UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

MAY 28 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Enforcement Response Policy for TSCA §4 Test Rules

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the final Enforcement Response Policy (ERP) for TSCA §4 Test Rules. This ERP addresses test rules only. A separate ERP was issued by the Office of Compliance Monitoring (OCM) on April 9, 1985 to address violations of the TSCA §4 Good Laboratory Practices Rule which appears at 40 CFR Part 792. The interim final rule for test rules appears at 50 FR 20652 (May 17, 1985) and amends 40 CFR Part 790 which was published in the Federal Register on October 10, 1984 (49 FR 39774).

Thank you for reviewing and commenting on the draft policy. The comments and responses are attached for your information. If you have any questions concerning the ERP, please call Richard Green of my staff at (FTS) 382-5567.

Attachments

MAY 28 1986

ENFORCEMENT RESPONSE POLICY

FOR TEST RULES UNDER

SECTION 4 OF THE

TOXIC SUBSTANCES CONTROL ACT

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ENFORCEMENT RESPONSE POLICY FOR TSCA §4 TEST RULES

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TSCA SECTION 4 TEST RULES

ENFORCEMENT RESPONSE POLICY

OVERVIEW

Under section 4 of the Toxic Substances Control Act (TSCA), EPA is authorized to promulgate rules which require that selected chemical substances or mixtures be tested to evaluate concerns for specific effects on human health or the environment. The Agency shall promulgate a TSCA §4 test rule if it finds that a) the substance or mixture may present an unreasonable risk of injury to health or the environment or b) it enters or may enter into the environment in substantial quantities or it poses or may pose significant human exposure. EPA must also find that there are insufficient data and experience to reasonably determine health and environmental effects and that testing is necessary to develop such data.

APPLICABILITY

Specific Chemical Substance and Mixture Test Rules (40 CFR 799) apply to persons who manufacture or intend to manufacture (including import) and/or persons who process or intend to process specific chemical substances or mixtures identified in 40 CFR 799, Subpart B during the period commencing with the effective date of the specific test rule until the end of the reimbursement period. Each set of testing requirements in Subpart B specifies whether those requirements apply to manufacturers, processors, or both. This policy does not address violations which are associated with good laboratory practice (GLP) requirements for these specific test rules. However, the Office of Compliance Monitoring (OCM) issued a separate enforcement response policy on April 9, 1985 to address GLP violations.

LEVELS OF ACTION

NOTICES OF NONCOMPLIANCE (NON)

All notices of noncompliance will involve minor violations of the TSCA §4 test rule which are not considered substantive.

An example would be the submission of a timely letter of intent to conduct testing or a timely request for exemption from testing for each required test but failure to provide all the required information. However, the submitter provides the additional information to the Office of Toxic Substances (OTS) by a date acceptable to and specified by OTS.

CIVIL PENALTIES

Assessment of civil penalties will be appropriate for most violations of a TSCA §4 test rule. Specific violations are addressed in the ASSESSMENT OF CIVIL PENALTIES section under the CIRCUMSTANCES subsection.

CRIMINAL SANCTIONS

In some instances, the magnitude of a particular violation or the number of repeat offenses will warrant the use of criminal sanctions under TSCA §16 or 18 U.S.C. 2 or 1001.

Several factors distinguish criminal cases from administrative or civil actions. First, criminal sanctions will ordinarily be limited to cases in which the violation is accompanied by evidence of "guilty knowledge" or intent on the part of the responsible party. TSCA imposes criminal penalties only for violations of the Statute which are "knowingly or willfully" committed. For example, criminal prosecution may be appropriate where manufacturer or processor management personnel make a decision to violate the TSCA §4 test rule by falsifying data or intentionally concealing data through omission or selective reporting.

ASSESSMENT OF CIVIL PENALTIES

EPA will assess penalties against each manufacturer or processor in violation of a TSCA §4 test rule. The following Gravity-Based Civil Penalty (GBP) Matrix will be applied when assessing civil penalties.

GRAVITY-BASED PENALTY MATRIX

	Extent of Potential Damage		
Circumstances (probability of damages)	A Major	B Significant	C Minor
High Range:			
1	$25,000	17,000	5,000
2	-	-	-
Mid Range:			
3	15,000	10,000	1,500
4	10,000	6,000	1,000
Low Range			
5	5,000	3,000	500
6	2,000	1,300	200

The following general criteria will be applied in making Gravity Based Penalty determinations for violations of TSCA §4 test rules.

NATURE

All violations of TSCA §4 test rules will constitute "hazard assessment" violations, as defined in the TSCA Civil Penalty Policy (45 FR 59771, September 10, 1980).

