MATTERS TO BE CONSIDERED:

Week of October 9

Tuesday, October 9

10:00 a.m.
Discussion of Severe Accident Program for Nuclear Power Reactors—Revised Policy Statement (Public Meeting)
2:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

Wednesday, October 10

10:00 a.m.
Discussion of Proposed Rule on Decommissioning Nuclear Facilities (Public Meeting)

Thursday, October 11

2:00 p.m.
Periodic Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting)
3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Friday, October 12

9:30 a.m.
NUMARC Briefing on Fitness for Duty, Training and Requirements for Senior Managers (Public Meeting)

Week of October 15

Tentative

Tuesday, October 16

10:00 a.m.
Discussion of Material False Statements—Policy Options (Public Meeting) (Tentative)
2:00 p.m.
Discussion of QA Report to Congress (Public Meeting)

Wednesday, October 17

10:00 a.m.
Discussion with staff on Fitness for Duty, Training and Requirements for Senior Managers (Public Meeting)

Thursday, October 18

3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of October 22

Tentative

Monday, October 22

2:00 p.m.
Status of NTOL's (Public Meeting)

Tuesday, October 23

10:00 a.m.
Semi-Annual Briefing on Appraisal of Operating Experience (Public Meeting)
2:00 p.m.
Briefing and Discussion on the Hearing Process (Public Meeting)

Wednesday, October 24

10:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)
2:00 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of October 29

Tentative

Tuesday, October 30

10:00 a.m.
Discussion of Material False Statements—Policy Options (Public Meeting) (Tentative)

Thursday, November 1

3:30 p.m.
Affirmative Meeting (Public Meeting) (if needed)

Friday, November 2

10:00 a.m.
Continuation of Discussion on Indian Point (Public Meeting)

ADDITIONAL INFORMATION:

Briefing/Possible Vote on UCS 2.206 Petition on TMI–1 Emergency Feedwater scheduled for October 2, *postponed.*

Affirmation on Denial of Petition for Rulemaking Concerning Emergency Planning and Response for Transportation Accidents Involving Radioactive Materials (PRM–71–6) was held October 4 (Public Meeting).

TO VERIFY THE STATUS OF MEETINGS CALL: (Recording)—(202) 634–1498.

CONTACT PERSON FOR MORE INFORMATION: Julia Corrado (202) 634–1410.

George T. Mazuzan,

Office of the Secretary.

October 5, 1984

[FR Doc. 84–26859 Filed 10–5–84; 3:19 pm]

BILLING CODE 7590–01–M

7

TENNESSEE VALLEY AUTHORITY

[Meeting No. 1339]

TIME AND DATE: 10:15 a.m. (EDT), Wednesday, October 10, 1984.

PLACE: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Agenda Items

Approval of minutes of meeting held on September 27, 1984.

Discussion Item

1. TVA Raptor Restoration Activities.

Action Items

B—Purchase Awards

B1. Invitation C3–696073—Indefinite quantity term contract for unleaded gasoline for any TVA project or warehouse.

B2. Requisition 65–955600—Nuclear steam supply system project services for Sequoyah and Watts Bar nuclear plants units 1 and 2.

B3. Requisition 10—Coal for Johnsonvile Steam Plant.

C—Power Items

C1. Proposed form agreement covering PCB (polychlorinated biphenyls) capacitor replacement program.

C2. Proposed form agreement amending revised home insulation program agreements.

C3. Amendment to interconnection agreement between TVA and Union Electric Company, Illinois Power Company, and Central Illinois Public Service Company to modify provisions for emergency assistance and maintenance energy transactions.

C4. Supplement to contract No. TV–62313A with the State of Alabama for cooperation in the development and implementation of radiological emergency plans as required by the Nuclear Regulatory Commission and the Federal Emergency Management Agency.

E—Real Property Transactions

E1. Designation of an underground mining lease of the No. 8 seam of coal underlying approximately 76 acres in the Red Bird coal reserves located in Leslie County, Kentucky, as surplus and for sale at public auction—Tract No. XEKCR–14L.

F—Unclassified

F1. Authority to write off uncollectible accounts receivable.

CONTACT PERSON FOR MORE INFORMATION: Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632–8000. Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245–0101.

Dated: October 3, 1984.

John G. Stewart,

Manager of Corporate Administration and Planning.

[FR Doc. 84–26839 Filed 10–5–84; 2:19 pm]

Billing Code 8120–01–M

federal register

Wednesday
October 10, 1984

Part II

Environmental Protection Agency

40 CFR Part 790

Toxic Substances; Test Rule Development and Exemption Procedures; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 790

[OPTS-42052; FRL 2613-2]

Toxic Substances; Test Rule Development and Exemption Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a procedural rule describing a process it will use to develop certain test rules under section 4(a) of TSCA and to grant exemptions from those test rules under section 4(c) of TSCA. This rule sets forth certain methods for prescribing how data are to be developed in response to test rules and describes the procedures which persons subject to them must follow in order to obtain testing exemptions or receive EPA's approval to conduct testing.

EFFECTIVE DATE: Effective on November 9, 1984.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M Street, SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the United States: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: This rule prescribes how data are to be developed in response to test rules and describes the procedures to follow to obtain test exemptions or approval to conduct testing.

I. Introduction

When the Enviromental Protection Agency (EPA) promulgates a test rule under section 4 of the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) the responsibility for required tests is borne jointly by all manufacturers (including importers) and/or processors of the subject chemical, depending on which activities give rise to the testing requirement. Those persons subject to a test rule who do not directly sponsor testing must apply to EPA for exemption from testing. The test sponsor must conduct the required testing according to the standards provided in the test rule.

This rule establishes EPA's procedures for test rule development under TSCA section 4(a), for granting exemptions from test rules and for providing standards for the conduct of those tests. It includes changes in the Agency's original approach which were made in response to comments received on the Proposed Statement of Exemption Policy and Procedures as published in the **Federal Register** of July 18, 1980 (45 FR 48512), and Changes in Test Standards Policy and Test Rule Development Process as published in the **Federal Register** of March 26, 1982 (47 FR 13012). EPA is including both of these procedures in this final rule because the processes are inter-related. This rule does not include exemption procedures for chemicals being tested under a category-based rule. The Agency has not arrived at a final policy concerning the conduct of such testing. Final exemption procedures for category-based rules will be issued prior to or in conjunction with EPA's first category-based test rule.

Test rule development procedures, described in the **Federal Register** of March 26, 1982, were proposed for codification in Part 799 as part of specific chemical test rules (47 FR 18386, April 29, 1982; 48 FR 23080, May 23, 1983; 48 FR 23088, May 23, 1983; 48 FR 30699, July 5, 1983; 48 FR 57686, December 30, 1983; 49 FR 430, January 4, 1984; 49 FR 438, January 4, 1984; 49 FR 456, January 4, 1984; 49 FR 899, January 6, 1984; 49 FR 1760, January 13, 1984). The final procedures are being codified as general test rule development procedures in Part 790.

The proposed exemption procedures, as published in the **Federal Register** of July 18, 1980 were planned to be codified in 40 CFR Part 770. The final rule has been redesignated as part 790. The following table is provided to aid readers in relating sections in the proposed procedures to the corresponding sections in the final rule.

CONVERSION TABLE

Proposed rule Part 770	Section title	Final rule Part 790
770.400	Scope, purpose, and authority	790.1
770.401	Applicability	790.2
770.402	Definitions	790.3
	Submission of information	790.5
	Confidentiality	790.7
	Phase I test rule	790.20
	Persons subject to Phase I test rule	790.22
	Submission of letter of intent to test or exemption application.	790.25
	Procedure if no one submits a letter of intent to conduct testing.	790.28
	Submission of proposed study plans	790.30
	Proposed Phase II test rule	790.32
	Final Phase II test rule	790.34
	Modification of study plans during conduct of study.	790.35
	Failure to comply with a test rule	790.39
770.405	Submission of exemption applications	790.80
770.406	Content of exemption application	790.82
770.420	Submission of equivalence data	790.85
770.410	Approval of exemption applications	790.87
770.410	Denial of exemption application	790.88
770.430	Appeal of denial of exemption application.	790.90
770.431	Termination of conditional exemption	790.93
	Hearing procedures	790.97
770.440	Statement of financial responsibility	790.99

II. Statutory Background

Section 4(a) of TSCA authorizes EPA to require manufacturers (including importers) and/or processors of identified chemical substances and mixtures to test the chemicals in accordance with applicable EPA test rules. Section 4(b) of TSCA requires that each section 4(a) test rule identify the chemical substance or mixture for which testing is being required, and provide standards for the development of test data. These standards are to prescribe the health and environmental effects, and information relating to toxicity, persistence and other characteristics which affect health and the environment for which test data are to be developed and, to the extent necessary to assure development of adequate and reliable data, the manner in which the data are to be developed, the test protocol or methodology to be employed, and such other requirements as are necessary to provide such assurance (section 3(12)(B)).

Manufacturers or processors required by rule to sponsor testing may do so either individually, or jointly through formation of a testing consortium (section 4(b)(3)(A)). Alternatively, they may choose to apply for a testing exemption under TSCA section 4(c) based on the belief that the required testing will be performed by another person subject to the rule. In order to approve an exemption application, EPA must find that: (1) The applicant's product is equivalent to the substance or mixture for which test data have been submitted or are being developed, and (2) data submitted by the applicant under a section 4 test rule would be duplicative of data already submitted or being developed pursuant to the rule.

TSCA does not define what constitutes "duplicative data" or what criteria should be used in determining whether chemicals are "equivalent." However, TSCA's legislative history states that Congress expected EPA's Administrator to consider whether any additives or impurities in the substance or mixture for which the exemption is being sought might cause "significant" differences in test data and thereby

render the substances "nonequivalent" (H.R. No. 94–1679 94th Cong., 2d Sess. 9/23/76, p. 61, Legis. Hist. 674). For purposes of determining equivalence under section 4, EPA interprets this to mean that the Agency must take into consideration the presence of any additive or impurity in a chemical which might cause differences in test data which are significant for the purposes of assessing the risk associated with the chemical. That is, if the presence of such an additive or impurity is likely to produce differences in the test data which may affect those data's value in assessing the risk presented by the chemical, the Agency must find that forms of the chemical containing that additive or impurity are not equivalent to those not containing it and require testing of the non-equivalent substance.

The Agency is interpreting the term "duplicative data" to mean duplicative for purposes of the test rule. A variety of factors in a test's design can affect the data generated by it. In order to assure the development of data which are adequate and reliable for purposes of individual test rules, EPA will provide standards for the conduct of that testing. So long as the substances being tested are equivalent, EPA will assume that all tests adhering to these standards will produce data which are duplicative for the purposes of determining the effects identified in the test rule.

III. Prior Proposals

A. Testing Standards and Test Rule Development

Under EPA's original approach to providing testing guidance, the Agency proposed to publish and codify in the Code of Federal Regulations (CFR), a number of model test methodologies. A number of proposed "test standards" for health effects were published in the **Federal Register** of May 9, 1979 (44 FR 27334) and on July 26, 1979 (44 FR 44054), while similar proposed standards for chemical fate and ecological effects were published on November 21, 1980 (45 FR 77332). The Agency planned to adopt such "test standards" or "generic methodology requirements" for all of the major types of tests which might be required under section 4 test rules. The Agency planned to incorporate, by reference, whichever of these test methodologies was appropriate for use in each chemical-specific test rule.

In response to comments that the codified testing standards approach would provide insufficient flexibility in test design, EPA proposed a different approach for providing testing standards in the **Federal Register** of March 26, 1982 (47 FR 13012). In that notice, the Agency proposed to abandon the idea of codifying its approved generic test methodologies and to publish them as guidelines instead. It planned to make test rule development a two-phase process. In the first phase, EPA would establish by rule the effects and characteristics for which a given chemical must be tested and refer subject manufacturers and/or processors to suitable guidelines for how the testing should be performed. The subject firms would be required by a specified date to submit study plans detailing the methodologies and protocols they intended to use to perform the required tests. In the second phase, after consideration of public comment on the proposed study plans, the Agency would promulgate another rule adopting specific test requirements reflecting any modifications deemed necessary by EPA to assure the development of reliable and adequate data.

B. Exemptions

EPA's exemption proposal published in the **Federal Register** of July 18, 1980 (45 FR 48512) called upon each exemption applicant to submit data establishing that the chemical for which the exemption was being sought was equivalent to the one being tested and that duplicative data would result from its testing. The Agency stated its belief that one properly designed and executed study will normally provide a sufficient basis for making a regulatory decision on a given characteristic or effect of a chemical and proposed to consider all tests meeting its standards to be duplicative of each other as long as the substances being tested were equivalent. Therefore, if an exemption applicant established that its chemical was equivalent to a substance which was to be tested according to the standards described in the test rule, the Agency would accept the contention that testing of that applicant's chemical would yield duplicative data.

EPA's determination of equivalence was to be a two-stage process. In the first stage, the Agency would select a test substance or several test substances representative of all forms of the chemical subject to the rule. The selection was to involve among other factors consideration of the nature of the test, the various grades of the chemical on the market, the toxicity of the various components found in those different grades of the chemical, and the effects that various additives and impurities might have on the outcome of the testing. Where possible, EPA planned to select a single representative test substance and to consider all forms of the chemical "equivalent" to each other for exemption purposes.

However, if it was necessary to require testing of two or more test substances, the Agency proposed to require that each exemption applicant provide biological, chemical, manufacturing or processing data "as appropriate" in order to establish which test substance its chemical was to be considered equivalent to. Evaluating these data and determining which test substance the applicant's chemical would be considered equivalent to constituted the second and final stage of the Agency's equivalence determination process.

If, after evaluating the information provided in the exemption application, EPA found the applicant's chemical to be equivalent to one for which testing plans had been submitted and approved, the Agency would then proceed to grant an exemption. All exemptions granted prior to completion of testing were to be conditional upon the sponsor's proper completion of the required tests.

IV. Summary of Final Rule

A. Testing Standards and Test Rule Development

EPA has considered carefully the public comments received on both proposals in arriving at this final rule. Under these revised procedures, EPA is adopting a two-phase process as was proposed and published in the **Federal Register** of March 26, 1982 (47 FR 13012). The first phase will consist of the proposal and adoption of a test rule specifying what chemical substance or substances are to be tested and for what effects. The Phase I test rule will provide testing guidance in the form of specific suggestions and/or reference to published testing methodologies, but test sponsors may also propose their own test methods. EPA's provision of final standards for the development of data and time deadlines and reporting schedules will occur during Phase II of the rulemaking as part of the study plan approval process. The second phase will involve submission of industry's proposed study plans for conducting the required testing and public comment on those study plans. At that time, EPA will make whatever modifications in the proposed study plans that it finds necessary to assure development of adequate and reliable data. The approved testing plans then will be adopted as test standards and schedules in the final Phase II rule and will be binding on the test sponsor(s). These procedures will be applicable to each

test rule promulgated under section 4 of TSCA that are designated as two phase.

B. Exemptions

The Agency has not changed its approach to determining whether data that would be generated by testing an exemption applicant's chemical would be duplicative of those which will be under development. If the exemption applicant demonstrates his chemical to be equivalent to one which is being or will be tested according to the study plans adopted in the Phase II rule, EPA will consider this condition to have been met.

In response to industry comments that EPA had not adequately explained what criteria would be used to evaluate equivalence, the Agency has modified its approach to the issue. Rather than leave substantiation of equivalence claims to the discretion of the exemption applicant, EPA will provide guidance concerning equivalence substantiation in each proposed test rule. As proposed, EPA will grant a conditional exemption provided that the applicant's chemical is equivalent to the one which is to be tested and that study plans have been approved for all of the required tests.

Unless otherwise indicated in the test rule, only manufacturers (including importers) will be expected to submit exemption applications or study plans. Normally, processors will share the testing costs with the manufacturer through the pricing mechanism. However, if the exposure or risk upon which the test rule is based is associated with processing as well as manufacturing or with other downstream activities (use, distribution in commerce, and disposal), and if manufacturers fail to submit study plans, the Agency will publish a notice in the **Federal Register** and call upon processors to submit study plans or exemption applications.

V. Discussion of Final Rule

A. Steps in Test Rule Development

EPA's decision to utilize a two-phase rulemaking process employing test guidelines rather than mandatory test methodologies was made in response to comments that its original approach could prevent test sponsors from using new, more economical testing methodologies or making modifications in the recommended protocol that would yield more reliable data when testing a specific chemical. In order to provide this flexibility, while retaining EPA's opportunity to assure that the tests are designed so as to yield adequate and reliable data, the Agency is adopting a two-phase process composed of the following steps:

1. *Proposals of a Phase I test rule.* The proposed Phase I rule will discuss who should conduct testing (manufacturers or processors or both), the health and environmental effects or other characteristics for which testing will be required, appropriate Good Laboratory Practice requirements, EPA's recommendations for testing methodologies, and the representative substance or substances to be tested. Selection of a representative test substance or substances will be made based on information available in the literature and data EPA has received from industry, environmental groups and other members of the public. In making this selection, EPA will consider the effects of additives and impurities and how they might affect the risk which various forms or formulations of the chemical may present to human health or the environment.

Normally, EPA expects to select a single test substance to be representative of all forms of the chemical subject to the rule. Under these circumstances all other forms of the subject chemical will be considered "equivalent" for purposes of granting exemptions. In those rare cases in which the effects of additives and impurities or other differences in forms of the subject chemical make it necessary to test more than one test substance, the Phase I rule will define the substances for which the Agency proposes to require testing, its rationale for choosing those test substances, and how it proposes to determine equivalence.

2. *Public comment on proposed Phase I rule.* The Agency will accept comment on its proposal for 60 days. Comments will be solicited on EPA's findings under section 4(a), on the particular health or environmental effects or other characteristics for which testing is proposed, and on the test substance or substances proposed to be tested. EPA will be particularly interested in obtaining comment on additives and impurities which may significantly affect the outcome of testing. Commercial chemical formulations may contain many additives or contaminants which may or may not create differences in test data significant for assessing the risk which that chemical presents to human health or the environment. To test each of the many individual components of a commercial chemical separately would be costly, time consuming, and in most cases unnecessary. Therefore, EPA will ask the assistance of the public in identifying any additives and impurities which may be toxicologically significant as relating to a particular chemical under consideration. Public comments on EPA's proposed test substance(s) and its criteria for determining equivalence will be used to supplement information obtained earlier in the information-gathering phase of the test rule development process and may lead EPA to modify its proposals.

Shifting consideration of equivalency to an earlier phase of rulemaking will also address the concern expressed by several commenters that EPA was inappropriately assuming the burden of proving equivalency by assuming that, absent evidence to the contrary, a single test substance was representative of all forms of the chemical subject to the test rule. It was never the Agency's intent to disregard information concerning the effects of contaminants or to ignore such data in selecting a test substance. In the process adopted today, by considering additives and impurities early in the rulemaking process, the Agency will be better able to select representative test substances and to determine whether additives or impurities may make a significant difference in a chemical's effects and what types of data should be required to substantiate equivalency claims. The burden for providing equivalence information remains on the applicant; but it will be submitted in response to specific Agency guidance in the final Phase I test rule. It is in the public interest to eliminate unnecessary data submissions whenever possible by specifying what data are needed.

The Natural Resources Defense Council (NRDC) commented, and the Agency agrees, that EPA cannot guarantee that it will be able to identify, in advance, all of the toxicologically significant impurities in a chemical required to be tested. Nevertheless, due to the many diverse ways in which chemicals may be marketed or used, to absolutely "guarantee" that data generated will provide full answers for the many forms of a chemical, each form of the chemical would need to be tested at huge costs to society. Test rules are designed to gather information concerning subjects about which existing information is limited. They are, by necessity, written in a climate of uncertainty. Congress limited the time available for Agency response to ITC designations to 12 months (section 4(e)(1)(A)). A chemical designated for testing consideration may be manufactured in a variety of formulations and mixtures which can contain may additives and impurities. Any of these may or may not create significant differences in the data which

are obtained from testing. Just as it is impractical and unnecessary to require testing for all effects for all chemicals, so it is infeasible to require or evaluate detailed information concerning all of the additives and impurities that may be present. The Agency believes that by considering the effects of additives and impurities early in the rulemaking process, and by soliciting aid from the public in identifying those which may significantly affect test results, it is making the most efficient use practicable of the time and resources available for assessing risk.

Potential exemption applicants and other members of the public will have an opportunity to carefully examine EPA's plans for selection of test substances and determination of equivalence in the Phase I rule. It will also establish how equivalency claims are to be supported and judged. By commenting on EPA's proposals in the Phase I rule, the public will have an opportunity to provide information which may modify those plans.

3. *Publication of final Phase I test rule.* After considering public comments, EPA will publish a final Phase I rule specifying the health and environmental effects and other characteristics for which data are required to be developed, a reference to guidelines for the development of test data, the persons responsible for testing, and the required test substance(s), and, if more than one substance is to be tested, it will also give instructions for showing equivalence. The rule will specify who must respond by submitting either a notice of intent to conduct testing or an application for exemption based on the belief that testing will be performed by another. Who must respond and the form of the required response will vary as follows:

a. *Persons subject to final Phase I test rule.* Although both manufacturers and processors may be found under section 4(b)(3)(B) to be responsible for testing, EPA expects that only manufacturers ordinarily will be subject to the reporting provisions of the test rule. Once the test rule is in effect, 44 days after publication in the **Federal Register**, each current manufacturer will have 30 days to submit, for each required test, either a letter of intent to perform the test or an application for exemption. Each manufacturer who submits a letter of intent to perform a specific test will be obligated, first, to submit, within 90 days of the effective date of the Phase I test rule, a proposed study plan for that test and, ultimately, to perform testing.

If manufacturers perform all the required tests, processors will not be required to test or to submit exemption applications. EPA will automatically grant such processors exemptions without requiring the submission of exemption applications.

Manufacturers who wish to sponsor testing as part of a consortium may submit a single letter of intent to test provided that all members of the consortium sign it. If the rule requires testing of more than one representative substance, each member of the consortium must also provide equivalence data.

EPA believes that processors will rarely be called upon to sponsor testing directly. However, if the test rule's findings are based solely on exposure associated with processing, the rule will require processors to submit notices of intent to test or exemption applications and to follow the same study plan submission and approval steps as described in this rule for manufacturers.

It is expected that, in most cases, testing will be performed by the manufacturers and that part of the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the costs of testing. However, in those instances where manufacturers (including importers) and processors are jointly responsible under TSCA for the conduct and financing of testing, processors will be called upon to sponsor tests if manufacturers fail to do so, or may be required to provide reimbursement directly to those sponsoring this testing unless the exposure or possible risk associated with the chemical is due solely to manufacturing. (See Data Reimbursement rule 40 CFR 791.45.)

If no manufacturer submits a letter of intent to perform a particular test within the 30-day period, EPA will publish a notice in the **Federal Register** to notify all processors of the subject chemical. The notice will state that EPA has not received letters of intent to perform certain tests and that current processors will have 30 days to submit, for each test remaining, either a letter of intent to perform the test or an exemption application for that test. Each processor who submits a letter of intent to perform a specific test will be obligated, first, to submit, within 90 days of the publication of the **Federal Register** notice, a proposed study plan for the test and, ultimately, to perform the testing.

If no manufacturer or processor submits a letter of intent to perform a particular test, EPA will notify all manufacturers and processors, either by letter or by notice in the **Federal Register**, that all exemption applications will be denied and that within 30 days all manufacturers and processors will be in violation of the rule until a proposed study plan is submitted for that test.

Any person not manufacturing the chemical at the time the rule goes into effect or within the first 30 days after the rule goes into effect, who later begins manufacturing before the end of the reimbursement period, will be required to submit a letter of intent to test or an exemption application for each required test by the day the person begins manufacture. If EPA has published a notice in the **Federal Register** telling processors to submit letters of intent or exemption applications for certain tests, any person not processing the chemical at the time the rule goes into effect or within 30 days after the publication of the notice, who later begins processing before the end of the reimbursement period, will be required to submit a letter of intent to test or an exemption application for each test specified in the **Federal Register** notice by the day the person begins processing.

b. *Submission of letter of intent to test or exemption application.* Those responding to a Phase I test rule may do so either by submitting a letter of intent to perform testing, or by requesting an exemption from one or more of those testing requirements based on the belief that the tests will be performed by another.

Letters of intent to conduct testing must specify which study or studies the respondent will sponsor and, if more than one substance is to be tested, which test substance will be used in those studies. EPA will consider such notices as commitments to perform testing.

Exemption applications must list the test requirements for which an exemption is being sought and discuss the applicant's basis for believing that the tests will be performed by another party. If more than one representative substance is to be tested, the applicant must also state which test substance it believes its chemical to be equivalent to and support this assertion with the types of data called for in the test rule.

All responses must include the following:

i. The name, address and phone number of the applicant and the rule to which it is responding.

ii. The name, address and telephone number of the appropriate individual EPA should contact for further information.

iii. For applicants participating in a testing consortium, the names of all consortium members and the identity of the primary spokesperson for the consortium.

iv. The test requirements for which the applicant intends to submit study plans and conduct testing.

v. The test requirements, if any, for which the applicant is requesting an exemption, and its basis for believing that the tests will be performed by another.

Responses must also include any additional information called for in the test rule. In those cases in which more than one representative form of the chemical is to be tested this will include:

(1) For those indicating an intent to test—which test substance the submitter intends to use in each of the planned tests.

(2) For those requesting exemptions—the test substance the applicant believes its product to be equivalent to and all data supporting this assertion which were required in the test rule.

4. *Submission of study plans.* All those who submitted letters of intent to conduct tests must submit study plans for those tests unless EPA agrees to their substitution of an exemption application in instances where more than one company indicates an intent to sponsor equivalent tests. If testing is to be sponsored by a consortium, its spokesperson may submit study plans on behalf of all those who have given EPA notice of their intent to participate in that consortium. The procedural rule published today requires proposed study plans to be submitted by manufacturers within 90 days after the effective date of the Phase I rule unless: (1) The plans are being submitted by processors after manufacturers failed to do so; or (2) the Agency has granted those responsible for preparing the plans an extension of the deadline. In the first case, processors must submit study plans within 90 days from the publication of the notice requiring them to submit letters of intent.

