

### Sulfuric Acid Mist From Existing Sulfuric Acid Plants

#### § 62.9110 Identification of sources.

(a) *Identification of sources:* The plan includes the following sulfuric acid production plants.

(1) National Zinc Co. in Bartlesville, Oklahoma.

(2) Tulsa Chemical Co. in Tulsa, Oklahoma.

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### 40 CFR Part 421

[OW-FRL-3149-8]

### Nonferrous Metals Manufacturing Point Source Category; Effluent Limitations Guidelines for the Primary Rare Earth Metals Subcategory

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; removal.

**SUMMARY:** On September 20, 1985 the EPA promulgated a final regulation establishing best practicable control technology currently available (BPT), best available technology economically achievable (BAT), new source performance standards (NSPS), pretreatment standards for existing sources and pretreatment standards for new sources (PSES and PSNS) for the Nonferrous Metals Manufacturing industry under the Clean Water Act. One August 4, 1986, portions of the final regulation establishing BPT and BAT for the Primary Rare Earth Metals subcategory were remanded to the EPA by the Third Circuit Court of Appeals with directions to vacate those portions of the regulations. EPA is today removing those portions of the regulation from the Code of Federal Regulations so as to inform the public that the regulation is no longer effective.

**EFFECTIVE DATE:** The remand of these portions of the Nonferrous Metals Manufacturing regulation is effective as of August 4, 1986, the date of the Court's order.

**FOR FURTHER INFORMATION CONTACT:** Eleanor Zimmerman, 202-382-7126.

**SUPPLEMENTARY INFORMATION:** On September 20, 1985, EPA issued a final rule entitled "Nonferrous Metals Manufacturing Point Source Category; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule," published at 50 FR 38276. That rule limited the discharge of pollutants into navigable waters of the United States and into publicly owned

treatment works by existing and new nonferrous metals manufacturing facilities that process ore concentrates and scrap metals to recover and increase the metal purity contained in those materials. Specifically, the Agency established best practicable control technology currently available (BPT) effluent limitations guidelines, best available technology economically achievable (BAT) effluent limitations guidelines, new source performance standards (NSPS), and pretreatment standards for existing and new sources (PSES and PSNS) in the nonferrous metals manufacturing regulation.

Several parties filed petitions in the Court of Appeals challenging various aspects of this regulation. *AMAX INC., et al., v. EPA* (85-3580). One petitioner in particular, Reactive Metals & Alloys Corp. (Remacor), submitted an issues list raising *inter alia* procedural issues with respect to the promulgation of limitations in the Primary Rare Earth Metals subcategory. Remacor is the only known existing direct discharger in this subcategory and, hence appears to be the only facility subject to the BPT and BAT requirements within the subcategory. In reviewing Remacor's issue list, the Agency found that formal written responses to Remacor's comments on both the proposed rule (49 FR 26352) and the notice of data availability (50 FR 10918) had not been prepared or placed in the record. The Agency, therefore, determined to seek a remand of those portions of the rulemaking affecting Remacor.

The Agency and Remacor filed a Joint Motion for Voluntary Remand of the regulation in the Third Circuit Court of Appeals. On August 4, 1986, in response to the Joint Motion, the Court remanded the regulations at 40 CFR 421.272 and 40 CFR 421.273 with instructions to vacate those provisions.

Today's rulemaking formally removes the BPT and BAT limitations for the Primary Rare Earth Metals Subcategory (40 CFR 421.272 and 421.273) from the Code of Federal regulations. These effluent limitations have not been effective since August 4, 1986, the date the Court remanded these limitations.

Today's action does not in any way affect other limitations and standards established for the Nonferrous Metals Manufacturing Category which were published on September 20, 1985. These other limitations are still effective.

#### List of Subjects in 40 CFR Part 421

Metals, Nonferrous metals, Waste treatment and disposal, Water pollution control.

Dated: January 27, 1987.

Lee M. Thomas,  
Administrator.

For the reasons stated above, 40 CFR Part 421 is amended as follows:

### PART 421—NONFERROUS METALS MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 421 continues to read as follows:

Authority: Secs. 301, 304(b), (c), (e), and (g), 306(b) and (c), 307(b) and (c), 308, and 501 of Federal Water Pollution Control Act as amended (the "Act"); 33 U.S.C. 1251, 1311, 1314(b), (c), (e), and (g), 1316(b) and (c), 1317(b) and (c), and 1361; 86 Stat. 816, Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

#### § 421.272 [Removed and Reserved]

2. Section 421.272 is removed and reserved.

#### § 421.273 [Removed and Reserved]

3. Section 421.273 is removed and reserved.

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### 40 CFR Part 799

[OPTS-42012D; FRL-3150-7]

### Diethylenetriamine; Final Test Standards and Reporting Requirements

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** On May 23, 1985, EPA issued a final rule under section 4(a) of the Toxic Substances Control Act (TSCA) requiring that manufacturers and processors of diethylenetriamine (DETA; CAS No. 111-40-0) test this substance for (1) oral subchronic (90-day) toxicity in at least one mammalian species, (2) dermal absorption in the same mammalian species used for the subchronic testing, (3) chemical fate under aerobic conditions, and (4) mutagenicity (including tests for both gene mutations and chromosomal aberrations). On April 10, 1986, the Agency proposed that the study plans submitted by an industry consortium be adopted, with certain revisions, as the test standards and reporting requirements for DETA under this test rule. EPA has reviewed the public comments on this proposal, and has decided to promulgate a final rule that specifies that these revised study plans, with certain additional revisions in response to public comment and Agency review, shall constitute the test

standards and reporting requirements for DETA.

**DATES:** In accordance with 40 CFR 23.5 (50 FR 7271; February 21, 1985), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ("daylight" or "standard", as appropriate) time on February 17, 1987. This rule shall become effective on March 19, 1987.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460 (202-554-1404).

**SUPPLEMENTARY INFORMATION:** In the Federal Register of May 23, 1985 (50 FR 21398), EPA issued a final Phase I rule under section 4(a) of TSCA to require testing of DETA for (1) oral subchronic (90-day) toxicity in at least one mammalian species, (2) dermal absorption in the same species used for the subchronic testing, (3) chemical fate under aerobic conditions, and (4) mutagenicity (including tests for both gene mutations and chromosomal aberrations). The Agency is now promulgating a final Phase II rule specifying that the EPA-modified industry-submitted study plans, with certain revisions, shall constitute the test standards and reporting requirements for this testing. This test rule is being promulgated under 40 CFR 799.1575.

