods are capable can be enormously expensive. Treating water with PCBs down to the level at which water quality standards are being set, for example, might cost a single facility $3,500,000 in capital costs and $600,000 per year in operating costs, depending on flows, concentrations, type of facility, and whether or not sanitary sewage flows are included.

In a larger sense, this issue involves the principle that analytical methods must be properly "validated" before they are approved in 40 C.F.R. Part 136 for use in the Clean Water Act regulatory program. Measurements of environmental pollution are at the heart of the regulatory program. Regulatory decisions can only be as good as the quality of the measurements (the data) on which they are based.

EPA seems to have accepted the idea that it should "validate" an analytical method by testing it under controlled conditions in a variety of labs, but EPA's rules for validation, particularly its criteria for deciding when a method has been adequately validated, are not

entirely clear to the regulated community. EPA needs to articulate a more systematic decision process for validating analytical methods, and this should include an appropriate procedure for determining the variability of test results among multiple laboratories, known as "interlaboratory" variability.

2. The Proper Use of WET Methods Needs to Be Clarified

The WET Coalition has asked the D.C. Circuit Court of Appeals to review EPA's approval of WET test methods. *Edison Elec. Institute v. EPA*, No. 96-1062 (D.C. Cir.). More recently, EPA proposes to approve an additional WET method, known as Microtox 1010, using bacteria as test organisms. 69 Fed. Reg. 18,171 col. 3 (April 6, 2004). Because of the inherent variability of test organisms, special precautions should be taken when using WET test results in legal decisions.

Apart from the litigation in the D.C. Circuit, EPA is drafting guidance on using WET methods to make regulatory decisions. One such guidance document, still being prepared, we understand will address using WET tests to make the "reasonable potential" decision, which determines whether an NPDES permit limit is required for "toxicity," and perhaps other WET issues as well.

There are many unresolved technical issues about the proper use of WET test methods to make regulatory decisions. Many of those issues are embodied in a statement of principles developed by WET Coalition members in connection with the D.C. Circuit litigation, which is attached to these comments.

The use of WET test methods to generate "toxicity" data on which regulatory decisions are based goes to the heart of the issue of quality data. It goes also to the issue of wise use of resources. Many thousands of dollars can be spent investigating "phantom" toxicity revealed only by the failure of a WET test.

Compliance with environmental law and permit limits is a serious matter, and it is taken seriously by WET Coalition members. Given the potential for false positives and variability in WET test methods, we believe that EPA should not use WET methods as legal limit. We would prefer to reach agreement on a workable solution with EPA. However, we have been discussing this issue with EPA for years, without a great deal of success. It is our hope that OMB can act as an objective third party to review our claims and bring resolution to this longstanding dispute.

Accordingly, the IIAG and WET Coalition ask OMB to address the proper validation and use of WET test methods in the regulatory process. We also ask OMB to address EPA's need to recommend or promulgate safeguards for using WET test results to support regulatory decisions.

3. A Systematic Program for Developing and Validating Analytical Methods

Both the above issues are part of a larger, systemic issue about making EPA's approach to measurement issues clear to the public and the regulated community. EPA has published a number of guidelines and protocols for writing and approving test methods, including alternate test procedures under 40 C.F.R. 136.4 and .5. See http://www.epa.gov/ost/methods/. Nevertheless, EPA's process for deciding what analytical methods to develop and what ones to approve is not transparent to the outside world, and disputes with the regulated community over how to validate methods and how to use them to make compliance decisions have consumed enormous resources for a decade or more. EPA would benefit, first, from a systematic process for determining what analytical methods need to be developed for regulatory use and, second, from formal criteria for approving analytical methods, once developed, for incorporation into 40 C.F.R. Part 136. To give just one example, EPA has recently justified approving new methods by comparing their variability to the variability of methods that have been approved in the past, without ever adequately justifying the past approvals in the first place. See EPA Protocol for EPA Approval of New or Alternate Test Procedures for Whole Effluent Toxicity 30 (Draft of January 1998). This is one of the issues in the challenge to WET methods in the D.C. Circuit Court of Appeals.

The IIAG and WET Coalition urge OMB to address the issue of how EPA could make more transparent its process for deciding what analytical methods to develop and then for validating them for regulatory use. This might also be an opportunity to address how EPA's use of analytical methods can be made more consistent from one EPA office to another and more consistent with international standards.