Some commenters remarked that EPA's plan to allow 30 days for formation of a testing consortium and/or to indicate an intent to test, with an additional 60 days for study plan development, may not give sponsors adequate time. EPA's experience in negotiating testing agreements indicates that, in most cases, the 90 days allotted for development of study plans will be sufficient. However, if unusual circumstances make this difficult, EPA may grant requests for additional time for study plan development on a case-by-case basis.

Unless EPA has granted additional time for study plan development, manufacturers who indicate thay will perform testing, but do not submit proposed study plans within 90 days after the effective date of the rule, will be considered in violation of the test rule. Processors who indicate they will test, but do not submit a study plan by 90 days after the publication of the **Federal Register** notice requiring them to submit letters of intent, will be considered in violation of the rule.

The categories of information which must be contained in the proposed study plans are described in EPA's Good Laboratory Practice (GLP) Standards for use in testing under the Toxic Substances Control Act (40 CFR Part 792). They include the proposed test protocols and the rationale for their selection, as well as the identities of the sponsor(s) and the testing organization, and proposed schedule for conducting the testing and submitting required reports to EPA.

Test protocols must comply with EPA's GLP requirements and any specific requirements given in the test rule. TSCA, Organization for Economic Cooperation and Development (OECD), and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) guidelines, as well as methods described in the scientific literature, may be referenced in the test rules as guidance for test methodology development. Sponsors may elect to use one of the protocols referenced in these guidelines, or they may develop their own. If testing is to be sponsored jointly by members of a consortium, that member who has been designated primary contact with EPA should submit study plans on behalf of the entire group.

5. *Proposed Phase II rule.* The proposed study plans will be made available for a 45-day public comment period during a second phase of the rulemaking. The proposed Phase II test rule will summarize the proposed study plans and inform the public that the detailed plans are available for review in EPA's public docket. The Agency will hold a public meeting if one is requested. Following the comment period, EPA will evaluate the proposed study plans in view of public comments and the data requirements in the test rule. The Agency will require whatever modifications of the study plans that it finds necessary to assure the development of adequate and reliable data for the purposes of the test rule. If substantial issues arise or substantial modifications of the study plans are required, the Agency may extend the 45-day comment period.

The Agency's evaluation of the study plans will include an assessment of the quality of the study design, including evidence of adherence to EPA GLP Standards, a determination as to whether the study as proposed will yield the proper types of data for the purposes of the test rule, and an assessment of the probability that the study design can be successfully implemented within the time specified in the test rule. These specific considerations will vary with the chemical being tested and the types of tests required in each test rule. The Agency cannot, therefore, as one commenter suggested, discuss all of the criteria for study plan evaluation in this procedural rule. Certain aspects of the evaluation will vary with the type of testing being required and the purposes for which the data are to be developed. Specific guidance concerning the factors which EPA considers important in the design of specific studies will be provided in the individual test rules and the testing guidelines referenced in those rules.

6. *Evaluation of exemption applications.* During the comment period on proposed study plans, EPA will examine exemption applications. Its review will be to determine that properly completed exemption applications have been received from all those not sponsoring testing or participating in a consortium sponsoring testing, and to evaluate equivalency claims. When a single representative substance is to be tested, all forms of the chemical will be considered equivalent to it, and the Agency will contact the applicant only if information is missing or unclear.

If two or more chemical substances are to be tested, equivalency claims will be assessed according to the criteria in the test rule. If the Agency finds an equivalency claim to be in error, or if information needed to make an equivalency determination is missing, the applicant will be notified. If the equivalency claim is being questioned because supporting data are inadequate, the applicant will be given 15 days to provide explanatory information. If EPA finds the applicant's chemical equivalent to a different test substance than was claimed in its application, EPA will notify the applicant in writing and explain why.

Exemption applications will receive notification that their applications for equivalency have been accepted or rejected. Those who have met the requirement for showing equivalency will be eligible for exemptions after study plans have been approved.

7. *Final Phase II test rule.* The Phase II test rule will summarize the testing requirements set forth in the Phase I rule, and the study plans which were approved and adopted by EPA for conducting those tests. It will also note that exemption applicants have been granted conditional exemptions.

Exemptions will be granted on the condition that the required testing is completed according to the study plans and the data submitted according to the prescribed schedules. The approved study plans will describe, in detail, the manner in which the study is to be conducted and will include protocols, rationale, testing facilities, schedules and reporting requirements. The study plans will serve as enforceable test requirements for the test rule and will constitute the chemical-specific test standards required by TSCA section 4(b)(1)(B). The study plans adopted in the Phase II test rule will also specify the time period during which persons subject to the test rule must submit test data as required by TSCA section 4(b)(1)(C).

This approach to providing test standards differs from EPA's May 9, 1979 (44 FR 27334) proposal in that the Agency will be providing standards for the development of data in the approved study plans, rather than through separate promulgation of standardized test methodology requirements. EPA has noted the point made by the Natural Resources Defense Council, that this approach may pose a greater administrative burden for the Agency than the use of codified test standards. EPA does not, however, agree that this burden will be so great that it will outweigh the benefit derived by allowing for the tailoring of test methodologies to specific testing requirements. Industry will not be the sole beneficiary of this approach. In addition to providing potential test sponsors the flexibility in test design requested in their comments, the revised approach allows EPA more control over the final testing scheme through the study plan approval process. By modifying protocols after public comment, the Agency will be able to tailor the test designs to the needs expressed in the specific test rules in a way that would not have been possible under a system of annually updated standardized methodologies.

Public comment on proposed study plans is an important part of this tailoring process. EPA disagrees with those commenters who believed that the requirement for submission of study plans should be eliminated or that only a general study design should be incorporated in the final test rule. General information concerning study objectives and methods will not provide EPA or the public with needed assurance that data are being developed in an adequate and reliable manner. Detailed protocols, schedules and reporting requirements are needed as well. Nor does EPA believe that it would be in the best interests of the regulated industries or the public as a whole to, as one commenter suggested, allow data to be developed with only general guidance and then require that testing be repeated if data were found to be inadequate. Such repetition would impose additional costs on the regulated industries, which would ultimately be passed on to the consuming public, would impose unnecessary administrative burdens on the Agency, and would cause serious delays in the identification and control of health and environmental risks.

Additionally, generic test standards developed for use on a number of chemicals might make chemical-specific test modifications which would produce fully adequate and reliable data at a reduced cost more difficult. Modifications which reduce testing costs for industry can be expected to reduce costs to the public at large and are to be encouraged so long as they do not jeopardize the validity or reliability of the data under development. More flexibility to allow for such modifications is provided for under the Agency's revised test rule development process.

The same commenter who advocated retaining rigid generic test methodology requirements for incorporation into chemical-specific rules approved of the two-phase test rule development process proposal only if it would result in the publication of a final rule containing specific test protocols within a year of EPA's receipt of the ITC's recommendations. The Agency maintains that such a schedule is impracticable and is not required under the law. Using the approach set forth in this notice, the Agency will satisfy TSCA's requirement that a rulemaking proceeding, if required, be "initiated" within 12 months of a chemical's designation by the ITC. At the same time it will allow public participation in the evaluation of testing plans, and the tailoring of those plans to chemical-specific testing needs.

8. *Approval of exemption applications.* Provided that the first condition for granting exemptions (equivalence to the test substance) has been satisfied, the second, duplicativeness of data, will be considered to have been met and conditional exemptions will be granted following EPA's approval of the study plans. Exemption applicants will be notified by certified mail or in the final Phase II rule thay they have received conditional exemptions. The exemptions will be conditional because they will be given based on the assumption that the test sponsors will complete the required testing according to the specifications and schedules in the adopted study plans. 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.

9. *Appeal of exemption denials.* Persons whose exemption applications are denied will be notified by certified mail or by **Federal Register** notice and may appeal that denial. Appeals must be filed with EPA within 30 days of the receipt of the letter or publication of the **Federal Register** notice denying the exemption. Appeals should include a detailed explanation of why the applicant disagrees with EPA's decision. The applicant may request a hearing. EPA will notify applicants of its decision within 60 days after EPA receives the appeal or 60 days after the hearing if the request for a hearing is granted.

10. *Termination of conditional exemptions.* Exemptions granted prospectively in the Phase II rule are conditional. The Agency will terminate the exemption if the test sponsors do not comply with the test rule. If EPA determines that one or more of the test requirements contained in a test rule has not been fully complied with either because: (a) No one subject to the rule has started testing by the date specified in the rule, (b) data required by the rule were not submitted by the date specified in the rule, or (c) data were not generated according to approved potocols or in accordance with EPA's Good Laboratory Practice requirements, EPA will notify holders of exemptions based on that testing by certified letter or **Federal Register** notice as to its basis for believing that the testing supporting the exemptions has not satisfied the test rule's requirements and of EPA's intent to terminate those conditional exemptions.

Such exemption holders may file written comments concerning EPA's intent to terminate such exemptions and may request an opportunity for a hearing to refute EPA's tenative decision or may submit a letter of intent to conduct the required test. Comments, hearing requests and letters of intent to test must be in writing and must be received by EPA within 30 days of receipt of the letter or publication of the **Federal Register** notice announcing the Agency's intent to terminate the exemptions. Persons who notify EPA of

their intent to conduct a test must submit study plan modifications concerning test sponsor, test facility and schedules within 60 days of receipt of the letter or notice announcing EPA's intent to terminate the exemptions. The comments and hearing requests should include a brief statement of the basis for the exemption holder's belief that the conditional exemption should not be terminated. If an exemption holder requests a hearing, a single hearing will be held by EPA to address the concerns of all conditional exemption holders objecting to the termination unless confidentiality claims preclude a joint hearing. Exemption holders will receive written notification of EPA's final decision as to whether the exemption will be terminated.

If the Agency finds it necessary to terminate conditional exemptions, it will notify the exemption holders to that effect, will explain the reason for the Agency's decision and will give instructions as to what actions the former exemption holders must take to avoid being found in violation of the test rule.

B. Confidentiality Issues

In addition to the topics discussed in the preceding sections of this preamble, the Agency also received comments concerning certain confidentiality aspects of its test rule and exemption process.

1. *Proposed confidentiality policy and public comment.* Under section 14(c) of TSCA, any person submitting data under the Act may assert a claim of confidentiality with regard to any piece of information. Sections 14 (a) and (b) of TSCA provide the criteria for the Agency's decision on whether a particular claim of confidentiality should be upheld by the Agency. As a general rule, under section 14(a) the Agency may not disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential. Section 14(a) contains several exceptions to this general rule of non-disclosure. Among these is section 14(a)(4), which provides that information may be disclosed "when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding." Section 14(b) substantially modifies the effect of section 14(a) by stating that if the information submitted to EPA is a "health and safety study" section 14(a) does not prohibit disclosure of the information unless it "discloses processes used in the manufacturing or processing of a chemical substance or mixture, or in the case of a mixture, * * * disclos[es] the portion of the mixture comprised by any of the chemical substances in the mixture."

In the proposed exemption policy, EPA discussed what types of information submitted in conjunction with exemptions might be considered confidential, and how EPA intended to treat such claims. The Agency indicated that it regarded as "health and safety" data the identity and analysis of the test substance, the processes of manufacturing and processing of the test substance (to the extent necessary to identify the test substance), information on test protocols, and biological information submitted to establish equivalence. Under section 14(b), any of this information which revealed "process" or "mixture" information would normally be withheld; however, EPA reserved the right to release such data under section 14(a)(4) if the Agency determined this was necessary to avoid impairment of the test rule proceeding. Furthermore, the Agency indicated that it could not conceive of a situation in which the identity of the testing lab would be held confidential. EPA indicated that it did not consider information on the identity of the test sponsor or joint sponsors, or on the identity of exemption applicants to be health and safety data. However, the Agency stated that it was considering disclosing this information, under the authority of section 14(a)(4), to facilitate the exemption and reimbursement process. Finally, EPA proposed that persons submitting a claim of confidentiality for the identity of the principal test sponsor, identity of the test substance, or the process for manufacturing or processing the test substance, be required to substantiate these claims at the time the information is submitted to EPA.

Public comments generally concurred with EPA's belief that exemption application and study plan information would not usually be considered confidential by the submitter. Some commenters noted their view that, in any case, the entire study plan should be considered health and safety data and made public unless to do so revealed process or mixture information. On the other hand, many industry comments indicate a belief that the Agency's definition of health and safety study is too broad, and that only information "directly" related to the chemical substance's effects or constituting the basis for a study's conclusions falls into this category. In particular, these commenters objected to the general policy of including identity of the test substance and test protocol information as underlying data to a health and safety study. A comment also stated that, although identity of the testing laboratory would rarely be claimed confidential, if the submitter established grounds for confidential treatment, this information could only be released in accordance with section 14(a)(4). Finally, several commenters stated that there is no justification under TSCA for requiring that certain confidentiality claims be substantiated at the time the information is submitted.

2. *Final confidentiality procedures and policy.* Since the proposal, many aspects of EPA's test rule process have been modified. In addition, EPA has reexamined the need for disclosure of information in the process. As is explained below, because of these changes, many of the issues raised in the comments have been eliminated.

The question of confidential treatment for the identity of the test substance submitted by a test sponsor has been largely eliminated by the revisions to EPA's test rule development process. Comments pointed out that confidentiality only becomes an issue when EPA fails to specify a test substance. However, EPA will always specify a test substance or test substances in the final Phase I test rule. If a tester believes that the test substance's identity is not confidential *per se*, but rather because it is linked with the test sponsor's identification, it can address this problem by claiming its corporate identity to be confidential business information, as discussed below.

Under EPA's final exemption procedures, if the Agency identifies a single test substance, persons applying for exemption will not be required to provide any specific information on the identity of the substance they are manufacturing, because either all varieties of the chemical substance will be equivalent to the test substances, or the test rule itself will define which substances are equivalent to the test substance. (If a person believes that the fact that it is manufacturing a substance equivalent to the test substance is confidential business information, it would be necessary for the person to claim its corporate identity confidential.) However, if EPA identifies more than one test substance, an exemption applicant will be required to indicate to which of the chosen test substances equivalence is claimed, the identity of the applicant's substance, and to submit required data supporting this assertion. If a confidentiality claim is established adequately for the

identity of the substance that the exemption applicant manufactures or processes, EPA will not disclose the identity of the applicant.

If the exemption applicant claims data supporting its equivalence claim to be confidential, EPA will generally judge the confidentiality of this information under section 14(a) of TSCA. However, the Agency will generally consider data from biological tests submitted in support of a claim of equivalence to be health and safety data, and under section 14(b) such data will be withheld only if it would reveal "process" or "proportions of a mixture," which such information would not generally do. Manufacturers and processors may also in some cases be required to submit information on the manufacturing process for their substance, or proportions of a mixture, in order to establish equivalence. EPA will withhold this information if the submitter adequately asserts the claim that it is confidential business information.

EPA has reevaluated its proposed approach to the question of claims of confidentiality of the identity of the test sponsor. The Agency continues to believe that this information would rarely, if ever, be claimed confidential. EPA would expect it to be claimed confidential only when a person wishes to avoid disclosing that it manufactures or processes the substance subject to the rule. If a valid claim of confidentiality is asserted, the Agency no longer intends generally to disclose this information under section 14(a)(4) to facilitate the reimbursement process. The study sponsor is responsible, in the first instance, for paying the cost of the testing. If the sponsor, for whatever reason, does not seek reimbursement from an exemption holder, there would be no need to reveal the sponsor's identity. If the sponsor seeks reimbursement from any person, the sponsor can arrange for a third party to represent it in negotiations or in a reimbursement proceeding under the Agency's rules. Only if the confidentiality of the test sponsor's identity prevented a full and fair resolution of a formal reimbursement dispute would EPA consider it necessary to reveal this information under the authority of section 14(a)(4).

A claim of confidentiality for the identity of an exemption applicant poses a somewhat different problem. An exemption holder has an obligation under TSCA to provide reimbursement to the test sponsor. The test sponsor or a person who has already paid reimbursement to a test sponsor, and thus may wish a contribution from others subject to the rule, are the only persons who have a specific need to identify the exemption holders so that they can seek reimbursement from them. If exemption applicants assert a claim of confidentiality, EPA will withhold this information until the Agency receives a notification from a test sponsor of an intent to seek reimbursement from exemption holders. Then, under EPA confidentiality procedures, EPA will notify the exemption holders that it intends to release this information under section 14(a)(4) unless the exemption holder immediately takes steps to contact the requesting party (directly, or through an intermediary) or proposes a way for the reimbursement process to proceed without release of the exempted company's identity.

Under EPA's current process for developing enforceable test standards for test rules, the final Phase II test rule for a substance will specify the protocols which must be used for a particular test. While comments asserted that a study plan submitted by a party could contain confidential business information, EPA does not believe any test sponsor could assert a valid claim for confidentiality for the design of the proposed study. However, if such a claim were asserted, EPA believes that such protocol information is clearly included in the concept of "data underlying a health and safety study" and thus would disclose such information. The only statutory basis under section 14(b) for withholding such information would be that it revealed "process" or "mixture" information, and EPA cannot envision how a testing protocol could reveal such data. EPA will withhold this information only if the submitter substantiates the claim that it is confidential business information.

The only circumstance suggested by the comments under which the identity of the laboratory performing a test would be confidential would be if the test sponsor's identity were confidential and revealing the name of the lab would reveal the identity of the test sponsor. EPA has concluded that the identity of the lab performing a test is data underlying a health and safety study because the quality of testing may vary according to the caliber of the laboratory performing the test. Therefore, the disclosure of such information is governed by section 14(b) and would be released. EPA does not believe that revealing the identity of a lab would ever reveal process or mixture information. If a test sponsor is concerned about revealing its identity, it should select a test lab whose identity would not reveal this information.

EPA is requiring that test sponsors substantiate at the time of submission confidentiality claims for certain types of study plan information. EPA believes that unexpected disruption to the process may result if substantiation is not required at the time study plan information is submitted. EPA believes that its revised approach will severely limit the necessity for confidentiality claims and that this requirement for substantiation will not place a significant burden on the regulated industry.

VI. Rulemaking Record

EPA has established a public record for this rulemaking, docket number [OPTS–42052], which contains the following information:

(1) **Federal Register** notices pertaining directly to this rule consisting of:

(a) Notice of proposed rule pertaining to exemptions (45 FR 48512).

(b) Proposed rule related notice describing changes in EPA's test standards policy and test rule development process (47 FR 13012).

(2) **Federal Register** notices related to this rule consisting of:

(a) Proposed health effects testing standards (44 FR 27334 and 44 FR 44054).

(b) Proposed chemical fate and ecological effects testing standards 45 FR 77332).

(c) Final rule concerning EPA's good laboratory practice standards (48 FR 53922).

(d) Final rule concerning data reimbursement (48 FR 31786).

(3) List of comments pertaining to this rule.

(4) List of comment submitters.

(5) Written communications pertaining to this rule.

This record, which includes basic information considered by the Agency in developing this proposal and appropriate **Federal Register** notices, is available for inspection in the OPTS Reading Room, Room E–107, 401 M St., SW., Washington, D.C., from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. The Agency will supplement the record with additional information as it is received.

VII. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This rule on test rule development and exemption application procedures is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The regulation is a procedural rule and will have virtually no effect on the economy. The rule describes the process EPA will use to develop test rules under section 4(a)

of TSCA and to grant exemptions from those test rules under section 4(c) of TSCA. It will not cause major price or cost increases but rather provides a mechanism to avoid duplicative testing, thereby reducing costs to the regulated community. The regulation will not significantly affect competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; rather, it encourages the development of innovative and cost-effective testing methodologies.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, will be included in the rulemaking record.

VIII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, Sept. 19, 1980), EPA is certifying that this rule will not have a significant impact on a substantial number of small entities.

By facilitating an exemption process in which a single manufacturer or processor can sponsor tests on behalf of all those subject to a TSCA section 4 test rule, this rule reduces the administrative and financial burden which those testing rules might otherwise impose on regulated industries. The impact which test rules are expected to have on small entities was discussed in the Dichloromethane, Nitrobenzene, and 1,1,1-Trichloroethane Proposed Rule, published in the Federal Register of June 5, 1981 (46 FR 30300). The revised exemption procedures described in this rule are expected to present an even smaller burden to the exemption applicant than those referred to in that test rule because test rules will henceforth give specific guidance as to what types of data, if any, are required to support equivalence assertions. This will reduce the possibility that an applicant may submit more data than the Agency requires to make a decision.

EPA's decision to provide testing guidance in the form of suggested guidelines rather than required protocols is also expected to reduce the administrative and financial burden on affected industries. Under this approach, firms whose existing testing facilities or practices differ from those described in EPA's recommended protocols need not modify their procedures unless EPA finds that these variations are great enough to significantly affect the data generated. Therefore, companies sponsoring testing are less likely to find it necessary to modify existing testing practices and will have more flexibility in selecting new ones.

IX. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070-0033.

List of Subjects in 40 CFR Part 790

Testing, Exemptions, Environmental protection, Hazardous materials, Chemicals.

Dated: September 28, 1984.

William D. Ruckelshaus,

Administrator.

Therefore, Chapter I of 40 CFR is amended by adding a new Part 790 to read as follows:

PART 790—TEST RULE DEVELOPMENT AND EXEMPTION PROCEDURES

Subpart A—General Provisions

Sec.

Subpart B—Two Phase Test Rule Development

Subparts C-D—[Reserved]

Subpart E—Exemptions

Authority: [TSCA, 15 U.S.C. 2603(b)(3)(A), 2603(c)].

Subpart A—General Provisions

§ 790.1 Scope, purpose, and authority.

(a) This part establishes the procedures to be used in promulgating test rules under section 4(a) of the Act and sets forth the process by which exemptions from those test rules will be granted.

(b)(1) Section 4(a) of the Act authorizes EPA to require manufacturers and processors of chemical substances and mixtures to test chemical substances and mixtures for health and/or environmental effects.

(2) Sections 4(b)(1) and 3(12)(A) of the Act specify that each test rule must include standards for the development of test data which prescribe the "health and environmental effects" and the "information relating to toxicity, persistence, and other characteristics which affect health and the environment" for which test data are to be developed.

(3) Sections 4(b)(1) and 3(12) of the Act authorize EPA to prescribe the manner in which tests are to be conducted in the development of such data and any other such requirements as are necessary to assure the development of adequate and reliable data.

(4) Section 4(c) of the Act permits any person subject to a test rule promulgated under section 4(a) of the Act to request an exemption from the requirements of such a rule. The Administrator is directed to approve an application for exemption if he/she determines that:

(i) The chemical to which the application pertains is equivalent to one for which data have been or are being developed pursuant to the same testing rule; and

(ii) Submission of additional data by the applicant would be duplicative of data already submitted or under development.

(5) Section 4(b)(3)(A) of the Act authorizes the Administrator to permit two or more persons subject to a test rule to designate one of themselves or a qualified third party to conduct testing and submit data on their behalf.

(6) Sections 4(c)(3) and 4(c)(4) of the Act provide that persons receiving exemptions provide reimbursement to all those persons who have contributed or are contributing to financing the development of the data on the basis of which the exemption was granted. Such reimbursement is to be for a portion of the costs incurred. If the persons involved cannot agree on the amount and method of reimbursement, EPA is required to order the person granted the exemption to provide fair and equitable

reimbursement to the appropriate parties.

§ 790.2 Applicability.

This part is applicable to manufacturers and processors of chemical substances or mixtures who are subject to the testing requirements of a rule promulgated under section 4(a) of the Act. These procedures are applicable to each test rule in Part 799 of this Chapter unless otherwise stated in specific test rules in Part 799 of this Chapter.

§ 790.3 Definitions.

Terms defined in the Act and not explicitly defined herein are used with the meaning given in the Act. For the purpose of this part:

"Act" means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

"Additive" means a chemical substance that is intentionally added to another chemical substance to improve its stability or impart some other desirable quality.

"Chemical" means a chemical substance or mixture.

"Consortium" means an association of manufacturers and/or processors who have made an agreement to jointly sponsor testing.

"EPA" means the U.S. Environmental Protection Agency.

"Equivalence data" means chemical data or biological test data intended to show that two substances or mixtures are equivalent.

"Equivalent" means that a chemical substance or mixture is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance.

"Exemption" means an exemption from a testing requirement of a test rule promulgated under section 4 of the Act and Part 799 of this Chapter.

"Impurity" means a chemical substance which is unintentionally present with another chemical substance.

"Joint sponsor" means a person who sponsors testing pursuant to section 4(b)(3)(A) of the Act.

"Joint sponsorship" means the sponsorship of testing by two or more persons in accordance with section 4(b)(3)(A) of the Act.

"Person" means an individual, partnership, corporation, association, scientific or academic establishment, or organizational unit thereof, and any other legal entity.

"Principal sponsor" means an individual sponsor or the joint sponsor who assumes primary responsibility for the direction of a study and for oral and written communication with EPA.

"Protocol" means the plan and procedures which are to be followed in conducting a test.

"Reimbursement period" refers to a period that begins when the data from the last non-duplicative test to be completed under a test rule are submitted to EPA and ends after an amount of time equal to that which had been required to develop data or after five years, whichever is later.

"Sponsor" means the person or persons who design, direct and finance the testing of a substance or mixture subject to a test rule in Part 799 of this chapter.

"Test substance" means the form of chemical substance or mixture that is specified for use in testing.

§ 790.5 Submission of information.

All submissions to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule (e.g. § 799.4400 for 1,1,1-trichloroethane) and must be addressed to:

Document Control Office (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460.

In addition, a copy of the cover memo for all submissions must be addressed to:

Director, Compliance Monitoring Staff (EN–342), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460.

§ 790.7 Confidentiality.

(a) Any person subject to the requirements of a test rule promulgated under section 4 of the Act may assert a claim of confidentiality for certain information submitted to EPA in response to the test rule. Any information claimed as confidential will be treated in accordance with the procedures in Part 2 of this title and section 14 of the Act. Failure to assert a claim of confidentiality at the time the information is submitted will result in the information being made available to the public without further notice to the submitter.