### I. Background

This document is part of the implementation of section 4 of the Toxic Substances Control Act (TSCA, Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to human health and the environment posed by exposure to particular chemical substances or mixtures.

Diethylenetriamine (DETA; CAS No. 111-40-0) was designated by the Interagency Testing Committee (ITC) for priority testing consideration (46 FR 28138; May 22, 1981). EPA responded to the ITC's designation by issuing a proposed test rule for DETA, published in the Federal Register of April 29, 1982 (47 FR 18386). Subsequently, in the Federal Register of May 23, 1985 (50 FR 21398), EPA promulgated a final Phase I rule requiring testing of DETA. EPA based the final testing requirements for DETA (for all effects except oncogenicity) on the authority of section 4(a)(1)(A) of TSCA. The Agency found that the manufacture, processing, use, and disposal of DETA may present an

unreasonable risk of injury to human health due to potential mutagenic, oncogenic (after transformation to a *N*-nitrosamine derivative under environmental conditions), and subchronic effects of the substance. For a detailed discussion of EPA's findings and testing requirements for DETA, refer to the final Phase I rule. In accordance with the Test Rule Development and Exemption Procedures for two-phase rulemaking in 40 CFR Part 790, persons subject to this rule were required to submit letters of intent to perform the testing or exemption applications. Those submitting letters of intent were required to submit proposed study plans (including time schedules) for the testing required in the final Phase I rule.

On August 6, 1985 (Refs. 1 through 3), three U.S. manufacturers of DETA notified EPA of their intent to sponsor the testing required in the final Phase I test rule for DETA. Subsequently, an industry consortium (composed of these three manufacturers of DETA, one future manufacturer, and other current manufacturers or importers) known as the Diethylenetriamine Producers/Importers Alliance (DPIA) submitted an initial complete set of study plans for all of the testing required for DETA on October 7, 1985, and a set of study plans containing some revisions on December 2, 1985. In the Federal Register of April 10, 1986 (51 FR 12344), EPA proposed that the study plans submitted by the DPIA on December 2, 1985, be adopted, with certain revisions [referred to as the EPA-approved modified study plans for DETA (Ref. 4)], as the test standards and reporting requirements for the testing of DETA. After review of public comments, EPA is now promulgating a final Phase II rule requiring the DPIA, or its member companies, to conduct this testing in accordance with the revised EPA-approved modified study plans for DETA (Ref. 5). These plans incorporated revisions of Ref. 4 in response to public comments and shall constitute the test standards and reporting requirements for this substance.

### II. Proposed Test Standards

The following member companies of the DPIA, Union Carbide Corporation, Dow Chemical Company, and Texaco Chemical Company, notified EPA by letter (Refs. 1 through 3) of their intent to sponsor the testing required in the final Phase I rule for DETA (40 CFR 799.1575). The DPIA, composed of the aforementioned three companies and Berol Chemicals, Inc., AZS Corporation, BASF Wyandotte Corporation, and Air Products and Chemicals, Inc., has submitted proposed study plans for the required testing, which, after evaluation,

the EPA has revised, resulting in the EPA-approved modified study plans for DETA (Ref. 4). The study plans include the following studies: Fourteen-Day (Range-Finding) Dietary Toxicity Study with Diethylenetriamine in Albino Rats, Ninety-Day (Subchronic) Dietary Toxicity Study with Diethylenetriamine in Albino Rats, Absorption/Elimination Study of Diethylenetriamine following Dermal Application in Male and Female Fischer-344 Rats, Testing to Assess the Potential Environmental Production of *N*-Nitroso Adducts of Diethylenetriamine, Sex-linked Recessive Lethal Gene Mutation Test in *Drosophila melanogaster*, and an Evaluation of Diethylenetriamine in an *In Vitro* Chromosomal Aberration Assay Utilizing Chinese Hamster Ovary Cells. In addition, should the appropriate lower-tier mutagenicity tests yield certain results for DETA, the following mutagenicity tests will also be performed: Mouse Specific Locus Test for Visible Markers, Evaluation of Diethylenetriamine in the Mouse Bone Marrow Micronucleus Test, Dominant Lethal Assay of Diethylenetriamine in CD Rats, and Heritable Translocation Assay of Diethylenetriamine in CD-1 Mice.

The EPA-approved modified study plans for all of these tests (Ref. 4) are available for inspection in the public docket for this rulemaking. The Agency had previously proposed these plans as the test standards for conducting the testing of DETA required under 40 CFR 799.1575 in the proposed Phase II test rule for DETA, published in the Federal Register of April 10, 1986 (51 FR 12344). The Agency proposed that all of the testing be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards as set forth in 40 CFR Part 792. In addition, the EPA-approved modified health effects study plans all conform to the appropriate TSCA Health Effects Test Guidelines (40 CFR Part 798) or contain justified deviations from the appropriate guidelines.

### III. Proposed Reporting Requirements

EPA proposed (51 FR 12344; April 10, 1986) the schedules contained in the EPA-approved modified study plans for DETA (Ref. 4) as the reporting requirements for DETA. The proposed reporting deadlines for the submission of final reports are essentially in agreement with those suggested by the DPIA; however, for all testing required for DETA, the Agency proposed that brief interim progress reports be submitted to EPA at consecutive 3-month intervals following the date on which each test becomes mandatory

until the submission of the final report to EPA.

Subsequent to the issuance of the proposed Phase II test rule for DETA, the Agency has decided that interim reports for the testing required for substances under section 4 of TSCA at 6-month intervals, rather than at 3-month intervals, will be sufficient to keep EPA informed of the current status of required testing and of any difficulties which the testing facilities may encounter during the course of testing. In addition, this change will also lessen the reporting burden of test sponsors. Accordingly, the final reporting requirements for the testing required for DETA will reflect a requirement for 6-month, rather than 3-month, interim testing reports.

As required by TSCA section 4(d), the Agency plans to publish in the Federal Register a notice of the receipt of any test data submitted under this test rule within 15 days after receipt of the data. Except as otherwise provided in TSCA section 14, such data will be made available for examination by any person.

**IV. Response to Public Comments**

The only comments received by the Agency in response to the proposed Phase II test rule for DETA were from the Diethylenetriamine Producers/Importers Alliance (DPIA). The major issues identified during the comment period are discussed below.