Yours very truly,

James N. Christman
for
Inter-Industry Analytical Group
WET Coalition

Attachment

May 30, 2003

Permit Writing and Enforcement

A. Permit Requirements that Would Be Enforceable But Still Account for the Variability and Lack of Accuracy of WET Methods

1. Where WET testing is necessary, a "tiered" or "stepwise" approach to WET testing must be prescribed for both compliance testing and "reasonable potential" decisions.

a. Step 1: Characterize the effluent

i. WET monitoring must be required for some specific time interval (e.g., one year) to characterize the effluent and to establish the baseline toxicity level and the need for WET triggers.

ii. At the end of this effluent characterization period, it must be determined whether the performance standards have been met for acute or chronic toxicity or both, using the following criteria:

- For acute tests: Develop a more realistic approach to determining reasonable potential which employs such items as actual CVs, considers "less-than" values as zeros, does not use assumed relationships of data such as the LC1/LC50 ratio, and appropriately considers the use of the CV with the average values and not the maximum value in the dataset.

- For chronic tests: There must be no detectable chronic toxicity (determined using detection limits) at an effluent concentration representing the edge of the mixing zone.

- EPA's procedures should not preclude the alternate use of Percent Effect approaches.

iii. If the effluent does not meet these performance standards, WET permit triggers must be required.

b. Step 2: Set the WET Triggers

i. Acute trigger: The permit trigger must be the LC_{50} at the compliance point concentration. This would constitute the numeric acute limit.

ii. Chronic triggers:

- Chronic triggers must be used only as a guide for further analysis

- The chronic trigger must be set at a level ensuring, with 99% confidence, that the response measured is different from responses observed in non-toxic exposures.

  For example, for the fathead minnow (based on EPA's interlaboratory validation study data), the mortality must be >17%, and the growth effects compared to controls must be >27%.

- Alternatively, express chronic triggers as an average and a maximum value for each endpoint.

  For example, for the fathead minnow survival endpoint (based on EPA's interlaboratory validation study data), the average mortality must be > 12% at a 95% confidence level, and the maximum mortality must be >17% at a 99% confidence level.

c. Step 3: Actions to be taken if a WET test is failed:

  i. Failure of an acute test:

  - Retest within 30 days.
  - If the second test is failed, develop and implement a TIE/TRE.
  - If the second test is passed, resume normal testing.

  ii. Failure of a chronic test:

  - If the trigger is set at a 99% confidence level for each endpoint:
    - Perform two additional tests within six weeks of collecting the sample for the original test.
    - If at least two out of the three total tests fail, develop and implement a TIE/TRE.
    - If the permittee passes at least two out of the three tests, resume normal testing.
  - If the trigger is set as an average and a maximum:
    - If a test result exceeds the "maximum" trigger, develop and implement a TIE/TRE.
    - If a test result exceeds the "average" trigger:
      - If the permittee performs additional testing and the average of the test results exceeds the average trigger, develop and implement a TIE/TRE.

- If the permittee does *not* perform additional testing, develop and implement a TIE/TRE.

- If the permittee performs additional testing and the tests do *not* exceed the average trigger, resume normal testing.

d. "Off-ramps" from a TIE/TRE

i. If the permittee cannot identify the cause of toxicity within 18 months of implementing a TIE and there have been no further test failures, end the TIE and resume the normal testing schedule.

ii. If the permittee continues to fail WET tests but is unable to identify the cause of toxicity within 18 months after implementing an exhaustive TIE plan and applying appropriate influent and effluent controls, special technical evaluation with the assistance of EPA or the state will be warranted and civil penalty relief granted.

iii. If WET tests are failed but no pattern of toxicity can be found, require additional monitoring of effluent or the receiving stream to provide data to determine appropriate actions. A TIE is not appropriate and must not be required absent a pattern of toxicity.

2. For special situations, WET requirements in permits should be risk-based.

a. For storm water and other intermittent discharges, WET testing is not appropriate.

b. For effluent-dominated streams, a WET requirement must not be imposed if it will cause the discharger to eliminate the discharge and with it the habitat it provides.

c. EPA must advise permitters that WET requirements for *small* discharges to *large* waterbodies may not be appropriate.

B. Enforcement of WET Permit Requirements to Avoid Unfairness

1. Acute Test Failure

a. Failure of one acute test must not be a "violation" of an NPDES permit unless there is demonstrable instream effect.

b. Failure of two acute tests remote in time (for example 3-5 years apart) must not be a violation.

c. Failure of two consecutive acute tests, on the other hand, can be violation unless the permittee demonstrates no instream effect or that the test results reflect conditions that were beyond the permittee's control.

2. Chronic Test Failure

a. Failure of a chronic test must never, by itself, be the basis for a violation.

b. Failure of chronic tests may be a "violation" where the test results, considered with other evidence, indicate environmental toxicity.

c. Failure to comply with accelerated testing or a TIE/TRE is a violation. If a permittee fails to complete any step required by the permit on time, its failure is a violation of the permit.

May 30, 2003

Changes to the WET Test Methods

1. **Specify a detection limit for each WET test and each endpoint that protects against false positives due to inherent variability in organism response.**

   Having a detection limit would be analogous to the MDL for traditional chemical methods. The current lack of detection limits for WET is, in our view, a critical flaw in the effort to transform WET from a tool for investigative work into enforceable NPDES permit conditions. Therefore, detection limits are critical to being able to utilize WET data fully.