(b) A claim of confidentiality must be asserted by circling or otherwise marking the specific information claimed as confidential and designating it with the words "confidential business information," "trade secret," or another appropriate phrase indicating its confidential character.

(c) If a person asserts a claim of confidentiality for study plan information described in § 790.30(c)(1)(iii)(D), (iv), (v), and (vi) of the part, the person must provide a detailed written substantiation of the claim by answering the questions in this paragraph. Failure to provide written substantiation at the time the study plan information is submitted will be considered a waiver of the claim of confidentiality, and the study plan information will be disclosed to the public without further notice.

(1) Would disclosure of the study plan information disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur.

(2) Would disclosure of the study plan information disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur.

(3) What harmful effects to your competitive position, if any, do you think would result from disclosure of this information? How would a competitor use such information? How substantial would the harmful effects be? What is the causal relationship between disclosure and the harmful effects?

(4) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(5) What measures have you taken to guard against disclosure of this information to others?

(6) To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?

(7) Has this information been disclosed to the public in any forms? Describe the circumstances.

(8) Has the information been disclosed in a patent?

(9) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determination regarding this information? If so, copies of such determinations must be included in the substantiation.

(d) If the substantiation provided under paragraph (c) of this section contains information which the submitter considers confidential, the submitter must assert a separate claim of confidentiality for that information at the time of submission in accordance with paragraph (b) of this section.

Subpart B—Two Phase Test Rule Development

§ 790.20 Phase I test rule.

(a) If EPA determines that it is necessary to test a chemical substance or mixture under section 4 of the Act, it will promulgate a Phase I test rule in Part 799 of this chapter through a notice-

and-comment rulemaking which specifies the following:

(1) Identification of the chemical for which testing is required under the rule.

(2) The health or environmental effect or effects or other characteristics for which testing is being required.

(3) Which test substance(s) must be tested.

(4) A reference to appropriate guidelines for the development of test data.

(5) The EPA Good Laboratory Practice requirements for the required testing.

(6) Who must submit either letters of intent to conduct testing or exemption applications.

(7) What types of data EPA will examine in determining equivalence if more than one test substance is to be tested.

(b) [Reserved].

§ 790.22 Persons subject to Phase I test rule.

(a) Each Phase I test rule will specify whether manufacturers, processors, or both are subject to the requirement for testing of the subject chemical under section 4(b)(3)(B) of the Act and will indicate who will be required to submit letters of intent to submit study plans and to conduct testing.

(1) If testing is being required to allow evaluation of risks:

(i) Primarily associated with manufacture of the chemical, or

(ii) Associated with both manufacture and processing of the chemical, or

(iii) Associated with distribution in commerce, use, and/or disposal activities concerning the chemical, each manufacturer of the chemical will be subject and must respond to the test rule. While legally subject to the test rule in circumstances described in paragraph (a)(1) (ii) and (iii) of this section, processors of the chemical have no obligation to respond unless directed to do so in a subsequent notice as set forth in § 790.28(b) or § 790.39(a)(2) of this part.

(2) If testing is being required to allow evaluation of risks associated soley with processing of the chemical, processors will be subject and must respond to the test rule.

(b) [Reserved].

§ 790.25 Submission of letter of intent to test or exemption application.

(a) No later than 30 days after the effective date of a Phase I test rule, each person subject to that rule and required to respond to that rule as provided in § 790.22(a) must, for each test required, either notify EPA by letter of their intent to submit study plans and to conduct testing or submit to EPA an application for an exemption from the study plan submission and testing requirements for the test.

(b) EPA will consider letters of intent to test as commitments to submit study plans and to sponsor the tests for which they are submitted unless EPA agrees to the substitution of an exemption application in instances where more than one person indicates an intent to sponsor equivalent tests. Each letter of intent to conduct testing must include:

(1) Identification of test rule.

(2) Name, address, and telephone number of the firm(s) which will be sponsoring the tests.

(3) Name, address, and telephone number of the appropriate individual to contact for further information.

(4) For sponsors participating in a testing consortium—a listing of other members of the consortium signed by each member, and a designation of who is to serve as principal sponsor.

(5) A list of the testing requirements for which the sponsor(s) intends to submit study plans and conduct tests.

(6) If EPA is requiring testing of more than one representative substance—which test substance the sponsor(s) intends to use in each of the tests.

(c) Any person not manufacturing or processing the subject chemical as of the effective date of the final Phase I test rule or by 30 days after the effective date of the rule or, when both manufacturers and processors are subject to the rule, not processing as of the effective date of the final Phase I test rule or by 30 days after publication of the **Federal Register** notice described in § 790.28(b)(2) of this part who, before the end of the reimbursement period, manufactures or processes the test chemical and who is subject to and required to respond to the test rule must submit the letter of intent to test or exemption application required by paragraph (a) of this section or § 790.28(b)(3) of this part by the date manufacture or processing begins.

(d) Manufacturers subject to a Phase I test rule who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption from testing for each test for which testing is required in a Phase I test rule will be considered in violation of that rule beginning on the 31st day after the effective date of the Phase I test rule or on the date manufacturer begins as described in paragraph (c) of this section.

(e) Processors subject to a Phase I test rule and required to respond pursuant to § 790.22(a)(2) or a **Federal Register** notice as described in § 790.28(b)(2) of this part who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption for each test for which testing is required in a Phase I test rule will be considered in violation of that rule beginning on the 31st day after the effective date of the Phase I test rule or 31 days after publication of the **Federal Register** notice described in § 790.28(b)(2) of this part or on the date processing begins as described in paragraph (c) of this section, as appropriate.

§ 790.28 Procedure if no one submits a letter of intent to conduct testing.

(a) *If only manufacturers are subject to rule.* (1) This paragraph applies if testing is being required solely to allow evaluation of risks associated with manufacturing and the final Phase I test rule states that manufacturers only are responsible for testing.

(2) If no manufacturer subject to the rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the final Phase I test rule, EPA will notify all the manufacturers by certified mail or publish a notice in the **Federal Register** of this fact specifying the tests for which no letter of intent has been submitted and will give the manufacturers an opportunity to take corrective action. If no manufacturer submits a letter of intent to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the **Federal Register** notice described in this paragraph, all manufacturers subject to the rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the **Federal Register** notice described in this paragraph until a proposed study plan has been submitted for each required test.

(b) *If manufacturers and processors are subject to the rule.* (1) This paragraph applies if testing is being required to allow evaluation of risks associated with manufacturing and processing or with distribution in commerce, use or disposal of the chemical and the final Phase I test rule states that manufacturers and processors are responsible for testing.

(2) If no manufacturer subject to the rule has notified EPA of its intent to conduct testing for one or more of the required tests within 30 days after the effective date of the final Phase I test rule, EPA will publish a notice in the **Federal Register** of this fact specifying the tests for which no letter of intent has been submitted.

(3) No later than 30 days from the date of publication of the **Federal Register** notice described above in paragraph (b)(2) of this section, each person

processing the subject chemical as of the effective date of the final Phase I test rule or by 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section must, for each test specified in the **Federal Register** notice, either notify EPA by letter of their intent to submit study plans and conduct testing or submit to EPA an application for an exemption from the study plan submission and testing requirements for the test.

(4) If no manufacturer or processor of the test chemical has submitted a letter of intent to conduct one or more of the required tests within 30 days from the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, EPA will notify all manufacturers and processors by certified mail or publish a **Federal Register** notice of this fact specifying the tests for which no letter of intent has been submitted. This letter or **Federal Register** notice will give the manufacturers and processors an opportunity to take corrective action. If no person submits a letter of intent to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the **Federal Register** notice, all manufacturers and processors subject to the rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the **Federal Register** notice until a proposed study plan has been submitted for each required test.

(c) *Only processors are subject to rule.* (1) This paragraph applies if testing is being required solely to allow evaluation of risks associated with processing and the final Phase I test rule states that only processors are responsible for testing.

(2) If no processor subject to the rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule, EPA will notify all the processors by certified mail or publish a notice in the **Federal Register** of this fact, specifying the tests for which no letter of intent has been submitted and give the processors an opportunity to take corrective action. If no processor submits a letter of intent to conduct one or more of the required tests within 30 days after receipt of the certified letter or publication of the **Federal Register** notice described in this paragraph, all processors subject to the rule will be in violation of the test rule from the 31st day after receipt of the certified letter or publication of the **Federal Register** notice described in this paragraph until a proposed study plan has been submitted for each required test.

§ 790.30 Submission of proposed study plans.

(a) *Who must submit study plans.* (1) Persons who notify EPA of their intent to conduct tests must submit proposed study plans for those tests on or before 90 days after the effective date of the Phase I rule; or, for processors responding to the notice described in § 790.28(b)(2) of this part, 90 days after the publication date of that notice; or 60 days after the date manufacture or processing begins as described in § 790.25(c) of this part, as appropriate. Only one set of study plans should be prepared and submitted by persons who are jointly sponsoring testing. Study plans must be prepared according to the requirements of this subpart and Part 792 of this chapter.

(2) Any person subject to a test rule may submit a proposed study plan for any test required by the rule at any time, regardless of whether the person previously submitted an application for exemption from testing for that test.

(3) Unless EPA has granted an extension of time for submission of study plans, manufacturers who notify EPA that they intend to conduct testing and who do not submit proposed study plans for those tests on or before 90 days after the effective date of the Phase I test rule or 60 days after the date manufacture begins as described in § 790.25(c) of this part will be considered in violation of the test rule as if no letter of intent to test had been submitted.

(4) Unless EPA has granted an extension of time for submission of study plans, processors who notify EPA that they intend to conduct testing and who do not submit proposed study plans for those tests on or before 90 days after the effective date of the Phase I test rule or 90 days after the publication date of the notice described in § 790.28(b)(2) of this part, or 60 days after the date processing begins as described in § 790.25(c) of this part, as appropriate, will be considered in violation of the test rule as if no letter of intent to test had been submitted.

(b) *Extensions of time for submission of study plans.* (1) The Agency may grant requests for additional time for study plan development on a case-by-case basis. Requests for additional time for study plan development must be made in writing to EPA. Each extension request must demonstrate why that extension should be granted. EPA will notify the submitter by certified mail of EPA's decision to grant or deny an extension request.

(2) Persons who have been granted an extension of time for submission of study plans as described in paragraph (b)(1) of this section and who do not submit proposed study plans in accordance with the new deadline granted by EPA will be considered in violation of the test rule as if no letter of intent to test had been submitted.

(c) *Content of study plans.* (1) All study plans are required to contain the following information:

(i) Identity of the test rule.

(ii) The specific test requirements of that rule to be covered by the study plan.

(iii)(A) The names and addresses of the test sponsors.

(B) The names, addresses and telephone numbers of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(C) The name, address, and telephone number of the appropriate individual to contact for oral and written communications with EPA.

(D)(*1*) The names and addresses of the testing facilities and the names, addresses, and telephone numbers of the testing facilities, administrative officials and project manager(s) responsible for the testing.

(*2*) Brief summaries of the training and experience of each professional involved in the study, including study director, veterinarian(s), toxicologist(s), pathologist(s), chemist(s), microbiologist(s), and laboratory assistants.

(iv) Identity and data on the chemical substance(s) being tested, including physical constants, spectral data, chemical analysis, and stability under test and storage conditions, as appropriate.

(v) Study protocol, including rationale for species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; description of diet to be used and its source, including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(vi) Schedule for initiation and completion of each short-term test and of each major phase of long-term tests; schedule for submission of interim progress and final reports to EPA.

(2) Information required under paragraph (c)(1)(iii)(D) of this section is not required in proposed study plans if the information is not available at the time of study plan submission; however,

the information must be submitted before the initiation of testing.

(d) *Incomplete study plans.* Upon receipt of a proposed study plan, EPA will review the study plan to determine whether it complies with paragraph (c) of this section. If EPA determines that the proposed study plan does not comply with paragraph (c) of this section, EPA will notify the submitter that the submission is incomplete and will identify the deficiencies and the steps necessary to complete the submission. The submitter will have 15 days from the day it receives this notice to submit appropriate information to make the study plan complete. If the submitter fails to provide appropriate information to complete the study plan on or before 15 days after receipt of the notice, the submitter will be considered in violation of the test rule as if no letter of intent to conduct the test had been submitted.

§ 790.32 Proposed Phase II test rule.

If EPA determines that the proposed study plan complies with § 790.30(c) of this part, EPA will publish a proposed Phase II test rule in the **Federal Register** requesting comments on the ability of the study plan to ensure that data from the test will be reliable and adequate. EPA will provide a 45-day comment period and will provide an opportunity for an oral presentation upon the request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or from public comments that further comment is warranted.

§ 790.34 Final Phase II test rule.

After receiving and considering public comment, EPA will adopt the study plan, including the time deadlines and reporting schedules, as proposed or as modified in response to EPA review and public comments, in a final Phase II test rule as test standards and schedules for the required testing.

§ 790.35 Modification of study plans during conduct of study.

(a) *Application.* Any test sponsor who wishes to modify the adopted study plan for any test required under a test rule must submit an application in accordance with this paragraph. Application for modification must be made in writing to the Director, Compliance Monitoring Staff (EN-342), Office of Pesticides and Toxic Substances, EPA, or by phone, with written confirmation to follow within 10 working days. Applications must include appropriate explanation of why the modification is necessary.

(b) *Adoption.* To the extent feasible, EPA will seek public comment on all substantive changes in study plans. EPA will issue a notice in the **Federal Register** requesting comments on requested modifications. However, EPA will act on the requested modification without seeking public comment if either:

(1) EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy or validity of an ongoing study, or

(2) EPA determines that a modification clearly does not pose any substantive issues. EPA will notify the sponsor of EPA's approval or disapproval. When EPA approves a modification, it will publish a notice in the **Federal Register** indicating that the study plan has been modified.

§ 790.39 Failure to comply with a test rule.

(a)(1) Persons who notified EPA of their intent to conduct a test required in a test rule in Part 799 of this chapter and who fail to conduct the test in accordance with the test standards and schedules adopted in the final Phase II test rule, or as modified in accordance with § 790.35 of this part, will be in violation of the rule.

(2)(i) If a person fails to conduct a test in accordance with the test standards and schedules adopted in the test rule, EPA will notify each holder of an affected conditional exemption by certified letter or by notice in the **Federal Register** that all conditional exemptions from performance of that test will be terminated unless, within 30 days of receipt of the certified letter or the publication of the notice, a person subject to the rule provides adequate information to rebut EPA's preliminary decision or notifies EPA by letter that they intend to perform that test in accordance with the test standards adopted in the test rule. Exemption holders may also request a hearing in accordance with the procedures in § 790.93 and § 790.97 of this part.

(ii) Within 60 days of receipt of the certified letter or publication of the **Federal Register** notice described in paragraph (a)(2)(i) of this section, persons who notify EPA of their intent to conduct a test must submit the study plan information described in § 790.30(c)(1) (iii), (iv), and (vi) of this part that requires modification from that in the test standards and schedules adopted in the test rule. EPA will adopt modifications to the test standards and schedules in accordance with the procedures described in § 790.35(b) of this part.

(iii) If no person subject to the rules provides adequate information to rebut EPA's preliminary decision or notifies EPA by letter of its intent to conduct the required test, EPA will notify all affected exemption holders by certified letter or **Federal Register** notice that all conditional exemptions for performance of that test are terminated.

(b) Any person who fails or refuses to comply with any aspect of this Part or a test rule under Part 799 of this chapter is in violation of section 15 of the Act. EPA will treat violations of the Good Laboratory Practice standards as indicated in § 792.17 of this part.

Subparts C–D—[Reserved]

Subpart E—Exemptions

§ 790.80 Submission of exemption applications.

(a) *Who should file applications.* (1) Any manufacturer or processor subject to a test rule in Part 799 of this chapter may submit an application to EPA for an exemption from submitting proposed study plans for and from performing any or all of the tests required under the test rule.

(2) Processors will not be required to apply for an exemption or conduct testing unless EPA so specifies in a test rule or in a special **Federal Register** notice as described in § 790.28(b)(2) of this part under the following circumstances:

(i) If testing is being required to allow evaluation of risks associated with manufacturing and processing or with distribution in commerce, disposal or use of the chemical and manufacturers do not submit notice(s) of intent to conduct the required testing; or

(ii) If testing is being required solely to allow evaluation of risks associated with processing of the chemical.

(b) *When applications must be filed.* Exemption applications must be filed within 30 days of the effective date of the final Phase I test rule or, if being submitted in response to the **Federal Register** notice described in § 790.28(b)(2) of this part, within 30 days of the publication of that notice. Exemption applications must be filed by the date manufacture or processing begins by any person not manufacturing or processing the subject chemical as of the effective date of the final Phase I test rule or by 30 days after the effective date of the Phase I test rule, or, when both manufacturers and processors are subject to the rule, not processing as of the effective date of the final Phase I test rule or by 30 days after publication of the **Federal Register** notice described

in § 790.28(b)(2) of this part who, before the end of the reimbursement period, manufactures or processes the test substance and who is subject to the requirement to submit either a letter of intent to test or an exemption application.

(c) *Scope of application.* A person may apply for an exemption from all, or one or more, specific testing requirements in a test rule in Part 799 of this chapter.

§ 790.82 Content of exemption application.

The exemption application must contain:

(a) The identity of the test rule and specific testing requirement(s) from which an exemption is sought.

(b) Name, address, and telephone number of applicant.

(c) Name, address, and telephone number of appropriate individual to contact for further information.

(d)(1) If required in the test rule to establish equivalence:

(i) The chemical identity of the test substance on which the application is based.

(ii) Equivalence data specified in § 790.85 of this part.

(2) If a test rule requires testing of a single representative substance, EPA will consider all forms of the chemical subject to that rule to be equivalent and will not require the submission of equivalence data as described in § 790.85 of this part.

§ 790.85 Submission of equivalence data.

If EPA requires in a test rule promulgated under section 4 of the Act the testing of two or more test substances which are forms of the same chemical, each exemption applicant must submit the following data:

(a) The chemical identity of each technical grade chemical substance or mixture manufactured and/or processed by the applicant for which the exemption is sought. The exact type of identifying data required will be specified in the test rule, but may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining that the applicant's substance or mixture is equivalent to the specific test substance.

(b) The basis for the applicant's belief that the substance or mixture is equivalent to the test substance or mixture.

(c) Any other data which exemption applicants are directed to submit in the test rule which may bear on a determination of equivalence. This may include a description of the process by which each technical grade chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

§ 790.87 Approval of exemption applications.

(a) EPA will conditionally approve exemption applications if:

(1) EPA has received a complete proposed study plan for the testing from which exemption is sought and has adopted the study plan, as proposed or modified, as test standards in a final Phase II test rule, and

(2) The chemical substance or mixture with respect to which the application was submitted is equivalent to a test substance or mixture for which the required data have been or are being submitted in accordance with a final Phase II test rule, and

(3) Submission of the required test data concerning that chemical substance or mixture would be duplicative of data which have been or are being submitted to EPA in accordance with a test rule.

(b)(1) If a single representative substance is to be tested under a test rule, EPA will consider all forms of the chemical subject to that rule to be equivalent and will contact the exemption applicant only if information is missing or unclear.

(2) If two or more representative substances are to be tested under a test rule, EPA will evaluate equivalence claims made in each exemption application according to the criteria discussed in the test rule.

(i) If EPA finds an equivalence claim to be in error or inadequately supported, the applicant will be notified by certified mail. The applicant will be given 15 days to provide clarifying information.

(ii) Exemption applicants will be notified that equivalence has been accepted or rejected.

(c) The final Phase II test rule which adopts the study plans or a letter by certified mail will give exemption applicants final notice that they have received a conditional exemption. All conditional exemptions thus granted are contingent upon the test sponsors' successful completion of testing according to the specifications in the approved study plans.

§ 790.88 Denial of exemption application.

(a) EPA may deny any exemption application if:

(1) EPA determines that the applicant has failed to demonstrate that the applicant's chemical is equivalent to the test substance; or

(2) The exemption applicant fails to submit any of the information specified in § 790.82 of this part; or

(3) The exemption applicant fails to submit any of the information specified in § 790.85 of this part if required in the test rule; or

(4) EPA has not received an adequate study plan for the test for which exemption is sought; or

(5) The study sponsor(s) fails to initiate the required testing by the deadlines adopted in the final Phase II test rule; or

(6) The study sponsor(s) fails to submit data as required in the test standard and deadlines for submission of test data as adopted in the final Phase II test rule or as modified in accordance with § 790.35 of this part.

(b) EPA will notify the exemption applicant by certified mail or **Federal Register** notice of EPA's determination that the exemption application is denied.

§ 790.90 Appeal of denial of exemption application.

(a) Within 30 days after receipt of notification that EPA has denied an application for exemption, the applicant may file an appeal with EPA.

(b) The appeal shall indicate the basis for the applicant's request for reconsideration.

(c)(1) The applicant may also include a request for a hearing. Hearings will be held according to the procedures described in § 790.97 of this part.

(2) Hearing requests must be in writing and must be received by EPA within 30 days of receipt of the letter or publication of the **Federal Register** notice described in § 790.88(b) of this part. Hearing requests must provide reasons why a hearing is necessary.

(d) If EPA determines that there are material issues of fact, then the request for a hearing will be granted. If EPA denies a hearing request, EPA will base its decision on the written submission.

(e) EPA will notify the applicant of its decision within 60 days after EPA receives the appeal described in paragraph (a) of this section or within 60 days after completion of a hearing described in paragraph (c) of this section.

(f) The filing of an appeal from the denial of an exemption shall not act to stay the applicant's legal obligation under section 4 of the Act.

§ 790.93 Termination of conditional exemption.

(a) EPA shall terminate a conditional exemption if it determines that:

(1) The test which provided the basis for approval of the exemption application has not been started by the deadlines for initiation of testing adopted in the final Phase II test rule or modified in accordance with § 790.35 of this part; or

(2) Data required by the test rule have not been generated in accordance with the test standards or submitted in accordance with the deadlines for submission of test data that were adopted in the final Phase II test rule or modified in accordance with § 790.35 of this part; or

(3) The testing has not been conducted or the data have not been generated in accordance with the Good Laboratory Practice requirements in Part 792 of this chapter.

(b) If EPA determines that one or more of the criteria listed in paragraph (a) of this section has been met, EPA will notify each holder of an affected conditional exemption by certified mail or Federal Register notice of EPA's intent to terminate that conditional exemption.

(c) Within 30 days after receipt of a letter of notification or publication of a notice in the Federal Register that EPA intends to terminate a conditional exemption, the exemption holder may submit information to rebut EPA's preliminary decision or notify EPA by letter of its intent to conduct the required test.

(d)(1) The exemption holder may also include a request for a hearing. Hearings will be held in accordance with the procedures set forth in § 790.97 of this part.

(2) Hearing requests must be in writing and must be received by EPA within 30 days of receipt of the letter or publication in the Federal Register notice described in paragraph (b) of this section.

(e) EPA will notify the exemption holder by certified letter or by Federal Register notice of EPA's final decision concerning termination of conditional exemptions.

§ 790.97 Hearing procedures.

(a) Hearing requests must be in writing to EPA and must include the applicant's basis for appealing EPA's decision.

(b) If more than one applicant has requested a hearing on similar grounds, all of those appeals will be considered at the same hearing unless confidentiality claims preclude a joint hearing.

(c) EPA will notify each applicant of EPA's decision within 60 days after the hearing.

§ 790.99 Statement of financial responsibility.

Each applicant for an exemption shall submit the following sworn statement with his application:

I understand that if this application is granted before the reimbursement period described in section 4(c)(3)(B) of TSCA expires, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit data and upon whose data the granting of my application was based.

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Wednesday
October 10, 1984

Part III

Consumer Product Safety Commission

16 CFR Part 1632

Standard for the Flammability of Mattresses (and Mattress Pads); Final Rule

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1632

Standard for the Flammability of Mattresses (and Mattress Pads); Final Amendment

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission issues final amendments of the flammability standard for mattresses and mattress pads to eliminate requirements for production testing of mattresses and mattress pads by manufacturers of these products. The amendments issued below also make other changes to to the standard and implementing regulations to improve their clarity, precision, and practicability. The Commission has considered comments received in response to the notice of proposed rulemaking published on December 30, 1983, and has responded to significant issues raised by those comments. The Commission concludes that the amendments issued in this notice will reduce costs of testing and recordkeeping for manufacturers of products subject to the standard without decreasing protection to the public from risks of fires associated with ignition of mattresses and mattress pads from smoldering cigarettes.

EFFECTIVE DATE: The amendments will become effective on April 10, 1985.

FOR FURTHER INFORMATION CONTACT: Elizabeth Gomilla, Division of Regulatory Management, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 492-6400.

SUPPLEMENTARY INFORMATION:

Background

The Standard for the Flammability of Mattresses (and Mattress Pads) (16 CFR Part 1632) was issued in 1972 to protect the public from risks of death, personal injury, and property damage associated with fires which have resulted from ignition of mattresses by cigarettes. (*1, 2*) *

The standard was issued by the Department of Commerce under provisions of the Flammable Fabrics Act (FFA, 15 U.S.C. 1191 *et seq.*), and has been in effect since June 22, 1973. In 1973, responsibility for issuance and amendment of flammability standards under the FFA was transferred to the Consumer Products Safety Commission by section 30(d) of the Consumer Product Safety Act (CPSA, 15 U.S.C. 2079(b)).

As originally issued, the standard required manufacturers of mattresses to perform both prototype and production testing. A prototype test involves the testing of a mattress design prior to production to demonstrate that the materials and method of construction will resist cigarette ignition. Prototype testing must be repeated if any of the materials which influence resistance to cigarette ignition are changed. Prototype testing is essentially a one-time test of the design of each basic type of mattress.

After successful completion of requirements for prototype testing, the standard in its original form required manufacturers to group mattresses which they manufactured into "production units," and to sample and test mattresses from each production unit. The original standard required manufacturers to perform production testing at specified intervals as long as a particular mattress type is manufactured. (*1, 4*)

As issued in 1972, the standard prescribed procedures for both prototype and production testing. Both prototype and production testing involved placement of lighted cigarettes at specified locations on the surface of a mattress. The standard set forth pass/fail criteria for both types of tests.