**A. Sponsorship of Required Testing**

The DPIA, a group of producers and importers and a future manufacturer of DETA organized as a special project of the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA), commented that EPA had incorrectly indicated in the proposed Phase II test rule for DETA that the DPIA itself is sponsoring the testing required for DETA in 40 CFR 799.1575. The DPIA asserts that each test has a single member company as the sponsor and, thus, neither the DPIA nor SOCMA is a sponsor of any of the tests. As the Agency stated in the proposed Phase II test rule for DETA, EPA received letters (Refs. 1 through 3) from three member companies of the DPIA on August 6, 1985, notifying the Agency of their intent to sponsor certain of the tests required for DETA. On the same date, the Agency received exemption requests (Refs. 6 through 9) from all other member companies of the DPIA for all of the testing required for DETA. Each of these exemption requests noted that another member company of the DPIA had

agreed to sponsor the testing for which the exemption was requested, and also indicated that the requester would enter into an agreement with the sponsoring companies regarding reimbursement of the sponsors' costs for testing. In addition, the revised study plans for the testing required for DETA, which were received by the Agency on December 2, 1985, were submitted by the DPIA itself rather than by the three individual member companies which had earlier indicated by letter to the Agency their intent to sponsor certain tests for this substance, and were accompanied with a cover letter from the DPIA referring to the study plans as "the DPIA study plans" (Ref. 4). Thus, from a financial and organizational point of view, the Agency asserted in the proposed Phase II test rule for DETA that the DPIA had, due to its submission of revised study plans to the Agency on December 2, 1985, notified the EPA of their agreement to sponsor the testing required for DETA in 40 CFR 799.1575, for which letters of intent to sponsor testing had been previously received from three separate member companies (Refs. 1 through 3). However, from a strictly technical point of view, the EPA agrees with the DPIA that neither the DPIA nor SOCMA is a sponsor of any of the tests required for DETA. The individual sponsoring companies of the DPIA, together with a list of the tests which each company is sponsoring, is presented here in tabular form for clarification.

For the sake of brevity however, the study plans submitted collectively to the Agency by the DPIA on December 2, 1985, as revised by EPA, shall be referred to as the EPA-approved modified study plans for DETA (Ref. 4), originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA). The study plans resulting from revisions to Ref. 4 due to public comment and Agency review shall be referred to as the revised EPA-approved modified study plans for DETA (Ref. 5), originally submitted by the DPIA.

SPONSORS OF TESTING FOR DETA

Sponsoring Co.	Test(s) sponsored
Dow Chemical Company.	Sex-linked recessive lethal test in <i>Drosophila</i> . <i>In vitro</i> cytogenetics test. <i>In vivo</i> cytogenetics test. Dermal absorption test. Chemical fate test.
Union Carbide Corporation.	Dominant lethal test. Heritable translocation test.

SPONSORS OF TESTING FOR DETA

Sponsoring Co.	Test(s) sponsored
Texaco Chemical Company.	90-Day subchronic toxicity test. Mouse visible specific locus test.

**B. Mouse Visible Specific Locus Assay**

The DPIA commented on a number of issues related to the mouse visible specific locus (MSL) assay which it believes should be discussed during the Agency's public program review of all of the then available mutagenicity data for DETA which, as described in the final Phase I test rule for DETA, published in the Federal Register of May 23, 1985 (50 FR 21398), will precede the initiation of the testing of DETA in the MSL test. The DPIA correctly comments that, by modifying the study plan contained in Ref. 4 identified as the "Mouse Specific Locus Test for Visible Markers" by changing the last sentence in section D.1. on page 4 of the study plan to read: "A laboratory with no prior experience with the test shall provide negative and positive control validation data conforming to the requirements of 40 CFR 798.2500(d)(4)(i), prior to performing the assay," the EPA is requiring that a laboratory with no previous experience with the test must create an adequate historical data base before the Agency would view the testing facility as a "qualified" or "available" one.

The DPIA further comments that an industrial testing laboratory which it consulted estimates that the cost of obtaining such control validation data would be very high [probably exceeding the cost of a 104-week rodent carcinogenicity bioassay (over 1 million dollars)], and that it is clear from the Agency's economic analysis for all of the testing required for DETA in the final Phase I test rule for this substance (50 FR at 21410; May 23, 1985) that the development of historical control data for the MSL was not considered to be included in the test requirement for the assay itself. Additionally, the DPIA requests that the proposed final Phase II test rule for DETA be amended to reflect that the development of adequate control data for the MSL assay is not included in the test requirement for the assay itself but is a precondition to the qualification of a laboratory to conduct the test.

The DPIA also suggests that EPA might use the authority of section 10(a) of TSCA to enter into contracts with or make grants to several laboratories for developing adequate control data for the MSL assay to insure that adequate and qualified testing facilities are available for the testing of substances having TSCA section 4(a) testing requirements for this assay. The DPIA asserts that the use of TSCA section 10(a) authority in this regard should not be limited to a single testing facility, since this might result in a monopoly with respect to testing in the MSL assay.

The Agency agrees with the DPIA that the issues which it has raised and which are presented above are appropriate topics, among others, to be discussed during the EPA's public program review of all of the then available mutagenicity data for DETA which, as described in the final Phase I test rule for DETA, will precede the initiation of the testing of DETA in the MSL test. The EPA also agrees with DPIA that, for a laboratory to be considered a qualified and available testing facility for the MSL assay, it must have or develop adequate control validation data in conformance to the requirements of 40 CFR 798.2500(d)(4)(i).

On the other hand, the Agency disagrees with the DPIA's assertion that a potential requirement for the development of the positive and negative control data necessary for a laboratory which has had no prior experience with the MSL assay is not an integral part of the testing requirement for DETA (or other substances subject to a similar test rule requirement) in the MSL assay. This potential requirement is clearly stated in the revised EPA-approved modified study plan for the testing of DETA in the MSL assay (Ref. 5), which conforms to the requirements for this assay described in 40 CFR 798.2500(d)(4)(i). However, this is a potential requirement, because any laboratory having previous experience with this assay will most likely already possess the required control data and, therefore, will not need to expend any additional time for financial resources to develop such data prior to the testing of DETA in the MSL assay. Thus, the development of positive and negative control data for the testing of DETA in the MSL is a potential mandatory activity contained in the requirement for this assay established for DETA in the final Phase I test rule for this substance. However, should the required testing of DETA in the MSL assay be performed by a laboratory having had previous experience with this assay, and possessing the required positive and

negative control data, development of additional control data will not be required.