2. **Abandon hypothesis testing as a stand-alone or primary determinant of WET.**

   a. EPA might retain hypothesis testing, but only to confirm results obtained by point-estimation or direct measurement of biological effect.

   b. Results from hypothesis testing must never be used by themselves for "reasonable potential" determinations, limit derivation, or numeric limit compliance.

3. **Develop parametric point estimation models that work for all test endpoints and generate reliable confidence intervals.**

   a. None of EPA's models for continuous data is parametric. Some methods, such as the IC_p, assume that there is no fixed mathematical relationship among testing concentrations but require a monotonic relationship between concentrations. This requirement forces data into a model that cannot reliably represent them. EPA should provide parametric alternatives such as general linearized models.

   b. In 1995 EPA recommended using point estimates (rather than NOECs) because confidence intervals can be placed around a point estimate (see 60 Fed. Reg. 53,539). In the final 2002 WET methods, however, EPA's method of calculating point estimates often fails to generate appropriate confidence intervals. EPA accepts this failure on the basis that confidence intervals are not reported in the Permit Compliance System or used to determine compliance. Confidence intervals should be used to account for the test result uncertainty when determining compliance.

4. **Require a dose-response relationship.**

   a. EPA must include a statistically-based procedure in the methods to define this relationship and require the presence of this relationship to identify valid tests when toxicity is indicated in at least one dilution.

Chapter 4 of EPA's guidance document, *Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing* (EPA 821-B-00-004 July 2000), describes how to evaluate ten data patterns. This would be the first step to be used with all data patterns. For example, WET data with a series of dilutions could be subjected to a linear regression analysis. A dose-response relationship would be inferred only if the slope of the regression line is negative and significantly different from zero at the 95% probability level. Retesting when a WET test does not meet this criterion must be required to determine the presence of toxicity.

b. Some test results should be declared anomalous.

The evaluation of some of the data patterns in Chapter 4 of the *Method Guidance* should be reevaluated and the reporting conditions changed. For example, we have specific technical problems with the fifth and sixth patterns in Chapter 4.

5. Withdraw the Federal Register language recommending the "West Coast methods" for limited, localized, or regional use (67 Fed. Reg. 69,955 col. 1-2 (Nov. 19, 2002)).

EPA did not approve the "West Coast methods" (e.g., *Holmesimysis costata*) because it did not have a minimum of six laboratories qualified and willing to perform the tests as part of the Interlaboratory Validation Studies. EPA should not support the use of test methods that have not been validated or approved for inclusion in Part 136.

6. Restore the method for calculating growth endpoints that was proposed in 1989.

a. In the 1995 version of the chronic methods, EPA adopted a procedure that was different from the procedure proposed for comment in 1989. The new procedure calculates growth based on the number of organisms starting a test instead of those surviving the test as in the 1989 proposal.

b. There is nothing in the record to show that sublethal endpoints need to be more sensitive. There was no comment from the public or scientific community urging EPA to make this change.

7. Add Data Quality Objectives (DQOs) to the WET methods.

Data Quality Objectives (DQOs), particularly "acceptance criteria," are necessary to determine whether WET monitoring data are suitable for their intended purpose. (This principle is discussed by EPA in its Guidance for the Data Quality Objectives Process, EPA QA/G-4 (August 2000), and in EPA Order 5360.1-A2, which requires EPA to establish DQOs.) For WET test method results to be

sufficiently reliable for regulatory use, they must satisfy several DQOs, including mandatory testing protocols. EPA should do the following:

a. Require the use of WET Data Acceptance Criteria which address the same QA/QC issues raised in the attached checklist.

b. Identify national norms for all QA/QC metrics and establish acceptable ranges which must be met to validate sample results.

c. Clarify that inconsistent results from split samples are not a violation but instead may trigger additional testing.

d. Explain how to interpret results when stress and test interferences (pH shift, pH shock, ionic imbalance, or pathogens) are suspected, particularly when the problem cannot be eliminated entirely.

e. Revise the test acceptance criteria to account for natural sources of biological stress.

f. Provide upper and lower limits for the response of *controls* (nontoxic water).

    i. This would preclude unrepresentative organisms from influencing test results.

    ii. The upper and lower limits must be identified from control charts kept by each laboratory.

    iii. Keeping such charts and identifying upper and lower limits must be a mandatory QC requirement.

    iv. The upper and lower limits will be defined by a 95% confidence interval.

g. A reference toxicant which demonstrates that the control population of organisms is responding according to historical testing.

h. The IC_{25} can only be used with the current statistical program if all approved parametric models do not fit the data and there is a reliable dose-response curve.