Regulations issued at the same time as the original standard required manufacturers to maintain records demonstrating compliance with the requirements for prototype and production testing. The records required by these regulations included written results of both prototype and production tests, and photographic evidence of each test of a mattress. (*1, 4*)

Review of Standard

In 1978, Congress enacted legislation (Pub. L. 97-631, 92 Stat. 3742, 15 U.S.C. 2076(m)) which required the Commission to review existing rules and standards with a view toward elimination or modification of requirements in appropriate cases. In 1979, the Commission voted to include the mattress standard among the first three rules to be reviewed. (*3*)

After the Commission staff completed its review of the mattress standard, the Commission voted in 1980 to direct the staff to prepare appropriate documents to amend the standard and implementing regulations to reduce or simplify the requirements of the standard for sampling and testing; to reduce the recordkeeping requirements; to simplify the language used in the standard; and to make technical changes needed to improve the clarity and precision of the standard. (*1*)

Thereafter, Congress enacted the Consumer Product Safety Amendments of 1981 (Pub. L. 97-35, 95 Stat. 703, 752). This legislation amends section 4 of the FFA to provide that any proceeding for the issuance or amendment of a flammability standard shall be initiated by publication of an advance notice of proposed rulemaking (ANPR) which must include information about the product, the risk of injury, and regulatory alternatives under consideration. The requirement for publication of an ANPR is codified at 15 U.S.C. 1193(g).

In the **Federal Register** of June 10, 1982 (47 FR 25159), the Commission published the ANPR to begin a proceeding for amendment of the mattress standard. (*9*)

If, after considering comments and other submissions received in response to an ANPR, the Commission decides to continue a proceeding for the issuance or amendment of a flammability standard, sections 4 (d) and (i) of the FFA (15 U.S.C. 1193 (d) and (i)) require publication of a second notice in the **Federal Register** to propose the amendment, invite written comments and oral presentations on the proposal, and describe potential costs and benefits of the proposed amendment, as well as alternatives considered by the Commission before proposing the amendment.

In the **Federal Register** of December 30, 1983 (48 FR 57502), the Commission proposed amendments of the mattress standard, and solicited written comments and oral presentations on the proposal. (*33*) As required by section 4(i) of the FFA, the notice of proposal contained the Commission's preliminary analysis of the anticipated costs and benefits of the proposed amendments, and discussed regulatory alternatives considered.

After consideration of comments received in response to the proposal, a briefing package prepared by the Commission staff, and other relevant information, the Commission issues the amendments on a final basis by publication of this notice. In compliance with requirements of section 4(j) of the FFA, this notice contains the Commission's final regulatory analysis of the amendments, including a description of potential costs and benefits and alternatives to the final amendments considered by the

* Numbers in parentheses identify reference documents listed in Bibliography at the end of this notice. Requests for inspection of any of these documents should be made at the Commission's public reading room, 1111 18th Street, NW., Washington, D.C., or by calling the Office of the Secretary at (301) 492-6800.

Commission, as well as a summary of significant issues raised by the comments and the Commission's assessment of those issues.

Summary of Final Amendments

A major change to the standard made by the amendments issued below is the elimination of requirements for periodic sampling and testing of mattresses from manufacturers' production. The requirements for production testing were contained in the "basic sampling plan" of the standard as originally issued at § 1632.4(b)(2)(i)(B). Section 1632.4(b)(1) of the original standard authorized the Commission to approve "alternate sampling plans," and the Commission has approved four such alternate sampling plans. (These alternate sampling plans were codified at 16 CFR 1632.11, 1632.12, 1632.14, and 1632.15.) Because these alternate sampling plans are concerned only with the selection of samples for production testing, they have been revoked by the amendments issued below.

Another major change to the standard contained in the amendments issued below is the elimination of provisions in the original standard which allowed two or more individual firms or plants to collaborate in the qualification of a mattress design by prototype testing. These provisions were codified at § 1632.4(b)(2)(i)(A) of the original standard, and had the effect of allowing some of the firms or plants using a common mattress design to perform fewer of the prototype qualification tests than would otherwise be required by the standard. Written comments objecting to the elimination of these provisions and the Commission's reasons for making this change are discussed below.

Several technical changes have been made to the text of the standard to improve its clarity, precision, and practicability. These changes affect language in the standard which describes various products subject to and exempted from the requirements of the standard; one item of test apparatus; and some aspects of the test procedure.

As proposed in the notice of December 30, 1983, the Commission issues final amendments of § 1632.1 of the standard which:

1. Provide that a product utilizing a water or air-filled core covered with upholstery and ticking materials is a mattress subject to the requirements of the standard;

2. Add "futons" to the list of products which fall within the standard's definition of the term "mattress" (a futon is a flexible sleeping mat consisting of a ticking filled with resilient material); and

3. Specifically exclude convoluted foam pads not totally encased in ticking from the standard's definition of the term "mattress pad."

The amendments issued below also eliminate language from § 1632.2(c) of the original standard which purported to exclude mattresses from the coverage of the standard if they were subject to Motor Vehicle Safety Standard No. 302 (MVSS 302), administered by the National Highway Traffic Safety Administration. The Commission proposed this change after receiving information to the effect that MVSS 302 applies only to mattress tickings, and not assembled mattresses.

As proposed in the notice of December 30, 1983, the Commission issues final amendments to specify a particular kind of nonmetallic surface to be used as the top surface of the mattress support system when testing thin mattresses and mattress pads. Specifications for the nonmetallic surface are in § 1632.4(a)(1)(ii) of the amended standard, published below.

Additionally, provisions of § 1632.4(d) have been amended to provide that if a test is not conducted in a test room which has been conditioned to the temperature and relative humidity specified in § 1632.4(c), the test must begin within 10 minutes after the mattress is removed from the conditioning room. The amendments issued below also modify § 1632.4(d)(1)(iii) to provide that if a cigarette pops out of position when tested on a tuft, or rolls off a test location, the test must be repeated with a freshly lit cigarette on a different location of the same type.

Finally, the amendments issued below modify language in § 1632.3(b) of the standard to specify that in determining the extent of charring at any individual cigarette test location, measurements shall be made in all directions, including downward into the mattress in case of burns which penetrate through the surface of the mattress.

Comments on Proposal

In response to the notice of December 30, 1983, the Commission received written comments from the National Association of Bedding Manufacturers (*34,35*), National Retail Merchants Association (*40*), Citizens Committee for Fire Protection (*36*), Burn Foundation (*37*), Trauma Center Foundation (*38*), and Senator Edward Zorinsky. (*39*)

Although the Commission announced opportunity for oral presentations of data, views, and arguments concerning the proposed amendments, no person requested to make an oral presentation.

Comments from the National Association of Bedding Manufacturers (NABM) (*34,35*), and National Retail Merchants Association (*40*) express support for the proposal to modify the standard by elimination of requirements for production testing. These comments state that the mattress industry's experience with production testing indicates that once a mattress or mattress pad design has been qualified by prototype testing in accordance with the standard, the likelihood is small that a mattress or mattress pad produced in accordance with that prototype will fail the test in the standard for resistance to cigarette ignition.

Comments from Citizens Committee for Fire Protection (CCFP) (*36*), Burn Foundation (*37*), and Trauma Center Foundation (*38*) oppose elimination of requirements for production testing. These comments express the view that the record of compliance with the standard by the mattress industry is poor and does not justify elimination of production testing.

These comments also express the view that in the absence of requirements for production testing, small manufacturing plants, which compromise the majority of production facilities within the mattress industry, will not maintain adequate control to assure that their products consistently pass the test in the standard.

The Commission decided to propose amendments eliminating requirements for production testing after considering results of testing conducted by mattress manufacturers, the Commission's laboratory, and the Bureau of Home Furnishings of the State of California. (*16,24,33*)

In response to the advance notice of proposed rulemaking, NABM submitted results of testing conducted by four large mattress manufacturers and eleven small firms during the years 1977, 1978, and 1979. (*16*)

The information submitted by NABM showed that during each of those three years, the fifteen firms had manufactured a total of about 6,300 production units of mattresses. (The basic sampling plan in the standard defines a "production unit" as 500 mattresses, or three months' production, whichever occurs first.) All of these production units were sampled, tested in accordance with the standard, and found to be acceptable. In a few cases, the first test of the production unit did not yield passing results, but the production unit was found to be acceptable after a second test yielded no failure at any cigarette test location,

as provided by § 1632.4(b)(2)(i)(B) of the original standard. (*16*)

Additionally, before deciding to propose elimination of requirements for production testing, the Commission considered test results from a sample collected by the Commission staff in 1982. This sample consisted of 25 mattresses, each produced by a different manufacturer. When tested by the Commission's laboratory in accordance with the standard, 24 of the mattresses yielded passing results. (*24*) Commission investigators found that the failing mattress was a renovated mattress which had not been qualified by prototype testing because the renovating firm mistakenly believed that it was not subject to the requirements of the standard. (*24*)

In a separate investigation, another mattress renovated by a different firm was tested and yielded failing results. This particular mattress was not subject to the requirements of the standard and had not been qualified by prototype testing. (*24*)

The Commission had also considered results of testing conducted by the Bureau of Home Furnishings of the State of California before publishing the notice of December 30. During 1983, that agency tested 52 mattresses. Forty-nine of these mattresses passed the test in the standard. Investigation by the state agency disclosed that two of the three mattresses which yielded failing results had not been subjected to production testing. (*24*)

The comment from CCFP refers to the results of testing by the Commission and the California Bureau of Home Furnishings and on the basis of these results argues that one of every 16 mattresses offered for sale today will not pass the test in the standard. (*36*)

After reviewing and reconsidering the results of testing conducted by the Commission and the State of California, the Commission concludes that they do not support the argument that one of every 16 mattresses sold at this time will fail the test in the standard.

Of the 78 mattresses tested by the California Bureau of Home Furnishings and the Commission's laboratory, about one-third were produced by manufacturers known to be large firms. CCFP is correct in asserting that the majority of mattress manufacturers are small firms; however the vast majority of mattresses manufactured in the United States, 86 to 90 percent, are produced by large firms. The total production of all small manufacturers accounts for only about 10 to 14 percent of the mattresses produced each year. (*41, 44*). Thus, the test results under consideration involved a sample of mattresses which was not truly representative of all mattresses sold in the United States because of the disproportionately large number of tests units produced by small manufacturers.

Additionally, as stated in the notice of proposal, no more than three, and possibly only two, of the five test failures were attributable to factors which might have been detected by production testing. (*33*)

After consideration of the comments from both CCFP and NABM, the results of testing conducted by the California Bureau of Home Furnishings and the Commission laboratory, and the results of other testing described above and in the notice of proposal, the Commission concludes that elimination of requirements for production testing is not likely to lead to a deterioration of quality control programs by small or large manufacturers, or an increase in the rate of test failures in mattresses produced by those firms. (*41, 44*)

The comment from CCFP also contends that because entry into the mattress manufacturing industry is "relatively easy," many small firms may begin production of mattresses within the next few years. (*36*) The comment states that if requirements for production testing are eliminated, within a decade a substantial portion of the mattress industry may not be aware of the existence of the standard because prototype testing is required only when the basic design of a mattress is changed. Comments from CCFP (*36*) and Burn Foundation (*37*) assert that requirements for production testing are necessary to remind mattress manufacturers of the standard's existence and of the test which it prescribes.

Although CCFP is correct in asserting that the cost of entering the mattress industry is relatively low, in the past new firms were frequently founded by individuals who had some experience in the production of mattresses, usually as employees of an established mattress manufacturer. The comment from CCFP does not contain any information to show that this pattern is not likely to continue in the future. Consequently, the Commission anticipates that most firms which enter the mattress industry after the amended standard becomes effective will continue to be founded by persons with previous experience in the industry, including some knowledge of the existence and requirements of the mattress flammability standard.

Moreover, as noted above, small manufacturers account for only about 10 to 14 percent of the total production in terms of numbers of units manufactured. Whatever the number of small firms that enter or leave the industry, most mattresses will continue to be produced by large manufacturers.

Having considered all comments favoring and opposing elimination of requirements for production testing from the standard, the Commission concludes that once a mattress design has been qualified as acceptable by prototype testing, the likelihood is small that mattresses manufactured by using the same materials and methods of construction will yield failing test results. For this reason, the Commission concludes that requirements for production testing can be removed from the standard without significantly reducing the level of protection from risks of fires associated with ignition of mattresses by smoldering cigarettes.

Because provisions of alternate sampling plans codified at 16 CFR 1632.11, 1632.12, 1632.14, and 1632.15 are concerned exclusively with selection of samples for production testing, these alternate sampling plans have also been eliminated from the amended standard issued below.

As noted above, comments from CCFP, the Burn Foundation, and the Trauma Center Foundation expressed concern about quality control methods of small manufacturers, and questioned whether those methods would be adequate to assure continued production of mattresses which pass the test in the standard if requirements for production testing are eliminated.

The Commission observes that after the amendments issued below become effective, the standard will continue to require each manufacturer to perform prototype qualification testing with acceptable results for each basic combination of materials and construction methods used to manufacture mattresses before beginning production for sale in commerce. All mattresses of a particular prototype subsequently manufactured for sale to consumers must continue to be assembled from the same materials and by using the same construction methods as those utilized in the mattress prototype which has been accepted after prototype qualification testing. Materials may be substituted in the production of mattresses for sale in commerce only after successful completion of new prototype qualification testing, or after performing the ticking or tape edge substitution tests in the amended standard.

Additionally, § 1632.31(c) of the regulations issued below to implement the amended standard continues to require each manufacturer to maintain records of the manufacturing

specifications and description of each mattress prototype qualified by prototype testing. Such records should describe all materials used in each mattress prototype and the methods of assembly used to construct each mattress prototype in sufficient detail that in any subsequent examination by the Commission of mattresses currently being produced, the manufacturer can demonstrate that no changes have been made from the mattresses qualified by prototype testing. The description of each mattress prototype should indicate the order in which the component materials appear in the finished mattress from the outermost layer of material to the core; the composition of each component and amount of flame-retardant treatment, if any, which is present; and the type, density and thickness of any foam used in the mattress.

The implementing regulations also require the maintenance of records to demonstrate successful completion of all required prototype testing, as well as results of any testing in accordance with the amended standard relied upon to support substitution of ticking or tape edge materials.

On the basis of all currently available information, the Commission believes that compliance with the requirements of the amended standard and implementing regulations will assure that mattresses offered for sale to consumers will resist ignition from smoldering cigarettes.

During the months immediately following the effective date of the amended standard, the Commission will conduct a compliance program involving inspection of mattress manufacturing plants and collection of sample mattresses for testing. The FFA authorizes the Commission to initiate judicial and administrative proceedings to enforce flammability standards issued under that act. In its enforcement of the amended standard, the Commission can seek orders for flammability testing of mattresses or component materials if the circumstances of a particular case warrant such measures.

Change in Test Procedures

A comment from Trauma Center Foundation suggests that the test procedure in the amended standard should provide that certain cigarette test locations must be covered by two layers of sheeting material rather than one layer as specified in the notice of proposal and in the standard as originally issued.(*38*)

The comment does not furnish test data or other information demonstrating the effect of the requested change, and does not explain how such a change would improve the standard.

The change requested by this comment has not been incorporated in the amended standard issued below.

"Pooling" Prototype Test Results

In its original form, the standard contained provisions allowing two or more firms or plants producing mattresses from the same basic materials and methods of construction to "pool" prototype testing. Under the "pooling" provisions, if six surfaces of the common prototype are tested with acceptable results at a central location, every other firm or plant producing mattresses from that prototype is required to test only two surfaces with acceptable results to satisfy the requirements of the standard for prototype testing.

The notice of December 30, 1983, proposed to eliminate the provisions for "pooling" of prototype testing set forth in § 1632.4(b)(2)(i)(A) of the standard as originally issued.

A comment from NABM (*34*) urged the Commission not to eliminate provisions allowing firms and plants to "pool" prototype test results. NABM argues that such a change would result in a substantial increase in costs and burden to firms and plants which now rely on the prototype "pooling" provisions in the standard. NABM argues that requiring each firm or plant producing mattresses from a common prototype design will not reveal any defects in the prototype design beyond those which would be found if the prototype were qualified under existing provisions of the standard which allow "pooling" of prototype test results.

The Commission observes that two factors influence the ability of a mattress to withstand ignition from cigarettes: (a) The design of the mattress, and (b) the materials used in the construction of the mattress. (*41,46*)

When two or more firms "pool" prototype test results, six surfaces must be tested successfully at one production facility. The other plants or firms producing mattresses from the common prototype must each test two more surfaces with acceptable results.

All mattresses of any given prototype must be made from the same materials. However, when two or more plants at widely separated locations purchase the same component materials from local suppliers, some differences may exist in the materials received at each plant. To assure that any differences which may be present in the materials utilized by each manufacturing facility will not affect cigarette ignition, six mattress surfaces must be tested with acceptable results by each plant. (*41,46*)

When the standard contained requirements for sampling and testing mattresses from each plant's regular production, any differences which might be present in the materials used at each plant were of less significance, because any local variation great enough to adversely affect ignition resistance of any mattress prototype qualified by "pooled" prototype testing probably would be detected during the first two production tests. (*41,46*)

However, since requirements for production testing are eliminated by the amendments issued below, no further evaluation of materials used in the construction of a mattress is required once prototype testing is successfully completed. The Commission concludes that testing six mattress surfaces of each mattress prototype at each plant where those mattresses will be manufactured is a reasonable step to detect any differences in materials which may exist from one plant to another and adversely influence the ability of the mattress to pass the test in the standard. (*41,46*)

NABM is correct in asserting that elimination of the "pooling" provisions will increase costs of prototype testing. However, the increase would be equivalent to requiring two production tests following successful completion of prototype testing under the provisions which allowed "pooling" of prototype tests. The Commission does not believe that elimination of the "pooling" provisions for prototype testing will impose a significant increase in costs of prototype testing when that change is made together with the elimination of all requirements for production testing of mattresses.

For these reasons, the Commission has eliminated provisions which allowed "pooling" of prototype test results from the amended standard issued below.

Ticking Classification and Substitution

Included in the proposed amendments were provisions which set forth a test for classification of ticking materials (the outer covering of fabric on a mattress) and allowed substitution of certain ticking materials without the requirement for additional prototype testing.

Use of the ticking classification test is not mandatory. However, if ticking materials are not classified by using this test, a mattress manufacturer must perform new prototype qualification testing whenever the manufacturer changes ticking materials. As proposed in the notice of December 30, 1983, the

test for classification of ticking materials could be performed by a manufacturer of ticking materials on products which that firm sells to mattress manufacturers, or by a mattress manufacturer on ticking materials purchased from suppliers.

Comments from NABM and NRMA favored issuance of these provisions on a final basis. (*34,40*) The comment from NABM urged the Commission to add provisions for quilted tickings sewn together from two or more layers of fabric. (*34*)

The comment from NABM indicates that in some cases, mattress manufacturers produce quilted tickings from fabric, thread, and backing materials purchased from several suppliers. NABM requested addition of language to provide that mattress manufacturers which produce quilted tickings may rely on certifications from suppliers to the effect that a change in the component material produced by the supplier will not affect the classification of a quilted ticking assembled by using that particular material. (*34*)

NABM contends that if a mattress manufacturer assembling its own quilted ticking is required to perform the ticking classification test whenever any component material used in the quilted ticking is changed, the provision in the proposed amendments allowing substitution of ticking materials without performing additional prototype tests will be of little benefit to such a manufacturer.

As noted above, the ticking classification test can be performed either by the mattress manufacturer, or by the ticking supplier. A mattress manufacturer assembling its own quilted ticking from component materials assumes the function of a ticking supplier.

The ticking classification test measures the performance of the ticking material as it is used in the construction of a mattress. That test does not measure the performance of any individual component used in the production of ticking material. Consequently, the provisions for classification of ticking material in the proposed amendment furnish no basis for any supplier of thread, fabric, or backing material used in production of quilted ticking to certify that substitution of one particular component material for another will not affect the classification of a quilted ticking.

For this reason, the additional provision concerning certification by suppliers of materials used to produce quilted tickings requested in the comment from NABM have not been included in the amended standard issued below.

Substitution of Tape Edge Materials

The proposal of December 30, 1983, also prescribed a test to measure performance of binding tape materials used at the edges of the sleeping surfaces of a mattress, and allowed substitution of one tape edge material for another without requirements for additional prototype testing under specified conditions. A comment from NRMA expressed the view that the tape edge test provisions in the proposal were incomplete because they did not specify the procedure to be used. The provisions relating to testing of tape edge materials in the notice of proposal stated:

> A prototype mattress or mattress pad incorporating the substitute materials has been tested with 36 cigarettes [18 per surface—9 bare and 9 two-sheet) placed at tape edge locations with no ignitions occurring * * *.

The comment from NRMA suggests that language should be added to specify that the testing shall be performed by following the applicable procedures of § 1632.4 of the amended standard and applying the test criterion of § 1632.3(b). (*40*) While the test procedures of § 1632.4 are the only ones which could be used under the conditions specified in the language quoted above, the Commission finds that addition of the language suggested in this comment would not detract from, and might improve, the clarity of the amended standard, particularly to persons not familiar with the standard as originally issued. The change requested in the comment from NRMA has been incorporated in § 1632.7(b)(3) of the amended standard issued below.

Effective Date of Amended Standard

Section 4(b) of the FFA [15 U.S.C. 1193(b)] provides that an amendment of a flammability standard shall become effective twelve months after the date of its issuance on a final basis, unless the Commission finds for good cause shown that an earlier or later effective date is in the public interest, and publishes its reasons for that finding.

In the notice of proposal, the Commission solicited comments addressed to the issue of an appropriate effective date for the amended standard if it is issued on a final basis.

Two comments from NABM (*34,35*) and a third from Senator Edward Zorinsky (*39*) addressed the issue of an effective date for the amendment of the mattress standard.

A comment from a member firm of NABM which is a small business urged the Commission to make the amendment of the standard effective immediately upon publication. (*35*) This comment asserts that because the amendment eliminates existing requirements for production testing, any delay in the effective date of the amendment will result in unnecessary costs of such testing and recordkeeping for manufacturers. (*35*)

This comment states that the costs of production testing can be significant for small manufacturers. (*35*)

This comment also expresses the view that the only purpose of the statutory requirement for a delayed effective date of one year is to afford manufacturers of products which may be subject to a new or amended flammability standard adequate time to develop complying products and to obtain test equipment or locate commercial testing facilities. Since the proposed amendment of the standard eliminates requirements for production testing, this comment states that no delay is needed. (*35*)

The comment from Senator Zorinsky expressed support for the arguments advanced by the small manufacturer for an immediate effective date. (*39*)

A separate comment from NABM also expressed support for the small manufacturer's comment regarding the effective date of the amended standard. (*34*) However, NABM requested that all ticking material in production or in inventory on the effective date of the standard be exempted from provisions of § 1632.6 of the amended standard which concern classification of ticking materials. (*34*)

NABM states that exemption of ticking materials in production or in inventory is needed because mattress manufacturers will have unclassified ticking materials in their inventories on the effective date of the amended standard, and will not have the expertise to classify those materials in accordance with provisions of the amended standard. This comment contends that without the requested exemption of ticking materials in production or in inventory, mattress manufacturers will be required to return those materials to ticking suppliers for classification. (*34*)

As stated earlier, classification of ticking materials in accordance with provisions of § 1632.6 of the amended standard issued below is not mandatory. Rather, the amended standard allows substitution of certain ticking materials classified in accordance with provisions of § 1632.6 without the necessity of additional prototype testing.

However, the Commission acknowledges that the ability to

substitute one ticking material for another without the necessity for additional prototype testing will be of great practical value for most mattress manufacturers. The Commission also acknowledges that many mattress manufacturers may not have the expertise to classify ticking materials in accordance with provisions of the amended standard. (*41,47*)

Information about manufacturing practices within the mattress industry indicates to the Commission that some manufacturers turn over their inventories of component materials as frequently as ten times a year; others turn over inventories of component materials only two times a year. (*41,44*)

From this information, the Commission concludes that if the amended standard became effective six months after publication, almost all mattress manufacturers would have depleted their inventories of component materials, and would be able to obtain ticking materials classified in accordance with provisions of § 1632.6 of the amended standard by its effective date.

A delayed effective date of six months would reduce to a large extent the costs of production testing which were the concern of the comment from the small manufacturer. At the same time, such an effective date would provide almost all manufacturers the opportunity to exhaust existing inventories of unclassified ticking materials and to obtain new ticking materials classified in accordance with provisions of the amended standard.

Therefore, the Commission finds for good cause shown that an effective date six months after publication of the amended standard is in the public interest, for the reasons set forth above.

As provided by section 4(b) of the FFA (15 U.S.C. 1193(b)), mattresses and mattress pads which are "in inventory or with the trade" on the effective date of the amended standard are exempt from its requirements, but must comply with applicable requirments of the original standard.

Final Regulatory Analysis

Section 4(j) of the FFA (15 U.S.C. 1193(j)) requires the Commission to include a final regulatory analysis of potential costs and benefits in the notice by which it issues a final amendment of a flammability standard.

Information considered by the Commission at the time it proposed amendments of the mattress standard indicated that if the standard were modified to eliminate requirements for production testing, total savings to all mattress manufacturers might amount to as much as $2.4 million each year. At that time, the Commission also expressed the expectation that elimination of requirements for production testing from the standard would not have a significant adverse affect on resistance to cigarette ignition of mattresses offered for sale to consumers.

A comment from Burn Foundation (*37*) expressed the view that the proposed amendments would "considerably weaken" protection of the public from bedding fires without "a significant reduction of the economic impact" of standards as originally issued. In support of that assertion, the comment relied on information contained in the comment from CCFP (*36*) discussed above under the heading "Comments on Proposal."