The DPIA is correct in asserting that the economic analysis for the testing required for DETA contained in the final Phase I test rule for this substance did not include the cost of developing the positive and negative control data for the MSL assay. This cost was not included in the economic analysis because the Agency believes it to be highly unlikely that this expense will have to be incurred by the test sponsor for this required testing for DETA. As stated in the final Phase I test rule for this substance, the Agency believes that commercial testing facilities may decide to develop the required control data to enable them to perform this assay as these laboratories become familiar with the fact that the MSL assay is being required in many TSCA section 4(a) test rules for substances requiring testing for eliciting gene mutations.

In addition, EPA met with representatives from the U.S. Department of Energy (DOE) on October 3, 1986, to discuss the feasibility of having Oak Ridge National Laboratory (ORNL; operated by DOE) perform the MSL assay for test sponsors of chemical substances having a TSCA section 4(a) test rule requirement for this assay, should no other qualified testing facility offer this assay at the time such a requirement becomes mandatory. As outlined in EPA's summary of this meeting, ORNL already possesses the required historical control data for the MSL assay, and is capable of performing the assay for test sponsors in compliance with EPA's Good Laboratory Practice Standards. Test sponsors wishing to utilize ORNL for this purpose would contract with and reimburse ORNL directly, and would supply the additional personnel and funding required by ORNL to comply with EPA's Good Laboratory Practice Standards. As discussed at the DOE/EPA meeting, ORNL has previously performed the MSL assay for the artificial sweetener, cyclamate, in compliance with the U.S. Food and Drug Administration's (FDA's) Good Laboratory Practice Standards at an industry group's expense. Discussions at the DOE/EPA meeting did indicate that some financial issues remain to be resolved regarding ORNL's performing the MSL assay for test sponsors, but those test sponsors wishing to utilize ORNL for this purpose should discuss these issues directly with ORNL prior to EPA's public program review of all of the available mutagenicity data for substances subject to a test rule requirement for the

MSL assay. Test sponsors could then discuss with EPA the results of their preliminary contract negotiations with ORNL during the public program review. A summary of the DOE/EPA meeting held on October 3, 1986 has been placed in the docket for this rulemaking. Because of its discussion with DOE, EPA does not now contemplate exercising its authority under section 10(a) of TSCA to fund the development of the required control data for the MSL assay by a commercial laboratory. Should it become apparent that the number of substances requiring this assay as a result of TSCA section 4(a) test rules is substantial, commercial laboratories may well decide to expend the necessary funds to develop the control data to enable them to offer the assay on a commercial basis.

### C. Reporting Requirements.

The DPIA commented that the proposed reporting requirements for all of the testing required for DETA contained in the EPA-approved modified study plans for DETA (Ref. 4) are reasonable, except for those proposed for the mouse visible specific locus (MSL) assay and the heritable translocation assay. With respect to the MSL assay, the proposed reporting requirement mandated that the final report be submitted to the Agency within 62 months of the effective date of the final Phase II test rule for DETA. This proposed reporting requirement allowed 48 months for the completion of the MSL assay itself, with 14 months after the effective date of the final Phase II test rule for DETA being added to this figure for the previous completion of the required sex-linked recessive lethal assay of DETA in *Drosophila melanogaster*. A positive response in the latter assay is necessary before EPA initiates a public program review of all of the mutagenicity data on DETA available at that time to determine if the required testing in the MSL assay should be initiated (50 FR 21396; May 23, 1985). The DPIA asserts that, if the time required for EPA to conduct the public program review is for some reason prolonged, the proposed reporting requirement for the MSL assay would result in significantly shortening the 48-month time period allowed for performing this assay. Therefore, DPIA suggests that the proposed reporting requirement for the MSL assay be changed to indicate that the final report shall be submitted to the Agency within 48 months after the test sponsor has been notified of EPA's decision, after the public program review, that the required testing of DETA in this assay should be

initiated. In addition, the DPIA suggests that, should EPA decide that the initiation of testing in the MSL assay is necessary, and no testing facility willing to perform the testing in a manner consistent with test rule requirements possesses the necessary control validation data, then up to 30 months should be added to the time period allowed of the performance of the MSL assay (a total of 78 months) to allow for the development of the necessary control data.

The Agency has carefully considered these comments. Although EPA does not expect the time period required for its public program review preceding the decision on the initiation of the testing of DETA in the MSL assay to significantly shorten the 48-month period allowed for performance of this assay, the Agency does agree that the 48-month period allowed for testing would be significantly shortened under the proposed reporting requirement for this assay (Ref. 4), should some unforeseen circumstances lengthen the period required for EPA's public program review. On the other hand, as discussed in Unit IV.B. of this preamble, it is likely that the test sponsor for the MSL assay of DETA will be able to contract for this testing with the Oak Ridge National Laboratory (ORNL); or another qualified testing facility which may exist when testing is required, and, therefore, additional time and funds for the development of the necessary control data will not be required.

The Agency recognizes that scheduling problems at ORNL, or at a qualified commercial laboratory which may be offering the MSL assay at the time that this assay is required for DETA, might significantly decrease the 48-month period allowed for completion of this testing following EPA's notification of the test sponsor. However, the test sponsor for this assay will have ample time to investigate any such scheduling problem during the period from EPA's notification by industry of a positive test result for DETA in the sex-linked recessive lethal test in *Drosophila* until the time of EPA's public program review of all of the then available mutagenicity data for DETA, which, as described in the final Phase I test rule for this substance, will precede EPA's decision whether or not testing in the MSL assay should be initiated for DETA. Thus, the test sponsor may discuss any scheduling concerns with EPA during the public program review.

In view of these comments, the EPA is requiring in the final Phase II test rule for DETA that the final report resulting

from the testing of this substance in the MSL assay shall be submitted to the Agency within 48 months from the designated date contained in EPA's notification of the test sponsor by certified letter or Federal Register notice of the Agency's decision, following a public program review of all of the then available mutagenicity data for DETA resulting from a positive test result for this substance in the sex-linked recessive lethal assay in *Drosophila melanogaster*, that the required testing must be initiated. Seven interim (6-month) reports shall be submitted to the Agency, commencing at 6 months following the designated date. These reporting requirements, incorporated into the final Phase II test rule for DETA, are contained in the revised EPA-approved modified study plans for DETA (Ref. 5) and are reflected in Unit V.B. of this preamble.