EXTENT

The TSCA Civil Penalty Policy provides for three measures of the extent of a violation: Major, Significant, and Minor. Extent is used to take into consideration the degree, range, or scope of the violation. The criteria are generally based upon the disruption to an EPA review due to the increased time to generate acceptable data. The following criteria will apply to this consideration:

A) Major - Studies requiring at least 90 days to perform. Examples would include two-year bioassays and avian reproduction tests.

B) Significant - Studies requiring at least 14 days but less than 90 days to perform. Examples would include a 21-day Daphnid chronic toxicity test and a 21 to 42 day hen acute delayed neurotoxicity test.

C) Minor - Studies requiring less than 14 days to perform. Examples would include a 48-hour EC50 Daphnid acute toxicity test and a rat oral LD50 test.

Note: The time periods are the time spent in the laboratory exclusive of the time spent to write reports, analyze data, etc.

CIRCUMSTANCES

The matrix retains five levels of the "Circumstances" axis. The following criteria will apply to this consideration.

1) High Range (Level 1) - Violations which seriously impair the Agency's ability to evaluate the hazards of chemicals. Level 1 violations include the following categories:

Level 1

(1) Falsification of submitted data.

(2) Failure to test.

(3) Failure to complete required testing after making a commitment to conduct testing.

(4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the failure seriously impairs the Agency's ability to evaluate the substance (GLP violations addressed in a separate ERP).

(5) Failure to submit letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.

(6) Submitting a letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.

2) Middle Range (Levels 3 and 4) - Violations which impair the Agency's ability to evaluate chemicals in an important but less than critical way. Level 3 and 4 violations include the following categories:

Level 3

(1) Completing a study but submitting it to EPA more than 30 days after the required date without having an EPA written approved modification to the schedule.

(2) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is impaired in an important but less than critical way.

(3) Failure to submit study plans or submitting study plans more than 30 days after the required date taking into consideration any extensions approved in writing by EPA.

(4) Submitting letters of intent to test or submitting a valid request for exemption from testing more than 30 but within 60 days after the letter of intent to test is required.

Level 4

(1) Failure to submit or submitting interim progress reports more than 30 days after the documents are required.

3) Low Range (Levels 5 and 6) - Violations which minimally impair the Agency's ability to evaluate the hazards of a chemical. Level 5 and 6 violations include the following categories:

Level 5

(1) Completing a study and submitting it to EPA more than 15 but within 30 days after the required date but without an EPA written approved modification to the schedule.

(2) Submitting a letter of intent to test or valid request for exemption from testing more than 15 but within 30 days after the letter of intent to test is required.

(3) Submitting study plans, interim progress reports or submitting final reports more than 15 but within 30 days after the required date without an EPA written approved modification to the schedule.

(4) Initiating a study after the date indicated in the approved study plan without an EPA written approved modification to the schedule but the final report is submitted by the required date and accepted by EPA (late initiated studies resulting in late final reports shall be dealt with as late final reports or late study submissions).

(5) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is minimally impaired.

Level 6

(1) Categories 1, 2, and 3 described under Level 5 above if submitted not more than 15 days after the required date.

CONTINUING VIOLATIONS

Under section 16 of TSCA, EPA may assess penalties for each day a violation continues. Per day assessments will apply when the gravity of the violation warrants a higher penalty than can be assessed through a single day penalty assessment.

Continuing violations include the following categories described in the CIRCUMSTANCES subsection of this ERP:

(1) Falsification of data.

(2) Failure to test.

(3) Failure to complete tests after making a commitment to conduct testing.

(4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in a serious impairment or impairment in an important but less than critical way of the Agency's ability to evaluate the substance.

(5) Failure to submit or late submission of letters of intent to test after required date.

(6) Failure to submit valid requests or submission of invalid requests for exemption from testing after the letter of intent to test is required.

The period of violation should apply from the date the violative action begins to the date EPA grants a modification to the standards or schedule. The number of days for the violation shall be calculated based on the number of days a manufacturer manufactures (imports); or when a processor is required to test, the number of days a processor processes a substance during the entire violative period. When a person both processes and manufactures during the violative period, the number of days shall be based on the greater of the two (either processing or manufacture only when the test rule requires manufacturers and processors to test. If the rule requires only the manufacturer to test, then the violative period is based on the days of manufacture. If a single batch is manufactured or processed in more than one day, each batch shall be calculated as one day in violation, except for continuous operations. Two or more batches manufactured or processed in a single day at the same site shall be calculated as one day in violation.