After consideration of the comments from Burn Foundation and CCFP, and all others submitted in response to the notice of proposal, the staff briefing package, and other relevant information, the Commission concludes that the estimated reduction in costs of testing to the mattress industry cited in the notice of proposal is generally accurate. The Commission affirms the expectation that the modifications to the standard made by the amendments issued below, including elimination of requirements for production testing, will not have a significant adverse affect on the ability of mattresses offered for sale to consumers to resist ignition from cigarettes.

An additional but unquantifiable benefit of the amended standard issued below is that it is shorter, easier to understand, and more precise than the standard in its original form.

As an alternative to the provisions of the amended standard issued below, the Commission considered the possibility of allowing manufacturers to collaborate in qualification of mattress designs by "pooling" prototype qualification test results, as discussed above. However, the Commission finds that provisions to allow "pooling" of prototype test results could result in failure to detect differences in materials which may exist from one manufacturing facility to another and which may adversely affect resistance of mattresses to cigarette ignition. The Commission concludes that any additional costs imposed by provisions in the amended standard which require each manufacturing facility to test six surfaces of each mattress prototype will not be significant if those provisions become effective at the same time that all requirements for production testing are eliminated.

The Commission also considered the possibility of allowing mattress manufacturers who assemble quilted ticking to rely on certifications from suppliers of component materials that a change in those materials will not affect the classification of a quilted ticking assembled from such component materials. However, the Commission concluded that no provision of the amended standard furnishes a basis to support such a certification by a supplier of materials used in the assembly of a quilted ticking.

Finally, the Commission considered the possibility of modifying the standard to require certain cigarette test locations to be covered with two layers of sheeting material rather than one. The Commission did not include such a requirement in the amended standard issued below because it has no information to show what effect such a change would have on the test in the standard.

As required by section 4(j)(2) of the FFA, the Commission finds that the benefits expected from the amended standard issued below bear a reasonable relationship to its costs, and that the amended standard imposes the least burdensome requirement which prevents or adequately reduces risks of injury associated with fires from mattresses ignited by cigarettes.

As required by section 4(b) of the FFA (15 U.S.C. 1193(b)), the Commission finds that the amended standard issued below:

- Is needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage;
- Is limited to the products which have been determined to present such unreasonable risks;
- Is reasonable, technologically practicable, and appropriate; and
- Is stated in objective terms.

Environmental Considerations

As stated in the notice of proposal, the Commission's environmental review procedures provide at 16 CFR 1021.5(c)(1) that issuance or amendment of safety standards falls within the categories of Commission actions that have little or no potential for affecting the human environment.

The Commission does not foresee any special or unusual circumstances surrounding the amended standard issued below. For this reason, neither an environmental assessment or an environmental impact statement is required.

List of Subjects in 16 CFR Part 1632

Consumer protection, Flammable materials, Labeling, Mattresses and mattress pads, Records, Textiles, Warranties.

Conclusion and Promulgation

Therefore, having considered the products and the nature of the risks of the occurrence of fires leading to death, personal injury, or significant property damage which are addressed by the mattress flammability standard, comments received in response to the notice proposing amendment of the mattress standard, alternative provisions for amendment of the mattress standard, potential costs and benefits of an amendment of the standard, and other relevant information, pursuant to provisions of the Flammable Fabrics Act (15 U.S.C. 1193, 1194) and the Consumer Product Safety Act (15 U.S.C. 2079(b)), the Commission hereby amends Title 16, Chapter XVI, Chapter II, Subchapter D by revising Part 1632 to read as follows:

PART 1632—STANDARD FOR THE FLAMMABILITY OF MATTRESSES AND MATTRESS PADS (FF 4-72, AMENDED)

Subpart A—The Standard

Sec.

Subpart B—Rules and Regulations

Subpart C—Interpretations and Policies

Subpart A—The Standard

§ 1632.1 Definitions.

In addition to the definitions given in section 2 of the Flammable Fabrics Act as amended (15 U.S.C. 1191), the following definitions apply for the purpose of the standard.

(a) "Mattress" means a ticking filled with a resilient material used alone or in combination with other products intended or promoted for sleeping upon.

(1) This definition includes, but is not limited to, adult mattresses, youth mattresses, crib mattresses including portable crib mattresses, bunk bed mattresses, futons, water beds and air mattresses which contain upholstery material between the ticking and the mattress core, and any detachable mattresses used in any item of upholstered furniture such as convertible sofa bed mattresses, corner group mattresses, day bed mattresses, roll-a-way bed mattresses, high risers, and trundle bed mattresses. See § 1632.8 Glossary of terms, for definitions of these items.

(2) This definition excludes sleeping bags, pillows, mattress foundations, liquid and gaseous filled tickings such as water beds and air mattresses which do not contain upholstery material between the ticking and the mattress core, upholstered furniture which does not contain a detachable mattress such as chaise lounges, drop-arm love seats, press-back lounges, push-back sofas, sleep lounges, sofa beds (including jackknife sofa beds), sofa lounges (including glide-outs), studio couches and studio divans (including twin studio divans and studio beds), and juvenile product pads such as car bed pads, carriage pads, basket pads, infant carrier and lounge pads, dressing table pads, stroller pads, crib bumpers, and playpen pads. See § 1632.8 Glossary of terms, for definitions of these items.

(b) "Mattress Pad" means a thin, flat mat or cushion, and/or ticking filled with resilient material for use on top of a mattress. This definition includes, but is not limited to, absorbent mattress pads, flat decubitus pads, and convoluted foam pads which are totally enclosed in ticking. This definition excludes convoluted foam pads which are not totally encased in ticking.

(c) "Ticking" means the outermost layer of fabric or related material that encloses the core and upholstery materials of a mattress or mattress pad. A mattress ticking may consist of several layers of fabric or related materials quilted together.

(d) "Core" means the main support system that may be present in a mattress, such as springs, foam, hair block, water bladder, air bladder, or resilient filling.

(e) "Upholstery material" means all material, either loose or attached, between the mattress or mattress pad ticking and the core of a mattress, if a core is present.

(f) "Tape edge" (edge) means the seam or border edge of a mattress or mattress pad.

(g) "Quilted" means stitched with thread or by fusion through the ticking and one or more layers of upholstery material.

(h) "Tufted" means buttoned or laced through the ticking and upholstery material and/or core, or having the ticking and upholstery material and/or core drawn together at intervals by any other method which produces a series of depressions on the surface.

(i) "Manufacturer" means an individual plant or factory at which mattresses and/or mattress pads are produced or assembled.

(j) "Mattress prototype" means mattresses of a particular design, sharing all materials and methods of assembly, but excluding differences in mattress size. If it has been shown as a result of prototype qualification testing that an upholstery material or core will not reduce the ignition resistance of the mattress prototype, substitution of another material for such material shall not be deemed a difference in materials for prototype definition. (See § 1632.31(c)(4) for records required to demonstrate that a change of materials has not reduced ignition resistance of a mattress prototype.) If it is determined or suspected that a material has influenced the ignition resistance of the mattress prototype, a change in that material, excluding an increase in thickness, shall be deemed a difference in materials for purposes of prototype definition unless it is previously shown to the satisfaction of the Consumer Product Safety Commission that such change will not reduce the ignition resstance of the mattress prototype. Ticking materials may be substituted in accordance with § 1632.6. Tape edge materials may be substituted in accordance with § 1632.7.

(k) "Mattress pad prototype" means mattress pads of a particular design, sharing all materials and methods of assembly, but excluding differences in mattress pad size. A change in existing material, except an increase in thickness, shall be deemed a difference in materials for purposes of prototype definition unless it is previously shown to the satisfaction of the Consumer Product Safety Commission that such change will not reduce the ignition resistance of the mattress pad prototype. Ticking materials may be substituted in accordance with § 1632.6. Tape edge materials may be substituted in accordance with § 1632.7.

(l) "Surface" means one side of a mattress or mattress pad which is intended for sleeping upon and which can be tested.

§ 1632.2 Purpose, scope, and applicability.

(a) *Purpose.* (1) This standard prescribes requirements for testing of prototype designs of mattresses and mattress pads before the sale in commerce or the introduction in commerce of any mattress or mattress

pad which is subject to the standard. The standard prescribes a test to determine the ignition resistance of a mattress or a mattress pad when exposed to a lighted cigarette.

(2) The standard sets forth a test at § 1632.6 which may be used to classify ticking materials for resistance to cigarette ignition.

(3) The standard sets forth a test at § 1632.7 which may be used to demonstrate that the substitution of tape edge materials will not reduce the ignition resistance of a mattress prototype or a mattress pad prototype.

(b) *Scope.* (1) All mattresses, as defined in § 1632.1(a), and all mattress pads, as defined in § 1632.1(b), manufactured or imported after the effective date of this amendment are subject to the requirements of the standard as amended.

(2) All mattresses, as defined in § 1632.1(a), and all mattress pads, as defined in § 1632.1(b), manufactured or imported after June 22, 1973, and before the effective date of this amendment are subject to those requirements of the Standard for the Flammability of Mattresses (and Mattress Pads) (16 CFR Part 1632) which were in effect before the effective date of this amendment.

(3) Manufacturers or importers desiring to use the ticking substitution procedure provided in § 1632.6 may classify the ticking being used on each mattress prototype before or after the effective date of this amendment using the test procedure set forth in that section.

(4) One-of-a-kind mattresses and mattress pads may be excluded from testing under this standard in accordance with rules established by the Consumer Product Safety Commission. (See § 1632.31(f): exemption for mattresses and mattress pads prescribed by a physician.)

(c) *Applicability.* (1) The requirements for prototype testing prescribed by this standard are applicable to each "manufacturer" (as that term is defined in § 1632.1(i)) of mattresses or mattress pads subject to the standard which are manufactured for sale in commerce. The requirements of this standard for prototype testing are also applicable to all other persons or firms initially introducing mattresses or mattress pads into commerce, including importers; each such firm shall be deemed to be a "manufacturer" for purposes of this standard.

(2) The test at § 1632.6 for classification of ticking materials may be used by manufacturers of mattresses or mattress pads and by manufacturers of ticking materials. The test at § 1632.7 may be used by manufacturers of mattresses to demonstrate that substitution of tape edge materials will not reduce ignition resistance of a mattress prototype or a mattress pad prototype. Use of the tests in §§ 1632.6 and 1632.7 is optional.

§ 1632.3 General requirements.

(a) *Summary of test method.* The method measures the ignition resistance of a mattress or mattress pad by exposing the surface to lighted cigarettes in a draft-protected environment. The surfaces to be tested include smooth, tape edge, and quilted or tufted locations, if they exist on the mattress or mattress pad surface. A two-sheet test is also conducted on similar surface locations. In the latter test, the burining cigarettes are placed between the sheets.

(b) *Test criterion.* When testing the mattress or mattress pad surface in accordance with the testing procedure set forth in § 1632.4 *Mattress test procedure,* individual cigarette test locations pass the test if the char length is not more than 2 inches (5.1 cm) in any direction from the nearest point of the cigarette. In the interest of safety, the test operator should discontinue the test and record a failure before reaching the 2 inch char length if an obvious ignition has occurred.

(c) *Pre-market testing.* Each manufacturer required to perform prototype testing by the standard shall perform the testing required by the standard with acceptable results before selling in commerce or introducing in commerce any mattress or mattress pad which is subject to the standard.

(d) *Specimen selection and qualification.* (1) Each manufacturer required to perform prototype testing by the standard shall construct or select enough units of each proposed mattress prototype or proposed mattress pad prototype to provide six surfaces for testing. A minimum of three mattresses or mattress pads are required if both sides can be tested; six mattresses or mattress pads are required if only one side can be tested. Test each of the six surfaces according to § 1632.4(d). If all the cigarette test locations on all six mattress surfaces yield passing results using the criterion specified in § 1632.3(b), accept the mattress prototype. If all six surfaces of a mattress pad yield passing results using the criterion in § 1632.3(b), and all other applicable requirements prescribed by § 1632.5 are met, accept the mattress pad prototype. If one or more of the cigarette test locations on any of the six surfaces fail to meet the test criterion of § 1632.3(b), reject the mattress prototype or the mattress pad prototype.

(2) Prototype qualification testing may be repeated after action has been taken to improve the resistance of the mattress prototype or the mattress pad prototype to cigarette ignition by changes in design, construction methods, materials selection, or other means. When prototype qualification is repeated after rejection of a prototype, such qualification testing shall be conducted in the same manner as original qualification testing.

(3) Each mattress prototype and each mattress pad prototype must be accepted in prototype qualification before any mattress or mattress pad manufactured in accordance with such mattress prototype or mattress pad prototype is sold in commerce or introduced in commerce. Any manufacturer required to perform testing by the standard may rely on prototype tests performed before the effective date of this amended standard, provided that such tests were conducted in accordance with all requirements of §§ 1632.1(i), 1632.3(d), and 1632.4, and yield passing results when the test criterion of § 1632.3(b) is applied. If the ticking classification test at § 1632.6 is to be used when relying on prototype tests performed before the effective date of the standard, the ticking currently used on that mattress prototype must be classified before substitution of ticking using § 1632.6.

(4) Rejected prototype mattresses or prototype mattress pads shall not be retested, offered for sale, sold, or promoted for use as a mattress (as defined in § 1632.1(a)) or for use as a mattress pad (as defined in § 1632.1(b)) except after reworking to improve the resistance to ignition by cigarettes, and subsequent retesting and acceptance of the mattress prototype (as defined in § 1632.1(j)) or the mattress pad prototype (as defined in § 1632.1(k)).

§ 1632.4 Mattress Test Procedure.

(a) *Appraratus and Test Materials.—(1) Testroom.* The testroom shall be large enough to accommodate a full-scale mattress in a horizontal position and to allow for free movement of personnel and air around the test mattress. The test area shall be draft-protected and equipped with a suitable system for exhausting smoke and/or noxious gases produced by testing. The testroom atmospheric conditions shall be greater than 18°C (65°F) and at less than 55 percent relative humidity.

(i) The room shall be equipped with a support system (*e.g.* platform, bench) upon which a mattress may be placed flat in a horizontal position at a

reasonable height for making observations.

(ii) If thin flexible mattresses or mattress pads are being testing the room shall also be equipped with a glass fiberboard test surface. The glass fiberboard shall be approximately 1 inch (2.5 cm) thick and have a thermal conductivity of 0.30 ± 0.05 cal (g) / hr cm^2 °C/cm (0.24 ± 0.04 Btu/hr ft^2 °F/in) at 23.9°C (75°F).[1]

(2) *Ignition source.* The ignition source shall be cigarettes without filter tips made from natural tobacco, 85 ±2 mm long with a tobacco packing density of 0.270 ± 0.02 g/cm^3 and a total weight of 1.1 ± gm.

(3) *Fire extinguisher.* A pressurized water fire extinguisher, or other suitable fire extinguishing equipment, shall be immediately avaliable.

(4) *Water bottle.* A water bottle fitted with a spray nozzle shall be used to extinguish the ignited portions of the mattress.

(5) *Scale.* A linear scale graduated in millimeters, 0.1 inch, or 1/16 inch divisions shall be used to measure char length.

(6) *Sheets or Sheeting Material.* White, 100 percent cotton sheets or sheeting material shall be used. It shall not be treated with a chemical finish which imparts a characteristic such as permanent press or flame resistance. It shall have 120–210 threads per square inch and fabric weight of 3.7±0.8 oz/yd^2 (125±28 gm/m^2). The size of the sheet or sheeting material shall be appropriate for the mattress being tested.

(7) *Other apparatus.* In addition to the above, a thermometer, a relative humidity measuring instrument, a thin rod, straight pins, a knife or scissors, and tongs are required to carry out the testing.

(b) *Test Preparation.*

(1) *Mattress samples.* The mattress shall be removed from any packaging prior to conditioning. The mattress surface shall be divided laterally into two sections (see fig. 1), one section for the bare mattress tests and the other for the two-sheet tests.

(2) *Sheets or sheeting material.* The sheets or sheeting material shall be laundered once before use in an automatic home washer using the hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.

(i) The sheet shall be cut across the width into two equal parts after washing.

(ii) Sheeting material shall be cut in lengths to cover ½ of a mattress as described in § 1632.4(d)(3).

(3) *Cigarettes.* Unopened packages of cigarettes shall be selected for each series of tests. The cigarettes shall be removed from packaging prior to conditioning.

(c) *Conditioning.* The mattresses, laundered sheets or sheeting material, and loose cigarettes shall be conditioned in air at a temperature greater than 18°C (65°F) and a relative humidity less than 55 percent for at least 48 continuous hours prior to test. The mattresses, laundered sheets or sheeting material, and cigarettes shall be supported in a suitable manner to permit free movement of air around them during conditioning. The mattress meets this conditioning requirement if the mattress and/or all its component materials, except the metallic core, if present, have been exposed only to the above temperature and humidity conditions for at least 48 continuous hours prior to testing the mattress.

(d) *Testing—(1) General.* Mattress specimens shall be tested in a testroom with atmospheric conditions of a temperature greater than 18°C (65°F) and a relative humidity less than 55 percent. If the test is not performed in the conditioning room, at least one lit cigarette shall be placed on the mattress surface within 10 minutes of removal from the conditioning room. The other side of the mattress shall be tested immediately after completion of the first side.

(i) At least 18 cigarettes shall be burned on each mattress test surface, 9 in the bare mattress tests and 9 in the 2-sheet tests. If three or more mattress surface locations (smooth surface, tape edge, quilted, or tufted areas) exist in the particular mattress surface under test, three cigarettes shall be burned on each different surface location. If only two mattress surface locations exist in the particular mattress surface under test (tape edge and smooth surface), four cigarettes shall be burned on the smooth surface and five cigarettes shall be burned on the tape edge.

(ii) Light and place one cigarette at a time on the mattress surface. (If previous experience with a similar type of mattress has indicated that ignition is not likely, the number of cigarettes which may be lighted and placed on the mattress at one time is left to the test operator's judgment. The number of cigarettes must be carefully considered because a smoldering or burning mattress is extremely hazardous and difficult to extinguish.) The cigarettes must be positioned no less than 6 inches apart on the mattress surface. Each cigarette used as an ignition source shall be well lighted but not burned more than 4 mm (0.16 inch) when placed on the mattress. (Fire extinguishing equipment must be readily available at all times.)

(iii) If a cigarette extinguishes before burning its full length on any mattress surface location, pops out of position when tested on a tuft, or rolls off a test location, the test must be repeated with a freshly lit cigarette on a different portion of the same type of location on the mattress surface until either: the number of cigarettes specified in § 1632.4(d)(1)(i) have burned their full lengths; the number of cigarettes specified in § 1632.4(d)(1)(i) have extinguished before burning their full lengths; or failure has occurred according to § 1632.3(b) *Test criterion.*

(2) *Bare mattress tests*—(i) *Smooth surface.* Each burning cigarette shall be placed directly on a smooth surface location on the test surface on the half reserved for bare mattress tests. The cigarettes should burn their full lengths on a smooth surface without burning across a tuft, or stitching of a quilted area. However, if this is not possible because of mattress design, then the cigarettes shall be positioned on the mattress in a manner which will allow as much of the butt ends as possible to burn on smooth surfaces. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)). CAUTION: Even under the most carefully observed conditions, smoldering combustion can progress to the point where it cannot be readily extinguished. It is imperative that a test be discontinued as soon as ignition has definitely occurred. Immediately wet the exposed area with a water spray (from water bottle), cut around the burning material with a knife or scissors and pull the material out of the mattress with tongs. Make sure that all charred or burned material is removed. Ventilate the room.

(ii) *Tape edge.* Each burning cigarette shall be placed in the depression between the mattress top surface and the tape edge, parallel to the tape edge of the half of the test surface reserved for bare mattress tests. If there is only a seam or no depression at the edge, support the cigarettes in place along the edge and parallel to the edge with straight pins. Three straight pins may be inserted through the edge at a 45° angle such that one pin supports the cigarette at the burned end, one at the center, and

[1] Class fiberboard that meets Federal Specification HH–I–558B is acceptable. Under this specification, the board must be Form A, Class 1, and plain faced. Copies of the specifications may be obtained from the Business Service Centers of the General Services Administration Regional Offices.

one at the butt. The heads of the pins must be below the upper surface of the cigarette (see fig. 2). Report results for each cigarette as pass of fail as defined in the test criterion (see § 1632.3(b)).

MATTRESS PREPARATION

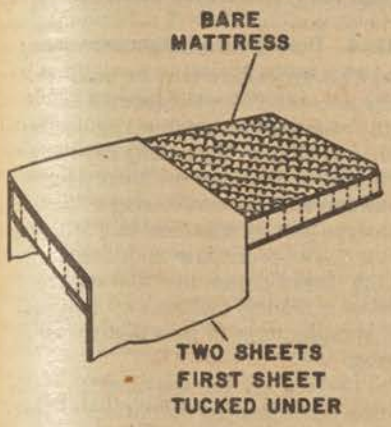

FIGURE 1

CIGARETTE LOCATION

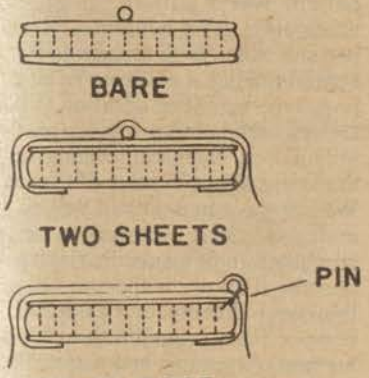

FIGURE 2

(iii) *Quilted location.* If quilting exists on the test surface, each burning cigarette shall be placed on quilted locations of the test surface. The cigarettes shall be positioned directly over the thread or in the depression created by the quilting process on the half of the test surface reserved for bare mattress tests. If the quilt design is such that the cigarettes cannot burn their full lengths over the thread or depression, then the cigarettes shall be positioned in a manner which will allow as much of the butt ends as possible to burn on the thread or depression. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(iv) *Tufted location.* If tufting exists on the test surface, each burning cigarette shall be placed on tufted locations of the test surface. The cigarettes shall be positioned so that they burn down into the depression caused by the tufts and so that the butt ends of the cigarettes burn out over the buttons or laces used in the tufts or the depressions made by the tufts on the half of the test surface reserved for bare mattress tests. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(3) *Two-sheet tests.* Spread a section of sheet or sheeting material smoothly over the mattress surface which has been reserved for the two-sheet test and tuck under the mattress. Care must be taken that hems or any other portion of the sheet which is more than one fabric thickness, is neither directly under nor directly over the test cigarette in the two-sheet test.

(i) *Smooth surfaces.* Each burning cigarette shall be placed directly on the sheet covered mattress in a smooth surface location as defined in the bare mattress test. Immediately cover the first sheet and the burning cigarette loosely with a second, or top sheet (see fig. 2). Do not raise or lift the top sheet during testing unless obvious ignition has occurred or until the cigarette has burned out. Whether a cigarette has extinguished may be determined by holding the hand near the surface of the top sheet over the test location. If no heat is felt or smoked observed, the cigarette has burned out. (If ignition occurs, immediately remove the sheets and cigarette and follow the cautionary procedures outlined in the bare mattress test. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(ii) *Tape edge.* (A) Each burning cigarette shall be placed in the depression between the top surface and the tape edge on top of the sheet, and immediately covered with a second sheet. It is important the air space be eliminated, as much as possible, between the mattress and the bottom sheet at the test location before testing. Depress the bottom sheet into the depression using a thin rod or other suitable instrument.

(B) In most cases, the cigarettes will remain in place throughout the test. However, if the cigarettes show a marked tendency to roll off the tape edge location, they may be supported with straight pins. Three straight pins may be inserted through the bottom sheet and tape at a 45° angle such that one pin supports the cigarette at the burning end, one at the center, and one at the butt. The heads of the pins must be below the upper surface of the cigarette (see fig. 2). Report results for

each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(iii) *Quilted locations.* If quilting exists on the test surface, each burning cigarette shall be placed in a depression caused by quilting, directly over the thread and on the bottom sheet, and immediately covered with the top sheet. It is important that the air space be eliminated, as much as possible, between the mattress and the bottom sheet at the test location before testing. Depress the bottom sheet into the depression using a thin rod or other suitable instrument. If the quilt design is such that the cigarettes cannot burn their full lengths over the thread or depression, then the cigarettes shall be positioned in a manner which will allow as much of the butt ends as possible to burn on the thread or depresssion. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(iv) *Tufted locations.* If tufting exists on the test surface, each burning cigarette shall be placed in the depression caused by tufting, directly over the tuft and on the bottom sheet, and immediately covered with the top sheet. It is important that the air space be eliminated, as much as possible, between the mattress and the bottom sheet at the test location before testing. Depress the bottom sheet into the depression using a thin rod or other suitable instrument. The cigarettes shall be positioned so that they burn down into the depression caused by the tuft and so that the butt ends of the cigarettes burn out over the buttons or laces, if used in the tufts. Report results for each cigarette as pass or fail as defined in the test criterion (see § 1632.3(b)).

(e) *Records.* Records of all prototype test results, and the disposition of rejected prototypes shall be maintained by the person or firm required to perform testing by the standard in accordance with § 1632.31(c).

§ 1632.5 Mattress pad test procedure.

(a) *Testing.* All mattress pads shall be tested, in the condition in which they are intended to be sold, according to § 1632.4 Mattress test procedure, using the glass fiberboard substrate.

(b) *Flame Resistant Mattress Pads.* The following additional requirements shall be applicable to mattress pads which contain a chemical fire retardant.

(1) These mattress pads shall be tested in accordance with § 1632.4 Mattress test procedure after they have been washed and dried 10 times as described in § 1632.5(b)(2).

(i) Such laundering is not required of mattress pads which are intended for one time use and/or are not intended to be laundered, as determined by the Consumer Product Safety Commission.

(ii) Mattress pads which are not susceptible to being laundered and are labeled "dryclean only" shall be drycleaned by a procedure which has previously been found acceptable by the Consumer Product Safety Commission.

(2) *Laundering Procedure.*

(i) The washing procedure to be used for flame resistant mattress pads is prescribed in AATCC Test Method 124–82, "Appearance of Durable Press Fabrics After Repeated Home Laundering" washing procedures 6.2(III), with a water temperature of 60°±2.8 °C (140°±5 °F)

(ii) The drying procedure to be used for flame resistant mattress pads is prescribed in AATCC Test Method 124–82, "Appearance of Durable Press Fabrics After Repeated Home Laundering," drying procedure 6.3.2(b).