With respect to the heritable translocation assay, the proposed reporting requirement (Ref. 4) mandated that the final report be submitted to the Agency within 38 months of the effective date of the final Phase II test rule for DETA. This proposed reporting requirement allowed 18 months for the completion of the heritable translocation assay itself, with 20 months after the effective date of the final Phase II rule for DETA being added to this figure for the previous completion of the required *in vitro* cytogenetics test, the potentially required *in vivo* cytogenetics test, and the dominant lethal test of DETA. A positive response in the dominant lethal assay is necessary before the EPA initiates a public program review of all of the then available mutagenicity data on DETA to determine if the required testing in the heritable translocation assay should be initiated (50 FR 21398; May 23, 1985). The DPIA asserts that, if the time required to conduct the public program review is for some reason prolonged, the proposed reporting requirement for the heritable translocation assay (Ref. 4) would result in significantly shortening the 18-month time period allowed for performing this assay. Therefore, the DPIA suggests that the proposed reporting requirement for the heritable translocation assay be changed to indicate that the final report shall be submitted to the Agency within 18 months after the test sponsor has been notified of EPA's decision, following the public program review, that the required testing of DETA in this assay should be initiated.

In view of these comments, the EPA is requiring in this final Phase II test rule for DETA that the final report resulting from the testing of this substance in the

heritable translocation assay should be submitted to the Agency within 18 months from the designated date contained in EPA's notification of the test sponsor by certified mail or Federal Register notice of the Agency's decision, following public program review of the then available mutagenicity data for DETA (resulting from a positive test result for DETA in the dominant lethal assay), that the required testing in the heritable translocation assay should be initiated. Two interim (6-month) reports shall be submitted to the Agency, commencing at 6 months following the designated date. These reporting requirements, incorporated into this final Phase II test rule for DETA, are contained in the revised EPA-approved modified study plans for DETA (Ref. 5) and are reflected in Unit V.B. of this preamble.

#### D. Chemical Fate Testing

The DPIA correctly noted that the EPA-approved modified study plan entitled "Potential Environmental Production of *N*-Nitroso Adducts of Diethylenetriamine", contained in Ref. 4 and proposed as the test standard and reporting requirements for DETA in the proposed Phase II test rule for this substance, differed from the DPIA-submitted study plan in that Alternative 1 was deleted from the industry-submitted plan and Alternative 2 was mandated for use. Alternative 1 in the DPIA-submitted study plan stipulated that the chemical fate of DETA would first be investigated in samples of sewage; however, if no *N*-nitroso derivatives of DETA were found to be produced in sewage, chemical fate studies of DETA would not then be conducted in samples of lake water and soil. Alternative 2 in the DPIA-submitted study plan stipulated that the chemical fate studies would be conducted in samples of sewage, as well as in samples of lake water and soil, whether or not a *N*-nitroso derivative of DETA was found to be produced in sewage samples. As explained in the proposed Phase II test rule for DETA, this change in the DPIA-submitted study plan was necessary because only Alternative 2 of the plan meets the testing specified to be performed for DETA in the final Phase I test rule for DETA, which clearly indicates that chemical fate testing is to be performed in samples of sewage, lake water, and soil, regardless of the test results obtained in any one or more of these environmental media [40 CFR 799.1575(d)(1)]. If it had been the intent of the Agency to predicate the requirement for the chemical fate testing of DETA in lake water and soil upon

positive test results in tests with sewage, the language used in final Phase I test rule would have so stated. The DPIA, in its comments on the proposed Phase II test rule for DETA asserts that it believes the chemical fate testing requirement established for DETA in the final Phase I test rule for this substance is unreasonable and may impose upon industry entirely unnecessary testing, continuing to assert that Alternative 1 in the DPIA-submitted study plan for the chemical fate testing of DETA should be followed.

As described in the final rule for test rule development and exemption procedures (49 FR 39774; October 10, 1984), it is the final Phase I test rule which, in a two-phase rulemaking such as that employed for DETA, specifies the health and environmental effects and other characteristics for which data are required to be developed. With respect to the chemical fate testing of DETA, the data required to be developed are clearly stated in the final Phase I test rule for this substance to be: "Testing to assess *N*-nitrosamine formation, resulting from aerobic biological and/or chemical transformation, shall be conducted with DETA using environmental samples of lake water, sewage, and soil" (40 CFR 799.1575(d)(1)). Thus, the required chemical fate tests mandated for DETA are already determined by final rule, and are not an appropriate subject for comments on the proposed Phase II test rule for DETA, which proposes test standards (methodology) and reporting requirements for conducting the already required tests. As stated in Unit V.D. of this preamble, EPA received no petitions for review of the final Phase I rule for DETA, and accordingly any petition for judicial review of this final Phase II test rule for DETA will be limited to a review of the test standards (methodology employed to perform the tests required in the final Phase I rule) and reporting requirements for this substance which are established in this notice. In view of these facts, the Agency believes that it is not legally obligated to respond to the DPIA's comments regarding the required chemical fate tests to be conducted with DETA which have already been established [40 CFR 799.1575(d)(1)].

Notwithstanding the lack of a legal obligation to respond to the DPIA's comments on the required chemical fate tests for DETA, the Agency has decided to respond to these comments to further clarify the scientific basis and rationale supporting the selection of the chemical fate tests required for DETA in the final Phase I test rule for this substance. The

DPIA believes that the aerobic chemical and/or biological transformation of DETA to a *N*-nitrosamine derivative(s) will be much greater in samples of sewage than in samples of lake water or soil; therefore, the DPIA maintains that testing should be conducted in aerobic sewage first, with no further testing in lake water or soil if no *N*-nitrosamine derivative(s) of DETA are produced in sewage samples. The DPIA cites a memorandum of February 27, 1984, from Dr. Robert Brink, Senior Scientist, Exposure Assessment Branch, Exposure Evaluation Division, EPA, to Mr. Raymond K. Locke, Test Rules Development Branch, Existing Chemical Assessment Division, EPA (Ref. 10), in support of this position. Dr. Brink's position on this matter, as well as the positions of others, were carefully considered by EPA, which, for the reasons outlined below, decided that the chemical fate testing of DETA was necessary in all three environmental media (sewage, lake water, and soil) to develop the data necessary to determine the risks posed to human health due to drinking water potentially contaminated with a *N*-nitrosamine derivative(s) of DETA which might enter the drinking water supply via any one of these three environmental media.