MULTIPLE VIOLATIONS

Multiple violations will apply to situations where a single manufacturer or processor, or consortium commits to perform more than one test required by a TSCA §4 test rule. Each test found with violations shall warrant the assessment of a separate penalty.

Multiple violations include all of the categories described in the CIRCUMSTANCES subsection of this ERP except for certain instances involving failure to submit study plans. A multiple violation situation shall not exist for study plans if they address all required tests under one test rule and are submitted at the same time by one company or consortium.

ADJUSTMENT FACTORS

Once the GBP has been determined, upward and downward adjustments to the penalty amount may be made in consideration of culpability, history of violations, ability to pay, and such other matters as justice may require. EPA will apply these adjustment factors as described in the TSCA Civil Penalty Policy (45 FR 59770, September 10, 1980). Considerations unique to TSCA §4 test rules are discussed below.

1. Voluntary Disclosure

Penalty reductions up to 25% will be applied for voluntary disclosure of violations by manufacturers or processors subject to a TSCA §4 rule. To be eligible, a manufacturer or processor must make the disclosure prior to being notified of a pending inspection and prior to EPA receiving any information relating to the alleged violation. This reduction may be made in calculating the proposed penalty before issuing a civil complaint. The complaint should state the original penalty, the reduced penalty, and the reason for reduction. All other reductions in the GBP should be made after the complaint is issued.

2. Immediate Voluntary Disclosure

In cases where manufacturers or processors subject to a TSCA §4 rule report potential violations to EPA within 30 days of having reason to believe that they may have a violation, additional penalty reductions up to 25% may be applied.

3. Gains from Noncompliance

Noncompliance with a TSCA §4 test rule may enable a person to accrue significant economic gains, since the responsible party may not expend the necessary funds to properly conduct the required testing or to conduct the test at all. Gains may also be realized because EPA does not regulate many substances or mixtures until required testing is submitted and evaluated. Therefore, the penalty policy specifies that violations likely to result in economic gain result in level 1 penalty calculations for each day the chemical is manufactured, processed or imported. The extent category for level 1 violations depends on the type of study, i.e., chronic, subchronic, or acute and is therefore relative to the costs for such tests. In settling cases, the Agency should assure that the final penalty is greater than the economic gain.

N - Hazard Assessment only

CIRCUMSTANCES	EXTENT OF POTENTI MAGE MAJOR	SIGNIFICANT	MINOR
LEVEL 1 *+ 1) Falsification of submitted data *+ 2) Failure to test *+ 3) Failure to complete required tests after making commitment to conduct testing *+ 4) Failure to adhere to test standard r failure to obtain writt EPA approval on modifications to test standards befo which ults in an OTS determination that the Agency's ability ubstance is seriously impaired *+ 5) Failure to submit letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required *+ 6) Submitting a letter of intent to test more than 60 days after the required date + 7) Submitting a valid request for exemption more than 60 days after the letter of intent to test is required	$25,000	$17,000	$5,000
LEVEL 2	-	-	-
Level 3 + 1) Completing a study but failing to submit it to EPA more than 30 days after the required date without having an approved modification to the schedule + 2) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is impaired in an important but less than critical way 3) Failure to submit study plans**or submitting study plans more than 30 days after the required date taking into consideration any extensions approved in writing by EPA +* 4) Submitting a letter of intent to test more than 30 but within 60 days after the required date + 5) Submitting a valid request for exemption from testing more than 30 but within 60 days after the letter of intent to test is required	$15,000	$10,000	$1,500
LEVEL 4 + 1) Failure to submit or submitting interim progress reports more than 30 days after the documents are required	$10,000	$ 6,000	$1,000
LEVEL 5 + 1) Completing a study and submitting it to EPA more than 15 days but within 30 days after the required date but without an approved modification to the schedule *+ 2) Submitting a letter of intent to test more than 15 but within 30 days after the required date + 3) Submitting a valid request for exemption from testing more than 15 but within 30 days after the letter of intent to test is required + 4) Submitting study plans**, interim progress reports or submitting final reports more than 15 days but within 30 days after the required date without an EPA written approved modification to the schedule 5) Initiating a study after the date indicated in the approved study plan without an EPA written approved modification to the schedule but the final report is submitted by the required date and accepted by EPA 6) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is minimally impaired	$ 5,000	$ 3,000	$ 500
LEVEL 6 + 1) Same as numbers 1, 2*, 3, or 4 under level 5 violations except submitted within 15 days after the required date	$ 2,000	$ 1,300	$ 200

* Subject to Continuing Day Assessment

\+ Subject to Multiple Violation factor

** A multiple violation situation shall not exist if study plans to address all required tests are submitted at the same time under one test rule by one company or consortium