EXAMPLE of WET DATA ACCEPTANCE CHECKLIST

#	Acceptance Category	Data Validation Criteria	Action for Non-Conformance
1	Sampling	Was sample a 24-hour composite?	If "No," Retest with composite sample (or equivalent).
2	Sampling	Was sample taken from official permit compliance location (discharge outfall)?	If "No," Retest with sample taken at approved discharge location.
3	Sampling	Was sample bottle pre-rinsed 3-times prior to filling with effluent sample?	If "No," Re-test optional.
4	Sampling	Was sample bottle filled and sealed with minimal head space?	If "No," Re-test optional.
5	Sampling	Was sample temperature <4°C when it arrived at the laboratory?	If "No," Invalid sample; Re-test required.
6	Protocol	Was sample first used within the maximum allowed holding time (<36 hours after it was collected)?	If "No," Invalid sample; Re-test required.*
7	Protocol	Was dilution water chemistry within EPA specifications (alkalinity, hardness, conductivity, pH)?	If "No," Invalid test conditions; Re-test required.*
8	Protocol	Did organisms selected for inclusion in the toxicity test meet EPA age requirements?	If "No," Invalid test conditions; Re-test required.
9	Protocol	Did organisms selected for inclusion in the toxicity test meet EPA requirements for parental productivity?	If "No," Invalid test conditions; Re-test required.
10	Protocol	Were test organisms randomly-distributed according to EPA's recommendations for "blocking-by-parentage?"	If "No," Invalid test conditions; Re-test required.
11	Protocol	Did all test conditions comply with EPA's required protocols for temperature, dissolved oxygen, and feeding.	If "No," Invalid test conditions; Re-test required.*
12	Sensitivity	Was the most recent reference toxicant test within laboratory control limits?	If "No," Invalid test; Re-test required.
13	Sensitivity	Was the most recent valid reference toxicant test completed less than 30-days prior to the completion of the WET test?	If "No," Invalid test; Re-test required.
14	Sensitivity	Did the toxicity test meet EPA's minimum significant difference (MSD) criteria?	If "No," Invalid test; Retest required if MSD exceeded and test passed.
15	Sensitivity	Was the coefficient-of-variation for inter-replicate response among controls <40%?**	If "No," Invalid test; Re-test required.

** Deviations from some test conditions may be conditionally-accepted if approved by the permitting authority.*

*** North Carolina procedures as described in EPA's new WET guidance (June , 2000, appendix E & F)*

WHOLE EFFLUENT TOXICITY DATA ACCEPTANCE CHECKLIST *(continued)*

#	Acceptance Category	Data Validation Criteria	Action for Non-Conformance
16	Termination	Was the test terminated no less than 7 days or more than 8 days after the test was initiated?**	If "No," Invalid test; Re-test required.
17	Termination	Did 80% of control organisms produce at least three broods?**	If "No," Invalid test; Re-test required.
18	Results	Was reproduction calculated using only offspring from the first three broods?	If "No," Recalculate statistics using only first 3 broods.
19	Results	Was there a statistically-significant increase in mortality at all concentrations greater than or equal to the maximum permitted instream waste concentration (@99% confidence)?	If "No," then Not-Toxic If "Yes," probable toxicity when corroborated by a valid dose-response relationship.
20	Results	Was there a statistically-significant reduction in reproduction at all concentrations greater than or equal to the maximum permitted instream waste concentration (@99% confidence).	If "No," then Not-Toxic If "Yes," probable toxicity when corroborated by a valid dose-response relationship.
21	Corroboration	Is there a valid concentration response relationship confirmed by a statistically significant negative slope coefficient in a linear regression equation (@ 99% confidence)?	If "No," Sample is not certifiably toxic.
22	Corroboration	Was a statistically-significant increase in mortality corroborated by a statistically significant reduction in reproduction?	If "No," Inconsistent results; re-testing optional.
23	Corroboration	Do the NOAEC and IC-25 both confirm the presence of toxicity?**	If "No," Inconsistent Results; Report all results, unable to certify noncompliance.
24	Corroboration	If available, do identical split samples agree on the presence of toxicity at the maximum permitted instream waste concentration?	If "No," Inconsistent results; Report both tests, unable to certify noncompliance.
25	Anomalies	Was the mean control reproduction at least 15 but not more than 30 offspring per female?	If "No," Test out of control; Optional re-test.
26	Anomalies	Was the inter-replicate coefficient-of-variation abnormally low for control organisms?	If "Yes," Test out of control; Optional re-test.
27	Anomalies	Was the estimated IC-25 miscalculated due to bias introduced by required "data smoothing?"	If "Yes," recalculate IC-25 using 3-parameter logistic regression.
28	Anomalies	Was the reported toxicity test result likely to be an outlier as defined by the ASTM *h* and *k* statistics?	If "Yes," Optional re-test.