The DPIA asserts that it is well known that sewage contains higher concentrations of nitrites (a necessary reactant for *N*-nitrosamine formation) than either lake water or soil; thus, aerobic sewage would provide a more favorable environment for the direct chemical production of *N*-nitrosamine derivative(s) of DETA than either lake water or soil. The Agency agrees with this comment, but, as pointed out in the final Phase I test rule for this substance, the Agency is concerned about the total transformation, whether biological or purely chemical in nature, of DETA present in water, sewage, or soils to an *N*-nitrosamine derivative of the substance, which the Agency views as a potential carcinogen and which may enter the drinking water supply.

The DPIA asserts that aerobic sewage would also provide a more favorable environment for formation of *N*-nitrosamine derivatives of DETA through biological activity, since sewage is a richer source of both bacteria and the nutrients required for their growth than is soil or lake water. The Agency notes that it is a well known fact that the types of microorganisms expected to be present in sewage will differ from those expected to be present in soil and lake water, both with respect to their concentration and species. The enzymatic activities present in these

organisms are also well known to differ; therefore, without testing, it is not possible to predict that the greater concentration of microorganisms present in sewage, with respect to soil and lake water, would necessarily lead to a greater biological transformation of DETA to a *N*-nitrosamine derivative(s) in sewage as opposed to the other two environmental media. Even though the concentration of the microorganisms is greater in sewage, their enzymatic capability to effect the transformation of DETA to a *N*-nitrosamine derivative may be less than that possessed by the different microorganisms present in soil and lake water. Thus, it is not possible to predict, without testing, that the total chemical and biological transformation of DETA to a *N*-nitrosamine derivative(s) will necessarily be greater in sewage than in either soil or lake water, and testing is necessary in all three environmental media.

The DPIA correctly observes that Yordy and Alexander (Ref. 11) demonstrated that a chemical analogue of DETA, diethanolamine, was transformed to an *N*-nitrosamine derivative in sewage at a rate much greater than that observed in lake water. From these data, the DPIA concludes that, if a *N*-nitrosamine derivative(s) is produced from DETA, the amount of the derivative(s) generated in sewage would be higher than that generated in lake water or soil. The Agency disagrees with the DPIA's conclusions from these data. First, the data presented by Yordy and Alexander (Ref. 11) do not deal in any respect with the transformation of diethanolamine, an analogue of DETA, to its *N*-nitrosamine derivative in samples of soil. Secondly, these data on diethanolamine, a chemical analogue of DETA, cannot even be used to reliably predict that the transformation of DETA itself to a *N*-nitrosamine derivative(s) would necessarily be greater in sewage than in lake water. The biological transformation of DETA to such a derivative(s) in all three of these environmental media is dependent upon the enzymatic activities present in the microorganisms occurring in these media. Enzymatically catalyzed transformations are very much dependent upon the chemical structure of the substance undergoing reaction. It is well known that very small changes in the chemical structure of a substance known to be readily transformed to another substance by an enzymatic reaction can lead to a total loss of the enzyme's ability to catalyze the transformation. Although diethanolamine and DETA are chemically similar, they are different in

that the two primary amino groups present in DETA have been replaced by two hydroxyl groups in diethanolamine. This difference in chemical structure may well result in great differences in the relative extent of the enzymatic biological transformation of DETA to a *N*-nitrosamine derivative(s) in samples of sewage and lake water with respect to those observed for diethanolamine by Yordy and Alexander (Ref. 11). No data are available for diethanolamine with respect to soil. Thus, without testing, it is impossible to predict that DETA would be biologically transformed to a *N*-nitrosamine derivative(s) in aerobic sewage to a much greater extent than in aerobic soil or lake water, and the testing of DETA in all three environmental media is, therefore, necessary.

The DPIA correctly comments that an earlier study by Yordy and Alexander (Ref. 12) demonstrates that there is no significant difference in the degradation rate of the *N*-nitrosamine derivative of diethanolamine with respect to samples of sewage and lake water. The DPIA concludes from these data that one could not expect any significant difference in degradation rates for any *N*-nitrosamine derivative formed from DETA in samples of sewage and lake water. The Agency agrees that the data of Yordy and Alexander (Ref. 12) do not demonstrate a significant difference in the degradation of pure *N*-nitrosodiethanolamine in samples of sewage and two lake waters. However, the salient points to be derived from this study are that the degradation of this carcinogenic substance was slow in all three media and that this substance may persist in freshwater lakes for long periods of time during the winter months. The Agency disagrees with the DPIA's conclusion that these data indicate that one would not expect significant differences in degradation rates for any *N*-nitrosamine derivative formed from DETA in sewage or lake water. Once again, the rates of degradation of the *N*-nitrosamine derivatives of DETA and diethanolamine are dependent upon enzymatically catalyzed reactions. Since the chemical structures of these *N*-nitrosamine derivatives are different, without testing one cannot reliably predict that results observed with the *N*-nitrosamine derivative of diethanolamine are those that would be observed for the *N*-nitrosamine derivative of DETA.

Finally, the DPIA asserts that the EPA is incorrect in asserting that the final Phase I test rule for DETA (50 FR 21398; May 23, 1985) precludes the use of

Alternative 1 in the DPIA-submitted study plan for chemical fate studies of DETA. The DPIA asserts that 40 CFR 799.1575(d)(i) addresses testing in lake water, sewage, and soil, but does not specify the method for conducting such testing. The DPIA believes that Alternative 1 contained in the DPIA-submitted study plan for chemical fate studies of DETA is consistent with the requirements of the final Phase I test rule for DETA. As previously discussed in the second paragraph of Unit IV.D. of this preamble, the methodology for conducting the chemical fate testing of DETA presented in Alternative 1 of the DPIA-submitted study plan actually would change the required chemical fate tests mandated for DETA in 40 CFR 799.1575(d)(i), and Alternative 1 is, therefore, unacceptable.