(iii) Maximum load shall be 3.46 kg (8 lb) and may consist of any combination of test items and dummy pieces.

(iv) AATCC Test Method 124–82, "Appearance of Durable Press Fabrics After Repeated Home Laundering," is found in the Technical Manual of the American Association of Textile Chemist and Colorists, Vol. 58, 1982 (incorporated by reference). Copies of this document are available from the American Association of Textile Chemist and Colorists, Post Office Box 12215, Research Triangle Park, North Carolina 27709.

This document is also available for inspection at the Office of the Federal Register, Room 8401, 1100 L Street, NW., Washington, D.C. 20408. This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as—they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

(v) A different number of wash and dry cycles using another procedure may be specified and used, if that procedure has previously been found to be equivalent by the Consumer Product Safety Commission.

(3) *Labeling*—(i) *Treatment label.* If a mattress pad contains a chemical fire retardant, it shall be labeled with the letter "T" pursuant to rules and regulations established by the Consumer Product Safety Commission.

(ii) *Care label.* All mattress pads which contain a chemical fire retardant treatment shall be labeled with precautionary instructions to protect the pads from agents or treatments which are known to cause deterioration of their flame resistance. Such labels shall be permanent and otherwise in accordance with rules and regulations established by the Consumer Product Safety Commission in § 1632.31(b).

(iii) *Exception.* One time use products as defined in § 1632.5(b)(1)(i) are not subject to these labeling requirements.

§ 1632.6 Ticking substitution procedure.

(a) This procedure may be used to verify acceptable equivalency if a mattress or mattress pad manufacturer wishes to change the ticking used on a particular mattress or mattress pad prototype without conducting a prototype test as specified in § 1632.4 or § 1632.5. The procedure includes a ticking classification test that may be used by a ticking, mattress or mattress pad manufacturer or by a distributor of ticking.

(b) *Definitions.* For the purpose of this section the following definitions apply in addition to those in § 1632.1.

(1) *Mattress Ticking Prototype.* Means a ticking of a specific construction, color, or combination of colors or color pattern, weave pattern design, finish application, fiber content, and weight per unit area. With respect to film-coated ticking, a mattress ticking prototype means in addition to the factors listed above, a given method of application, chemical formula, and thickness of application of film coating. With respect to a quilted ticking, a mattress ticking prototype means the combination of a specific ticking as described above; a specific filling, thickness, density, and chemical composition; a specific thread; a specific method of quilting; and a specific backing fabric construction, weave, finish, fiber content, and weight.

(2) *Mattress Pad Ticking Prototype* (i) Means a ticking of a specific construction, color, or combination of colors or color pattern, weave pattern design, finish application, fiber content, and weight per unit area. With respect to film-coated ticking, a mattress pad ticking prototype means in addition to the factors listed above, a given method of application, chemical formula, and thickness of application of film coating.

(ii) Quilted ticking is excluded from this definition. Therefore, the following procedures may not be used to substitute quilted ticking used on or as a mattress pad.

(c) *Scope and application.* (1) This procedure provides an independent evaluation of the cigarette ignition characteristics of ticking and for the classification of ticking into one of three performance classes. Class A represents tickings evaluated as acting as barriers

against cigarette ignition; Class B represents tickings evaluated as having no effect on cigarette ignition; and Class C represents tickings evaluated as having the potential, in some manner, to act as a contributor to cigarette ignition.

(2) Substitution of any ticking which has been evaluated as Class A using the procedure in this § 1632.6 for any other ticking material shall not be a "difference in materials" as that phrase is used in §§ 1632.1 (j) and (k). Consequently, any ticking material evaluated as Class A under this test procedure may be used on any qualified mattress prototype or on any qualified mattress pad prototype without conducting new prototype tests.

(3) Substitution of any ticking which has been evaluated as Class B using the procedure in this § 1632.6 for the ticking material used on any mattress prototype or on any mattress pad prototype which was qualified in prototype testing with a testing material evaluated as Class B or a Class C shall not be a "difference in materials" as that phrase is used in §§ 1632.1 (j) and (k). Consequently, any ticking material evaluated as Class B under this test procedure may be used on any mattress or mattress pad which wa qualified in prototype testing with a Class B or Class C ticking material without conducting new prototype tests. However, if Class B ticking material is to be used on any mattress or mattress pad which was qualified in prototype testing with a Class A ticking material, the mattress prototype or mattress pad prototype must be requalified, using a Class B ticking.

(4) A ticking material which has been evaluated as Class C using the procedure in this § 1632.6 may be used only on a mattress or mattress pad which was qualified in prototype testing with that particular Class C ticking material. Consequently, a ticking material evaluated as Class C under this test procedure may not be used on any mattress or mattress pad which was qualified in prototype testing using another Class C ticking material, or a Class A or Class B ticking material, without conducting new prototype tests.

(d) *General Requirements.*

(1) This procedure is a ticking prototype performance classification test. Ticking not classified according to this procedure may be used on mattresses or mattress pads if the mattress prototype or mattress pad prototype has been qualified utilizing the unclassified ticking in question.

(2) *Test Criterion.*

(i) Cigarette—An individual cigarette test location passes the test if the char length is not more than 1 inch (2.54 cm) in any direction from the nearest point of the cigarette, and the cotton felt is not ignited.

CAUTION: In the interest of safety, the test operator should discontinue the test and record a failure before reaching the 1 inch (2.54 cm) char length if, in his opinion, an obvious ignition has occurred.

(ii) Test Specimen—An individual test specimen passes the test if all three cigarette test locations meet the cigarette test criterion of this paragraph.

(3) *Specimen selection.* Three specimens shall be used for each ticking prototype classification test, with each specimen measuring no less than 20 inches by 20 inches (50.8 cm x 50.8 cm) square. The three specimens shall be selected from any fabric piece taken from a ticking prototype. The specimens shall be representative of the ticking prototype.

(4) *Ticking Classification.* A ticking prototype is classified as Class A, Class B, or Class C, in accordance with the following schedules.

(i) Class A—A ticking prototype is classified as Class A when three specimens, tested in accordance with § 1632.6(e), meet the test criterion in § 1632.6(d)(2) when the ticking is tested directly over the cotton felt on the test box.

(ii) Class B—A ticking prototype is classified as Class B when three specimens, tested according to § 1632.6(e), meet the test criterion in § 1632.6(d)(2) when the ticking is tested on a ¼ inch ± 1/32 inch (6.3 mm ± .8 mm) thick urethane foam pad covering the cotton felt on the test box.

(iii) Class C—A ticking prototype is classified as Class C when any specimen tested according to § 1632.6(e), fails to meet the test criterion in § 1632.6(d)(2) when the ticking is tested on a ¼ inch ± 1/32 inch (6.3 mm ± .8 mm) thick urethane foam pad covering the cotton felt on the test box.

(e) *Test Procedure.*

(1) *Apparatus.* For the purpose of this section the following apparatus and materials are required in addition to that which is listed in § 1632.4 (a) and (b).

(i) *Sheet and Sheeting Material.* Test covers made from sheets or sheeting material shall not be less than 12 inches by 12 inches (30.48 cm by 30.48 cm) square.

(ii) *Template.* Designed to allow for a one inch marking around the placement of the cigarette (see figure 3). Use of this template is optional.

(iii) *Stapler or masking tape* or other means of attachment to secure fabric to test box.

(iv) *Mounting Box.* A 6 inch deep, 12 inch square plywood box. The box contains two ½ inch in diameter ventilation holes. (See figure 4.)

(v) *Cotton Felt.* (A) The cotton felt shall be a thoroughly-garnetted mixture of all new material consisting of not less than 67% linters and of not more than 33% clean picker blend or equivalent binder and not more than 5% non-cellulosic total content. The felt shall not be bleached, moistened or chemically treated in any way.

(B) The felt may be re-used repeatedly after completion of each test by removing all of the smoldering, charred, heat-discolored fibers, or fibers exposed to water as a result of extinguishing the cotton ignited by previous test.

(vi) *Urethane Foam.* The urethane foam shall have a density of 1.2 to 1.5 pounds per cubic foot, an indention load deflection of 22 to 35 pounds, with each test specimen measuring no less than 12 inches by 12 inches (30.48 cm by 30.48 cm) square, having a thickness of ¼ inch ± 1/32 inch (6.3 mm ± .8 mm). The foam shall not be treated with a flame retardant chemical.

(2) *Conditioning.* The test specimens, cigarettes, laundered sheets or sheeting material, foam and felt shall be conditioned as described in § 1632.4(c).

(3) *Specimen Preparation.*

(i) Place 907.2 ± 4 grams (two pounds) of cotton felt in the test box, allowing the felt to protrude above the opening of the box to a height of up to 3 inches (7.62 cm) at the crown.

(ii) For the first part of this test, place a 12 inches by 12 inches (30.48 cm by 30.48 cm) square urethane foam pad on top of the cotton felt. Stretch the ticking specimen over the foam pad and fasten it to the sides of the test box using a stapler or tape. Be careful to avoid wrinkles in the fabric and have sufficient tautness to assure firm contact between the fabric and the filling materials in the test box.

(4) *Testing.*

(i) Ticking specimens shall be tested in a testroom with atmospheric conditions of a temperature greater than 18 °C (65 °F) and a relative humidity less than 55%.

(ii) Three cigarettes shall be burned on each ticking specimen, with no more than one cigarette burning at any time. At least one cigarette shall be placed on the most prominent part of the color and weave pattern design in the ticking. If the ticking is quilted, one cigarette shall be placed over the thread or in the depression created by the quilting process. Each cigarette must be positioned no less than two inches (5.08 cm) from any other cigarette or the edge of the box.

(iii) Light and place one cigarette on the test specimen. Immediately cover the burning cigarette with a sheet test cover. The cigarette shall be well lighted but not burned more than 4 mm (0.16 inch) when placed on the test specimen. The cigarette may be supported by three straight pins such that one pin supports the cigarette at the burning end, one at the center and one at the butt. The heads of the pins must be below the upper surface of the cigarette. Upon completion of the three cigarette burns and removal of the fabric and foam specimens, remove all of the char or heat discoloration on the cotton felt as stated in § 1632.6(e)(v)(B). Fresh new felt shall be added to replace the discarded fibers in the amount necessary to maintain the full 907.2±4 grams (two pounds) of felt for each test.

(iv) If the cigarette extinguishes before burning its full length, the test must be repeated with a freshly lit cigarette on a different portion of the ticking specimen until either three cigarettes have burned their full lengths or three cigarettes have extinguished. Report result for each cigarette as pass or fail as defined in Test Criterion § 1632.6(d)(2). An obvious ignition is recorded as a failure.

(v) If ignition occurs with any of the three cigarette burns on the ticking specimen, terminate testing of that specimen and classify according to § 1632.6(d)(4).

(vi) If all cigarette test locations meet the Test Criterion in § 1632.6(d)(2), repeat procedure outlined in § 1632.6(e)(4)(iii) for the second part of the test with new ticking specimens that will be retested directly over the cotton felt, without the urethane foam pad. Remove the urethane foam pad and charred or heat discolored area from the cotton felt as specified in § 1632.6(e)(v)(B) prior to testing. Record the test results as pass or fail as defined in *Test Criterion* § 1632.6(d)(2) and classify according to § 1632.6(d)(4).

(5) *Records.* Records of any ticking classification test results relied upon by the mattress or mattress pad manufacturer or importer shall be maintained in accordance with rules and regulations established by the Consumer Product Safety Commission in § 1632.31(c). As provided by § 1632.31(c)(6), manufacturers or importers of mattresses or mattress pads may rely on a certification of compliance with this section of the standard provided by the ticking manufacturer or distributor; however, if a mattress or mattress pad fails to comply with the standard, the mattress or mattress pad manufacturer or importer must assume full responsibility under the standard. The Commission has no authority under this standard to compel ticking manufacturers or distributors to comply with this section or to establish, maintain and provide upon request, the records specified in § 1632.31(c).

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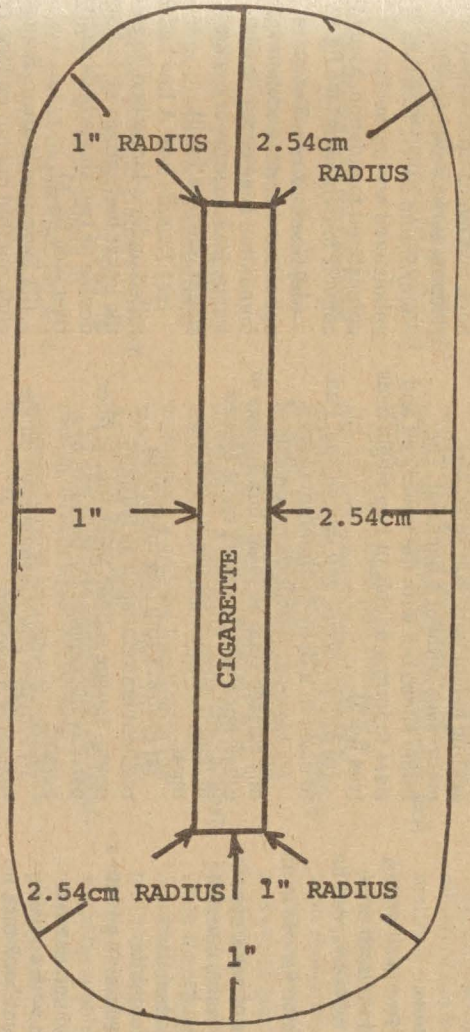
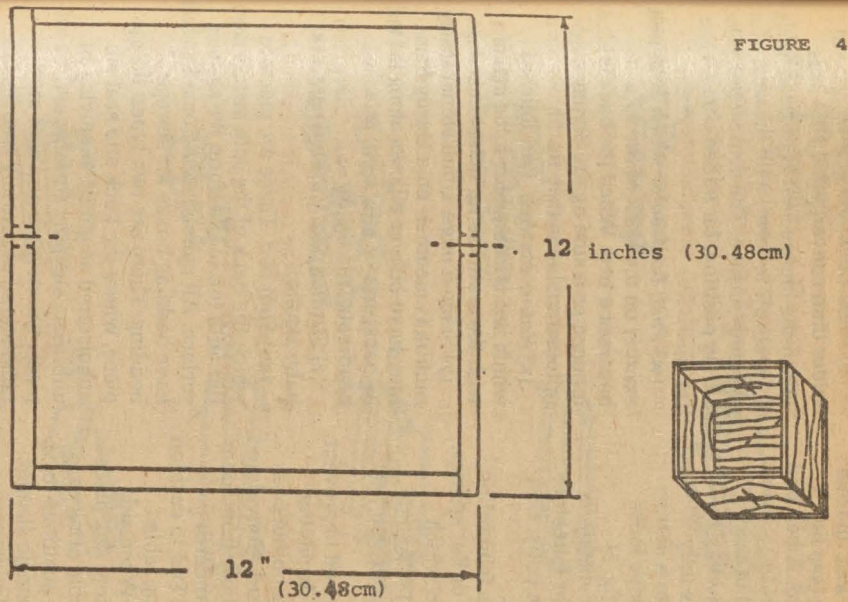
FIGURE 3

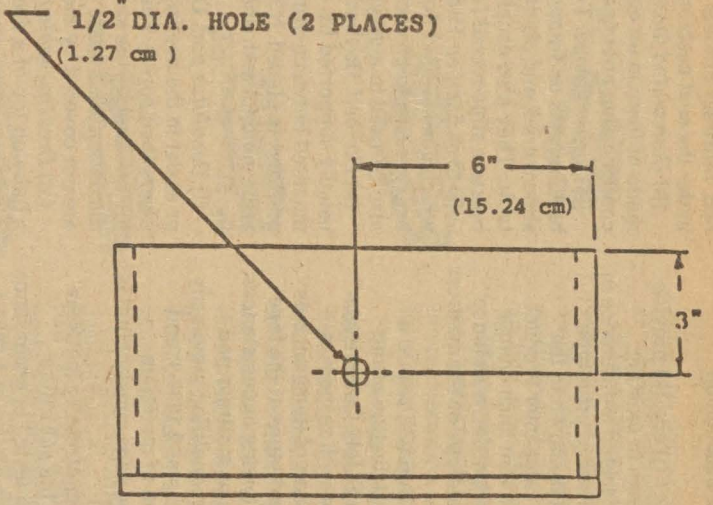


1 INCH (2.54cm) TEMPLATE

TOLERANCES + 1/32" - 0"

FIGURE 4





TEST BOX

MATERIAL 1/2" PLYWOOD

TOLERANCES + 1/32 " - 0"

§ 1632.7 Tape edge substitution procedure.

(a) Sections 1632.1 (j) and (k) provide in part that "a change in existing material shall be deemed a difference in materials for purposes of prototype definition unless it is shown to the satisfaction of the Consumer Product Safety Commission that such change will not reduce the ignition resistance" of the mattress prototype or the mattress pad prototype.

(b) The Commission will regard a showing "to the satisfaction of the Consumer Product Safety Commission" to have been made with respect to materials substitution of items such as flange materials and tapes at the tape edge under the following circumstances:

(1) The mattress or mattress pad prototype has been qualified previously under the provisions of § 1632.3; and

(2) A substitution of materials involving only tape edge construction is contemplated; and

(3) A prototype mattress or mattress pad incorporating the substitute materials has been tested in accordance with applicable procedures in § 1632.4 by placing 36 cigarettes (18 per surface—9 bare and 9 two-sheet) at tape edge locations with no test failure as determined by applying the test criterion of § 1632.3(b); and

(4) Records are maintained setting forth the details of the materials substitution and showing the results of the testing referred to in paragraph (b)(3) of this section. The records are to be maintained in accordance with regulations established by the Consumer Product Safety Commission (see § 1632.31).

§ 1632.8 Glossary of terms.

(a) *Absorbent pads.* Pad used on top of mattress. Designed to absorb urine thereby reducing skin irritation, can be one time use.

(b) *Basket pad.* Cushion for use in an infant basket.

(c) *Bunk beds.* A tier of beds, usually two or three, in a high frame complete with mattresses (see fig. 5).

(d) *Car bed.* Portable bed used to carry a baby in an automobile.

(e) *Carriage pad.* Cushion to go into a baby carriage.

(f) *Chaise lounge.* An upholstered couch chair or a couch with a chair back. It has a permanent back rest, no arms, and sleeps one (see fig. 5).

(g) *Convertible sofa.* An upholstered sofa that converts into an adult sized bed. Mattress unfolds out and up from under the seat cushioning (see fig. 5).

(h) *Convoluted foam pad.* A bed pad made of foam in an egg-crate configuration not encased in ticking.

(i) *Corner groups.* Two twin size bedding sets on frames, usually slipcovered, and abutted to a corner table. They also usually have loose bolsters slipcovered (see fig. 5).

(j) *Crib bumper.* Padded cushion which goes around three or four sides inside a crib to protect the baby. Can also be used in a playpen.

(k) *Daybed.* Daybed has foundation, usually supported by coil or flat springs, mounted between arms on which mattress is placed. It has permanent arms, no backrest, and sleeps one (see fig. 5).

(l) *Decubitus pad.* Designed to prevent or assist in the healing of decubitus ulcers (bed sores). Flat decubitus pads are covered by the standard. Convoluted decubitus pads made entirely from foam are not covered by the standard.

(m) *Dressing table pad.* Pad to cushion a baby on top of a dressing table.

(n) *Drop-arm loveseat.* When side arms are in vertical position, this piece is a loveseat. The adjustable arms can be lowered to one of four positions for a chaise lounge effect or a single sleeper. The vertical back support always remains upright and stationary (see fig. 5).

(o) *Futon.* A flexible mattress generally used on the floor that can be folded or rolled up for storage. It usually consists of resilient material covered by ticking.

(p) *High riser.* This is a frame of sofa seating height with two equal size mattresses without a backrest. The frame slides out with the lower bed and rises to form a double or two single beds (see fig. 5).

(q) *Infant carrier and lounge pad.* Pad to cushion a baby in an infant carrier.

(r) *Mattress foundation.* Consists of any surface such as foam, box springs or other, upon which a mattress is placed to lend it support for use in sleeping upon.

(s) *Pillow.* Cloth bag filled with resilient material such as feathers, down, sponge rubber, urethane, or fiber used as the support for the head of a person.

(t) *Playpen pad.* Cushion used on the bottom of a playpen.

(u) *Portable crib.* Smaller size than a conventional crib. Can usually be converted into a playpen.

(v) *Press-back lounges.* Longer and wider than conventional sofa beds. When the lounge seat is pressed lightly, it levels off to form, with the seat, a flat sleeping surface. The seat slopes, in the sitting position, for added comfort (see fig. 5).

(w) *Push-back sofa.* When pressure is exerted on the back of the sofa, it becomes a bed. When the back is lifted, it becomes a sofa again. Styled in tight or loose cushions (see fig. 5).

(x) *Roll-away-bed.* Portable bed which has frame which folds in half with the mattress for compact storage.

(y) *Sleep lounge.* Upholstered seating section is mounted on a sturdy frame. May have bolster pillows along the wall as backrests or may have attached headrests (see fig. 5).

(z) *Stroller pad.* Cushion used in a baby stroller.

(aa) *Sofa bed.* These are pieces in which the back of the sofa swings down flat with the seat to form the sleeping surface. All upholstered. Some sofa beds have bedding boxes for storage of bedding. There are two types: the one-piece, where the back and seat are upholstered as a unit, supplying an unbroken sleeping surface; and the two-piece, where back and seat are upholstered separately (see fig. 5).

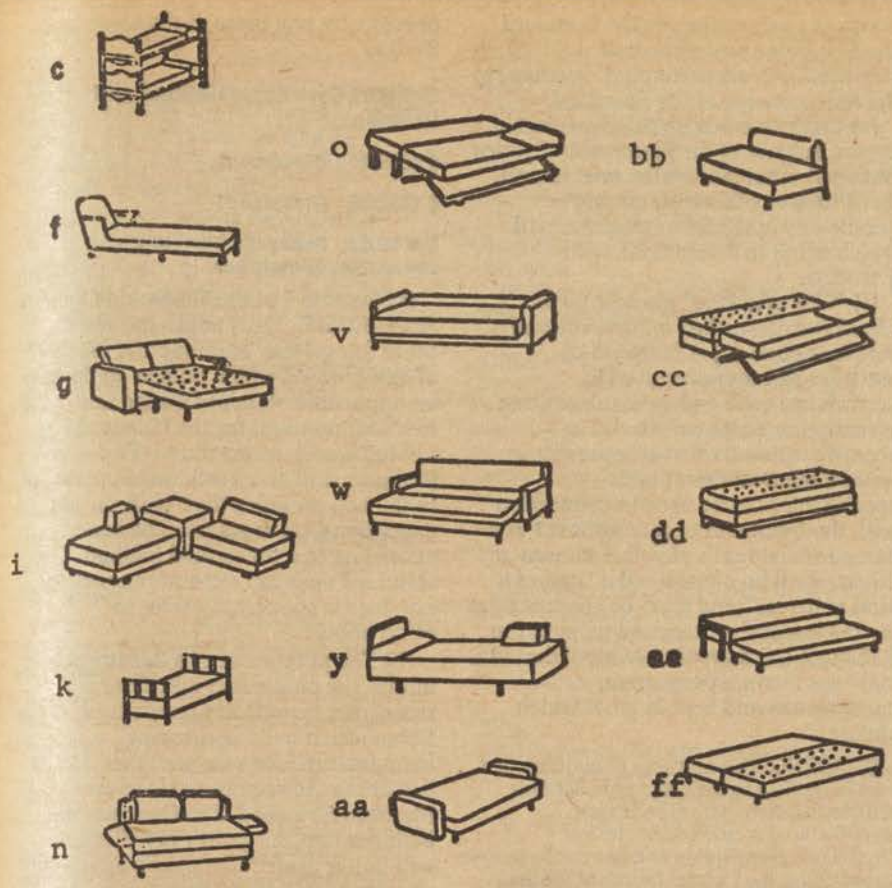
(bb) *Sofa lounge*—(includes glideouts). Upholstered seating section is mounted on springs and in a special frame that permit it to be pulled out for sleeping. Has upholstered backrest bedding box that is hinged. Glideouts are single sleepers with sloping seats and backrests. Seat pulls out from beneath back and evens up to supply level sleeping surface (see fig. 5).

(cc) *Studio couch.* Consists of upholstered seating section on upholstered foundation. Many types convert to twin beds (see fig. 5).

(dd) *Studio divan.* Twin size upholstered seating section with foundation is mounted on metal bed frame. Has no arms or backrest, and sleeps one (see fig. 5).

(ee) *Trundle bed.* A low bed which is rolled under a larger bed. In some lines, the lower bed springs up to form a double or two single beds as in a high riser (see fig. 5).

(ff) *Twin studio divan.* Frames which glide out (but not up) and use seat cushions, in addition to upholstered foundation to sleep two. Has neither arms nor back rest (see fig. 5).



Effective date: The amended standard shall become effective on April 10, 1985. As required by section 4(b) of the Flammable Fabrics Act (15 U.S.C. 1193(b)), mattresses and mattress pads which are in inventory or with the trade on the effective date of the amended standard are exempt from its requirements, but must comply with all applicable requirements of the original standard.

Subpart B—Rules and Regulations

§ 1632.31 Mattresses/Mattress Pads—Labeling, recordkeeping, guaranties and "one of a kind" exemption.

(a) *Definitions.* For the purposes of this section, the following definitions apply:

(1) "Standard for the Flammability of Mattresses" or "Standard" means the Standard for the Flammability of Mattresses and Mattress Pads (FF 4–72, amended), (16 CFR Part 1632, Subpart A).

(2) The definition of terms set forth in the § 1632.1 of the Standard shall also apply to this section.

(b) *Labeling.* (1) All mattress pads which contain a chemical fire retardant shall be labeled with precautionary instructions to protect the pads from agents or treatments which are known to cause deterioration of their flame resistance. Such labels shall be permanent, prominent, conspicuous, and legible.

(2) If a mattress pad contains a chemical fire retardant, it shall be prominently, conspicuously, and legibly labeled with the letter "T".