In view of these comments, the Agency continues to require that testing to assess *N*-nitrosamine formation, resulting from aerobic biological and/or chemical transformation, shall be conducted with DETA using environmental samples of lake water, sewage, and soil. This requirement is contained both in this final Phase II test rule for DETA and in the revised EPA-approved modified study plans for DETA (Ref. 5).

#### V. Final Phase II Test Rule

##### A. Test Standards

The test protocols contained in the revised EPA-approved modified study plans for DETA (Ref. 5) shall be the test standards for the testing of DETA required under 40 CFR 799.1575. The Agency believes that the conduct of the required tests in accordance with the revised EPA-approved modified study plans for DETA will insure that the resulting data are reliable and adequate.

##### B. Reporting Requirements

The Agency is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) Standards (40 CFR Part 792).

The Agency is required by TSCA section 4(b)(1)(C) to specify the time periods during which persons subject to a test rule must submit test data. On the basis of the Agency's regulatory experience for the tests required for DETA, as well as in response to certain public comments, EPA is adopting the reporting requirements for these tests which are contained in the revised EPA-approved modified study plans for this substance (Ref. 5), and which are presented below.

#### REPORTING REQUIREMENTS FOR DETA

Test	Reporting deadline for final report (months after the effective date of final phase II rule, except as indicated)	Number of interim (6-month) reports required
Sex-linked recessive lethal test in <i>Drosophila</i> .....	14	2
Mouse visible specific locus assay .....	14 <sup>8</sup>	7
<i>In vitro</i> cytogenetics test .....	6	0
<i>In vivo</i> cytogenetics test .....	14 <sup>8</sup> (8)	1
Dominant lethal test .....	20 <sup>8</sup> (6)	0
Heritable translocation assay .....	18	2
90-Day subchronic toxicity test .....	15	2
Dermal absorption test .....	20	3
Chemical fate test .....	18	2

<sup>1</sup> Figure indicates the reporting deadline in months, calculated from the designated date contained in the notification of the test sponsor by certified letter or FEDERAL REGISTER notice that, following public program review of all of the then existing mutagenicity data for DETA, the Agency has determined that the required testing must be performed.

<sup>2</sup> Figure includes the time periods required for previous required testing.

<sup>3</sup> Figure in parentheses indicates the time period allowed for completion of the test itself, not including the time periods for previous required testing.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

##### C. Conditional Exemptions Granted

The final rule for test rule development and exemption procedures (40 CFR 790.87) indicates that, when certain conditions are met, exemption applicants will be notified by certified mail or in the final Phase II test rule for a give substance that they have received conditional exemptions from test rule requirements. The exemptions granted

are conditional because they will be given based on the assumption that the test sponsors will complete the required testing according to the test standards and reporting requirements established in the final Phase II test rule for the given substance. TSCA section 4(c)(4)(B) provides that if an exemption is granted prospectively (that is, on the basis that one or more persons are developing test data, rather than on the basis of prior test data submissions), the Agency must terminate the exemption if any test sponsor has not complied with the test rule.

Since sponsors have indicated to EPA by letters of intent (Refs. 1 through 3) their agreement to sponsor all of the test required for DETA in the final Phase I test rule for this substance (50 FR 21398; May 23, 1985) according to the test standards and reporting requirements established in this final Phase II test rule for DETA, the Agency is hereby granting conditional exemptions to all exemption applicants for all of the testing required for DETA in 40 CFR 799.1575.

#### D. Judicial Review

The promulgation date for the final Phase I test rule for DETA was established as 1:00 p.m. eastern daylight time on June 6, 1985 (50 FR 21398; May 23, 1985). EPA received no petitions for review of that Phase I final rule. Accordingly, any petition for judicial review of this final Phase II test rule for DETA will be limited to a review of the test standards and reporting requirements for this substance which are established in this notice.

#### E. Other Provisions

TSCA section 4 findings, required testing, test substance specifications, persons required to test, enforcement provisions, and the economic analysis are all presented in the final Phase I test rule for DETA (50 FR 21398; May 23, 1985).

#### VI. Rulemaking Record

EPA has established a record for this rulemaking, [Docket Number OPTS-42012D]. This record includes the basic information considered by the Agency in developing this rule and appropriate Federal Register notices.

This record currently includes the following information:

##### A. Supporting Documentation

- (1) Final Phase I rule on diethylenetriamine (50 FR 21398; May 23, 1985).
- (2) Proposed Phase II rule on diethylenetriamine (51 FR 12344; April 10, 1986).
- (3) Contact reports of telephone conversations.

(4) Letters, memoranda, and meeting summaries related to this rulemaking.

(5) Public comments on the proposed Phase II rule on diethylenetriamine.

#### B. References

(1) Union Carbide Corporation. Letter from J. Cole to TSCA Public Information Office, USEPA. (August 2, 1985).

(2) Dow Chemical Company. Letter from W. Cornelius to TSCA Public Information Office, USEPA. (July 29, 1985).

(3) Texaco Chemical Company. Letter from F. Bentley to TSCA Public Information Office, USEPA. (August 5, 1985).

(4) Diethylenetriamine Producers/Importers Alliance (DPIA). Letter from A. Rautio (and attached study plans and associated cover letters for diethylenetriamine) to G. Timm, USEPA. (November 27, 1985). [And attached Confirmation of EPA's Receipt, Evaluation, and Revision. (February 10, 1986).]

(5) Diethylenetriamine Producers/Importers Alliance (DPIA). Letter from A. Rautio (and attached study plans and associated cover letters for diethylenetriamine) to G. Timm, USEPA. (November 27, 1985). [And attached Final EPA Revisions of Study Plans for Diethylenetriamine. (June 19, 1986).]

(6) Berol Chemicals, Inc. Letter from K. Dahlin to TSCA Public Information Office, USEPA. (August 2, 1985).

(7) Industrial Chemicals Division, Air Products and Chemicals, Inc. Letter from D. Hartter to TSCA Public Information Office, USEPA. (August 5, 1985).

(8) AZS Corporation. Letter from J. Cook to TSCA Public Information Office, USEPA. (August 2, 1985).

(9) BASF Wyandotte Corporation. Letter from R. Elaherty to TSCA Public Information Office, USEPA. (August 5, 1985).

(10) USEPA. Memorandum from R. Brink, Exposure Evaluation Division, to R. Locke, Test Rules Development Branch. (February 27, 1984).

(11) Yordy, J., and Alexander, M. "Formation of N-nitrosodiethanolamine from diethanolamine in lake water and sewage." *Journal of Environmental Quality*, 10:266-270. (1981).

(12) Yordy, J.R., and Alexander, M. "Microbial metabolism of N-nitrosodiethanolamine in lake water and sewage." *Applied and Environmental Microbiology* 39:559-565. (1980).

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

#### VII. Other Regulatory Requirements

##### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing required for DETA is discussed

in the Phase I test rule (50 FR 21398; May 23, 1985).

This final Phase II test rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments received from OMB, together with any EPA response to these comments, are included in the public record for this rulemaking.

#### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354; September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses for the following reasons:

1. There is not a significant number of small businesses manufacturing DETA.

2. Small manufacturers and small processors of DETA are not expected to perform testing themselves or to participate in the organization of the testing efforts.

3. Small manufacturers and small processors of DETA will experience only minor costs, if any, in securing exemption for testing requirements.

4. Small manufacturers and small processors are unlikely to be affected by reimbursement requirements.

#### C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980; 44 U.S.C. 3501 *et seq.*, and has assigned the OMB control number 2070-0033. No public comments on these same requirements contained in the proposed Phase II rule for DETA (51 FR 12344; April 10, 1986) were submitted to the Office of Information and Regulatory Affairs of OMB.

#### List of Subjects in 40 CFR Part 799:

Testing, Environmental protection, Hazardous substances; Chemicals, Recordkeeping, and reporting requirements.

Dated: January 22, 1987.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

#### PART 799—[AMENDED]

Therefore, Chapter I of 40 CFR Part 799 is amended as follows:

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By amending § 799.1575 by revising paragraphs (c)(1)(ii), (2)(ii), (3)(ii), (4)(ii),

(d) and (e); and adding paragraphs (c)(1)(iii), (2)(iii), (3)(iii), (4)(iii) and (f) to read as follows:

§ 799.1575 Diethylenetriamine (DETA).

(c) \* \* \*  
(1) \* \* \*

(ii) *Test standards.* The testing shall be conducted in accordance with the following revised EPA-approved modified study plans (June 19, 1986) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Sex-linked recessive lethal test in *Drosophila melanogaster*," and "Mouse specific locus test for visible markers." These revised EPA-approved modified study plans are available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

(iii) *Reporting requirements.* (A) The sex-linked recessive lethal test of DETA in *Drosophila melanogaster* shall be completed and a final report submitted to the Agency within 14 months from the effective date of the final Phase II rule. Two interim progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(B) If required pursuant to paragraph (c)(1)(i)(B) of this section, the mouse specific locus test of DETA for visible markers shall be completed and a final report submitted to the Agency within 48 months from the designated date contained in EPA's notification of the test sponsor by certified letter or Federal Register notice that testing should be initiated. Seven interim progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of EPA's designated date.

(2) \* \* \*

(ii) *Test standards.* The testing shall be conducted in accordance with the following revised EPA-approved modified study plans (June 19, 1986) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "In vitro cytogenetics test," "In vivo cytogenetics test," "Dominant lethal assay of diethylenetriamine in CD rats," and "Heritable translocation assay of diethylenetriamine in CD-1 mice." These revised EPA-approved modified study plans are available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

(iii) *Reporting requirements.* (A) The in vitro cytogenetics testing of DETA shall be completed and a final report submitted to the Agency within 6 months of the effective date of the final Phase II rule.

(B) If required pursuant to paragraph (c)(2)(i)(B) of this section, the in vivo cytogenetics testing of DETA shall be completed and final report submitted to the Agency within 14 months of the effective date of the final Phase II rule. One interim progress report shall be submitted within 12 months of the final rule's effective date.

(C) If required pursuant to paragraph (c)(2)(i)(C) of this section, the dominant lethal testing of DETA shall be completed and a final report submitted to the Agency within 20 months of the effective date of the final Phase II rule.

(D) If required pursuant to paragraph (c)(2)(i)(D) of this section, the heritable translocation testing of DETA shall be completed and a final report submitted to the Agency within 18 months of the designated date contained in EPA's notification of the test sponsor by certified letter or Federal Register notice that testing should be initiated. Two interim progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of EPA's designated date.

(3) \* \* \*

(ii) *Test standard.* The testing shall be conducted in accordance with the following revised EPA-approved modified study plan (June 19, 1986) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Ninety-day (subchronic) dietary toxicity study with diethylenetriamine in albino rats." This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

(iii) *Reporting requirements.* The testing shall be completed and a final report submitted to the Agency within 15 months of the effective date of the final Phase II rule. Two interim progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(4) \* \* \*

(ii) *Test standard.* The testing shall be conducted in accordance with the following revised EPA-approved modified study plan (June 19, 1986) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Dermal absorption." This revised EPA-approved modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

(iii) *Reporting requirements.* The testing shall be completed and the final report submitted to the Agency within 20 months of the effective date of the final Phase II rule. Three interim

progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(d) *Chemical fate testing—(1) Required testing.* Testing to assess N-nitrosamine formation, resulting from aerobic biological and/or chemical transformation, shall be conducted with DETA using environmental samples of lake water, sewage, and soil.

(2) *Test standard.* The testing shall be conducted in accordance with the following revised EPA-approved modified study plan (June 19, 1986) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Chemical fate." This revised EPA-modified study plan is available for inspection in EPA's OPTS Reading Room, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

(3) *Reporting requirements.* The testing shall be completed and a final report submitted to the Agency within 18 months of the effective date of the final Phase II rule. Two interim progress reports shall be submitted at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(e) *Modifications.* Persons subject to this section are not subject to the requirements of § 790.50(a)(2)(ii) of this chapter.

(f) *Effective date.* The effective date of the final Phase II rule for diethylenetriamine is March 19, 1987.

[FR Doc. 87-2080 Filed 2-2-87; 8:45 am]  
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## FEDERAL EMERGENCY MANAGEMENT AGENCY

### 44 CFR Part 65

[Docket No. FEMA-6904]

### Changes in Flood Elevation Determinations

**AGENCY:** Federal Insurance Administration, Federal Emergency Management Agency.

**ACTION:** Interim rule.

**SUMMARY:** This rule lists those communities where modification of the base (100-year) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base (100-year) elevations for new buildings and their contents and for second layer insurance on existing buildings and their contents.