(3) Each mattress or mattress pad subject to the Standard shall bear a permanent, accessible, and legible label containing the month and year of manufacture and the location of the manufacturer. (See § 1632.1(i) of the Amended Standard).

(4) The information required on labels by this section shall be set forth separately from any other information appearing on such label. Other information, representations, or disclosures, appearing on labels required by this section or elsewhere on the item, shall not interfere with, minimize, detract from, or conflict with the required information.

(5) No person, other than the ultimate consumer, shall remove or mutilate, or cause or participate in the removal or mutilation of, any label required by this section to be affixed to any item.

(6) Products intended for one time use (see § 1632.5(b)(1)(i)) are not subject to the requirements of paragraphs (1) and (2) of this § 1632.31(b).

(c) *Records—manufacturers, importers, or persons initially introducing items into commerce.* Every manufacturer, importer, or other person initially introducing into commerce mattresses or mattress pads subject to the standard, irrespective of whether guarantees are issued relative thereto, shall maintain the records hereinafter specified.

(1) Manufacturing specifications and description of each mattress or mattress pad prototype with an assigned prototype identification number.

(2) Test results and details of each prototype test performed in accordance with § 1632.4 or § 1632.5, including prototype identification number, ticking classification if known, test room condition, cigarette locations, number of relights for each location, whether each cigarette location passed or failed, name and signature of person conducting the test and date of test. These records shall include a certification by the person overseeing the testing as to the test results and that the test was carried out in accordance with the Standard.

(3) Photograph (color or black and white) of the bare surface of each mattress or mattress pad tested, in accordance with § 1632.4 or § 1632.5, with the prototype identification number of the mattress or mattress pad and a clear designation as to which part of the mattress or mattress pad was sheeted and which part was tested bare.

(4) Records to support any determination that a particular material, other than the ticking or tape edge material used in a mattress or mattress pad prototype, did not influence the ignition resistance of the prototype and could be substituted by another material. Such record should include photographs or physical specimens.

(5) Manufacturing specifications and description of any new ticking or tape edge material substituted in accordance

with § 1632.6 or § 1632.7, with the identification number of the prototype involved.

(6) The test results and details of any ticking classification test conducted in accordance with § 1632.6, including the ticking classification (A, B, or C), the test room condition, the number of relights, whether each cigarette location passed or failed, the name and signature of the person conducting the test and the date of the test, *or* a certification from the ticking supplier. The certification should state the ticking classification and that the ticking was tested in accordance with § 1632.6.

(7) The test results and details of any test of tape edge materials conducted in accordance with § 1632.7, including prototype identification number, test room condition, number of relights, whether each cigarette passed or failed, name and signature of person conducting the test and date of test. The record shall include a certification by the person overseeing the testing as to the test results and that the test was carried out in accordance with § 1632.7.

(8) Photograph (color or black and white) of the bare surface of each mattress or mattress pad tested in accordance with § 1632.7, with the prototype identification number of the mattress or mattress pad and a clear designation as to which part of the mattress or mattress pad was sheeted and which part was tested bare.

(9) Details of any approved alternate laundering procedure used in laundering mattress pads required by the Standard to be laundered during testing.

(10) Identification, composition, and details of the application of any flame retardant treatments employed relative to mattress pads or mattress pad components.

(11) Disposition of all failing or rejected prototype mattress or mattress pads. Such records must demonstrate that the items were retested and reworked in accordance with the Standard prior to sale or distribution and that such retested or reworked mattresses or mattress pads comply with the Standard, or must otherwise show the disposition of such items.

(12) The records required by this paragraph shall be maintained for as long as the prototype is in production, the ticking is being used on the mattresses or mattress pad prototype, and/or the tape edge material is being used on the mattress or mattress pad prototype, and shall be retained for 3 years thereafter.

(d) *Tests for guaranty purposes.* Reasonable and representative tests for the purpose of issuing a guaranty under section 8 of the Act for mattress or mattress pads subject to the Standard shall be those prototype and substitution tests performed, pursuant to the requirements of the Standard.

(e) *Compliance with this section.* No person subject to the Flammable Fabrics Act shall manufacture for sale, import, distribute, or otherwise market or handle any mattress or mattress pad which is not in compliance with § 1632.31.

(f) *"One of a kind" exemption for physician prescribed mattresses and mattress pads.* (1) A mattress or mattress pad manufactured in accordance with a physician's written prescription or manufactured in accordance with other comparable written medical therapeutic specification, to be used in connection with the treatment or management of a named individual's physical illiness or injury, shall be considered a "one of a kind mattress" and shall be exempt from testing under the Standard pursuant to § 1632.2(b)(4) thereof: Provided, that the mattress bears a permanent, conspicuous and legible label which states:

WARNING: This mattress or mattress pad may be subject to ignition and hazardous smoldering from cigarettes. It was manufactured in accordance with a physician's prescription and has not been tested under the Federal Standard for the Flammability of Mattresses (FF 4–72).

Such labeling must be attached to the mattress or mattress pad so as to remain on or affixed thereto for the useful life of the mattress or mattress pad. The label must be at least 40 square inches (250 sq. cm) with no linear dimension less than 5 inches (12.5 cm). The letters in the word "WARNING" shall be no less than 0.5 inch (1.27 cm) in height and all letters on the label shall be in a color which contrasts with the background of the label. The warning statement which appears on the label must also be conspicuously displayed on the invoice or other sales papers that accompany the mattress in commerce from the manufacturer to the final point of sale to a consumer.

(2) The manfacturer of a mattress or mattress pad exempted from testing under this paragraph shall, in lieu of the records required to be kept by paragraph (c) of this section, retain a copy of the written prescription or other comparable written medical therapeutic specification for such mattress or mattress pad during a period of three years, measured from the date of manufacture.

(3) For purposes of this regulation the term "physician" shall mean a physician, chiropractor or osteopath licensed or otherwise permitted to practice by any State of the United States.

Subpart C—Interpretations and Policies

§ 1632.61 [Reserved]

§ 1632.62 [Reserved]

§ 1632.63 Policy clarification on renovation of mattress.

(a) Section 3 of the Flammable Fabrics Act (15 U.S.C. 1192) prohibits, among other things, the "manufacture for sale" of any product which fails to conform to an applicable standard issued under the act. The standard for the Flammability of Mattresses, as amended (FF 4–72) (Subpart A of this part), issued pursuant to the act, provides that, with certain exceptions, mattress must be tested according to a prescribed method. The standard does not exempt renovation; nor does it specifically refer to renovation.

(b) The purpose of this document is to inform the public that mattresses renovated for sale are considered by the Commission to be mattresses manufactured for sale and, therefore, subject to the requirements of the Mattress Standard. The Commission believes that this policy clarification will better protect the public against the unreasonable risk of fires leading to death, personal injury or significant property damage, and assure that purchasers of renovated mattresses receive the same protection under the Flammable Fabrics Act as purchasers of new mattresses.

(c) For purposes of this document, mattress renovation includes a wide range of operations. Replacing the ticking or batting, stripping a mattress to its springs, rebuilding a mattress, or replacing components with new or recycled materials, are all part of the process of renovation. Any one, or any combination of one or more, of these steps in mattress renovation is considered to be mattress manufacture.

(d) If the person who renovates the mattress intends to retain the renovated mattress for his or her own use, or if a customer or a renovator merely hires the services of the renovator and intends to take back the renovated mattress for his or her own use, "manufacture for sale" has not occurred and such a renovated mattress is not subject to the mattress standard.

(e) However, if a renovated mattress is sold or intended for sale, either by the renovator or the owner of the mattress who hires the services of the renovator, such a transaction is considered to be "manufacture for sale".

(f) Accordingly, mattress renovation is considered by the Commission to be "manufacture for sale" and, therefore, subject to the Mattress Standard, when renovated mattresses are sold or intended for sale by a renovator or the customer of the renovator.

(g) A renovator who believes that certain mattresses are entitled to one-of-a-kind exemption, may present relevant facts to the Commission and petition for an exemption. Renovators are expected to comply with all the testing requirements of the Mattress Standard until an exemption is approved.

Authority: 15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b).

Dated: October 2, 1984.

Sheldon D. Butts,

Deputy Secretary, Consumer Product Safety Commission.

Bibliography

(*1*) Briefing paper concerning amendments to the mattress flammability standard; 9 pages; March 30, 1982.

(*2*) Rule Review Report, TAB 3—Mattress Flammability Standard, by J.F.Hoebel; 23 pages; February 14, 1980.

(*3*) Report of Consumer Product Safety Commission to Congress concerning review of Commission rules; 44 pages; May 1980.

(*4*) Memorandum from Liz Jones, CARM, to James F. Hoebel, OPM, concerning amendment of mattress standard; 9 pages; April 24, 1981.

(*5*) Evaluation of the impact of the mattress and carpet and rug flammability standard upon industry, by Technology and Economics, Inc.; 107 pages; February 2, 1981.

(*6*) Memorandum from Bea Harwood, HIEI, to Jim Hoebel, OPM, concerning injury findings to support amendment of mattress standard; 3 pages; September 8, 1981.

(*7*) Memorandum from Patricia Fairall, ESMT, to Harleigh Ewell, OGC, concerning amendment of the mattress flammability standard, with attachments; 64 pages; April 24, 1981.

(*8*) Current Industrial Reports, Mattresses, Foundations, and Sleep Furniture, Summary for 1980; issued by the U.S. Department of Commerce; 6 pages; August 1981.

(*9*) **Federal Register** notice, "Standard for the Flammability of Mattresses (and Mattress Pads): Advance Notice of Proposed Rulemaking," published by Consumer Product Safety Commission; 6 pages; June 10, 1982 (47 FR 25159).

(*10*) Comments on ANPR from Meridian Mattress Factory, Inc.; 5 pages; June 15 and June 22, 1982.

(*11*) Comment on ANPR from the Govmark Organization, Inc.: 1 page; June 24, 1982.

(*12*) Comment on ANPR from Doris Eichenwald; 1 page; July 22, 1982.

(*13*) Comment on ANPR from Bureau of Home Furnishings, Department of Consumer Affairs, State of California; 3 pages; July 21, 1982.

(*14*) Comment on ANPR from National Fire Protection Association; 6 pages; August 6, 1982.

(*15*) Comment on ANPR from Juanita W. Fleming, R.N., Ph.D., F.A.A.N.; 1 page; July 23, 1982.

(*16*) Comment on ANPR from National Association of Bedding Manufacturers, with attachments; 64 pages; undated.

(*17*) Comment on ANPR from the Procter & Gamble Company; 1 page; August 2, 1982.

(*18*) Comment on ANPR from Citizens Committee for Fire Protection; 7 pages; undated.

(*19*) Comment on ANPR from Flexible Polyurethane Foam Manufacturers Association; 3 pages; August 9, 1983.

(*20*) Staff briefing package, including transmittal memorandum from Office of Program Management to the Commission concerning comments on ANPR and staff recommendations for amendment of the mattress standard; 16 pages; December 12, 1983. The tabs of this package are listed separately below.

Tab A

Advance notice of proposed rulemaking; same document as item 9, above.

(*21*) Draft **Federal Register** notice to propose amendments of the mattress standard; 105 pages; undated.

Tab B

(*22*) Summary of comments in response to ANPR: 4 pages; undated. Comments received in response to ANPR; same documents as items 10 through 19, above.

Tab C

(*23*) Memorandum from L.J. Sharman, OPM, to Edgar Morgan, Executive Director, concerning amendment of the mattress flammability standard; 5 pages; October 25, 1982.

Tab D

(*24*) Memorandum from Liz Gomilla, CARM, to L.J. Sharman, Fire Program Officer, concerning results of testing to determine compliance with the mattress standard, with attachments; 23 pages; June 13, 1983.

(*25*) Memorandum from Liz Gomilla, CARM, to L.J. Sharman, Fire Program Officer, concerning analysis of comments received in response to ANPR; 4 pages; June 24, 1983.

(*26*) Memorandum from Liz Gomilla, CARM, to L.J. Sharman, Fire Program Officer, concerning mattress compliance program for fiscal year 1985; 1 page; June 24, 1983.

Tab E

(*27*) Memorandum from Patricia Fairall, ESMT, to L.J. Sharman, OPM, concerning analysis of comments received in response to ANPR; 6 pages; July 27, 1983.

(*28*) Memoradum from Pat Fairall and Jean Williams, ESMT, to L. James Sharman, OPM, concerning technical changes to amended mattress standard; 8 pages; July 29, 1983.

(*29*) Technical rationale for mattress ticking substitution test, by Patricia Fairall, Engineering Sciences; 15 pages; July 1983.

Tab F

(*30*) Memorandum from Barbara Morton, ECCP, to L.J. Sharman, OPM, concerning comments received in response to ANPR: 2 pages; April 26, 1983.

(*31*) Minutes of executive session of Consumer Product Safety Commission on October 3, 1975, with attachment; 8 pages; undated.

(*32*) Vote Sheet concerning proposal of amendments to the mattress standard; 2 pages; December 14, 1983.

(*33*) **Federal Register** notice proposing amendments to the mattress standard; 23 pages; December 30, 1983.

(*34*) Comment on proposed amendments from National Association of Bedding Manufacturers; 6 pages; undated.

(*35*) Comment on proposed amendments from Irving Veitzman for National Association of Bedding Manufacturers; 6 pages; undated.

(*36*) Comment on proposed amendments from Citizens Committee for Fire Protection; 3 pages; February 23, 1984.

(*37*) Comment on proposed amendments from Burn Foundation; 2 pages; February 27, 1984.

(*38*) Comment on proposed amendments from Trauma Center Foundation; 1 page; February 27, 1984.

(*39*) Comment on proposed amendments from Senator Edward Zorinsky; 1 page; February 10, 1984.

(*40*) Comment on proposed amendments from National Retail Merchants Association; 2 pages; March 14, 1984.

(*41*) Staff briefing package including transmittal memorandum from Office of Program Management to the Commission concerning comments on proposal for amendment of the mattress standard and recommendations for issuance of final amendments; 5 pages; July 6, 1984. The tabs of this package are listed separately below

Tab A

Notice of proposed rulemaking for amendment of the mattress standard; same document as item 33, above.

(*42*) Draft **Federal Register** notice to issue amended standard on final basis; 81 pages; undated.

Tab B

(*43*) Summary of comments in response to notice proposing amendments of mattress standard; 2 pages; undated.

Comments received in response to notice of proposed rulemaking; same documents as items 34 through 40, above.

Tab C

(*44*) Memorandum from Barbara J. Morton, Directorate for Economic Analysis to L. James Sharman, Office of Program Management concerning economic aspects of comments on proposed amendments of the mattress standard; 5 pages; April 20, 1984.

(*45*) "Market Sketch—Mattresses" by Barbara J. Morton, Directorate for Economic Analysis; 11 pages; March, 1984.

Tab D

(*46*) Memorandum from Linda Fansler, Directorate for Engineering Sciences to James Sharman, Office of Program Management concerning engineering aspects of comments on proposed amendments of mattress standard; 2 pages; April 20, 1984.

Tab E

(*47*) Memorandum from Elizabeth Gomilla, Directorate for Compliance and Administrative Litigation, to L.J. Sharman, Office of Program Management, concerning issues raised by comments on proposed amendments of the mattress standard; 4 pages; April 20, 1984.

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BILLING CODE 6355-01-M

federal register

Wednesday
October 10, 1984

Part IV

Environmental Protection Agency

40 CFR Part 799

Identification of Specific Chemical 1 Substance and Mixture Testing Requirements; 1,1,1-Trichloroethane; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42059; FRL-2626-7]

Identification of Specific Chemical Substance and Mixture Testing Requirements; 1,1,1-Trichloroethane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In June 1981, the EPA proposed the testing of 1,1,1-trichloroethane (TCEA) under section 4(a) of the Toxic Substances Control Act (TSCA) for teratogenicity and for a number of environmental effects (46 FR 30300). Public comments on the proposal have been received and reviewed. The EPA has decided to promulgate a final test rule requiring that manufacturers and processors of 1,1,1-trichloroethane test this chemical for teratogenic effects or, more appropriately, developmentally toxic effects. EPA has decided not to require any environmental effects testing at this time due to its reevaluation of the available data. This rule requires that testing of this chemical be performed according to protocols submitted to and approved by the Agency.

DATES: These regulations shall be promulgated for purposes of judicial review at 1:00 p.m. eastern standard time on October 24, 1984. These regulations shall become effective on November 23, 1984.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543; 401 M St., SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 5, 1981 (46 FR 30300), EPA issued a proposed rule under section 4(a) of TSCA to require testing of TCEA for teratogenic effects and a number of environmental effects. The Agency is now promulgating a final rule requiring testing of TCEA for teratogenic effects or, more appropriately, develop mentally toxic effects, but not for environmental effects due to reevaluation of available data.

The rule was originally proposed under 40 CFR Part 773—Identification of Chemical Substances and Mixtures to be Tested. Part 773 has since been recodified to Part 799—Identification of Specific Chemical Substance Testing Requirements. This test rule for 1,1,1-trichloroethane is now being promulgated under 40 CFR 799.4400.

I. Introduction

This notice is part of the overall 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 health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator finds that:

(A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed test rule package (chloromethane and chlorinated benzenes, published July 18, 1980; 45 FR 48510) and to the second package (dichloromethane, nitrobenzene, and 1,1,1-trichloroethane, published June 5, 1981; 46 FR 30300) for in-depth discussions of the general issues applicable to this action.

II. Background

A. Profile

1,1,1-Trichloroethane ($Cl_3C_2H_3$, methyl chloroform, TCEA, CAS No. 71-55-6) is a colorless, non-flammable, volatile liquid at standard temperature and pressure. Approximately 586 million pounds of TCEA were produced in the United States in 1983, of which about 57 million pounds were exported. Imports of the chemical were essentially negligible (Ref. 8).

The major use of TCEA is in the metal cleaning industry, primarily in cold cleaning and vapor degreasing processes. It is also used as a solvent in commercial and consumer products such as aerosols, adhesives, textiles, paints, inks, drain cleaners, film cleaners, spot removers, pharmaceuticals, and leather tanners (Ref. 6).

In the National Occupational Hazard Survey, approximately 2.6 million workers were estimated to be exposed to TCEA (Ref. 3), largely through inhalation during industrial uses of the chemical. Consumers are exposed to unknown levels of TCEA through use of the many consumer products containing it.

TCEA is released to the environment from evaporative losses during manufacture, processing, use and disposal. It has been found at levels of 1-10 ppb in air, soil, fresh and marine water, groundwater and rainwater (Ref. 6).

B. ITC Recommendations

The Interagency Testing Committee (ITC) designated 1,1,1-trichloroethane for priority testing consideration in its Second Report, published in the **Federal Register** on April 19, 1978 (43 FR 16684). The ITC recommended that the Agency consider requiring industry to test TCEA for the following health effects: carcinogenicity, mutagenicity, teratogenicity, other chronic effects (with specific attention to the neurological, cardiovascular and renal systems) and that an epidemiologic study be performed. The ITC did not recommend that environmental effects testing for TCEA be considered.

The ITC's recommendations were based on U.S. production in 1976 of approximately 630 million pounds, an estimated 300 million pounds which could be released to the atmosphere, an estimation on the part of the ITC of 3 million persons exposed to TCEA in the workplace, and its view that there was a lack of data from which to reasonably determine or predict the various effects for which it recommended testing.

C. Proposed Rule

EPA issued a proposed rule published in the **Federal Register** of June 5, 1981 (46 FR 30300) which would require that testing of TCEA be performed for teratogenicity and for the effects listed below:

1. Aquatic vertebrates-acute toxicity and chronic toxicity.
2. Aquatic invertebrates-chronic toxicity.
3. Terrestrial plants-root elongation/seed germination and early seedling growth.
4. Bioconcentration-plant uptake/translocation.

In the proposal, the EPA based its testing requirements on the authority of section 4(a)(1)(B) of TSCA. It found that: 1,1,1-trichloroethane was produced in substantial quantities; substantial numbers of persons were exposed to 1,1,1-trichloroethane both in occupational settings involving the manufacture, processing and use of the chemical, and as consumers of products containing the chemical; there was substantial release to the environment; and, with respect to the above listed areas, there were insufficient data and experience to reasonably determine or predict the effects on health and the environment of the manufacture, processing, distribution in commerce, use or disposal of 1,1,1-trichloroethane and that testing was necessary to develop such data.

EPA also presented its reasons for not proposing testing for several other effects of concern. Testing was not proposed for acute health effects, reproductive effects, chemical fate or for certain environmental effects (acute toxicity to aquatic invertebrates, toxicity to mammals, acute bird toxicity, toxicity to algae, and aquatic vertebrate and invertebrate bioconcentration) because EPA had concluded that existing information was sufficient to reasonably predict or determine these effects. EPA planned to perform testing for some environmental effects for which no test standards were available at the time.

Oncogenicity testing of 1,1,1-trichloroethane was being performed by the National Toxicology Program (NTP), and EPA believed that the NTP studies would be sufficient to reasonably predict or determine the oncogenicity of TCEA; therefore, no oncogenicity testing was proposed. Similarly, no chronic effects testing was proposed because EPA was awaiting the results of the NTP study which it expected to provide sufficient data on chronic effects.

EPA believed that mutagencity testing according to a testing sequence would be appropriate, and planned to perform the initial testing itself because no criteria specifying the progression from initial tests to higher level tests were available at the time the proposed rule was issued. EPA planned to propose a test rule requiring manufacturers and processors of TCEA to perform higher tier tests if needed, based on analysis of lower tier results.

The EPA also decided not to propose an epidemiologic study at the time because a suitable study population had not been identified. The scientific support used by EPA at that time for the proposed section 4 findings and the proposed rule was set forth in the 1,1,1-Trichloroethane Support Document (Ref. 6), which is available from the Office of Toxic Substances' TSCA Assistance Office and in the public record for this rulemaking.

III. Public Comment

The comments received by the Agency in response to the proposed rule for TCEA were from the affected industry and several trade associations. The Agency did not receive any comments which in the Agency's judgment rebutted the substantial production and substantial human exposure findings for TCEA. Major issues identified during the comment period are discussed below.

A. Health Effects Testing

1. Developmental Toxicity

a. *Terminology.* Comments on EPA's proposed test rule for the testing of TCEA for teratogenicity in June 1981, have shown that use of the term "teratogenicity" may be interpreted differently by different scientists and in its strictest definition could be limited to just the production of structural malformations. Recognizing that abnormal development may be manifested not only as the production of structural malformations, but also as *in utero* death, growth retardation, or functional deficits (Ref. 14), the Agency believes that the term "developmental toxicity" is more appropriate in summarizing its concern for agents that adversely affect development. Although the terminology in this final rule may be different from that in the proposed rule, the Agency in its proposed rule clearly expressed the concern that TCEA should be evaluated not only for structural malformations, but also for fetal resorptions, decreased fetal body weight, and other adverse developmental effects which are encompassed by the term "developmental toxicity." *See* 46 FR 30300, 30303 and 30311 (June 5, 1981) and 44 FR 44054, 44088 (July 29, 1979).

b. *Review of existing teratology studies.* The Agency has identified three studies that address the potential of 1,1,1-trichloroethane to cause adverse developmental effects: Schwetz et al. (Ref. 5), York et al. (Ref. 7), and Lane et al. (Ref. 1). The Schwetz and York studies were evaluated by the Agency in preparing the proposed rule (46 FR 30300; June 5, 1981) and were discussed in its accompanying support document (Ref. 6).

In the Schwetz et al. study pregnant female rats and mice were exposed by the inhalation route of exposure to 875, ppm of TCEA for 7 hours daily at days 6–15 of gestation. Schwetz et al. concluded that TCEA did not cause significant maternal, embryonal or fetal toxicity and was not teratogenic in either mice or rats at 875 ppm.

In the York et al. study, female rats were exposed by inhalation to TCEA at a concentration of 2,100 ppm. Study animals were divided into the following three groups depending upon the timing of exposure to TCEA: (A) those exposed for two weeks prior to mating and during pregnancy, (B) those exposed prior to mating only, and (C) those rats exposed during pregnancy only. The control group was exposed to filtered air before mating and during pregnancy. The York study reported decreased fetal weights and some developmental anomalies (predominantly skeletal and kidney development) in offspring of exposed dams. However, the developmental anomalies occurred only in the offspring of those rats exposed to 2,100 ppm two weeks prior to mating and then during gestation. Although there were statistically significant decreases in fetal bodyweight in exposure groups A and C, soft-tissue and skeletal anomalies were not significant in the offspring of rats exposed to 2,100 ppm TCEA during gestation only, possibly due to the shorter dosing period. York et al. questioned the biological significance of the skeletal anomalies and fetal weight reductions, noting that the skeletal malformations were relatively rare structural changes not obviously detrimental to the offspring and that the depression in body weights was not present postnatally. The York et al. study reported no evidence of maternal toxicity in any of three exposure groups.

In its proposed test rule for TCEA (46 FR 30300, June 5, 1981), EPA concluded that the Schwetz et al. and York et al. studies were insufficient to reasonably determine whether exposure to TCEA would pose a risk of developmental effects in humans. The Agency reached this conclusion in large part because although developmental effects had not been observed in the Schwetz et al. study or in the offspring of animals in the York et al. study exposed only during gestation, the failure of both studies to employ a maternally toxic dose level fails to provide adequate

assurance that developmentally toxic effects will not occur at exposure levels designed to protect adult humans from adverse health effects.

In a study obtained after publication of the proposal, Lane et al. (Ref. 1) examined the effects of TCEA in drinking water on reproduction and development in mice. Concentration levels of 0, 0.58, 1.75, and 5.83 mg/ml were administered; these concentrations were designed by the investigators to yield doses of 0, 100, 300 or 1,000 mg/kg/day. Nine to fifteen litters were examined per dose group. The authors reported no evidence of reproductive or teratologic effects in this study and no evidence of maternal toxicity.

c. *EPA response to industry comments.* Industry commentors (Dow and Vulcan) took the position that the three studies taken together clearly demonstrate that TCEA does not represent a teratogenic risk to humans. With regard to the lack of maternal toxicity, they pointed out that TCEA is of very low toxicity in adult animals and that the primary adverse effect of TCEA is central nervous system (CNS) depression. In their view, conventional measurements of maternal toxicity, such as weight loss, would not be observed at test concentrations below those which produce CNS depression. The commentors further stated that the studies have been conducted at sufficiently high levels and that, in the light of the available data, EPA cannot justify a finding of insufficient data to determine or reasonably predict the teratogenic effects of TCEA.

EPA had seriously considered these points. The results of these studies (Refs. 1, 5 and 7) do not preclude the possibility that the conceptus may be uniquely susceptible to adverse effects of TCEA. None of these studies reported evidence of biologically significant teratogenic effects; however, maternal toxicity at the highest dose level, a requirement of an adequate teratogenicity of developmental toxicity test according to the TSCA Guidelines (Ref. 17), was not demonstrated in any of the studies.

With regard to their comments on CNS depression, the Agency believes that Dow and Vulcan have failed to demonstrate that signs of CNS depression will indeed occur prior to other indications of maternal toxicity, such as weight loss. In none of the three available developmental toxicity studies which the Agency has reviewed was there any evidence that adverse CNS effects would occur prior to other signs of maternal toxicity. In fact, there were no indications of CNS depression or maternal toxicity in any of the three studies.

The Agency also disagrees with the commentors' position that the studies have been conducted at sufficiently high dose levels. In general, the Agency believes that the highest dose level delivered to an animal in a developmental toxicity study should produce maternal toxicity; this is to ensure that a chemical has been tested at a high enough exposure level. If the highest dose delivered to an animal produces neither maternal toxicity nor development toxicity, one would not be able to determine if the chemical would be a hazard to the developing embryo or fetus at some higher exposure level in the absence of maternal effects. Most teratology/developmental toxicity guidelines (i.e. TSCA, OECD, FDA's Segment II) recommend testing of a substance at at least three dose or exposure levels with the highest producing some degree of maternal toxicity and the lowest producing no effect on either the embryo/fetus or the dam. This view is in agreement with recognized developmental toxicologists who have conducted state-of-the-art studies (Refs. 13 and 14). This approach allows for assessment of the relationship between the concentration needed to adversely affect the dam and that needed to adversely affect the developing organism and, as such, enables the identification of those agents to which the embryo/fetus is more susceptible than the dam. This dose regimen not only establishes potential developmental effects which may occur independent of adult toxicity, but also establishes a no effect level for developmental effects.

There may be some instances where the Agency will not need to require testing at a dose level that produces maternal toxicity. If developmental effects have been identified at doses below the maternally toxic dose of the chemical, then higher dose levels that would exhibit some form of maternal toxicity are not essential because exposure reduction would be based on developmental toxicity rather than on maternal toxicity. There is uncertainty that the effects observed in the York et al. study indicate biologically significant developmental toxicity. The Agency does not believe the York et al. study or the other studies discussed above are sufficient to reasonably determine or predict the developmental toxicity of TCEA. Another instance where the Agency may not need to require maternal toxicity is when the no observed effect levels are well above those levels identified for human exposure. However, in this particular case, the Agency believes that the difference between the levels of TCEA workplace exposures (Refs. 16 and 18) and the highest dose levels of TCEA utilized in the existing teratogenicity studies (Refs. 1, 5, and 7) do not enable EPA to reasonably predict that offspring of female workers exposed to TCEA would be adequately protected from adverse developmental effects. Therefore, EPA finds that further testing of TCEA for developmental toxicity is necessary.

2. *Chronic effects and oncogenicity.* The Agency identified two chronic studies when preparing the proposed rule: NCI (Ref. 2) and Quast et al. (Ref. 4). EPA concluded that neither study was adequate to characterize the chronic effects of TCEA. However, EPA did not propose chronic effects or oncogenicity testing for TCEA because a National Toxicology Program (NTP/NCI) oncogenicity study underway at the time was expected to be sufficient to reasonably determine or predict the chronic effects and oncogenicity of TCEA. The NTP study has since been completed. The results are still being evaluated and the final report has not yet been released by NTP.

Dow commented that the NTP study could suffer from shortcomings such as grossly high exposure levels which would make it inappropriate for assessing chronic effects. Dow noted that it is currently conducting a "state of the art" study which should more adequately characterize the chronic effects of 1,1,1-trichloroethane. According to Dow, they are in the final stages of a 2-year chronic toxicity/oncogenicity study of TCEA in rats and mice. Both species were exposed using the inhalation route to 150, 500, or 1,500 ppm of TCEA for 6 hours/day, 5 days/week for 24 months. Dow Chemical Company has submitted to the Agency a final report on the chronic inhalation toxicity and oncogenicity of a commercial preparation containing greater than 90% TCEA (Ref. 23). The Agency is currently evaluating the study and the evaluation will be placed into the public docket when completed. The Agency is awaiting the final report from the NTP study. Should the Agency decide that a data insufficiency exists after Agency review of the final NTP report then EPA reserves the right to require an additional oncogenicity study.

3. *Mutagenicity.* Industry commentors stated that the preponderance of available data support the position that 1,1,1-trichloroethane lacks any significant genetic activity and,

therefore, mutagenicity testing is unnecessary. The Agency did not believe existing data were sufficient to predict the mutagenicity of TCEA and has gone forward with its own testing as outlined in the notice of proposed rulemaking (46 FR 30300).

EPA has examined 1,1,1-trichloroethane (Aldrich Chemical Co., 97 percent pure) in a number of *in vitro* assays for genotoxicity. Specifically, TCEA was found to be non-mutagenic under the conditions of the test for Salmonella tester strains TA1535, TA1537, and TA100 in the Ames test in the presence and absence of S–9 activation systems. When examined in the hepatocyte primary culture/DNA repair test, TCEA elicited a positive response at 10^{-6} to 10^{-3}M (noncytotoxic doses) using hepatoytes from male B6C3F1 mice, but did not affect DNA repair when hepatocytes from Osborne Mendel rats were used. TCEA was also able to transform BALB/C–3T3 cells, *in vitro*, at noncytotoxic doses of 20 μg/ml to 250 μg/ml. In addition, TCEA significantly enhanced transformation of Syrian hamster embryo cells by SA7 adenovirus (Refs. 19, 20, 21, and 22).

Experiments to test TCEA in the Drosphila sex-linked recessive lethal assay are currently underway and results from this assay are expected to be available to the Agency in October, 1984. The Agency reserves the right to initiate rulemaking to require higher-tiered mutagenicity studies after it has completed a review of all the ongoing lower-tiered study results (see Unit III. D).

B. Environmental Effects Testing

A number of industry commentors addressed issues involving environmental testing of 1,1,1-trichloroethane. Although the commentors agreed that TCEA is produced in substantial quantities, they believed that the volatility (vapor pressure equals 99.75 mm Hg at 20 °C) of TCEA would not allow TCEA to be found in the environment in concentrations sufficient to produce adverse environmental effects. The commentors further maintained that the environmental information submitted to the Agency is sufficient to reasonably determine or predict the risk that TCEA may present to the environment. In support of their contention, the commentors supplied the Agency with information on the environmental concentrations of TCEA, the chemical fate of TCEA, and the aquatic and avian toxicity of TCEA.

Subsequent to the proposed rule, the Agency has performed a materials balance analysis for TCEA, has reevaluated the chemical and physical properties of TCEA, and has reexamined the toxicity data in relation to both the monitoring and environmental fate data. In addition, the Agency has reviewed and evaluated the comments and data submitted by industry. Based on its review of industry comments and the evaluation of the available data, the Agency now believes that sufficient data are available to reasonably predict the environmental effects of TCEA.

EPA agrees with the comments noted above which state that TCEA's volatility make it unlikely that substantial concentrations of the chemical will be found in the aquatic or terrestrial environments. Available monitoring data confirm that environmental concentrations are quite low. Most of these reported levels are in the low ppb range (water=8–17 ppb, soil/sediments=3–6 ppb, air=10–15 ppb) (Ref. 6).

Moreover, these measured concentration levels of TCEA are far below those concentrations which cause acute toxicity in mammalian, aquatic, avian and terrestrial species. For example, the acute oral toxicity (LD_{50}'s) for TCEA in the mouse and rat are between 11 to 12 g/kg. Acute toxicity tests performed on aquatic vertebrates and invertebrates yielded LC_{50} values of 9.7 to 52.8 mg/l (9.7 to 52.8 ppm) in flow-through experiments or in experiments where procedures to limit losses due to volatilty were followed (Ref. 6). Studies done on species of algae gave EC_{50}'s greater than 669 mg/l (669 ppm). Acute toxicity in avian species produced an oral LD_{50} greater than 2,510 mg/kg. As shown above, levels of TCEA in water, air and soil are in the low ppb range. Because TCEA produces toxicity in a large variety of sensitive species only at doses which are far above (by a factor of 500 or greater) the levels found in the environment, the Agency has concluded that it can reasonably predict that the chemical (at present levels of environmental exposure) does not pose an unreasonable risk to mammalian, aquatic, avian, or terrestrial species.

Finally, the materials balance analysis and environmental fate data (Ref. 12) also allow the Agency to predict TCEA's fate and distribution in the environment. These data provide additional support for the belief that the concentrations of TCEA found in the environment are low.

Therefore, taking all of these data into consideration, EPA believes that sufficient data are now available to reasonably determine or predict the environmental effects of TCEA. Thus, EPA is withdrawing its proposal to require environmental effects testing of TCEA.

C. Test Substance

Bendix Environmental Research stated that a test substance stabilized with 0.5 percent butylene oxide is not appropriate because if positive results are seen in any test it will have to be repeated to find out whether TCEA or butylene oxide is responsible for the effect observed. The Agency agrees that this is a problem encountered when testing mixtures. However, the Agency has chosen TCEA stabilized with butylene oxide because of the difficulty in obtaining and working with the pure chemical. Based on the NTP testing experience, the Agency has decided to require that testing be conducted utilizing a TCEA of purity greater than 99.7 percent and stabilized with less than 0.1 percent butylene oxide. NTP obtained this formulation from the Dow Chemical Company.

D. EPA Testing

Both Proctor and Gamble and Atlantic Richfield noted that EPA intended to perform certain tests (i.e., mutagenicity) for which test standards had not yet been adopted by EPA. They questioned how the Agency will be able to perform the tests itself if it is unable to provide suitable guidance to others.

Subsequent to the proposal, the Agency developed guidelines for conducting mutagenicity testing, including triggers to go from lower to higher tier testing. However, in the case of TCEA a separate proposal would be required if the Agency wanted to have industry conduct the mutagenicity testing. Because it wanted at least preliminary mutagenicity results sooner than would be possible through rulemaking, the Agency decided to proceed with EPA-sponsored testing. After the Agency has evaluated the results of the lower-tiered mutagenicity tests, EPA may propose a test rule to require higher tiered mutagenicity tests if needed.

IV. Final Test Rule for 1,1,1-Trichloroethane

A. Findings

The EPA is basing the final testing requirements for TCEA on the authority of section 4(a)(1)(B). of TSCA. EPA finds that TCEA is produced in substantial quantities and that there is substantial occupational and consumer exposure to TCEA resulting from its manufacture, processing, and use. The bases for these findings, which are summarized below, are set forth in the Agency's TCEA support document (Ref. 6), which is hereby incorporated by reference.

Approximately 586 million pounds of TCEA were produced in the United States in 1983 (Ref. 8). TCEA is used in the metal cleaning industry which provides the potential for a large number of people to be exposed to TCEA. In the National Occupational Hazard Survey (NOHS) approximately 2.6 million workers were estimated to be exposed to TCEA (Ref. 3). TCEA has been identified in a substantial number of consumer products with the potential for many millions of people exposed to TCEA as a consequence of consumer use (Ref. 6).

In addition, the Agency believes that available data are insufficient to reasonably predict or determine the developmental toxicity of TCEA and that testing is necessary to develop such data. (See Unit III.A.1)

B. Required Testing

The Agency believes that adequate developmental toxicity tests for TCEA should be done in two mammalian species (a rat and a non-rodent species). It is well documented that various animal species have differing sensitivities to chemicals being tested for developmental toxicity (Refs. 9, 10, and 11). Thus, a negative developmentally toxic response in a single mammalian species does not necessarily mean that the chemical being tested is not a developmental hazard. The Agency believes that multispecies testing is a more sensitive means of detecting developmental hazards than single species testing (Refs. 9, 10 and 11). Testing TCEA in the rat and a non-rodent mammalian species will provide the Agency with the data needed to reasonably determine or predict whether TCEA poses a risk of developmental toxicity to humans.

Therefore, the Agency believes that developmental toxicity testing should be performed via inhalation in the rat and a non-rodent mammalian species and that some sign of maternal toxicity should be demonstrated at the highest dose in each species.

The EPA is requiring that a developmental toxicity study or studies on TCEA be conducted by the inhalation route. Although the Agency is currently preparing a guideline for inhalation developmental toxicity, which is expected to be available by Fall, 1984, at the present time there is no TSCA Guideline for this test and EPA suggests using a modified version of the protocol submitted by the Chemical Manufacturers Association (CMA) for inhalation teratogenicity of isophorone in the rat and mouse. A copy of this protocol is in the public record for this rulemaking, docket number [OPTS-42029]. The Agency believes that two modifications should be made to this protocol:

1. Rats and a non-rodent mammalian species should be utilized instead of rats and mice. EPA recommends, but does not require, rabbits as the non-rodent species.

2. EPA does not specify the strains or precise ages of the animals to be used; it recommends only that young adult rats and rabbits be used. The CMA protocol can be easily revised to reflect developmental toxicity protocols for TCEA and test sponsors will need to specify species, age, strain and number of animals used, dose delivery system for inhalation exposure, and chamber monitoring procedures. All data must be developed and reported in accordance with the TSCA Good Laboratory Practice Standards in 40 CFR Part 792.

Should the TSCA Guideline for inhalation developmental toxicity become available at a time consistent with the time requirements for submission of study plans, then the Guideline should also be consulted for appropriate study design.

C. Test Substance

EPA is requiring a 1,1,1-trichloroethane test substance containing less than 0.1 percent butylene oxide stabilizer for use in the test required in this rule. This product is 99.7 percent pure and contains the least amount of stabilizer of any product available. It is similar to the formulation used in NTP's oncogenicity bioassay on 1,1,1-trichloroethane and can be obtained from the Dow Chemical Company.

D. Persons Required To Test

Several industry commentors stated that only manufacturers and not processors should be required to conduct the tests. One commentor recommended that the Agency categorically exclude "downstream or indirect processors."

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the manufacturing, processing, and use of 1,1,1-trichloroethane give rise to substantial human exposure to TCEA, EPA is requiring that persons who manufacture or process, or who intend to manufacture or process this chemical, at any time from the effective date of this test rule to the end of the reimbursement period, be subject to the rule. The end of the reimbursement period will be 5 years after the final TCEA developmental toxicity report is submitted. As discussed in the Agency's test rule and exemption procedures (40 CFR Part 790), EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

EPA is, however, exempting those manufacturers and processors which produce and process TCEA only as an impurity from these testing requirements. "Impurity" is defined in 40 CFR 790.3 to mean "a chemical substance which is unintentionally present with another chemical substance." The Agency is exempting those manufacturers and processors because the EPA's findings under section 4(a)(1)(B) are based on exposures to TCEA which are a result of intentional manufacture, processing, and use. In addition, it will be difficult for both EPA and manufacturers and processors to identify with complete assurance all chemical substances which contain TCEA as an impurity. Finally, the Agency would find it difficult to apply both the exemption and reimbursement processes to those who manufacture and/or process TCEA as an impurity. In fact, the Agency's reimbursement regulations issued pursuant to section 4(c) state that those who manufacture or process chemical substances as impurities will not be subject to test requirements unless the rule specifically states otherwise (40 CFR 791.48b).

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to a test rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement. The Agency anticipates that the current manufacturers of 1,1,1-trichloroethane will form the reimbursement pool and sponsor the testing required. Manufacturers and processors who are subject to the testing requirements of

this rule must comply with the test rules and exemption procedures in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing. As noted in Unit IV. C, EPA is interested in evaluating the effects attributable to TCEA itself and has specified a relatively pure substance for testing.

E. Test Rule Development

Under the regulations in 40 CFR Part 790, test rule development for TCEA will be a two-phase process. In the two-phase process, Phase I test rules will be promulgated for individual chemicals specifying the health and environmental effects and other characteristics for which test data are to be developed. In Phase II, following promulgation of the Phase I test rule, those persons subject to the rule will be required to develop study plans for the development of data pertaining to the effects and characteristics specified in the Phase I rule. Within 30 days from the effective date of the final Phase I test rule, manufacturers must submit to EPA a letter stating their intention to sponsor testing or an application for exemption. Test sponsors must submit their study plans to EPA within 90 days from the effective date of the Phase I test rule. After an opportunity for public comment, EPA will promulgate a rule adopting the study plans, as proposed or modified, as the chemical-specific test standards and schedules for the tests required by the Phase I rule. Testing would also be subject to EPA's generic TSCA GLP standards. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards and schedules developed. Modification to the adopted study plans can be made only with EPA approval.

Processors of TCEA will not be required to submit letters of intent, exemption applications and study plans and to conduct testing unless manufacturers fail to sponsor the required tests. The basis for this decision is that manufacturers are expected to indirectly pass the costs of testing on to processors through any price increase of TCEA.

F. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice (GLP) standards which were published in 40 CFR Part 792 (See 48 FR 53922, November 29, 1983). These final GLP standards apply to this rule.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. These deadlines will be established in the second phase of this rulemaking in which study plans are approved. The procedures for the second phase rulemaking are described in 40 CFR Part 790.

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).

G. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory audits/inspections will be conducted periodically in accordance with the procedures outlined in TSCA section 11 by designated representatives of the EPA for the purpose of determining compliance with the final rule for 1,1,1-trichloroethane. These inspections may be conducted for purpsoes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to the TSCA GLP standards and the test standards established in the second phase of this rulemaking.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties calculated as if they had never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation. Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Economic Analysis of Rule

To assess the economic impact of this rule, EPA has prepared an economic evaluation (Ref. 8) that examines the cost to the required testing and analyzes four market characteristics of TCEA: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. The costs of conducting the developmental toxicity test are estimated to range from $62,134 to $186,403, with annualized costs ranging from $16,000 to $48,300 (Ref. 8). Based on these test costs and an analysis of the four market characteristics of TCEA, the economic evaluation indicates that the potential for a significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations (Ref. 8):

1. The demand for 1,1,1-trichloroethane is relatively inelastic due to select performance advantages in its major uses.

2. The market expectations for 1,1,1-trichloroethane are generally favorable.

3. The relative magnitude of the test cost is negligible (i.e., an estimated 0.008 cents per pound in the upper bound case); this represents 0.03% of the sales value of TCEA.

VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October, 1981, can be obtained through the NTIS under publication number PB 82–140773.

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this test rule.

VII. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so-called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the **Federal Register**, as reflected in **"DATES"** in this notice. The effective date has, in turn, been calculated from the promulgation date.

VIII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS–42059). This record includes the basic information the Agency considered in developing this rule, and appropriate **Federal Register** notices. The Agency will supplement the record with additional information as it is received. Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Room E–107, 401 M Street, SW, Washington, D.C.

This record includes the following information:

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice of final rule on 1,1,1-trichloroethane.

(b) Notice of proposed rule on 1,1,1-trichloroethane (46 FR 30300).

(c) Notice containing the ITC designation of 1,1,1-trichloroethane to the Priority List (43 FR 16684).

(d) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922).

(e) Notice of final rule on test rule development and exemption procedures.

(f) Notice of final rule concerning data reimbursement.

(2) Supports documents consisting of:

(a) 1,1,1-trichloroethane support document.

(b) Economic impact analysis of final test rule for 1,1,1-trichloroethane.

(3) Communications consisting of:

(a) Written public comments.

(b) Summaries of telephone conservations.

(c) Meeting summaries.

(d) Reports—published and unpublished factual materials, including contractors' reports.

(4) Test protocol for an inhalation teratogenicity study.

IX. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The regulation for this chemical substance is not major because it does not meet any of the criteria set forth in section 1(b) of the order. First, the annual costs of testing are less than $50,000 over the expected market life of TCEA. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on producers' costs or users' prices for this chemical substance. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic impact of any type as a result of this rule.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, are included in the public record.

X. Regulatory Flexibility Act

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

1. There are no small manufacturers of 1,1,1-trichloroethane.

2. Small processors will not perform testing themselves, or will not participate in the organization of the testing effort.

3. Small processors will experience only minor costs if any in securing exemption from testing requirements.

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

XI. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB number 2070–0033.

XII. References

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(3) NIOSH. National Institute for Occupational Safety and Health. National Occupational Hazard Survey Data Base (NOHS). Washington, D.C. U.S. Department of Health, Education and Welfare. Computer printout. 1980.

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(11) USEPA. U.S. Environmental Protection Agency. Rationale for Requiring Teratogenicity Testing in Two Species. Washington, D.C.: Office of Pesticides and Toxic Substances, USEPA. 1981.

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List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94–469, 90 Stat. 2006; 15 U.S.C. 2603)

Dated: September 14, 1984.

William D. Ruckelshaus,

Administrator.

Therefore, Chapter I of 40 CFR is amended by adding Part 799 to read as follows:

PART 799—IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE AND MIXTURE TESTING REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Specific Chemical Test Rules

Authority: Section 4, Section 12, and Section 26, Toxic Substances Control Act (TSCA, 90 Stat. 2006, 2033, 2047; 15 U.S.C. 2603, 2611, 2625).

Subpart A—General Provisions

§ 799.1 Scope and purpose.

(a) This part identifies the chemical substances, mixtures, and categories of substances and mixtures for which data are to be developed, specifies the persons required to test (manufacturers, including importers, and/or processors), specifies the test substance(s) in each case, prescribes the tests that are required including the test standards, and provides deadlines for the submission of reports and data to EPA.

(b) This part requires manufacturers and/or processors of chemical substances or mixtures ("chemicals") identified in Subpart B to submit letters of intent to test, exemption applications, and study plans in accordance with EPA test rule development and exemption procedures contained in Part 790 of this chapter and any modifications to such procedures contained in this part.

(c) This part requires manufacturers and/or processors of chemicals identified in Subpart B to conduct tests and submit data in accordance with the test standards contained in this part in order to develop data on the health and environmental effects and other characteristics of these chemicals. These data will be used to assess the risk of injury to human health or the environment presented by these chemicals.

§ 799.2 Applicability.

This part is applicable to each person who manufactures or intends to manufacture (including import) and/or to each person who processes or intends to process a chemical substance or mixture identified in Subpart B for testing during the period commencing with the effective date of the specific chemical test rule until the end of the reimbursement period. Each set of testing requirements in Subpart B specifies whether those requirements apply to manufacturers only, to processors only, or to both manufacturers and processors.

§ 799.3 Definitions.

The definitions in section 3 of the Toxic Substances Control Act (TSCA) and the definitions of § 790.3 of this chapter apply to this part.

§ 799.5 Submission of information.

Information (letters, study plans, reports) submitted to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule (e.g. § 799.4400 for 1,1,1-trichloroethane) and must be addressed to: Document Control Office (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460.

§ 799.10 Test standards.

Testing required under Subpart B must be performed using a study plan prepared according to the requirements of Parts 790 and 792 of this chapter unless modified in specific chemical test rules in Subpart B. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study under Subpart B must be developed, reported, and retained in accordance with TSCA Good Laboratory Practice Standards (GLP's) in Part 792 of this chapter. These items must be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to the Agency in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA GLP's. Sponsors must notify the laboratory that the study is being conducted pursuant to TSCA § 4. Sponsors are also responsible for ensuring that laboratories conducting the test abide by the TSCA GLP standards. In accordance with § 792.12 of this chapter, a certification concerning adherence to the TSCA GLP's must be submitted to EPA.

§ 799.11 Availability of test guidelines.

The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650).

The OECD guidelines for the various study plans are available from the following address: OECD Publication and Information Center, 1750 Pennsylvania Ave., NW., Washington, D.C. 20006 (202–724–1857).

§ 799.12 Test results.

Except as set forth in specific chemical test rules in Subpart B of this part, a positive or negative test result in any of the tests required under Subpart B is defined in the TSCA test guidelines published by NTIS.

§ 799.17 Effects of non-compliance.

Any person who fails or refuses to comply with any aspect of this part or Part 790 is in violation of section 15 of TSCA. EPA will treat violations of Good Laboratory Practice Standards as indicated in § 792.17 of this chapter.

Subpart B—Specific Chemical Test Rules

§ 799.4400 1,1,1-Trichloroethane.

(a) *Identification of chemical test substance.* 1,1,1-Trichloroethane (CAS No. 71–55–6, also known as methyl chloroform) shall be tested in accordance with this part.

(b) *Identification of test substance.* 1,1,1-Trichloroethane stabilized with less than 0.1 percent butylene oxide shall be used as the test substance in all tests.

(c) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture or process 1,1,1-trichloroethane, other than as an impurity, from November 23, 1984, to the end of the reimbursement period shall submit letters of intent to test, exemption applications, and study plans and shall conduct tests and submit data as specified in this section, Subpart A of this part and Part 790 of this chapter (Test Rule Development and Exemption Procedures). (Information collection requirements approved by the Office of Management and Budget under control number 2070–0033.)

(d) *Health effects testing*—(1) Developmental toxicity—(i) *Required testing.* A test for developmental toxicity shall be conducted with 1,1,1-trichloroethane.

(ii) *Study plans.* For guidance in preparing study plans, it is recommended that the inhalation teratogenicity study design submitted by the Chemical Manufacturers Association (CMA) for inhalation teratology of isophorone in the rat and mouse be consulted. A TSCA Guideline for inhalation developmental toxicity is currently being prepared by the Agency and is expected to be available by Fall, 1984. If available, it should also be consulted for appropriate study design. A copy of the CMA protocol is available in the public record for this rulemaking, docket number (OPTS–42059). Testing should, however, be conducted on the rat and a non-rodent mammalian species.

(2) [Reserved].

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